

An International Guide to Patent Case Management for Judges



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*An International Guide to Patent Case
Management for Judges***

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Introduction (Chapter 1)

Ms. Eun-Joo Min is Director of the WIPO Judicial Institute. Prior to her current position, she headed the policy and international cooperation work of the WIPO Building Respect for IP Division, and the legal development section of the WIPO Arbitration and Mediation Center. Ms. Min was a member of the Expert Advisory Group of the Medicines Patent Pool from 2011 to 2018, and is the author of a number of publications on IP enforcement and dispute resolution, including a chapter on cross-border intellectual property enforcement in *The Oxford Handbook of Intellectual Property Law* (Oxford University Press, 2018). Ms. Min holds a Ph.D. in law from Yonsei University in the Republic of Korea, and was a Fulbright Scholar at the University of Michigan Law School, USA. She taught law at Yonsei University prior to joining WIPO, and was an Adjunct Professor at Sogang Law School in 2013 and 2014.

Australia (Chapter 2)

Justice Annabelle Bennett (ret.) studied science at the University of Sydney, where she completed a PhD in cell biology, before studying law at the University of New South Wales. Justice Bennett went on to practice as a barrister, later specializing in intellectual property. Between 2003 and 2016, Justice Bennett served as a Judge of the Federal Court of Australia, sitting on many intellectual property cases at first instance and on appeal. She has also served as President of the Copyright Tribunal of Australia. Justice Bennett chaired the WIPO's Advisory Board of Judges from 2018 to 2022. Justice Bennett has returned to the Bar and practices as a barrister (advisory only), a mediator, and an arbitrator. Justice Bennett is a Fellow of both the Australian Academy of Science and the Australian Academy of Law.

Justice Stephen Burley was appointed to the Federal Court of Australia in 2016. As a Judge in the Intellectual Property National Practice Area, he hears many intellectual property cases at first instance and on appeal. Justice Burley practiced at the Bar from 5 Wentworth Chambers, Sydney, from 1993 until 2016. He was appointed Senior Counsel in 2007. While at the Bar, Justice Burley practiced commercial law, specializing in patent, copyright, trademark, design, and confidential information cases. Many of Justice Burley's patent cases involved pharmaceutical, telecommunications, or other high-tech subject matter. Justice Burley regularly contributes to publications and events hosted by WIPO and frequently presents and publishes on intellectual property subjects in Australia and abroad.

Mr. Robert Clark's broad practice from 5 Wentworth Chambers spans intellectual property, general commercial litigation, tax, and administrative law. He has appeared in the Federal Court and High Court and Courts and Tribunals in New South Wales, South Australia and Western Australia. Mr. Clark has been recognized in Best Lawyers in Australia for his expertise in both litigation and IP law. Mr. Clark completed a Bachelor of Civil Law at the University of Oxford, graduating with a distinction average, and he received the Law Faculty Prize for International Intellectual Property. Prior to this, he completed a Bachelor of Arts and Bachelor of Laws (LLB) from the University of Sydney with first-class honors and received the Minter Ellison Prize for IP. Mr. Clark previously worked as a solicitor in the intellectual property teams at Allens Linklaters and as an associate to Honorable Justice Cowdroy AO on the Federal Court of Australia.

Ms. Cynthia Cochrane specializes in patent cases at 5 Wentworth Chambers, with expertise in vaccines and biological medicines, and commercial cases, including competition law. Ms. Cochrane appears regularly in the Federal Court, at trial and on appeal, and at the Patent Office. Her High Court experience spans over 15 years, and she recently addressed a six-member bench in relation to the patentability of computer-implemented inventions. She appears in the New

South Wales Supreme Court and conducts examinations for the competition regulator regarding potential cartel conduct. Ms. Cochrane is recognized in Chambers Asia-Pacific, Best Lawyers, Doyles, and Legal 500. She was a solicitor at Allens Linklaters, articulated to Prof. Bob Baxt AO in competition law, and, prior to her law career, was an investment banker at Macquarie Bank.

Mr. Julian Cooke specializes in intellectual property law, including trade practices, from 5 Wentworth Chambers. His expertise spans patents, trademarks, copyright, designs, confidential information and consumer protection. Mr. Cooke frequently represents clients in the pharmaceutical, chemical, telecommunications, mining, media, and consumer goods industries. He has appeared in a number of leading intellectual property cases in the High Court and the Federal Court of Australia.

Ms. Anna Elizabeth's broad commercial practice from 5 Wentworth Chambers has considerable experience in complex commercial disputes and her clients include the mining and energy industries. In addition to Commerce and Law degrees, Ms. Elizabeth holds a Master of Energy and Resource Law from the University of Western Australia, where she finished with the highest mark in her course and received the Johnson Winter and Slatery Prize in Law and the Clayton Utz Postgraduate Award for Energy and Resources Law. She is a member of the Energy & Resources Law Association and a reporter for the *Australian Resources Law Reports*. Prior to commencing at the Bar, Ms. Elizabeth was a litigator in the commercial disputes team at Arnold Bloch Leibler and served as an Associate to Foster J in the Federal Court of Australia for 18 months.

Mr. Joseph Elks has a broad practice from 5 Wentworth Chambers and specializes in all areas of intellectual property, complex commercial disputes, sports law, defamation and competition law. Mr. Elks appears in the Federal Court as well as in the New South Wales Supreme Court and lower courts and tribunals. He is recognized in Doyle's Guide as a "recommended" junior counsel in intellectual property litigation. Prior to being called to the Bar, Mr. Elks was a Senior Associate at Herbert Smith Freehills in Sydney and a Senior Associate at a leading firm in New York. He obtained his Bachelor of Laws (Hons I) and Bachelor of Commerce from UQ, receiving the Freehills Prize in. He also has a Master of Laws from New York University (NYU), where he attended as a Hauser Global Scholar, graduating first in NYU's Competition Law and IP program.

Mr. Andrew Fox's practice from 5 Wentworth Chambers focuses on intellectual property and commercial litigation. His intellectual property experience spans the full spectrum, including patents, trademarks, copyright, designs, confidential information and consumer protection. His court appearances include a number of leading cases in the High Court, and the Federal Court of Australia, and in patent and trademark oppositions held at IP Australia. Mr. Fox's patent experience spans a range of technology fields and his general commercial litigation practice has brought him before the Supreme Court of New South Wales, the District Court of New South Wales, and interstate courts. Mr. Fox is recognized in Chambers and Partners Asia Pacific as a leading barrister in IP; Doyle's Guide to Australian Leading Lawyers; Best Lawyers in Australia; The World's Leading Trademark Professionals; and The Legal 500 – Australian Bar – IP. He is also admitted to practice as a barrister in New Zealand.

Ms. Sue Gilchrist is the leader of the Herbert Smith Freehills IP group in Australia, a member of the HSF Global board, and chair of the HSF Global Pro Bono & Responsible Business Council. Ms. Gilchrist is a senior IP litigation partner, ranked one of the top practitioners by the leading legal directories, including Chambers & Partners, Legal 500, Benchmark Litigation, IAM Patent 1000, and Managing IP: IP STARS. She is one of only six practitioners in Australia to be recognized in the Top 100 Women in Litigation (2021 and 2022) Benchmark Litigation Asia-Pacific. Ms. Gilchrist has a particular focus on representing clients in high-tech patent litigation and leads HSF's global High Tech Patent focus group. Sue is also a member and previous chair of the IP Committee of the Law Council of Australia, a body that engages with the government on intellectual property policy issues.

Mr. Timothy Gollan is a solicitor in the Intellectual Property Disputes team at Herbert Smith Freehills. He has been involved in working on a range of intellectual property disputes involving patents, trademarks and copyright across a range of fields, including pharmaceuticals, telecommunications, mining, and mechanical devices. Previously, Mr. Gollan worked as an Associate to Justice Stephen Burley in the Federal Court of Australia. He has a Bachelor of Law and a Bachelor of Engineering from the University of Sydney.

Mr. Samuel Hallahan practices commercial litigation from 5 Wentworth Chambers, with particular expertise in intellectual property. Before coming to the Bar, he practiced as a solicitor for seven years in intellectual property and general commercial litigation, where his work included matters for large pharmaceutical and commercial clients. At the Bar, Mr. Hallahan has appeared in first instance and appeal proceedings in the Federal Court of Australia, and in the Federal Circuit Court, the Supreme Court of New South Wales, the Local Court of New South Wales, the New South Wales Civil and Administrative Tribunal (NCAT), and in opposition proceedings at IP Australia. In 2020, 2021, and 2022, Mr. Hallahan was listed in Doyle's Guide "Leading Intellectual Property Law Junior Counsel – New South Wales." In 2021, he was listed in Doyle's Guide "Leading Intellectual Property Law Junior Counsel – Australia."

Ms. Irini Lantis is a senior lawyer in Gilbert + Tobin's Tech and IP practice. She has extensive experience in patent litigation proceedings before the Federal Court and the High Court of Australia. Ms. Lantis has litigated patents across a range of industries, including mining and resources, gaming, ecommerce, and life sciences. She also has extensive experience in the commercialization and transactional aspects of intellectual property.

Mr. David Larish received his LLB from the University of New South Wales (UNSW) (Hons Class I, University Medal) and his LLM from New York University (Frank T. Diersen prize). His practice from 5 Wentworth Chambers focuses primarily on intellectual property and commercial disputes. He has been briefed in a number of the leading intellectual property cases in the High Court and the Federal Court. He regularly appears in the Federal Court, Supreme Court and at IP Australia. Mr. Larish is recognized in Doyle's Guide as a 'pre-eminent' junior counsel in intellectual property in Australia and a 'leading' junior counsel in Technology, Media & Telecommunications. He is also recognized in Chambers and Partners Asia Pacific, Best Lawyers in Australia and The Legal 500. Before coming to the Bar, Mr. Larish was a Judge's Associate at the Federal Court and a solicitor at King & Wood Mallesons.

Mr. John Lee is a partner in Gilbert + Tobin's Tech + IP group and leads the firm's Patent practice. He has both legal and technical qualifications and has many years' experience dealing with all aspects of intellectual property law. Mr. Lee has a particular focus on patent litigation and trade secrets across a range of industries, including life sciences, resources and digital technologies.

Ms. Angela McDonald practices from 5 Wentworth Chambers, in all aspects of intellectual property, including patents, trademarks, copyright, designs and consumer protection. She has been featured in Doyle's Intellectual Property List since 2021. Ms. McDonald regularly appears in the Federal Court of Australia, including the Full Court, various state Supreme Courts, the Patent Office, and the Trade Mark Office. Prior to coming to Bar, she was a solicitor in two specialist intellectual property firms. She was also an Associate to Justice Nicholas of the Federal Court of Australia. Ms. McDonald graduated with first-class honors in law from the University of New South Wales. She is also on the Editorial Panel for the Australian Intellectual Property Law Bulletin, a co-author of the LexisNexis Australia Copyright & Designs chapter on International Copyright, and the author of a number of publications on intellectual property law.

Mr. Benjamin Mee specializes in intellectual property law from 5 Wentworth Chambers, and holds a BSc (Biochemistry)-LLB (Hons I, University Medal) and an LLM in Commercial Law (Hons I) from Cambridge University. Prior to being called to the Bar in 2014, he practiced as a solicitor with Allens in intellectual property and competition and consumer law, and was an Associate to former Chief Justice RS French AC of the High Court. At the Bar, Mr. Mee has developed a busy trial and appellate practice, with particular strength in patent matters in the pharmaceutical, biotechnology, and information technology/software sectors, as well as appellate work. He regularly appears led and unled in the Federal Court, Patent Office, and Trade Marks Office. He is recognized in Chambers and Partners, Doyle's Guide, and Best Lawyers Australia.

Ms. Anna Spies' practice from 5 Wentworth Chambers includes consumer law, confidential information, restraints of trade, media and defamation, commissions and inquiries, and a focus on intellectual property litigation. Her experience in complex cases spans copyright, patent and trademark law at the Bar and as a solicitor. Before coming to the Bar in 2016, Ms. Spies was a Senior Associate in King & Wood Mallesons' IP litigation team and an Associate to Justice Annabelle Bennett at the Federal Court of Australia. Doyle's Guide lists Ms. Spies as 'Recommended' junior counsel in New South Wales for intellectual property and for Technology, Media & Telecommunications. She received the Christopher Gee QC Memorial Prize for evidence

and advocacy for the August 2016 Bar Practice Course. Ms. Spies received her LLM in Media and Technology (with excellence) and LLB (with first class honors) from the University of New South Wales.

Mr. Edward Thompson practices from 5 Wentworth Chambers, principally in intellectual property matters but has experience in a broad range of commercial disputes. He has degrees in law and arts from the University of Melbourne (2008) and a Master of Laws from University College London (2011), graduating as the top student in the LLM program. Before commencing at the Bar, Mr. Thompson was an Associate to Justice John Nicholas at the Federal Court of Australia, and a solicitor for over seven years in the intellectual property department of a national law firm. He was also a lecturer in corporation law at the University of Melbourne.

Mr. Byron Turner is a solicitor in the Intellectual Property Disputes team at Herbert Smith Freehills (HSF) and advises clients on trademark, patent and copyright disputes in the Federal Court. He has further experience advising clients on consumer law issues, as well as legal issues arising from new technologies, including digital assets. Mr. Turner has a Bachelor of Mathematics Advanced degree from the University of Wollongong, majoring in applied statistics and risk management & insurance. He is Byron is a member of HSF's High Tech Patent focus group, and of HSF's Digital Law Group, and was a recipient of the HSF Digital Scholar Fellowship (2021), reflecting his interest and skills in the high tech field.

Brazil (Chapter 3)

Judge Regis de Castilho Barbosa Filho sits on the 41st Civil Court of the Central Forum of the Capital of São Paulo. He graduated in law from the University of São Paulo.

Judge Luís Felipe Bedendi serves as the Assistant Judge of the 1st and 2nd Business and Arbitration Courts of São Paulo. He received his Master's Degree in Commercial Law from the University of São Paulo and graduated in law from the University of São Paulo.

Judge Maria Rita Rebello Pinho Dias sits on the 3rd Bankruptcy and Judicial Recovery Court of the Capital of São Paulo State Court. She received her Master in Constitutional Law from the Pontifical Catholic University of São Paulo and PhD in Civil Procedure from the University of São Paulo. She graduated in law from the University of São Paulo.

Judge Eduardo Azuma Nishi sits on the São Paulo State Court, and is a member of the First Specialized Business Law Chamber. Judge Azuma Nishi received his Master in Business Law from the Pontifical Catholic University of São Paulo. He also graduated in law from the University of São Paulo and in Business Administration from the Getúlio Vargas Foundation in São Paulo, Brazil.

Judge João de Oliveira Rodrigues Filho sits on the 1st Court of Bankruptcy and Judicial Reorganizations of the Capital of São Paulo. He received his specialization in Business Law from the Paulista School of Magistrates (Escola Paulista da Magistratura (EPM)) and is a professor of the postgraduate course in Bankruptcy and Judicial Recovery at the Faculdade Autônoma de Direito (FADISP).

Judge Leandro Galluzzi dos Santos sits on the Criminal Court of Jaboticabal in the state of São Paulo. He graduated in law from the University of São Paulo.

China (Chapter 4)

Judge Du Weike is a Senior Judge and has served on the Intellectual Property Rights Division of the Supreme People's Court of China since 2010. Prior to his appointment, he worked as a patent examiner at the Board of Reexamination of the State Intellectual Property Office of China from 2004 to 2009, handling over 150 patent administrative cases. Judge Du has rendered a number of landmark intellectual property cases in China and has published more than twenty articles on intellectual property law. Judge Du holds a BA in Electric Engineering and Law from Huazhong University of Science and Technology, a Juris Master Degree from Xiamen University, and an LLM Degree from Temple University, which he attended as a DuPont Scholar.

Judge He Juan was appointed as a Senior Judge of the Intellectual Property Court of the Supreme People's Court of China in 2020. Judge He conducted her postdoctoral research at Tsinghua University and the University of Turku, Finland. From 2013 to 2020, she served in the following roles at Tsinghua University: lecturer, associate professor, and Deputy Director of Social Science and Management at the Shenzhen International Graduate School, and Deputy Director of the Office of Technology Licensing. She has also led a number of research projects in the area of intellectual property, and authored numerous publications on intellectual property topics, including monographs, books (as editor-in-chief or co-translator) and journal articles. Judge He holds a Bachelor of Engineering degree from the Hefei University of Technology, and degrees in law from Tsinghua University (Bachelor and Master of Law) and Peking University (PhD).

Germany (Chapter 5)

Dr. Thorsten Bausch is a German and European patent attorney. He is a partner in HOFFMAN EITLE's Chemistry and Biotech practice group and focuses on European Patent Office Opposition and Appeal Proceedings, as well as German revocation and infringement proceedings. Dr. Bausch represents clients through all strata, from startups to Fortune 500 companies, as well as some of the most prestigious universities and research institutions in the world. He has particular expertise in the fields of pharmaceuticals, immunology, and polymers. Many pharmaceutical patents of major commercial value have been entrusted to him and his team at HOFFMANN EITLE. In addition to his client service, Dr. Bausch has edited the book series "Nichtigkeitsrechtsprechung in Patentsachen," a collection of decisions in patent nullity matters from the German Federal Patent Court and Federal Court of Justice. In his personal time, Dr. Bausch regularly blogs on www.kluwerpatentblog.com on patent policy issues and interesting decisions.

Justice Klaus Grabinski was appointed President of the Court of Appeal of the Unified Patent Court in 2022, and serves as the chairperson of the Presidium. Prior to this role, he served on the German Federal Court of Justice's 10th Civil Division, including as the Deputy Presiding Justice of the Division. Before joining the German Federal Court of Justice, he held a number of judicial roles, including as a judge at the Düsseldorf Higher Regional Court, and Presiding Judge of a patent litigation division at the Düsseldorf District Court. Justice Grabinski studied law at the Universities of Trier, Geneva, and Cologne and was a university assistant in Trier. He co-authored a commentary on the European Patent Convention (Benkard, *Europäisches Patentübereinkommen*, 3rd ed., 2019) and a commentary on the German Patent Law (Benkard, *Patentgesetz*, 10th ed., 2015). He has authored many articles concerning patent law, civil procedure, and international private law.

Dr. Marcus Grosch is the managing partner of Quinn Emanuel Urquhart & Sullivan, LLP, in Germany. Dr. Grosch has more than 20 years of experience in patent litigation, in which he has represented clients from various technical fields before all major German courts, the German Patent and Trademark Office, as well as the European Patent Office. He holds degrees from the University of Mannheim (PhD in Law and JD equivalent) and Yale University School of Law (LLM). Dr. Grosch has authored books, treatises, and articles on patent law and civil procedure.

Mr. Klaus Haft As a German qualified attorney (Rechtsanwalt) and physicist (Master's degree), Mr. Klaus Haft is a trial lawyer in the field of intellectual property law with particular emphasis on patent litigation. In addition, he advises on license agreements, research and development agreements, the law on employee inventions, and trade secrets. Mr. Haft studied in Würzburg and Munich. He wrote his diploma thesis at the European Organization for Nuclear Research (CERN), in Geneva. Mr. Haft has served as a member of the Board of the European Patent Lawyers Association (EPLAW) for seven years, the last two as its President, and currently serves as a member of the advisory board. In addition, he is President of the Licensing Executives Society (LES) Germany and a member of the Executive Board of the Munich IP Dispute Resolution Forum.

Dr. Julia Nobbe is Of Counsel at the Mannheim office of Quinn Emanuel Urquhart & Sullivan, LLP, and has developed an expertise in German patent litigation. She represents clients in patent infringement and nullity proceedings before the courts of first instance and before the courts of appeal. Dr. Nobbe graduated from the University of Konstanz, where she also worked as a research assistant at the Chair of Professor Dr. Karl-Heinz Fezer, before starting her legal clerkship at the Higher Regional Court of Karlsruhe. She obtained her doctorate degree (summa cum laude) from Munich University and has published on the subject of patent litigation in

Germany. Dr. Nobbe's varied practice includes working in international law firms, in a law firm that exclusively represents clients before the German Federal Court of Justice, and as in-house legal counsel in the intellectual property department of an international chemical company.

Judge Peter Tochtermann was appointed in 2022 as Judge of the Court of First Instance (local division Mannheim) of the Unified Patent Court and a member of its Presidium. Prior to this appointment, he served on the Regional Court of Mannheim, including as Presiding Judge of the Patent Chamber, and as a Mediator Judge. He also sat on the Patent Senate of the Higher Regional Court of Karlsruhe and served as a clerk of the German Federal Court of Justice. Judge Tochtermann has worked as a Research Fellow and Visiting Scholar at a number of institutions such as the Program on Negotiation at Harvard Law School. He holds a PhD in law from the University of Heidelberg, where he serves as a lecturer for IP law and is the recipient of several academic achievement awards.

India (Chapter 6)

Justice Madan B. Lokur (ret.), a graduate of Delhi University, was enrolled as a lawyer in 1977 and, in 1997, was designated a Senior Advocate. He was appointed Additional Solicitor General of India and a Judge of the Delhi High Court (1999). His judicial appointments include Acting Chief Justice of the Delhi High Court, Chief Justice of the Gauhati and Andhra Pradesh High Courts, the Supreme Court of India (2012–2018) and the Supreme Court of Fiji (2019). Justice Lokur served as: chairperson of the Supreme Court Mediation & Conciliation Project Committee; judge of the Supreme Court E-Committee for the computerization of the Indian courts; a one-man committee to improve the working of homes and organizations under the Juvenile Justice Act and Rules; and Executive Chairman of the Supreme Court Legal Services Committee and National Legal Services Authority. Currently, he has a professional chamber practice and is an independent arbitrator.

Justice Gautam Patel was appointed a judge of the Bombay High Court in 2013. Before taking judicial office, he practiced civil, commercial law and environmental law at the Bombay High Court and in the Supreme Court. In 2015, he was one of the three persons from India cited among the 50 most influential persons in IP law by *Managing IP*. *For nearly three years, he handled the bulk of the intellectual property work in the Bombay High Court and has delivered judgments on copyright, trademark, designs and patent law.*

Justice Manmohan Singh (ret.) was the Chairman of the Intellectual Property Appellate Board in New Delhi until his retirement in 2019. He was appointed judge of the High Court of Delhi in 2008 and served until his retirement in 2016. Justice Singh began his career as an advocate in 1980 and practiced trademark, copyright, and patent matters in the Delhi High Court and Supreme Court of India. He has attended many national and international seminars and presented a number of papers on intellectual property issues.

Justice Prathiba M. Singh was elevated as Permanent Judge of the High Court of Delhi in 2017. She joined the Bar in 1991 and appeared before the Supreme Court of India, High Court of Delhi, Telecom Disputes Settlement and Appellate Tribunal (TDSAT), IP Appellate Board (IPAB), and Indian Patent Office. Her advisory work includes streamlining the Copyright Office (*amicus curiae*, High Court of Delhi), streamlining patent examination processes (member, High-Level Committee), and intellectual property legislative amendments (Parliamentary Committees). Her honors include awards for best IP lawyer, Managing IP's Asia Women in Business Law Award, and the 30 Most Powerful Business Women in India in 2018. After obtaining her LLB from the University Law College, Bangalore, Justice Singh received her LLM (ODASSS scholarship) from the University of Cambridge, where the Prathiba M. Singh Scholarship for LLM students was created in 2013. She serves on their Circle of Advisors for India.

Japan (Chapter 7)

Mr. Jonathan Dobinson is an Australian lawyer and adjunct researcher at the Research Center for the Legal System of Intellectual Property, Waseda University, Tokyo. He obtained Bachelor of Arts and Bachelor of Law degrees from the University of Wollongong, Australia; a Master's degree in intellectual property from Hongik University, Republic of Korea; and is admitted as

a lawyer in Australia. For over 25 years, he has provided legal policy, communications, and international relations advice to organizations in Australia and Asia, including as a senior lawyer, director of research and director of communications for Australian government agencies; as a consultant to Republic of Korea government agencies; and as a project manager, researcher, and editor for Japanese universities. His publications include *History of Design and Design Law: An International and Interdisciplinary Perspective* (Springer 2022), as a co-editor and co-author.

Mr. Makoto Hattori was admitted to the Japanese Bar and joined Abe, Ikubo & Katayama in 1998. In 2001, he was seconded to the Intellectual Property Policy Office in the Ministry of Economy, Trade and Industry (METI). From 2002 to 2004, after completing an LLM at the University of Pennsylvania Law School, he worked as a visiting researcher at the Max Planck Institute for Intellectual Property and Competition Law. He was admitted to the New York Bar in 2003. Mr. Hattori's areas of expertise include litigation and contracts concerning patents, copyright, trademarks, and unfair competition law. His other roles include adjunct instructor at the Graduate School of Science and Technology, Keio University, from 2007 to 2018; visiting professor at the Graduate School of Law, Kobe University, since 2016; and Chairperson of the Intellectual Property Center of the Japan Federation of Bar Associations (JFBA) in 2021.

Ms. Izumi Hayashi is a founding partner of Sakurazaka Law Offices. She graduated from Waseda University Faculty of Law, and after passing the bar exam in 1983, worked as a public prosecutor before registering as an attorney with the Tokyo Bar Association. After working at a Tokyo-based law firm with an international practice and a U.S. law firm in San Francisco, she was a partner at Eitai Sogo Law Office (Tokyo) from 1993 to 2014. Ms. Hayashi has served as the President of the Japan Intellectual Property Arbitration Center (2011–2012) and the Chairperson of the Intellectual Property Committee of the Japan Federation of Bar Associations (2013–2014). She is also the Executive Director of IP Lawyers Network Japan, an outside director of several listed companies, a member of the Regulatory Reform Council of the Cabinet Office, and a member of the Intellectual Property Strategy Headquarters of the Cabinet Office.

Ms. Mami Hino is a Japanese patent attorney and a partner at Abe Ikubo & Katayama. She is admitted to practice in New York and has represented the world's leading technology companies for many years in litigation and transactions. Ms. Hino's practice is focused on invalidity trials and resultant IP High Court appeals, cross-border infringement litigation, strategic patent prosecution, client counseling, and opinions. Due to her background as a registered pharmacist, Ms. Hino has extensive experience representing innovative pharmaceutical companies to protect their patents, including by filing patent term extension applications, defending patents in invalidity trials and IP High Court appeals, and filing preliminary injunction requests and patent infringement suits against generic drug companies. She obtained a Bachelor of Science degree in pharmaceutical sciences from Kyoto University and a JD from Seton Hall University School of Law.

Mr. Yoshinori Horigome is a founding partner of Sakurazaka Law Offices. He has extensive experience advising on intellectual property matters, including patent, copyright, trademark and unfair competition law. He also practices in the areas of corporate and commercial law (specifically with respect to employment and contract law issues) as well as litigation. Mr. Horigome has represented various companies and individuals in Japan in a variety of industries, including trading, computer software, communications, chemicals, construction and art. He has a Bachelor of Mathematics from the Tokyo Institute of Technology, one of Japan's most prestigious national universities of science, and holds an LLM degree from Duke University School of Law (2004).

Mr. Eiji Katayama is an experienced practitioner of patent litigation in Japan. He received a Bachelor of Engineering from Kyoto University in 1973 and a Bachelor of Law from Kobe University in 1982. He joined Abe, Ikubo & Katayama in 1984 and has been a partner since 1991. He is admitted to practice in Japan and in New York. He has worked with the pharmaceutical industry and represented clients in many patent infringement cases concerning various technical fields. Mr. Katayama has served as President of the International Association for the Protection of Intellectual Property (AIPPI) Japan, the Chairman of the Intellectual Property Committee of the Japan Bar Association, and the President of the Tokyo IP American Inns of Court. He is a professor at the Munich Intellectual Property Law Center (MIPLC) where he teaches Japanese patent law.

Judge Takafumi Kokubu graduated from the Faculty of Law, University of Kyoto. He served as a judge of the Tokyo District Court (Intellectual Property Division, 2005–2007) and of the Intellectual Property High Court (2019–2020). Since 2020, he has been the Presiding Judge of the Intellectual Property Division of the Tokyo District Court and a member of the Trademark System Subcommittee of the Ministry of Economy, Trade and Industry (METI). While serving as a judge, he was posted to Hanoi, Viet Nam, as a long-term expert on the Japan International Cooperation Agency project and assisted the legal and judicial development of Viet Nam for two years.

Mr. Toru Matsuoka graduated from the University of Tokyo and joined the Japan Patent Office (JPO) in 2003. From 2003 to 2022, he worked in various roles, including Patent Examiner and Administrative Patent Judge in the field of Polymer chemistry, Electrochemistry, Biotechnology; Deputy Director, Legislative Affairs Office (Patent Act, etc.); Deputy Director, Examination Standards Office (Patent Examination Guidelines etc.); and Deputy Director, Trial and Appeal Division. Since April 2022, he has been the Associate Managing Examiner, Material Processing Division, and has been responsible for examination management issues in the JPO.

Professor Christoph Rademacher is at Waseda University School of Law. He teaches graduate- and undergraduate-level courses in the field of business law and intellectual property law, in both Japanese and English. His research focuses on the protection of technical innovation by means of patents and other rights. His publications include *Patent Enforcement in the USA, Germany and Japan* (Oxford University Press, 2015) as a co-author; *Japanese Design Law and Practice* (Wolters Kluwer, 2021); and *History of Design and Design Law: An International and Interdisciplinary Perspective* (Springer, 2022) as a co-editor and co-author. He was the recipient of the 2019 Waseda University Research Award for High-Impact Publications. He is admitted to practice in New York and in the Republic of Ireland. He obtained his first degree in business and law and his doctorate degree in law from the University of Siegen, Germany, and an LLM from Stanford Law School.

Ms. Yuriko Sagara studied at the University of Tokyo Faculty of Law (LLB) and the Legal Training Institute, and on graduation passed the Japanese Bar Examination. She went on to be admitted to the New York State Bar after additional studies at Duke University School of Law. Ms. Sagara has been a partner at Nakamura & Partners since 2013. She has experience in a wide variety of intellectual property legal areas, especially intellectual property litigation and contracts. She is a member of various organizations and committees, such as the Intellectual Property Center of the Japan Federation of Bar Associations (JFBA), the Copyright Law Association of Japan, the Japan Trademark Association, and the Asia Patent Attorneys Association, among others. She has also served as a panelist at the Judicial Symposium on Intellectual Property several times.

Mr. Yasufumi Shiroyama is a partner at Anderson Mori & Tomotsune, a general practice law firm in Tokyo comprising over 420 lawyers and patent attorneys. He graduated from the University of Tokyo, Faculty of Law in 1992 and was admitted to the bar in 1994. He also obtained an LLM from University of California Davis Law School. Mr. Shiroyama has focused on domestic and global intellectual property dispute resolution in various forms, including patent, trademark, copyright and trade secrets. His practice also includes the transactional aspects of intellectual property, such as licensing and assignment. In addition, from 2004 to 2022, Mr. Shiroyama taught courses, including on intellectual property law, at the University of Tokyo School of Law, and in 2017, he served as Chairperson of the Intellectual Property Committee of the Japan Federation of Bar Associations (JFBA).

Chief Judge Ryuichi Shitara (ret.) graduated from the Faculty of Law, University of Tokyo. He served as a judge of the Tokyo District Court (Intellectual Property Division, 1979–1983, 1986–1990, 1993–1997) and Tokyo High Court (Intellectual Property Division, 2001–2004). From 2004 to 2007, Judge Shitara was the Presiding Judge of the Intellectual Property Division of the Tokyo District Court, and from 2011 to 2014, Presiding Judge of the Tokyo High Court and the Intellectual Property High Court. From 2014 to 2017, he served as Chief Judge of the Intellectual Property High Court. While serving as Presiding Judge and Chief Judge, he adjudicated four Grand Panel cases, including the famous standard essential patent and doctrine of equivalents cases. After retiring from the Court, he was an attorney-at-law (Mori Hamada & Matsumoto, 2017–2018) and is currently Joint Partner & Chairman (SOEI Patent & Law Firm, from 2018–present).

Judge Aya Takahashi graduated from the Faculty of Law, University of Tokyo, and holds an LLM from Harvard Law School. She served as a judge of the Tokyo District Court (Intellectual Property Division) from 2013 to 2016, and as a judge of the Intellectual Property High Court from 2018 to 2021. During her time at the Intellectual Property High Court, she served as a member of the panel in a Grand Panel case concerning the calculation of the amount of damages in patent infringement cases. Judge Takahashi currently serves as a presiding judge of the medical division of the Sendai District Court.

Mr. Hideki Takaishi is an attorney at law and patent attorney at Nakamura & Partners (since 2002) and focuses on industrial property rights law, trademark law, design law, unfair competition prevention law, copyright law, antimonopoly law (antitrust), contract law, joint development and development consignment, corporate legal affairs and international transaction law. He graduated from the Faculty of Engineering at the Tokyo Institute of Technology and went on to complete his graduate studies there. Later, he studied at the Duke University School of Law, where, upon completion of his program, he passed the California Bar Exam. He also passed the U.S. Patent Exam. Mr. Takaishi is a member of various domestic and international organizations, including the International Association for the Protection of Intellectual Property (AIPPI) Japan, the Japan Academic Society for Ventures and Entrepreneurs (JASVE), and Japan Customs as an expert advisor.

Judge Koichi Tanaka graduated from the Faculty of Law, University of Tokyo. He was appointed a judge of the Tokyo District Court in 1995 and later as a judge of the Tokyo District Court (Intellectual Property Division) (2000–2003 and 2012–2013) and the Intellectual Property High Court (2006–2009). From 2013 to 2017, he was a Judicial Research Official of the Supreme Court (Civil/Intellectual Property). From 2019 to 2022, Judge Tanaka was the Presiding Judge of the Intellectual Property Division of the Tokyo District Court. He has adjudicated cases at the Tokyo High Court (Civil Division), Morioka District/Family Court, Saku Branch of Nagano District/Family Court and Naha Family/District Court. He was a visiting scholar at the State Court of New Jersey, United States of America (7 months) and the Max Planck Institute in Germany (6 months).

Mr. Koichi Tsujii graduated from the Faculty of Law, Chuo University (1979) and Cornell Law School (LLM, 1989). He is admitted to the bar in Japan and the State of New York. He has experience in a wide range of intellectual property areas, including patents, trademarks, copyright, and unfair competition, and he represents clients in matters relating to the enforcement of intellectual property rights. In particular, he has a wide range of experience in international patent litigation. Mr. Tsujii has been a partner at Nakamura & Partners since 1993. Since June 2019, he has been the President of the International Association for the Protection of Intellectual Property (AIPPI) Japan; and since October 2020, he has been a member of the Intellectual Property Mediation Panel appointed by the Tokyo District Court.

Mr. Masayuki Yamanouchi is a partner at Anderson Mori & Tomotsune, a general practice law firm in Tokyo comprising over 420 lawyers and patent attorneys. He holds a Master's degree in science, and specializes in intellectual property matters and legal issues relating to cutting-edge technologies. Mr. Yamanouchi has been engaged in a number of patent infringement lawsuits and other intellectual property related matters for more than ten years. His main focus is the pharmaceutical industry, patent infringement actions, licensing negotiations, joint development projects and technology transfer projects. He has expertise and experience in other forms of intellectual property, including trademarks, copyright and trade secrets. In addition, with his experience in the U.S. (both at a law school and at a law firm focusing on patent matters), Mr. Yamanouchi provides advice to clients involved in patent lawsuits in the U.S.

Mr. Takashi Yamashita joined the Japan Patent Office (JPO) in 1988 after obtaining a Master's degree in science in physics from the University of Tokyo. He worked as a Patent Examiner and Administrative Patent Judge in technological fields such as physics, optics, and semiconductors. He has also worked on various policy issues and international affairs projects related to intellectual property, including patent law revisions, and WIPO and WTO negotiations. Mr. Yamashita for WIPO as Director of Patent Cooperation Treaty International Cooperation from 2010 to 2013. Afterwards, he took on various roles at the JPO: Senior Director, Applied Optics Division; Director, Trial and Appeal Division; Director General, Patent Examination Department in Electronics and ICT; and Director General, Trial and Appeal Department. He now works as a patent attorney after leaving the JPO in 2021.

Republic of Korea (Chapter 8)

Mr. Sang-Wook Han is a senior attorney at Kim & Chang. He is one of the most experienced intellectual property lawyers in the Republic of Korea. For over thirty years, Mr. Han has advised multinational companies in worldwide patent disputes, IP portfolio management and major licensing negotiations. His expertise has been repeatedly recognized by Chambers, Who's Who Legal and Managing Intellectual Property. He served as the president of the Korean Intellectual Property Lawyers Association and was a member of the National Intellectual Property Committee. He co-authored "Future of Intellectual Property Right" with Professor Nobuhiro Nakayama (published in the Republic of Korea and Japan in 2011). Mr. Han earned an LLB and an LLM from Seoul National University, as well as an LLM from Harvard Law School. He is a member of the Korean Bar and the New York Bar.

Judge Kwangnam Kim is currently at the Seoul High Court and was at the Patent Court until early 2021. During his years at the Patent Court, he also served as the Director of the International IP Law Research Center. He first took the bench in 2010 at the Daegu District Court and then the Suwon District Court. Judge Kim earned a Bachelor's degree in law from Yonsei University and received an LLM Certificate in Law & Technology from Berkeley Law School. He also did fellowships as a visiting judge in the California Superior Court and the U.S. District Court for the Northern District of California. His published articles include *The Challenges and Innovation of Patent Law in the AI Era* (2021). He currently serves in the advisory committee of the Korean Intellectual Property Office.

Judge Kyuhong Lee is a Presiding Judge of the Seoul High Court. After taking the bench in 1995, he served as a judge at the Seoul High Court (Intellectual Property Division) and as a Presiding Judge at the Patent Court, among others. He also worked as a constitutional researcher at the Constitutional Court and taught judges at the Judicial Research and Training Institutes. He received two Bachelor's degrees (Economics and Law) and his PhD in Intellectual Property Law from Yonsei University. He was a visiting scholar at the University of New Hampshire Franklin Pierce Law Center. Judge Lee served as the Chairman of Korea Patent Law Society. He authored *Korean Business Law* (IP chapter; published in the U.S. in 2010); *Copyright and Infringement* (2016) and articles, such as "A Review on the Environmental Right, Science & Technology and Patent System in Ecological Transition" (2021).

Ms. Unjung Park has mainly practiced intellectual property and product liability laws since joining Kim & Chang in 2022. She was previously a senior researcher at the International IP Law Research Center of the Patent Court, where she co-authored comparative research papers on indirect patent infringement and selection invention, and a Korean-English IP Law Dictionary. She published articles, such as "Evidencing Consumer Perception with Surveys" (2021) and "Revisiting Inventive Step Standard of Selection Inventions" (2022). Ms. Park received a JD from George Washington University Law School, an LLM from American University, and a BA in Economics from Yonsei University. She is a member of the New York Bar.

United Kingdom (Chapter 9)

Lord Justice Colin Birss was appointed as a judge of the Court of Appeal of England and Wales and as Deputy Head of Civil Justice in 2021. Lord Justice Birss was called to the Bar in 1990 and practiced in intellectual property law. In 2010 he became the judge of what is now the Intellectual Property Enterprise Court (IPEC) and in 2013 was appointed to the High Court.

Mr. Andrew Bowler is joint head of patent litigation at Bristows LLP in London. He has acted for clients in intellectual property disputes for 25 years at first instance, in the Court of Appeal and before the Supreme Court. Mr. Bowler's cases have covered a wide range of technologies, including complex mechanical and FMCG products, pharmaceuticals, mobile phones, automobiles, electronics and medical devices. He also frequently coordinates cross-border patent litigation. Mr. Bowler is often asked to comment and lecture on intellectual property issues and is a regular speaker at international conferences on strategic considerations for European and international patent litigation.

Mr. Brian Cordery is a partner at Bristows. Since qualifying in 1996, Mr. Cordery has worked almost exclusively in the field of life sciences patent litigation, mainly for originators. Since 2001, Brian has authored an annual review of U.K. patent cases which is published in the CIPA Journal. Mr. Cordery lectures on patent litigation on the post-graduate diploma in intellectual property law and practice run by Oxford University and he presently sits on the Exam Board for this diploma. Prior to joining Bristows, Mr. Cordery studied law at Oxford University.

Ms. Anna Edwards-Stuart has a degree in Natural Sciences from the University of Cambridge and a doctorate in molecular biology from the University of Oxford. She was called to the Bar of England and Wales in 2002 and has practiced in intellectual property law in chambers at 11 South Square, Gray's Inn, London since then. In 2019 she was appointed standing counsel to the U.K. Comptroller-General of Patents, Designs and Trade Marks.

Ms. Alice Hart was called to the Bar of England and Wales by the Inner Temple in 2018 and has practiced at Three New Square Chambers since 2019. Her practice spans all areas of intellectual property law, with a focus on patents. She has a First class degree in Biochemistry from the University of Oxford, and legal qualifications from City University London.

Ms. Roisin Higgins KC is a U.K. advocate, member of the Scottish Faculty of Advocates and a door tenant of 8 New Square, barristers' chambers in London. She is a specialist in intellectual property and commercial law.

Ms. Morag Macdonald has been a partner in the Intellectual Property group of International law firm Bird & Bird since 1989. In that role she has conducted patent litigation in the UK and coordinated multi-jurisdictional patent litigation for over 30 years. She was co-head of the international IP group of Bird & Bird from 1995 to the end of 2022. She has a Master's degree in Mathematics, Physics and Law from Newnham College Cambridge.

Madam Justice Denise McBride is a member of the Judiciary of Northern Ireland and a High Court Judge, dealing with civil, commercial and chancery matters, amongst other things.

Mr. Michael Tappin KC was awarded a first class degree in chemistry and a doctorate in biochemistry from the University of Oxford. He was called to the Bar of England and Wales in 1991 and has practiced in intellectual property law in chambers at 8 New Square, Lincoln's Inn, London since 1992. Between 2003 and 2008, he was standing counsel to the U.K. Comptroller-General of Patents, Designs and Trade Marks. He took silk in 2009. In 2018, he was called to the Bar of Ireland and in 2021, was appointed as a Deputy Judge of the High Court of England and Wales.

United States of America (Chapter 10)

Professor Peter S. Menell is the Koret Professor of Law at University of California Berkeley School of Law, co-founder and Director of the Berkeley Center for Law & Technology, and co-founder and Faculty Director of the Berkeley Judicial Institute. Professor Menell earned his SB from MIT, his PhD (economics) from Stanford University, and his JD from Harvard Law School. Professor Menell joined the law faculty at the University of California at Berkeley in 1990, where his research and teaching have focused on intellectual property law. Professor Menell has authored more than 100 articles and 15 books, including leading casebooks and intellectual property treatises.

Ms. Allison A. Schmitt is a Fellow at the University of California, Berkeley School of Law and the inaugural Director of the Berkeley Center for Law and Technology's Life Sciences Project. After graduating with a JD from Berkeley Law in 2015, Ms. Schmitt clerked for Judge Stanley R. Chesler at the United States District Court for the District of New Jersey, and Judge Kathleen M. O'Malley at the United States Court of Appeals for the Federal Circuit. She spent several years in private practice, focused on life science patent litigation, counseling and policy matters. Ms. Schmitt holds a PhD in chemistry from Duke University.

The Boards of Appeal of the European Patent Office (Chapter 11)

Mr. Frédéric Bostedt is a legally qualified member of the Boards of Appeal of the European Patent Office. Previously, he was the Head of the Legal Research Service of the Boards of Appeal. Before joining the Boards of Appeal, he worked as a lawyer for the European Court of Human Rights in Strasbourg, France, and for the International Criminal Tribunal for the former Yugoslavia in The Hague, Netherlands. He obtained law degrees in Germany (Ludwig-Maximilians-University of Munich), New Zealand (LLM, Wellington Victoria University) and France (Master 2 Droits de l'homme, Université de Strasbourg), and a doctorate degree in Germany (Dr. jur.).

Mr. Nikolaus Obrovski was appointed as a legally qualified member of the European Patent Office Boards of Appeal in 2020. He entered the Austrian judiciary in 2003, working at various courts, including the Intellectual Property Division of the Commercial Court of Vienna, and received a lifetime appointment as a federal Austrian judge in 2008. Mr. Obrovski also worked as an Intellectual Property Attaché at the Permanent Representation of Austria to the European Union, as a legal adviser on intellectual property at the European Commission in Brussels, and as a lawyer in the Legal Services of the European Patent Office Boards of Appeal. Mr. Obrovski earned Master's degrees in law and applied economics.

About the World Intellectual Property Organization (WIPO)

World Intellectual Property Organization (WIPO) is the global forum for intellectual property (IP) services, policy, information and cooperation. It is a self-funding agency of the United Nations with 193 Member States.

WIPO's mission is to lead the development of a balanced and effective international IP system that enables innovation and creativity for the benefit of all. WIPO's mandate, governing bodies and procedures are set out in the WIPO Convention, which established WIPO in 1967.

WIPO helps governments, businesses and society realize the benefits of IP. WIPO provides:

- a policy forum to shape balanced international IP rules for a changing world;
- global services to protect IP across borders and to resolve disputes;
- technical infrastructure to connect IP systems and share knowledge;
- cooperation and capacity- building programs to enable all countries to use IP for economic, social and cultural development; and
- a world reference source of IP information.

About the WIPO Judicial Institute and the WIPO IP and Innovation Ecosystems Sector

The WIPO Judicial Institute works to strengthen judiciaries as part of the IP and innovation ecosystems in Member States. It fosters transnational dialogue on IP for the judicial community; conducts targeted studies to promote in-depth understanding of topics of relevance to the global IP judiciary; provides education and resources for IP judges, and through WIPO Lex, contributes to the wider availability of legal knowledge on IP-related treaties, laws, and judicial decisions.

The WIPO Judicial Institute is part of WIPO's IP and Innovation Ecosystems Sector, which supports Member States in developing their IP and innovation ecosystems to drive economic growth.

The IP and Innovation Ecosystems Sector's work also includes:

- support for researchers, innovators, and enterprises, including small and medium-sized enterprises (SMEs);
- IP commercialization for business growth;
- emergence of IP as an asset class;
- development of advisory expertise on national IP strategies;
- economic analysis on the role IP plays in promoting innovation and creativity; and
- strengthening alternative dispute resolution and the services provided by the Arbitration and Mediation Center.

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Foreword by WIPO

Patents tell the story of innovation today and the technologies of tomorrow. As well as serving as powerful catalysts for technology dissemination, business growth and economic development, their dynamic nature means that patent laws and jurisprudence must keep pace with ever-changing circumstances.

Given this, patent disputes often take on a larger significance, requiring courts to be the final arbiters of issues with far-reaching legal, social and economic implications. Countries are therefore exploring new ways of enhancing the judicial administration of patent disputes, particularly through the introduction or amendment of specialized rules and practices.

Despite this, few publications address the procedural aspects of patent case management from a judge's perspective. *An International Guide to Patent Case Management for Judges* aims to fill this gap. This is a comprehensive, accessible and practical guide, organized around the different stages of patent litigation in ten patent-heavy jurisdictions, but with applicability around the world.

We are grateful to our esteemed group of authors comprising renowned judges, practitioners and academics for their outstanding contributions. We would also like to thank the 360 judges from almost 90 countries and six regional courts who participated in the 2021 WIPO Intellectual Property Judges Forum, under the special theme of judicial patent case management and which greatly informed the evolution of this *Guide*.

In particular, Judge Jeremy Fogel, Executive Director of the Berkeley Judicial Institute and Professor Peter Menell at Berkeley Law, have been formidable partners in conceiving and steering this document to publication. Their expertise and insight into judicial education and research have ensured that this is a meaningful and functional resource for judges worldwide.

WIPO's vision is for a balanced and effective approach to intellectual property that works for everyone, everywhere. This requires that the judicial structures around IP respond effectively to the needs of each Member State while, at the same time, working harmoniously across territorial boundaries to engage with the demands of an interconnected and increasingly digital world. We hope that the *Guide* will promote greater knowledge, as well as the cross-pollination of judicial approaches and best practices as we work towards this important global goal.

Daren Tang

Director General

World Intellectual Property Organization

Foreword by Berkeley Judicial Institute

Since 2018, the World Intellectual Property Organization (WIPO) has convened leading jurists representing more than eighty countries to discuss trends and developments in the law resulting from the increasingly global reach of innovation. WIPO's annual IP Judges Forum has provided invaluable opportunities both for the exchange of views and for the development of collaborative relationships across countries and legal systems.

An International Guide to Patent Case Management for Judges, which owes its existence directly to dialogues that began at the WIPO IP Judges Forum, is the culmination of a remarkable effort on the part of prominent judges, noted practitioners, and leading legal academics representing ten dynamic and unique legal systems. Each national team has worked diligently to make the infrastructure and inner workings of its system for adjudication of patent cases transparent and understandable to those who otherwise might not be familiar with them. My University of California at Berkeley School of Law colleague, Professor Peter Menell, played a key role in framing the project. He and Berkeley Center for Law & Technology Fellow Allison Schmitt produced the U.S. chapter and supported the overall effort. Eun-Joo Min and her colleagues at WIPO have done a masterful job of editing the final product and organizing it in a way that makes it easily accessible to users.

Technological innovation is vital to economic and social progress, public health, and environmental protection. Patent protection plays a central role in promoting innovation, and as the impacts of innovation have increasingly transcended international boundaries, the need for a working familiarity with different national and sub-national patent systems has increased. Although their work often is the subject of international treaties and cooperation agreements, national patent systems, judicial institutions, and enforcement regimes vary significantly across jurisdictions. The overarching goals of this project are to enhance understanding of international patent protection, share best practices for improving patent case management, and promote international comity.

Among other things, the *Guide* explores, catalogs, and compares how major industrial nations structure their patent enforcement regimes: whether and to what extent judicial officers who adjudicate patent cases are required or expected to have relevant subject matter or technical expertise; whether determinations of patent validity and infringement are the subject of bifurcated or unified proceedings; the process and legal effect of judicial claim construction; and each system's approach to pre-hearing investigation, including the role of the parties in presenting and arguing the significance of references to prior art. Each country has its own way of addressing these questions, and each has a wealth of experience and perspective as to which this *Guide* is intended to provide substantive and procedural details.

Each constituency within the scope of WIPO's broader mandate will find value in these pages. Judges who preside over cases involving parallel proceedings in different countries will have access to more specific and practical information about how matters are handled in other jurisdictions and may bear upon their own adjudicative process. Lawyers and litigants considering the strategic interplay among cases in multiple countries involving the same technology will gain additional insight into the frameworks of the legal systems involved. And scholars who study patent litigation and its impact on technology and innovation generally will find experience-based detail not readily apparent in the language of statutes and treatises.

The *Guide* is also intended as a source of good ideas as nations and the global community struggle to address many of the greatest challenges, from climate change to pandemics. Even as each country has chosen to promote innovation in a manner that reflects its own history, culture and values, the success of WIPO's annual IP Judges Forum has shown that judges truly value learning from each other. The wisdom and insights shared by the national teams that have contributed to this publication are likely to affect their international colleagues in subtle yet important ways.

Jeremy Fogel

Executive Director, Berkeley Judicial Institute
Former Judge and Director of the Federal Judicial Center
in the United States of America

Chapter 1

Introduction

Author:
Eun-Joo Min

1.1 Patent litigation and the role of the justice system

The patent system encourages and protects inventions to develop and improve technologies in support of innovation. For this instrumental purpose of the patent system to be fully realized, patentees must be able to enforce their rights and alleged infringers must be allowed to effectively defend their rights, including by challenging a patent's validity. This requires not only a robust legal framework for patents, but also a fair and effective justice system that provides predictability for market structures and contributes to the broad balance of public considerations envisaged in the patent system.

Any justice system for patents will be molded by the technical specificities of patent disputes, which are frequently characterized by complex procedures that address dynamic technological facts. Patent disputes commonly raise questions relating to the boundaries of innovative activities such as patentable subject matter, as well as infringing activities enabled by technologies unforeseen at the time the patent was filed. In addition, they may involve high economic stakes – resulting in business-altering injunctions or multi-million dollar damages – and require significant legal costs, amid uncertain outcome. Furthermore, the resolution of patent disputes may have a wider impact beyond the parties involved, altering the direction of an industry and carrying broader economic and social consequences. Courts are called upon to calibrate the balance between the public interest in effectively enforcing patent monopolies to advance the innovation-promoting purposes of the patent system, and other public interests, such as ensuring fair competition in the marketplace by preventing anticompetitive practices, or ensuring fair access to life-saving technologies in the domain of public health.

The ramifications of patent litigation may even extend beyond the territorial boundaries of the patent rights and of the court's jurisdiction. In today's global market, where technology products are enforced by a web of territorial patent rights, it is not unusual for major patent disputes to be litigated in multiple jurisdictions. For example, a party who is a defendant to an infringement suit in one jurisdiction may initiate a patent revocation action or seek a declaration of non-infringement in a different jurisdiction, or a deep-pocketed patentee may initiate legal battles in multiple countries, leading to a series of lawsuits in various courts around the world. Courts are then asked to resolve complex disputes that involve non-domestic elements – such as foreign parties, foreign IP rights, or infringing acts committed in foreign territories – and at times manage interaction with parallel proceedings in foreign courts.

While the time and cost of patent proceedings will vary considerably among different countries, the complexities of patent proceedings frequently result in longer and more costly legal processes in comparison to other types of litigation. The high cost of patent litigation is a concern not only for parties – whose unequal access to financial resources may lead to suboptimal litigation outcomes – but also for judicial systems, with the absorption of their public resources raising concerns about fair delivery of justice.

Given these unique aspects of patent litigation, judicial authorities in many countries are working to streamline patent proceedings with the overarching goal of providing justice expeditiously, with reasonable costs, and ensuring that parties, in particular small and medium-sized enterprises, can present their case and participate in the proceedings efficiently and fairly.

1.1.1 *An International Guide to Patent Case Management for Judges* – its purpose

An International Guide to Patent Case Management for Judges highlights the significant progress achieved in patent case management in ten patent-heavy jurisdictions, through structural reform of courts, statutory revisions, and implementation of innovative court practices, supported by judicial education.

As globalization leads to the homogenization of legal problems, it is hoped that this publication will serve as a source of inspiration and comparison for procedural innovation and improved solutions in patent case management, and contribute to coherence and mutual respect between distinct legal systems and judicial structures across different countries. At the same time, the approaches described in the *Guide* reveal that the unique characteristics of patent case management by courts have intimate connections with the normative, structural and

socio-economic background of each jurisdiction, and any consideration for enhanced efficiencies in judicial case management must take into account the unique characteristics of that jurisdiction.

Each chapter of the *Guide* offers an overview of the patent system in the respective jurisdiction, including information on the role of patent offices in evaluating and deciding on patent validity, as well as the judicial structures responsible for resolving patent disputes. Thereafter, the chapters are structured based on the different stages of patent litigation in civil infringement cases. These stages include early case management, claim construction, provisional measures, discovery and gathering of information, summary judgment, evidence, trial and remedies. The chapters detail the procedures and practices of case management, while integrating pertinent patent law doctrines.

The features of judicial case management grow out of distinctive legal traditions (common law or civil law), court structures (unified or bifurcated for patent validity and infringement questions), levels of specialization and division of competence (general or specialized courts, at first or appellate instance), the use of discovery (general or limited) or experts (court or party-appointed), and the type and qualification of adjudicators (legally or technically qualified judges or juries). Some chapters address issues that are particularly relevant in their jurisdiction, such as case management for standard essential patents,¹ pharmaceutical patents,² compulsory licenses,³ or criminal liability for patent infringement.⁴

The features addressed by the *Guide* are summarized briefly below.

1.2 Patent systems and patent institutions

1.2.1 Overview of the patent system

Every chapter starts with a general description of the patent system in that jurisdiction, including the origins of the patent law and the types of patents protected under each respective regime. In addition to invention patents protected in all jurisdictions, some countries provide protection for so-called “minor inventions,” frequently in the form of utility models, which may play a significant role in the local innovation system.⁵ This *Guide* primarily addresses judicial proceedings for invention patents. The chapters also note, where available, mechanisms to extend the scope of protection for an improvement introduced in the object of the invention,⁶ or duration of (invention) patent rights to compensate for the long time required to obtain regulatory approval.⁷

While in most countries patent rights are obtained through national processes and these national rights are mutually independent, in some jurisdictions patent rights may also come into existence through regional patent instruments that facilitate protection across borders. This feature gives rise to unique considerations in judicial proceedings.⁸

1.2.2 Patent offices and administrative proceedings

Patent offices are responsible for administering the patent system, including the examination and grant of patents. Frequently, these offices administer opposition or third party observation mechanisms that make it possible for third parties to intervene in the patent examination process before the grant of a patent, as well as administrative revocation and invalidation mechanisms to challenge a patent after its grant.⁹ Some jurisdictions also make available procedures to oppose a patent for a limited time after grant, in addition to other ways of challenging validity. Post-grant mechanisms usually allow for the correction of the scope of the patent by way of limiting the claims. In some jurisdictions, patent offices determine applications for declarations of non-infringement; claims of infringement (with the agreement of the parties); entitlement to

1 See sections 4.5.4; and 10.13.1.

2 See sections 3.11.2; 4.5.5; and 10.13.2.

3 See sections 2.10.1; 3.11.1; 5.11.1; and 6.10.1.

4 See sections 3.10; 4.9; 8.9; and 10.11.

5 See sections 3.1.2; 4.3.1; 7.1.2; and 8.2.1. See also sections 2.2.1 and 4.8.

6 E.g., section 3.1.2.

7 E.g., section 9.1.1.2.

8 See sections 5.1.2; 9.1.1.3; and chapter 11.

9 See sections 2.2.2; 3.3.3; 5.2; 6.2.2; 7.2.3; 8.2.2; 9.2; 10.2.2; and 11.2.2.

patents; compensation for employees; and licenses, including compulsory licenses.¹⁰ Some patent offices also operate opinion schemes through which they issue nonbinding, advisory opinions on various patent issues including infringement, patentability or (in)sufficiency of disclosure.¹¹

While the design of such patent office administrative review mechanisms differs in each of the reviewed jurisdictions, the common objective is to provide an effective and cost-efficient means of increasing patent quality and resolving patent disputes, particularly those related to validity. These mechanisms serve as an alternative to potentially lengthy and costly judicial proceedings.

1.2.3 Judicial institutions and their specialization

The judicial structure responsible for handling patent disputes is discussed in the ten chapters, highlighting the specialized elements specific to patents.¹² The nature of judicial specialization varies among countries and takes different forms, including specialized divisions within existing civil or commercial courts,¹³ stand-alone courts specialized in patent cases,¹⁴ or a combination of both.¹⁵ Specialization can occur at the first instance or appeal level, and the final decision is often made by a non-specialized higher court.¹⁶ In some jurisdictions, there is no specific assignment of patent cases, but courts can attain specialization through the concentration of patent cases.¹⁷

The type and profile of the adjudicators who make up the court may also differ, including legally qualified or technically qualified¹⁸ judges, as well as juries.¹⁹ Some jurisdictions are based on a judicial career system, where judges normally embark on a judicial career early on and, at times, with mandatory rotation between courts on a regular basis.²⁰ In those jurisdictions, efforts will be made for patent cases to secure judges who have studied science or engineering and provide regular training on technical matters. In other jurisdictions, judges are recruited from the ranks of qualified lawyers who have practiced patent law for a substantial time.²¹

Many jurisdictions have court personnel who are well-versed in technology and in analyzing technical evidence to support the judges during the pendency of the patent case.²² Their role may range from recording evidence when manufacturing processes need to be ascertained to inquiring about and reporting upon any question of fact or opinion. They do not address questions of interpretation of the law and do not assist the judge in deciding the case. In some jurisdictions, courts have the authority to appoint advisers who can assist the court in understanding the technology and the technical evidence presented in the case.²³

1.3 Patent infringement proceedings and case management

The fundamental characteristics of patent proceedings are predominantly shaped by the jurisdiction's legal system, specifically whether it operates under a common law or civil law system.

In civil law systems, proceedings tend to be front-loaded, prioritizing written pleadings submitted by parties before the trial, and allowing the court to have a good understanding of the facts and arguments when they start examining the case.²⁴ Experts may be appointed by the court or by the parties. The appointment of experts by the parties is less frequent in these systems, and cross-examination of party-appointed experts found in trial-based systems tends to be an exception.²⁵ Conversely, in a common law system, evidence is generally presented during trial

10 E.g., section 9.2.

11 See sections 7.2.4.6; and 9.2.

12 See sections 2.3; 3.3; 4.1.5; 5.3; 6.3; 7.3; 8.3; 9.3; 10.3; and 11.3.

13 See sections 2.3.1; 6.3.1; and 6.11.1.3.

14 See chapter 11.

15 See sections 3.3.1; 4.1.5; 5.3.1; 7.3.1; 8.3.2; 9.3.1; 9.9; and 10.3.2.

16 But see sections 4.1.5; and 5.9.2.

17 See section 3.2.2.

18 See sections 5.3.1; and 11.3.2.2.

19 See section 10.3.2.

20 E.g., sections 5.6.3.2; 7.3.2.2; and 8.3.2.3.

21 E.g., sections 2.3.1.2; 6.3.1.3; and 9.3.1.2.

22 See sections 2.3.1.1; 4.6.3.1; 6.6.4.2.1; 7.3.2.2.3; and 8.3.1.4.

23 See sections 9.3.1.2 and 10.3.2.

24 See chapters 3, 4, 5, 7, 8 and 11.

25 See sections 5.6.1; and 11.6.6.

through party-appointed experts witnesses, with less importance placed on written pleadings.²⁶ In these systems, the initial statements from parties may be brief and the details of the allegations are usually developed as the discovery process progresses. Trial can take several days or longer, depending on the amount and complexity of evidence, and pre-trial discovery and motions (e.g., motions to dismiss or summary judgment motions) are significant components of the process.

In the jurisdictions reviewed in this *Guide*, the conduct of civil patent proceedings is governed by civil procedure law. However, the analysis of patent claims and allegedly infringing products or processes involved in patent litigation requires specific approaches and considerations. These are typically addressed through specialized sets of procedural rules, or court practice directions or notes that supplement civil procedure rules.²⁷ These specialized rules and practices govern the conduct of patent cases by setting out judicial assignment procedures and bench composition. They also address the key principles of case management applied by the court, which include early case management, specified deadlines for parties' contentions, claim construction, the use of court- or party-appointed experts, the extent of discovery or any dispositive, and pre-trial motion practice. These specialized rules and practices will have a direct impact on the accessibility of justice, as well as the potential for forum shopping by parties.

In addition to patent-specific rules, there are general rules that have particular influence in patent disputes. The modernization of court systems, supported by the active utilization of technology, has improved the efficiency of patent trials. The enhanced case management tools include electronic case filing systems that allow exchange and storage of court documents, briefs and digital evidence, as well as speedy check of the case statuses; videoconferencing facilities for remote participation in hearings; and remote recording of evidence.²⁸ Some jurisdictions have also introduced the option of making oral arguments or submitting documents in a foreign language, such as English, to enhance access to justice for foreign parties in response to the growing number of patent cases involving foreign parties.²⁹

The diversity of approaches in the different phases of patent proceedings is described below.

1.3.1 Early case management

In some jurisdictions, litigation is primarily conducted through the exchange of written briefs, with directions on matters of procedure given through written communication, and case management hearings with the participation of parties held only in exceptional cases.³⁰ In some jurisdictions, the court may issue a communication prior to oral proceedings, drawing attention to matters of particular significance, which may include a preliminary opinion on the decisive points in their communications.³¹

In other jurisdictions, there is a strong emphasis on early case management with active participation of parties, including through the holding of case management hearings.³² These hearings are intended for the court to identify and narrow down disputed issues of fact and law, to establish a timetable for the entire case (including party submissions and their maximum length, the discovery and production of evidence, or the production of a technical primer), and to consider alternative dispute resolution options. Through these hearings, the judge can gain an early understanding of the patents and claims, the technology involved, and potential defenses and counterclaims. The judge may also address issues such as the use of technical advisors, protective orders, and parallel proceedings.

1.3.2 Claim construction

The methods of interpreting patent claims, a crucial aspect of patent litigation, vary across jurisdictions. Claim construction, typically considered a question of law rather than fact, involves

²⁶ See chapters 2, 6, 9 and 10.

²⁷ See sections 2.6.1; 4.1.3; 6.11.1.3; 7.3; 9.1.1.2; and 10.6.6.1.

²⁸ See sections 4.1.5; 6.6.7; 8.6.1.2; 9.6.13.1.2; and 11.6.2.1.

²⁹ See section 8.3.2.2.

³⁰ See chapters 3, 4, 5, 7, 8 and 11, in particular sections 3.6.3; 8.6.5; and 11.6.5.3.

³¹ See section 11.6.8.2.

³² See sections 2.6.3; 6.6.3; 9.6.4; and 10.6.6.

examining a claim's wording, as well as the descriptions and drawings, from the point of view of a person having ordinary skill in the art. In some jurisdictions, patent prosecution files may be part of claim construction,³³ while they are inadmissible in other jurisdictions.³⁴ Separate hearings specifically for claim construction (known as *Markman* hearings) are common practice in some jurisdictions,³⁵ whereas in others they are not used.³⁶

1.3.3 Preliminary injunction

Different jurisdictions offer various forms of provisional measures in patent disputes, including freezing assets, search and seizure orders, and temporary restraining orders. A frequently requested type of provisional measure is a preliminary injunction, whose availability and utilization will vary based on the jurisdiction and the individual case circumstances.

The factors considered by courts in weighing the grant of a preliminary injunction differ among jurisdictions.³⁷ These factors can consist of variations of the following components: the establishment of a *prima facie* case or likelihood of success on the merits; the balance of convenience; whether damages are an adequate remedy or specific legal interest for preliminary relief; the potential for irreparable or imminent harm to either party if the injunction is granted or denied; and urgency. Some jurisdictions will also assess the impact of the injunction on the public interest. Most jurisdictions require the applicant to post a security deposit (also known as an undertaking for damages) to compensate the enjoined party if the injunction is later reversed or lifted.³⁸ While *ex parte* preliminary relief may be granted in patent cases, it is typically rare due to the often significant potential consequences for the defendant to be considered in balancing the right of the defendant to be heard, as well as the technical and legal complexity of these disputes, which often require input from the defendant.³⁹

In some jurisdictions, the courts having jurisdiction over the merits exercise jurisdiction over preliminary injunction trials.⁴⁰ In others, actions for preliminary relief take the form of a separate and independent action from the action for permanent relief. As such, the action for preliminary relief can be filed with a court other than the court with jurisdiction over the permanent relief, and a ruling on permanent relief does not automatically affect a prior ruling on preliminary relief. Any preliminary injunction will therefore need to be set aside by a court within the framework of the proceedings for preliminary relief.⁴¹

Adjudicating an application for a preliminary injunction in patent cases can be challenging. Preliminary injunction proceedings frequently involve urgency and must take into account parties' need to carry on with their business in the meantime; whereas establishing a strong likelihood of success on the merits often requires a thorough examination of the evidence, including all substantive and technical issues that will ultimately be presented at trial.

1.3.4 Gathering of information

Another area of significant difference in the judicial case management of patent disputes is the gathering of information, and in particular the extent of discovery (or disclosure), a court-mandated process that requires one party to litigation to disclose documents (or the existence of documents) to another.

All jurisdictions under review in this *Guide* apply the fundamental principle that requires the parties to present all relevant facts and evidence pertaining to their substantive claims. In patent infringement disputes, the party alleging infringement of their patent must make all necessary factual allegations and, when contested, must take recourse to evidence. Patentees will frequently seek to "test buy" the allegedly infringing device to procure necessary information for the infringement action.⁴²

33 See sections 4.3.1; and 8.5.1.

34 See section 5.5.1.

35 E.g., section 10.6.6.2.

36 E.g., section 5.6.1.

37 See sections 2.6.4; 3.7.1; 4.6.2; 5.6.5; 6.6.4; 7.6.4; 8.6.6; 9.6.5; and 10.6.7.

38 See sections 2.6.4.3; 3.7.1; 7.6.4.4; 8.6.6; 9.6.5.1; and 10.6.7.1.3; see also 4.6.2.2.4; 5.6.5.3; and 6.6.4.

39 See sections 5.6.5.2; 10.6.7.2; see also 6.6.4.

40 See sections 7.6.4; and 8.6.2.1.3.

41 See section 5.6.5.1.

42 E.g., section 5.6.6.2.

In some jurisdictions, there is no general discovery system. Rather, there are limited and specific instruments for the plaintiff to discover facts that are not publicly available. These include inspection systems, where alleged infringers will be ordered to submit for inspection documents or items that lie within their control, including by acquiescing to inspection by a neutral technical expert.⁴³

On the other hand, other jurisdictions provide broad and extensive pre-trial discovery to enable the parties to obtain full knowledge of critical facts and issues bearing on the litigation.⁴⁴ In these jurisdictions, discovery in patent cases is rendered especially complex by the wide range of claims and defenses, the high stakes, the sensitivity of trade secrets and the extensive use of electronic record-keeping by companies. This requires courts to carefully supervise and balance the discovery process, moderating the extent and costs of discovery based on the nature and scope of the case, the amount of any damages sought, and how the case compares to other patent cases. In some jurisdictions, procedures alternative to discovery are introduced to promote a more targeted process, with parties accused of infringement having the option to provide a full and accurate product and process description of the alleged infringing product or process, rather than requiring the disclosure of documents.⁴⁵ An approach favoring general discovery will necessitate the establishment of a comprehensive system of attorney–client privileges and protective orders in those jurisdictions.

The variation in approaches among countries has led some parties to seek the provisions of jurisdictions with broader discovery mechanisms, which permit a court in that jurisdiction to order individuals within its district to provide testimony or produce documents for use in a foreign proceeding that has limited discovery mechanisms.⁴⁶

1.3.5 Summary proceedings

In some jurisdictions, the court may grant summary judgment in favor of an applicant if there is no reasonable prospect of the respondent defending the proceeding. The court may dismiss a proceeding if there is no reasonable prospect of the patentee successfully prosecuting the case; or if there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.⁴⁷ In other jurisdictions, summary proceedings do not apply to patent actions, which are governed only by the ordinary procedure.⁴⁸

1.3.6 Evidence

The role and utilization of experts in patent cases differ among jurisdictions, with reliance on expert opinion varying in light of the sitting judge's specialized expertise. Some jurisdictions rarely use technical experts and only consider court-appointed experts as formal sources of evidence.⁴⁹ Party-appointed experts and their reports are not considered as evidence, but as submissions by the respective parties – albeit with some additional weight. In other jurisdictions, expert testimony plays a critical role, with courts frequently relying on expert opinions, and both party-appointed and court-appointed experts are treated as expert evidence.⁵⁰ Some countries actively use the procedure of “hot-tubbing,” where multiple party-appointed experts participate in a conclave of experts to prepare a joint report prior to the trial, and give their evidence concurrently at trial rather than through serial cross-examination.⁵¹

1.3.7 Technology tutorials and technology briefing sessions

Courts in different jurisdictions have diverse mechanisms to assist the court to better understand the disputed technology. These mechanisms include technical explanatory sessions, with or without parties depending on the complexity of the technology; technology tutorials; or agreed technical primers produced by the parties that contain the basic undisputed technology relevant

43 See sections 5.6.6.3; 7.6.5.2; and 8.6.7.

44 E.g., section 10.6.8.

45 See sections 2.6.5.4; and 9.6.7; see also section 6.6.5.

46 See section 5.6.6.4.

47 See sections 2.6.6; 6.6.6; and 10.6.9.

48 E.g., section 3.6.4.

49 See sections 3.6.5.1; 4.6.3.3; and 5.6.7.1; see also sections 8.6.7.5; and 11.6.6.

50 E.g., section 10.6.10.1.

51 See sections 2.4.2; and 6.6.5.

to the case; or statements of agreed (and disputed) common general knowledge, intended to set out where the parties agree (and disagree) on aspects of the common general knowledge.⁵²

1.3.8 Confidentiality

All jurisdictions under review operate under the principle of open justice. This must be balanced with other considerations, including confidentiality issues which can arise in patent litigation through the disclosure of confidential information to the opposing party during the proceedings. Appropriately preserving confidentiality is an important element of judicial case management, and protective measures may include: requiring a party that receives confidential documents to use those documents only for the purposes of the litigation; requiring an undertaking restricting the use and disclosure of the confidential documents; allowing only the patentee's lawyers, but not the patentee, to attend the inspection; issuing protective orders such as prohibiting the expert and the lawyers from discussing the findings from an inspection with others, including the patentee; and the court sitting in private (known as sitting *in camera*).⁵³

1.3.9 Trial

The following ten chapters in this *Guide* highlight the differences in the structure and importance of trial in patent litigation across different jurisdictions. In some jurisdictions, trials in patent infringement cases are limited to document analysis and the court usually does not hear from parties or witnesses.⁵⁴ In these countries, the court may hold a technical briefing session in the form of an oral hearing. In other jurisdictions, trials can last for several days or weeks, with multiple trial sessions held at intervals over several months, where the parties submit briefs and evidence, and the court holds technology review sessions and evidence or witness examination.⁵⁵ In some jurisdictions, there is only one dense hearing,⁵⁶ while in others, the court may order separate trials for separate issues or claims.⁵⁷

1.3.10 Mediation

In many jurisdictions, the courts will explore possibilities for settlement and encourage parties to attend mediation as a standard part of patent proceedings. Mediators may be appointed by the court or chosen by the parties.⁵⁸ In some jurisdictions, the court may render a ruling of settlement recommendation *ex officio* during the pendency of the action, in order to fairly settle the case by taking account of the parties' interests and all other circumstances.⁵⁹ In others, mediation agreements may be approved by a judge and have the effect of an instrument enforceable in court.⁶⁰

1.3.11 Remedies

Turning to the final stage of patent proceedings, the typical remedies for patent infringement include: a final injunction restraining the defendant from infringing the patent; damages in respect of the infringement; an account of the profits derived from the infringement; an order for the infringer to deliver up or destroy any patent infringing products; publication of the decision; and revocation of the patent or a declaration that the patent is valid. Each jurisdiction may give priority to different forms of remedies: some may prioritize injunctive relief, while others may place more significance on monetary damages.

In all jurisdictions in this *Guide*, patentees may seek a permanent injunction as a final remedy. There are varying approaches as to the discretion of the court in ordering injunctions. Some jurisdictions will grant a permanent injunction automatically following a finding of infringement and validity in favor of the patentee, without weighing the interests of the parties or affected

52 See sections 2.6.8; 8.6.8.1; 9.6.9; and 10.6.11.

53 See sections 2.6.9; 3.6.6; 5.6.8; 8.6.9; 9.6.10; 10.6.12; and 11.6.7.

54 E.g., section 7.6.6.

55 See sections 8.6.10; 9.6.13; 10.6.13; and 11.6.8.

56 E.g., section 5.6.9.

57 E.g., sections 8.6.10; 9.6.5.2; 10.6.13.1.1.

58 See sections 2.6.10; 3.6.7; 6.6.9; 7.6.8; 8.6.11; 9.6.17; and 10.6.4.

59 E.g., section 8.6.11.2.3.

60 E.g., section 3.6.7.

third parties. In these jurisdictions, only in very exceptional circumstances will a claim for injunctive relief be denied for disproportionality.⁶¹ In other jurisdictions, courts retain broad discretion to deny injunctions, and the threshold for obtaining injunctive relief is higher.⁶² Generally speaking, an injunction is only available as long as the patent is in force.⁶³ However, in some cases, the courts may grant an injunction that extends beyond the lifetime of a patent in order to prevent the defendant from continuing to benefit from the infringement established during the patent's lifetime.⁶⁴

It is common practice to award compensatory damages. In many jurisdictions,⁶⁵ courts adopt a two-stage process separating the questions of liability from the amount of relief, so that the court first determines liability and thereafter considers the calculation of monetary damages in follow-up proceedings.

The methods for damage calculation include: the patentee's lost sales or profits resulting from the infringement; profit made by the infringer as a result of the infringement; or a reasonable royalty rate, estimated as the amount a licensee would pay for the rights to the invention.⁶⁶ In some jurisdictions, where there is insufficient evidence to prove the facts necessary to establish the amount of damages under the three aforementioned methods, courts can exercise discretion to calculate the amount based on the overall arguments and the evidence provided⁶⁷ or rely on statutory compensation rates.⁶⁸

Some, but not all, jurisdictions provide for enhanced damages in civil patent actions, also referred to as "punitive" or "exemplary" damages or "additional damages."⁶⁹ The amounts typically range between three times the amount of compensatory damage up to five times the damage caused. Enhanced damages may be awarded in cases of flagrant, intentional and serious infringement, to deter similar future infringements. Among jurisdictions that provide for enhanced damages, there is varying practice. Courts in some jurisdictions frequently order enhanced damages, while in others, although they are provided for by law, they are rarely used, if at all.

Some jurisdictions also provide for an account of profits, requiring an infringer to account for and disgorge the profits it made through the infringing conduct. In these jurisdictions, the patentee has the choice of seeking financial compensation by way of either damages or an account of profits, but not both.⁷⁰

In addition to injunctive relief and damages, there are other remedies available to patent litigants, such as recall, removal, destruction or delivery up of patent infringing products.⁷¹ These may be ordered in addition to an injunction in cases of direct infringement, but typically not for indirect infringement. The infringing goods need to be in the territory of the court's jurisdiction. In some jurisdictions, the claim for destruction is available even when the patent has expired during the course of litigation, since the infringer must not benefit from infringing acts committed in the past. The duty to destroy may also be fulfilled by design-arounds to avoid the use of the patent.

Another remedy available in some jurisdictions is the publication of the court decision by placing advertisements in newspapers or any other periodical publication, intended to reinstate the plaintiff's goodwill or reputation.⁷²

Finally, disputes challenging a patent's validity may result in an order for the revocation of the patent, or a certificate of contested validity when the challenge is unsuccessful.⁷³

61 E.g., section 5.7.1.

62 E.g., sections 6.7.1, 9.7.1 and 10.7.1.

63 See section 5.7.1.

64 See section 9.7.1.

65 See sections 2.7.2; 3.7.2; 5.7.4; and 7.7.2.

66 See sections 2.7.2; 3.7.2; 4.4.2; 5.7.4; 6.7.2; 7.7.2; 8.7.4; 9.7.2; and 10.7.2.

67 See section 8.7.4.2.

68 See section 4.4.2.1.

69 See sections 2.7.2; 3.7.2.1; 4.4.3, 6.7.2; 8.7.4; and 10.7.2.

70 See sections 2.7.2.2; 5.7.3; 6.7.2; and 9.7.2.

71 See sections 2.7.3; and 5.7.2.

72 See sections 7.1; and 9.7.3.

73 See sections 9.7.3.1 and 9.7.3.2.

1.3.12 Costs

Patent litigation costs include court fees, lawyers' fees, and expenses for witnesses or experts. In general, each party is responsible for its own costs. However, in some jurisdictions, costs may be awarded to the prevailing party in order to discourage unnecessary and vexatious litigation.⁷⁴

1.4 Interplay of multiple patent proceedings in different fora

Patents may be reviewed and enforced in different fora, at times comprising a complex and overlapping mandate of institutions.

Most countries provide for mechanisms to appeal a decision of the patent office to a judicial court. However, this is not an appeal in the strict sense and the court adjudicates the case *de novo*, unconfined by the arguments or evidence that were presented before the patent office.

In some jurisdictions, administrative proceedings challenging patent validity may run in parallel with civil judicial proceedings.⁷⁵ For example, a defendant in a patent infringement lawsuit can assert the defense of invalidity in court, and in parallel request an administrative proceeding for invalidation before the patent office. The patentee may also attempt to correct the patent claims during patent infringement proceedings. Different scenarios then become possible. The infringement court may rule to: stay court proceedings pending review by the patent office;⁷⁶ continue with the infringement proceedings, with the possibility of a finding of infringement for a patent that is subsequently invalidated by the patent office; or dismiss the lawsuit without waiting for the final result of the administrative case.⁷⁷ In these circumstances, the *erga omnes* effect of the patent office's decision invalidates the patent for all parties including those involved in parallel judicial proceedings.⁷⁸ Accordingly, a decision by the patent office finding the patent to be invalid will result in the court deciding the patent infringement dispute to decide against the patentee. On the other hand, if the patent office finds the patent to be valid, a defense of invalidity may not be asserted in court on the same grounds.

In these situations, some jurisdictions have mechanisms to promote efficiency and coherence, to ensure that the claims made during the patent granting or invalidation procedure and the claims made during the infringement proceedings do not differ.⁷⁹

In some jurisdictions, proceedings may occur in parallel in different courts, with parties opting for the more convenient forum and seeking to take advantage of the distinctive characteristics of various court venues. For instance, a patentee may file a patent infringement lawsuit in one court and the accused infringer may initiate a declaratory judgment action in another court. Then, the first case filed (usually the infringement action) will have priority and the second case may be transferred, postponed, or dismissed.⁸⁰

Importantly, parallel judicial proceedings may be inherent to and envisaged through the design of the patent litigation system. One of the most important differences in patent litigation systems is whether they follow a unified or a bifurcated approach to handling patent validity and infringement cases. In a unified system, both validity and infringement are heard by the same court at the same time, with the defense of invalidity usually raised by the defendant to an infringement claim by the patentee. In a bifurcated system, the validity and infringement cases are dealt with in separate venues, and the defense of invalidity may not be accepted in infringement proceedings.⁸¹ The alleged infringer will concentrate on non-infringement defenses in one court while potentially seeking to invalidate the patent in another court. In these bifurcated systems, the infringement court has the discretion to stay infringement proceedings in view of a nullity action pending before another court.⁸² In some bifurcated systems, the

74 See sections 2.7.4; 5.7.7; 6.7.4; 9.7.4; 9.7.5; 10.7.3; and 11.6.10.

75 E.g., 7.5.3.2; and 10.3.3.

76 See section 10.3.3.3.

77 See section 4.3.2.7.

78 See section 7.5.3.2.

79 See sections 4.3.2.4; 7.5.2; and 10.2.2.4.5.

80 See sections 2.4; and 10.3.3.1.

81 See section 5.3.2.

82 See sections 3.4; and 5.3.2.

infringement court may, however, rule on nullity of a patent when it is raised as an incidental question, in which case the nullity ruling would only have *inter partes* effect.⁸³

In some jurisdictions, other quasi-judicial institutions may also play an adjudicatory role, for example, investigating complaints alleging patent infringement with respect to imported goods.⁸⁴ Additionally, in jurisdictions with regional patents, national courts and regional courts may hold parallel proceedings, which can sometimes lead to differing outcomes and require specific management.⁸⁵

Finally, parallel proceedings can take place between actions initiated in different countries. If a party receives an unfavorable decision in a court of one country, they may attempt to change the outcome of the dispute through an action in another country. A party may also request an order from a court perceived as more favorable, prohibiting the other party from commencing or continuing a parallel proceeding in another jurisdiction, known as an anti-suit injunction. This type of injunction is becoming more frequently utilized in certain patent disputes.

These scenarios, in which patent disputes occur concurrently in two or more venues, either within the same or with a foreign jurisdiction, necessitate the existence of rules and practices that govern their interactions.

83 See section 3.4.

84 See sections 5.10; 7.9; and 10.12.

85 See section 9.1.1.3.

Chapter 2

Australia

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2.1 Overview of the patent system

2.1.1 Evolution of the patent system

The Australian patent system is governed by the Patents Act 1990 (Cth). The origins of that Act, and the Australian patent system generally, can be traced back to English law and the Statute of Monopolies 1623.¹

Section 6 of the Statute of Monopolies 1623 (which is expressly referred to in Section 18(1)(a) of the Patents Act 1990 (Cth)) provided an exception for patents to the general position that monopolies were contrary to law. Section 6 described the carve-out for patentable inventions in the following terms:

Provided alsoe That any Declaracion before mencioned shall not extend to any tres Patents and Graunt of Privilege for the tearme of fowerteene yeares or under, hereafter to be made of the sole working or makinge of any manner of new Manufactures within this Realme, to the true and first Inventor and Inventors of such Manufactures, which others at the tyme of makinge such tres Patents and Graunts shall not use, soe as alsoe they be not contrary to the Lawe nor mischievous to the State, by raisinge prices of Commodities at home, or hurt of Trade, or generallie inconvenient.

In broad terms, the Statute of Monopolies restricted the grant of patents to “any manner of new Manufactures” to the true and first inventor and imposed a limited term of 14 years for the grant of letters patent. By the early 1600s, the grant of letters patent and other privileges by the Crown had become controversial: they were being used merely as a convenient way for the Crown to raise revenue and were being granted in respect of products and processes that were already being used in the public domain, thereby harming trade and commerce.² The Statute of Monopolies sought to address these concerns by, among other things, limiting the grant of letters patent to particular subject matter (namely, any manner of *new* manufacture) and restricting the grant to a limited term. Following the passing of the Statute of Monopolies, the patent system in England continued to develop, eventually leading to the enactment of the Patents, Designs and Trade Marks Act 1883 (U.K.), which is the basis of the modern patent system in the United Kingdom and in Commonwealth countries.

Prior to Federation in 1901, each Australian colony had its own Patents Act that was modeled on the Patents, Designs and Trade Marks Act 1883 (U.K.). These Acts continued in force until the Australian Parliament enacted the Patents Act 1903 (Cth) pursuant to its legislative powers under Section 51(xviii) of the Commonwealth Constitution. The Patents Act 1903 (Cth) was replaced by Patents Act 1952 (Cth), which was in turn replaced by the Patents Act 1990 (Cth). The Patents Act 1990 (Cth), together with the Patents Regulations 1991 (Cth), came into operation on May 1, 1991.

The Patents Act 1990 (Cth) provides protection for two types of patents in Australia: the “standard” patent and the “innovation” patent. The main difference is that “innovation” patents have a shorter term of eight years and involve the lower threshold of an “innovative” step when compared to the prior art basis (as opposed to the “inventive step” required for standard patents).

The Patents Act 1990 (Cth) has undergone amendment several times since its enactment, including the reforms introduced by the Intellectual Property Laws Amendment (Raising the Bar) Act 2012 (Cth). These reforms apply largely in relation to patents requested for examination after April 15, 2013, and are designed to raise patentability thresholds to align more closely with the laws of overseas jurisdictions. More recently, the Australian Government passed the Intellectual Property Laws Amendment (Productivity Commission Response Part 1 and Other Measures) Act 2018 (Cth). These reforms involved, among other things, the introduction of an objects clause into the Patents Act 1990 (Cth), the phasing out of Australia’s “innovation” patent system³ and amendments to the compulsory licensing scheme in Chapter 12 of the Patents Act 1990 (Cth).

1 21 Jac. 1, ch. 3.

2 See generally Justine Pila, “The Common Law Invention in its Original Form,” 3 *Intellect. Prop. Q.* 209 (2001); *Darcy v. Allin* (1602) 77 ER 120; Mark J Davison *et al.*, *Australian Intellectual Property Law* (3rd ed. 2016) 426–29.

3 As discussed below, the Patents Act 1990 (Cth) provides protection for two types of patents: “standard” patents and “innovation” patents. Under the Intellectual Property Laws Amendment (Productivity Commission Response Part 1 and Other Measures) Act 2018 (Cth), innovation patents will not be able to be filed from Aug. 26, 2021. Existing innovation patents filed on or before Aug. 25, 2021, however, will continue in force until their expiry.

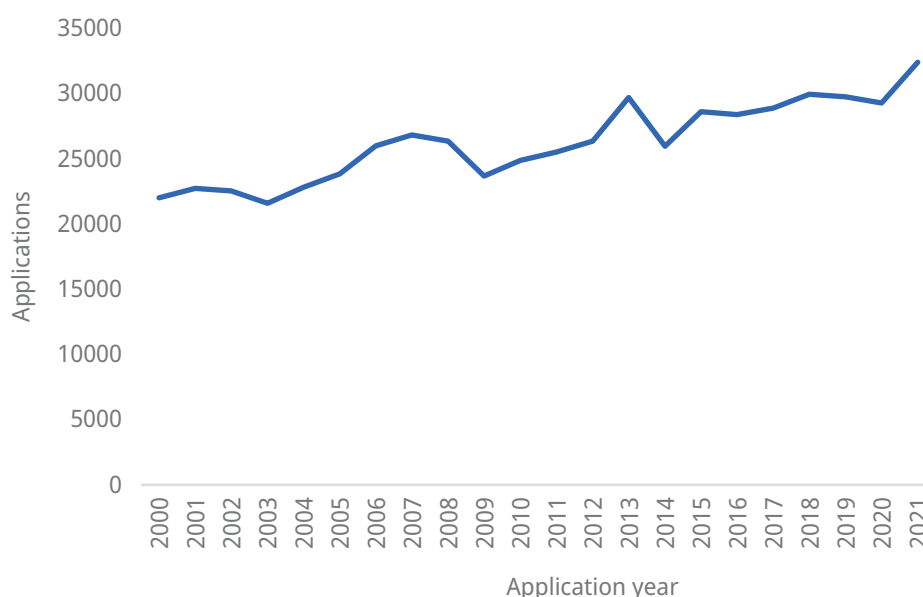
Australia is also signatory to a number of international treaties relating to patent rights, including the Paris Convention for the Protection of Industrial Property,⁴ the Patent Cooperation Treaty,⁵ the Agreement on Trade-Related Aspects of Intellectual Property Rights⁶ and various free trade agreements. Australia's obligations under these treaties in relation to patent rights are reflected in the Patents Act 1990 (Cth).

Patent disputes are determined under the Patents Act 1990 (Cth) as interpreted by the case law that has developed under it, and its predecessor Acts. The development of modern Australian patent law has most closely followed that of the law of the United Kingdom, although there has been a measure of divergence from that law since that country joined the European Patent Convention in 1977. Often, during the course of patent trials, the parties inform the court of developments in the United States, the United Kingdom and Europe.

2.1.2 Patent application trends

Figure 2.1 shows the total number of patent applications (direct and Patent Cooperation Treaty (PCT) national phase entry) filed in Australia from 2000 to 2021.

Figure 2.1 Patent applications filed in Australia, 2000–2021



Source: WIPO IP Statistics Data Center, available at www3.wipo.int/ipstats/index.htm?tab=patent

2.2 Patent institutions and administrative review proceedings

2.2.1 Patent institutions

The Australian patent system is administered by the Australian Patent Office⁷ (which is responsible for the administrative aspects of the patent system, including filing, examination and pre-grant “opposition” proceedings) and the Federal Court of Australia.⁸

As noted above, Australia has recently abolished its second-tier “innovation” patent system, and applications for innovation patents ceased on August 26, 2021. The Australian Patent Office also

4 Paris Convention for the Protection of Industrial Property, March 20, 1883, 828 UNTS 305.

5 Patent Cooperation Treaty, June 19, 1970, 1160 UNTS 231.

6 Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, annex 1C, 1869 UNTS 299.

7 Patents Act 1990 (Cth) s. 205(1). The Australia Patent Office is part of the government agency “IP Australia,” which administers patents, trademarks, designs and plant breeders’ rights (see www.ipaustralia.gov.au).

8 Patents Act 1990 (Cth) s. 154. State or territory supreme courts may hear patent infringement proceedings only to the extent that Constitution permits and so long as the patentee is a resident or has its principal place of business in that state or territory. Patents Act 1990 (Cth) s. 155. In practice, almost all patent disputes are commenced in the Federal Court rather than in the state courts.

facilitates the registration of overseas patent applications in Australia through the Paris Convention and the Patent Cooperation Treaty.

The Federal Court has jurisdiction to hear patent infringement, invalidity, entitlement and related disputes, together with appeals from the Australian Patent Office. It has jurisdiction in a number of other areas of law, including commercial and corporations laws, administrative law, industrial law, federal crime, admiralty and taxation. The Federal Court is located in the capital city of each state and territory, has a specialized panel of judges for patent matters and has a dedicated practice note for intellectual property matters, including patent disputes.⁹

2.2.2 Administrative review proceedings

2.2.2.1 Avenues of review

The Federal Court of Australia is the institution in which the validity of a patent may be challenged. Prior to grant, patents can be opposed in the Australian Patent Office. The available avenues for review of an invalidity determination depend upon the decision-maker, the type of decision and whether the determination was made pre-grant or post-grant.

The Intellectual Property Law Amendment (Raising the Bar) Act 2012 (Cth) made a number of amendments to the Patents Act 1990 (Cth), including the internal grounds of invalidity and examination and opposition procedures in the Patent Office. The present section refers to the law that applies following those changes. However, it is important to be aware that, depending on the date on which an application was filed, an examination was requested, or the application was accepted, it will be necessary to consider the provisions in the Patents Act 1990 (Cth) prior to the amendments.

2.2.2.1.1 Pre-grant – refusal of acceptance

Following examination of a patent, the Commissioner of Patents may refuse to accept a request for a standard patent or specification.¹⁰ The grounds of refusal for invalidity include a failure to comply with the internal requirements for invalidity (including sufficiency, best method and support) and that the invention is not a patentable invention (it is not a manner of manufacture, lacks utility, is not novel or does not involve an inventive step).

The decision of the Commissioner to refuse to accept a patent request or specification may be appealed to the Federal Court of Australia.¹¹

An examiner will issue reports if they reasonably believe that there are grounds of objection to a patent, and an applicant will be provided with opportunities to respond to and overcome the objections until the deadline for acceptance. In practice, most patents lapse rather than being formally refused.

2.2.2.1.2 Pre-grant – opposition

Once acceptance of a standard patent has been advertised, the grant of the patent may be opposed by any person. The notice of opposition must be filed within three months from the date acceptance is published.¹² The grounds on which the grant may be opposed include the internal requirements for invalidity and that the invention is not a patentable invention.¹³

If the Commissioner of Patents is satisfied that a ground of opposition exists on the balance of probabilities, the Commissioner may refuse the patent application.¹⁴ However, the Commissioner must first give the parties a reasonable opportunity to be heard and (where appropriate) allow the applicant an opportunity to amend the specification.

The decision of the Commissioner following an opposition may be appealed to the Federal Court of Australia by either the opponent or the applicant.¹⁵

⁹ See generally www.fedcourt.gov.au/law-and-practice/national-practice-areas/ip

¹⁰ Patents Act 1990 (Cth) s. 49.

¹¹ Patents Act 1990 (Cth) s. 51.

¹² Patent Regulations 1991 (Cth) reg. 5.4.

¹³ Patents Act 1990 (Cth) s. 59.

¹⁴ Patents Act 1990 (Cth) s. 60.

¹⁵ Patents Act 1990 (Cth) s. 60(4).

2.2.2.1.3 Pre-grant and post-grant – reexamination

The Commissioner of Patents may reexamine a standard patent if it has been accepted but not yet granted. The decision to reexamine pre-grant is at the discretion of the Commissioner but may occur, for example, following the identification of new prior art or the receipt of a notice from a third party.¹⁶ Following grant, the Commissioner may reexamine a patent on their own initiative and must reexamine the patent if formally requested to do so by a third party in the approved form or following a direction from a court.¹⁷ However, the Commissioner may not reexamine a patent if court proceedings are pending.

The Commissioner may refuse to grant the patent, or may revoke the patent, if the Commissioner makes an adverse report on reexamination (which includes on invalidity grounds) and is satisfied on the balance of probabilities that there is a lawful ground of objection to the specification.¹⁸ However, the Commissioner must first provide the applicant or patentee an opportunity to respond to the report and be heard and (where appropriate) allow the applicant an opportunity to amend the specification.

The decision of the Commissioner to refuse an application or to revoke the patent following reexamination may be appealed by an applicant to the Federal Court of Australia.¹⁹

A third party that has requested reexamination has no right of appeal of the decision of the Commissioner to the Federal Court. However, the third party may apply to the court for revocation of the patent or may seek judicial review, as discussed in Sections 2.2.2.4 and 2.2.2.5.

2.2.2.2 Claim construction

Allowing for the differences in procedure between them, the process for and the procedures governing claim construction in the Australian Patent Office are generally the same as in the Federal Court of Australia. In particular:

- Claims are generally construed in the Patent Office at the same hearing as that involving whether a patent is valid and ought to be granted.
- Although expert evidence on the meaning that the skilled addressee would give to technical or scientific terms and phrases may be submitted, claim construction is a matter for the Patent Office.

However, the Australian Patent Office only construes a claim in the context of a determination of validity or in claim amendment, not infringement (for a further discussion on claim construction with respect to infringement, see Section 2.5.1).

2.2.2.3 Role of experts

2.2.2.3.1 Australian Patent Office (IP Australia)

Expert evidence may be filed in the Australian Patent Office in the following invalidity proceedings:

- oppositions to the grant of a standard patent;²⁰
- reexamination of an application or granted patent;²¹ or
- Section 27 and 28 submissions.²²

Generally, expert evidence is given by way of declaration under the Patents Regulations.²³ While the Patent Office has the power to require witnesses (including expert witnesses) to give oral evidence at a hearing, such evidence is, in practice, rarely required.²⁴ The rules of evidence do not

¹⁶ Patents Act 1990 (Cth) s. 27.

¹⁷ Patents Act 1990 (Cth) s. 97; Patent Regulations 1991 (Cth) reg. 9.2.

¹⁸ Patents Act 1990 (Cth) ss. 100A, 101.

¹⁹ Patents Act 1990 (Cth) ss. 100(4), 101(4).

²⁰ See, e.g., Patents Act 1990 (Cth) ss. 59, 101M.

²¹ See Patents Act 1990 (Cth) ss. 97, 101G.

²² Pursuant to Sections 27–28 of the Patents Act 1990 (Cth), a person may notify the Commissioner that the person asserts, for reasons stated in the notice, that the invention concerned is not a patentable invention because it does not comply with Section 18(1)(b) or (1A)(b) of the Patents Act 1990 (Cth) (i.e., the invention lacks an inventive or innovative step).

²³ Pursuant to Regulation 22.13 of the Patents Regulations 1991 (Cth), a declaration required or permitted by the Patents Act 1990 (Cth) or Patent Regulations 1991 (Cth) must be in the approved form. Declaration forms in the approved form are available on the IP Australia website at www.ipaustralia.gov.au

²⁴ Patent Regulations 1991 (Cth) reg. 22.12.

apply in the Patent Office. However, greater weight is likely to be given to expert evidence that complies with the rules of evidence on admissibility.

Expert evidence in the Australian Patent Office is generally directed to the following topics:

- claim construction and prior art;
- common general knowledge (CGK); and
- obviousness.

2.2.2.3.2 Claim construction and prior art

While claim construction is ultimately a matter for the Patent Office, the claims are read through the eyes of the skilled addressee in light of the specification as a whole and the CGK before the priority date.²⁵ Expert evidence can assist the Patent Office in placing itself in the position of a person acquainted with the surrounding circumstances as to the state of the art at the time.²⁶ Expert evidence is particularly important where the words used in a patent claim or prior art document have a technical or special meaning in the relevant field.²⁷

2.2.2.3.3 Common general knowledge

The state of the relevant CGK for a patent or pending application is established by evidence from experts in the technical field concerning the extent to which certain information was known and accepted by others in the field.²⁸

2.2.2.3.4 Obviousness

An opinion from an expert as to whether an invention is obvious is unlikely to be helpful. This is because questions of obviousness and inventive step are ultimately for the court or Patent Office to determine, irrespective of the opinion expressed by any number of experts.²⁹

However, where obviousness is sought to be established, it is common for parties to set a design task for an expert representing the person skilled in the art. For example, an expert may be asked to solve the problem identified in the patent or pending application using only information that was CGK at the priority date.

2.2.2.3.5 Hindsight

When briefing an expert to provide evidence in relation to obviousness or inventive step, care must be taken to ensure that the evidence is not tainted by hindsight, either as a result of the witness applying hindsight or from the instructions given to the witness. Accordingly, where obviousness evidence is required, it is generally prudent for those taking the evidence to proceed in the following manner:

1. Prior to providing the expert with the patent specification or any prior art documents, take the witness's evidence of the CGK at the relevant date. It is important to use nonleading questions when taking this evidence.
2. If undertaking a design task, this evidence should be based on the CGK evidence given by the witness in the preceding step and any prior art information (document or act) that may permissibly supplement the CGK pursuant to Section 7(3) of the Patents Act 1990 (Cth).
3. Only after obtaining the evidence in Steps 1 and 2 should the expert be given a copy of the patent-in-suit for the purposes of construction and comparison with the prior art.

2.2.2.4 Appeals to the Federal Court of Australia, Full Court of the Federal Court and High Court of Australia

An appeal from a decision of the Commissioner of Patents (including to refuse acceptance or revoke grant) lies to a single judge of the Federal Court of Australia.³⁰ A party may appeal this decision of a single judge to the Full Court of the Federal Court only with leave.

An appeal from a decision of a state or territory supreme court lies to the Full Court Federal Court.

²⁵ *Jupiters v. Neurizon* (2005) 65 IPR 86, [67(ii)-(iii)]; *Australian Mud Company v. Coretell* (2011) 93 IPR 188, [64]-[68]; *Sachtler v. RE Miller* (2005) 65 IPR 605, [42].

²⁶ *Jupiters*, 65 IPR, [67(ii)]; *Kimberly-Clark v. Arico* (2001) 207 CLR 1, [24].

²⁷ *Kimberly-Clark v. Multigate* (2011) 92 IPR 21, [12], [39]-[42].

²⁸ See, e.g., *Graham Hart (1971) Pty. Ltd. v. SW Hart and Co. Pty. Ltd.* (1978) 141 CLR 305, 330-31.

²⁹ *Minnesota Mining and Manufacturing Co v. Tyco Electronics Pty. Ltd.* (2002) 56 IPR 248.

³⁰ Patents Act 1990 (Cth) ss. 156, 158.

The question of whether leave to appeal to the Full Court should be granted may be decided by a single judge or may be referred to the Full Court. The grant of leave to appeal is discretionary, and relevant factors may include whether the decision is attended with sufficient doubt, whether substantial injustice will result from a refusal to grant leave and whether the appeal involves a question of public importance or of pure law. Where a party has unsuccessfully opposed the grant of a patent twice, there is limited scope for a further appeal.³¹ Conversely, the grant of leave to appeal is more likely where the grant of a patent has been refused, as this would be determinative of the patentee's rights.³²

An appeal from a first-instance court decision on invalidity (such as an application for revocation) lies to the Full Court of the Federal Court.³³ Leave to appeal is not required for a final decision on invalidity.

A party may seek special leave to appeal to the High Court of Australia from a decision of the Full Court. However, the grant of special leave to appeal such a decision is rare.

2.2.2.5 Judicial review and review by the Administrative Appeals Tribunal

The Patent Office is an administrative decision-maker. A person aggrieved by a decision of the Commissioner of Patents that is of an administrative character may therefore seek judicial review in the Federal Court or Federal Circuit Court. The nature of a judicial review is more limited than an appeal and focuses not on the merits of the decision but on the legality of the decision and the processes followed. Grounds of judicial review include that the decision involved a breach of the rules of natural justice, a failure to observe required procedures, the absence of jurisdiction or authority, an improper exercise of power, an error of law or that it was induced or affected by fraud.³⁴

An affected person may also seek a merits review of certain specified decisions of the Commissioner in the Administrative Appeals Tribunal.³⁵ However, this does not include the final decisions of the Commissioner on invalidity that have been discussed in this section.

2.2.2.6 Nature of appeal from an invalidity decision of the Commissioner of Patents

An appeal from a decision of the Commissioner of Patents to the Federal Court of Australia must be filed within 21 days of the date of the decision unless an extension of time is granted.³⁶ The Commissioner is entitled to appear and be heard in any appeal against a decision of the Commissioner.³⁷ However, the Commissioner is not automatically a party to any appeal unless there is no other party opposing the appeal.³⁸

An appeal to the Federal Court from a decision of the Commissioner is not an "appeal" in the strict sense – it is in the Federal Court's original jurisdiction and conducted as a hearing *de novo*.³⁹ This means that the court stands in the shoes of the Commissioner and makes the decision afresh. The court is not confined by the arguments or evidence that were before the Commissioner, including the grounds of invalidity. The court may receive fresh evidence and direct that the proceeding be conducted as it thinks fit.⁴⁰ Evidence that was before the Commissioner may be admitted with leave⁴¹ but must also comply with the general rules of evidence.

The Federal Court may affirm, vary or reverse the decision of the Commissioner and may give any judgment or make any order that, in all the circumstances, it thinks fit.⁴² While the Federal Court is generally confined to the subject matter of the controversy that was before the Commissioner, the court also has the power to direct the amendment of a patent application on an appeal.⁴³

31 *Genetics Institute Inc. v. Kirin-Amgen Inc.* (1999) 92 FCR 106, [23].

32 *Imperial Chemical Industries plc v. EI Dupont de Nemours and Co.* [2002] FCAFC 264.

33 Patents Act 1990 (Cth) ss. 158, 156.

34 *Administrative Decisions (Judicial Review) Act 1977* (Cth) s. 5.

35 Patents Act 1990 (Cth) s. 224; Patent Regulations 1991 (Cth) reg. 22.26.

36 Federal Court Rules 2011 (Cth) rr. 34.24–34.25.

37 Patents Act 1990 (Cth) s. 159.

38 Federal Court Rules 2011 (Cth) r. 34.23.

39 *Commissioner of Patents v. Sherman* (2008) 172 FCR 394, [18] (Heerey, Kenny and Middleton JJ).

40 Patents Act 1990 (Cth) s. 160.

41 Patent Regulations 1991 (Cth) r. 34.31.

42 Patents Act 1990 (Cth) s. 160.

43 *Meat and Livestock Australia Ltd. v. Branhaven LLC* [2020] FCAFC 171, [91]–[93].

2.2.2.7 Innovation patents

This section has focused on the avenues for review of decisions relating to the validity of standard patents. Key differences in relation to the review of invalidity decisions relating to an innovation patent, by contrast, are that an innovation patent is examined only after grant and reexamined or opposed only after certification. Following examination, reexamination or opposition, the Commissioner of Patents may decide to revoke the grant of an innovation patent, including on invalidity grounds.⁴⁴ An appeal lies to the Federal Court of Australia in relation to a decision to revoke an innovation patent. Innovation patents are being phased out, with the last date for filing an application having been August 25, 2021.

2.3 Judicial institutions

2.3.1 Judicial administration structure

2.3.1.1 National judicial structure

Almost all patent infringement and revocation proceedings are heard in the Federal Court of Australia. As a matter of theory, state and territory supreme courts also have jurisdiction to hear such proceedings, although this rarely occurs. Appeals from decisions of the Commissioner of Patents, who is responsible for granting patents under the Patents Act 1990 (Cth), are heard by the Federal Court. All appeals from first-instance infringement and revocation decisions, or from Federal Court decisions made with respect to decisions of the Commissioner, must be heard by the Full Court of the Federal Court.

The Federal Court is composed of a Chief Justice and judges who are appointed from time to time. It is a national court with registries located in each capital city and operates under a policy known as the National Courts Framework. A key feature of the National Courts Framework is the organization of matters filed in the court into national practice areas (NPAs) and subareas. One of the NPAs is Intellectual Property, which has a subarea dedicated to disputes relating to patents and associated statutes. Presently, there are 15 judges who are allocated to the Patents and Associated Statutes subarea of the Intellectual Property NPA. Many of these judges have extensive experience in the conduct of patent trials, as a result either of their work in practice before being appointed to the court or since their appointment. As a general rule, once a case is allocated to a particular judge, that judge retains that case in their docket through the case management, to hearing and judgment.

Individual judges are principally situated in their local registry; however, they are able to hear matters filed in different state or territory registries. Each registry is staffed by registrars and support staff, including lawyers, senior coordinators, client service officers and court officers. In addition to providing operational support to the judges in each state, registrars perform statutory functions assigned to them by the Federal Court of Australia Act 1976 (Cth) and the Federal Court Rules 2011 (Cth). These registrars often have expertise in intellectual property matters, including patents, and provide assistance to judges during the interlocutory phases of case preparation. Where the parties to a patent dispute agree to a mediation being facilitated by a registrar, a registrar with experience in patent cases will frequently be allocated. In addition, registrars will often provide assistance in the preparation of the joint expert report by facilitating the meeting of the experts. Furthermore, disputes relating to the production of documents or costs and other such matters may be delegated to registrars for adjudication. The registries also provide registry services to legal practitioners and members of the public, including by providing information regarding the practices and procedures of the court.

Individual judges of the Federal Court sit at first instance and also as appellate judges. Appeals from decisions of a single judge of the Federal Court, or from decisions of state or territory supreme courts, are heard by the Full Court of the Federal Court, the appellate division of the Federal Court. The Full Court is typically composed of three judges of the Federal Court who are selected for each appeal. Where an appeal is challenging the correctness of a previous decision of the Full Court, an expanded bench of five judges may be constituted.

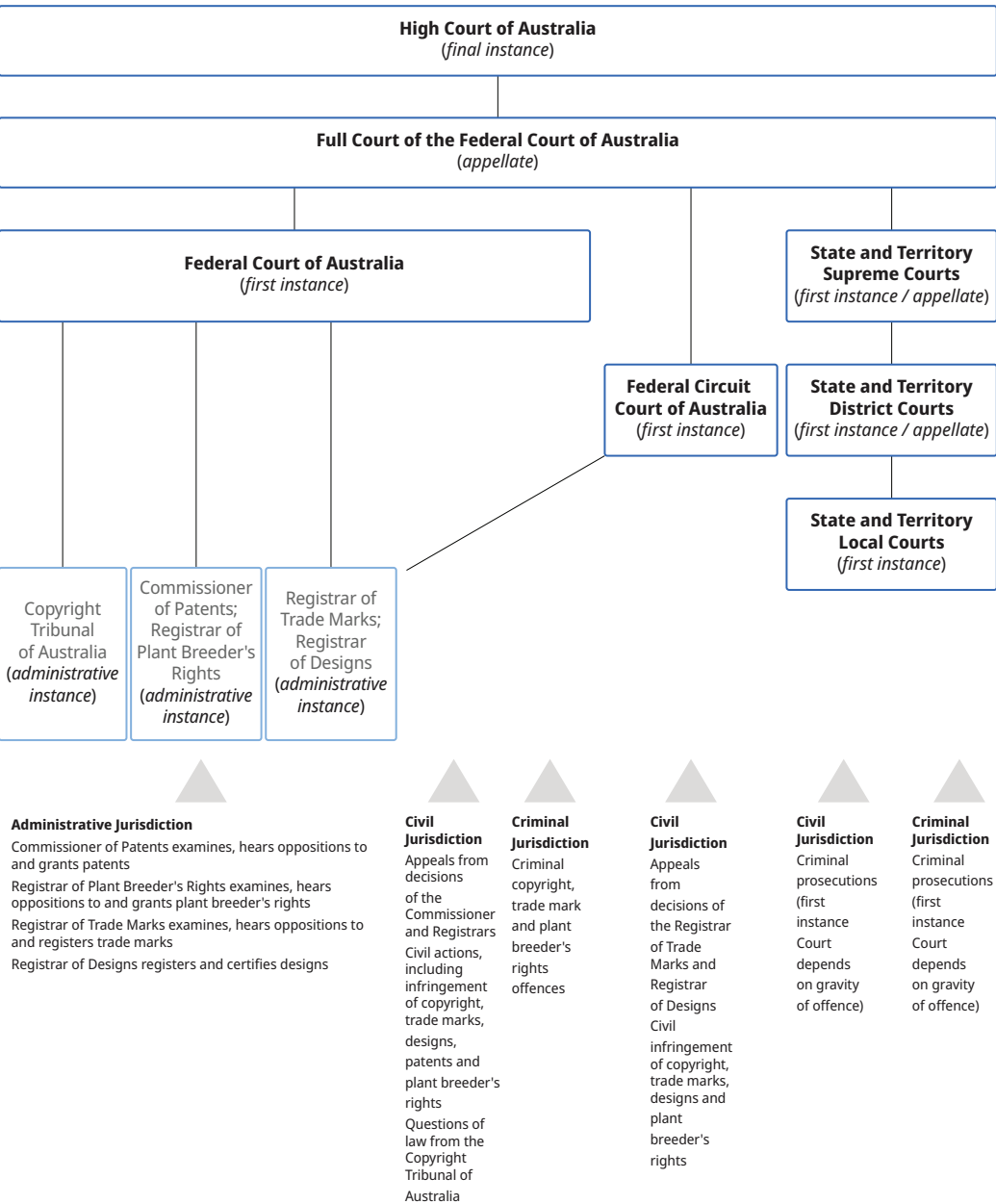
Appeals from the Full Court of the Federal Court are heard by the High Court of Australia. The High Court is a separate court composed of a Chief Justice and six judges. In order to have an appeal

44 Patents Act 1990 (Cth) ss. 101E, 101F, 101J, 101N.

heard by the High Court, parties are required to make an application for special leave to appeal. Special leave applications are determined on the papers or at short contested hearings usually heard by one or two judges of the High Court. If special leave to appeal is granted, the matter will be heard and determined by the Full Court of the High Court, which will usually be composed of between three and seven judges. There is no avenue of appeal beyond the High Court.

Figure 2.2 shows the judicial administration structure in Australia.

Figure 2.2 The judicial administration structure for IP in Australia



Source: Judicial Administration Structure for IP Disputes provided by the Federal Court of Australia, available at www.wipo.int/wipolex/en/judgments/j-admin/au.html

2.3.1.2 Selection process

Judges of the Federal Court of Australia are appointed by the Governor-General of the Commonwealth of Australia by commission. Judges are appointed from the ranks of qualified legal practitioners of significant standing in the legal community. They are most typically appointed from the ranks of barristers or, less frequently, solicitors, who have practiced law for decades before being appointed. All Federal Court judges must retire at the age of 70 years.

Judges of the Federal Court exercise the judicial power of the Commonwealth and are independent from Parliament and the executive branches of the government. As the Federal Court is a court created by Parliament under Chapter III of the Constitution, judges may not be removed from office except by the Governor-General on an address from both houses of Parliament in the same session on the ground of proven misbehavior or incapacity.

2.3.2 Judicial education on intellectual property

The Intellectual Property NPA is coordinated by a select group of national coordinating judges who have expertise in intellectual property law. These national coordinating judges are responsible for the operation and administration of the Intellectual Property NPA, including the Patents and Associated Statutes sub-area. This involves, among other things, overseeing the ongoing development of a program of education for judges and the profession.

2.4 Patent invalidity

In addition to its jurisdiction to review determinations of the Patent Office as to invalidity in relation to patent applications (see Section 2.2.2.4), the Federal Court is frequently asked to adjudicate allegations of invalidity in the context of proceedings seeking revocation of a granted patent or where invalidity is raised as a defense in infringement proceedings brought by the patentee or its exclusive licensee.

When patent invalidity cases are filed, they are allocated to judges in the registry of filing who are within the Patents and Associated Statutes subarea of the Intellectual Property NPA. This allocation principle is subject to:

- the availability of judges in the registry of filing in the Patents and Associated Statutes subarea of the Intellectual Property NPA;
- considerations of the balance of workload and commitments of judges; and
- the character of a matter calling for a different approach.

Typically, complex patent matters, such as those involving pharmaceuticals or other complex scientific subject matter, are allocated to judges with significant experience in the field. As noted above in Section 2.3.1.1, and below in Section 2.6, the individual docket system means that, once a matter has been allocated to a judge, it is intended that the case will remain with that judge for case management and disposition.

If infringement proceedings are already in progress when proceedings alleging the invalidity of the same patent are commenced (either by cross-claim or otherwise), the invalidity proceedings will most likely be allocated to the docket of the judge hearing the infringement proceedings and the matters heard together, as in a single proceeding.

2.4.1 Process

Proceedings seeking revocation of a patent for invalidity are usually commenced by pleadings. The applicant will typically commence proceedings by filing an originating application and statement of claim. The originating application will set out the nature of the orders being sought in the proceedings (e.g., a declaration that particular claims of a patent are invalid). The statement of claim will provide further detail about the invalidity challenge, including the grounds upon which it is alleged that the patent is invalid. In addition, the applicant must also provide particulars of invalidity setting out with more precision the basis upon which each of the grounds of invalidity is said to be established.

In response, the respondent patentee will file a defense to the statement of claim. In its defense, the respondent will either admit, deny or otherwise provide an explanation in response to the allegations contained in the statement of claim. The applicant will then be able to file a reply to the defense or, failing this, be taken to join issue and deny the allegations made in the defense.

Once the pleadings have been finalized and closed, it is typical for the preparation of evidence in the proceedings to be commenced. This topic is discussed in Section 2.6.7.

2.4.2 Role of experts – Federal Court of Australia (invalidity proceedings)

Expert evidence in patent litigation in the Federal Court of Australia is almost exclusively given on affidavit and by way of joint report. Expert evidence is expected to comply with the requirements set out in the applicable practice note (at the time of writing, the *Expert Evidence Practice Note (GPN-EXPT)*, dated October 25, 2016) as well as the relevant rules of court.⁴⁵ These requirements place particular focus on the importance of the expert's independence as well as matters going to admissibility and the manner in which experts' evidence will be prepared and presented at trial. The practice note specifically requires every expert witness to read the *Harmonised Expert Witness Code of Conduct*⁴⁶ and agree to be bound by it. Unlike in the Patent Office, the rules of evidence apply in Federal Court proceedings.

Where an allegation of invalidity is raised in answer to an application for preliminary injunctive relief, expert evidence bearing on questions of construction of the specification or the contents of prior art documents will usually be given on affidavit. Cross-examination is rare in interlocutory applications of this kind.

In the case of invalidity evidence to be received at trial, the following procedural matters should be noted:

- First, the practice note requires litigants intending to rely on expert evidence to consider and inform the court at the earliest opportunity of a range of matters, including the number and identity of proposed experts and the issues that each is expected to address.
- Second, although the practice note and rules of court make provision for the engagement of common or joint experts and court-appointed experts, such witnesses have rarely been utilized to date.
- Third, the court will often require experts with the same or overlapping expertise (or experts giving evidence on particular issues) to participate in a conference or conclave of experts and in the preparation of a joint report prior to the trial. Although the parties' lawyers will usually be involved in formulating the list of issues for the conference or conclave, the ordinary course is for the conclave to proceed and for the report to be drafted without any involvement from the parties or their lawyers. In some cases, this will result in a series of joint reports being prepared by different pairs or groups of experts. In others (particularly where the fields of expertise overlap), there may be a larger report with input from a larger number of witnesses. It is not uncommon to see joint reports with four or five participants (or more) contributing.
- Fourth, particularly in cases where the joint report process is being used, the court will commonly direct that the experts give some or all of their evidence concurrently at trial rather than through traditional processes of experts being called and cross-examined serially. This process, colloquially known as a "hot tub," may take a number of forms but will commonly be structured by reference to topics or issues dealt with in the joint report. For each topic or issue, there may be an opportunity for the experts to give "opening statements" or to answer questions from the presiding judge. One party's legal representative will often begin questioning by asking a question of an expert called by the opposing party. Each expert will have an opportunity to comment on any answers given by other experts orally or in written evidence. Once the parties' legal representatives have exhausted their questions for the concurrent session on a topic, there may be an opportunity for "traditional" individual cross-examination of experts on matters arising from their oral or written evidence.⁴⁷

Expert evidence relating to invalidity will generally pertain to the same issues discussed at Section 2.2.2.3 in relation to Patent Office proceedings (in particular, evidence assisting the court in understanding the patent specification, the prior art, the state of knowledge – including CGK – in the relevant field at the priority date). In cases relating to older patents, there may be expert evidence establishing that a particular document would have been ascertained and regarded as relevant to a particular technical problem by the skilled addressee.

⁴⁵ In particular, Federal Court Rules 2011 (Cth) r. 23.13.

⁴⁶ Available from www.fedcourt.gov.au/law-and-practice/practice-documents/practice-notes/gpn-expt#_ftnref2

⁴⁷ Further information is available in the *Concurrent Expert Evidence Guidelines*, available from www.fedcourt.gov.au/law-and-practice/practice-documents/practice-notes/gpn-expt#AnnexureB

2.5 Patent infringement

2.5.1 Claim construction

This section focuses on claim construction in the Federal Court of Australia, given that patent matters are primarily conducted in that jurisdiction.

2.5.1.1 The role of claim construction

The proper construction of a patent is a question of law. The construction of the patent in question is important to most issues in patent disputes and can often be determinative of them. In particular, the proper construction of a patent may:

- indicate the meaning to be attributed to the claim features (integers) for the purposes of determining whether the allegedly infringing product or method, or prior art said to anticipate the claim or render it obvious, possesses those features;
- determine whether the words of the claim meet the requirement for the claim to be clear;
- determine the breadth of the monopoly claimed. This is particularly important for the “internal” grounds of invalidity, including:
 - a lack of fair basis and insufficiency (the relevant law for these grounds is that applying before the 2013 amendments brought about by the Intellectual Property Laws Amendment (Raising the Bar) Act 2012 (Cth));
 - a lack of support and no clear and complete enough disclosure of the invention (the relevant law is that applying after the 2013 amendments brought about by the Intellectual Property Laws Amendment (Raising the Bar) Act 2012 (Cth));
- determine the standard, if any, of the claimed product or process. This is particularly important for grounds, including:
 - a lack of inventive step (a claim with a higher “standard” is less likely to be obvious); and
 - utility (a broader claim, or one that does not have a limitation by result, is more likely to include within it things that do not work).

2.5.1.2 When claim construction occurs

Argument about the proper construction of a patent generally takes place at a final hearing and at the same time as argument about infringement, invalidity and associated legal and factual issues. Determination of the proper construction of a patent before a hearing on infringement and invalidity is rare. However, the court may choose to follow this course, especially if this leads to efficiencies in how the case will be run.

One consequence of the construction of a patent being determined at the same time as issues of infringement and invalidity is that, often, evidence is prepared and argument occurs based on more than one possible claim construction. It is common for the alleged infringer to argue that it wins the case on any construction; for example, if the construction is X, then there is no infringement, but if the construction is Y, then the claim is invalid.

That said, the alleged infringement or prior art is to be ignored when construing the patent. Although the forensic contest in any patent dispute will raise the particular construction issues to be resolved, a patent must “be construed as if the infringer had never been born”⁴⁸ and without “an eye to the prior art.”⁴⁹

The court does not need to adopt a construction put forward by any of the parties or their expert witnesses and may come up with its own construction. Further, as there are often multiple construction issues in a case, it is common for different construction issues to be determined both in favor of and against a party.

The construction of a patent is often an issue on appeal. While an appeal court may give some deference to a trial judge’s construction, it generally will not hesitate to adopt and apply a different construction if it perceives that the trial judge’s construction involved error(s). This is because the construction of a patent is a question of law, and, generally, the appeal court is in as good a position as the primary judge to construe the patent.

48 *Australian Mud Company Pty Ltd v. Coretell Pty Ltd (No. 4)* [2015] FCA 1372, citing *Welcome Real-Time SA v. Catuity Inc.* (2001) 51 IPR 327.

49 *Danisco A/S v. Novozymes A/S (No. 2)* (2011) 91 IPR 209 at [38].

2.5.1.3 Pleadings and claim construction

When filing originating documents alleging infringement or invalidity, a party does not generally need to indicate its position as to how the claim is to be construed.

Nonetheless, in some cases, the court may require the parties to indicate their position on construction at an early stage of the proceeding either directly (e.g., by requiring it to plead the various consequences for infringement and invalidity if a particular construction is adopted) or indirectly (e.g., by requiring the filing of position statements on infringement or a claim chart regarding invalidity).⁵⁰

2.5.1.4 How claim construction occurs

The principles of claim construction are settled. Disputes about construction usually concern the language of a particular claim rather than matters of principle. The determination of the proper construction of a patent specification including the claims is based on how the person skilled in the relevant art would understand it. Such a person is regarded as being neither particularly imaginative nor particularly inventive (or innovative).

The court seeks to determine how the skilled addressee would have understood the patentee to be using the words of the claim in the context in which they appear. The construction of a patent is objective in the sense that it is concerned with what the skilled addressee would understand from the patent, not what the patentee meant to say. The claims must be construed in the context of the specification read as a whole and in light of the CGK. However, it is not permissible to alter the words of a claim by adding glosses drawn from other parts of the specification. Further, if a claim is clear, it is not to be made obscure simply because obscurities can be found in parts of the specification.

It is often said that claims should be given a purposive – not a purely literal – construction and that a too “technical” or “narrow” construction should be avoided.⁵¹ In construing claims, “a generous measure of common sense should be used,” and a literal construction devoid of practicality and context is to be avoided.⁵² Claims should be construed while bearing in mind that the invention is to be put to practical use. A claim should not be construed to give a foolish result. Where possible, different claims in the same patent should be construed in such a way that their scopes are different. This is known as the presumption against redundancy.

The patentee may provide a “dictionary” of the jargon used in the claims, in which case that dictionary definition of the term generally applies. There are two kinds of terms for which a dictionary may be used: words that otherwise do not appear to have a positive meaning and common words that are to be given a different meaning.

2.5.1.5 The role of evidence in claim construction

Construction is a matter for the court. Although expert evidence regarding the meaning that the skilled addressee would give to technical or scientific terms and phrases may be submitted, it is for the court to interpret words bearing ordinary meaning. Indeed, the court can construe the claims without reference to expert evidence.

Despite this, it is relatively common for parties to adduce expert evidence that solely concerns the meaning a skilled person would attribute to a claim that does not contain technical or scientific terms. Often, however, the court gives such evidence little weight, although it is rare for the court to hold that it is inadmissible.

2.5.1.6 Patent Office file wrapper

The general rule in Australia is that the file wrapper is neither relevant nor admissible in construing the claim. The only qualification to this is Section 116 of the Patents Act 1990 (Cth), which, in interpreting a complete specification as amended, allows the court to refer to the specification without amendment. Besides this narrow exception, Section 116 does not permit recourse to other documents on the Patent Office file.

⁵⁰ Federal Court of Australia, Intellectual Property Practice Note (IP-1), Dec. 20, 2019, [6.12]–[6.13], [6.17]–[6.19], [6.23].

⁵¹ *Australian Mud Company Pty Ltd v. Coretell Pty Ltd* [2011] FCAFC 121, [65].

⁵² *Product Management Group Pty Ltd v. Blue Gentian LLC* (2015) 240 FCR 85, [36], citing *Ranbaxy Laboratories Ltd v. AstraZeneca AB* (2013) 101 IPR 11, [108].

2.6 Judicial patent proceedings and case management

2.6.1 Venue, jurisdiction and case assignment rules

The Federal Court of Australia and the state and territory supreme courts have jurisdiction to hear patent infringement matters. The Federal Court is granted jurisdiction directly from the Patents Act 1990 (Cth).⁵³ In addition, state and territory supreme courts, as “prescribed courts,” are also granted jurisdiction directly from the Patents Act 1990 (Cth) in respect of a number of discrete matters (this relevantly includes infringement proceedings).⁵⁴

Patent infringement proceedings are typically commenced in the Federal Court. This is a national jurisdiction with numerous judges who have extensive patent litigation expertise, often including practice at the bar prior to being appointed. First-instance proceedings in the Federal Court are heard and determined by a single judge. There are no jury trials for patent cases in Australia.

A party can commence patent proceedings before the Federal Court sitting in any Australian state or territory. The procedural rules and processes are standardized across Australia. Typically, a party will choose to commence a proceeding in the Federal Court registry that is in the state or territory in which they operate or where their legal representatives are located. Due to the standardized procedural rules and depth of experience of the Federal Court judiciary across the national Federal Court jurisdiction, there is no perceived benefit or disadvantage in commencing a proceeding in any particular venue.

Post-grant patent revocation proceedings can also be initiated in the federal (most commonly) or supreme courts. These can be commenced by a party seeking to “clear the path” ahead of the commercialization of a technology. However, in most instances, post-grant revocation is brought as a cross-claim to an infringement proceeding.

In the Federal Court, there are a number of NPAs, one of which is Intellectual Property, which includes the subarea of Patents and Associated Statutes.⁵⁵ This subarea includes:

- patent disputes – essentially infringement and validity disputes; and
- appeals from the Commissioner of Patents – for example, refusal by the Commissioner to grant a patent application.

There are approximately 54 Federal Court judges across the Federal Court. All Federal Court judges sit in multiple national practice areas although only 15 sit in the Patents and Associated Statutes subarea, as noted on the Federal Court portal.⁵⁶

The Federal Court operates an individual docket system, under which a case is allocated to a judge from filing to final hearing. Proceedings relating to patents are subject to the Intellectual Property Practice Note (IP-1).⁵⁷ This practice note provides guidelines for how patent proceedings – both validity and infringement – must be case-managed, including the use of agreed primers and position statements on infringement.

Federal Court judges actively manage cases in their docket, and parties are required by Federal Court legislation to conduct proceedings as quickly, inexpensively and efficiently as possible.⁵⁸ Consistent with its drive for efficiency, the Federal Court is increasingly limiting the scope of pre-trial processes, in particular discovery. The docket judge sets a timetable for steps such as discovery, evidence and pre-trial steps and will seek to minimize the extent of interlocutory disputes about these procedural steps. Although it varies depending on the nature of the case, the docket judge will often, at an early stage, set the matter down for a final hearing, which then provides a practical end point to the timetable for the steps of discovery, evidence and pre-trial matters.

53 Patents Act 1990 (Cth) s. 154.

54 Patents Act 1990 (Cth) ss. 42(1), 97(3), 101K, 120, 125, 128, 138, 165, 169, 171, 192.

55 See www.fedcourt.gov.au/law-and-practice/national-practice-areas/ip/patents

56 See www.fedcourt.gov.au/law-and-practice/national-practice-areas/ip/judges

57 See Federal Court of Australia, Intellectual Property Practice Note (IP-1), Dec. 20, 2019.

58 Federal Court of Australia Act 1976 (Cth) ss. 37M, 37N.

Parties may be represented by lawyers, being either barristers, solicitors or, as is often the case, a combination of both. If a party is a natural person, they may also choose to represent themselves. Corporate parties must be represented by lawyers; however, with the leave of the court, they may be represented by a nonlawyer.

2.6.2 Statements of case

In order to commence proceedings in the Federal Court of Australia for patent infringement or for the revocation of a patent on the grounds of invalidity, a party must file an originating application setting out the form of relief sought.⁵⁹ Generally, the originating application will be accompanied by a statement of claim or affidavit, setting out further information regarding the basis of the claim.⁶⁰ The applicant must also file a “genuine steps statement” specifying the steps taken to resolve the issues in dispute prior to instituting proceedings.⁶¹ Generally, this is satisfied by a patentee sending a letter of demand before commencement and allowing an appropriate period (which may be only a short period for urgent matters) for the other party to respond. These documents must be served on the other party in accordance with the court rules.⁶²

A respondent in patent infringement proceedings must file a defense to the claim within 28 days of service of the statement of claim.⁶³ However, the timing of the filing of the defense may, in some cases, be varied by order of the court. For example, a respondent may require further time to respond, particularly if they require further particulars of infringement from the applicant prior to being able to respond to the claim.

Alternatively, in certain circumstances, the Federal Court also allows parties to file a concise statement, which is limited to a statement of five pages, setting out the key facts giving rise to the claim, the relief sought, the primary legal grounds and the alleged harm suffered by the applicant.⁶⁴

Importantly, in Australia, it is possible for an applicant to seek an interim and interlocutory injunction in relation to potential patent infringement. The applicant may approach the duty judge of the Federal Court for orders expediting the filing and service of the originating application and pleadings to facilitate an urgent hearing of the application for interlocutory relief.

2.6.3 Early case management

Specific rules of the Federal Court of Australia govern the conduct of intellectual property cases. Those rules are supplemented by the Intellectual Property Practice Note (*IP-1*), which, when read with the *Central Practice Note: National Court Framework and Case Management (CPN-1)*, sets out the key principles of case management procedure applied by the court.

The rules concerning the management of patent cases are structured to have a strong emphasis on the quick, efficient and as-inexpensive-as-practicable disposition of each matter. The key objective of case management is to reduce costs and delay so that there are fewer issues in contest, promote the effective use of expert evidence and ensure both that there is no greater factual investigation than justice requires and that there are as few interlocutory applications as necessary for the just and efficient disposition of cases.

The court recognizes that proceedings in the Patents and Associated Statutes subarea of the Intellectual Property NPA will vary in complexity, and so a flexible approach is taken to the conduct of proceedings, which enables practitioners to tailor the conduct of the case according to need. Case management hearings are integral to case management; they are conducted by the docket judge, and one of their aims is to identify the genuine issues in dispute between the parties at the earliest stage. At the first case management hearing, the parties’ legal representatives are expected to have an understanding of the case such that they can assist in developing directions for the conduct of the matter to ensure that it is swiftly and economically brought to trial.

⁵⁹ Federal Court Rules 2011 (Cth) r. 8.01.

⁶⁰ Federal Court Rules 2011 (Cth) r. 8.05.

⁶¹ Federal Court Rules 2011 (Cth) r. 8.02.

⁶² Federal Court Rules 2011 (Cth) r. 8.06.

⁶³ Federal Court Rules 2011 (Cth) r. 8.06.

⁶⁴ Federal Court of Australia, *Central Practice Note: National Court Framework and Case Management (CPN-1)*, Dec. 20, 2019, [6.10].

The following matters routinely arise in discussion during the course of the initial and any subsequent case management hearings:

- the size and scope of the claim and any cross-claim, including the likely areas of dispute in relation to infringement and the likely grounds of any cross-claim seeking revocation of the patent;
- whether the patentee intends to seek leave to amend the patent claims;
- how the patentee intends to prove infringement (if in dispute) and how to limit the disputes to those central to the determination of the issues, such as by requiring the accused infringer to provide a product, method or process description;
- where it is alleged that there are multiple types of allegedly infringing activity, how the infringement case can be organized by reference to agreed representative examples of infringing conduct;
- whether it is expected that either party will seek leave to adduce evidence of experiments conducted for the purpose of the proceedings;
- the expertise of any expert witnesses, including whether it is proposed that more than one expert witness will be called by each party and, if so, why;
- pre-trial discovery of documents. The court does not permit discovery as of right, and it is incumbent on parties to establish the appropriateness of discovery;
- the early preparation of an agreed primer that sets out undisputed matters going to the CGK, including aspects of the technology relevant for the court to understand the patent, the case advanced in relation to the allegations of infringement and any cross-claim seeking revocation of the patent;
- the timetable for the preparation of lay and expert evidence;
- typically, it will be agreed between the parties that it is efficient for questions of liability to be considered separately and before questions of quantum of any damages or account of profits. Orders are made early for the separation of these issues in the appropriate case; and
- whether and when it is appropriate for the proceedings to be referred to mediation. Frequently, the parties agree – or the court orders – that, after the pleadings are closed, the parties should attend a mediation conducted either by a registrar of the court or an external mediator, who will facilitate settlement negotiations.

The court will seek to set down the proceedings for a final hearing as soon as it becomes apparent when the parties will be in a position to complete the necessary pre-trial steps.

Practitioners are encouraged to discuss the proceedings from an early stage to determine whether alternative procedures that will facilitate the efficient disposition of proceedings can be adopted by the court. The court has the power to appoint:

- a court expert to inquire into and report on any question or facts relevant to the proceedings;
- a referee to consider and determine specific matters before the final hearing; or
- an assessor to assist in the hearing and trial or in the determination of the proceedings.

As a matter of practice, these steps are rarely taken in patent cases during the liability phase of the proceedings.

A regular topic for discussion at case management hearings is whether, having regard to the manner in which the dispute between the parties has developed, the proceedings can be more efficiently conducted by either or both:

- the patentee reducing the number of claims that it sues on or the number of patents upon which the proceedings are advanced; or
- the party seeking revocation limiting the number of prior art documents relied upon in its case based on lack of inventive step or lack of novelty.

After any expert evidence in chief has been filed and answered, the court will frequently direct that the experts meet and prepare a joint expert report. This process facilitates the commencement of a direct dialogue between the experts that is intended to ensure that the subject matter of their oral evidence is confined to relevant matters that are genuinely in dispute. Experience has demonstrated that the process of preparing the joint expert report frequently eliminates semantic or peripheral disputes that otherwise appear significant in written reports.

After most of the preparatory steps have been taken, the docket judge will conduct a more detailed pre-trial case management hearing, wherein the conduct of the hearing will be considered. During this hearing, the parties discuss the timetable for the hearing, whether witnesses can appear by video link or in person, the conduct of the joint expert evidence by the giving of concurrent evidence (as to which, see Section 2.6.7.4), the order of submissions and other practical matters.

2.6.3.1 Scheduling

When a proceeding for patent infringement or revocation is filed in the Federal Court of Australia, it will typically be allocated by the court to a docket judge, who will conduct all case management hearings of the proceedings and will also conduct the final hearing. There are a number of advantages of this docket system, including that the trial judge is familiar with the matter by the time of the final hearing. It is also a useful discipline for the parties that the judge hearing their procedural applications throughout the proceedings is the same judge who will be conducting the final hearing.

Generally, a judge from the Patents and Associated Statutes subarea (that is, a judge with experience in patent cases) will be allocated to the patent infringement or revocation proceeding as the docket judge.

The docket judge will determine when to set the hearing date for the final trial in the proceedings. In some cases, this may be done at an early stage of the proceeding. However, it is not uncommon for a hearing date to be set later in the proceedings, such as after the pleadings or after evidence has been filed.

2.6.4 Provisional measures and preliminary injunctive relief

The Federal Court of Australia has equitable jurisdiction to grant temporary injunctions restraining an alleged infringer from engaging in certain conduct until the substantive merits of a proceeding can be determined.⁶⁵ Such injunctions are referred to as interlocutory injunctions or, if they are granted pending an application for an interlocutory injunction, interim injunctions.

Such injunctions can be a useful tool for patentee applicants to preserve the status quo in the market during the preparation period for trial and hearing and while judgment is reserved. It is important to bear in mind that the “price” of an interlocutory or interim injunction is the applicant’s giving of the “usual undertaking as to damages” to the court – a matter which is discussed in Section 2.6.4.3 of this chapter. Another matter for practitioners to bear in mind is that, in lieu of granting an interlocutory injunction, the court may be willing to grant an early final hearing. Such a course may benefit either or both parties, and it removes the need for the patentee applicant to give the usual undertaking as to damages. It is also likely to hasten the final determination of the dispute, including by removing the potential for delay arising from any appeal of the court’s decision to grant or refuse an interlocutory injunction.

Applications for interlocutory injunctions should be brought as quickly as reasonably practicable after an applicant becomes aware of allegedly infringing conduct. The granting of interlocutory injunctions is at the court’s discretion. Factors that militate against the grant of equitable relief generally apply equally with respect to interlocutory injunctions, such as laches (delay). Further, the failure of an applicant to move with haste to seek an interim or interlocutory injunction tends to undercut any submission by the applicant that an interim or interlocutory injunction is urgently required to maintain the status quo to protect the applicant’s position prior to the substantive determination of the rights of the parties.

In circumstances where interlocutory injunctive relief needs to be sought urgently (subject to the practicalities of obtaining evidence to establish a *prima facie* case of patent infringement), practitioners should be familiar with paragraphs 3.1–3.5 of the Intellectual Property Practice Note (IP-1). It provides that, where urgent relief is sought, once appropriate documentation has been prepared in support of such an application, the associate (or “clerk”) of the duty judge should be contacted in order to allocate a hearing time for such an application. The allocated Federal Court

65 Federal Court Act 1976 (Cth) s. 23.

duty judge changes from time to time, and they are identified on the Federal Court daily list on the Federal Court's website.

When deciding whether to grant an interlocutory injunction, the court will consider whether the applicant has established a *prima facie* case (often framed by asking whether there is a serious question to be tried) and whether the balance of convenience favors granting the interlocutory injunction).⁶⁶ Almost invariably, the applicant will also be required to give an undertaking to the court as to damages. These concepts are outlined in more detail below.

2.6.4.1 *Prima facie* case (or serious question to be tried)

When hearing an application for an interlocutory injunction, the court is not making a final determination as to the parties' rights and the merits of the case. Instead, the court will seek to determine, on a preliminary basis, the strength of the applicant's case. The applicant does not have to prove that it is more probable than not that it will make out a claim of infringement at a trial of the proceeding – merely that it has a sufficiently strong case in the circumstances to justify the grant of the interlocutory injunction to preserve the status quo pending trial. As in any substantive proceeding, evidence – and often expert evidence – will be required to make out a *prima facie* case. However, given the often urgent circumstances in which relief will need to be sought, the evidence may be less detailed and expressed in a more contingent way than would be the case at trial.

While a patentee need only establish a *prima facie* case, or that there is a serious question to be tried, the stronger the case of the applicant, the more likely it is that the balance of convenience will favor the granting of an interlocutory injunction, as discussed further in Section 2.6.4.2.

As in all patent proceedings, when defending against an application for an interlocutory injunction based on a claim of patent infringement, an alleged infringer may seek to challenge the validity of the patent. However, if all that a respondent can establish is that it has an arguable case that the patent is invalid, that will be insufficient to displace the applicant's *prima facie* case of patent infringement. The respondent will need to establish a sufficiently strong case that the patent is invalid with the result that it cannot be said that the applicant has made out a *prima facie* case, given that an invalid patent cannot be infringed.

2.6.4.2 Balance of convenience

When considering whether the balance of convenience is in favor or against the granting of an interlocutory injunction, the court considers the respective impacts of an interlocutory injunction on the applicant, the respondent and third parties. As referred to at Section 2.6.4.1, the balance of convenience is considered in light of the strength of the applicant's case. All other matters being equal, a stronger case will suggest the balance of convenience lies in favor of granting an injunction than a weaker case.

As a starting point, a key factor to consider in determining where the balance of convenience lies is whether damages would be an adequate remedy for the applicant. That is to say, determining whether, if an interlocutory injunction were not granted and the respondent carried out the actions of which the applicant complains, the applicant would be adequately compensated for that conduct by an order for damages if the matter is ultimately determined in the applicant's favor. If damages are an adequate remedy, an interlocutory injunction will not be granted because there is no need to preserve the status quo pending trial.

Factors that militate against such a finding include (a) the respondent not being in a financial position to pay any damages awarded, (b) the likely difficulty in quantifying damage, (c) whether some of the damage likely to be suffered by the patentee is unlikely to be recoverable as damages for patent infringement, and (d) the irreversibility of the effect on the applicant of the respondent's conduct even if the respondent is ultimately enjoined at trial (e.g., if the respondent's entry into a market will irrevocably change the nature of the market).

In respect of pharmaceutical patents, the operation of the Pharmaceutical Benefits Scheme, being the vehicle by which the Australian Government subsidizes the purchase of pharmaceutical products in Australia, has important effects on the balance of convenience. Under the

66 *Samsung Electronics Co Ltd v. Apple Inc.* [2011] FCAFC 146; 217 FCR 238 (Dowsett, Foster, Yates JJ).

Pharmaceutical Benefits Scheme legislation, the entry of a second brand of pharmaceutical product into the Australian market has the effect of reducing the price at which the first brand of pharmaceutical product may be sold by the patentee in Australia and, therefore, the quantum of the subsidies paid by the Australian Government under the Pharmaceutical Benefits Scheme. The court may be willing to grant an interlocutory injunction to restrain the exploitation of the second brand on the basis that, if the second brand enters the market, the patentee will suffer irrevocable damage because the price at which the patentee may sell the first brand will be reduced.⁶⁷

As well as considering how the applicant will be affected if an interlocutory injunction is not granted, the court will also consider the effect upon the respondent and third parties if the interlocutory injunction is granted. In so doing, the court will bear in mind that the respondent and third parties may have the benefit of the usual undertaking as to damages given by the applicant to the court. If the interlocutory injunction would, in practical effect, bring the dispute to an end (e.g., because the respondent's business would be irreversibly affected, or the fast-moving nature of the market is such that, by the time the dispute is ultimately determined, the respondent's product will no longer be commercially valuable), then this is a matter that can weigh against granting the injunction or at least suggest that the applicant has to make out a stronger *prima facie* case. Equally, if third parties would be adversely affected in a way that is unlikely to be compensated by the usual undertaking as to damages, then this can also be a matter weighing against an interlocutory injunction.

Ultimately, the balancing exercise is a discretionary one and an exercise that depends on the particular circumstances of each case.

2.6.4.3 Undertaking as to damages

If an applicant seeks an interlocutory injunction, it will almost always be required to give an undertaking as to damages. The form of the undertaking is as set out in the *Usual Undertaking as to Damages Practice Note (GPN-UNDR)*.⁶⁸ In essence, the undertaking requires the applicant to undertake to the court to submit to such order as the court may consider to be "just" for the payment of compensation to any person (whether or not that person is a party) affected by the operation of the interlocutory injunction and to pay such compensation. That is, if at the final hearing (and after exhausting appeals) the applicant is unsuccessful in establishing an entitlement to a final injunction for patent infringement, it will be required to compensate those who have been adversely affected by the interlocutory injunction, which may be the respondent and any third parties, in the period in which it operated.

In pharmaceutical patent matters, the Australian Government has adopted a practice of making substantial claims on the usual undertaking as to damages in circumstances where a patentee applicant has succeeded in obtaining an interlocutory injunction to restrain exploitation in Australia of a second brand of the patentee's product but has ultimately failed (whether at trial or on appeal) to secure a final injunction.

Claims on the usual undertaking as to damages in the context of pharmaceutical patent cases have tended to become protracted and difficult, with the result that it cannot be assumed that claims on the usual undertaking as to damages will be successful. This is relevant to assessing the balance of convenience.

2.6.4.4 *Quia timet* injunctions

It may be the case that a patentee applicant becomes aware that a respondent is taking preliminary steps toward undertaking actions that would infringe a patent, but the respondent has not yet undertaken any act that infringes the patent. In that case, an applicant can seek an interlocutory injunction on a *quia timet* basis – that is, an injunction to stop threatened patent infringement. The same principles as outlined above apply, but, in this case, the applicant will also have to establish with some degree of probability that a respondent intends to ultimately do something that will infringe the patent. *Quia timet* injunctions are often sought in the context of pharmaceutical patents, where the highly regulated nature of the market is such that certain public steps have to be undertaken before a product can be launched on the market.

67 *Sanofi-Aventis Deutschland GmbH v. Alphapharm Pty Ltd (No. 3)* [2018] FCA 2060; 138 IPR 242 (Burley J) at [120]–[185].

68 Federal Court of Australia, *Usual Undertaking as to Damages Practice Note (GPN-UNDR)*, Oct. 25, 2016.

2.6.5 Discovery and gathering of information

This section focuses on discovery processes in the Federal Court of Australia, given that patent matters are primarily conducted in that jurisdiction. Discovery is one type of court-mandated process that requires one party to litigation to disclose documents (or the existence of documents) to another.⁶⁹ Three other court-mandated document disclosure processes are: notices to produce and subpoenas, which are addressed briefly in Section 2.6.5.4, and preliminary discovery, which is addressed in 2.6.5.5.

Discovery in the Federal Court is governed by Part 20 of the Federal Court Rules 2011 (Cth) as elucidated in the Federal Court's *Central Practice Note: National Court Framework and Case Management (CPN-1)* Part 10, the Intellectual Property Practice Note (IP-1) paragraphs 6.14–6.16 and 9.1, and the *Technology and the Court Practice Note (GPN-TECH)* Part 3, which all also relate to the court's processes regarding discovery.

2.6.5.1 Circumstances in which discovery will be ordered

Discovery may only occur by order of the court.⁷⁰ An order for discovery will only be made if it would “facilitate the just resolution of the proceeding as quickly, inexpensively and efficiently as possible.”⁷¹ That is, there is no right to discovery, and the court is not bound by any agreement between the parties regarding discovery. A court may refuse to order discovery, amend its scope or defer consideration of it until a later point in the proceeding. If a party seeks discovery in advance of all parties filing and serving their affidavit evidence, it is likely that the party will need to justify to the court why discovery should be ordered at that stage of the proceeding. The court may consider that the goals in Rule 20.11 of the Federal Court Rules 2011 (Cth) are more likely to be achieved if discovery is ordered after all parties have filed and served their affidavit evidence. By adopting such a course, the burden of discovery may be minimized on the basis that any specific gaps in the evidence that need to be filled by way of discovery are more likely to be known.⁷²

“Standard discovery” refers to a party being ordered to produce all documents that are directly relevant to the issues raised on the pleadings that can be located after a reasonable search. The burden of such discovery can be significant. *Central Practice Note* paragraph 10.7 states that discovery should be proportionate to the nature, size and complexity of the case. However, the usual course in patent matters is for parties to negotiate “categories” of discovery, in which documents answering certain specific descriptions are sought. This is known as “nonstandard discovery” and is dealt with in Rule 20.15. For example, a category might seek documents recording or evidencing the steps undertaken in a particular manufacturing process where that would be relevant to proving infringement of a method or process claim.

There is no formal process for negotiating discovery categories. Usually, at a suitable stage of the litigation, parties will exchange correspondence outlining the categories they seek and then negotiate to reach agreement, for example, on the wording of those categories and the timing of document production. If agreement cannot be reached on some issues, the matter is usually brought before the docket judge by way of an interlocutory application, supported by an affidavit or a list of correspondence or undisputed documents under Rule 17.02. A judge will expect parties to have attempted to resolve differences regarding the categories as far as possible before ruling on the categories to be ordered. The judge will also expect the parties to have determined a suitable timetable for production – that is, to have considered how long the discovery process is likely to take given the scope of searches, investigations and reviews of the documents that need to be undertaken.

A party may oppose categories of discovery sought by another party on various bases. Grounds often include that (a) the documents sought are not directly relevant to an issue in the

69 The Federal Court Rules 2011 (Cth) also provide for nonparties to litigation to give discovery (rr. 20.23–20.25, 20.33), but, in practice, the primary process by which third party documents are sought and disclosed is through subpoenas.

70 Federal Court Rules 2011 (Cth) r. 20.12. Despite this, it is commonplace for parties to litigation to make limited requests for the disclosure of documents and for such disclosure to be provided on an informal basis, to avoid the cost and expense of going through formal court processes to obtain those documents. Indeed, this process is encouraged by the court. Federal Court of Australia, *Central Practice Note: National Court Framework and Case Management (CPN-1)*, Dec. 20, 2019, [10.3].

71 Federal Court Rules 2011 (Cth) r. 20.11.

72 The earliest point in time a party can seek discovery is 14 days after a defense has been filed. Federal Court Rules 2011 (Cth) r. 20.13(3).

proceedings, (b) the documents are not necessary for a party to prove its case or impugn the case of its opponent, (c) the request is “fishing” (e.g., a speculative attempt to locate documents that would allow the requesting party to plead a new case), (d) the category is unnecessarily broad or is oppressive in that it would be unreasonably burdensome for the receiving party to comply with the category, and (e) the category would only produce documents that would be privileged, and there is no reasonable submission that such privilege has been waived. These matters are usually resolved at a hearing by reference to the pleadings; however, in contending that a category is oppressive, parties tend to file affidavit evidence from a solicitor outlining the scope of searches, investigations and reviews of documents required to satisfy the category. Notwithstanding such evidence, the court may order discovery in the category on the basis that the party need only conduct a reasonable search for documents as set out in Rule 20.14(3).

2.6.5.2 Process of giving discovery

Unless otherwise ordered, a party must undertake a reasonable search for documents falling within the scope of any discovery categories ordered that are in its possession, power or control. Rule 20.14(3) of the Federal Court Rules 2011 (Cth) outlines matters to consider when determining what constitutes a “reasonable” search in the particular circumstances of a proceeding.

There are two distinct steps in giving discovery: (a) the provision of a list of documents and (b) the production of the documents themselves. Rule 20.17(1) provides that a party “gives discovery” to another by providing a list of documents in accordance with Rule 20.18. A list of documents is prepared in the form of Federal Court Form 38, which is available from the Federal Court website. The list of documents must be sworn or affirmed by a suitable representative of a party: that is, someone with sufficient knowledge regarding the documents to which the list of documents relates.⁷³ Rule 20.17 provides that a list of documents must outline, in some degree of detail, the documents falling within the categories that are or were in a party’s possession or control. Where a document is no longer, but once was, in the party’s possession or control, an explanation must be given as to when and how the document left the party’s possession. The list of documents must also set out documents over which a party claims privilege.

Rule 20.32 provides that a party may seek an order from the court for the production of documents referred to in a list of documents. Such an order is usually made prospectively at the same time as other orders regarding discovery. The usual course is for copies of documents to be produced electronically from one party to another unless there is some particular reason for some other order (e.g., if the authenticity of a document is disputed, it may be necessary to produce the original version of the document).

A party’s discovery obligations are ongoing.⁷⁴ That is, after the provision of the list of documents occurs, a party is under an ongoing obligation to notify the other party if it uncovers a document that is within the discovery categories ordered but which is not in the list of documents. This may be due to oversight or because the document was created after the list of documents was created. However, a party does not have to produce privileged documents that are created after the proceeding commenced.⁷⁵

2.6.5.3 Refusal to produce documents

There are two bases on which a party can seek to restrict production of a document, whether in whole or in part (i.e., by masking parts of the document).

First, a party may refuse to produce a document on the grounds of legal professional privilege or public interest privilege.⁷⁶ Procedurally, the usual course in relation to disputed claims of privilege involves (a) a party, in its list of documents, asserting that a document is privileged from production; (b) if there is a dispute about the claim of privilege (e.g., on the basis that such a document could not be privileged, or that privilege in the document has been waived either expressly or implicitly), the other party filing an interlocutory application seeking an order compelling production of the document, for example, under Rule 20.32 of the Federal Court Rules 2011 (Cth), supported by an affidavit or a list of correspondence or undisputed documents under

⁷³ Federal Court Rules 2011 (Cth) rr. 20.17(4), 20.22.

⁷⁴ Federal Court Rules 2011 (Cth) r. 20.20.

⁷⁵ Federal Court Rules 2011 (Cth) r. 20.20(2).

⁷⁶ Federal Court Rules 2011 (Cth) rr. 20.01–20.02.

Rule 17.02; and (c) the court deciding whether to grant the order compelling production of the document at a hearing.

Second, a party may seek to restrict production of a document on the basis of commercial confidentiality. Often, in patent proceedings, the litigants will be competitors. Documents produced may disclose commercially confidential matters. The usual course is for parties to negotiate a suitable protocol for dealing with such documents prior to production. For example, the parties may agree that the documents are only to be produced to external lawyers and counsel and to expert witnesses, but not to representatives of the party themselves. If the parties are unable to agree on a suitable protocol for dealing with confidentiality, it may be necessary to seek orders dealing with such issue from the docket judge.

2.6.5.4 Alternative procedures to discovery

The Federal Court of Australia encourages flexible and alternative ways of obtaining evidence that a party may otherwise seek by way of discovery. Examples of this in a patent context are product and process descriptions. In the context of proving infringement of a product or process claim, it may often be difficult for a party to know which documents to seek from the other or to prove from documents alone whether such a process infringes all the integers of a claim. Intellectual Property Practice Note (*IP-1*) paragraphs 6.14–6.16 state that, in such a situation, a court may order an alleged infringer to prepare and serve a sworn statement from a suitably knowledgeable person as to the nature of the alleged infringer's product or process to allow the other party to make out its case on infringement or to seek documents in a more targeted manner.

Notices to produce are another process by which a party can seek documents from another party. While the precise boundaries between a notice to produce and discovery by way of categories can appear unclear, the primary difference is that notices to produce are a more targeted process and must be directed to the production of specifically identified documents. There are two kinds of notices to produce. The first is requests for documents referred to in a party's pleading or affidavit, which occurs without the supervision of the court unless there is a dispute as to the notice (e.g., a dispute as to whether the pleading or affidavit in fact "refers to" the document sought in the notice).⁷⁷ The second is orders for the production to the court of certain documents.⁷⁸ Production under Rule 30.28 of the Federal Court Rules 2011 (Cth) is not limited to during trials, and a practice has developed of parties seeking production of documents before the registrar under Rule 30.28 at any time in a proceeding. Documents sought under this rule are not only limited to documents referred to in an affidavit or pleading.⁷⁹

Finally, documents may be sought from nonparties by way of subpoenas for the production of documents.⁸⁰ Subpoenas are governed by Part 24 of the Federal Court Rules 2011 (Cth) and are also addressed in Parts 1–10 of the *Subpoenas and Notices to Produce Practice Note (GPN-SUBP)*. Subpoenas are a substantial topic in their own right, and it is beyond the scope of this section to deal with them in any detail. Like discovery, there is not a "right" to a subpoena. Subpoenas may only be issued with leave of the court.⁸¹ Subpoenas are issued by the court, not a party, so compliance is owed to the court, not the party seeking the subpoena. Given that a failure to comply with a subpoena constitutes contempt of court,⁸² and subpoenas impose burdens on nonparties to the litigation, there are detailed and strict rules regarding the form and service of subpoenas.⁸³ Like discovery, subpoenas will usually seek the production of categories of documents. However, those categories will usually need to be more confined and prescriptive than categories sought on discovery, owing to the fact that the subpoena recipient is a nonparty and will not be familiar with the issues in a proceeding.

A further difference between discovery on the one hand and notices to produce and subpoenas on the other is that a category for discovery may be more broadly described and a party giving discovery has the obligation to search for and produce all documents relevant to the proceedings within that category. A notice to produce and a subpoena generally require greater specificity of

⁷⁷ Federal Court Rules 2011 (Cth) r. 20.31.

⁷⁸ Federal Court Rules 2011 (Cth) r. 30.28.

⁷⁹ See also Federal Court of Australia, *Subpoenas and Notices to Produce Practice Note (GPN-SUBP)*, Oct. 25, 2016, pt 11.

⁸⁰ Subpoenas may also be sought to require a person to attend court to give evidence.

⁸¹ Federal Court Rules 2011 (Cth) r. 24.01.

⁸² Federal Court Rules 2011 (Cth) r. 24.23.

⁸³ Federal Court Rules 2011 (Cth) rr. 24.12–24.13, 24.16.

description of the documents sought and the recipient is entitled to read the described category sought narrowly and produce only documents strictly within that category.

2.6.5.5 Pre-action or preliminary discovery

Rules 7.22 and 7.23 of the Federal Court Rules 2011 (Cth) provide for two types of pre-action discovery. Rule 7.22 allows a prospective applicant to obtain discovery from a third party to ascertain the description of a prospective respondent, subject to satisfying the jurisdictional prerequisites set out in Rule 7.22(1) and the court's discretion in Rule 7.22(2). Rule 7.23 allows a prospective applicant to obtain discovery from a prospective respondent of documents directly relevant to the question of whether the prospective applicant has a right to obtain relief, subject to satisfying the jurisdictional prerequisites in Rule 7.23(1) and the court's discretion in Rule 7.23(2). That is, subject to those matters, Rule 7.23 allows a prospective applicant to "fish" for a case against a prospective respondent.

Each of the jurisdictional prerequisites in Rule 7.23(1) must be satisfied. A prospective applicant must satisfy the court that it reasonably believes that it "may" have the right to obtain relief in the court from a prospective respondent and that, after making reasonable inquiries, it does not have sufficient information to decide whether to start a proceeding in circumstances where the documents sought by discovery would assist in making the decision.

The mechanism under Rule 7.23 can be useful for obtaining documents to determine whether a product being sold in Australia is being made using a patented process.

2.6.6 Summary proceedings (summary adjudication)

2.6.6.1 Availability of summary adjudication

In the Federal Court of Australia summary adjudication is available both to applicants (i.e., the party alleging infringement of a patent) and respondents (i.e., the party defending an allegation of infringement of a patent).

The procedural rules relating to summary adjudication are set out in Rule 26.01 of the Federal Court Rules 2011 (Cth). An application for summary adjudication requires an affidavit stating the grounds of the application and the facts and circumstances relied on to support those grounds.⁸⁴

2.6.6.2 Basis for summary adjudication – "no reasonable prospect" of success

The power of the court to give summary adjudication is provided by Section 31A of the Federal Court of Australia Act 1976 (Cth). The court may give summary judgment in favor of an applicant if the court is satisfied that the respondent "has no reasonable prospect of successfully defending the proceeding,"⁸⁵ and it may summarily dismiss a proceeding if it is satisfied that the applicant "has no reasonable prospect of successfully prosecuting the proceeding or that part of the proceeding."⁸⁶

Section 31A(3) specifies that a defense or proceeding need not be "hopeless" or "bound to fail" for it to have "no reasonable prospect of success." This is because the "no reasonable prospect of success" standard was adopted in Section 31A to make it easier for a party to obtain summary adjudication, in comparison with the common-law standard that previously applied, which required a proceeding or defense to be "hopeless" or "bound to fail" before summary judgment or summary dismissal could be ordered. A "reasonable prospect of success" is a "real," rather than "fanciful," prospect.⁸⁷

The court's power to make orders for summary judgment or summary dismissal is discretionary.⁸⁸ The court will exercise its powers in relation to summary adjudication with caution.⁸⁹ This is particularly so where an application for summary judgment or summary dismissal requires consideration of apparently complex questions of fact, law, or mixed law and

⁸⁴ Federal Court Rules 2011 (Cth) r. 26.01(2).

⁸⁵ Federal Court of Australia Act 1976 (Cth) s. 31A(1)(b).

⁸⁶ Federal Court of Australia Act 1976 (Cth) s. 31A(2)(b).

⁸⁷ *Spencer v. Commonwealth* (2010) 241 CLR 118, [22].

⁸⁸ *Australian Securities and Investments Commission v. Cassimatis* (2013) 220 FCR 256, [50].

⁸⁹ *Spencer*, 241 CLR, [24].

fact.⁹⁰ Where there are factual issues capable of being disputed and in dispute, the summary disposition of the proceeding would not be appropriate.⁹¹ A proceeding will not be determined summarily unless it is clear that there is no real question to be tried.

The party bringing the application for summary determination bears the onus of persuading the court that the proceedings should be determined summarily prior to a full hearing (and prior to other court processes that may not yet have occurred, such as discovery). That onus is “heavy.”⁹² If a *prima facie* case in support of summary determination is established, the onus shifts to the opposing party to point to some issue that makes a trial necessary.⁹³

2.6.6.3 Summary adjudication in patent litigation

A summary judgment application could be brought by a patentee on the basis that the respondent has “no reasonable prospect” of defending the allegation that its product or method infringes the patent. For example, the respondent may admit to the factual allegations of making, using or selling the relevant product or method, with the only issue needing to be determined by the court being whether that product or method infringes the patent. In these circumstances, the applicant could consider its case on infringement to be so clear that the respondent has “no reasonable prospect of successfully defending” the allegations of infringement.

By the same token, a respondent who is alleged to have infringed a patent could bring a summary dismissal application on the basis that its product or method plainly does not infringe the patent such that the applicant has “no reasonable prospect of successfully prosecuting the proceeding.”

A respondent could also bring a summary dismissal application on the basis that the patent is invalid. For example, if there is a publication that disclosed all of the integers of the invention claimed in the patent, but there is a dispute about the priority date of the patent and therefore a dispute about whether the publication is relevant prior art, then the respondent may decide to make an application for summary dismissal on the basis that the priority date issue can be determined without extensive evidence.⁹⁴ In such a case, determination of the priority date issue would effectively determine the issue of patent validity.

In practice, however, summary adjudication is rarely sought in patent litigation in Australia, either by applicants or by respondents. This is likely due to the fact that patent proceedings generally involve complex questions of fact and law, which are generally not appropriate for summary determination.⁹⁵

2.6.7 Evidence

Patent litigation proceedings are typically commenced by a patentee alleging infringement, with the respondent denying infringement and cross-claiming for revocation of the patent. The court typically hears and determines infringement and invalidity simultaneously.

Once initial procedural steps, including the filing of pleadings, are completed, each party prepares evidence in accordance with a timetable set by the court. Evidence in patent cases is usually provided in the form of written and verified affidavits. Documents can be annexed or exhibited to affidavits, which are then tendered in court and admitted as evidence. Prior to trial, there will usually be one or more case management conferences and procedural steps to identify which affidavit evidence will be relied on at trial. Each party also notifies which of the opposing parties’ witnesses it will call for cross-examination.

At the trial, any affidavit evidence upon which a party intends to rely will be formally “read” by the party relying on it and admitted into evidence. A person that has given evidence in affidavit form may be required to appear for oral cross-examination by the opposing party. Cross-examination of the witness is not confined solely to matters in the witness’s affidavit: any issue relevant to the proceedings can be canvassed. After cross-examination is completed, the party calling the witness has the right to reexamine the witness in relation to matters arising out of cross-examination.

⁹⁰ *Spencer*, 241 CLR, [24].

⁹¹ *Spencer*, 241 CLR, [24], [25].

⁹² *Australian Competition and Consumer Commissions v. FDRA Pty. Ltd.* [2016] FCA 429, [27].

⁹³ *Jefferson Ford Pty Ltd v. Ford Motor Company of Australia Ltd* (2008) 167 FCR 372, [127].

⁹⁴ See, e.g., *Pilkin v. Sony Australia Limited (No. 2)* [2019] FCA 980.

⁹⁵ See, e.g., *Expo-Net Danmark A/S v. Buono-Net Australia Pty. Ltd. (No. 2)* [2011] FCA 710, [12], [55].

2.6.7.1 Expert evidence

Issues of patent construction and, consequently, infringement and validity are considered through the lens of a notional addressee of the patent specification – a person skilled in the art. The background and experience of the person skilled in the art will differ depending on the subject matter of the specification. Of course, ultimately, these issues are determined by the court. While the Federal Court judges who hear patent cases are generally highly experienced and often former patent counsel themselves, they do not always have technical qualifications. Consequently, in almost all patent cases, independent expert evidence is called to assist the court in placing itself in the position of the person skilled in the art.

While the Federal Court of Australia can appoint its own expert or assessor (technical assistant), these powers are rarely used, and, in the majority of cases, competing experts are engaged by the parties themselves. The purpose of expert evidence is for the court to receive the benefit of the objective and impartial assessment of an issue using the specialized knowledge of the expert.⁹⁶

Where an expert witness is retained for the purpose of preparing a report or giving evidence as to an opinion held by the expert based on their specialized knowledge, the expert is provided with the Federal Court's *Expert Evidence Practice Note (GPN-EXPT)* and all relevant information so as to enable the expert to prepare an independent report. The expert's ultimate obligation is to assist the court rather than act as an advocate for a party. The parties and their legal representatives have obligations to maintain the independence of the expert witness and must not pressure or influence the expert into conforming their views with the parties' interests.

Expert evidence can assist the court on a number of issues arising in a patent case. Importantly, in relation to patent construction, expert evidence can assist the court in understanding the context of a patent and the meaning of any technical terms or "terms of art."⁹⁷ On infringement, expert evidence can assist the court in understanding the functionality and features of an alleged infringing product or process and how it may map to the patent claims in issue. In relation to validity, expert evidence can assist the court in understanding the extent and nature of disclosures in the prior art to assist in a novelty assessment. Further, expert evidence is often relied on to establish the state of the CGK in the relevant field before the priority date. This is an important step in assessing whether the claimed invention would have been "obvious" to a person skilled in the art.

The court will hear and assess the evidence from the competing persons skilled in the art called by the parties, but, ultimately, all these issues are for determination by the court.

2.6.7.2 Position statements, product descriptions and "primers"

In appropriate cases, the party alleging patent infringement may be required to provide a position statement on infringement. This is a document that supplements an infringement pleading and provides more detail on how the patentee alleges the impugned product takes the features of the patent claims. It concisely states the facts and matters relied upon in support of the infringement allegation, including reference to the integers of any claim alleged to have been infringed. While it does not constitute evidence in the case, it will often be prepared with input from an expert.

The respondent is often required to provide a position statement on (non)infringement in response. In some cases, the respondent may also be required to provide a product description. This is a detailed description of the product or process alleged to be infringed. This procedure has been developed in an attempt to avoid time-consuming and costly discovery or experimental procedures for establishing the form and functionality of the alleged infringement. The product description is generally verified by an officer of the respondent with knowledge of the product.

In an appropriate case, the court may require the parties to produce an agreed primer. This identifies the agreed technical background to the invention claimed in the patent. The primer typically includes an agreed description of the CGK at the priority date. In an appropriate case, the primer may be accompanied by an agreed glossary of key terms. The primer provides a starting point for the court in addressing the state of the art, particularly in relation to validity.

⁹⁶ See generally Federal Court of Australia, *Expert Evidence Practice Note (GPN-EXPT)*, Oct. 25, 2016.

⁹⁷ *Commissioner of Patents v. Rokt* [2020] FCAFC 86, [73].

2.6.7.3 Conference of experts and joint report

Where multiple experts are retained to provide evidence to the court, the court increasingly requires that experts meet in a conference ahead of the trial to attempt to narrow the issues between them. There is often a lot of background information in the experts' affidavit evidence in relation to the technology in issue and the CGK that is not controversial. The parties and their legal representatives do not participate in the expert conference, but, often, a court officer such as a registrar will be called on to facilitate.

At the conclusion of the conference, the experts prepare a joint report, which identifies the issues in respect of which they agree or disagree. The joint report typically contains a succinct explanation for any differences of opinion. This procedure enables the court and the parties to focus on the issues that are genuinely in dispute at the trial.

2.6.7.4 Concurrent evidence

In most patent cases, the Federal Court of Australia has adopted the practice of concurrent expert evidence (also colloquially known as "hot-tubbing"). At the trial, after being sworn in, the experts engaged by each party are questioned together. Prior to a hearing at which concurrent expert evidence is to be given, the parties and their legal representatives confer and consider an agenda, an order and manner in which questions are to be asked, and whether cross-examination will take place during concurrent with evidence, or after its conclusion.

Concurrent expert evidence typically involves the following process:

1. The parties' experts prepare a joint report, identifying their areas of agreement and disagreement.
2. The experts are called into the witness box together.
3. Each expert takes turns in giving evidence.
4. An expert can comment on another expert's evidence.
5. The parties' representatives cross-examine the experts, with each expert being able to give evidence and comment on another expert's evidence.

This practice allows an expert to consider and comment on another expert's opinion in real time and allows the court and the parties to focus on the real issues in dispute. The objective is to facilitate an environment whereby the experts, the parties and the court can engage in a dialogue that enables a thorough and frank examination of the issues.

2.6.7.5 Expert evidence in infringement proceedings

Expert evidence relating to infringement claims is prepared and presented in a similar fashion to invalidity evidence.

The infringement issues on which expert evidence is commonly received include:

- technical matters bearing on the proper construction of the specification and claims;
- evaluation of whether a product or process possesses the integers of relevant claims (e.g., by an engineer, clinician, industry expert or patent attorney);
- matters of industry knowledge relevant to infringement (e.g., the uses to which a particular product may be put or the characteristics of a market in which the product is supplied); and
- calculations bearing on the quantum of relief to which an applicant may be entitled on an account of profits or by way of compensatory damages.

Although infringement issues may, to an extent, be separated from invalidity issues in joint report and concurrent evidence processes, there is a significant degree of overlap between the issues (particularly in relation to construction and CGK) such that a party will often have one or more experts giving evidence on infringement and invalidity issues in the proceeding.

2.6.8 Case-specific education of decision-makers

In patent cases, there are a number of tools used by the court to familiarize the judges with the technology of the patent(s) in issue. These tools have been outlined earlier in this section and include the use of expert affidavits, product and process descriptions, agreed primers, joint expert reports and concurrent evidence.

In complex matters, the court may direct opposing experts to commence their oral evidence by each presenting a short tutorial addressing the background technology to the dispute. This may be accompanied by such PowerPoint or other presentation material as the expert thinks fit. To the extent necessary, the opposing expert may point out areas of disagreement or expand on the subjects addressed by the other expert. The purpose of doing so is to allow for the court to be educated in the relevant background material to the dispute in a way that permits the judge to engage with the presentation and develop an introductory understanding of the subject matter. The transcript of the tutorial and any supporting material stands as evidence, and the legal representatives are permitted to cross-examine on its contents.

The Federal Court employs a number of processes which facilitate the case specific education of decision-makers.

Once the case has proceeded to trial, the Court regularly employs a number of innovative processes aimed toward educating trial judges in the specifics of the case. Most notably, in patent cases involving several expert witnesses it is common for the Court to order the preparation of a joint expert report following the filing of expert affidavits. This will involve a meeting being convened between the experts, often facilitated by a registrar of the Court, aimed at synthesizing the issues in respect of which the experts agree and disagree. During this meeting, the experts are encouraged to reach agreement on the issues relevant to the case and, where that is not possible, provide a brief explanation of the reasons for their disagreement. This meeting will culminate in the production of a joint expert report to be tendered in evidence. At the hearing, it is likely that the evidence of the experts who contributed to the preparation of the joint expert report will be given concurrently. This means that the experts will be questioned together, promoting a frank dialogue between the experts and enabling the further clarification of any differences of opinion.

2.6.9 Confidentiality

Australian courts operate under a principle of open justice. However, open justice is not an absolute concept, and, on occasion, it must be balanced with other considerations, including commercial confidentiality.

During patent-related court proceedings, the first stage at which issues concerning confidentiality are likely to arise is during either disclosure processes (e.g., discovery) or the service of evidence. At these stages, the confidentiality issues that arise are more likely to concern the disclosure of confidential information to the opposing party (who is often a commercial competitor) rather than to the public at large. Generally, a party that receives documents that have been served for the purposes of litigation will be under an obligation to use those documents only for the purposes of the proceedings in respect of which the documents were served (i.e., not for the purposes of other proceedings or for other commercial or noncommercial purposes).⁹⁸

Beyond that general obligation, it is common for parties serving documents containing confidential information to require the party receiving the documents to give an undertaking restricting the use and disclosure of those documents. The undertakings are given either *inter partes*, to the court, or to both. The form of such undertakings is often resolved between the parties without the intervention of the court; however, the court may become involved if a dispute about confidentiality arises that the parties are unable to resolve between themselves. For example, there may be a dispute about whether access to documents should be restricted to external legal representatives or whether it is necessary that the party or its employees also have access to the documents. In such circumstances, the court balances the competing considerations of the risk of inadvertent or accidental disclosure against the benefits of a party having access to relevant information so that appropriate advice can be given to the client and informed instructions may be received from the client.⁹⁹

In accordance with the principle of open justice, hearings of court proceedings in Australia are conducted in public, and evidence adduced in proceedings at a hearing becomes public. Any agreement between the parties to keep information confidential will not keep evidence given in

⁹⁸ *Hearne v. Street* (2008) 235 CLR 125.

⁹⁹ See, e.g., *AstraZeneca AB v. Medis Pharma Pty. Ltd.* [2014] FCA 549.

open court from becoming public. Any party wishing to rely on evidence at trial while keeping that evidence confidential will need to seek suppression or nonpublication orders from the court. Such orders may also be sought from the court at earlier stages of the proceedings if the parties are unable to agree on a confidentiality regime between themselves.

In the Federal Court of Australia, the power to make these orders is provided by Section 37AF of the Federal Court of Australia Act 1976 (Cth). The most relevant ground for making such orders is that the order is necessary to prevent prejudice to the proper administration of justice.¹⁰⁰ In deciding whether to make an order, the Court must take into account that a primary objective of the administration of justice is to safeguard the public interest in open justice. Commercial disadvantage that may arise from the disclosure of confidential information may be a basis for the making of a suppression or nonpublication order because the occasioning of such disadvantage may prejudice the proper administration of justice.¹⁰¹ Such orders are not made in perpetuity, and the Court is to ensure that the order operates for no longer than is reasonably necessary to achieve the purpose for which it is made.¹⁰² Interim confidentiality orders may also be made under Section 37AI, pending the Court's determination of whether an order should be made under Section 37AF.

2.6.10 Alternative dispute resolution

Under the legislation and court rules of the Federal Court, there are mechanisms by which parties may elect to participate in, or be referred by the Court to, a number of alternative dispute resolution (ADR) processes. Further, under the court rules, the parties are required to "consider options for alternative dispute resolution, including mediation, as early as is reasonably practicable."¹⁰³

The court may refer the entire proceedings or part of a proceeding to mediation (or arbitration).¹⁰⁴ In patent litigation in Australia, mediation is far more common than arbitration. This may reflect the fact that an arbitrator cannot revoke a patent. Alternatively, the parties to the proceedings may also make an application to the court for an order to be referred to mediation or arbitration.¹⁰⁵ Parties may also arrange for ADR processes to be initiated with a private mediator outside of the court proceedings, although if this is the case, the parties are obliged to seek directions regarding the case management of the proceedings from the court.¹⁰⁶

In some cases, the entire patent infringement or validity case may be referred to a form of ADR early in the proceedings. However, parts of the proceedings may be referred to ADR. For example, an interlocutory dispute between the parties regarding the scope of discovery or the quantum of costs may be referred to mediation, to be conducted by a registrar of the court acting as mediator.

If a proceeding is referred to mediation or arbitration, and the parties do not nominate a mediator or arbitrator, a registrar of the Federal Court may be nominated to conduct the ADR process.¹⁰⁷ The registrars are trained in ADR processes and regularly act as mediators in court-facilitated mediations, including in patent matters. The Federal Court's *Central Practice Note* explains:

Where appropriate, the ADR skills of registrars will be drawn on by the Court to help parties resolve issues (whether substantive or procedural) at the earliest and most effective stage of the proceeding and the Court will utilise its technology and innovative meeting arrangements to help to conduct ADR processes in an efficient and cost-effective manner.¹⁰⁸

¹⁰⁰ Federal Court of Australia Act 1976 (Cth) s. 37AG(1)(a).

¹⁰¹ See, e.g., *Vehicle Monitoring Systems Pty. Ltd v. Sarb Management Group Pty. Ltd.* (No. 3) [2020] FCA 7.

¹⁰² Federal Court of Australia Act 1976 (Cth) s. 37AJ(2).

¹⁰³ Federal Court Rules 2011 (Cth) r. 28.01.

¹⁰⁴ Federal Court of Australia Act 1976 (Cth) s. 53A(1).

¹⁰⁵ Federal Court Rules 2011 (Cth) r. 28.02.

¹⁰⁶ Federal Court Rules 2011 (Cth) r. 28.05.

¹⁰⁷ Federal Court Rules 2011 (Cth) r. 28.31.

¹⁰⁸ Federal Court of Australia, *Central Practice Note: National Court Framework and Case Management (CPN-1)*, Dec. 20, 2019, [9.3].

As a result of the COVID-19 pandemic, there has been increasing use of videoconferencing platforms by the Federal Court, and this technology has been used to facilitate mediations conducted by registrars of the court. Generally, these mediations are conducted on the Microsoft Teams videoconferencing platform, and parties are given access to a joint meeting room (where all parties and the registrar will meet concurrently) as well as individual party meeting rooms (which are used by individual parties to confer during the course of the mediation).

Where mediation is to be conducted by a registrar of the court, the parties may be asked to prepare a nonconfidential position statement (which is exchanged between the parties) and a confidential report (which is shared only with the registrar, on a confidential and without-prejudice basis). Generally, the nonconfidential position statement will set out, at a high level, the parties' arguments on the disputed issue, and the confidential report to the registrar will set out confidential information regarding the parties' assessments of their prospects, costs and other objectives that may be relevant to the mediation.

Mediations conducted by registrars of the court are typically listed for one day, although if the dispute is not resolved, the registrar may extend that period. The parties may be represented by their legal representatives (including their solicitors and barristers). The party will generally also need to have an officer or employee of the party present at the mediation who has authority to agree to any settlement during the mediation. The *Central Practice Note* of the Federal Court explains:

When attending mediation, parties and their legal representatives must attend for the purpose of participating in good faith negotiations and must have the ability, in a practical way and with flexible instructions, to participate meaningfully in negotiations with a view to narrowing the issues in dispute and reaching a mutually acceptable resolution between them by way of compromise.¹⁰⁹

2.7 Civil remedies

Section 122 of the Patents Act 1990 (Cth) provides for the relief available to a patentee where a claim of an asserted patent is found by a court to be infringed. Such relief includes:

- an injunction (subject to such terms, if any, as the court thinks fit);
- either damages or an account of profits (at the election of the patentee); and
- an additional amount in an assessment of damages if the court considers it appropriate to include such an amount (commonly referred to as “additional damages”).

Each form of remedy is discussed in turn below.

2.7.1 Injunctive relief

In addition to pecuniary remedies (outlined in the next section), permanent injunctive relief is also available.¹¹⁰ In the ordinary course, a successful patentee will be granted a permanent injunction for the life of a patent.

However, injunctive relief is subject to equitable and discretionary considerations and, therefore, may not be an appropriate remedy in all cases. For example, the appropriateness of a permanent injunction has been queried by the Federal Court of Australia in respect of infringement of a patent claiming a new method of a medical treatment using a therapeutic agent that is also widely used for other non-infringing medical treatments.¹¹¹

Further, the form of the injunctive relief will depend on the specific circumstances of each case. A court can grant a permanent injunction prohibiting infringement in “general form” (i.e., restraining the infringer from infringing a particular patent or patents) or an injunction in terms

¹⁰⁹ Federal Court of Australia, *Central Practice Note: National Court Framework and Case Management*, [9.5].

¹¹⁰ Patents Act 1990 (Cth) s. 122(1).

¹¹¹ *Mylan Health Pty Ltd (formerly BGP Products Pty Ltd) v. Sun Pharma ANZ Pty Ltd (formerly Ranbaxy Australia Pty Ltd)* [2019] FCA 28 [255]–[259].

limited to the specific infringements established at trial, known as a “conduct-based injunction” (where an infringer is restrained from doing those certain acts).¹¹²

2.7.2 Separation of quantum and liability

It is common in patent infringement proceedings for liability to be heard and determined before considering the quantum of pecuniary relief. This is because parties often agree, and the court considers it appropriate, for questions of liability (i.e., infringement and validity issues) to be heard and determined as a separate and preliminary question prior to any hearing on quantum of pecuniary relief.¹¹³

Due to this bifurcation of liability and quantum, and as a matter of commercial practicalities and convenience, issues relating to pecuniary relief are often resolved *inter partes* after the liability judgment has been given and any appeals have been determined, and before the hearing on pecuniary relief.

A patentee must elect pecuniary relief in the way of either damages or an account of profits: a patentee cannot choose *both* damages and an account of profits. Discovery can also be sought and obtained following a finding of patent infringement to assist the patentee in making the election. An infringer can also be ordered to provide an affidavit or audited accounts with respect to its infringing sales or profits.

2.7.2.1 Damages

Damages is a common law remedy, and damages for patent infringement are awarded according to the ordinary principles relevant to tort law. The rationale for an award of damages in patent infringement is to restore the patentee as much as reasonably possible to the position as if the infringement had not occurred. Damages should be assessed liberally and to the best possible approximation. However, a patentee must first demonstrate the requisite threshold elements of causation and reasonable foreseeability in accordance with common law.

The Federal Court of Australia has recognized that there are a number of different ways to calculate damages for patent infringement, including on a “lost sales” basis, using a “reasonable license fee,” or a “user principle” basis, depending on the facts of the particular case. Further, provided foreseeability and causation are demonstrated, damages for patent infringement can also be claimed for the loss of goods that commonly would have been sold with the patented goods, springboarding or on other grounds.

Damages may also attract interest under Section 51A of the Federal Court of Australia Act 1976 (Cth).

2.7.2.1.1 Lost sales

The “lost sales” methodology is often used where the patentee has exploited the patent by manufacturing, production or direct sales, and the infringer is a competitor in the relevant market. However, the onus is on the patentee to show that the relevant sales are actually “lost.” This can be problematic for certain patentees: often, the sale of an infringing item does not (without more) equate to one unit of a lost sale for the patentee. Relatedly, the patentee may also need to prove that the patentee could have satisfied the additional demand and would have made a profit on that sale.

2.7.2.1.2 Reasonable license fee

Conversely, a “reasonable license fee” approach is generally employed by a patentee who exploits a patent through licensing to others. In implementing this methodology, the appropriate measure of damages is considered to be the determination of a license fee, either as would have been agreed to by the patentee or on a notional basis. Again, the onus is on the patentee to demonstrate the amount of a reasonable license fee.

¹¹² *Calidad Pty Ltd v Seiko Epson Corporation (No. 2)* [2019] FCAFC 168 at [44].

¹¹³ See Federal Court Rules 2011 (Cth) r. 30.01.

2.7.2.1.3 “User principle” basis

The “user principle” basis of damages is where a successful patentee can recover a reasonable sum of damages from an infringer who has wrongfully “used” the patentee’s property, even, for example, where the evidence is that the patentee would not have granted a license at all, or if it cannot be shown that the patentee has suffered an actual loss. Using the “user principle” methodology, the quantum of damages is often determined by assessing the amount the infringer would have had to pay for the “use” of the patent, for example, by way of a notional license fee.

2.7.2.2 Account of profits

An account of profits requires an infringer to account for and disgorge the profits it made through the infringing conduct. As an account of profits is an equitable remedy, equitable considerations apply, including knowledge of wrongful conduct on the part of the infringer and equitable defenses such as estoppel, laches, acquiescence and delay.

An account of profits is generally calculated by taking the revenue made by the infringer and subtracting any reasonable costs expended that are attributable to the infringing sales, such as costs in respect of manufacturing, marketing and distribution.

Further, if the patent in issue is for a product that is a single component within a larger product (e.g., a SIM card inside a smartphone), a court may require an apportionment of the profits to take into account there being a large proportion of non-infringing parts within the relevant article. This analysis will also depend on whether the infringing part is considered an “essential part” of the article.

2.7.2.3 Additional damages

Where a patentee has elected to seek damages for patent infringement, the court also has the discretion to include an “additional amount in the assessment of damages” if it considers it appropriate to do so.¹¹⁴ Importantly, there is no requirement for any proportionality or relationship between the amount of actual damages awarded and the quantum of any “additional damages.” Relatedly, there is no limit to the quantum of additional damages prescribed by the Patents Act or accompanying regulations. Discovery can also be ordered if considered by the court to be relevant to the additional damages claim.

Section 122(1A) of the Act relevantly sets out the factors that a court can “have regard to” if the court “considers it appropriate to do so.” Importantly, these factors are nonlimiting and include:

- (a) the flagrancy of the infringement; and
- (b) the need to deter similar infringements of patents; and
- (c) the conduct of the party that infringed the patent that occurred:
 - (i) after the act constituting the infringement; or
 - (ii) after that party was informed that it had allegedly infringed the patent; and
- (d) any benefit shown to have accrued to that party because of the infringement; and
- (e) all other relevant matters.

The last criterion – namely, “all other relevant matters” – has been construed to allow parties to seek to rely on a variety of conduct in seeking an award for additional damages.¹¹⁵

Additionally, more than mere “copying” is required to enliven the application of Section 122(1A), as the purpose of the additional damages regime is to award such damages in cases of *wilful* infringement of a patent. For example, it is considered not to be a “flagrant” or illegitimate act for a potential competitor to attempt to “work around” a particular patent.

Further, the Federal Court of Australia has found that the fact that an infringer possessed a reasonably arguable belief that the relevant patent was invalid or not infringed is an important factor tending against an award of additional damages. This is so, even if those non-infringement or invalidity defenses are ultimately unsuccessful at trial.¹¹⁶

¹¹⁴ Patents Act 1990 (Cth) s. 122(1A).

¹¹⁵ See, e.g., *Oxworks Trading Pty Ltd v. Gram Engineering Pty Ltd* [2019] FCAFC 240 [78].

¹¹⁶ See, e.g., *Zetco Pty Ltd v. Austworld Commodities Pty Ltd (No. 2)* [2011] FCA 848 [267]–[268]; *Oxworks Trading Pty Ltd v. Gram Engineering Pty Ltd* [2019] FCAFC 240 [73], [78].

2.7.3 Other remedies

There are number of other remedies available to patent litigants in Australia, including *Mareva* injunctions, *Anton Piller* orders and orders for ancillary final relief (such as the destruction or delivery up of infringing articles).

In broad terms, an Australian court may order a *Mareva* injunction (also known as a “freezing” or “asset protection” order) if it is satisfied that:

- judgment has been given in favor of the applicant, or the applicant has a “good arguable case on an accrued or prospective cause of action”; and
- there is a danger that the judgment or prospective judgment will be wholly or partially unsatisfied because the judgment debtor or prospective judgment debtor has either absconded or removed, disposed of or diminished the value of their assets.¹¹⁷

Freezing orders are exceptional in nature, and the applicant for such an order will need to provide the usual undertaking as to damages, being to submit to any order as the court may consider just for the payment of compensation to any person (whether or not that person is a party) affected by the operation of the order. Further guidance on freezing orders, including a sample form of a freezing order, appears in the Federal Court of Australia’s *Freezing Orders Practice Note* (GPN-FRZG).¹¹⁸

In Australia, an *Anton Piller* order (also called a “search” order) may be made if the court is satisfied that (i) the applicant has a “strong *prima facie*” case and will suffer “serious” loss or damage if the search order is not made, and (ii) there is “sufficient evidence” that the respondent possesses important evidentiary material and that there is a real possibility that such material might be destroyed or otherwise unavailable for use in evidence in the proceeding or anticipated proceeding.¹¹⁹ Applications for search orders are generally made on an *ex parte* basis, require the usual undertaking as to damages and involve the court appointing an independent solicitor to supervise the execution of the search order. Further guidance on search orders, including a sample form of a search order, appears in the Federal Court’s *Search Orders Practice Note* (GPN-SRCH).¹²⁰

In addition to injunctive relief, it is common for patentees following a successful patent infringement action to request orders for the delivery up or destruction of infringing articles. Whether such ancillary relief should be awarded is ultimately a discretionary question for the court. Among other things, it needs to be shown that the infringing articles that are the subject of the delivery up or destruction order do, in fact, fall within the scope of the claims and that the orders are required (over and above any order for injunctive relief) as additional protection against the risk of future infringement.¹²¹

It is also not uncommon for successful patentees in Australia to seek declarations of infringement and, if the validity of a patent claim has been questioned and its validity upheld, an order for a certificate of validity under Section 19 of the Patents Act 1990 (Cth). The effect of a certificate under Section 19 is that, if a subsequent revocation proceeding is issued in respect of the claim that is the subject of the certificate, and the patentee is successful in that subsequent proceeding, then the patentee may be entitled to costs on a solicitor and client basis in that subsequent proceeding.¹²²

2.7.4 Costs

2.7.4.1 General approach to costs

In all courts in Australia, including the Federal Court of Australia, costs are at the discretion of the court. That is, the court may make an order that one party pay the other party’s legal costs for the

¹¹⁷ Federal Court Rules 2011 (Cth) r. 7.35.

¹¹⁸ See Federal Court of Australia, *Freezing Orders Practice Note* (GPN-FRZG), Oct. 25, 2016.

¹¹⁹ Federal Court Rules 2011 (Cth) r. 7.43.

¹²⁰ See Federal Court of Australia, *Search Orders Practice Note* (GPN-SRCH), Oct. 25, 2016.

¹²¹ *Streetworx Pty. Ltd v. Artcraft Urban Group Pty. Ltd.* (No. 2) (2015) 322 ALR 557, [109]–[110]; see also *Roussel Uclaf v. Pan Laboratories Pty. Ltd.* (1994) 29 IPR 556, 599–561.

¹²² See, e.g., *AstraZeneca AB v. Alphapharm Pty. Ltd.* [2014] FCA 419.

proceedings. Legal costs will include the costs of legal representation, including any disbursements such as barristers' fees and expert costs.

Where a costs order is made, the usual rule is that "costs follow the event," meaning that the unsuccessful party will pay the legal costs of the successful party. The total costs ordered against the unsuccessful party are typically payable on a "party and party" basis.¹²³ Party/party costs are costs that have been fairly and reasonably incurred by the party in the conduct of the litigation. But, as the order is at the court's discretion, on application by a party, the court may order that costs be paid on a different basis, including on an indemnity basis.¹²⁴ Indemnity costs allow for the recovery of all of a party's costs except those that have been unreasonably incurred. Under any costs order, a party does not have to pay any costs that have been improperly, unreasonably or negligently incurred.¹²⁵

In most cases, it is not possible for a successful party, even on an indemnity basis, to recover all of their costs. For example, a party awarded costs on a party and party basis may only be entitled to recover approximately 60 percent of these costs once their costs are assessed on a fair and reasonable basis. One reason for this gap between actual costs and what is assessed to be fair and reasonable (on a party and party basis) is that the actual cost of counsel and experts and other legal costs is higher than is allowed for under the court scale.

If a party is only partially successful – or for other reasons – a judge may make no order as to costs, order the unsuccessful party to pay less than 100 percent of the successful party's costs on a party and party basis, or make an order that the successful party pay the unsuccessful party's costs in full or in part. This may occur where one party has not complied with the overarching purpose set out in Sections 37M and 37N of the *Federal Court Act 1976* (Cth) – facilitating the just resolution of disputes according to law and as quickly, inexpensively and efficiently as possible – or has otherwise acted in a way that has wasted costs. It has also become commonplace in patent cases for courts to adopt an issues-based approach to the award of costs – for example, by only requiring an unsuccessful patentee in a revocation action to pay a portion of the successful revoker's costs on the basis that the revoker was successful on some but not other grounds.

Particular reference should be made to Part 40 of the Federal Court Rules 2011 (Cth) concerning costs and the *Costs Practice Note (GPN-COSTS)*¹²⁶ in respect of costs in the Federal Court. If the matter is listed in a state court, the equivalent practice notes, rules and legislation applicable in that jurisdiction should be consulted.

The above applies both to first-instance hearings and on appeal. In either case, costs are ordinarily sought by the applicant in the originating application commencing proceedings. Parties are usually heard on the question of costs by the court by way of either or both oral and written submissions at the end of the trial, once reasons for judgment are delivered or when orders are made in relation to the substantive issues in the proceedings.

2.7.4.2 Interlocutory proceedings and other issues

Parties may apply for costs orders in interlocutory applications. Where a party has been wholly successful in an interlocutory application, they may obtain an order that the other party pay their costs of the application, to be determined similarly to the above.

Where there have been wasted costs, the affected party may seek an order for "costs thrown away." An order of this kind means that, whatever the outcome of the proceedings, a party will be entitled to recovery of those costs. For example, where an applicant has amended its pleadings, resulting in the removal of a cause of action that the respondent has already spent time and money responding to, the respondent may apply for an order for costs thrown away.

If an applicant or cross-claimant discontinues proceedings,¹²⁷ an adverse costs order, usually on an indemnity basis, is ordinarily made.¹²⁸

¹²³ Federal Court Rules 2011 (Cth) r. 40.01.

¹²⁴ Federal Court Rules 2011 (Cth) r. 40.02.

¹²⁵ Federal Court Rules 2011 (Cth) r. 40.06.

¹²⁶ Federal Court of Australia, *Costs Practice Note (GPN-COSTS)*, Oct. 25, 2016.

¹²⁷ Federal Court Rules 2011 (Cth) r. 26.12.

¹²⁸ Federal Court Rules 2011 (Cth) r. 26.12(7); see also *id.* r. 26.15 (allowing for a stay of a subsequent proceeding where the costs of an earlier discontinued proceeding have not been paid).

2.7.4.3 Security for costs

Where a respondent has reason to believe that an applicant may not be able to cover an adverse cost order if its claim is unsuccessful, it may apply for security for costs orders.¹²⁹ Upon an interlocutory application seeking security for costs being filed in an existing proceeding, a court will consider the applicant's ability to meet an adverse costs order. This includes whether there is reason to believe that the applicant will be unable to pay the respondent's costs if ordered to do so, whether the applicant ordinarily resides outside Australia, is suing for someone else's benefit, is impecunious or any other relevant matter. These matters should be dealt with by affidavit evidence.

A party may seek further orders that proceedings be stayed until any security ordered has been paid into court. Once paid, the security is held by the court until the conclusion of the proceedings. If security is not paid as ordered, a respondent may apply for the proceedings to be dismissed.¹³⁰

2.7.4.4 Offers of compromise and *Calderbank* offers

The costs a party is liable to pay may also be affected by the existence of a valid offer of compromise made under the Federal Court Rules¹³¹ or of a *Calderbank* offer.¹³² In both cases, form requirements must be met for the offers to be accepted by the court as within these categories. If accepted, and depending on the offer made and the outcome of the case, one or the other party may be entitled to have their costs paid on an indemnity basis from the date of the offer or as otherwise provided for by the Federal Court Rules.

Such offers are frequently made throughout proceedings to protect a party's costs position with the aim of efficiently settling proceedings to avoid incurring unnecessary costs. The court should not be informed of any settlement offers before the substantive issues in the proceedings have been determined.

2.7.4.5 Assessment of costs

Where a court makes an order for payment of a party's costs, and failing agreement by the parties as to the quantum to be paid, the costs must be taxed in accordance with the Federal Court Rules (e.g., on a party and party basis or an indemnity basis). As part of this process, a costs assessor will be engaged to assess the costs payable to the party in whose benefit the order was made.¹³³ This is known as the taxation process. A costs assessor is an independent specialist knowledgeable about the costs rules and industry costs.

Once the costs assessor has assessed the costs, a report is provided to the court, and, if there is no dispute, orders will be made that the liable party pay the assessed amount. If the parties are unable to agree on the assessment of costs, there may be a hearing to determine the costs payable. However, courts seek to avoid hearings on costs, which are lengthy and expensive. Party cooperation in respect of costs is therefore expected in order to avoid a contested costs hearing.

Compromises such as an agreed lump sum payment for costs are another way to streamline the costs process, orders for which the court may make upon application by the parties.¹³⁴

2.8 Other patent-related actions

2.8.1 Actions for declarations of non-infringement

A person who has done, is doing or is intending to do an act may apply to the court for a declaration that the doing of the act does not or would not infringe a patent.¹³⁵ An application may be made whether or not the patentee has made any assertion to the effect that the doing of the act has or would infringe the claim.¹³⁶

¹²⁹ Federal Court Rules 2011 (Cth) r. 19.01.

¹³⁰ Federal Court Rules 2011 (Cth) r. 19.01.

¹³¹ Federal Court Rules 2011 (Cth) pt 25.

¹³² Based on the principle in *Calderbank v. Calderbank* [1975] 3 All ER 333, which has been applied by Australian courts in innumerable cases.

¹³³ Federal Court Rules 2011 (Cth) div. 40.2.

¹³⁴ Federal Court Rules 2011 (Cth) r. 40.02.

¹³⁵ Patents Act 1990 (Cth) s. 125(1).

¹³⁶ Patents Act 1990 (Cth) s. 125(2).

The court must not make a non-infringement declaration unless

- (a) the applicant for the declaration:
 - (i) has asked the patentee in writing for a written admission that the doing of the act has not infringed, or would not infringe, the patent; and
 - (ii) has given the patentee full written particulars of the act done, or proposed to be done; and
 - (iii) has undertaken to pay a reasonable sum for the patentee's expenses in obtaining advice about whether the act has infringed or would infringe the claim; and,
- (b) the patentee has refused to make the admission.¹³⁷

Where a declaration has been made, and the patentee later obtains an injunction restraining the person from doing the act, or the declaration is revoked, the holder of the non-infringement declaration is not liable to account to the patentee for any profits made, or pay damages for any loss suffered, as a result of doing the act as specified in the declaration before the date on which the injunction was granted or the declaration was revoked.¹³⁸ The same applies if an admission is made by the patentee.¹³⁹

2.8.2 Actions for threats of infringement proceedings

Section 128 of the Patents Act 1990 (Cth) permits a person who is aggrieved by unjustified threats of patent infringement to apply to a court for an injunction against the continuance of those threats, declaratory relief and recovery of any damages sustained as a result of the threats. A person "aggrieved" includes any person adversely affected by the threats. This may be the direct recipient of the threat (e.g., a competitor of the patentee receiving a letter of demand) but may also include others that may be indirectly affected by such threat, including the person's customers or suppliers.

However, "threat" is not defined in the Act. Whether a communication or an act constitutes a threat is a question of fact considered objectively. A court will consider the relevant communication and the context in accordance with "the understanding of an ordinary recipient, standing in the position of the actual recipient, reading the letter or communication said to contain the threat, in the normal course of business."¹⁴⁰ However, the threat must pertain to an Australian patent and proceedings in Australia. Importantly, the "mere notification" of the existence of a patent does not constitute a threat for the purposes of Section 128.¹⁴¹ The onus is on the party making the threat to prove that the threat was justified, by satisfying the court that the relevant acts infringed (or would infringe) a valid claim.¹⁴² If this onus is not dislodged, the threats are considered unjustified.

Damages may be sought; however, it must be shown that such damage was caused "as a result of the threats." A court also has the discretion to award additional damages, taking into account various matters, including the flagrancy of the threats.¹⁴³ Finally, in practice, an action under Section 128 will often result in a cross-claim for infringement.¹⁴⁴ The recipient of the threat can then also elect to seek revocation of the patent.¹⁴⁵

2.9 Appellate review

2.9.1 Appeal from an invalidity decision of a court

An appeal from an invalidity decision of a court must be filed within 28 days of the date of the judgment or order unless an extension is granted.¹⁴⁶ The appellate court is usually the Full Court

¹³⁷ Patents Act 1990 (Cth) s. 126(1).

¹³⁸ Patents Act 1990 (Cth) s. 127.

¹³⁹ Patents Act 1990 (Cth) s. 127.

¹⁴⁰ *Liberation Developments Pty Ltd v. Lomax Group Pty Ltd* [2019] FCA 1180, [150].

¹⁴¹ Patents Act 1990 (Cth) s. 131.

¹⁴² Patents Act 1990 (Cth) s. 129.

¹⁴³ Patents Act 1990 (Cth) s. 128(1A).

¹⁴⁴ Patents Act 1990 (Cth) s. 130(1).

¹⁴⁵ Patents Act 1990 (Cth) s. 130(2).

¹⁴⁶ Federal Court Rules 2011 (Cth) rr. 36.03, 36.05.

of the Federal Court of Australia. The appeal will be heard by three judges of the Federal Court, although, in some cases of particular significance (e.g., where a previous appellate authority is called into question), the appeal may be heard by five judges. Such an appeal is not a hearing *de novo* but is an appeal by way of rehearing.

The Full Court conducts a review of the trial judge's reasons and the evidence to determine whether the judge has made an error – legal, factual or discretionary.¹⁴⁷ The Full Court may affirm, reverse or vary the judgment appealed from and may give such judgment or make such orders as in all the circumstances it thinks fit. The Full Court may grant relief itself or may remit the proceeding for further hearing and determination.¹⁴⁸ The Full Court will consider the evidence that was before the trial judge and may draw inferences of fact from such evidence. In special and limited circumstances, the Full Court may, in its discretion, receive further evidence. The Full Court will similarly not usually allow a party to raise a ground or an issue that was not raised at first instance.

If an error of fact is found to have been made, the Full Court will substitute its own findings of fact. In fact-finding circumstances involving the credibility of witnesses, the Full Court will generally not interfere with a trial judge's finding of fact unless it is demonstrated to be wrong by "incontrovertible facts or uncontested testimony," "glaringly improbable" or "contrary to compelling inferences."¹⁴⁹ This recognizes the special advantages of a trial judge. Where matters of impression or evaluative judgment are concerned, the Full Court will accord proper weight to the views and advantages of the trial judge.

The filing of an appeal does not itself operate to stay the first-instance decision. Therefore, a stay of the whole or part of the orders is often sought pending the determination of the appeal. In deciding whether to grant a stay, the court will consider whether an arguable ground has been raised on the appeal and whether the balance of convenience favors the granting of a stay. A stay will be granted where there is a likelihood that a successful appeal will be rendered nugatory. For this reason, an order revoking a patent is usually stayed, as there is some uncertainty as to the ability of the court on appeal to reinstate a patent once revoked.¹⁵⁰

2.9.2 Appeal from an infringement decision of a court

An infringement decision made by a court (whether in proceedings for infringement or for a non-infringement declaration) may be reviewed by way of an appeal to the Full Court of the Federal Court of Australia. An appeal to the Full Court will be by way of a rehearing. The principles of appellate review were discussed in the previous section.

2.10 Selected topics

2.10.1 Compulsory licenses

The Federal Court of Australia is empowered to make orders requiring the grant of a compulsory license to exploit a patented invention if certain conditions are met.¹⁵¹ An application cannot be made until after the expiration of the prescribed period, which is currently three years from the date of grant.¹⁵² There are three circumstances in which the court may grant a compulsory license:

- where there has been an inadequate working of the invention;¹⁵³
 - where the patentee has engaged in restrictive trade practices in connection with the patent;¹⁵⁴
- or

147 *Aldi Foods Pty. Ltd. v. Moroccanoil Israel Ltd.* [2018] 261 FCR 301 (Allsop and Perram, JJ).

148 Federal Court of Australia Act 1976 (Cth) s. 28.

149 *Robinson Helicopter Company Inc. v. McDermott* (2016) 331 ALR 550, [43].

150 *Alphapharm Pty. Ltd v. H Lundbeck A/S (No. 2)* (2009) 78 IPR 338.

151 See Patents Act 1990 (Cth) ch. 12.

152 Patent Regulations 1991 (Cth) reg. 12.1.

153 Patents Act 1990 (Cth) s. 133(2)(a).

154 Patents Act 1990 (Cth) s. 133(2)(b); Competition and Consumer Act 2010 (Cth) pt IV, or an application law as defined in s. 150A of that Act.

- where the manufacture and export of a patented pharmaceutical invention is needed to address a public health issue in an eligible importing country.¹⁵⁵

In an application for a compulsory license based on an inadequate working of the invention, the applicant must prove the existence of all of the following conditions:

- (a) demand in Australia for the original invention is not being met on reasonable terms; and
- (b) authorisation to exploit the original invention is essential to meet that demand; and
- (c) the applicant has tried for a reasonable period, but without success, to obtain authority from the patentee to exploit the original invention on reasonable terms and conditions; and
- (d) the patentee has given no satisfactory reason for failing to exploit the patent to the extent necessary to meet the demand for the original invention in Australia; and
- (e) it is in the public interest¹⁵⁶ to provide the applicant with authorisation to exploit the original invention, having regard to the following:
 - (i) the benefits to the public from meeting the demand for the original invention;
 - (ii) the commercial costs and benefits to the patentee and the applicant from providing authorisation to exploit the original invention;
 - (iii) any other matters the court considers relevant, including matters relating to greater competition and any impact on innovation; and
- (f) if the applicant is the patentee of another invention (the dependent invention) and is seeking the authorisation for the purposes of exploiting the dependent invention:
 - (i) the dependent invention cannot be exploited by the applicant without exploiting the original invention; and
 - (ii) the dependent invention involves an important technical advance of considerable economic significance on the original invention.¹⁵⁷

An applicant for a compulsory license based on restrictive trade practices must prove the alleged contraventions of the Competition and Consumer Act 2010 (Cth).

An applicant for a license to exploit a patented pharmaceutical invention must prove, *inter alia*, that:

- the application is made in good faith;
- the pharmaceutical product is to be imported by the eligible importing country or on its behalf;
- proposed use of the pharmaceutical product is to address a public health problem in the eligible importing country in circumstances of national emergency or other circumstances of extreme urgency or, in other circumstances, by the public noncommercial use of the pharmaceutical product; and
- exploiting the patented pharmaceutical invention is necessary to enable the import and proposed use of the pharmaceutical product.¹⁵⁸

An eligible importing country is “a WTO [World Trade Organization] member that notifies the Council for TRIPS [Trade-Related Aspects of Intellectual Property Rights] of the member’s intention to use the system set out in Article 31 of the TRIPS Agreement and the Annex to that Agreement as an importer” or “a country included in the list of least-developed countries maintained by the United Nations, as in force from time to time.”¹⁵⁹

If the parties cannot agree on the amount of remuneration for the compulsory license, then it is determined by the court.¹⁶⁰

¹⁵⁵ Patents Act 1990 (Cth) s. 136E.

¹⁵⁶ The public interest test was introduced by the Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Act 2020 (Cth) and replaced the previous “reasonable requirements of the public” test.

¹⁵⁷ Patents Act 1990 (Cth) s. 133(3).

¹⁵⁸ Patents Act 1990 (Cth) s. 136E.

¹⁵⁹ Patents Act 1990 (Cth) sch. 1; Patents Regulations 1991 (Cth) regs 1.3 (definition of “least developed country”), 1.4A.

¹⁶⁰ Patents Act 1990 (Cth) ss. 133(5), 136J.

The compulsory license may be revoked by agreement or by application to the court.¹⁶¹

The Crown may also exploit a patented invention for Crown purposes in certain circumstances.¹⁶²

Perhaps due to the stringency of the mandated conditions for the grant of a compulsory license, there have been no decisions on the grant of such a license under the Patents Act 1990 (Cth),¹⁶³ and few decisions under its predecessor, Section 108 of the Patents Act 1952 (Cth).¹⁶⁴

¹⁶¹ Patents Act 1990 (Cth) ss. 133(6), 136H.

¹⁶² Patents Act 1990 (Cth) ch. 17.

¹⁶³ *Amrad Operations Pty. Ltd v. Genelabs Technologies Inc.* [1999] FCA 633 considered a claim for a compulsory license pursuant to Section 133 of the Patents Act 1990 (Cth) but only in the context of an application for service outside the jurisdiction.

¹⁶⁴ See *Fastening Supplies Pty. Ltd v. Olin Mathieson Chemical Corporation* (1969) 119 CLR 572; *Wissen Pty. Ltd v. Kenneth Mervyn Lown* (1987) 9 IPR 124.

Chapter 3

Brazil

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In Brazil, legislative and judicial materials are published in Portuguese, generally with no official English-language translation. In this chapter, translations of text from Portuguese-language sources are done by the authors, except where indicated in the citation.

3.1 Overview of the patent system

3.1.1 Evolution of the patent system

There was a time when, due to the lack of a mechanism to ensure exclusivity for a certain period, inventors preferred to keep their inventions secret. This allowed the inventor to take advantage of their results, it being normal for their inventions and findings never to be known by anyone else. The basic idea of granting inventors temporary exclusivity over the commercialization of their inventions is old, although the most remembered milestone is the institutionalization and internationalization of intellectual property statutes, including for patents, provided for in the Paris Convention for the Protection of Industrial Property of 1883 (Paris Convention).¹

However, the idea of granting temporary exclusivity to inventors dates back to the fifteenth century, specifically the year 1449, in England, and was related to the manufacturing of stained glass, especially those that were used in the Catholic churches of the Middle Ages. At that time, King Henry VI gave a Flemish immigrant, John of Utynam, 20-year exclusivity for the manufacturing of a kind of colored stained glass he had invented – which can still be seen in the chapel of Eton College in England. At the time, the inventor had the duty to teach English stained-glass manufacturers the manufacturing process. It is interesting to note that the pressure to grant inventors some kind of exclusivity began in the Middle Ages “corporations.” Also in the fifteenth century, the famous Venetian crystal glassblowers, for example, created a similar system to protect their knowledge.

The topic of intellectual property has been discussed internationally for many decades and has involved political disputes due to unresolved issues, such as the definition of the subject matter and limits of protection, reconciliation of the interests of innovative companies and holders of intellectual property rights with those of society, and even the balance between developed countries (which dominate knowledge and make use of protection mechanisms) and countries that need to promote development to reduce poverty and improve their populations' quality of life.

Patenting a product or process seems to be one of the most used resources in the country to avoid copies and to guarantee exclusivity in commercial exploitation. Indeed, the patent is a protection mechanism most used by the pharmaceutical industry. The basic premise for the pharmaceutical industry is to achieve a reasonable return on the investment made in research and development. A patent guarantees exclusivity and helps the company charge prices that allow it to cover the costs of research and finance other innovation activities.

The monopoly provided by a patent is essential to make it difficult for competitors – for the period limited by statute – to copy inventions freely. This discourages other companies from entering the technological segment or field of interest. Holding patents can influence investors' perceptions, especially in publicly held companies, as patents provide investors with confidence and reflect the financing of innovative activities.

Having patents shows – not only to investors but also to other institutions (e.g., competitors and universities) – who these companies are and where they are going in terms of technology and innovation. It also helps to disseminate knowledge of their technological competence, which can help generate different opportunities: licensing, mergers, acquisitions and so on.

Another point of interest for companies in relation to pharmaceutical patents, especially among smaller companies, is the possibility of raising resources through licensing. Smaller laboratories find it difficult to bear development costs and need to collaborate with large companies for this process. Without patent protection, and given the small size of their businesses, these companies can be at a disadvantage in negotiations with large corporations. For larger laboratories, which tend to have global businesses, technology licensing can be a strategy to access certain markets. In any case, patent protection is a fundamental requirement for guaranteeing royalty revenues.

The long development period for new products, including clinical trials and regulatory processes, and the high costs of development, reinforce the importance of patents, especially in the

1 Paris Convention for the Protection of Industrial Property, March 20, 1883, 828 UNTS 305 [hereinafter Paris Convention], enacted in Brazil by Decree No. 9,233, of June 28, 1884.

pharmaceutical sector. However, there is a cost in obtaining and maintaining patents, as well as in enforcing against their infringement. We can also raise rhetorical questions about whether the temporary monopoly ensures a return on investments, on the risks of research development activities, on expenses incurred in the general and special registration of medicines, and on the placing of the product in the market.

This incentive given by the State in the form of the patent is made to establish an exchange with the inventor, since the inventor presents a useful invention for society (e.g., machines, medicines, tools and industrial processes), thereby justifying a reward by the State in ensuring this temporary protection and establishing “the right to prevent third parties from exploiting this invention without the inventor’s consent.”²

In Brazil, the patent system is based on Article 5(XXIX) of the Constitution, which provides for this temporary privilege and the protection guaranteed by patents, with a view to promoting social interest and the technological and economic development of the country.³ The patent system is governed, in particular, by Federal Law No. 9,279, of May 14, 1996 (Industrial Property Act; Lei da Propriedade Industrial (LPI)),⁴ enacted following the ratification, by Congress, of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement),⁵ incorporated into the Brazilian legal system by Decree No. 1,355, of December 30, 1994.⁶

While the LPI has substantially innovated the matter of industrial property in national legislation, little progress has been made in defining procedural aspects. Thus, a considerable part of the standards and rules applicable to patent lawsuits derive from general procedural rules and have been adapted by the national case law to the inherent peculiarities of patent litigation. Thus, it is worth noting that the civil procedure in these patent cases is substantially guided by the general procedural rules provided for in Federal Law No. 13,105, of March 16, 2015 (Code of Civil Procedure; Código de Processo Civil (CPC))⁷ and by court resolutions, while complying with the specific provisions of the LPI itself.

In Brazilian law, intellectual property encompasses copyright and related rights, and industrial property rights. The LPI generally regulates industrial property rights, and, in some specific cases, there is special legislation that has priority over the general law insofar as it is special. This is the case, for example, of Law No. 9,456, of April 25, 1997,⁸ concerning the reproductive material or vegetative multiplication material of the entire plant.

A patent is granted by the State – in Brazil, it is granted by the National Institute of Industrial Property (Instituto Nacional da Propriedade Industrial; INPI), to inventors or legal entities holding exploitation rights (i.e., a monopoly on the exploitation of an invention or utility model). In Brazil, a patent is granted only if the novelty, inventive step and industrial application requirements are met.

The word “patent” comes from Latin, from the singular nominative word *patens*, the genitive of which is *patentis*,⁹ and means something that is clear, accessible, exposed and, for our study, evident to everyone.

A patent, in simple terms, is a contract between the inventor and society. In this contract, inventors make their inventions public, binding upon everyone (*erga omnes*) and receiving in return, for a fixed period, the right to exploit the invention commercially and exclusively. This system guarantees the transfer of knowledge from the inventor to others interested in producing and marketing that product because, after the patent term, anyone can copy the product and use the information contained in the original patent application.

2 Ivan B Ahlert and Eduardo G Camara Junior, *Patentes: Proteção na Lei de Propriedade Industrial* 2 (2019) [hereinafter Ahlert and Camara Junior, *Patentes: Proteção na Lei de Propriedade Industrial*].

3 Constituição Federal (Federal Constitution) art. 5(XXIX) (“the law will ensure the authors of industrial inventions temporary privilege for their use, as well as protection of industrial creations, trademark ownership, company names, and other distinctive signs, in view of the social interest and the technological and economic development of the Country”).

4 Diário Oficial da União (DOU) of May 15, 1996.

5 Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, annex 1C, 1869 UNTS 299 [hereinafter TRIPS Agreement].

6 DOU of Dec. 30, 1994.

7 DOU of March 17, 2015.

8 DOU of April 4, 1997.

9 See PGW Glare ed., *A Latin Dictionary*, www.oxfordscholarlyeditions.com/page/the-oxford-latin-dictionary

With the rights afforded by a patent, patent holders have the right to prevent third parties, without their consent, from producing, using, offering for sale, selling or importing a product that is under the patent – including processes or products obtained directly by a patented process. Conversely, the patent holder undertakes to reveal, in detail, the entire technical content of the subject protected by the patent.

3.1.2 Types of patents

There are two types of patents. An invention patent protects a creation resulting from the exercise of creative capacity that represents a new solution to a technical problem existing within a given technological field and that can be manufactured. Inventions may refer to industrial products (e.g., compounds, compositions, objects, apparatus and devices) and industrial activities (e.g., processes and methods). An invention is patentable when it simultaneously meets three basic requirements: novelty, inventive step and industrial application (Article 8 of the LPI). Invention patents provide protection to creations of a technical nature that aim at a particular technical effect. The term of protection of this type of patent is 20 years from the date of filing.

An object of practical use (or part thereof) is patentable as a utility model if it is susceptible of industrial application, has a new form or arrangement, and involves an inventive act, that together result in functional improvement in the object's use or manufacture (Article 9 of the LPI). This object must be three-dimensional (e.g., instruments, utensils and tools). The term of protection for this type of patent is 15 years from the date of filing.

Additionally, the applicant or holder of an invention patent may request, upon payment of a specific fee, a certificate of addition of invention to protect an improvement or development introduced in the object of the invention, even if it lacks inventive step, as long as the subject matter is included within the same inventive concept (Article 76 of the LPI). The application for a certificate of addition is rejected if its subject matter does not present the same inventive concept (Article 76(3) of the LPI).

The certificate of addition is an accessory to the patent; it has the same expiration date as the patent and follows the patent for all legal purposes (Article 77 of the LPI). In nullity proceedings, the holder may request that the matter contained in the certificate of addition be examined to verify the possibility of its subsistence, without prejudice to the patent's term (Article 77(1) of the LPI).

3.1.3 The granting of a patent

The granting of a patent is an administrative act of declaration (after which the patent holder's right is recognized) and attribution (constitution), requiring the patent application and its processing before the government.

3.1.3.1 Drawings

Drawings must be presented clearly in firm, uniform lines and in indelible ink. There must be as many drawings as necessary for the perfect understanding of the patent object and they must be numbered consecutively. Each part, piece or element of a drawing must contain numerical references, which must be described in the specifications and in the claims.

In a patent application for a utility model, it is essential to present one or more drawings, since the reading of the claims is always associated with them, considering that the utility model patents refer specifically to three-dimensional objects.

3.1.3.2 Specifications

A patent application or certificate of addition must be sufficiently specified, which means that it must contain all the details necessary to allow a person skilled in the art to reproduce the object, and it must indicate, where appropriate, the best way of execution (Article 24 of the LPI). The specifications should also point out the existing problem in the state of the art and the proposed solution, specifying the technical sector in which it is intended to be used. Additionally, the specification must clearly highlight the novelty, the technical effect achieved (in the case of an invention) and its advantages in relation to the state of the art. The specifications for a utility model patent application must additionally highlight the conditions under which the object (or

part thereof) is better used as a result of the new shape or layout introduced, showing the functional improvement achieved.

An application must start with a title (it cannot be a brand or invented name). This title must define concisely, clearly and precisely the technical scope of the invention and must be the same for the request, specifications, abstract and sequence listing, if any. A patent application must refer to a single invention – or to a group of interrelated inventions in such a way that they constitute a single inventive concept – and describe the invention's purpose, application and technical field of use, comparing the subject matter of the protection with the state of the art, highlighting its advantages and the problem that it intends to solve. It must then list the drawings, if any, numbering them consecutively and describing their meaning. Then, it must describe, in detail, the subject matter of the patent application according to those drawings, referring to the numerical references of each part of the drawing.

Finally, there must be an abstract summarizing the subject matter of the patent application, following the title, clearly highlighting the subject matter. It must contain between 50 and 200 words and be a maximum of 25 lines of text. The abstract should encompass the technical characteristics, the solution to the problem described and its main uses. The main purpose of this is to facilitate a researcher's search in the patent banks.

3.1.3.3 Claims

The wording of the claims is of the utmost importance in the preparation of a patent application. The extent of the protection granted by a patent is determined by the content of these claims as interpreted based on the specifications and drawings – that is, the claims define and limit the extent of protection conferred by the patent (Article 41 of the LPI). The claims must be based on the specifications, which characterize the particularities of the application and clearly and precisely define the subject matter of protection, avoiding expressions that lead to uncertainties (Article 25 of the LPI).

Claims can be classified either into:

- independent claims: claims that, while maintaining the invention unity, or the technical-functional and bodily unity of the object (in the case of utility models), aim at the protection of essential and specific technical characteristics of the invention, or of the utility model, in its integral concept. Independent claims may serve as the basis for one or more dependent claims; or
- dependent claims: claims that, while maintaining the invention unity, or the technical-functional and bodily unity of the object (in the case of utility models), include features of other previous claims and define details of these features or additional features, containing an indication of their dependence on those claims.

In an invention patent application, there must be a definition, after the expression “characterized by,” of the essential and particular technical features that, combined with the aspects explained in the preamble, are to be protected.

In the case of a patent application for an invention, the claims chart may consist of more than one independent claim, since, in this case, the claims may fall into one or several categories (e.g., product and process; or process and apparatus). However, they must be connected by the same inventive concept and arranged in the most practical way possible, admitting more than one independent claim of the same category if it defines different sets of alternative and essential characteristics to the realization of the invention. Independent claims of different categories in which one of the categories is specially adapted to the other should be preferably drafted to show their interconnection, using expressions in the initial part of the claim such as “apparatus for carrying out the process defined in the claim” and “process to obtain the product defined in the claim.”¹⁰

In the case of a utility model patent application, after the expression “characterized by,” all the elements that constitute the model must be defined, as well as their positions and

¹⁰ When the subject matter of a patent application contains one or more nucleotide or amino acid sequences that are fundamental to the description of the invention, the applicant must present them in a sequence listing, to enable an assessment of the sufficiency of the description to the extent referred to in Article 24 of the LPI. PR Resolution No. 81, of March 28, 2013, sets forth the procedures for the electronic presentation of a sequence listing.

interconnections in relation to the whole. In a utility model patent application, the set of arrangements and forms responsible for the best use of the object must be fully characterized in a single and independent main claim. The utility model may include complementary elements of optional use or variations of form characterized in dependent claims, defined in the main claim, that do not change the unity of the model and its operation. If the utility model has a flat structure, as defined in the main claim, a dependent claim describing the secondary three-dimensional shape of the object arising from that flat structure is admitted.

3.1.3.4 Novelty

An invention or utility model is considered new when it is not comprised by the state of the art – that is, when it is not fully described by a single document in the state of the art (Article 11 of the LPI) existing prior to the filing date, except if the inventor uses the grace period or claims priority of a former application. The invention or utility model must not have been revealed to the public in any form – written or spoken – by any means of communication, use, presentation at trade shows or sale anywhere in the world.

However, the disclosure of an invention or utility model, if it occurs during the 12 months preceding the filing date or the priority date of the patent application, is not considered as part of the state of the art if such a disclosure is made by the inventor or by a person authorized by the inventor, whether in exhibitions, lectures or publications (Article 12 of the LPI). It is worth noting that the INPI may require a statement from the inventor concerning the disclosure, accompanied or not by evidence, indicating the form, place and date of the disclosure. Also, the inventor may indicate this information when filing the application.

The unionist priority established by Article 4 of the Paris Convention ensures that, within 12 months, the disclosure of an invention or utility model – resulting from the first filing of an application in one of the signatory countries of the Convention, other than Brazil – does not jeopardize the subsequent filing of a corresponding application in Brazil (Article 16 of the LPI). Therefore, any disclosure occurring between the claimed priority date and the date on which the application was filed in Brazil does not affect the novelty and inventive step of the application in Brazil.

If the application filed in Brazil presents additional material in relation to the first filing abroad – whose priority is being claimed – the date of the examination of the state of the art is the date of filing in Brazil. It should be noted that the term of protection for a patent is counted from its filing date in Brazil.

An invention or utility model patent application originally filed in Brazil (without priority claim and not yet published) guarantees the right of priority to a subsequent application on the same subject matter filed in Brazil by the same applicant or successors within a period of one year (Article 17 of the LPI). Upon the filing of the subsequent application, the priority claim must be presented by indicating on the filing form the number and date of the previous application. Thus, the earlier application that serves as the basis for the internal priority claim cannot be used to invalidate the novelty of the later one. Additionally, the previous application is considered definitively dismissed.

Priority is admitted only for the subject matter disclosed in the previous application, not extending to any new matter introduced (Article 17(1) of the LPI). Both the previous and the subsequent application must have complete technical content (with specifications, drawings and a claim chart), each with its own numbering. It should be noted that a patent application originating from the division of a previous application cannot serve as the basis for claiming priority (Article 17(3) of the LPI).

Internal priority does not extend the time limits for claiming unionist priority. That is, if the applicant wishes to file corresponding applications in other countries, they must do so within 12 months of filing the first application (i.e., the application that served as the basis for the internal priority).

3.1.3.5 Inventive step

An invention presents an inventive step if it is not derived from the state of the art in a manner that is evident or obvious to a person skilled in the art (Article 13 of the LPI). That is, a solution

presented in an invention has an inventive step if it is not obvious to a person skilled in the art, with the resources available in the state of the art, at the time of filing. Therefore, an invention with an inventive step must represent something more than the result of a mere combination of known characteristics or of the simple application of knowledge usual to a person skilled in the art.

A utility model presents an inventive step if, for a person skilled in the art, the subject matter of the protection is not derived, in a common or ordinary manner, from the state of the art (Article 14 of the LPI). In utility models that involve an inventive step, obvious or simple combinations of characteristics in the state of the art are accepted, as are predictable technical effects, provided that the model to be patented presents a new shape or layout that results in a functional improvement in the use or manufacture of the object to which the model applies.

The legal literature comments that

[a]s a general rule, novelty is understood to exist whenever the invention or model is not fully provided for by a single state of the art document. This is because if two or more state of the art documents need to be combined in order to provide for the invention, the issue shifts to determining the inventive step, in other words, it should be determined whether or not the combination of those documents was obvious to the person skilled in the art.¹¹

3.1.3.6 Industrial application

An invention or utility model is considered susceptible to industrial application if it can be used or produced in any type of industry (Article 15 of the LPI).

3.1.3.7 Non-patentable inventions and utility models

A subject matter is patentable if it is not prohibited by law, and it meets the legal requirements established in Articles 8, 9, 11, 13, 14 and 15 of the LPI and the conditions set out in Articles 24 and 25 of the LPI.

Brazilian legislation does not have the concept of patent eligibility. Instead, it clarifies what subject matters are patentable and requires that they derive from an inventive step.

According to Article 18 of the LPI, the following items are not patentable:

- I – anything that is contrary to morals, good customs and public security, order, and health;
- II – the substances, materials, mixtures, elements, or products of any kind, as well as the modification of their physical-chemical properties and the respective processes for obtaining or modifying them, when resulting from the transformation of the atomic nucleus; and
- III – the whole or part of living beings, except for transgenic microorganisms that meet the three requirements for patentability – novelty, inventive step, and industrial application – provided for in Article 8, and that are not a mere discoveries.

Article 18 defines “transgenic microorganisms” as

organisms, except the whole or parts of plants or animals, that express, through direct human intervention in their genetic composition, a characteristic not normally attainable by the species under natural conditions.

Article 10 of the LPI also indicates several subject matters that are considered neither inventions nor utility models:

- I – discoveries, scientific theories, and mathematical methods;
- II – purely abstract conceptions;

11 Instituto Dannemann Siemsen de Estudos Jurídicos e Técnicos, *Comentário à Lei de Propriedade Industrial* 22 (3rd ed. 2013) [hereinafter IDS, *Comentário à Lei de Propriedade Industrial* 22] at 34.

- III – commercial, accounting, financial, educational, advertising, raffling, and inspection schemes, plans, principles, or methods;
- IV – literary, architectural, artistic, and scientific works or any aesthetic creation;
- V – computer programs;
- VI – presentation of information;
- VII – rules of games;
- VIII – operating or surgical techniques and methods, as well as therapeutic or diagnostic methods, for application to the human or animal body; and
- IX – the whole or part of natural living beings and biological material found in nature, or even if isolated therefrom, including the genome or germoplasm of any natural living being and natural biological processes.

3.1.4 Inventor and ownership

Articles 6–7 of the LPI govern patent ownership. The author of an invention or utility model is assured the right to obtain a patent that guarantees ownership, under the conditions established in the LPI (Article 6). If this rule is not complied with, the inventor may, alternatively, claim the grant of a patent through judicial proceedings (Article 49 of the LPI).

Under the law, a patent applicant is presumed to be entitled to obtain the patent unless proven otherwise (Article 6(1) of the LPI). This is a legal presumption, but it can be ruled out; administrative or judicial nullity can be determined (Articles 50(I) and 46 of the LPI, respectively).

A patent may be applied for under the author's own name, by the author's heirs or successors, by the assignee, or by the person to whom the ownership belongs according to the law or the employment or service agreement (Article 6(2) of the LPI). The inventor will be named and qualified and may request the nondisclosure of their name (Article 6(4) of the LPI).

Where an invention or utility model has been developed jointly by two or more persons, the patent may be applied for by all or any of them upon indication and qualification of the others, as a disclaimer of their rights (Article 6(3) of the LPI). If two or more authors have developed the same invention or utility model independently, the right to obtain the patent is guaranteed to the one who proves to have made the filing first, regardless of the dates of invention or creation (Article 7 of the LPI); this article establishes the first-to-file rule in Brazil.¹² Withdrawing a previous patent filing that had not produced any effect gives priority to the immediately subsequent filing (Article 29(2) of the LPI).

According to Article 42 of the LPI, a patent entitles its holder the right to prevent third parties from producing, using, putting on sale or selling – or importing for these purposes – without the holder's consent:

- I – a product that is the object of the patent;
- II – a process or product obtained directly through a patented process.

The patent holder is also granted the right to prevent third parties from contributing to the practice of these acts by others (Article 42(1) of the LPI). If the possessor or owner fails to prove, by specific judicial determination, that their product was obtained by a manufacturing process different from that protected by the patent, the process patent right will be deemed infringed (Article 42(2) of the LPI).

However, the patent holder may not prevent a third party from producing, using, putting on sale or selling – or importing for these purposes – in the following cases:

- I – acts performed by unauthorized third parties, on a private and non-commercial basis, provided that they do not harm the economic interest of the patent holder;
- II – acts performed by unauthorized third parties for experimental purposes, related to scientific or technological studies or research;
- III – preparation of drugs according to a medical prescription for individual cases, conducted by a qualified professional, as well as the drug itself thus prepared;

12 Instituto Dannemann Siemsen de Estudos Jurídicos e Técnicos, *Comentário à Lei de Propriedade Industrial*, at 22.

- IV – a product manufactured according to process or product patent that has been placed on the domestic market directly by the patent holder or with their consent;
- V – third parties who, in the case of patents relating to a living matter, use the patented product, without economic purposes, as an initial source of variation or propagation to obtain other products; and
- VI – third parties who, in the case of patents relating to a living matter, use, circulate, or market a patented product that has been lawfully introduced into the market by the patent holder or the license holder, provided that the patented product is not used to commercially multiply or propagate the living matter in question.
- VII – acts committed by unauthorized third parties, related to the patent-protected invention, intended exclusively to produce information, data, and test results, aiming at obtaining a trade license in Brazil or any other country, for the exploitation and sale of the patent-protected product, after expiration of the time limits set forth in Article 40. (Article 43 of the LPI)

In addition to preventing the infringement of their patent, a patent holder also has the right to obtain compensation for the improper exploitation of the patented object (Article 44 of the LPI).

3.1.5 Properties of invention patents or utility models developed in labor relationships

Articles 88–93 of the LPI govern the ownership of invention patents or utility models developed in labor relations.

The invention and the utility model belong exclusively to the employer if they arise from an employment contract, the performance of which takes place in Brazil and that has research or inventive activity as its object, or when an invention results from the nature of the services for which the employee was hired (Article 88 of the LPI). Unless it is expressly determined otherwise in the contract, the compensation for the work referred to in this article is limited to the agreed salary (Article 88(1) of the LPI). Unless proven otherwise, an invention or utility model whose patent is applied by the employee up to one year after the termination of the employment relationship is considered to have been developed during the term of the contract (Article 88(2) of the LPI).

The employer (i.e., the patent holder) may grant to the employee (i.e., the author of an invention or improvement) a share in the economic gains resulting from the exploitation of the patent upon negotiation with the interested party or as provided for in the company's bylaws (Article 89 of the LPI). The share referred to here is not incorporated, in any way, into the employee's salary. Nevertheless, the invention or utility model developed by the employee belongs exclusively to the employee, provided that it is unrelated to the employment contract and does not arise from the use of the employer's resources, means, data, materials, facilities or equipment (Article 90 of the LPI).

The ownership of an invention or utility model is shared, in equal parts, when it results from the personal contribution of the employee and from the employer's resources, data, means, materials, facilities or equipment, except if the contract expressly determines otherwise (Article 91 of the LPI). If more than one employee is involved, their share is divided equally among all of them unless otherwise determined (Article 91(1) of the LPI).

The employer has exclusive exploitation rights, and the employee is ensured fair compensation (Article 91(2) of the LPI). In the absence of an agreement, the exploitation of the patented object must be initiated by the employer within one year of the date of its grant. Otherwise, the patent's ownership may be transferred exclusively to the employee, except in cases where the failure to exploit is due to legitimate reasons (Article 91(3) of the LPI).

In case of assignment, any of the co-titleholders, on equal terms, may exercise the pre-emptive right (Article 91(4) of the LPI).

The above-mentioned rules apply, where appropriate, to relations between self-employed workers or trainees and the contracting companies, as well as between contractors and contracting companies (Article 92 of the LPI).

3.1.6 Patent term and expiration

Invention patents have a term of 20 years, and utility model patents have a term of 15 years from the date of filing (Article 49 of the LPI).

According to this legal provision, if the INPI took more than 10 years to grant a patent, this time would be included to the term of the patent.

In 2015, the average time for administrative processing was 11 years or, in certain technological areas, 14 years.¹³ The INPI engaged in a plan to combat the backlog, which led to a reduction in the average time to grant a patent to approximately eight years.¹⁴

Article 40 of the LPI previously provided a minimum term of ten years for invention patents and of seven years for utility model patents. This was to ensure that patents were in force for a reasonable term, and avoid granting patents close to expiration of their term. In other countries (e.g., Australia, China, the Republic of Korea and the United States), where patents are granted in less than four years on average,¹⁵ patent holders enjoy more than 16 years of market exclusivity.

The constitutionality of the provision that ensures a minimum term for patents is not only to ensure for the private sector but also for publicly held companies and universities to exploit their patents. However, recently, the Federal Supreme Court (Supremo Tribunal Federal; STF) declared the aforementioned provision unconstitutional when it decided on Direct Action of Unconstitutionality (ADI) No. 5,529/DF.¹⁶ The decision is valid for any and all categories of inventions, encompassing both applications already filed and awaiting a resolution from the INPI and new applications. On May 12, 2021, modulating the effects of the previous week's decision, the STF, *en banc*, decided that patents that had already been granted for pharmaceutical products and processes and equipment or materials for health-care use no longer had the extended term provided for in Article 40(1) of the LPI. However, the declaration of unconstitutionality of the provision does not reach other patents already granted and still in force as a result of the extension of the term and becomes effective from the publication of the minutes of the trial of ADI No. 5,529. Article 40 (1) was further revoked by the Law no. 14.195, promulgated on August 26, 2021.

A patent is granted after the application is approved and the payment of the corresponding fee is proven, with the issuance of the respective letters patent (Article 38 of the LPI). The payment of the fee and respective evidence of payment must be made within 60 days of the granting date (Article 38(1) of the LPI). A patent is deemed granted on the date of publication of the respective act (Article 38(3) of the LPI). The letters patent must contain the number, title and nature of the patent; the name of the inventor; the holder's identification and address; the term of validity; the specifications; the claims; the drawings; and the data relating to priority (Article 39 of the LPI).

A patent is valid only in the countries in which it has been applied for and granted protection. Each country is sovereign to grant a patent or not, regardless of the decision in other countries on corresponding patent applications filed there (Article 4*bis* of the Paris Convention).

3.1.7 Patent application trends

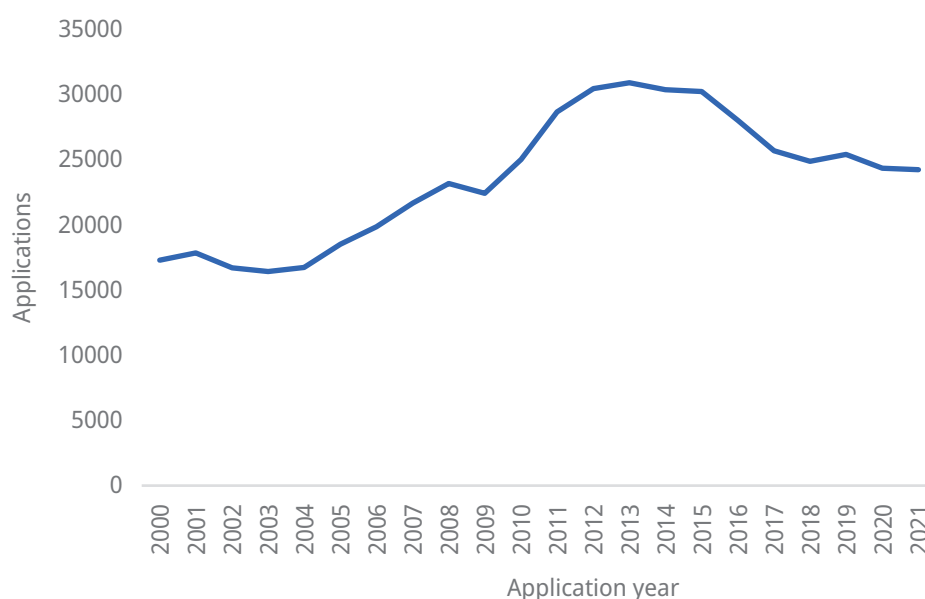
Figure 3.1 shows the total number of patent applications (direct and Patent Cooperation Treaty (PCT) national phase entry) filed in Brazil from 2000 to 2021.

13 Mark Schultz and Kevin Madigan. *The Long Wait for Innovation: The Global Patent Pendency Problem* (2016) [hereinafter Schultz and Madigan, *The Long Wait for Innovation*], <https://sls.gmu.edu/cpip/wp-content/uploads/sites/31/2016/10/Schultz-Madigan-The-Long-Wait-for-Innovation-The-Global-Patent-Pendency-Problem.pdf>

14 Cf., Luiz Augusto Lopes Paulino and Willian Leccioli, *O Supremo Tribunal Federal e a ADI No. 5,529: Os Rumos da Inovação*, Migalhas (Oct. 13, 2020), www.migalhas.com.br/depeso/334718/o-supremo-tribunal-federal-e-a-adin-5-529-os-rumos-da-inovacao

15 Schultz and Madigan, *The Long Wait for Innovation*.

16 Supremo Tribunal Federal (STF) (Federal Supreme Court), Ação Direta de Inconstitucionalidade (ADI) (Direct Action of Unconstitutionality) No. 5,529/DF, Rapporteur Dias Toffoli, May 12, 2021.

Figure 3.1 Patent applications filed in Brazil, 2000-2021

Source: WIPO IP Statistics Data Center, available at www3.wipo.int/ipstats/index.htm?tab=patent

3.2 Patent office and administrative review proceedings

3.2.1 National Institute of Industrial Property

The INPI is a federal autonomous government agency linked to the Ministry of Economy and was created in 1970 by Law No. 5,648, of December 11, 1970.¹⁷ The agency's main purpose is to implement, nationally, the rules governing intellectual property for industry. Thus, it is responsible for the registration of marks, industrial designs, geographical indications, computer programs and circuit topographies; the granting of patents; and the annotation of franchising agreements. It also provides its opinion regarding the signing, ratifying and terminating of conventions, treaties, agreements and arrangements on industrial property.

The INPI must observe, regarding patent protection, the LPI and Law No. 10,196, of February 14, 2001,¹⁸ which govern the protection of industrial property in Brazil. It must also observe the Paris Convention and the TRIPS Agreement. Law No. 13,123, of May 20, 2015, also governs the matter. Brazil is also a signatory to the PCT,¹⁹ which provides for the filing of an international application to seek protection for an invention in different countries.

Article 227 of the LPI provides that the classifications related to the matters of marks, patents and industrial designs are established by the INPI when they are not set forth in a treaty or an international agreement in force in Brazil. Specifically, regarding patents, their grant is established in Article 2 of the LPI and regulated in Articles 3–93 and 212–244 of the LPI. The INPI issued Normative Rulings No. 30, of March 18, 2013, and No. 31, of December 4, 2013, which are administrative rules that help to understand and apply the LPI. A number of additional INPI ordinances and rulings establish guidelines for the examination of patent applications.²⁰

The INPI has, in its organizational structure, the Intellectual Property, Innovation, and Development Academy (Academia de Propriedade Intelectual, Inovação e Desenvolvimento),

¹⁷ DOU of Dec. 14, 1970. Decree No. 8,854, of September 22, 2016 (DOU of Sep. 23, 2016), established INPI's organizational structure and approved a chart outlining the INPI's noncareer appointments and positions of trust. Ordinance No. 11, of January 27, 2017 (DOU of Jan. 30, 2017), approved the INPI's bylaws.

¹⁸ DOU of Feb. 16, 2001.

¹⁹ Patent Cooperation Treaty, June 19, 1970, 1160 UNTS 231.

²⁰ INPI, *Laws and Regulations* (Dec. 1, 2020), www.gov.br/inpi/en/services/patents/laws-and-regulations

whose authority is described in Article 140 of the Internal Rules of the INPI²¹ and whose primary role is the dissemination of knowledge in the field of industrial property. Another body within the INPI – the Intellectual Property Training and Continued Education Division (Divisão de Formação e Extensão em Propriedade Intelectual),²² provided for in Article 141 of the Internal Rules of the INPI – has a purpose similar to that of the Intellectual Property, Innovation, and Development Academy but is focused on the relations with other public and private bodies.

Both bodies are competent for the training of administrative agents and for their constant improvement throughout their careers, which is also essential for receiving appropriate remuneration and functional evolution. This can be seen from the INPI's Normative Ruling No. 48, of February 18, 2016, which “addresses the individual performance assessment of INPI's employees, focusing on the development in the effective position, for purposes of stability in the public service during the probation period, to receive the Industrial Property Field Activity Performance Bonus [...] and functional evolution and promotion in INPI's Career and Positions Plan.”

Beyond the internal limits, the aforementioned bodies dedicate themselves to the indistinct dissemination of knowledge in the industrial property field, promoting courses – taught face-to-face or at a distance, of short or long durations – to the external public.

It should be noted that, as they come from the initiative of the entity responsible for the control of the industrial property in the country, the courses provided by the INPI are one of the main sources of this knowledge in Brazil.

3.2.2 Patent attorneys

Any attorney regularly enrolled with the Brazilian Bar Association may act in the administrative stage before the INPI. However, the application may be filed by an individual or legal entity domiciled in the country and who does not have an attorney-in-fact appointed. It may also be filed by any citizen, on behalf of third parties, by means of a power of attorney, under the terms of Article 216 of the LPI, whether an attorney or attorney-in-fact, without special powers, or an industrial property agent. In the case of foreign applicants, the individual or legal entity is required to appoint and maintain an attorney-in-fact in Brazil with powers to represent them in the administrative and judicial proceedings, including to receive service of process (Article 217 of the LPI).

The power of attorney – whether original, transcript or authenticated photocopy – must be in Portuguese. Consular authentication and notarization of signature is not required (Article 216(1) of the LPI). The power of attorney must be submitted within 60 days from the date of the first act of the party in the proceedings, regardless of notification or requirement, under penalty of dismissal. The dismissal of the patent application is final (Article 216(2) of the LPI).

3.2.3 Patent application

Patent applications can be filed through the “e-Patentes” platform, which can be accessed from the INPI's portal www.gov.br/inpi/en. For the international filing of applications and associated

21 Ordinance No. 11, of Jan. 27, 2017, DOU of Jan. 30, 2017, art. 140 (“The Intellectual Property, Innovation, and Development Academy is responsible for: I – coordinating and monitoring teaching, research, and continued education activities at the graduate level of intellectual property studies, highlighting its relationship with innovation and technological, economic, social, and cultural development; II – coordinating and monitoring intellectual property and innovation training activities, in collaboration with the final areas; III – proposing and implementing dissemination actions related to intellectual property; IV – encouraging exchanges with teaching, research, and continued education institutions and with similar institutions, at national and international levels, for the development of activities of mutual interest in collaboration with INPI's areas of cooperation; V – coordinating actions related to the provision of information to internal and external users, by means of access to the bibliographic collection and non-patent databases for better use of the intellectual property system; VI – creating, developing, and implementing actions for management of the knowledge produced within the scope of the Intellectual Property, Innovation, and Development Academy; VII – coordinating the activities related to the academic mobility of researchers, professors and students”).

22 Ordinance No. 11, of Jan. 27, 2017, DOU of Jan. 30, 2017, art. 141 (“The Intellectual Property Training and Continued Education Division is responsible for: I – implementing the intellectual property continued education and innovation activities promoted by INPI or in partnership with other institutions, at national and international levels; II – training professionals of the National Innovation System with the execution, monitoring, and evaluation of Intellectual Property training courses, in face-to-face and distance learning modalities, promoted by INPI, or in partnership with other national and international institutions; III – participating in the planning and implementation of international intellectual property training actions; and IV – implementing actions for the management of the knowledge produced within the scope of the Intellectual Property Training and Continued Education Division”).

documents, the INPI has recommended ePCT-filing – the World Intellectual Property Organization's online service – since October 20, 2014.

Articles 19–20 of the LPI govern the filing of patent applications with the INPI. A patent application, under the conditions established by the INPI, must contain the

- I – request;
- II – specifications;
- III – claims;
- IV – drawings, if applicable;
- V – abstract; and
- VI – proof of payment of the filing fee. (Article 19 of the LPI)

Articles 22–26 of the LPI and Normative Rulings No. 30, of December 4, 2013, and No. 31, of December 4, 2013, regulate the conditions of a patent application.

The object of the patent must be sufficiently described in the specifications, clearly and completely, to allow its reproduction by a person skilled in the art and must indicate, when appropriate, the best way to execute it (Article 24 of the LPI). When an application deals with biological material, and this is essential to the practical execution of the object of the application, which cannot be described pursuant to Article 24 of the LPI and is not available to the public, the report must be supplemented, even after the examination request, with the deposit of the material at an institution authorized by the INPI or indicated in an international agreement in force. If there is no such institution in the country, the user may deposit the biological material in any of the international deposit authorities recognized by the Budapest Treaty,²³ and it must be done before the filing date of the patent application, and such data must integrate its specifications.

The forms required to file the application are available from INPI's website (www.gov.br/inpi/en). After filing the application, the applicant must regularly consult the Journal of Industrial Property (*Revista da Propriedade Industrial*; RPI), an official publication of the INPI, published weekly and free of charge on the INPI's website. When the documentation is received, the minimum conditions for accepting the patent application or the certificate of addition are verified – namely, that it contains technical content, the application and the proof of payment of the filing fee. If the application is insufficient but contains data regarding the object, the applicant and the inventor, it may be delivered to the INPI by means of a dated receipt, which establishes the requirements to be met, within 30 days (Article 21 of the LPI).

The submission of additional documentation both in relation to the filing of the application and at later stages is by means of petitions using the forms titled “Petition Related to Application, Patent or Certificate of Addition” (*Petição Relacionada com Pedido, Patente ou Certificado de Adição*). There are some specific situations, listed on the INPI's website, that exempt the use of these petitions.

3.2.3.1 Dissemination of the state of the art

In order for novelty to exist, which is paramount for the granting of a patent, the object must be beyond the state of the art. The state of the art refers to everything that has become accessible to the public before the filing date of the patent application, by written or oral description, by use or any other means, in Brazil or abroad (Article 11(1) of the LPI), with exceptions in the provisions of Articles 12 (grace period), 16 (unionist priority) and 17 (internal priority) and excluding that which is kept under industrial secret.

For the purposes of assessing novelty, the full content of an application filed in Brazil and not yet published are considered as state of the art from the date of filing or of the priority claimed, provided that it is published, even if subsequently (Article 11(2) of the LPI). In this case, the subject matter of an application that has not yet been published is considered as state of the art solely for the analysis of the novelty requirement, not the inventive step requirement. This

23 Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (with Regulations), Apr. 28, 1977, 1861 UNTS 362.

provision also applies to international patent applications filed in accordance with a treaty or convention in force in Brazil if there is national processing (Article 11(3) of the LPI).

Inventors are able to better identify the nature of their creation (the invention or utility model) based on the prior knowledge of the state of the art to properly apply for protection. The INPI recommends conducting a preliminary search before filing a patent application to assess the state of the art related to the subject matter to be claimed and to check whether the invention is new or inventive. If the invention is not new but is, for example, a functional improvement to an existing object, a utility model application can be filed.

3.2.3.2 Disclosure of the state of the art by third parties

If a third party discloses the invention or utility model in the 12 months preceding the filing date or the priority date of the patent application, based on information obtained directly or indirectly from the inventor or as a result of acts performed by the inventor (Article 12(III) of the LPI), or is disclosed by the INPI by means of the official publication of the patent application filed without the inventor's consent, based on information obtained directly or indirectly from the inventor or as a result of acts performed by the inventor (Article 12(II) of the LPI), a grace period will be considered and will not affect the assessment of novelty. However, the INPI may require from the inventor a statement concerning the disclosure, whether or not accompanied by evidence, under the conditions established in the regulation (Article 12(1) of the LPI).

3.2.3.3 Priority date

The priority date is the date of filing the application. A patent application filed in a country that has an agreement with Brazil, or in an international organization, producing the effect of a national filing, will be ensured the right of priority within the time limits established in the agreement, and the filing will not be invalidated or jeopardized by events occurring within these time limits (Article 16 of the LPI). This article of the LPI ensures the right of priority provided for in Article 4 of the Paris Convention.

A priority claim is made upon filing and may be supplemented within 60 days by other priorities prior to the date of filing in Brazil (Article 16(1) of the LPI). The priority claim is supported by an appropriate document of origin, containing the number, date, title, specifications and, if applicable, claims and drawings, accompanied by a translation of the filing certificate or equivalent document, containing data identifying the application, whose content is the entire responsibility of the applicant in Brazil (Article 16(2) of the LPI). If proof is not presented at the time of filing, it must be provided within 180 days of the date of filing (Article 16(3) of the LPI).

For international applications filed under a treaty in force in Brazil, the translation must be submitted within 60 days of the date on which national processing starts in Brazil (Article 16(4) of the LPI). Where the application filed in Brazil is faithfully contained in the document of origin, a statement by the applicant in this respect is sufficient to replace the translation (Article 16(5) of the LPI). In case of priority obtained by assignment, the corresponding document must be presented within 180 days of the filing date or, if this is the case, within 60 days from the date on which national processing starts, waiving consular legalization in the country of origin (Article 16(6) of the LPI).

Failure to provide evidence within the time limits established in Article 16 of the LPI results in loss of priority (Article 16(7) of the LPI). This penalty applies to the lack of evidence mentioned in Article 16(2)–(3) of the LPI. In the event of priority of a PCT application made in the international phase, part of the Brazilian legal scholarship argues that the application of this penalty is questionable.

If the application filed in Brazil presents additional matters in relation to the first filing abroad – whose priority is being claimed – the date for the examination of the state of the art is the date of filing in Brazil. It should be noted that the patent term of the application is counted from its filing date.

When interested parties file a patent application, they start to enjoy an expectation of rights. A patent holder's exclusive right arises only with the granting of the patent, formalized by the issuance of the letters patent. Only after the granting can holders prevent third parties not authorized by them from performing the activities that are exclusive to the holders, under

penalty of civil and criminal penalties and according to the prerogatives and limitations set forth in the legislation.

Within three years of the grant of the patent, the patent holder must start exploiting or commercializing the product and exercising their right, otherwise the holder may be subject to having the patent compulsorily licensed (Article 68(5) of the LPI). A compulsorily licensed patent may lapse for lack of exploitation if, after two years from the first compulsory license, the nonuse is not justified (Article 80 of the LPI).

3.2.3.4 Publication

Publications are made in the RPI. According to Article 226 of the LPI, the INPI's acts in administrative proceedings related to industrial property are effective only from their publication in the respective official body, except for

- I – those that expressly do not require notification or publication under the provisions of this Law;
- II – administrative decisions, when the notification is made by mail or by information provided to the interested party to the case; and
- III – opinions and internal orders that do not need to be known by the parties.

3.2.3.5 Disclosure

A patent application is kept secret for 18 months from the filing date or earliest priority date, if any, after which it is published, except as provided for in Article 75 of the LPI (Article 30 of the LPI). However, the publication of the application may be brought forward at the applicant's request (Article 30(1) of the LPI). This publication must contain data identifying the patent application, and a copy of the specifications, claims, abstract and drawings must be made available to the public by the INPI (Article 30(2) of the LPI). In the cases set forth in Article 24(1) of the LPI, biological material becomes available to the public with such a publication (Article 30(3) of the LPI).

3.2.3.6 Applications of interest to national defense

Article 75 of the LPI regulates patent applications originating in Brazil whose subject matter is of interest to national defense and is therefore processed confidentially, not being subject to the provisions of the LPI. Unless expressly authorized by the competent entity, it is prohibited to file or disclose abroad a patent application whose subject matter has been considered of interest to national defense (Article 75(2) of the LPI). Additionally, the exploitation and assignment of the application or patent that is of interest to the national defense depend on the prior authorization of the competent body. Indemnity is guaranteed whenever the filer's or holder's rights are restricted (Article 75(3) of the LPI).

3.2.3.7 Patent term restoration

A patent holder may request the restoration of an application or patent within three months from the date of publication of the shelving in the RPI or from the expiry of the patent. For this, the holder must prove to the INPI that the annual fee and restoration fee have been paid (Article 87 of the LPI). Failure to request restoration will lead to definitive shelving.

3.2.3.8 Post-issuance corrections and administrative proceedings

Once the patent application is published, and until the end of the examination, interested parties may present documents and information to challenge the examination (Article 31 of the LPI). The examination does not begin until 60 days have elapsed from the publication of the application (Article 31(1) of the LPI).

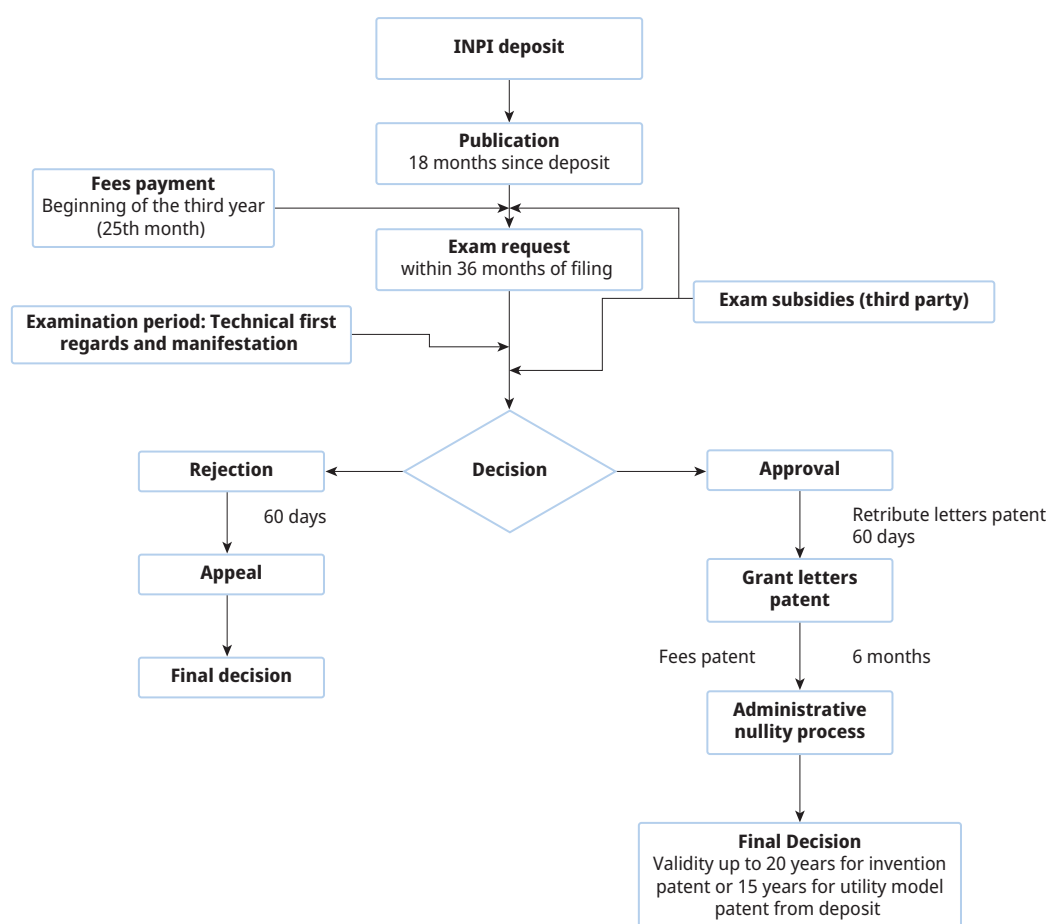
In order to better clarify or define the patent application, the applicant may amend the application up until the request for examination, as long as the amendments are limited to the subject matter initially disclosed in the application (Article 32 of the LPI).

Once a patent is granted, there is no specific provision in the law for its correction. However, in the administrative sphere, it is possible to request administrative nullity before the INPI, as governed by Articles 50–55 of the LPI.

3.2.4 Administrative review proceedings

The procedures for filing and granting patents are considered administrative proceedings, which are governed by the LPI and by specific INPI rules (Figure 3.2). An appeal may be filed against the decisions rendered by the INPI regarding the granting or not of a patent within 60 days of the decision (Article 212 of the LPI). A decision that determines the final dismissal of a patent application or that grants a patent application, a certificate of addition is not appealable (Article 212(2) of the LPI).

Figure 3.2 Administrative review proceedings



Source: Adapted and translated (by the authors) from Núcleo de Inovação Tecnológica, *Processo Resumido para Requerimento de Patentes* (June 5, 2016), pt.slideshare.net/AntnioSilva61/fluxograma-de-patente-resumido

According to Article 221 of the LPI, the time limits for the administrative proceedings for granting a patent are continuous, automatically extinguishing the right to perform the act after its expiry, unless the party proves that they did not perform the act for a just cause – that is, if the party demonstrates that an unexpected event occurred beyond their will and that prevented them from performing the act. In counting the time limits, the start day is excluded, and the due date is included (Article 222 of the LPI). The time limits only start being counted from the first business day after the notification, which is made upon publication in the INPI's official body (Article 223 of the LPI). Regarding the administrative proceedings governed by the LPI, Article 224 clarifies that, if there is no express determination, 60 days is the time limit that must be considered for the practice of the act.

It should be noted that judicial acts in relation to a patent protection matter or possible questioning regarding the granting of its registration are governed by the CPC, which has specific rules regarding time limits and their counting.

The INPI's acts, orders and decisions regarding industrial property are published in the RPI. To facilitate reading, a table of codes of orders and a numerical index on the RPI's initial pages allow

for the identification of the progress of the application or patent. Users must monitor their applications through the RPI with the number assigned to their application. The request for a patent application or certificate of addition is notified in the RPI with Order Code 2.10.

Next is the formal examination regarding the provisions of Article 19 of the LPI, the other provisions regarding its form or both. If such provisions have not been met, the formal requirements are published with Order Code 2.5. The user is required to meet the requirements within 30 days, free of charge, under penalty of the documentation being returned or the application being dismissed (Article 20 of the LPI). If the requirements are not met by this deadline, the filing is not accepted, and its numbering is canceled.

If there are no formal requirements, Order Code 2.1 is notified. If the application is properly supported with documents, then, after formal analysis, it will be filed, and the filing date will be the date of its submission (Article 20 of the LPI). The application is kept confidential for 18 months from the earliest priority date (Article 30 of the LPI). After 18 months, the application is published (Order Code 3.1).

In the case of a certificate of addition, the confidential period is 18 months from the filing date of the main application. When publication of the main application has occurred, the application for a certificate of addition is published immediately. The user may request early publication of their application (Order Code 3.2); however, this does not mean that the technical examination will be advanced.

A withdrawn or abandoned patent application must also be published (Article 29 of the LPI). A request for withdrawal must be submitted within 16 months of the filing date or earliest priority date (Article 29(1) of the LPI). The withdrawal of a previous filing without producing any effect gives priority to the immediately subsequent filing (Article 29(2) of the LPI).

It is the applicant's responsibility to follow up on the processing of their patent application. This can be done by the PUSH-INPI system by registering the desired process and receiving the publications at the registered email address; however, this does not replace the follow-up made via RPI.

The applicant or patent holder has 60 days (ordinary term) from the publication of the granting in the RPI (Order Code 9.1) to present evidence they have paid the fee for the issuance of the letters patent. The mentioned payment can also be made within 30 days (extraordinary term) from the end of the previous term by means of a payment of a specific fee, providing evidence of such to the INPI,²⁴ under penalty of final dismissal of the application (Order Code 11.4). PR Resolution No. 13, of March 18, 2013, regulates the delivery of letters patent in electronic format only and presents other provisions.

The substantive examination of the patent application must be requested by the applicant or by any interested party within 36 months of the filing date, under penalty of the application being dismissed (Article 33 of the LPI). In this case, upon notification of the dismissal in the RPI (Order Code 11.1), the applicant has 60 days to pay a reinstatement fee, together with a request for application examination, under penalty of final dismissal (Order Code 11.1.1; Article 33(1) of the LPI), thus restoring the application. The reinstatement must be requested using the form Petition Related to Application, Patent or Certificate of Addition. If the reinstatement is not requested, the matter subject to the patent application becomes available in the public domain. To better clarify or define the patent application, an applicant may make amendments up to the request for examination, provided that they are limited to the matter initially disclosed in the application (Article 32 of the LPI).

Once the examination is requested, the following must be submitted within 60 days, whenever requested, under penalty of having the application dismissed:

I – objections, search for prior art and examination results for the granting of a corresponding application in other countries, when priority is claimed;

24 See PR Resolution No. 72, of March 18, 2013.

- II – documents required for the regularization of the process and examination of the application; and
- III – a simple translation of the appropriate document referred to in Paragraph 2 of Article 16 of the LPI, if it has been replaced by the declaration provided for in Paragraph 5 of the same article. (Article 34 of the LPI)

During the technical examination, a search report and opinion concerning the following are prepared:

- I – patentability of the application;
- II – suitability of the application given the nature claimed;
- III – reformulation of the application or division; or
- IV – technical requirements. (Article 35 of the LPI)

This search is conducted, in general, by engineers and technicians specialized in the patent system and in various technological fields. They check whether the wording of the application complies with legal standards, as well as with the state of the art, in a survey that may include technology from all over the world. At this stage of examination, any interested party can submit comments and documents.

When the opinion ascertains the non-patentability or the lack of suitability of the application to the nature claimed, or makes any requirement, the applicant will be notified to provide their comments within 90 days (Article 36 of the LPI). If the requirement is not met, the application will be definitively dismissed (Article 36(1) of the LPI). If the requirement is answered, even if not satisfied, or its formulation is contested, with or without a statement on patentability or suitability, the examination will proceed (Article 36(2) of the LPI).

The examination may conclude that the application is patentable (Order Code 9.1); that it is necessary to adapt the application to the claimed nature, to reformulate or divide the application or to meet technical requirements (Order Code 6.1); or that the application is unpatentable (Order Code 7.1). The fulfillment of the requirements set out or the opinion on the patentability of the application must be met within the period determined by Article 36 of the LPI – that is, within 90 days.

Once the examination is concluded, a decision is rendered, either granting or rejecting the application (Article 37 of the LPI).

3.2.4.1 Declaration of patent nullity

The patent's nullity is declared administratively when:

- I – any one of the legal requirements has not been met;
- II – the specifications and the claims do not comply with the provisions of Articles 24 and 25 of the LPI, respectively;
- III – the subject matter of the patent extends beyond the content of the application originally filed; or
- IV – any of the formalities essential to the granting have not been met during the patent's processing. (Article 50 of the LPI)

It is possible that the nullity does not affect all claims. The condition for a partial nullity is that the remaining claims be patentable by themselves (Article 47 of the LPI).

Patent nullity takes effect from the date the application is filed (Article 48 of the LPI). An action for nullity may be filed at the INPI's own initiative or at the request of any person with a legitimate interest, within six months counted from the grant of the patent (Article 51 of the LPI). The nullity proceedings continue even if the patent's term has expired (Article 51(1) of the LPI).

The first hypothesis of an administrative declaration of nullity is the one that occurs before the INPI in cases where the offense is due to other legal provisions contained in the LPI,²⁵ as provided

25 André Luiz Santa Cruz Ramos, *Direito Empresarial* 398 (10th ed. 2020) [hereinafter Ramos, *Direito Empresarial*].

for in Article 50 of the LPI.²⁶ In this case, even if the interested party does not request the declaration of nullity of the patent, the INPI has jurisdiction to file the administrative proceedings at its own initiative, pursuant to Article 51 of the LPI.²⁷ Therefore, it is important to highlight the rule provided for in Article 51(1), which governs the continuation of nullity proceedings even if the patent has been terminated. As André Luiz Santa Cruz Ramos has stated, “this rule is explained by the declaration of *ex tunc* (retroactive) effects of the patent nullity declaration.”²⁸ After all, even if the patent has already been terminated, patent nullity necessarily nullifies all effects produced during the patent’s existence as well.

From the moment that administrative proceedings are filed, the due process of law is followed. Patent holders may exercise their right of defense²⁹ and must make a statement within 60 days.³⁰ The INPI then issues an opinion and notifies the holder and the claimant in the same period above.³¹ The INPI’s president then decides on the matter, thus closing the administrative proceedings.³² The INPI publishes the decision of the action for nullity once it has become final and unappealable, in order to notify third parties (Article 57(2) of the LPI).

3.2.4.2 Appeals

As for the appeals that may be filed in the administrative phase before the INPI, the provisions of Articles 212–220 of the LPI are applicable.

Article 212 of the LPI establishes that, unless expressly provided otherwise, the decisions mentioned in the law may be appealed, though they must be filed within 60 days. Appeals are entertained with *supersedeas* and full review effects, applying all the relevant provisions to the lower court’s examination as applicable.

A decision that determines the definitive dismissal of a patent application or that grants the application for a patent, a certificate of addition is unappealable (Article 212(2) of the LPI).

A petition will not be entertained:

- I – if it is submitted after the time limit set in the law; or
- II – if it is not accompanied by the proof of payment of the respective fee in the amount in effect on the date of its presentation. (Article 218 of the LPI)

A petition, the opposition and the appeal, will not be entertained when:

- I – it is submitted after the time limit set in the law;
- II – it does not contain legal grounds; or
- III – it is not accompanied by the proof of payment of the corresponding fee. (Article 219 of the LPI)

The INPI will take advantage of the parties’ acts, whenever possible, establishing the appropriate requirements (Article 220 of the LPI).

Interested parties are notified, within 60 days, to submit their briefs on the appeal (Article 213 of the LPI). For the purposes of complementing the appeal brief, the INPI may impose requirements, which must be met within 60 days (Article 214 of the LPI). After this deadline, the appeal is decided (Article 214(1) of the LPI).

26 Law No. 9,279, of May 14, 1996, DOU of May 15, 1996, art. 50 (“The patent’s nullity will be declared administratively when: I – any one of the legal requirements has not been met; II – the specifications and the claims do not comply with the provisions of Articles 24 and 25, respectively; III – the subject matter of the patent extends beyond the content of the application originally filed; or IV – any of the formalities essential to the granting have not been met during the patent’s processing”).

27 Law No. 9,279, of May 14, 1996, DOU of May 15, 1996, art. 51 (“The nullity proceedings may be filed at the authority’s own initiative or at the request of any person with a legitimate interest, within 6 (six) months counted from the granting of the patent. Sole Paragraph. The nullity proceedings will continue even if the patent has been terminated”).

28 Ramos, *Direito Empresarial*, at 399.

29 Ramos, *Direito Empresarial*, at 399.

30 Law No. 9,279/96, art. 52 (“The holder will be notified to provide his statement within 60 (sixty) days”).

31 Law No. 9,279/96, art. 53 (“Whether or not they choose to make a statement, after the lapse of the period set in the previous article, INPI will issue an opinion and will notify the holder and the claimant to provide their statements within the common period of 60 (sixty) days”).

32 Law No. 9,279/96, art. 54.

Appeals are entertained with full *supersedeas* and review effects and are decided by the INPI's president. The decision, being final and unappealable, ends the administrative proceeding (Article 215 of the LPI).

3.3 Judicial institutions

3.3.1 Judicial administration structure, decision-makers and procedures

To clarify the functioning of the Brazilian justice system in conflicts involving patents, it is necessary to briefly present the Brazilian judicial procedure, the organization of the judiciary and, finally, the powers attributed to judges and the limits of their performance. With this information, it will be possible to understand the management limits of proceedings involving patent litigation under Brazilian law.

The Brazilian civil procedure is divided into what is known as the “cognizance” phase – in which disputes and controversial issues between the disputing parties are decided by the judge – followed by the “judgment satisfaction” phase – in which sanctions are imposed by the judges if their decisions are not voluntarily satisfied. The cognizance phase ends, as a rule, with the rendering of a final order by the judge, either ending the case without prejudice or deciding on the relief requested by the parties, known as “judgment.”

It is interesting to note that, although Brazil has its own patent law (i.e., the LPI), procedural matters are basically governed by the general civil procedural law (i.e., the CPC). In other words, based on the general procedural rules, judicial practice has adapted the civil procedure to the peculiarities of the issues related to the judicialization of patents in Brazil. The CPC is applied nationally, binding both the federal and state courts.

There are two main rules that guide the assignment of jurisdiction in cases involving patent litigation. Cases that claim patent nullity are heard by the federal courts, with mandatory intervention by the INPI (Article 57 of the LPI and Article 109 of the Constitution). Being a matter of absolute *rationae personae* jurisdiction, cases involving discussions regarding patent infringement are heard by state courts. Cases related to patent infringements can be filed before any of the trial courts that make up the state courts, which are organized and have their competence distributed according to Article 92 of the Constitution. Any trial court can accept such cases as long as the criteria for the definition of jurisdiction are observed.

With respect to the organization of courts and the judicial districts that make up each of the state courts, the Constitution exclusively grants, to each state's courts, the authority to propose to the legislative power of the federative entity to which it belongs the creation, organization and distribution of jurisdiction. Therefore, each state court may organize itself differently, including with regard to matters involving patents. The same applies to each of the five regional federal courts with regard to its organization.

What defines the number of courts and their degree of specialization in a certain city or judicial district is the judicial workload. Consequently, jurisdiction is regulated by the resolutions of the state and regional federal courts.

Regardless of whether it is at a federal or state court, all patent litigation goes through first instance jurisdiction – in which the issues are analyzed by a single judge – and through appellate instance jurisdiction (state or regional federal appeal courts) – in which appeals are addressed and tried by a panel of judges. In exceptional circumstances, it is also possible to submit a court of appeal's decisions for review by the Superior Court of Justice (Superior Tribunal de Justiça; STJ), which analyzes, in summary, allegations of infringement of the federal law, or even by the STF, which is responsible for constitutional issues.

3.3.2 Specialized intellectual property judiciary

The judicial courts, to which the patent cases are assigned, are not specialized in Brazil, except for the courts in the jurisdictions where the patent caseload justifies specialization. This is the case of the State Court of São Paulo (first and appellate instance), and more recently the State Court of Rio Grande do Sul (appellate instance). The Federal Court of the 2nd Region (which is located in

the city of Rio de Janeiro and covers the states of Rio de Janeiro and Espírito Santo) is also a specialized intellectual property court at the first instance as well as at the appeal level. Nonspecialized courts may have jurisdiction over other matters (e.g., civil, corporate, childhood and youth, and criminal matters), which is why they are not considered specialized courts.

Specifically, in the case of the São Paulo State Court at first instance, there are, in the judicial district of the state capital, two trial courts specialized in business and arbitration matters, which entertain litigation involving issues related to business law (Book II of the Special Part of the CC), joint-stock corporations (Law No. 6,404, of December 15, 1976),³³ industrial property and unfair competition (addressed, in particular, in the LPI), franchising (Law No. 8,955, of December 15, 1994),³⁴ as well as cases arising from the arbitration law (Law No. 9,307, of September 23, 1996).³⁵ Consequently, industrial property issues that comprise patents and trademarks are judged, in the first instance jurisdiction, as business law matters. There are also, in the first instance jurisdiction, additional specialized trial courts in business and arbitration matters encompassing the districts outside the capital city called 1st Judicial Administrative Region for the greater São Paulo metropolitan area, 4th Judicial Administrative Region of Campinas, 6th Judicial Administrative Region of Ribeirão Preto, 7th Judicial Administrative Region of Santos, 8th Administrative Region of São José do Rio Preto, 9th Judicial Administrative Region of São José dos Campos, and 10th Judicial Administrative Region of Sorocaba. In addition, the São Paulo State Court has, in its Court of Appeals (appellate jurisdiction), specialized chambers for analyzing issues involving corporate (including intellectual property) and bankruptcy matters, with competencies as in the first instance business trial courts.

At the Federal Court of the 2nd Region, there are, in the instance jurisdiction, four federal trial courts specialized in industrial property, with jurisdiction to prosecute and decide cases filed against the INPI on such matters. These trial courts are located in the city of Rio de Janeiro, where the INPI is headquartered. In the appellate jurisdiction, there are specialized business chambers which adjudicate intellectual property issues, as well as criminal and social security matters.

Thus, in Brazil, the only specialized courts in intellectual property are the first and second instance jurisdiction in the São Paulo State Court, the Rio Grande de Sul Court at second instance, and first and appellate instance jurisdiction in the Regional Federal Court of the 2nd Region (Rio de Janeiro). However, there are no courts, either trial or appeal courts, in the state or regional federal courts with exclusive jurisdiction to address patent issues.

Figure 3.3 shows the judicial administration structure in Brazil.

3.3.3 Relationship between invalidity and infringement proceedings

Regarding the standing to sue to file lawsuits related to patent protection, it is necessary to understand what the main existing actions are – namely:

- action for prohibition;
- action for damages;
- invention patent claim action;
- action for patent nullity;
- action for a writ of mandamus;
- provisional remedies; and
- criminal action, which is usually of the victim's private initiative.

According to Humberto Theodoro Junior,³⁶ in an action for prohibition, the holder of the industrial property right can discuss the possibility of imposing on a third party a prohibition regarding the holder's privilege. Such a judgment prohibits the infringer from carrying out the particular act. The standing to sue belongs to the holder of the privilege, and the standing to be sued belongs to the infringer.

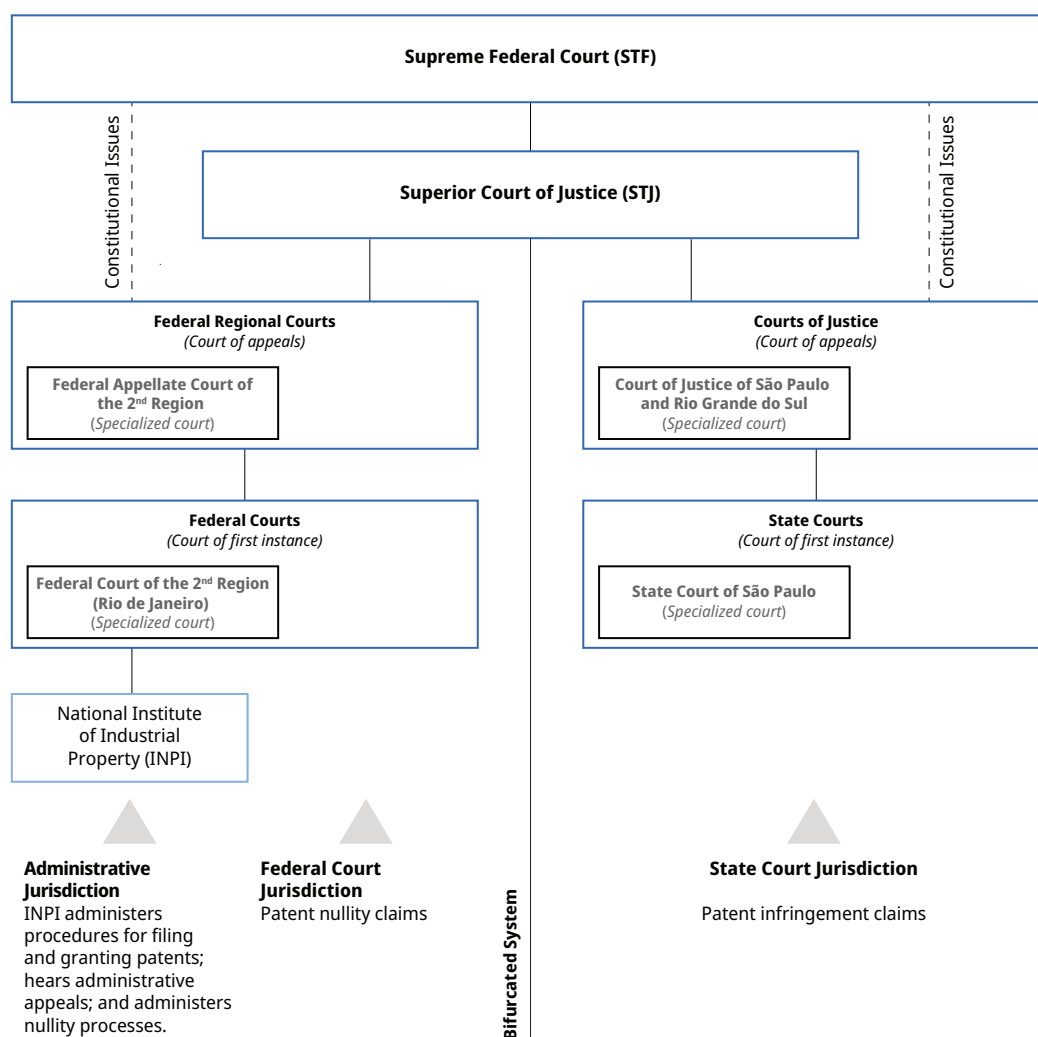
33 DOU of Dec. 17, 1976.

34 DOU of Dec. 16, 1994.

35 DOU of Sep. 24, 1996.

36 Humberto Theodoro Junior, "Tutela Jurisdicional da Propriedade Industrial," 145 Rev. Trib. Fed. Recur. 98–102 (1987).

Figure 3.3 The judicial administration structure in Brazil



Also, according to Humberto Theodoro Junior,³⁷ an action for damages can be filed by a patent holder, their successors or by a total or partial assignee. The standing to be sued belongs to the person who infringes the privilege, including against a partial assignee if the assignment is abused, and also to the assignor of the privilege if, after the assignment, the assignor uses the invention again.

A patent claim action can be filed by the inventor, with standing to sue, if someone usurps the inventor's invention and patents it in their own name.³⁸

An action for patent nullity can be filed by any person who has a legitimate interest: that is, anyone who is being harmed by the alleged improper patent. In this action, the INPI must appear as the defendant in the action; this is the only action involving patent law that is filed in the federal courts. An action for a writ of mandamus may also be filed in the federal courts: it is a procedural remedy of a constitutional nature, intended to obtain the immediate protection of a liquidated and certain individual right against any abuse or irregularity by the authority.

3.3.4 Judicial education on intellectual property

Judges, unlike the administrative agents who work at the INPI, do not have specific training in the field of intellectual property from the schools of judges – both as they enter the career and throughout it – except for the federal judges who are members of the Regional Federal Appellate

37 Humberto Theodoro Junior, "Tutela Jurisdicional da Propriedade Industrial," 145 Rev. Trib. Fed. Recur. 98–102 (1987).

38 Humberto Theodoro Junior, "Tutela Jurisdicional da Propriedade Industrial," 145 Rev. Trib. Fed. Recur. 98–102 (1987).

Court of the 2nd Region. This court is a pioneer in the propagation of knowledge in the field of intellectual property, and its respective school, the School of Judges of the Regional Federal Court of the 2nd Region (Escola da Magistratura Regional Federal 2^a Região), which has a specific commission in the field of intellectual property,³⁹ because the city of Rio de Janeiro is the home of the INPI's headquarters and where, consequently, most of the actions for the annulment of patents and registrations granted by the INPI are concentrated.

In this way, to guarantee the scope of specialization, the São Paulo School of Judges (Escola Paulista da Magistratura) is making progress on the dissemination of knowledge in the field – even if, for now, sporadically and nonsystematically – such as through the seminar that was held in June 2021, titled “Contencioso Patentário no Judiciário – Análise e Aprimoramentos” (Patent Litigation in the Judiciary – Analysis and Improvements), and the Intellectual Property Expertise Course held from March to May 2022.

In addition, the importance of training a robust and qualified body of professionals has been identified. These professionals may be chosen by judges in patent disputes as experts to improve the management of cases. Consequently, two important initiatives that could be adopted by Brazilian courts were identified:

- training courses to be constantly offered by schools of judges – some in collaboration with the INPI – for the improvement of experts; and
- the preparation of a list of specialized professionals from which judges could choose during the evidentiary stage of the cases.

3.4 Patent invalidity

The law considers a patent null if it has been granted while violating legal provisions (Article 46 of the LPI). However, some have argued that this provision is too broad and endangers legal certainty because the failure to comply with formal or procedural requirements would also give rise to the nullity of the patent.⁴⁰ A solution to the issue of generality arose from the Patent Law Treaty,⁴¹ a multilateral treaty adopted in Geneva in June 2000. Article 10 of the Patent Law Treaty forbids the invalidation of a patent for noncompliance with formal requirements if there is no fraud.⁴² Although Brazil is a signatory to the treaty, it has not yet ratified it internally, so the scope of Article 46 of the LPI is still applicable in Brazil.

As per the LPI, a patent can be invalidated either administratively or judicially. Articles 46–49 of the LPI govern the possibility of patent nullity. Given the intense judicialization of procedures in Brazil and the principle of nonnegation of judicial review, it is possible to resort to the judiciary to request the nullity in an action that may be filed by either the INPI or any interested party during the patent term,⁴³ following the provisions of Article 56 of the LPI.⁴⁴

Additionally, Article 56(1) and 56(2) determine, respectively, that nullity may be argued at any time as a matter of defense and that a judge may, preventively or incidentally, suspend the effects of the patent since the due procedural requirements are attended. According to Ramos, this provision seems to refer, obviously, to the general power of caution of the judge, which requires

39 “Created in March 2006 to comply with the provisions of [Article 93(II)(c)] of the Federal Constitution, the Improvement and Specialization Course – CAE [Curso de Aperfeiçoamento e Especialização] offers Federal Judges of the 2nd Region a set of Thematic Commissions dedicated to the creation of the Initial Training, Continued Training and Preparation for Reinstatement Subprograms.” Escola da Magistratura Regional Federal 2^a Região, *Aperfeiçoamento e Especialização*, <https://emarf.trf2.jus.br/site/cae.php>

40 See IDS, *Comentário à Lei de Propriedade Industrial* [hereinafter IDS, *Comentário à Lei de Propriedade Industrial*], at 115–16 (“This article is dangerously broad, as it does not limit itself to punishing with nullity only patents granted with noncompliance with substantive requirements, such as those that refer to inventions that do not meet the patentability requirements (novelty, inventive step, and industrial application), those whose object is not considered an invention as per definitions (Article 10 of the LPI), or those whose object is simply non-patentable (Article 18 of the LPI). By the wording of the article, even patents granted with the noncompliance of mere legal formalities would be null, even if no rights of third parties have been curtailed or no damage has been caused”).

41 Patent Law Treaty, June 1, 2000, 2340 UNTS 3.

42 Patent Law Treaty, art. 10(1) (prohibiting, in the absence of fraud, the invalidation of a patent on the basis of noncompliance with certain formal requirements during the application stage).

43 Ramos, *Direito Empresarial*, at 399.

44 Law No. 9,279/96, art. 56 (“The action for nullity may also be filed at any time during the patent’s term, by INPI or by any person with a legitimate interest”).

the presence of *periculum in mora* (danger of delay) and *fumus boni iuris* (plausibility).⁴⁵ In this case, as already mentioned, the lawsuit must be filed before the federal courts. If the relief sought in the lawsuit is granted, the INPI is required to nullify the patent and make the appropriate official records regarding such an annulment⁴⁶ in accordance with Article 57 of the LPI.⁴⁷

Given the technical complexity involved in such lawsuits, Article 57(1) establishes a term of 60 days for the defendant to submit an answer. A judge may, throughout this action, choose to provisionally suspend the effects of the patent under the terms provided for in Article 300 of the CPC if this is requested by the plaintiff.⁴⁸

At the end of the case, when the preliminary and priority issues provided for in Article 485 of the CPC⁴⁹ have been overcome, “the patent may be declared null, if it has been granted in violation of any of the rules of the [LPI], such as the requirements of novelty and inventive step,” producing *ex tunc* (retroactive) effects, as shown above, and *erga omnes* (binding upon everyone) effects, given that this nullity produces effects from the filing of the patent application with the INPI.⁵⁰

It is important to remember that, while actions for damages are filed before the state courts, patent nullity actions are filed before the federal courts because the INPI is an indispensable party. Something interesting happens when there is an incidental argument in an action for damages for patent infringement regarding a claim for its nullity. Theoretically, nullity can be argued as a defense, according to Article 56(1) of the LPI. However, superior courts have adopted the opinion that, due to the INPI’s personal jurisdiction, the connection between these actions cannot be recognized – only the relationship of external priority between the action for nullity and the action that discusses the infringement, thus suspending the latter, based on Article 313(V)(a) of the CPC.⁵¹ The STJ, in Special Appeal (Recurso Especial) No. 1,132,449/PR, recognized that a state court would lack jurisdiction to assess and judge the incidental claim of nullity presented by the defendant for defense in the acts of the infringement action, thus demanding its own action before the federal courts.⁵²

Recently, however, the STJ presented a different opinion, recognizing the feasibility of incidental nullity for patents, which would generate *inter partes* effects:

although it is not possible to incidentally recognize the nullity of marks, the *incidenter tantum* examination of the nullity of patents and industrial designs is perfectly possible. This possibility comes from an express determination of law [...] as a defense matter in infringement actions, over which the State Courts have jurisdiction. In such cases, INPI’s participation becomes unnecessary.⁵³

Jurists’ opinions diverge on the procedural moment of recognition of external priority. Some have said that priority should be applied after the filing of the proceedings. Others have said that it should be applied only after the judgment on the merits of the priority legal proceedings in which state courts determine that the patent had been infringed because, if no infringement is found, there is no priority. Finally, some have argued that it should be recognized as soon as evidence of priority is presented.

45 Ramos, *Direito Empresarial*, at 400.

46 Ahlert and Camara Junior, *Patentes: Proteção na Lei de Propriedade Industrial*, at 223.

47 Law No. 9,279/96, art. 57 (“The patent nullity action will be filed before the Federal Courts[,] and INPI, if it is not the plaintiff, will intervene in the case”).

48 Ahlert and Camara Junior, *Patentes: Proteção na Lei de Propriedade Industrial*, at 225.

49 Art. 485 of CPC. The judge will not decide on the merits when: I – reject the initial petition; II – the process is stopped for more than 1 (one) year due to the negligence of the parties; III – for not promoting the acts and diligences that he is responsible for, the plaintiff abandons the case for more than 30 (thirty) days; IV – verify the absence of presupposition for the constitution and valid and regular development of the process; V – recognize the existence of preemptions, *lis pendens* or *res judicata*; VI – verify absence of legitimacy or procedural interest; VII – accept the allegation of the existence of an arbitration agreement or when the arbitration court recognizes its jurisdiction; VIII – ratify the withdrawal of the action; IX – in case of death of the party, the share is considered non-transferable by legal provision; and X – in the other cases prescribed in this Code.

50 Ahlert and Camara Junior, *Patentes: Proteção na Lei de Propriedade Industrial*, at 225.

51 Superior Tribunal de Justiça (STJ) (Superior Court of Justice), Recurso Especial (REsp.) (Special Appeal) No. 742,428/DF.

52 STJ (Superior Court of Justice), REsp. (Special Appeal) No. 1,132,449/PR, Rapporteur Nancy Andriighi, March 13, 2012, Diário da Justiça Eletrônico (DJe), March 23, 2012.

53 STJ (Superior Court of Justice), REsp. (Special Appeal) No. 1,843,507/SP, Rapporteur Paulo de Tarso Sanseverino, Oct. 6, 2020, DJe, Oct. 10, 2020.

3.5 Patent infringement

Patent infringement actions are governed by the CPC and are a common proceeding.

3.5.1 Infringement analysis

Patent infringement is analyzed by considering the scope of the claims, as established in the provisions of Article 41 of the LPI:

as a general basic rule for determining an infringement, one must verify whether the accused product or process has all the characteristics of a patent's independent claims – or of one of them. This is because, strictly speaking, an independent claim is one that defines all the essential characteristics of the invention claimed; dependent claims define only optional characteristics of the invention. Although they do not limit the scope of the patent, dependent claims can be helpful in interpreting the terms of the independent claims to which they are subordinated. This is because dependent claims detail terms more clearly, whereas independent claims define them more broadly. Dependent claims may also help detect an infringement, i.e., after a product or process has been found to infringe any of the broad terms of an independent claim, one can verify whether the infringement also extends to the more specific terms of dependent claims. In such situations, infringements become more apparent.⁵⁴

Infringement of a claim may occur directly (or literally) or by equivalence. Direct or literal infringement occurs when

each element of the infringing product coincides with the definition contained in the claim. [...] In the direct infringement, the meaning or scope of a particular expression in the claim may need to be interpreted [...]; however, once the expression has been interpreted and its extension has been established, correspondence with the element of the infringing product is immediate.⁵⁵

By contrast, an infringement by equivalence “is a form of non-literal infringement; it occurs when the element of the infringing product does not fall directly under the definition of the element claimed, but it constitutes a technical equivalent of the latter.”⁵⁶

Regarding the infringement of a utility model patent, attempts to expand the scope of a claim beyond its literal meaning should be used carefully in addition to investigating the state of the art,⁵⁷ because the protection of a claim is defined by the preamble and the characterizing part.

3.5.1.1 Direct patent infringement

The patent holder has more than just the right to own the patent (Article 6 of the LPI); they also have the right to prevent third parties, with or without consent, from producing, using, putting up for sale, selling or importing for these purposes a product subject to patent or a process or product obtained directly through a patented process (Article 42 of the LPI). Thus, legal protection encompasses both the product subject to the patent (Article 42(I) of the LPI) and the “process or product obtained directly through a patented process” (Article 42(II) of the LPI). It also protects both from others selling, buying, manufacturing, using, putting up for sale or importing a product and from others engaging in a process arising “directly” from a patented process.⁵⁸ The expression “directly” may be interpreted in different ways. This divergence should be assessed by considering the possibility of the patent holder obtaining the appropriate compensation for the exploitation, examining whether undue economic exploitation by a third party has occurred and whether the solution is consistent with the purpose of ensuring legal protection.⁵⁹ The misuse of patents constitutes a civil wrong liable to compensation.

Thus, Brazilian law gives a patent holder the power to prevent third parties from engaging in acts that infringe the right of ownership. Such power exists even if such acts have occurred

⁵⁴ Ahlert and Camara Junior, *Patentes: Proteção na Lei de Propriedade Industrial*, at 166.

⁵⁵ Ahlert and Camara Junior, *Patentes: Proteção na Lei de Propriedade Industrial*, at 168.

⁵⁶ Ahlert and Camara Junior, *Patentes: Proteção na Lei de Propriedade Industrial*, at 169.

⁵⁷ Ahlert and Camara Junior, *Patentes: Proteção na Lei de Propriedade Industrial*, at 205–06.

⁵⁸ IDS, *Comentário à Lei de Propriedade Industrial*, at 108.

⁵⁹ Ahlert and Camara Junior, *Patentes: Proteção na Lei de Propriedade Industrial*, at 57.

independently, unless they fall under the cases of Articles 43 and 45 of the LPI, in which case they would be in accordance with Article 28(1) of the TRIPS Agreement.⁶⁰ So, any of these activities listed in Article 42, when unauthorized, constitutes a direct infringement of the right of the patent holder. Thus, Brazilian law gives a patent holder the power to prevent third parties from engaging in acts that infringe the right of ownership. Such power exists even if such acts have occurred independently, unless they fall under the cases of Articles 43 and 45 of the LPI, in which case they would be in accordance with Article 28(1) of the TRIPS Agreement.⁶¹ So, any of these activities listed in Article 42, when unauthorized, constitutes a direct infringement of the right of the patent holder.

The criminal aspect of patent infringement is somewhat distinct and is defined by Article 184 of the LPI:

It is a crime against the patented invention or utility model to:

*I – export, sell, expose or put up for sale, stock, conceal, or receive, for economic purposes, a product whose manufacturing infringes a patent for invention or utility model, or a product obtained through a patented process; or
II – import a product protected by an invention patent or utility model patent, or a product obtained through a process patented in the country, for the purposes set out in the item above, and that has not been placed on the foreign market directly by the patent holder or with their consent.*

Article 42(2) of the LPI clarifies that a process patent, referred to in Article 42(II), is infringed when the processor fails to prove that their product was obtained by a manufacturing process other than that protected by the patent. This rule reverses the burden of proof, placing it on the infringer.

Direct or literal infringement occurs when each element of the infringing product coincides with the definitions contained in the claim.⁶² In literal infringement, the meaning or scope of an expression in the claim may need to be interpreted; however, once the expression has been interpreted, and its extension has been established, correspondence with the infringing product is immediate.⁶³

3.5.1.2 Indirect patent infringement

A patent holder may also prevent third parties from contributing to the practice of such infringing acts by others (Article 42(1) of the LPI).

The description of the criminal offense, contained in Article 185 of the LPI, is somewhat more limited: “To provide a component of a patented product, or material or equipment to carry out a patented process, provided that the final application of such component, material, or equipment necessarily entails the exploitation of the object of the patent. Penalty – imprisonment, from 1 (one) to 3 (three) months, or fine.”

Jurists believe that an extensive interpretation of the wording of Article 42(1) of the LPI could hold accountable anyone who sells common spare parts, which can be used for purposes unrelated to a patented invention. This could unduly favor the patent holder. For this reason, it has been argued that a more balanced interpretation would be that a person allegedly committing the indirect or contributory infringement induces someone else, at least partially, to commit some of the infringements listed in Article 42 of the LPI.⁶⁴

3.5.1.3 Infringement by equivalence

Infringement by equivalence occurs when an element of a product does not fall directly under the definition of the element in the patent claim but instead constitutes a technical equivalent of it.⁶⁵ Such equivalence may be direct – for the purpose of extending the scope of the terms of a

60 IDS, *Comentário à Lei de Propriedade Industrial*, at 108.

61 IDS, *Comentário à Lei de Propriedade Industrial*, at 108.

62 Ahlert and Camara Junior, *Patentes: Proteção na Lei de Propriedade Industrial*, at 166.

63 Ahlert and Camara Junior, *Patentes: Proteção na Lei de Propriedade Industrial*, at 168.

64 Ahlert and Camara Junior, *Patentes: Proteção na Lei de Propriedade Industrial*, at 59.

65 Ahlert and Camara Junior, *Patentes: Proteção na Lei de Propriedade Industrial*, at 169.

claim – or inverse – for the purpose of restricting the scope of the claim to terms equivalent to those mentioned in the specifications.⁶⁶ In this sense, Article 186 of the LPI describes the following: “The crimes mentioned in this Chapter [referring to Articles 183–186 of the LPI] are characterized even if the infringement does not reach all claims of the patent or is restricted to the use of means equivalent to the object of the patent.” Although providing for criminal wrongs, they also indicate civil wrongs.

According to jurists, although there are no positive rules, there are two limiting inferences from the finding that equivalence cannot be extended to an accused product that is within the state of the art, nor can it be extended to allow the patent holder to recover protection that they gave up during the processing of the patent application.⁶⁷ Although the LPI does not provide for the application of process history, it is possible to support the possibility of its compliance given the principle that does not allow the *venire contra factum proprium* (acting in a contradictory manner) that arises from objective good faith.

The LPI does not establish criteria for interpreting claims by equivalence. However, jurists have suggested that claims should be interpreted considering the legal meaning of their terms, the specifications and additional information from the available state of the art, the history of processing, and the general meanings of the words in the claim in the technical field.⁶⁸

3.5.1.4 The reverse doctrine of equivalents

The LPI does not expressly provide for the application of reverse equivalence. However, jurists have held that, when a restrictive interpretation is needed to avoid the determination of nullity of a patent, the patent holder may request this restrictive interpretation to obtain partial nullity.

3.5.1.5 Extraterritorial infringement

If an unauthorized third party seeks undue economic advantage over a patented invention, an infringement may be recognized, even if it occurred outside Brazilian territory.⁶⁹

In the case of imports for patent exploitation and of imports provided for in Article 68(3) of the LPI, Article 68(4) of the LPI allows third-party imports of a product manufactured according to a process or product patent, as long as it has been placed on the market directly by the holder or with their consent.

3.5.2 Defenses

A third party may claim that they did not violate patent law. However, in this case, when it comes to the infringement of a process patent, the burden of proof is reversed (Article 42(2) of the LPI).

3.5.2.1 Absence of liability

For an accused infringer to avoid being held liable, it is possible to claim the provisions of Articles 43 and 45 of the LPI, which, by express legal definition, stipulate circumstances in which a patent is not infringed. Patent nullity may also be claimed, at any time, as a defense.

Article 43 of the LPI provides for cases in which a patent is not infringed. For example, acts committed privately and without commercial purposes by unauthorized third parties do not infringe a patent as long as they do not harm the patent holder’s economic interests (Article 43(I) of the LPI).

A person who exploited, in good faith, the subject matter of a patent in Brazil before the filing or priority date of a patent application is ensured the right to continue with such exploitation, without burden, as before (Article 45 of the LPI). This right is not ensured to a person who became aware of the patent’s subject matter by the disclosure made pursuant to Article 12 of the LPI, as long as the application has been filed within one year of the disclosure (Article 45(2) of the LPI). The right granted pursuant to this article may be assigned only to the business or company, or a company representative directly related to the exploitation of the patented object, by disposal or lease (Article 45(1) of the LPI).

66 Ahlert and Camara Junior, *Patentes: Proteção na Lei de Propriedade Industrial*, at 181.

67 Ahlert and Camara Junior, *Patentes: Proteção na Lei de Propriedade Industrial*, at 186.

68 Ahlert and Camara Junior, *Patentes: Proteção na Lei de Propriedade Industrial*, at 183.

69 Ahlert and Camara Junior, *Patentes: Proteção na Lei de Propriedade Industrial*, at 63.

3.5.2.2 Consent or license

Third parties may claim to have a license authorizing their use of the patent. This would exempt them from liability for alleged infringement.

3.5.2.3 First-sale (exhaustion) doctrine

The principle of the exhaustion of patent rights is provided for in Article 43(IV) of the LPI. Under this provision, a third party may also claim to have a product that has been manufactured according to a process or product patent and that has been placed on the domestic market directly by the patent holder or with their consent. Consent or placement on the market by the patent holder are conditions for the exhaustion of the patent holder's right. Exhaustion refers to the product sold, not to the patent as a whole. However even if primary exploitation is not carried out by the patent holder, the acts of the secondary exploitation may still constitute an infringement.⁷⁰

If there is more than one holder of the patent, it is necessary to check whether any of them had the right to place the product on the market or to grant a license. If so, this right is exhausted in relation to the others. Otherwise, there may be no exhaustion.

For patents relating to living matter, patent law is also not infringed if third parties use, circulate or sell a patented product that has been lawfully introduced into the market by the patent holder or license holder, provided that the patented product is not used to multiply or propagate the living matter for commercial purposes (Article 43(VI) of the LPI). Additionally, patent law is not infringed if third parties use the patented product as an initial source of variation or propagation to obtain other products without commercial purposes. Finally, there is no infringement for acts performed by unauthorized third parties, related to the protected invention and intended exclusively for the production of information, data and test results aimed at obtaining a trade license – in Brazil or in any other country – for the exploitation and sale of the patented product after expiration of the time limits set forth in Article 40 (Article 43(VII) of the LPI).

Article 43(IV) of the LPI provides for exhaustion only for products placed on the *domestic* market by the patent holder or with their consent. Therefore, holders may exercise their right to prevent the parallel importation if they import their product, even if the product is placed on the foreign market by the patent holder or with their consent.⁷¹

3.6 Judicial patent proceedings and case management

3.6.1 Venue, jurisdiction and case assignment rules

Whenever the INPI takes part in the case, which happens in patent nullity proceedings, the federal courts have absolute jurisdiction, *intuito personae*, which must be declared by the judge on their own initiative, under penalty of nullity of the proceedings. However, jurisdiction of the federal courts is not attracted if the patent nullity claim is merely incidental as a defense in an action where there is an allegation of patent infringement.

Regarding state courts' jurisdiction to decide on cases of patent infringement, such cases must be assigned according to territorial jurisdiction. If there is specialization, as it is a matter of judicial organization, then it is a case of absolute jurisdiction. Where it is not a case of absolute jurisdiction, there is a possibility of choosing the venue to file the action. Such an option is limited to the provisions set forth by law – that is, the legal system may establish more than one legal venue for the processing of the same case.

The Brazilian legal system admits two types of jurisdiction: absolute and relative. The difference between them is based on the mandatory establishment of a certain court for the processing and trial of the case. In absolute jurisdiction, once the appropriate court is defined by the legal system, the case assigned to it cannot, under any circumstance, be processed and tried in another judicial unit other than that set forth by the law. The trial of a case by a court that has not been previously defined as appropriate for doing so by law necessarily implies nullity of the judgment, even if none of the parties contests this point in the case.

⁷⁰ Ahlert and Camara Junior, *Patentes: Proteção na Lei de Propriedade Industrial*, at 105.

⁷¹ IDS, *Comentário à Lei de Propriedade Industrial*, at 121.

It should be noted that the procedural law imposes on the judge the duty to examine, on their own initiative, the case of absolute jurisdiction, pursuant to Article 64(1) of CPC. In addition, if the defendant challenges the jurisdiction and its nature, Article 64(2) also requires the judge to analyze this defense argument immediately, regardless of the stage of the case. Where a lack of absolute jurisdiction is found, the judge must order the case to be sent to the court of competent jurisdiction as defined by the law.

In the case of relative jurisdiction, although the law establishes, a priori, the court where the case must be processed, should the plaintiff file the case before another court, any processing by the latter does not imply nullity of the case or trial. Furthermore, the STJ has settled case law in the sense that a judge is prohibited from analyzing, by their own initiative, a dispute regarding the existence of relative lack of jurisdiction.⁷²

This does not mean, however, that a party is free not to follow the legal provision regarding relative jurisdiction. A case remains permanently with the judge to whom the case was assigned only if the opposing party does not challenge it. However, this challenge cannot be presented at any time: Article 65 of the CPC determines that a challenge to relative jurisdiction must be presented in the answer. If the judge finds that their jurisdiction is not included among those provided by law, they must refer the case to the legally indicated judicial unit. Even if a case is filed before a court that lacks relative jurisdiction, there is no nullity if the issue is not expressly contested (*perpetuatio jurisdictionis*).

This system of absolute and relative jurisdiction is also applicable to urgent reliefs and has consequences for the court's definition of the definitive proceedings (i.e., prevention).

After defining the jurisdiction of the federal and state courts and for nullity and patent infringement cases, it is necessary to then verify which court is competent. To do so, the criteria established in Articles 42–53 of the CPC must be observed. Jurisdiction is determined at the time of filing or assignment of the complaint, and subsequent changes in the factual or legal status that may occur are irrelevant, except when they suppress the judicial body or change the absolute jurisdiction (Article 43 of the CPC). Subject to the provisions of the Federal Constitution and the CPC, the court with jurisdiction over the case is defined based on the rules of judicial organization.

For cases based on personal rights, the court with jurisdiction is defined as the court located in the jurisdiction of the defendant's domicile (Article 46 of the CPC). If there is more than one domicile, the defendant can be sued in any of them. If two or more defendants have different domiciles, they can be sued in any of their venues at the plaintiff's choice (Article 46(2) of the CPC). Where the defendant does not have a domicile or residence in Brazil, the case must be filed in the venue of the plaintiff's domicile, and, if the plaintiff also resides outside Brazil, the case can be filed in any venue (Article 46(3) of the CPC). When a case addresses damages, Article 53(IV) of the CPC defines the court with jurisdiction as the venue of the place of the act or fact related to the action.

An interesting peculiarity regarding the defense of defendants and the Brazilian judicial organization is that it is possible to claim the nullity of the patent incidentally in an action for damages or for the declaration of non-infringement (Article 56(1) of the LPI), although the nullity action is processed at the federal level (Article 57 of the LPI), and the other actions are processed at the state level.

It is possible for actions for annulment and for damages to be processed simultaneously. In this scenario, the judge of the action for damages may recognize the external priority of the former over the latter, suspending the progress of the latter (Article 313(V) of the CPC). In this sense, "[e]xternal priority is characterized if there is a pending lawsuit, in a case extrinsic to the present one, in which the nullity of the patents on which the main subject matter of this action is based, even if the appellant is not a party to the cases."⁷³

Recently, there has been a change in the case law of the STJ. Previously, it did not allow state courts to analyze the nullity of patents, even incidentally,⁷⁴ but now it does:

72 STJ (Superior Court of Justice), Precedent No. 33.

73 STJ (Superior Court of Justice), REsp. (Special Appeal) No. 1,558,149/SP, Rapporteur Marco Aurélio Bellizze, Nov. 26, 2019.

74 STJ (Superior Court of Justice), REsp. (Special Appeal) No. 1,132,449/PR, Rapporteur Nancy Andriighi, March 13, 2012, DJe, March 23, 2012; STJ, REsp. (Special Appeal) No. 1,558,149/SP, Rapporteur Marco Aurélio Bellizze, Nov. 26, 2019, DJe, Dec. 3, 2019.

although the incidental recognition of the nullity of trademarks is not possible, the incident tantum (incidental) examination of the nullity of patents and industrial designs is perfectly possible; this possibility results from the express determination under the law [...] as a matter of defense in infringement actions, within the jurisdiction of the State Courts; in these cases, INPI's participation is waived.⁷⁵

This change in the STJ's understanding raises questions that still need time to be debated by the Brazilian case law – namely, is it possible for the evidence produced in state courts to be presented in federal courts? Does one action suspend the other? Is it possible for the evidence to be produced in judicial cooperation, and what does the CPC say about it? As this is a recent change, there are yet no answers to these questions.

3.6.1.1 Interaction with other types of cases

Brazilian law admits the possibility of the joinder of two distinct actions upon the occurrence of a “connection” (“*continência*”). Under the terms of Article 55 of the CPC, two or more actions are considered connected when they have a common request or cause of action. Cases that could imply a risk of rendering conflicting or contradictory decisions if decided separately, even without any connection between them, may also be brought together to be decided jointly. However, to allow the joinder of the cases, it is essential that none of them have yet been decided.

Cases may also be considered connected and can therefore be joined when there is an identity as to the parties and to the cause of action, but the relief sought in one, being broader, embraces the relief sought in the other cases (Article 56 of the CPC).

The joinder of the actions filed separately takes place in the court that obtained jurisdiction by prevention, in which they will be decided simultaneously (Article 58 of the CPC). In this context, the filing or assignment of the oldest complaint to the court is considered to be obtaining prevention (Article 59 of the CPC).

As for patent nullity actions and actions for damages, although there may be a connection between these actions, it is not possible to join these cases due to the absolute jurisdiction of the federal and the state courts, respectively. In this case, the state court with jurisdiction over the action for damages may determine its suspension if it understands that there is an external priority.

Pursuant to Article 313(V)(a)-(b) of the CPC, a case is suspended when the judgment on its merits (a) depends on the judgment of another case or the declaration of the existence or nonexistence of a legal relationship that constitutes the main subject matter of another pending case, or (b) needs to be rendered only after the verification of a certain fact or the production of certain evidence as requested by another court. During such a suspension, it is forbidden to practice any procedural act; nonetheless, the judge may order the execution of urgent acts to avoid irreparable damage (Article 314 of the CPC).

It is possible to suspend civil proceedings, at the discretion of the civil judge, if the entertainment of the merits depends on verification of the existence of a criminal offense (Article 315 of the CPC). If the criminal action is not filed within three months of the notification of the suspension, the effect of the latter ceases, and the civil judge is responsible for examining the priority issue incidentally (Article 315(1) of the CPC). If the criminal action is filed, then the case is suspended for a maximum of one year, at the end of which the civil judge will be responsible for examining the priority issue incidentally (Article 315(2) of the CPC).

3.6.1.2 Bankruptcy

Article 6 of Law No. 11,101, of February 9, 2005 (a law regulating bankruptcy and court-supervised reorganization in Brazil),⁷⁶ provides that a declaration of bankruptcy or the granting of a court-supervised reorganization procedure does not affect the processing of actions that demand illiquid amounts or that request a declaration of nullity. The illiquid actions continue to be conducted by the judge of the case, to whom they would have been assigned had there

⁷⁵ STJ (Superior Court of Justice), REsp. (Special Appeal) No. 1,843,507/SP, Rapporteur Paulo de Tarso Sanseverino, Oct. 6, 2020, DJe, Oct. 10, 2020.

⁷⁶ DOU of Feb. 9, 2005, as amended by Law No. 14,112 of Dec. 24, 2020, DOU of Dec. 24, 2020, art. 1.

been no bankruptcy, considering ordinary rules and assignment of jurisdiction. Once the sentencing of a bankrupt company for patent infringement is determined, the creditor must file a proof of claim within the scope of the bankruptcy procedure.

3.6.2 Statements of case

In Brazil, the delimitation of a dispute is defined in the procedural system by the complaint, the answer or even the counterclaims. Equally, there is no provision in Brazilian law for an evidentiary or construction stage by the parties to the claim prior to the submission of the case to the judge. For a judge to be able to conduct a dispute, there must be a presentation of the theory and the legal claim (Article 2 of the CPC).

3.6.2.1 Complaint

Brazilian law determines that the requests that one intends to make before another party must be made immediately in a procedural document called “complaint,” which initiates the lawsuit before a judge. According to express legal determination, the legal theories, presentation of the factual circumstances and existing documentary evidence must be indicated at the first opportunity in which the party is to make a statement in the case record (i.e., at the initial moment, for the plaintiff; at the time of presentation of the defense, for the defendant). Requests before the other party delimit the judge’s scope of cognizance, which will be further delimited after the answer is presented. This is because the judge cannot, under penalty of nullity, decide neither more nor less nor different from what was requested (Article 141 of the CPC).⁷⁷

Holders of patent registrations, licenses and preference requests have standing to sue before the judiciary. With respect to the documents that must be attached to the complaint for such entities, the following are mandatory: power of attorney, articles of incorporation, proof of payment of costs, power of attorney of the foreign interested party (and valid in Brazil), proof of the security deposit (when required). Besides these, essential documents for verifying the standing of the parties include letters patent, licenses, registrations, receipts of priority requests before the INPI.

Thus, there is no preparatory phase, prior to the filing of an action, in which the parties may have the opportunity to present evidence and theories (Article 347 of the CPC). Instead, this dialogue between the parties, in Brazilian law, only occurs after the action is filed, in a procedure conducted by a judge, the rules of which are provided for in law and which largely, given the public nature of procedural law rules, cannot be changed by the parties or by the judge, under penalty of nullity.

The law provides that, after the initial request has been made, the legal provisions that allow its change are restricted. After the initial presentation, the plaintiff can change the request or cause of action until the service of process, without the defendant’s consent. After the service of process, the plaintiff can still make such changes until the pre-trial order, though, in this case, it requires the defendant’s consent (Article 329 of the CPC). After the pre-trial order, the plaintiff can no longer change the request. Conversely, the defendant has the burden of the specific objection.

Thus, it is reasonable to state that all legal theories and all important facts must be mentioned in the complaint or answer, upon express legal imposition. The plaintiff may also, in view of defendant’s defense, present a new statement, rebutting the clarifications provided, after which the case will be considered by the court. The defendant may present, in addition to the defense, a request against the plaintiff, in which case the latter must subsequently present a defense. This request against the plaintiff can be done in the same case, provided that there is no procedural incompatibility.

Before the pre-trial order, the judge will determine that the parties, in view of the statements made and the documentary evidence produced in this first stage of the process, present requests for evidence. After such a statement, the judge assigns the burden of proof between the parties and analyzes the possible occurrence of nullity defects to remedy them, if possible, and to define the disputed points between the parties, as well as the facts and rights.

There is, therefore, the presentation of the initial request, accompanied by the presentation of the legal theories and of the facts (i.e., the cause of action), as well as the request itself

⁷⁷ Art. 141 of CPC. The judge will decide on the merits within the limits proposed by the parties, being forbidden to hear questions that have not been raised in respect of which the law requires the initiative of the party.

(Article 319 of the CPC). This must also contain the documents that already exist and are necessary for the cognizance of the action (Articles 320 and 434 of the CPC).

Exceptionally, a judge may admit the subsequent presentation of documents: in cases of Article 435 of the CPC and of court authorization for additional documentary evidence and complementation during expert analysis (Article 473(3) of the CPC).

3.6.2.2 Answer

The defendant, in their answer, has the burden of objecting all aspects of what was alleged in the complaint, under penalty of preclusion (Articles 335–342 of the CPC). That is, the defendant does not have another opportunity in the case to make such objections (Article 336 of the CPC). Additionally, facts alleged by the plaintiff and not objected by the defendant are considered true (Article 341 of the CPC).

Therefore, a failure to present a defense has two consequences: the loss of the burden of objection and the assumption that the facts presented by the plaintiff are undisputed. However, procedural defenses may be alleged, such as lack of jurisdiction and parallel litigation; an allegation of connection, suspension or priority; an allegation of an arbitration agreement or the plaintiff's lack of standing; and other preliminary matters. The merits and scope of the complaint may also be objected to.

Unlike the complaint, however, the defense may be less exhaustive in explaining opposing points. This is because, in view of the dynamics of the burden of proof, it is, in theory, the plaintiff's duty to detail what is necessary to explain how a given process, object, manufacturing or element has been violated by the defendant. In this case, if the defense is limited to objecting the occurrence of these facts, there is no need for further detail, although it is recommended that the defendant has their own structure to present its opposition to the allegation. Conversely, if the defense results in the presentation of facts that "modify, extinguish or prevent" the plaintiff's rights – that is, facts that change the dynamics of the narrative exposed in the complaint – the defendant is subject to the same standard of reasoning, including the attribution of the burden of proof, pursuant to Article 373 of the CPC.

It is possible to establish joinders of defendants due to a multiplicity of parties responsible for the undue exploitation of the same patent (Article 113 of the CPC).

3.6.2.3 Counterclaim

During the term for the answer, which is 15 business days (Article 335 of the CPC), the defendant may also, if it is in their interest, make their own requests against the plaintiff (Article 343 of the CPC). The defendant can present these requests regardless of whether they present an answer (Article 343(6) of the CPC). In theory, such requests must be made and articulated as if they were a separate case against the plaintiff. However, the procedural legislation allows these requests to be made during the case filed by the plaintiff (Article 343(6) of the CPC).

It is required of counterclaims that the request be connected with the main action or with the ground of the defense. It must also comply with the assumptions of the complaint (because they have the nature of a request) and requires that the plaintiff has standing to be sued by the defendant, though it is possible, however, for a third party to also act as the defendant in the counterclaim (Article 343(3) of the CPC).

After the counterclaim is filed, the plaintiff is summoned, by means of their attorney, to file an answer within 15 days. The withdrawal of the main action or the occurrence of an extinguishing cause that prevents the examination of its merits does not prevent the continuation of the counterclaim proceeding (Article 343(2) of the CPC).

3.6.3 Case management

In the ordinary procedure, which is applied to civil lawsuits filed in accordance with the LPI provisions, there is a provision for a prior conciliation hearing before the presentation of the answer (Article 334 of the CPC). However, although the wording of the CPC suggests that this hearing is mandatory, it is not carried out in many cases.

Thus, in Brazilian law, the plaintiff has the autonomy to make a request as they wish, and the defendant has the burden of questioning it, in view of the principle of preclusion. The parties also have a duty to act in good faith and to cooperate (Articles 5–6 of the CPC). These factors guide the case management that can be performed by the judge, which is based on the powers granted to them by the CPC:

The judge will conduct the case according to the provisions of this Code, being responsible for:

- I – ensuring the parties equal treatment;
 - II – ensuring the reasonable duration of the case;
 - III – preventing or repressing any act contrary to the dignity of justice and rejecting merely delaying requests;
 - IV – determining all inductive, coercive, mandatory or subrogatory measures necessary to ensure compliance with a court order, including in cases in which the subject matter is a monetary obligation;
 - V – promoting, at any time, the resolution of the dispute by the parties themselves, preferably with the aid of court conciliators and mediators;
 - VI – extending procedural terms and changing the order of production of evidence, adjusting them to the needs of the conflict so as to grant greater effectiveness to the protection of the right;
 - VII – exercising police power, requesting, when necessary, police force, in addition to the internal security of the courts and venues;
 - VIII – ordering, at any time, the personal presence of the parties to question them about the facts of the case, in which case the confession penalty will not apply;
 - IX – determining the compliance with procedural requirements and the resolution of other procedural defects;
 - X – when facing several repeated individual claims, notifying the Public Prosecutor's Office, the Public Defender's Office, and, as far as possible, the other legal entities referred to in Article 5 of Law No. 7,347, of July 24, 1985, and Article 82 of Law No. 8,078, of September 11, 1990, so that, if applicable, they may promote the filing of the respective class action.
- Sole Paragraph. The extension of terms provided for in item VI can only be determined before the regular term is ended. (Article 139 of the CPC)

Considering the legal powers granted to the judge, it is possible to identify the following case management tools that are at the judges' disposal:

- referral of the case to conciliation or mediation;
- pre-trial order;
- trial hearing;
- flexibility of procedures;
- scheduling of procedural acts and terms (Article 191 of the CPC);
- extension of dilatory terms;
- change in the order in which evidence is to be produced;
- use of expert evidence, the judge being able to use the traditional model, informal expert evidence or out-of-court expert evidence; and
- procedural legal transactions (Article 190 of the CPC).

The Brazilian civil procedure adopts an eclectic theory of the right of action. Thus, the action itself must be understood as a right to take a certain dispute to the judiciary, which analyzes it upon compliance with certain conditions (i.e., the interest in the action and legal standing). The lack of such compliance imposes the dismissal of the case without prejudice (allowing the filing of a new lawsuit upon rectification of the defect). For part of the Brazilian judiciary, when the analysis of these conditions depends on evidence to be produced during the case, there is no analysis of conditions per se but of the merits themselves, which affect the possibility of bringing a new claim. Conversely, procedural interest is defined based on adequacy and necessity. Procedural adequacy may be limited when an administrative proceeding is pending, especially with regard to the designation of coauthorship of the invention, because in those situations the necessity of a judicial claim is unclear.

Therefore, considering the regulation of procedure in Brazilian legislation, a party is compelled to allege all possible issues – either in the complaint or in the answer – to avoid the risk of preclusion. Furthermore, as this exposition of legal theory and evidence is already made within the scope of the court case, subjecting the losing party to the payment of procedural costs and expenses, it can be observed that settlements are infrequent in the initial phase of the trial, when it is before the lower court.

After the parties have expressed their opinion, the organization of the case is then made by a judge. In addition to verifying whether there are procedural defects for remediation, the judge may verify the possibility of judging the case as found without additional evidence, partially judging the case or determining the evidence to be produced (Article 357 of the CPC). To adopt the best possible direction for the case, the judge must, therefore, consider the limits that are provided for in law – namely:

- the limit of disputed issues between the parties that were defined based on their previous statements in the case (complaint, answer and reply or, occasionally, a procedural legal transaction between them relating to this topic). It is important for the judge to consider the limits defined by the parties for the cognizance of the disputed issue, since the judge's performance beyond, more or less than what was requested will be considered irregular (Article 141 of the CPC); and
- the limit defined in law for the freedom to act, since, in Brazilian law, there are formal issues that cannot be changed even upon an agreement between the parties or upon determination of the court, under penalty of nullity of the procedure.

Although there is no legal definition of absolute and relative nullities, jurists have agreed that the former must be acknowledged at the judge's own initiative and cannot be remedied (see Article 278 of the CPC), while the latter can be validated, if not mentioned, and if, in any other way, they achieve the intended purpose (see Articles 276–277 of the CPC). This way, for example, a judge cannot rule out the action of the Public Prosecutor's Office, whose function is to protect the unable, under penalty of nullity. Defects in the service of process are also not validated unless the party spontaneously makes a statement in the case record.

With regard to the procedure itself, some issues have already been predefined in law: for example, the terms for defense, the assignment of the burden of proof, the hypotheses of procedural preclusions and the assignment of jurisdiction, which can only be changed by the parties or by the judge if there is an express provision, as will be seen below.

To assign the burden of proof, the judge must delimit the issues of law and fact that are the subject matter of the dispute; assign the burden of proof between the parties; determine the evidence that is to be produced (Article 357 of the CPC) – granting or not the request of the parties in this regard; and, as the case may be, designating a trial hearing. The law provides for a general rule on the assignment of the procedural burden of producing evidence. Article 373 of the CPC clearly assigns the burden of proof between the parties:

The burden of proof is incumbent upon:

I– plaintiff, as to the fact constituting his/her right;

II– defendant, as to the existence of a fact that prevents, modifies, or extinguishes plaintiff's right.

Paragraph 1. In the cases provided for in law or in view of peculiarities of the case related to the impossibility or excessive difficulty in fulfilling the charge under the terms of the head provision or the greater ease of obtaining proof to the contrary, the judge may assign the burden of proof in a different manner, provided that the judge does so by means of a reasoned decision, in which case the judge must give the party the opportunity to claim the discharge of the burden assigned to it.

Paragraph 2. The decision provided for in Paragraph 1 of this article cannot generate a situation in which the discharge of the burden by the party is impossible or excessively difficult.

Paragraph 3. The different assignment of the burden of proof may also occur upon agreement between the parties, except when:

I– it falls on the party's unwaivable right;

II– it makes it excessively difficult for a party to exercise the right. Paragraph 4. The agreement referred to in Paragraph 3 may be entered into before or during the case.

Regarding the plaintiff's procedural burden, the CPC establishes the need for a precise definition of the cause of action and, above all, of the request, since both will limit the scope of the judge's actions.

This general rule on the assignment of the burden of proof is strict, but it may be waived by the judge in specific cases. The judge cannot make exceptions to the general rule on the assignment of the burden of producing proof if the discharge of the party is impossible or excessively difficult.

If the issues are very complex, the judge may schedule a cooperative pre-trial hearing so that the parties can clarify their allegations and contribute to the definition of the disputed points and the assignment of the burden of proof, which always remains under the responsibility of the judge (Article 357(3) of the CPC). The parties may also, by mutual agreement, present to the judge the delimitation of the disputed matters of fact and of law (Article 357(2) of the CPC).

If the judge determines the production of expert evidence, the judge must, as far as possible, immediately present a procedural schedule for its realization (Article 357(8) of the CPC) and also a possible trial hearing for the hearing of witnesses.

It is also necessary to state that a judge cannot render decisions without having given the opposing party an opportunity to express its opinion, even though the judge may decide at their own initiative, except in exceptional cases, such as those of interlocutory relief and relief based on evidence (Articles 9–10 of the CPC).

As a rule, procedural terms are defined by law. The term for filing and objecting appeals is considered a rule of public law, as it is directly related to the exercise of the constitutional guarantee of adversarial procedure and of the opportunity to be heard, which cannot be changed by the judge. The judge can only extend – not reduce – secondary terms of the procedure, such as the presentation of documents, the indication of the list of witnesses and the statements on documents, among others (Article 139(VI) of the CPC).

For cases that admit resolution by the parties themselves, the CPC allows the parties to stipulate changes to the procedural timelines to adjust them to the specificities of the case and to agree on the procedural burdens, powers, rights and duties before or during the case (Article 190 of the CPC). In this case, the judge, at their initiative or at the request of the opposing party, controls the validity of such agreements, refusing their application only in cases of nullity, abusive insertion in an adhesion contract or where any party is in a manifest situation of vulnerability (Article 190(1) of the CPC). The scheduling was an innovation of the CPC/2015, not allowed in the CPC/73.

It is also possible for the parties, together with the judge, to set a calendar for the practice of procedural acts, when applicable (Article 191 of the CPC). Such a calendar is binding upon the parties and the judge, provided that the terms therein are only modified in exceptional cases and if duly justified (Article 191(1) of the CPC). The parties need not be notified to perform a procedural act or to hold a hearing when the dates have been designated in such a calendar (Article 191(2) of the CPC).

In the absence of any specific provision by the parties, by mutual agreement and considered valid by the judge, it is common (though not a rule) for many judges, after the complaint and answer, to grant a common term for the parties to reiterate their requests for evidence, specifying and justifying their need in light of the theories presented during the course of the case. Although a common practice, this expectation should not replace the 'parties' precaution of submitting, in the complaint or answer, an express request for evidence. This is because only an express request for evidence may be the basis for a possible appeal seeking the annulment of a trial due to the denial of the opportunity to be heard.

With respect to requests for the production of evidence, or in the absence thereof, the judge proceeds with the pre-trial order, assigning the burden of proof according to the general rule in Article 373 of the CPC, considering, occasionally, the terms of the procedural agreement entered into between the parties (Article 190 of the CPC). It is also possible for the burden of proof to be reallocated in the course of the case upon a reasoned decision of the judge (Article 373(1) of the CPC). Note that this reallocation can occur either upon request or by a decision of the judge at their own initiative. It is worth noting that the special industrial property legislation, the LPI, does not have specific standards for proof, so the general rule of Article 373 of the CPC applies.

The pre-trial order and organization of a case occur by means of the judge's decision. This decision marks the end of the so-called pleading stage. This means that, as of this decision, it is no longer possible to change the facts and the requests presented. It is in this decision that the judge determines the removal of pending procedural issues, determining their correction when applicable, and establishes the factual and legal disputed points that will be taken to trial. The requests for evidence are also analyzed in this decision.

Exceptionally, a judge may analyze the requests for evidence separately when the judge understands that several pieces of requested evidence are related with respect to priority. That is, if the production of a piece of evidence may fully define the outcome of the case, the judge may order the production of this evidence and, only after it is produced, verify if it is still necessary to produce evidence related to subsidiary issues.

In the Brazilian system, it is exclusively incumbent upon the judge to define which points are accepted as the subject matter of the evidentiary stage. There is no legal rule or case law that limits the points to be heard. In practice, judges tend to establish only factual points because, in theory, it is not necessary for the judge to follow only the legal theories presented by the parties. Exceptionally, however, judges may choose to define disputed legal points when they believe that they are dealing with matters complex or unusual in the daily life of the court. It is important to point out that the judge's nonacceptance of certain points for the analysis of the dispute may be subject to objection by the parties.

Exceptionally, the presentation of the disputed points may be performed in a hearing specially designated for this purpose. This possibility is provided for in law (Article 357(3) of the CPC). However, such a hearing is not a necessary step in the procedure, and even upon request, the judge may refuse to hold one. Conversely, considering the complexity of some cases involving patents, such hearings may be an important tool for rationalizing the case, provided that the interested party does not disregard this possibility. This is because, at the specially designated hearing, it is possible to present the judicial treatment and the possibility of acts to be performed at the hearing: the presentation of a report, approval of a procedural agreement, mutual definition of the disputed points, definition of the limits of expert analysis, presentation of video material and so on.

3.6.4 Summary proceedings

Lawsuits involving patents are all governed by the ordinary procedure; summary proceedings do not apply to such matters (Article 318 of the CPC). If a judgment can be rendered solely based on documentary evidence presented by the parties in the complaint or defense, then it is possible for the judge to render such a decision pursuant to the case record at the moment, without the need for the production of additional evidence.

3.6.5 Evidence

3.6.5.1 Expert evidence

A major challenge to be faced by cases involving patent law is the production of expert evidence because, as a rule, they are complex and require professionals with specialized knowledge. It is necessary to note that, although expert evidence is important – because it is a technical opinion that contributes to the assessment of a potential infringement of patent law – it does not bind the judge. This is because the principle in Brazilian law is that a judge has exclusive jurisdiction to apply the law after examining the facts alleged and the evidence produced.

As a rule, the expert is appointed by the judge (Article 465 of the CPC). Nevertheless, it is possible for parties to present, by mutual agreement, another expert they wish to analyze the case. In addition to the official expert, parties are entitled to appoint technical assistants, who will be allowed to follow up on the steps taken by the expert. In case of a complex expert analysis that covers more than one area of specialized knowledge, the judge may appoint more than one expert, and the party may appoint more than one technical assistant (Article 475 of the CPC). Experts must be registered with each court's system.

Expert evidence comprises an examination, inspection or evaluation but is rejected by the judge if the evidence of the fact does not depend on the special knowledge of a technician, if it is unnecessary in view of other evidence produced, or if verification of the evidence is impossible.

The expert must ensure that the technical assistants of the parties have access to and follow up on the measures and examinations that the expert carries out, provided that the assistants are previously notified of the acts. The parties will be notified of the date and place designated by the judge or indicated by the expert to start the production of evidence.

The expert may be replaced if they lack technical or scientific knowledge or if, for no legitimate reason, they fail to comply with the assignment within the term they were granted. The expert and the technical assistants must deliver the report and opinions, respectively, within a period set by the judge.

After the expert is appointed, the parties must present their questions to the expert. These items are answered by the expert together with the disputed points established by the judge in the pre-trial order. This is the moment when the party must go deep in attributing the technical details about the kind of patent infringement.

Parties may also, within 15 days from the notice of the order appointing the expert, argue for the refusal of the expert due to a conflict of interest or disqualification and submit questions. They may present additional questions during the measure, which may be answered by the expert in advance or at the trial hearing. The judge has a duty to dismiss impertinent questions and put forward questions that the judge deems necessary to clarify the case (Article 470 of the CPC).

There is no legal limitation to the number of questions; however, the opposing party may object to questions that are not covered by the disputed points established in the pre-trial order or that go beyond the limits of the expert evidence also defined by the judge. Since the judge may divide the production of evidence, it is possible for questions related to the part postponed to a subsequent examination to be rejected, without prejudice to resubmission, if a new expert examination is granted on that part of the evidence.

The expert is prohibited from exceeding the limits of their designation and from issuing personal opinions that exceed the technical or scientific examination of the subject matter of the expert analysis. Their report must contain the following:

- I – the exposition of the subject matter of the expert analysis;
- II – the technical or scientific analysis carried out by the expert;
- III– the indication of the method used, clarifying it and demonstrating that it is predominantly accepted by specialists in the field of knowledge from which it originated; [and]
- IV– the conclusive answer to all the questions presented by the judge, the parties, and the Public Prosecutor's Office. (Article 473 of the CPC)

The expert must file a report in court within the term set by the judge and at least 20 days before the trial hearing. The parties can be summoned, if they wish, to express their opinion on the expert's report within a common term of 15 days, provided that the technical assistant of each party may, within the same term, present their respective opinions.

The expert of the court has the duty to clarify, within 15 days, any point on which there is disagreement or doubt by either party, by the judge, by the Public Prosecutor's Office or in the opinion of the technical assistant of a party. If further clarification is still necessary, a party can request the judge to summon the expert or technical assistant to attend the trial hearing, making, at that moment, the questions in the form of requirements. If a matter is not sufficiently clarified, the judge will determine, at their own initiative or at the request of a party, the carrying out of new expert analysis.

Finally, the Brazilian system also admits a simplified model of technical evidence consisting of the presentation of an expert opinion. In this kind of evidence, the expert does not focus on a specific factual dispute. Instead, the purpose is only to solve technical doubts – based on the state of the art and on specialized literature – that will help the judge understand and decide the case. As it is a simplified model, it can be used only in specific cases, at the judge's discretion, enabling cost reduction.

3.6.5.2 Testimonial evidence

The convenience of producing testimonial evidence is analyzed by the judge at the moment of the pre-trial order, assigning procedural burdens. As a rule, it is incumbent upon the parties to request the production of testimonial evidence and justify its need. It is possible, however, that even without a request by the parties, the judge determines at their own initiative that it is necessary to carry it out.

A list of witnesses is to be presented at least prior to the trial hearing. Procedural legislation provides for limits on the maximum number of witnesses allowed (Articles 357 (6)–(7), 450–463 of the CPC).

Questions are asked by the parties directly to the witness, starting with the party that called the witness. The judge will disallow questions that may induce the answer, that are not related to the matters of fact of the subject matter of the evidentiary stage, or that imply a repetition of another question already answered (Article 459 of the CPC). The judge may question the witness either before or after the inquiry made by the parties (Article 459(1) of the CPC).

3.6.6 Confidentiality

Intellectual property cases are, in principle, public. The interested party is responsible for requesting the granting of confidentiality in the case, which is at the discretion of the judge, who bases their decision on the provisions of Article 189 of the CPC, according to which

[p]rocedural acts are public, however, the following cases are processed closed to the public:

I – when the public or social interest so requires;

II – if the case concerns marriage, separation, divorce, steady union, filiation, support, and custody of children and adolescents;

III – cases containing data protected by the constitutional right to privacy; [and]

IV – cases that concern arbitration, including on compliance with the arbitration clause, provided that the confidentiality stipulated in the arbitration is evidenced before the court.

Paragraph 1. The right to consult the case record that is being processed closed to the public and to request certificates of their acts is restricted to the parties and their attorneys-in-fact.

Paragraph 2. The third party who demonstrates a legal interest may request from the judge a certificate of the judgment, as well as of the inventory and sharing resulting from a divorce or separation.

A request for closing the proceedings to the public must be accompanied by the grounds that justify its granting. The decision that considers this request is subject to an interlocutory appeal.

During search and seizure in a crime against a process patent, the court officer will be accompanied by an expert, who preliminarily verifies the existence of the illicit act, provided that the judge may order the seizure of products obtained by the infringing party by means of the patented process.

Article 206 of the LPI provides that, in the event of disclosure in court – for the defense of the interests of any party – of information that is characterized as confidential (whether industrial or commercial secrets), the judge must determine that the case proceeds closed to the public. In this situation, the use of such information by the other party for other purposes is also prohibited.

3.6.7 Alternative dispute resolution

Although the ordinary procedure provides for a conciliation or mediation hearing soon after the filing of the complaint (Article 334 of the CPC), a judge may adopt the use of alternative methods of conciliation at any time (Article 3 of the CPC). It is even possible to hold a conciliation phase before the procedure at the parties' discretion. The agreement entered into, approved by a judge, has the effect of an instrument enforceable in court.

Mediation is governed by Law No. 13,140, of June 26, 2015,⁷⁸ and consists of a technical activity exercised by an impartial third party without decision-making power who assists and encourages the parties to identify or develop mutually agreed solutions to the dispute. Mediation may be used in conflicts that involve waivable or unavailable rights that admit settlement.

The mediator is appointed by the court or chosen by the parties. A competent person, having graduated at least two years prior from a higher education course of an institution recognized by the Ministry of Education and who has been trained in a mediation school or institution recognized by the Brazilian National School for the Graduation and Development of Judges (Escola Nacional de Formação e Aperfeiçoamento de Magistrados) or by the courts, may act as a mediator, subject to the minimum requirements established by the National Council of Justice together with the Ministry of Justice (Article 11 of Law No. 13,140/15). The courts create and maintain updated registers of mediators who are qualified and authorized to act in court mediation (Article 12 of Law No. 13,140/15). The compensation paid to court mediators is set by the courts and borne by the parties (Article 13 of Law No. 13,140/15).

The law ensures the confidentiality of the procedure (Article 14 of Law No. 13,140/15). Additionally,

[a]ny and all information relating to the mediation procedure will be confidential with respect to third parties and may not be disclosed even in arbitration or court proceedings, unless the parties expressly decide otherwise or when its disclosure is required by law or necessary for compliance with the agreement reached by mediation.

Paragraph 1. The duty of confidentiality applies to the mediator, the parties, their representatives, lawyers, technical advisors and other persons of their confidence who have, directly or indirectly, participated in the mediation procedure, reaching:

I – statement, opinion, suggestion, promise, or proposal made by one party to the other in the search for an understanding on the conflict;

II – recognition of a fact by any of the parties during the mediation procedure;

III – statement of acceptance of a proposal for agreement presented by the mediator; [or]

IV – document prepared solely for the purposes of the mediation procedure.

Paragraph 2. The evidence presented in disagreement with these provisions will not be admitted in an arbitral or judicial proceedings. (Article 30 of Law No. 13,140/15)

The mediation procedure is closed with the drawing up of its final instrument, when an agreement is entered into or when new efforts to reach a mutual agreement are not justified, either by declaration of the mediator or by a statement of any of the parties (Article 20 of Law No. 13,140/15). The final instrument of mediation, in the event of an agreement, constitutes an instrument enforceable out of court and, when approved in court, becomes an instrument enforceable in court (Article 20(1) of Law No. 13,140/15).

3.7 Civil remedies

3.7.1 Injunction

In Brazilian law, in order to avoid urgent and potentially harmful situations (in many such cases, the main action cannot be filed), injunctive reliefs, regulated by Articles 300–311 of the CPC, are available. In the LPI, this is specifically provided for in Article 209(1), which authorizes the granting of an injunctive relief even before the service of process to the opposing party.

Injunctive relief is granted when there is evidence of the likelihood of the right and the danger of damage or risk to the useful outcome of the case (Article 300 of the CPC). For the granting of interlocutory relief, the judge may, depending on the case, require a security interest or personal guarantee for compensating the damage that the other party may suffer. The security interest or personal guarantee may be waived if the economically disadvantaged party is unable to offer it (Article 300(1) of the CPC). Interlocutory reliefs may be granted before the final decision or after prior justification (Article 300(2) of the CPC). They may seek to anticipate the content of the final

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claim, but, in this case, they can only be granted when the decision's effects are reversible (Article 300(3) of the CPC).

Interlocutory relief may be provisional, in which case it intends to ensure the useful outcome of the case. The interlocutory relief can be effected by means of an attachment, sequestration, listing of property, registration of protest against the disposition of property, or any other suitable measure to ensure the right (Article 301 of the CPC).

Regardless of the redress for procedural damage, a party is liable for the damage that the effectiveness of the interlocutory relief causes to the other party if:

- I – the judgment is unfavorable to them;
- II – the party fails to provide the necessary means for the service of process to defendant within 5 (five) days once the interlocutory relief has been obtained in advance;
- III – the effectiveness of the measure in any legal case is ceased; [or]
- IV – the judge accepts the claim of preemption or limitation of plaintiff's claim. (Article 302 of the CPC)

The interlocutory relief may be simultaneous to the filing of the action. This is an interlocutory relief requested in advance. In this case, the complaint may be limited to the request for an interlocutory relief and to the indication of the final injunction request, showing the dispute, the right being pursued, and the danger of damage or risk to the useful result of the case (Article 303 of the CPC). If an interlocutory relief is granted:

- I – the plaintiff must amend the complaint, complementing the arguments, attaching new documents, and confirming the final injunction request within 15 (fifteen) days or a longer period set by the judge [under the penalty of termination of the case without prejudice (Article 303(2) of the CPC)];
- II – the defendant will be served process and notified to attend the conciliation or mediation hearing [if the judge so determines]; [and]
- III – if the dispute is not resolved by the parties themselves, the term for answer will [begin]. (Article 303 of the CPC)

The interlocutory relief requested in advance becomes final if the decision granting it is not appealed (Article 304 of the CPC). In this case, the case is terminated (Article 304(1) of the CPC). Either party may request the unfiled of the case record in which this measure was granted, in order to provide evidence to the complaint of the action (Article 304(4) of the CPC).

The right to review, change or invalidate an interlocutory relief requested in advance that was not questioned and that was terminated and filed terminates after two years, counted from the moment the decision terminating the case is disclosed (Article 304(5) of the CPC). The decision granting the relief is not *res judicata*. However, the stability of the respective effects is only removed by a decision that reviews, changes or invalidates it, rendered in an action brought by one of the parties (Article 304(6) of the CPC).

A provisional injunction may also be requested in advance, indicating the dispute and its grounds, the right being pursued, as well as the possible damage or risk to the useful outcome of the case (Article 305 of the CPC). In this case, the defendant is served process and given five days to answer the request and indicate the evidence they intend to produce (Article 306 of the CPC). If the request is not answered, the facts alleged by the plaintiff are considered accepted by the defendant as having truly occurred, in which case the judge will make a decision on the provisional injunction within five days (Article 307 of the CPC).

Once the provisional injunction has been effected, the main request must be made by the plaintiff within 30 days. In this case, it is presented in the same case record as that in which the request for the provisional injunction was made, regardless of the advance of new procedural costs (Article 308 of the CPC). However, the provisional injunction granted in advance ceases to be effective if:

- I – the plaintiff does not make the main request within the legal term;
- II – the injunction is not effected within 30 (thirty) days; [or]
- III – the judge dismisses the main request made by the plaintiff or dismisses the case without prejudice. (Article 309 of the CPC)

The rejection of the request for provisional injunction does not prevent the party requesting it from making the main request, nor does it influence the judgment of the latter, unless the reason for the dismissal is the recognition of preemption or limitation (Article 310 of the CPC).

Finally, there is also the possibility of granting interlocutory relief based on evidence. This is governed by Article 311 of the CPC. Such relief is granted, regardless of the demonstration of the danger of damage or risk to the useful outcome of the case, when:

- I – there is an abuse of the right of defense or obvious dilatory intentions by the party;
 - II – the allegations can be actually evidenced only through documents and there is a theory confirmed in the trial of repeated cases or in a binding precedent;
 - III – it is a claim for repossession based on adequate documentary evidence of the deposit contract, in which case the order of delivery of the object under custody will be decreed, under penalty of fine; [or]
 - IV – the complaint is accompanied by sufficient documentary evidence of the facts constituting the plaintiff's right to which the defendant does not present opposing evidence capable of generating reasonable doubt.
- Sole Paragraph. In the cases indicated in items II and III, the judge may decide in advance. (Article 311 of the CPC)

Since the grant of interlocutory relief – whether of a provisional or anticipatory nature – requires evidence of the plausibility of the alleged facts, the judge may anticipate the production of expert evidence if the judge fears that the grant of the request may result in the risk of irreversible damage.⁷⁹

3.7.2 Damages

The right to damages refers to the right to compensation for the improper exploitation of a patent's subject matter, including exploitation that occurred between the date of publication of the patent application and that of the grant of the patent. The patent holder whose right has been violated has the right to obtain compensation for the undue exploitation of their object (Article 44 of the LPI). If the infringer obtained, by any means, knowledge of the content of the application filed, prior to its publication, the period of undue exploitation is counted, for the purpose of compensation, from the date the exploitation began (Article 44(1) of the LPI). If the subject matter of the patent application refers to biological material, deposited according to Article 24(1) of the LPI, the right to compensation will be granted only when the biological material has become accessible to the public (Article 44(2) of the LPI). The right to obtain compensation for undue exploitation is limited to the content of the patent's subject matter according to Article 41, even in relation to the period prior to the granting of the patent (Article 44(3) of the LPI).

An injured party may file civil actions that they consider applicable pursuant to the CPC. Damages are determined by the benefits that the injured party would have received if the infringement had not taken place (Article 208 of the LPI). Article 225 of the LPI allows five years for the action for damages in view of the loss to the industrial property right.

The injured party also has a right to compensation for losses and damage caused by acts of infringement of industrial property rights and acts of unfair competition not provided for in the LPI – acts that damage the reputation or business of others or that create confusion among commercial, industrial, or service establishments, or among products and services being traded (Article 209 of the LPI).

Jurists have indicated the main challenges to ascertaining patent infringements:⁸⁰

- a disregard for limitations in independent claims, in which the infringement is determined without observing the essential characteristics of the product or process under consideration and the existence of complete coincidence with the characteristics of the infringing product or process;

⁷⁹ See, e.g., Tribunal de Justiça do Estado de São Paulo (TJSP) (Court of Appeals of the State of São Paulo), Agravo de Instrumento (AI) (Interlocutory Appeal) No. 2200797-60.2020.8.26.0000, Rapporteur JB Franco de Godoi, May 26, 2021.

⁸⁰ Ahlert and Camara Junior, *Patentes: Proteção na Lei de Propriedade Industrial*, at 218.

- when analyzing the basic inventive idea, or the general principle upon which the invention is based, not considering how the invention is claimed – “it is not the idea underlying the invention that is subject to protection, but the way the inventor materialized this idea, as claimed in the patent”;⁸¹
- product-to-product comparison – “the existence of coincidence between these products is utterly irrelevant, since the holder’s product may correspond to only one of the possible modalities of invention as claimed or even not correspond at all”;⁸²
- the infringement of dependent claims – “[t]he distortion here lies in trying to assign dependent claims the same function of an independent claim by completely disregarding the limitations imposed by dependence”;⁸³
- the protection of the inventive function – “[a]nother example of undue extrapolation of the scope of a claim lies in the notion that the patent protects the function performed by the invention, regardless of the restrictions imposed by the elements of the claim”;⁸⁴
- the dependence on patents – “there is a common misconception that obtaining a patent grants its holder the unconditional right to exploit the patented invention. Of course, the fundamental right granted by the patent is not a right provided for in law, but rather the right to exclude third parties from using its subject matter”;⁸⁵ and
- the characterizing part of the claims – “[a]nother common error is believing that, as the characterizing part of the claims defines the characteristics of the invention that are new to the state of the art, it is precisely this characterizing part that determines the protection granted by the patent. [...] We reiterate that the scope of a claim is determined by the sum of the characteristics defined before and after the expression ‘characterized by.’”⁸⁶

3.7.2.1 Compensatory damages

Articles 208–209 of the LPI provide for the possibility of full compensation for damage suffered, including property damage and loss of profits. Additionally, Article 207 provides that the injured party may file any civil action they deem necessary. Damages, however, are not restricted to the cases of Articles 208–209 because the LPI assures a patent holder all the rights arising from civil legislation. Thus, Brazilian jurists and case law also recognize the possibility of claiming damages for pain and suffering. Pain and suffering are *in re ipsa*, and their compensation must reflect “both the punitive function in relation to the agent and the compensatory function in relation to the victim.”⁸⁷ Therefore, according to Brazilian law, potential damages correspond to what was lost (i.e., emerging damage) and what was reasonably no longer gained (i.e., loss of profits), in addition to the possibility of compensation for pain and suffering, which are punitive in nature.

Article 208 of the LPI provides that the amount of damages is determined by the benefits that the injured party would have received had the infringement not taken place. Article 210 of the LPI, by contrast, stipulates that the loss of profits is determined by one of the following criteria – whichever is most favorable to the injured party:

- I – the benefits that the injured party would have received had violation not taken place; or
- II – the benefits that the infringing party received; or
- III – the compensation that the infringing party would have paid to the holder of the right for the grant of a license legally allowing them to exploit the subject matter.

These two provisions must be interpreted jointly, and the difficulty of proof determines which of the Article 210 criteria will be chosen by the winning patent holder in the action, considering what is most favorable given the factual circumstances. Damages may be defined in the settlement of the judgment⁸⁸ or indicated in the complaint itself at the discretion of the injured party.⁸⁹

81 Ahlert and Camara Junior, *Patentes: Proteção na Lei de Propriedade Industrial*, at 220.

82 Ahlert and Camara Junior, *Patentes: Proteção na Lei de Propriedade Industrial*, at 220.

83 Ahlert and Camara Junior, *Patentes: Proteção na Lei de Propriedade Industrial*, at 221.

84 Ahlert and Camara Junior, *Patentes: Proteção na Lei de Propriedade Industrial*, at 222.

85 Ahlert and Camara Junior, *Patentes: Proteção na Lei de Propriedade Industrial*, at 223.

86 Ahlert and Camara Junior, *Patentes: Proteção na Lei de Propriedade Industrial*, at 223.

87 TJSP (Court of Appeals of the State of São Paulo), *Apelação Cível (AC) (Civil Appeal)* No. 1004417-66.2018.8.26.0157, Rapporteur Azuma Nishi, May 31, 2021.

88 STJ, REsp. No. 646,911/SP, Rapporteur Carlos Alberto Menezes Direito, June 2, 2005, *Diário da Justiça (DJ) (Court Register)*, Aug. 22, 2005, 266, 266 (“the recognition of forgery gives rise to award of damages determined in the settlement of the judgment”).

89 Tribunal de Justiça do Estado do Rio de Janeiro (TJRJ) (Court of Appeals of the State of Rio de Janeiro), *AI (Interlocutory Appeal)* No. 0045503-59.2011.8.19.0000, Rapporteur Edson Aguiar de Vasconcelos, Oct. 26, 2011.

3.7.2.2 Attorneys' fees

The party in a lawsuit is also subject to paying loss-of-suit fees, which correspond to the costs (fees owed to the state for filing actions) and procedural expenses (including expert fees) that both parties have incurred, in addition to paying the opposing party's attorneys' fees.

Attorneys' fees are regulated by Article 85 of the CPC and are set by the judge, in the decision, at 10 percent to 20 percent of the decision amount, the economic benefit obtained or – if this cannot be measured – the adjusted amount of the case, considering the professional's degree of diligence, the place where the service was provided, the nature and importance of the case, and the work carried out (Article 85(2) of the CPC).

3.7.3 Other remedies

Articles 201–204 of the LPI specify provisional measures of search and seizure that may be requested without prejudice to any additional requests for the granting of interlocutory reliefs in the situations previously outlined. Article 201 of the LPI regulates search and seizure procedures in crimes against process invention patents. In these cases, the court officer is accompanied by an expert, who preliminarily verifies the existence of the illicit act. The judge may order the seizure of products obtained by the infringing party through the use of the patented process. This procedure may also be requested in civil actions.

If the search and seizure procedure has been carried out and the party who requested it did so in bad faith due to rivalry, mere whim or gross error, they are liable for damages (Article 204 of the LPI).

In case of industrial or commercial establishments legally organized and publicly functioning, preliminary procedures ordered by the judge are limited to the inspection and seizure of products. Such establishments' lawfully exercised activities cannot be interrupted (Article 203 of the LPI).

3.8 Enforcement of judgments

There is no specific provision in the LPI regarding the enforcement of judgment of cases involving patents. However, as we will see, appeals filed against decisions rendered by judges that remit the analysis of the matter to the court have an effect of *supersedeas*: they suspend the effects of the decision, which can only produce effects when no further appeal is possible.

Provisional compliance with a decision is regulated by Articles 513–522 of the CPC, whereas final compliance with a decision, only occurring after the final and unappealable decision, is regulated by Articles 523–538 of the CPC.

3.8.1 Provisional compliance with the decision

It is possible for a judge to determine a provisional decision due to an urgent situation, either during the case or in the judgment itself (Articles 300–302 of the CPC). In this case, the part of the decision that grants this provisional decision or confirms its effects continues to produce effects, though provisionally.

A judgment debtor is notified to comply with the decision through the Court Register (Diário da Justiça) by the attorney appointed in the case record; by letter with an acknowledgment of receipt, when represented by the Public Defender's Office or when there is no attorney appointed in the case record; or by notice, when, having been served process by notice, the judgment debtor was in default during the cognizance phase (Article 513(2) of the CPC).

If the request for compliance with the decision is filed one year after the decision has become final and unappealable, notification is served to the debtor by means of a letter with an acknowledgment of receipt, sent to the address stated in the case record (Article 513(4) of the CPC). Compliance with the decision is carried out before the lower court.

Article 515 of the CPC lists the instruments that are enforceable in court, including decisions rendered in civil proceedings that recognize the enforceability of an obligation to pay a sum of money, to do something, not to do something or to deliver something (Article 515(I) of the CPC).

A final and unappealable decision may be protested after the term for voluntary payment (Article 517 of the CPC). Provisions regarding compliance with the decision, either provisional or final compliance, and the settlement, as applicable, apply to decisions that grant interlocutory relief (Article 519 of the CPC).

Provisional compliance with the decision objected to by an appeal that does not have the effect of *supersedeas* is performed in the same way as the final compliance, having the following particularities:

- I – it is incumbent upon the judgment creditor, who undertakes, if the decision is changed, to repair the damage that the judgment debtor has suffered;
- II – it becomes ineffective upon the occurrence of a decision that modifies or annuls the decision subject matter of the execution, the parties being restored to the previous status and any losses being settled in the same case record;
- III – if the decision subject matter of the provisional compliance is modified or annulled only in part, the execution will be ineffective only regarding this part; [and]
- IV – the withdrawal of a cash deposit and the performance of acts involving the transfer of possession or disposal of property or other real property rights, or which may result in serious damage to the judgment debtor, are subject to sufficient and suitable bond, to be arbitrated in advance by the judge and posted in the case record itself. (Article 520 of the CPC)

The bond referred to in Article 520(IV) of the CPC may be waived:

- I – if the credit is of a support nature, regardless of its origin;
 - II – if the creditor demonstrates need;
 - III – if an interlocutory appeal under Article 1,042 [of the CPC] is pending;
 - IV – the decision to be provisionally enforced is in line with a precedent of the case law of the Federal Supreme Court or the Superior Court of Justice or in accordance with an appellate decision rendered in the judgment of repeated cases.
- Sole Paragraph. The requirement for bond shall be maintained when the dismissal may result in a manifest risk of serious damage of difficult or uncertain redress. (Article 521 of the CPC)

Regarding provisional compliance with a decision, the judgment debtor may file an objection, if they so desire, as in the final compliance with the decision, a fine and the fees provided for in the final compliance with the decision being also due for the payment of a certain amount. The provisions mentioned above apply to the provisional compliance with a decision that recognizes the obligation to do, not to do or to give something, as applicable.

Where the judgment debtor appears on time and deposits the amount to be exempted from the fine, this act is not deemed incompatible with their filing of an appeal (Article 520(3) of the CPC).

3.8.2 Final compliance with the decision

The final compliance with a decision is regulated by Articles 523–538 of the CPC. For a decision of a certain amount or of an amount that has already been defined in the settlement, and for a decision on an undisputed part, the final compliance with the decision is made upon request by the judgment creditor, the judgment debtor being notified to pay the debt within 15 days, plus costs, if any (Article 523 of the CPC).

If the voluntary payment is not made within the term established by law, including costs, the debt is increased by a 10 percent fine and, additionally, a 10 percent attorney's fee (Article 523(1) of the CPC). If the payment is partial, the fine and fees are only levied on the remainder (Article 523(2) of the CPC). Additionally, if the voluntary payment is not made in time, a writ of execution and assessment will be issued, followed by expropriation proceedings (Article 523(3) of the CPC), after which a term of 15 days begins for the judgment debtor to file an objection in the case record, regardless of the levy of execution or new notification (Article 525 of the CPC). In this objection, the judgment debtor may claim the:

- I – lack of or nullity in the service of process if, in the cognizance phase, the case was processed in default;

- II – lack of standing of a party;
- III – unenforceability of the instrument or unenforceability of the obligation;
- IV – incorrect levy of execution or erroneous assessment;
- V – excess in the execution or undue accumulation of executions, in which case they should indicate the amount they understand to be correct, under penalty of having their objection immediately rejected;
- VI – absolute or relative lack of jurisdiction of the enforcement court; [or]
- VII – any modifying or extinguishing cause of the obligation, such as payment, novation, offsetting, transaction, or limitation, as long as after the decision (Article 525(1) of the CPC).

The presentation of an objection does not prevent the practice of execution acts, including expropriation acts, and the judge may, at the judgment debtor's request and provided that the court is secured by a sufficient levy of execution, bond or deposit, grant a stay of execution if the grounds thereof are relevant and if the execution proceedings are manifestly likely to cause the judgment debtor serious damage that would be difficult to redress or the repair of which would be uncertain (Article 525(6) of the CPC). When the effect of *supersedeas* granted to the objection concerns only part of the subject matter of the execution, the execution continues for the remaining part (Article 525(8) of the CPC).

The granting of effects of *supersedeas* to an objection filed by one of the judgment debtors does not suspend enforcement against those who did not make an objection if the respective grounds exclusively concern the objecting party (Article 525(9) of the CPC). Even if the effect of *supersedeas* is granted to the objection, it is lawful for the judgment creditor to request that the execution proceeds, by offering and posting, in the case record itself, a sufficient and suitable bond to be arbitrated by the judge (Article 525(10) of the CPC).

Issues relating to a fact occurring after the expiration of the term for filing an objection, as well as those relating to the validity and suitability of the levy of execution, assessment or subsequent enforcement acts, may be argued by a simple complaint. The judgment debtor, in either case, has 15 days – as of the proven knowledge of the fact or of the notification of the act – to make this argument (Article 525(11) of the CPC).

The defendant may, before being notified to comply with the decision, appear before the court and offer to pay the amount they consider due, submitting a detailed statement of the calculation (Article 526 of the CPC). However, the plaintiff may object the amount deposited, without prejudice to the withdrawal of the amount they consider undisputed (Article 526(1) of the CPC). If there is no such objection, the judge will declare the obligation satisfied and extinguish the case (Article 526(3) of the CPC).

In the enforcement of a decision that recognizes the enforceability of an obligation to do or not to do, the judge may, at their own initiative or upon request, and to enforce the specific injunction or obtain an injunction for an equivalent practical result, determine the necessary measures satisfactory to the judgment creditor (Article 536 of the CPC). To enforce the specific injunction of an obligation to do or not to do, the judge may order, among other measures, the imposition of a fine, search and seizure, removal of people and things, destruction of works and the prevention of harmful activities and, if necessary, request the assistance of the police (Article 536(1) of the CPC). The judgment debtor incurs bad faith litigation penalties if they unjustifiably fail to comply with the court order, without prejudice to being held liable for the crime of disobedience (Article 536(3) of the CPC).

Regarding the enforcement of decisions concerning the obligation to do or not to do something, the fine does not depend on the request of the party and may be applied in the cognizance phase, in the provisional injunction or in the decision, as well as in the enforcement phase, provided that it is sufficient and compatible with the obligation and that a reasonable term for compliance is established (Article 537 of the CPC). The amount of the fine is due to the judgment creditor (Article 537(2) of the CPC). Additionally, the judge may, at their own initiative or upon request, modify the amount or periodicity of the fine or exclude it if they find that it has become insufficient or excessive or that the debtor has demonstrated supervening partial compliance with the obligation or cause for noncompliance (Article 537(1) of the CPC).

The decision that sets the fine may be provisionally enforced, provided that the fine is deposited in court. It is possible to withdraw the amount after the final and unappealable decision in favor of the party (Article 537(3) of the CPC). The fine is due from the day the noncompliance with the decision is verified and is applied while the decision that imposed the fine is not complied with (Article 537(4) of the CPC).

In a case of noncompliance with the obligation to deliver something within the term established in the decision, a search warrant or warrant for vesting of possession will be issued in favor of the creditor, depending on whether the property is personal or a real estate property (Article 538 of the CPC).

3.9 Appellate review

In a very synthetic way, the cognizance phase is composed of the pleading, evidentiary and judgment phases. Consequently, the limits of a judge's cognizance, whether with regard to matters of fact or matters of law, are defined during the pleading phase, in which the parties have the burden of discharging their procedural burden, clearly indicating all their theories and the evidence in their favor, under penalty of procedural preclusion. That is, if a party does not discharge its procedural burden of exposing all matters of facts in their favor with regard to the conflict in judgment, their opportunity to carry out any questioning will be precluded.

The burden is particularly serious for the defendant, who has the procedural burden of objecting all factual and legal arguments presented by the plaintiff, under penalty of being considered in default. Conversely, as already discussed, if the plaintiff does not adequately make their claim, the judge's cognizance will be limited to what was requested since it cannot go beyond what was requested (Article 141 of the CPC). Therefore, after the disputed points of fact and law are defined by the judge in the pre-trial order, the limits of the judge's cognizance are also defined and bind the judgment. This decision can be appealed by means of an interlocutory appeal to a court of appeals.

After the evidentiary phase, the parties present final arguments, in which they make final considerations on the evidence produced, comparing them with their arguments, before allowing the judge to decide on the action. The judge's final judgment, by which the action ends, may be with or without prejudice – that is, with or without consideration of the disputed matter.

According to Article 487 of the CPC, there is a resolution on the merits if the judge:

- I – accepts or rejects the request made in the action or counterclaim;
- II – decides, at the judge's own initiative or upon request, on the occurrence of preemption or limitation; [or]
- III – approves:
 - a) the acknowledgement of the merits of the request made in the action or in the counterclaim;
 - b) the transaction; [or]
 - c) the waiver of the request made in the action or counterclaim.

The following situations may also result in the termination of a case by means of a decision:

- I – dismissal of the complaint;
- II – the lawsuit is stayed for more than 1 (one) year due to negligence of the parties;
- III – by failing to promote the acts and diligences incumbent upon them, the plaintiff abandons the case for more than 30 (thirty) days;
- IV – the absence of assumptions for the establishment and valid and regular development of the procedure;
- V – recognizing the existence of preemption, *lis pendens*, or *res judicata*;
- VI – verifying the lack of standing or procedural interest;
- VII – accepting the allegation of the existence of an arbitration clause or when the arbitration court recognizes its jurisdiction;
- VIII – ratifying the withdrawal of the case;
- IX – in the event of the party's death, the lawsuit is deemed non-transferable by legal provision; and
- X – in the other cases provided for in [the CPC]. (Article 485 of the CPC)

During the course of a case, it is possible for the judge to render decisions necessary to ensure its progress, with or without a decision, known respectively as interlocutory decisions or orders. Against interlocutory decisions, it is possible to file certain appeals according to their nature. Orders cannot be appealed (Article 1,001 of the CPC). A party that expressly or tacitly accepts the decision cannot appeal it. Tacit acceptance is the practice, without any exception, of an act incompatible with the will to appeal (Article 1,000 of the CPC). The term for appeals is, as a rule, 15 days from the date of publication of the decision (Article 1,003 of the CPC), except for motions for clarification, for which it is five days, all counted in business days (Article 219 of the CPC).

At first, court decisions may be subject to motions for clarification, appeals that, as will be discussed, aim to clarify the decision on a certain point or to remedy an omission or contradiction (Articles 1,022–1,027 of the CPC). As a rule, such motions are not intended to modify the decision rendered, but, occasionally, depending on the clarification or omission remedied, it may result in a change in the understanding. Motions for clarification are directed to the court that rendered the disputed decision – that is, in this case, the appeal is to the trial court.

Article 994 of the CPC provides for appeals allowed under Brazilian law: appeal from final judgment, interlocutory appeal, internal interlocutory appeal, motion for clarification, ordinary appeal, appeal to the STJ, appeal to the STF, interlocutory appeal from an appeal to the STJ or to the STF, and appeal against a divergent decision. Appeals do not prevent the effectiveness of the decision unless otherwise provided for in law or in a court decision in this sense (Article 995 of the CPC).

At the trial court, in view of interlocutory decisions and partial decisions on the merits by the judge, it is possible to file an interlocutory appeal after the motion for clarification has been filed (or is not applicable) without extinguishing the action. In view of decisions definitively resolving the action, the judge closing or not the merits, (Article 1,009 of the CPC) it is possible to file an appeal from the final judgment after the motion for clarification has been filed (or is not applicable). Interlocutory appeals and appeals from final judgment are filed before the courts immediately higher than the trial courts – the courts of appeal (or higher courts).

Appeals may be filed by the losing party, by an aggrieved third party or by the Public Prosecutor's Office as a party or as a legal guardian. If filed by a third party, the third party must demonstrate that the decision on the legal relationship submitted to judicial review may affect the right that they claim to have or that they may discuss in court as a procedural substitute (Article 996 of the CPC).

If the plaintiff and defendant are defeated, an appeal filed by either of them may be joined by the other in case of an appeal from final judgment, an appeal to the STF or an appeal to the STF (Article 997(1) of the CPC). Such a cross-appeal is subordinated to the independent appeal, the same rules being applicable to it as to the admissibility requirements and trial in court (Article 997(2) of the CPC). Thus, a cross-appeal will not be heard if the main appeal is withdrawn or if it is considered inadmissible (Article 997(2)(III) of the CPC).

The appellant may, at any time, without the consent of the respondent, withdraw the appeal (Article 998 of the CPC), except if it involves a matter in which general repercussion has already been recognized and that is the subject matter of a trial of repeated appeals to the STF or to the STJ (Article 998(1) of the CPC). For the same reason, parties can, before or after trial, enter into an agreement and request its judicial ratification, thus overruling whatever may have been decided.

When filing an appeal, the appellant must evidence, when required by the relevant legislation, the payment of the appeal bond, including the remittance and return fees, under penalty of being dismissed (Article 1,007 of the CPC). Appeals filed by the Public Prosecutor's Office, the Federal Government, the federal district, the states, the municipalities or their respective autonomous agencies, or by those that enjoy legal exemption, are exempt from the payment of an appeal bond, including remittance and return fees (Article 1,007(1) of the CPC). Insufficient payment of the appeal bond, including the remittance and return fees, leads to dismissal if the appellant, notified by means of the attorney, does not make the payment within five days (Article 1,007(2) of the CPC). The payment of remittance and return fees is not required in electronic proceedings (Article 1,007(3) of the CPC).

If no appeal is filed within the term, the party's right to object the decision is precluded.

The decision rendered by the appeal court replaces the decision objected to with respect to the appealed part (Article 1,008 of the CPC). The competent court for the judgment of interlocutory appeals or appeals from final judgment may fully review the matter that was submitted to it – both the matters of fact and matters of law. The competent court for the judgment may even determine measures to the lower court if deemed necessary.

In view of the decisions rendered by the higher courts (i.e., appellate decisions), it is still possible to file a motion for clarification, addressed to the higher court itself, to clarify the decision or to remedy an omission, contradiction or ambiguity. Once such a motion for clarification is resolved, it is possible to file appeals to the STJ or to the STF against the appellate decision. In these cases, the matters that allow an appeal are more restricted, because they are exhaustively foreseen in the Federal Constitution, and it is not possible to rediscuss evidence.

3.9.1 Appeal from final judgment

An appeal from final judgment is an objection to decisions. Such appeals are regulated by Articles 1,009–1,014 of the CPC. These appeals must be filed by a petition addressed to the trial court, containing:

- I – the names and identification of the parties;
 - II – the description of the fact and of the right;
 - III – the reasons for the request for change or for declaration of nullity; [and]
 - IV – the request for a new decision.
- Paragraph 1. The appellee will be notified to file the appellee's brief within 15 (fifteen) days.
- Paragraph 2. If the appellee files a cross-appeal, the judge will notify the appellant to file the brief.
- Paragraph 3. [...] [t]he case will then be forwarded to the court [...], without any judgment of admissibility. (Article 1,010 of the CPC)

As a rule, such appeals have the effect of *supersedeas* (Article 1,012 of the CPC). However, effective immediately after publication is a decision that:

- I – approves land division or allotment;
- II – sentences the payment of support;
- III – dismisses the case without prejudice or dismisses the judgment debtor objections;
- IV – grants the request for arbitration;
- V – confirms, grants, or revokes provisional injunction;
- VI – decrees interdiction;
- VII – other hypothesis provided for in law. (Article 1,012(1) of the CPC)

For these cases, in which the decision produces an immediate effect, the interested party may file for provisional enforcement after the decision is published (Article 1,012(2) of the CPC). Additionally, the interested party may request the granting of the effect of *supersedeas*, provided that the interested party demonstrates the likelihood of the appeal being granted or, if the grounds are relevant, that there is the risk of serious damage or damage difficult to repair. This is done by a request addressed to:

- I – the court, in the period between the filing of the appeal from final judgment and its assignment, the rapporteur designated for its examination being prevented from judging it; [or]
 - II – the rapporteur, if the appeal from final judgment has already been assigned.
- (Article 1,012(3)–(4) of the CPC)

The appeal from final judgment returns the cognizance of the disputed matter to the higher court, which is able to appreciate and judge all the matters raised and discussed in the case, even if they have not been resolved, so long as they are related to the matter discussed in the appeal (Article 1,013 of the CPC).

The court, when reviewing an appeal, may:

- I – change the decision that dismissed the case without prejudice;

- II – decree the decision null and void, as it is not congruent with the limits of the request or cause of action;
- III – verify the omission in the examination of one of the requests, a case in which the court may judge it; [or]
- IV – decree the decision nullity due to lack of grounds. (Article 1,013(3) of the CPC)

When changing a decision that recognizes pre-emption or limitation, the court, if possible, judges the merits, examining the other matters, without determining the return of the case to the lower court (Article 1,013(4) of the CPC).

When the request or the defense has more than one ground, and the judge grants only one of them, the appeal from final judgment returns the cognizance of the others to the court (Article 1,013(2) of the CPC).

Matters of fact not presented in the lower court may be raised in the appeal from final judgment if the party proves that it failed to do so due to *force majeure* (Article 1,014 of the CPC).

3.9.2 Interlocutory appeal

An interlocutory appeal is intended to object to interlocutory decisions (Articles 1,015–1,020 of the CPC). According to Article 1,015 of the CPC, an interlocutory appeal can be filed against:

- I – provisional injunctions;
- II – case merits;
- III – rejection of the arbitration clause claim;
- IV – request for piercing the corporate veil;
- V – rejection of the request for free legal aid or acceptance of the request for its revocation;
- VI – exhibition or possession of a document or thing;
- VII – exclusion of a joint party;
- VIII – rejection of the request for limitation of the joinder of parties;
- IX – admission or non-admission of third-party intervention;
- X – granting, modification or revocation of the effect of *supersedeas* to motions to stay execution;
- XI – reassignment of the burden of proof pursuant to Article 373, Paragraph 1;
- XII – (vetoed);
- XIII – other cases expressly referred to in law.

An interlocutory appeal may also be filed against interlocutory decisions rendered in the decision settlement or judgment enforcement phases, in the process of execution or in the inventory process (Article 1,015(1) of the CPC).

Interlocutory appeals are addressed directly to the competent court by means of a petition stating the names of the parties, the description of the fact and right, the reasons for the request to change or invalidate the decision and the request itself, and the names and full addresses of the attorneys in the case (Article 1,016 of the CPC).

The rapporteur to whom the appeal is assigned may grant the effect of *supersedeas* to the appeal or grant, as interlocutory relief (totally or partially), or the appeal request, informing the judge of their decision; order that the appellee be personally notified – by letter with acknowledgment of receipt (if appellee does not have an attorney), by the Court Register or by letter with acknowledgment of receipt addressed to the attorney – so that they may respond within 15 days, allowing them to attach the documentation the rapporteur deems necessary to judge the appeal (Article 1,019 of the CPC). The rapporteur will also request a trial date within a period not more than one month from notification of appellee (Article 1,020 of the CPC).

3.9.3 Motion for clarification

A motion for clarification is an appeal regulated by Articles 1,022–1,026 of the CPC. A motion for clarification may be filed against any court decision in order to:

- I – clarify obscurity or eliminate contradiction;

- II – supply the omission of a point or issue on which the judge should have discussed at his own initiative or upon request; [or]
- III – correct material error. (Article 1,022 of the CPC)

Such a motion must be filed, within five days, in a petition addressed to the judge, indicating the error, obscurity, contradiction or omission, and it is not subject to an appeal bond (Article 1,023 of the CPC). The judge will notify the respondent so that, if they so wish, they can comment, within five days, on the motions filed, in the event that the motion's possible acceptance implies a change in the decision that is the subject of the motion for clarification (Article 1,023(2) of the CPC). Afterward, the judge will judge the motion within five days and remedy the matter (Article 1,024 of the CPC).

In the courts, the rapporteur presents the motion at the next session, casting their vote, and, if no judgment is rendered at this session, the appeal will be automatically included in the agenda (Article 1,024(1) of the CPC). When a motion for clarification is filed against the decision of the rapporteur or against another decision rendered by a single judge in court, the body that rendered the decision that is the subject of the motion decides on the matter monocratically (Article 1,024(2) of the CPC).

If the acceptance of a motion for clarification implies a change to the decision being objected, the respondent who has already filed another appeal against the original decision has the right to supplement or amend their briefs within the exact limits of the change and within 15 days from the date of notification of the decision that is the subject of the motion (Article 1,024(4) of the CPC). If the motion for clarification is rejected or does not change the conclusion of the previous judgment, the appeal filed by the other party before the publication of the judgment of the motion for clarification will be processed and judged regardless of its ratification (Article 1,024(5) of the CPC).

Motions for clarification have no effect of *supersedeas* and interrupt the term for filing an appeal (Article 1,026 of the CPC). The effectiveness of a decision by a single judge or group of judges may be suspended by the respective judge or rapporteur if the likelihood of the appeal being granted is demonstrated or, if the grounds are relevant, if there is a risk of serious damage or damage that would be difficult to repair (Article 1,026(1) of the CPC). When a motion for clarification is manifestly frivolous, the judge or the court, by means of a grounded decision, can order the party that made the motion to pay a fine not exceeding two percent of the adjusted amount in dispute (Article 1,026(2) of the CPC). Where there is a repetition of manifestly frivolous motions for clarification, the fine is increased to up to 10 percent of the adjusted amount in dispute, and the filing of any appeal will be conditional upon the deposit of the fine amount, except in the case of the Public Treasury and the beneficiary of free legal aid, who pays this amount at the end, after all the possible appeals to higher instances have been exhausted (Article 1,026(3) of the CPC).

3.9.4 Internal interlocutory appeal

An internal interlocutory appeal is an appeal that may be filed against a decision rendered by the rapporteur and is regulated by Article 1,021 of the CPC. Such an appeal is addressed to the rapporteur, who notifies the respondent to manifest on the appeal within 15 days, at the end of which, if there is no retraction, the rapporteur submits the appeal to judgment by the panel, including it in the agenda (Article 1,021 of the CPC).

3.9.5 Appeals to the Federal Supreme Court and to the Superior Court of Justice

After an appeal from the final judgment has been decided, there is still the possibility of filing appeals to the STF and to the STJ. Such appeals are provided for in Articles 1,029–1,440 of the CPC. However, the matters that may be appealed are restricted and specific. While appeals to the STF aim to verify violations of the Constitution, appeals to the STJ deal with violations of federal law. In both cases, it is possible to argue a divergence in the already understandings of the STF or of the STJ.

The STJ or STF may disregard formal defects in a timely appeal or order its correction, provided that the defect is correctable and not considered serious (Article 1,029(3) of the CPC).

As a rule, the decisions of the STF and STJ do not have the effect of *supersedeas*. For this effect to be granted, it is necessary to apply to the respective higher court (if the appeal has been admitted but not yet assigned) or to the rapporteur, the president or vice-president of the court of origin (if the appeal has already been assigned), as long as the appeal has not yet had its admissibility examined (Article 1,029(5) of the CPC). Once the appeals have been admitted, Article 1,034 of the CPC provides that they can only be about matters of law, not allowing a review of facts or evidence. The appeal, however, has the effect of review, allowing the court to also hear the other causes of action or grounds when recognizing the illegality or unconstitutionality with general repercussion.

Article 1,035 of the CPC highlights the importance of the general repercussion for appeals to the STF, stating that the STF may, in an unappealable decision, not hear an appeal to the STF that does not have a matter recognized as having general repercussion (meaning the existence of relevant economic, political, social or legal issues that go beyond the interests of the parties in the case). The general repercussion must be demonstrated in a specific chapter of the appeal. Once the general repercussion is recognized in an appeal to the STF, the rapporteur orders the stay of all pending individual or class proceedings in Brazil on the same issue, and the appeal must be heard within one year (Article 1,035(9) of the CPC).

3.9.6 Internal interlocutory appeal against a decision rejecting an appeal to the Federal Supreme Court or to the Superior Court of Justice

Article 1,042 of the CPC provides for an internal interlocutory appeal against a court decision that rejects an appeal to the STF or to the STJ. Such interlocutory appeals are addressed to the STF or the STJ, respectively.

3.9.7 Appeals against divergent decisions

Articles 1,043–1,044 of the CPC provide for appeals against divergent decisions.

Article 1,043. An appeal may be lodged against the judgment of a fractional court:
 I – in an [appeal to the STF or the STJ], diverges from the judgment of any other body of the same court, either in appellate decisions, motions and leading cases, on the merits;
 [...]
 III – in an [appeal to the STF or the STJ], diverges from the judgment of any other body of the same court, either in an appellate decision on the merits and another that has not heard the appeal, although it has examined the dispute.
 [...]
 Paragraph 2. The divergence that authorizes the filing of an appeal against a divergent decision may occur in the application of substantive law or procedural law.
 Paragraph 3. An appeal against a divergent decision may be filed when the leading appellate decision belongs to the same panel that rendered the decision objected, provided that its composition has been altered by more than half of its members.
 [...]

Article 1,044. In the appeal against a divergent decision, the procedure established in the internal rules of the respective higher court will be observed.

3.10 Criminal proceedings

The LPI criminalizes certain conducts, though it does not specify special rules for the processing of their criminal prosecution. The Code of Criminal Procedure (Código de Processo Penal)⁹⁰ regulates criminal prosecution and the preliminary measures of search and seizure, in crimes against industrial property.

The crimes provided for in the LPI are crimes for which a complaint by the interested party is required for initiating criminal prosecution, except for the crime provided for in Article 191, for which the criminal prosecution is public (Article 199 of the LPI). These actions are processed by

90 Law No. 3,689, of Oct. 3, 1941, DOU of Oct. 13, 1941.

courts that, as a rule, are different from those that process civil claims and that are not necessarily specialized in industrial property crime, but exclusively in criminal matters as a whole. Criminal prosecutions do not depend on civil lawsuits.

The LPI provides that an allegation of nullity of the patent or registration on which the action is based may constitute a defense in criminal prosecution. The acquittal of the defendant, however, does not imply the nullity of the patent or registration, which can only be demanded by the competent action (Article 205 of the LPI).

3.11 Selected topics

3.11.1 Licenses

The various types of licenses allowed under Brazilian legislation are provided for in Articles 61–74 of the LPI.

3.11.1.1 Voluntary license

Voluntary license is provided for in Articles 61–63 of the LPI. Under the legislation, the patent holder or the applicant may enter into a license contract for exploitation (Article 61 of the LPI). The license contract must be registered with the INPI so that it can produce effects in relation to third parties from the date of its publication (Article 62 of the LPI). However, for the purpose of validating evidence of use, this registration is not required (Article 62(2) of the LPI).

The licensee may be vested by the holder with all powers to act in the defense of the patent (Article 61(1) of the LPI). The improvement introduced in a licensed patent belongs to the one who makes it. However, the other contracting party is assured the right of first refusal for its licensing (Article 63 of the LPI).

3.11.1.2 Offer of license

Articles 64–67 of the LPI provide for the offer of license. A patent holder may request the INPI to place the patent on offer for exploitation purposes (Article 64 of the LPI). The INPI will then arrange the publication of the offer (Article 64(1) of the LPI). The holder may, at any time, before the express acceptance of its terms by the interested party, withdraw the offer (Article 64(4) of the LPI).

No voluntary license contract of an exclusive nature can be registered with the INPI without the holder having desisted from the offer, nor can it be offered (Article 64(2)–(3) of the LPI).

In the absence of an agreement between the holder and the licensee, the parties may request the INPI to arbitrate the remuneration (Article 65 of the LPI). The remuneration may be reviewed after one year from its establishment (Article 65(2) of the LPI).

The patent holder may request the cancellation of the license if the licensee does not begin effective exploitation within one year of the grant, interrupts exploitation for a period exceeding one year or if the conditions for exploitation are not met (Article 67 of the LPI).

3.11.1.3 Compulsory license

Finally, Articles 68–74 of the LPI provide for compulsory license. A patent holder is subject to having the patent licensed compulsorily if they exercise their rights in an abusive manner or engage in abuse of economic power, evidenced pursuant to the law, by means of an administrative or court decision (Article 68 of the LPI). Such licenses are always granted on a non-exclusive basis, and sublicenses are not permitted (Article 72 of the LPI).

3.11.1.3.1 *Compulsory license for lack of exploitation, commercialization, manufacturing full use or for insufficiency*

Article 68 of the LPI, lists, as examples, certain situations that occasion compulsory licensing:

Paragraph 1. [...]:

I – the non-exploitation of the subject matter of the patent in the Brazilian territory due to lack of manufacturing or incomplete manufacturing of the product, or, further,

the lack of full use of the patented process, except in cases of economic impracticability, when import will be allowed; or

II – the commercialization that does not meet the market's needs.

Paragraph 2. The license can only be requested by a person with a legitimate interest and who has the technical and economic capacity to efficiently exploit the subject matter of the patent, which must be intended, predominantly, for the domestic market.

3.11.1.3.2 Patent-dependent compulsory license

The compulsory license will also be granted when, cumulatively, the following circumstances are verified:

I – a situation of dependence of one patent on another is characterized;

II – the subject matter of the dependent patent constitutes substantial technical progress in relation to the previous patent; and

III – the holder does not reach an agreement with the holder of the dependent patent to exploit the previous patent. (Article 70 of the LPI)

The legislation defines a “dependent patent” as a patent for which exploitation obligatorily depends on the use of the subject matter of a previous patent (Article 70(1) of the LPI). A process patent may depend on its respective product patent or vice versa (Article 70(2) of the LPI). The holder of a patent licensed under the terms of this provision is entitled to a cross-compulsory license of the dependent patent (Article 70(3) of the LPI).

3.11.1.3.3 Compulsory license for national emergency or public interest

In cases of national emergency or public interest, declared in an instrument of the federal executive branch, and provided that a patent holder or their licensee does not meet the need, a temporary, nonexclusive compulsory license may be granted, at the judge's own initiative, for the exploitation of the patent, without prejudice to the rights of the holder (Article 71 of the LPI). In these cases, the instrument for the granting of the license establishes its term and the possibility of extension (Article 71(1) of the LPI).

3.11.1.3.4 Cases for not granting the compulsory license

The compulsory license will not be granted if, on the date of the application, the holder:

I – justifies the non-use for legitimate reasons;

II – proves that serious and effective preparations for exploration have been carried out; or

III – justifies the lack of manufacturing or commercialization on the grounds of an obstacle of legal nature. (Article 69 of the LPI)

3.11.1.3.5 Administrative request

The request for a compulsory license must be made indicating the conditions offered to the patent holder.

Paragraph 1. Once the license request is presented, the holder will be notified to present his opinion within sixty (60) days, after which, if he does not present his opinion, the proposal will be considered accepted under the conditions offered.

Paragraph 2. The license applicant that invokes abuse of patent rights or abuse of economic power must attach documentation that evidences it.

Paragraph 3. [and, if the license is] requested on the grounds of lack of exploitation, the patent holder will be responsible for evidencing exploitation. (Article 73 of the LPI)

In the event an answer to the request is presented, the INPI may take the necessary measures, as well as designate a commission, which may include specialists who are not members of the INPI's staff, to decide on the compensation to be paid to the holder (Article 73(4) of the LPI). The bodies and entities of the direct or indirect federal, state or municipal governments will provide the INPI with the information requested for the purpose of basing the decision on the compensation (Article 73(5) of the LPI). Once this information has been provided, the INPI will decide on the granting and conditions of the compulsory license within 60 days (Article 73(7) of the LPI). An appeal against a decision granting the compulsory license does not have an effect of *supersedes* (Article 73(8) of the LPI).

Except for legitimate reasons, the licensee must begin exploiting the subject matter of the patent within one year of the license being granted, though an interruption for the same period is permitted (Article 74 of the LPI). If this does not happen, the patent holder may request the revocation of the license (Article 74(1) of the LPI).

A licensee is vested with all powers to act in the defense of the patent (Article 74(2) of the LPI). After the compulsory license is granted, its assignment is only allowed when performed jointly with the assignment, disposal or leasing of the part that explores it (Article 74(3) of the LPI).

Where a compulsory license is granted due to an abuse of economic power, the licensee, who proposes local manufacturing, is granted a term, limited to one year, to import the object of the license, provided that it has been placed on the market directly by the holder or with their consent (Article 68(3) of the LPI). In the case of such import or import for patent exploitation, the import by third parties of a product manufactured in accordance with a process or product patent is also admitted, provided that it has been placed on the market directly by the holder or with their consent (Article 68(4) of the LPI).

3.11.2 Pharmaceutical patents

3.11.2.1 Applications filed before the ratification of the treaty – the pipeline system

Specific considerations applied to patent applications that were filed before Brazil's ratification of the TRIPS Agreement treaty and that became known as the "pipeline." Law No. 10,196/01⁹¹ (formerly Provisional Presidential Decree No. 2006/99, which was reissued 15 times) amended the LPI, establishing in Article 229 that patent applications filed up to December 31, 1994, concerning chemico-pharmaceutical products and drugs, as well as processes for obtaining or modifying them, should be rejected. In turn, Article 229-A of the LPI imposed the rejection of patent applications for processes for obtaining chemico-pharmaceutical products and drugs if they were filed between January 1, 1995, and May 14, 1997.

Law No. 10,196/01 also created Article 229-C of the LPI, according to which the granting of patents for pharmaceutical products and processes must have the prior consent of the Brazilian Health Regulatory Agency (Agência Nacional de Vigilância Sanitária; ANVISA). This procedure gave rise to several discussions, to the point that the Brazilian Intellectual Property Association (Associação Brasileira da Propriedade Intelectual), which brings together companies, firms of industrial property agents, law firms and experts in intellectual property matters, amended its Resolution No. 2, of January 27, 2000,⁹² to state that requirement was a trespass of the INPI's substantive jurisdiction as established in Article 240 of the LPI and, in addition, directly violated the provisions of Article 4(A)(1) of the Paris Convention.⁹³

Here, there was an issue of objective and subjective jurisdiction regarding the regulation for patent granting. Subsequently, the Brazilian Intellectual Property Association published a resolution in which it stated that ANVISA could not analyze or review the patentability requirements (novelty, inventive step and utility) and should limit itself to verifying whether the patent application is harmful to public health.⁹⁴

3.11.2.2 Prior consent by the Brazilian Health Regulatory Agency (ANVISA)

The debate consists of knowing whether the prior consent requirement has, in addition to assisting in the technical examination without the concern related to the power "to deny consent," in view of Article 31 of the LPI (which already provides for the submission of documents and information by the interested parties to support the technical examination). The institute allows for prior consent, which has been deemed relevant for national policies on access to drugs and has also been implemented in the intellectual property legislation of countries in the La Plata basin, such as Paraguay.

91 DOU of Feb. 16, 2001.

92 Associação Brasileira de Propriedade Intelectual Resolution No. 2 of Jan. 27, 2000, <https://abpi.org.br/resolucoes-da-abpi/resolucao-no-2-publicada-em-27-01-2000>

93 Decree No. 75,572, of Apr. 8, 1975, DOU of April 10, 1975, art. 4 *quarter* ("The granting of a patent may not be rejected and a patent may not be invalidated because the patented product is on sale or obtained by a patented process subject to restrictions or limitations resulting from the national legislation") (enacting the Paris Convention).

94 Associação Brasileira de Propriedade Intelectual Resolution No. 16, of Sep. 27, 2001, <https://abpi.org.br/resolucoes-da-abpi/resolucao-no-16-publicada-em-27-09-2001>

Regardless of the limits of ANVISA's rulemaking power regarding its prior consent, there are currently two other public institutions performing similar work. In addition to assessing patentability requirements, ANVISA also observes aspects relevant for public health, such as whether the granting of the patent will result in limited access to drugs.

In the event of a difference of opinion between the INPI and ANVISA regarding the granting of protection, the patent is not granted, and the process is stayed within the administrative scope of the INPI. The direct consequence of this is that, in the event of a delay in the granting of pharmaceutical patents in the country, the foreign companies (that hold a large part of the filings in the area) may have their patents extended, delaying the entry of generic products into the market.

Conversely, some legal remedies can be used to alleviate this situation, such as compulsory licensing, provided for in the LPI (in cases of abuse of economic power, lack of commercial exploitation, national emergency or public interest) and the "*Bolar* exception" (an exception to the extension of patent protection, which specifically addresses the use of a currently patented invention for research without the need for authorization from the patent holder). In the latter case, acts intended exclusively for the production of information, data and test results for obtaining the registration needed to market the patented product do not constitute infringement.⁹⁵

This issue was settled with the ratification of Opinion No. 337/PGF/AE/2011, by the Office of the General Counsel for the Federal Government, according to which ANVISA's authority was established as being solely to examine whether a pharmaceutical product or process submitted to the patent process is potentially harmful to human health, which could lead to the rejection of the application by the INPI, regardless of the verification of the other criteria of incumbent upon this ANVISA's body.

3.11.2.3 New use and new therapeutic application

The LPI is silent on the protection of "use": it does not provide for such claims expressly. For the INPI, second medical use claims are possible, provided that they are intended for a new and nonobvious therapeutic application and that the mechanism of drug action is different from that described for the first use. Thus, inventions related to substances or compositions that aim to protect use in the treatment of certain diseases, according to the INPI's examination guidelines, can be one of two types:

- a product already known to be used outside the medical field has a new use as a drug, which is said to be the first medical use; or
- a product already known as a drug has a new therapeutic application, which is defined as a second medical use. Although legislation prevents the protection of products isolated from nature, such products are patentable when they are given practical use.

Regarding the second medical use, the solution found to disconnect the new use of a therapeutic method was to link that use to a drug manufacturing process. While claims for the use of the specific product are characterized for the treatment of a given disease, such uses are not considered inventions because they are therapeutic methods under our rules, though not according to the Treaty of Paris. Thus, claims in which the use of a specific product is characterized for the preparation of a drug to treat a given disease are accepted as well. This type of claim is known as a "Swiss formula," and it aims to protect the second medical use of a known product.

Consequently, new and improved methods of extraction, purification, elucidation, synthesis or semisynthesis of natural compounds, the production of industrial drugs, and genetic engineering are considered patentable. When they are nonobvious, it is also possible to patent chemically modified natural compounds; pharmaceutical, nutraceutical or cosmetic compositions containing one or more natural or modified compounds; transgenic microorganisms and modified biological processes; and the first or second therapeutic use of a described compound. In addition, many patents, despite being granted, prove to be of little or no real value to their owners. This may be

95 Both cases are covered by the provisions of the LPI, as follows: "The provisions of the previous article are not applicable: [...] III – to the preparation of drugs according to the medical prescription for individual cases, performed by a qualified professional, as well as to the drug prepared as such." Law No. 9,279, of May 14, 1996, DOU of May 15, 1996, art. 43.

particularly true for patent applications for “new drugs,” especially those patented very early in their development process when there is still little certainty of their actual efficacy, low toxicity or economic viability.

3.12 Key challenges and efforts to improve patent case management

By way of this project, after hearing from not only judges but also other legal practitioners, we identified the main challenges to be faced in adjudicating patent disputes in Brazil:

- The lack of specialization of some courts was a challenge for the adequate processing of actions involving patents, due to the specificity of the technical and legal matters in this kind of action. Some regions have already adopted some specialized courts, and, in the higher courts, some have specialized chambers as well.
- There is difficulty in producing expert evidence because this requires a professional with specialized technical knowledge.
- The uncertain relation between patent nullity actions, which are processed before the federal courts, and actions for infringement in which patent nullity is incidentally alleged.

The CPC provides, in Articles 67–69, rules that govern collaboration between judges. It is, however, a recent rule that needs to be incorporated into the Brazilian judicial culture. The articles provide that:

Article 67. The bodies of the Judiciary, state or federal, specialized or common, in all levels and degrees of jurisdiction, including the higher courts, have the duty of reciprocal cooperation, through their judges and servants.

Article 68. The courts may make a request for cooperation to each other for the performance of any procedural act.

Article 69. The request for judicial cooperation must be promptly met, does not require a specific manner, and can be executed as:

I – direct assistance;

II – joining or attachment of cases;

III – provision of information;

IV – acts between the judges in cooperation.

Paragraph 1. The letters of order, of request and of arbitration shall follow the regime provided for in this Code.

Paragraph 2. The acts agreed between the judges in cooperation may consist, in addition to others, of the establishment of a procedure for:

I – the service of process, summons or notification of an act;

II – the obtaining and presentation of evidence and the hearing of testimonies;

III – the granting of a provisional injunction;

IV – the implementation of measures for the recovery and preservation of companies;

V – the facilitation of proof of claim in bankruptcy and court-supervised reorganization;

VI – the centralization of repeated cases;

VII – the execution of a court decision.

Paragraph 3. The request for judicial cooperation may be made among judicial bodies from different branches of the Judiciary. (Articles 67–69 of the CPC)

Recently, Resolution No. 350, of October 27, 2020, of the National Justice Council (Conselho Nacional de Justiça) was issued to regulate the guidelines and procedures on national judicial cooperation among bodies of the judiciary.

Chapter 4

China

Authors:
Judge Du Weike and Judge He Juan

4.1 Outline of China's Patent Law and patent case trials

4.1.1 Formulation and evolution of China's Patent Law

4.1.1.1 Promulgation of the Patent Law

The Temporary Regulations for the Protection of Invention Right and Patent Right and its detailed implementation rules, which were enacted in 1950, were the first regulations on patent rights since the founding of the People's Republic of China.

On March 12, 1984, the Standing Committee of the Sixth National People's Congress (NPC) reviewed and adopted the 1984 Patent Law.¹ The 1984 Patent Law had 69 articles. The then Director General of the World Intellectual Property Organization (WIPO), Mr. Árpád Bogsch, commented that the Chinese language was wonderful, as the three types of patents (invention, utility model, and design) were clearly stated in only 60-odd articles.²

4.1.1.2 Four amendments to the Patent Law

The first amendment to the Patent Law,³ in 1992, included:

- deleting the provision in the 1984 Patent Law that no patent right shall be granted for drugs, foodstuffs, beverages and condiments;
- additionally granting a right of importation to the patentee;
- extending the protection of method patents to products directly obtained by those methods;
- increasing the term of protection of invention patents from 15 years to 20 years and increasing the term of protection of utility model patent and design patent rights from 5 years with a 3-year renewal to 10 years;
- abolishing the obligation of the patentee to implement patents in China and amending the conditions of compulsory licensing; and
- improving the patent application and approval procedures, adding domestic priority and replacing the pre-grant opposition procedure with a post-grant revocation procedure.

The second amendment to the Patent Law,⁴ in 2000, included:

- clarifying that the legislative purpose of the Patent Law included "promoting scientific and technological progress and innovation";
- improving the system of invention and creation ownership and allowing the employer of an inventor or designer to make an agreement on the ownership of a patent to inventions and creations made with the material and technical conditions of the employer;
- abolishing the requirement that state-owned units hold the patent rights to enable the state-owned units to enjoy the full right to dispose of the patent rights acquired by them as other economic entities;
- giving a patentee the right to offer to sell;
- consolidating the revocation and the invalidation procedures into a single invalidation procedure;
- abolishing the power of the Patent Reexamination Board to make final decisions on utility model patents and design patents and stipulating that parties have the right to appeal to a people's court with respect to the reexamination decision or invalidation decision made by the Patent Reexamination Board on utility model patents and design patents;
- defining the obligations to be performed by China as a contracting state of the Patent Cooperation Treaty;
- providing for a search report system for utility model patents; and
- strengthening the protection of patent rights by introducing pre-litigation temporary injunction and property preservation measures and stipulating that the amount of compensation for infringement may be determined by reference to a reasonable multiple of the patent license fee.

1 Patent Law (promulgated by the Standing Comm. Nat'l People's Cong., March 12, 1984, effective April 1, 1985) [hereinafter 1984 Patent Law]

2 Wang Meng and Peng Xunwen, *Narration by Four Experts – The Story of Reform and Legislation*, People's Daily (Overseas ed.), Dec. 24, 2018, at 5.

3 Patent Law (1992 Amendment) (promulgated by the Standing Comm. Nat'l People's Cong., Sep. 4, 1992, effective Jan. 1, 1993) [hereinafter 1992 Patent Law].

4 Patent Law (2000 Amendment) (promulgated by the Standing Comm. Nat'l People's Cong., Aug. 25, 2000, effective July 1, 2001) [hereinafter 2000 Patent Law].

In June 2008, the Outline of the National Intellectual Property Strategy was officially promulgated.⁵ A third amendment to the Patent Law was consequently necessary for the implementation of the National Intellectual Property Strategy, for the development of an innovative country, for adapting to the international development trend of intellectual property rights and for China to adjust its economic structure, transform its development model and achieve sustainable scientific development. The third amendment to the Patent Law,⁶ in 2008, included:

- the explicit inclusion of “enhancing innovation capability” in the legislative purpose;
- setting higher requirements for granting design patents by replacing the standard of “relative novelty” with “absolute novelty”;
- making further stipulations regarding the conditions for granting design patents;
- extending the scope of “conflicting applications” that undermine novelty to include the applicant’s own prior applications;
- stipulating that only one patent right can be granted for the same invention and creation and defining the conditions for transfer between invention patents and utility model patents;
- stipulating that offering to sell constitutes an infringement of design patents;
- collectively referring to the acts of “counterfeiting another person’s patent” and “passes off any unpatented product or method as a patented one” as “counterfeiting a patent” and setting higher administrative penalty standards;
- clarifying that the amount of compensation also includes the reasonable expenses paid by the right holder to stop infringements;
- imposing pre-litigation evidence preservation measures and delegating the administrative power to the patent administration department of the State Council to investigate and handle patent counterfeiting;
- amending the provisions on compulsory licensing for patents in accordance with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement);⁷
- stipulating exceptions to the administrative approval of patents for pharmaceuticals and medical devices; and
- introducing provisions on genetic resources and traditional knowledge.

The fourth amendment to the Patent Law,⁸ in 2020, included:

- increasing the amount of statutory compensation and introducing a punitive damage system;
- improving the rules of evidence relating to compensation for infringement and reducing the burden of proof on the right holder;
- improving relevant provisions on patent administrative enforcement, imposing more severe penalties on patent counterfeiting and raising the amount of penalty;
- stipulating a new system for drug patent term extension and a mechanism for early settlement of drug patent disputes;
- extending the term of a design patent to 15 years, providing protection for partial designs and stipulating the domestic priority system for design patent applications;
- further improving the provisions related to service invention-creation, providing that the State encourages the entities to which the patent rights are granted to implement property right incentives and to share innovation returns reasonably with inventors or designers by means of equity, options, dividends and so on;
- stipulating an open licensing system for patents;
- improving the provisions on the grace period of novelty and supplementing a circumstance where the first disclosure is made for the purpose of public interest in case of national emergency or extraordinary circumstances;
- improving the system of patent evaluation reporting and expanding the scope of subjects entitled to apply for a patent evaluation report; and
- optimizing the provisions on the procedure for claiming priority and extending the time limit for submitting copies of priority documents.

5 Outline of the National Intellectual Property Strategy (promulgated by the State Council, June 5, 2008, effective June 5, 2008).

6 Patent Law (2008 Amendment) (promulgated by the Standing Comm. Nat’l People’s Cong., Dec. 27, 2008, effective Oct. 1, 2009) [hereinafter 2008 Patent Law].

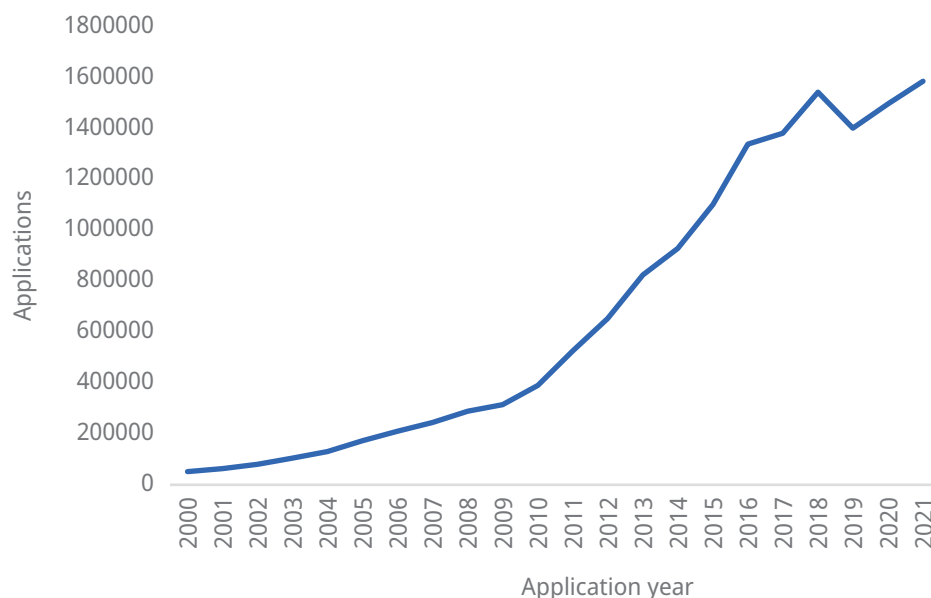
7 Agreement on Trade-Related Aspects of Intellectual Property Rights, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, annex 1C, 1869 UNTS 299 [hereinafter TRIPS Agreement].

8 Patent Law (2020 Amendment) (promulgated by the Standing Comm. Nat’l People’s Cong., Oct. 17, 2020, effective June 1, 2021). “Patent Law” hereinafter refers to this amendment unless otherwise indicated.

4.1.2 Patent application trends

Figure 4.1 shows the total number of patent applications (direct and Patent Cooperation Treaty (PCT) national phase entry) filed in China from 2000 to 2021.

Figure 4.1 Patent applications filed in China 2000–2021



Source: WIPO IP Statistics Data Center, available at www3.wipo.int/ipstats/index.htm?tab=patent

4.1.3 Legal basis to hear patent cases

China's legal system is a civil-law system, as opposed to a common-law system, with only statutory law, not case law. Chinese courts adjudicate civil and administrative patent cases in accordance with laws such as the Patent Law, administrative regulations such as the Rules for the Implementation of the Patent Law, judicial interpretations and by reference to guiding cases.

According to Article 63 paragraph 3 of the Administrative Procedure Law,⁹ "the people's courts shall refer to the regulations when hearing administrative cases." Therefore, Chinese courts may refer to the Guidelines for Patent Examination formulated by the China National Intellectual Property Administration (CNIPA) when hearing administrative patent cases involving a reexamination or invalidation procedure.

4.1.3.1 Laws

Laws are enacted by the top legislative body of the State – namely the NPC and its Standing Committee – and promulgated by the Order of the President of the People's Republic of China, signed by the President. Laws have higher authority compared to administrative regulations, local regulations and rules. In addition to the Patent Law, Chinese courts that hear patent cases are also governed by applicable substantive laws, including the Civil Code.¹⁰

The Civil Code, reviewed and passed on May 28, 2020, at the Third Session of the 13th NPC, is the first law to be named a "code" since the founding of the People's Republic of China. The Civil Code has no separate section on intellectual property but has some special provisions on the same in Chapter V ("Civil-Law Rights"). Article 123 of the Civil Code stipulates the following:

The persons of the civil law enjoy intellectual property rights in accordance with the law.

⁹ Administrative Procedure Law (2017 Amendment) (promulgated by the Standing Comm. Nat'l People's Cong., June 27, 2017, effective July 1, 2017).

¹⁰ Civil Code (promulgated by the Standing Comm. Nat'l People's Cong., May 28, 2020, effective Jan. 1, 2021).

Intellectual property rights are the exclusive rights enjoyed by the right holders in accordance with the law over the following subject matters:

- (1) works;
- (2) inventions, utility models, or designs;
- (3) trademarks;
- (4) geographical indications;
- (5) trade secrets;
- (6) layout designs of integrated circuits;
- (7) new plant varieties; and
- (8) other subject matters as provided by law.

Article 1185 of the Civil Code stipulates the following: “In case of an intentional infringement of another person’s intellectual property rights, where the circumstances are serious, the infringed party has the right to request for corresponding punitive damages.” The provisions of the Civil Code apply to co-ownership, contracts, security, succession, joint infringement, aiding and abetting infringement, civil liability and so on when they are related to patent rights.

In terms of procedural law, Chinese courts hear patent cases, enforce decisions and make decisions related to the preservation of evidence, property or acts in accordance with the provisions of the Civil Procedure Law,¹¹ Administrative Procedure Law, Criminal Procedure Law¹² and applicable judicial interpretations. On October 26, 2018, the Decision on the Litigation of Intellectual Property Cases was revised and adopted at the Sixth Session of the Standing Committee of the 13th NPC.¹³ According to the decision, the Supreme People’s Court shall hear cases on appeal over patent and other intellectual property rights involving professional technologies throughout the country.

According to Article 42 of the Legislation Law:¹⁴

The power to interpret a law shall be vested in the Standing Committee of the National People’s Congress.

Under any of the following circumstances, a law shall be interpreted by the Standing Committee of the National People’s Congress if:

- (1) the specific meaning of any provisions of a law requires further clarification; or
- (2) any new circumstances appearing after the issuance of a law require clarification of the basis for the application of the law.

The interpretation of law adopted by the Standing Committee of the NPC has the same effect as the laws enacted by it. The Standing Committee of the NPC has not made any legislative interpretation of the Patent Law.

4.1.3.2 Administrative regulations

Administrative regulations are drafted by relevant departments under the State Council or by the State Council’s legal affairs organ and are promulgated by the Decree of the State Council of the People’s Republic of China, signed by the Premier of the State Council. Administrative regulations in the field of patent law include the Rules for the Implementation of the Patent Law and the Regulations on Patent Commissioning.¹⁵

Alongside the amendments to the Patent Law, the Rules for the Implementation of the Patent Law have been amended several times accordingly. After the promulgation of the 1984 Patent Law, the State Council approved the Rules for the Implementation of the Patent Law – which was formulated by the Patent Office of China – on January 19, 1985, and it came into force together with the Patent Law on April 1, 1985. In 1992, the Standing Committee of the NPC made the first

11 Civil Procedure Law (2017 Amendment) (promulgated by the Standing Comm. Nat’l People’s Cong., June 27, 2017, effective July 1, 2017).

12 Criminal Procedure Law (2018 Amendment) (promulgated by the Standing Comm. Nat’l People’s Cong., Oct. 26, 2018, effective Oct. 26, 2018).

13 Decision on Several Issues concerning Litigation Procedures of Patent and Other Intellectual Property Cases (promulgated by the Standing Comm. Nat’l People’s Cong., Oct. 26, 2018, effective Jan. 1, 2019).

14 Legislation Law (promulgated by the Standing Comm. Nat’l People’s Cong., March 15, 2000, effective July 1, 2000).

15 Detailed Rules for the Implementation of the Patent Law (2010 Revision) (promulgated by the State Council, Jan. 19, 2010, effective Feb. 1, 2010); Regulations on Patent Commissioning (promulgated by the State Council, March 4, 1991, rev’d Nov. 6, 2018, effective March 1, 2019).

amendment to the Patent Law, and, on December 12 of the same year, the State Council approved the amended Rules for the Implementation of the Patent Law, which came into force together with the amended Patent Law on January 1, 1993. In 2000, the Standing Committee of the NPC made the second amendment to the Patent Law, and, on June 15, 2001, the State Council promulgated the new Rules for the Implementation of the Patent Law, which came into effect together with the second amended Patent Law on July 1, 2001. At the same time, the rules that were approved by the State Council for amendment in 1992 were repealed. The existing rules were amended in 2002 and 2010.

To be consistent with the fourth amendment to the Patent Law, the CNIPA worked on amendments to the Rules for the Implementation of the Patent Law and developed a draft accompanying explanatory notes, which were published in November 2020 for comment from all sectors of society. As the Rules for the Implementation of the Patent Law are still in the process of amendment, the CNIPA formulated the Interim Measures for the Amended Patent Law to ensure the appropriate implementation of the amended Patent Law.¹⁶

4.1.3.3 Judicial interpretations

Article 18 paragraph 1 of the Law on the Organization of the People's Courts¹⁷ stipulates the following: "The Supreme People's Court may interpret the issues concerning the application of law in trial." According to Article 104 of the Legislation Law:¹⁸ "The interpretation of the application of specific law in the judicial or procuratorial work made by the Supreme People's Court or the Supreme People's Procuratorate shall be aimed at the specific legal provisions and in line with the legislative purpose, principle, and original intention in respect of the legislation."

According to the Provisions on Judicial Interpretation Work,¹⁹ the judicial interpretation issued by the Supreme People's Court shall have legal force. The judicial interpretation shall be given in accordance with law and legislative spirit and depend on the actual needs of trial. Judicial interpretations may be made in any of five forms: "interpretations," "provisions," "rules," "replies" and "decisions." Judicial interpretations on the specific application of a certain law in the trial work or the application of law in the trials of cases of a certain category or of certain kinds of problems are made as "interpretations." Judicial interpretations on the formulation of the norms or opinions that are necessary for the trial work based on the legislative spirit are made as "provisions." Judicial interpretations on the regulation of trial and enforcement of decisions are made as "rules." Judicial interpretations on the requests for instructions on the specific application of law in the trial work by the higher people's courts or the Military Court of the People's Liberation Army are made as "replies." The amendment or abolishment of judicial interpretations is made as a "decision."

Draft judicial interpretations made by the Supreme People's Court are adopted after discussion by the Adjudication Committee, issued by the president or executive vice-president of the Supreme People's Court, published in the form of a public announcement by the Supreme People's Court and submitted to the Standing Committee of the NPC for the record within 30 days from the date of publication.

In the field of patent law, there are primarily the following judicial interpretations:

- judicial interpretations related to jurisdiction over cases, including:
 - Provisions on the Jurisdiction of the Intellectual Property Courts;²⁰
 - Provisions on the Intellectual Property Court;²¹
 - Interpretation of the Civil Procedure Law;²²

16 Interim Measures for the Processing of Patent-Related Examination for the Implementation of the Amended Patent Law (promulgated by the CNIPA, May 25, 2021, effective June 1, 2021).

17 Law on the Organization of the People's Courts (2018 Revision) (promulgated by the Standing Comm. Nat'l People's Cong., Oct. 26, 2018, effective Jan. 2019).

18 Legislation Law (2015 Amendment) (promulgated by the Standing Comm. Nat'l People's Cong., March 15, 2015, effective March 15, 2015).

19 Provisions on Judicial Interpretation Work (2021 Amendment) (promulgated by the Sup. People's Ct, June 9, 2021, effective June 16, 2021).

20 Provisions on the Jurisdiction of the Intellectual Property Courts of Beijing, Shanghai and Guangzhou (2020 Amendment) (promulgated by the Sup. People's Ct, Dec. 29, 2020, effective Jan. 1, 2021).

21 Provisions on Several Issues concerning the Intellectual Property Court (promulgated by the Sup. People's Ct, Nov. 26, 2018, effective Jan. 1, 2019).

22 Interpretations of Several Issues concerning the Enforcement Procedures in the Application of the Civil Procedure Law (2020 Amendment) (promulgated by the Sup. People's Ct, Dec. 29, 2020, effective Jan. 1, 2021).

- judicial interpretations related to procedure and evidence, including:
 - Provisions on Act Preservation in Intellectual Property Disputes;²³
 - Provisions on Evidence in Civil Procedures;²⁴
 - Provisions on Evidence in Civil Procedures involving Intellectual Property Rights;²⁵
- judicial interpretations related to substantial issues of the Patent Law, including:
 - Provisions on the Trial of Patent Disputes;²⁶
 - Interpretation of Patent Infringement Dispute Cases;²⁷
 - Interpretation (II) of Patent Infringement Dispute Cases;²⁸
 - Provisions on Patent Grant and Confirmation;²⁹
 - Provisions on the Patent Rights of Drugs;³⁰
 - Interpretation of Punitive Damages in Intellectual Property Civil Cases;³¹ and
 - Reply on Compensation for a Plaintiff's Abuse of Rights.³²

4.1.3.4 Departmental rules

The Guidelines for Patent Examination are department rules formulated by the CNIPA. It details and supplements the provisions of the Patent Law and the Rules for the Implementation of the Patent Law. It also serves as the basis and standard for the legal administration of the CNIPA to refer to and follow in enforcing the relevant laws and regulations. The guidelines were amended in accordance with the 2008 Patent Law, the Rules for the Implementation of the Patent Law (2010 Revision) and based on actual requirements. The Guidelines for Patent Examination first came into effect on February 1, 2010, and have been amended six times since.

The first amendment came into effect on October 15, 2013, and primarily concerned the preliminary examination procedure for utility model and design patent applications. The second amendment came into effect on May 1, 2014, and primarily concerned the scope for the granting of design patents for graphical user interfaces. The third amendment came into effect on April 1, 2017, and primarily concerned the conditions for granting patents related to business models, the examination of patent applications for inventions involving computer programs, the supplemental submission of experimental data, and the examination of requests for the invalidation of a patent right. The fourth amendment came into effect on November 1, 2019, and primarily concerned the preliminary examination and substantive examination of patent applications for inventions, drafting requirements for graphical user interface design patents, and examination standards for patents related to human embryonic stem cells. The fifth amendment came into effect on February 1, 2020, and primarily concerned the examination of patent applications for inventions related to artificial intelligence, "internet+," big data and blockchain, and the examination of patent applications for inventions having algorithmic features or business rules and method features. The sixth amendment came into effect on January 15, 2021, and primarily concerned the examination of invention patent applications in the field of chemistry, including the supplemental submission of experimental data, rules for determining the novelty and creativity of compounds, and the examination of monoclonal antibodies.

4.1.3.5 International treaties

International treaties are written agreements on mutual rights and obligations concluded between subjects of international law. To have a legal basis in China, such international treaties

- 23 Provisions on Several Issues concerning the Application of Law in Cases Involving the Review of Act Preservation in Intellectual Property Disputes (promulgated by the Sup. People's Ct, Dec. 12, 2018, effective Jan. 1, 2019).
- 24 Several Provisions on Evidence in Civil Procedures (promulgated by the Sup. People's Ct, April 1, 2001, rev'd Dec. 25, 2019, effective May 1, 2020).
- 25 Several Provisions on Evidence in Civil Procedures involving Intellectual Property Rights (promulgated by the Sup. People's Ct, Nov. 16, 2020, effective Nov. 18, 2020).
- 26 Several Provisions on Issues concerning the Application of Law in the Trial of Patent Disputes (2020 Amendment) (promulgated by the Sup. People's Ct, Dec. 29, 2020, effective Jan. 1, 2021).
- 27 Interpretation on Several Issues concerning the Application of Law in the Trial of Patent Infringement Dispute Cases (promulgated by the Sup. People's Ct, Dec. 28, 2009, effective Jan. 1, 2010).
- 28 Interpretation (II) on Several Issues concerning the Application of Law in the Trial of Patent Infringement Dispute Cases (2020 Amendment) (promulgated by the Sup. People's Ct, Dec. 29, 2020, effective Jan. 1, 2021).
- 29 Provisions (I) on Several Issues concerning the Application of Law in the Trial of Administrative Cases involving Patent Grant and Confirmation (promulgated by the Sup. People's Ct, Sep. 10, 2020, effective Sep. 12, 2020).
- 30 Provisions on Several Issues concerning the Application of Law in the Trial of Civil Cases involving Patent Disputes Related to Drugs of Which Applications for Registration are Filed (promulgated by the Sup. People's Ct, July 4, 2021, effective July 5, 2021).
- 31 Interpretation on the Application of Punitive Damages in the Trial of Civil Cases of Intellectual Property Infringement (promulgated by the Sup. People's Ct, March 2, 2021, effective March 3, 2021).
- 32 Reply on Issues concerning the Claim of the Defendant for Compensation for Reasonable Expenses on the Ground that the Plaintiff Abuses Rights in the Action of Infringement on Intellectual Property Rights (promulgated by the Sup. People's Ct, June 3, 2021, effective June 3, 2021).

must have entered into force in China. If an international treaty concluded by China – or to which China is a party and has come into force in China – has different provisions compared to Chinese laws on the same matter, the provisions of the international treaty take precedence, except for such provisions for which China has declared its reservations. China has adopted a model of transformative application with respect to the TRIPS Agreement.

In terms of patent law, multilateral international treaties to which China is a party and that have come into force in China include:

- the Convention establishing the World Intellectual Property Organization (effective in China from June 3, 1980),³³ administered by WIPO;
- the Paris Convention for the Protection of Industrial Property (effective in China from March 19, 1985);³⁴
- the Patent Cooperation Treaty (effective in China from January 1, 1994);³⁵
- the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (effective in China from July 1, 1995);³⁶
- the Locarno Agreement establishing an International Classification for Industrial Designs (effective in China from September 19, 1996);³⁷
- the Strasbourg Agreement concerning the International Patent Classification (effective in China from June 19, 1997);³⁸ and
- the TRIPS Agreement (effective in China from December 11, 2001), administered by the World Trade Organization.

The Regional Comprehensive Economic Partnership was officially signed on November 15, 2020, by 15 Asia-Pacific countries (including China, Japan, Republic of Korea, Australia and New Zealand) and has been ratified by six Association of South-East Asian Nations countries (including Brunei Darussalam) and four non-Association countries (China, Japan, New Zealand and Australia). The Regional Comprehensive Economic Partnership entered into force on January 1, 2022. The agreement has a special chapter on intellectual property, covering copyright, trademarks, geographical indications, patents, designs, genetic resources, traditional knowledge and folklore, anti-unfair competition, intellectual property enforcement, cooperation, transparency, technical assistance and other fields.

Bilateral international treaties regarding patent law concluded by China and that have come into force in China include:

- the Memorandum of Understanding between the Government of China and the Government of the United States of America on the Protection of Intellectual Property (effective January 1, 1993);³⁹
- the Economic and Trade Agreement between the Government of the United States of America and the Government of the People's Republic of China (effective February 14, 2020; a first-stage economic and trade agreement between the US and China);⁴⁰
- the New Zealand–China Free Trade Agreement (effective October 1, 2008);⁴¹
- the China–Peru Free Trade Agreement (effective March 1, 2010);⁴²
- the China–Costa Rica Free Trade Agreement (effective August 1, 2011);⁴³
- the China–Australia Free Trade Agreement (effective December 20, 2015);⁴⁴

33 Convention establishing the World Intellectual Property Organization, July 14, 1967, 828 UNTS 5.

34 Paris Convention for the Protection of Industrial Property, March 20, 1883, 828 UNTS 305.

35 Patent Cooperation Treaty, June 19, 1970, 1160 UNTS 231.

36 Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (with Regulations), April 28, 1977, 1861 UNTS 362.

37 Locarno Agreement establishing an International Classification for Industrial Designs, Oct. 8, 1968, 828 UNTS 435.

38 Strasbourg Agreement concerning the International Patent Classification, March 24, 1971, 1160 UNTS 483.

39 Memorandum of understanding between the Government of the United States of America and the Government of the People's Republic of China on the protection of intellectual property, Jan. 17, 1992, 2249 UNTS 303.

40 Economic and Trade Agreement between the Government of the People's Republic of China and the Government of the United States of America, Jan. 15, 2020.

41 Free Trade Agreement between the Government of the People's Republic of China and the Government of New Zealand, April 7, 2008, 2590 UNTS 101.

42 Free Trade Agreement between the Government of the People's Republic of China and the Government of the Republic of Peru, April 28, 2009.

43 Free Trade Agreement between the Government of the People's Republic of China and the Government of the Republic of Costa Rica, April 8, 2010.

44 Free Trade Agreement between the Government of Australia and the Government of the People's Republic of China, June 17, 2015.

- the China–Republic of Korea Free Trade Agreement (effective December 20, 2015);⁴⁵
- the China–Georgia Free Trade Agreement (effective from January 1, 2018);⁴⁶ and
- the China–Mauritius Free Trade Agreement (effective from January 1, 2021).⁴⁷

4.1.4 Guiding case system

Article 18 paragraph 2 of the Law on the Organization of the People's Courts provides that "the Supreme People's Court may publish guiding cases." Cases that have a guiding effect on the judicial and enforcement work of Chinese courts are determined and released by the Supreme People's Court, and the people's courts at all levels refer to them when hearing similar cases. As of September 14, 2021, the Supreme People's Court has issued 165 guiding cases in 29 batches, of which seven are related to patents.

Article 2 of the Provisions on Case Guidance Work⁴⁸ stipulates that the guiding cases are those that have legally effective judgments and:

- are of widespread concern to society;
- involve legal provisions that are relatively general;
- are typical;
- are difficult, complicated or of a new type; or
- have a guiding effect.

According to Articles 9–11 of the Rules for the Implementation of the Provisions on Case Guidance,⁴⁹ the application of guiding cases by reference involves the following aspects:

- At all levels, in trials of cases that are similar to the guiding cases issued by the Supreme People's Court in terms of basic facts and the application of the law, the courts shall make decisions by reference to the rules of the decision in the applicable guiding cases.
- In dealing with cases, judges shall inquire about applicable guiding cases. Where any applicable guiding case is cited in the decision, the number of the guiding case and the main points of the decision shall be outlined in the reasoning for the decision section.
- If the public prosecution, the parties to the case and their defenders and litigants cite a guiding case as a reason, the judge shall respond in the reasons for the judgment whether the guiding case has been referred to and explain the reasons for the same.
- Guiding cases shall be cited as reasons for a decision but not as the basis for the decision.

4.1.5 Reform and development of China's intellectual property case trials

Patent trials are an important part of the intellectual property trial system and are related to three trial areas: civil, administrative and criminal trials. Since 2012, firmly adhering to the concept that protecting intellectual property is to protect innovation, Chinese courts have put into practice the Opinions on Strengthening Reform and Innovation in Intellectual Property Adjudication and the Opinions on Strengthening the Protection of Intellectual Property Rights.⁵⁰ They have further deepened reform and innovation in the field of intellectual property case trials to ensure the strict protection of intellectual property, resulting in beneficial results, as required in the Guidelines for Building a Powerful Country with Intellectual Property Rights (2021–2035).⁵¹

45 Free Trade Agreement between the Government of the People's Republic of China and the Government of the Republic of Korea, June 1, 2015.

46 Free Trade Agreement between the Government of the People's Republic of China and the Government of Georgia, May 13, 2017.

47 Free Trade Agreement between the Government of the People's Republic of China and the Government of the Republic of Mauritius, Oct. 17, 2019.

48 Provisions concerning Work on Case Guidance (promulgated by the Sup. People's Ct, Nov. 26, 2010, effective Nov. 26, 2010).

49 Rules for the Implementation of the Provisions on Case Guidance (promulgated by the Sup. People's Ct, May 13, 2015, effective May 13, 2015).

50 Opinions on Several Issues concerning Strengthening Reform and Innovation in the Field of Intellectual Property Adjudication (promulgated by the Gen. Off. CPC Cent. Comm. and the Gen. Off. State Council, Feb. 1, 2018, effective Feb. 1, 2018); Opinions on Strengthening the Protection of Intellectual Property Rights (promulgated by the Gen. Off. CPC Cent. Comm. and the Gen. Off. State Council, Nov. 24, 2019, effective Nov. 24, 2019).

51 Guidelines for Building a Powerful Country with Intellectual Property Rights (2021–2035) (promulgated by the State Council, Sep. 22, 2021, effective Sep. 22, 2021).

Continuously improve the capacity to try intellectual property cases. The Supreme People's Court has formulated a series of judicial interpretations on patent infringement, the grant and confirmation of patents, pharmaceutical patents, e-commerce platform and network infringement, monopoly disputes, rules of evidence, preservation of acts, punitive damages and so on. This has helped consistently improve litigation standards in line with the trial rules of intellectual property cases, especially technical patent cases and universal adjudication standards; effectively solved the problems of "difficulty in providing evidence, long duration, low compensation, and high cost" in intellectual property litigation; and significantly increased the cost and price of infringement.

The Supreme People's Court has formulated a series of judicial policies, including the China Program for Judicial Protection of Intellectual Property Rights, Opinions on Comprehensively Strengthening Judicial Protection of Intellectual Property, and the Plan for the Judicial Protection of Intellectual Property Rights by the People's Courts (2021–2025) to promote the high-quality development of intellectual property case trials.⁵² It has exerted the demonstrating and leading role of judicial rules and issued timely guiding cases and typical cases. The Supreme People's Court effectively performs the function of judicial review and supervision of administrative acts to promote the unification of standards for administrative enforcement and judicial adjudication of intellectual property rights. It has strengthened civil judicial protection, equally protected the legitimate rights and interests of Chinese and foreign right holders in accordance with the law, and properly heard major intellectual property cases involving standard-essential patents, information and communication, integrated circuits, artificial intelligence, big data, gene technology and other high technologies and emerging industries.

The Supreme People's Court has significantly improved judicial protection capability and influence, safeguarded the legitimate rights and interests of right holders and service inventors in accordance with the law, and promoted the transfer and transformation of scientific and technological achievements. It also properly handles patent disputes arising from the determination of ownership, transfer of rights and determination of value and handles the distribution of benefits of scientific and technological achievements. China has become the country with the greatest number of intellectual property cases – especially patent cases – and one of the countries with the shortest trial periods. Between 2013 and June 2021, there were 143,000 patent cases concluded by the courts nationwide.

Deepen judicial reform in intellectual property case trials. Since 2014, intellectual property courts have been established in Beijing, Shanghai, Guangzhou and the Hainan free trade port. On January 1, 2019, the Intellectual Property Court of the Supreme People's Court was set up and given the responsibility of further unifying the trial criteria of cases on patent and other intellectual property rights involving professional technologies, putting into operation the major reform task of "establishing a national-level appeal hearing mechanism for intellectual property cases." Special intellectual property trial agencies have been founded in 24 places, including Nanjing, Wuhan and Shenzhen, with cross-regional jurisdiction over intellectual property cases involving professional technologies. The comprehensive "three-in-one" reform of criminal, civil and administrative trials over intellectual property cases has been carried out in an orderly manner in 21 high courts, 164 intermediate courts and 134 primary courts nationwide. Judicial interpretations and judicial policies related to technical investigators have been formulated to continuously improve the mechanism of ascertaining technical facts by technical investigators, technical consulting experts, technical appraisers and expert assistants when participating in litigation activities. A "national court technical investigator pool" and a sharing mechanism have also been established, including more than 450 expert technical investigators covering more than 30 technical fields.

Continuously optimize the working mechanism of intellectual property protection. The working mechanisms of intellectual property protection have been optimized by strengthening guidance on intellectual property cases; establishing a case guidance system consisting of guiding cases, gazetted cases and typical cases; building a database of intellectual property cases and rules for adjudication; providing guidance on strengthening the search of similar cases. This has also been achieved through actively carrying out the pilot work of diversification of simple cases from

52 China Program for Judicial Protection of Intellectual Property Rights (promulgated by the Sup. People's Ct, April 20, 2017, effective April 20, 2017); Opinions on Comprehensively Strengthening Judicial Protection of Intellectual Property (promulgated by the Sup. People's Ct, April 15, 2020, effective April 15, 2020); Plan for the Judicial Protection of Intellectual Property Rights by the People's Courts (2021–2025) (promulgated by the Sup. People's Ct, April 22, 2021).

complicated ones and improving online and offline integration of trial methods to vigorously shorten the duration of intellectual property litigation. The Supreme People's Court, in conjunction with the CNIPA, has established an online cooperation mechanism for the litigation and mediation of intellectual property disputes, improved the judicial confirmation system for administrative mediation agreements and improved the mechanism for the diversified settlement of intellectual property disputes. It has jointly promoted the specialized sharing of data and has continued to cooperate with the CNIPA in sharing patent talents.

Actively participate in international exchanges and cooperation on intellectual property. To comprehensively implement relevant cooperation matters outlined in the Memorandum of Understanding on Strengthening Exchanges and Cooperation signed with WIPO,⁵³ the Supreme People's Court has continuously developed and enriched the scope of cooperation and participated in global intellectual property governance under the WIPO framework. In addition to signing the memorandum of understanding with WIPO, the Supreme People's Court has also co-organized WIPO's "Master Class on Intellectual Property Adjudication," jointly published the "WIPO Collection of Leading Judgments on Intellectual Property Rights – People's Republic of China (2011–2018)"⁵⁴ and participated in the development of the WIPO Lex-Judgments database. It has also coordinated the establishment of the WIPO Arbitration and Mediation Shanghai Service,⁵⁵ which has successfully administered mediation of more than 60 intellectual property disputes involving multinational enterprises and broadened the channels for participation in resolutions of international intellectual property disputes. Judges of the Supreme People's Court have been invited to serve as members of the WIPO Advisory Board of Judges to promote the international exchange of intellectual property judicial protection experiences.

Promote information and intelligence-based intellectual property trials and enforcement. Chinese courts have made full use of smart-court development, accelerated the development of technology-based courts adapted to intellectual property trials and actively used modern technologies such as 5G, augmented reality and artificial intelligence to improve the quality and efficiency of trials. The Rules of Online Litigation of People's Courts and the Provisions on the Trial of Cases by Internet Courts have also been formulated,⁵⁶ and a unified judicial blockchain platform for courts nationwide to support parties in online data storage and verification has been established. The Beijing, Hangzhou and Guangzhou internet courts have been actively exploring new internet judicial models. They have handled a large number of intellectual property cases online and have effectively overcome the impact of COVID-19.

4.2 Overview on patent-related civil cases

4.2.1 Causes of action

The cause of action in a civil case is determined by the nature of the civil legal relationship in dispute between parties of the case. It constitutes an important element in the name of each civil case and an important means for people's courts to manage civil cases. According to the Provisions on the Causes of Action in Civil Cases⁵⁷ and Article 1 of the Provisions on the Trial of Patent Disputes, the causes of action in patent-related civil cases include:

- disputes over the ownership of patent application rights;
- disputes over patent ownership;
- disputes over patent contracts;
- patent infringement disputes;
- disputes over patent counterfeiting;
- disputes over royalties of invention patents during the temporary protection period;
- disputes over rewards and remuneration for inventors or designers of service invention-creations;

53 Memorandum of Understanding on Judicial Exchanges and Cooperation between WIPO and Supreme People's Court of China, April 2017.

54 Supreme People's Court of China and WIPO, *WIPO Collection of Leading Judgments on Intellectual Property Rights – People's Republic of China (2011–2018)* (2019).

55 See www.wipo.int/amc/en/center/specific-sectors/ipoffices/national-courts/china/spc.html

56 Rules of Online Litigation of People's Courts (promulgated by the Sup. People's Ct, June 16, 2021, effective Aug. 1, 2021); Provisions on Several Issues concerning the Trial of Cases by Internet Courts (promulgated by the Sup. People's Ct, Sep. 6, 2018, effective Sep. 7, 2018).

57 Provisions on the Causes of Action in Civil Cases (promulgated by the Sup. People's Ct, Feb. 4, 2008, effective April 1, 2008. Amended up to Doc. No. 346 [2020] of the Sup. People's Ct, promulgated Dec. 29, 2020, effective Jan. 1, 2021).

- disputes over an application for pre-litigation act preservation;
- disputes over an application for pre-litigation property preservation;
- disputes over liabilities for damages due to an application for act preservation;
- disputes over liabilities for damages due to an application for property preservation;
- disputes over the right of authorship of inventors or designers of invention-creations;
- disputes over a declaration of patent non-infringement;
- disputes over the refund of royalties after a declaration of patent invalidation;
- disputes over liabilities for damages due to malicious patent litigation;
- disputes over royalties of standard-essential patents;
- disputes over whether a technical solution falls within the protection scope of a pharmaceutical product patent; and
- other patent disputes.

4.2.2 Jurisdiction

Jurisdiction of civil cases is determined by such provisions in Chapter II of the Civil Procedure Law and in Part 1 of the Interpretation of the Civil Procedure Law.

4.2.2.1 Jurisdiction by court level and territorial jurisdiction

Jurisdiction by court level refers to the practice of defining the acceptance of first-instance civil cases by courts of different hierarchical levels according to certain criteria. According to Articles 17–20 of the Civil Procedure Law, primary people's courts have jurisdiction as courts of first instance over all civil cases unless otherwise stipulated. Intermediate people's courts have jurisdiction as courts of first instance over major cases involving foreign elements, cases with significant impact in the areas over which they exercise jurisdiction and cases determined by the Supreme People's Court. High people's courts have jurisdiction as courts of first instance over civil cases with significant impact in the areas over which they exercise jurisdiction. The Supreme People's Court has jurisdiction as the court of first instance over cases with significant impact in the whole country and cases that should be tried by the Supreme People's Court according to its own opinion.

Regarding the jurisdiction of patent-related civil cases by court level, Article 2 paragraph 1 of the Interpretation of the Civil Procedure Law stipulates the following: "Patent dispute cases shall come under the jurisdiction of intellectual property courts or intermediate people's courts and primary people's courts determined by the Supreme People's Court."

Territorial jurisdiction refers to the division of the jurisdiction of people's courts at the same level to hear cases of first instance based on the scope of jurisdiction of those courts and the places of domicile of the parties. Territorial jurisdiction determines which people's court has jurisdiction after jurisdiction by court level has been determined. Jurisdiction by court level defines the respective jurisdiction of superior and inferior people's courts within the people's court system over civil cases of first instance, while territorial jurisdiction defines the scope of jurisdiction of people's courts at the same level to hear civil cases of first instance. In other words, jurisdiction by court level determines the vertical division of scope for case trials, whereas territorial jurisdiction determines the horizontal division of scope. Territorial jurisdiction needs to be determined based on the characteristics of different civil cases.

According to Article 35 of the Civil Procedure Law, when two or more people's courts each have jurisdiction over a lawsuit, the plaintiff may file a lawsuit in any one of those courts. If the plaintiff files the lawsuit in two or more people's courts with jurisdiction thereof, the people's court that first registers the case shall have jurisdiction.

4.2.2.2 Jurisdiction transfer and designation of jurisdiction

According to Article 36 of the Civil Procedure Law, if a people's court finds that a case it has accepted is not under its jurisdiction, it shall transfer the case to the people's court with jurisdiction, which shall accept the case. If the people's court to which the case is transferred considers that the case does not come under its jurisdiction in accordance with laws and regulations, it shall report to a superior people's court for designation of jurisdiction but shall not further transfer the case at its own discretion. The transfer of jurisdiction is, in essence, a procedure to correct mistakes in the registration of cases and includes transfer to another court at the same level and to a superior or inferior court arising from mistakes in territorial jurisdiction and jurisdiction by court level.

According to Article 37 of the Civil Procedure Law, if a people's court with jurisdiction over a case is unable to exercise jurisdiction due to special reasons, the superior people's court shall designate jurisdiction. A dispute over jurisdiction between people's courts shall be resolved by the disputing courts through consultation. If the consultation fails, the dispute shall be submitted to the people's court that is their common superior people's court for the designation of jurisdiction. In the transfer of jurisdiction, if the court to which a case is transferred considers that the case is not under its jurisdiction, it shall report to the superior people's court for the designation of jurisdiction.

4.2.2.3 Objection and submission to jurisdiction

If a party objects to the jurisdiction over a case after it is accepted by a people's court, the party may raise an objection during the time limit for filing the statement of defense. The people's court shall examine such an objection. If the objection is upheld, the people's court shall rule to transfer the case to another people's court with jurisdiction over the case; if the objection is not upheld, it shall be dismissed. If the party disagrees with the ruling on the objection to jurisdiction, it has the right to appeal to a superior people's court within the statutory time limit.

Where a party does not raise any objection to the jurisdiction over the case and responds to the action with a defense, the party shall be deemed to have agreed that the people's court accepting the case has jurisdiction over the case unless that court is in violation of the provisions regarding jurisdiction by court level and exclusive jurisdiction.

4.2.3 Special provisions on jurisdiction

4.2.3.1 Jurisdiction over patent-related civil cases by court level

According to Article 20 paragraph 1 of the Interpretation of the Civil Procedure Law, patent dispute cases come under the jurisdiction of intellectual property courts or intermediate people's courts and of primary people's courts determined by the Supreme People's Court.

In provinces, municipalities directly under the central government, and autonomous regions that have established intellectual property courts or intellectual property tribunals, patent-related civil cases of first instance come under the centralized jurisdiction of the relevant intellectual property courts or tribunals. In other provinces, municipalities and autonomous regions, patent-related civil cases of first instance come under the jurisdiction of the intermediate people's courts that originally held the jurisdiction.

On October 26, 2018, the Sixth Session of the 13th NPC Standing Committee deliberated and adopted the Decision on the Litigation of Intellectual Property Cases, which came into effect on January 1, 2019. This decision states that the Supreme People's Court shall uniformly hear civil and administrative appeal cases involving patents and other intellectual property rights involving professional technologies.

The Provisions on the Intellectual Property Court also came into effect on January 1, 2019. Article 1 of this judicial interpretation stipulates that the Supreme People's Court shall establish the Intellectual Property Court to hear cases on appeal over patent and other intellectual property rights involving professional technologies. Article 2 of the provisions stipulates the category of cases to be heard by the Intellectual Property Court of the Supreme People's Court:

1. appeal cases filed because the interested parties disagree with the judgments and rulings made by high people's courts, intellectual property courts or intermediate people's courts on first-instance civil cases involving any invention patents, utility models, new plant varieties, layout designs of integrated circuits, technical secrets, computer software or monopoly;
2. appeal cases filed because the interested parties disagree with the judgments and rulings made by the Beijing Intellectual Property Court on first-instance administrative cases involving the granting and confirmation of any invention patents, utility models, design patents, new plant varieties or layout designs of integrated circuits;
3. appeal cases filed because the interested parties disagree with the judgments and rulings made by high people's courts, intellectual property courts or intermediate people's courts on first-instance administrative cases involving any invention

patents, utility models, design patents, new plant varieties, layout designs of integrated circuits, technical secrets, computer software or administrative penalty for monopoly;

4. nationwide significant and complex civil and administrative cases of first instance identified in Items 1, 2 or 3;
5. petitions for retrial, protests, retrials and so on in accordance with the law where adjudication supervision procedures are applicable with respect to legally effective judgments, rulings or written mediation statements of first-instance cases identified in Items 1, 2 or 3;
6. cases of objection to jurisdiction, petitions for reconsideration of penalty or detention decisions, or petitions for extension of a trial term with regard to first-instance cases identified in Items 1, 2 or 3; and
7. other cases that, in the opinion of the Supreme People's Court, should be heard by the Intellectual Property Court.

If a party disagrees with the second-instance judgment or ruling made by the Intellectual Property Court of the Supreme People's Court on a patent-related civil case, it may file a petition for retrial with the Supreme People's Court in accordance with the laws.

With respect to civil cases involving design patents, according to Article 164 of the Civil Procedure Law, if a party disagrees with a first-instance judgment or ruling made by a local people's court, the party has the right to file an appeal with a superior people's court. A party that considers a second-instance judgment or ruling to be wrong may file a petition for retrial in accordance with Article 199 of the Civil Procedure Law.

4.2.3.2 Territorial jurisdiction over some types of patent-related civil cases

4.2.3.2.1 Disputes over patent contracts

The territorial jurisdiction over civil cases of patent contract disputes is determined according to Articles 23 and 34 of the Civil Procedure Law. Such cases may come under the jurisdiction of the people's court at the place where the defendant is domiciled or where the contract is performed; or the parties may agree in writing to be subject to the jurisdiction of the people's court at the place having a connection with the dispute, such as where the defendant is domiciled, where the contract is performed, where the contract is signed, where the plaintiff is domiciled, where the subject matter is located and so on, provided that such an agreement does not violate the provisions of the Civil Procedure Law regarding jurisdiction by court level and exclusive jurisdiction.

4.2.3.2.2 Disputes over patent ownership and over patent infringement

For disputes over ownership of patent application rights and patent rights, territorial jurisdiction is determined after identifying whether the cause of the ownership disputes is a contractual relationship or acts of infringement.

The territorial jurisdiction of lawsuits filed due to acts of patent infringement is determined according to Articles 2–3 of the Provisions on the Trial of Patent Disputes:

Article 2. These lawsuits shall come under the jurisdiction of the people's court at the place where the acts of infringement are committed or where the defendant is domiciled.

The place where the acts of infringement are committed include: the place where acts of manufacturing, using, offering for sale, selling or importing the products alleged to have infringed the invention patent and/or utility model are performed; the place where the act of using the patented process is performed, and the place where the acts of manufacturing, using, offering for sale, selling or importing of the products directly obtained by the patented process are performed; the place where the acts of manufacturing, using, offering for sale, selling or importing the products incorporating the design patents are performed; the place where the act of counterfeiting others' patents is performed; and the place where the result of the said acts of patent infringement occurred.

Article 3. If the plaintiff only sues the manufacturer of the alleged infringing product but does not sue the seller thereof, and the infringing product is manufactured and

sold in different places, then the people's court at the place where the infringing product is manufactured may have jurisdiction; if the plaintiff files a lawsuit with the manufacturer and the seller as co-defendants, the people's court at the place where the infringing product is sold may have jurisdiction.

If the seller is a branch or subsidiary of the manufacturer, and the plaintiff files a lawsuit against the manufacturer for its acts of manufacturing and selling the infringing product, the people's court at the place where the infringing product is sold may have jurisdiction.

4.2.3.2.3 Disputes over whether the technical solution falls within the protection scope of pharmaceutical product patent rights

In accordance with Article 1 of the Provisions on the Patent Rights of Drugs, the party concerned may file a lawsuit in accordance with Article 76 of the Patent Law requesting a judgment on whether the technical solution related to the pharmaceutical product for which registration is applied falls within the protection scope of any pharmaceutical product patent right owned by others. This type of lawsuit comes under the jurisdiction of the Beijing Intellectual Property Court.

4.3 Civil cases of patent infringement

4.3.1 Protection scope of invention patents and utility models

The protection scope of patent rights defines the boundaries of the patent rights. Article 64 paragraph 1 of the Patent Law stipulates the following: "For the patent right of an invention or utility model, the scope of protection shall be confined to the contents of its claims. The description and the drawings attached can be used to explain the content of the claims." According to this provision, the protection scope of an invention patent or utility model is determined based on the content of its claims. Where parties have a dispute over the content of the claims, claims are interpreted to determine the protection scope of patent rights. People's courts must adhere to the adjudication idea of "strengthening protection and balancing interests" and interpret claims in a reasonable manner in accordance with laws, thereby ensuring that the protection scope of patent rights is compatible with the degree of novelty and inventive contribution.

4.3.1.1 Basis for determination

Article 20 paragraph 1 of the Rules for the Implementation of the Patent Law stipulates that claims must contain independent claims and may also contain dependent claims. Claims usually contain several claims, each claim being a complete technical solution. The right holder may choose any claim as the basis of the protection scope of patent rights asserted thereby.

In accordance with Article 1 of the Interpretation of Patent Infringement Dispute Cases, the right holder may choose one or more specific claims before the end of oral arguments in the court of first instance. Where the claims contain several claims, the right holder must specify in its complaint the claims based on which the lawsuit has been filed against the alleged patent infringement. Where such claims are not specified or not clearly specified in the complaint, then the people's court will require the right holder to specify the claims in accordance with Article 1 of the Interpretation (II) of Patent Infringement Dispute Cases. Where the right holder refuses to do so as required by the people's court, the latter may rule to dismiss the lawsuit.

4.3.1.2 Fundamental doctrines and judgment subject for determination

In interpreting claims, people's courts must adhere to the doctrine of compromise to strengthen the role of public notice of claims and increase certainty in the determination of the protection scope of patent rights, thereby providing clear legal anticipation for the public and facilitating the improvement of patent document drafting skills. People's courts must also adhere to the principle of "balancing interests" to protect the legitimate rights and interests of the right holder and encourage inventions and creations while avoiding the improper expansion of patent rights, which may reduce the potential for further innovation and damage public interests and others' lawful rights and interests. Regarding the doctrine of compromise, Article 2 of the Interpretation of Patent Infringement Dispute Cases stipulates the following: "People's courts shall determine the contents of claims as defined in Article 59(1) of the Patent Law based on the words of the claims and the understanding of the claims by a person skilled in the art, after reading the description and drawings."

The doctrine of equivalents is a principle for determining patent infringement. Equivalent technical features are also incorporated in the protection scope of patent rights. Article 13 paragraph 1 of the Provisions on the Trial of Patent Disputes stipulates the following: “the protection scope of a patent right shall be confined to the scope determined by all technical features contained in the claims and shall also include the scope determined by features equivalent to those technical features.”

In a retrial of a dispute over invention patent infringement, *Ningbo Dongfang Movement Plant v. Jiangyin Jinling Hardware Products Co.*,⁵⁸ the Supreme People's Court held the following:

In determining the protection scope of patent rights, people's courts shall neither confine the protection scope of patent rights to the strict literal meaning of the claims nor use the claims as the technical guidance for arbitrary expression. The protection scope of patent rights shall be determined based on the substantial content of the claims. Where the claims do not provide a clear description, the description and drawings may be used for clarification. The protection scope of patent rights may be extended to also cover equivalent features that a person skilled in the art can think of after reading the description and drawings without creative work.

In determining the protection scope of patent rights, “a person skilled in the art” shall be the judgment subject. “A person skilled in the art” are persons of legal fiction, and refer to technical personnel with average knowledge in the technical field related to the concerned patent. They are neither technical experts nor personnel who have no technical knowledge in the field. The protection scope of patent rights shall be confined to the scope of the understanding of the claims by a person skilled in the art after reading the description and drawings.

4.3.1.3 Specific methods for determination

Article 3 of the Interpretation of Patent Infringement Dispute Cases points out the specific methods for the interpretation of claims. It stipulates the following:

People's courts may interpret a claim using the description and drawings, relevant claim(s) in the claims, and the patent examination files. Specially defined expressions for the claims as contained in the description, if any, shall be adhered to.

In case of failure to clarify the meaning of the claims even after application of the abovementioned methods, an interpretation may be made in combination with published documents like reference books and textbooks, as well as the common understanding of the meaning by a person skilled in the art.

The application of this provision involves the following aspects:

- The description, drawings and related claims in the claim, as components of patent-granting documents that are the most closely related to the claims, are usually the best guideline for clarifying expressions in disputes.
- The patent examination files, although not a component of patent-granting documents, are available for public access. Since the expressions of claims have the same meaning in the patent examination procedure and in infringement lawsuits, patent examination files can play an important role in the interpretation of the claims.
- In contrast to the foregoing “internal evidence,” reference books and textbooks are “external evidence,” used only when the internal evidence is insufficient to provide a clear interpretation. The interpretation of claims does not necessarily require the application of these methods individually or jointly. Where the use of the description and drawings is sufficient to clarify the meaning of the claims, there is no need to resort to other means.

Generally, the expressions of the claims are understood as having the meaning that they usually have in the relevant technical field. If, under certain circumstances, the description defines a specific meaning for an expression due to which the protection scope of the claims is sufficiently defined, then that specific definition is taken as the meaning of that expression. At the same time, in interpreting the claims, “the limitations in the description shall not be read into the claims.” For example, illustrative explanations, like embodiments in the description, cannot be used to limit the protection scope of patent rights.

58 MSTZ No. 1 (Sup. People's Ct, 2001).

In a retrial of a dispute over invention patent infringement, *Wuxi Shenglong Cable Materials Plant v. Xi'an Qinbang Telecommunication Materials Co.*,⁵⁹ the Supreme People's Court held that, when a person skilled in the art can clearly determine the meaning of relevant expressions in the claims, and the description does not give specific definitions for relevant expressions in the claims, then the understanding of a person skilled in the art on the contents of the claims prevails, while the contents of the description cannot be used to negate the contents of the claims.

In a retrial of a dispute over invention patent infringement, *Xu Yongwei v. Ningbo Huatuo Solar Energy Technology Co.*,⁶⁰ the Supreme People's Court held that, when using a description and drawings to interpret the claims, an illustrative description therein cannot be used to limit the protection scope of the patent right because embodiments are only illustrations of the invention.

In a retrial of a dispute over utility model patent infringement, *Shenzhen Lanying Hardware and Plastic Products Plant v. Luo Shizhong*,⁶¹ the Supreme People's Court held that, when a description does not give specific definitions for expressions in the claims, the interpretation can generally be made based on the usual meaning as understood by a person skilled in the art rather than by narrowing the meaning of the expressions to the content reflected by a specific mode of carrying out the utility model described in the description.

With respect to technical terms created by patent applicants, in a retrial of a dispute over utility model patent infringement, *Shanghai Modiluke Locks Manufacturing Plant v. Shanghai Gujian Locks Co.*,⁶² the Supreme People's Court held that patent applicants are allowed to use technical terms created in drafting patent application documents to meet the objective need for describing the new technical solutions of patents. However, as the meanings of such technical terms are not known to a person skilled in the art, applicants are obliged to give clear and correct definitions, explanations or descriptions for such technical terms in the claims or the description where they are used. When such explanations or definitions are absent, then the working method, function and effect of the technical terms should be identified by reference to the background art, the purpose of the invention, technical effects and so on as recited in the claims, description and drawings so that the meanings of such technical terms in the overall technical solution can be determined.

With respect to examination files, Article 6 of the Interpretation (II) of Patent Infringement Dispute Cases stipulates the following:

People's courts may use another patent related to the involved patent due to a divisional application as well as the patent examination files of that other patent and effective judgments/rulings on patent granting and confirmation, to interpret the claims of the involved patent.

Patent examination files shall include written materials submitted by patent applicants or patentees during the patent examination, reexamination, and invalidation procedures, as well as the notices on examination opinions, meeting minutes, oral hearing records, effective decisions on patent reexamination requests or requests for declaration of patent invalidity, etc., issued by the patent administration department under the State Council.

4.3.1.4 Interpretation of functional features

Article 4 of the Interpretation of Patent Infringement Dispute Cases stipulates the following:

For technical features in the claims that are expressed in terms of functions or effects, people's courts shall determine the contents of such technical features in combination with the mode of carrying out the functions or effects and its equivalent mode(s), as depicted in the description and drawings.

As a type of technical feature with a relatively special nature, functional features define the protection scope of patent rights through the functions or effects to be achieved by relevant

59 MTZ No. 3 (Sup. People's Ct, 2012).

60 MTZ No. 64 (Sup. People's Ct, 2011).

61 MTZ No. 248 (Sup. People's Ct, 2011).

62 MTZ No. 113 (Sup. People's Ct, 2013).

technical features rather than through the specific technical means to achieve those functions or effects. As a result, the literal meaning of “functional features” is so extensive that it covers all modes of carrying out the invention that can achieve those functions or effects regardless of whether the modes already exist before the filing date of the patent or are discovered or invented after the filing date, whether the right holders are aware of them on the filing date or whether they are disclosed in the description.

In Part II(2) of the Guidelines for Patent Examination,⁶³ although it is permitted to use functional or effect-based features to define an invention in the claims, many restriction provisions are also made for this type of technical feature, requiring that “the use thereof shall be avoided as far as possible” (Part II(2) Article 26.4 of the Guidelines for Patent Examination). In a patent infringement lawsuit, if still following the general rules of interpreting claims to interpret the protection scope of “functional features” as covering all modes of carrying out the invention that can achieve those functions or effects, the protection scope of the patent right will not be compatible with the innovation degree and the information disclosed in the patent, inevitably unnecessarily limiting subsequent improvement and innovation and negatively affecting technological development and social and economic advances. Therefore, Article 4 of the Interpretation of Patent Infringement Dispute Cases offers a special provision regarding the interpretation of “functional features” such that the protection scope of patent rights can be compatible with the innovation degree of patents and the contents disclosed in the description and drawings, thereby balancing the interests of the public and the patent holders and leaving necessary space for subsequent improvement and innovation. According to current practices in patent examination, in rare instances, modes of carrying out the inventions are not described in the description and drawings; therefore, the expression “in combination with” is used in Article 4.

Determining whether a disputed technical feature is a “functional feature” has an important effect on the protection scope of a patent right. In this respect, Article 8 of the Interpretation (II) of Patent Infringement Dispute Cases further stipulates the following:

A functional feature refers to a technical feature in which the structures, components, steps, conditions, or the relations among them are defined by their functions or the effects achieved in the invention-creation, unless a mode of carrying out the invention for achieving the above functions or effects can be directly and specifically determined by a person skilled in the art by reading the claims alone.

According to this provision, in determining whether a disputed technical feature is a “functional feature,” it is necessary to not only consider the literal meaning of the expression of the technical feature but also incorporate the technical feature into the overall technical solution defined by the claims, for understanding. For a technical feature containing a specific function or effect, if a person skilled in the art can directly and specifically determine the mode for achieving that function or effect by reading the claims alone, then the technical feature is not a “functional feature” as stipulated in Article 4 of the Interpretation of Patent Infringement Dispute Cases. It should be noted the technical features stated in the above proviso are determined based on the knowledge and capability of a person skilled in the art, and relevant evidence should be produced by the concerned parties.

In an appeal of a dispute over invention patent infringement, *Valeo Cleaning System Co. v. Xiamen Lukasi Automotive Parts Co.*,⁶⁴ the Supreme People’s Court further specified that, if a technical feature in the claims of a patent has defined or implied specific structures, components, steps, conditions or the relations among them, then it is not a functional feature, even if it defines the functions or effects that can be achieved thereby simultaneously.

In a retrial case over utility model patent infringement, *Linhai Linong Machinery Plant v. Lu Jie*,⁶⁵ the Supreme People’s Court held that, if, apart from defining functions or effects, a technical feature also defines the structural feature corresponding to those functions or effects, and a person skilled in the art can directly and specifically determine the mode for achieving such a

63 Guidelines for Patent Examination (promulgated by China National Intellectual Property Administration (CNIPA), Jan. 21, 2010, effective Feb. 1, 2010. Amended up to Notice No. 391 of CNIPA, effective Jan. 15, 2021).

64 *Zuigao Renmin Fayuan Zhidao Anli* (Sup. People’s Ct Guiding Case) No. 115, Dec. 24, 2019.

65 MS No. 1804 (Sup. People’s Ct, 2017).

structural feature by reading the claims alone, and such a mode can achieve those functions or effects, then this technical feature, which simultaneously defines the structure and the functions or effects, is not a functional feature.

4.3.1.5 Use-environment features

Article 9 of the Interpretation (II) of Patent Infringement Dispute Cases stipulates the following: “Where an alleged infringing technical solution cannot be applied for the use environment defined by the use environment features in the claims, the people’s courts shall determine that the alleged infringing technical solution does not fall within the protection scope of the patent right.”

In a retrial of a dispute over invention patent infringement, *Shimano Inc. v. Ningbo Richeng Industry and Trade Co.*,⁶⁶ the Supreme People’s Court held that the use-environment features recited in the claims are necessary technical features that can help define the protection scope of claims; however, to what degree use-environment features can define the protection scope of claims needs to be determined on a case-by-case basis. The general understanding is that the subject matter to be protected *can* be – rather than *must* be – used in such a use environment, unless a person skilled in the art can specifically and reasonably conclude that the subject matter protected must be used in such a use environment after reading the claims, description and the patent examination files.

4.3.1.6 Closed composition claims

Article 7 of the Interpretation (II) of Patent Infringement Dispute Cases stipulates the following:

Where an alleged infringing technical solution has additional technical features based on all technical features contained in the closed composition claims, the people’s courts shall determine that the alleged infringing technical solution does not fall within the protection scope of the patent right, unless the additional technical features are unavoidable impurities that are present in normal amounts.

The closed composition claims stated in the preceding paragraph generally do not include claims of traditional Chinese medicine composition.

Although the Guidelines for Patent Examination have been amended several times, the provisions are consistent with respect to the typical limitations for open claims and closed claims and in the interpretation rules thereof. For example, the 2006 Guidelines for Patent Examination⁶⁷ stipulates, in the general rules for claims, the following:

Usually, open claims should use expressions like “comprising,” “including,” or “consisting essentially of,” which are interpreted as possibly containing additional structural elements or method steps not recited in the claims. Closed claims should use the expression “consisting of,” which is usually interpreted as excluding additional structural elements or method steps not recited in the claims.

Despite subsequent amendments, the Guidelines for Patent Examination have maintained the same provisions on closed composition claims (i.e., that they must not contain additional components other than the features recited in the claims, except for unavoidable impurities that are present in normal amounts).

Through long-term practice in patent examination and adjudication, the foregoing drafting manner and interpretation rule have become widely accepted by the industry. The interpretation rule stipulated in Article 7 paragraph 1 of the Interpretation (II) of Patent Infringement Dispute Cases is consistent with that in the Guidelines for Patent Examination. When applying for patents, patentees may make reasonable choices between open claims, closed claims and closed active component claims to obtain appropriate protection coverage.

The exclusion of other components is one of the inherent features of closed claims. If an alleged infringing technical solution contains additional components, it can be deemed as not “covering”

⁶⁶ MTZ No. 1 (Sup. People’s Ct, 2012).

⁶⁷ Guidelines for Patent Examination (2006) (promulgated by China National Intellectual Property Administration (CNIPA), May. 24, 2006, effective July 1, 2006).

all technical features and thus not falling within the protection scope of the patent right. If, for any reason, the patentee has chosen closed claims with a relatively small protection scope in a patent-granting procedure and due to which the protection scope of the claims of the granted patent is not as broad as expected, then the patentee, having failed to assert a broader protection scope despite having had the opportunity to do so, bears the corresponding legal consequences for the same. In other words, in a patent infringement lawsuit, the patentee's assertion that its closed claims do not exclude other undefined components shall not be supported.

In a retrial of a dispute over invention patent infringement, *Shanxi Zhendong Taisheng Pharmaceutical Co. v. Hu Xiaoquan*,⁶⁸ the Supreme People's Court held that closed claims should usually be interpreted as excluding structural elements or method steps not recited in the claims. Closed composition claims should usually be interpreted to mean that the composition contains the listed components, excluding all other components except for impurities present in normal amounts (excipients are not impurities). By choosing closed claims, patentees have indicated that they specifically intend to exclude other undefined structural elements or method steps from the protection scope of the patent rights and, therefore, cannot subsequently recapture them into the protection scope through applying the doctrine of equivalents.

In a retrial of a dispute over invention patent infringement, *Hebei Xinyu Welding Co. v. Yichang Houwang Welding Co.*,⁶⁹ the Supreme People's Court held that closed claims constitute a special type of claim that uses specific words or expressions to confine the protection scope to cover only the technical features specifically recited in the claims and the equivalents thereof, but excludes other components, structures or steps. Therefore, with respect to closed claims, if an alleged infringing product contains additional features apart from the technical features specifically recited in the claims, it shall be determined as not falling within the protection scope of the claims.

4.3.1.7 Handling of errors or defects in claims

According to Articles 45–46 of the Patent Law, from the date of the announcement of the grant of a patent right by the patent administration department of the State Council, any entity or individual may request the patent administration department to declare the patent right invalid. The patent administration department will then examine the request for declaring invalidation of a patent right and make a decision on it. If the parties concerned refuse to accept the decision, they may file an administrative lawsuit in the people's court. Therefore, in a civil case involving patent infringement, people's courts cannot directly examine the validity of the patent and declare it invalid. However, with respect to ambiguities and manifest errors in claims, people's courts can make corresponding determinations in accordance with the laws.

With respect to manifest errors in claims and description, Article 4 of the Interpretation (II) of Patent Infringement Dispute Cases stipulates the following:

Where the grammar, characters, punctuations, figures, symbols, etc. in the claims, the description, and drawings are ambiguous, but a person skilled in the art may derive a sole understanding by reading the claims, the description and drawings, the people's courts shall make a determination according to such a sole understanding.

According to this provision, despite ambiguities in the claims and other patent documents, if a person skilled in the art can derive a sole understanding, the people's courts shall correct the errors based on such an understanding. While emphasizing the basic orientation of the public notice of claims, it is necessary to keep some flexibility in interpreting the claims to avoid mechanistic submission to literal meanings so that patents with true technological contributions can be adequately protected.

In a retrial of a dispute over invention patent infringement, *Wuxi Shenglong Cable Materials Plant v. Xi'an Qinbang Telecommunication Materials Co.*,⁷⁰ the Supreme People's Court held that, when manifest errors exist in specific expressions in the claims, if a person skilled in the art can specifically and directly correct the meaning of the specific expressions therein without any doubt by reference to relevant contents in the description and drawings, then these expressions are to be interpreted as having the corrected meaning.

68 MTZ No. 10 (Sup. People's Ct, 2012).

69 MSZ No. 1201 (Sup. People's Ct, 2013).

70 MTZ No. 3 (Sup. People's Ct, 2012).

In a retrial of a dispute over utility model patent invalidation, *Hong Liang v. Patent Reexamination Board*,⁷¹ the Supreme People's Court held that "manifest errors" refers to errors in technical features that a person skilled in the art can identify immediately after reading the claims, based on their common technical knowledge, and the sole correct understanding of which such a person may be able to determine immediately after reading the relevant contents of the description and drawings, taking into account their common technical knowledge. The existence of manifest errors does not render the boundary of claims ambiguous. Where manifest errors exist in the claims, if a person skilled in the art can determine the sole correct understanding thereof based on the relevant contents of the description and drawings, then the technical solution protected by the claims is determined based on the corrected understanding.

4.3.2 Determination of infringement of invention patents and utility models

With respect to the protection scope of patent rights, Article 64 of the Patent Law stipulates the following: "The protection scope of an invention or utility model patent shall be determined by the contents of its claims, and the description and drawings can be used to interpret the content of the claims." This provision is clarified by Article 13 paragraph 1 of the Provisions on the Trial of Patent Disputes, which states that "the protection scope of a patent right shall be confined to the scope determined by all technical features recited in the claims, and shall also include the scope determined by features equivalent to those technical features."

According to these provisions, patent infringement includes two circumstances: first, that the alleged infringing technical solution falls within the protection scope of the patent right defined by "all technical features recited in the claims," which is a literal infringement; and second, that the alleged infringing technical solution falls within the "scope determined by equivalent features," which is an infringement under the doctrine of equivalents.

In a retrial of a dispute over utility model patent infringement, *Bai Wanqing v. Chengdu Nanxun Commodity Sales Service Center*,⁷² the Supreme People's Court held that the protection scope of patent rights must be clear. When manifest defects exist in the expressions of the claims of a utility model patent, if the protection scope of the patent right is obviously unclear because the specific meaning of technical terms in the claims cannot be determined by reference to the description and drawings of the involved patent, well-known general knowledge in the art, relevant prior art and so on, then it would be impossible to compare this with the alleged infringing technical solution. As a result, the alleged infringing technical solution cannot be identified as constituting an infringement.

4.3.2.1 Literal infringement

Article 13 paragraph 1 of the Provisions on the Trial of Patent Disputes stipulates the following: "The protection scope of a patent right shall be confined to the scope determined by all technical features recited in the claims." Article 7 of the Interpretation of Patent Infringement Dispute Cases further stipulates the following:

In determining whether an alleged infringing technical solution falls within the protection scope of the patent right, the people's courts shall examine all technical features recited in the claims asserted by the right holder.

If an alleged infringing technical solution contains technical features identical or equivalent to all technical features recited in the claims, the people's courts shall determine that such a technical solution falls within the protection scope of the patent right; if the alleged infringing technical solution lacks one or more technical features recited in the claims, or has one or more technical features that are neither identical nor equivalent, the people's courts shall determine that the alleged infringing technical solution does not fall within the protection scope of the patent right.

According to these provisions, the "all elements rule" applies in determining the infringement of invention patents and utility models. An alleged infringing technical solution will be determined as constituting a literal infringement only when it contains all of the technical features recited in the claims. Where the alleged infringing technical solution does not contain one or more

⁷¹ XTZ No. 13 (Sup. People's Ct, 2011).

⁷² Sup. People's Ct Guiding Case No. 55. Nov. 19, 2015.

technical features recited in the claims, it does not constitute infringement. Incorporation of additional technical features into the alleged infringing technical solution, if any, does not, in principle, affect the determination of infringement, provided that, in the case of closed claims, the additional technical features of the alleged infringing technical solution are considered.

In a retrial of a dispute over utility model patent infringement, *Zhang Jianhua v. Shenyang Zhilian Highrise Building Heating Technology Co.*,⁷³ the Supreme People's Court held that, if the alleged infringing technical solution lacks a technical feature recited in the claims, which leads to the deterioration of technical effects, it shall be determined as not falling within the protection scope of the patent right.

With respect to dependent claims, Article 1 paragraph 2 of the Interpretation of Patent Infringement Dispute Cases specifically stipulates the following:

Where a right holder asserts that the protection scope of the patent right shall be determined based on dependent claims, the people's courts shall determine the protection scope thereof based on both the additional technical features recited in such dependent claims and the technical features of the claims being referred.

Article 5 of the Interpretation (II) of Patent Infringement Dispute Cases further stipulates the following: "all technical features, whether recited in the preamble portion and characterizing portion of independent claims or recited in the reference portion and defining portion of dependent claims, have a defining role." Therefore, the protection scope of dependent claims is defined by technical features of two aspects: the additional technical features that are recited in the dependent claims, and all technical features in the claims being referred to in the dependent claims. If a claim being referred to is still a dependent claim, then it is necessary to further trace it until the independent claim that is referred to in the end is identified.

With respect to the defining role of the title of the subject matter in claims, in a retrial of a dispute over invention patent infringement, *Xinghe Industry Co. v. Jiangsu Runde Pipes Industry Co.*,⁷⁴ the Supreme People's Court held that the title of the subject matter recited in claims should be considered, and its actual defining role in the protection scope of the patent right depends on what impact it has on the subject matter to be protected by the claims.

4.3.2.2 Infringement under the doctrine of equivalents

With respect to infringement under the doctrine of equivalents, Article 13 paragraph 2 of the Provisions on the Trial of Patent Disputes stipulates the following:

Equivalent features are features that adopt basically the same means to perform basically the same functions and achieve basically the same effects as the technical features recited in a claim and a person skilled in the art can think of without creative work when the alleged act of infringement occurs.

The doctrine of equivalents is an important approach for overcoming the limitations of claims in expressions and for realizing the fair protection of patent rights. The doctrine of equivalents is used to compensate for the insufficiency of literal infringement. At the same time, the overly broad and excessive application of this doctrine is prevented through appropriately strict limitations, thereby avoiding the improper expansion of the protection scope of patent rights based on the doctrine, which may limit innovation and damage public interests. Limitations to the doctrine of equivalents are primarily reflected in two aspects. First, the doctrine is applied to the technical features in the claims but not to the technical solution as a whole, and the determination criteria are relatively strict and as objective as possible. Second, the estoppel rule and dedication rule are used to limit the application of the doctrine of equivalents. A determination of infringement under the doctrine of equivalents is made based on the circumstances at the time the alleged act of infringement occurred.

Applying the doctrine of equivalents expands the protection scope literally defined by the claims and adds uncertainty to the determination of the protection scope, which may affect the

⁷³ MTZ No. 83 (Sup. People's Ct, 2009).

⁷⁴ MSZ No. 790 (Sup. People's Ct, 2013).

reasonable expectation of the public on the protection scope of patent rights. Therefore, the determination of infringement under the doctrine of equivalents must adhere to the principle of prudent application in accordance with the laws. In terms of the determination criteria, two conditions must be met simultaneously to permit a finding of equivalent features. First, these features must adopt basically the same means to perform basically the same functions and achieve basically the same effects as the technical features recited in the claims. Second, a person skilled in the art is able to think of these features without creative work (i.e., they are obvious to a person skilled in the art). Article 12 of the Interpretation (II) of Patent Infringement Dispute Cases stipulates that, when expressions like “at least,” “not more than,” and so on are recited in the claims to define numeric features, and a person skilled in the art concludes that the patented technical solution has specifically emphasized the limiting role of such expressions in technical features after reading the claims, the description and drawings, then a right holder’s argument that numeric features different therefrom constitute equivalent features shall be rejected by people’s courts.

In a retrial of a dispute over invention patent infringement, *Ningbo Dongfang Movement Plant v. Jiangyin Jinling Hardware Products Co.*,⁷⁵ the Supreme People’s Court held the following:

The patented technical solutions should be ascertained and the space for public to freely make use of technologies to achieve invention-creations should be available, therefore reasonable protection for patentees should be determined along with sufficient legal certainty for the public. In accordance with this principle, the protection scope of an invention patent or utility model includes the scope defined by necessary technical features specifically recited in the claims, and the features equivalent to those being recited.

In a retrial of a dispute over utility model patent infringement, *Beijing Jerrat Damping Elastomer Technical Research Center v. Beijing Jinzi Tianhe Buffer Technology Co.*,⁷⁶ the Supreme People’s Court held that, if an alleged infringing technical solution using technical means is opposite to technical features specifically recited in the claims, producing opposite technical effects, and the purpose of the invention is unachieved, then infringement under the doctrine of equivalents is not found.

In a retrial of a dispute over utility model patent infringement, *Sun Junyi v. Renqiu Bocheng Water Heating Apparatus Co.*,⁷⁷ the Supreme People’s Court held that, when applying the doctrine of equivalents, the level of technological development at the filing date and at the time of the alleged acts of infringement should be considered so as to prevent technical features in the patented technical solution from simply being replaced by new technologies occurring after the filing date for the purpose of avoiding infringement and so to determine the reasonable boundaries of the protection scope of patent rights.

4.3.2.3 Judgment on infringement of functional features

With respect to judgments on infringement related to functional features, Article 8 paragraph 2 of the Interpretation (II) of Patent Infringement Dispute Cases stipulates the following:

Where comparing with the technical features that are indispensable to achieve the functions or the effects mentioned in the preceding paragraph as recited in the description and drawings, the corresponding technical features of the alleged infringing technical solution adopt basically the same means to perform the same functions and achieve the same effects, and can be thought of by a person skilled in the art without creative work upon the occurrence of the alleged act of infringement, the people’s courts shall then determine that the said corresponding technical features are identical or equivalent to the functional features.

In this provision, “the said corresponding technical features [determined to be] identical or equivalent to the functional features” are different from the “equivalent features” stipulated in Article 13 paragraph 2 of the Provisions on the Trial of Patent Disputes. First, the bases of comparison are different: the former involves the technical features recited in the description and

75 MSTZ No. 1 (Sup. People’s Ct, 2001).

76 MSZ No. 1146 (Sup. People’s Ct, 2013).

77 MSZ No. 740 (Sup. People’s Ct, 2015).

drawings that are indispensable for achieving the functions or the effects, while the latter involves the features recited in the claims. Second, the criteria are different: the former requires the functions and effects to be the same, while the latter requires the functions and effects to be *basically* the same.

In a retrial of a dispute over utility model patent infringement, *Linhai Linong Machinery Plant v. Lu Jie*,⁷⁸ the Supreme People's Court held that the identification of equivalent features (in a case of infringement under the doctrine of equivalents) is not the same as the identification of "the corresponding technical features [determined to be] equivalent to the functional features" according to Article 8 paragraph 2 of the Interpretation (II) of Patent Infringement Dispute Cases. Although both require "basically the same means" and "can be thought of without creative work," they have essential differences in two main aspects. First, they have different objects of application and different bases of comparison. "Equivalent features," as stipulated in Article 13 of the Provisions on the Trial of Patent Disputes, applies to a broader range of objects, involving technical features other than "functional features," and the bases of comparison are the technical features recited in the claims. By contrast, Article 8 paragraph 2 of the Interpretation (II) of Patent Infringement Dispute Cases applies to the "functional features" stipulated, and the bases of comparison are the "technical features" recited in the description and drawings "that are indispensable" for achieving the functions or effects of the functional features. Second, the identification criteria are different. The "equivalent features" stipulated in Article 13 of the Provisions on the Trial of Patent Disputes are identified against the criteria of "performing basically the same functions" and "achieving basically the same effects," while "the corresponding technical features [determined to be] equivalent to the functional features" according to Article 8 paragraph 2 of the Interpretation (II) of Patent Infringement Dispute Cases has stricter identification criteria because these features must "perform the same functions and achieve the same effects."

4.3.2.4 Estoppel

The estoppel rule, as a necessary limitation to the doctrine of equivalents, aims to oblige parties to act in good faith during litigation activities and avoid interpreting claims in infringement litigation in ways different from those in related administrative patent-granting and confirmation procedures. The estoppel rule thus ensures that the protection scope of patent rights is determined in a reasonable manner and that the interests among patentees, alleged infringers and the public are balanced. Article 6 of the Interpretation of Patent Infringement Dispute Cases stipulates the following: "Where the patent applicant or the patentee surrenders a technical solution by observation or amendments to the claims and description during the patent-granting or invalidation procedure, the right holder's argument to regain the surrendered technical solution in a patent infringement lawsuit shall not be upheld by people's courts." Therefore, patent examination files are not only the basis for claim interpretation but also involve the application of the estoppel rule in determining infringement.

With respect to the understanding of "surrendered technical solution," Article 13 of the Interpretation (II) of Patent Infringement Dispute Cases stipulates the following:

Where the right holder has proved that the narrowing amendments to the claims, description, and drawings or observation made by the patent applicant or the patentee are specifically denied in patent granting and confirmation procedures, the people's courts shall determine that no technical solution is surrendered by such amendments or observation.

In this provision, the phrase "specifically denied" includes being denied by the CNIPA during the patent examination procedure and being denied by a people's court in administrative litigation. According to this provision, a right holder bears the burden of proving that the narrowing amendments have been "specifically denied"; otherwise, the surrender of a technical solution results in the application of the estoppel rule.

In a retrial of a dispute over utility model patent infringement, *Shen Qiheng v. Shanghai Shengmao Traffic Engineering Co.*,⁷⁹ the Supreme People's Court held the following:

⁷⁸ MS No. 1804 (Sup. People's Ct, 2017).

⁷⁹ MSZ No. 239 (Sup. People's Ct, 2009).

In determining whether there is an infringement under the doctrine of equivalents, even though the alleged infringer does not assert the application of the estoppel rule, the people's courts may apply the estoppel rule to impose necessary limitation to the scope of equivalents based on facts that have been found, to determine the protection scope of the patent right in a reasonable manner.

In a retrial of a dispute over utility model patent infringement, *Zhongyu Electronics (Shanghai) Co. v. Shanghai Jiuying Electronic Technology Co.*,⁸⁰ the Supreme People's Court held that, if an independent claim is declared invalid whereas the dependent claims remain valid, and the patentee does not surrender the claim, then the estoppel rule shall not be applied to those dependent claims and the application of the doctrine of equivalents shall not be limited.

In a retrial of a dispute over invention patent infringement, *Cao Guilan v. Chongqing Lifan Automobile Sales Co.*,⁸¹ the Supreme People's Court held that, in judging whether observations made by right holders are "specifically denied," the people's courts shall consider whether the narrowing statements with respect to the technical solution made by right holders are finally accepted by the decision-makers and whether, in that case, the patent was granted or was declared valid.

4.3.2.5 Issues related to process patent infringement

4.3.2.5.1 Determination of sequence of steps in process claims

Process patents are mainly defined by steps, a sequence of steps, process parameters and conditions and so on. With respect to the sequence of steps of a process patent, Article 11 of the Interpretation (II) of Patent Infringement Dispute Cases stipulates the following:

Where specific sequence of technical steps is not explicitly recited in process claims but can be directly and specifically concluded by a person skilled in the art after reading the claims, description, and drawings, then the people's courts shall determine that such a sequence of steps has a defining role with respect to the protection scope of the patent right.

In a retrial of a dispute over invention patent infringement, *OBE – Werk Ohnmacht and Baumgartner GmbH v. Zhejiang Kanghua Glasses Co.*,⁸² the Supreme People's Court held that, for a process invention with sequences of steps, both the steps and their sequences have a defining role in the protection scope of the patent right. The sequences of steps in the claims should not be ignored on the ground that the sequences are not recited in the claims. Instead, whether the steps are performed in a particular sequence should be determined from the perspective of a person skilled in the art by reference to the description and drawings, examination files, the overall technical solution recited in the claims and the logical relations between the steps.

In a retrial of a dispute over invention patent infringement, *Zhejiang Lexueer Household Supplies Co. v. Chen Shundi*,⁸³ the Supreme People's Court held that, in determining whether the sequence of steps of a process patent has a defining role in the protection scope of the patent right, which can limit the application of the doctrine of equivalents in the case of interchangeable step exits, the key is to consider whether those steps must be performed in a particular sequence and whether the interchangeable steps can bring about substantial differences in technical functions or technical effects.

4.3.2.5.2 Product-by-process claims

All features recited in the claims have a defining role in determining the protection scope of patent rights. According to Article 10 of the Interpretation (II) of Patent Infringement Dispute Cases, with respect to a technical feature in the claims in which a product is defined by its manufacturing method and where the manufacturing method of the alleged infringing product is neither identical nor equivalent to that method recited in the claim, then the people's court shall determine that the alleged infringing technical solution does not fall within the protection scope of the patent right. Thus, for a product claim containing a technical feature in the form of a

⁸⁰ MTZ No. 306 (Sup. People's Ct, 2011).

⁸¹ MS No. 1826 (Sup. People's Ct, 2017).

⁸² MSZ No. 980 (Sup. People's Ct, 2008).

⁸³ MTZ No. 225 (Sup. People's Ct, 2013).

manufacturing method, it is necessary to consider whether the alleged infringing product has a technical feature identical or equivalent to that manufacturing method.

4.3.2.5.3 Protection scope of process patents and infringement judgment

According to Article 11 of the Patent Law, acts of infringement with respect to process patent include “using the patented process” and “using, offering to sell, selling, and importing products obtained directly from the patented process.”

The understanding of “products obtained directly from the patented process” has a direct impact on the protection scope of a process patent. In this respect, Article 13 of the Interpretation of Patent Infringement Dispute Cases further stipulates the following:

Where a product is originally obtained from a patented process, the people's courts shall determine it as “the product directly obtained from the patented process,” as stipulated in Article 11 of the Patent Law. Where a subsequent product is obtained from further processing or treatment of the original product, the people's courts shall also determine such processing or treatment as “using products obtained directly from the patented process,” as stipulated in Article 11 of the Patent Law.

Article 20 of the Interpretation (II) of Patent Infringement Dispute Cases further stipulates the following:

Where a subsequent product, obtained from processing or treatment of a product that is directly obtained from the patented process, is further processed or treated, the people's courts shall determine that the act does not constitute “using products obtained directly from the patented process,” as stipulated in Article 11 of the Patent Law.

In an appeal of a dispute over invention patent infringement, *Shenzhen Dunjun Technology Co. v. Shenzhen Jixiang Tengda Technology Co.*,⁸⁴ the Supreme People's Court held that, if an alleged infringer solidifies the substantial contents of a patented process in the alleged infringing product for production and operation purposes, and this act or the result thereof plays an irreplaceable and substantial role in covering all technical features of the patent claims so that end users can naturally reproduce the patented process during normal use of the alleged infringing product, then the alleged infringer shall be determined as having exploited the patented process and thus as having infringed the right of the patentee.

4.3.2.5.4 Burden of proof in product-manufacturing process invention patent infringement cases

With respect to a patent for the invention of a manufacturing process for a new product, Article 66 paragraph 1 of the Patent Law stipulates, regarding the burden of proof, the following:

Where a patent infringement dispute involves a patent for an invention for a manufacturing process of a new product, the entity or individual manufacturing the identical product shall provide evidence to prove that the manufacturing process used in the manufacture of its or his product is different from the patented process.

This provision corresponds to Article 34 of the TRIPS Agreement.

Determination of whether an alleged infringing product constitutes a “new product” directly affects on which party the burden of proof rests. Article 17 of the Interpretation of Patent Infringement Dispute Cases stipulates the following: “Where a product or the technical solution for manufacturing the product is known to the public in China or abroad before the filing date, the people's courts shall determine that the product is not a new product as stipulated in Article 61 of the Patent Law.” This provision is co-opted from the novelty provisions of the Patent Law, according to which, if either a product or the technical solution for manufacturing the product is known to the public in China or abroad before the filing date, then the product does not constitute a new product.

84 Sup. People's Ct Guiding Case No. 159, July 23, 2021.

In a retrial of a dispute over invention patent infringement, *Yiwu Beige Plastic Products Co. v. Air-Paq Composite Material (Shanghai) Co.*,⁸⁵ the Supreme People's Court held that, if the right holder provides preliminary evidence to prove that a product manufactured from the patented process is a new product, then the preliminary evidence should be able to show that the involved product is significantly different to the same type of products existing before the filing date in terms of components and structure, or quality, performance and function.

In a retrial of a dispute over invention patent infringement, *CSPC Ouyi Pharmaceutical Co. v. Zhang Xitian*,⁸⁶ and in an appeal of a dispute over invention patent infringement, *Eli Lilly Co. v. Hansoh Pharma*,⁸⁷ the Supreme People's Court held that, for a new product-manufacturing process invention patent, prerequisites should be met to place the burden of proof on the alleged infringer to prove that the process for manufacturing the alleged infringing product is different from the patented process, and the right holder should be able to prove that the product manufactured from the patented process is a new product and is identical to the product manufactured by the alleged infringer. It was further pointed out in *CSPC Ouyi Pharmaceutical* that, to determine whether a process patent is a patent for the invention of a manufacturing process for a new product, the "product obtained directly from the patented process" – which refers to a product originally obtained from the patented process rather than a product subsequently obtained by further treatment of the product originally obtained – shall be considered.

If a product manufactured from a patented process is not a "new product," Article 66 paragraph 1 of the Patent Law does not directly apply to place the burden of proof on the alleged infringer to prove that their process for manufacturing the alleged infringing product is different from the patented process. However, when the evidence produced by the patentee meets particular requirements, the corresponding burden of proof may be placed on the alleged infringer. In this respect, Article 3 of the Provisions on Evidence in Civil Procedures involving Intellectual Property Rights stipulates the following:

the plaintiff of a patent infringement dispute case shall produce evidence to prove the following facts:

- (1) the product manufactured by the defendant is identical to the product manufactured from the patented process;
- (2) the probability of manufacturing the alleged infringing product from the patented process is relatively high; and
- (3) the plaintiff has made reasonable efforts to prove that the defendant has used the patented process.

After the plaintiff has produced evidence to prove the above, the people's courts may require the defendant to produce evidence to prove that the process for manufacturing its product is different from the patented process.

In a retrial of a dispute over invention patent infringement, *Weifang Henglian Pulp and Papermaking Co. v. Yibin Changyi Pulp Co.*,⁸⁸ the Supreme People's Court held that, where a patentee can prove that the alleged infringer has manufactured an identical product but cannot prove that the alleged infringer has used the patented process after reasonable efforts, and if it is highly probable that the identical product is manufactured from the patented process based on the specific circumstances of the case, known facts and daily life experience, and the alleged infringer refuses to cooperate in the collection or preservation of evidence by the people's courts, then it can be presumed that the alleged infringer has used the patented process.

4.3.2.5.5 Filed process and actual manufacturing process of alleged infringing pharmaceutical products

In an appeal of a dispute over invention patent infringement, *Eli Lilly Co. v. Changzhou Watson Pharmaceuticals Co.*,⁸⁹ the Supreme People's Court held that, in a pharmaceutical product manufacturing process patent infringement dispute, in the absence of any evidence to the contrary, the manufacturing process of the alleged infringing pharmaceutical product filed to the

85 MS No. 4149 (Sup. People's Ct, 2018).

86 MTZ No. 84 (Sup. People's Ct, 2009).

87 MSZZ No. 6 (Sup. People's Ct, 2009).

88 MSZ No. 309 (Sup. People's Ct, 2013).

89 Sup. People's Ct Guiding Case No. 84, March 6, 2017.

medical product regulatory department will be presumed to be the actual manufacturing process thereof. If there is evidence to prove that the filed process of the alleged infringing pharmaceutical product is unauthentic, then the technological source, manufacturing procedures, batch manufacturing records, documents filed to the medical product regulatory department and so on of the alleged infringing pharmaceutical product shall be fully examined to determine the actual manufacturing process thereof according to law. With respect to complicated technical facts like the manufacturing process of the alleged infringing pharmaceutical product, technical investigators, expert assistants, judicial appraisal and technological expert consultancy may be comprehensively employed.

4.3.2.6 Dedication rule

Article 5 of the Interpretation of Patent Infringement Dispute Cases stipulates the following: "For a technical solution that is solely described in the description or drawings but is not recited in the claims, the right holder's assertion to capture it in the protection scope of the patent right in a patent infringement dispute case shall not be supported by the people's courts." A technical solution that is recited in the description but not in the claims will be deemed as having been donated to the public by the patentee and thus cannot be recaptured into the protection scope defined by equivalent features in a patent infringement lawsuit. The dedication rule is, in essence, a limitation to the application of the doctrine of equivalents.

4.3.2.7 Impact of declaration of patent invalidity

In a civil case involving patent infringement, if the involved patent is declared invalid by the CNIPA, the effect of the administrative invalidation decision should be decided according to the enforcement or performance status of related civil judgments or written mediation documents regarding the patent infringement. Article 47 of the Patent Law stipulates the following:

Any patent right that has been declared invalid is deemed to be non-existent from the beginning.

The decision on declaring the patent right invalid shall have no retroactive effect on any judgment or mediation statement on patent infringement which has been made and enforced by the people's court, on any decision concerning the handling of a dispute over patent infringement which has been performed or compulsorily executed, or on any patent exploitation licensing contract or patent right transfer contract which has been performed—prior to the declaration of the invalidation of the patent right; however, the damage caused to other persons in bad faith by the patentee shall be compensated.

Where the monetary damage for patent infringement, the royalties for patent exploitation or the fees for the transfer of the patent right is not refunded pursuant to the provisions of the preceding paragraph, but such non-refund is obviously contrary to the principle of fairness, refund shall be made fully or partly.

"The decision on declaring the patent right invalid" described in Article 47 includes two circumstances: first, the concerned party fails to file an administrative lawsuit against the decision within the statutory period; and second, although an administrative lawsuit was filed, the administrative decision is not revoked by an effective administrative judgment or ruling. Therefore, whether the administrative invalidation decision has retroactive effect on any relevant administrative punishment decision, judgment, ruling, written mediation or contract should be determined based on the administrative judgment or ruling if the concerned party has filed an administrative lawsuit against an administrative invalidation decision.

Article 2 of the Interpretation (II) of Patent Infringement Dispute Cases stipulates the following:

Where a claim asserted by the right holder in a patent infringement lawsuit is declared invalid by the patent administration department under the State Council, the people's court trying the patent infringement dispute case may rule to dismiss the lawsuit based on the invalidated claim.

Where there is evidence to prove that the decision declaring the abovementioned claim invalid is revoked by an effective administrative judgment, the right holder may file another lawsuit.

Where the patentee files another lawsuit, the statute of limitations shall be counted from the date of service of the administrative judgment stated in paragraph 2 of this Article.

This provision is made to improve the trial efficiency of civil cases involving patent infringement and avoid unnecessary extension of the trial period. In judicial practice, only a relatively small ratio of administrative invalidation decisions is revoked in administrative cases. Therefore, after the CNIPA has made a decision declaring a patent right invalid, the people's court trying the civil case involving patent infringement may rule to dismiss the lawsuit without waiting for the final result of the administrative case. If the administrative invalidation decision is eventually revoked, the right holder may file another lawsuit.

If the CNIPA makes the administrative decision declaring a patent invalid during the second instance trial, the court of second instance may determine whether to rule to dismiss the lawsuit based on the circumstances of the case.

If, after the administrative invalidation decision is made and an effective civil judgment on infringement has not been fully enforced, a concerned party petitions for retrial in accordance with the administrative invalidation decision, the people's court may rule to suspend the examination of the retrial and the enforcement of the effective judgment in accordance with Article 29 of the Interpretation (II) of Patent Infringement Dispute Cases, taking into account whether the concerned party has filed an administrative lawsuit against the administrative invalidation decision. If the concerned party does not file an administrative lawsuit, or the administrative invalidation decision is not revoked by an effective administrative judgment, the people's court shall retrial the civil judgment or written mediation on infringement that has not been fully enforced.

In a retrial of a dispute over utility model patent infringement, *Shaanxi Dongming Agricultural Technology Co. v. Shaanxi Qinfeng Agricultural Machineries (Group) Co.*,⁹⁰ the Supreme People's Court held that the point in time at which a patent is declared invalid in accordance with Article 47 paragraph 2 of the Patent Law is the date of decision as indicated in the written decision on the examination of the request for a declaration of patent invalidity.

4.3.2.8 Temporary protection of invention patents

An invention patent application needs to go through procedures like early publication and substantive examination before the patent can be granted. Once the invention patent application is published, its technical contents will be known to the public. According to Article 11 of the Patent Law, acts of exploiting the technical solution of a patent before the patent is granted do not constitute acts of infringement. Therefore, the issue of temporary protection between the publication of the invention patent application and the announcement of the granting of the patent arises.

Article 13 of the Patent Law stipulates the following: "After the publication of an invention patent application, the applicant may require the entity or individual exploiting the said invention to pay an appropriate amount of royalties." These royalties can only be claimed after the invention patent is granted. Article 85 paragraph 2 of the Rules for the Implementation of the Patent Law also stipulates that a party's request to a patent administration department for mediation on the payment of the "appropriate amount of royalties" shall only be filed after the patent is granted. Article 18 paragraph 1 of the Interpretation (II) of Patent Infringement Dispute Cases specifies that the specific amount of the royalties can be reasonably determined by reference to royalties for the patent license.

As it is usually necessary to amend claims before granting, the protection scope claimed by the applicant on the publication date of the invention patent application may be different from the protection scope of the patent right once granted. In accordance with Article 18 paragraph 2 of the Interpretation (II) of Patent Infringement Dispute Cases, where the alleged infringing technical solution falls within both protection scopes, the people's court shall determine that the defendant has exploited the patent, in which case the right holder's request for an "appropriate

90 MTZ No. 110 (Sup. People's Ct, 2012).

amount of royalties” is supported. Where the alleged infringing technical solution falls within only one of the scopes, the assertion is rejected.

During the temporary protection period, the manufacturing, selling and importing of the product do not constitute acts of infringement, and the concerned party only bears the obligation to pay an “appropriate amount of royalties.” Article 18 paragraph 3 of the Interpretation (II) of Patent Infringement Dispute Cases stipulates the following:

where the appropriate amount of royalties stipulated in Article 13 of the Patent Law has been paid or a promise to pay has been made in writing, the right holder’s assertion that the acts of using, offering for sale, and selling constitute infringement shall not be supported by the people’s courts.

4.3.3 Joint infringement and aiding and abetting infringement

4.3.3.1 Joint infringement

Joint patent infringement refers to two or more persons conspiring or cooperating to perform acts that infringe patent rights. Various provisions of the Civil Code apply to the determination of such infringement. Article 1168 of the Civil Code stipulates the following: “Where two or more persons jointly commit a tortious act causing damage to another person, they shall bear joint and several liability.” With respect to the bearing of liabilities for joint infringement, external liability and internal liability are distinguished. In the former case, the co-infringers are jointly and severally liable. According to Article 178 of the Civil Code, joint and several liability is an overall liability to an external party. Thus, the right holder has the right to request some or all of the persons jointly and severally liable to bear the liability. In other words, each person liable bears full liability for the infringement.

In a retrial of a dispute over invention patent infringement, *SMC Inc. v. Leqing Zhongqi Pneumatic Technology Co.*,⁹¹ the Supreme People’s Court held that joint infringement has the following prerequisites: the infringers are two or more persons; each infringer subjectively has the joint intent; there is mutual use, cooperation or support between the acts of the infringers seen from an objective perspective; and the consequences of the damage resulting from the acts of each infringer falls within the scope of their joint intent.

Joint infringers are jointly and severally liable for acts of joint infringement. In an appeal of a dispute over utility model patent infringement, *Dongguan Hongding Home Co. v. Dongguan Kangsheng Furniture Co.*,⁹² the Supreme People’s Court held that, if some co-infringers have settled with and made compensation to the right holder for part of their losses, the remaining co-infringers will only be jointly and severally liable for compensation to the right holder for its losses as a result of the infringement after deducting the paid compensation, to avoid double enrichment of the right holder.

4.3.3.2 Aiding and abetting infringement

Article 1169 of the Civil Code stipulates the following:

A person who aids or abets an actor in the commission of a tortious act shall assume joint and several liability with the actor.

A person who aids or abets an actor with no or limited capacity for performing civil juristic acts in the commission of a tortious act shall assume tort liability. The guardian of the actor with no or limited capacity for performing civil juristic acts shall assume corresponding liability where he/she fails to fulfill the duties of a guardian.

Article 21 of the Interpretation (II) of Patent Infringement Dispute Cases stipulates the following:

Where a person knows that the relevant product is a raw material, equipment, component, or intermediate specially used for exploiting a patent, provides, without the authorization of the right holder and for production and business purposes, such a product to another person to commit patent infringement, the right holder’s assertion

91 MZ No. 199 (Sup. People’s Ct, 2018).

92 ZMZ No. 181 (Sup. People’s Ct, 2019).

that the provider's acts constitute aiding infringement shall be supported by the people's courts.

Where a person knows that a product or a process has been granted a patent right actively induces, without the authorization of the right holder and for production and business purposes, another person to commit patent infringement, the right holder's assertion that the inducer's acts constitute abetting others to commit infringement [...] shall be supported by the people's courts.

In a retrial of a dispute over utility model patent infringement, *Liu Hongbin v. Beijing Jinglianfa Digital Control Technology Co.*,⁹³ the Supreme People's Court held that aiding infringement, in the context of the Patent Law, does not refer to just any kind of aiding act but specifically refers to the act of providing to others a product specially used for infringement, to commit patent infringement without the authorization of the patentee and for production and operation purposes. If an actor knows that the relevant product is a raw material, equipment, component or intermediate specially used for exploiting the technical solution of the patent, and provides this to another party without the authorization of the right holder and for production and business purposes, and that other party subsequently commits patent infringement, then the actor's act of providing the product constitutes aiding others to commit patent infringement.

The "specially used product" is identified against the criterion of whether the raw material, product, component or intermediate is of substantial significance for realizing the technical solution protected by the patent and has "substantial non-infringing usages." If the raw material or product is indispensable for realizing the technical solution protected by the involved patent and has no other "substantial non-infringing usage" than for use in the protected technical solution, then the raw material or product is generally identified as being "specially used." The right holder bears the burden of proving that the relevant product is "specially used."

4.3.4 Defenses in patent infringement lawsuits

4.3.4.1 Prior art defense

According to Article 67 of the Patent Law, where an alleged infringer has evidence to prove that the technology or design they exploited forms part of the prior art or is a prior design, such exploitation does not constitute an infringement of the patent right. This provision was added to the 2008 Patent Law out of consideration that the protection scope of patent rights should not cover prior art and technologies that are obvious and equivalent to prior art (see Section 4.8.9 regarding the prior design defense).

With respect to the definition of prior art, Article 22 paragraph 5 of the Patent Law stipulates the following: "Prior art refers to any technology known to the public domestically and/or abroad before the filing date of patent application." This wording was inserted into the 2008 Patent Law. Previously, the provision had defined different geological scopes of public disclosure through publications, public use or other means. To determine the prior art for a patent, the version of this provision in the Patent Law that applied at the patent filing date is considered. Article 22 of the Interpretation (II) of Patent Infringement Dispute Cases stipulates the following: "Regarding the prior art defense or prior design defense asserted by an alleged infringer, the people's courts shall define the prior art or prior design in accordance with the Patent Law that was in effect upon the patent filing date."

In determining whether the prior art defense is sustained, the main factor to be considered is the relation between the alleged infringing technology solution and the prior art. Even though the alleged infringing technical solution constitutes literal infringement, so long as the alleged infringer can provide evidence to prove that the alleged infringing technology forms part of the prior art, the prior art defense may be sustained.

In a retrial of a dispute over invention patent infringement, *Strix Ltd v. Ningbo Shenglida Electric Manufacturing Co.*,⁹⁴ the Supreme People's Court held that whether a prior art defense applies depends only on whether all technical features in the alleged infringing product alleged to fall within the protection scope of the patent right are identical or equivalent to corresponding

93 MSZ No. 1070 (Sup. People's Ct, 2015).

94 MSJZ No. 51-1 (Sup. People's Ct, 2007).

technical features of technical solutions publicly disclosed in the prior art. A prior art defense cannot be excluded merely because the alleged infringing product is identical to the patent.

With respect to the judgment method for the prior art defense, Article 14 paragraph 1 of the Interpretation of Patent Infringement Dispute Cases stipulates the following:

Where all the technical features alleged to fall within the protection scope of a patent right are identical or have no substantial difference with the corresponding technical features of a prior art technical solution, the people's courts shall determine that the technical solution implemented by the alleged infringer forms part of the prior art as stipulated in Article 62 of the [2008] Patent Law.

This provision clarifies that the technical features alleged to fall within the protection scope of a patent right, rather than all technical features of the technology implemented by the alleged infringer, are compared with corresponding technical features of the prior art. If the two are identical or have no substantial difference, then the technology implemented by the alleged infringer forms part of the prior art.

In a retrial of a dispute over utility model patent infringement, *Yancheng Zetian Machinery Co. v. Yancheng Geruite Machinery Co.*,⁹⁵ the Supreme People's Court held that, in examining the prior art defense, the alleged infringing technical solution shall be compared with the prior art, rather than comparing the prior art with the patented technical solution. The examination method is to determine the technical features alleged to fall within the protection scope of the patent right with reference to the claims of the patent, and to judge whether identical or equivalent technical features are disclosed in prior art. Prior art defense does not require the alleged infringing technical solution to be completely identical to prior art. The technical features in the alleged infringing technical solution that are irrelevant to the protection scope of the patent right shall not be considered in determining the prior art defense.

In a retrial of a dispute over invention patent infringement, *Beijing Baidu Netcom Science and Technology Co. v. Beijing Sogou Technology Development Co.*,⁹⁶ the Supreme People's Court held that, in determining whether technical features alleged as falling within the protection scope of a patent right are identical to or have no substantial difference with the corresponding technical features in prior art, the focus should be on the technical problems to be solved by the patent and the functions and technical effects of the disputed technical features recited in the claims. The difference between the two in terms of means, functions, effects and the degree of impact thereof shall be considered.

To determine whether "substantial difference" exists in the prior art defense, the doctrine of equivalents may be used as a reference. In an appeal of a dispute over utility model patent infringement, *Foshan Shunde Fashion Electrical Appliances Mfg. Co. v. Zhejiang iSMAL Hi-Tech Electrics Co.*,⁹⁷ the Supreme People's Court held that, if a technical feature in the alleged infringing technical solution and the corresponding technical feature in a prior technical solution are directly interchangeable customary means in the technical field, then it can be determined that no substantial difference exists.

In an appeal of a dispute over invention patent infringement, *Wang Yeci v. Xuzhou Huasheng Industry Co.*,⁹⁸ the Supreme People's Court held that, where a patented technical solution has specifically indicated its invention points and emphasized that all technical features other than the invention points are general components, if the technical features corresponding to the invention points have been disclosed in prior art whereas other technical features have not, and if the combination of the prior technology and general components inevitably leads to an overall prior technical solution corresponding to the patented technical solution, then a prior art defense is sustained.

95 MSZ No. 18 (Sup. People's Ct, 2012).

96 MZ No. 82 (Sup. People's Ct, 2020).

97 ZMZ No. 804 (Sup. People's Ct, 2019).

98 ZMZ No. 89 (Sup. People's Ct, 2019).

4.3.4.2 Conflicting application defense

Article 22 paragraph 2 of the Patent Law stipulates the following:

Novelty means that, the invention or utility model does not form part of the prior art; no entity or individual has filed a patent application for the identical invention or utility model with the patent administration department under the State Council before the filing date and the content of the application is disclosed in patent application documents published or other patent documents announced after the filing date.

A “patent application for the identical invention or utility model [that is filed] before the filing date and the [content of which] is disclosed in patent application documents published or other patent documents announced after the filing date” is briefly referred to as a conflicting application. A conflicting application can be used for separate comparisons with a patent to assess the novelty of the patent but cannot be used in combination with other prior art, conflicting applications or well-known general knowledge to assess the inventiveness of the patent. If a technical solution has been disclosed in a conflicting application, then it has no novelty in comparison to the conflicting application and thus cannot be granted a patent. Therefore, an alleged infringing technical solution that has been disclosed in a conflicting application does not fall within the protection scope of the patent right, according to the same rationale as for a prior art defense.

In a retrial of a dispute over utility model patent infringement, *Cixi Bosheng Plastic Products Co. v. Chen Jian*,⁹⁹ the Supreme People’s Court held that, where an alleged infringer asserts that they did not infringe the patent on the ground that the alleged infringing technical solution was disclosed in a conflicting application, the people’s courts may examine whether the conflicting application defense is sustained with reference to provisions concerning the prior art defense. As conflicting application and prior art defenses differ in their definition and nature, the judgment criteria for examining a conflicting application defense are compatible with the nature of the conflicting application. Only when each technical feature in the alleged infringing technical solution has been separately and fully disclosed in a conflicting application and has no novelty compared with the conflicting application can it be determined that the conflicting application defense is sustained.

4.3.4.3 Legitimate source defense

Article 77 of the Patent Law stipulates the following: “Any person who, for production and business purposes, uses, offers to sell, or sells a patent-infringing product without knowing that it was manufactured and sold without the authorization of the patentee, may not be liable for compensation provided that he can prove the legitimate source of the product.” According to this provision, the legitimate source defense has two prerequisites. First, the person acted in good faith with no subjective fault in using, offering for sale or selling the infringing product, and the person did not know or should not have known that the relevant product was an infringing product. Second, a legitimate source of the infringing product used, offered for sale or sold by the defendant can be proved. If the legitimate source defense is sustained, the defendant is not liable for compensation.

With respect to the legitimate source defense, Article 25 paragraphs 2–3 of the Interpretation (II) of Patent Infringement Dispute Cases stipulates the following:

“Without knowing” [...] means neither actually know nor should have known.

“Legitimate source” [...] means the product is obtained through a normal commercial manner such as a legitimate sales channel or an ordinary sales contract. For a legitimate source, the person who uses, offers to sell, or sells the product shall provide relevant evidence in compliance with the course of dealing.

The course of dealing in the disputed case is determined based on whether the trading subjects are natural persons, “individual-run industrial and commercial households” or companies, the price of the subject matter, the customary ways of trading in the industry or region, and so on to determine the requirements for the evidence for proving a legitimate source.

With respect to whether cessation of the infringement is ordered when the legitimate source defense is sustained, Article 25 paragraph 1 of the Interpretation (II) of Patent Infringement Dispute Cases stipulates the following:

99 MSZ No. 188 (Sup. People’s Ct, 2015).

Where a person, for production and business purposes, uses, offers to sell, or sells a patent-infringing product without knowing that such product is made and sold without authorization of the patentee, and the legitimate source of the product can be proved by evidence, the people's courts shall support the right holder's assertion of ordering that person to stop aforesaid acts of using, offering for sale, or selling, unless the user of the alleged infringing product provides evidence to prove that reasonable consideration for such a product has been paid.

The "reasonable consideration" in this provision refers to a trading price or trading condition that is basically equivalent to or slightly lower than that of the patented product. If the consideration is significantly lower than the trading price or condition of the patented product, it is usually presumed that the purchaser should have known the purchased product was not authorized by the patentee.

In a retrial of a dispute over design patent infringement, *Guangdong Archie Hardware Co. v. Yang Jianzhong*,¹⁰⁰ the Supreme People's Court held that the legitimate source defense is a right granted by law to bona fide users and sellers of infringing products. According to the principle that "the burden of proof is on the party that raises claims," to claim the legitimate source defense, the user or seller of an infringing product must provide evidence (e.g., purchase invoices, receipts and payment vouchers) to prove that the infringing product was obtained legitimately. The legitimate source defense has two prerequisites: the user or seller has no subjective fault, and the alleged infringing product is obtained from a legitimate source. Regarding the subjective condition, the user or seller of the alleged infringing product needs to prove that they did not know they were using, offering for sale or selling an infringing product. As a negative fact, the burden of proof is usually on the right holder to prove the subjective status that the alleged infringer knew or should have known. As to whether there is a legitimate source for the alleged infringing product, the user or the seller bears the burden of proving that there is a legitimate purchasing channel, a reasonable price and a direct supplier for the alleged infringing product.

With respect to the determination of a legitimate source defense asserted by a seller, in an appeal of a dispute over utility model patent infringement *Baokou (Xiamen) Sanitary Ware Co. v. Guantao Peilong Water Heating Installation and Maintenance Store*,¹⁰¹ the Supreme People's Court held that, if a seller can prove that they have complied with legitimate and normal market trading rules, the product being sold was obtained from a clear source and a legitimate channel and at a reasonable price, and their act of selling it was in good faith and complied with the course of dealing, then it can be presumed that the seller has no subjective fault. Under this circumstance, the right holder should present evidence to the contrary.

With respect to the assumption of liability after a legitimate source defense is sustained, in an appeal of a dispute over utility model patent infringement, *Guangzhou Surui Mechanical Equipment Co. v. Shenzhen Helitai Technology Co.*,¹⁰² the Supreme People's Court held that a legitimate source defense is a defense for release from the liability of compensation but not a defense to infringement. A seller's legitimate source defense neither changes the tortious nature of the act of selling the infringing product nor releases the seller from the liability of stopping the sales of the infringing product. The seller still bears all reasonable costs of the right holder for obtaining the remedy of infringement cessation.

4.3.4.4 Prior-use rights defense

Article 9 paragraph 2 of the Patent Law states the following: "If two or more applicants file patent applications for the identical invention-creation, the patent right shall be granted to the applicant whose application was filed first." The prior-use rights defense aims to compensate for the deficiency of this first-to-file rule. According to Article 75(2) of the Patent Law, "before the filing date of the patent application, any person who has already manufactured the identical product, used the identical process, or made necessary preparations for its manufacturing or using and continues to manufacture or use it within the original scope," shall not be deemed as having infringed the patent right.

100 MTZ No. 187 (Sup. People's Ct, 2013).

101 ZMZ No. 118 (Sup. People's Ct, 2019).

102 ZMZ No. 25 (Sup. People's Ct, 2019).

With respect to the prior-use rights defense, Article 15 of the Interpretation of Patent Infringement Dispute Cases stipulates the following:

Where an alleged infringer asserts prior-use rights for an illegally acquired technology or design, the assertion shall not be supported by the people's courts.

Under either of the following circumstances, the people's courts shall determine the circumstance as "made necessary preparations for its manufacturing or using" as prescribed in Article 69(2) of the Patent Law:

- (1) the main technical drawings or process documents for implementing an invention-creation have been completed; or
- (2) the main equipment or raw materials for implementing an invention-creation have been made or purchased.

The "original scope" stipulated in Article 69(2) of the Patent Law includes the existing scale of production and the scale of production achievable by making use of existing production equipment or based on existing production preparations as of the filing date of a patent application.

Where the holder of the prior use right, after the filing date of the patent application, transfers, or licenses others to implement the technology or design that it has implemented or has made necessary preparations for implementing, the assertion by the alleged infringer that such act of implementation constitutes continuing implementation within the original scope shall not be supported by the people's courts, unless the technology or design is transferred or succeeded along with the original company.

In an appeal of a dispute over invention patent infringement, *Wang Yeci v. Xuzhou Huasheng Industry Co.*,¹⁰³ the Supreme People's Court held that design drawings are the fundamental basis for product processing and inspection in the machinery manufacturing field. Thus, where an alleged infringer has designed the drawings for key parts of the alleged infringing product, and all the other parts thereof are general parts, it can be determined that the alleged infringer has finished the main technical drawings essential to the implementation of the invention-creation and has made necessary preparations for manufacturing the alleged infringing product, and a prior-use rights defense can be sustained.

In a retrial of a dispute over invention patent infringement, *Jiangxi Yintao Pharmaceutical Co. v. Shaanxi Hanwang Pharmaceutical Co.*,¹⁰⁴ the Supreme People's Court held that whether a prior-use rights defense is sustained mainly depends on whether the alleged infringer had, before the filing date of the patent application, exploited the patent or made necessary preparations technically or in material form for exploiting the patent. If the registration application files of the alleged infringing product – in this case, a pharmaceutical product – show that the alleged infringer had finished the process documents and equipment for manufacturing the alleged infringing pharmaceutical product before the filing date of the patent application, then it shall be determined that they had made the necessary preparations for manufacturing or using the patent. As the manufacturing certification of a pharmaceutical product is reviewed and granted by a medical product regulatory department, the necessary preparations for manufacturing or using shall not be determined based on the approval of such a certification.

In a retrial of a dispute over invention patent infringement, *Beijing Yingtelai Technology Co. v. Beijing SinoShield Chuangzhan Doors Co.*,¹⁰⁵ the Supreme People's Court held that, where the manufacturer is not the defendant, but the seller can prove that the alleged infringing product was obtained from a legitimate source and that the manufacturer enjoyed prior-use rights, the seller can also raise a prior-use rights defense.

4.3.4.5 Other circumstances not deemed as patent infringement

In addition to the defenses described above, according to Article 75 of the Patent Law, none of the following shall be deemed patent infringement:

- intellectual property right exhaustion (i.e., after the sale of a patented product or a product acquired directly in accordance with a patented process by the patentee or any entity or

¹⁰³ ZMZ No. 89 (Sup. People's Ct, 2019).

¹⁰⁴ MSZ No. 1490 (Sup. People's Ct, 2011).

¹⁰⁵ MSZ No. 1255 (Sup. People's Ct, 2015).

- individual authorized by the patentee, any other person uses, offers to sell, sells or imports that product);
- any foreign means of transport – temporarily passing through the territory, territorial waters or territorial airspace of China – uses the relevant patent in its devices and installations for its own needs and in accordance with any agreement concluded between China and the country to which the foreign means of transport belongs, in accordance with any international treaties to which both countries are parties, or based on the principle of reciprocity;
 - any person uses the relevant patent specially for the purposes of scientific research and experimentation; and
 - *Bolar* exceptions (i.e., any person manufactures, uses, or imports a patented pharmaceutical product or patented medical apparatus for the purpose of providing the information needed for administrative examination and approval, and any other person manufactures or imports a patented pharmaceutical product or a patented medical apparatus for that person).

4.4 Civil liabilities for patent infringement

Patent rights are a subset of the intellectual property rights stipulated in Article 123 of the Civil Code, which are property rights. Any person who infringes patent rights assumes civil liabilities in accordance with the laws. Article 179 of the Civil Code stipulates the following:

The main forms of civil liabilities include:

- (1) cessation of infringement;
 - (2) removal of nuisance;
 - (3) elimination of the danger;
 - (4) restitution;
 - (5) restoration;
 - (6) repair, redoing, or replacement;
 - (7) continuation of performance;
 - (8) compensation for losses;
 - (9) payment of liquidated damages;
 - (10) elimination of adverse effects and rehabilitation of reputation; and
 - (11) extension of apologies.
- [...]

The forms of civil liabilities provided in this Article may be applied separately or concurrently.

In civil cases involving patent infringement, the main forms of civil liabilities are cessation of infringement and compensation for losses.

According to Article 1185 of the Civil Code and Article 71 paragraph 1 of the Patent Law, in a case of intentional infringement of patent rights, and where the circumstances are serious, the right holder has the right to request corresponding punitive damages.

4.4.1 Cessation of infringement

Where an alleged infringer has implemented any of the acts of infringement stipulated in Article 11 of the Patent Law, the people's courts will generally, based on the allegations of the right holder and in accordance with the laws, rule that the alleged infringer assume the civil liability of cessation of infringement so as to stop the acts of infringement.

However, under the following three circumstances, people's courts may not order the cessation of infringement:

- According to Article 26 of the Interpretation (II) of Patent Infringement Dispute Cases, "[c]onsidering national or public interests, the people's court may not order cessation of infringement, and instead order the defendant to pay corresponding reasonable fees."
- According to Article 25 paragraph 1 of the Interpretation (II) of Patent Infringement Dispute Cases, where the user of an alleged infringing product does not know the product was made and sold without authorization of the patentee, can produce evidence to prove that the product was obtained from a legitimate source, and a reasonable consideration has been paid

for the product, the people's courts shall not support the right holder's assertion for cessation of said use.

- According to the provision on relevant issues concerning standard-essential patents in Article 24 paragraph 2 of the Interpretation (II) of Patent Infringement Dispute Cases (see Section 4.5.4.1 for further detail).

4.4.2 Compensation for losses

4.4.2.1 Calculation method of compensation

According to Article 71 of the Patent Law, in trials of civil cases involving patent infringement, the people's courts shall determine the amount of compensation in one of the following four ways.

The first is a determination based on the actual losses suffered by the right holder due to the infringement. According to Article 14 paragraph 1 of the Provisions on the Trial of Patent Disputes, actual losses can be calculated by multiplying the total reduction in the sales volume of the patented product of the patentee due to the infringement by the reasonable profit of each piece of the patented product. Where it is difficult to determine the total reduction in the sales volume of the right holder, the product of multiplying the total sales volume of the infringing product in the market by the reasonable profit of each piece of the patented product is deemed to be the actual loss suffered by the right holder due to the infringement.

The second is a determination based on the profits earned by the infringer from the infringement. According to Article 14 paragraph 2 of the Provisions on the Trial of Patent Disputes, such profits can be calculated by multiplying the total sales volume of the infringing product in the market by the reasonable profit of each piece of the infringing product. The "reasonable profit" is generally calculated based on the operating profit of the infringer. For an infringer completely using infringement as its business, the reasonable profit can be calculated based on the sales profit.

Third, where it is difficult to determine the losses suffered by the right holder or the profits earned by the infringer, the amount of compensation can reasonably be determined by reference to a multiple of the royalties for the patent license. According to Article 15 of the Provisions on the Trial of Patent Disputes, the people's courts may consider factors like the category of patent, the nature and circumstance of the acts of infringement, and the nature, scope and duration of patent licensing. Article 32 of the Provisions on Evidence in Civil Procedures involving Intellectual Property Rights states the following:

Where the concerned party asserts to determine the amount of compensation with reference to a reasonable multiple of the royalties for the patent license, the people's courts may consider the following factors to examine and determine evidence related to the royalties for the patent license:

- (1) whether the royalties have been paid and method of payment, and whether the licensing contract has been performed or recorded;
- (2) the rights that have been licensed, and the manner, scope, and duration of license;
- (3) whether the licensee has an interest with the licensor; and
- (4) customary licensing standard in the industry.

Thus, the key factors include whether the royalties referred to were actually paid, whether the customary standard was met and whether the rights being licensed – and the manner, scope and duration of license – are comparable.

The fourth method for determining compensation is statutory compensation. According to Article 71 paragraph 2 of the Patent Law, where it is difficult to determine the losses suffered by the right holder, the profits earned by the infringer and the royalties for the patent license, the people's courts may, based on the type of the patent right, and the nature and circumstances of the infringement act, determine a compensation amount between RMB 30,000 and RMB 5 million. The nature and circumstances of acts of infringement refer primarily to the subjective fault of the infringer, the means of infringement, the duration of acts of infringement, the damaging consequences to the right holder and so on.

4.4.2.2 Compensation should have a causal relationship with and be proportional to the act of infringement

Article 16 of the Interpretation of Patent Infringement Dispute Cases stipulates the following:

In determining the profits earned by the infringer as a result of the infringement, the profits shall be confined to those acquired by the infringer from the acts of infringement, while profits earned from other rights shall be reasonably deducted.

Where the product infringing upon an invention or a utility model patent right is a component of another product, the people's courts shall reasonably determine the amount of compensation based on factors such as the value of the component itself and its role in achieving the profit of the final product.

The main consideration for this provision is that, if an alleged infringing product involves several patent rights or simultaneously involves a patent right and trademark right, then, in a lawsuit over infringement of one or part of the patent rights thereof, the profits earned by the infringer should be determined based on the profits earned as a result of the infringement of the involved patent, rather than the full profit of the product. In Article 16, "other rights" refers primarily to intellectual property rights. The profits earned from other rights can be reasonably determined based on the specific facts and overall circumstances of the case.

In an appeal of a dispute over patent infringement, *Hua Jiping v. Shanghai Oxylane Trade Co.*,¹⁰⁶ the Supreme People's Court held that, when considering relevant factors for determining the compensation, the focus is the reasonability and the proportionality thereof. In determining the amount of compensation for intellectual property infringement, the degree of subjective fault of the concerned party may be considered in determining the compensation liability, especially when it is necessary to use discretion to determine the specific calculation criterion.

In a retrial of a dispute over utility model patent infringement, *Wuxi Guowei Ceramic Electrical Appliances Co. v. Chagnshu Linzhi Electrical Heating Components Co.*,¹⁰⁷ the Supreme People's Court held that, in calculating the amount of compensation for patent infringement based on the profits earned by the infringer as a result of the infringement, for an alleged infringing product involving several components or several patents, the profits should, in principle, not be calculated by simply multiplying the total sales amount of the infringing product by the profit margin thereof. Instead, the involved patent's ratio of contribution to the profit of the infringing product should be considered, and profits as a result of the infringement may be calculated based on the following formula: total sales amount of the infringing product × profit margin × contribution ratio of the patented technology to the product value. The contribution ratio of the patented technology to the product's value can be determined with discretion by considering the importance of the involved patent to the product.

Where the acts of infringement are severable, in calculating the amount of compensation for the infringement, if a part of the losses suffered by the right holder or profits earned by the infringer can be relatively accurately calculated and a part thereof is difficult to calculate, then compensation for the former may be calculated based on the losses or profits, statutory compensation applies for the latter, and the sum of the two is used to determine the final amount of compensation.

4.4.2.3 Agreement on the amount or calculation method of compensation for patent infringement in accordance with the law

Article 28 of the Interpretation (II) of Patent Infringement Dispute Cases stipulates the following:

Where the right holder and the infringer agree, according to law, on the amount or the calculation method of compensation for patent infringement and assert during a patent infringement lawsuit that the compensation amount shall be determined in accordance with such an agreement, the people's courts shall support such an assertion.

For such an agreement, the people's courts will, in accordance with the provisions of the Civil Code and the assertion of the concerned parties, examine whether there is any circumstance that may render the agreement invalid or revocable.

¹⁰⁶ MSZZ No. 3 (Sup. People's Ct, 2007).

¹⁰⁷ MZ No. 111 (Sup. People's Ct, 2018).

In a retrial of a dispute over utility model patent infringement, *Zhongshan Longcheng Daily Products Co. v. Hubei Tongba Children's Appliances Co.*,¹⁰⁸ the Supreme People's Court held that the Tort Liability Law and Patent Law do not prohibit an infringed person and the corresponding infringer from making prior agreements on the form of tort liability and amount of compensation. The substance of such agreements is a previously agreed simple method for calculating and determining the losses of the right holder or the profits of the infringer with respect to an infringement that has not yet occurred. Such agreements include agreements made either after or before the acts of infringement.

4.4.2.4 Reasonable expenses of the right holder

Article 71 paragraph 3 of the Patent Law stipulates the following: "The amount of compensation shall also include the reasonable expenses of the right holder paid for putting an end to the infringement." According to Article 16 of the Provisions on the Trial of Patent Disputes, if a right holder asserts the reasonable expenses they paid for putting an end to the infringement, the people's courts may calculate such costs in addition to the compensation determined in accordance with Article 65 of the Patent Law.

In an appeal of a dispute over patent infringement, *Hua Jiping v. Shanghai Oxylane Trade Co.*,¹⁰⁹ the Supreme People's Court held that the costs of the right holder for investigating and putting an end to the infringement – so long as they are reasonable – can be incorporated into the amount of compensation. Such reasonable expenses do not necessarily need to be proved individually by vouchers. According to the specific circumstances of the case, the people's courts may consider the amount of reasonable expenses that can be proved by vouchers and other reasonable factors of expenditure to determine the amount of reasonable expenses but not exceeding the amount asserted by the right holder.

In judicial practice, circumstances also exist where right holders abuse their rights to bring infringement lawsuits, while alleged infringers require the right holders to compensate for reasonable expenses. In this respect, the Reply on Compensation for a Plaintiff's Abuse of Rights stipulates that, in an intellectual property infringement lawsuit, where the defendant submits evidence to prove the lawsuit filed by the plaintiff constitutes an abuse of rights according to law, which has damaged the defendant's legitimate rights and interests, and requests the plaintiff to compensate for the defendant's reasonable expenses (e.g., attorney's fees, travel expenses, and boarding and lodging expenses) arising from the lawsuit, the people's courts shall support such a request. The defendant may also file a separate lawsuit to request the plaintiff to compensate for the above reasonable expenses.

4.4.2.5 Rules of evidence related to compensation

Compensation is determined based on evidence. In judicial practice, evidence related to the nature and circumstances of acts of infringement and the profits earned by the infringer is usually held by the infringer and difficult for the right holder to obtain. To reduce right holders' difficulty in producing evidence, the Patent Law and related judicial interpretations have stipulated rules of evidence that are related to compensation and in compliance with the characteristics of civil cases involving intellectual property infringement generally.

Article 71 paragraph 4 of the Patent Law stipulates that, where a right holder has tried their best to provide evidence, but the account books or materials related to the patent infringement are mainly in the possession of the infringer, then, to determine the amount of compensation, the people's court may order the infringer to provide those account books or materials. Where the infringer refuses to provide the account books or materials or provides false account books or materials, the people's court may determine the amount of compensation by reference to the right holder's claims and the evidence provided.

According to Article 31 of the Provisions on Evidence in Civil Procedures involving Intellectual Property Rights, account books and documents, sales contracts, documents on the inflow and outflow of goods, annual reports of listed companies, prospectuses, websites or promotion catalogs, trading data stored in equipment and systems, commodity circulation data accounted by third-party platforms, assessment reports, intellectual property right licensing contracts, and

¹⁰⁸ MTZ No. 116 (Sup. People's Ct, 2013).

¹⁰⁹ MSZZ No. 3 (Sup. People's Ct, 2007).

records on market supervision, taxation and finance departments may be produced as evidence to prove the amount of compensation for intellectual property infringement asserted by the plaintiff.

4.4.3 Punitive damages

According to Article 1185 of the Civil Code and Article 71 of the Patent Law, in a case of intentional infringement of patent rights, and where the circumstances are serious, the people's courts may apply one to five times the punitive damages. In March 2021, the Interpretation of Punitive Damages in Intellectual Property Civil Cases was implemented. This judicial interpretation specifies the application scope of punitive damages, the contents and time of the request, the determination of intentional infringement and serious circumstances, the calculation basis and multiples, and so on. In civil cases involving patent infringement, the determination of punitive damages primarily involves the issues in the following sections.

4.4.3.1 Time limit for requesting punitive damages

Where a plaintiff requests punitive damages, they must clearly state the amount of the damages, the calculation method, and the facts and grounds serving as the basis thereof when filing the lawsuit. Where a plaintiff adds a request for punitive damages before the end of oral arguments in the court of first instance, the people's courts shall permit such an addition. Where a plaintiff adds a request for punitive damages during the trial of second instance, the people's courts may conduct mediation in the principle of voluntariness of the parties and, if the mediation fails, notify the concerned party to file a separate lawsuit.

4.4.3.2 Determination of intentional patent infringement

The people's courts need to consider the specific category of a patent right being infringed, the status of the right, the popularity of the relevant product, the relation between the defendant and the plaintiff or an interested party, and so on. According to Article 3 of the Interpretation of Punitive Damages in Intellectual Property Civil Cases, under the following circumstances, the people's courts may preliminarily determine that the defendant has intentionally infringed the intellectual property right:

- (1) the defendant continues the infringing act after being notified or warned by the plaintiff or an interested party;
- (2) the defendant or the legal representative or administrator thereof is the legal representative, administrator, or actual controller of the plaintiff or an interested party;
- (3) the defendant has a labor relation, service relation, cooperation relation, licensing relation, distribution relation, agency relation, representation relation, etc. with the plaintiff or an interested party, and had access to the infringed intellectual property;
- (4) the defendant and the plaintiff or an interested party have business dealings or have previously negotiated with each other to conclude a contract, and had access to the infringed intellectual property.

4.4.3.3 Identification of serious circumstances of patent infringement

The people's courts shall comprehensively consider the means and times of infringement; the duration, geographical coverage, scale and consequences of the acts of infringement; and the acts of the infringer during litigation. According to Article 4 of the Interpretation of Punitive Damages in Intellectual Property Civil Cases, the defendant can be identified as having serious circumstances in case of the following:

- (1) conducting the same or similar acts of infringement after being subject to administrative punishment or being ordered by a court to assume liability for infringement;
- (2) taking the infringement as occupation (business);
- (3) falsifying, destroying, or concealing evidence of infringement;
- (4) refusing to enforce preservation rulings;
- (5) acquiring huge profits or causing huge losses to the right holder due to the infringement;

- (6) national security, public interest, or personal health are possibly damaged because of the acts of infringement.

4.4.3.4 Basis for the calculation of punitive damages

The people's courts shall take the amount of losses actually suffered by the plaintiff, or the amount of illegal gains or profits earned by the infringer as a result of the infringement, as the basis for calculating punitive damages. This calculation basis does not include the reasonable expenses of the right holder paid in putting an end to the infringement. Where it is difficult to calculate the amount of actual losses, amount of illegal gains or amount of profits, these amounts shall be reasonably determined with reference to a multiple of the royalties for the license, which will then be taken as the calculation basis for punitive damages.

4.4.3.5 Determination of the multiple of punitive damages

To determine the multiple of punitive damages, the people's courts comprehensively consider the degree of subjective fault of the defendant, the severity of circumstances of infringement and so on. Where the defendant has been subject to administrative punishment or criminal penalty due to the same act of infringement, and this has been fully enforced, the defendant's assertion of reducing or exempting the liability for punitive damages will not be supported by the people's courts but may be considered in determining the multiple.

4.5 Other patent-related civil cases

4.5.1 Dispute cases over declarations of patent non-infringement

A dispute over the declaration of patent non-infringement refers to a lawsuit filed by an actor – whose interest is affected by a specific patent right against the right holder – to request a declaration that its act does not infringe the patent right. "Affected by a specific patent right" generally means that the actor has received a patent infringement warning from a specific patentee, but the right holder has not requested a people's court to resolve the dispute within a reasonable period, in accordance with statutory procedure. Through the (2001) Civil 3rd Request for Instruction No. 4 Reply dated July 12, 2002, the Supreme People's Court specified the non-infringement declaration system in the intellectual property field.

Further regulating and improving the non-infringement declaration litigation system, Article 18 of the Interpretation of Patent Infringement Dispute Cases stipulates the specific conditions for filing such lawsuits: where a right holder sends a patent infringement warning to others and neither withdraws the warning nor files a lawsuit within one month upon receiving a written reminder in which the warned person or interested party urges the right holder to exercise the right of action, or within two months since the issuance of the written reminder, then the people's courts shall accept the case if the warned person or interested party files a lawsuit requesting a declaration of non-infringement. "Others," in this provision, includes specific persons and nonspecific persons. "Interested party" is understood in a broad sense to include distributors and so on. To "file a lawsuit" means to file a lawsuit against patent infringement in a people's court. A right holder's request to a department in charge of patent administration work to handle the infringement dispute within a certain period after the issuance of the written reminder cannot prevent the warned person or the interested party from filing a lawsuit for a declaration of non-infringement. However, to file such a lawsuit for a declaration of non-infringement, the concerned party must also meet the conditions for filing a lawsuit stipulated in Article 108 of the Civil Procedure Law in addition to the conditions stipulated in Article 18 of the Interpretation of Patent Infringement Dispute Cases.

If a dispute between the parties over whether the relevant act constitutes patent infringement has entered a statutory dispute resolution procedure (e.g., the right holder has filed a lawsuit against infringement or has applied to a people's court for temporary measures like pre-litigation act preservation etc.), and if the relevant procedure is ongoing, then the concerned party cannot file a lawsuit for a declaration of intellectual property non-infringement.

In an appeal of a dispute over patent non-infringement declaration, *VMI Holland BV v. Safe-Run Machinery (Suzhou) Co.*,¹¹⁰ the Supreme People's Court held that, in respect of the lawsuit for a

110 ZMZ No. 5 (Sup. People's Ct, 2019).

declaration of patent non-infringement, the scope of the trial was to determine whether the technical solution implemented by the plaintiff fell within the protection scope of the defendant's patent right – thereby eliminating the plaintiff's uncertainty as to whether the technical solution implemented thereby fell within the protection scope of others' patent rights – to facilitate its operational decision-making. In a patent infringement dispute, the patentee can choose whether the dispute should be handled by a patent administration department or tried by a people's court. However, in either circumstance, the key lies in determining whether the alleged infringing product or process falls within the protection scope of the involved patent right.

In an appeal of a dispute over an objection to jurisdiction over design patent infringement, *Honda Motor Co. v. Shijiazhuang Shuanghuan Automobile Co.*,¹¹¹ the patent non-infringement declaration held that, with respect to a lawsuit for a declaration of patent non-infringement and a patent infringement lawsuit involving the same fact, the two cases shall be subject to transfer of jurisdiction and trialed concurrently to avoid the repeated trial of cases involving the same fact by different courts. The transfer of jurisdiction is determined as per the provisions on territorial jurisdiction and on jurisdiction by court level. If territorial jurisdiction is involved, then the cases will be transferred according to the temporal sequence of case acceptance: the court accepting the case later transfers the case to the court accepting the case first. If jurisdiction by court level is involved, then, generally, the inferior court will transfer the accepted case to the superior court.

4.5.2 Dispute cases over ownership of patent rights (patent application rights)

Dispute cases over the ownership of patent rights (patent application rights) primarily involve service invention-creations, invention-creations made through cooperative development or commissioned development, and the misappropriation of technical secrets.

4.5.2.1 Service invention-creations

Article 6 of the Patent Law stipulates the following:

An invention-creation that is accomplished in the course of performing the duties of the employee, or mainly by using the material and technological conditions of an employer, is a service invention-creation. For a service invention-creation, the right to apply for a patent belongs to the employer. After the application is approved, the employer shall be the patentee. The employer may, in accordance with the law, dispose of the right to apply for a patent for its service invention-creation and the patent right, there facilitating the exploitation and utilization of relevant invention-creation.

For a non-service invention-creation, the right to apply for a patent belongs to the inventor or designer. After the application is approved, the inventor or designer shall be the patentee.

For service invention-creations, Article 847 paragraph 2 of the Civil Code also stipulates the following: "A work for hire is a technological achievement that is accomplished as a result of performing the tasks assigned by a legal person or unincorporated organization or that is accomplished mainly by using the material and technical conditions of a legal person or unincorporated organization." It should be noted that the "work for hire" stipulated in this article has a broader meaning than the "service invention-creations" stipulated in Article 6 of the Patent Law: the former includes not only patent rights or patent application rights but also other types of intellectual property rights, like new plant varieties, computer software copyright and so on.

4.5.2.1.1 Invention-creations accomplished in the course of performing the duties of an employee

Article 12 paragraph 1 of the Rules for the Implementation of the Patent Law stipulates the following:

Invention-creations accomplished while performing the tasks assigned by employer referred to in Article 6 of the Patent Law means any invention-creation made:

- (1) in the course of performing an employee's own duty;
- (2) in execution of any task, other than his own duty, which was entrusted to him by the employer; or

111 MSZZ No. 1 (Sup. People's Ct, 2012).

- (3) within one year from his retirement, resignation or from termination of his employment or personnel relationship with the entity to which he previously belongs, where the invention-creation relates to his own duty or any other task entrusted to him by the entity to which he was previously employed.

With respect to “a technological achievement that is accomplished as a result of performing the tasks assigned by a legal person or unincorporated organization,” as mentioned in Article 847 paragraph 2 of the Civil Code, Article 2 of the Interpretation of Technology Contracts¹¹² stipulates the following two circumstances:

- (1) performing the employee's own duty or undertaking other technical development tasks assigned thereby;
- (2) continuing to perform technical development work that is related to the employee's own duty or tasks assigned by the former employer within one year after separation, unless otherwise provided for by laws or administrative regulations.

Compared with Article 12(3) of the Rules for the Implementation of the Patent Law, the second item in the above provision contains the additional phrase “unless otherwise provided for by laws or administrative regulations.”

4.5.2.1.2 Invention-creations made mainly by using the material and technical conditions of an employer

Article 6 paragraph 3 of the Patent Law states the following:

For an invention-creation that is accomplished by using the material and technical conditions of an employer, if the employer has concluded a contract with the inventor or designer providing the ownership of the right to apply for the patent or the ownership of the patent right, such provision shall prevail.

In practice, an invention-creation made by a former employee may involve performing the tasks assigned by a former employer but using the material and technical conditions of the current employer. According to Article 5 of the Interpretation of Technology Contracts, under such a circumstance, the rights and interests will be determined in accordance with an agreement reached between the former employer and the current employer. Otherwise, the rights and interests are shared between them based on their respective contributions to the technological achievement.

With respect to the phrase “material and technical conditions” in Article 6 of the Patent Law, Article 12 paragraph 2 of the Rules for the Implementation of the Patent Law stipulates that this means “the employer's money, equipment, spare parts, raw materials or technical materials which are not available to the public, etc.” Article 3 of the Interpretation of Technology Contracts stipulates the following: “‘material and technical conditions’ as depicted in Article 847 paragraph 2 of the Civil Code include money, equipment, apparatuses, raw materials, undisclosed technical information and documents, etc.”

In a retrial of a dispute over patent ownership, *Shenzhen Weibond Technology Co. v. Li Jianyi*,¹¹³ the determination of “invention-creations related to” an employee's own duty or any other task assigned to them by the former employer (as per Article 12(3) of the Rules for the Implementation of the Patent Law) was further clarified:

The interests of the employee, the former employer and the current employer shall be balanced and the following factors shall be comprehensively considered: first, the specific contents of the employee's duty or task assigned to him; second, specific circumstances of the involved patent and its relation with the employee's duty or task; third, whether the former employer has conducted technological development and research activities related to the involved patent or whether there is another legitimate source for the patented technology; fourth, whether the right holder or inventor of the involved patent (application) can make reasonable explanations on the development and research process or source of the patented technology.

¹¹² Interpretation on Several Issues concerning the Application of Laws in the Trial of Cases Involving Technology Contract Disputes (promulgated by the Sup. People's Ct, Dec. 16, 2004, rev'd Dec. 29, 2020, effective Jan. 1, 2021).

¹¹³ Sup. People's Ct Guiding Case No. 158, July 23, 2021.

4.5.2.1.3 Ownership and disposal of service invention-creations

According to Article 6 paragraph 1 of the Patent Law, “[f]or a service invention-creation, the right to apply for a patent belongs to the employer. After the application is approved, the employer shall be the patentee.” Article 2 paragraph 2 of the Interpretation of Technology Contracts stipulates the following: “Where a legal person or unincorporated organization has entered into an agreement with an employee, with respect to the rights and interests in and to a technological achievement accomplished by the employee when he or she was employed or after separation therefrom, the people’s courts shall consider the agreement.”

When the Patent Law was last amended in 2020, it was stipulated in Article 6 paragraph 1 that “[t]he employer may, in accordance with the law, dispose of the right to apply for a patent for its service invention-creation and the patent right, thereby facilitating the exploitation and utilization of the relevant invention-creation.” Article 847 paragraph 1 of the Civil Code stipulates the following:

Where a right to use or transfer a work for hire belongs to a legal person or unincorporated organization, the legal person or unincorporated organization may conclude a technology contract on the work for hire. Where the legal person or unincorporated organization concludes a technology contract to transfer the work for hire, the creator of the work for hire has right in priority to acquire it on equivalent conditions.

4.5.2.1.4 Remuneration, reward and authorship of the inventor or designer

Article 15 of the Patent Law stipulates the following: “The entity that is granted a patent right shall reward the inventor or designer of service invention-creation. After such patent is exploited, the entity shall pay the inventor or designer a reasonable remuneration based on the extent of spreading and application as well as the economic benefits yielded.” Articles 76–78 of the Rules for the Implementation of the Patent Law further provide for the methods and amounts of “reward and remuneration.”

According to Article 16 of the Patent Law, an inventor or designer has the right to name themselves as such in the patent documents. Article 849 of the Civil Code also stipulates the following: “An individual person who has accomplished a technological work product has the right to indicate on the relevant documents that the said person is the creator thereof and to receive certificate of honor and rewards.”

With respect to the identification of an inventor or designer, further provisions are made in Article 13 of the Rules for the Implementation of the Patent Law and Article 6 of the Interpretation of Technology Contracts.

4.5.2.2 Invention-creations made through cooperative or commissioned development

According to Article 8 of the Patent Law, for an invention-creation accomplished by two or more entities or individuals, or accomplished by an entity or individual in the execution of a commission given to them by another entity or individual, the right to apply for a patent belongs, unless otherwise agreed upon, to the entity or individual that accomplished the invention-creation, or to the entities or individuals that accomplished the invention-creation in collaboration. After the patent application is approved, the entity (or entities) or individual (or individuals) that filed the application shall be the patentee. Articles 859 and 860 of the Civil Code also provide for invention-creations accomplished through commissioned development and cooperative development, respectively.

4.5.2.3 Patent applications based on unauthorized use of others’ technical secrets

If an infringer, without the authorization of the right holder, applies for a patent for a technical secret – whether obtained legitimately from the right holder thereof or illegally through theft or other undue means – the right holder may file a civil lawsuit against trade secret misappropriation in accordance with the laws to request a judgment ordering that the infringer assume civil liabilities (e.g., cessation of misappropriation and compensation for losses) or to request the competent people’s court to declare that the right holder has the patent right over the patent unilaterally applied for by the infringer.

In an appeal of a dispute over patent ownership, *Tianjin Greenpine Pharma Co. v. Huabei Pharmaceutical Hebei Huamin Pharmaceutical Co.*,¹¹⁴ the Supreme People's Court held that, where a party asserts ownership of a patent right on the ground of misappropriation of a technical secret, the people's court shall examine whether the technical secret is disclosed in the patent documents and whether it is incorporated into the patented technical solution. If the answer to either question is in the affirmative, then the technical secret has been misappropriated. If the technical secret constitutes the substantial content of the patented technical solution, the right holder of the technical secret has lawful rights to the patent.

4.5.3 Dispute cases over patent contracts

For cases over patent contract disputes, the main provisions that apply include the relevant provisions in Book I(VI) ("Civil Juristic Acts") and Book III ("Contracts") of the Civil Code, in addition to relevant provisions in the Patent Law and the Rules for the Implementation of the Patent Law. Book III(XX) ("Technology Contracts") of the Civil Code also specifically provides for technology development, transfer, licensing, consultation and service contracts.

With respect to technology contracts, the Interpretation of Technology Contracts includes 47 articles divided into six parts:

- General Provisions;
- Technology Development Contracts;
- Technology Transfer Contracts and Technology Licensing Contracts;
- Technology Consultation Contracts and Technology Service Contracts;
- Procedural Issues Related to the Trial of Technology Contract Disputes; and
- Miscellaneous.

Technological cooperation involving foreign elements is regulated by relevant provisions of the Regulations on Technology Import and Export Administration and the Regulations on the Implementation of the Law on Chinese-Foreign Equity Joint Ventures.¹¹⁵ On March 18, 2019, the State Council announced Decree No. 709, which deleted Article 43(3)-(4) of the Regulations on the Implementation of the Law on Chinese-Foreign Equity Joint Ventures and Article 24 paragraph 3, Article 27 and Article 29 of the Regulations on Technology Import and Export Administration and amended the original Article 41 thereof to Article 39, as follows: "The competent foreign trade department under the State Council shall, within three working days from the date of receipt of the documents provided for in Article 38 hereof, register the technology export contract and issue the registration certificate of technology export." Article 22 of the Foreign Investment Law stipulates the following:¹¹⁶

The State protects the intellectual property rights of foreign investors and foreign-invested enterprises, protects the legitimate rights and interests of intellectual property rights holders and related rights holders, and strictly pursues legal liability for infringements of intellectual property rights in accordance with law.

The State encourages technical cooperation based on the voluntary principle and commercial rules in the process of foreign investment. The terms and conditions for technical cooperation are determined by the investing parties through negotiation on an equal basis in accordance with the principle of fairness. Administrative departments and their staff members shall not force the transfer of technology through administrative means.

4.5.4 Civil cases involving standard-essential patents

Civil cases involving standard-essential patents mainly involve civil disputes over patent infringement, patent contracts, royalties and abuse of market dominance involving standard-essential patents.

¹¹⁴ ZMZ No. 871 (Sup. People's Ct, 2020).

¹¹⁵ Regulations on Technology Import and Export Administration (promulgated by the State Council, March 2, 2019, rev'd Nov. 29, 2020, effective Nov. 29, 2020); Regulations on the Implementation of the Law on Chinese-Foreign Equity Joint Ventures (promulgated by the State Council, Sep. 20, 1983, rev'd July 22, 2001, effective July 22, 2001).

¹¹⁶ Foreign Investment Law (promulgated by the Nat'l People's Cong., March 15, 2019, effective Jan. 1, 2020).

4.5.4.1 Patent-related cases

In July 2008, in their Letter on Chaoyang Xingnuo Company's Act of Exploiting a Patent,¹¹⁷ the Supreme People's Court expressed the following opinion on the request for instruction raised by the High People's Court of Liaoning:

Given the reality that China's standard-setting organization has not established systems with respect to the public disclosure of information and exploitation of patents incorporated in relevant standards, where a patentee has participated in the formulation of a standard or has consented to the incorporation of a patent in a national, industrial, or local standard, then the patentee shall be deemed as having licensed others to exploit the patent while implementing the standard, and the relevant acts of exploiting the patent by others do not constitute acts of patent infringement as stipulated in Article 11 of the Patent Law. The patentee may require the exploiter to pay an amount of royalties which, however, shall be significantly lower than ordinary royalties; where the patentee has undertaken to waive the patent royalties, such an undertaking shall apply.

Article 24 of the Interpretation (II) of Patent Infringement Dispute Cases specifically provides for issues concerning standard-essential patents, which primarily involve important issues such as the disclosure of patent information related to technical standards; defenses against infringement; applicable conditions for the cessation of infringement; negotiation and adjudication of exploitation licensing conditions; and fair, reasonable and nondiscriminatory licensing obligations, among other issues. Paragraphs 1–3 of this article stipulate the following:

Where a recommended national, industrial, or local standard has explicitly indicated the information of an essential patent, an alleged infringer's non-infringement defense on the ground that such a standard may be implemented without license shall generally be rejected.

Where a recommended national, industrial, or local standard has explicitly indicated the information of an essential patent, when the patentee and an alleged infringer negotiate licensing terms for exploitation of the patent, if the patentee willfully violates the fair, reasonable, and nondiscriminatory licensing obligation undertaken thereby during the formulation of the standard, which results in failure to reach a patent exploitation licensing contract, and if the alleged infringer has no obvious fault in the negotiation, the patentee's request for cessation of implementation of the standard shall generally be rejected.

The exploitation licensing terms referred to in the preceding paragraph 2 shall be negotiated between the patentee and the alleged infringer. If the parties fail to reach an agreement after sufficient negotiation, they can request a people's court to determine the licensing terms. In determining the licensing terms, the people's court shall, in accordance with the principle of fairness, reasonableness and nondiscrimination, comprehensively consider such factors as the innovation level of the patent, its contribution in the standard, the technical field which the standard falls under, the nature and the implementation scope of the standard, and relevant licensing terms.

Before this judicial interpretation was issued, the Standardization Administration of China and the CNIPA had issued the Regulatory Measures on National Standards Involving Patents (Interim) in December 2013, which improved the procedure for the disclosure of patent information related to national standards and specifically stipulated that patents involved in national standards are essential patents. To maintain consistency with these interim measures, the Interpretation (II) of Patent Infringement Dispute Cases only provided for recommended standards (i.e., nonmandatory standards) and explicitly indicated their related patents but did not provide for issues such as standards without disclosure of patent information, mandatory standards, international standards and so on, which were also not mentioned in the foregoing interim measures.

¹¹⁷ Letter on the Issue of Whether Chaoyang Xingnuo Company's Act of Exploiting the Patent, in the Industrial Standard Promulgated by the Ministry of Construction's Specification for Design of Ram-Compaction Piles with Composite Bearing Base, during its Design and Construction in Accordance Therewith, Constitutes Patent Infringement, MSTZ No. 4 (Sup. People's Ct, 2008).

With respect to technical standards related to pharmaceutical products, in a retrial of a dispute over invention patent infringement, *Qilu Pharmaceutical Co. v. Beijing Sihuan Pharmaceutical Co.*,¹¹⁸ the Supreme People's Court held that the prevailing laws and administrative regulations involving pharmaceutical product administration and registration do not require right holders of pharmaceutical product patents to make "fair, reasonable and nondiscriminatory" undertakings in the licensing of such pharmaceutical product patents when cooperating in the formulation of national pharmaceutical product standards. There was no evidence in this case to prove that Beijing Sihuan Pharmaceutical had made "fair, reasonable and nondiscriminatory" undertakings in the licensing of the patent during the formulation of the national pharmaceutical product standard related to the involved patent. Therefore, the principle of "fairness, reasonableness and nondiscrimination" did not apply.

4.5.4.2 Monopoly-related cases

The Supreme People's Court issued the Provisions on Cases of Monopoly Disputes in 2012, amending it in 2020.¹¹⁹ This judicial interpretation includes 16 articles that specify issues such as the types of cases, the filing of lawsuits, jurisdiction and trial, the burden of proof, evidence, civil liabilities and the statute of limitations with respect to monopoly-related cases. It further clarified relevant provisions of the Anti-monopoly Law.¹²⁰ Article 3 of the provisions stipulates the following:

Monopoly-related civil dispute cases of first instance shall come under the jurisdiction of intellectual property courts or intermediate people's courts of cities where the governments of provinces, autonomous regions, or municipalities are located or of cities under separate state planning, or intermediate people's courts designated by the Supreme People's Court.

In addition to the above law and judicial interpretation, the Anti-monopoly Commission, under the State Council, issued the Guidelines on Anti-monopoly in the Field of Intellectual Property Rights on January 4, 2019, and the Guidelines on the Definition of Relevant Market on July 6, 2009.¹²¹

In an appeal of a dispute over an objection to jurisdiction over market dominance abuse, *Ericsson v. TCL Group Corp.*,¹²² the Supreme People's Court held that Article 2 of the Anti-monopoly Law specifies that the law is applicable to monopolistic conduct outside the territory of China. At the same time, it held that Article 2 also indicates that, for jurisdiction over monopoly dispute cases, the place where the alleged monopolistic conduct led to the elimination or restriction of competition can be the connecting point of jurisdiction.

4.5.5 Patent-related civil cases involving pharmaceutical products

The protection of pharmaceutical product patents is essential to the innovative development of the pharmaceutical industry and to the health and happiness of the people. While motivation systems and judicial safeguards are provided for the independent innovation and high-quality development of the pharmaceutical industry, the accessibility of pharmaceutical products and the health of the people are also considered. In particular, given the huge costs for the development and research of new pharmaceutical products, strong intellectual property protections are critical for motivating continuous innovation in the pharmaceutical industry.

To strengthen protections for pharmaceutical product patents and realize the early resolution of pharmaceutical product patent disputes, both the Opinion on Deepening the Reform of Examination and Approval Policy, issued in October 2017, and the Opinions on Strengthening the Protection of Intellectual Property Rights issued on November 24, 2019, were proposed to "explore and establish a pharmaceutical product patent linkage system."¹²³

¹¹⁸ MS No. 4107 (Sup. People's Ct, 2017).

¹¹⁹ Provisions on Several Issues concerning the Application of Laws in the Trial of Civil Dispute Cases Arising from Monopolistic Conduct (promulgated by the Sup. People's Ct, May 3, 2012, rev'd Dec. 29, 2020, effective Jan. 1, 2021).

¹²⁰ Anti-monopoly Law (promulgated by the Standing Comm. Nat'l People's Cong., Aug. 30, 2007, effective Aug. 1, 2008).

¹²¹ Guidelines for Countering Monopolization in the Field of Intellectual Property Rights (promulgated by the Anti-monopoly Comm. State Council, Jan. 4, 2019, effective Jan. 4, 2019); Guidelines on the Definition of Relevant Market (promulgated by the Anti-monopoly Comm. State Council, July 6, 2009, effective July 6, 2009).

¹²² ZMXZ No. 32 (Sup. People's Ct, 2019).

¹²³ Opinion on Deepening the Reform of Examination and Approval Policy and Encouraging Innovation in Pharmaceutical Products and Medical Appliances (promulgated by the Gen. Off. CPC Cent. Comm. and the Gen. Off. State Council, Oct. 1, 2017, effective Oct. 1, 2017); Opinions on Strengthening the Protection of Intellectual Property Rights (promulgated by the Gen. Off. CPC Cent. Comm. and the Gen. Off. State Council, Nov. 24, 2019, effective Nov. 24, 2019).

4.5.5.1 Amendments to the Patent Law related to pharmaceutical product patent disputes

During the fourth amendment to the Patent Law, the legislature stipulated an early resolution mechanism for pharmaceutical product patent disputes at the suggestion of relevant competent departments and by reference to the pharmaceutical product patent linkage systems of relevant countries. Consequently, Article 76 of the Patent Law now stipulates the following:

In the review and approval process before the marketing of a pharmaceutical product, where the applicant for marketing approval of the pharmaceutical product has any disputes over the relevant patent right associated with the pharmaceutical product applied for registration with the relevant patentee or interested party, the party concerned may file a lawsuit before the people's court and request a judgment on whether the technical solution related to the pharmaceutical product that is applied for registration falls within the protection scope of any pharmaceutical product patent right owned by others. The medical product regulatory department under the State Council may, within a prescribed time limit, make a decision on whether to suspend the marketing approval of the pharmaceutical product according to the effective judgment or written order of the people's court.

The applicant for marketing approval of the pharmaceutical product, the relevant patentee or the interested party may also petition the patent administration department under the State Council for an administrative adjudication on the disputes over the patent right associated with the drug applied for registration.

The medical products regulatory department under the State Council shall, in conjunction with the patent administration department under the State Council, formulate specific cohesive measures for patent right dispute resolutions at the stages of pharmaceutical product marketing license approval and pharmaceutical product marketing license application, which shall be implemented after the approval of the State Council.

In Article 42 paragraph 3 of the Patent Law, a provision on patent term compensation for pharmaceutical product patents was also added.

4.5.5.2 Formulation of relevant judicial interpretations and regulatory documents

To implement Article 76 of the Patent Law and improve the early resolution mechanism of pharmaceutical product patent disputes, the National Medical Products Administration and the CNIPA, in conjunction with relevant departments, issued the Implementation Measures for Pharmaceutical Product Patent Disputes on July 4, 2021.¹²⁴ Then, on July 5, 2021, the Supreme People's Court issued their Provisions on the Patent Rights of Drugs, and the CNIPA issued the Adjudication Measures for Pharmaceutical Product Patent Disputes.¹²⁵ Both documents came into effect on the same day.

The Provisions on the Patent Rights of Drugs focused on procedural issues to be resolved after the implementation of the pharmaceutical product patent linkage system and the connection and matching of litigation procedures with the review and approval process and administrative adjudication procedure. This thereby promoted the uniformity of administrative enforcement and judicial adjudication standards. The provisions included 14 articles to provide for jurisdiction, specific causes of action, materials required for filing a lawsuit, ways of filing such a lawsuit, the linkage between administrative and judicial procedures, defenses, the protection of trade secrets during litigation, act preservation, counterclaims for damages against the losing party, means of service and so on, thereby providing clear guidance for the fair and timely trial of such cases and promoting the implementation of the pharmaceutical product patent linkage system.

4.5.5.3 Main issues involved in the early resolution mechanism of pharmaceutical product patent disputes

4.5.5.3.1 Jurisdiction

Article 1 of the Provisions on the Patent Rights of Drugs stipulates the jurisdiction and causes of action over disputes related to pharmaceutical product patents. Civil cases of first instance

¹²⁴ Implementation Measures for the Early Resolution Mechanism of Pharmaceutical Product Patent Disputes (Trial) (promulgated by Nat'l Med. Prod. Admin. and the CNIPA, July 4, 2021, effective July 4, 2021).

¹²⁵ Administrative Adjudication Measures for the Early Resolution Mechanism of Pharmaceutical Product Patent Disputes (promulgated by the CNIPA, July 5, 2021, effective July 5, 2021).

involving lawsuits in relation to pharmaceutical product patents come under the concentrated jurisdiction of the Beijing Intellectual Property Court to facilitate the organization of superior judicial resources and unify the adjudication standard.

Furthermore, given that such civil cases often also involve administrative patent right confirmation cases related to the patent and administrative cases filed by the concerned parties because they disagree with administrative adjudications made by the CNIPA, centralized jurisdiction safeguards the organic linkage between different litigation procedures and facilitates work coordination with relevant administrative departments under the State Council.

With respect to jurisdiction over appeal cases, in accordance with the NPC Standing Committee's Decision on the Litigation of Intellectual Property Cases and Article 2 of the Provisions on the Intellectual Property Court, where a party disagrees with a first-instance judgment or ruling made by the Beijing Intellectual Property Court on a pharmaceutical product patent linkage lawsuit, that party may appeal to the Supreme People's Court.

4.5.5.3.2 Relation between pharmaceutical product patent linkage lawsuits and patent infringement lawsuits

Article 11 of the Patent Law specifically provides for acts of patent infringement. As the act of applying for review and approval before the marketing of a pharmaceutical product does not constitute an act of infringement according to Article 11 of the Patent Law, the provisions on remedies against patent infringement do not apply in such cases. For a civil lawsuit filed by a party in accordance with Article 76 of the Patent Law, the specific request is for a judgment on whether the technical solution related to the pharmaceutical product for which registration is applied "falls within the protection scope of any pharmaceutical product patent right owned by others pharmaceutical product." The nature of such a lawsuit is a lawsuit for confirmation. However, in a pharmaceutical product patent linkage lawsuit, the applicant for pharmaceutical product marketing approval may still raise a prior art defense or a prior-use rights defense in accordance with Articles 67 and 75(2) of the Patent Law, respectively. If a defense is sustained, the competent people's court may rule to confirm that the technical solution related to the pharmaceutical product for which registration is applied falls within the protection scope of related patent rights.

4.5.5.3.3 "Relevant patents" in Article 76 of the Patent Law

As a component of the pharmaceutical product patent linkage system, the Provisions on the Patent Rights of Drugs need to be coordinated with the specific measures for linking pharmaceutical product marketing approval with patent dispute resolution during the pharmaceutical product marketing approval application stage – as stipulated in Article 76 paragraph 3 of the Patent Law (i.e., the Implementation Measures for Pharmaceutical Product Patent Disputes) – to implement the provisions of that article.

The early resolution mechanism for pharmaceutical product patent disputes stipulated in Article 76 of the Patent Law only covers specific types of pharmaceutical product patents – "relevant patents." With respect to the scope of "relevant patents," Article 2 of the Implementation Measures for Pharmaceutical Product Patent Disputes stipulates the following:

The pharmaceutical product regulatory department under the State Council shall establish the Patent Information Registration Platform of Marketed Pharmaceutical Products in China, for pharmaceutical product marketing approval holders to register patent information related to pharmaceutical products registered and approved in China.

Where relevant patent information is not registered on the Patent Information Registration Platform of Marketed Pharmaceutical Products in China, the Measures shall not apply.

Article 5 of the measures stipulates the following: "Chemical pharmaceutical product marketing approval holders may register patents for compounds as active pharmaceutical ingredients, patents for pharmaceutical compositions containing active ingredient(s), and pharmaceutical use patents, on the Patent Information Registration Platform of Marketed Pharmaceutical Products in China." Article 12 stipulates the following: "For traditional Chinese medicines, patents concerning Chinese medicine compositions, Chinese medicine extracts, and pharmaceutical use can be

registered; for biological products, patents concerning sequence structure of active ingredients and pharmaceutical use can be registered.”

Without making additional provisions for “related patents” but keeping coordination with the above provisions of the implementation measures, Article 2 of the Provisions on the Patent Rights of Drugs stipulates the following: “Related patents’ stipulated in Article 76 of the Patent Law refer to those patents for which the measures of the relevant administration departments under the State Council for linking pharmaceutical product marketing approval and patent dispute resolution during the pharmaceutical product marketing approval application stage shall apply.”

4.5.5.3.4 Parties entitled to file lawsuits referred to in Article 76 of the Patent Law

Article 76 of the Patent Law stipulates that the applicant for pharmaceutical product marketing approval and the concerned patentee or an interested party may file a lawsuit before a people’s court. Article 2 paragraph 2 of the Provisions on the Patent Rights of Drugs stipulates the following: “The ‘interested party’ in Article 76 of the Patent Law refers to licensees of the patent referred to in the preceding paragraph and marketing approval holders of the related pharmaceutical product.”

According to Article 7 of the Implementation Measures for Pharmaceutical Product Patent Disputes,

[a]ny patentee or an interested party who objects to the fourth type of patent declarations may, within 45 days from the date when the application for pharmaceutical product marketing approval is published by the national pharmaceutical product evaluation institution, may file a lawsuit before people’s court regarding whether the technical solution of the pharmaceutical product for which marketing approval is applied falls within the protection scope of relevant patent rights, or apply to the patent administration department under the State Council for an administrative adjudication.

If a patentee or interested party fails to file a lawsuit within the said 45 days, the applicant for pharmaceutical product marketing approval may, in accordance with Article 4 of the judicial interpretation, “file a lawsuit before a people’s court to request for confirmation that the pharmaceutical product for which registration is applied does not fall within the protection scope of relevant patent rights.”

4.5.5.3.5 Act preservation

Article 10 of the Provisions on the Patent Rights of Drugs stipulates that, where a patentee or an interested party

requests for prohibiting an applicant for pharmaceutical product marketing approval from implementing the acts stipulated in Article 11 of the Patent Law within the term of the relevant patent right, the people’s courts shall handle such a request as per relevant provisions of the Patent Law and the Civil Procedure Law; requests thereof for prohibiting acts of applying for pharmaceutical product marketing approval or acts of pharmaceutical product marketing review and approval shall not be supported by the people’s courts.

Provisions on act preservation are made in Chapter IX (“Preservation and Preliminary Enforcement”) of the Civil Procedure Law, Chapter 7 (“Preservation and Preliminary Enforcement”) of the Interpretation of the Civil Procedure Law, and the Provisions on Act Preservation in Intellectual Property Disputes. Additionally, Article 105 of the Civil Procedure Law stipulates the following: “If an application is made wrongfully, the applicant shall compensate the person against whom the application is made for any loss incurred as a result of the act preservation.”

4.5.5.3.6 Counterclaim for compensation against vexatious litigation

To better balance the interests of patentees and interested parties and the applicants for pharmaceutical product marketing approval, Article 12 of the Provisions on the Patent Rights of Drugs provides for a counterclaim system for compensation against vexatious litigation, in accordance with Article 132 of the Civil Code, Article 13 of the Civil Procedure Law, and Articles 20 and 47 of the Patent Law.

There are two prerequisites for counterclaiming compensation against vexatious litigation. First, the subjective prerequisite is that the patentee or interested party knows or should have known that the patent right was declared invalid or that the technical solution related to the pharmaceutical product for which marketing approval is applied does not fall within the protection scope of the patent right. Here, “knows” or “should have known” are determined following the same criteria as for general infringement cases. Second, the objective prerequisite is that the applicant for pharmaceutical product marketing approval has suffered losses caused by the litigation.

With respect to jurisdiction over counterclaims for compensation against vexatious litigation, and given the close relation of such cases with pharmaceutical product patent lawsuits, it is stipulated that such cases also come under the jurisdiction of the Beijing Intellectual Property Court.

4.5.5.3.7 Administrative adjudication

With respect to the protection of patent rights, China adopts a dual-track system whereby judicial and administrative protections work in tandem. For “disputes arising from patents related to related to the pharmaceutical product for which marketing approval is applied” (Article 76 of the Patent Law), the concerned party may either file a lawsuit before a people’s court or “petition the patent administration department under the State Council for an administrative adjudication on the disputes” as per Article 76 paragraph 2 of the Patent Law.

Article 5 of the Provisions on the Patent Rights of Drugs stipulates the following:

Where a party asserts that a lawsuit referred to in Article 76 of the Patent Law should not be accepted or requests for suspension of the lawsuit on the ground that the patent administration department under the State Council has accepted the application for administrative adjudication referred to in Article 76 of the Patent Law, such an assertion or application shall not be supported by the people’s courts.

Article 4 of the Adjudication Measures for Pharmaceutical Product Patent Disputes stipulates the following: “Where a party applies for administrative adjudication, the prerequisite to be met is that no people’s court has accepted a case over the pharmaceutical product patent dispute.” A party having first chosen to apply for administrative adjudication can still file a lawsuit before a people’s court later. However, if a party has filed a lawsuit before a people’s court, and the case has been accepted, then the party can no longer apply to the CNIPA for administrative adjudication on the same pharmaceutical product and patent.

Both Article 7 of the Implementation Measures for Pharmaceutical Product Patent Disputes and Article 19 of the Adjudication Measures for Pharmaceutical Product Patent Disputes stipulate that, where a party disagrees with an administrative adjudication made by the CNIPA on a pharmaceutical product patent dispute, the party may file an administrative lawsuit before the Beijing Intellectual Property Court. Where the party still disagrees with the judgment made thereby, it may appeal to the Supreme People’s Court.

4.6 Procedural issues concerning patent-related civil cases

4.6.1 Evidence rules and evidence preservation

With respect to issues concerning evidence in civil lawsuits, detailed provisions exist in the Civil Procedure Law, Interpretation of the Civil Procedure Law, Provisions on Evidence in Civil Procedures, and related judicial interpretations. These generally apply to patent-related civil cases. Based on the characteristics of patent cases, the Patent Law and related judicial interpretations also contain some special provisions related to evidence. The Supreme People’s Court has also formulated the Provisions on Evidence in Civil Procedures involving Intellectual Property Rights.

4.6.1.1 Provisions related to evidence in the Civil Procedure Law and related judicial interpretations

With respect to evidence, detailed provisions exist in Chapter VI (Articles 63–81) of the Civil Procedure Law and Part 4 (Articles 90–124) of the Provisions on Evidence in Civil Procedures.

The latter provisions were issued in 2001 by the Supreme People's Court and later amended in 2008 and 2019. This judicial interpretation currently includes 100 articles.

China has set up three internet courts: in Hangzhou, Beijing and Shenzhen. In the Provisions on the Trial of Cases by Internet Courts, Article 11 stipulates rules for internet courts in determining the authenticity of electronic evidence, Article 13 clarifies the general requirements and legal basis for the examination of evidence in online lawsuits, and Articles 14–19 stipulate rules regarding evidence in online lawsuits. In particular, Articles 16–19 make special provisions regarding blockchain evidence deposits.

The Rules of Online Litigation of People's Courts came into effect on August 1, 2021. This judicial interpretation defines the scope of validity and determination criteria for blockchain evidence deposits.

4.6.1.2 Provisions related to evidence in the Patent Law

Regarding evidence, the Patent Law primarily covers the following four aspects:

- Article 66 paragraph 1 provides for the burden of proof in new product manufacturing process invention patent infringement cases (see Section 4.3.2.5.4 of this chapter for further detail).
- Article 66 paragraph 2 stipulates that people's courts may ask the patentee or any interested party to furnish a patent right evaluation report made by the patent administration department of the State Council after having conducted a search, analysis and evaluation of relevant utility models or designs. This provision makes it clear that the nature of such patent right evaluation reports is evidence. Patentees, interested parties or alleged infringers may take the initiative to present such a patent right evaluation report.
- Article 71 stipulates that people's courts may order an infringer to provide account books and materials related to patent infringement (see Section 4.4.3.4 of this chapter for further detail).
- Article 73 provides for the pre-litigation preservation of evidence. With respect to evidence preservation applied before the filing of a lawsuit or during a lawsuit, Article 81 of the Civil Procedure Law and Article 98 of the Interpretation of the Civil Procedure Law also provide relevant provisions.

4.6.1.3 The Provisions on Evidence in Civil Procedures involving Intellectual Property Rights

The Provisions on Evidence in Civil Procedures involving Intellectual Property Rights, while being an important component of the evidence system for civil lawsuits, has characteristics different from those of the traditional civil evidence system. In February 2018, the General Office of the Communist Party of China's Central Committee and the General Office of the State Council issued the Opinions on Strengthening Reform and Innovation in Intellectual Property Adjudication, specifically raising the reform target of "establishing evidence rules in compliance with characteristics of intellectual property cases." In November 2019, the two offices issued the Opinions on Strengthening the Protection of Intellectual Property Rights, specifically requiring the "strict regulation of evidence standards" and the "formulation of judicial interpretations on rules for evidence in civil lawsuits involving intellectual property."

To strengthen the judicial protection of intellectual property rights and to practically address intellectual property right holders' difficulties in producing evidence and the high costs of safeguarding rights and interests, the Supreme People's Court formulated the Provisions on Evidence in Civil Procedures involving Intellectual Property Rights, which included 33 articles. This further improved the system of evidence on important issues such as the submission of evidence, obstruction to proof, evidence preservation, judicial appraisal, identification of extraterritorial evidence, the protection of trade secrets during the litigation process and so on. These provisions came into effect on November 18, 2020.

4.6.2 Act preservation

4.6.2.1 Establishment of an act preservation system in intellectual property disputes

Article 61 of the Patent Law, as amended in 2000, stipulated the following:

Where a patentee or an interested party has evidence to prove that another person is infringing or is about to infringe its or his patent right, which, unless being stopped in

time, may cause irreparable damage to his lawful rights and interests, the patentee or interested party may, before filing a lawsuit, apply to the people's court for adopting measures for ordering to prohibit certain acts in accordance with the law.

The Supreme People's Court issued the Provisions on the Pre-litigation Cessation of Patent Infringement in June 2001.¹²⁶ Later, in December 2001, the Supreme People's Court issued the Interpretation of the Pre-litigation Cessation of Trademark Infringement and Preservation of Evidence.¹²⁷ Both judicial interpretations have played an important role in the people's courts' review of applications for the pre-litigation cessation of patent infringement.

Article 66 of the 2008 Patent Law further improved the act preservation system. The Civil Procedure Law, as amended in 2012, added relevant content on act preservation: Articles 100 and 101 provided for act preservation during and before litigation, respectively, thereby establishing an act preservation system for all civil cases, including those involving intellectual property rights. Articles 152–173 of the Interpretation of the Civil Procedure Law made further provisions regarding “preservation.”

In December 2018, the Supreme People's Court issued the Provisions on Act Preservation in Intellectual Property Disputes, which included 21 articles covering the subject of applications, the courts of jurisdiction, examination procedures, factors in determining the necessity of preservation, the term of preservation measures, the identification of wrongful applications and the lifting of preservation measures, among other matters.

4.6.2.2 Main contents of the Provisions on Act Preservation in Intellectual Property Disputes

4.6.2.2.1 Jurisdiction

According to Article 3 of the Provisions on Act Preservation in Intellectual Property Disputes,

[a]n application for pre-litigation act preservation shall be filed before the people's court with jurisdiction over intellectual property disputes at the place where the respondent is domiciled or before the people's court with jurisdiction over the case.

Where an arbitration clause has been agreed upon between the parties, then the application shall be filed before the people's court stipulated in the preceding paragraph.

4.6.2.2.2 Identification of “emergencies”

According to Articles 100–101 of the Civil Procedure Law, having an emergency is the prerequisite for applying for pre-litigation act preservation; the application for act preservation during litigation may also involve emergency circumstances; and, for any application for act preservation in an emergency, a people's court must decide the same within 48 hours after receipt of the application. According to Article 6 of the Provisions on Act Preservation in Intellectual Property Disputes, an emergency is a circumstance that “would damage the interests of the applicant if a preservation measure is not implemented immediately.” In patent-related civil cases, emergencies primarily include the following circumstances:

- the disputed patent will soon be illegally disposed of;
- the patent of the applicant is being or will soon be infringed during a time-sensitive occasion like a trade fair; and
- other circumstances that require the immediate implementation of act preservation measures.

4.6.2.2.3 Factors to be considered for determining the necessity of act preservation

Article 7 of the Provisions on Act Preservation in Intellectual Property Disputes stipulates the following:

People's courts shall comprehensively consider the following factors in examining an application for act preservation:

¹²⁶ Provisions on the Application of Laws concerning Preliminary Injunction for Patent Infringement (Judicial Interpretation No. 20 [2001], passed by the Sup. People's Ct, June 5, 2001, effective July 1, 2001).

¹²⁷ Interpretation on the Application of Laws concerning Preliminary Injunction for Trademark Infringement and Evidence Preservation (Judicial Interpretation No. 2 [2002], passed by the Sup. People's Ct, Dec. 25, 2002, effective Jan. 22, 2002).

- (1) whether the application has a factual and a legal basis, including whether the validity of the asserted intellectual property right is stable;
- (2) whether the applicant's legitimate rights and interests will be irreparably damaged or make it difficult to enforce the ruling of the case if act preservation measures are not implemented;
- (3) whether the damage caused to the applicant if act preservation measures are not implemented exceeds the damage caused to the respondent by implementing the act preservation measures;
- (4) whether implementing act preservation measures harms the public interest; [and]
- (5) other factors that should be considered.

According to Article 10 of these provisions, "irreparable damage," in patent-related civil cases, primarily includes the following:

- circumstances where the act of the respondent will make it difficult to control the infringement and significantly increase the losses suffered by the applicant; and
- circumstances where the act of infringement by the respondent will result in a significant reduction in the applicant's share in the relevant market.

Patent-related civil cases often involve judgment on whether the validity of a patent right is stable. Article 8 of the provisions stipulates the following:

People's courts shall comprehensively consider the following factors in examining and judging whether the validity of an intellectual property right asserted by the applicant is stable:

- (1) the type or nature of the involved intellectual property right;
- (2) whether the involved intellectual property right has been substantively examined;
- (3) whether the involved intellectual property right is in an invalidation or revocation procedure and has the possibility of being declared invalid or revoked;
- (4) whether there is a dispute over the ownership of the involved intellectual property right; [and]
- (5) other factors that may lead to instability of the validity of the involved intellectual property right.

With respect to applications for act preservation based on utility model patents or design patents, Article 9 of the provisions specifically stipulates the following:

Where an applicant applies for act preservation based on a utility model patent or design patent, the applicant shall submit a search report or an evaluation report issued by the patent administration department under the State Council or a decision maintaining the validity of the patent right made by the patent administration department under the State Council. Where the applicant refuses to submit such documents without justifiable reasons, the people's court shall rule to dismiss the application.

The main consideration here is that utility model patents and design patents are not substantively examined before granting according to the Patent Law and are therefore more likely to be declared invalid. The special requirements for applications for act preservation based on these two types of patent rights prevent the abuse of rights in applying for act preservation.

4.6.2.2.4 Identification of "wrongful application" and applicant's liability for compensation

Article 16 of the Provisions on Act Preservation in Intellectual Property Disputes interprets the phrase "wrongful application" from Article 105 of the Civil Procedure Law to mean:

- (1) where the applicant does not file a lawsuit or applies for arbitration within 30 days after implementing the act preservation measures;
- (2) where the act preservation measures are improper from the beginning because the intellectual property right asserted is declared invalid, or for other reasons;

- (3) where an application for ceasing the infringement of intellectual property right or unfair competition was filed, whereas an effective judgment was made holding that infringement or unfair competition is not constituted; [or]
- (4) other circumstances where the application is wrongfully made.

This provision is provided based on the objective principle of imputation, without considering the subjective fault of the applicant.

According to Article 105 of the Civil Procedure Law, where an application for act preservation is “wrongfully made,” the applicant shall compensate the respondent for losses suffered due to the act preservation. The Provisions on Act Preservation in Intellectual Property Disputes stipulate that, if the applicant does not file a lawsuit after applying for pre-litigation act preservation or if the parties agree to arbitration, then a lawsuit for losses filed by the respondent in accordance with Article 105 of the Civil Procedure Law will come under the jurisdiction of the people’s court that implemented the act preservation measures. However, if the applicant files a lawsuit, then it comes under the jurisdiction of the people’s court that accepts the lawsuit.

In the retrial case of *Anji Xueqiang Bamboo and Wood Products Co. v. Xu Zanyou*,¹²⁸ an infringement dispute, the Supreme People’s Court held that the property preservation ruling did not fall under the “rulings” stipulated in Article 47 paragraph 2 of the Patent Law (at that time, the 2008 Patent Law) and that the decision declaring the involved patent invalid had a retrospective effect on the property preservation ruling. If an alleged patent infringement has not yet been confirmed, and the patentee has failed to fulfill its duty of care when applying for measures like property preservation or act preservation, causing direct losses to the alleged infringer, then the patentee’s application is a “wrongful application” and constitutes a tort.

4.6.2.2.4.1 Application for act preservation and preliminary judgment for cessation of infringement at the same time

In an appeal of a dispute over invention patent infringement, *Valeo Cleaning System Co. v. Xiamen Lukasi Automotive Parts Co.*,¹²⁹ the Supreme People’s Court held that, in a patent infringement litigation procedure, the act preservation that orders the cessation of an alleged act of infringement has an independent value. Where a party applies simultaneously for act preservation and a preliminary judgment to cease the alleged infringement, and the people’s court holds that a preliminary judgment shall be made, then the application for act preservation shall be examined, and a ruling shall be made if the conditions for act preservation are met.

4.6.2.2.5 Reverse act preservation related to e-commerce platforms

In the case of *Yongkang Lianyue Industry and Trade Co. v. Cixi Bosheng Plastic Products Co.*,¹³⁰ a utility model patent infringement dispute, the Supreme People’s Court held that an operator of an e-commerce platform, upon the receipt of a notice from an intellectual property right holder showing preliminary evidence of infringement on their platform, has a statutory obligation to take necessary measures to stop the infringement, such as by deleting, blocking and disconnecting the link, and terminating the transactions and services. If, due to an emergency, the merchant’s legitimate rights and interests will suffer irreparable damage if the link is not restored, the merchant on the platform may apply for act preservation ordering the operator of the e-commerce platform to implement act preservation measures like restoring the link. In such a case, the people’s court shall accept such an application and examine it in accordance with Article 100 of the Civil Procedure Law and related judicial interpretations. When determining whether to implement the act preservation measures based on the application of the alleged infringer, the major factors to be considered include:

- whether the applicant’s request has a factual basis and a legal basis;
- whether the applicant will suffer irreparable damage if the link is not restored;
- whether the damage caused to the patentee by restoring the link exceeds the damage caused to the alleged infringer if the link is not restored;
- whether the public interest will be harmed if the link is restored; and
- other factors.

¹²⁸ MSZ No. 762 (Sup. People’s Ct, 2008).

¹²⁹ Sup. People’s Ct Guiding Case No. 115, Dec. 24, 2019.

¹³⁰ ZMZ No. 993 (Sup. People’s Ct, 2020).

4.6.3 Finding of technical facts

Technical facts are facts involving specialized technical content that need to be found in the trial of civil cases involving intellectual property. As trials of technology-related cases involve the finding of complex technical facts, people's courts have established a diversified technical fact-finding mechanism based on the technical investigation officer system, with technical consultancy, expert assessors, expert assistants and technical appraisals as its important components.

4.6.3.1 Technical investigation officer system

To align with the establishment of the intellectual property courts in Beijing, Shanghai and Guangzhou, the Supreme People's Court issued the Interim Provisions on Technical Investigation Officers on December 31, 2014, formally establishing the technical investigation officer system.¹³¹ On August 8, 2017, the Supreme People's Court issued the Guiding Opinions on the Selection of Technical Investigation Officers to provide for the selection and qualification requirements of technical investigation officers and related procedures.¹³² Article 13 of the guiding opinions stipulates the following: "Other people's court with jurisdiction over technology-related intellectual property cases may select and appoint technical investigation officers with reference to these Guiding Opinions after reporting to the Supreme People's Court for approval."

Article 51 of the Law on the Organization of the People's Courts stipulates the following: "People's courts may set up positions for judicial technical personnel based on the needs of adjudication work, to take charge of relevant issues." Technical investigation officers are not adjudication personnel but are judicial technical personnel among adjudication assistance personnel. The technical investigation officer system has played an active role in increasing the neutrality, objectivity and scientificity of the identification of technical facts and in improving the quality and efficiency of technology-related case adjudication.

The Supreme People's Court also formulated the Provisions on Technical Investigation Officers, which came into effect on May 1, 2019.¹³³ These provisions contain 15 articles regarding technical investigation officers participating in different litigation procedures in the adjudication of intellectual property cases. The provisions relate to the procedure, duties, validity and legal responsibilities of such officers, as well as the types of cases, positioning of identity, appointment and dispatching of personnel, notification and recusal, work duties, the validity of technical investigation opinions, signatures on adjudication documents, and the assumption of responsibilities, among other matters. Article 1 of the provisions stipulates the following: "In the trial of intellectual property cases involving patents, new plant varieties, layout designs of integrated circuits, technical secrets, computer software, and monopoly, which have high professional and technical requirements, the people's courts may appoint technical investigation officers to participate in the litigation activities."

4.6.3.2 Entrusted technical appraisal

Appraisal conclusions form a type of statutory evidence in civil lawsuits. According to Article 76 of the Civil Procedure Law,

[a] party may apply to a people's court for the appraisal of a specialized issue for the verification of a fact. When a party so applies, both parties shall determine qualified appraisers through negotiation; where such negotiation fails, the people's court shall designate appraisers.

Where the parties do not apply for appraisal, but the people's court deems it necessary to examine a specialized issue, it shall appoint qualified appraisers to conduct the appraisal.

Appraisal opinions belong to evidence, as stipulated in Article 63 of the Civil Procedure Law.

¹³¹ Interim Provisions on Several Issues concerning the Participation of Technical Investigation Officer in Litigation Activities in Intellectual Property Courts (promulgated by the Sup. People's Ct, Dec. 31, 2014, effective Dec. 31, 2014).

¹³² Guiding Opinions on the Selection of Technical Investigation Officers for Intellectual Property Courts (for Trial Implementation) (promulgated by the Sup. People's Ct, Aug. 8, 2017, effective Aug. 14, 2017).

¹³³ Several Provisions on the Participation of Technical Investigation Officers in Litigation Activities of Intellectual Property Cases (promulgated by the Sup. People's Ct, March 18, 2019, effective May 1, 2019).

In addition to the Civil Procedure Law, the Interpretation of the Civil Procedure Law and the Provisions on Evidence in Civil Procedures involving Intellectual Property Rights make specific provisions on issues concerning such appraisals.

4.6.3.3 Persons with specialized expertise

According to Article 79 of the Civil Procedure Law, “[a] party may apply to a people’s court to notify person(s) with specialized expertise to appear in court and provide opinions on an appraisers’ opinions or specialized issues.” According to Articles 122–123 of the Interpretation of the Civil Procedure Law,

[a] party may, according to Article 79 of the Civil Procedure Law, file an application prior to the expiry of the time limit for producing evidence, to have one to two persons with specialized expertise to appear in court to cross-examine appraisal opinions on behalf of the party, or to provide opinions on the specialized issues involved in the fact-finding of the case.

The opinions provided in court on specialized issues by persons with specialized expertise shall be deemed as the statements of the concerned parties.

[...]

A people’s court may query the persons with specialized expertise who appear in court. With the permission of the people’s court, a concerned party may query the persons with specialized expertise who appear in court. Persons with specialized expertise who appear in court upon separate applications by different concerned parties may cross-examine each other on relevant issues involved in the case at hand.

Persons with specialized expertise shall not participate in court trial activities not involving specialized issues.

Both the Provisions on Evidence in Civil Procedures and the Provisions on Evidence in Civil Procedures involving Intellectual Property Rights provide for issues concerning persons with specialized expertise.

4.6.4 Relevant issues in patent cases involving foreign elements

For the trial of civil patent cases involving foreign elements, the Law on the Laws Applicable to Foreign-Related Civil Relations¹³⁴ and Part 4 (“Special Provisions on Foreign-Related Civil Procedures”) of the Civil Procedure Law apply. Chapter 22 (“Special Provisions on Foreign-Related Civil Procedures”) of the Interpretation of the Civil Procedure Law further interprets relevant provisions of the Civil Procedure Law.

Article 522 of the Interpretation of the Civil Procedure Law stipulates that a people’s court may determine a case as a foreign-related civil case if:

- (1) one or both concerned parties are foreigners, stateless persons, or foreign enterprises or organizations; or
- (2) the habitual residences of one or both concerned parties are outside the territory of the People’s Republic of China; or
- (3) the subject matter is located outside the territory of the People’s Republic of China; or
- (4) the legal facts resulted in generating, altering, or terminating of civil relations occur outside the territory of the People’s Republic of China; or
- (5) other circumstances based on which the case can be identified as a foreign-related civil case.

Chapter VII (“Intellectual Property Rights”) of the Law on the Laws Applicable to Foreign-Related Civil Relations includes three articles:

Article 48. The ownership and content of intellectual property rights are governed by the law of the place where protection is sought.

¹³⁴ Law on the Laws Applicable to Foreign-Related Civil Relations (promulgated by the Standing Comm. Nat’l People’s Cong., Oct. 28, 2010, effective April 1, 2011).

Article 49. The parties may by agreement choose the law applicable to the transfer and license of intellectual property rights. In the absence of any choice by the parties, the relevant provisions of this law on contracts shall apply.

Article 50. Liability for infringement of intellectual property rights is governed by the law of the place where protection is sought. The parties may also by agreement choose to apply the law of the place where the court is located after the infringement occurs.

On December 10, 2012, the Supreme People's Court issued the Interpretation of the Law on the Laws Applicable to Foreign-Related Civil Relations, which came into effect on January 7, 2013, and was later amended on December 29, 2020.¹³⁵

Articles 8–10 of the Provisions on Evidence in Civil Procedures involving Intellectual Property Rights provide for the exemption and streamlining of notarization and authentication procedures for extraterritorial evidence in civil cases involving intellectual property. In particular, Article 8 lists circumstances under which the notarization and authentication of extraterritorial evidence can be exempted, including, *inter alia*, where there is other evidence to prove the authenticity of the extraterritorial evidence. Where the conditions stipulated in Article 8 are not met, but the circumstances stipulated in Article 9 are met, then the authentication of relevant extraterritorial evidence can be exempted.

To facilitate the parties and improve litigation efficiency, Article 10 of the Provisions on Evidence in Civil Procedures involving Intellectual Property Rights also specifically stipulates the following:

Where the formalities for the notarization or authentication of a power of attorney or other certification formalities have been undergone in accordance with the provisions of Articles 59 and 264 of the Civil Procedure Law under the procedure at first instance, a people's court may no longer require the relevant party to undergo the aforesaid formalities concerning the power of attorney in subsequent civil procedures.

With respect to foreign-related patent administrative cases, relevant provisions in Chapter IX ("Foreign-Related Administrative Procedure") of the Administrative Procedure Law apply.

4.7 Administrative cases involving invention and utility model patent grant and confirmation

4.7.1 Administrative cases

Article 1 of the Provisions on Patent Grant and Confirmation defines administrative cases involving patent grant and confirmation as:

For the purposes of these Provisions, "administrative case involving the grant of a patent" means a case in which a patent applicant files a lawsuit with the people's court against a decision on a patent reexamination request made by the patent administrative department of the State Council.

For the purposes of these Provisions, "an administrative case involving the confirmation of a patent" means a case in which a patentee or a person requesting the declaration of invalidation of a patent, files a lawsuit with the people's court against a decision on the examination of a request for declaring the invalidation of a patent made by the patent administrative department of the State Council.

For the purposes of these Provisions, "the accused decision" means a decision made by the patent administrative department of the State Council with respect to a request for declaring the invalidation of a patent or a request for reexamination.

Article 44 paragraph 1, Article 53, and Article 65 paragraph 2 of the Rules for the Implementation of the Patent Law specify that the relevant provisions based on which a patent application is rejected or a patent declared invalid are those of the substantive laws involved in the administrative cases involving patent grant and confirmation.

¹³⁵ Interpretations on Several Issues concerning the Application of the Law on the Laws Applicable to Foreign-Related Civil Relations (I) (promulgated by the Sup. People's Ct, Dec. 28, 2012, rev'd Dec. 29, 2020, effective Jan. 1, 2021).

The people's courts hear cases involving patent grant and confirmation in accordance with the Patent Law, the Rules for the Implementation of the Patent Law, and the Provisions on Patent Grant and Confirmation. The Guidelines for Patent Examination are administrative regulations and may be referred to when people's courts hear administrative cases involving patent grant and confirmation according to Article 63 paragraph 3 of the Administrative Procedure Law. When people's courts hear administrative cases involving patent grant and confirmation, the procedural issues refer to the provisions of the Administrative Procedure Law and relevant judicial interpretations.

4.7.2 Examination of a patent's subject matter

4.7.2.1 The subject matter of invention and utility model patents

Article 2 paragraphs 2 and 3 of the Patent Law define inventions and utility models, respectively: "Invention" means any new technical solution proposed for a product, a process, or the improvement thereof. "Utility model" means any new technical solution proposed for the shape, the structure, or their combination, of a product, which is fit for practical use."

4.7.2.2 Circumstances where no patent shall be granted

4.7.2.2.1 Violation of the law or of social morality, or detrimental to public interests

Article 5 paragraph 1 of the Patent Law stipulates the following: "No patent shall be granted for invention-creation that violates laws or social morality or is detrimental to the public interests." In this paragraph, "violates laws" means that the purpose of the invention is against the law. Where the purpose of the invention does not violate the law, but its abuse may be contrary to the law, the invention will not be excluded from patent protection.

4.7.2.2.2 Violation of regulations related to genetic resources

Article 5 paragraph 2 of the Patent Law specifies the following: "No patent right shall be granted for invention-creation where the acquisition or utilization of the genetic resources, on which the development of the invention-creation relies, violates the provisions of laws and administrative regulations." This provision was added in the 2008 Patent Law.

4.7.2.2.3 Circumstances stipulated in Article 25 of the Patent Law

According to Article 25 of the Patent Law,

[N]o patent right shall be granted [for]:

- (1) scientific discoveries;
- (2) rules and methods for intellectual activities;
- (3) methods for the diagnosis or treatment of diseases;
- (4) animal and plant varieties species; [and]
- (5) nuclear transformation methods and substances obtained by means of nuclear transformation.

Regarding the invention of the medical use of chemical substances, in a retrial of an administrative dispute over the invalidation of an invention patent right, *Cubist Pharmaceuticals v. Patent Reexamination Board*,¹³⁶ the Supreme People's Court held that an application related to the medical use of a substance shall not be granted if its claims are drafted using the wording "for the treatment of diseases," "for diagnosis of diseases" or "use of substance X as a medicament" because such claims are ones for "method for the diagnosis or treatment of disease" as referred to in the Patent Law. However, since a medicament and its method of manufacture are patentable, an application related to the medical use of a substance adopting a pharmaceutical or use claim in the form of "use of a substance for the manufacturing of a medicament" or "use of a substance for the manufacturing of a medicament for the treatment of a disease" is not excluded by the Patent Law.

4.7.3 Interpretation of claims

Article 64 paragraph 1 of the Patent Law provides the following: "For the patent right of an invention or a utility model, the scope of protection shall be confined to the content of the claims.

136 ZXZ No. 75 (Sup. People's Ct, 2012).

The description and the drawings attached may be used to interpret the content of the claims.” In cases involving patent grant and confirmation, it is necessary to interpret the claims to determine the meaning of the disputed content in the claims and, therefore, whether the claims meet the relevant provisions of the Patent Law and the Rules for the Implementation of the Patent Law.

4.7.3.1 Relevant provisions in the Provisions on Patent Grant and Confirmation

Article 2 of the Provisions on Patent Grant and Confirmation stipulates the following:

The people's court shall interpret the terms used in the claims based on the ordinary meaning understood by a person skilled in the relevant field of technology after reading the claims, specifications and drawings attached. If the terms used in the claims are clearly defined or explained in the specification and drawings attached, such definitions shall be adopted.

The terms that cannot be defined according to the provisions of the preceding paragraph may be defined based on the technical dictionaries, technical manuals, reference books, textbooks, and national or industry technical standards, inter alia, generally used by a person skilled in the relevant field of technology.

According to these provisions, for administrative cases involving patent grant and confirmation, the people's court should also follow the principle of “intrinsic evidence first” when defining the terms of the claims. This provision is consistent with those of Articles 2–3 of the Interpretation of Patent Infringement Dispute Cases.

Article 3 of the Provisions on Patent Grant and Confirmation clearly indicates that the people's courts may, when interpreting terms in the claims, “refer to relevant statements of the patentee that have been adopted by an effective judgment of a civil case involving patent infringement.” The purpose of this provision is to guide and motivate patentees to make cautious and honest statements during patent confirmation procedures and infringement proceedings and to interpret the terms of the claims. This is so as to prevent them from making different statements and thus gain benefits in different proceedings.

Article 4 stipulates that, where there is any manifest error or ambiguity in the claims, descriptions or drawings attached, the people's court shall “correct” that error based on the sole understanding gained by a person skilled in the relevant field of technology after reading the claims, descriptions and drawings attached. This provision is consistent with Article 4 of the Interpretation (II) of Patent Infringement Dispute Cases.

Regarding technical features defined by functions or effects, Article 9 paragraph 1 of the Provisions on Patent Grant and Confirmation is consistent with Article 8 paragraph 1 of the Interpretation (II) of Patent Infringement Dispute Cases (see Section 4.3.1.4 of this chapter for further detail). Article 9 paragraph 2 of the Provisions on Patent Grant and Confirmation further provides that, if the description and drawings attached disclose no embodiments corresponding to the functional features, the people's court can determine that it fails to fulfill the requirements of Article 26 paragraph 3 of the Patent Law. Therefore, a patentee must disclose at least one embodiment corresponding to the functional feature in the description to comply with the provision that the invention be sufficiently disclosed in the description.

4.7.3.2 Related typical cases

In a retrial of an administrative dispute over the invalidation of an invention patent, *Seiko Epson Corp. v. Patent Reexamination Board*,¹³⁷ the Supreme People's Court held as follows: when comparing patent grant and confirmation procedures and civil proceedings for patent infringement, the interpretations of the content of claims are highly consistent yet different to a certain extent. Consistency is reflected in at least two aspects. First, claim interpretation is a kind of text interpretation and should follow the general rules of text interpretation both in patent grant and confirmation procedures and in civil proceedings for patent infringement. Second, the same general rules of claim interpretation should be followed both in patent grant and confirmation procedures and in civil proceedings for patent infringement. However, due to the different purposes of claim interpretation in patent grant and confirmation procedures and in civil proceedings for patent infringement, there are certain differences between them in specific

¹³⁷ ZXZ No. 53–1 (Sup. People's Ct, 2010).

circumstances. One difference is in the role of the observations submitted by parties: in patent grant and confirmation procedures, the applicant's observations, as recorded in the examination files, are generally used as a reference for facilitating the understanding of claims and descriptions rather than as conclusive evidence.

4.7.4 Avoidance of double patenting

Article 9 of the Patent Law stipulates the following:

For any identical invention-creation, only one patent shall be granted. However, where the same applicant files applications for both a utility model patent and an invention patent with regard to the identical invention-creation on the same day, if the utility model patent granted earlier has not been terminated and the applicant declares to abandon the utility model patent, the invention patent may be granted.

If two or more applicants file patent applications for the identical invention-creation, the patent right shall be granted to the applicant whose application was filed first.

The main consideration of this provision is that, to avoid conflicts between patent rights, no more than one patent right can be granted for identical invention-creations. The provision that "the patent right shall be granted to the applicant whose application was filed first" reflects the first-to-file principle.

In a retrial of an administrative dispute over the invalidation of an invention patent, *Jining Pressureless Boiler Factory v. Patent Reexamination Board*,¹³⁸ the Supreme People's Court held that the "identical invention-creation" referred to in the Patent Law means patent applications or patents with the same protection scope. For such applications or patents, a judgment can be made by simply comparing the content of the claims. It was also held that, for the purpose of the Patent Law, the principle of avoidance of double patenting means that two or more valid patents for identical invention-creations cannot co-exist, not that the patent can be granted for the identical invention-creations only once.

4.7.5 Novelty

Article 22 paragraph 2 of the Patent Law stipulates the following:

Novelty means that, the invention or utility model does not form part of the prior art; no entity or individual has filed a patent application for the identical invention or utility model with the patent administration department under the State Council before the filing date and the content of the application is disclosed in patent application documents published or patent documents announced after the filing date.

Determining novelty involves two aspects: first, that the invention or utility model does not "form part of the prior art" and, second, that there is no "conflicting application" – that is, no patent application has been filed for an identical invention or utility model with the patent administration department before the filing date and subsequently recorded in the patent application documents or patent documentations that are published or announced after the filing date. The expression "no entity or individual" in Article 22 paragraph 2 of the Patent Law means that conflicting applications also include prior (i.e., filed before the filing date) patent applications filed by the patent applicant.

4.7.5.1 Prior art

Prior art is a fundamental concept in Patent Law. Its assessment has an important impact on the trial of cases involving patent grant and confirmation. When the Patent Law was amended for the third time in 2008, the concept of "prior art" was added to Article 22 paragraph 5: "Prior art means any technology known to the public domestically and/or abroad before the filing date of patent application." To improve the quality of patents, the criterion determining prior art was changed to "absolute novelty" – that is, "prior art" referred to technologies known to the public domestically or abroad before the filing date, irrespective of how it was disclosed.

138 XTZ No. 4 (Sup. People's Ct, 2007).

The technical content disclosed in prior art and in conflicting applications includes both the technical content clearly recorded therein and the technical content that can be directly and undoubtedly determined by a person skilled in the relevant field of technology.

Regarding whether the materials filed and recorded as an enterprise's standards constitute prior art under the Patent Law, in a retrial of an administrative dispute over the invalidation of a utility model patent, *Textile Machinery Co. v. Patent Reexamination Board*,¹³⁹ the Supreme People's Court held that the filing and recording of such materials do not mean that the specific content of the standards has been publicized or made freely accessible and available to the public; therefore, such materials do not constitute prior art under the Patent Law.

In an appeal of an administrative dispute over the invalidation of a design patent, *Liu Xiaosheng v. Chaozhou Chaoan Xiangxingfa Electronic Technology Co.*,¹⁴⁰ the Supreme People's Court held that, when determining whether information in cyberspace that requires authorization to access (such as found in Qzone and WeChat Moments) constitutes prior design or prior art, a people's court should make a comprehensive analysis on the main purpose of the cyberspace, the upload time, accessibility of the information and so on and make the judgment based on whether the information was publicly available before the filing date of the patent. If a cyberspace requiring access authorization is primarily for commercial use, then it may be presumed that that cyberspace is accessible to the public unless there is evidence to the contrary.

Regarding the determination of prior art, in an appeal of an administrative dispute over the invalidation of an invention patent, *Beijing Baidu Netcom Science and Technology Co. v. China National Intellectual Property Administration*,¹⁴¹ the Supreme People's Court held that "known to the public" means that the public could know the prior art if they want to, rather than that the public actually knows. It also held that, where a party claims prior art by virtue of a physical object, they must clarify the claimed prior technical solution and the corresponding relationship between the object and the solution and produce sufficient evidence to prove or fully explain how the public can intuitively obtain the technical solution from the physical object.

4.7.5.2 Criteria for examining novelty

When determining whether an invention or utility model patent forms part of the prior art or whether there is any conflicting application, the people's courts consider whether the patented technical solution is substantially the same as any technical solution disclosed in the prior art or in a potentially conflicting application and whether it could be used in the same technical field, solve the same technical problem or have the same expected effect.

The assessment of novelty adopts the principle of separate comparison – that is, separately comparing each of the claims with the relevant technical content disclosed in each item of the prior art or conflicting application rather than comparing a combination of the contents disclosed in multiple items of the prior art or conflicting application or a combination of several technical solutions disclosed in one reference document.

In an appeal of an administrative dispute over the invalidation of an invention patent, *Tong Kening v. Zhejiang Shuangyu Industrial Co.*,¹⁴² the Supreme People's Court held that, when determining the novelty of an invention patent, the people's court should adhere to the principle of separate comparison and compare each of the claims with each prior art separately, rather than with the combination of two or more technical solutions disclosed in one or more reference documents.

In an appeal of an administrative dispute over the reexamination of the rejection of an invention patent application, *Albemarle Corp. v. China National Intellectual Property Administration*,¹⁴³ the Supreme People's Court held that, if the prior art has disclosed the compound for which the patent application or the patent seeks protection, then it can be presumed that the application or patent does not have novelty unless the applicant or patentee can provide evidence proving that the compound could not be manufactured before the filing date.

139 XTZ No.3 (Sup. People's Ct, 2007).

140 ZXZ No. 422 (Sup. People's Ct, 2020).

141 ZXZ No. 1 (Sup. People's Ct, 2019).

142 ZXZ No. 53 (Sup. People's Ct, 2019).

143 ZXZ No. 97 (Sup. People's Ct, 2020).

4.7.5.3 Grace period concerning novelty

With respect to the “grace period” concerning novelty, Article 24 of the Patent Law provides the following:

Within six months before the filing date, an invention-creation for which a patent application is filed does not lose its novelty under any of the following circumstances:

- (1) where it was made public for the first time for the public interests when a state of emergency or an extraordinary situation occurred in the country;
- (2) where it was exhibited for the first time at an international exhibition sponsored or recognized by the Chinese Government;
- (3) where it was published for the first time at a prescribed academic or technological conference; [or]
- (4) where its contents are divulged by another person without the consent of the applicant.

In an appeal of an administrative dispute over the invalidation of a design patent, *Beijing Qihoo Technology Co. v. China National Intellectual Property Administration*,¹⁴⁴ the Supreme People's Court held that, if another person, within six months before the filing date, violates the expressed or implied obligation of confidentiality under social values or business practices, and the patentee or patent applicant claims that the novelty of the invention-creation should not be taken away because of such a violation, then such a claim should be supported by the people's court.

4.7.6 Inventiveness

Article 22 paragraph 3 of the Patent Law provides the following: “Inventiveness means that, as compared with the prior art, the invention has prominent substantive features and represents an obvious progress, and that the utility model has substantive features and represents a progress.” For the examination of inventiveness, the Guidelines for Patent Examination have detailed provisions, including those on “prominent substantive features” and “obvious progress.”

That an invention has “prominent substantive features” means that the invention is distinctly and substantially different from the prior art; the “three-step approach” is usually followed in examining this. That an invention “represents obvious progress” means that the invention can produce advantageous technical effects as compared with the prior art.

When evaluating whether or not an invention possesses inventiveness, not only is the technical solution itself considered, but also the technical field to which the invention pertains, the technical problem solved and the technical effects produced by the invention. The invention should be considered as a whole. In assessing inventiveness, it is permissible to combine together different technical solutions disclosed in one or more prior arts to assess the claimed invention. This differs from the principle of “separate comparison” in the assessment of novelty.

4.7.6.1 Assessment of prominent substantive features

To determine whether an invention has prominent substantive features is to determine whether, to a person skilled in the relevant field of technology, the claimed invention is nonobvious as compared with the prior art. If the claimed invention is obvious as compared with the prior art, then it does not have prominent substantive features; if it is nonobvious, then it has prominent substantive features.

Usually, three steps are followed in determining whether a claimed invention is obvious as compared with the prior art. The first step is determining the closest prior art. The closest prior art refers to a technical solution in the prior art that is the most closely related to the claimed invention. This becomes the basis for determining whether or not the claimed invention has prominent substantive features. It should be noted that, when determining the closest prior art, prior art in the same or similar technical fields is considered first. The second step is determining the distinguishing features of the invention and the technical problem actually solved by the invention. The third and final step is determining whether or not the claimed invention is obvious to a person skilled in the relevant field of technology.

144 ZXZ No. 588 (Sup. People's Ct, 2019).

4.7.6.1.1 Determination of distinguishing technical features

In an appeal of an administrative dispute over the invalidation of an invention patent, *Oerlikon Textile GmbH v. Zhejiang Yuejian Intelligent Equipment Co.*,¹⁴⁵ the Supreme People's Court held that the inventive concept of an invention is considered when determining the technical differences between the invention and the closest prior art. If the inventive concept of the invention is the combination of corresponding technical elements, and the prior art has neither explicitly nor implicitly disclosed the teachings of such a combination nor disclosed the technical effects that can be produced by such a combination, then such a combination of technical elements claimed by the invention should be treated as a whole in determining the distinguishing technical features. It is inappropriate to determine the distinguishing technical features based on a single technical element.

4.7.6.1.2 The technical problem actually solved

To determine the "technical problem actually solved" – as mentioned in the second step of the three-step approach – the distinguishing technical features of the claimed invention, when compared with the closest prior art, are first analyzed. The technical problem actually solved by the invention is then determined based on the technical effects that the distinguishing technical features achieve in the claimed invention.

Article 13 of the Provisions on Patent Grant and Confirmation stipulates the following:

Where the technical effects that the distinguishing features achieve in the technical solution defined in the claims are not specified in the description and the drawings attached, the people's court may determine the technical problem actually solved that can be identified by a person skilled in the relevant field of technology based on the general common knowledge in the art, the relationship between the distinguishing technical features and other technical features in the claims, and the role of distinguishing technical features in the technical solution defined in the claims.

If the determination made by the accused decision fails to identify or incorrectly identifies the technical problem actually solved by the claims, the people's court's assessment of the inventiveness of the claims in accordance with the law shall not be affected.

In a retrial of an administrative dispute over the invalidation of an invention patent, *Edan v. Patent Reexamination Board*,¹⁴⁶ the Supreme People's Court held that "the technical problem actually solved by the invention" refers to the technical task that improves the closest prior art to achieve better technical effects. The technical problem is identified by comparing the invention with the closest prior art rather than on the basis of the background art described in the description.

In a retrial of an administrative dispute over the reexamination of the rejection of an invention patent application, *Strix Ltd v. Patent Reexamination Board*,¹⁴⁷ the Supreme People's Court held that the functions and technical effects of distinguishing technical features are the fundamental basis for identifying the technical problem actually solved by the claims. When identifying the functions and technical effects, the people's court shall pay attention to whether the technical solution defined in the claims corresponds to the technical solution with specific functions and technical effects described in the description. If there is a substantial difference between them, the functions and technical effects that can be achieved by the distinguishing technical features shall then be determined according to the specific circumstances of the technical solution defined in the claims.

In an appeal of an administrative dispute over the invalidation of a utility model patent, *China National Intellectual Property Administration v. Shandong Haowo Electric Co.*,¹⁴⁸ the Supreme People's Court held that, when determining the technical problem actually solved by the invention, the people's court shall neither underestimate the inventiveness of the patent by demanding generalization nor overestimate the inventiveness by simply regarding the roles, functions or technical effects of the distinguishing technical features in the patented technical solution as the technical problem actually solved by the invention.

¹⁴⁵ ZXZ No. 279 (Sup. People's Ct, 2020).

¹⁴⁶ ZXZ No. 6 (Sup. People's Ct, 2014).

¹⁴⁷ XZ No. 131 (Sup. People's Ct, 2018).

¹⁴⁸ ZMZ No. 32 (Sup. People's Ct, 2019).

4.7.6.1.3 Technical motivation

Technical motivation should be determined in light of the prior art as a whole – that is, whether there is the technical motivation of applying the distinguishing technical features to the closest prior art to solve the existing technical problem (i.e., the technical problem actually solved by the invention). The technical motivation prompts a person skilled in the relevant field of technology to improve the closest prior art and reach the claimed invention when confronted with a technical problem. Under the following circumstances, it is usually held there exists such a technical motivation in the prior art:

- The distinguishing technical features are common knowledge (e.g., customary means in the art, or technical means disclosed in textbooks or reference books, to solve the redetermined technical problem).
- The distinguishing technical features are technical means related to the closest prior art (e.g., technical means disclosed in other parts of the same reference document, and such means are the same as the function of the distinguishing features in the claimed invention in solving the redetermined technical problem).
- The distinguishing technical features are relevant technical means disclosed in another reference document, and such means are the same as the function of the distinguishing technical features in the claimed invention in solving the redetermined technical problem.

In a retrial of an administrative dispute over the invalidation of an invention patent, *Ningbo Zhantong Telecom Equipment Co. v. Patent Reexamination Board*,¹⁴⁹ the Supreme People's Court held that the technical solution of the patent in this case was a whole and that the technical features contained in it were not isolated. Therefore, the technical features could not be separated, and their function in the entire technical solution could not be ignored. When determining whether a certain technical feature in the prior art is the same as or equivalent to an essential technical feature of the patent, the people's court shall consider whether it plays the same role in the respective technical solutions.

In an appeal of an administrative dispute over the reexamination of the rejection of an invention patent application, *China National Intellectual Property Administration v. Erasmus University Medical Center*,¹⁵⁰ the Supreme People's Court held that, when confronted with the technical problem to be solved, the technical motivation that a person skilled in the relevant field of technology can learn from the prior art must, in principle, be specific and definite technical means rather than abstract ideas or general research directions. Determining the technical motivation of the prior art based only on the consistency of a research direction or abstract and general demands in the technical field may result in the mistake of *ex post facto* analysis, and the inventiveness of the invention may be underestimated.

In an appeal of an administrative dispute over the invalidation of a utility model patent, *Shenzhen DJ Lingmou Technology Co. v. China National Intellectual Property Administration*,¹⁵¹ the Supreme People's Court held as follows: whether the raising of a new technical problem or the discovery of a technical defect in the prior art is considered in the assessment of inventiveness depends on the specific circumstances of the case. In certain circumstances, "raising a new technical problem" and "discovering a technical defect" may be more important than "solving a technical problem." In the assessment of inventiveness, a lack of consideration as to whether the problem raised is obvious to a person skilled in the relevant field of technology may lead to the mistake of *ex post facto* analysis.

4.7.6.2 Assessment of obvious progress

When evaluating whether or not an invention represents obvious progress, the main consideration should be whether or not the invention produces advantageous technical effects. Usually, an invention is regarded as producing advantageous technical effects and representing obvious progress when:

- the invention produces better technical effects compared with the prior art;
- the invention provides a technical solution with a different technical concept that can produce technical effects that are substantially the same level as those of the prior art;

¹⁴⁹ ZXZ No. 43 (Sup. People's Ct, 2014).

¹⁵⁰ ZXZ No. 127 (Sup. People's Ct, 2019).

¹⁵¹ ZXZ No. 183 (Sup. People's Ct, 2020).

- the invention represents a new trend of technical development; or
- despite negative effects in some aspects, the invention produces outstanding positive technical effects in other aspects.

4.7.6.2.1 Other factors to be considered in the assessment of inventiveness

4.7.6.2.2 Producing unexpected technical effects

The technical effect of an invention is an important factor in the assessment of inventiveness. If, compared with the prior art, the technical effects produced by the invention obviously represent a qualitative change, or a quantitative change that cannot be reasonably expected by a person skilled in the relevant field of technology, then unexpected technical effects are produced. When determining whether there are unexpected technical effects, it is necessary to comprehensively consider the characteristics of the technical field to which the invention pertains, especially the predictability of the technical effects and the technical motivation in the prior art.

In a retrial of an administrative dispute over the invalidation of an invention patent, *Boehringer Ingelheim GmbH v. Patent Reexamination Board*,¹⁵² the Supreme People's Court assessed the inventiveness of a novel crystalline compound and held that, although crystalline compounds may differ in physical and chemical parameters due to differing molecular arrangements, they are still compounds. Thus, the provisions related to the inventiveness of chemical inventions in the Guidelines for Patent Examination are applicable to the assessment of their inventiveness. For the assessment of the inventiveness of crystals, the microscopic crystal structure is to be considered in conjunction with whether or not it brings unexpected technical effects.

4.7.6.2.3 Achieving commercial success

When it is difficult to assess the inventiveness of a technical solution with the three-step approach, or it is preliminarily concluded that a technical solution lacks inventiveness, from the perspective of the motivational effect on society and the economy, commercial success can be considered. If the technical solution's commercial success is attributed to other reasons, such as an advance in selling skills or advertising, it is not used as a basis for assessing inventiveness.

In a retrial of an administrative dispute over the invalidity of a utility model patent, *Patent Reexamination Board v. Hu Ying*,¹⁵³ the Supreme People's Court held that commercial success is a secondary consideration in the assessment of inventiveness. What is to be assessed is whether the invention or utility model has truly achieved commercial success and whether the commercial success is directly brought about by the technical features of the technical solution of the invention or utility model (which are improved compared with the prior art), rather than by other factors. The immediate cause for the commercial success of an invention or utility model shall be emphasized in assessing inventiveness. Therefore, in such cases, it is necessary to conduct a detailed analysis of the causes of commercial success to exclude the influence of factors other than the technical features on that success.

4.7.6.2.4 Determination of opposite teachings

In a retrial of an administrative dispute over the invalidation of an invention patent, *Chongqing Lifan Automobile Sales Co. v. China National Intellectual Property Administration*,¹⁵⁴ the Supreme People's Court held that an "opposite teaching" determined in the accused's decision is usually relative to technical motivations. When considering whether or not there is an opposite teaching in the prior art, the people's court shall make the analysis and determination based on the knowledge and cognitive abilities of a person skilled in the relevant field of technology and take the prior art as a whole. For a patent document constituting a prior art, the technical defect recorded in the background art is considered the subjective perception of the patent applicant rather than the objective knowledge of a person skilled in the relevant field of technology. A person skilled in the relevant field of technology shall not necessarily be limited by the content related to the technical defect and therefore be unable to find corresponding technical motivation from the prior art. Moreover, even if a technical defect is indicated, it is still necessary to consider whether the technical defect is related to the technical problem actually solved by the distinguishing technical features and to the determination of the technical motivation.

¹⁵² ZXZ No. 86 (Sup. People's Ct, 2011).

¹⁵³ XTZ No. 8 (Sup. People's Ct, 2012).

¹⁵⁴ XZ No. 268 (Sup. People's Ct, 2019).

4.7.7 Practical use

Article 22 paragraph 4 of the Patent Law stipulates the following: "Practical use means that the invention or utility model can be manufactured or used and can produce positive effects." In a retrial of an administrative dispute over the reexamination of the rejection of an invention patent application, *Gu Qingliang v. Patent Reexamination Board*,¹⁵⁵ the Supreme People's Court held that "can be manufactured or used" means that the technical solution of the invention or utility model can be made or used in an industry. The practical use of an invention patent application means that the technical solution itself conforms with the laws of nature, can be applied in practice and can be reproduced industrially. In this case, the application in dispute violated the law of conservation of energy and thus could not be manufactured or used in industry.

4.7.8 Claims shall be clearly defined

Article 26 paragraph 4 of the Patent Law provides the following: "The claims shall be based on the description, and clearly and concisely define the scope of protection conferred by the patent."

Article 7 of the Provisions on Patent Grant and Confirmation stipulates the following:

Where, based on the description and drawings attached, a person skilled in the relevant field of technology is of the opinion that the claims fall under any of the following circumstances, the people's court shall determine that the claims fail to comply with the provisions of paragraph 4, Article 26 of the Patent Law on clearly defining the scope of patent protection:

- (1) The type of subject matter of the invention is not specified;
- (2) The meaning of technical features in the claims cannot be reasonably determined; and
- (3) There are evident contradictions between technical features, and such contradictions cannot be reasonably explained.

That the claims should be clear means, first, that each claim should be clear and, second, that all the claims should be clear as a whole.

4.7.9 Sufficient disclosure of the description

Article 26 paragraph 3 of the Patent Law stipulates the following: "The description shall contain a clear and comprehensive description of the invention or utility model so that a person skilled in the relevant field can carry it out." In judicial practice, this requirement for the description is generally referred to as "sufficient disclosure."

4.7.9.1 Relevant provisions in the Provisions on Patent Grant and Confirmation

Article 6 paragraph 1 of the Provisions on Patent Grant and Confirmation stipulates the following:

Where the failure to sufficiently disclose specific technical content in the description results in any of the following circumstances on the filing date, the people's court shall determine that the description and claims relating to the specific technical content fail to comply with paragraph 3, Article 26 of the Patent Law:

- (1) The technical solution specified in the claims cannot be implemented;
- (2) The technical problem of the invention or utility model can't be solved by implementing the technical solution defined in the claims; and
- (3) To determine whether the technical solution defined in a claim can solve the technical problem of the invention or utility model, excessive work is indispensable.

Where specific technical content is not sufficiently disclosed in the description, the people's court will determine that the specific claims related to the specific technical content violate the provisions of Article 26 paragraph 3 of the Patent Law rather than generally determining that the entire patent or all claims do not comply with those provisions.

¹⁵⁵ XS No. 789 (Sup. People's Ct, 2016).

Regarding supplementary experimental data, Article 10 of the Provisions on Patent Grant and Confirmation stipulates the following: "Where a pharmaceutical product patent applicant submits supplementary experimental data after the filing date to prove that the patent application is in conformity with paragraph 3, Article 22 and paragraph 3, Article 26 of the Patent Law, among other provisions, the people's court shall examine the data."

4.7.9.2 Relevant typical cases

Regarding the relationship between the inventiveness and the sufficient disclosure of the description, in an appeal of an administrative dispute over the reexamination of the rejection of an invention patent, *China National Intellectual Property Administration v. Erasmus University Medical Center*,¹⁵⁶ the Supreme People's Court held that the two have different functions in patent law and follow different logics. In principle, what should be examined under the legal requirements of sufficient disclosure should not be taken into consideration in the assessment of inventiveness.

With regard to the sufficient disclosure of the description of a compound product invention, in a retrial of an administrative dispute over the invalidation of an invention patent, *Patent Reexamination Board v. Warner-Lambert Co.*,¹⁵⁷ the Supreme People's Court held the following:

- To comply with the provisions of Article 26 paragraph 3 of the Patent Law, all three requirements – that the specified technical solution can be implemented, that the technical problems can be solved and that the expected results can be produced – must be met at the same time. The people's court shall first determine whether a person skilled in the relevant field of technology can implement the technical solution according to the content disclosed in the description. It will then determine whether the technical problem can be solved and whether the desired technical effects are produced. It is pointless to confirm, before determining whether the technical solution can actually be implemented, whether the technical solution can solve the corresponding technical problems and achieve the technical effects in comparison with the prior art.
- The identification, manufacture and use of the chemical product shall be recorded in the description of the chemical product invention.

If the invention is a compound, the description must state the chemical structure of the compound and the chemical and physical performance parameters related to the technical problem to be solved by the invention so that a person skilled in the relevant field of technology can clearly identify the chemical product based on that description.

Regarding the determination of sufficient disclosure regarding a product invention in the field of chemistry, in a retrial of an administrative dispute over the reexamination of the rejection of an invention patent application, *Mitsubishi Tanabe Pharma Corp. v. Patent Reexamination Board*,¹⁵⁸ the Supreme People's Court held that the requirements for the disclosure of the uses and effects of such inventions are determined by the characteristics of inventions in that field. In most cases, it is difficult to predict, without experimental evidence, whether a chemical invention can be implemented and what uses or effects it has. Therefore, where a person skilled in the relevant field of technology would not be able to predict, based on the prior art, whether a novel compound has the uses or effects described in the description, the patent description must specify the qualitative or quantitative experimental data showing that the compound can achieve the stated uses or the expected effects.

4.7.10 Claims shall be supported by the description

Article 26 paragraph 4 of the Patent Law stipulates the following: "The claims shall be based on the description, and clearly and concisely define the scope of protection conferred by the patent."

4.7.10.1 Relevant provisions in the Provisions on Patent Grant and Confirmation

Regarding the stipulation in the Patent Law that claims be supported by the description, Article 8 of the Provisions on Patent Grant and Confirmation further stipulates the following:

¹⁵⁶ ZXZ No. 127 (Sup. People's Ct, 2019).

¹⁵⁷ XTZ No. 8 (Sup. People's Ct, 2014).

¹⁵⁸ ZXZ No. 352 (Sup. People's Ct, 2015).

If after reading the description and drawings attached, a person skilled in the relevant field of technology can not directly reach or reasonably generalize the technical solution as defined in a claim on the filing date, the people's court shall determine that the claim fails to comply with the provisions of paragraph 4, Article 26 of the Patent Law that "the claims shall be based on the description."

The main consideration of this provision is that patentees and patent applicants may reasonably generalize a claim on the basis of the technical content disclosed in the description and attached drawings rather than being limited to the embodiments. Accordingly, the protection scope of a patent is adaptive to the technical contribution, the degree of innovation and the technical content disclosed in the description.

As provided in Article 6 paragraph 2 of the Provisions on Patent Grant and Confirmation, where a concerned party's argument that a claim complies with the provision of Article 26 paragraph 4 of the Patent Law is based only on specific technical content that is insufficiently disclosed in the description, the people's court shall reject such an argument.

4.7.10.2 Relevant typical cases

In a retrial of an administrative dispute over the invalidation of an invention patent, *Sensing Electronics Co. v. Patent Reexamination Board*,¹⁵⁹ the Supreme People's Court held that "[b]ased on the description" in Article 26 paragraph 4 of the Patent Law primarily involves the relationship between the claims and the description. Accordingly, relevant content in the description shall be used as the basis for determining the technical problem solved and the technical effect achieved by the patent. Even if the claims have inventiveness, it is still necessary to determine whether the technical features recited in the claims (including the distinguishing technical features) and the technical solutions defined by the claims as a whole are appropriately generalized in accordance with Article 26 paragraph 4 of the Patent Law.

In an appeal of an administrative dispute over the invalidation of an invention patent, *Ren Xiaoping v. Apple Electronic Products Commerce (Beijing) Co.*,¹⁶⁰ the Supreme People's Court held that a claim that defines the protection scope using two or more different numerical-range technical features is considered to be supported by the description if a person skilled in the relevant field of technology can find a correspondence between those technical features and figure out the specific exploitation method in line with the purpose of the invention through a limited number of experiments and can exclude technical solutions that cannot achieve the invention's purpose of the invention without excessive labor.

4.7.11 An independent claim shall state the essential technical features necessary for the solution of the technical problem

Article 20 paragraph 2 of the Rules for the Implementation of the Patent Law stipulates the following: "The independent claim shall outline the technical solution of an invention or utility model and state the essential technical features necessary for the solution of the technical problem." According to this provision, it is only necessary to consider whether the independent claim lacks the essential technical features. If an independent claim is declared invalid or abandoned, or other claims dependent on the independent claim become new independent claims, then these provisions shall also be complied with.

Regarding the determination of the lack of essential technical features and its relationship with the requirement that the claims be supported by the description, in a retrial of an administrative dispute over the invalidation of an invention patent, *Elecon Asia SA v. Patent Reexamination Board*,¹⁶¹ the Supreme People's Court held that, in determining whether an independent claim lacks essential technical features, the key is whether the independent claim has recited the essential technical features for solving the technical problem – that is, whether or not there are essential technical features. As to whether the essential technical features are adequately generalized and whether they can be supported by the description, such an examination shall be made separately, in accordance with Article 26 paragraph 4 of the Patent Law.

¹⁵⁹ XZ No. 19 (Sup. People's Ct, 2016).

¹⁶⁰ ZXZ No. 406 and No. 407 (Sup. People's Ct, 2020).

¹⁶¹ XTZ No. 13 (Sup. People's Ct, 2014).

4.7.12 Amendments may not go beyond the scope of the disclosure contained in the original description and claims

Article 33 of the Patent Law stipulates the following:

An applicant may amend his or her patent application documents, but the amendment to the patent application documents for an invention or utility model may not go beyond the scope of the disclosure contained in the original description and the claims, and the amendment to the patent application documents for a design may not go beyond the scope of the disclosure as shown in the original drawings or photographs.

In judicial practice, such an amendment is also referred to as an “amendment going beyond the scope.”

4.7.12.1 Assessment

In a retrial of an administrative dispute over the invalidation of an invention patent, *Zheng Yali v. Seiko Epson Corp.*,¹⁶² the Supreme People's Court held that the contents of the original description and claims include, first, the contents expressly recited in texts or graphics in the original description (and attached drawings) and claims; and second, the contents that can be directly and explicitly derived by a person skilled in the relevant field of technology after comprehensively considering the original description (and the attached drawings) and claims, as long as the derived content is obvious to a person skilled in the relevant field of technology.

In a retrial of an administrative dispute over the invalidation of an invention patent, *Shimano v. Patent Reexamination Board*,¹⁶³ the Supreme People's Court held that “the contents contained in the original description and the claims” can be embodied by the content disclosed in text and graphics in the original description (and attached drawings) and claims and by the content that can be determined by a person skilled in the relevant field of technology based on the original description (and attached drawings) and claims. In determining whether the amendment of a patent application goes beyond the scope of disclosure contained in the original description and claims, the observations submitted by parties can only be used as a reference for understanding the description and claims rather than as conclusive evidence.

4.7.12.2 Amendment of claims in invalidation procedures

Article 69 of the Rules on the Implementation of the Patent Law provides as follows:

In the course of the examination of a request for invalidation, the patentee of the concerned invention patent or utility model may amend the claims but may not broaden the scope of protection of the original patent.

The patentee of the concerned invention patent or utility model shall not amend the description or drawings attached, and the patentee of the concerned design patent shall not amend the drawings, photographs, or the brief explanation of the design.

In the Guidelines for Patent Examination, the principles and manners of amendment in invalidation procedures are provided.

In an appeal of an administrative dispute over the invalidation of an invention patent, *Alfa Laval Corporate AB v. China National Intellectual Property Administration*,¹⁶⁴ the Supreme People's Court held that, in invalidation procedures, amendments of claims must not go beyond the contents contained in the original description and claims and must not broaden the protection scope of the original patent. Accordingly, both the efficiency of administrative examination and the fair protection of the patentee's contribution should be considered. It is inappropriate to impose an excessively strict restriction on the manners of amendment; otherwise, such restrictions will be a punishment for the claims inappropriately drafted. By adding to an independent claim the additional technical features recited in a dependent claim, the independent claim is further defined, and the protection scope of the original independent claim is narrowed rather than broadened. It does not impair the publicity effect of the original patent or harm the public's

¹⁶² ZXZ No. 53 (Sup. People's Ct, 2010).

¹⁶³ XTZ No. 21 (Sup. People's Ct, 2013).

¹⁶⁴ ZXZ No. 19 (Sup. People's Ct, 2019).

reliance interest based on the original patent documents. Thus, such amendments shall be accepted.

In a retrial of an administrative dispute over the invalidation of an invention patent, *Patent Reexamination Board v. Beijing Winsunny Pharmaceuticals Co.*,¹⁶⁵ the Supreme People's Court held that the principle of amendment of a Markush claim is that the amendment will not generate a single compound or class of compounds with new properties and functions; however, the specific circumstances in each case should be considered.

4.8 Design patents

Article 2 of the Patent Law stipulates that

“Invention-creations,” as used in this Law, refers to inventions, utility models, and designs.

[...]

“Design” means, with respect to an overall or partial product, any new design of the shape, the pattern, or the combination, or their combination of the color with shape or pattern, which is rich in aesthetic appeal and is fit for industrial application.

Thus, the overall or partial design of a product may be protected by a patent right, according to law.

4.8.1 Main features of design patents

Although design, invention and utility model patents are stipulated in the Patent Law as possessing common characteristics, the design patent has several unique characteristics. First, a design patent protects “a new design, which creates an aesthetic appeal and is fit for industrial application.” This differs from the “technical solution” protected by invention and utility model patents. Consequently, there are differences between design patents and invention and utility model patents in terms of the subject of evaluation, grant and confirmation criteria, protection scope, infringement judgment, acts of infringement, terms of protection and so on. Second, a design cannot exist alone without the corresponding product. The category of this product also has an important impact on the determination of protection scope, the grant and confirmation of design patents and determinations of infringement. Third, a design protected in accordance with the Patent Law includes both the overall and partial design of the product.

Provisions regarding partial designs were added to the fourth amendment of the Patent Law in 2020. All cases described in the following sections were decided before this amendment – thus, they concern only the overall designs of products. Fourth, the elements of a design include shapes, patterns or the combination thereof, as well as the combination of colors, shapes and patterns. Colors cannot be protected by design alone. Fifth, design patents are not subject to a substantive examination but only to a preliminary examination before they are granted. Finally, in addition to the Patent Law, product designs can also be protected like other types of intellectual property rights in accordance with the Copyright Law,¹⁶⁶ the Law on Anti-unfair Competition,¹⁶⁷ and other relevant laws and regulations.

4.8.2 Grant and confirmation procedures for design patents

4.8.2.1 Grant procedures and administrative cases

The application for a design patent is not subject to a substantive examination but only to a preliminary examination before the patent is granted. A preliminary examination includes:

- a formal examination of application documents;
- an examination of obvious substantive defects in the application documents (Article 44 of the Rules for the Implementation of the Patent Law);

¹⁶⁵ XZ No. 41 (Sup. People's Ct, 2016).

¹⁶⁶ Copyright Law (2020 Amendment) (promulgated by the Sup. People's Ct, Nov.11, 2020, effective June 1, 2021).

¹⁶⁷ Anti-unfair Competition Law (2019 Amendment) (promulgated by the Sup. People's Ct, April 23, 2019, effective April 23, 2019).

- a formal examination of other related documents; and
- an examination of related costs.

Where it is found, after the preliminary examination, that there is no reason to reject the application, the patent administration department of the State Council will decide whether to grant a design patent right. After the applicant has made, supplemented or rectified the statements of opinion, the patent administration department will consider whether the application for the design patent conforms with the Patent Law and the Rules for the Implementation of the Patent Law. If not, the application will be rejected.

If the applicant is not satisfied with the rejection decision, they may file a reexamination request with the CNIPA. If the applicant is still not satisfied with the reexamination decision, the applicant may bring an administrative lawsuit (i.e., an administrative case involving the grant of the design patent) to the Beijing Intellectual Property Court, according to law.

4.8.2.2 Invalidation declaration and confirmation procedures and administrative cases

According to Articles 45–46 of the Patent Law, any entity or individual can request the patent administration department of the State Council to declare a design patent right invalid. If the entity or individual is not satisfied with the decision of the patent administration department, they may bring a lawsuit to the people's court within three months from the date of receiving the notice. The people's court will notify the person who is the opponent party in the invalidation procedure to participate in the litigation as a third party.

Reasons for requesting invalidation of a design patent right include that the patent:

- does not conform with Article 2 of the Patent Law regarding the object of protection of the design patent;
- does not conform with Article 23 of the Patent Law, which provides that the design patent must not be part of a prior design or have a conflicting design, that it is significantly different from prior designs or the combination of prior design features, and that there is no conflict of rights;
- does not conform with Article 27 paragraph 2 of the Patent Law, which specifies that the relevant drawings or photographs submitted by the applicant must clearly indicate the design of the product for which patent protection is sought;
- does not conform with Article 33 of the Patent Law, which specifies that amendments to design patent application documents must not go beyond the scope of the disclosure as shown in the original drawings or photographs;
- does not conform with Article 43 paragraph 1 of the Rules for the Implementation of the Patent Law, which specifies that divisional applications must not go beyond the scope of the disclosure in the original application;
- falls within the scope of Article 5 of the Patent Law, which specifies that no patent right will be granted for any invention-creation that violates laws or social morality or that is detrimental to the public interests;
- falls within the scope of Article 25(6) of the Patent Law, which specifies that no patent right will be granted for "designs of two-dimensional printing goods, made of the pattern, the color or the combination of the two, which serve mainly as indicators"; and
- does not conform with Article 9 of the Patent Law, which prohibits double patenting.

4.8.3 Ordinary consumers

A design patent does not protect the technical solution but the innovation of the visual effect in product design. Therefore, the grant, confirmation or infringement of a design patent is determined based on ordinary consumers' understanding of the design product. In this respect, Article 10 of the Interpretation of Patent Infringement Dispute Cases stipulates the following: "The people's court shall determine whether designs are identical or similar based on ordinary consumers' knowledge level and cognitive ability as to a product having a design patent." Articles 14–15 and 20 of the Provisions on Patent Grant and Confirmation are all related to ordinary consumers. Each category of products has a specific consumer group, and not all products share the same consumer group; which group constitutes the "ordinary consumers" is determined according to the actual purchase and use of the product.

In an administrative dispute case over the invalidation of design patent rights, *Honda Technology Research Industry Co. v. China National Intellectual Property Administration*,¹⁶⁸ the Supreme People's Court held that the term "ordinary consumers" refers to consumers that have a commonsense understanding of the design status of the same or similar categories of design products and have a certain ability to distinguish the shape, pattern and color of the design products. However, such consumers would not notice minor changes in the shape, pattern and color of the products. Consumers having a "commonsense understanding" means that they have the ability to know the design status of relevant products but are not skilled in the design; the term does not mean that they have only an elementary or simple understanding.

Article 14 paragraph 1 of the Provisions on Patent Grant and Confirmation stipulates that, in determining the knowledge level and cognitive ability of ordinary consumers regarding a product with a design patent, the court must consider the design space or the designer's freedom of creation of the product on the date of application. If the design space is relatively large, the court may determine that it is generally not easy for ordinary consumers to notice minor differences among different designs; if the design space is relatively small, the court may determine that it is generally easy for ordinary consumers to notice minor differences among different designs. This provision is consistent with Article 14 of the Interpretation (II) of Patent Infringement Dispute Cases.

According to Article 14 paragraph 2 of the Provisions on Patent Grant and Confirmation,

[i]n determining the design space provided for in [Article 14 paragraph 1], the people's court may comprehensively consider the following factors:

- (1) The function and use of the product;
- (2) The overall conditions of the prior design;
- (3) Usual design;
- (4) Compulsory provisions of laws and administrative regulations;
- (5) National and industrial technical standards; and
- (6) Other factors that need to be considered.

In an administrative dispute case over the invalidation of the design patent of *Zhejiang Jin Fei Machinery Co. v. Zhejiang Wanfeng Motorcycle Co.*,¹⁶⁹ the Supreme People's Court held that the design freedom of designers in the field of specific products is usually restricted and affected by many factors, such as prior designs, technology, laws and concepts. With the accumulation of prior designs, technological progress, legal changes and conceptual changes, the design space may change. In a patent invalidation declaration procedure, when considering the design space of a design product, the design space at the date of the patent application is applicable.

4.8.4 Protection scope of a design patent

4.8.4.1 Design of the product

According to the provisions in Article 64 paragraph 2 of the Patent Law, "[f]or the patent right for design, the scope of protection shall be confined to the design of the product as shown in the drawings or photographs. The brief description may be used to explain the design of the product as shown in the drawings or photographs."

The 2008 Patent Law added the requirements that the "brief description to the design shall be submitted when applying for a patent for design" (Article 27 paragraph 1) and that "[t]he relevant drawings or photographs submitted by the applicant shall clearly indicate the design of the product for which patent protection is sought" (Article 27 paragraph 2). Thus, a design patent application requires a request, pictures or photos of the design, a brief description of the design, and other documents. According to Article 15 of the Provisions on Patent Grant and Confirmation, where the pictures or photos of a design are contradictory, missing or vague, making it impossible for ordinary consumers to determine the design to be protected based on such pictures or photos and brief descriptions, the court shall determine that those items fail to comply with the requirement of Article 27 paragraph 2 of the Patent Law that they "clearly indicate the design of the product for which patent protection is sought."

¹⁶⁸ XTZ No. 3 (Sup. People's Ct, 2010).

¹⁶⁹ XTZ No. 5 (Sup. People's Ct, 2010).

4.8.4.2 Brief description

With respect to the brief description, Article 28 of the Rules for the Implementation of the Patent Law stipulates the following:

The brief description of a design shall indicate the title and use of the product incorporating the design and the essential feature of the design, and designate a drawing or photograph which best shows the essential feature of the design. Where the view of the product incorporating the design is omitted or where concurrent protection of colors is sought, this shall be indicated in the brief description.

Where an application for a design patent is filed for two or more similar designs incorporated in the same product, one of these designs shall be indicated as the main design in the brief description.

The brief description shall not contain any commercial advertising and shall not be used to indicate the functions of the product.

The reference in paragraph 2 to applications filed for two or more similar designs refers to the provision for the same in Article 31 paragraph 2 of the Patent Law.

In a design patent right infringement dispute case, *Beijing Huajiesheng Electromechanical Equipment Co. v. Dingsheng Door Control Technology Co.*,¹⁷⁰ the Supreme People's Court held that the brief description is a document that must be submitted when applying for a design patent and that it plays an explanatory role in determining the scope of protection of the design patent right. If the reference drawing of the use state is not considered, then an obvious conflict with the brief description of the design may occur. Therefore, a people's court must consider the reference drawing of the use state when determining the protection scope of the design patent right.

4.8.4.3 Product category

A design cannot be independently protected without the presence of the designed product. Therefore, when determining the protection scope of a design patent right, both the design and the category of the product are considered. If only the alleged infringing design is similar or identical to the patented design (i.e., their products are not similar or identical), or only the alleged infringing design's product is similar or identical to the patented design's product (i.e., the designs are not similar or identical), then the alleged infringing design does not fall within the scope of protection of the design patent right. Article 8 of the Interpretation of Patent Infringement Dispute Cases stipulates the following:

Where a design identical or similar to a design patent is applied to a category of products identical or similar to the products carrying the design patent, the court shall determine that the alleged infringing design falls into the scope of protection of a design patent right as provided for in paragraph 2 of Article 59 of the Patent Law.¹⁷¹

In an administrative case involving patent grant and confirmation, the court must also consider the product categories of the design and the prior design, in accordance with Article 23 of the Patent Law, when determining whether the design is a prior design, whether there is a conflicting application and whether it is obviously different from the prior design or a combination of prior design features. Articles 17–21 of the Provisions on Patent Grant and Confirmation have corresponding provisions.

According to Article 9 of the Interpretation of Patent Infringement Dispute Cases and Article 17 paragraph 3 of the Provisions on Patent Grant and Confirmation, the court must determine the category of a design product according to the use of the product. To determine the use of a product, the court may refer to the brief description of the design, the international classification for industrial designs, the functions of the product, the sale and real use of the product, and other such factors. With respect to the product category, the applicant must, in accordance with Article 47 of the Rules for the Implementation of the Patent Law, indicate "a product incorporating the design and the class to which that product belongs, [referring] to the classification of products for designs published by the patent administration department of the State Council."

¹⁷⁰ MZ No. 8 (Sup. People's Ct, 2018).

¹⁷¹ This reference here, to Article 59 paragraph 2 of the 2008 Patent Law, would be to Article 64 paragraph 2 of the current Patent Law.

4.8.5 Identifying “prior design” and “priority date”

Article 23 paragraph 4 of the Patent Law specifies the following: “For the purpose of this Law, ‘a prior design’ refers to any design known to the public domestically and/or abroad before the filing date.” The definition of prior design is consistent with that of “prior art” in Article 22 paragraph 4 of the Patent Law.

With respect to priority rights, according to Article 11 of the Rules for the Implementation of the Patent Law, except for the circumstances provided for in Article 28 (determination of the date of filing) and Article 42 (the term of patent rights) of the 2008 Patent Law, “[t]he date of filing referred to in the Patent Law” means “the priority date where priority is claimed.” A priority right can be a foreign priority right or a domestic priority right, according to whether the first patent application is filed abroad or in China, respectively. China’s 1984 Patent Law only referred to foreign priority (Article 29 of the 1984 Patent Law). In 1992, the Patent Law was amended by adding the domestic priority of inventions and utility models (Article 29 of the 1992 Patent Law). In the fourth amendment to the Patent Law, the domestic priority of design patents was added. It is stipulated in Article 29 paragraph 2 of the Patent Law that priority may be enjoyed if a patent application for the same subject is filed with the patent administration department of the State Council within six months from the date of the first design patent application in China.

The determination of the filing date and priority date has an important impact on a court’s finding of whether a design patent meets the grant and confirmation conditions stipulated in the Patent Law and whether a prior design and prior design defense are established in civil patent infringement cases.

4.8.6 Application of Article 23 of the Patent Law

Article 23 of the Patent Law is the most important legal basis for the grant and confirmation of a design patent. To further increase the requirements for being granted a design patent right and to improve patent quality, the provision in Article 25(1) of the TRIPS Agreement – referring to designs that “do not significantly differ from prior designs or combinations of prior design features” – was incorporated into Article 23 of the Patent Law in 2008. Article 23 paragraphs 1–3 of the Patent Law stipulates that a design for which a patent may be granted

shall not be a prior design, and no entity or individual has filed a patent application for the identical design with the patent administration department of the State Council before the filing date, and the content of the application is disclosed in patent documents announced after the filing date[;]

[...] shall significantly differ from a prior design or the combination of prior design features[; and]

[...] must not conflict with the lawful rights acquired by any other person before the filing date.

Article 23 paragraph 4 of the Patent Law stipulates that the term “prior design” means “any design known to the public domestically and/or abroad before the filing date.”

According to Article 16 of the Provisions on Patent Grant and Confirmation, the people’s court shall, when determining whether a design complies with Article 23 of the Patent Law, “comprehensively judge the overall visual effect of the design.”

4.8.6.1 Identifying a “prior design”

The stipulations that a design “not be a prior design” (Article 23 paragraph 1 of the Patent Law) and that an invention or utility model “not form part of the prior art” (in Article 22 paragraph 2 of the Patent Law) correspond with each other.

Article 17 paragraph 1 of the Provisions on Patent Grant and Confirmation defines a design as being a prior design if “compared with a prior design of any product of a same or similar category, the overall visual effect of a design is identical or substantially identical only with partial and subtle differences.”

4.8.6.2 Identifying a “conflicting application” (conflicting design)

To prevent the same application or different applications for the same design from being successively granted, the notion of conflicting applications (conflicting designs) was added in Article 23 paragraph 1 of the Patent Law: “no entity or individual has filed a patent application for the identical design with the patent administration department of the State Council before the filing date, and the content of the application is disclosed in patent documents announced after the filing date.” “Any entity or individual” also includes the patentee or patent applicant. The provisions on conflicting applications are important for prohibiting double patenting.

Article 19 of the Provisions on Patent Grant and Confirmation further stipulates that an “identical design,” as set out in Article 23 paragraph 1 of the Patent Law, includes

[w]here, in comparison with another design of a product of a same or similar category [and] for which a patent application is filed before the filing date and the content of the application is disclosed in patent documents announced after the filing date, [...] the overall visual effect of a design is identical or substantially identical only with partial and subtle differences, among others.

4.8.6.3 Identifying significant differences

To “significantly differ from,” as specified in Article 23 paragraph 2 of the Patent Law, includes two cases. First, the design for which the patent right is granted is significantly different from the prior design (i.e., a separate comparison). Second, the design is significantly different from the combination of prior design features (i.e., comparing the combined design features of the prior design with the patented design). This is similar to the determination of inventiveness for invention and utility model patents.

4.8.6.3.1 Identifying “significant impact”

With respect to separate comparisons between the patented design and a prior design, Article 17 paragraph 2 of the Provisions on Patent Grant and Confirmation stipulates the following:

If the difference between a design and a prior design of a product of a same or similar category has no significant impact on the overall visual effect, the court shall determine that the design has no ‘significant difference’ as provided for in paragraph 2, Article 23 of the Patent Law.

The provision is consistent with the requirement in Article 23 of the 2000 Patent Law that a design “not be similar with or similar to” a prior design. It is also consistent with the criteria with respect to the determination of design patent infringement as stipulated in Article 11 of the Interpretation of Patent Infringement Dispute Cases, which states, “if there is no substantive difference in the overall visual effect between the alleged infringing design and a patented design, the court shall determine that they are similar.”

With respect to the determination of similarity as stipulated in the 2000 Patent Law, in an administrative dispute case over the invalidation of design patent rights, *Honda Technology Research Industry Co. v. Patent Reexamination Board*,¹⁷² the Supreme People’s Court held that the basic method to determine whether a patented design is identical or similar to a prior design is to observe each design as a whole, based on the knowledge level and cognitive ability of ordinary consumers, and comprehensively determine whether the differences between the two have a significant impact on the visual effect of the product design. The term “as a whole” means that all design features of the visual part of the product should be considered, not just specific parts thereof. “Comprehensive” refers to the combination of all factors affecting the overall visual effect of the product design.

In a case involving an administrative dispute over the invalidation of design patent rights, *Gree Electric Appliances, Inc. v. GD Midea Holding Co.*,¹⁷³ the Supreme People’s Court further highlighted that an overall observation and comprehensive judgment refers to whether ordinary consumers can determine significant differences in the visual effect between the patented patent and a prior design as a whole, rather than in partial design changes. In such determinations, ordinary

172 XTZ No. 3 (Sup. People’s Ct, 2010).

173 XTZ No. 1 (Sup. People’s Ct, 2011).

consumers will observe the similarities and differences between the visual parts of the patented design and the prior design and comprehensively consider their respective impacts on the overall visual effect.

4.8.6.3.2 Comparing combined prior design features with the design patent

With respect to comparing the combined design features of a prior design with a design patent, Article 20 paragraph 1 of the Provisions on Patent Grant and Confirmation stipulates the following:

Where, based on design motivation from prior designs on the whole, a design with an overall visual effect identical or substantially identical only with partial and subtle differences, among others, with a design patent, and without unique visual effect is obtained through the conversion, combination, or replacement of design features, which ordinary consumers can easily think of, the people's court shall determine that the design patent has "no significant difference" as provided for in paragraph 2, Article 23 of the Patent Law in comparison with the combination of prior design features.

This provision refers to the relevant provisions and experiences in the determination of inventiveness for invention and utility model patents. First, it draws lessons from the concept of "technical motivation" in determining inventiveness, giving the provision on "design motivation." The overall conditions of a prior design can be comprehensively considered, and the determination can be made according to the design motivation provided by the prior design as a whole. This makes the determination criteria more objective. Second, ordinary consumers are in the position to make the determination – not the designers of the product – to avoid determining the legitimacy of a design patent based on a different subject. Third, the key to determining whether a design patent has any "significant difference" is to find out whether its overall visual effect is easy to think of. That is, according to the prior design, whether it is easy to think of obtaining an identical or substantially identical overall visual effect (only with partial and subtle differences) through conventional design methods, including through the conversion, combination or replacement of design features. Fourth, the factor of "unexpected technical effects," considered in determining inventiveness, is used as a reference, and it is necessary to consider whether a design patent has a "unique visual effect." Article 20 paragraph 2 of the Provisions on Patent Grant and Confirmation lists seven circumstances wherein "design motivation" may be found, and Article 21 stipulates the factors to be fully considered in determining the "unique visual effect."

4.8.6.3.3 "Aesthetic appeal" and functional design features

Article 2 paragraph 4 of the Patent Law stipulates that "'[d]esign' means, with respect to an overall or partial product, any new design of the shape, the pattern, or their combination, or the combination of the color with shape or pattern, which is rich in an aesthetic appeal and is fit for industrial application." With respect to the "aesthetic appeal" required for a design, it is not about whether the product aesthetically looks good, but about whether the visual effect of the product is "decorative," which is a concept relative to functionality. Article 16 paragraph 2 of the Provisions on Patent Grant and Confirmation stipulates the following: "Design features required for realizing particular technical function or only with limited choices shall have no significant impact on the overall observation and comprehensive judgment of the visual effect of a patent for a design."

In a dispute over the infringement of design patent rights, *Friedrich Grohe AG v. Zhejiang Jianlong Sanitary Ware Co.*,¹⁷⁴ it was pointed out that the identification of functional design features depends on whether the feature, in the opinion of ordinary consumers of the design product, is solely determined by the specific function, without considering whether the feature has aesthetic appeal. Functional design features have no significant impact on the overall visual effect of the design. When it comes to the impact of design features with both functionality and decorativeness on the overall visual effect, its degree of decorativeness shall be considered; the stronger the decorativeness, the greater the impact on the overall visual effect, and vice versa.

In a case involving an administrative dispute over the invalidation of design patent rights, *Gree Electric Appliances, Inc. v. GD Midea Holding Co.*,¹⁷⁵ the Supreme People's Court pointed out that, to

¹⁷⁴ Sup. People's Ct Guiding Case No. 85, March 6, 2017.

¹⁷⁵ XTZ No. 1 (Sup. People's Ct, 2011).

obtain the protection of a design patent right, the design must have aesthetic appeal as set out in the Patent Law: that is, on the basis of realizing the specific function of the product, innovative improvements have been made to the visual effect of the product so that the product presents the combination of functionality and aesthetic appeal. A product design with functionality but no aesthetic appeal can be protected by applying for an invention or utility model patent rather than a design patent.

With respect to the identification of functional design features, the Supreme People's Court pointed out, in a case involving an administrative dispute over the invalidation of design patent rights, *China National Intellectual Property Administration v. Zhang Dijun*,¹⁷⁶ that functional design features refer to those design features that, in the view of ordinary consumers, are determined solely by the specific function to be realized without considering aesthetic factors. Functional design features are related, to some degree, to the selectivity of the design features. If a design feature is the only design for a specific function, then aesthetic factors are excluded from such a design feature, and the design feature is obviously a functional design feature. If a design feature is one of a limited number of design choices for realizing a specific function, then this firmly shows that the design feature is a kind of functional feature. However, even if a design feature is only one of multiple design methods for realizing a specific function, it can still be considered a functional design feature so long as the design feature is determined only by the specific function to be realized and irrelevant to aesthetic considerations.

4.8.6.3.4 No conflict with lawful rights

The constituent elements of a design include its shape, pattern and color, which may involve a work, business logo, name, portrait and elements protected by lawful rights acquired by another person before the filing date. So long as a design patent is exploited, the prior lawful rights or interests of others might be infringed or damaged. Article 23 paragraph 3 of the Patent Law stipulates the following: "Any design for which a patent right is granted must not conflict with the lawful rights acquired by any other person before the filing date."

For the determination of the conflict of rights, Article 11 of the Interpretation of Patent Infringement Dispute Cases stipulates that "where a patent infringement case involves any conflict of rights, the people's court shall protect the lawful rights and interests of the party with a prior right in accordance with the law." Article 12 stipulates the following: "The lawful rights mentioned in paragraph 3, Article 23 of the Patent Law include the lawful rights or interests in works, trademarks, geographical indications, names, enterprise names, portraits, as well as influential commodity names, packaging, decoration, etc." These provisions also apply as references in the trial of cases involving patent grant and confirmation.

In a case involving an administrative dispute over the invalidation of design patent rights, *China National Intellectual Property Administration v. Baixiang Foods Co.*,¹⁷⁷ the Supreme People's Court held that the right to apply for the registration of a trademark is of great significance in determining whether a design patent right and an exclusive right to use a registered trademark constitute a conflict of rights. As a kind of expected right, the right holder related to a trademark application ultimately seeks the right to exclusively make use of the registered trademark. Only when the trademark is registered can the ultimate interest from the application be realized. In this case, the right to apply for a trademark should be protected retroactively, and the legal significance of the filing date of the trademark application should be recognized. If the trademark application filing date is earlier than the design patent filing date, then the exclusive right to the registered trademark can prevail against the design patent right. Once the trademark has been registered, the exploitation of the design patent will objectively conflict with the trademark rights; therefore, in this case, the court decided in accordance with the principle of protecting prior rights.

4.8.7 Infringement of design patent rights

With respect to the infringement of a design patent right, Article 11 paragraph 2 of the Patent Law stipulates the following: "After the grant of a design patent, no entity or individual may, without the authorization of the patentee, exploit the patent, that is, for production or business

¹⁷⁶ XTZ No. 14 (Sup. People's Ct, 2012).

¹⁷⁷ ZXZ No. 4 (Sup. People's Ct, 2014).

purposes, manufacture, offer to sell, sell, or import the product incorporating the patentee's patented design." Among the types of acts infringing a design patent, "use" is not included.

According to Article 12 of the Interpretation of Patent Infringement Dispute Cases:

Where a product infringing a design patent right is used as a part or component for manufacturing and selling another product, the people's court shall determine it as an act of selling as provided for in Article 11 of the Patent Law, unless the product which infringes the design patent only has a technical function in such other product.

The main consideration of this provision is that, when a product that infringes a design patent right is used as a part or component for manufacturing and selling another product, such activity is deemed to be selling, since use alone would not constitute an infringement of the design patent according to the Patent Law. However, because a design patent right protects the appearance of the product, if the part and component only play a technical function without producing any visual effect during the normal use of the final product, then selling infringement shall not be established.

In a case involving a dispute over the infringement of design patent rights, *Ou Jieren v. Taizhou Jinshen Household Products Co.*,¹⁷⁸ it was recorded in the brief description of the patent, titled "aluminum profile," that the picture to best indicate the key design elements was the main view, which showed the end face shape of the aluminum profile. The alleged infringing product was a glass sliding door. As a component of the glass sliding door, the aluminum profile was embedded with the glass on the sliding door as a whole, and the end face of the aluminum profile could not be observed under normal use, so the aluminum profile played only a technical function. Therefore, the act of using the aluminum profile as a part in the manufacture and selling of glass sliding doors was judged not to constitute infringement.

4.8.8 Judgment of infringement of design patents

The scope of protection of a design patent is subject to the design shown in the picture or photograph. Article 8 of the Interpretation of Patent Infringement Dispute Cases stipulates the following:

Where a design identical or similar to a design patent is applied to a category of products identical or similar to the products carrying the design patent, the people's court shall determine that the alleged infringing design falls within the scope of protection of the design patent as provided for in Article 59 paragraph 2 of the [2008] Patent Law.

In the judgment of patent infringement, the people's court does not only determine whether the design is identical or similar but also determines whether the categories of products are identical or similar. The criteria for determining the product category in a patent infringement case are consistent with those in the procedures involving patent grant and confirmation: both are based on the use of the product.

When determining whether designs are identical or similar, ordinary consumers are the subject to make such a determination, and it is necessary to accurately clarify the knowledge and cognitive ability of these ordinary consumers and carry out the "overall observation" and "comprehensive judgment" of the visual effect of the whole. Article 11 of the Interpretation of Patent Infringement Dispute Cases stipulates the following:

When determining whether designs are identical or similar, the people's court shall consider the design features of the patented design and the alleged infringing design, and make a comprehensive judgment depending on the overall visual effect of the designs; and the people's court shall not consider design features mainly determined by technical functions, and material, internal structure, and other features of a product which have no effect on the overall visual effect.

178 MS No. 2649 (Sup. People's Ct, 2017).

In the following circumstances, the overall visual effect of a design is usually more significantly affected:

- (1) The part of a product that is easy to be directly observed during normal use as opposed to other parts;
- (2) design features that are distinct from those of the prior designs as opposed to other design features of the patented design.

Where there is no difference in the overall visual effect between the alleged infringing design and a patented design, the people's court shall determine that the two designs are identical; or if there is no substantive difference in the overall visual effect between them, the people's court shall determine that they are similar.

There are two main considerations for these provisions. First, a design patent protects the improvement and innovation of the visual effect of the product's appearance rather than the innovation of its function and technical effects. Hence, any material, internal structure or other features of the product that have no impact on the overall visual effect – and any design features determined primarily by a technical function – are not considered in the determination of infringement. Accordingly, the parts of a product that can easily be directly observed during normal use will be more likely to have a significant impact on the visual effect; and, conversely, parts that cannot be observed or are almost impossible to be observed during normal use will not have a significant impact on the overall visual effect. Second, the fundamental criterion for determining whether a design is identical or similar is the overall visual effect, and the design features of the innovative part are an important part affecting the overall visual effect. The features distinct from the prior design are identified based on evidence cross-examined by the parties. Since design patents in China are not substantially examined before granting, the essential features described in the brief description of the design can be used as a reference for finding the innovative part.

In *Friedrich Grohe AG v. Zhejiang Jianlong Sanitary Ware Co.*,¹⁷⁹ a dispute over the infringement of design patent rights, it was indicated that the design features of a patented design not only reflect the innovative features, which are different from those in prior designs, but also reflect the designer's inventive contribution to the prior designs. Thus, if an alleged infringing design does not include all of the design features distinguishing the patented design from prior designs, it can be presumed that the alleged infringing design is not similar to the patented design. For the determination of design features, the patentee must present evidence for the design features claimed. Based on hearing the cross-examination opinions of the parties, the court shall fully examine the evidence and determine the design features of the patented design according to the law.

In a case involving a dispute over the infringement of design patent rights, *Lanxi Changcheng Food Co. v. Chen Chunbin*,¹⁸⁰ the Supreme People's Court held that the protection scope of the design patent was the shape of the product without claiming the pattern of the design. Although the alleged infringing product used a pattern on the product, this additional pattern did not have a substantive or significant impact on the overall visual effect. Therefore, the alleged infringing product fell within the protection scope of the involved patent.

In a case involving a dispute over the infringement of design patent rights, *Arc International v. Yiwu Lanzhiyun Glass Crafts Factory*,¹⁸¹ the Supreme People's Court pointed out that a design protected under Patent Law should be incorporated into products and cannot exist independently. The product category of a design patent should be determined based on the use of the product, which has a form independent of the design and can be sold separately. In a case involving a dispute over the infringement of design patent rights, *Fujian Jinjiang Qingyang Weiduoli Food Co. v. Zhangzhou Yueyuan Food Co.*,¹⁸² the Supreme People's Court pointed out that the object to be protected by a design patent is neither the product alone nor the design independent of the product category defined by the design patent. The determination of whether the product category is identical or similar should be based on whether the use of the product is identical or similar. The sale and actual use of a product can be a reference for determining the use of the product.

179 Sup. People's Ct Guiding Case No. 85, March 6, 2017.

180 MSZ No. 438 (Sup. People's Ct, 2014).

181 MSZ No. 41 and No. 54 (Sup. People's Ct, 2012).

182 MSZ No. 1658 (Sup. People's Ct, 2013).

Articles 15–17 of the Interpretation (II) of Patent Infringement Dispute Cases contain the provisions on the determination of infringement of design patents for combination products, products in a set and products having variable states.

4.8.9 Prior design defense

Article 67 of the Patent Law stipulates the following: “In a dispute over patent infringement, if the alleged infringer has evidence to prove that the technology or design that the alleged infringer has exploited is a prior art or prior design, such exploitation shall not constitute an infringement of the patent right.” With respect to the prior design defense, this provision means that a patentee can apply for a patent and obtain protection only for their innovative contribution relative to the prior design; they are not allowed to include, in the protection scope, designs that have entered the public domain or that belong to the innovative contribution of others. According to Article 14 paragraph 2 of the Interpretation of Patent Infringement Dispute Cases, “[w]here an alleged design is identical to or is not substantively different from a prior design,” a prior design defense shall be sustained.

After the 2008 Patent Law, the geographical scope of public use or publication disclosure was no longer distinguished, and the recognition criteria for prior designs were changed. Article 22 of the Interpretation (II) of Patent Infringement Dispute Cases stipulates the following: “Regarding the prior art defense or prior design defense asserted by an alleged infringer, the people’s courts shall define the prior art or prior design in accordance with the Patent Law that was in effect upon the patent filing date.” Therefore, regarding design patents applied for before the 2008 Patent Law, prior designs must still be determined according to the specific methods of disclosure: a design used abroad cannot constitute a disclosure and cannot be used for prior design defense.

With respect to the judgment criteria for prior design defense, in a case involving a dispute over design patent rights, *Bridgestone Corp. v. Zhejiang Huntington Bull Rubber Co.*,¹⁸³ the Supreme People’s Court held that, to determine whether an alleged infringer’s prior design defense is sustained, the design of the alleged infringing product must first be compared with a prior design to determine whether they are identical or have no substantive differences. If the design of the alleged infringing product is identical to a prior design, it can be directly determined that the design exploited by the alleged infringer is part of the prior design and does not fall within the protection scope of the design patent. If the design of the alleged infringing product is not identical to the prior design, then it must further be judged whether they are substantively different or similar. The judgment of any substantive difference or similarity is relative. If the design of the alleged infringing product is simply compared with the prior design, the differences between the two and the impacts of these differences on their respective overall visual effects may be ignored, resulting in wrong judgment (i.e., similarities between the alleged infringing product design, prior design and design patent are established). Therefore, where an alleged infringing product design is not identical to the prior design, to ensure an accurate conclusion regarding infringement of the design patent, the prior design is used as the basis for comparison with the alleged infringing product design and design patent before a comprehensive judgment is made. In this process, attention is paid not only to the similarities and differences between the alleged infringing product design and the prior design, as well as their impacts on their respective overall visual effects, but also to the differences between the design patent and the prior design (and their impacts on their respective overall visual effect). Attention is paid to clarifying whether the design of the alleged infringing product takes advantage of the differences between the design patent and the prior design. If so, a determination can be made as to whether there is a substantial difference between the design of the alleged infringing product and the prior design.

4.9 Patent-related criminal cases

Part 2(III)(7) of China’s Criminal Law¹⁸⁴ stipulates the “crimes of infringing upon intellectual property rights” and includes a total of eight articles (Articles 213–220). Article 216 stipulates the crime of counterfeiting a patent: “Whoever counterfeits other people’s patents, and when the circumstances are serious, is to be sentenced to not more than three years of fixed-term imprisonment, criminal detention, and may in addition or exclusively be sentenced to a fine.”

183 MTZ No. 189 (Sup. People’s Ct, 2010).

184 Criminal Law (2020 Amendment) (promulgated by the Sup. People’s Ct, Dec. 26, 2020, effective March 1, 2021).

Article 10 of the Interpretation of Criminal Infringement of Intellectual Property Rights stipulates the following:¹⁸⁵

Any of the following acts shall be deemed as “counterfeiting of the patent of others” as prescribed in Article 216 of the Criminal Law:

- (1) Marking, without permission, other’s patent number on the manufactured or sold product or its packaging;
- (2) Using, without permission, other’s patent number in advertisements or other advertising materials, thus misleading people to believe that the technology involved is patented;
- (3) Using, without permission, other’s patent number in a contract, thus misleading people to believe that the technology as described in the contract is patented; and
- (4) Forging or altering other’s patent certificate, patent document or patent application document.

Article 4 defines the specific conviction and sentencing criteria for the crime of counterfeiting a patent:

Any person who counterfeits the patent of another and presents it as his/her own shall, in any of the following circumstances, be deemed to have caused “the serious consequences” as prescribed in Article 216 of the Criminal Law, and shall be sentenced to a fixed-term imprisonment for not more than three years or criminal detention for the crime of counterfeiting patent, and/or be imposed a fine:

- (1) The amount of proceeds arising from illegal business operations is no less than RMB 200,000 or the amount of illegal proceeds is no less than RMB 100,000;
- (2) The direct economic losses caused to the patentee are no less than RMB 500,000;
- (3) The person counterfeits two or more patents, with the proceeds arising from illegal business operations being not less than RMB 100,000 or the amount of illegal proceeds being not less than RMB 50,000; and
- (4) Other circumstances in which the consequences are serious.

According to Article 1 of the Provisions on the Trial of Patent Disputes, the people’s court shall accept cases involving counterfeiting of patents. Article 68 of the Patent Law stipulates the legal liabilities to be assumed for counterfeiting patents:

Where any person counterfeits a patent of another person, then such a person shall, in addition to bearing civil liabilities in accordance with the law, be ordered by the department in charge of patent enforcement to make rectifications, and the department shall make the matter known to the public. Such a person’s illegal earnings shall be confiscated and, in addition, a fine of not more than five times the illegal earnings may be imposed. If there are no illegal earnings or the illegal earnings are less than RMB 50,000, a fine of not more than RMB 250,000 may be imposed.

Where the infringement constitutes a crime, then such a person shall be investigated for criminal responsibility in accordance with the law.

Article 84 of the Rules for the Implementation of the Patent Law further stipulates five specific circumstances under which an act constitutes an act of counterfeiting a patent. It is worth noting that the scope of “counterfeiting the patent of another person,” as defined in the Rules for the Implementation of the Patent Law, is broader than that in Article 216 of the Criminal Law. For instance, the former also includes “any other acts of misleading the general public into considering a technology or design which has not been granted a patent, as being patented.”

¹⁸⁵ Interpretation concerning Several Issues on the Specific Application of Law for Handling Criminal Cases of Infringement upon Intellectual Property Rights (promulgated by the Sup. People’s Ct and Sup. People’s Procuratorate, Dec. 8, 2004, effective Dec. 22, 2004).

Chapter 5

Germany

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5.1 Overview of the patent system

5.1.1 Evolution of the patent system

The German Patent Act ("Patentgesetz") finds its roots in the Reichspatentgesetz of May 25, 1877, which has since undergone numerous revisions and consolidations. The current version is based on the 1981 revision, with the latest significant modification having entered into force in August 2021. In this modification, the right to a permanent injunction, above all, was adapted so as to clarify that, under exceptional circumstances, the claim for injunctive relief may be precluded by the objection of disproportionality.

Since its beginnings, patents have been granted throughout all federal states in Germany by a centralized federal body – first the Imperial Patent Office in Berlin, now the German Patent and Trademark Office (PTO) having its seat in Munich. A major change to the organizational structure of the granting authority was triggered by a landmark decision of the Federal Administrative Court ("Bundesverwaltungsgericht") in 1959,¹ which found that it was not in line with the fundamental right to judicial review that decisions of the Patent Office could only be appealed to an internal appellate body of the Office. It further held that this appellate body could not be regarded as a court since its decisions were rendered by civil servants not being furnished with the independence and impartiality of a judge. This led to the establishment of the Federal Patent Court (FPC; "Bundespatentgericht")² in Munich in 1961 after necessary changes to the German Constitution had been made.³

5.1.2 Importance of the European Patent Convention and EU law

Despite the principle of territoriality, which limits the geographical scope of protection of patents to the country of grant, German patent law is continuously and increasingly subject to international – primarily European – influences as part of the European integration. These influences are multifaceted and reach from the granting of patents to their enforcement.

A major influence on German patent law is the European Patent Convention (EPC),⁴ which entered into force on October 7, 1977. The Convention not only contains substantive provisions, but is also the legal basis for the establishment of the European Patent Office (EPO), an international organization separate from the European Union (EU), with additional member states such as Norway, Switzerland, Turkey and the United Kingdom. One of the most prominent examples of this influence concerns the grant of patents. Until the EPC became effective in 1977, it was only possible to apply for German patents at the German PTO. Since then, applications for so-called European patents can also be filed with the European Patent Office.⁵ The application can request protection for one or – typically – more member state signatories of the EPC. According to Article 64(1) of the EPC, a European patent has the same effect as a nationally granted patent. Germany has been a signatory of the EPC since its entry into force, and many patents enforced in Germany are European patents.

The enforcement of patents in Germany is also shaped to a large extent by EU law: Directive 2004/48/EC, on the enforcement of intellectual property rights (the "Enforcement Directive");⁶ and the case law of the Court of Justice of the European Union, in the context of standard-essential patents.⁷ The Enforcement Directive is aimed at harmonizing the EU's legislation in the field of intellectual property and at ensuring a high, equivalent and homogeneous level of protection of intellectual property, including patent law.⁸ The Enforcement Directive has been implemented

1 Bundesverwaltungsgericht (BVerwG) (Federal Administrative Court), June 13, 1959, I C 66.57.

2 For further information see below and www.bundespatentgericht.de/EN/TheCourt/theCourt_node.html

3 6th Transitional Act (Überleitungsgesetz) of March, 23, 1961, BGBl. I, 274.

4 Convention on the Grant of European Patents, Oct. 5, 1973, 1065 UNTS 199, revised by the Act revising art. 63 of the EPC, Dec. 17, 1991, and the Act revising the EPC, Nov. 29, 2000, www.epo.org/law-practice/legal-texts/html/epc/2020/e/ma1.html

5 The term "European patent" can be slightly misleading. While the granting of these patents is done centrally by the EPO, they subsequently break down into national parts, so that enforcement and validity is solely considered at the national level.

6 Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the Enforcement of Intellectual Property Rights, 2004 OJ (L 157) 45, <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32004L0048>

7 Most notably the Court of Justice of the European Union's decision in Case C-170/13, *Huawei Technologies Co. Ltd. v. ZTE Corp.*, <https://curia.europa.eu/juris/document/document.jsf?text=&docid=165911&pageIndex=0&doclang=EN&mode=Cf>

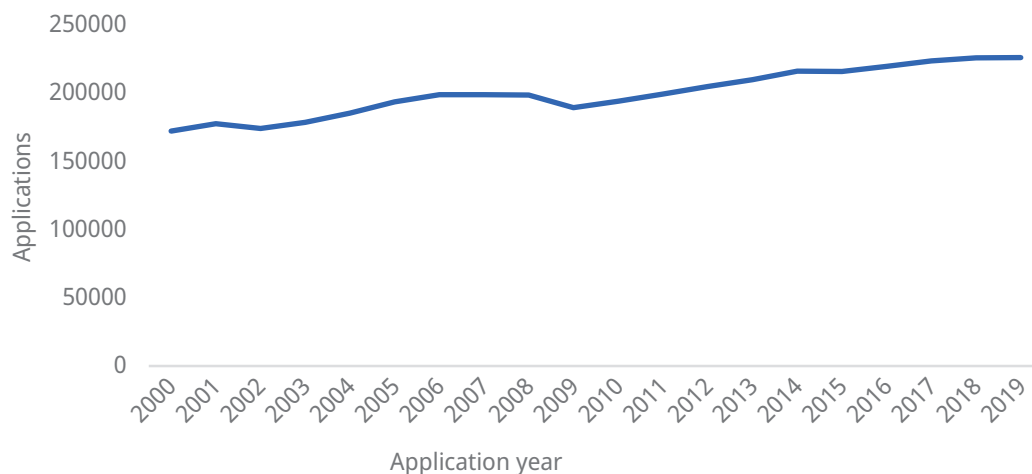
8 Cf. Recital 10 of the Enforcement Directive.

into German intellectual property law, including patent law, to the extent needed but is also relied upon by German courts when interpreting national law.

5.1.3 Patent application trends

Figure 5.1 shows the total number of patent applications (direct, Patent Cooperation Treaty (PCT) national phase entry and European patent DE designation) filed in Germany from 2000 to 2019.

Figure 5.1 Patent applications filed in Germany, 2000–2019



Source: WIPO IP Statistics Data Center, available at www3.wipo.int/ipstats/index.htm?tab=patent and EPO PATSTAT, available at www.epo.org/searching-for-patents/business/patstat.html

5.2 Patent institutions and administrative review proceedings

Since its beginnings, Germany has followed a double-track system – the so-called bifurcation system – with the patent infringement courts, being part of the ordinary judiciary and adjudicating on the question of infringement, and separate granting authorities, with their own track of judicial review on the validity of the patent. Infringement proceedings are handled by specialized civil courts having exclusive jurisdiction in patent matters with legally-trained judges sitting on the bench.

The validity of a German patent may be challenged within nine months after its grant in an opposition procedure before a board of the German PTO. As a court of judicial review, the FPC hears appeals against the decisions of the PTO on patents. Additionally, a patent's validity may be put into question by a nullity action before the FPC at any time. Decisions of the FPC, which are rendered by a senate consisting of three technical and two legally-qualified judges (including the presiding judge), may be appealed to the Federal Court of Justice (FCJ; "Bundesgerichtshof") (Xth Senate) so that the separate tracks – validity and infringement – can be finally aligned by the jurisprudence of the FCJ.

5.3 Judicial institutions

5.3.1 Judicial administration structure

Germany is constituted as a federal republic of 16 states ("Länder"). According to Article 92 of the German Constitution,⁹ there are both federal courts and state courts. To preserve uniformity of decisions, according to Article 95(1) of the Constitution, the FCJ was established as the appellate court for state courts in the last instance. If all other legal remedies are exhausted, then, under specific circumstances, a constitutional complaint may be filed to the Federal Constitutional Court ("Bundesverfassungsgericht") established under Articles 92–94 of the Constitution.

⁹ Grundgesetz (Basic Law), www.gesetze-im-internet.de/englisch_gg/englisch_gg.html

Despite the general competence of regional courts, an infringement suit cannot be filed with just any regional court in Germany; rather, there are 12 (out of 115) regional courts that have been designated to hear patent infringement cases. Most cases are heard by the Regional Court ("Landgericht") of Düsseldorf, the Regional Court of Mannheim or the Regional Court of Munich. While the jurisdiction of each regional court is limited to a certain geographical area – that is, one or several states – all courts will assume jurisdiction if infringing products are offered on the internet. The Regional Court of Düsseldorf and the Regional Court of Munich both have three specialized chambers for patent matters, whereas there are two specialized chambers at the Regional Court of Mannheim.¹⁰ The chambers at the regional court level consist of three specialized judges. Although these judges are trained lawyers – most of them without technical backgrounds – they generally have significant experience in patent cases and have a profound understanding of various technical fields.

For each regional court, there is a corresponding higher regional court ("Oberlandesgericht") as the appellate court. Due to the focus on the regional courts of Düsseldorf, Munich and Mannheim in the first instance, most appeals are filed to the higher regional courts of Düsseldorf, Munich and Karlsruhe respectively. At the higher regional court level, designated senates of three judges hear appeals in patent infringement cases. Notably, at the Higher Regional Court of Düsseldorf, there are two senates established to hear patent infringement appeals.

At the FCJ, the X Senate hears appeals from the higher regional court level, with a bench of five judges on questions of law. The senate, however, will only hear appeals from a higher regional court if leave was given either by the higher regional court or, upon appeal against a negative decision by the regional court, by the FCJ itself.

The FPC in Munich has exclusive jurisdiction over patent nullity actions. Depending on the International Patent Classification (IPC) classification of the patent-in-suit, cases are assigned to one of the seven nullity senates ("Nichtigkeitssenate") at the FPC. Cases at the FPC are decided by a panel of five judges. In contrast to infringement proceedings, only the presiding judge and one associate judge are lawyers, while three associate judges have a technical education and have often been patent examiners prior to their appointment as judges. Decisions by the FPC can be appealed to the FCJ, where the X Senate (the same senate as in infringement cases) is competent. The judges at the FCJ are all lawyers without necessarily having an additional technical background.

In patent infringement cases, representation by a fully qualified lawyer ("Rechtsanwalt") is required. Regularly, especially in cases concerning complex technologies, lawyers will be supported by patent attorneys ("Patentanwalt") who have a technical background in the respective field of technology. By contrast, in validity proceedings at the FPC and invalidity appeal proceedings at the FCJ, aside from lawyers, patent attorneys are entitled to represent clients. Typically, a close alignment is required between lawyers acting in the infringement proceedings and the patent attorneys handling the validity proceedings.

Figure 5.2 shows the judicial administration structure in Germany.

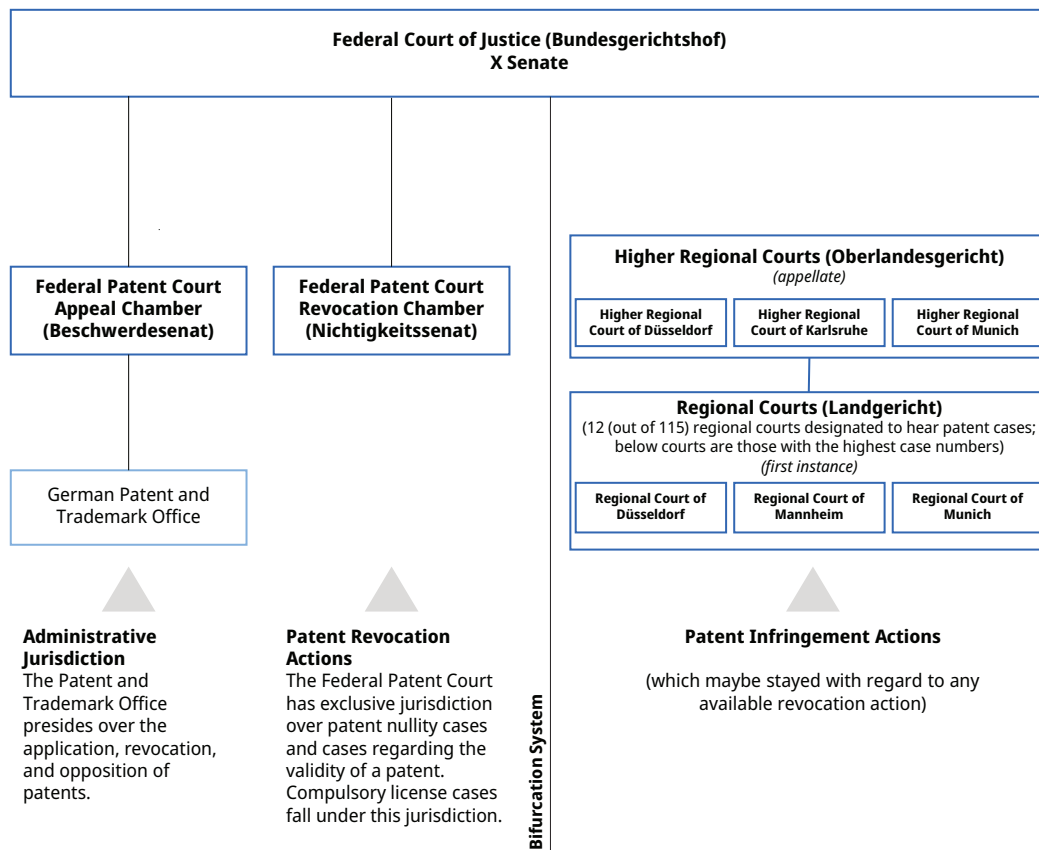
5.3.2 Double-track system: patent infringement and patent validity proceedings

One of the distinguishing features of the German patent system is its double-track system: patent infringement and patent validity proceedings are separated.

Infringement proceedings are heard by regional courts in the first instance and can be appealed to higher regional courts and, eventually, if leave was given, to the FCJ. By contrast, nullity actions addressing a patent's validity must be filed with the FPC, with the FCJ as the appellate court. Only at the FCJ do the separate jurisdictions converge; however, invalidity and infringement proceedings are also heard separately here.

Infringement courts have no jurisdiction to review whether a ground for the revocation of the patent-in-suit is given. Rather, the infringement court is bound by the grant of the patent.

10 The Regional Court of Munich just recently introduced a third chamber, which commenced work on Aug. 16, 2021.

Figure 5.2 The judicial administration structure in Germany

Consequently, the defense of invalidity is not admitted in infringement proceedings as it is in other jurisdictions. However, the infringement court has discretion to stay infringement proceedings in view of a pending nullity action before the FPC or an opposition proceeding pending before the German PTO or the EPO. Commonly, defendants in an infringement litigation will file nullity proceedings at the same time as their statement of defense. This allows them to request a stay of the infringement proceedings.

In the first instance, a stay is generally only issued if there is a high likelihood that the patent-in-suit will be invalidated in the opposition or nullity proceedings. This legal standard is applied with varying degrees of strictness by the regional courts, some of which follow a slightly more generous approach regarding the stay of proceedings than others. If infringement proceedings are stayed, the stay generally lasts until the first-instance decision in the nullity proceedings or the opposition proceedings is handed down.

If infringement proceedings are not stayed, this leads to comparatively speedy infringement proceedings, with a first-instance decision within 8 to 20 months, depending on the complexity of the case and the current workload of the respective regional court.¹¹ Conversely, the stay of proceedings can prevent the plaintiff from enforcing their patent for a considerable period, as in nullity proceedings, where a first-instance decision can typically only be expected within 15 to 30 months. The situation (often referred to as an “injunction gap”) puts plaintiffs at an advantage: the plaintiff can enforce a first-instance injunction (if a security bond is provided) before there is a decision on the patent’s validity.

In this respect, the up-front preliminary opinions of the FPC given under Section 83(1) of the Patent Act¹² in writing early in nullity proceedings play an important role in the infringement

11 As of Oct. 2021, a first-instance decision could be expected within 12–20 months in cases pending at the Regional Court of Düsseldorf, in 8–18 months for cases pending at the Regional Court of Mannheim and in 8–20 months for cases at the Regional Court of Munich I.

12 Patentgesetz (Patent Act), Dec. 16, 1980, BGBl I at 1, amended by the Act of Oct. 8, 2017, BGBl I at 3546, art. 4, www.gesetze-im-internet.de/englisch_patg/index.html

court's exercise of discretion as to whether to stay the infringement proceedings. If the FPC indicates in such a preliminary opinion that it tends to consider a patent not to be valid, the infringement court will usually stay proceedings. In the future, the lack of synchronization between infringement and validity proceedings may be further mitigated, as Section 83(1) of the Patent Act has been amended recently¹³ to stipulate that the FPC should issue a qualified opinion within six months after service of the action.

5.4 Patent invalidity proceedings and invalidity grounds

5.4.1 First-instance proceedings

5.4.1.1 Court

The revocation action is not to be filed with the infringement court but with the FPC based in Munich. The FPC has a total of 25 panels, seven of which are nullity senates concerned with patent revocation proceedings. Each panel has a focus on particular technical areas, and, therefore, revocation actions are assigned to the respective panel based on the technical field of the patent-in-suit.

5.4.1.2 Admissibility

The threshold for filing an admissible revocation action against a German patent is rather low.

5.4.1.2.1 Form and timing

The revocation action must be in German (Section 126 of the Patent Act)¹⁴ and be filed in writing or as an electronic document using the communication methods provided by the FPC. If the patent-in-suit is a European patent that was filed and granted in another official language (e.g., English or French), a German translation should be provided. Translations of prior art references in English need not be filed in the first instance, but the FCJ usually requests German translations of the pertinent references on appeal. The claimant's request may be for revocation of the patent either in its entirety or a part thereof.

With regard to the timing of a revocation action, Section 81(2) provides for a restriction: a revocation action cannot be filed as long as a notice for opposition can be filed with the respective patent office or as long as opposition proceedings are pending before the patent office. If a revocation action is nevertheless filed, it is rejected as inadmissible.

Besides this, there is no deadline or other timewise constraint. A revocation action can even be filed against a patent that is no longer in force if the plaintiff can show a special interest in the nullification of the patent. Such interest could, for example, result from the owner of the patent asserting or threatening to assert claims for damages arising from allegedly infringing activities during the lifespan of the patent. Such interest could also arise if the term of the patent lapses in the course of pending revocation proceedings and the plaintiff wants to continue the proceedings.

5.4.1.2.2 Content

Section 80(5) defines the mandatory content of a revocation action: naming the parties of the proceedings (i.e., the plaintiff and defendant), indicating the subject matter of the case, and the facts and evidence in support of the grounds. Moreover, the revocation action must contain a specific motion.

5.4.1.2.2.1 Parties

The defendant is defined in Section 81(1), according to which the revocation action shall be directed against the proprietor of the patent as named in the official register of the German PTO. Even if the register does not reflect recent changes in the ownership of the patent and is thus incorrect, the proprietor of the patent named in the register is still the legitimate defendant. If a plurality of proprietors is named in the official register of the PTO, the action must be directed against all of them.

¹³ The Patent Act was amended by the *Zweites Gesetz zur Vereinfachung und Modernisierung des Patentrechts* (Second Act on the Simplification and Modernization of Patent Law), Aug. 10, 2021, BGBl I at 3490. The new sec. 83 of the Patent Act entered into force on May 1, 2022. For its wording see: www.gesetze-im-internet.de/patg/BJNR201170936.html

¹⁴ In the following text until the end of Chapter V, references to sections without a reference to a particular law refer to the German Patent Act.

With regard to the plaintiff's standing to sue, there are nearly no restrictions. As a general rule, anyone can file a revocation action against a German patent unless the plaintiff has concluded an agreement with the patent proprietor precluding such an attack. If the person interested in the revocation of the patent prefers to remain unknown, the action for revocation can even be filed by a strawman (e.g., a patent attorney), but a strawman is subject to the same legal constraints as the truly interested party. If and when the revocation action is based on usurpation, only the aggrieved person is entitled to file the complaint (cf. Section 81(3)). Said person can, of course, additionally reason the revocation action with other grounds for revocation (e.g., lack of novelty or inventive step). As already mentioned, a further exception applies for a revocation action against a patent that has elapsed when the plaintiff needs to have a special legal interest in the nullification of the patent.

The action for revocation of a patent can also be jointly filed by two or more plaintiffs. If several actions for revocation are pending against the same patent, the proceedings are often merged into one. Furthermore, instead of filing a separate action for revocation, it is also possible for a party to join pending revocation proceedings. A joinder of parties on the plaintiff's side is, however, only possible if the joining party has a special legal interest in joining the proceedings. Such interest could, for example, result from the patent proprietor asserting or threatening to assert the patent against the joining party.

German parties can pursue the proceedings before the FPC themselves: it is not mandatory to be represented by an attorney-at-law or a patent attorney (cf. Section 97(1)). The parties may, of course, choose to be represented by an attorney-at-law or a patent attorney or by another agent. Suitable other agents are defined in Section 97(2), according to which a party can also be represented by its employees or the employees of an affiliate company (Section 15 of the Stock Corporation Act of 6 September 1965),¹⁵ family members of full age, persons qualified to hold judicial offices, and joined parties, if the representation is not linked to a paid activity. Representation by an agent who does not fall within the above categories is not admissible. However, foreign parties must be represented by a patent attorney or an attorney-at-law (cf. Sections 97(1) and 25).

5.4.1.2.2.2 Motion

Since the subject matter of a revocation action is the nullification of a patent, the motion must be directed at a specific patent being nullified either in its entirety or partially with regard to certain claims. Other motions – for example, motions requesting that certain features of a patent claim be nullified or that certain clarifying passages be added to the specification of the patent-in-suit – are not admissible.

5.4.1.2.2.3 Subject matter and facts and evidence supporting the grounds

In the grounds of the revocation action, the plaintiff must set out the reasons for which the patent-in-suit is to be revoked either entirely or partially. This does not only require naming a reason for revocation (e.g., lack of novelty, lack of inventive step, added subject matter, or sufficiency) but also requires detailed argumentation. The plaintiff must detail why a certain claim of the patent-in-suit lacks, for example, novelty or inventive step over a certain piece of prior art. This includes identifying a specific passage of the prior art document for each of the claim's features. Similarly detailed argumentation is also required for the other grounds for revocation. It is not sufficient to submit a number of prior art documents accompanied by the general statement that the patent lacks novelty or inventive step in view of those documents.

5.4.1.2.2.4 Security bond

If the plaintiff does not live in or has their place of business in a member state of the EU, in a contracting party to the Agreement of the European Economic Area or in a state where, due to international treaties, no such security deposit may be requested, the defendant may request that the court order the plaintiff to submit a security bond that covers the costs of the proceedings. The rationale behind this is to ensure that the defendant is reimbursed the costs of the proceedings if the plaintiff must bear the costs of the proceedings after the action for revocation is dismissed. Without a security bond, the defendant would need to enforce its claim for reimbursement abroad, which may be very time-consuming and costly.

¹⁵ https://www.gesetze-im-internet.de/englisch_aktg/

Just like infringement proceedings, German revocation proceedings are front-loaded – that is, they are initiated by a written complaint (a revocation action) setting forth in detail why the patent-in-suit is invalid for at least one of the statutory grounds for revocation.

5.4.1.2.3 Front-loaded written proceedings

Once filed, a revocation action is transferred to the competent board within the FPC. The assignment of cases follows the main IPC class of the patent so as to ensure that technically competent boards deal with the respective actions.

The competent board then checks whether the action meets the formal requirements and, in particular, whether the appropriate court fees have been paid in advance. As these fees directly depend on the estimated value of the matter in dispute, the court also checks the claimant's proposal in this regard, if any, and then preliminarily fixes the value of the matter in dispute by a decision. It may happen that the court disagrees with the claimant's proposal and sets a higher value; in such a case, the claimant must pay the fees accruing from this higher value as well. The court will not process the revocation action until all requisite fees have been paid.

Court fees in German actions for revocation can be quite significant. This is because the value of the matter in dispute is normally assumed to be in the range of EUR 250,000 to EUR 30,000,000, which translates into court fees of about EUR 10,000 to about EUR 545,000. If an infringement action based on the patent-in-suit is already pending, the rule of thumb for calculating the value of the revocation action is the value of the infringement action plus a lump sum of 25 percent for own use and licensing of the patent.

Once the formalities have been checked and the requisite fees have been paid, the revocation action is served on the defendant by the FPC, and the defendant is invited to (formally) respond thereto within a one-month deadline (Section 82). Should the defendant fail to respond in due time, a decision on the action may be taken immediately without oral proceedings, wherein each fact asserted by the claimant is deemed to be proven. If the defendant declares that they will not defend the patent, it must be declared null and void without examination on the merits.¹⁶ If the defendant objects to the revocation action in due time, as is normal, they are usually granted a two- to three-month deadline for filing a fully substantiated defense.

The defendant (patentee) can either defend the patent in full or in an amended (limited) form. The court normally does not consider other claim versions than those defended by the patentee. Similarly, the court can revoke the patent only to the extent requested by the claimant, even if it is convinced that the entire patent is invalid. For the same reason, the defendant can only defend the patent in a limited form to the extent that it has been attacked; nonattacked claims are maintained but must not be amended.¹⁷ This follows from the principle of party disposition in civil proceedings, which also underlies the respective procedural provisions in the Patent Act (Section 99).

Conversely, this principle is overlaid by – and to some extent in tension with – the principle of *ex officio* examination enshrined in Section 87: “The Patent Court shall investigate *ex officio* the facts of the case. It shall not be bound by the factual statements and the requests to take evidence of the parties.” In practice, this means that the FPC can, for example, deem a prior art reference relevant for novelty, even though it was only asserted under lack of inventive step or vice versa. The court may also find a prior art reference on which the claimant has not particularly focused to be highly pertinent. In some past cases, the FPC has even introduced prior art references into the proceedings of its own motion. While this practice has since stopped, the FPC may still draw parties' attention to references reflecting what it deems to have been common general knowledge at the priority day.

5.4.1.2.4 Preliminary evaluation by the court

Once all parties have had the possibility to submit their observations, the presiding judge of the competent board sets a date for oral proceedings and summons the parties to attend the same.

¹⁶ BPatG (FPC), March 5, 2009, 3 Ni 27/08 (EU) (*Oxaliplatin*).

¹⁷ BGH (FCJ), March 1, 2017, X ZR 10/15 (*Ankopplungssystem*).

Moreover, the board deliberates on the case and issues a first communication. According to Section 83(1), the purpose of this communication is merely

to draw the attention of the parties to matters which are likely to be of particular importance for the decision or which are conducive to concentrating the hearing on the issues essential for the decision. Such indication is not required if the aspects to be discussed appear obvious from the arguments of the parties.

In practice, however, the communication represents a reasoned preliminary opinion on the merits of the revocation action, which is already a fairly good indicator of the final outcome in most (but not all!) cases. This preliminary opinion is binding for the court insofar that deviating from it requires the issuance of a further preliminary opinion, either in writing or orally at the hearing. This is to prevent any surprising outcome for the parties and to safeguard the losing party's right to be heard.¹⁸

According to Section 83(1), the board's communication, including its preliminary opinion, should be issued within six months after service of the revocation action. In preparation of the preliminary opinion, the court may set a deadline for the final submissions of the parties. In pending infringement proceedings, the infringement court should also be provided with the preliminary opinion. The rationale behind this statutory provision is to safeguard that the FPC's preliminary opinion on the validity of the patent-in-suit can be taken into consideration by the infringement court in deciding whether the infringement proceedings should be stayed.

5.4.1.2.5 Written statements

In accordance with the principle of party disposition, the parties to the proceedings are basically free to file submissions or replies at will, although the court will be entirely satisfied with the revocation action and a reasoned reply and will not invite the parties to file additional observations or requests unless some matters or requests need to be clarified.

However, pursuant to Section 83(2), the board usually sets a deadline for both parties for filing their final submissions and requests when issuing the preliminary opinion. This will normally also be the last chance to introduce auxiliary requests in time. Only if the board, before or at the trial, comes to a view different from what has been held in the preliminary opinion can the party adversely affected by this development be allowed to file a further request. It is at the discretion of the court whether to reject late-filed means of attack or defense, or a further amended version of the patent, if considering these new submissions would necessitate postponing the oral proceedings and if the party has not sufficiently excused the delay (Section 83(4)).

Overall, the written proceedings mainly serve the purpose of preparing the final oral proceedings to the maximum extent possible so that the requests, the means of evidence and the main lines of argumentation have been clarified before the hearing starts. The procedure in writing is open to public file inspection upon request except where the patentee proves a conflicting interest warranting protection (Section 99(3)).

5.4.1.2.6 Auxiliary defense by amendments of the patent

As mentioned above, a defendant patentee may elect to either defend the patent as granted or in an amended (limited) form. For a limited defense to be successful, it is required that the amendment be admissible as such – that is, that the subject matter of the amended claims does not extend beyond the content of the application as originally filed (Section 21(1)(4)) and that it does not extend the scope of the protection of the patent (Section 22(2)). Moreover, the limited subject matter must meet the patentability and sufficiency requirements (Section 21(1)(1)–(2)). The admissibility of the amendment and its compliance with the other requirements of the Patent Act are examined in the revocation proceedings. Thus, no separate proceedings for amendment or limitation need to be initiated.

In addition, the defendant (patentee) in a German revocation action has the option of a staggered defense. They may defend the patent-in-suit in the form of a main request (e.g., patent as granted or a limited version thereof) and one or several auxiliary requests presenting further limited sets of claims. This is quite similar to the procedure in German and EPO opposition

¹⁸ BGH (FCJ), Dec. 20, 2011, X ZB 6/10 (*Installiereinrichtung II*).

proceedings. To the extent that the defendant does not defend certain claims against the revocation action, those claims are to be revoked without examination on the merits.¹⁹

The patentee is not limited in their defense to a subset of the claims as granted but may also amend the claims by including features from the description. The only limitation is the prohibition of adding matter (Section 21(1)(4)) and expanding the scope of the patent (Section 22(1)), which also excludes replacing the claimed subject matter by an *aliud*. Conversely, when resorting to an example or a particularly preferred embodiment disclosed in the description of the patent application as the basis for an amendment, the patentee is usually not obliged to include all features of this example or preferred embodiment in the claim. This is as long as the features taken from the example or embodiment were disclosed as belonging to the invention as originally disclosed and contribute to the claimed solution.²⁰

As a lack of clarity is no ground for revocation, claims that are attacked merely for this reason must be maintained as they are and cannot be amended. Even in the case of a limited defense by the patent proprietor in revocation proceedings, an examination of the clarity of the limited patent claim is not admissible, at least to the extent that the presumed ambiguity was already contained in the granted claims.²¹

The declaration that the patent is only defended in a limited form, or any auxiliary requests, do not need to be filed immediately when submitting the substantiated response to the revocation action, even though this is highly recommended to streamline proceedings and to assist the court in drafting a meaningful preliminary opinion (see above at 5.3.2). As a ground rule, it is advisable for the parties to front-load their complete cases in the first instance, similar to EPO opposition proceedings. The court may reject amendments filed after the expiration of a term set by the court under Section 83(4).

The FPC does not examine the unity or convergence of auxiliary requests. Furthermore, the FPC is not bound to examine the different auxiliary requests in the order used by patentee, but it will usually follow that order.

If the defendant (patentee) admissibly limits the patent of their own volition and the claimant withdraws the request for revocation to this extent, the patent is maintained in part based on said limitation, and declared null and void to the extent that it extends beyond this limitation, without further substantive examination. This may be one way for parties to settle the lawsuit, although the much more frequently used method to end revocation proceedings is by a withdrawal of the revocation action by the claimant. Such a withdrawal has immediate effect, even on appeal, and does not require the patentee's consent.²² The patent is then maintained as granted.

5.4.1.2.7 Oral hearing

The final hearing concluding revocation proceedings follows a certain structure. First, the presiding judge opens the proceedings and checks the attendance of the parties and of the witnesses and so on, if any. Then, the value of the matter in dispute is finally set after having given all parties an opportunity to comment. Often, the court gives a reasoned indication based on the submissions of both parties and possibly also on general knowledge. This indication is then briefly discussed and usually accepted by the parties.

The presiding judge may then try to explore possibilities for settlement. Where appropriate, the court tries to "catalyze" such an agreement or may even gently push the parties to agree. The representatives are therefore expected to discuss the possibilities of a settlement with their respective clients before the hearing.

If no settlement is achieved, the presiding judge confirms and records the parties' motions. Then they (or the reporting judge in exceptional cases) present the essential content of the files and explain the court's provisional assessment of the case. This is followed by the parties' pleadings and a discussion of the case (Section 91(1)). Judges may ask questions to the parties and

19 BGH (FCJ), Dec. 19, 2006, X ZR 236/01, 2007 IIC 479 (*Carvedilol II*).

20 BGH (FCJ), Sep. 11, 2001, X ZB 18/00 (*Drehmomentübertragungseinrichtung*).

21 BGH (FCJ), Oct. 27, 2015, X ZR 11/13 (*Fugenband*), 2016 IIC 727.

22 BGH (FCJ), June 22, 1993, X ZR 25/86 (*Hartschaumplatten*).

occasionally avail themselves of this opportunity. Depending on the complexity of the case, the debate (including breaks) may take up to one full day.

The hearing is public (Section 69) except in extremely rare cases where the public is excluded from the proceedings at the request of one of the parties because the public nature of the proceedings threatens to endanger any interests of the requestor that warrant protection. Pursuant to Section 92, minutes of the hearing (including the taking of any evidence) are taken, but there is no transcript of the hearing. The minutes are often quite brief, though this varies from board to board.

After the parties have been heard and the case has been exhaustively discussed, the presiding judge closes the oral hearing, and the court retires for deliberation. The board may decide to reopen the hearing after deliberation or may proceed with giving the decision. Alternatively, the court may set a date for giving the decision (Section 94). It may also serve the decision on the parties rather than giving the decision orally in session. In practice, the FPC announces its decision most of the time on the same day after deliberation.

5.4.1.2.8 Decision

Pursuant to Section 84(1), the decision on the revocation action is rendered in the form of a judgment. The judgment normally concludes the dispute in this instance but is appealable. The FPC shall make its decision on the basis of its independent conviction gained in light of the results of the proceedings as a whole. The judgment contains the grounds for the decision (Section 93(1)).

The court's judgment has an operative part wherein the patent-in-suit is either declared null and void in its entirety or partially or wherein the revocation action is dismissed. The operative part also contains a decision on the costs of the proceedings. In accordance with Section 84(2) and the applicable rules of the Code of Civil Procedure, the costs will usually be imposed on the losing party to the extent it lost the revocation action unless equity requires otherwise. Finally, the court usually orders that its decision be provisionally enforceable with regard to the costs if the cost creditor provides a security amounting to 120 percent of the amount to which they are entitled. The actual amount of the reimbursable costs is determined in a separate cost-fixation proceeding.

The fully reasoned decision in writing must be delivered within five months of the announcement of the decision. It should provide comprehensible reasoning on all points in dispute that were necessary for the court to arrive at its decision. However, the court does not need to give reasons for each attack or defense raised by one of the parties. For example, the FPC sometimes leaves the question of novelty undecided, even if it was controversial, but invalidates patents for lack of inventive step.

When a parallel decision from an EPO opposition division, a board of appeal or a national court of another EPC country is submitted by one of the parties, German courts are supposed to take note thereof and, as far as relevant for the decision in the case at hand, discuss such a decision as a weighty but not binding authority.²³ Generally, the FPC is relatively little influenced by the outcome of preceding EPO opposition or appeal proceedings or invalidation proceedings in other countries.

5.4.1.3 Evidence

The FPC may take evidence in oral proceedings pursuant to Section 88(1) of the Patent Act in connection with Section 355(1) of the Code of Civil Procedure. The necessity of taking evidence depends on whether relevant questions of fact that cannot be clarified otherwise are in dispute between the parties. Questions regarding the content or interpretation of the patent or prior art reference, as well as the evaluation of novelty, inventive step, sufficiency of disclosure and added matter, are considered to be legal questions that are not subject to the taking of evidence. Therefore, the taking of evidence before the FPC is the exception rather than the rule, particularly since the court is normally convinced that it has the necessary expertise to deal with all technical questions in dispute. Whether evidence is to be taken is determined by the court *ex officio*.

The type of evidence to be considered particularly includes the hearing of witnesses, experts and parties; inspections; and the consultation of documents. In practice, only experts, inspections and witnesses of fact play some role in revocation proceedings.

23 BGH (FCJ), April 15, 2010, Xa ZB 10/09, 2011 IIC 363 (*Walzenformgebungsmaschine*).

5.4.1.3.1 Experts

According to German civil procedural law, a strict distinction is to be made between experts appointed by the court (according to the procedure stipulated in Sections 402 et seq. of the Code of Civil Procedure) and party experts. Only the former are considered formal “means of evidence” and heard in court, whereas the opinions of the latter are simply assumed to be part of the submissions of the party that files them. Therefore, it is a rare exception for the FPC to interrogate a party expert in oral proceedings, even though it is possible.

If the FPC wants to consult a court expert, it must take a formal decision to this effect after hearing the parties. This normally takes place in the oral proceedings and may significantly extend the duration of the proceedings since an expert must first be identified, appointed and properly summoned. As this is hardly efficient – and, as the technical judges, due to their technical background, understand the technical aspects of the case at issue – appointing a court expert is a very rare event. Nonetheless, a specialist expert may be very helpful and advisable in complex cases or in cases involving new or specialist areas of technology. The FCJ expects the FPC to ensure that its decision is based on adequate technical expertise, either by means of the court’s technical judges or by means of a court-appointed expert.

The remuneration of the court expert (and any witnesses) is governed by Section 128a Patent Act and the Judicial Remuneration and Compensation Act.²⁴

5.4.1.3.2 Witnesses

Pursuant to Section 373 of the Code of Civil Procedure, evidence by hearing witnesses shall be offered by naming the witnesses and designating the facts regarding which the witnesses are to be examined. The general rules of taking evidence in revocation proceedings (Section 88(3) of the Patent Act) apply: that is, parties need to be notified of the decision to take evidence and need to have the opportunity to attend the taking of evidence. They are allowed to direct appropriate questions to witnesses or court-appointed experts in the hearing. Witnesses of fact mainly play a role in cases of an alleged public prior use.

5.4.1.3.3 Inspection

Inspection of a model or an apparatus can also serve as a means of evidence. This occasionally plays a role in mechanical engineering cases, particularly if a public prior use of the apparatus is asserted and the exact functionality or composition of the apparatus or parts thereof are in dispute.

5.4.1.4 Access to court files

The parties to the proceedings and third parties may request access to court files. A third party’s request is granted unless a party to the revocation proceedings can show that legitimate confidentiality interests would be affected by allowing a third party’s access to the court files (e.g., owing to commercial or technical aspects or trade secrets). In general, a legitimate interest of a party cannot justify a complete denial of access to the court files, because information that is to be kept confidential is usually only part of specific briefs or passages thereof. Therefore, access to the files is only excluded with regard to the respective specific briefs or respective confidential passages. These will be blackened prior to granting inspection of the files.

5.4.2 Grounds for revocation

5.4.2.1 Lack of patentability

Pursuant to Section 21(1), in conjunction with Section 22(1), a German patent shall be revoked or declared null and void if it arises that the subject matter of the patent is not patentable according to Sections 1–5. These sections cover patent eligibility and statutory exclusions (Sections 1, 1a); *ordre public*, the cloning or genetic manipulation of humans, embryos or animals, plant or animal varieties, and methods of treatment of the human or animal body (Section 2); novelty (Section 3); inventive step (Section 4); and industrial applicability (Section 5). The very same applies to the revocation of a European patent with effect in Germany (with regard to the German part), pursuant to Article II(6) of the Act on International Patent Conventions.²⁵ The subsections can only provide a very brief overview of these issues and will focus on aspects that have arisen in practice.

²⁴ <http://www.gesetze-im-internet.de/jveg/>

²⁵ http://www.gesetze-im-internet.de/intpat_bkg/

5.4.2.1.1 Lack of patent eligibility

Patents can only be granted for inventions in a technical field (Section 1(1)). The FCJ has defined a technical teaching in patent law as “a teaching to methodically utilize controllable natural forces to achieve a causal, perceivable result.”²⁶ Later, the Federal Supreme Court put the definition into perspective by stating that the concept of technology must leave room for future developments and therefore cannot be given a final definition.²⁷ Today, the main applicability of Section 1 is in the field of computer-implemented inventions and business methods. While discoveries, scientific theories, mathematical methods, aesthetic creations, schemes, rules and methods for performing mental acts, playing games or doing business, as well as programs for computers and presentations of information, are specifically excluded from being “inventions” under Section 1, this exclusion only applies to the subject matter or activity “as such” and is generally construed narrowly. For example, the FCJ has decided that a mathematical method can only be considered nontechnical if it has no relation to the specific application of forces of nature in the context of the claimed teaching. Conversely, a sufficient connection to the specific application of forces of nature exists if a mathematical method is used for the purpose of gaining more reliable knowledge about the condition of, for example, an aircraft on the basis of available measured values and influencing the functioning of the system used to determine this condition.²⁸

Currently, German courts examine the patentability of computer-implemented inventions and business-method-related patents using the following three-step approach:

1. Is at least part of the application in the technical field? (Section 1(1))
2. Is the subject matter of the patent a computer program as such (or business activity or mathematical method)? (Section 1(3), in conjunction with (4))²⁹
3. If the application contains instructions that serve to solve a concrete technical problem by technical means, then examine for novelty and inventive step, but “nontechnical” features are not to be taken into account.

Most computer-implemented invention patents therefore pass the initial hurdle of patent eligibility, but an appreciable number of them fail on the inventive-step hurdle, particularly if the crux of the invention is “only” an improvement in the software or algorithm driving a certain technical system (such as a computer). The German approach is quite similar to the EPO’s “Comvik” approach,³⁰ and the same applies to the results.

Conversely, German jurisprudence has no problem in patenting inventions that are (mainly) based on the discovery of a natural law, including the biological function of a DNA sequence or the like. The FCJ has decided that a teaching on a technical action that teaches the use of a discovery to bring about a certain success is amenable to patent protection irrespective of whether the teaching contains an “inventive surplus” over and above the purpose-directed use of the discovered natural law. This also applies to the provision of a nucleic acid sequence coding for a human protein.³¹

5.4.2.1.2 Lack of novelty

Section 3 of the German Patent Act substantially corresponds to Articles 54 and 55 of the EPC. An invention is deemed to be novel if it does not form part of the state of the art, which includes all knowledge made available to the public by any means before the date relevant for the priority of the application. Additionally, German, European and international applications with earlier relevant filing dates, and that have been made available to the public only after the date relevant to the priority date of the later application, also count as (fictitious) state of the art but only for the purposes of novelty (Section 3(2) and 4). Novelty of any substance or substance mixture included in the state of the art is not excluded when such is intended for use in a method for surgical or therapeutic application to the human or animal body or for diagnostic methods used on the human or animal body and when its use for such a process is not included in the state of the art (Section 3(3) and (4)).

26 BGH (FCJ), March 27, 1969 – X ZB 15/67, 1970 IIC 136 (*Rote Taube*).

27 BGH (FCJ), May 11, 2000 – X ZB 15/98, 2002 IIC 136 (*Sprachanalyseeinrichtung*).

28 BGH (FCJ), June 30, 2015, X ZB 1/15 (*Flugzeugzustand*).

29 This condition only applies if the teaching does not contain instructions that serve to solve a concrete problem by technical means.

30 EPO, *Case Law of the Boards of Appeal*, I(D)(9.1.3)(b) (9th ed. 2019); G 1/19.

31 BGH (FCJ), Jan. 19, 2016, X ZR 141/13, 2018 IIC 221 (*Rezeptortyrosinkinase I*) (a decision wherein the U.S. Supreme Court’s approach in *Mayo v. Prometheus*, 566 U.S. 66 (2012) was explicitly rejected).

In view of the identical statutory foundation, German courts have endeavored to bring their case law on novelty into harmony with that of the EPO. As a result, only small differences, if any, are still noticeable from time to time. Following the FCJ's landmark decision in *Olanzapin*³² it is now established case law that a (prior art) disclosure may also include that which is not expressly mentioned in the patent claim or the description yet is plainly evident, from the point of view of a person skilled in the art, such that they are able to carry out the protected teaching and which therefore does not need to be specifically disclosed but will be "read in." The inclusion of plainly evident subject matter, does not, however, permit that the disclosure be supplemented by expert knowledge. Instead, it only serves the purpose of full ascertainment of the content and its meaning – that is, the technical information, which the skilled reader will infer from the source against the background of their expert knowledge.³³

A particularly interesting pair of decisions on the scope and boundaries of implicit disclosure in an Article 54(3) (fictitious) prior art document are the FCJ's two decisions on a patent pertaining to a method of separating therapeutic blood-clotting proteins from human or animal plasma. In the first decision, the patent was maintained because the critical prior art document was found not to have implicitly disclosed a final lyophilization step, even though such a lyophilization step was considered as the "means of choice" and might "in most cases be nearly indispensable."³⁴ However, the FCJ found in this decision that the skilled person also had alternative means at their disposal to make a Factor VIII concentrate suitable for therapeutic use. The revocation action was, therefore, finally dismissed. However, an affiliated company of the claimant in the revocation action [hereinafter claimant], which the patentee had also sued for patent infringement, filed another revocation action based on the same ground and prior art reference. This time, the claimant succeeded on appeal, and the patent was declared null and void for lack of novelty.³⁵ The FCJ found that the alternative it had recognized in its first judgment – filling the preparation into ampoules – was, in fact, no "alternative" but a preparatory step for the subsequent lyophilization, which was the common means at the priority date to secure a long-term therapeutic use. If it is apparent to a person skilled in the art, from the description of a process for the production of a protein concentrate suitable for therapeutic use, that further process steps are required to bring about therapeutic usability, then the measure that was the means generally used in practice at the priority date to achieve this goal is covered by the disclosure content of the publication.

5.4.2.1.3 Lack of inventive step (obviousness)

Pursuant to Section 4 of the Patent Act and Article 56 of the EPC, an invention is deemed to involve an inventive step if it is not obvious to a person skilled in the art from the state of the art. While the applicable statute is the same, the methodology for determining inventive step greatly differs between the EPO and the German courts. In particular, the German courts do not apply the EPO-specific problem–solution approach.

The starting point for evaluating inventive step, according to German jurisprudence, is any reference(s) that a skilled person would find realistic *ante inventionem*; there is no preference for a "closest prior art." However, the choice of the starting point(s) should be justified.³⁶

The problem underlying the invention should likewise not be defined by merely determining the difference between the invention and the closest prior art, because this would again be hindsight. Sometimes, it is plausible that the skilled person would have solved this problem; sometimes, the problem construed that way may be artificial. Generally, the German courts strive to define the problem in general and realistic terms and without hints to its solution.³⁷ It is true, though, that the formulation of the problem is of relatively little impact on the final and determinative question of obviousness. The problem stated in the patent is not always relevant for the evaluation of obviousness; a different problem may also have suggested its solution to the skilled person.³⁸

German case law on obviousness is both voluminous and complex and cannot be discussed in depth in a treatise like the present one. Particularly in chemical and biotechnology cases, the

32 BGH (FCJ), Dec. 16, 2008, X ZR 89/07, 2009 IIC 596.

33 BGH (FCJ), Dec. 16, 2008, X ZR 89/07, 2009 IIC 596.

34 BGH (FCJ), July 13, 2010, Xa ZR 10/07 (*Proteintrennung*).

35 BGH (FCJ), March 18, 2014, X ZR 77/12, 2015 IIC 473 (*Proteintrennung II*).

36 BGH (FCJ), June 18, 2009, Xa ZR 138/05 (*Fischbissanzeiger*); *Olanzapin*, X ZR 89/07.

37 BGH (FCJ), Jan. 13, 2015, X ZR 41/13, 2015 IIC 720 (*Quetiapin*).

38 BGH (FCJ), March 1, 2011, X ZR 72/08. (*Kosmetisches Sonnenschutzmittel III*).

criterion of a reasonable expectation of success has recently been applied several times.³⁹ Generally, a finding of obviousness requires that a skilled person *would* have arrived at the invention rather than that they merely *could* have done so,⁴⁰ which means that the relevant state of the art must have contained a teaching, suggestion or motivation for arriving at the invention. Exceptionally, a person skilled in the art may also have reason to use, for solving the problem, a means that belongs to general technical knowledge and that could be considered for a multitude of applications. This requires that the use of the means is objectively suitable for solving the problem due to its functionality and that there are no special circumstances that make its use seem impossible, difficult or otherwise impractical from a technical point of view.⁴¹ The burden of proof for all these requirements is on the claimant.⁴² Secondary indicia may neither substantiate an inventive step nor replace a critical examination thereof.⁴³

5.4.2.1.4 Others

Other grounds covered by lack of patentability – such as a lack of industrial applicability (Section 5), violation of *ordre public* (Section 2), exclusion of plant and animal varieties (Section 2a(1)(1)), exclusion of methods for the surgical or therapeutic treatment of the human or animal body (Section 2a(1)(2)) and so on – have played almost no role in practice so far.

5.4.2.2 Insufficient disclosure

A patent must be revoked or declared null and void if it does not disclose the invention in a manner clear and complete enough for it to be carried out by a skilled person (Section 21(1)(2), in conjunction with Section 22). Invalidations of patents in their entirety for this reason are fairly rare in Germany, where relatively high levels of skill are imputed to the skilled person, and it is recognized that one way to practice the invention is generally sufficient, even if many other ways that fall under a generic expression in a claim do not work.⁴⁴ Also, broad functional claims (reach-through claims) have been approved by the FCJ in one case,⁴⁵ contrary to the practice before the EPO. The FCJ's generosity reaches certain limits in the case of claims containing open ranges that generalize the subject matter beyond the invention's contribution to the state of the art.⁴⁶ The degree of generalization that is permissible in this context depends, in each individual case, on whether the protection afforded by the respective version of the claim is within the scope of what, from the point of view of a person skilled in the art, can be inferred from the patent, taking into account the description and the embodiments contained therein, as the most general form of the technical teaching by which the problem underlying the invention is solved.⁴⁷

5.4.2.3 Usurpation

According to Section 21(1)(3), a patent shall also be revoked if the essential contents of the patent have been taken from the descriptions, drawings, models, appliances or equipment of another or from a process used by another without the consent of said person (usurpation). However, this ground for revocation plays no role in practice since, in the case of usurpation, the entitled owner may also demand that the patentee assigns the patent to them (Section 8), and this is usually the more attractive means of redress.

5.4.2.4 Added matter

Section 21(1)(4), in conjunction with Section 22(1), stipulates that the patent shall be revoked or declared null and void if the subject matter of the patent extends beyond the content of the application as originally filed. Thus, the applicable provisions on added matter correspond to those enshrined in Articles 123(2), 100(c) and 138(1)(c) of the EPC.

Therefore, the jurisprudence of the German courts on added matter is, by and large, consistent with the EPO's jurisprudence. In particular, both German and EPO decisions frequently refer to the "gold standard" for added matter, which is whether the amendments are directly and

39 BGH (FCJ), May 15, 2012, X ZR 98/09 (*Calcipotriol*); BGH (FCJ), April 16, 2019, X ZR 59/17 (*Fulvestrant*).

40 Established case law, cf., e.g., BGH (FCJ), April 30, 2009, Xa ZR 92/05, 2010 IIC 231 (*Betrieb einer Sicherheitseinrichtung*); BGH (FCJ), Jan. 21, 2020, X ZR 65/18 (*Tadalafil*).

41 BGH (FCJ), March 11, 2014, X ZR 139/10 (*Farbversorgungssystem*).

42 BGH (FCJ), Sep. 26, 2017, X ZR 109/15 (*Spinfrequenz*).

43 BGH (FCJ), July 30, 2009, Xa ZR 22/06, 2010 IIC 468 (*Dreihnachtschlauchfolienbeutel*).

44 BGH (FCJ), May 3, 2001, X ZR 168/97 (*Taxol*).

45 BGH (FCJ), Sep. 11, 2013, X ZB 8/12, 2014 IIC 700 (*Dipeptidylpeptidase-Inhibitoren*).

46 BGH (FCJ), Feb. 25, 2010, Xa ZR 100/05 (*Thermoplastische Zusammensetzung*).

47 BGH (FCJ), March 12, 2019, X ZR 32/17 (*Cer-Zirkonium-Mischoxid I*).

unambiguously derivable from the application as filed.⁴⁸ Nonetheless, the concept of “direct and unambiguous” disclosure in Germany is interpreted more broadly and seeks to avoid unduly limiting the applicant or patentee in exhausting the disclosure content of either the application as filed or the priority application, if priority is at stake.⁴⁹ Moreover, German courts spend considerable effort to carefully construe the claimed subject matter, sometimes even against its literal wording, when it results from a description that two terms in the claims are to be substituted for each other, which may help against an added-matter attack.⁵⁰

Under German case law, not only the original claims and the general description but also the examples and drawings can, in principle, be used as the basis for an amendment, since they are considered part of the application’s disclosure. The main question to be asked is whether the feature to be included in the claim can be seen as a possible embodiment of the invention. Therefore, an amendment made by taking one feature from an example, rather than limiting the claim to the example as a whole, is allowable as long as it appears from the patent claim or the application as filed that the new combination of selected features is a possible embodiment of the invention.⁵¹ The same test is applied in cases of generalizations from drawings.

The FCJ’s jurisprudence is certainly much less formalistic compared to the EPO when it comes to limitations from numerical ranges in the application as filed. A numerical range is generally considered to disclose all possible intermediate values between the lower and upper limit – that is, every value and subrange within that range is equally disclosed.⁵² The FCJ is also less formalistic than the EPO when it comes to admitting disclaimers and has found a pragmatic solution for cases in which a patent application has been limited by an unallowable amendment during prosecution and is attacked later in opposition or revocation proceedings. While, in the EPO, this situation may put the patentee in an “inescapable trap,” where no option remains that ensures compliance with both Article 123(2) and 123(3) of the EPC, German jurisprudence still offers a solution: if the insertion of a feature that has not been disclosed in the application as filed results in a mere restriction of the protected subject matter, then the feature in question can remain in the claim but may not be relied upon in support of patentability.⁵³ If, by contrast, the inserted feature deals with an aspect that has not been disclosed in the application as being part of the invention at all (*aliud*), the patent must be revoked or declared null and void.⁵⁴

5.4.3 Appeal proceedings

5.4.3.1 Court

An appeal against a judgment in revocation proceedings is to be filed with the FCJ. Since the FCJ is also the final instance in the infringement proceedings, it can assure that the patent is interpreted in the same way in infringement and revocation proceedings.⁵⁵

Within the FCJ, the Xth civil senate is responsible for appeals in revocation proceedings. The Xth civil senate currently has eight members, all of whom are fully qualified lawyers. Before being promoted to the FCJ, the members of the Xth civil senate were (presiding) judges either at district courts, courts of appeals or the FPC. Not all members of the Xth civil senate are involved in every case. Cases are handled by a panel of five judges: the presiding judge or their deputy, and four associate judges one of whom is the reporting judge (the judge who is mainly responsible for handling the case prior to the oral hearing).

5.4.3.2 Limited de novo appeal

The purpose of appeal proceedings is not to reevaluate all facts and legal arguments brought forward in the course of the first instance. Therefore, experts or witnesses are rarely heard by the FCJ. The appeal proceedings are instead directed at evaluating whether the judgment of the FPC was based on a violation of federal law or if facts that are to be considered by the FCJ justify a different decision (cf. Section 111(1)). The latter aspect is the limiting factor: the basis of the FCJ’s

48 G 2/10.

49 BGH (FCJ), Feb. 11, 2014, X ZR 107/12, 2015 IIC 590 (*Kommunikationskanal*).

50 BGH (FCJ), May 12, 2015, X ZR 43/13, 2016 IIC 354 (*Rotorelemente*).

51 BGH (FCJ), July 17, 2012, X ZR 117/11, 2013 IIC 464 (*Polymerschäum*).

52 BGH (FCJ), Sep. 15, 2015, X ZR 112/13, 2016 IIC 355 (*Teilreflektierende Folie*).

53 BGH (FCJ), Oct. 21, 2010, Xa ZB 14/09 (*Winkelmesseinrichtung*).

54 BGH (FCJ), June 21, 2011, X ZR 43/09 (*Integrationsselement*).

55 BGH (FCJ), June 29, 2010, X ZR 193/03 (*Crimpwerkzeug III*).

decision is, first and foremost, the facts determined in the judgment of the FPC, whereas new facts and new means for challenge and defense (e.g., new evidence, new objections, new interpretations of or new arguments based on prior art documents that are already part of the proceedings) can only be considered to a very limited extent (cf. Section 117).

According to Section 117, which refers to certain provisions of the German Code of Civil Procedure, new means for challenge and defense are only admitted for consideration (1) if they concern an aspect that the FPC had recognizably failed to see or had held to be insignificant, (2) if they were not asserted in the first instance due to a defect in the proceedings, or (3) if their nonassertion in the first instance was not due to the party's negligence. In practice, the last aspect is the most relevant. The standards for showing that the nonassertion of a means for challenge and defense was not due to the party's negligence are rather high. For example, a party that wants to introduce a newly found prior art document in the appeal proceedings must reason why this piece of prior art was not found during the prior art search conducted in (the preparation of) the first-instance proceedings. This reasoning must include a detailed explanation as to the scope and content of said search and as to why the search profile that led to the prior art document had not been chosen back then. Parties are thus forced to carefully consider their position and bring all relevant arguments, as well as their means for challenge and defense already in the proceedings before the FPC, because an argument that has been held back in the first instance may not be considered in the appeal proceedings.

Moreover, Section 117 of the Patent Act and the applicable provisions of the Code of Civil Procedure state the means for challenge and defense that have been correctly rejected by the FPC must also not be considered by the FCJ, and that delayed means for challenge and defense may only be considered if their consideration does not defer the appeal proceedings (e.g., require a postponement of the oral hearing).

Whether or not an amendment of the action or a limited defense of the patent-in-suit with new claims is admissible follows the provisions set forth in Section 116. Admission requires the consent of the opposing party or that the FCJ deems the amendment to be expedient and that the amendment can be based on facts that are to be considered by the FCJ anyway. The threshold for expediency of a limited defense of the patent-in-suit is lower than that of an amendment of the action because the patent proprietor has no second chance to defend the patent-in-suit if it is revoked by the FCJ, whereas the plaintiff may file a new revocation action if the amendment is inadmissible.

5.4.3.3 Representation

In appeal proceedings before the FCJ, the parties need to be represented by an attorney-at-law or a patent attorney, either of whom may be accompanied by a technical adviser. Unlike in most other proceedings before the FCJ, the parties in patent revocation proceedings on appeal do not need to be represented by an attorney who is admitted to the bar at the FCJ but can choose any attorney-at-law or patent attorney who is admitted to practice in Germany.

5.4.3.4 Course of proceedings

5.4.3.4.1 Notice of appeal and statement of grounds for appeal

The deadline for filing a notice of appeal with the FCJ is one month from the service of the judgment in complete form (and five months following delivery at the latest if the judgment has not been served). The notice of appeal is a short brief whose mandatory content is a declaration that an appeal is being filed and an indication of the judgment against which the appeal is being filed. The mandatory statement of grounds for appeal does not need to be part of the notice of appeal but can be filed in a separate brief within three months from service of the judgment in complete form (and five months following delivery at the latest). Contrary to the deadline for filing the notice of appeal, the deadline for filing the detailed statement of grounds may be extended upon request by one month or, but only with the counterpart's consent, longer.

The statement of grounds must contain a specific motion that sets out to what extent the judgment of the FPC is being contested and the extent to which its setting aside is requested. Moreover, the appellant must specifically deal with the reasoning of the FPC's judgment and set out for which legal or factual grounds the judgment is considered to be incorrect. This requires pointing out that the FPC's judgment violates the law *and* showing that the judgment was based

on this violation of law – that is, that the decision would have been different without the alleged violation of law. Against this background, Section 112(3) states that the statement of grounds must contain the following:

- If a violation of law is alleged, the circumstances from which said violation of the law resulted need to be specified in the statement of grounds. The main scenario for this provision is that the appellant assesses the patent's patentability in the light of the prior art differently than the FPC does. Thus, the appellant must explain why the assessment of the FPC is incorrect and why a correct assessment would result in a more favorable decision. The extent to which the grounds for revocation needs to be discussed depends on the person of the appellant: if this is the plaintiff, they must deal not only with the grounds for revocation discussed in the judgment but also with all other grounds for revocation that have been discussed in the course of the first-instance proceedings and that they want to pursue in the appeal proceedings. If this is the defendant (i.e., the patent proprietor is the appellant), they need deal only with all those grounds for revocation that led to the FPC (partially) revoking the patent.
- If a violation of procedural law is alleged, the circumstances that resulted in said deficiency need to be indicated. For example, if a violation of the right to be heard is alleged because the FPC did not inform the parties that it would no longer follow the assessment set out in the preliminary opinion, the appellant must set out in their statement of grounds for appeal which submission would have been made had they been informed of the change in the FPC's opinion and why due consideration of this submission would have resulted in a more favorable decision.
- Finally, if the appellant wishes to introduce new means of challenge or defense (e.g., new prior art documents), these new means need to be mentioned in the statement of grounds for appeal, and the appellant also must set out why these new means are to be admitted in accordance with Section 111 (cf. Section 5.4.3.2).

5.4.3.4.2 Examination of admissibility and preparation of oral hearing

If the appeal is an available remedy, the FCJ checks whether the notice of appeal and the statement of grounds for appeal have been filed in due form and within the legal deadlines. If one of these requirements is not met, the appeal is dismissed as inadmissible; otherwise, an oral hearing is scheduled, which is further prepared by written statements from the parties. Following the appellant's statement of grounds for appeal, the appellee can submit a written statement in defense of the FPC's judgment setting out why the appeal should not be successful. Subsequently, further briefs may be exchanged in preparation for the oral hearing.

5.4.3.4.3 Cross-appeal

If the judgment of the FPC aggrieves both parties, but, at first, only one party appealed the judgment, the other party may file a cross-appeal. The deadline for filing the notice of cross-appeal is either two months from service of the statement of grounds for appeal or within the deadline set for responding to the statement of grounds for appeal. Unlike the notice of appeal, the notice of cross-appeal must include the statement of grounds. The cross-appeal is not an independent remedy and ceases to be effective if the appeal is withdrawn or dismissed.

5.4.3.4.4 Oral hearing and judgment

If the appeal is not dismissed as inadmissible, an oral hearing will be scheduled, and the parties will be informed of the oral hearing. The law requires that the parties be informed of the date of the oral hearing at least two weeks in advance, but, in practice, the oral hearing is generally scheduled roughly one year in advance. While the parties to infringement proceedings may request that the oral hearing be rescheduled if it is scheduled for July or August, such a possibility is not open to the parties of revocation proceedings, for whom oral hearings may also take place during the summer months.

The law provides for the possibility of dispensing the oral hearing if the parties consent, but this rarely happens. At the beginning of an oral hearing, the presiding judge will summarize the facts of the case and give a preliminary assessment of the case based on the deliberations of the senate that usually take place the day before the oral hearing. This assessment may include open questions on which the panel could not even form a preliminary view. The parties' representatives will then plead their cases, and, depending on the case, there may also be a discussion between the judges and the party representatives about specific technical or legal questions.

In patent revocation appeal proceedings, the oral hearing may also be conducted and a judgment rendered if one party does not appear at the oral hearing. Even if both parties do not appear at the oral hearing, the court may render a judgment.

The FCJ gives its judgment on the basis of the oral hearing, but only after having been extensively briefed by the parties in the written proceedings. Thus, careful preparation of the court by the parties is essential. While the judgment is normally given directly after the oral hearing and deliberations, the court may also set a date a few weeks after the oral hearing for giving the judgment.

The appeal is dismissed if the judgment of the FPC is found to be correct or if its reasoning contains a violation of law but is correct for other reasons. If the appeal is deemed to be well founded, the judgment of the FPC is set aside or amended. The FCJ may remit the case to the FPC for new proceedings and a new decision, in which the FPC is bound to the legal assessment that led to the judgment being set aside. However, the FCJ may decide itself, if this is expedient,⁵⁶ and it must decide if the case is ready for a final decision. In practice, the FCJ almost always decides the case finally and does not remit it to the FPC.

The judgment of the FCJ needs to be reasoned. Only to the extent that the FCJ considers alleged violations of procedural law not effective, a reasoning is not necessary.

The judgment also contains a decision on the costs of the proceedings. Moreover, the FCJ must set a value in dispute. With regard to the setting of the value in dispute and the costs, the considerations set out above in the context of the first-instance proceedings apply accordingly (cf. Section 5.4.1.2.3 with regard to the determination of the value in dispute). In appeal proceedings before the FCJ, the court fees and the attorneys' fees, which both are calculated according to a statutory schedule of fees, are significantly higher than those for the first-instance proceedings.

5.5 Patent infringement

5.5.1 Claim construction

According to Section 14 of the Patent Act and Article 69 of the EPC, the scope of protection of a patent is determined by the patent claims, whereby the description of the patent and (if available) the drawings are considered for the interpretation of the claims. Different from other jurisdictions, it is not admissible to use the files of a grant procedure as interpretation material. Conversely, prior art mentioned in the description of the patent can be used for interpretation purposes as well as opposition or nullity decisions.⁵⁷

Patents are construed from the perspective of the so-called average person skilled in the art on the filing date or priority date of the patent. The person skilled in the art is defined as an imaginary person with professional training or qualifications (e.g., a skilled worker, master or engineer) and practical experience of the kind usually gained by those who have worked in the operational or industrial practice of relevant companies in the field to which the teaching of the patent belongs.

Patent protection cannot be derived from the patent description or the drawings alone: a technical teaching that is exclusively described there (both in terms of an extension or a limitation of the claim) but that is not reflected in the patent claims is not covered by the patent.⁵⁸ Conversely, the claim must always be interpreted, not only if the wording of the claim is unclear, to determine the technical meaning associated with the wording of the claim.⁵⁹ This is mandatory for the simple reason that the patent specification is its own dictionary for the terms used in it, and, therefore, only by referring to the description can information be gained about what the claim means and intends to protect with a certain wording.

⁵⁶ E.g. when the FCJ comes to the result that the case is best handled if expert evidence is taken by the court itself rather than remitting the case to the FPC.

⁵⁷ BGH (FCJ), May 5, 1998 - X ZR 57/96 (*Regenbecken*).

⁵⁸ BGH (FCJ), April 17, 2007, X ZR 72/05 (*Ziehmaschinenzugeinheit*); BGH (FCJ), Sept. 7, 2004, X ZR 255/01 (*Bodenseitige Vereinzelungseinrichtung*); BGH (FCJ), May 10, 2016, X ZR 114/13 (*Wärmetauscher*).

⁵⁹ BGH (FCJ), Oct. 27, 2015, X ZR 11/13 (*Fugenband*); BGH (FCJ), May 12, 2015, X ZR 43/13 (*Rotorelemente*).

In principle, the claim, description and drawings form a coherent unit and must be interpreted in a way such that contradictions do not arise unless contradictions are irreconcilable, in which case the patent claim prevails over the description or the drawings. Embodiments mentioned in the description must therefore give reason to ask whether it is possible to interpret the features of the main claim such that all variants described as being in accordance with the invention are also covered by the wording of the claim. Only if such an interpretation is precluded by the specific wording of the claim is there room for an interpretation that an embodiment disclosed in the description is not covered by the claim. However, such cases are rare exceptions.⁶⁰

Furthermore, the technical meaning or function of the individual feature and the extent to which it contributes to the invention laid down in the patent claim (a so-called functional interpretation) should always be considered.⁶¹ However, in the case of spatially, physically or substance-defined features, this should not be reduced to the mere function of the feature. Rather, the feature should be interpreted in a sense that is consistent with the spatially, physically or substance-defined nature of the feature.⁶² The function-oriented interpretation may exceptionally give rise to a situation wherein the meanings of terms used in different contexts in the patent claim do not necessarily mean the same thing but are instead defined according to the technical functions given by each individual context.⁶³ This may also result in a feature having different content than the corresponding feature in another publication in the state of the art.⁶⁴

In addition, it must also be ensured that the wording of the claim is fully understood and that the necessary infringement argument is therefore also made with regard to those implicit features that follow only indirectly from the other features of the claim. The following aspects also need to be taken into account when interpreting the features of the claim:

- References in the claim do not limit the protection to an exemplary embodiment.
- It cannot be concluded from the absence of a feature in a drawing (that it is part of the technical teaching) that the feature in question is not present.
- A claim feature may merely express a technical matter of course for the skilled person in the art.
- Features in a patent claim that do not leave any gaps to be filled on the basis of the self-evident knowledge of the average person skilled in the art are to be interpreted in such a way that, from the entirety of the claim features, a suitable subject matter for the purposes of the invention results.
- Most often, the term “in particular” introduces an optional feature. However, this might not be the case when the text following the phrase contains an exemplary concretization of a more general feature that has been mentioned in advance.
- The terms “contains” and “comprises” allow additional components besides those explicitly mentioned in the claim; the terms “consists of” and “is composed of” are to be understood as an exhaustive list such that no additional components are allowed.
- The designation of a component in the plural may suggest the possibility of the use of a generic designation; however, this only applies if there are positive indications in the description that an object with the component as singularly designated is also intended to be in accordance with the invention.
- An obviously false designation (*falsa demonstratio*) in the claim may be corrected based on the description and the drawings.
- Patents need to be interpreted by considering the description and the drawings. It should not influence the interpretation of the patent claim whether this results in an inadmissible extension patent beyond the content of the application. Patent interpretation and added matter are two different issues that should not be mingled.⁶⁵ The same is true with regard to patentability: a patent should not be interpreted narrowly just because that would allow its delineation from prior art.

60 BGH (FCJ), June 2, 2015, X ZR 103/13 (*Kreuzgestaenge*).

61 BGH (FCJ), Feb. 12, 2009, Xa ZR 116/07 (*Traegerplatte*).

62 BGH (FCJ), June 14, 2016, X ZR 29/15 (*Pemetrexed*).

63 Oberlandesgericht Düsseldorf (OLG Düsseldorf) (Higher Regional Court of Düsseldorf), Jan. 29, 2015, I-2 U 28/13.

64 *Polymerschaum*, X ZR 117/11.

65 *Polymerschaum*, X ZR 117/11.

5.5.2 Infringement analysis

5.5.2.1 Direct patent infringement

The patent owner generally has an exclusive right to use the invention. Which specific acts are prohibited to third parties depends on whether a product or a method is protected. The different acts that constitute a direct patent infringement are set out in Section 9.

In terms of product claims, third parties are not entitled to manufacture, offer, put on the market or use a product that is the subject matter of the patent. Moreover, they are not entitled to import or possess such a product for the aforementioned purposes (Section 9 no. 1). “Manufacture” covers the entire creation process of the product, not only the final step.⁶⁶ The manufacturer of individual parts could also be considered the manufacturer of the overall product if the manufacturer supplies the individual parts to a third party that assembles them into the protected overall product.⁶⁷ An offer is any act by which the product is made available to third parties. It does not need to be an offer for a contract but could also be a mere (internet) advertisement.⁶⁸ The offered product does not need to be manufactured or brought within the territory of Germany. However, the mere transit of infringing products does not constitute an act of infringement in Germany.

In terms of process claims, a third party is not entitled to use, or offer for use, a process that is the subject matter of the patent if the third party knows or if it is obvious from the circumstances that use of the process is prohibited in the absence of the consent of the proprietor of the patent (Section 9 no. 2). A use of a process requires, in principle, that all the steps of the method are carried out within Germany. However, if the method is carried out partly within Germany and partly abroad, the method claim could nevertheless be infringed. This would require that the method steps carried out abroad can be attributed to the person who carried out the method steps within Germany.⁶⁹

Furthermore, a third party is not entitled to offer, place on the market or use a product that is produced directly by a process that is the subject matter of the patent, or to either import or possess such a product for the aforementioned purposes (Section 9 no. 3). This refers to a product obtained directly by the process, which is at least the case when the process is not followed by any further processing or treatment operations. According to case law, however, the process does not need to be the last step in any case, but the decisive fact is whether the further-treated product obtained by the patented process maintains its characteristics.⁷⁰

5.5.2.2 Indirect patent infringement

According to the concept of indirect infringement, any party is prohibited, in the absence of the consent of the proprietor of the patent, from supplying or offering to supply, within Germany, persons other than those entitled to exploit the patented invention with means relating to an essential element of the invention for use within Germany if the third party knows or if it is obvious from the circumstances that those means are suitable and intended for using that invention (Section 10(1)). Typical cases of indirect patent infringement are, for example:

- the offer and supply of a device with which a patented method can be carried out;⁷¹
- the offer and supply of a component of a device that can be combined with other components to form the complete patented combination; and
- the offer and supply of a machine with which a patented device can be manufactured.

The offered or supplied means must relate to an essential element of the patented invention. According to the case law of the FCJ, such a means relates to an element of the invention if it is capable of interacting with the element of the invention realizing the invention.⁷² If the means are mentioned in the patent claim, they are generally considered to relate to an essential element of the invention.

66 BGH (FCJ), June 15, 1951, I ZR 59/50 (*Mülltone*).

67 BGH (FCJ), May 14, 2019, X ZR 95/18 (*Schutzverkleidung*).

68 BGH (FCJ), May 16, 2006, X ZR 169/04 (*Kunststoffbügel*).

69 OLG Düsseldorf (Higher Regional Court of Düsseldorf), Dec. 10, 2009, I-2 U 51/08 (*Prepaid-Telefonkarte*).

70 OLG Karlsruhe (Higher Regional Court of Karlsruhe), Jan. 14, 2009, 6 U 54/06 (*SMD-Widerstand*).

71 BGH (FCJ), Feb. 27, 2007, X ZR 113/04 (*Rohrschweißverfahren*); BGH (FCJ), Feb. 3, 2015, X ZR 69/13 (*Audiosignalcodierung*).

72 BGH (FCJ), May 5, 2004, X ZR 48/03 (*Fluegelradzaehler*).

The means must be objectively suitable for a direct patent infringement. Thus, if the means are used together with other means or for use of a method, a direct patent infringement must be possible.⁷³ However, an indirect infringement does not require a direct infringement by the offered or supplied person.

Furthermore, the means must be offered or supplied within Germany,⁷⁴ for use in Germany⁷⁵ and must be delivered to a person who is not entitled to exploit the invention. Thus, an export of the means would, in principle, not constitute an indirect infringement. However, according to case law, the supply of parts to a person abroad could constitute an indirect infringement if the products containing those parts are reimported to Germany.

The offered or supplied person must intend to use the means in an infringing way, and the person offering or supplying the means must know that the means are suitable and intended for exploiting the invention, or it must be at least obvious to them. If the means could also be used in a noninfringing way, the injunction could be limited to an infringing use, for instance, by way of a specific warning notice.⁷⁶ The means must not be generally available commercial products, such as nails or screws, except where the supplier induces the supplied person to use the products in an infringing way (Section 10(3)).

5.5.2.3 Infringement by equivalent means

The scope of protection is not limited to literal patent infringement. When an element specified in the patent claim is replaced by a variant, a patent infringement by equivalent means could be considered. According to the case law of the FCJ, three requirements must then be fulfilled:⁷⁷

1. The variant must solve the problem according to the patent with means having essentially the same effect as the element specified in the patent claim.
2. The skilled person must be able, due to their expert skill, to find the variant as having essentially the same effect as the element in the patent claim.
3. The skilled person must be able to find the variant as having the same effect by considerations oriented to the technical teaching protected by the patent claim.

In terms of the first requirement, it is decisive that the overall effects according to the patent – specifically those advantages of the element specified in the claim – are essentially achieved.⁷⁸ This requirement is not met if the variant achieves the effects of the element specified in the patent claim only in part. It is also not met if the variant has disadvantageous properties that the embodiment, as specified in the patent claim, does not have or that are to be avoided according to the teaching of the patent claim.

The third requirement is not met if the variant is a technical means that the patent seeks to avoid or a means that the patent-in-suit intends for the same technical effect only in a different context. Furthermore, an infringement is usually excluded if it is clear from the overall context of the patent claim that it is limited to a specific solution. Furthermore, the third requirement is not met if the variant is a means that the patent specification refers to as an alternative to the claimed solution⁷⁹ or if the patent specification discloses several possibilities as to how a given technical effect of the invention can be achieved but where only one of these possibilities has been specified in the claim.⁸⁰ However, an infringement by equivalent means cannot be denied only because the embodiment claimed by the patent would have been understood by the person skilled in the art as a special application of a more general solution principle with regard to the description or for other reasons even if, on the basis of this knowledge, the person skilled in the art would have been able to find further embodiments corresponding to this solution principle.⁸¹

73 BGH (FCJ), June 6, 2005, X ZR 247/02 (*Antriebsscheibenaufzug*).

74 In case of an offer, the sending or receiving place of the offer must be in Germany. In case of a supply, the shipment must take place partly in Germany.

75 BGH (FCJ), July 5, 2005, X ZR 14/03 (*Abgasreinigungsvorrichtung*).

76 BGH (FCJ), Jan. 9, 2007, X ZR 173/02 (*Haubenstretchautomat*).

77 BGH (FCJ), March 12, 2002, X ZR 168/00 (*Schneidmesser I*).

78 BGH (FCJ), July 17, 2012, X ZR 113/11 (*Palettenbehälter II*).

79 BGH (FCJ), May 10, 2011, X ZR 16/09 (*Okklusionsvorrichtung*).

80 *Pemetrexed*, X ZR 29/15; BGH (FCJ), Aug. 23, 2016, X ZR 76/14 (*V-förmige Fuehrungsanordnung*).

81 *Pemetrexed*, X ZR 29/15.

Even if the court finds the three requirements to be met, the so-called Formstein defense⁸² can be raised. Under this defense, it could be objected that the embodiment making use of the patent by equivalent means is not patentable because it lacks novelty or does not involve an inventive step and that the patent cannot be extended to a nonpatentable subject matter.

5.5.3 Defenses

5.5.3.1 Noninfringement

According to a core principle of German procedural law, any allegation made by the plaintiff that is not expressly denied by the defendant is taken as granted. Thereby, both parties need to comply with the procedural obligation for a truthful presentation of facts pursuant to Section 138(1) of the Code of Civil Procedure.⁸³ The level of substantiation expected from the defendant's explanations depends on the level of substantiation of the plaintiff's allegation. The defendant's burden of proof is higher when the facts concerned are those that only they – but not the plaintiff – have knowledge of. The FCJ has held that the defendant must disclose information on which the plaintiff bears the burden of proof in cases where the relevant information is not accessible to the plaintiff but can easily and reasonably be provided by the defendant.⁸⁴ Similarly, on facts that do not concern the defendant's own actions or perceptions, the defendant may contest by “declaring their lack of knowledge” pursuant to Section 138(4) of the Code of Civil Procedure.

Defendants can dispute the description of the attacked embodiment and – if the latter is described correctly – the infringement allegation itself by demonstrating that the attacked embodiment is, in fact, not covered by the scope of protection of the patent. In this case, noninfringement is to be demonstrated on the basis of the relevant limitations.

If the subject matter of the patent is a process for manufacturing a new product, it is deemed that the same product produced by someone else is produced using the patented process until there is proof to the contrary pursuant to Section 139(3). In their noninfringement argumentation, the defendant can demonstrate that the attacked embodiment does not contain elements of the “new product.” They can also demonstrate that their product is manufactured according to a process that differs from the patented process.

5.5.3.2 Right of prior use

Public prior use can be used as novelty-destroying prior art or to demonstrate obviousness in proceedings on the validity of a patent. Private prior use pursuant to Section 12 constitutes a defense in infringement proceedings: “the patent shall have no effect in respect of a person who, at the time the application was filed, had already begun to use the invention in Germany or had made the necessary arrangements for doing so.” Legally, it is a vindicatory defense that resolves the infringement's unlawfulness. It gives the prior user the right to use the invention “for the needs of [their] own business.”

Section 12 has two main requirements: (i) possession of the invention and (ii) use of the invention. Both requirements need to have been fulfilled on the day the application was filed (Section 12(1)) or – if priority is effectively claimed – on the priority date (Section 12(2)). The defendant is said to have “possession” of the invention when they knew what to do in order to carry out the invention completely. The defendant must either have used the invention by, for example, producing, offering or marketing the product or, at least, have made necessary arrangements for so doing. In the latter case, the defendant must additionally show their intention to use the invention.

The scope of the right to private prior use is limited. Territorially, it is limited to the use of the invention in Germany. Personally, the right is limited to the specific company that had possession of the invention and can only be transferred together with that company: it cannot be licensed or sold independently. Further, it is limited to the product used by the defendant on the priority date and does not comprise any products developed from that unless the product used by the defendant before the priority date and the variation used by the defendant after the priority date are mentioned in the patent claim as two equal alternatives of an element, or the variation was self-evident for the person skilled in the art at the priority date.⁸⁵

82 BGH (FCJ), April 29, 1986, X ZR 28/85 (*Formstein*).

83 Zivilprozessordnung (Code of Civil Procedure), Dec. 5, 2005.

84 BGH (FCJ), Sep. 30, 2003, X ZR 114/00 (*Blasenfreie Gummibahn II*).

85 BGH (FCJ), May 14, 2019, X ZR 95/18 (*Schutzverkleidung*).

5.5.3.3 Exhaustion, license and compulsory license

The exhaustion defense requires that the patent proprietor or a third party acting with its consent deliberately placed the patented product or the direct product of a patented method on the market in Germany or any state of the European Economic Area.⁸⁶ It is sufficient that the product was placed on the market with the explicit or implied consent of the patent proprietor, not necessarily by the patent proprietor themselves.⁸⁷ The person acquiring such a product is then free to use it without infringing the patent.

The exhaustion defense relates strictly to the specific product placed on the market with the patent proprietor's consent. This means that the entirety of the patented product needs to have been placed on the market. Exceptions discussed in the literature relate to whether a patent can already be exhausted when the crucial part of the device (e.g., a chip as the crucial part of a phone) is placed on the market, because marketing the part implicitly allows the use in and for the whole device.⁸⁸

For process patents, the patent is not exhausted by, for example, placing on the market a machine that is suitable for the patented process if the machine itself is not protected by the patent.⁸⁹

Section 15(2) stipulates exclusive and nonexclusive licenses. If the alleged infringer demonstrates that the use of the patent is covered by a license, this license constitutes consent regarding the use of the patent, thereby excluding infringement. Section 15(3) protects the rights conferred to the licensee if the patent is transferred to a third party or if a further license is granted.

A license between the patent owner and the alleged infringer's manufacturers or suppliers also covers their direct or indirect customers. In the likely case that the defendant is not aware of the details of a (confidential) license agreement between their manufacturer or supplier and the (former) patent owner, the defendant may request that the court order the plaintiff to provide the license agreement pursuant to Section 142 of the Code of Civil Procedure. Upon request, the court may take measures necessary to safeguard the legitimate confidentiality interests of the plaintiff.

Section 24 of the Patent Act regulates compulsory licenses. While such licenses had little practical relevance in the past, they have become more important, especially in pharmaceutical patent cases. In 2017, the first compulsory license was successfully confirmed by the FCJ for the AIDS medicament *Isentress*.⁹⁰ Compulsory licenses can be requested in separate proceedings before the FPC. On the basis of these proceedings, a stay might be requested in patent infringement proceedings pursuant to Section 148(1) of the Code of Civil Procedure, similar to a nullity action against the patent.

5.5.3.4 Experimental and other privileges

The Patent Act knows both a research (or experimental use) exemption, which applies to all fields of technology, as well as a "*Bolar*" exemption, limited to pharmaceutical inventions and products. Both are provided for in Section 11, which determines to which acts the effect of the patent shall not extend.

The research exemption, regulated in Section 11(2), determines that the effect of the patent shall not extend to acts "done for experimental purposes relating to the subject matter of the patented invention." The provision's aim is to guarantee the freedom of research and teaching as laid down in Article 5(3) of the German Constitution.

An "experiment," according to this provision, is a "planned action to acquire knowledge." The purpose of the experiment must be to acquire knowledge about the invention. While the

86 In its Judgment of Feb. 2, 2011, I ZR 26/10 (*Kuchenbesteck-Set*), the FCJ held that "placing on the market" is also given when a person economically associated with the proprietor of the right willingly transfers control of the protected item to a third party within the European Economic Area.

87 This was confirmed in various judgments relating to trademarks and is applicable to patents. CJEU, Oct. 15, 2009, C-324/08, *Makro Zelfbedieningsgroothandel CV v. Diesel SpA*, 2009 ECR I-10019; April 23, 2009 - C-59/08, *Copad SA v. Christian Dior Couture SA*, 2009 ECR I-03421.

88 Klaus Haft and Friedrich R von Samson-Himmelstjerna, "Kerntheorie bei der Erschöpfung von Patenten, insbesondere von 'standard-essentiellen' 'Hightech'-Patenten?" ("Core theory in the exhaustion of patents, especially of 'standard essential' 'hightech' patents?"), in *Patentrecht. Festschrift für Thomas Reimann* (2009), 175.

89 BGH (FCJ), Nov. 14, 2000, X ZR 137/99 (*Bodenwaschanlage*).

90 BGH (FCJ), July 11, 2017, X ZB 2/17 (*Raltegravir*). The decision confirmed the earlier decision by the FPC on the basis that a sufficient public interest for the grant of a compulsory license had been credibly demonstrated. It had been demonstrated in this case that certain groups of patients relied on treatment with this medicament and were in danger of suffering severe damages and side effects if they were to switch to a different medicament.

knowledge must be of scientific interest, this term is interpreted broadly. The scientific interest must be prevailing; however, it is not harmful if there are additional commercial interests. For example, a purely scientific interest is given if clinical trials are conducted to find out whether an active ingredient covered by the subject matter of the patent can be used in treating other diseases. A mixed scientific and commercial interest is given if these scientific insights can and are intended to be used in a later market authorization procedure. Conversely, purely commercial interests – which are not covered by the exemption – are given when the only purpose is to gain commercial insights about the market structure or to calculate the price of a product.

The *Bolar* exemption, also referred to as the “*Roche-Bolar* rule,” regulated in Section 11(2b), was introduced in 2005, implementing EU Directives 2001/82⁹¹ and 2001/83.⁹² The aim of this exemption is to privilege generic and biosimilar manufacturers in preparing their market authorization. However, in contrast to the EU directives and other EU member states’ provisions, its wording is broader and not limited to generic manufacturers (it also applies to researching pharmaceutical companies) or in terms of territorial scope. It goes further than the research exemption, as it is not limited to trials related to the patented invention itself. The scope of “necessary” studies, trials and resulting practical requirements is defined by the national rules of the state in which the market authorization is applied for.

5.6 Judicial patent proceedings and case management

5.6.1 Key features in patent proceedings and differences to a trial-based system

Patent infringement actions are genuine civil actions whose procedure is governed by the German Code of Civil Procedure (“Zivilprozessordnung”).⁹³ Further basic provisions are contained in the Courts Constitution Act (“Gerichtsverfassungsgesetz”).⁹⁴ The German Patent Act, however, also provides for a number of specific procedural elements that supplement the general provisions on civil procedure for patent infringement cases (e.g., Section 140c on pretrial inspection orders). One characteristic fundamentally distinguishes German civil actions (of continental European style) from Anglo-American civil actions, and appreciating this distinction is a way to summarize the key features of a German patent infringement action that will be addressed in this section: German civil actions do not take a trial-based form.

In a typical Anglo-American trial, the facts are presented by the parties to the fact finder through evidence, particularly party-retained expert witnesses, during the main trial hearing rather than through written pleadings.⁹⁵ This trial typically takes some days – sometimes weeks or months – depending on the amount and complexity of the evidence. Pretrial discovery and pretrial motions (motions to dismiss or summary judgment motions) are important in such a trial-based process.

By contrast, none of these features are present in German civil litigation, with the absolutely rare exception of court-appointed experts and the rare necessity to submit party expert opinions. There are no juries, so the bench (consisting of specialized judges) is the only fact finder and final decision-maker. The proceedings are front-loaded, and most of the input comes through written briefs filed by the parties. There is typically only one final and very dense and concise substantive hearing toward the end of the process. This hearing is only rarely about evidence; in most cases, it is on claim construction and infringement as well as validity. However, validity is only at stake with regard to the decision whether the court, if it finds an infringement of the patent, should stay the proceedings with regard to parallel validity proceedings before the EPO or the FPC pursuant to Section 148 of the Code of Civil Procedure. While these arguments are typically highly fact-specific and therefore technical, the basic technical facts are mostly not in dispute between the parties but rather the correct interpretation of those facts for the purpose of infringement

91 Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to Veterinary Medicinal Products, 2001 OJ (L 311), 1, <https://eur-lex.europa.eu/legal-content/DE/ALL/?uri=CELEX%3A32001L0082>

92 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to Medicinal Products for Human Use, 2001 OJ (L 311), 7, <https://eur-lex.europa.eu/legal-content/DE/ALL/?uri=celex%3A32001L0083>

93 For an English translation of the Code of Civil Procedure, see www.gesetze-im-internet.de/englisch_zpo

94 For an English translation of the Courts Constitution Act, see www.gesetze-im-internet.de/englisch_gvg

95 Both bench trials and jury trials are possible, but jury trials are conceptually the genuine form of a trial because facts and evidence are exclusively presented to the fact finder through the main trial hearing, while, outside the taking of evidence (particularly the cross-examination of witnesses), only opening and closing statements provide for the room to assess the facts and evidence.

(based on proper claim construction) and validity (based on the proper claim construction and the proper determination of the disclosure of the prior art references). In this process, there are, for the most part, no pretrial motions that could result in early dismissal of the action before the final hearing. Thus, any lack of “conclusiveness” (“Schlüssigkeit”) will only be identified and disposed of by way of dismissing the case at the end of the regular process (i.e., following the briefing and the final hearing).

As there is no specific fact finder (jury), there are no early hearings on certain issues of law, like the “*Markman* hearing” on claim construction.⁹⁶ As the substantive input is fed into proceedings by the parties not through the evidence but through the mostly written party submissions, experts do not play an essential role, and there is no cross-examination of party-appointed experts like in a trial-based system. The bench can, however, resort to independent (technical) experts if relevant facts are in dispute between the parties, but this is the exception.

There is also no general discovery system. Rather, there are limited and specific instruments for the plaintiff to discover facts that are not publicly available (e.g., “inspection orders”). As there is no general discovery, there is also no comprehensive system of privileges and protective orders as is well established in the Anglo-American realm. Both the lack of a discovery and of a general confidentiality system have, over the last two decades, been addressed in the German system by a number of statutory changes and case law. Different from a trial-court system, the court of first instance is not the only “court of record.” Rather – and mostly because the process is less time- and resource-consuming – the appellate level is typically also called upon to engage in further fact-finding within certain limits. Thus, there is no clear-cut distinction between trial and appellate levels along the lines of “fact-finding” and “issues of law.”

5.6.2 Preaction and pretrial

5.6.2.1 Cease and desist warnings and requests for right to use

5.6.2.1.1 Relevance of out-of-court communications

One of the most critical points in any patent litigation is how to initially raise the infringement issue with the potential infringer. This is critical because, depending on the way the infringement issue is addressed, the potential infringer can take action against the right holder (e.g., a declaratory judgment action for noninfringement). Furthermore, the form of addressing the infringement issue could open procedural ways for the defendant to dispose of a subsequently filed offensive infringement litigation such that the patentee (plaintiff) would need to bear the costs.

In many jurisdictions, a key point of the analysis is the threshold for filing a declaratory judgment action. In other words, when does flagging a potential infringement issue give the counterpart sufficient reason to file an action seeking declaratory relief for noninfringement? In U.S. practice, this is known as the “case-or-controversy” requirement for filing a declaratory judgment action. A similar requirement exists under German law (cf. Section 256(1) of the Code of Civil Procedure, “Feststellungsinteresse”). The impact on the strategy is less significant, however, because filing the declaratory judgment action does not give that case priority over any subsequently filed offensive infringement action.

Depending on how possible infringers are approached out of court, remedies under unfair competition law could apply (e.g., when warning letters are sent to customers).

5.6.2.1.2 Request for a right to use as opposed to a cease and desist letter

The “safe harbor” in terms of avoiding a declaratory judgment action or any other possible remedy that the potential infringer might be considering is raising the infringement issue in the form of a “request for a right to use.” The distinction of such a request compared to a cease-and-desist letter is that this specific form does not conclude that there is infringement or requests that the addressee should cease and desist. Rather, the right holder asks for the reasons that the addressee considers themselves “entitled” to make use of the patented teaching. This category is designed to enable the right holder to enter into a discussion with the addressee

⁹⁶ A “*Markman*” hearing is a U.S. district court hearing in a patent infringement case in which a judge determines the proper interpretation and scope of disputed terms in the patent claims asserted by the plaintiff, see Thomson Reuters, Practical law, [https://uk.practicallaw.thomsonreuters.com/3-514-7689?transitionType=Default&contextData=\(sc.Default\)&](https://uk.practicallaw.thomsonreuters.com/3-514-7689?transitionType=Default&contextData=(sc.Default)&)

without subjecting themselves to possible counterclaims. It is generally not recommended to simply allege infringement of a certain patent but rather to give the request a factual and legal basis in terms of the patent claims and the accused devices or methods.

The alternative is a cease and desist letter, which formally requests that the addressee cease and desist the infringing activity and also requests that the addressee declares a formal undertaking to cease and desist, with any infringement of that obligation triggering a financial penalty (a “cease and desist declaration”).⁹⁷ If the defendant actually submits such a declaration whose scope and financial penalty are sufficient, the plaintiff cannot assert any claims for injunctive relief in court anymore. The cease and desist declaration is legally considered a functional equivalent to a court judgment, so the patentee (plaintiff) would lack the legal interest in pursuing a claim for injunctive relief notwithstanding the cease and desist declaration.

5.6.2.1.3 Procedural mechanics in connection with a cease and desist letter

It is important to note that there is an enormous amount of case law regarding the requirements that such cease and desist declarations need to meet to be effective. For example, they cannot be conditioned on “actual infringement” because that very issue is meant to be disposed of by the declaration. They also can not only narrowly cover the very devices (in terms of model numbers) identified by the patentee, but they would need to cover any and all devices that are substantially similar to the actually identified devices in terms of the technical characteristics relevant for the infringement mapping.⁹⁸ The latter point can cause significant issues in terms of the right way to phrase the key part of the declaration (defining the accused device or method). It is typically done by way of using the pertinent patent claim language. This does not mean, however, that the scope of the declaration would be as broad as the scope of protection of the patent-in-suit. Rather, it is done in an attempt to sufficiently abstract from the specific device. Different from a court judgment, there is usually no reasoning, so the main source for guiding the operation of correctly interpreting the scope of the declaration would not be available. Therefore, it is recommended to specify some of the claim language by introducing critical factual aspects that realize the pertinent features in the accused devices. This can open the door to discussions between the parties, but it is typically better to deal with this up front, particularly if a certain modification or work-around is conceivable at a later point in time.

If the patentee does not send a formal letter requesting that the defendant submit a cease and desist declaration, there is a risk that the subsequently filed infringement case for injunctive relief would be “acknowledged” by the defendant right away. Based on this, the court would enter into a judgment by consent (“Anerkenntnisurteil”; Section 307), but the plaintiff would need to bear the costs.

One important consideration is that any warning given to the potential infringer prior to filing an infringement case would enable the potential infringer to react by resorting to abusive procedural measures, particularly by way of filing declaratory judgment actions (noninfringement) in other EU jurisdictions, including for the German part of a European patent, even if no jurisdictions exist, with the sole purpose of slowing down the process of a subsequent infringement action in Germany. This practice – which came to be known as an “Italian torpedo” some 20 years ago due to the generally quite slow proceedings before Italian courts – is not common anymore, but it still presents a risk that should be considered depending on an analysis of the parties and the developing dispute at issue.

5.6.3 Venue, jurisdiction and case assignment rules

5.6.3.1 Venue and jurisdictions

The German system conceptually distinguishes “venue” (“örtliche Zuständigkeit”) and “international jurisdiction” (“internationale Zuständigkeit”). The rules on venue, as provided for in the Code of Civil Procedure (Section 12 et seq.), are considered to also implicitly establish international jurisdiction for the German courts unless an international agreement takes priority.

⁹⁷ The details can vary. It can be a fixed amount for each infringing activity, or it can be an amount that is subject to the patentee's discretion and subsequently subject to judicial review.

⁹⁸ BGH (FCJ), Nov. 9, 1995, I ZR 212/93 (*Wegfall der Wiederholungsgefahr I*); BGH (FCJ), Nov. 16, 1995, I ZR 229/93 (*Wegfall der Wiederholungsgefahr II*).

These rules distinguish between courts of “general jurisdiction” (“allgemeiner Gerichtsstand”)⁹⁹ and courts of “specific jurisdiction” (“besonderer Gerichtsstand”).

A court that has general jurisdiction over a person is competent for any and all claims against that person unless there is a specific “exclusive jurisdiction” pertaining to certain claims. Generally, the courts at the individual’s residence (Section 13) and the courts at a company’s principal place of business (Section 17) are courts of general jurisdiction. The most important “exclusive jurisdiction” is that of the German FPC, which has exclusive jurisdiction over all nullity actions (Section 81). The most relevant rule on specific jurisdiction is that of Section 32, providing that tort-law-based actions can be filed in the court where the tortious action was committed (*forum loci delicti commissi*). This provision is the typical basis for venue and international jurisdiction in patent infringement actions. As most of the infringing activities are practiced nationwide (e.g., sales), the plaintiff can pick the venue based on criteria like quality and speed of adjudication – or any other criteria for that matter – instead of being bound to sue at the court of general jurisdiction. This “forum shopping” has been subject to controversy, yet the provision has not been applied restrictively by German courts. It has, for example, been considered sufficient for nationwide jurisdiction if the defendant supplies a product to one customer and that customer distributes the product nationwide (like in the automotive industry).¹⁰⁰

Infringement of a German patent (or the German part of a European patent) automatically implies international jurisdiction of the German courts (“double-relevant facts”). If the facts presented by the plaintiff do not support the infringement of a German patent, then there is no international jurisdiction as well. Based on general doctrines of tort law (Section 823 et seq. of the Civil Code),¹⁰¹ the case law of the FCJ has been relatively far reaching in terms of infringement of a German patent by way of acts committed abroad. Thus, seen as infringer is not only the entity who carries out the act of use themselves, but also the person who objectively enables or promotes the realization of the act of use by another person, even though they were able to obtain knowledge with reasonable effort that the act supported by him infringes the patent.¹⁰² Hence, even if the defendant’s activities are exclusively conducted abroad (e.g., supplying certain parts to a customer who imports the products as part of a bigger and complex product) those actions can result in infringement of a German patent and thereby jurisdiction of German courts, if an examination of the property rights was indicated.¹⁰³

If one of the parties has its residence or principal place of business in another member state of the EU, the Brussels Ia Regulation¹⁰⁴ applies. This regulation generally follows the same concept of general jurisdiction for the courts of the member state in which the defendant resides (Article 4(1) of the Brussels Ia Regulation) and of specific jurisdiction for the courts of the member state wherein the infringing activity occurs (Article 7(2) of the Brussels Ia Regulation). If a non-EU country in Europe is involved (particularly Switzerland), the Lugano Convention¹⁰⁵ must be considered. Its structure is similar to the Brussels Ia Regulation. Based on the general jurisdictional rule – according to which a party can be sued with regard to any claims in the courts of the country in which the party has its residence or principal place of business – it is generally possible to also assert patents other than the national patents of the forum. This would also apply to other national (non-German) parts of a European patent if the defendant resides in Germany. Under Article 8(1) of the Brussels Ia Regulation, jurisdiction could also be established for non-German resident defendants.

These vehicles enabling “cross border” patent litigation have not yet played a significant role, since the European Court of Justice, in *Gesellschaft für Antriebstechnik v. Lamellen und Kupplungsbau Beteiligungs*,¹⁰⁶ held that exclusive jurisdiction is automatically established as soon

99 Some translations choose “general venue” and “specific jurisdiction” rather than “specific venue” (cf. the translation of the Code of Civil Procedure by the German Ministry of Justice, www.gesetze-im-internet.de/englisch_zpo/englisch_zpo.html#p0955).

100 BGH (FCJ), May 16, 2017, X ZR 120/15, 2018 IIC 466 (*Abdichtsystem*); BGH (FCJ), June 8, 2021, X ZR 47/19 (*Ultraschallwandler*).

101 For an English translation of the Civil Code (“Bürgerliches Gesetzbuch”), see www.gesetze-im-internet.de/englisch_bgb.

102 BGH (FCJ), Sep. 17, 2009, Xa ZR 2/08, 2010 IIC 471 (*MP3 Player Import*).

103 BGH (FCJ), May 16, 2017, X ZR 120/15, 2018 IIC 466 (*Abdichtsystem*); BGH (FCJ), June 8, 2021, X ZR 47/19 (*Ultraschallwandler*).

104 Regulation (EU) 1215/2012 of the European Parliament and of the Council of 12 December 2012 on Jurisdiction and the Recognition and Enforcement of Judgments in Civil and Commercial Matters, 2012 OJ (L 351) 1.

105 Convention on Jurisdiction and the Recognition and Enforcement of Judgments in Civil and Commercial Matters, Oct. 30, 2007, 1659 UNTS 203, <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A22007A1221%2803%29>.

106 CJEU, July 13, 2006, Case C-4/03, *Gesellschaft für Antriebstechnik mbH & Co. KG v. Lamellen und Kupplungsbau Beteiligungs KG*, 2006 ECR I-06509.

as the defendant requests the nullification of the patent-in-suit by way of a counterclaim or even only requests the dismissal of the infringement action based on the invalidity of the patent-in-suit. The sole exception to this rule has been cases for preliminary relief, but, so far, no German court has entertained any genuine cross border actions in the form of an interim relief.

5.6.3.2 Case assignment

Patent infringement matters are regular civil law matters assigned to the civil court system, which includes state and federal courts. The entry level is at the regional courts ("Landgerichte"; Section 143(1)), 12 of which have jurisdiction over patent disputes.¹⁰⁷ Typically, there is one regional court with jurisdiction for all the appellate circuits of one state or even multiple states.¹⁰⁸ The Regional Court of Düsseldorf ("Landgericht Düsseldorf") has exclusive jurisdiction for all patent infringement matters in the state of North Rhine-Westphalia (about 18 million inhabitants), and the Regional Court of Mannheim ("Landgericht Mannheim") has exclusive jurisdiction for all patent infringement matters in the state of Baden-Württemberg (about 11 million inhabitants). While generally, according to Section 32, all 12 regional courts have nationwide jurisdiction, the regional courts of Düsseldorf, Mannheim and Munich ("Landgericht München I") are the busiest.

These courts each have two or three panels. Each panel ("Kammer"; more literally translated as "chamber") has three members on the bench for each case, while, in most cases, more than three judges are permanent members of the bench. Individual cases are assigned to the competent chambers on an abstract case allocation scheme, which is set up for each calendar year in advance by the presidium of the respective court.

The German judiciary is based on a judicial career system, so judges embark on a judicial career early on – in most cases after having graduated from university (legal studies) and upon completion of a two-year judicial trainee program, finishing with the second state examination, which is the entry requirement for both bar admission and for a judicial career.¹⁰⁹ Traditionally, the judiciary aims to recruit graduates in the top 10 to 20 percent of their class years. In many cases, the judges assigned to the patent panels hold even better credentials than the average judge. The presiding judge of a panel typically has more than 10 years of experience and will have served some time at an appellate court or as a clerk at the FCJ.

5.6.3.3 Parties

5.6.3.3.1 Plaintiff

Any civil patent action is filed by one or several plaintiffs. It can be a regular infringement action in which the plaintiff claims to be entitled to claims for relief against the defendant's allegedly infringing activities, or it can be a declaratory action in which the alleged infringer acts as plaintiff seeking declaratory relief denying any liability. The plaintiff in a regular infringement action requires standing to sue ("Aktivlegitimation"). The patent proprietor has standing to sue for injunctive relief and any further reliefs, in particular claims for damages. The exclusive licensee also has standing for those types of relief.¹¹⁰ Indeed, the patent owner and the exclusive licensee can generally both sue for the same relief, but, of course, that does not lead to a duplication of claims for damages.¹¹¹ However, the requirements for an exclusive licensee to establish such a standing are strict.

Agreements governed by foreign law are generally possible, but they must be checked carefully as to whether they meet the thresholds for a genuine exclusive license for the purposes of standing to sue. Any party other than the patent owner or the exclusive licensee must establish standing to sue based on a transfer, either from the proprietor or the exclusive licensee. Such "title holders" can, without any limitation, assign claims for past damages to any third party, who can then assert those in a patent infringement action. Claims for injunction relief, however, cannot be assigned without transferring the property title to the patent.¹¹² If there are specific

¹⁰⁷ Regional courts with patent litigation chambers are located in Düsseldorf, Mannheim, Munich, Hamburg, Frankfurt, Nuremberg-Fuerth, Saarbruecken, Erfurt, Leipzig, Magdeburg, Braunschweig and Berlin.

¹⁰⁸ Sec. 143(2) of the Patent Act; the only state in which this is not the case is Bavaria, where the Regional Court of Munich I and the Regional Court of Nuremberg-Fuerth both have jurisdiction.

¹⁰⁹ An article on the judicial university education and traineeship: Johannes Riedel, "Training and Recruitment of Judges in Germany," 5 Int. J. Ct Admin. 42 (2013), www.iacajournal.org/articles/abstract/10.18352/ijca.12

¹¹⁰ BGH (FCJ), May 20, 2008, X ZR 180/05, 2009 IIC 475 (*Tintenpatrone*).

¹¹¹ *Tintenpatrone*, X ZR 180/05.

¹¹² BGH (FCJ), April 21, 2016, I ZR 43/14, 2017 IIC 353 (*An Evening with Marlene Dietrich*); OLG Düsseldorf (Higher Regional Court of Düsseldorf), Dec. 18, 2014, I-2 19/14.

legal interests present (e.g., if a nonexclusive licensee wants to assert claims), the proprietor can “authorize” the plaintiff (nonexclusive licensee) to also assert claims for injunctive relief.¹¹³ Again, neither the proprietor nor the exclusive licensee would need to be party to such litigation. In this regard, there are no “necessary parties” that need to be included as “coplaintiffs.”

An action for declaratory relief requires a specific “interest,” which is similar to what is known as the “case-or-controversy” requirement in the U.S. federal system (Section 256 of the Code of Civil Procedure).

5.6.3.3.2 Defendant

For the plaintiff to prevail on claims for infringement, the defendant must be liable. Liability is generally established by any of the activities specifically set forth in the statute (Section 9) pertaining to devices or methods protected by the patent-in-suit – that is, falling within the scope of protection of the patent-in-suit as defined by its claims (Article 69 of the EPC; Section 14 of the Patent Act). Such activities can be summarized as manufacturing and distributing the accused device or performing the protected process (i.e., method). However, it is not necessary that any of these activities are performed by the defendant in person. Rather, there is a well-settled, highly sophisticated jurisprudence based on general tort law also establishing liability in scenarios in which the defendant only causes those subsequent activities by third parties to occur.

One practically and highly relevant example is the supply of accused devices abroad. The defendant might ship chips abroad to a separate party, who uses the chip to assemble an electronic device. Yet, another, commercially separate entity might import the device into Germany to distribute it. Even though only the last entity in the chain performs any of the statutorily specified activities (importing), the first entity in the chain can also be separately liable for infringement, even in the absence of any concerned activities. Rather, it suffices that the source knew that the products were, in part, also ultimately destined for the German market.¹¹⁴ Any of the parties in the chain can be separately sued for patent infringement in Germany. Thus, suing the entity that is the source of the chip does not implicate or necessitate also suing the importing entity (importer of the assembled electronic device). In German procedure, there is no teaching similar to the “party of interest” doctrine in U.S. federal practice.

5.6.3.4 Party representation

Parties need to be represented by an attorney-at-law admitted to practice in Germany (Section 78(1) of the Code of Civil Procedure). Patent attorneys who are not members of the general attorneys’ bar, but only of the patent bar, can only act to support the attorneys-at-law but cannot represent a party independently. This is different for nullity actions, both before the FPC and on appeal before the FCJ, in which both (independent) representation by a patent attorney or an attorney-at-law are permitted (Sections 97(2) and 113).

5.6.4 Statements of case and front-loading proceedings

5.6.4.1 Initial phase of the patent infringement action

The process starts, and the civil action becomes formally pending (“Rechtshängigkeit”), by serving the complaint (Sections 253(1) and 261(1) of the Code of Civil Procedure). Service of process is to be effected either under national rules¹¹⁵ (service on entities or individuals residing or present in Germany), European rules¹¹⁶ or the Hague Service Convention.¹¹⁷ It involves serving the complaint together with the court order setting a term for the defendant to file a response to the complaint (answer) and summoning the parties to the oral hearing (Sections 274(2) and 275(1)). Alternatively, the court can order preliminary proceedings in writing (“schriftliches Vorverfahren”), which is usually done if service is to be effected abroad (Section 271(2)).

If preliminary proceedings in writing are ordered, the defendant must file a notice of defense (“Verteidigungsanzeige”) to avoid a default judgment (Section 276(1) of the Code of Civil

113 BGH (FCJ), April 21, 2016, I ZR 43/14, 2017 IIC 353 (*An Evening with Marlene Dietrich*); OLG Düsseldorf (Higher Regional Court of Düsseldorf), Dec. 18, 2014, I-2 19/14.

114 BGH (FCJ), Sep. 17, 2009, Xa ZR 2/08, 2010 IIC 471 (*MP3 Player Import*).

115 Sec. 166–195 of the Code of Civil Procedure.

116 Regulation (EC) 1393/2007 of the European Parliament and of the Council of 12 November 2007 on the Service in the Member States of Judicial and Extrajudicial Documents in Civil or Commercial Matters (Service of Documents), and Repealing Council Regulation (EC) 1348/2000, 2007 OJ (L 324) 79.

117 Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters, Nov. 15, 1965. 658 UNTS 163.

Procedure). The term for filing such a notice varies between two and four weeks. Upon filing the notice of defense, the court sets a hearing date. This hearing date is, using a *terminus technicus* of the Code of Civil Procedure, referred to as “advanced first hearing” (“früher erster Termin”). This term is misleading, however, as the hearing is typically the only oral hearing of the case (Section 275(2)). It is set toward the end of the expected process.

The first-instance proceedings before the regional court, by and large, take one year from the filing of the complaint to judgment, even though the details vary depending on the venue and the current workload in each venue, which change over time. Before the hearing, there is typically at least another round of briefing (reply and rejoinder). In many cases, the parties tend to file further briefs, which is possible even though, in many venues, this is not the bench's most favored approach.

Certain venues have varied this general process. In Düsseldorf, for example, there can be a further (genuine) early hearing date following the service of process. The purpose of that early hearing is to record the prayers for relief (taking into account comments from the bench regarding the right way to phrase the prayers for relief). Furthermore, the date for the main hearing is set, as are the terms for all the briefs to be filed up to the final hearing date. The procedure of the Regional Court of Munich implements yet another variant, according to which there are two substantive hearing dates. The first hearing occurs right after the filing of the response brief and typically covers claim construction and infringement. The second hearing date is the final point in the process (at least two weeks after the rejoinder) and primarily deals with validity issues (e.g., with the stay motion with regard to ongoing nullity proceedings). The Regional Court of Mannheim generally discusses all relevant questions of the case within a single hearing.

5.6.4.2 Pendency of the action

Whenever pendency of an action is required by other statutes or international treaties, it is of paramount importance to appreciate that a German civil action (including a patent infringement action) is only considered pending upon service of process (Section 261(1) of the Code of Civil Procedure). Previously, this was a relevant point under the previously applicable Brussels I Regulation but this has now been resolved by Article 30 of the Brussels Ia Regulation, which uniformly refers to the filing of action as the decisive point in time. It is, however, still a crucial issue for entitlement actions (Article 61(1) of the EPC) filed with the German courts, particularly with the Munich court (situs of the EPO). For the European patent prosecution to be stayed, those actions need to become “instituted” before the grant of the European patent at issue (Rule 14(1) of the EPC), which is taken as technically “pending” with the meaning of the German Code of Civil Procedure. Thus, pendency must be achieved as early as possible, which is why, particularly when service abroad is at issue (e.g., through the Hague Convention process), filing the entitlement action in a different German judicial branch (e.g., administrative rather than civil) could be recommended to achieve pendency with the filing, rather than with the service.¹¹⁸

5.6.4.3 Basic requirements regarding the admissibility of the action in connection with the prayers for relief

Under the German Code of Civil Procedure, there are certain basic requirements that an infringement complaint must meet in order to be admissible: The complaint must name the parties (plaintiff and defendant) and the court (Section 253(2)(1)). The complaint must set forth the prayers for relief, also referred to as “requests” (“Klageanträge”). The infringement complaint must also set forth all of the specific facts that are required to arrive at the conclusions presented by the plaintiff to be the basis for the requested relief (Sections 253(2) and 138(1)). This includes not only the facts pertaining to standing to sue but also the infringing activities and the defendant's liability. While issues of law, strictly speaking, do not need to be addressed by the parties (*iura novit curia*), claim construction, which is considered an issue of law, needs to be addressed to a certain minimum extent in order for the facts establishing infringement to be meaningful. Without a specific infringement mapping (i.e., putting the technical facts in the context of meaningfully explained terms of the claims), the infringement contentions are not sufficiently “specific.” Furthermore, setting aside the formal requirements under Section 253, the success of the proceedings is hinged upon a clear analysis of claim construction and

¹¹⁸ The case would then be subsequently transferred to the competent civil branch.

infringement and how well the potentially critical issues are already set forth in the complaint, putting the plaintiff's case on the right track.

Even though Section 253(2)(2) of the Code of Civil Procedure expressly states that the requests need to be "specific," the courts are generally still satisfied with the use of the patent claim language for phrasing the requests. However, the case law of the FCJ encourages plaintiffs to specifically adopt certain key features to better caption the specific infringement mapping in the accused device or accused method.¹¹⁹ As a rule, this is no requirement for admissibility, though plaintiffs typically are better off waiting for a formal note from the bench before engaging in this exercise. It is important to realize that, in this regard, using the broader claim language or a more specific language taking up the infringement mapping does not per se affect the scope of the requested relief, as will be explained in the following section.

5.6.4.4 The scope of the action and the relief (the accused device and "Streitgegenstand")

The relief based on the language of the patent claims is procedurally not tantamount to the scope of protection of the patent-in-suit (as defined in Article 69 of the EPC). On the contrary, the scope is – as a rule – limited to the accused device. "Accused device," in this sense, is more of a conceptual or abstract term than a tangible term that would be limited to the very products as identified in the complaint by way of, for example, a product number. Under the case law of the FCJ, the accused device is defined by the specific technical characteristics that are referred to and relied upon for the infringement contention (complaint) or holding (judgment) under the asserted patent claim.¹²⁰ Thus, the accused device does not encompass any and all devices falling within the scope of protection of the patent-in-suit, but its definition extends beyond the very products at issue.

Other products not mentioned in the complaint – and perhaps even unknown to the plaintiff – also (*eo ipso*) fall in that category if those are identical with respect to the technical characteristics on which the infringement mapping is based.¹²¹ Hence, it follows that, if a further product line becomes available during the course of the litigation, the plaintiff does not necessarily need to introduce it into the litigation. A different product line would also be part of the litigation – and form part of the accused device – if the relevant technical characteristics are identical. In this respect, the accused device in patent litigation is tantamount to the "procedural claim" (Section 322 of the Code of Civil Procedure), also referred to as "Streitgegenstand" (subject matter) of the litigation. This is a core feature in German jurisprudence.

The subject matter is defined by both the requests and the facts presented by the plaintiff to justify the underlying legal conclusions. It forms the groundwork for a number of further procedural elements, including the scope of the requested (injunctive) relief that is decisive for subsequent contempt proceedings. It is also relevant for assessing the admissibility of a claim modification during pendency of the action.

5.6.4.5 Modifications of the pending claim

The German process is generally very flexible, and changes can be accommodated even at a late stage of the proceedings. If new facts are introduced that change the "procedural claim" within the meaning of Section 322 of the Code of Civil Procedure, this is considered a "Klageänderung" (claim modification; Sections 263, 264). In a patent infringement case, this is typically the case if a different or modified "accused device" is introduced. It could, for example, be that the very same product as identified in the complaint implements several accused devices because different sets of technical aspects in that product can be invoked for independent infringement mappings of the same patent claims. The same would be true if a different product line was identified during the course of the litigation, and the infringement mapping resorts to technical characteristics whose essence deviates from the products previously identified in the complaint. Such a "claim extension" is very generously admitted into the proceedings. However, if introduced very late into the proceedings, the court could order a new schedule (i.e., push back the final hearing date and extend the terms in order to give the defendant a chance to address those changes).

119 BGH (FCJ), Feb. 21, 2005, X ZR 126/01 (*Blasfolienherstellung*).

120 BGH (FCJ), Feb. 21, 2012, X ZR 111/09, 2013 IIC 232 (*Rohrreinigungsdüse II*).

121 This is why the FCJ encourages plaintiffs to more precisely reflect the essence of the infringement mapping in the terms of the requests.

5.6.4.6 Pleading standards

The facts presented in the complaint for showing infringement need to be sufficiently substantiated: the facts need to be specific, and the plaintiff must be concrete in showing how these facts are considered to realize the features of the asserted independent claims of the patent-in-suit. While no evidence for any of the asserted facts needs to be presented at this stage, there must be a sufficient basis for factual contentions. They cannot present pure speculation. If they do, the defendant does not need to contest the allegation at all – it would be procedurally discounted as insufficiently stated.

If the facts, however, are sufficiently specified, the defendant must react in substance by either admitting or denying (Section 138(2) of the Code of Civil Procedure). This implies that the defendant must specifically deny the individual factual items of the plaintiff's factual infringement contentions. The defendant cannot just generally deny the factual allegations. It is also not sufficient to argue that the plaintiff's conclusions as to why the accused device or accused method must work in a certain way (which frequently happens, e.g., in the field of electronics) are flawed, unless the factual allegation pertaining to the relevant characteristic of the device or method itself is expressly disputed. Facts that are not expressly disputed are generally to be deemed as having been acknowledged (Section 138(3)). While it is generally sufficient to just deny a certain factual allegation and not necessarily disclose what the pertinent mechanism actually looks like, there are significant exceptions to this procedural rule that are referred to under the keyword of "secondary burden to substantiate" ("sekundäre Darlegungslast").

While this is a general category of civil litigation, it has become particularly important in patent infringement cases in order to compensate for the lack of a general discovery. Based on the general principle of good faith, this also applies to the rules of civil procedure. The defendant in a patent infringement action is under an obligation to specify how certain aspects that are only known to them and that could only be discovered by the plaintiff with disproportionate effort actually function.¹²²

Furthermore, the defendant's denial ought to be as specific as the plaintiff's contention. Thus, if the plaintiff presents a detailed and consistent explanation as to why and how the specifics of the accused device work, the defendant cannot just generally deny that. Rather, the defendant must engage in specific and detailed explanations at the same level. While there are generally limits in terms of equitable considerations ("Zumutbarkeit") that can also accommodate relying on trade secrets, it is not sufficient to just refer to this without further detail. Furthermore, the defendant can be expected to make use of the legal means to protect confidential information (see Section 5.6.8 of this chapter, which is particularly relevant in connection with the most recent changes to the Patent Act (cf. Section 145a). If anything in this regime does not satisfy specific confidentiality interests, the defendant would need to substantiate this and would need to ask for a separate agreement with the plaintiff.

The same rationale just set forth for Section 138(3) applies to limiting the cases in which the defendant can deny an allegation by referring to their lack of knowledge. While this is generally possible if the facts concerned were neither actions of the party itself nor within its ken (cf. Section 138(4) Code of Civil Procedure), this rule is limited by establishing obligations to procure sufficient information. This is, for example, the case if the defendant has retained a third party to manufacture the product or perform the accused process:¹²³ it cannot work to the advantage of the defendant that they use third parties to leverage its business. Furthermore, a dealer cannot claim to not have any detailed knowledge of the accused device because it is manufactured elsewhere and that the plaintiff should therefore turn to the manufacturer.¹²⁴ Rather, the dealer must look into the facts – that is, examine the device or turn to the manufacturer for the specifics. The dealer can rely, however, on information from a trustworthy source (e.g., the manufacturer) and, unless the plaintiff shows that the information is flawed, does not need to engage in independent efforts to further explore the facts by examining the accused device.

¹²² BGH (FCJ), Sep. 30, 2003, X ZR 114/00, 2004 IIC 577 (*Blasenfreie Gummibahn II*).

¹²³ BGH (FCJ), Sep. 17, 2009, Xa ZR 2/08, 2010 IIC 471 (*MP3 Player Import*).

¹²⁴ OLG Düsseldorf (Higher Regional Court of Düsseldorf), Dec. 17, 2015, I-2 U 34/10.

5.6.4.7 Further briefs

Up to the hearing, the parties typically file at least two rounds of briefs (complaint, response, reply and rejoinder). Usually, there are further briefs exchanged right up to the hearing date, even though the judges do not tend to like this approach. The only practical and effective way to avoid it, however, is for the court to push back the hearing date if the plaintiff files late briefs too soon before the hearing.

5.6.5 Provisional measures

5.6.5.1 Proceedings for preliminary relief are independent of the proceedings for permanent relief

The German Code of Civil Procedure provides for summary proceedings –that is, for civil actions for preliminary relief, particularly in the form of preliminary injunctive relief (Sections 916 to 945b). This is not designed as a form of “interim relief” within the action for permanent relief but rather takes the form of a separate and independent action. Thus, all requirements (jurisdiction and venue) ought to be checked independently. Actions for interim relief and for permanent relief can therefore be entertained in different venues, and, indeed, plaintiffs often seek preliminary injunctive relief in venues whose practice is generally considered more favorable to preliminary relief. The sole exception applies to cases in which an action for permanent relief has already been filed, in which case that court would also have exclusive jurisdiction for the corresponding summary proceedings, even if the action is already pending on appeal (Section 937(1)).

The principle of separate actions also entails that a ruling on permanent relief does not automatically affect a prior ruling on preliminary relief.¹²⁵ Any preliminary injunction will therefore need to be set aside by a court within the framework of the proceedings for preliminary relief. It does not cease to exist just because the court in the action for permanent relief dismisses the action.¹²⁶

5.6.5.2 *Ex parte* proceedings: protective writ

Preliminary injunctive relief can be granted *ex parte*, and, indeed, *ex parte* injunctions are still common in trademark or unfair competition matters; but it is the real exception in patent cases because the complexity of the matters makes it mostly indispensable to give the defendant its day in court before making a decision.¹²⁷ To avoid *ex parte* decisions, the potential defendant can file a “protective letter” with the possible infringement courts (Section 945a of the Code of Civil Procedure). This is an anticipated defense brief whose purpose is to establish at least sufficient doubt with regard to the merits of the case for a preliminary injunction such that the court does not grant it without a hearing. However, filing such a protective letter is not univocally advantageous for the plaintiff. Rather, there are two main risks to be considered:

- The plaintiff and the court can argue that, by virtue of the protective letter, the defendant had a chance to be heard, so an *ex parte* injunction could be issued, and the general concerns of not hearing the defendant would be mitigated. Thus, filing the protective letter could have the reverse effect and enable an *ex parte* injunction rather than avoiding it.
- If the injunction is nevertheless issued, it can be served directly on the defendant’s counsel, which is a very significant shortening of regular service, particularly of service abroad under the Hague Service Convention.¹²⁸

If the injunction is granted *ex parte*, the plaintiff must serve it within a one-month term; otherwise, it becomes void (Section 929(2) of the Code of Civil Procedure). The service is typically done through a bailiff that the plaintiff’s counsel must retain. It must be effected on the defendant’s counsel if such counsel for the proceedings exists (e.g., when a protective writ was already filed). Only if the preliminary injunction is actually served (in time) does it become binding on the defendant. The defendant can oppose the *ex parte* injunction, and the court will schedule a hearing day following such opposition (Section 924).

If the court is of the preliminary view, having analyzed the plaintiff’s application, that the grant of an *ex parte* injunction is not possible, the court will typically issue a notice to that extent to the

¹²⁵ BGH (FCJ), Oct. 9, 1986, I ZR 158/84.

¹²⁶ BGH (FCJ), Oct. 9, 1986, I ZR 158/84.

¹²⁷ Under the recent case law of the Federal Constitutional Court, *ex parte* injunctions have been significantly limited; cf. Bundesverfassungsgericht (BVerfGE) (Federal Constitutional Court), June 6, 2017, 1 BvQ 16/17.

¹²⁸ Sec. 936, 922 (2), 195 of the Code of Civil Procedure.

plaintiff (sometimes also by way of a phone call). It is then up to the plaintiff to either withdraw the action or to maintain it. If maintained, the court can either dismiss the application right away (*ex parte*) or schedule a hearing date and effect service of process (application and summons) on the defendant. The *ex parte* dismissal can be appealed by the plaintiff, and this proceeding would continue *ex parte* at the appellate level. The appellate court can grant the requested relief *ex parte* or can affirm the dismissal, summon the defendant or remand the case for further *inter partes* proceedings.

5.6.5.3 Distinct procedural characteristics of proceedings for preliminary relief compared to permanent relief

The process of *inter partes* summary proceedings for preliminary relief is generally similar to that described above for the main proceedings for permanent relief. The process is significantly more accelerated, however, so a hearing date should take place a couple of weeks or a few months after the service of the application. Furthermore, there are a number of procedural differences that are due to the inherently accelerated nature of the proceedings:

- Expert evidence is not available in interim proceedings (Sections 920(2) and 294(2) of the Code of Civil Procedure).
- There is no separate hearing date scheduled for the taking of evidence, so witnesses will not be summoned; rather, the parties need to ensure that they are readily available for the hearing date ("präsenzer Zeuge"; cf. Section 294(2)).
- There is no preclusion of facts or evidence. Thus, even if the court sets a term, the parties can push back submitting any facts or evidence to the final hearing.
- There is also no stay of the proceedings pending the nullity action or opposition. Rather, if there are concerns regarding the validity of the patent-in-suit, the application must be dismissed.
- The evidentiary threshold is lower, as "Glaubhaftmachung" (*prima facie* evidence) is sufficient, which can be better translated as "demonstrating an allegation as to fact to the satisfaction of the court" (official translation of the Ministry of Justice: cf. Sections 920(2) and 294). There is no limitation to the formal evidence set forth above, so affidavits are also possible and frequently used.
- The decision of the court is typically pronounced on the day of the hearing, so no separate hearing date for pronouncing the ruling is set as for most of the cases in the main action.
- The relief granted in the court's ruling is *eo ipso* enforceable, so the court does not need to separately pronounce the preliminary enforceability (Section 928) and therefore typically does not also set a security bond to be posted for making the injunction enforceable (even though that is possible, cf. Section 921).

5.6.5.4 Requirements for preliminary injunctive relief

5.6.5.4.1 Requirements for interim relief: "Verfügungsanspruch" (substantive infringement claim) and "Verfügungsgrund" (specific legal interest for preliminary relief)

As to the requirements for interim relief under the general provisions of the Code of Civil Procedure, two categories can be distinguished: the substantive requirements regarding the asserted claim ("Verfügungsanspruch") and the specific reason or interest justifying interim relief prior to permanent relief ("Verfügungsgrund"). Within the analysis regarding the "specific interest," both "urgency" and "balancing the equities" of the matter ("Verfügungsanspruch") need to be addressed, while the balancing of interests also encompasses the analysis regarding the validity of the patent-in-suit.

The standards for the "Verfügungsanspruch" – mainly for claim construction and infringement issues – are generally the same that apply in the main proceedings with the above-described difference regarding evidence. Thus, different from other jurisdictions, the merits of infringement play a decisive role in the grant of preliminary injunctive relief rather than putting the primary focus on an equity analysis weighing the interests affected by granting or not granting the requested preliminary relief.

This being the case, the practically most critical part of German patent infringement proceedings is the "Verfügungsgrund": the specific legal interest that the plaintiff must show for pursuing its claims in the form of interim proceedings. In this regard, it must be considered that preliminary relief under the German Code of Civil Procedure, as a rule, should only preserve the status, ensuring that the enforcement of rights following an action for permanent relief will not

be frustrated.¹²⁹ In matters for injunctive relief, by definition and inevitably so, the permanent relief is not only preserved but “moved ahead” (“vorweggenommen”). Even so, such preliminary relief is possible and is not limited to cases of irreparable harm for the plaintiff. On the contrary, if the merits of the case are clear on the face of it, the threshold for the specific legal interest is generally not too high. Yet, the merits of a patent infringement case are only rarely sufficiently clear in this respect – neither on infringement nor on validity. This is due to both factual and legal reasons and is particularly the case for the validity side, for which the bifurcation element aggravates these problems.

Thus, while preliminary injunctive relief is the practically prevailing form of dealing with trademark and unfair competition disputes, the German courts are rather cautious when it comes to preliminary reliefs in patent matters. The rationale is that such matters are generally factually much more complex, and the impact of the injunction is generally much more severe than in, for example, trademark matters. Furthermore, the actions for permanent relief are much quicker in Germany compared to other jurisdictions, so the practical need for preliminary relief is less urgent. Yet, despite this general reservation, injunctive relief in patent matters is practically possible if the infringement analysis is not too complex. Thus, while it is possible to produce party expert opinions to corroborate the infringement analysis and its factual basis (genuine “expert evidence” is not available in summary proceedings, cf. Sections 920(2) and 294(2) of the Code of Civil Procedure), a “battle of experts” is, in many cases, taken as an indication that the matter at bar is unsuitable for preliminary proceedings. The more the plaintiff must argue to make the infringement case, particularly regarding the factual basis, the higher the likelihood the court deems the matter unsuitable for preliminary relief.

5.6.5.4.2 Validity

The most difficult factor in most of the patent infringement actions for preliminary relief is validity. As the German system provides for bifurcation, the infringement courts generally – and also in actions for permanent relief – do not rule conclusively on validity but only need to engage in a “prediction” as to the outcome of the (opposition or nullity) actions challenging the validity – that is, the infringement courts assess the prospects of success of the validity challenges. Such an assessment is similar in cases for preliminary relief. However, in many cases, due to the accelerated nature of actions for preliminary relief, the defendant may not have had sufficient time to put together a substantiated validity challenge (requiring searches of prior art and corresponding assessments).

Additionally, as the actions challenging the validity of the patent-in-suit take significantly longer than even the infringement actions for permanent relief, the resulting “injunction gap” considerably widens in the case of preliminary injunctions for patent infringement. Therefore, the case law of all of the relevant appellate circuits in Germany states that preliminary injunctions in patent infringement matters generally require that the patent-in-suit has already been sufficiently confirmed in opposition or nullity proceedings, at least in the first instance.¹³⁰

The Regional Court of Munich has held that this practice is at odds with the EU Enforcement Directive,¹³¹ according to which preliminary relief ought to be provided. The court has therefore referred a case to the European Court of Justice,¹³² asking it to clarify this issue of law: that is, whether the general requirement for an *inter partes* decision on validity contradicts EU law and should therefore be abandoned.¹³³ The referral has been criticized because it did not sufficiently describe the exceptions to the above-mentioned rule, according to which, for special scenarios (e.g., irreparable harm to the plaintiff in cases of an imminent market entry of a generic medical product, evident lack of merits of the validity attack, or general acceptance of a patent in the market), the grant of a preliminary injunction is possible even in the absence of a previous *inter partes* decision on validity. The prevailing literature considers that system adequate, with those exceptions, and not in violation of the EU Enforcement Directive.¹³⁴

129 OLG Hamburg (Higher Regional Court of Hamburg), June 14, 2006, 5 U 21/06 (*Cerebro Card*).

130 OLG Düsseldorf (Higher Regional Court of Düsseldorf), April 29, 2010, 2U 126/09; OLG München (Higher Regional Court of Munich), Dec. 12, 2019, 6 U 4009/19; OLG Karlsruhe (Higher Regional Court of Karlsruhe), Sep. 23, 2015, 6 U 52/15.

131 LG München (Regional Court Munich), Jan. 19, 2021, 21 O 16782/20.

132 CJEU, April 28, 2022, C-44/21 (*Phoenix Contact GmbH & Co. KG v. HARTING Deutschland GmbH & Co. KG and Harting Electric GmbH & Co. KG*).

133 Landgericht München I (LG München I) (Regional Court of Munich I), Jan. 19, 2021, 21 O 16782/20.

134 T. Kühnen, *ur Frage der Notwendigkeit einer erstinstanzlichen Einspruchs- oder Nichtigkeitsentscheidung vor Erlass einer einstweiligen Verfügung*, GRUR 466 (2021); H. Deichfuss, *Die Prüfung des Rechtsbestands des Patents im einstweiligen Rechtsschutz*, GRUR 33 et 800 (2022).

5.6.5.4.3 Urgency

Urgency is a necessary requirement for any action for preliminary relief. This requirement does not imply that the right holder would need to proactively check the market for infringing activities. However, once specific indications for infringement have been brought to the right holder's attention, they must act without undue delay to explore the facts. Once the facts and evidence have been explored without undue delay, case law expects that the motion for interim relief is filed within a month.¹³⁵ Some appellate circuits are more generous in this regard and let two or three months suffice.¹³⁶ Urgency also places significant limitations on the plaintiff's procedural strategy. The plaintiff must be very careful to engage in settlement negotiations and, in this connection, agree to extend terms or push back hearing dates, even dates for pronouncing a decision. Such acts can be taken as showing a lack of genuine urgency, so the case would need to be dismissed, even if already on appeal.

5.6.6 Gathering of information

5.6.6.1 Basic pleadings mechanics

It is one of the fundamental principles governing any civil action under the Code of Civil Procedure that all facts and evidence relevant to the substantive claims at bar must be presented by the parties ("Beibringungsgrundsatz"; Section 138(1) of the Code of Civil Procedure). The court cannot *ex officio* or otherwise *sua sponte*, explore facts or evidence (with some exceptions like court-appointed experts and orders to produce certain documents that will be discussed later). The party asserting the claims generally bears the burden of substantiating and, if contested by the opposing party, of proving the facts that form the basis for the asserted claim. Thus, in a patent infringement matter, the party claiming that the opposing party is liable for patent infringement (and therefore subject to certain relief) must make the necessary factual contentions and, if contested, must take recourse to evidence.

Nevertheless, this does not mean that such a party (the claimant or plaintiff)¹³⁷ must have conclusive knowledge of the facts, let alone hold evidence to that extent when filing a patent infringement action. It suffices to specify certain facts that the defendant can admit, or deny or dispute. The limits to this are pure speculation: the plaintiff cannot just allege certain facts without any basis so as to procedurally make the defendant address it. "Fishing expeditions" are not possible in the German procedural system. If there is a sufficient basis from which to infer a factual contention and the defendant nonetheless still chooses not to address certain factual contentions, then those are considered admitted (Section 138(3)). If the plaintiff's contentions are denied, the court must take evidence. The details of these pleading standards given in Section 5.6.4.6 of this chapter.

5.6.6.2 Test buy

The easiest way to ascertain factual information is by way of buying the accused devices and subjecting them to empirical analysis. It is well settled that any form of "test buy" is a legitimate way to procure the information necessary for initiating an infringement action even if the buyer (who can also be the plaintiff's counsel) does not disclose this context. Possible limits include illegal ways of procuring such information.

5.6.6.3 Limited pretrial discovery (inspection orders)

However, the patentee does not, in some cases, have access to the accused devices or the performance of the accused method. Furthermore, even reverse engineering might not be suitable for disclosing all relevant features (e.g., product-by-process features). Thus, even if the patentee would have a sufficient basis for making certain factual infringement allegations (see Section 5.6.4.6 of this chapter) and could file an action on that basis, the assumption could turn out to be wrong, and the action would be dismissed on the merits. While this is a general risk that a patentee (as plaintiff) must take when bringing an action, it is dissatisfying if that risk is based on insufficient factual information. Therefore, in implementing key points of the EU

¹³⁵ OLG Düsseldorf (Higher Regional Court of Düsseldorf), Feb. 15, 2021, 2 W 3/21; OLG München (Higher Regional Court of Munich), April 22, 2021, 6 U 6968/20; OLG Karlsruhe (Higher Regional Court of Karlsruhe), Sep. 23, 2015, 6 U 52/15.

¹³⁶ OLG Hamburg (Higher Regional Court of Hamburg), Sep. 3, 1987, 3 U 83/87 (*Verbandsmaterial*).

¹³⁷ In German, "claimant" ("Anspruchsinhaber") is used to describe that the party is substantively entitled to a certain relief, independent of any procedural action filed based on it. The procedural position of the party is herein referred to as "plaintiff." Those positions do not need to necessarily coincide: e.g., in a declaratory judgment action for noninfringement, the defendant would be the party claiming to be entitled to relief for patent infringement – i.e., claimant of the substantive right to that relief.

Enforcement Directive,¹³⁸ the Patent Act provides a specific procedural (also “pretrial”) system enabling the patentee to ascertain particular facts, which enables measures ahead of filing any action for permanent relief.

The key part of this statutory regime is provided for in Section 140c of Patent Act, under which any person who, with sufficient likelihood, infringes a patent, may be sued for submission of a document or for inspection of an item (e.g., a device or process) that lies in their control if this is necessary for the purpose of establishing infringement (cf. Section 140c(1) of the Patent Act). The basic requirement for such an inspection order is a certain likelihood of infringement. Thus, the patentee must substantiate infringement in terms of distinguishing the features for which there is certainty and those for which there is a factual uncertainty while explaining the basis for inferring a certain likelihood of the use of such features in the defendant’s devices or methods. These obligations to submit a document or to acquiesce the inspection can also be imposed by way of preliminary injunctive relief (Section 140c(3) of the Patent Act). This is the part that enables a pretrial discovery of facts ahead of filing an action for permanent relief.

Under the umbrella of this statutory regime,¹³⁹ case law – particularly of the Düsseldorf regional and higher regional courts¹⁴⁰ – has developed a highly balanced but rather sophisticated process for an *ex parte* inspection order pertaining to devices and processes possessed and respectively used by a likely patent infringer. While the nuances of this process are subtle, it is generally based on a combination of a preliminary injunction (based on Section 140c(3) of the Patent Act) with an “independent evidentiary proceeding” (based on Section 485(1) of the Code of Civil Procedure). With the former aspect, the likely patent infringer is ordered to acquiesce the inspection (by a court-appointed expert), while the latter enables the taking of evidence in the form of an expert opinion ahead of initiating any proceedings for permanent relief (the main action for infringement). In doing so, the corresponding expert opinion can be adopted as genuine expert evidence in possible subsequent proceedings on the merits for permanent relief (regarding expert evidence see Section 5.6.7.1 of this chapter). If the accused devices or methods to be inspected are located on the premises of the likely patent infringer, and access is denied, an additional search warrant (Section 758a) can be issued.¹⁴¹ Under specific circumstances, the inspection may even be carried out in the premises of a third party as long as the infringer can nonetheless be deemed to be in possession of the relevant products or has sufficient influence upon the carrying out of the protected procedure. If the likely patent infringer refuses the inspection or refuses access to the premises, the inspection order or search warrant needs to be enforced with the help of a bailiff, who, in turn, can call on the help of police officers.

The key point of this process is balancing the parties’ interests – that is, the interest in securing evidence for showing infringement against the interest to preserve confidential information. This is why the typical inspection process provides for a court-appointed independent expert to conduct the inspection. Only the patentee’s lawyers (including patent attorneys), but not the patentee, are admitted to attend the inspection, while both the expert and the lawyers also act under a protective order so that they cannot discuss the findings with others, including the patentee. In order to ensure that the defendant’s rights are preserved, the expert will typically be put under an obligation to give the defendant a certain time (e.g., two hours) to contact its lawyers while the inspection is deferred. It is in this regard recommended that companies, whose premises could be subject to such orders, retain lawyers who are available on short notice to appear in such a scenario.

While the expert cannot just seize devices or documents (unless such seizure is expressly ordered and conducted through the bailiff), the expert should be authorized in the order to document the findings of the inspection by way of photos, screenshots and the like, including deconstruction, if no damage remains. If digital data or code are at issue, it is possible to allow the expert to download such data, and the defendant would need to support this by way of providing passwords if ordered to do so in the inspection order.

138 Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the Enforcement of Intellectual Property Rights, 2004 OJ (L 157) 45, <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32004L0048>

139 And actually already in anticipation of its enactment based on the Enforcement Directive.

140 Therefore, the process is also called a “Düsseldorf inspection proceeding” (“Düsseldorfer Besichtigungsverfahren”); cf. T. Kühnen “Zivilprozessualer Geheimnisschutz in Patentstreitverfahren” GRUR 576 (2020).

141 The “independent evidentiary proceeding” under sec. 485 can also be meaningful, independent of the preliminary injunction pertaining to the inspection, if the device is publicly available, but there is a risk that the object of the evidence becomes lost (because it is, e.g., subject to degradation or other changes).

The court-appointed expert then drafts an expert opinion on the results of the inspection with regard to the facts and merits of infringement of the patent-in-suit. This report is released in an unredacted form to both the court and the likely patent infringer's lawyers, as well as the patentee's individual lawyers, who are bound by the protective obligation in the original inspection order. This order also includes, as discussed above, an obligation to also keep the confidentiality from their client (the patentee). The FCJ has confirmed that such an obligation is legally valid and sufficient to protect the defendant.¹⁴² Thus, the likely patent infringer cannot generally ask to only release a redacted version of the report to the patentee's lawyers bound by the protective order.

In this regard, the confidentiality regime differs from the new statutory regime under Section 145a of Patent Act in combination with Sections 16–20 of the new statute on the protection of confidential business information ("Geschäftsgeheimnisschutzgesetz")¹⁴³ because that new statutory regime requires that at least one individual of each party be granted access to the confidential and protected information (cf. Section 19(1)(2) Law on the Protection of Trade Secrets). This is the reason why Section 145a of the Patent Act, which enables the protective measures set forth in the new business information protection statute, expressly excludes the proceedings under Section 140c of the Patent Act.¹⁴⁴ In the first stage of the subsequent written proceedings following the submission of the expert opinion under Section 140c of the Patent Act, the expert opinion is therefore not released to the patentee (or to an individual employed or person retained by the patentee, other than outside counsel of record). Rather, an assessment ought to be made as to whether such release is justified in the light of possible confidential information contained in the expert opinion. In making this decision, the court must balance the parties' interests (i.e., the interest of showing infringement against the interest to protect confidential information). If there is confidential information involved, and the expert opinion has not confirmed the likelihood of infringement, then the release is not justified. If there is a significant likelihood of infringement, then the release might be justified even if confidential information is affected. In many instances, it is sufficient to release the expert opinion in a redacted form.¹⁴⁵ The number of applications for inspection orders is low – even the regional courts that regularly deal with patent matters only handle a handful of such cases per year.

5.6.6.4 28 USC § 1782

Due to the lack of sufficient discovery, it has become very popular for plaintiffs in German infringement actions (and sometimes also for defendants) to avail themselves of 28 USC § 1782. This provision allows a U.S. federal court to order a person residing in its district to give testimony or produce a document for use in a foreign or international proceeding. This provision is, in practice, not interpreted restrictively,¹⁴⁶ which is why this form of discovery has been frequently used in German patent litigation involving U.S. parties or U.S. third parties in possession of evidence relevant for the German litigation. This provision has become relevant not only for technical information but also for license agreements in the context of FRAND (fair, reasonable and nondiscriminatory) defenses.

It is important to note, however, that the plaintiff is not considered to be under any procedural obligation to make use of a § 1782 discovery in order to ascertain facts or evidence because, with regard to Article 23 of the Hague Evidence Convention,¹⁴⁷ Germany has declared its objection, so it will not comply with requests for pretrial discovery.¹⁴⁸ Indeed, in many scenarios, the results of the U.S. discovery could even delay the action. It might therefore be strategically advantageous to trust the pleading requirements provided for in the German practice of civil procedure, particularly the defendant's secondary burden to substantiate when it comes to the defendant's products (see Section 5.6.4.6 of this chapter).

¹⁴² BGH (FCJ), Nov. 16, 2011, X ZB 37/08, 2010 IIC 724 (*Lichtbogenschneidung*).

¹⁴³ German law on the Protection of trade secrets as of April, 18 2019 (BGBl. I 466).

¹⁴⁴ Cf. Ohly/Stierle, "Unverhältnismäßigkeit, Injunction Gap und Geheimnisschutz im Prozess", GRUR 1229, 1240 (2021). Also, the earlier remarks on why requiring one individual from the claimant would be at odds with the rationale underlying the "Düsseldorf inspection proceeding"; cf. T. Kühnen "Zivilprozessualer Geheimnisschutz in Patentstreitverfahren" GRUR 576 (2020).

¹⁴⁵ *Lichtbogenschneidung*, X ZB 37/08.

¹⁴⁶ Cf. the four *Intel* factors as set forth in the U.S. Supreme Court precedent *Intel Corp. v. Advanced Micro Devices, Inc.*, 542 U.S. 241 (2004). More details on this in Mirza, 2019 GRUR Int. 781.

¹⁴⁷ Convention on the Taking of Evidence Abroad in Civil or Commercial Matters, March 18, 1970, 847 UNTS 241.

¹⁴⁸ LG München (Regional Court of Munich), Dec. 20, 2018, 7 O 10495/17 (*Qualcomm v. Apple*).

5.6.7 Evidence

The taking of evidence only comes into play when there are contested issues of fact that turn out to be decisive for the court's ruling. As in any civil action, the court cannot just explore the facts if they are not relevant under the court's legal analysis and applicable to the requested relief based on the parties' factual contentions. Because of the above-explained, highly balanced and effective system of procedural obligations to substantiate contentions and denials, orders for evidence are clearly the exception in a German patent infringement action.

If the taking of evidence is necessary, the court must order to do so. This will typically only be done after an oral hearing, but it is procedurally also possible ahead of the first hearing, particularly if expert reports are involved (cf. Section 358a(4)). The order for evidence generally requires a formal written order identifying the contested facts and the evidence, particularly naming the witnesses and experts as well as the party that has taken recourse to the evidence (Section 359). The latter point is relevant because the taking of evidence is generally only admissible if one of the parties has taken recourse to the evidence at issue. Expert evidence is the most important exception: the court can call for an expert opinion even if the parties have not expressly requested it. Naming the party that has taken recourse does not yet imply anything on the burden of proof. The burden of proof only becomes relevant if the court, following the taking of evaluation of the evidence, cannot convince itself in a manner sufficient for ascertaining whether the contested issue of fact is true or not (Section 286). The party bearing the burden of proof bears the risk of this *non liquet* – that is, the risk that the court rules against the party bearing the burden of proof. In the German concept, these rules are considered substantive rather than procedural in nature.

The German Code of Civil Procedure provides for several means of evidence: experts, witnesses, records or documents, visual evidence taken on site and the examination of a party.

5.6.7.1 Experts

Only court-appointed experts are considered experts in terms of being a formal means of evidence. Experts retained by the parties to the litigation, and their corresponding reports, do not count as "evidence." Rather, such reports just generally count as submissions by the respective parties. However, they do carry more weight ("qualified party submission") depending on the qualifications and reasoning of the expert opinion, as the court cannot simply take on a different view without providing express reasons and sources as to why certain scientifically founded arguments are dismissed. Thus, filing party expert opinions can be a relevant element and can make the court more inclined to resort to an independent expert. Though rare in practice, a party expert may be allowed to speak during the hearing, but, again, this is procedurally only considered as a party representative – not an "expert witness" – speaking. Thus, there is no cross-examination or anything known from the Anglo-American trial-based system.

While the court has discretion as to expert selection (cf. Section 404(1)), the court usually asks the parties which experts are suitable for a specific technical field (cf. Section 404(4)). If the parties agree on an expert, the court generally must retain this expert (cf. Section 404(5)). The most difficult challenge is to identify experts in the pertinent technical field who are not (too) close to any of the parties (who are, in patent infringement cases, often leading companies in the field that also work closely with scientists), as the parties can reject experts for reasons of bias (cf. Section 406). This is also why the parties, when evaluating which experts are suitable, should be very careful when unilaterally contacting candidates. Once an expert has been identified and has indicated they are ready to render an opinion on the pertinent subject matter, the court formally appoints the expert and sets a term for the expert to submit a written report on certain issues set forth in the order for evidence (Section 411(1)).

The written report is submitted to the court, and the court provides it to the parties so that they have the opportunity to comment in writing on the report. Based on these statements, the court can specify further points, asking the expert to supplement the report. In many cases, the expert is summoned to a hearing to give the court and the parties a chance to ask questions about the report. The court may prepare such a hearing by way of a written order to give the expert a chance to prepare. During the hearing, the bench primarily leads the examination of the expert, but the parties (through their counsel) have the right to also ask questions. Even though the examination of experts is conducted in a manner similar to that of witnesses (the pertinent rules

on witnesses apply *mutatis mutandis* to experts; cf. Section 402), experts are not referred to as “expert witnesses.” The latter term only refers to “knowledgeable persons” who are to be examined to obtain evidence regarding past facts and circumstances, or situations given in the past, that require special technical competence to be perceived (Section 414). These genuine “expert witnesses” are procedurally treated as witnesses, not as experts, for the purposes of the rules on taking evidence.

As stated above, only contested issues of fact can be subject to an expert opinion. This could, for example, pertain to a characteristic of the accused device that is not readily ascertainable (e.g., visible). While issues of law cannot be subject to expert evidence, and claim construction is generally considered an issue of law, certain aspects relevant to claim interpretation can be referred to an expert. A typical example is cases in which specific technical terms are used in the claims and not defined in the description but for which the skilled person at the priority date could have a defined understanding. If a claim, for example, uses the term “solution,” the parties could argue whether the term is limited to a strict molecular solution or if it could also cover certain suspensions. The experienced German infringement courts are rather reluctant, though, to resort to expert opinions in such cases unless there is no clear function indication in the patent-in-suit or any other documents that form the undisputed basis for the common general knowledge at the priority date based on which the skilled person is considered to have been operating.

It is important to note, though, that the bench cannot just rely on the expert when it comes to claim construction. The FCJ has set aside a number of decisions that did not reflect a genuine and independent reasoning of the infringement regarding claim construction but rather generally referred to an expert’s reasoning.¹⁴⁹

While experts are typically retained to provide a written expert report on certain questions as set forth in the order for evidence, experts have also been retained by the court to attend a hearing and to assist the bench during the hearing by way of commenting on certain technical topics.¹⁵⁰

5.6.7.2 Witnesses

While the taking of evidence by hearing witnesses is a key part of the provisions on evidence in the Code of Civil Procedure (Section 373–401), witnesses are rarely examined in German patent infringement proceedings. The main issue for which witnesses play a role is a prior-use right according to Section 12 of the Patent Act. This is different from a public prior use that would count as prior art and thus only be relevant for a stay of infringement proceedings. The prior-use right, under Section 12, is a genuine defense that does not challenge the validity of the patent but only establishes a right for the defendant to continue a certain use of the invention that had to be started before the filing or priority date. Other fields where witnesses can be relevant are with respect to the standing to sue or the infringing activities of the defendant.

The taking of evidence by hearing a witness requires offering this evidence by naming the witness and designating the facts regarding which the witness is to be examined (Section 373). The court cannot *ex officio* name a witness. The witness must be summoned to the hearing (Section 377), and the summons must include the designation of the parties, the subject matter of the examination and an instruction of the witness to appear at the set hearing date for the purpose of testifying before the court. The summons must also include the warning that failure to do so may be sanctioned by means of administrative coercion provided for in the law.

While affidavits do not count as witness evidence (only as a document), Section 377(3) provides that the court may instruct that the question regarding which evidence is to be taken be answered in writing should it believe that, in light of the content of the question regarding which evidence is to be taken and taking into consideration the person of the witness, it suffices to proceed in this matter. This written answer would qualify as witness testimony. Any other written declaration (or affidavit), or the record of witness testimony from another proceeding, would not qualify as witness evidence but only as evidence in the form of a “record or document.” While it is not excluded to tender and take evidence in this form, the court would need to take evidence by also hearing the witness if the opposing party requests this.¹⁵¹ Thus, while there is no general

149 BGH (FCJ), March 31, 2009, X ZR 95-05, 2009 IIC 868 (*Straßenbaumaschine*).

150 An example is *Qualcomm v. Apple*, 7 O 10495/17.

151 BGH (FCJ), July 12, 2013, V ZR 85/12 (*Unmittelbarkeitsgrundsatz*).

principle that the most direct evidence ought to be taken, the taking of evidence in the form of hearing a witness cannot be easily avoided by referring to written statements or affidavits.

Witnesses are only entitled to refuse to testify on the specific personal and factual grounds provided for in Sections 383 and 384. Among the personal grounds are certain personal relationships with any of the parties, as well as professional duties of confidentiality. Among the factual grounds is the right to refuse answers to questions that the witness would not be able to answer without disclosing a technical or trade secret.

5.6.7.3 Documents

The production of records or documents requires the party tendering the evidence to actually produce it (Section 420). If the document is in the possession of the opposing party, the evidence can only be offered by filing a petition that the court direct the opponent to produce the record or document (Section 421). Unless there is a specific substantive obligation under civil law to produce such a document (Section 422), the opposing party only has a procedural obligation to produce such a record or document when it previously also tendered evidence to that extent, even if this was only in the written stage of the proceedings (Section 423).

Thus, generally speaking, the parties are under no procedural obligation to voluntarily produce any documents in their possession. However, the court can order one of the parties or a third party to submit records or documents in their possession if any of the parties has made reference to it (Section 142(1)). The same applies for items that are in the defendant's or a third party's possession (Section 144(1)) if such items ought to be examined by the court or a court-appointed expert. While this modifies the general principle of the production of evidence by the party referring to it, it is not meant to enable full-scale document discovery. Rather, the record or document must be specifically referred to, and it must be substantiated why it is assumed to be in the possession of any of the parties or a third party. It is not possible to ask for the production of an entire document collection without specifying the relevance of its individual parts.

Furthermore, this mechanism is not meant to enable the conclusive pleading by the plaintiff, as a typical discovery mechanism would. Rather, the plaintiff must sufficiently substantiate the facts on which the asserted claims are based rather than just explore the facts that could enable such pleading by way of document production. With regard to patent infringement actions in particular, the case law of the FCJ has aligned the infringement court's duties to issue such orders with the statutory requirements for an independent inspection claim provided for in Section 140c of the Patent Act (see 5.6.6.3 of this chapter). Thus, the defendant need only submit certain documents referred to by the plaintiff and pertaining to the showing of infringement if there is a certain likelihood of infringement and the production is necessary for showing infringement.¹⁵²

5.6.8 Confidentiality

Protecting parties' confidential information is a critical aspect in many patent infringement actions. While a discovery-based system conceptually provides for a sophisticated confidentiality regime in the form of protective orders or similar instruments, this is not the case in the German legal system, which does not provide for any general pretrial discovery. Thus, originally, the only statutory regime for protecting confidential information was provided for in the Courts Constitution Act, particularly in Sections 172–174. These provisions are exceptions to the general principle that all court hearings need to be public (Section 169 of the Courts Constitution Act). On this basis, the court can exclude the public from a hearing if confidential business information is discussed. The parties and their attorneys can remain in the hearing, but all people attending can be subjected to a confidentiality order (Section 174(3) of the Courts Constitution Act) whose breach triggers a criminal liability (Section 353d(2) of the Criminal Code).¹⁵³

This regime has been frequently used to protect not only technical information but also business information (e.g., in FRAND cases). However, the regime within the Courts Constitution Act has its obvious shortcomings, because the court cannot order confidentiality ahead of a hearing, so the function of the front-loaded proceedings, with the focus on the written briefs, is impaired. These issues have been addressed by way of Section 145a of the Patent Act, which was very

¹⁵² BGH (FCJ), Dec. 18, 2012, X ZR 7/12 (*Rohrmuffe*).

¹⁵³ For an English translation of the Criminal Code ("Strafgesetzbuch"), see www.gesetze-im-internet.de/englisch_stgb

recently enacted.¹⁵⁴ In referring to the recent statute on the protection of confidential business information (Sections 16–20 of the Trade Secrets Protection Act), Section 145a of the Patent Act gives the court sufficient flexibility and discretion to order suitable regimes for protecting confidential information already in the initial stages of the proceedings. Based on a request from any of the parties, the court can issue protective orders according to which certain information ought to be kept confidential. This encompasses any information that has been introduced into the proceedings if it could qualify as a trade secret or confidential business information. All individuals that are part of the proceedings (parties, outside counsel, experts and witnesses) and all third parties that have access to the documents of the proceedings are bound by the order. The court can also limit access to confidential information, contained in documents submitted by the parties or by third parties, to a certain number of individuals.

The same is true for the attendance of the oral hearing in which this information is to be discussed. However, at least one individual of each party and each party's outside counsel must have access (Section 19(1)). Sanctions for violation of the orders are limited to fines of EUR 100,000 or up to six months' detention.

5.6.9 Oral hearing

The rule is to hold only one oral hearing toward the end of the process. The regional court typically has one hearing day per week (e.g., Friday for the VII Civil Panel of the Mannheim court), for which more than one case is scheduled. Depending on the complexity of the matter, the court reserves one or several hours for the hearing. Occasionally, hearings in complex cases go on for eight hours or more. There are no time limits for the pleadings of the parties, and the parties do not need to turn in pleading notes ahead of the hearing.

The hearings need to be public (cf. Section 169(1) of the Courts Constitution Act) unless the public is excluded, for example, to protect trade secret information that might be discussed during the hearing. Excluding the public requires a nonpublic hearing on the ground for exclusion and can only last for as long as necessary (cf. Section 174(1) of the Courts Constitution Act). Because the public must be given the chance to attend a hearing, the name of the parties, the time of the hearing and the case number need to be put on a panel in front of the courtroom.¹⁵⁵ Furthermore, the public must have access to the court building and the courtroom.¹⁵⁶ However, the docket is not public. Thus, it is generally not possible to ascertain whether a certain case is pending by looking into the docket or calling the court's registry. As a matter of course, the parties do not need to keep the case confidential.

The hearing must always take place physically at the court room, so this is the relevant location for ensuring that the hearing is open to the general public. However, the court can, under Section 128a Code of Civil Procedure, also permit the parties and lawyers to stay at another location and broadcast the hearing in real time to that location. This formed the basis for the frequently used video hearings that were welcomed during the COVID-19 pandemic. Additionally, witnesses and experts may be permitted to stay in another location and be connected through video for their examination.

All patent infringement matters are heard by a bench of three judges (Section 75 of the Courts Constitution Act). While it is generally possible to delegate a civil action to one member of the bench, that possibility is basically never used in patent infringement matters. One of the three judges on the bench (but typically not the presiding judge) acts as a reporting member. This reporting member prepares a detailed analysis of the case and makes a preliminary opinion as a basis for the deliberation of the three judges taking place, as a matter of practice, on the day before the hearing. The reporting judge and the presiding judge are expected to know the files at a great level of detail, while the third judge receives most of the information from the deliberation and the hearing (but does have the same vote regarding the decision). In most cases, the presiding judge speaks for the bench in the hearing, but, selectively, the reporting judge or the third judge may also ask the parties questions during the hearing.

¹⁵⁴ Second Act on the Simplification and Modernization of Patent Law, Aug. 10, 2021, BGBl I at 3490.

¹⁵⁵ BGH (FCJ), Jan. 22, 1981, 4 StR 97/80.

¹⁵⁶ BGH (FCJ), March 23, 2006, 1 StR 20/06.

The hearing starts with the presiding judge calling the matter by naming the parties and the case number (Section 220(1)). Different from a trial-based system, there are no comprehensive minutes that would form part of the record. Rather, the presiding judge only records specific aspects of the hearing.¹⁵⁷ At the outset of the hearing, the presiding judge records the attendance of the parties and their representatives as well as that of the bench. In some cases, the presiding judge also records the prayers for relief (requests) at the outset of the hearing, unless those requests were already recorded in an earlier hearing date, which is possible according to the practice of the Munich court and the Düsseldorf court. In most cases, however, the prayers for relief are only recorded toward the end of the oral hearing as certain aspects might change during the course of the hearing. The recording is either performed by a record clerk (cf. Section 159(1)) of the court registry or by the presiding judge using a recording device (the latter has become most common).

After recording attendance, the presiding judge first asks the parties if there is any possibility of settling the dispute (Section 278(2)). While, in most cases, those discussions will be cut short by the parties, the parties can point out certain considerations that have so far guided them or that have turned out to be a problem in settling the case. Based on the court's initial assessment of the merits of the case, the court could revisit the discussions later again. Thus, the bench is not just strictly observing the presentation of the matter, but it also has an active role in terms of encouraging and possibly facilitating settlement as well as engaging in a discussion of the key points of the dispute with the parties. The Code of Civil Procedure expressly provides that, to the extent required, the court is to discuss with the parties the key points of the dispute, both in terms of factual aspects of the matter and of its legal ramifications (Section 139(1)). In this regard, the court is also to ask questions and work toward ensuring that the parties' contentions are complete with regard to all the relevant facts and evidence. The court must also ensure that the prayers for relief are correctly phrased. So, for example, if the court has concerns regarding the admissibility of the requests because they only repeat the claim language, the court would need to give a formal notice under Section 139(1) indicating that the language of the requests would need to be amended in order to be admissible.

To ensure the court has completely understood the parties' submissions and has complied with its duties under Section 139(1), the presiding judge gives an introduction to the matter (Section 278(2)). This is, in most cases, a concise account of the bench's understanding of the parties' key points. While the court cannot form a conclusive opinion at this stage but must rather stay open, the presiding judge will typically also present the bench's preliminary view on the merits in order to give the parties an adequate chance to address the court's view. The preliminary opinion is based on the deliberation of the bench.

While it is not easy to "turn around" the bench, it does happen, particularly in complex cases, that the bench changes its mind. If new points that the counsel would want to discuss with the client before responding in the hearing are raised, it is also common for either side to ask for a break after the introduction. It is standing practice that the bench gives the word first to the party disadvantaged by the majority of the points in the introduction. As stated before, there is no time limit for oral pleadings, but the bench expects (and regularly states) that the points in its introduction be specifically addressed rather than repeating just the essence of the written briefs.

It can be important for the parties to have certain statements recorded. This is the case, for example, if a certain factual aspect pertaining to the accused device is described in more detail only during the hearing. Otherwise, it will be difficult to base a decision on remarks made during the oral hearing. The court must also record notices under Section 139 (cf. Section 139(4)) unless those have been given ahead of the hearing in writing.

At the end of the hearing, the presiding judge will typically record the requests and set a date for pronouncing the ruling on the case (Section 310(1)). This is typically about four to eight weeks after the hearing. The presiding judge then announces that the hearing is closed. This point of closing the hearing is the final point of the process. Any decision will procedurally refer back to that point. No later-filed facts or evidence can be considered for making the ruling (Section 296a). In rare cases, the court retires for further deliberation before closing the case and returns to pronounce a decision in the hearing. Such an ad hoc verdict is procedurally possible but

157 Regarding the content of the record, cf. sec. 160.

practically very rare and, in those rare cases, is almost always against the plaintiff dismissing the action. It presents the court's firm conviction that the case is without basis.

Nevertheless, post-hearing briefs are always a significant point. These are possible if new points have arisen in briefs of the opposing side or if notices from the court came to the party's attention without sufficient time to allow them to be adequately addressed during the court hearing (Sections 283 and 139(5)). It cannot be generally said at what point prior to the oral hearing such new points will be considered too late for adequate comment in the hearing. Sometimes, lawyers refer to a one-week term, but this is not conclusive in this regard. A new factual point can be raised two weeks before the hearing and yet justify a leave for the opposing party to file a post-hearing brief, provided that the given points are sufficiently complex. If it is the plaintiff that files new points shortly before the hearing, the courts have a tendency to push back the hearing date so that the defendant can adequately respond before the hearing, enabling sufficient preparation of the matter ahead of the hearing.

A post-hearing brief is also possible if new points were only raised during the hearing. The problem with post-hearing briefs is that new facts can be introduced into the proceedings that, by the time of the decision, were not necessarily discussed in the proceedings, as the proceedings formally closed with the end of the oral hearing. Thus, if a new point relevant to the decision-making is raised in a post-hearing brief, the court might need to reopen proceedings (Section 156(1)), which means that another hearing date is required unless the parties agree to a decision in written proceedings according to Section 128(2). This can, of course, significantly delay the proceedings.

However, it is rather difficult to reject new facts or evidence as late-filed. Even though the Code of Civil Procedure provides for this in Section 296, under the case law of the Federal Constitutional Court, there is a requirement to show an actual delay of the action if the late-filed contention is admitted into the proceedings.¹⁵⁸ This means showing that the action would be delayed compared to a scenario in which the file was made on time (relative delay).¹⁵⁹ Even if a contention is contested, it might not delay the case because any order for evidence would have only been made following the ("final") hearing anyway. Only if the hearing date could have already been used for disposing of an evidentiary point triggered by the late filing would a preclusion be realistically possible.

The parties can file post-hearing briefs even in the absence of an express leave to that extent. As the hearing is closed, new facts in post-hearing briefs cannot be considered for the decision (Section 296a). However, the court is under the duty to read all post-hearing briefs to determine whether any further submissions in those briefs would warrant reopening the matter under Section 156. Such a reopening is within the court's discretion; it must balance the further delay against points of judicial economy.

5.6.10 Decision

A decision can be a decision on the merits (e.g., entering into the relief as requested by the plaintiff) or a dismissal of the case for lack of infringement or lack of standing (Section 300(1)). It can, however, also be an order for evidence or a stay of the infringement proceedings pending a nullity action or opposition proceedings (Section 148). The decision can also be to reopen the case, scheduling another hearing date (Section 156). The pronouncement takes place in a separate oral hearing, typically in the morning of the court's respective weekly hearing day and before the first hearing on the scheduled case starts. On the date for pronouncing the decision, the fully worded ruling must be ready (Section 310(2)), which is why, though not frequent, dates for pronouncing a decision might be postponed.

The parties do not need to attend the pronouncement (Section 312(1)). Typically, no counsel attends, but somebody from the outside counsel's office would attend the pronouncement as part of the public. The pronouncement only repeats the court's order (i.e., the ordered relief or dismissal) and the decision on costs and enforceability. In almost all cases, no further reasons are

158 BVerfGE (Federal Constitutional Court), Jan. 27, 1997, 1 BvR 1430/94.

159 BVerfGE (Federal Constitutional Court), Jan. 27, 1997, 1 BvR 1430/94.

given orally, but the written opinion is already available. Depending on the court, the parties' counsel can obtain a copy of the decision at the clerk's office.

After pronouncing the decision, the ordered relief is already legally existing, even though the fully worded judgment is only officially served on the parties some days later.¹⁶⁰ Thus, if an injunction is at issue, the pronouncement is the earliest point at which it can be effective. For a first-instance decision to be actually "binding" in the sense of "enforceable," the plaintiff must post a security bond (which is ordered as part of the relief in the ruling; cf. Section 709). Any first-instance decision needs to be accompanied by a decision on its "preliminary enforceability," which means defining the requirement for enforcing the decision before it becomes final, particularly pending appeal.

The plaintiff can already be prepared for such a security bond, which is typically provided as a bank guarantee. It can be served on the defendant's counsel on the very same day if the process is completed. Consequently, the defendant would need to immediately honor the injunction even if the reasons of the decision have not been served. However, filing any measures of contempt requires the service of the ruling, and it also requires an "enforceable" copy of the judgment, which the clerk provides (Section 750(1)).

There are several special forms of decisions. If either of the parties do not attend the hearing (despite being properly summoned), a default judgment can be pronounced. A default judgment against the plaintiff (Section 330) only requires a corresponding petition from the defendant. If the defendant fails to appear, it is presumed that the facts as submitted to the court by the plaintiff in oral argument have been acknowledged by the defendant (Section 331). Thus, the court can only render a default judgment against the defendant if the legal conclusions based on the plaintiff's factual contentions support the plaintiff's requests. A default judgment is very dangerous, as it is enforceable without the posting of a security bond.

On special occasions, either side might be under pressure to concede. For the plaintiff, this is possible in the form of a procedural "waiver" under Section 306. According to this provision, during the hearing, the plaintiff can waive the claim asserted so that they shall be dismissed with their claim should the defendant apply for such a dismissal. This is a dismissal with full prejudice. A mere voluntary withdrawal under Section 269 does not have this procedural prejudice, which is why defendants have the right to refuse consent to the plaintiff's withdrawal if a hearing on the merits has already taken place (Section 269(3)). However, a withdrawn claim can, of course, not be reasserted if there is an underlying settlement. Based on this, the defendant could have a reasserted claim dismissed as inadmissible. Yet, sometimes, defendants in these scenarios insist on a waiver judgment under Section 306 and are not content with a withdrawal.

For the defendant, conceding can be done in the form of an "acknowledgment" under Section 307. This might happen if the plaintiff did not send a warning letter before filing the action, and the defendant wants to avoid the costs. In such a scenario, if the acknowledgment is presented without undue delay, the plaintiff would need to bear the costs of the proceedings (Section 93).

5.7 Civil remedies

5.7.1 Permanent injunction

By far the most important remedy available under German patent law is the permanent injunction, by which the defendant is ordered to completely refrain from engaging in acts that have been found to infringe upon the patent. Moreover, all such acts that fall within the scope of the judgment for the same reasons, relying exclusively on the considerations of that judgment, are prohibited. Thus, minor modifications of the attacked embodiment, if it still fulfills the features of the patent claim as construed in the reasoning of the decision, will not suffice to avoid infringement ("core theory").

As this is true for direct infringement, in cases of indirect infringement, the court will only grant an unlimited injunction if the means contributing to the infringement can only be reasonably used under infringing circumstances. If this is not the case, the court may not grant an unlimited

¹⁶⁰ Sec. 317 gives specifics regarding the service of the decision.

injunction but may order the defendant to warn its customers that use of the invention is prohibited without the prior consent of the patentee and to put respective warning notices on the products. Alternatively, the court may oblige the infringer to conclude a cease and desist agreement, including a penalty clause, with its customers.

So far – except for extraordinary circumstances of the case – a permanent injunction is automatically granted if infringement is found, without weighing the interests of the parties or affected third parties. An injunction is, therefore, not dependent on the claimant being a practicing entity, so nonpracticing entities are, in principle, also entitled to injunctive relief. Since August 2021 the German legislator introduced wording into Section 139 of the Patent Act so as to exclude the right to an injunction where such a remedy appears to be disproportionate for the defendant or a third party, taking into account the circumstances of the case as well as the principle of good faith. Where a permanent injunction is excluded for these reasons, the infringed party is entitled to reasonable monetary compensation. However, the new law is not expected to change current court practice significantly because the principle of proportionality is already taken into consideration for exceptional cases, in which a use-by period may be granted.¹⁶¹

A central question next to that of whether infringement (direct, indirect or equivalent) is found is whether there is a risk of a first-time infringement or whether the defendant has already infringed upon the patent in the past and is therefore deemed to commit future infringement as well. This must be shown by the claimant. In almost all cases handled by the courts, an alleged infringement has already occurred in the past, whereas future infringement may sometimes play a role in preliminary proceedings to stop an alleged infringer from entering the market with its products. The courts will find in the affirmative even where the defendant has already desisted from selling the infringing products, as long as it did not sign a cease and desist declaration promising to pay damages owed under this declaration in case of an ongoing breach. Important to remark is that finding fault – be it negligence or willful misconduct – on the side of the infringer is not a prerequisite for a permanent injunction. An injunction is only available as long as the patent is in force.

5.7.2 Recall, removal and destruction of patent-infringing products

Accompanying a claimant's right to an injunction, the infringement court will grant an order to have infringing products recalled, removed from the distribution channels and destroyed pursuant to Section 140a of the Patent Act. These claims will only be allowed where direct infringement occurred but not in cases of indirect infringement.¹⁶² As a consequence of the territoriality of the German patent or the German part of a European patent, it is a prerequisite that the defendant owns or possesses infringing goods in Germany. The claim for destruction is available even when the patent has meanwhile expired because the infringer must not benefit from infringing acts committed in the past. The court will not order the products or – where a process is protected by the patent – the direct products manufactured by making use of that process, to be destroyed when such destruction seems disproportionate. However, this is rarely found to be the case. Destruction in the sense of the law does not necessarily mean physical destruction of the whole product but rather that the protected feature must not be used any longer. Thus, the duty to destroy may also be fulfilled by design-arounds to avoid use of the patent. If physical destruction is the only alternative, the defendant may do so itself or hand the attacked embodiments over to a bailiff for destruction at the defendant's cost.

Supporting the right to have infringing products destroyed, the claimant may also be granted a right to remove all infringing goods from distribution channels by a recall (e.g., in a situation where the goods have not yet arrived at their final destination). Consequently, the infringer must approach its customers to return affected goods, which may cause negative publicity and be harmful for customer relations.

5.7.3 Information and rendering accounts

Where the claimant is aware of past use, it may request information on such use and force the defendant to render accounts. With such information, the claimant is able to identify third parties

161 BGH (FCJ), May 10, 2016, X ZR 114/13 (*Wärmetauscher*).

162 BGH (FCJ), Nov. 22, 2005, X ZR 79/04 (*Extracoronares Geschiebe*).

involved in the infringement (e.g., within a supply chain) and bring proceedings against them. Moreover, this information puts the claimant in a position to calculate the damages that result from the infringement. In most cases, this alone is enough to enable settlement between the parties after the duty has been enforced. The defendant – in accordance with the judgment – will normally need to furnish particulars on:

- manufacturing quantities and times regarding affected products;
- deliveries (quantity, time of delivery, prices, type designations, and addresses and names of customers);
- individual offers; and
- production costs (including individual cost factors and profits).

Where particular details being given to the claimant would affect the defendant's right to keep such information of private customers confidential, such information may only be shared with an accountant, being bound by confidentiality, upon request of the defendant and if they pay for such an accountant.

If there is sufficient reason to believe that the defendant has not provided the information correctly and with the requisite care, the claimant may force the infringer to declare for the record, in lieu of an oath, that they have indicated the earnings as completely as they are able to (Section 259(2) of the Civil Code).

5.7.4 Award of damages

For negligent or intentional infringement, the patentee or its exclusive licensee is entitled to damages. Nonexclusive licensees may only claim damages from the patent owner or exclusive licensee if such an entitlement has been assigned. The German courts take a strict approach such that anyone engaging in commercial activities is expected to be aware of all relevant patents and patent applications in their business sector and must seek professional legal advice when in doubt. This strict liability is also true for directors, who have an influence upon the infringing activity.

It is a particularity of German proceedings that, initially, the determination of the amount of damages is not part of the infringement proceedings. Rather, the courts find that the claimant is entitled to damages on the merits and leaves the details to be determined in follow-up proceedings, which rarely occur in practice because most parties – after infringement has been found and the claimant has enforced its judgment and forced the defendant to open its books – find a way to settle this dispute without the support of the courts.

The amount of damages may be calculated in three different ways. The claimant has a free choice between all three methods until a specific damage claim has been brought or a final and binding court decision has been rendered:

- The claimant may request the profits of the infringer that directly resulted from the infringement and are causally linked to it (infringer's profits).
- The claimant is entitled to ask for compensation for its lost profits (lost profits).
- The claimant may calculate the damages on the basis of a license fee that would have been paid by a reasonable licensee (license analogy).

In most cases, damages are calculated by way of a license analogy. This method is the easiest for collecting damages because the claimant is usually in a position to establish the amount of a reasonable license fee by making reference to other license contracts with third parties or established license rates in the industry sector, which are deemed to be paid by a hypothetical licensee.

In contrast, enforcing a judgment granting damages calculated via one of the other two methods against an unwilling counterpart can be a cumbersome procedure. Using the infringer's profits method, it may be difficult to determine the causal share of the infringement on the profits, the core question being how significant the patented technology was for the customer's decision to buy the infringing products or pay for the use of the respective procedure. Furthermore, where the patented feature only forms part of a larger system being sold, the calculation will need to

take this into due account by making a corresponding deduction. As part of the damages, side-by-side sales will need to be taken into account (e.g., where such products are not patented themselves but are sold with the patented product or subsequent to the sale of the patented product as a replacement part). The infringer may then deduct only the overheads that can clearly be attributed to the manufacture and distribution of the attacked embodiment infringing upon the patent. Thus, the true general costs of production and distribution may not be taken into account.¹⁶³

Where the claimant seeks to enforce the amount of lost profits as damages, it is difficult to provide evidence for the actual damage incurred (such as a specific lost order that would have been placed with the claimant instead of the defendant). If no such specific transaction was lost, the claimant will need to argue on an abstract basis and convince the court that certain transactions and sales would have taken place in the course of its usual business.

It is important to note that exemplary or punitive damages are not available under German law of torts.

5.7.5 Publication of court decision

According to Section 140e of the Patent Act, the prevailing party may be furnished with the right to publish the decision at the defendant's cost where it has a legitimate interest to do so. This section was introduced to transpose the EU Enforcement Directive into German law. However, only a few court decisions have granted such a request for reasons of proportionality. In recent years, fewer and fewer parties have applied for it.

5.7.6 Declaration of non-infringement

Under German law, there is no special remedy as part of the substantive law that entitles a declaration of non-infringement. Rather, a party that is substantially confronted with an alleged infringement may ask the court to find in a procedural declaration that there is no infringement (declaratory judgment of non-infringement). The alleged infringer will need to provide a detailed description of a specific embodiment of a product or process to put the court in a position to determine that a respective infringement claim by the patent's proprietor would not prevail.

As the relevant procedural provision in the Code of Civil Procedure (Section 256) only allows such a procedure where the claimant has a legitimate interest that non-infringement be declared, the claimant will need to assert that it not only has an abstract interest in such a court declaration but that it has been approached by its opponent in such manner that it has a legitimate interest to defend against the respective allegation. This normally will not be the case where the opponent has only asked the claimant to explain why it feels entitled to make free use of the patented process or sell its goods in the light of the patent and has sought to start an exchange of ideas and arguments. Rather, before an application in court for a declaration of non-infringement will be allowed, such a substantive attack will only be found where the patent owner has furnished the claimant with a warning or cease and desist letter by which it maintains having a claim against its opponent. However, it is not necessary that the patent owner asserts having an enforceable claim against the opponent,¹⁶⁴ though the mere announcement that it will review potential claims is not sufficient¹⁶⁵ nor is the mere initiation of inspection proceedings, except for specific circumstances.¹⁶⁶

There is no remedy to a declaration of invalidity or unenforceability that may be brought before the civil infringement courts. In this case, a nullity action must be filed with the FPC. The arguments on invalidity may only be taken into account by the infringement court in its decision on whether to stay its proceedings and wait for the outcome of the nullity action.

¹⁶³ BGH (FCJ), Nov. 2, 2000, I ZR 246/98 (*Gemeinkostenanteil*).

¹⁶⁴ BGH (FCJ), Oct. 10, 1991, IX ZR 38/91.

¹⁶⁵ BGH (FCJ), July 12 2011, X ZR 56/09 (*Besonderer Mechanismus*).

¹⁶⁶ BGH (FCJ), Oct. 2, 2018, X ZR 62/16 (*Schneckenkoeder*).

5.7.7 Costs

In Germany, the court costs for infringement proceedings as well as for invalidity proceedings are determined according to the value in dispute.

5.7.7.1 Determination of the value in dispute

The determination of the value in dispute in Germany is at the equitable discretion of the court, Section 3 Code of Civil Procedure, res. Section 51 (1) Court Costs Act (Gerichtskostengesetz, GKG). The amount in dispute shall at first be determined provisionally without hearing the parties and then finally after the conclusion of the proceedings and hearing of the parties. For this reason the statement of claim is to provide information on the value of the subject matter of the litigation wherever such subject matter does not consist of a specific amount of money (Section 253 (3) No. 2 Code of Civil Procedure). This is the case in patent infringement cases where the claimant typically seeks injunctive relief, rendering of accounts, recall/destruction and declaratory entitlement to damages. Where the claimant files these requests, the value of each request has to be determined separately in case separate enforcement of these requests is intended. The request for injunctive relief usually makes up for 80 % of the total sum in dispute and moreover serves as a point of reference to set the value of the other requests. In setting the value for permanent injunctive relief, the court has to make a reasonable prognosis by which the future value of the patent right for the claimant as well as the risk that the monetary realization of such value is endangered by the allegedly infringing act is to be assessed.¹⁶⁷ Elements to be taken into account are the importance of the protected invention, the remaining time of protection, the future risk put at the realization of the monetary value of the invention by the allegedly infringing acts, which may best be assessed on the basis of the unjustified past use, the economic force of claimant and defendant, like existing streams of distribution and manufacturing possibilities, as well as the degree of fault (intent or (gross) negligence) on the side of the defendant.¹⁶⁸ The market value of the patent is of particular importance in determining the amount in dispute. A valuation method for determining the market value is, in particular, the exploitation interest, which can be determined by the possible license fees. To determine potential license rates, there are, for example, catalogues of license fees typical for certain industries. In most cases, the courts will – for lack of better sources of information and knowledge – adopt the sum in dispute as indicated in the statement of claim as long there is mutual consent between the parties that this value adequately reflects the true value of the dispute, except where such sum obviously is set too low. As a rule of thumb the value of small patent infringement cases regularly is set to EUR 250,000–500,000, to EUR 1,000,000–5,000,000, in medium and to more than EUR 10,000,000 in large cases (with a statutory ceiling set at EUR 30,000,000).

For nullity proceedings, a higher amount in dispute is assessed than for infringement proceedings concerning the same patent in dispute. When determining the amount in dispute in nullity proceedings, the FCJ adds a surcharge of 25% to the amount in dispute in the patent infringement proceeding. This is justified by the fact that the infringement action does not yet include the patent owner's interest in using the patent for its own purposes for the remaining lifetime of the patent.¹⁶⁹

5.7.7.2 Calculation of statutory court fees

The Court Costs Act and the corresponding schedule of costs included in an Annex are the relevant law to determine the concrete court fees, which have to be paid in advance to have the claim served on the opponent (Section 12 (1) Court Costs Act). A table of fees determines the amount of the single court fee (1.0) for certain values in dispute. The fee only increases if there is a jump in value. For amounts in dispute of EUR 500,000 or more, these jumps in value occur each time the amount in dispute is increased by EUR 50,000.

Depending on the type of proceedings or the instance, the multiplication factor for the calculation of the fee amount varies. Thus, for infringement proceedings in the first instance a 3-fold fee must be paid, in the second instance a 4-fold fee. For a nullity action, the court fees amount to a 4.5-fold fee in the first instance and a 6.0-fold fee in the second instance.

¹⁶⁷ BGH (FCJ), Nov. 13. 2013 – X ZR 171/12 (*Einkaufskühltasche*).

¹⁶⁸ *Einkaufskühltasche*, X ZR 171/12.

¹⁶⁹ BGH (FCJ), April 12 2011 – X ZR 28/09 GRUR 2011, 757 (*Nichtigkeitsstreitwert I*).

The court costs are to be paid by the plaintiff in advance and are fully refundable, if the plaintiff is successful.

5.7.7.3 Reimbursable lawyer's and patent lawyer's fees

The reimbursable lawyer's fees are the statutory minimum fees for a party's own counsel, which at the same time correspond to what has to be reimbursed to the other side in case of loss. They as well depend on the value in dispute. Higher legal fees that have been agreed upon between client and lawyer that were actually incurred are not recoverable. Most specialized patent lawyers charge more than the statutory minimum fee, so that even the prevailing party has a certain non-refundable cost burden.

The German Lawyers' Fees Act (Rechtsanwaltsvergütungsgesetz, RVG) applies to the calculation of recoverable lawyers' fees in Germany. This is completed by the schedule of fees to the RVG. The simple lawyer's fee (1.0) is determined in exactly the same way as the court fee, on the basis of a table of amounts in dispute. Also in this respect, the fees are leveled in steps of 50,000 (starting at EUR 500,000). The Act stipulates that a fee of 1.3 (or 1.6 in the second instance) can be charged for legal services in a case, and if court hearings take place in the case, an additional fee of 1.2 can be charged.

The German Lawyers' Fees Act is not only applicable to determine the attorney's fees, but also to the patent attorney's fees. Due to the close cooperation of attorneys-at-law and patent attorneys in infringement actions and nullity actions, both attorney's fees and patent attorney's fees are recoverable in each type of proceedings (see Section 143 (3) Patent Act). The only requirement is that the cooperation was indicated in each case. However, the Court of Justice of the European Union (CJEU) recently held in a trademark case that the fees of a patent attorney only have to be reimbursed where these costs incurred by the successful party are reasonable and proportionate, which has to be decided in taking the specific characteristics of the case into due account.¹⁷⁰

Whereas in trademark cases there may be circumstances where a patent lawyer's involvement is not necessary in this sense, the patent lawyer's technical expertise will be unavoidable and therefore refundable in most patent cases. Conversely, it is established case law that the involvement of a lawyer in nullity proceedings is necessary, if there is a simultaneously pending infringement proceeding concerning the patent-in-suit between the identical parties.

5.7.7.4 Cost Example

For a typical patent infringement case where the sum in dispute is set to EUR 1,000,000 and where there is one party on each side the costs according to the above mentioned cost regulations (without costs of taking evidence, translation costs, costs for travel arrangements etc.) are as follows:

	Regional Court	Higher Regional Court	Federal Court of Justice
Court fees	17,643	23,524	29,405
Lawyer Cl.	15,461.08	17,313.55	23,488.46
Lawyer Def.	15,461.08	17,313.55	23,488.46
Patent Att. Cl.	15,461.08	17,313.55	23,488.46
Patent Att. Def.	15,461.08	17,313.55	23,488.46
	79,487.32	92,778.2	123,358.84
Total:	295,624.36 €		

The respective costs for nullity proceedings before the German Patent Court and the FCJ, which are initiated by most defendants in response to an infringement action, will have to be added.

5.8 Enforcement of judgments

5.8.1 Prerequisites of enforcement

Decisions of German courts are not self-enforcing. Therefore, to enforce a decision, the favored party must become active in bringing about the necessary prerequisites. As a general rule, compulsory enforcement requires:

- an enforceable title (e.g., a judgment or court order; Sections 704 and 794 of the Code of Civil Procedure);

170 CJEU, April 28 2022, C 531/20 – NovaTex GmbH v. Ruprecht-Karls-Universität Heidelberg

- (a title) provided with a clause (“enforceable execution copy”; Sections 724 and 725);¹⁷¹ and
- the service of the title on the debtor (Section 750).

Titles for decisions that are appealable and therefore not yet final and binding (*res judicata*) may be provisionally enforceable (Sections 708, 709). In patent infringement proceedings, judgments of lower regional courts are declared provisionally enforceable against the provision of security (e.g., by escrow or bank guarantee),¹⁷² the amount of which is determined in the operative part of the judgment on the basis of the corresponding value in suit (see Section 709).¹⁷³ Decisions of higher regional courts, by contrast, are provisionally enforceable without the provision of security (Section 708(10)).

5.8.2 Violation of cease and desist order (penalty proceedings)

In practice, upon a corresponding petition, any judgment or court order containing an injunction is accompanied by a court warning in the operative part, according to which the defendant shall be subject to penalty measures in case of failure to comply with the cease and desist obligation (see Section 890(2) of the Code of Civil Procedure). Pursuant to Section 890(1), the court of first instance hearing the case, upon request of the creditor, is to sentence the debtor culpably (i.e., at least negligently)¹⁷⁴ violating its obligation to cease and desist. For each count of the violation, the debtor, at the discretion of the court, is sentenced to a coercive fine (up to EUR 250,000)¹⁷⁵ or to coercive detention¹⁷⁶ (up to six months but no more than two years in total).

The scope of the injunction is limited to the actions described as infringing in the operative part. Thus, only if it is apparent from the reasons of the enforced judgment that a variation or modification (in comparison to the infringing embodiment(s)) is also to be regarded as an illegal use of the patent-in-suit does the cease and desist order extend to said variation or modification.¹⁷⁷

The decision on penalties is issued by a court order (Section 891) and can be immediately appealed to the higher regional court within two weeks of service (Sections 793 and 567(1)(1)). The appeal has suspensive effect (Section 570(1)).

5.8.3 Failure to comply with further obligations (coercive measure proceedings)

In accordance with Section 888 of the Code of Civil Procedure, where actions may not be taken by anyone other than the debtor, the court of first instance hearing the case, upon request of the creditor, is to urge the debtor to take the action by levying a coercive penalty payment (up to EUR 25,000 for each violation) or coercive punitive detention (up to six months but no more than two years in total). This manner of enforcement, in particular, relates to the claims for the provision of information and the rendering of accounts (Section 140b of the Patent Act; Sections 242 and 259 of the Civil Code),¹⁷⁸ destruction (Section 140a(1) of the Patent Act) and recall (Section 140a(3) of the Patent Act).

Just as with penalty proceedings, the decision on coercive measures is issued by a court order (Section 891 of the Code of Civil Procedure) and can immediately be appealed to the higher regional court within two weeks of service (Sections 793 and 567(1)). Likewise, the appeal has suspensive effect (Section 570(1)). However, unlike for penalty proceedings, the creditor is responsible for the enforcement.¹⁷⁹

171 Enforcement of decisions in preliminary injunction proceedings usually does not require a clause (secs 936, 929(1) of the Code of Civil Procedure).

172 The security payment serves to secure the debtor's rights to claim its attorney and court fees as well as compensation of enforcement damages (sec. 717(2) of the Code of Civil Procedure) in case a provisionally enforced judgment is reversed or later modified.

173 To cover potential loss of interest, the amount usually equates to between 110 percent and 120 percent of the enforceable value in suit.

174 Which, in practice, is usually assumed.

175 Payable to the district cashier's office.

176 Detention may be ordered against the culpably acting organ of a legal entity (e.g., the legal representative).

177 OLG Düsseldorf (Higher Regional Court of Düsseldorf), June 27, 2012 - I-2 W 14/12; on the “core theory”: OLG Frankfurt aM (Higher Regional Court of Frankfurt am Main), April 26, 2012, 6 U 2/11.

178 Bürgerliches Gesetzbuch (Civil Code), Jan. 2, 2002, BGBl I at 42, 2909, last amended by the Act of Aug. 10, 2021, BGBl I at 3515, art. 1, www.gesetze-im-internet.de/englisch_bgb

179 Even though the fine is payable to the district cashier's office.

5.8.4 Provisional termination of compulsory enforcement

If a provisionally enforceable judgment is appealed, upon a corresponding request by the debtor and appellant, the court may direct a temporary suspension of the enforcement, either against or without provision of security (Sections 719 and 707 of the Code of Civil Procedure). Possible reasons for a suspension, *inter alia*, are that:

- based on a summary examination, it must be assumed that the appealed judgment will not be upheld (obvious incorrectness); or
- according to *prima facie* evidence,¹⁸⁰ the debtor may suffer extraordinary, irreparable damages (exceptional disadvantages); or
- a crucial aspect that raises difficult legal questions was left unexamined in the appealed judgment.

Obvious incorrectness may, for example, be assumed if the legal assessment with regard to infringement, right to sue or the capacity to be sued was evidently erroneous. In addition, the (partial) revocation of the patent-in-suit subsequent to the pronouncement of the appealed judgment can justify the provisional suspension of enforcement.¹⁸¹ Exceptional disadvantages, in particular, include the sufficiently likely possibility that the economic existence of the debtor is threatened by the enforcement. Given that – *a fortiori*, if a security has already been submitted by the enforcing party – the provisional termination of enforcement is the exception to the rule, and due to the fact that the judgment will be examined in the course of the appeals proceedings anyway, the chances of a suspension are generally rather low in practice.

The decision on the question of provisional termination is delivered by court order and is incontestable (Section 707(2)).

5.9 Appellate review

5.9.1 Limited *de novo* appeal

There is an appeal as of right against any final decision of a regional court to be filed with the competent higher regional court as the appellate court (Section 511(1)). Generally, preliminary rulings are not subject to appeal and cannot be “certified” for appeal unless the statute provides for it.¹⁸²

The appellate court is also a “court of record,” so it is not strictly bound by the factual and evidentiary record of the “trial court.” Thus, the appellate court’s competence is not limited to genuine issues of law (Section 513(1)), but it can and must look *de novo* into the facts and can take new evidence if needed (Sections 529(1) and 538(1)).¹⁸³ In 2002, this concept was modified as part of a comprehensive civil procedure law reform:¹⁸⁴ the appellant can now only rely on new facts and evidence if there is a good reason for not having introduced those before the regional court (Section 531). Uncontested facts can, however, never be rejected as late-filed. In light of this reform, it is important to ensure that facts and evidence are submitted at the entry-level court, even if they possibly might not be relevant for the decision at that point (e.g., in light of a certain approach in claim construction).

5.9.1.1 Requirements of the appeal and particulars of appeal

The appeal must be filed within one month following the service of the regional court’s fully worded ruling on the losing party or appellant (Section 517). This is a statutory term that cannot be extended. The appeal is lodged by way of filing a notice of appeal with the appellate court (Section 519(1)). The appellant¹⁸⁵ must provide “particulars of the appeal” (substantiating the basis for the appeal), which need to be filed within two months following the service of the decision (Section 520(2)). Without the appellee’s consent, that term can be extended by the

180 Sec. 294 of the Code of Civil Procedure.

181 BGH (FCJ), Sep. 16, 2014, X ZR 61/13 (*Kurznachrichtendienst*).

182 Regarding the admissibility of the preliminary ruling, an intermediate decision (“Zwischenurteil”) may be given, which may be appealed; cf. sec. 280.

183 A limitation to genuine issues of law only exists with regard to the further appeal/cassation (“Revision”) (sec. 545(1)).

184 Zivilprozessreformgesetz (Civil Procedure Reform Act), July 27, 2001, BGBl. I 1887.

185 In some translations, this is also referred to as the “plaintiff in the appeal.”

presiding judge by up to one month.¹⁸⁶ The extent to which the judgment is being contested must be set forth in the particulars, as well as a specific petition (request) as to how the judgment is to be modified. If the appellant has only lost in part, the judgment can only be contested to the extent the appellant's requests were dismissed by the lower court. In such a scenario, both parties can appeal the decision.

5.9.1.2 Cross-appeal

If only one party files an appeal in time, the other party – that is, the appellee (“defendant in the appeal”) – can file a cross-appeal (Section 524). Such a cross-appeal must be filed within the appellee's term for filing a response to the appeal (“statement of defense in the appeal”; cf. Section 524(2)). This term is important for the plaintiff that won before the regional court and wants to extend the claims on appeal (“modification of the suit filed” on appeal; cf. Section 533) because this is only possible by way of cross-appeal as this requires modifying the requests that were affirmed by the lower court. Such scenarios can, for example, arise if a further patent is to be added to the previous patent-in-suit. Such a claim extension through the introduction of a further patent-in-suit (and corresponding further requests) is also possible on appeal, even in the absence of the defendant's consent, if it serves judicial economy. Indeed, it can even be required for a plaintiff under Section 145 of the Patent Act to add a related patent if there is a significant overlap in the features of the claims and the pertinent characteristics of the accused device relevant for infringement.¹⁸⁷ A cross-appeal can only be directed against the appellant and not against a third party. Thus, it is not possible to add another defendant to the action even though this is possible under the general doctrine of claim modification (Sections 263 and 533).

5.9.1.3 Appeal process

The structure of the proceedings before the appellate court is similar to that of the proceedings before the lower court (Section 525). Thus, there is typically a further reply and rejoinder brief and only one final hearing unless the taking of evidence becomes necessary. With regard to the taking of evidence, the appellate courts are generally more prone than the lower courts to take expert evidence in complex matters. The structure of the hearing is also similar. Different from the practice of the regional courts, the appellate courts typically rule on the day of the hearing. While a remand to the lower court is possible, this is the exception and limited to certain cases in which the lower court only ruled on admissibility or in which the proceedings before the court of first instance were subject to a material irregularity (Section 538(2)). The general rule is that the appellate court decides “on the matter as such,” – that is, it makes a full decision on the merits of the case (Section 538(1)). This decision can be a judgment dismissing the appeal or affirming the appeal in modifying the judgment based on the appellant's specific petitions (requests). It can also partially dismiss or affirm the appeal in that manner. The decision, however, does not need to be a judgment. It can also be an order for evidence or an order to stay the proceedings pending a nullity action. The appellate court generally exercises its discretion to stay the proceedings pending the nullity action or opposition against the patent in the same way as the court of first instance.

If, however, the plaintiff prevailed before the regional court – so that the plaintiff is the defendant in the appeal and therefore disposes of an enforceable injunctive relief – the appellate court ought to lower the standards for staying the case.¹⁸⁸ The difference in this approach becomes clear when focusing on the consequences of enforcing an injunction that is subsequently reversed. If a first-instance decision granting permanent injunctive relief is reversed by an appellate judgment, the plaintiff is liable for damages the defendant suffered by the judgment being enforced (Section 717(2)). This is not the case for the enforcement of any relief granted or affirmed by an appellate judgment. The obligation of the plaintiff to reimburse the defendant in these cases is only determined by the rules of unjust enrichment, not damages (Section 717(3)).

5.9.1.4 Motions for a provisional termination of the enforcement of injunctive relief pending appeal

Motions for a provisional termination of the enforcement of injunctive relief have become practically very important in patent infringement matters. Injunctive relief is a relief as of right, so

¹⁸⁶ This limitation does not apply if the appellee agrees with the extension. Otherwise, this is the only non-statutory term for which such a limitation is provided for in the Code of Civil Procedure. Other terms can be extended for more and multiple times provided that the opponent is given a chance to comment on the request for a further term extension; cf. sec. 225(2).

¹⁸⁷ BGH (FCJ), Jan. 25, 2011, X ZR 69/08 (*Raffvorhang*).

¹⁸⁸ OLG Karlsruhe (Higher Regional Court of Karlsruhe), Feb. 11, 2015, 6 U 160/13; OLG Düsseldorf (Higher Regional Court of Düsseldorf), Dec. 21, 2006, I-2 U 58/05.

the court of first instance (even under the recently amended law), once infringement has been ascertained, does not have a general discretion with regard to ordering injunctive relief. Thus, injunctive relief is still the rule. However, the defendant can, upon filing the notice of appeal, turn to the appellate court requesting that the enforcement of the injunction be provisionally stayed (pending appeal; cf. Section 719(1)). This remedy has been frequently used by defendants in patent infringement matters. While originally such provisional terminations were absolutely exceptional, over the last decade, the appellate courts have been more prone to step in. This requires a determination that, based on a *prima facie* analysis, there are sufficient prospects for the appeal.¹⁸⁹ Furthermore, it requires balancing the equities of the matter in terms of weighing the plaintiff's interests in enjoining the defendant against the potentially irreversible harm inflicted on the defendant when enforcing the injunction. Thus, genuine equitable considerations that are typically considered in the Anglo-American system when making the decision whether to grant the injunction can be accommodated in the German system in connection with such a stay motion filed with the appellate court. However, one must bear in mind that notwithstanding the appellate courts' increased awareness and sensitivity in this regard, such provisional terminations are still the clear exception. The plaintiff's interest in enforcing the injunction generally outweighs that of the defendant, and the defendant is protected by way of the security bond that the plaintiff had to post to make the judgment enforceable pending appeal.

5.9.2 Further appeal on points of law (cassation)

A further appeal on points of law ("Revision") may be filed against a judgment delivered by the appellate court on fact and law in proceedings on the merits. In preliminary proceedings, a further appeal on points of law is not admissible.

A request for a further appeal on points of law may be filed with the FCJ, which has its seat in Karlsruhe. The FCJ is Germany's highest court with regard to civil and criminal jurisdiction, including patent infringement matters. The function of the FCJ as a cassation court is to ensure uniform application of the law, clarify fundamental points of the law and develop the law.

In proceedings on a further appeal on points of law, including those in patent infringement matters, no fact-finding will be undertaken. Rather, the FCJ will confine itself to reviewing the legal assessment of a case by the lower courts. The facts established by these courts are binding on the FCJ unless such findings are affected by a procedural error at the lower court indicated in the statement of grounds for the appeal.

In light of the double-track system in German patent litigation as explained above, it must be noted that, even though the FCJ is also Germany's highest court in patent nullification proceedings, its role in these particular proceedings is exceptionally not that of a cassation court but rather that of an appellate court. Accordingly, from a judgment of the FPC, an appeal ("Berufung") can be filed with the FCJ, not a further appeal on points of law ("Revision"). And, in the appeal proceedings, different from cassation proceedings, fact-finding can be undertaken to a limited extent (limited *de novo* appeal), as explained more in detail below.

5.9.2.1 Admission and grounds for admission for a further appeal on points of law

The request for a further appeal on points of law requires admission. A further appeal on points of law may be admitted by the appellate court; or on a complaint against the refusal of the appellate court to grant leave to such an appeal, by the FCJ. Admission or leave may only be granted if a ground for admission is to be affirmed. Grounds for admission are that

1. the legal matter is of fundamental significance; or
2. the further development of the law or the interests in ensuring uniform adjudication require a decision to be handed down by the court hearing the appeal on points of law.¹⁹⁰

A legal matter is of fundamental significance when it can be expected to arise in a number of cases and therefore concerns the abstract interest in uniform application of the law. According to

¹⁸⁹ OLG Karlsruhe (Higher Regional Court of Karlsruhe), April 9, 2015, 6 U 168/14; OLG Düsseldorf (Higher Regional Court of Düsseldorf), July 1, 2009, I-2 U 51/08.

¹⁹⁰ Sec. 543(2).

the case law of the Federal Constitutional Court, infringements of a fundamental procedural right – in particular, infringements of the right to be heard (Article 103(1) of the Basic Law) – even if they are in issue only in a single case, are considered to be of fundamental significance and, thus, a ground for admission.¹⁹¹

The further development of law is of concern when, in view of general (e.g., technical) developments, there is reason to provide guiding principles for the interpretation of the law. The interests in ensuring uniform adjudication require a decision from the FCJ when appellate courts disagree in the interpretation of the law or when an appellate court deviates from the interpretation of the law as decided by the FCJ in a symptomatic way.¹⁹²

To harmonize irreconcilable interpretations of patent claims in parallel infringement and nullification proceedings, the FCJ decided in 2010 that a ground for admission is also given when the FCJ has based its decision in nullification appeal proceedings on an interpretation of the patent claim that deviated, in a point relevant to the decision in parallel patent infringement proceedings, from the interpretation on which the appellate court had based its judgment and which was challenged in a complaint against denial of leave to a further appeal on points of law.¹⁹³

5.9.2.2 Complaint against the refusal of the appellate court to grant leave

The appellate court must always decide whether leave to an appeal on points of law is to be granted. If the decision is negative, the party adversely affected by the decision may file a complaint, provided the value of the adverse effect amounts to more than EUR 20,000 (Section 544(2)), which is regularly the case in patent infringement litigation. The opposite party will be given the opportunity to be heard in writing. The complaint suspends the judgment from becoming final and binding. The FCJ will decide on the complaint by order. In most cases, reasons are not given. If the complaint is rejected, the judgment becomes final and binding. If the complaint is successful, the proceeding will be continued as appellate proceedings on points of law. The complaint may also be partially successful and partially rejected.

When an action for nullification of the patent that is found to be infringed by the appellate court is still pending before the FPC or, upon appeal, before the FCJ, the FCJ in proceedings on the complaint against the refusal of the appellate court to grant leave may decide to stay proceedings until a final decision in the nullification proceedings has been rendered, provided there is a risk of irreconcilable decisions in the parallel infringement and nullification proceedings.¹⁹⁴ This is of relevance in the following two scenarios.

First, the appellate court finds a patent to be infringed and refuses to grant leave. However, later, the FPC or the FCJ nullifies the patent in whole or in the parts relevant for the decision of the appellate court on infringement. If the defendant in the infringement case files a complaint against the refusal of the appellate court to grant leave, and the FCJ stays proceedings, proceedings could be continued after the final decision in the nullification proceeding. If the patent is nullified in the final decision in whole there, the basis for the appellate court (that the patent is infringed) has fallen away, and the plaintiff will normally withdraw the infringement action. If not, proceedings on appeal on a point of law will be continued, the decision of the appellate court will be set aside, and the action for infringement will be dismissed by the FCJ. If the patent has been nullified in the final decision only in part, proceedings will also be continued, and the case will be remitted to the appellate court if further fact-finding is necessary to decide on infringement. But, even if the defendant in the infringement proceedings had not filed a complaint against the refusal of the appellate court to grant leave, they may file an action for retrial (“Restitutionsklage”) pursuant to Section 580(6) within one month after the day on which the defendant became aware of the final judgment by which the patent had been nullified.¹⁹⁵

Second, the appellate court finds a patent to be infringed after having given a broad interpretation to the patent and refused to grant leave. Later, the FCJ dismisses the action for

191 BVerfGE (Federal Constitutional Court), April 30, 2000, 1 PBvU 1/02.

192 BGH (FCJ), May 29, 2002, V ZB 11/02; BGH (FCJ) Oct. 1, 2002, XI ZR 71/02.

193 BGH (FCJ), June 29, 2010, X ZR 193/03 (*Crimpwerkzeug III*).

194 BGH (FCJ), April 6, 2004, X ZR 272/02 (*Druckmaschinen-Temperierungssystem*); BGH (FCJ), Sep. 28, 2011, X ZR 68/10 (*Klimaschrank*).

195 BGH (FCJ), July 29, 2010, Xa ZR 118/09 (*Bordako*); BGH (FCJ), April 17, 2021, X ZR 55/09 (*Tintenpatrone III*). The former case concerns a plant variety right and the latter case concerns the revocation of a European patent by an EPC board of appeal.

declaration of nullification of the patent on the basis of an interpretation of the patent claim that deviates from the understanding of the appellate court in a way relevant for the decision in the infringement litigation (e.g., by interpreting the patent narrowly). If the defendant in the infringement case files a complaint against the refusal of the appellate court to grant leave, and the FCJ stays proceedings, proceedings can be continued after the final decision in the nullification proceeding has been rendered in order to reconcile the claim interpretation in the infringement case with the claim interpretation in the nullification case.¹⁹⁶ However, in contrast to the first scenario, filing an action for retrial ("Restitutionsklage") would not be available where there is a lack of ground for retrial ("Restitutionsgrund").

5.9.2.3 Requirements for a further appeal on law

Like the appeal, the request for a further appeal on law must be filed within one month following the service of the regional court's fully worded ruling on the losing party or appellant (Section 548). This is a statutory term that cannot be extended. The appeal is lodged by way of filing a notice of appeal with the FCJ (Section 549(1)). The appellant must provide "particulars of the request" (substantiating the basis for the request), which need to be filed within two months following the service of the decision (Section 551(2)).

The further appeal on points of law may only be based on an erroneous application of the law by the contested decision (Section 545). This is the case when a legal norm has not been applied or has not been applied properly (Section 546). In particular cases enumerated in Section 547 (e.g., the composition of the court was not compliant with the law, or there was a violation of the rules regarding public admission to the oral hearing), it is to be presumed irrefutably that the decision has been based on an erroneous application of the law.

5.9.2.4 Proceedings and decision

The structure of proceedings before the FCJ has many similarities with the proceedings before the lower courts (Section 555). However, there is typically just one round of briefings (reasoning of the appeal and reasoning of defense), since only those party submissions that are apparent from the appellate judgment or the record of the session of the court are subject to assessment by the court. Moreover, with regard to an erroneous application of procedural law, the FCJ will take solely those facts that were put forward into account in order to show these irregularities. As mentioned already, no fact-finding will be undertaken, and the court will only review the legal assessment of the case by the lower courts.

The case is heard by a bench of five judges who have a legal background. Many of them have gained experience in patent litigation as judges in the lower courts. At the beginning of the hearing, the presiding judge summarizes the facts and gives a preliminary assessment of the case based on deliberations the court had prior. This is followed by pleadings of party representatives. The judges may and often will ask questions to the representatives. A typical hearing in a patent infringement case takes between one and two hours. After the hearing, and possibly also other hearings in different cases that were scheduled the same day, the court will deliberate again and will typically rule on the same day but provide reasons later.

The decision depends on the assessment of the further appeal on points of law. The FCJ will dismiss the appeal when the reasoning of the appellate court's judgment does not contain an error of law or does contain an error of law but is correctly based on other grounds (Section 561). The appellate court's judgment will be set aside to the extent the appeal on points of law is justified (Section 562), and the matter will be remitted to the appellate court, which, once again, is to hear and decide on it (Section 563(1)) while being bound to the legal assessment of the FCJ to the extent that the reversal of the appellate judgment is based on it (Section 563(2)). The FCJ will decide and not remit the matter if the appellate court's decision must be set aside because the further appeal on points of law was justified, but the matter is ready for a final decision based on the facts established by the appellate court.

5.10 Border measures

Border seizures are generally possible in Germany. However, seizures at the German land borders (under Section 142a of the Patent Act) normally do not take place because Customs, in general,

¹⁹⁶ *Crimpwerkzeug III*, X ZR 193/03; BGH (FCJ), Dec. 14, 2010, X ZR 193/03 (*Crimpwerkzeug IV*).

does not control borders between member states of the EU and those of the Schengen Area (which includes Switzerland in particular), and Germany borders solely with member states of the Schengen area. Border seizures are therefore primarily relevant with regard to imports and exports via German airports and harbors from or to countries not part of the Schengen area and at the EU's external borders. The basis for such seizures is Regulation (EU) 608/2013.¹⁹⁷ According to Article 1(1), within the scope of the Regulation are, in particular, the following especially relevant seizure situations: the release of goods for free circulation, the transfer of goods into or out of the customs territory of the EU, and the transfer of goods into a free zone or free warehouse.

Seizure proceedings are initiated by filing an application with the competent customs department of the member state. The competent agency for applications in Germany is the Federal Finance Directorate Southeast ("Bundesfinanzdirektion Südost"), based in Munich. The application is to be made either on a case-by-case basis or for a maximum of one year during which time the customs authorities are to take action (Article 11(1)–(2)) and needs to provide information regarding the applicant and the patent that is to be enforced according to Article 11(3). The application must also substantiate how to identify the infringing devices and why there is a plausible case of infringement; otherwise, seizures are not practically possible. This is typically a limiting factor, because the agency dealing with the applications is not equipped to determine issues of patent infringement (let alone validity). Thus, some sort of *prima facie* plausibility is needed to allow this determination and also enable the identification of the pertinent devices. This is facilitated if standard essential devices are at issue (e.g., "mp3 players"), and a number of court decisions corroborating the showing of infringement of the patent named in the application are already available.

If the application is successful, goods will be seized in each case if there is an indication of an infringement of the patent. After potentially infringing devices have been seized, the proprietor, as well as the holder of the goods, will be informed (Article 17(3)–(4)). The patent holder is given the possibility to inspect the seized devices (Article 19). If the patent holder, after inspection and examination, has confirmed the infringement, and the patent holder and goods holder agree within 10 working days, the goods will be destroyed (Article 23(1)). If the proprietor does not provide both their agreement with the destruction and their confirmation of infringement in due time, the goods will be released (Article 23(1)). If the holder of the goods opposes the destruction (which is the practically relevant case), the proprietor needs to file an infringement proceeding (Article 23(3)) within 10 working days. An action for preliminary relief is also suitable in this regard. Otherwise, the goods will be released (Article 23(4)). The holder of the goods may request early release according to Article 24.

5.11 Selected topics

5.11.1 Action for the grant of a compulsory license

5.11.1.1 Grounds for applying for a compulsory license

A compulsory license is the nonexclusive right to commercially use a granted patent. This license is not granted voluntarily by the patent proprietor but by the FPC upon request of the license seeker. The prerequisites for granting a compulsory license by a court are set out in the German Patent Act and require, first of all, that the license seeker has, within a reasonable period of time, unsuccessfully attempted to obtain the patent proprietor's permission to use the invention on reasonable terms and conditions. The primacy of the unsuccessful licensing attempts is the consequence of granting a compulsory license being an *ultima ratio*: the patent proprietor must only be forced to grant a license if they have refused to grant a license – at all or on reasonable conditions – even though a license would be required to satisfy superior interests. The superior interests that constitute grounds for granting a compulsory license are set out in Section 24 of the Patent Act.

The most important ground is the public interest calling for the grant of a compulsory license (cf. Section 24(1) of the Patent Act) – in particular, public health and public security are considered to be relevant public interests. A special form of the public interest is codified in Section 24(5) of

¹⁹⁷ Regulation (EU) No 608/2013 of the European Parliament and of the Council of 12 June 2013 concerning customs enforcement of intellectual property rights and repealing Council Regulation (EC) No 1383/2003, 2013 OJ (L 181), 15.

the Patent Act, according to which a compulsory license may be granted to ensure an adequate supply of the patented product on the German market if the patented invention is not (predominantly) used in Germany. The mere existence of a public interest per se does not, however, justify the grant of a compulsory license. Rather, it is necessary to consider the particular circumstances of a specific case and to balance the interests at issue. Only if this results in the public interest overruling the patent proprietor's interest in maintaining their monopoly position may a compulsory license be granted. Pursuant to established FCJ case law, a public interest in the granting of a compulsory license is to be affirmed if a medicament for the treatment of a serious disease has therapeutic properties that medicaments available on the market do not have or do not need to the same extent, or if its use avoids undesirable side effects that would need to be accepted if other medicaments were administered.¹⁹⁸

According to Section 24(2) of the Patent Act, a compulsory license may also be granted for a patent that hinders the holder of a patent with a later filing or priority date to exploit their invention because making use of said patent infringes the older patent (i.e., the patent with an earlier filing or priority date). In this situation, it is further required that the invention protected by the younger patent demonstrates an important technological advance of substantial economic significance compared to the invention claimed by the older patent. In situations covered by Section 24(2) of the Patent Act, the patent proprietor may, in return, request the grant of a cross-license for the use of the invention protected by the younger patent.

The provision of Section 24(2) of the Patent Act also applies to cases where a plant breeder cannot obtain or exploit a patented variety without infringing an older patent. Granting a compulsory license for a patent claiming an invention in the field of semiconductor technology is only possible when the license is necessary to eliminate the anticompetitive practices pursued by the patent proprietor that have been established in court or administrative proceedings (cf. Section 24(4) of the Patent Act).

5.11.1.2 Scope of a compulsory license

By means of a compulsory license, the license seeker is given a nonexclusive right (not duty) to commercially use an invention protected by a granted patent. The right is limited to the purpose for which it has been granted and may also be subject to further conditions and limitations. For example, it may be required that a notice concerning the patent covered by the compulsory license be attached to the product, or the compulsory license may only be granted for certain claims of the patent, be limited to certain activities (e.g., dosage forms of a medicament)¹⁹⁹ or contain timewise or geographic constraints. Further, the grant of a compulsory license may be made dependent on a security bond to be provided by the license seeker.

Since the grant of a compulsory license does not establish an ordinary license agreement, the parties do not need to act like normal parties to a license agreement. The patent proprietor only must tolerate the use of their patent; they are not precluded from exploiting the patent as they like and are not obliged to maintain or defend the patent. Moreover, they do not need to warrant that the invention is feasible or suitable for the intended purpose, and they also do not need to provide know-how required for the use of the invention. Obviously, the license seeker must pay license fees for their right to use the invention in an amount determined by the court considering the circumstances of the specific case, which include, *inter alia*, the economic value of the right to use the invention. The license seeker is allowed to challenge the patent's validity by filing a revocation action or an opposition. Contrary to a normal nonexclusive license, a compulsory license could also be granted for a patent for which an exclusive license has already been granted.

A compulsory license is bound to the business that makes use of the invention for which the compulsory license was granted and can only be assigned in combination with said business; assigning only the compulsory license is not possible.

The duration of the compulsory license may be set by the FPC either directly or by means of a resolutive condition. If no duration has been set, the patent proprietor can request that the FPC withdraws the compulsory license if the prerequisites for its grant are no longer met. The compulsory license ends *ipso iure* when the patent expires.

¹⁹⁸ *Raltegravir*, X ZB 1/17, 2018 IIC 94; BGH (FCJ), June 4, 2019, X ZB 2/19 (*Alirocumab*).

¹⁹⁹ BPatG (FPC), Aug. 31, 2016, 3 LiQ 1/16 (EP) (*Isentress*).

5.11.1.3 Procedural aspects

5.11.1.3.1 Proceedings on the merits

The proceedings on the merits concerning a compulsory license follow the same rules and are handled by the same courts as set out above with regard to the revocation proceedings (cf. Section 5.4.1.1). The subject matter of the action can be the grant, the adaptation or the withdrawal of a compulsory license; the parties to the proceedings are the patent proprietor as licensor and the license seeker.

When filing a complaint for the grant of a compulsory license, the license seeker does not need to specify the conditions of the requested compulsory license. If, at the time of filing the action for the grant of a compulsory license, the license seeker has not yet sufficiently attempted to obtain a license on reasonable conditions, they can continue their efforts during the proceedings. If their attempts were successful, and a license agreement is concluded after the action for the grant of a compulsory license has been filed, the action may be withdrawn or, alternatively, the plaintiff or both parties may submit a declaration that there is no need to adjudicate (*“einseitige oder übereinstimmende Erledigungserklärung”*).

A judgment granting a compulsory license does not oblige the patent proprietor to enter into a license agreement but directly establishes the license seeker's right (yet not their duty) to use the patented invention and their obligation to comply with the conditions set out in the judgment (in particular, paying license fees). Like in revocation proceedings, the costs will usually be imposed on the losing party or, in a case where both parties declared that there was no need to adjudicate (*“übereinstimmende Erledigungserklärung”*), the party that would have lost, unless equity requires otherwise: Section 81(1) and 84(2) of the Patent Act and the applicable rules of the Code of Civil Procedure.

5.11.1.3.2 Summary proceedings

If an action for the grant of a compulsory license is pending, the license seeker may additionally initiate preliminary injunction proceedings directed at the grant of a compulsory license; it is, however, not possible to request a preliminary injunction if no proceedings on the merits are pending. The request for a preliminary injunction must be filed with the FPC, which must schedule an oral hearing that is prepared by written statements of the parties and after which a judgment will be rendered. The judgment will have the same effect as the judgment in the proceedings on the merits (cf. Section 5.11.1.3.1).

A preliminary injunction is granted if the license seeker substantiates (not proves) that the material requirements for the grant of a compulsory license are met and that there is an urgent need in the public interest for the immediate grant of the compulsory license. The threshold for the latter requirement is rather high and only met if an immediate decision is required to avert severe disadvantages from the public were the outcome of the proceedings on the merits to be awaited. In recent times, a preliminary injunction has been issued only once in a compulsory license case.²⁰⁰ The preliminary injunction is dependent on the proceedings on the merits. Thus, if the complaint is withdrawn or dismissed, the effect of the preliminary injunction ceases.

The grant of a compulsory license by way of a preliminary injunction may be dependent on a security bond to be provided by the license seeker in order to cover potential damages of the patent proprietor. Another security bond may need to be provided by the license seeker for the enforcement of the nonfinal judgment granting the compulsory license. This must be considered carefully: if preliminary injunction proceedings are initiated, and a nonfinal judgment is enforced because the grant of a compulsory license by way of a preliminary injunction proves unjustified from the outset, or if the judgment is lifted later on, the license seeker must compensate the patent proprietor for any damages arising therefrom.

5.11.1.3.3 Appeal

Against the judgment – both in proceedings on the merits and in preliminary injunction proceedings – an appeal with the FCJ can be filed. The appeal proceedings are very similar and basically follow the rules set out above for the appeal in revocation proceedings.

200 Issued in *Raltegravir*, X ZB 1/17; denied in *Alirocumab*, X ZB 2/19.

Chapter 6

India

Authors:

Justice Madan B. Lokur (ret.), Justice Gautam Patel, Justice Prathiba M. Singh and Justice Manmohan Singh (ret.)

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6.1 Overview of the patent system

6.1.1 Evolution of the patent system

Intellectual property (IP) rights are governed by national law, which for members of the World Trade Organization (WTO), shall be in conformity with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).¹ The TRIPS Agreement sets out the objective of IP rights in Article 7:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

As a member-nation of the WTO, India was required to amend or enact laws to conform to the TRIPS Agreement. However, this was a challenge for India. A significant reason was that, unlike many other countries, such as the United States of America (U.S.), where the Constitution *recognizes* the promotion and progress of science and arts and *secures* exclusivity granted to authors and inventors, the Constitution of India only *encourages* Indian citizens to have a scientific temper and prescribes a duty to *develop* the spirit of inquiry and reform.² The Constitution of India mandates that no one shall be deprived of “property” except with the authority of law.³ Since patents are “property,” there is a positive constitutional entitlement to the grant and recognition of patents. The non-enforceable – but critical – chapter of the “Directive Principles of State Policy” in the Constitution of India further directs the Government to ensure the promotion of public health,⁴ the reduction of inequalities⁵ and the securing of systems that ensure ownership and control of resources for the common good.⁶ The basis and limitations for IP rights are, therefore, the right to property, the directive principles of state policy and the fundamental duties of citizens, apart from the various laws enacted periodically.

The journey of the Indian patent regime is reflected in three different periods: colonization, post-independence and globalization.⁷

Colonization. India inherited its patent regime from the British rule. When the British colonization of India ended, the Indian Patents and Designs Act, 1911, was in force and had created a system of patent administration in India under an administrative office – the Controller of Patents and Designs.

Post-independence. India enacted its first independent patent law in 1970. It came in the backdrop of two committees constituted to make recommendations: the Bakshi Tekchand Committee in 1949 and, later, the Justice Rajagopal Ayyangar Committee. Focusing on the special socioeconomic conditions in India, the recommendations of these two committees resulted in far-reaching changes in patent laws. Some of the significant changes introduced were with respect to food and drug patents, compulsory licensing, and connected working requirements. The law enacted in 1970 is credited with the growth of various industries, including the pharmaceutical industry, which, in two decades, gave India the distinction of being called “the pharmacy of the world” as Indian drug companies began exporting reasonably priced medicines to many countries.

Globalization. In 1991, India liberalized its economy and adhered to the General Agreement on Tariffs and Trade (GATT 1947), which was succeeded by the WTO, resulting in amendments being introduced in line with the TRIPS Agreement. These amendments saw India bring about fundamental changes permitting product patents in food, medicines and agrochemicals. The

1 Trade-Related Aspects of Intellectual Property Rights, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, annex 1C, 1869 UNTS 299.

2 India Constitution, art. 51A(h).

3 India Constitution, art. 300A.

4 India Constitution, art. 47.

5 India Constitution, art. 38(2).

6 India Constitution, art. 39(b).

7 Janice M Mueller, “The Tiger Awakens: The Tumultuous Transformation of India’s Patent System and the Rise of Indian Pharmaceutical Innovation,” 68 Univ. Pitt. L. Rev. (2007), <https://ssrn.com/abstract=923538>

flexibilities in the TRIPS Agreement were used to maintain a balance: ensuring that the amendments would be gradually made systemic rather than forcing the closure of already-functioning industries. Statutory provisions relating to chemical and drug patents, patentability and other aspects of the amendments were tested repeatedly in the courts and were upheld as being within the Constitutional scheme while being fully compliant with the TRIPS Agreement. The judgment of the Supreme Court in *Novartis v. Union of India*⁸ recognized the need to curb the “evergreening” of patents while acknowledging the need to grant patent protection to incremental innovations. After *Novartis*, Indian courts have granted interim injunctions to protect patentees’ rights in pharmaceutical⁹ and agrochemical inventions.¹⁰ The courts have also protected claims to standard-essential patents (SEPs) by granting interim injunctions to secure the patentee’s right to royalties even pending trial.¹¹ Courts have granted permanent injunctions¹² and damages (in quite significant amounts)¹³ in cases of patent infringement and have also denied interim injunctions in appropriate cases.¹⁴ Each case has been decided on its own facts on the basis of settled legal principles. A current review of decisions would show no pro- or anti-patentee bias in the adjudication of patent cases.

6.1.2 The Justice N Rajagopala Ayyangar Committee Report

In 1957, the Government of India appointed a committee led by a distinguished retired Justice of the Supreme Court of India, Justice N Rajagopala Ayyangar, to examine the revision of the Patents Act and advise the Government in this respect.

The Justice N Rajagopala Ayyangar Committee report stated, in no uncertain terms, that the patent system was a quid pro quo system: the monopoly that a patentee obtains is only in exchange for the disclosure of the invention to the public, free to be used after the monopoly period is over. The quid pro quo, according to the report, also included the obligation on the part of the patentee to work the invention in India. The report also underscored, rather emphatically, that the patent system had failed in India because it had failed to spark the kind of innovation that it sought to encourage – underdeveloped countries could not yield the same result from the patent system as their more developed counterparts could. The patent system was recommended to be continued only because there was no better alternative to achieve better results – in their form at the time, patents were the lesser evil. The report was unequivocal in its apprehension that foreign patentees could misuse the patent system to capture large markets in India at the cost of domestic innovation while simultaneously not investing in the manufacture of the patented product.

The committee’s recommendations were a catalyst for wide changes in Indian patent law, eventually leading to the Patents Act of 1970, replacing the Indian Patents and Designs Act, 1911. The Patents Bill was introduced in 1965 and amended in 1967. The Patents Act, 1970, and Patents Rules, 1972 came into force on April 20, 1972.

6.1.3 The Patents Act, 1970 (pre-TRIPS Agreement)

The Patents Act, 1970, incorporated major provisions to reduce the social costs of foreign-owned patents. It prohibited patents on products useful as medicines and food, shortened the term of chemical process patents, and significantly expanded the availability of compulsory licensing. This spawned a powerful Indian pharmaceutical generic drugs industry.

8 AIR 2013 SC 1311.

9 E.g., *Merck Sharp and Dohme Corp. v. Glenmark Pharmaceuticals*, 2015 SCC Online Del. 8227; *Cipla Ltd v. Novartis AG*, 2017 SCC Online Del. 7393; *Symed Labs v. Glenmark Pharma Ltd*, 2015 SCC Online Del. 6745.

10 E.g., *UPL Ltd v. Pradeep Sharma*, 2018 SCC Online Del. 7315.

11 E.g., *Koninklijke Philips NV v. Amazestore*, 260 (2019) DLT 135; *Telefonaktiebolaget LM Ericsson (Publ.) v. Intex Technologies (India) Ltd*, 2015 SCC Online Del. 8229 (a final decree concerning SEPs); *Koninklijke Philips NV v. Vivo Mobile Communications Co. Ltd*, CS (COMM) 383 of 2020; *Koninklijke Philips NV v. Xiaomi Inc.*, CS (COMM) 502 of 2020.

12 E.g., *Shogun Organics Ltd v. Gaur Hari Guchhait*, 263 (2019) DLT 516; *Eisai Co. Ltd v. Satish Reddy*, 2019 SCC Online Del. 8496.

13 E.g., *F Hoffmann-La Roche Ltd v. Cipla Ltd*, MIPR 2016 (1) 1; *Koninklijke Philips*, 260 DLT; *Shogun Organics*, 263 DLT (damages were awarded in the sum of about USD 25 million).

14 E.g., *AstraZeneca AB v. Intas Pharmaceuticals Ltd*, MANU/DE/1939/2020; *B Braun Melsungen AG v. Rishi Baid*, MANU/DE/0376/2009; *Arif Abdul Kader Fazlani v. Hitesh Raojibhai Patel and Co.*, MANU/GJ/1304/2011; *F Hoffmann-La Roche Ltd v. Cipla*, 159 (2009) DLT 243 (DB).

In *Bishwanath Prasad Radhey Shyam v. HM Industries*,¹⁵ deciding an appeal in a case for infringement of a patent called “Means for Holding Utensils for Turning Purposes,” the Supreme Court said:

The object of the patent law is to encourage scientific research, new technology and industrial progress. Grant of exclusive privilege to own, use or sell the method or the product patented for the limited period, stimulates new inventions of commercial utility. The price of the grant of the monopoly is the disclosure of the invention at the Patent Office, which after the expiry of the fixed period of the monopoly passes into public domain.

The salient features of the Act (as enacted) were:

- the reduction of the term of patent from 16 to 14 years;
- a maximum of seven years for the term of a patent for the processes for drugs and foods;
- no product patents available for food, drugs and medicines, including the products produced or obtained by chemical processes;
- provisions prescribing nonworking as a ground for the grant of compulsory licenses, licenses of right and the revocation of patents;
- the empowerment of government to use inventions for its own use;
- provisions for the use of inventions for government purposes, research or instruction to pupils;
- the endorsement of a “license of right” to patents related to drugs, foods and products of chemical reactions;
- the codification of certain inventions as non-patentable;
- the expansion of the grounds for opposition to the grant of a patent;
- exemption from anticipation in respect of certain categories of prior publication, prior communication and prior use;
- provisions for the secrecy of inventions relevant for defense purposes;
- the mandatory furnishing of information regarding foreign applications;
- the prevention of abuse of patent rights by voiding restrictive conditions in license agreements and contracts;
- a provision for appeal to the High Court from decisions of the Controller General of Patents, Designs and Trade Marks (“the Controller”); and
- the separation of industrial designs from the law of patents.

However, many provisions changed after the TRIPS Agreement, as discussed in Sections 6.1.4.4.3 to 6.1.4.4.5.

6.1.4 International obligations and commitments

India is a member of the WTO, which came into being on January 1, 1995. The WTO administers the General Agreement on Tariffs and Trade (GATT),¹⁶ which is an international agreement among countries to promote free international trade in goods. The WTO is a package deal in that its members must abide by the GATT agreement and a series of other international agreements. One such agreement is the TRIPS Agreement. India is also a member of the Paris Convention for the Protection of Industrial Property,¹⁷ the Patent Cooperation Treaty (PCT),¹⁸ as well as the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.

6.1.4.1 The TRIPS Agreement

TRIPS is one of the most comprehensive multilateral agreements on intellectual property rights.

Section 5 of TRIPS deals with patents. Article 27(1) of TRIPS provides that patents will be available for products or processes of inventions in *all* fields of technology, provided they are new, involve an inventive step and are capable of industrial application. This was a departure from what the Patents Act, 1970 allowed at the time since no patents were allowed for “substances intended for

15 AIR 1982 SC 1444, para. 17.

16 General Agreement on Tariffs and Trade, Oct. 30, 1947, 55 UNTS 194.

17 Paris Convention for the Protection of Industrial Property, March 20, 1883, 828 UNTS 305.

18 Patent Cooperation Treaty, June 19, 1970, 1160 UNTS 231.

use, or capable of being used, as food or as medicine or as drug.”¹⁹ In such cases, only method or process patents were allowed for such substances.

Article 70(8)–(9) of the TRIPS Agreement stipulates that, during the transition period, a country should provide a mechanism for patent protection for pharmaceutical and agricultural chemical products, including the grant of exclusive marketing rights (EMRs). On July 2, 1995, the U.S. alleged that India had not complied with these provisions. It requested the WTO for dispute consultations. A panel to hear the dispute issued a report on September 5, 1997, finding that India was indeed in violation of these TRIPS Agreement provisions.²⁰ India’s appeal also failed. The appellate body found that, as on January 1, 1995, India was required to have a legal mechanism for patent protection as provided under Article 70(8)–(9) of the TRIPS Agreement.²¹

In 1997, the European Community requested another dispute consultation on similar grounds. The panel set up in this regard also ruled against India.²² Accordingly, in 1999, India introduced an amendment to comply with these requirements. These, and other amendments of 2002 and 2005, are discussed in Sections 6.1.4.4.3 to 6.1.4.4.5.

6.1.4.2 The Doha Declaration

Prior to the adoption of the TRIPS Agreement, most countries did not grant patents for medicines. This helped keep costs affordable and ensured access to medicines. The introduction of product patents for medicines under the TRIPS agreement was a matter of concern for developing countries and least-developed countries. Increasing the number of product patents for medicines implied that the cost of medications would increase and thwart access to medication.

The TRIPS Agreement required, among other things, that all WTO members introduce product and process patents in all fields of technology. Exceptions in fields related to the fulfillment of basic needs, such as in health, were not recognized or permitted.

In 2001, WTO members adopted a declaration at the WTO Ministerial Conference in Doha, Qatar, stating that it was important to interpret the TRIPS Agreement to support public health by promoting access to medicine and the creation of medicines.²³ This was important for developing economies, including India, which had stressed the need to expand public health coverage at low and affordable costs. The Doha Declaration agreed that the TRIPS Agreement did not and should not prevent WTO members from taking measures to protect public health.²⁴

The Doha Declaration recognized that the TRIPS Agreement should be interpreted and implemented in a manner conducive to its members, deploying the flexibilities built into the TRIPS Agreement.²⁵ Consequently, each WTO member was free to determine the grounds on which compulsory licenses were to be granted and what constituted a national emergency or other circumstances of extreme urgency for invoking compulsory licensing provisions.²⁶ The Doha Declaration also recognized that many countries had little or no manufacturing capacity in

19 Section 5, Indian Patents Act, 1970. Section 5 was later repealed completely by the Patents (Amendment) Act, 2005 (Act No. 15 of 2005).

20 Panel Report, *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WTO Doc. WT/DS50/R (Sep. 5, 1997).

21 Appellate Body Report, *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WTO Doc. WT/DS50/AB/R (Dec. 19, 1997).

22 Panel Report, *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WTO Doc. WT/DS79/R.

23 WTO, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002), para. 17 (“We stress the importance we attach to implementation and interpretation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines and, in this connection, are adopting a separate Declaration”).

24 WTO, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002), para. 4 (“We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose”).

25 Trade-Related Aspects of Intellectual Property Rights, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, art. 8.1 (“Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement”).

26 WTO, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002), para. 5 (“Accordingly, and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include: [...] (b). Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted”).

the pharmaceutical sector and might face difficulties in the effective use of the TRIPS Agreement's compulsory licensing provisions.²⁷ Pursuant to this, an amendment was accepted in Article 31*bis* of the TRIPS Agreement, permitting countries to grant compulsory licenses even for export to other countries with insufficient or no manufacturing capacity.

The Doha Declaration also clarified flexibilities for members to adopt an international principle of exhaustion of rights²⁸ in accordance with Article 6 of the TRIPS Agreement.²⁹ The principle of exhaustion means that, once patent holders sell a patented product, they cannot prohibit the subsequent resale of that product, since their rights in respect of that product have been "exhausted" by the act of selling the product. The Doha Declaration reaffirmed that members were free to establish their own regime for such exhaustion to ensure that patent rights did not impede legitimate products entering global supply chains.

6.1.4.3 The Patent Cooperation Treaty

The PCT provides a platform to facilitate the filing of a single international patent application to seek protection across PCT contracting states. This is beneficial for an applicant because, in the traditional system, separate applications for patents had to be made in each jurisdiction across the world. The international search reports and written reports generated by the International Searching Authorities as well as International Preliminary Reports on Patentability (Chapter II) drawn by the International Preliminary Examining Authorities assist the applicant in deciding whether to proceed with the national phase and, if so, in which countries, based on the likelihood of success as per the search report. The PCT system has also resulted in a considerable reduction in costs for applicants.

6.1.4.4 Amendments and implementation in India

6.1.4.4.1 Patent Cooperation Treaty implementation in India

India signed and acceded to the PCT in September 1998, which entered into force in India in December 1998. The provisions relating to applications under the PCT were incorporated under the Patents (Amendment) Act, 2002. Under the Patents Act, 1970, an "international application" was defined as an application made as per the provisions of the PCT.³⁰ Four offices in India (New Delhi, Kolkata, Chennai and Mumbai) and the International Bureau in Geneva, Switzerland were designated as receiving offices for international applications. Section 7 of Act prescribes the form in which an applicant makes an application for its invention and also provides for making a simultaneous application under both the PCT and the Act if a corresponding application has been filed before the Controller in India.³¹

Chapter III of the Patents Rules, 2003, contains the provisions for filing an international application, the form in which an application is to be made, fees payable to the examining authority, time limits for establishing an international search report and other related rules for applications under the PCT. The term of a patent granted in India for a PCT international application is 20 years from the date of its filing under the PCT.³²

6.1.4.4.2 Patent prosecution highway

Apart from the PCT system, several countries and regions have recently created "patent prosecution highways" which provide for accelerated examination, the sharing of search reports and so on, which result in the speedier examination and grant of patents. Such prosecution highways can either be bilateral or multilateral. In India, the first patent prosecution highway was initiated in 2019 by the Indian Patent Office as a bilateral pilot patent prosecution highway program with the Japan Patent Office. Guidelines for the same were published, though the pilot is

27 WTO, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002), para. 6.

28 WTO, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002), para. 5(d) ("Accordingly, and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include: [...] (d). The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN [most-favored nation] and national treatment provisions of Articles 3 and 4").

29 Trade-Related Aspects of Intellectual Property Rights, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, art. 6 ("For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of exhaustion of the intellectual property rights").

30 Patents Act, 1970, §2(1)(ia). This was inserted by the Patents (Amendment) Act, 2002 (see Section 6.1.4.4.4 of this chapter), and came into effect on May 5, 2003.

31 Patents Act, 1970, §7(1A).

32 Patents Act, 1970, §53.

limited to 100 cases per year, on a first-come-first-served basis. Depending on the evaluation of this pilot highway, long-term patent prosecution highways with one or more patent offices across the country may be a reality.

6.1.4.4.3 The 1999 amendment, post-TRIPS Agreement

Upon coming into effect on January 1, 1995, the TRIPS Agreement provided for transitional periods for WTO members to introduce legislation complying with the obligations under the agreement. India has been a WTO member since January 1995.

For developing countries like India, the deadline for complying with the TRIPS Agreement was the year 2000. Article 65(4) of the TRIPS Agreement provided a special transitional provision for those countries that did not grant product patents. As per this provision, an additional period of five years (i.e., until 2005) on the initial TRIPS Agreement transitional period was permitted for introducing product patent protection.

India needed to provide a means for filing patent applications during the transitional period. The “mailbox provision” allowed applicants to file for patents, thereby establishing filing dates, while at the same time permitting members to defer the granting of product patents. In addition, India also needed to provide EMRs in exchange for permission to delay the grant of product patents until January 1, 2005.

Transitional arrangements were introduced through Section 2 of the Patents (Amendment) Act, 1999, through the insertion of Section 5(2) of the Patents Act, 1970, allowing product patent applications to be filed through a “mailbox,” while Chapter IVA provided for the grant of EMRs if certain conditions were fulfilled

EMRs were introduced as a transitory provision to help developing countries that followed a *process* patent regime to slowly phase into a *product* patent regime. In order to bring in transitional measures for the recognition of the TRIPS Agreement obligations, the Patents (Amendment) Act, 1999, introduced a system for the grant of EMRs. This allowed inventors to file early applications for the grant of patents and to establish filing dates so that, when patent protection was ultimately granted, these applications would be considered on the basis of the date of filing or priority dates. These provisions were considered necessary under the TRIPS Agreement,³³ pending the initiation of a streamlined process in India for granting product patents relating to drugs, pharmaceutical and agricultural chemical products.

EMRs are applicable where a patent is granted for the same product in another WTO member after 1995 (the date of entry into force of the TRIPS Agreement), provided marketing approval for the product was obtained in such other WTO member. However, EMRs are limited only to pharmaceutical and agricultural chemical products. From a simple dictionary definition of the term, the meaning of “exclusive marketing rights” appears to be very similar to that of patent rights; however, in theory, EMRs prevent others from making or using patented products. The rights holder can indirectly prevent others from marketing products based on such use since they would lack the authorization to do so. Patent protection and EMRs are alternatives to each other and are not used concurrently.

EMRs under the 1999 amendment could only be granted for products intended for or capable of being used as a medicine or drug. For an applicant to have the exclusive right to sell or distribute the product in India, pending the grant or rejection of the application for the product patent, the following conditions needed to be fulfilled:

- a patent and approval to sell the same invention applied for (on or after January 1, 1995) in another WTO member had been granted after the date of making an application for the product patent;³⁴ or
- a patent for the method, process or manufacture of the invention applied for (on or after January 1, 1995) and relating to the same product had been granted in India on or after the date of making an application for the product patent;³⁵ and

33 Trade-Related Aspects of Intellectual Property Rights, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, art. 70(8)–(9).

34 Patents Act, 1970, §24B(1)(a). §24A to 24F were later repealed completely by the Patents (Amendment) Act, 2005 (Act No. 15 of 2005).

35 Patents Act, 1970, §24B(1)(b).

- approval to sell or distribute the product had been received from the Central Government.³⁶

EMRs were granted for a period of five years from the date of such approval or until the grant or rejection of the application for the product patent, whichever was earlier.

As per the 1999 amendment, no application for the grant of a product patent could be referred by the Controller to an examiner for making a report until December 31, 2004.³⁷ For the said 10-year period, the applications were kept in a “black box,” a figurative expression for applications pending examination. After this date, the application would be referred to an examiner for a report on whether the claimed invention was within the meaning under Section 3 of the Patents Act, 1970, or whether the invention was such for which no patent could be granted under Section 4 of the Act. If the necessary preconditions were not met, the application would be rejected.³⁸ If the preconditions were fulfilled, the Controller could proceed to consider the application for the grant of a patent.³⁹

The 1999 amendment also included provisions authorizing the Central Government – under expedient circumstances and keeping in mind the public interest at large – to sell or distribute the product by itself or through an authority so empowered in writing.⁴⁰ Moreover, the Central Government also had the power to direct that the product be sold at a price determined by it after specifying its reasons and the public interest involved.

All suits relating to infringement under Section 24B of the Act would be dealt with in the same manner as suits concerning infringement of patents under Chapter XVIII.

In India, some EMRs were granted relating to medicinal products. Suits for infringement restraining violation of EMR rights were also instituted. However, all EMRs came to an end after the full-scale implementation of the amendments with effect from January 1, 2005. With the introduction of the 2005 amendments, all pending applications for the grant of EMRs were automatically considered as applications for product patents and dealt with accordingly.

6.1.4.4.4 The 2002 amendment, post-TRIPS Agreement

This 2002 amendment to the Patents Act, 1970, was introduced to (a) bring the patent regime in India in line with the TRIPS Agreement; (b) bring the law on patents in line with the increasing development of technological capability of India; (c) provide the necessary safeguards for the protection of public interest and national security; (d) harmonize the procedure for the grant of patents in accordance with the international practices; and (e) make the system more user-friendly.

Some of the salient features of the Patents (Amendment) Act, 2002, were as follows:

- The term of every patent granted after the commencement of the Patents (Amendment) Act, 2002, was increased to 20 years from the date of filing of the application.⁴¹
- The time for restoration of a lapsed patent was increased to 18 months.⁴²
- A new definition for “invention” was added: a patent could be for a process or product that was new, involved an inventive step or was capable of industrial application.⁴³
- A new definition for “inventive step” was added.⁴⁴
- The negative list of what were not considered inventions (i.e., non-patentable subject matter) was amended and expanded in light of Article 27(2)–(3) of the TRIPS Agreement.⁴⁵
- The concept of a request for the publication of a patent application was introduced.⁴⁶
- An onus-of-proof provision was introduced, requiring the defendant to prove that its process for obtaining the product in question was different from the patented process in cases where an identical final product was obtained from such a process.⁴⁷

36 Patents Act, 1970, §24B(1).

37 Patents Act, 1970, §24A(1).

38 Patents Act, 1970, §24A(2).

39 Patents Act, 1970, §24A(3).

40 Patents Act, 1970, §24D.

41 Patents Act, 1970, §53. This was in line with Article 33 of the TRIPS Agreement.

42 Patents Act, 1970, §60.

43 Patents Act, 1970, §2(1)(j).

44 Patents Act, 1970, §2(1)(ja).

45 Patents Act, 1970, §3.

46 Patents Act, 1970, §11-A.

47 Patents Act, 1970, §104-A.

- The chapter on compulsory licensing was substituted with provisions and procedures consistent with the TRIPS Agreement,⁴⁸ and the provisions relating to the license of rights were omitted.⁴⁹
- The *Bolar* exemption was introduced.⁵⁰
- The parallel import of patented products was introduced.⁵¹
- All appeals under the Act were redirected from the High Courts to a specialized tribunal (i.e., the Intellectual Property Appellate Board (IPAB)⁵² since abolished in 2021).⁵³
- National security provisions were amended.⁵⁴

6.1.4.4.5 The 2005 amendment, post-TRIPS Agreement

The amendments of 2005 were introduced to bring Indian patent laws into further compliance with the TRIPS Agreement because the transitional period available to India was ending in 2005. Some of the salient features of the Patents (Amendment) Act, 2005, were as follows:

- The definition of “inventive step” was amended.⁵⁵
- The definition of “new invention” was added.⁵⁶
- The definition of “patent” was amended.⁵⁷
- The negative list of what were not considered inventions (i.e., non-patentable subject matter) was amended.⁵⁸
- The provisions that provided that only the process and not the product itself would be patented in cases of inventions relating to food, drugs and medicines were deleted.⁵⁹ This ensured that product patent protection was available for all fields.
- The chapter relating to EMRs was omitted,⁶⁰ and the provisions relating to it were modified.
- Two levels of opposition were introduced – pre-grant and post-grant. All grounds available for pre-grant opposition were also made available to interested parties for challenging a patent in post-grant opposition within one year from the date of publication of the grant of patent.⁶¹
- Pursuant to the Doha Declaration, the grounds for seeking compulsory licensing were expanded by adding a provision for the issuance of compulsory licenses for the manufacture and export of patented pharmaceutical products to countries that had insufficient manufacturing capacity in the pharmaceutical sector if that country had allowed such importation by notification.⁶²
- Jurisdiction for trying revocation petitions to revoke granted patents was shifted from the High Courts to the IPAB with a view to extending its jurisdiction to the revocation of patents.⁶³ This now stands reversed in 2021.⁶⁴
- Certain provisions were amended to bring the patent regime in India in line with the PCT, to which India is a signatory.⁶⁵

6.1.5 Patent application trends

Figure 6.1 shows the total number of patent applications (direct and Patent Cooperation Treaty (PCT) national phase entry) filed in India from 2000 to 2021.

48 Patents Act, 1970, ch. VI.

49 Patents Act, 1970, §86.

50 Patents Act, 1970, §107-A(a). Also known as the “Roche – Bolar exemption” after *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F 2d 858 (Fed. Cir. 1984). In patent law, the “research exemption” or “safe harbor exemption” is an exception to the rights conferred by patents, especially relevant to drugs. Patent rights are not infringed when performing research and tests for preparing regulatory approval for a limited term before the end of patent term. The exemption, permitted by Article 30 of the TRIPS Agreement, allows generic manufacturers to prepare generic drugs in advance of the patent expiration.

51 Patents Act, 1970, §107A(b).

52 Patents Act, 1970, ch. XIX.

53 The Tribunals Reforms (Rationalisation and Conditions of Service) Ordinance, 2021 (April 4, 2021).

54 Patents Act, 1970, §157-A.

55 Patents Act, 1970, §2(1)(ja).

56 Patents Act, 1970, §2(1)(l).

57 Patents Act, 1970, §2(1)(m).

58 Patents Act, 1970, §3.

59 Patents Act, 1970, §5.

60 Patents Act, 1970, ch. IV-A.

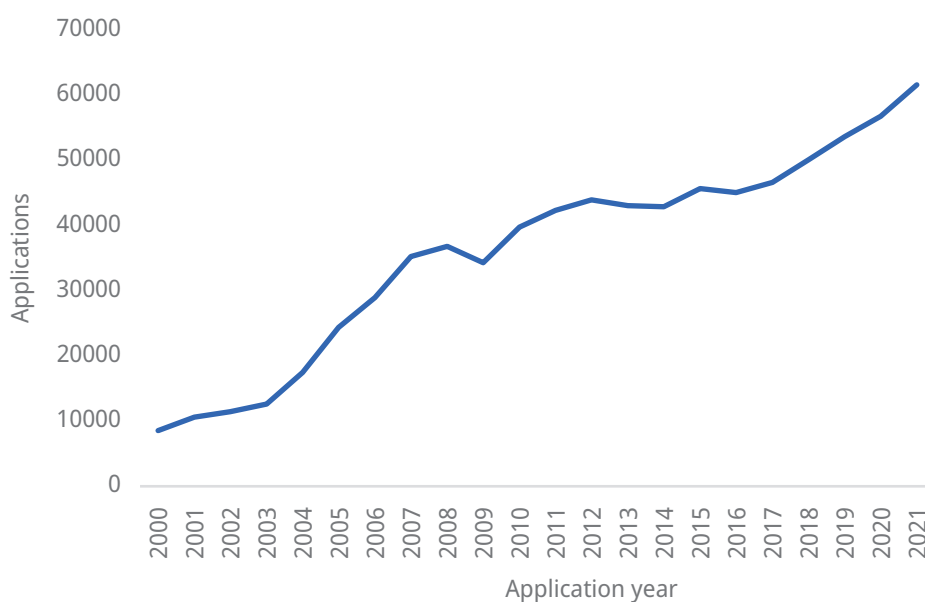
61 Patents Act, 1970, §25(2).

62 Patents Act, 1970, §92A.

63 Patents Act, 1970, §§64(1), 117G.

64 The Tribunals Reforms (Rationalisation and Conditions of Service) Ordinance, 2021 (April 4, 2021).

65 Patents Act, 1970, §§7(1B), 7(4), 9(1), 9(3), 21, 52(1), 135(3).

Figure 6.1 Patent applications filed in India, 2000–2021

Source: WIPO IP Statistics Data Center, available at www3.wipo.int/ipstats/index.htm?tab=patent

6.2 Patent institutions and administrative review proceedings

6.2.1 Patent institutions

6.2.1.1 Office of the Controller General of Patents, Designs and Trade Marks

The Office of the Controller General of Patents, Designs and Trade Marks is located in Mumbai. The Controller supervises the working of the Patents Act, 1970, the Designs Act, 2000, and the Trade Marks Act, 1999, and also renders advice to the Government on matters relating to these subjects.

The Central Government may appoint as many examiners and other officers with such designations as it thinks fit.⁶⁶ Minimum qualifications are prescribed. These officers function under the Controller's superintendence. Higher qualifications are prescribed for the position of Senior Joint Controller of Patents and Designs. The organizational structure of the Office is shown in Figure 6.2.

6.2.1.2 The Department for Promotion of Industry and Internal Trade

The Department for Promotion of Industry and Internal Trade was established in 1995 and reconstituted in 2000 when it was merged with the Department of Industrial Development. The department's purpose is to promote and accelerate the industrial development of the country by facilitating investment in new and upcoming technologies, foreign direct investment and supporting the balanced development of industries.

The department is the nodal department for all matters related to the protection of IP rights in the fields of patents, trademarks, copyrights, industrial designs and geographical indications.

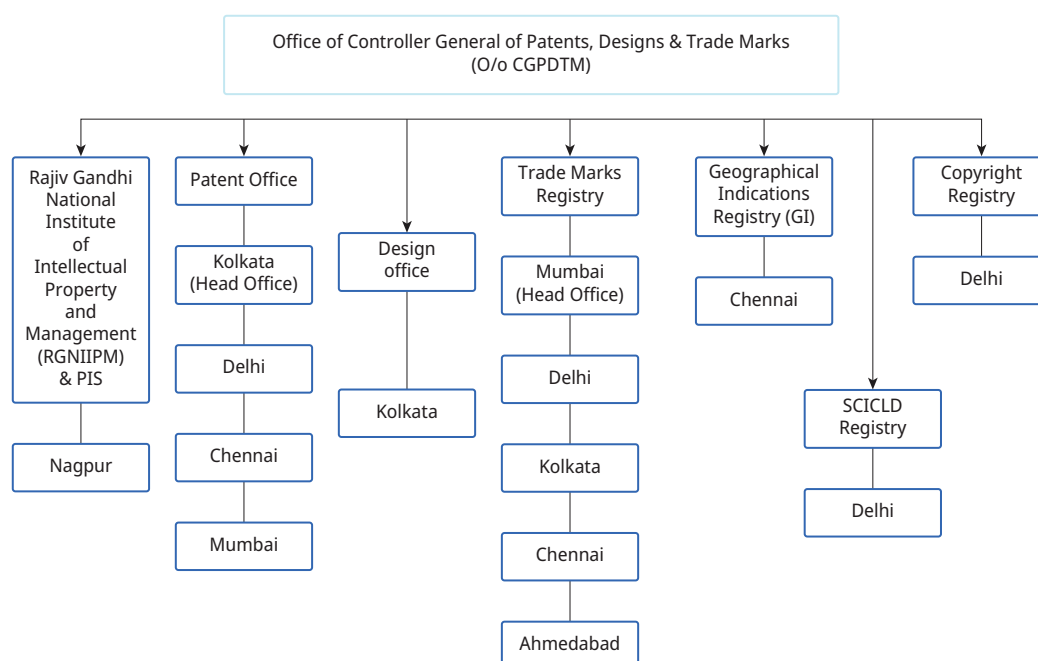
6.2.1.3 National Institute of Intellectual Property Management, Nagpur

The National Institute of Intellectual Property Management is a national center for excellence in training, management, research and education in IP rights. The institute trains examiners of patents and designs, examiners of trademarks and geographical indications, IP professionals and IP managers in the country. The institute also facilitates research on IP-related issues.

The Patent Information System was established by the Indian Government in 1980 to maintain a comprehensive collection of patent specifications and patent-related literature worldwide. It is

66 Patents Act, 1970, §73.

Figure 6.2 Organizational structure of the Office of the Controller General of Patents, Designs and Trade Marks



Source: Office of the Controller General of Patents, Designs and Trade Marks, *About Us*, ipindia.gov.in/about-us.htm

also located in Nagpur within the premises of the National Institute of Intellectual Property Management.

6.2.1.4 Cell for IPR Promotion and Management, constituted under the National Intellectual Property Rights Policy

The Cabinet of Ministers of the Central Government approved the National Intellectual Property Rights Policy on May 12, 2016.⁶⁷ This policy drew a future roadmap for IP rights in India and made several recommendations. Following one of the recommendations of the 2016 policy, a specialized professional body – the Cell for IPR Promotion and Management – was created under the aegis of the Department for Promotion of Industry and Internal Trade, and it has been instrumental in taking forward the objectives and visions of the policy. Since the adoption of the policy, the cell has worked toward changing the IP landscape of the country, which among other things, has included:

- IP rights awareness programs, which are conducted in over 200 academic institutions for the industry, police, customs and the judiciary;
- reaching out to rural areas – awareness programs are being conducted using satellite communication (EduSat). In one such program, 46 rural schools, with a combined total of 2,700 students, were reached. Over 300 schools and more than 12,000 students have been reached;
- more focus on developing e-content and disseminating content through online channels;
- including content on IP rights in the National Council of Educational Research and Training commerce curriculum. Work is ongoing to include IP rights in other academic streams; and
- conducting competitions in conjunction with industry for school and college students to develop the “innovative spirit.” Some competitions have included the development of mobile applications, videos and online games.

As part of the awareness campaign, the Cell for IPR Promotion and Management also launched India's first IP mascot – “IP Nani” – in collaboration with the European Union Intellectual Property Office. IP Nani is an animated grandmother who sends out messages for the protection and

⁶⁷ Department of Industrial Policy and Promotion, Government of India, *National Intellectual Property Rights Policy* (May 12, 2016), https://dpiit.gov.in/sites/default/files/National_IPR_Policy_English.pdf

enforcement of IP. There are also a series of animated videos on IP rights for school students.⁶⁸ These videos are available for viewing on platforms such as YouTube.⁶⁹

6.2.1.5 The Department of Science and Technology – Patent Facilitation Programme

The Department of Science and Technology, under the Ministry of Science and Technology, has been implementing its Patent Facilitation Programme since 1995. It has established a Patent Facilitating Cell at the Technology, Information, Forecasting Assessment Council (an autonomous body of the department) and, subsequently, 26 patent information centers in various states. The patent facilitating cells and patent information centers create awareness of and extend assistance in protecting IP rights at the state level, including for patents, copyright, industrial designs, geographical indications and so on.

These patent information centers have also established IP cells in universities in their respective states to enlarge the network. Today, more than one hundred such cells have been created in different state universities. In addition, these centers are also mandated to provide assistance to inventors from government organizations and from central and state universities. They also render ongoing technical and financial assistance in filing, prosecuting and maintaining patents on behalf of the Government, research and development institutes, and academic institutions.⁷⁰ The mandate of the program is:

- providing patent information as a vital input to research and development;
- facilitating patent and IP rights facilitation for academic institutions and Government research and development institutions;
- providing IP rights policy input to the Government; and
- conducting IP rights training and awareness programs in the country.

6.2.1.6 Traditional Knowledge Digital Library

The Traditional Knowledge Digital Library (TKDL) is a pioneering initiative in India to protect Indian traditional medicinal knowledge and prevent its misappropriation. It was set up in 2001 as a collaboration between the Council of Scientific and Industrial Research and the Ministry of Ayush, Government of India. The Council of Scientific and Industrial Research is a contemporary research and development organization and a pioneer in India's IP movement.

The TKDL has overcome the language and format barrier by systematically and scientifically converting and structuring the available contents of ancient texts on Indian systems of medicine (i.e., Ayurveda, Siddha, Unani, Sowa Rigpa and Yoga) into five international languages – English, Japanese, French, German and Spanish – with the help of information technology tools and an innovative classification system called the Traditional Knowledge Resource Classification. More than 360,000 formulations and practices have been transcribed into the TKDL database.

The classification has also structured and classified the Indian traditional medicine system into several thousand subgroups for Ayurveda, Unani, Siddha and Yoga. The Traditional Knowledge Resource Classification has enabled the incorporation of about 200 subgroups under International Patent Classification A61K 36/00, more than the few subgroups earlier available on medicinal plants under A61K 35/00, thus enhancing the quality of search and examination of prior art for patent applications in the area of traditional knowledge.

The TKDL has also established international specifications and standards for setting up traditional knowledge databases based on TKDL specifications. These standards were adopted in 2003 by the committee in the fifth session of the World Intellectual Property Organization's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Expression of Folklore.

Currently, the TKDL is based on open-source and open-domain texts of Indian systems of medicine. The TKDL acts as a bridge between these books (prior art) and patent examiners. Access to the TKDL is available to 13 patent offices under the TKDL Access (Non-disclosure)

68 Department for Promotion of Industry and Internal Trade, *IP Nani*, <https://dpiit.gov.in/ip-nani>

69 E.g., the first episode of the series can be found at www.youtube.com/watch?v=5rEpNp00iqU

70 Department of Science and Technology, Government of India, *Compendium on IP Activities under Patent Facilitation Programme 2016–2019*, http://dst.gov.in/sites/default/files/PIC_Compendium_16-19_0.pdf

Agreement,⁷¹ which has inbuilt safeguards on nondisclosure to protect India's interest against any possible misuse.

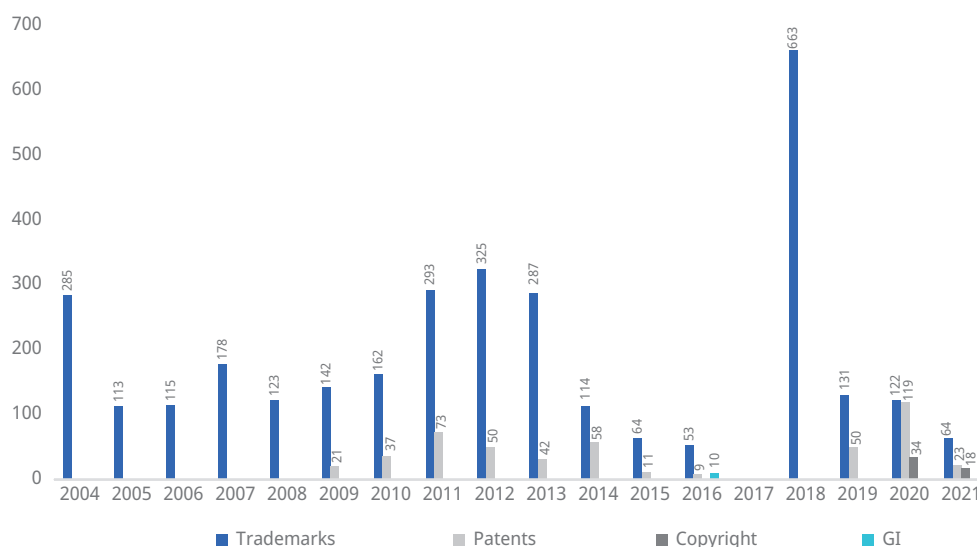
The TKDL is proving to be an effective deterrent against biopiracy and has been recognized internationally as a unique effort. It has set a benchmark in traditional-knowledge protection around the world, particularly in traditional-knowledge-rich countries, by demonstrating the advantages of proactive action and the power of strong deterrence. The key here is preventing the grant of incorrect patents conferring monopolies on aspects of traditional knowledge, by ensuring access to prior art relating to traditional knowledge for patent examiners without restricting the use of that traditional knowledge.

6.2.2 Administrative review proceedings

6.2.2.1 Intellectual Property Appellate Board

Under the Patents Act, 1970, the appellate jurisdiction to hear appeals and the original jurisdiction to revoke patents was conferred on the High Courts in India. Both these jurisdictions were redirected to the IPAB as a specialized IP tribunal in 2002 and 2005. This was to enable the speedy disposal of such matters (see Figure 6.3 regarding the disposal of cases by the IPAB).⁷² However, in 2021, the Central Government was of the view that this stated objective of speedy disposal was not being achieved and abolished the IPAB, redirecting such matters back to the High Courts.⁷³

Figure 6.3 Disposal of cases at the Intellectual Property Appellate Board, up to February 13, 2021



Note: GI = geographical indication.

Source: Jacob Schindler, *Top Judge's Blueprint for the Future in IP Litigation in India*, IAM Media (May 5, 2021), www.iam-media.com/law-policy/specialised-ip-bench-in-india-long-overdue-says-delhi-high-court-veteran

6.2.2.2 Pre-grant opposition

The scheme of pre-grant oppositions was streamlined by the Patents (Amendment) Act, 2005. Prior to this, a pre-grant opposition could only be filed by a "person interested." The amendment now allows *any* person to file a pre-grant opposition. It can be filed when an application for a patent has been published, but the patent has not yet been granted under Section 25(1) of the

71 These patent offices are the European Patent Office, United State Patent and Trademark Office, Japan Patent Office, United Kingdom Intellectual Property Office, Canadian Intellectual Property Office, German Patent and Trade Mark Office, Intellectual Property Australia, India Office of the Controller General of Patents, Designs and Trade Marks, National Institute of Industrial Property of Chile, Intellectual Property Corporation of Malaysia, Russian Federal Service for Intellectual Property, Peru National Institute for the Defense of Competition and Protection of Intellectual Property and Spanish Patent and Trademark Office.

72 See Discussion on the Trade Marks Bill, 1999, *Lok Sabha Debates*, Session No. 2, Dec. 22, 1999, 454, at 455 ("[The Trade Marks Bill, 1999] seeks to provide for an Appellate Board for the speedy disposal of appeals and rectification of application which presently before the High Court").

73 The Tribunals Reforms (Rationalisation and Conditions of Service) Ordinance, 2021.

Patents Act, 1970. There is no time limit within which a pre-grant opposition must be filed after publication.

6.2.2.2.1 Procedure of pre-grant opposition

The pre-grant opposition procedure broadly follows these steps:

1. The pre-grant opposition is filed, along with evidence, if any.⁷⁴
2. The Controller forms a *prima facie* opinion on the pre-grant opposition filed. They decide either to issue notice of the opposition to the patent applicant or to reject the opposition *prima facie* without issuing notice to the patent applicant.⁷⁵
3. If notice has been issued, the patent applicant may reply (along with evidence, if any) within three months from the date of the notice by the Controller.⁷⁶
4. The Controller may hold a "hearing." This is followed by a decision, ordinarily within one month.⁷⁷ The Controller is required to either reject or grant the patent.

6.2.2.2.2 Grounds on which pre-grant opposition can be filed

Section 25(1) of the Patents Act, 1970, provides a list of grounds on which a pre-grant opposition can be filed. The list is exhaustive:

- (a) that the applicant for the patent or the person under or through whom he claims, *wrongfully* [emphasis added] obtained the invention or any part thereof from him or from a person under or through whom he claims;
- (b) that the invention so far as claimed in any claim of the complete specification has been published before the priority date of the claim –
 - (i) in any specification filed in pursuance of an application for a patent made in India on or after the 1st day of January, 1912; or
 - (ii) in India or elsewhere, in any other document:
Provided that the ground specified in sub-clause (ii) shall not be available where such publication does not constitute an anticipation of the invention by virtue of sub-section (2) or subsection (3) of section 29;
- (c) that the invention so far as claimed in any claim of the complete specification is claimed in a claim of a complete specification published on or after priority date of the applicant's claim and filed in pursuance of an application for a patent in India, being a claim of which the priority date is earlier than that of the applicant's claim;
- (d) that the invention so far as claimed in any claim of the complete specification was publicly known or publicly used in India before the priority date of that claim.
Explanation. – For the purposes of this clause, an invention relating to a process for which a patent is claimed shall be deemed to have been publicly known or publicly used in India before the priority date of the claim if a product made by that process had already been imported into India before that date except where such importation has been for the purpose of reasonable trial or experiment only;
- (e) that the invention so far as claimed in any claim of the complete specification is obvious and clearly does not involve any inventive step, having regard to the matter published as mentioned in clause (b) or having regard to what was used in India before the priority date of the applicant's claim;
- (f) that the subject of any claim of the complete specification is not an invention within the meaning of this Act, or is not patentable under this Act;
- (g) that the complete specification does not sufficiently and clearly describe the invention or the method by which it is to be performed;
- (h) that the applicant has failed to disclose to the Controller the information required by section 8 or has furnished the information which in any material particular was false to his knowledge;
- (i) that in the case of a convention application, the application was not made within twelve months from the date of the first application for protection for the invention made in a convention country by the applicant or a person from whom he derives title;

74 Patents Rules, 2003, r. 55(1).

75 Patents Rules, 2003, r. 55(3).

76 Patents Rules, 2003, r. 55(4).

77 Patents Rules, 2003, r. 55(5).

- (j) that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention;
- (k) that the invention so far as claimed in any claim of the complete specification is anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere, but on no other ground, and the Controller shall, if requested by such person for being heard, hear him and dispose of such representation in such manner and within such period as may be prescribed.

6.2.2.2.3 *Locus standi to file pre-grant oppositions*

Under Section 25(1) of the Patents Act, 1970, “any” person can file a pre-grant opposition. A pre-grant opposition is deemed to be an extension of the examination by the Patent Office, and, thus, the standing requirement is diluted. Nevertheless, precedents demonstrate that courts come down heavily against fake pre-grant oppositions or those filed by impostors solely to harass or to delay the grant rather than with any genuine intent to remove invalid patents.⁷⁸

6.2.2.3 Post-grant opposition

A post-grant opposition can be filed under Section 25(2) of the Patents Act, 1970, by a “person interested” after the grant of patent but within one year from the date of publication of the grant of a patent.

6.2.2.3.1 *Procedure in filing post-grant opposition*

The post-grant opposition procedure broadly follows these steps:

1. A post-grant opposition is filed, along with evidence, if any.⁷⁹ A copy must be supplied to the patentee.⁸⁰
2. The Controller constitutes an opposition board of three examiners (other than the examiner who examined the patent).⁸¹
3. The patent applicant may reply to the opposition, providing evidence, if any, within two months.⁸² If no reply is filed, the patent is deemed to be abandoned.⁸³ The Controller also notifies the patentee.⁸⁴ The time for this reply begins from the date the patent applicant is served with the opposition by the opponent.
4. The opponent then has one month to respond to the patent applicant’s reply statement.⁸⁵
5. The opposition board prepares a report with reasons on each ground taken in the notice of opposition. The report contains the board’s joint recommendation and is made within three months of the date on which the documents were forwarded to the board.⁸⁶
6. The Controller schedules a hearing. This is followed by a decision.⁸⁷ At the hearing, the Controller may require members of the opposition board to be present. If either of the parties wishes to be heard, this is permitted on payment of a fee and after notice. If no notice to attend the hearing is received from either party, the Controller can decide the opposition without a hearing. The order must be reasoned. The recommendation of the opposition board is not binding, though it is of persuasive value. Thus, the board’s recommendation should not be lightly ignored without stated reasons.

A party can also file new documents before the scheduling of the hearing, provided prior leave of the Controller is obtained.⁸⁸ Further, a party can rely upon “any publication” that may not have been filed earlier, provided that there has been five days’ notice and that the details of the publication are given to the other party.⁸⁹

78 *Pfizer Products Inc. v. Controller of Patents and Designs*, 2020 SCC Online IPAB 19; *Dhaval Diyora v. Union of India*, 2020 SCC Online Bom. 2550; *Anaghaya Million Pharma LLP v. Nippon Soda Co. Ltd.*, MANU/IC/0074/2020.

79 Patents Rules, 2003, r. 55A.

80 Patents Rules, 2003 r. 57.

81 Patents Act, 1970, §25(3)(b); Patents Rules, 2003, r. 56(1)–(3).

82 Patents Rules, 2003, r. 58(1).

83 Patents Rules, 2003, r. 58(2).

84 Patents Act, 1970, §25(3)(a).

85 Patents Rules, 2003, r. 59.

86 Patents Rules, 2003, r. 56(4).

87 Patents Rules, 2003, r. 55(5).

88 Patents Rules, 2003, r. 60.

89 Patents Rules, 2003, r. 62(4).

In *Cipla Ltd v. Union of India*, the Supreme Court held that it would be mandatory to issue a copy of the recommendation of the Opposition Board to the parties, so that the principles of natural justice are duly adhered to.⁹⁰

6.2.2.3.2 Grounds on which post-grant opposition can be filed

The grounds for post-grant opposition are the same as those for pre-grant opposition. The grounds are exhaustive.

6.2.2.3.3 Locus standi to file post-grant oppositions

Section 2(1)(t) of the Patents Act, 1970, defines “person interested” in an inclusive manner to include a person engaged in or promoting research in the same field as that to which the invention relates. Precedents have interpreted the term “person interested” broadly to cover any person who has a direct, present and tangible interest in the patent and those whose interests are adversely affected because of the patent.⁹¹ The term has been construed to include even nongovernmental organizations that have an interest or stake in the existence or invalidity of the patent – commercial interest is not a necessary condition.⁹²

6.2.2.3.4 Appeals from pre-grant and post-grant oppositions

An appeal lies to the jurisdictionally competent High Court from an order of rejection of a patent application in a pre-grant opposition and from an order revoking or maintaining the grant of patent in a post-grant opposition. No appeal lies from the grant of a patent in a pre-grant opposition.⁹³

6.3 Judicial institutions

6.3.1 Court system in India

6.3.1.1 Hierarchy of courts

There is a common court structure across India, with the Supreme Court of India at its apex. The Supreme Court of India is a court established under the Constitution of India. It is located in New Delhi and is the final appellate authority in the Indian judicial system. The Supreme Court has appellate, constitutional, review and special jurisdictions. It also has limited original jurisdiction for constitutional matters, though not for IP matters.

Below the Supreme Court of India are the various High Courts of India. The Supreme Court exercises appellate jurisdiction over High Court decisions. However, all High Courts and the Supreme Court of India occupy equal constitutional status. While, typically, each federal Indian state has a designated High Court, some states share a High Court. There are 24 High Courts in India.

All High Courts have appellate, constitutional and review jurisdiction. A few High Courts also have “original” jurisdiction – civil cases, including IP suits, can be directly filed in these High Courts, subject to a certain minimum pecuniary value that may vary from one state to another. Such High Courts are those of Delhi, Bombay (Mumbai), Madras (Chennai), Calcutta (Kolkata) and Himachal Pradesh (Shimla). All appeals from a High Court lie to the Supreme Court, though some High Courts also possess an intracourt appeal system from a single judge of the High Court to a bench comprising two judges (i.e., division bench).⁹⁴

Each federal Indian state is typically divided into several districts. Below the High Courts of each state are the district and sessions courts for each such district. The district court is for civil matters, and the sessions court is for criminal matters. Below these courts are the courts of sub-judges for civil matters and the magistrates’ courts for criminal matters.

90 (2012) 13 SCC 429, at 432. The Court held: “considering the fact that the Report of the Opposition Board can be crucial in the decision making process, while passing order by the Controller under Section 25(4), principles of natural justice must be read into those provisions. Copy of the Report/recommendation of Opposition Board, therefore, should be made available to the parties before the Controller passes orders under Section 25(4) of the Act.”

91 *Aloys Wobben v. Enercon*, 2010 SCC Online Mad. 4668.

92 *Sankalp Rehabilitation Trust v. F Hoffmann La-Roche*, 2012 SCC Online IPAB 167.

93 *UCB Farchim v. Cipla Ltd*, 2010 SCC Online Del. 523.

94 Such High Courts are those of Allahabad, Chennai, Mumbai, Calcutta, Punjab and Haryana, Delhi, Madhya Pradesh, Patna, and Jammu and Kashmir.

6.3.1.2 Commercial courts

The Commercial Courts Act, 2015, was enacted to provide fast-track courts for the resolution of certain commercial disputes, which includes IP rights disputes. All commercial disputes beyond a certain minimum specified value must be filed under the fast-track system of the Commercial Courts Act, 2015. Each district now has designated commercial courts for such disputes. Each High Court having original jurisdiction also has a Commercial division to hear such fast-tracked commercial disputes. Further, every High Court has a Commercial Appellate division to hear appeals for fast-tracked commercial disputes.

6.3.1.3 Appointment and tenure of judges

Judges of the High Courts and the Supreme Court of India are selected by a committee (called “the Collegium”) consisting of the three or five seniormost judges of the Supreme Court and headed by the Chief Justice. The executive can give its views on specific candidates, though the Collegium has the final say. A High Court judge could be from the district judiciary⁹⁵ (or a practicing advocate with a minimum of 10 years’ practice).

Appointments to the subordinate judiciary (i.e., lower than the district court: the Provincial Civil Service–Judicial) are made by either the state public service commissions or the High Court concerned. The selection process involves written tests and an interview. Selected candidates are appointed as judges in the subordinate judiciary as sub-judges. High Courts also conduct the selection process for the Higher Judicial Service’s appointment of district judges. Candidates for the Higher Judicial Service are sub-judges and advocates with a minimum of seven years’ practice.

6.3.2 Judicial education on intellectual property

The National Judicial Academy (NJA) is a training institute located in Bhopal, Madhya Pradesh, established and fully funded by the Government of India. The NJA is an independent society established in 1993 under the Societies Registration Act, 1860. The Honorable Chief Justice of India is the Chairman of the General Body of the NJA and the Chairman of the Governing Council, the Executive Committee and the Academic Council of the NJA.

The NJA’s academic programs are guided by the National Judicial Education Strategy, launched in 2007. Under this strategy, the NJA has established a national system for judicial education. The NJA conducts a vibrant training program for judges at all levels throughout the year. The program is addressed by speakers who may be lawyers or people with specialized knowledge, including economists and foreign experts.

As a joint initiative of the World Intellectual Property Organization and the NJA, seminars, talks and so on are organized by the NJA for the benefit of lawyers, academics and students.

6.4 Challenges to patents

Under Section 13(4) of the Patents Act, 1970, the grant of a patent does not guarantee its validity.⁹⁶ The underlying principle is that allowing an invalid patent to continue on the register is against the public interest, so every opportunity is provided to remove invalid patents. There are various levels of challenges provided in the Act against a patent application or a granted patent. Such challenges can be made either prior to or after the grant:

- Pre-grant opposition under Section 25(1);
- Post-grant opposition under Section 25(2) before the Patent Office, introduced in 2005;
- revocation under Section 64(1) before the High Court;⁹⁷ and
- a counterclaim seeking revocation in a suit for infringement under Section 64(1), in which case the infringement suit and the counterclaim are both transferred to the relevant High Court.⁹⁸

Other challenges to patents or the exercisable rights are compulsory licenses and government use (under Sections 84, 92, 102 and others) and revocation (under Section 66).

⁹⁵ India Constitution, art. 217(2)(a).

⁹⁶ Patents Act, 1970, §13(4); see also *Biswanath Prasad Radhey Shyam v. Hindustan Metal Industries*, AIR 1982 SC 1444.

⁹⁷ Until 2021, this was the IPAB. Following the Tribunals Reforms (Rationalisation and Conditions of Service) Ordinance, 2021, this jurisdiction is vested with the High Court.

⁹⁸ Patents Act, 1970, §104 proviso; see Section 6.5.4 of this chapter.

There has been significant discontent – especially after the 2002 and 2005 amendments – about the multitude of challenge avenues. These provisions for patent challenges may appear to encourage abuse by patent opponents and result in patent grants being held up or delayed almost indefinitely. These apprehensions have been assuaged to a large extent by judicial precedents, which have streamlined the filing of oppositions and dealt with challenges to orders passed in oppositions. In *UCB Farchim v. Cipla Ltd.*,⁹⁹ the Delhi High Court confirmed that, once a pre-grant opposition is dismissed and the patent is granted, the order granting the patent cannot be challenged by way of an appeal. The only remedy available is to file a post-grant opposition or a revocation. In *Snehlata C Gupte v. Union of India*,¹⁰⁰ the practice of filing serial oppositions to hold up the grant of a patent was stopped by the Delhi High Court. The court issued a series of directions preventing delays in patent grants. In *Aloys Wobben v. Yogesh Mehra*,¹⁰¹ the Supreme Court categorically held that one person cannot pursue both a revocation application and a counterclaim seeking revocation. These and other decisions have ensured that duplicity and parallel proceedings are avoided to the extent possible.

6.5 Patent infringement

The ability to enforce patents is a crucial right for any patentee. Chapter XVIII of the Patents Act, 1970, addresses infringement, forums, remedies, defenses and counterclaims.

6.5.1 Claim construction

Claim construction forms a critical component of patent enforcement and invalidity challenges. Claim construction is a prerequisite for infringement analysis because the claims determine the scope of protection afforded to the patentee. Similarly, only after claims are construed to determine the invention can invalidity analysis proceed.

6.5.1.1 Procedure

Unlike the mechanism of a “*Markman*” hearing in the U.S., there is no separate procedural step for claim construction. Instead, claim construction is handled as part of the trial. Any disputes concerning the construction of claims will be framed as issues during the case management hearing. In the High Court of Delhi Rules Governing Patent Suits, 2022, it has been recommended that parties file a claim-construction brief before the case management hearing to enable courts and parties to assess whether there are any disputes in relation to the claims.¹⁰²

6.5.1.2 Principles

In the context of India’s predecessor legislation, the Supreme Court of India has held that claims must be given an effective meaning and that the specification and claims must be examined and construed together.¹⁰³ The Supreme Court followed English precedents when coming to this conclusion.

Under the Patents Act, 1970, the Delhi High Court, in *F Hoffmann-La Roche Ltd v. Cipla Ltd.*,¹⁰⁴ held that one must undertake a “purposive construction” of the claims. The Delhi High Court drew inspiration from the concept of purposive construction that was formulated in the seminal English judgment *Catnic Components Ltd v. Hill and Smith Ltd*.¹⁰⁵ This principle is captured in the following two dicta in the *Catnic Components* case:

whether persons with practical knowledge and experience of the kind of work in which the invention was intended to be used, would understand that strict compliance with a particular descriptive word or phrase appearing in a claim was intended by the patentee to be an essential requirement of the invention so that any variant would fall outside the monopoly claimed, even though it could have no material effect upon the way the invention worked.

99 See Patents Act, 1970, §13(4); see also *Biswanath Prasad Radhey Shyam v. Hindustan Metal Industries*, AIR 1982 SC 1444.

100 2012 SCC Online Del. 2259.

101 *Aloys Wobben v. Yogesh Mehra*, (2014) 15 SCC 360.

102 High Court of Delhi Rules Governing Patent Suits, 2022, r. 7(v) r/w, r. 2(c).

103 *Biswanath Prasad v. Hindustan Metal Industries*, (1979) 2 SCC 511. But see *Farbwerke Hoechst v. Unichem Laboratories*, AIR 1969 Bom. 255 (holding that specification must be referred to only in the case of ambiguity. However, the Supreme Court’s judgment in *Biswanath Prasad v. Hindustan Metal Industries* effectively overrules this judgment).

104 MIPR 2016 (1) 1.

105 (1982) RPC 183.

No plausible reason has been advanced why any rational patentee should want to place so narrow a limitation on his invention. On the contrary, to do so would render his monopoly for practical purposes worthless, since any imitator could avoid it and take all the benefit of the invention by the simple expedient of positioning the back plate a degree or two from the exact vertical.¹⁰⁶

This principle of purposive construction was streamlined in the form of “*Improver*” questions in a subsequent judgment in the United Kingdom (U.K.)¹⁰⁷ and later approved by the House of Lords.¹⁰⁸ However, the U.K. Supreme Court, in *Actavis UK Ltd v. Eli Lilly and Co.*,¹⁰⁹ disagreed with the earlier line of cases. According to the U.K. Supreme Court, this earlier line of case law on purposive construction conflated the issue of claim construction and infringement analysis.

The current standard in the U.K. requires a court to adopt a “normal interpretation” approach. For infringement purposes, according to the U.K. Supreme Court, one must examine whether the infringing device or process infringes the claim as construed by such normal interpretation. If not, the U.K. Supreme Court dictates that a court must thereafter assess whether the claim is infringed by equivalents. It has formulated a test for assessing such equivalents. The U.K. Supreme Court’s judgments in *Actavis UK Ltd* and subsequently in *Icescape Ltd v. Ice-World International BV*¹¹⁰ have clarified that the normal interpretation of claims is also purposive. Such interpretations are purposive because courts are to construe claims as per their ordinary language, in their context (description and drawings) and in the light of the factual background (common general knowledge in the art).

There has been no subsequent judgment in India addressing these jurisprudential developments. However, since even the earlier rulings of the Supreme Court of India and the Delhi High Court were guided by the English precedents, it is expected that Indian courts will take a similar approach to claim construction.

6.5.2 Infringement analysis

6.5.2.1 What is “infringement”?

The Patents Act, 1970, does not separately define “infringement,” but courts regard any violation of the rights accorded under Section 48 of the Act as an infringement. Like most international jurisdictions, and consistent with Article 28 of the TRIPS Agreement, Section 48 of the Act confers an exclusive right on the patentee to prevent third parties from “making, using, offering for sale, selling or importing for those purposes” the patented product.¹¹¹ In the case of process patents, the patentee has the exclusive right to prevent third parties from using the process and from “using, offering for sale, selling or importing for those purposes” the “product obtained directly by the patented process.”¹¹² Committing these acts without the patentee’s consent constitutes infringement.

6.5.2.2 Exports as infringement

The Delhi High Court has held that the term “sale,” in the context of another provision of the Patents Act, 1970, includes “exports.”¹¹³ The Delhi High Court has also recently granted an interim injunction because exports from India would have also amounted to use in India.¹¹⁴

6.5.2.3 Proving infringement

A plaintiff must compare the alleged infringing product or process with the granted claim or claims to prove infringement.¹¹⁵ Claim construction precedes this exercise of comparison.¹¹⁶

106 [1982] RPC at 244.

107 *Improver Corp. v. Remington Consumer Products Ltd*, [1990] FSR 181.

108 *Kirin-Amgen Inc. v. Hoechst Marion Roussel Ltd*, [2005] RPC 9.

109 [2017] UKSC 48.

110 [2019] FSR 5.

111 Patents Act, 1970, §48(a).

112 Patents Act, 1970, §48(b).

113 *Bayer Corp. v. Union of India*, 2019 SCC Online 8209 (this judgment was in the context of the *Bolar* provision under Section 107A(a) of the Patents Act, 1970).

114 *H Lundbeck A/S v. Hetro Drugs Ltd*, CS (COMM) 565 of 2020, order dated Dec. 23, 2020.

115 *F Hoffmann-La Roche Ltd v. Cipla Ltd*, MIPR 2016 (1) 1.

116 For a detailed discussion on how claims are to be construed, see Section 6.5.1 of this chapter.

The Patents Act, 1970, is silent on the doctrine of equivalence and other analogous concepts. The predecessor legislation allowed patentees to sue for infringement even when the infringers counterfeited or imitated the invention.¹¹⁷ Case law under the predecessor legislation suggested that courts would ignore “trifling or unessential variation.”¹¹⁸ Defendants were guilty of infringement if they made “what is in substance the equivalent of the patented article.”¹¹⁹ Case law under the current Act suggests that a similar approach may be followed.¹²⁰

6.5.3 Defenses to infringement

The rights under Section 48 of the Patents Act, 1970, are expressly subject to other provisions of the Act. Section 107(1) states that all the grounds for revoking a patent for invalidity can be used as defenses to a claim for patent infringement. Defendants can, thus, contest the suit patent’s validity even without filing a counterclaim.

Section 107A recognizes the *Bolar* exception for defendants to use the patented product or process for developing information for regulatory filings both in India and abroad. The Delhi High Court’s judgment in *Bayer Corp. v. Union of India*¹²¹ carries a detailed discussion of the *Bolar* exception.

India follows the rule of international exhaustion regarding patents. Under Section 107A(b) of the Act, importing a duly authorized product from a foreign jurisdiction is not an infringement. Thus, the position is similar to that under the Trade Marks Act, 1999,¹²² but different from the domestic exhaustion rule followed under the Indian Copyright Act, 1957.¹²³

Section 107(2), read with Section 47, contains well-known exclusions from the scope of a patent’s exclusivity, such as the research exemption, educational use and governmental use.

6.5.4 Counterclaim of invalidity

Defendants invariably file a counterclaim seeking revocation under Section 64(1) of the Patents Act, 1970. The grounds provided for revocation under Section 64(1) are exhaustive. There is a view that courts retain the discretion not to revoke a patent despite the fulfillment of one or more of the grounds under Section 64(1),¹²⁴ though this does not seem to be the correct position in law. Proving any one of the grounds under Section 64(1) ought to lead to revocation of the patent.

The grounds for revocation usually taken in a counterclaim include lack of novelty or inventive step and non-patentable subject matter. It is also usual for defendants to support the grounds for revocation, especially in respect of lack of novelty and inventive step, by relying upon claims granted in other jurisdictions. If, in any other foreign jurisdiction, claims granted in corresponding patents are narrower than those granted in India, it is common for defendants in India to question the validity of the Indian patent by referring to such claims. Thus, it is advisable for patentee-plaintiffs in infringement actions in India to check whether the scope of claims in other significant jurisdictions differs, at least broadly, from that of the claims in India. If the patentee narrows the claims in other jurisdictions, it is advisable to make similarly narrower claims in India at the prosecution stage.

The citing of corresponding claims from foreign jurisdictions relates to the concept of “file-wrapper estoppel.” Although patent rights are strictly territorial, defendants argue that the patentee ought to be bound by statements, concessions and amendments made by the patentee before foreign patent offices concerning the same invention. Usually, such narrowing amendments in foreign jurisdictions, without corresponding Indian amendments, could adversely impact the grant of interim relief.

117 Indian Patents and Designs Act, 1911, §29(1).

118 *Raj Parkash v. Mangat Ram Chowdhry*, 1977 SCC Online Del. 33, para. 25.

119 *Parkash*, 1977 SCC Online Del. 33, para. 25.

120 *CTR Manufacturing Industries Ltd v. Sergi Transformer Explosion Prevention Technologies Pvt. Ltd*, 2015 SCC Online Bom. 5538; *Novartis AG v. Adarsh Pharma*, 2004 SCC Online Mad. 402.

121 WP (C) 1971 of 2014, order dated March 8, 2017, appealed in 2019 SCC Online Del. 8209.

122 *Kapil Wadhwa v. Samsung Electronics Co. Ltd*, 2012 SCC Online Del. 5172, appeal filed, *Samsung Electronics Co. Ltd v. Kapil Wadhwa*, CA 8600 of 2013.

123 *Warner Bros. Entertainment Inc. v. Santosh VG*, CS (OS) 1682 of 2006, order dated April 13, 2009; *Engineering Analysis Centre of Excellence Pvt. Ltd v. Commissioner of Income Tax*, 2021 SCC Online SC 159.

124 *F Hoffmann-La Roche Ltd v. Cipla Ltd*, MIPR 2016 (1) 1.

Another ground that defendants often rely upon is noncompliance with Section 8 obligations. Section 8(1) of the Act requires mandatory disclosure of the details of all corresponding foreign applications. Section 8(2) requires the filing of the prosecution history of corresponding foreign applications if so directed by the Indian Patent Office.

An issue frequently agitated in Indian courts, in invalidity challenges to pharmaceutical patents, concerns coverage and disclosure. In *Novartis AG v. Union of India*,¹²⁵ the Supreme Court held that a patentee cannot contend that a patent's coverage is more expansive than its disclosure. The following observation by Justice Jacob in the English case of *European Central Bank v. Document Security Systems Inc.* is often cited in the Indian context:

Professor Mario Franzosi likens a patentee to an Angora cat. When validity is challenged, the patentee says his patent is very small: the cat with its fur smoothed down, cuddly and sleepy. But when the patentee goes on the attack, the fur bristles, the cat is twice the size with teeth bared and eyes ablaze.¹²⁶

Since claims are granted only upon an enabling disclosure, courts must presume that a prior patent discloses the claimed subject matter in an enabling manner. However, there have been various opinions expressed that the patent coverage could be wider than the disclosure, leading to multiple patents thereafter. The Delhi High Court has recently considered this issue in a series of interim orders, wherein the preponderance of the view favored the interpretation in *Novartis*.¹²⁷ This view is presently the prevalent one.

6.6 Judicial patent proceedings and case management

6.6.1 Key features in patent proceedings

As in all civil cases, the onus of proving infringement is on the plaintiff suing for infringement.¹²⁸ The court may shift the evidentiary burden and call upon the defendants to establish the noninfringement of process claims in specific circumstances consistent with Article 34 of the TRIPS Agreement. Section 104A of the Patents Act, 1970, provides for two situations in which the defendant can be asked to prove noninfringement of a process claim. One condition precedent common to both situations is that the defendant's product must be identical to the product directly obtained by the patented process. Once this condition is fulfilled, the court retains the power to demand that the defendant prove noninfringement if the process is for obtaining a new product¹²⁹ or if the plaintiff shows a substantial likelihood that the defendant is using the patented process and is unable to determine the defendant's process despite reasonable efforts.

The court may not require the defendant to disclose its process if such disclosure would result in the disclosure of any trade, manufacturing or commercial secrets that form part of the defendant's process, but only if the disclosure appears reasonable to the court.¹³⁰ The use of confidentiality clubs, however, may aid even in such disclosure.¹³¹

6.6.2 Forum and *locus standi* to initiate infringement actions

A patent enforcement action under Section 104 of the Patents Act, 1970, can be initiated before a district court or higher. The court will try a patent suit as a commercial suit under the Commercial Courts Act, 2015.¹³² This also applies to a suit seeking a declaration of noninfringement.¹³³ However, if a defendant in an infringement action counterclaims the patent's invalidity, the suit and the counterclaim are automatically transferred to the High Court for further adjudication.¹³⁴ A declaratory suit for noninfringement cannot question the patent's validity.¹³⁵ The registered

125 (2013) 6 SCC 1.

126 [2008] EWCA Civ 192; see also Richard Miller *et al.*, *Terrell on the Law of Patents*, para. 9.14 (18th ed. 2016).

127 *AstraZeneca AB v. P. Kumar*, 262 (2019) DLT 118; *AstraZeneca AB v. Intas Pharmaceuticals*, I.A. 8826/2020 in CS (COMM) 410 of 2020, order dated Nov. 2, 2020. But see *AstraZeneca AB v. Zydus Healthcare*, CS (COMM) 414 of 2020, order dated Nov. 18, 2020. The 2020 orders are presently under appeal before a division bench of the Delhi High Court.

128 Indian Evidence Act, 1872, §101.

129 Patents Act, 1970, §104A(1)(a).

130 Patents Act, 1970, §104(2).

131 For discussion on confidentiality clubs, see Section 6.6.5 of this chapter.

132 Commercial Courts Act, 2015, §2(1)(c)(vii).

133 Patents Act, 1970, §105.

134 Patents Act, 1970, §104 proviso.

135 Patents Act, 1970, §105(3).

owner of the patent, or the assignee thereof, is entitled to sue for infringement. Section 109 of the Patents Act, 1970, provides that an exclusive licensee may sue for patent infringement but must implead the patent's registered owner as a defendant. Under Section 110 of the Act, a person who has been granted a compulsory license may also sue for patent infringement if, upon notification of infringement to the patentee, the patentee fails to take action within two months.

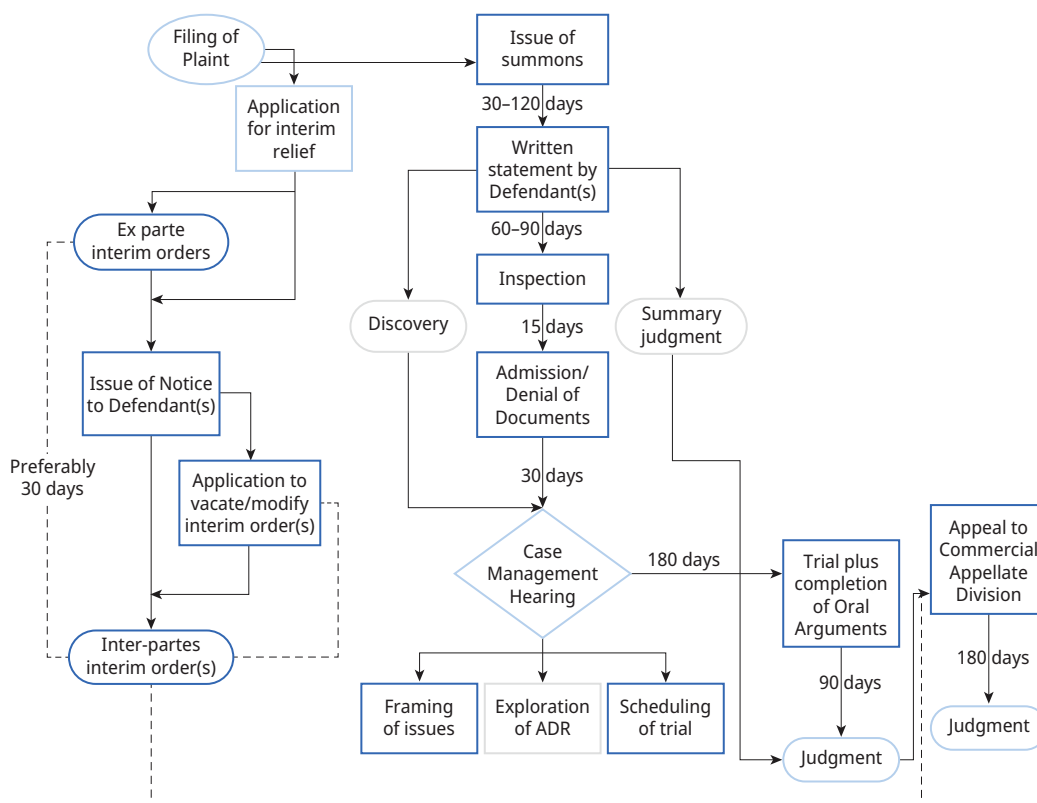
6.6.3 Early case management

Once all pleadings are complete, the suit is listed before a designated commercial court single-judge bench in a case management hearing for framing issues. The court identifies, as precisely as possible, the issues that arise for determination; directs the filing of witness statements; and sets the schedule for trial. The Commercial Courts Act, 2015, prescribes short time limits for completing pleadings. Pending interim applications do not (and should not) delay the case management hearing for framing issues.

6.6.3.1 Pleadings and overall case schedule

The Commercial Courts Act, 2015, fixes mandatory timelines for filing all pleadings. The Supreme Court of India, in *SCG Contracts India Pvt. Ltd v. KS Chamankar Infrastructure Pvt. Ltd.*¹³⁶ confirmed that the timelines fixed under the Act are mandatory. The Act also prescribes a schedule for the entire case (see Figure 6.4).

Figure 6.4 Overall case schedule according to the Commercial Courts Act, 2015



Note: ADR = alternative dispute resolution.

The rigidity of timelines under the Act has been of some concern in patent litigation, given the technical complexity involved. However, most practitioners and litigants agree that, without fixed timelines, litigation tends to become unnecessarily protracted. The strict scheduling ensures that pleadings are completed on time and that trials are expedited. The real bottleneck is the final arguments post-trial, which has systemic causes: chiefly, the enormous number of unfilled

positions of judges. Recent trends in filling these vacancies, coupled with specialized training in IP-related matters of judges rostered to IP cases, ought to address the bottleneck problem.

6.6.3.2 Case management hearing

Case management is mandatory under the Commercial Courts Act, 2015. The first case management hearing must be mandatorily held not later than four weeks from the date of filing of an affidavit of admission or denial of documents by the parties. It is intended for the court to engage in the early identification of disputed issues of fact and law, the establishment of a procedural calendar for the entire case (including trial and final hearing), and the exploration of the possibility of dispute resolution other than by trial.

6.6.4 Provisional measures

As a common-law jurisdiction, Indian courts are vested with extensive discretionary powers to grant interim relief. The usual determinants apply: whether the plaintiff has a *prima facie* case, where the balance of convenience lies, and to whom irreparable injury is likely if the order is or is not granted. An interim order may subject the plaintiff to conditions, including security. Injunctions can be tailored to suit the remedy.¹³⁷

In general, interim reliefs can be in various forms, including interim injunctions; *Mareva* orders or freezing orders; *Anton Piller* orders, where local commissioners (LCs) are appointed with powers of search and seizure; and directions for keeping accounts. Under Order XXXIX(1)–(2) of the Code of Civil Procedure, 1908 [hereinafter the “Code of Civil Procedure”], patentees may also seek interim and ad interim injunctions. Indian courts have regularly considered the grant of interim injunction orders, *Anton Piller* orders, *Mareva* orders, *Norwich Pharmacal* orders or *John Doe* orders in fitting cases.

It is usual to seek even *ex parte* ad interim relief in suits for patent infringement. In some cases, where the patent has been tested multiple times in litigation, courts usually even grant the ad interim injunction *ex parte*; there is no strict rule. For instance, in the case of SEPs, defendants are usually called upon before the grant of an injunction for a response as to whether they are willing to take a license on fair, reasonable and nondiscriminatory terms.

Irrespective of the outcome of the interim proceedings, the parties (usually the unsuccessful party at the interim stage) usually seek an expeditious trial and final hearing. In fact, in one case where the interim injunction was granted in favor of the patentee (i.e., *Merck Sharp and Dohme Corp. v. Glenmark Pharmaceuticals*),¹³⁸ the Supreme Court allowed the sale of the existing stock already manufactured by the defendant and directed a day-to-day trial, saying that this was in the national interest, one that demanded a suitable commercial environment for the immediate resolution and adjudication of contentious commercial cases.¹³⁹ In that case, due to the intervention of the Supreme Court, the time from the suit’s filing to final judgment was only about 30 months. The trial concluded in a record time of less than 30 days. Final arguments were heard for three weeks, and judgment followed very soon thereafter. The Supreme Court has also issued general directions for such expedited hearings in other patent matters.¹⁴⁰

In cases where a patent has been tried and tested in prior litigation, courts have not hesitated to grant interim injunctions, though the defendant may be permitted to exhaust existing stocks along with accounts. Some perceive the Delhi High Court to be quite liberal in granting interim injunctions to patentees, though there have been some instances in which the court has refused interim injunctions owing to the complexity of the invalidity defense. In other cases, the court has crafted alternative arrangements for the interim period. Where an interim injunction is refused, courts almost always direct the defendant to maintain and file accounts.

6.6.4.1 Governing legal standards and burdens

Courts see growing numbers of patent litigation, with a corresponding increase in the grant of injunctions (both permanent and interlocutory). Temporary injunctions are regulated by Sections

137 Yogesh Pai, “Patent Injunction Heuristics in India,” in *Patent Law Injunctions* (Rafal Sikorski ed., 2019), <https://ssrn.com/abstract=3305029>

138 2015 SCC Online Del. 8227.

139 *Glenmark Pharmaceuticals Ltd v. Merck Sharp and Dohme Corp.*, (2015) 6 SCC 807.

140 *Bajaj Auto v. TVS Motors*, (2009) 9 SCC 797; *Az Tech (India) v. Intex Technologies (India)*, SLP (C) 18892 of 2017, order dated Aug. 16, 2017.

94 and 95 and Order XXXIX of the Civil Procedure Code. The substantive law on temporary and perpetual injunctions can be found in Sections 36–42 of the Specific Relief Act, 1963.

The general principles for grant or denial of such interim orders are well known: a *prima facie* case, the balance of convenience, irreparable injury and public interest factors.¹⁴¹ Indian courts have derived principles following the decision of the House of Lords in *American Cyanamid v. Ethicon Ltd.*¹⁴² though the Supreme Court of India has observed that the relatively diluted standard of “*prima facie* case” in *American Cyanamid* will not apply in India.¹⁴³ Similarly, whereas *American Cyanamid* suggests that more weight must be attached to patents granted after a detailed examination procedure, Section 13(4) of the Patents Act, 1970, and some judicial precedents in India suggest that this proposition is inapplicable to Indian patent law.¹⁴⁴

6.6.4.1.1 *Prima facie* case

The *prima facie* case requirement is used to discern whether the plaintiff has a reasonable case on merits. It does not finally or conclusively decide issues of fact. It weeds out frivolous or vexatious claims – ones manifestly without merit. As part of this assessment, courts also assess whether defendants have a credible challenge to the suit patent’s validity.¹⁴⁵

Initially, in India, a few judicial pronouncements referred to a six-year rule (i.e., a presumption that there could be an increased probability a patent could be treated as valid on the expiry of six years from the date of grant). The genesis of the six-year rule approach can be traced to the Madras High Court’s ruling in *Manicka Thevar v. Star Ploro Works* case,¹⁴⁶ which was subsequently picked up in other judgments.¹⁴⁷ However, none of the provisions of law appears to suggest or support this numerical fixation with six years. The *Manicka Thevar* case was subsequently held not to be correct law by another division bench of the Madras High Court.¹⁴⁸ In *F Hoffmann-La Roche Ltd v. Cipla Ltd*, a single judge of the Delhi High Court also held that there was no basis for the six-year rule and rejected the application of the said rule in patent cases.¹⁴⁹ Thus, one will not find a discussion of any such six-year rule in most recent patent cases across India.

6.6.4.1.2 *Balance of convenience and public interest*

The second requirement for the grant or denial of an interim injunction is that the balance of convenience must be in favor of granting an injunction. The court, while granting or refusing to grant an injunction, should exercise sound judicial discretion to compare and determine the amount of mischief or injury likely to be caused to the respective parties if the injunction is refused and if it is granted. The court would weigh competing possibilities or probabilities.

In India, public interest has been recognized both as a separate factor and as a factor read into the test for the balance of convenience.¹⁵⁰ For instance, the public interest in enabling access to lifesaving drugs (both supply and pricing considerations) has been considered a relevant factor when deciding on an application for an interim injunction.¹⁵¹ Recently, given the influence of comorbidity factors such as diabetes and obesity in the severity of COVID-19 infections, the pricing of antidiabetic medications was considered one of the relevant factors when assessing interim injunction applications.¹⁵²

The defense of public interest is not a complete exception to a legally valid patent and must not be too broadly interpreted, as it would undermine “the rights granted by the sovereign towards monopoly.”¹⁵³ The Delhi High Court has recognized that upholding the enforcement of patents is

141 *F Hoffman-La Roche Ltd v. Cipla Ltd*, 2009 (110) DRJ 452 (DB); *Merck Sharp and Dohme Corp. v. Glenmark Pharmaceuticals*, 2015 SCC Online Del. 8227.

142 [1975] AC 396.

143 *SM Dyechem Ltd v. Cadbury (India) Ltd*, (2000) 5 SCC 573.

144 *F Hoffman-La Roche*, (110) DRJ, paras 53–55 (DB).

145 *F Hoffman-La Roche*, (110) DRJ, paras 53–55 (DB).

146 AIR 1965 Mad. 327.

147 *National Research and Development Corp.’s, Bilcare v. Amartara Pvt. Ltd.*, 2007 (34) PTC 419 (Del).

148 *Mariappan v. AR Safiullah*, 2008 (5) CTC 97.

149 2008 (37) PTC 71 (Del.) (SJ), *aff’d*, 159 (2009) DLT 243 (DB) (though there is no express discussion on the six-year rule).

150 *F Hoffmann-La Roche*, 159 DLT (DB).

151 *F Hoffmann-La Roche*, 159 DLT (DB).

152 *AstraZeneca AB v. Intas Pharmaceuticals Ltd*, MANU/DE/1939/2020.

153 *Novartis AG v. Cipla Ltd*, 2015 SCC Online Del. 6430, para 88.

also in the public interest.¹⁵⁴ Thus, often, public interest factors are considered along with the *prima facie* strength of the infringement case or the invalidity defense.¹⁵⁵

Public interest forms part of the matrix considered by the court and need not always be a dispositive factor in every case. For instance, in *Bayer Intellectual Property GmbH v. Ajanta Pharma Ltd.*,¹⁵⁶ factors such as loss of employment and revenue earned by the state – even in cases where the patented drugs were not of a lifesaving nature – were considered by the Delhi High Court. However, in a subsequent decision, *Bayer Intellectual Property GmbH v. BDR Pharmaceuticals International Pvt. Ltd.*,¹⁵⁷ another judge of the same High Court held that the export of non-lifesaving drugs would not qualify under the test of public interest merely due to encouraging economic activity and the country earning foreign exchange revenue.

The Delhi High Court, in *Merck Sharp and Dohme Corp. v. Glenmark Pharmaceuticals*,¹⁵⁸ invoked several equitable principles to guide the exercise of discretion in granting injunctions. These included an assessment of the parties' conduct, whether the defendant attempted to clear the way by filing oppositions or seeking revocation, and so on.

It is also common for defendants to raise pleas of nonworking of patents or nonfiling of working statements to defend against interim injunctions as part of the balance of convenience and public interest factors. The working requirements under the Patents Act, 1970, are stringent. The legislative history shows that the nonworking of patents by foreign companies was one of India's most significant concerns when drafting the legislation. In a case concerning a patented respiratory disorder drug, the Delhi High Court, in *Cipla Ltd v. Novartis AG*,¹⁵⁹ held that the mere nonmanufacturing of sufficient quantities in India alone could not result in the denial of an interim injunction. However, defendants are free to apply for a compulsory license in such cases. There is an earlier opposing view suggesting that the nonworking of a patent could lead to denial of injunctive relief.¹⁶⁰ The later view in *Cipla* is now the more prevalent view. Though no compulsory license was granted during the COVID-19 pandemic, in dealing with cases relating to shortages of essential medicines used in the treatment of COVID-19, both the Supreme Court and the High Court have made observations favoring such steps being taken by the Government.¹⁶¹

6.6.4.1.3 Irreparable injury

The third and equally important consideration is the condition of irreparable injury. This refers to the patentee having no other remedy available other than an injunction. Irreparable injury, however, does not mean that there must be no physical possibility of repairing the injury. Instead, it means only that the injury must be a material one – namely, one that cannot be adequately compensated in damages.

In *Merck Sharp and Dohme Corp. v. Glenmark Pharmaceuticals*,¹⁶² the Delhi High Court recognized that, in cases where the patentee has been the sole supplier of the patented technology, allowing a defendant to enter the market may cause irreparable injury.

6.6.4.2 Other preliminary reliefs

6.6.4.2.1 Local commissioners

Order XXVI(9) of the Code of Civil Procedure provides for the appointment of LCs. Such LCs are appointed upon the establishment of a strong *prima facie* case. In cases of a patent infringement action, LCs have been appointed by the Indian courts to record evidence.

154 *Merck Sharp and Dohme Corp. v. Glenmark Pharmaceuticals*, 2015 SCC Online Del. 8227.

155 *Merck Sharp and Dohme*, 2015 SCC Online Del.; see also *Bristol-Myers Squibb Co. v. JD Joshi*, CS (OS) 2303 of 2009; *Bristol-Myers Squibb Co. v. D Shah*, CS (OS) 679 of 2013.

156 CS (COMM) 1648 of 2016, order dated Jan. 4, 2017.

157 CS (COMM) 107 of 2017, order dated Feb. 16, 2017.

158 *Merck Sharp and Dohme*, 2015 SCC Online Del.

159 2017 SCC Online Del. 7393.

160 See *Franz Xaver Humer v. New Yash Engineers*, (1996) ILR 2 Del. 791.

161 *In re Distribution of Essential Supplies and Services during Pandemic*, Suo Motu Writ Petition (Civil) 3 of 2021, order dated April 30, 2021; *Rakesh Malhotra v. Government of National Capital Territory of Delhi*, WP (C) 3031 of 2020, order dated April 20, 2021.

162 *Merck Sharp and Dohme*, 2015 SCC Online Del. 8227.

An order for the appointment of an LC is usually made in patent litigation if, for example, the manufacturing processes need to be ascertained. The LC is then appointed by the court with strict terms and conditions. Typical conditions imposed include:¹⁶³

- that the LC visits the premises of the defendant or plaintiff, as the case may be;
- that the LC ascertain the manufacturing process being used, including inspection of the raw material registers, excipient data, the quantum of manufacturing and so on;
- that the accounts of manufacture, sales and so on are inspected;
- that the LC visits the Customs authorities to retrieve samples of alleged infringing products;
- permitting the LC to take photographs and videotape the proceedings; and
- permitting party representatives to accompany the LC, including counsel, to render assistance.

At the end of the execution of the commission, a memorandum of proceedings is prepared by the LC, recording the chronology of events that transpired in the commission and the observations of the LC. This is signed by the LC and the parties, and the LC must give copies of the same to each party. Thereafter, a report is filed before the court, giving a full account of the proceedings. Such a report filed by the LC can be read in evidence without the statement of the LC being recorded in terms of Order XXVI(14)(2) of the Code of Civil Procedure. So long as the court can confirm that the report is genuine and authentic, it forms part of the record. Parties may have objections to the contents of the LC's report, in which case they can file objections. The objections are then adjudicated by the court before the report is fully read as evidence.

The LC so appointed is not performing a judicial act but a "ministerial act." Nothing is left to the discretion of the LC, and there is no occasion to use judgment or adjudicate the issues involved. The LC only notes details and reports the actual state of affairs. The LC cannot decide the dispute, but their report helps the court in doing so.¹⁶⁴ In short, the LC's report is one of fact-gathering, not adjudication or determination.

6.6.4.2.2 Interim deposits and other ad interim arrangements

The interim injunction stage may become protracted owing to the technical issues surrounding patents. In such instances, and in a fitting case, courts usually put in an ad interim arrangement. In general, courts enjoy extensive discretion to mold the interim relief to suit the circumstances. For example, courts have directed interim deposits by defendants in SEP cases or have directed the submission of bank guarantees or some form of security to secure the plaintiff's interest.¹⁶⁵ In the recent non-SEP case of *Communication Components Antenna Inc. v. Ace Technologies Corp.*,¹⁶⁶ the High Court's interim direction to secure the plaintiff by way of a deposit of royalties and bank guarantee was upheld by the Supreme Court of India.¹⁶⁷

Equally, in such cases of interim deposits, courts have required the patentee to furnish surety bonds for the amount received on a quarterly basis with advance copies.¹⁶⁸

6.6.5 Discovery and gathering of information

At or before the case management hearing, it is usual for parties to admit and deny the respective documents filed by the other party and to also seek discovery, inspection or the production of documents from the other party.¹⁶⁹ Upon an appropriate application by one party, the court may direct the other party to respond to written interrogatories on affidavit,¹⁷⁰ permit the inspection of documents relied upon or referred by the other party,¹⁷¹ allow discovery of relevant documents on affidavit,¹⁷² or direct the production of documents.¹⁷³

163 E.g., *Victoria Foods Private Limited v. Rajdhani Masala Co. & Anr.*, CS(COMM) 108 of 2021, order dated March 24, 2022; *Sun Pharma Laboratories Ltd. v. Interio International P. Ltd & Ors.*, CS(COMM) 184 of 2022, order dated March 28, 2022.

164 *Saraswathy v. Viswanathan*, 2002 (2) CTC 199.

165 E.g., *Telefonaktiebolaget LM Ericsson (Publ.) v. Intex Technologies (India) Ltd.*, CS (OS) 1045 of 2014, judgment and order dated March 13, 2015; *Dolby International v. GDN Enterprises Pvt. Ltd.*, CS (COMM) 1425 of 2016, orders dated Oct. 27, 2016, and Nov. 23, 2016; *Koninklijke Philips NV v. Vivo Mobile Communications Co. Ltd.*, CS (COMM) 383 of 2020; *Koninklijke Philips NV v. Xiaomi Inc.*, CS (COMM) 502 of 2020.

166 CS (COMM) 1222 of 2018, order dated July 12, 2019.

167 *Communication Components Antenna Inc. v. Ace Technologies Corp.*, SLP (C) 21938 of 2019, order dated Sep. 20, 2019.

168 *Telefonaktiebolaget LM Ericsson v. Mercury Electronics*, 2015 (64) PTC 105 (DEL).

169 Code of Civil Procedure, 1908, Order XI.

170 Code of Civil Procedure, 1908, ord. XI rr. 1–8.

171 Code of Civil Procedure, 1908, ord. XI rr. 15, 17–18.

172 Code of Civil Procedure, 1908, ord. XI rr. 12–13.

173 Code of Civil Procedure, 1908, ord. XI rr. 14, 16.

Courts are always empowered to dismiss the suit or defense for want of prosecution if a party does not comply with an order to answer interrogatories or the order for discovery, inspection or the production of documents.¹⁷⁴ For instance, in SEP cases, the defendants or the plaintiff would be made to share the claim-mapping charts as part of the exchange of documents to prove that the patents map the standards for which they are sought to be enforced.

Often, discovery and inspection procedures are used to seek irrelevant information and protract litigation. For instance, defendants may seek entire file wrappers from all jurisdictions just as a matter of course. However, courts do not permit such a roving inquiry or fishing expedition, and the party concerned is entitled to move the court to curtail the kind of information or type of documents being sought. The other side of this is “data-swamping” or “data-flooding,” whereby a party against whom disclosure is ordered inundates the other party with all manner of documentation in an attempt to bury the crucial material in a mountain of irrelevance. The Code of Civil Procedure enables parties to seek and defend against any discovery tool, with the courts being the final arbiter if disputes arise in this context. Again, this process demands judicial time (and enough human resources on the bench) and well-honed forensic skills on all sides.

Courts also retain wide discretion in directing the production of documents under certain conditions. To enable discovery and inspection of license agreements, manufacturing processes followed and so on – which may be confidential – courts usually constitute confidentiality clubs to maintain the confidentiality of the information disclosed.¹⁷⁵ There has been recent debate as to whether litigants can be part of these confidentiality clubs.¹⁷⁶ However, as far as the constitution of the clubs is concerned, there appears to be no dispute; the confidentiality club, once constituted, considerably streamlines the process of discovery and inspection of documents.

Recently, the High Court of Delhi Rules Governing Patent Suits, 2022 have been notified. These rules provide for a minimum mandatory content for pleadings in patent suits,¹⁷⁷ a minimum set of mandatory documents to be filed by the parties,¹⁷⁸ and specific tweaks in patent suit procedures. For instance, in addition to regular pleadings, the rules provide that parties be allowed to file claim construction, invalidity, infringement briefs and technical primers based on which the court is to frame issues in the first case management hearing.¹⁷⁹ A second case management hearing is provided for streamlining the recording of evidence, including the protocol for a hot-tubbing mechanism.¹⁸⁰ A reserve third management hearing is provided to address any pending pre-trial concerns.¹⁸¹ Importantly, the rules contemplate the creation of a panel of scientific experts to assist the court.¹⁸² While setting the calendar and protocols for a final hearing, the court may also direct that a technical expert of each party may also be present to assist the court.¹⁸³

6.6.6 Summary proceedings

The Commercial Courts Act, 2015, through its amendment to the Code of Civil Procedure, permits parties to seek summary adjudication.¹⁸⁴ Either party may seek such summary disposal if the other party has no real prospect of succeeding and if there is no other compelling reason why the claim should not be disposed of before recording oral evidence.¹⁸⁵

Such summary adjudication under Order XIII-A of the Code of Civil Procedure can be sought by filing a specific application and setting out the specific grounds.¹⁸⁶ The application is to be filed before issues are framed.¹⁸⁷ When adjudicating such an application for summary disposal, courts

174 Code of Civil Procedure, 1908, ord. XI rr. 21.

175 *M Sivasamy v. Vestergaard Frandsen A/S*, 2009 (113) DRJ 820 (DB); *Telefonaktiebolaget LM Ericsson (Publ.) v. Lava International Ltd*, CS (OS) 764 of 2015, order dated March 1, 2016; *Pfizer Inc v. Union Remedies Ltd*, 2016 SCC Online Bom. 8599; Delhi High Court (Original Side) Rules 2018, ch. VII r. 17.

176 *Interdigital Technology v. Xiaomi Corp.*, CS (COMM) 295 of 2019, order dated Oct. 9, 2020.

177 High Court of Delhi Rules Governing Patent Suits, 2022, r. 3.

178 High Court of Delhi Rules Governing Patent Suits, 2022, r. 4.

179 High Court of Delhi Rules Governing Patent Suits, 2022, rr. 7(v), 8.

180 High Court of Delhi Rules Governing Patent Suits, 2022, r. 9.

181 High Court of Delhi Rules Governing Patent Suits, 2022, r. 10.

182 High Court of Delhi Rules Governing Patent Suits, 2022, r. 13.

183 High Court of Delhi Rules Governing Patent Suits, 2022, r. 15.

184 Code of Civil Procedure, 1908, ord. XIII-A. This order was inserted by the Commercial Courts Act, 2015.

185 Code of Civil Procedure, 1908, ord. XIII-A r. 1(3).

186 Code of Civil Procedure, 1908, ord. XIII-A r. 1(4).

187 Code of Civil Procedure, 1908, ord. XIII-A r. 1(2) proviso.

enjoy broad discretion to pass a variety of orders, including, for instance, conditional orders that require the deposit of money or furnishing security.¹⁸⁸

Another possibility of summary disposal is under Order XII(6), by which the court is empowered to pass judgment based on admissions of fact made either in the pleading or even otherwise. The admissions made by patentees during prosecution, whether in India or any foreign jurisdiction, can be construed as admissions under the Code of Civil Procedure and result in summary disposals. The logic is straightforward and self-evident: no patentee should be permitted to make conflicting claims in different jurisdictions. A patentee must be held to be bound by statements made with regard to that specific patent claim, irrespective of where and when that claim is made. This is a species of estoppel.

Such summary procedures help the court to considerably narrow the scope of controversy. For instance, in negotiations for licensing, defendants usually admit that they need the license, and the only dispute that remains is about the licensing amount. In such suits, the court can rely on the correspondence between the parties to issue summary judgments.

Similarly, such summary adjudication has proved workable in SEP litigation: for example, where an ex-licensee of the SEP has refused to renew the license due to a failure of commercial discussions. The dispute is then restricted only to the monetary claim of the licensing fee, and other issues, such as infringement or validity, do not arise. While an ex-licensee is not estopped or precluded from challenging the validity of a patent at any time, courts are reluctant to entertain validity challenges when an erstwhile licensee elects to challenge the patent's validity only at the time of a license renewal agreement after having enjoyed a license for several years. A court will permit such a challenge to proceed only on a demonstration of some glaring fact that goes to the root of validity and which was noticed at the time of the original licensing.

6.6.7 Evidence

6.6.7.1 Oral evidence and trial

The examination in chief (direct examination) of witnesses is compulsorily on affidavit.¹⁸⁹ Cross-examination and reexamination ("redirect") are taken orally live and transcribed. Often, to save the court's time, the recording of the oral evidence is done either before the registrar of the court or before an LC. Unlike a court, LCs and registrars are not empowered to rule on objections raised during the evidence.¹⁹⁰ However, the commissioner is entitled to enter notes they think material, about a witness' demeanor so that the same is available to the court at the time of final hearing.¹⁹¹

Usually, trials take between three and five years from the date of filing to conclude, though there have been some patent cases where the trial concluded in six months to a year. Under the Commercial Courts Act, 2015, the court schedules the entire trial so that the recording of evidence is not drawn out. The trial could be day-to-day, and it is common for the courts to explicitly direct as such to reduce inconvenience to witnesses.¹⁹² Once the trial of a suit concludes, the matter proceeds to a final hearing.

It is usual for witnesses from foreign jurisdictions to record their statements through videoconferencing. Following the COVID-19 pandemic, virtual courts and online platforms are usually used even for court hearings. Litigants can join proceedings physically, and, if the court has the facility, they can also join the hearing through a videoconferencing facility.

Witnesses are usually in-house representatives or attorneys from the respective parties who have themselves dealt with the litigation and the correspondence between the parties. A witness is not expected to have direct personal knowledge of every part of the deposition; it is enough if the witness can depose to company records and the record of the suit. In some areas, the testimony of people with personal knowledge is preferred – for example, for evidence about discussions in

188 Code of Civil Procedure, 1908, ord. XIII-A r. 1(6).

189 Code of Civil Procedure, 1908, ord. XVIII r. 4(1).

190 Code of Civil Procedure, 1908, ord. XVIII proviso.

191 Code of Civil Procedure, 1908, ord. XVIII r. 4(4).

192 See Section 6.6.4 of this chapter.

negotiations, the exchange of correspondence, some technical knowledge leading to the grant of the patent and so on.

Other witnesses are usually technical witnesses. In some cases, the inventor is also produced as a witness to strengthen the case of the plaintiff. Experts such as doctors, specialists, economists and accountants have also been produced in the court to establish other aspects of the litigation, such as the calculation of damages, distinguishing the prior art, mapping standards and so on. The inquiry into damages is crucial at the final stage, and, therefore, economists, financial experts or accountants who can analyze and depose to the computation of damages or royalties payable are vitally important in establishing the monetary aspect of the infringement case. Thus, the general practice is to have both in-house and expert witnesses.

6.6.7.2 Who leads evidence first? Can a defendant be directed to lead evidence first?

The Patents Act, 1970, does not specifically provide a procedure for evidence in cases of patent infringement. Instead, the procedure adopted for leading evidence in suits for infringement is in accordance with the Code of Civil Procedure¹⁹³ and the Indian Evidence Act, 1872. Under the latter, the onus of proof is on the person making a positive assertion. Thus, the patentee-plaintiff must lead evidence first to establish infringement. The defendant leads evidence thereafter to support its defenses or its counterclaim of invalidity. However, this is not a rigid rule. In a case where the defendant admits infringement, and the only question for decision is validity, the court may direct the defendant to lead evidence first. Thus, as provided under Order XVIII, the right to begin is generally granted to the plaintiff:

- 1. Right to begin.** – The plaintiff has the right to begin unless the defendant admits the facts alleged by the plaintiff and contends that either in point of law or on some additional facts alleged by the defendant the plaintiff is not entitled to any part of the relief which he seeks, in which case the defendant has the right to begin.
- 2. Statement and production of evidence.** –
 - (1) On the day fixed for the hearing of the suit or on any other day to which the hearing is adjourned, the party having the right to begin shall state his case and produce his evidence in support of the issues which he is bound to prove.
 - (2) The other party shall then state his case and produce his evidence (if any) and may then address the Court generally on the whole case.
 - (3) The party beginning may then reply generally on the whole case.

Moreover, where a process claim is asserted, depending on the facts, the burden of proof may shift to the defendant to prove non-infringement. This exceptional situation is provided for under Section 104A of the Patents Act, 1970:

Burden of proof in case of suits concerning infringement.

- (1) In any suit for infringement of a patent, where the subject matter of patent is a process for obtaining a product, the court may direct the defendant to prove that the process used by him to obtain the product, identical to the product of the patented process, is different from the patented process if, –
 - (a) the subject matter of the patent is a process for obtaining a new product; or
 - (b) there is a substantial likelihood that the identical product is made by the process, and the patentee or a person deriving title or interest in the patent from him, has been unable through reasonable efforts to determine the process actually used:
Provided that the patentee or a person deriving title or interest in the patent from him first proves that the product is identical to the product directly obtained by the patented process.
- (2) In considering whether a party has discharged the burden imposed upon him by subsection (1), the court shall not require him to disclose any manufacturing or commercial secrets, if it appears to the court that it would be unreasonable to do so.

Subject to the fulfillment of the condition precedents noted in Section 104A, this is another circumstance in which the defendant may be asked to lead evidence first.¹⁹⁴

¹⁹³ *Monsanto Technology LLC v. Nuziveedu Seeds Ltd*, (2019) 3 SCC 381.

¹⁹⁴ See also Section 6.6.1 of this chapter for a detailed discussion.

In *Bajaj Auto Ltd v. TVS Motor Co. Ltd.*,¹⁹⁵ the Madras High Court was confronted with a unique situation – a suit against the groundless threat of infringement and non-infringement *against* the patentee, as well as a subsequent suit for infringement *by* the patentee. On the limited issue of who should lead evidence first, the court held that the plaintiff in the earlier suit must lead the evidence first since the subsequent suit was more in the nature of a counterclaim of infringement by the patentee. This is yet another unique situation wherein the alleged infringer led evidence first.

6.6.7.3 Filing of affidavits of witnesses in evidence: not treated as evidence till tendered

According to Order XVIII(4) of the Code of Civil Procedure:

Recording of evidence.

- (1) In every case, the examination-in-chief of a witness shall be on affidavit and copies thereof shall be supplied to the opposite party by the party who calls him for evidence:
Provided that where documents are filed and the parties rely upon the documents, the proof and admissibility of such documents which are filed along with an affidavit shall be subject to the orders of the Court.
- (1A) The affidavits of evidence of all witnesses whose evidence is proposed to be led by a party shall be filed simultaneously by that party at the time directed in the first Case Management Hearing.
- (1B) A party shall not lead additional evidence by the affidavit of any witness (including of a witness who has already filed an affidavit) unless sufficient cause is made out in an application for that purpose and an order, giving reasons, permitting such additional affidavit is passed by the Court.
- (1C) A party shall however have the right to withdraw any of the affidavits so filed at any time prior to commencement of cross-examination of that witness, without any adverse inference being drawn based on such withdrawal: Provided that any other party shall be entitled to tender as evidence and rely upon any admission made in such withdrawn affidavit.

As per Section 1 of the Indian Evidence Act, 1872, affidavits are not included in the ambit of “evidence.” Thus, typically, the affidavit of the witness goes through the process of “tendering” – the witness is put on oath and affirms the contents of the affidavit, and, thus, the affidavit contents effectively become oral evidence. Such oral evidence is normally taken into consideration by the court when facts need to be proved.

6.6.8 Experts

6.6.8.1 Role of experts and expert bodies and institutions

Although not strictly a separate institution, experts and expert bodies and institutions play a key practical role in patent matters. In this context, the Supreme Court of India, in *Monsanto Technology LLC v. Nuziveedu Seeds Ltd.*,¹⁹⁶ held that:

Summary adjudication of a technically complex suit requiring expert evidence also, at the stage of injunction in the manner done, was certainly neither desirable or permissible in the law. [...]
[...] We are therefore satisfied that the Division Bench ought not to have disposed of the suit in a summary manner by relying on documents only, extracted from the public domain, and not even filed as exhibits in the suit, much less examination of expert witnesses, in the facts of the present case. There is no gain saying that the issues raised were complicated requiring technological and expert evidence with regard to issues of chemical process, biochemical, biotechnical and micro biological processes and more importantly whether the nucleic acid sequence trait once inserted could be removed from that variety or not and whether the patented DNA sequence was a plant or a part of a plant etc. are again all matters which were required to be considered at the final hearing of the suit.

¹⁹⁵ 2010 SCC Online Mad. 5031.

¹⁹⁶ (2019) 3 SCC 381, paras 22–23.

Thus, experts and expert bodies and institutions are a critical component of proceedings where a patent's validity is questioned. Most oppositions and revocations typically involve one or more opinions from experts or expert bodies, and the legal framework contains sufficient provisions to deal with expert opinions and evidence. For instance, under the Patents Act, 1970, the Indian Patent Office has the power to receive evidence on affidavits, issue commissions for the examination of witnesses or documents and so on.¹⁹⁷ The Indian Patent Office may also allow any person to be cross-examined on the contents of their affidavit.¹⁹⁸

6.6.8.2 Expert evidence under the Indian Evidence Act, 1872

The Indian Evidence Act, 1872, governs the rules of evidence applicable to enforcement proceedings under the Patents Act, 1970. It applies to all civil and criminal proceedings. This legislation has been amended and updated from time to time, including on the use of electronic documents and evidence.

Section 45 of the Indian Evidence Act, 1872, declares that the opinions of experts are “relevant facts.” Therefore, these opinions must be considered by courts in patent matters when forming an opinion on the point of science or art. The law only requires such experts to be “especially skilled” in the relevant area of science or art without specifying a minimum threshold. The Supreme Court of India has held that an individual could be an expert not just by the special study of the subject but also by acquiring experience in the field.¹⁹⁹ Similar is the view of the Delhi High Court which, in a patent case where the expert witness produced did not hold a technology or engineering degree but had proven experience, held that an expert could be a person who possesses experience even if they did not have the educational qualification.²⁰⁰ What is relevant is whether the person is skilled and has adequate knowledge of the subject. The observation of the court reads as follows:

Be that as it may, it is accepted and recognised that a person could be an expert in an area of specialised knowledge by experience and he or she need not hold a degree in the field of specialised knowledge. A person can also become an expert by virtue of one's avocation or occupation.²⁰¹

It is generally understood that, in patent matters, the opinions of experts are critical to understanding the background in the art, as well as to appreciating the contents of the prior art and the invention. An expert could also testify as to the meaning of the terms in the claim as understood in the art. Typically, both parties to a patent enforcement action will produce such expert evidence on infringement, novelty and inventive step.

The expert will usually be highly qualified and would exceed the threshold of a person having ordinary skill in the art.

There is a view expressed that the expert in a patent matter must have *personal* knowledge of the prior arts,²⁰² though this view is not correct. In law, all aspects of patent matters are viewed through the lens of a hypothetical person skilled in the art, who is normally deemed in law to automatically have knowledge of the prior arts. The correct view appears to be that the expert could testify as to their opinion on how a person skilled in the art would consider the matter.

The opinions of such experts are meant for matters of science or art, but, usually, such experts also give their opinions on infringement, novelty, obviousness and other grounds of invalidity. Even though such statements or conclusions on obviousness, novelty or infringement may also involve matters of law, it is not fatal to the admissibility of the expert opinion. Courts will focus more on the reasoning offered by the expert in the opinion. Expert opinions of the experts are not binding on the court.

¹⁹⁷ Patents Act, 1970, §77(c)–(d).

¹⁹⁸ Patents Act, 1970, §79.

¹⁹⁹ *State of Himachal Pradesh v. Jai Lal*, (1999) 7 SCC 280.

²⁰⁰ *Vringo Infrastructure Inc. v. ZTE Corp.*, FAO (OS) 369 of 2014, order dated Aug. 13, 2014.

²⁰¹ *Vringo Infrastructure*, FAO (OS) at para. 11.

²⁰² *F Hoffmann-La Roche Ltd Cipla Ltd*, MIPR 2016 (1) 1.

6.6.8.3 Court-appointed scientific advisers

Section 115 of the Patents Act, 1970, empowers the court to appoint an independent scientific adviser to assist the court or to enquire and report upon any question of fact or opinion (but not involving a question of interpretation of the law). The Indian Patent Office maintains a roster of such scientific experts.²⁰³ Courts usually resort to these scientific experts to gain an independent assessment. These assessments are considered valuable in highly contested matters where the parties' expert testimonies have offered widely disagreeing opinions. Like any other expert opinion, the opinion of a court-appointed scientific adviser is also not binding on the court.

As per Rule 103 of the Patents Rules, 2003, the Controller is to maintain a roll of scientific advisers, to be updated annually. The roll contains the names, addresses, specimen signatures and photographs of scientific advisers; their designations; and information regarding their educational qualifications, the disciplines of their specialization and their technical, practical and research experience.

A person must possess the following qualifications to be enrolled as a scientific adviser:

- a degree in science, engineering or technology or equivalent;
- at least 15 years of technical, practical or research experience; and
- holds or has held a responsible post in a scientific or technical department of the central or state governments or in any organization.²⁰⁴

The law provides that the fee or remuneration for such scientific advisers be provided by the Parliament, by law, for this purpose. However, usually, the parties share the costs of independent scientific experts.

The recently notified draft of the High Court of Delhi Rules Governing Patent Suits, 2020, also proposes the maintenance of a panel of scientific advisers to assist the court.

6.6.8.4 Hot-tubbing procedure

The procedure of hot-tubbing, where multiple expert witnesses give their evidence concurrently – and which has its origin in Australian law – is also permissible in India and has recently been ordered in some cases.²⁰⁵ The procedure for recording expert evidence through a hot-tubbing protocol was specified in *Micromax Informatics Ltd v. Telefonaktiebolaget LM Ericsson*.²⁰⁶ The Delhi High Court Rules have also been amended to incorporate this procedure,²⁰⁷ including its protocol.²⁰⁸

Though there has yet to be a patent infringement action concluded in which evidence has been given by the hot-tubbing procedure, hot-tubbing is expected to be applied more frequently in the future.

6.6.9 Alternative dispute resolution: pre- and post-litigation mediation

Under the Commercial Courts Act, 2015, parties are usually expected to explore pre-litigation mediation. If the plaintiff does not seek urgent relief, Section 12A of the Commercial Courts Act, 2015, mandates pre-litigation mediation.

Section 89 of the Code of Civil Procedure also recognizes courts' inherent power to refer parties to arbitration, conciliation, mediation or other forms of alternative dispute resolution. A court can exercise this power at any stage if there exist elements of an acceptable settlement. The parties may also request such a referral themselves.

Almost all district courts and High Courts in India have mediation centers for pre- and post-litigation mediation. These mediation centers are usually attached to each of the High

203 A list of scientific advisers under Rule 103 of the Patents Rules, 2003, is available at <https://ipindia.gov.in/sciadvisers-patents.htm>

204 Patents Rules, 2003, r. 103(2).

205 E.g., *Micromax Informatics Ltd v. Telefonaktiebolaget LM Ericsson*, MANU/DE/1477/2019; *Telefonaktiebolaget LM Ericsson (Publ.) v. Intex Technologies (India) Ltd*, CS (COMM) 769 of 2016, order dated Jan. 30, 2019.

206 MANU/DE/1477/2019.

207 Delhi High Court (Original Side) Rules 2018, ch. XI r. 6.

208 Delhi High Court (Original Side) Rules 2018, annex G.

Courts or district courts and are managed by a fully functional secretariat. The mediators at these centers are trained professionals. It is also possible for parties to seek the appointment of an expert mediator with specialized technical learning, skills, experience and domain knowledge. Mediation proceedings have proved to be quite efficient in almost all parts of the country. Significant success has been generally observed in resolving IP rights disputes and, most recently, in the resolution of certain SEP-related disputes.²⁰⁹

6.7 Civil remedies

In a suit for patent infringement, plaintiffs are entitled to seek both interim remedies and final remedies. Section 108 of the Patents Act, 1970, concerns final remedies, whereas Section 94(c) and Order XXXIX of the Code of Civil Procedure concerns interim remedies. The usual types of interim and final remedies – and their governing standards – are discussed in Sections 6.6.4 and 6.7.1–6.7.4 of this chapter, respectively.

6.7.1 Permanent injunction

Under Section 108(1) of the Patents Act, 1970, a patentee may seek a permanent injunction as a final remedy. The Specific Relief Act, 1963, regulates the relief of permanent injunction, and courts retain discretion to deny permanent injunctions in some cases. For instance, in *F Hoffmann-La Roche Ltd v. Cipla Ltd*,²¹⁰ a permanent injunction was not granted because the defendant had already been in the market for several years, and the patent was about to expire. Usually, however, permanent injunctions follow a finding of infringement and validity in favor of the patentee.

The court may grant relief by way of an injunction for infringement of a partially valid specification where the invalid claim was framed in good faith and with reasonable skill and knowledge.²¹¹ A permanent injunction may be granted only in cases where there is a valid patent, and the defendant has infringed that patent.

6.7.2 Damages or an account of profits

Under Section 108(1) of the Patents Act, 1970, the patentee has the choice of seeking either damages or an account of profits.²¹² Plaintiffs cannot claim both as per settled law. The Act is silent on the quantification of damages. Unlike the US statute, for instance, the Act does not prescribe a lower threshold of reasonable royalty that has been interpreted to involve the application of the *Georgia-Pacific* factors.²¹³

The general principle under Indian law is that damages will be compensatory in nature (i.e., the patentee should be restored to the position if the wrongful acts of the defendant had not occurred). Consequently, the measure of the damages is to be, as far as possible, akin to the sum of money that puts the plaintiff in the same position as they would have been in had they not sustained the wrong. Thus, for instance, if the patentee has shown a propensity to license the patent in the past, such licensing arrangements can become the guiding basis in assessing damages.

The reluctance of Indian courts to grant high-value damages is a thing of the past. It is usual, especially in pharmaceutical and SEP cases, for courts to grant damages or accounts of profits determined by the evidence, even if they seem of high value. In a few recent SEP disputes, the royalties payable ran into millions of dollars, even in interim arrangements, though this has not

209 Justice Prathiba M. Singh, “Samadhan-Mediation in Delhi” in *National Conference on Mediation and Information Technology* (High Court of Gujarat ed., 2022). “In Intellectual property rights (“IPR”) disputes however, the average percentage of settlements arrived at is a whopping 84.50%...Notably, 2017 was a rare year for the [Delhi High Court Mediation and Conciliation] Centre which saw 100% of all IPR matters referred, being settled. Even thereafter the percentages of settlement in IPR matters are hovering around 85% to 95% in the pre-pandemic years. Compared to IPR matters, the percentage of commercial disputes that are settled is comparatively lesser...”

210 MIPR 2016 (1) 1.

211 Patents Act, 1970, §114.

212 Patents Act, 1970, §108(1).

213 *Georgia-Pacific Corp. v. United States Plywood Corp.*, 318 F. Supp. 1116 (S.D.N.Y. 1970), mod. and aff’d, 446 F. 2d 295 (2d Cir. 1971), cert. denied, 404 U.S. 870 (1971).

been made known internationally.²¹⁴ Thus, even in non-SEP cases, damages or accounts of profits are reasonable possibilities, especially if infringement is established by the patentee.

The purpose of an account of profits is to prevent the unjust enrichment of the defendant by the use of the patented invention. The patentee is treated as if they are conducting the business of the defendant and made the profits that the defendant made. As such, the upper limit of an award is the sum of profits made by the patent-infringing defendant. In most cases, an award of damages will equal or exceed the maximum award in an account of profits; however, an account of profits may greatly outstrip an award of damages in the right case.

For an account of profits, the profits must have been earned from the use of the patentee's invention, and, if the infringed invention formed only *part* of the overall product or process, then only that part of the profit attributable to the patented invention is recoverable. This is where the most difficulty is experienced in assessing the profits earned by the defendant, and a number of approaches may be taken during the assessment. Courts take the view that it would be unfair to the defendant to award a claim for all the profits where attribution of profits is possible. Where it is appropriate to apportion losses, the reference for the assessment will involve splitting the profits between the infringing and non-infringing parts of the process. Conversely, the patentee could also recover all of the profits of an invention; however, this turns on the facts of the case.

In the event that an infringer makes a loss in a manufacturing process, the sum by which the infringing process reduces those losses are recoverable on account.

Sometimes the patented invention has a readily discernible impact on profits, either positively or negatively. For instance, the patented invention may reduce the costs associated with the manufacturing process, making the process more efficient. In this case, a larger share of the profits would be payable to the patentee on an empirical basis. This would involve a comparison between the profitability achieved when the patented invention was used and when it was not. This brings the efficiencies introduced by the invention into consideration for the calculation of the portion of the profits to be awarded to the patentee.

As per Section 62(2) of the Act, no suit or other proceeding in respect of an infringement of a patent can be instituted during the period between the lapse of the patent (i.e., it had ceased to exist) and the publication of the application restoring the patent.²¹⁵ A patentee enjoys all entitlements and rights from the date of the patent's publication.²¹⁶ However, this right does not extend to instituting any proceedings for infringement until a patent has been validly and finally granted.²¹⁷ Nevertheless, the claim for damages would also be subject to the laws of limitation.

6.7.2.1 Punitive damages

Along with an account of profits or damages, courts can also impose punitive damages in the following exceptional circumstance: "wrongful conduct by the defendant, which has been calculated by him for himself, which may well exceed the compensation payable to the claimant."²¹⁸

The above principle was applied by a single judge of the Delhi High Court recently in *Koninklijke Philips NV v. Amazestore*,²¹⁹ which was an SEP case. Indian courts have granted punitive damages in many other cases.²²⁰

6.7.2.2 Defenses to avoid damages or an account of profits

Courts refuse a grant of damages or an account of profits if the defendant proves that, at the date of the infringement, they were not aware and had no reasonable grounds for believing that the patent existed.²²¹

214 See *Telefonaktiebolaget LM Ericsson v. Mercury Electronics*, 2015 (64) PTC 105 (DEL).

215 In *G Srinivasan v. Voltamp Transformers*, AIR 2017 Mad. 144, and *Koninklijke Philips Electronics NV v. Rajesh Bansal*, 251 (2018) DLT 602, the courts refused damages for the period after the expiry of the patent.

216 Patents Act, 1970, §11A(7).

217 Patents Act, 1970, §11A(7) proviso.

218 *Hindustan Unilever Ltd v. Reckitt Benckiser India Ltd*, (2014) ILR 2 Del. 1288, para 66 (citing *Rookes v. Barnard*, [1964] AC 1129).

219 260 (2019) DLT 135.

220 See *Vior (International) Ltd v. Maxycon Health Care Pvt. Ltd*, 2018 (74) PTC 87 (Del.).

221 Patents Act, 1970, §111(1).

The court may also refuse a grant of damages or an account of profits:

- “in respect of any infringement committed after a failure to pay any renewal fee within the prescribed period and before any extension of that period”;²²² or
- “where an amendment of a specification by way of disclaimer, correction or explanation is allowed under [the Patents Act] after the publication of the specification [...] in respect of the use of the invention before the date of the decision allowing the amendment.” However, damages or an account of profits may be granted if “the court is satisfied that the specification as originally published was framed in good faith and with reasonable skill and knowledge.”²²³

6.7.3 Other remedies

The patentee may further seek the seizure, forfeiture or destruction of infringing articles, as well as of materials and implements predominantly used for the infringing activities.²²⁴

6.7.4 Costs

The court may, in its discretion, order the unsuccessful party to pay costs to the successful party in an infringement suit. The Code of Civil Procedure provides for the recovery of costs by and under Sections 35 and 35A.

While imposing costs, the court may weigh several factors: for instance, (i) the conduct of the parties; (ii) whether a party has succeeded only in part, even if that party has not been wholly successful; and (iii) whether the party had made a frivolous claim or counterclaim leading to delay in the disposal of the case, or had instituted a vexatious proceeding wasting the time of the court.

Certain guidelines have been laid down in the case of *Ten XC Wireless v. Mobi Antenna*²²⁵ for determining costs in patent infringement suits, including that

- the parties shall submit their estimated future cost at the commencement of trial;
- the parties and court master shall maintain a record of the court time consumed; and
- the unsuccessful party is liable to pay costs to the successful party.

Costs awarded by the court may include:

- the actual costs of litigation;²²⁶
- a proportion of another party's costs;
- a stated amount in respect of another party's costs;
- costs from or until a certain date;
- costs incurred before proceedings began;
- costs relating to particular steps taken in the proceedings;
- costs relating to a distinct part of the proceedings; and
- interest on costs from or until a certain date.

6.8 Other actions

6.8.1 Cases involving groundless threats of illegal proceedings

6.8.1.1 What constitutes a “threat”?

Keeping in mind the serious negative effects and consequences associated with infringement proceedings, the stated policy of the law is that no person should unnecessarily be subjected to baseless threats of infringement. Under the Patents Act, 1970, groundless threats of infringement are considered civil wrongs.

²²² Patents Act, 1970, §111(2).

²²³ Patents Act, 1970, §111(3).

²²⁴ Patents Act, 1970, §108(2).

²²⁵ 2011 SCC Online Del. 4648.

²²⁶ E.g., *Merck Sharp and Dohme Corp. v. Glenmark Pharmaceuticals Ltd.*, (2015) 6 SCC 807 (the plaintiffs were granted actual costs of the entire litigation proceedings); *Austin Nichols and Co. v. Arvind Behl*, 2005 SCC Online Del. 1276 (the Delhi High Court awarded INR 1,885,000 in favor of the plaintiff). No general or statutory rules apply; the same is at the discretion of the court.

A “groundless threat” under the Act is an unjustified or wrongful threat by which any person, whether having an interest in the patent or not,²²⁷ threatens another with legal proceedings without a reasonable basis. It is important to note that the mere notification of the existence of a patent does not constitute a threat of proceedings within the meaning of the relevant section. In *LG Electronics India Pvt. Ltd v. Bharat Bhogilal Patel*,²²⁸ the Delhi High Court clarified that

if any proprietor or the right holder issues a notice to the custom officials and the custom officials act upon the same by restricting the imports of consignments of any party without the determination (prima facie or otherwise) of the factum of infringement of patent by the appropriate designated authority, then such notice by the right holder to the customs and the actions thereof by the customs either in the form of notice to that party or otherwise calling upon the party to explain its stand are all unnecessary illegal threats to that party.

In *Bata India Ltd v. Vitaflex Mauch GmbH*,²²⁹ even a legal notice was considered a “threat,” and, on facts, it was concluded that threats made by the defendant to the plaintiff were groundless, unjustifiable and wrongful.

6.8.1.2 Remedies

The court typically considers the grant of the following reliefs:

- (a) a declaration to the effect that the threats are unjustifiable;
- (b) an injunction against the continuance of the threats; and
- (c) such damages, if any, as he has sustained thereby.²³⁰

The court is also empowered to pass interim orders, as in any other civil suit. For instance, in *LG Electronics*,²³¹ a suit was initiated on the basis that the filing of a border enforcement action with customs without a finding of infringement from the court amounted to a groundless threat. In the facts of the case, the Delhi High Court passed an interim order staying the operation of a border enforcement action to stop the import of allegedly infringing goods, pending a final decision from a civil court on the issue of infringement.

6.8.2 Declaration of non-infringement

Declaration of non-infringement refers to an application to the court for a declaration that any new process or article does not infringe an existing patent.²³² Under Section 105 of the Patents Act, 1970, in order to object to declaratory relief, the following conditions precedent need to be fulfilled:

- The plaintiff has applied in writing to the defendant for a written acknowledgment to the effect of the declaration claimed.
- The plaintiff has furnished to the defendant the full particulars in writing of its products or process in question.

The defendant has refused or neglected to give such an acknowledgment. Normally, in civil suits, the plaintiff who has sought the relief of non-infringement bears the burden of proof. This was confirmed by the Madras High Court in *Bajaj Auto Ltd v. TVS Motor Co. Ltd*,²³³ which went on to hold that, even though the defendant-patentee in the non-infringement filed a counterclaim of infringement, the burden of proof on the person seeking the declaration of non-infringement cannot be reduced or changed.

If the plaintiff in such a declaratory suit is successful, the court can issue a declaratory judgment that the specific product or process of the plaintiff does not infringe the identified patent. At the same time, Section 105(3) of the Patents Act, 1970, stipulates that the court cannot examine the patent's validity in such proceedings.

227 Patents Act, 1970, §106(1).

228 2012 (51) PTC 513 (Del.), para 97.

229 222 (2015) DLT 498.

230 Patents Act, 1970, §106(1).

231 (51) PTC.

232 Patents Act, 1970, §105.

233 2010 SCC Online Mad. 5031.

6.9 Appellate review

This section is limited to the miscellaneous aspects of review and appeal procedures not otherwise covered in Section 6.2.2. Appeals from orders of the Controller lie to the High Court. Appeals from the orders of a single judge of the High Court usually lie before the division bench of that court or the Supreme Court. Appeals from a commercial court (below the rank of the High Court) lie to the High Court.

Review, in Indian law, is only in case of an error apparent on the face of the record. A party who feels that the forum that rendered the judgment or order committed an error apparent on the face of the record can seek review.

6.9.1 Power of review of the Controller

The Controller has the powers of a civil court in any proceedings filed before it under the Patents Act, 1970, in respect of, among other things, reviewing²³⁴ their own decision on an application made²³⁵ within one month from the date of communication of such a decision or within an extended period not exceeding one month thereafter as the Controller may allow²³⁶ in a prescribed manner.²³⁷

6.9.2 Review against civil court orders

Even in civil suits dealing with infringement, review applications may be preferred by parties when the condition for filing a review under Section 114 of the Code of Civil Procedure is fulfilled²³⁸. Section 114 of the Code provides as under:

Subject as aforesaid, any person considering himself aggrieved—

- (a) by a decree or order from which an appeal is allowed by this Code, but from which no appeal has been preferred.
 - (b) by a decree or order from which no appeal is allowed by this Code, or
 - (c) by a decision on a reference from a Court of Small Causes,
- may apply for a review of judgment to the Court which passed the decree or made the order, and the Court may make such order thereon as it thinks fit.

6.9.3 Grounds for review

A review can be filed by any person aggrieved by an order or decree of the Controller or court from which an appeal is allowed, but no appeal has been preferred, or from which no appeal is allowed:

and who, from the discovery of new and important matter or evidence which, after the exercise of due diligence was not within his knowledge or could not be produced by him at the time when the decree was passed or order made, or on account of some mistake or error apparent on the face of the record or for any other sufficient reason, desires to obtain a review of the decree passed or order made against him.²³⁹

An application for review must be accompanied by a statement setting forth the grounds on which the review is sought. Where the decision in question concerns any other person in addition to the applicant, the Controller shall forthwith transmit a copy of the application and the statement to the other person concerned.

²³⁴ Patents Act, 1970, §77(1)(f).

²³⁵ The application for review must be made in the format provided under Form 24 of the Patents Rules, 2003.

²³⁶ The application for extension must be made in the format provided under Form 4 of the Patents Rules, 2003.

²³⁷ Patents Rules, 2003, r. 130.

²³⁸ Grounds for review could be “a mistake” or “error apparent on the face of the record” or “any analogous ground” or “to prevent miscarriage of justice”. See *Shivdev Singh & Ors. v. State of Punjab & Ors.*, AIR 1963 SC 1909.

²³⁹ Code of Civil Procedure, 1908, §114 r/w ord. XLVII.

6.9.4 Appeals from review

No appeal lies from the decision of a Controller rejecting an application for review.²⁴⁰ Even under the Code of Civil Procedure, while an order allowing an application for review is appealable, an order rejecting an application for review is not.²⁴¹

6.10 Selected topics

6.10.1 Compulsory licenses and public prejudice

Compulsory license is not directly relevant to the revocation of a patent. However, unlike voluntary licensing, it is a form of licensing that is involuntary and coercive in nature. Consistent with Article 31 of the TRIPS Agreement and the Doha Declaration, where there is a failure to fulfill the reasonable demand for the patented invention, or in a case of unreasonable pricing or failure to work the invention on a commercial scale, an interested person can seek a compulsory license.²⁴² The conditions for invoking compulsory licensing provisions are strict and must be fulfilled before such a license can be issued. Thus, there are hardly any compulsory licenses issued in India. The rare occasion when such a license was issued is a case of a cancer drug in which the courts came to the conclusion that the requirements of the public were not being met.²⁴³

Such compulsory licenses, if issued, would ordinarily only be for the domestic market and, among other stipulations, upon payment of a reasonable royalty.²⁴⁴ Pursuant to Article 31*bis* of the TRIPS Agreement, a compulsory license can also be granted for the export of pharmaceutical products to countries with insufficient or no manufacturing capacity for that product. Although it is directed toward the greater public interest, compulsory license proceedings are adversarial in nature, and a detailed procedure complying with natural justice has been prescribed,²⁴⁵ as have appeals from such decisions.²⁴⁶ Under Section 92(3), the Central Government may notify the existence of a national emergency, extreme emergency or a case of public noncommercial use, and the detailed procedure would stand suspended.

However, in the unique and exceptional situation where the underlying cause resulting in the compulsory license is not addressed even after two years from the date of granting the compulsory license, the Central Government may, for any interested person, apply to the Controller to revoke the patent.²⁴⁷ Interestingly, the Justice N Rajagopala Ayyangar Committee had proposed this provision on the logic that the threat of revocation was a sufficient incentive for the patentee to share any know-how associated with the working of the invention. This relation between the working of the invention and the sharing of associated know-how has been raised in the context of COVID-19 vaccination.²⁴⁸

Similarly, the Patents Act, 1970, also empowers the Central Government to use the invention for the purposes of the Government,²⁴⁹ and, if the patentee refuses to comply with the Government's request and on unreasonable terms, the Central Government is authorized to seek revocation of the patent before the High Court.²⁵⁰

Independently, Section 66 of the Act reserves to the Central Government the residual power to declare a patent as revoked if the patent or the mode in which it is exercised is mischievous to the state or generally prejudicial to the public. This provision requires an opportunity for hearing being granted to the patentee before any such declaration or decision.

240 See Patents Act, 1970, §117A(2) (which prescribes appealable orders).

241 Code of Civil Procedure, 1908, ord. XLVII r/w ord. XLIII r. 1(w).

242 Patents Act, 1970, §§84(1), 92A.

243 *Bayer v. Union of India*, AIR 2014 Bom. 178.

244 Patents Act, 1970, §90 (detailing the terms and conditions imposed in such cases).

245 Patents Act, 1970, §§84–87.

246 Patents Act, 1970, §117-A(2).

247 Patents Act, 1970, §85(1).

248 *In Re: Distribution of Essential Supplies and Services during the Pandemic*, *Suo Motu Writ Petition (Civil) No.3 of 2021*, Order dated April 30, 2021; *Dharmendra Kumar Aggarwal v. GNCTD*, W.P.(C) 5173/2021, Order dated May 5, 2021.

249 Patents Act, 1970, §100(1).

250 Patents Act, 1970, §64(4).

6.11 Key challenges and efforts to improve patent case management

6.11.1 Lack of uniformity in decisions and specialized knowledge

Infringement cases are heard by judges of either the district courts or the High Courts not specially trained in the subject of patent law. A challenge that arises under the current regime of trial, especially before the district courts, is that the judges are not equipped to understand technical issues that arise in respect of patents. As the disputes arising under the Patents Act, 1970, are often highly technical in nature, a higher degree of understanding of the subject matter is required to ascertain a question of infringement or lack thereof.²⁵¹ For this purpose, specific rules of procedure, including for leading and examination of evidence, are desirable.

6.11.2 Delays in disposing of suits

The Supreme Court has held, pertaining to the issue of delays in the hearing and disposal of matters, that, in matters of patents, trademarks and copyrights, the state of affairs due to such delays is unsatisfactory.²⁵² It was held that there is a need to adhere to the provisions of Order XVII(1)(2) of the Code of Civil Procedure, whereby proceedings are to be held on a daily basis for quick disposal of the suit. The streamlined and expedited procedure under the Commercial Courts Act, 2015, has significantly helped in reducing delays, though more groundwork is needed. A recent development which has given further impetus to speedier adjudication of IP disputes is the establishment of the Intellectual Property Division in the Delhi High Court.

6.11.3 The IP Division, Delhi High Court

Post the abolition of the IPAB,²⁵³ all pending cases before the IPAB were transferred to High Courts. The High Courts were thus faced with the task of managing both the already pending IPR cases before them as well as the transferred IPAB cases. In the Delhi High Court, this number of pending IP cases was expected to be around 4,000–5,000. With a view to streamlining dispute resolution of IP cases, including patent litigation, the Delhi High Court constituted India's first "IP Division."²⁵⁴ The Division uses specialized sets of Rules, specifically, the Delhi High Court Intellectual Property Rights Division Rules, 2022²⁵⁵ and the High Court of Delhi Rules Governing Patent Suits, 2022. The Division is vested with various jurisdictions, including the original jurisdiction, the infringement jurisdiction, commercial suits, the appellate jurisdiction from the IP offices, the revisional jurisdiction from the commercial courts, and the extraordinary writ jurisdiction supervising all IP offices, including the Controller of Patents' Office.²⁵⁶ Further, the Division provides for various novel features which are, illustratively, as under:

- (i) New forms of evidence recording such as hot-tubbing and remote recording of evidence.²⁵⁷
- (ii) Preservation of evidence and litigation hold notice.²⁵⁸
- (iii) Guidance on computation of damages.²⁵⁹
- (iv) Direction of consolidation of cases.²⁶⁰
- (v) Constitution of Confidentiality Clubs and redaction of information.²⁶¹
- (vi) Summary adjudication of disputes.²⁶²
- (vii) Panel of experts and recruitment of law researchers who are technically qualified like engineers, chemists, pharmacists, or civil engineers, to assist the IP Division.²⁶³
- (viii) Mediation and Early Neutral Evaluation.²⁶⁴

251 *Onyx Therapeutics Inc. v. Union of India*, 2019 SCC Online Del. 11881.

252 *Bajaj Auto Ltd v. TVS Motor Co. Ltd.*, 2009 (3) ARC 414.

253 Ministry of Commerce and Industry (IPR-Estt. Section), Government of India, Notification S.O.1668(E), April, 22, 2021.

254 High Court of Delhi, Office Order No.667/Original Side/DHC, July, 7, 2021.

255 Delhi High Court Intellectual Property Rights Division Rules, 2022.

256 Delhi High Court Intellectual Property Rights Division Rules, 2022, rr. 2(d), 2(l) and 2(i).

257 Delhi High Court Intellectual Property Rights Division Rules, 2022, rr. 15 and 16.

258 Delhi High Court Intellectual Property Rights Division Rules, 2022, r. 18.

259 Delhi High Court Intellectual Property Rights Division Rules, 2022, r. 20.

260 Delhi High Court Intellectual Property Rights Division Rules, 2022, r. 26.

261 Delhi High Court Intellectual Property Rights Division Rules, 2022, r. 19.

262 Delhi High Court Intellectual Property Rights Division Rules, 2022, r. 27.

263 Delhi High Court Intellectual Property Rights Division Rules, 2022, rr. 31 and 32.

264 Delhi High Court Intellectual Property Rights Division Rules, 2022, r. 37.

While the creation of the Division on a non-exclusive basis was notified in July, 2021,²⁶⁵ the Rules for the Division in its current form, that is the Delhi High Court Intellectual Property Rights Division Rules, 2022, vesting exclusive jurisdiction in the IP Division and laying down procedure for IP disputes, were notified in February 2022. This Division now consists of three Single Judge Benches exclusively dealing with IPR disputes. Since the setting up of the Division, the disposal rate for IP cases, specifically in patent matters, has witnessed substantial improvement. In addition the Delhi High Court has also nominated a non-exclusive IP Appellate Division consisting of a Bench of two Judges which hears appeals from the IP Division.

As of July 2022, the IP Division of the Delhi High Court has approximately 4,000 pending IP disputes out of which a substantial number are trademark and copyright disputes. Patent cases account for approximately 600–650 cases, most of which are appeals transferred from the IPAB. Notably, the filing of patent infringement actions has risen in recent times and approximately 50–60 actions are filed annually before the Court. In the IP Division, trends show that the disposal figures are rising and it is estimated that the Division should bring in greater efficiency.

The IP Division of the Delhi High Court has also been received well internationally. The recent USTR 2022 Special 301 Report discusses the establishment of the Delhi High Court's IP Division as a positive development and emphasizes continued engagement of the U.S. with India on IP matters.²⁶⁶

As far as other states are concerned, in the Bombay High Court and the Madras High Court, post the abolition of the IPAB, the total number of pending patent disputes is, approximately, around 450–500 cases and 264 cases respectively. The Gujarat High Court has in fact nominated a non-exclusive bench for adjudication of all IP disputes.

On this note, a testament to the Delhi High Court IP Division's efficacy in streamlining dispute resolution of IP cases may also be found in the fact that the Parliamentary Committee which had been set up to look into IP issues in India had earlier recommended (in 2021), to re-establish the IPAB, stating that the abolition decision was one taken in a hurry and there should have been stakeholder consultation.²⁶⁷ However, post-establishment of the IP Division in the Delhi High Court, in April 2022 the Committee revised its recommendation²⁶⁸ and recommended that IP divisions like at the Delhi High Court should be established in all High Courts in the country. The relevant observations of the Report dated April 6, 2022 read:

3.12 The Committee notes that the dissolution of IPAB would lead to transferring of all IP-related appeals including the pending cases to High Courts and Commercial Courts (in copyright matters). This may create additional burden on such courts which are already reeling under huge backlog of cases with inadequate expertise in hand to deal with IPR matters. It, therefore, opines that establishing an Intellectual Property Division (IPD) with dedicated IP benches as done by Delhi High Court in the wake of abolition of IPAB would ensure effective resolution of IPR cases on a timely basis. The Committee, therefore, recommends that the Government should take appropriate measures to encourage setting up of IPD in High Courts for providing alternative solution to resolve IPR cases.

Thus, the constitution of specialized IP Divisions for speedier and efficacious resolution of IP disputes, specifically patent litigation, seems to be the way forward for India.

265 High Court of Delhi, Office Order No.667/Original Side/DHC, July 7, 2021.

266 Office of the United States Trade Representative, 2022 Special 301 Report, April 2022, page 56.

267 Department Related Parliamentary Standing Committee on Commerce (Rajya Sabha, Parliament of India), Review of the Intellectual Property Rights Regime in India, Report No.161, July, 2021/ Shravana, 1943 (Saka), July 23, 2021, paras. 9.7–9.8.

268 Department Related Parliamentary Standing Committee on Commerce (Rajya Sabha, Parliament of India), Action Taken by Government on the Recommendations/ Observations of the Committee contained in its One Hundred and Sixty First Report on "Review of the Intellectual Property Rights Regime in India," Report No. 169, April, 2022/ Chaitra 1944 (Saka), April 6, 2022, para. 3.12.

Chapter 7

Japan

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In this chapter, the authors have provided the English translations of quotations from court judgments. When possible, a link is provided to English translations of quoted judgments made available via *IP Judgments in Japan*, www.ip.courts.go.jp/eng/hanrei/index.html and *Courts in Japan, Judgments of the Supreme Court*, www.courts.go.jp/app/hanrei_en/search. The translations on these websites are not official translations. English translations of statutes are from Ministry of Justice, Japan. *Japanese Law Translation Database System*, www.japaneselawtranslation.go.jp.

7.1 History of the patent system

This section outlines a brief history of the patent system in Japan, including the patent law, the Japan Patent Office (JPO), the Intellectual Property High Court (IP High Court) and the intellectual property (IP) divisions of other courts.¹

7.1.1 History of patent law

The establishment of a patent system in Japan coincided with the opening of the country and its emergence as a modern industrialized nation state during the Meiji era.² A patent system was considered necessary to support modernization efforts during this period. The Meiji Government enacted a patent law in 1871. However, it was not used and so was abandoned the following year. The first substantial patent law – the Patent Monopoly Act – was enacted on April 18, 1885, and the first patents were granted in August 1885, the very first being for “Hotta’s Method for Rust Stopping Paint and Painting Method.”³ In 1899, Japan became a member of the Paris Convention for the Protection of Industrial Property.⁴ At this time, foreigners were admitted into the Japanese industrial property system.

A 1921 revision of the patent law formed the basis of the current patent system in Japan. Its provisions included a “first-to-file” system, employee ownership of patent rights and an opposition system.⁵ The 1921 law was replaced in 1959 by the current Patent Act,⁶ which has been the subject of a number of amendments, including to ensure compliance with the Patent Cooperation Treaty (PCT).⁷

7.1.2 Japan Patent Office

The JPO was first established in 1885. Korekiyo Takahashi was its first Director General and was also instrumental in the development of the Patent Monopoly Act of 1885.⁸ By 1886, the JPO had received 1,384 applications and granted 205 patents. In 1968, Japan became the country with the highest number of patent and utility model applications filed per year – a position it held until 2005.⁹ When Japan acceded to the PCT in 1978, the JPO became an international searching authority under the PCT.¹⁰ The JPO is now one of the world’s largest patent offices, and its examination departments and Trial and Appeal department (TAD) are organized across a wide range of technical fields.¹¹

7.1.3 Patent application trends

The number of patent applications filed with the JPO increased as Japan’s economy grew. However, patent applications have decreased in recent years. For example, in 1970, approximately 459,000 patent applications were filed with the JPO, compared to 289,200 patent applications in 2021.¹² As for the number of PCT applications by country of origin, Japanese PCT applications have increased since the ratification of the PCT in 1978, with the exception of 2014, 2020 and 2021. In 2021, 49,040 Japanese applications were filed using the PCT procedure, behind China and the United States of America (U.S.).¹³

1 For further information on the history of the patent system, see JPO, *History of Industrial Property Rights* [hereinafter JPO, *History of IP Rights*], www.jpo.go.jp/e/introduction/rekishi/index.html. See Section 7.3 of this chapter for further information on the JPO, IP High Court and the IP divisions of other courts.

2 The Meiji era of Japanese history extended from 1868 to 1912.

3 JPO, *History of IP Rights*.

4 Paris Convention for the Protection of Industrial Property, March 20, 1883, 828 UNTS 305.

5 Ove Granstrand, *History of Patenting and IP Management – The Case of Japan* 6–7 (2016) [hereinafter Granstrand, *History of Patenting and IP Management*], www.ip-research.org/wp-content/uploads/2016/09/Granstrand-2016-history-of-patenting-in-japan.pdf

6 Tokkyohō (Patent Act), Act No. 121 of April 13, 1959 (Patent Act).

7 Patent Cooperation Treaty, June 19, 1970, 1160 UNTS 231 (Patent Cooperation Treaty).

8 Korekiyo Takahashi later served as the 20th Prime Minister of Japan (from 1921 to 1922).

9 See, e.g., World Intellectual Property Organization, *World Intellectual Property Indicators 2020* [hereinafter WIPO, *WIPI 2020*], at 14 (2020), www.wipo.int/edocs/pubdocs/en/wipo_pub_941_2020.pdf

10 Granstrand, *History of Patenting and IP Management*, at 7.

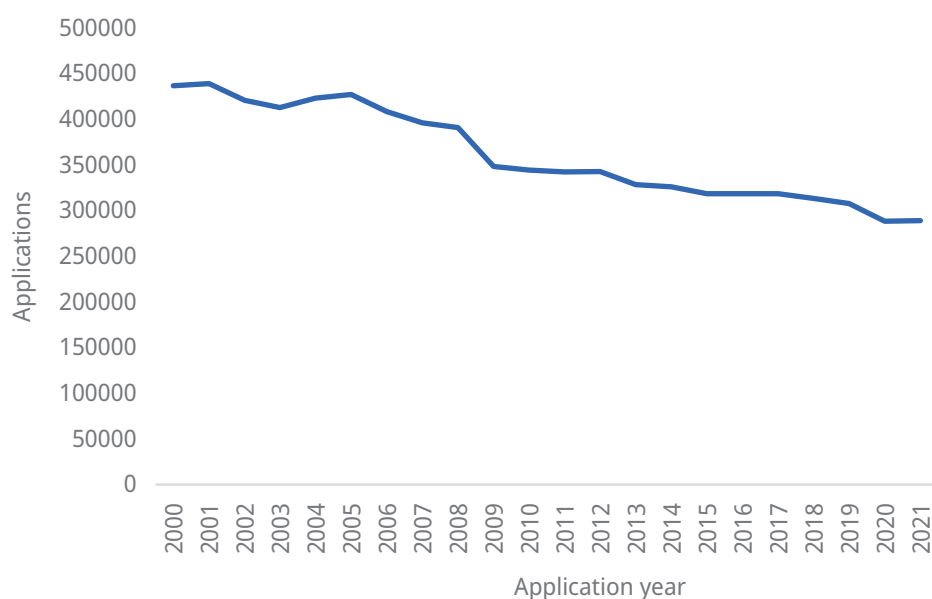
11 See Section 7.2 for further information about the JPO examination departments and the TAD.

12 For statistics from 2012 to 2021, see JPO, *JPO Report 2022* (March 2022) [hereinafter JPO, *Status Report*], www.jpo.go.jp/e/resources/report/statusreport/2022/document/index/all.pdf

13 JPO, *Status Report*, at 18. World Intellectual Property Organization, *PCT Yearly Review 2022* (2022), at 12, www.wipo.int/edocs/pubdocs/en/wipo-pub-901-2022-en-patent-cooperation-treaty-yearly-review-2022.pdf

Figure 7.1 shows the total number of patent applications (direct and Patent Cooperation Treaty (PCT) national phase entry) filed in Japan from 2000 to 2021.

Figure 7.1 Patent applications filed in Japan, 2000–2021



Source: WIPO IP Statistics Data Center, available at www3.wipo.int/ipstats/index.htm?tab=patent

7.1.4 History of specialized intellectual property courts

Japanese courts have worked for many years to establish a specialized and expert system to handle cases related to IP rights. The IP High Court and IP divisions of the district courts have developed through a series of steps, the most significant of which are set out below.¹⁴

7.1.4.1 Intellectual property divisions of the Tokyo High Court

Prior to the establishment of the IP High Court, IP-related cases were dealt with by specialized divisions of the Tokyo High Court. A 1948 amendment of the Patent Act vested the Tokyo High Court with exclusive jurisdiction in relation to appeals against decisions of the JPO. This led to the creation of the Fifth Special Division in November 1950, which handled all IP-related cases in the Tokyo High Court alongside general civil appeal cases.

In March 1958, a division that specialized in IP and handled only IP-related cases was established as one of the civil divisions of the Tokyo High Court to replace the Fifth Special Division. Over time, the number of specialized divisions increased to four.

A Grand Panel system was introduced by the Act for Partial Revision of the Code of Civil Procedure, etc., which came into effect on April 1, 2004.¹⁵ The Grand Panel consists of five judges who hear actions relating to patents (so-called technology-related actions).¹⁶ At the same time, the Sixth Special Division was created within the Tokyo High Court to handle Grand Panel cases.

7.1.4.2 Intellectual property divisions of other courts

In 1961, a special division that handled IP-related cases and general civil cases was established within the Tokyo District Court. In 1964, a similar division was established in the Osaka District Court. Currently, the Tokyo District Court has four divisions that specialize in IP-related cases, and

¹⁴ See Section 7.3 for information on the role of the Supreme Court of Japan in the patent system.

¹⁵ Minji Sosyōhō no Ichibu wo Kaisei Suru Houritsu (Act for Partial Revision of the Code of Civil Procedure, etc.), Act No. 108 of July 16, 2003.

¹⁶ See Section 7.3 for further information on the Grand Panel system. The district courts may also convene a Grand Panel for certain actions involving a patent right. Minjisōyōhō (Code of Civil Procedure), Act No. 109 of June 26, 1996, art. 6(1) (Code of Civil Procedure).

the Osaka District Court has two such divisions. The Osaka High Court also has a division that handles IP-related cases as well as general civil cases.¹⁷

7.1.4.3 Act for Establishment of the Intellectual Property High Court of 2004

The slowed economy of Japan increased awareness of the need to promote the creation, protection and use of IP in order to revitalize the economy. In June 2001, the Justice System Reform Council released an opinion paper that recommended the reform of various court processes, including those related to cases that required expertise for the purpose of “enhancing comprehensive measures.”¹⁸

The *Intellectual Property Policy Outline*, published in July 2002, included a suggestion for the creation of an exclusive jurisdiction of the Tokyo District Court and the Osaka District Court, so that specialized IP divisions in those courts could function as an independent “patent court.”¹⁹ These recommendations led to discussions of the possibility of creating an IP High Court to enhance the resolution of litigated disputes relating to IP rights.

In June 2004, the Act for Establishment of the Intellectual Property High Court was enacted.²⁰ The purpose of the Act was to increase the effectiveness and efficiency of court proceedings for IP-related cases and to foster a specialized judicial system. The IP High Court was established on April 1, 2005, as a special branch of the Tokyo High Court. At this time, the four specialized divisions for IP-related cases and the Sixth Special Division of the Tokyo High Court were converted into four divisions and a Special Division of the IP High Court.

As of July 2021, the Grand Panel of the IP High Court has delivered 14 judgments.

7.2 The Japan Patent Office and administrative review proceedings

7.2.1 The Japan Patent Office

The JPO is the administrative agency of the Government of Japan responsible for the administration of industrial property laws, including the Patent Act. It is headed by a commissioner and includes examination departments, which examine patent applications,²¹ and a TAD, which conducts trial and appeal processes related to the validity and scope of granted patents.²²

The JPO is one of the world’s largest patent offices. In terms of a global comparison, the JPO generally receives the third-highest number of patent applications per year, behind the China National Intellectual Property Administration and the United States Patent and Trademark Office.²³ It also cooperates with other countries on the protection and exploitation of IP rights. For example, in 2021, the JPO issued 48,502 international search reports under the PCT as an international searching authority and 1,562 international preliminary examination reports as an international preliminary examining authority.²⁴

17 See Section 7.3 for further information on the IP divisions of other courts.

18 Justice System Reform Council, *Recommendations of the Justice System Reform Council — For a Justice System to Support Japan in the 21st Century* (June 12, 2001), in particular “Chapter II. Justice System Responding to Public Expectations,” Part 1.3 “(1) Necessity of Strengthening Comprehensive Response” and “(2) Concrete Measures to Strengthen Comprehensive Response”. The Japanese version of the *Shihō seido kaikaku shingikai iken-shō 21 seiki no Nihon o sasaeru shihō seidō* (Recommendations of the Justice System Reform Council — For a Justice System to Support Japan in the 21st Century) is available here: <https://warp.ndl.go.jp/info:ndljp/pid/284573/www.kantei.go.jp/jp/singi/sihou/ikensyo/index.html>. An unofficial English translation is available via the *Prime Minister of Japan and Cabinet* website: https://japan.kantei.go.jp/policy/sihou/singikai/990612_e.html

19 Strategic Council on Intellectual Property, *Chiteki Zaisan Senryaku Taikō (Intellectual Property Policy Outline)* (2002). An unofficial English translation is available via the *Prime Minister of Japan and Cabinet* website: https://japan.kantei.go.jp/policy/titeki/kettei/020703taikou_e.html

20 Chitekizaisankōtōsaibansyosettihō (Act for Establishment of the Intellectual Property High Court), Act No. 119 of June 18, 2004 (Act for Establishment of the IP High Court). See Sections 7.3, 7.4, 7.5 and 7.6 of this chapter for further information on the IP High Court.

21 See, e.g., Patent Act, ch. III.

22 See, e.g., Patent Act, art. 136.

23 See, e.g., WIPO, *WIPI 2020*, at 11.

24 See, e.g., JPO, *Status Report*, at 47. World Intellectual Property Organization, *PCT Yearly Review 2022* (2022), at 84, www.wipo.int/edocs/pubdocs/en/wipo-pub-901-2022-en-patent-cooperation-treaty-yearly-review-2022.pdf. Patent Cooperation Treaty.

7.2.2 Examiners and the examination of patent applications

The JPO's examination departments are organized into four technical fields: physics, optics and social infrastructure; mechanical technology; chemistry, life science and material science; and electronic technology.²⁵ JPO examiners are experts in technology and patent law, and are responsible for the examination of patent applications to ensure compliance with the requirements set out in the Patent Act.

Examinations are conducted in accordance with the *Examination Guidelines for Patent and Utility Model in Japan* ("*Examination Guidelines*").²⁶ The *Examination Guidelines* are prepared by the JPO to help ensure consistent decisions and transparent processes and to address a range of matters, including the principles and procedures of examination, the requirements for patentability, descriptions and claims, priority, applications written in foreign languages, and the extension of the patent term. An English version of the *Examination Guidelines* is available on the JPO's website.

An examiner must refuse a patent application if it does not comply with the requirements set out in the Patent Act. However, before reaching that decision, an examiner must notify the applicant of the grounds for refusing the application and give them an opportunity to submit a written opinion within a specified period of time.²⁷

7.2.3 The Trial and Appeal department

The TAD of the JPO is comprised of 38 boards arranged across technical fields. Of these, 33 boards oversee patents and utility models.²⁸ The remaining boards are the design board and four trademark boards.²⁹ The TAD has two important roles:

- to consider appeals against a JPO examiner's decision as an internal review; and
- the resolution of disputes concerning the grant of IP rights.

7.2.3.1 Appeals against examiner decisions

This role of the TAD in appeals involves determining whether an examination conducted by the JPO's examination department was appropriate and ensuring the accuracy of the granted patent right. In particular, the TAD examines demandant appeals against an examiner's decision of refusal (sometimes referred to as a "decision of rejection").³⁰ Appeals against an examiner's decision of refusal play an important role in ensuring the appropriate examination of patent applications.

The TAD is also responsible for examining oppositions to the grant of a patent. A third party may file an opposition to a patent within six months from the publication date of a gazette containing the patent.³¹ Oppositions to the grant of a patent help ensure the accuracy of a patent right.³²

7.2.3.2 Resolution of disputes

The TAD's dispute resolution role includes:

- determining the validity of patent rights (trials for invalidation);
- correcting the scope of patent claims (trials for correction); and

25 See Section 7.2 for information about the JPO examination and trial and appeal processes. See Section 7.4 for information about the review of JPO decisions by the IP High Court.

26 JPO, *Examination Guidelines for Patent and Utility Model in Japan* [hereinafter JPO, *Examination Guidelines*], www.jpo.go.jp/e/system/laws/rule/guideline/patent/tukujitu_kijun/index.html. As of July 2022, there were approximately 1,700 JPO examiners responsible for patent applications. In 2021, approximately 230,000 patent applications were examined by JPO examiners. JPO, *Tokkyo Gyōsei Nenji Hōkokusho 2022 (Annual Patent Administration Report 2022)*, main vol. pt 1(1) fig. 1-1-5, statistics/materials vol. ch. 5.5 (2021) [hereinafter JPO, *Annual Report*], www.jpo.go.jp/resources/report/nenji/2021/index.html (in Japanese).

27 See, e.g., Patent Act, arts 49, 50.

28 See JPO, *Appeals Department – Field Outline of the Section*, www.jpo.go.jp/e/system/trial_appeal/info-general-shinketsu-sinpanga1.html

29 For a range of trial and appeal resources, including the *Manual for Trial and Appeal Proceedings* and *Questions and Answers about Trial and Appeal System*, see JPO, *Appeals/Trials*, www.jpo.go.jp/e/system/trial_appeal

30 Patent Act, art. 121(1).

31 Patent Act, art. 113.

32 See Section 7.4 for further information about this process. In 2021, there were 16,894 requests for an appeal against an examiner's decision of refusal and 106 requests for a trial for patent invalidation; additionally, 1,260 requests for an "opposition to grant of patent" were examined. JPO, *Status Report*, pt 1 ch. 1(5).

- providing an official advisory opinion in relation to the technical scope of a patented invention (Hantei (advisory opinion)).

In a trial for invalidation, an interested person in relation to a granted patent files a request with the JPO for a trial decision that the patent is invalid, indicating the reasons why the patent should be invalidated.³³ A trial for invalidation is a means of invalidating a patent that should not have been granted and deeming that it never existed.³⁴

In a trial for correction, a patentee files a request with the JPO to correct the scope of patent claims.³⁵ However, a request for a trial for correction cannot be filed in the period between when an invalidation trial has become pending at the JPO and the time when the trial decision has become final and binding. Instead, a request for correction may only be filed at a prescribed time within this period.³⁶

In Hantei, at the request of a party, the TAD delivers and then publishes an official advisory opinion with respect to the technical scope of a patented invention.³⁷

The TAD conducts proceedings for appeals against an examiner's decision of refusal, oppositions to the grant of patents, trials for invalidation, trials for correction and Hantei in accordance with the *Manual for Trial and Appeal Proceedings* ("*Manual for Proceedings*"), the *Examination Guidelines*, court decisions and other trial and appeal decisions.

7.2.3.3 Administrative patent judges, executive advisors and consultants

TAD proceedings are conducted by administrative patent judges who have a technical background. They are experts in particular technologies and are required to have more than 10 years of experience in patent examination. As of June 2021, there were approximately 380 administrative patent judges.

Administrative patent judges are able to hear explanations of technical matters directly from inventors in oral proceedings or via oral inquiries and interviews. Administrative patent judges who are experts in a relevant specialized field may also be appointed to a panel in cases that involve complex technologies.

Administrative patent judges are provided legal support by part-time executive advisors on trials and appeals, who have experience as judges and lawyers, and full-time consultants on trial decisions and court judgments, who consult with administrative patent judges in relation to individual cases.

7.2.3.4 Appeal of Trial and Appeal department decisions to the Intellectual Property High Court

Persons may file a revocation action (an administrative lawsuit) with the IP High Court against the following TAD decisions: an appeal decision to refuse an invention in an appeal against an examiner's decision of refusal; a decision to revoke a patent in an opposition to the grant of a patent; or a trial decision in either a trial for invalidation or a trial for correction. The IP High Court's exclusive jurisdiction in relation to these lawsuits and its key personnel are discussed in Section 7.4.

7.2.4 Patent validity and scope: the Japan Patent Office's trial and appeal system

This section outlines the trial and appeal system administered by the TAD of the JPO. This section first sets out some features that are common to JPO trial and appeal processes concerning patents. It then describes the following processes that relate to patent validity and scope: appeals against an examiner's decision of refusal, oppositions to the grant of a patent, trials for invalidation and trials for correction.³⁸ The Hantei (infringement advisory opinion) system is also described.

33 Patent Act, art. 123(1).

34 See Section 7.2.4.5 for a detailed description of the process of trial for invalidation.

35 Patent Act, art. 126(1).

36 See Sections 7.2.4 and 7.4.5.2.7 for further information on the process for trials for correction and requests for correction. See also Section 7.5.4 for a discussion of trials for correction and requests for correction in the context of patent infringement lawsuits.

37 Patent Act, art. 71(1). See Section 7.2.4.6 for further information on the Hantei process.

38 The exclusive jurisdiction of the IP High Court to review some TAD decisions is the subject of Section 7.4 of this chapter.

7.2.4.1 Common features of the Japan Patent Office's trial and appeal processes

JPO examiners are responsible for the examination of patent applications to ensure compliance with the requirements set out in the Patent Act. Examinations are conducted in accordance with the *Examination Guidelines*.³⁹

The TAD of the JPO conducts a number of trials and appeals. Panels of administrative patent judges may examine appeals against an examiner's decision to refuse a patent application, as well as oppositions to the grant of a patent. They also conduct trial proceedings, including trials for correction of the scope of patent claims and trials for invalidation to determine the validity of patent rights. On request, the TAD may also provide Hantei, a nonbinding official infringement advisory opinion in relation to the technical scope of a patented invention.⁴⁰

7.2.4.1.1 Formality check

When demandants file a request for a trial or an appeal with the TAD of the JPO, trial clerks will first conduct a formality check to assess, for example, whether the purpose of and reason for the request is stated, whether the fees have been paid and whether the necessary documents, such as a power of attorney, are attached. After completing a formality check, the trial clerks will send the requested cases to the specialized TAD board in charge of the proceedings.⁴¹

7.2.4.1.2 Panels of administrative patent judges and ex officio proceedings

Appeals and trials are conducted by a panel consisting of three or five administrative patent judges.⁴² *Ex officio* proceedings allow a panel to investigate facts and examine evidence on its own authority.⁴³

7.2.4.1.3 The Manual for Trial and Appeal Proceedings

Administrative patent judges conduct trial and appeal proceedings in accordance with the procedures set out in the *Manual for Proceedings*, as well as the *Examination Guidelines*, court decisions and other trial and appeal decisions.

The JPO prepares and publishes the *Manual for Proceedings* to ensure:

- a uniform understanding within the TAD of the purpose of laws and regulations and their interpretation in court decisions and other trial and appeal decisions;
- consistent and transparent trial and appeal procedures and decisions; and
- fair and accurate trial and appeal decisions.

An English version of parts of the *Manual for Proceedings* is available on the JPO's website.⁴⁴

7.2.4.1.4 Evidence

Parties may submit evidence to the JPO up until the conclusion of a trial or appeal process. Where there is evidence, the parties must state the means of proof in a written request for trial or appeal or a written reply and attach the evidence. When submitting evidence, the evidence and its relationship with the facts to be proved must be identified in writing.

Documentary evidence – including patent gazettes, books, magazines, academic journals, catalogs, blueprints, order forms and delivery slips – is usually submitted as a means of proof. When submitting a document prepared in a foreign language, the parties must attach a translation of the text of the part to be examined.

The examination of witnesses is possible in a trial for invalidation. Evidence may be obtained by hearing expert opinion and inspecting evidence, applying the rules of civil procedure. Panels of administrative patent judges may also examine a witness via videoconference.

39 JPO, *Examination Guidelines*.

40 For a useful overview of these processes, see TAD, JPO (2020). *Handbook for Trial and Appeal System in Japan* (2020), [hereinafter TAD, *Handbook*] www.jpo.go.jp/e/resources/report/sonota-info/document/pamphlet/shinpan_gaiyo_e.pdf

41 See Section 7.2 for a description of the structure of JPO TAD boards.

42 Patent Act, art. 136. See Section 7.2 for more information on administrative patent judges.

43 See, e.g., Patent Act, art. 150. *Ex officio* proceedings are discussed below in relation to oppositions to the grant of a patent and trials for invalidation.

44 JPO, *Manual for Trial and Appeal Proceedings* (19th ed. 2020) [hereinafter JPO, *Manual for Proceedings*], www.jpo.go.jp/e/system/trial_appeal/sinpan-binran.html

A panel may preserve evidence in accordance with the rules of civil procedure if it finds that it will be difficult to use the evidence unless the examination of evidence is conducted in advance.⁴⁵

7.2.4.1.5 Claim construction

A panel must specify the claimed invention based on the description of the claims. The panel construes the claims by referring to the description, drawings and common general knowledge in the technical field of the claimed invention at the time of filing. Even if the invention specified in the description of the claims and the invention described in the description or drawings do not correspond, the panel must not specify the claimed invention based only on the latter: the matters described in the claims must always be taken into consideration.⁴⁶

7.2.4.2 Appeal against an examiner's decision of refusal

An applicant who is dissatisfied with a JPO examiner's decision of refusal (sometimes referred to as a "decision of rejection") may file a request for appeal against the decision within three months (four months for a party residing outside of Japan) from the date on which a certified copy of the examiner's decision was served.⁴⁷

If a person has been unable to file an appeal against refusal within the prescribed period due to reasons beyond the person's control, they may file an appeal within 14 days (or within two months, if the person is an overseas resident) after the date on which those reasons cease to exist but no later than six months after the end of that period.⁴⁸

An appeal against an examiner's decision of refusal is an *ex parte* appeal initiated by an appellant (a demandant) against the JPO. It is conducted by a panel of administrative patent judges as documentary proceedings.⁴⁹ If a panel determines that the decision was inappropriate, it may conduct an *ex officio* investigation to determine whether there are other reasons for refusal.⁵⁰ If the examiner's decision is affirmed, the appellant may file an action with the IP High Court to revoke the appeal decision.⁵¹ Figure 7.2 summarizes this process.

In 2021, the JPO received 16,894 requests for an appeal against an examiner's decision of refusal. The JPO has reported that the rate of successful appeals resulting in the grant of a patent has increased since 2012, reaching 77 percent in 2021.⁵²

7.2.4.3 Opposition to the grant of a patent

Any person may file an opposition to the grant of a patent with the JPO. Oppositions do not require any "interest" on the part of the demandant.⁵³ However, anonymous patent oppositions are not possible.⁵⁴

Opposition to the grant of a patent may be made on a number of grounds, including, for example, that the patent claims an invention that falls under prior art within Japan or a foreign country at the time of the patent application's filing.⁵⁵

An opposition must be filed no later than six months from the publication of a gazette containing the patent. If a patent has two or more claims, an opposition to a granted patent may be filed for each claim.⁵⁶

The opposition to the grant of a patent process may be conducted by a panel consisting of three or five administrative patent judges (see Figure 7.3). However, it is usually conducted by a panel consisting of three administrative patent judges as documentary proceedings.⁵⁷

45 See, e.g., Patent Act, art. 150(2).

46 Patent Act, art. 70; JPO, *Examination Guidelines*, pt 3 ch. 2(3).

47 Patent Act, art. 121(1); JPO, *Manual for Proceedings*, s. 25-04, 2.(2).

48 Patent Act, art. 121(2).

49 Patent Act, art. 121(1).

50 TAD, *Handbook*, at 6.

51 See Section 7.4 for further information on IP High Court reviews of these decisions.

52 JPO, *Status Report*, at 30-31.

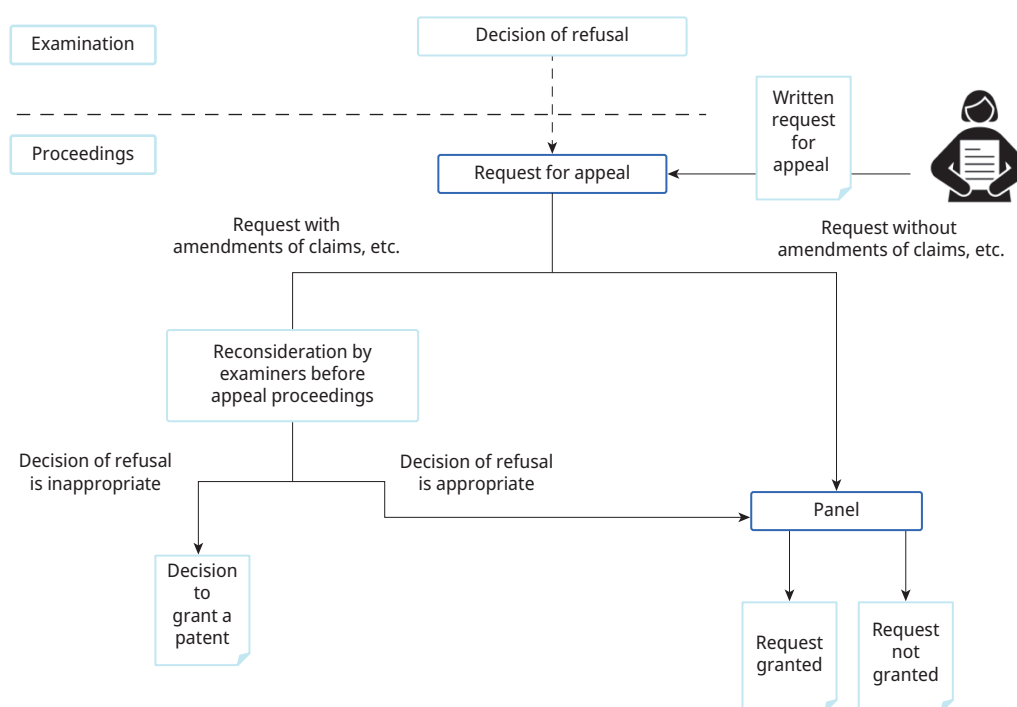
53 Patent Act, art. 113.

54 Patent Act, art. 115.

55 Patent Act, art. 113.

56 Patent Act, art. 113.

57 Patent Act, arts 114(1), 118.

Figure 7.2 Appeal against an examiner's decision of refusal

Source: Adapted from TAD, *Handbook*, at 6.

This process is conducted between the JPO and a patentee.⁵⁸ The JPO has noted that this is to ease any procedural burden on demandants, making it easier for them to use the process.⁵⁹ A demandant is entitled to express their opinion if requested by the JPO and may submit a written opinion if the patentee files a request for correction.⁶⁰

A panel will examine only the claims to which an opposition to the granted patent is filed and will conduct the examination on the basis of the reasons and evidence pleaded by the demandant.⁶¹ However, the panel may examine reasons that have not been pleaded in *ex officio* proceedings.⁶² A decision to invoke *ex officio* proceedings must take into consideration the public interest, the purpose of the process, any delay in the proceedings, and a possible accurate determination as a result of the *ex officio* examination of the evidence.⁶³

A panel must make a ruling that a patent is to be revoked if the grounds for opposition of the grant of the patent are established. A patent right is deemed never to have existed once a revocation decision becomes final and binding.⁶⁴ If a panel intends to render a revocation decision, the judge must notify the patentee and any intervenors of the grounds and provide them an opportunity to submit a written opinion within a reasonable specified period of time. The patentee may file a request for a correction of the description, claims or drawings attached to the written application only within this period.⁶⁵

If a panel decides to revoke a patent, the patentee may file an action to revoke that decision with the IP High Court, naming the Commissioner of the JPO as a defendant. However, if the administrative patent judges make a decision to maintain the patent, the decision becomes final

58 Any person that has a right or an interest in the patent may intervene in the opposition proceedings to assist the patentee until a decision is made. Patent Act, art. 119(1).

59 TAD, *Handbook*, at 9.

60 Patent Act, art. 120-5(5). Requests for correction are also discussed in the context of trial for correction and trials for invalidation.

61 Patent Act, art. 120-2(2).

62 Patent Act, art. 120-2(1).

63 See JPO, *Manual for Proceedings*, s. 67-05.

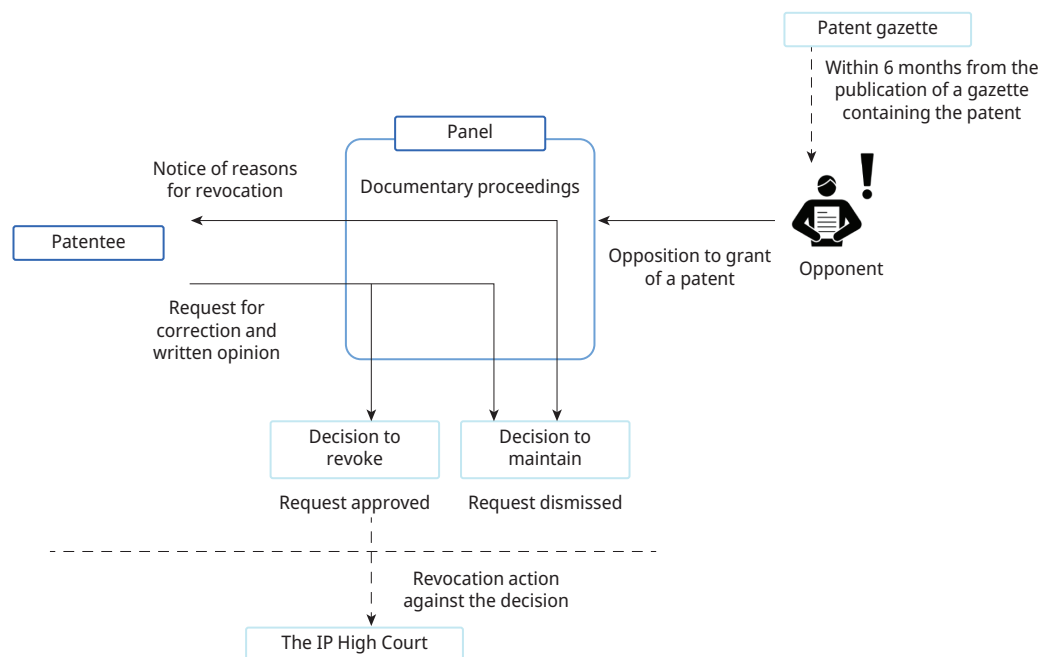
64 Patent Act, art. 114(2) and (3).

65 Patent Act, art. 125.

and binding upon service of a certified copy of the decision, and the parties who filed the opposition may not file a revocation action against the decision.⁶⁶

The number of requests for oppositions to the grant of a patent increased between 2015 (264 requests) and 2017 (1,251 requests). The number slightly decreased between 2018 (1,075 requests) and 2020 (1,029 requests), but increased again in 2021 (1,260 requests).⁶⁷ The JPO has reported that, out of the 4,977 opposition cases decided between April 2015 and December 2018, 32.3 percent of patents were maintained without corrections, 45.3 percent were maintained with corrections, and 10.2 percent were revoked.⁶⁸

Figure 7.3 Opposition to the grant of a patent



Source: Adapted from TAD, JPO (2020), at 8.

7.2.4.4 Trial for correction

A patentee may file a request for a trial for correction to correct the claims, description or drawings of the patent.⁶⁹ Trials for correction are *ex parte* proceedings conducted by a panel of administrative patent judges as documentary proceedings (see Figure 7.4).

A *trial* for correction allows a patentee to voluntarily correct the claims, description or drawings attached to an application. A correction is usually requested as a preventive measure to guard the patent against a trial for invalidation when a patent is partially defective or to preclude a dispute by clarifying an ambiguous part within the patent.

A *request* for correction in a trial for invalidation or in an opposition to the grant of a patent allows the correction of claims or drawings as a patentee's means of defending the validity of the patent during such proceedings.⁷⁰

Article 126(1) of the Patent Act provides that the corrections that may be requested in a trial for correction are limited to the following: a restriction of the claims, correction of errors or

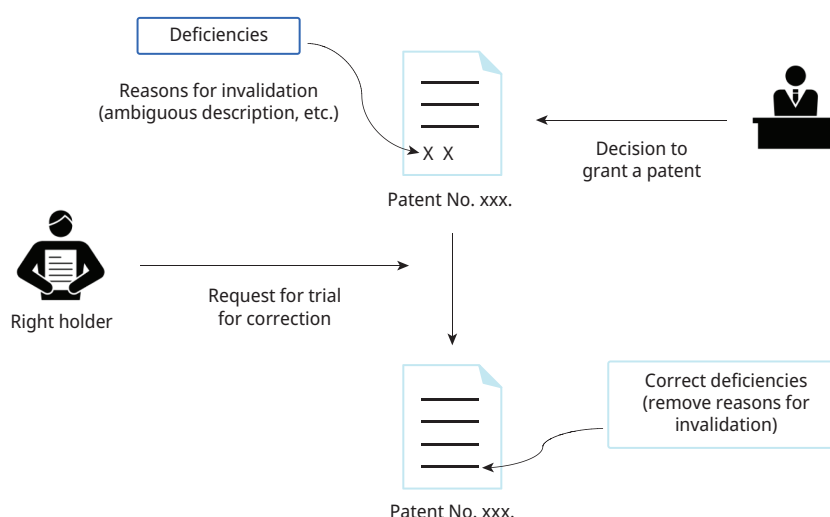
⁶⁶ Patent Act, art. 114(5). See Section 7.4 for further information on IP High Court review of these decisions.

⁶⁷ JPO, *Status Report*, at 33.

⁶⁸ The remainder were pending opposition cases (10.7 percent), dismissed with corrections (1.0 percent), dismissed without corrections (0.1 percent) or withdrawn (0.3 percent). TAD, *Handbook*, at 9.

⁶⁹ Patent Act, art. 126(1); see also Patent Act, arts 127, 132. Intervention is not permitted. Patent Act, art. 166.

⁷⁰ For more information on requests for correction see the section on trials for invalidation below.

Figure 7.4 Trial for correction

Source: Adapted from TAD, *Handbook*, at 13.

mistranslations, clarification of any ambiguous statement, or rewriting a claim that cites the preceding claim so that it does not cite the preceding claim.⁷¹

A request for a correction trial may not be filed between the time that a trial for invalidation or an opposition to the grant of a patent is pending before the JPO and the time that the ruling on the trial or opposition becomes final and binding.⁷² However, a request for correction may be filed at a prescribed time during this period.⁷³

A request for a trial for correction may be filed even after the forfeiture of the patent right. However, this does not apply after a patent has been revoked by a revocation decision or invalidated by a trial for invalidation.⁷⁴

Where a request for a trial for correction does not correspond to one of the purposes in Article 126(1) of the Patent Act or does not comply with other requirements, the chief administrative patent judge must notify the patentee of these reasons and provide the patentee an opportunity to submit a written opinion by designating an adequate time limit.⁷⁵

Where a written opinion has not been submitted within a designated time limit, or a written opinion has been submitted but not adopted, a notice of the conclusion of proceedings is issued, and a trial decision of disapproval (in some cases, partial approval) of the request must be made.⁷⁶

Where the purpose of the request described in a written request for trial has been amended in response to the notice of reasons for rejecting a request for correction, and the gist of the written request has not been changed by the amendment, the amended purpose of the request will be further examined. Where the gist of the written request has changed as a result of the amendment, the amendment will not be adopted, and a trial decision will be made by issuing a notice of the conclusion of proceedings. In this case, the reasons for the trial decision must contain the refusal of the amendment and reasons.⁷⁷

If a decision is made to allow a correction (either as a result of a trial or a request for correction) and that decision has become final and binding, the following are deemed to have been made

71 Patent Act, art. 126(1). An example of rewriting a claim so that it refers to two claims could include the following. Before the correction: (1) A process of X; (2) The process according to Claim 1, which further includes Y. After the correction: (1) A process of X; (2) A process of X + Y.

72 Patent Act, art. 126(2).

73 Patent Act, arts 120-5(2), 134-2(1); see also JPO, *Manual for Proceedings*, ss. 51-11, 67-05(2).

74 Patent Act, art. 126(8).

75 Patent Act, art. 165.

76 See JPO, *Manual for Proceedings*, s. 54-05.

77 See JPO, *Manual for Proceedings*.

based on the corrected claims, descriptions or drawings with retroactive effect: the filing and publication of the patent application; the examiner's decision or a trial or appeal decision to the effect that the patent is to be granted; and the registration of the patent right.⁷⁸

In 2021, the JPO received 196 requests for a trial for correction.⁷⁹

7.2.4.5 Trial for invalidation

Interested persons may file a request for a trial for invalidation if they wish to invalidate a patent that should not have been granted, with binding legal effect as to third parties. In 2021, there were 106 requests for a trial for the invalidation of a patent.⁸⁰ Trials for invalidation are to be distinguished from the "defense of invalidity," which may be raised in patent infringement lawsuits.⁸¹

7.2.4.5.1 Grounds for invalidation

Reasons for invalidation are any reason or fact invalidating a right. Such reasons are limited to the statutory reasons for invalidation under Article 123(1) of the Patent Act.⁸² If a patent falls under any of the following items – set out as an exhaustive list in Article 123(1)(i)–(viii) – a request for a trial for patent invalidation may be filed (if the request involves two or more claims, it may be filed on a claim-by-claim basis):

- the patent has been granted on a patent application (excluding an application written in a foreign language) with an amendment that does not comply with the requirements stipulated in Article 17-2(3) (i.e., any amendment of the description, scope of claims or drawings must be made within the scope of the matters described in the description, scope of claims or drawings originally attached to the application);
- the patent has been granted in violation of Article 25 (enjoyment of rights by foreign nationals), Articles 29 and 29-2 (conditions for patentability), Article 32 (unpatentable inventions, such as those likely to disrupt public order, corrupt public morals or harm public health) or Article 38 (joint applications), or Article 39(1)–(4) (prior application; if the patent has been obtained in violation of Article 38, excluding if the transfer of a patent right under that patent has been registered based on a request under Article 74(1));
- the patent has been granted in violation of a treaty;
- the patent has been granted on a patent application not complying with the requirements stipulated in Article 36(4)(i) or Article 36(6) (excluding Article 36(6)(iv)), which address the requirements for statements of the detailed explanation of the invention and statements of claims;
- the matters stated in the description, claims or drawings attached to the application written in a foreign language are not within the scope of matters stated in foreign-language documents;
- the patent has been granted on a patent application filed by a person that does not have the right to the grant of a patent for the invention (excluding when the transfer of a patent right under the patent has been registered based on a request under Article 74(1));
- after being granted a patent, the patentee comes to fall under a category of person that is not permitted the enjoyment of a patent right pursuant to Article 25, or the patent comes to violate a treaty after being granted; or
- the correction of the description, claims or drawings attached to the written application for the patent have been obtained in violation of the proviso to Article 126(1), Article 126(5)–(7) (including as applied *mutatis mutandis* pursuant to Article 120-5(9) or Article 134-2(9)), the provisos to Article 120-5(2) or Article 134-2(1).

No other reasons outside the statutory provisions constitute a reason for the request of a trial for invalidation.⁸³

⁷⁸ Patent Act, arts 120-5(9), 128, 134-2(9).

⁷⁹ JPO, *Status Report*, at 32.

⁸⁰ JPO, *Status Report*, at 31.

⁸¹ See Section 7.5.3 for more information on the defense of invalidity.

⁸² See JPO, *Manual for Proceedings*, s. 51-04.

⁸³ See JPO, *Manual for Proceedings*. Some of these reasons for invalidation (e.g., a violation of the conditions for patentability under Article 29(2) of the Patent Act, such as novelty and inventive step) are also set out in Section 7.4.5 of this chapter as a "substantive law defect" that the IP High Court may consider when reviewing a JPO decision.

7.2.4.5.2 Parties

Trials for invalidation are *inter partes* trials, involving a demandant (an interested person in relation to a granted patent) and demandee (the patentee). A trial for invalidation is conducted by a panel of either three or five TAD administrative patent judges.⁸⁴ The process commences when a demandant files a request with the JPO for a trial for patent invalidation, indicating the reasons why a patent should be invalidated. The demandant may file such a request any time after the registration of the establishment of a patent right.⁸⁵

Only an “interested person” may file a request for a trial for invalidation.⁸⁶ Whether a person is an “interested person” is determined on a case-by-case basis. The court has indicated that an interested person may include a person who is being sued for patent infringement or a person who manufactures the same kind of product as the patented invention.⁸⁷

Furthermore, persons who claim a legitimate right to obtain a patent can request a trial for invalidation on the grounds that the patent has been granted:

- in violation of the joint application requirements under Article 38 of the Patent Act; or
- on a patent application filed by a person who is not the inventor and has not succeeded to the right to obtain a patent for that invention (usurped application).⁸⁸

Persons having a legitimate right to obtain a patent include those who are actual co-owners of the right to obtain a patent and persons to whom the right to obtain a patent has been transferred by the actual inventor.

Figure 7.5 provides an overview of this process. A number of the steps in this process are discussed in detail below.

7.2.4.5.3 Patentee written reply and request for correction

After a demandant files a request for a trial for invalidation, a patentee may submit written replies and file a request for correction to protect their patent rights. In the written reply, the patentee will respond to the arguments made by the demandant in the request for a trial.

Patentees may request a correction of descriptions, claims or drawings to clarify and correct the scope of claims and to avoid invalidation. The corrections that may be requested include, for example, restriction of the claims and clarification of ambiguous statements. When a correction decision becomes final and binding, the original registration of the establishment of a patent right is deemed to have been made based on the corrected claims.⁸⁹

A request for correction:

- must identify the purpose of the correction (restriction of the scope of claims, correction of errors or incorrect translations, clarification of an ambiguous description etc.);
- must not add any new matter;
- must not substantially expand or change the scope of claims; and
- must fulfill the requirements for independent patentability.

Time limits apply to when corrections may be requested. For example, a patentee (demandee) may only file a request for correction within the time limit for submitting a written reply after receiving duplicates of the written request (i.e., within the first opportunity to reply to the alleged reasons for invalidation) or after the chief administrative patent judge provides advance notice of a trial decision.⁹⁰

84 Patent Act, art. 136. An example of a five-judge panel decision is available at TAD, JPO, *Trial Decision on the Trial for Correction Case That Includes a Change of Category from an Invention of a “Product” to an Invention of “a Manufacturing Process of the Product” Related to Product-by-Process Claims* (July 27, 2016), www.jpo.go.jp/e/system/trial_appeal/info-general-pbp_teisei_sinpan.html

85 When a patent right pertains to two or more claims, a demandant may file a request for a trial for invalidation for each claim. Patent Act, art. 123(1).

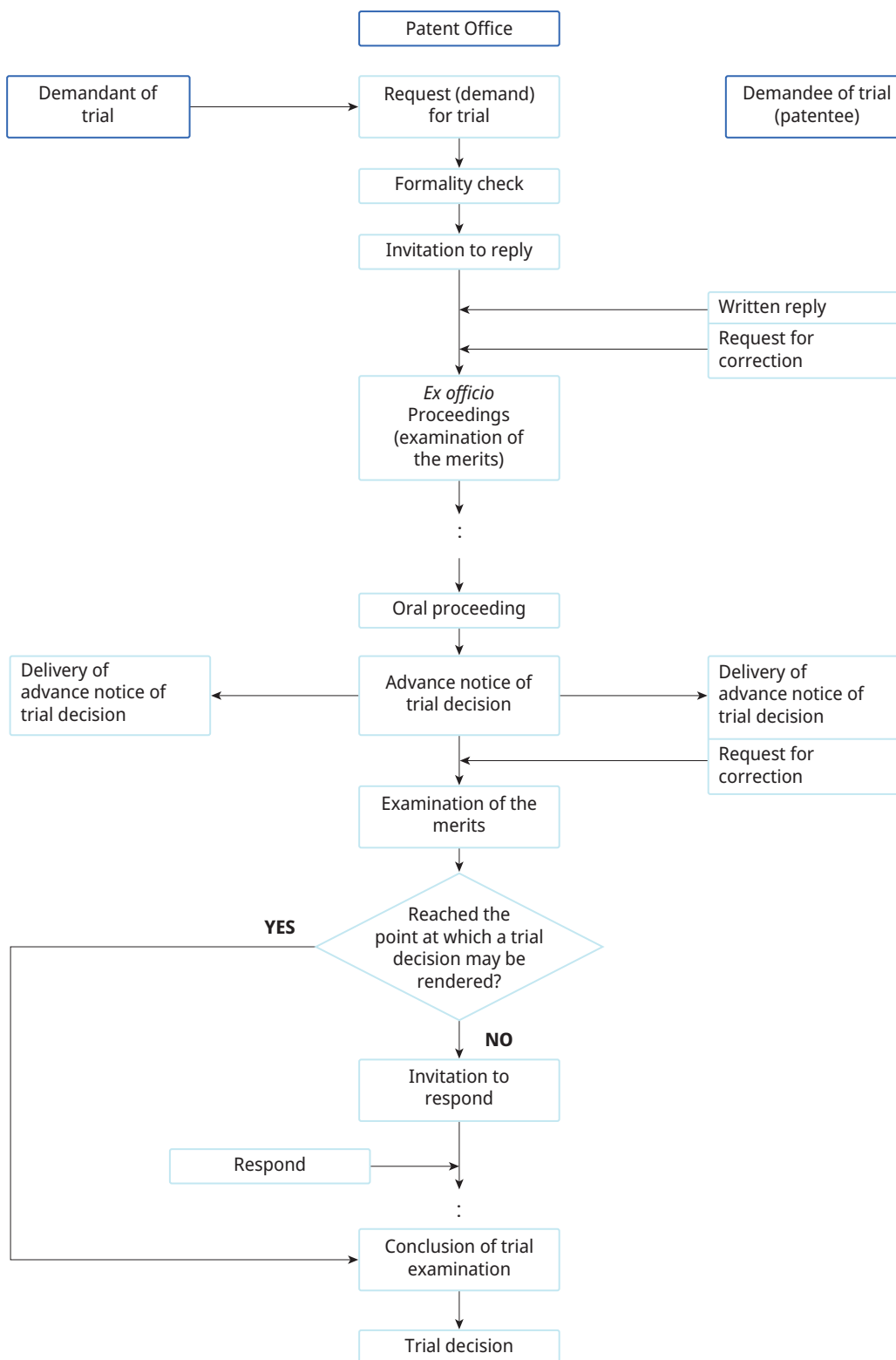
86 Patent Act, art. 123(2).

87 See the cases cited in JPO, *Manual for Proceedings*, s. 31-02 tbl. pp. 5–14.

88 Patent Act, art. 123(2).

89 Patent Act, art. 134-2(1), (9).

90 For other time limits, see Patent Act, arts 134(1)–(2), 134-3, 153(2), 164-2(2). Advance notice of a trial decision is discussed below.

Figure 7.5 Trial for the invalidation of a patent

Source: Adapted from JPO (2020), s. 51-03 fig 1-1 and 1-2.

7.2.4.5.4 Demandant response to patentee response

After demandants file a request for a trial for invalidation, they may submit written responses (reply briefs) or amend the request. A demandant may state their objections to statements made by a patentee in their response as to the validity of a patent.⁹¹

91 Tokkyo-hō shikōkiseki (Ordinance for Enforcement of the Patent Act), Ordinance of the METI No. 72 of September 30, 2021, art. 47-3(1); JPO, *Manual for Proceedings*, s. 51-03.

In order to avoid unreasonable delays in a proceeding, demandants may not, in principle, amend the request for a trial to change the gist of the reasons for the request (e.g., by changing the reason for invalidation from violation of the requirement for inventive step to violation of the clarity requirement).⁹² However, they may amend the request to change the gist of the reasons for the request if there is no risk of unreasonable delay in the proceedings and the amendment is in response to a patentee's request for correction.⁹³

7.2.4.5.5 *Ex officio proceedings*

A panel of administrative patent judges may conduct an *ex officio* examination of any grounds for invalidation not pleaded by a demandant or the violation of any correction requirements.⁹⁴ However, it cannot examine any claim not claimed by a demandant.⁹⁵

If a panel conducts *ex officio* proceedings, it must provide both parties with a "notice of reasons for invalidation" or a "notice of reasons for rejecting a request for correction." The parties may formally respond to such *ex officio* decisions.

7.2.4.5.6 *Oral proceedings*

Trials for invalidation are generally conducted as oral proceedings.⁹⁶ In oral proceedings, the panel and the parties communicate in order to understand and resolve the issues in dispute, including any technical matters.

A panel will generally conduct oral proceedings with parties appearing before a trial court. However, it is now also possible to conduct oral proceedings online.⁹⁷ The panel may ask the parties to address issues that have emerged as a result of an *ex officio* examination. The panel may also interrupt the proceedings to examine witnesses.

Oral proceedings provide both the demandant and patentee with an opportunity to present their arguments, eliminating the need for the exchange of multiple documents. They also provide an efficient means for the parties to present sufficient evidence so that a panel may establish the facts while also taking into consideration the binding legal effect of patent rights on third parties. Therefore, the binding effect of constructive admissions recognized in civil litigation proceedings does not apply.⁹⁸

Documentary allegations are permitted, and parties do not need to restate the allegations submitted in writing at oral proceedings.

Prior to oral proceedings, the panel will send a written "notice of proceedings matters" to both parties. The written notice clarifies the matters to be alleged and proved at the oral proceedings as well as the issues in dispute between the parties. This helps facilitate the proceedings and ensures that all relevant issues and matters are considered.

The written notice must contain the following matters:

- the preliminary view of the panel – the panel presents a preliminary view of the identical and differing features of the patented invention and cited invention;
- the matters concerning the allegations by the parties – to ensure that the parties can make allegations and present all the relevant evidence, the panel identifies the issues in dispute and those to be discussed by the panel when making a decision; and
- a request for technical explanations – the panel may request a technical explanation of the patented invention and its background (among other aspects) from the parties.

92 See Section 7.5 for further information on the clarity requirement.

93 Patent Act, art. 131-2.

94 Patent Act, art. 153(1).

95 Patent Act, art. 153(3). "The principle of *ex officio* is adopted in any trial because a trial serves not only to benefit the concerned parties but also to solve problems of broader perspectives wherein interest of any third parties might be involved." JPO, *Manual for Proceedings*, s. 51-09(4).

96 Patent Act, art. 145(1). Documentary proceedings are permitted in some circumstances. In some cases, a notice of documentary proceedings must be issued.

97 Tokkyo-hō-tō no ichibu o kaisei suru hōritsu (Act on the Partial Revision of the Patent Act and Other Acts), Act No. 42 of May 21, 2021.

98 Code of Civil Procedure, art. 159.

Based on the content of the written notice, the parties must submit in advance an “oral proceedings statement brief” (statement brief). The statement brief is prepared in order to ensure there are no omissions and to clarify the logical structure of the arguments so that the oral proceedings may be conducted efficiently.

7.2.4.5.7 Advance notice of a trial decision

The panel will provide the parties and intervenors with advance notice of a trial decision when:

- the panel is ready to make a trial decision following the oral proceedings; and
- the case is one, for example, where a reason for the request for trial is approved or when the request for correction is not approved).⁹⁹

In response to the advance notice, a patentee (demandee) may file a request for correction or to amend a corrected description, claim or drawing. If no such request is made, the panel will conclude the proceedings and deliver a trial decision.¹⁰⁰

The advance notice will contain the same matters as those that will be set out in the trial decision. The advance notice will describe all matters – including the conclusion, reasons for the trial decision, determination of the appropriateness of any corrections, and the validity of all the claims – in the same level of detail as in the final trial decision. The panel must also set out all the reasons for deciding the validity of a patent in the advance notice.¹⁰¹

The advance notice procedure was established to prevent “a catch-ball” situation between the IP High Court and the JPO. A “catch-ball” situation is one in which:

- either party files an action to revoke a JPO trial decision with the IP High Court;
- the patentee files a request for a trial for correction with the JPO;
- the IP High Court revokes the JPO’s trial decision because the claims on which the trial decision is based have changed as a result of the finalization of the trial for correction, and the court then remits the case back to the JPO.

The advance notice procedure avoids such a situation, where a trial for invalidation is remanded to the JPO. Instead of showing the final decision of the panel to the patentee (demandee) and allowing them to request corrections based on that decision, the IP High Court is prevented from weighing in before the trial for invalidation is properly concluded.

In principle, a panel will provide advance notice of a trial decision when it is ready to make the first trial decision (see Figure 7.6). However, it will not provide advance notice in the following cases:

- the patentee (demandee) has indicated that they do not wish to be given the advance notice;
- the patentee does not file a request for correction, and all the claims requested for trial are determined to be valid; or
- all the requested corrections to the claims are approved, and all the requested claims are determined to be valid.¹⁰²

If the patentee files a request for correction after they are given advance notice, the demandant is provided an opportunity to respond. If the patentee does not file a request for correction, the panel usually concludes the proceedings and renders a trial decision based on the contents of the determination described in the advance notice.

7.2.4.5.8 Reasons for trial decision

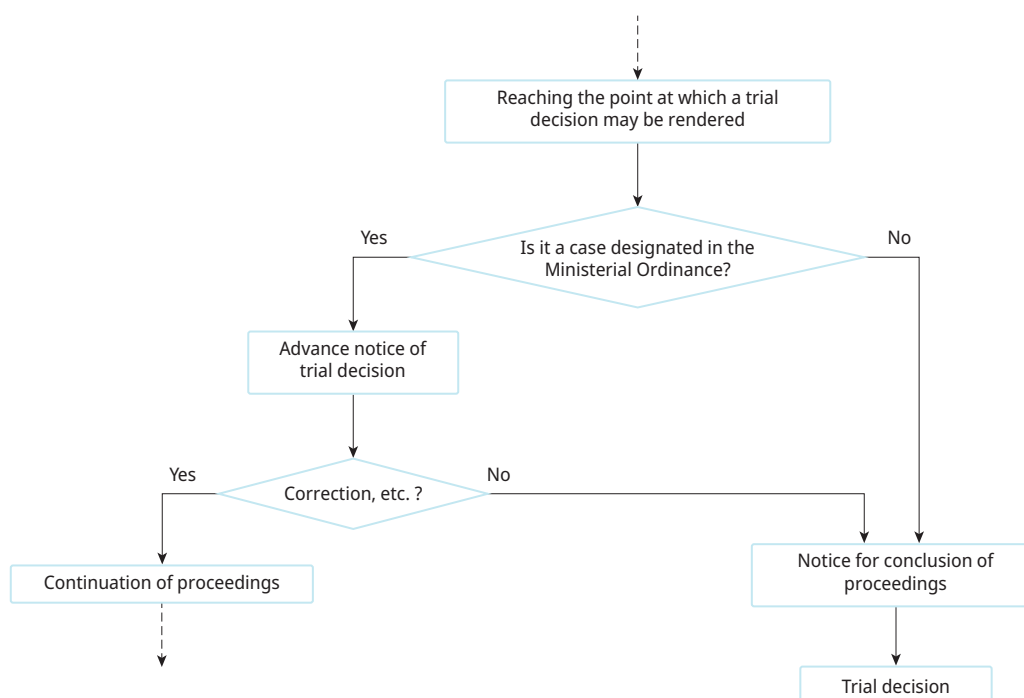
The trial decision of the panel includes the issues in dispute and the determination of those issues. In the trial decision, the panel will determine and decide all the reasons for invalidation (including the reasons alleged by the demandants and the reasons of which the panel have notified the parties *ex officio*) and present its conclusions and specific reasons for its decision.

99 Patent Act, art. 164-2(1).

100 Patent Act, art. 164-2(2).

101 Patent Act, arts 157, 164-2(3).

102 JPO, *Manual for Proceedings*, s. 51-17.

Figure 7.6 Advance notice of a trial decision

Source: Adapted from JPO (2020), s. 51–17 fig.

The panel will determine the degree to which it will address reasons for invalidation that are not directly related to the conclusion of the trial decision. These may include reasons for invalidation that the panel decided to dismiss when a demandant filed a request for a trial for invalidation on the basis of multiple reasons for invalidation. The trial decision must also describe the panel's reasons for not approving the amendment of the reasons for the request for a trial on the basis that it would change the gist of those reasons.¹⁰³

Any persons who are dissatisfied with the trial decision in a trial for invalidation may file an action to revoke a trial decision with the IP High Court. The person filing the action will be the plaintiff, and the opposing party will be the defendant. The JPO is not a party in a suit for the revocation of a trial decision.¹⁰⁴

7.2.4.6 Hantei system

Under the Hantei (infringement advisory opinion) system, a party may request that the TAD of the JPO deliver and publish an official advisory opinion with respect to the technical scope of a patented invention.¹⁰⁵ In 2021, the JPO received 24 requests for Hantei.¹⁰⁶

An advisory opinion's result has no legally binding force on a party to the case, and so no legal interest is required for demanding an advisory opinion. Nevertheless, it is necessary to show some benefit in obtaining an advisory opinion.¹⁰⁷ For example, a patentee (demandant) can request a determination as to whether the product of another person (demandee) falls within the technical scope of their patented invention. A person who is not the patentee (demandant) can also request a determination when they want to know whether a technology for which an investment or a project is planned or a technology that is being worked falls within the technical scope of a patented invention owned by a patentee (who, in that case, usually becomes the demandee).¹⁰⁸

¹⁰³ JPO, *Manual for Proceedings*, s. 51-19.

¹⁰⁴ See Section 7.4 for further information on IP High Court review of these decisions.

¹⁰⁵ Patent Act, art. 71. For detailed information about the Hantei process, see JPO, *Manual for Proceedings*, s. 58-00; JPO, *Hantei (Advisory Opinion)*, www.jpo.go.jp/e/system/trial_appeal/shubetu-hantei/index.html

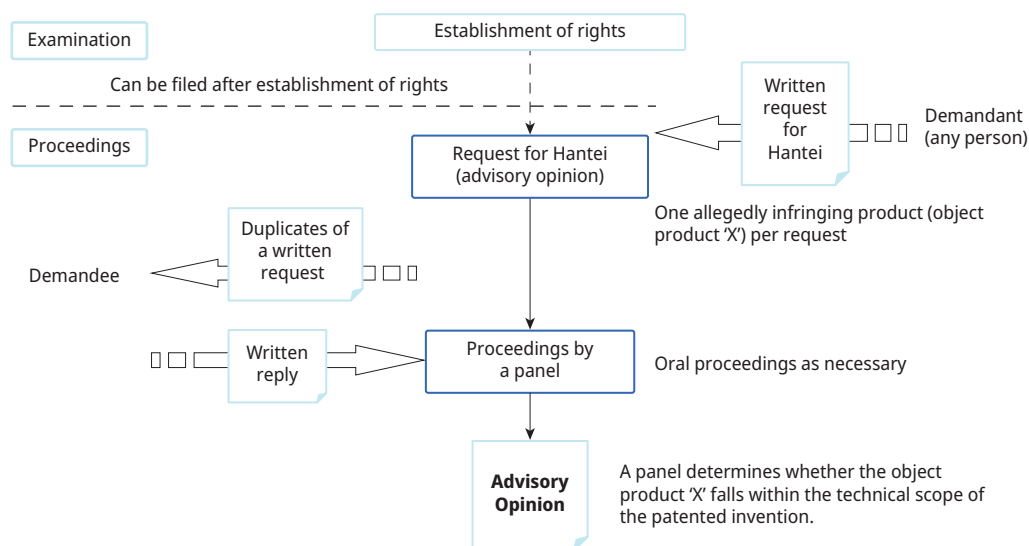
¹⁰⁶ JPO, *Status Report*, at 33.

¹⁰⁷ JPO, *Manual for Proceedings*, s. 58-01.

¹⁰⁸ TAD, *Handbook*, at 14; JPO, *Manual for Proceedings*, s. 58-00.

A demandant must submit a written request for an advisory opinion to the JPO.¹⁰⁹ When a request for an advisory opinion is filed, the panel must serve a copy of this written request to the demandee and give the demandee an opportunity to file a written answer. Upon accepting the written answer, the panel must forward a copy to a demandant (see Figure 7.7).¹¹⁰

Figure 7.7 The Hantei process



Source: Adapted from JPO (2019), s. 15.

During Hantei proceedings, the TAD examines the technical scope of a specific patented invention. Therefore, requests for examining an indirect infringement pursuant to Article 101 of the Patent Act will not be considered. A Hantei process on the technical scope of a patented invention will include, however, the determination of the doctrine of equivalents.¹¹¹ During the process, the TAD may examine evidence and request additional information and concludes by issuing a written advisory opinion that includes a statement as to the technical scope of the patent.

The Hantei system is an administrative service and is, therefore, neither legally binding nor appealable.

In 2018, the JPO implemented a new Hantei system in relation to standard-essential patents.¹¹² The aim of the new system is to facilitate license negotiations by improving the transparency of a standard-essential patent's actual essentiality. A request for Hantei in relation to a standard-essential patent can be made when the different views of a demandant and demandee on the "essentiality" of a patented invention become apparent, for example, in license negotiations. Demandants need to specifically identify a "virtual object" from a technical standard that is usually established by a standard-setting organization. A panel consisting of three administrative patent judges compares and determines the patented invention and the identified virtual object and assesses whether the virtual object falls within the technical scope of the patented invention. If so, the patent is determined to be a standard-essential patent.

7.2.4.7 Statistics

Tables 7.1 and 7.2 show the number of cases and the revocation rate of trial or appeal decisions – as *ex parte* and *inter partes* appeals, respectively – from 2012 to 2021.

¹⁰⁹ Patent Act, art. 71(3).

¹¹⁰ Patent Act, arts 71, 134.

¹¹¹ See Section 7.5.2 for more information on the doctrine of equivalents.

¹¹² See JPO, *Standard Essential Patent Portal Site*, www.jpo.go.jp/e/support/general/sep_portal; TAD, JPO, *Manual of "Hantei" (Advisory Opinion) for Essentiality Check (Revised Version)* (June 2019).

Table 7.1 Dismissal of action and revocation of decision – *ex parte* appeals, 2012–2021

Year	Patent		Design		Trademark	
	Dismissal of action	Revocation of decision	Dismissal of action	Revocation of decision	Dismissal of action	Revocation of decision
2012	113	37	9	7	13	7
2013	101	35	2	0	16	1
2014	83	21	13	1	15	0
2015	47	16	4	0	17	1
2016	48	11	1	13	12	3
2017	42	8	4	4	10	1
2018	29	6	4	0	12	0
2019	23	5	4	0	4	1
2020	15	9	0	0	17	2
2021	20	9	1	0	9	2

Source: Translated by the present authors from JPO (2022), at 65.¹¹³

Table 7.2 Dismissal of action and revocation of decision – *inter partes* appeals, 2012–2021

Year	Patent and utility model		Design		Trademark	
	Dismissal of action	Revocation of decision	Dismissal of action	Revocation of decision	Dismissal of action	Revocation of decision
2012	76	32	0	0	33	19
2013	79	27	1	0	37	15
2014	51	37	0	0	13	5
2015	48	30	1	0	17	14
2016	54	23	3	0	23	9
2017	58	36	3	0	27	10
2018	72	14	5	0	26	4
2019	47	19	2	0	18	10
2020	51	13	0	0	10	4
2021	40	24	0	0	25	10

Source: Translated by the present authors from JPO (2022), at 65.¹¹⁴

7.3 Judicial institutions, jurisdiction and personnel

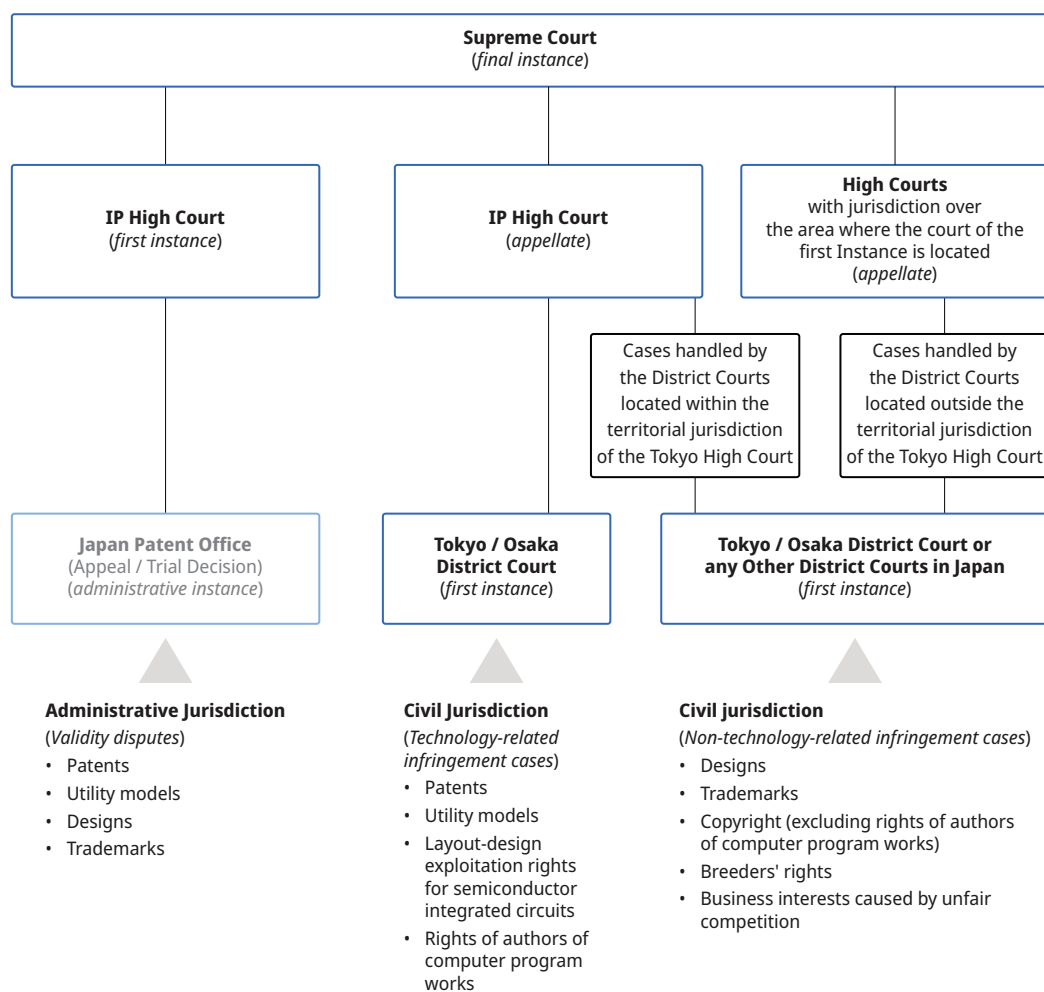
This section provides an overview of the key judicial institutions of the patent system in Japan, including IP divisions of the Tokyo District Court and Osaka District Court, the IP High Court and the Supreme Court. The role and jurisdiction of each institution are outlined, as well as the relevant review or appeal structure. This section also describes the role of key personnel at these institutions, including district court and IP High Court judges and Supreme Court Justices. The role of specialized court officers, such as judicial research officials and technical advisors, is also discussed. In Japan, there is no jury for civil cases including IP cases.

7.3.1 Specialized intellectual property judiciary

Japan has adopted a three-tier court system in relation to civil matters (see Figure 7.8), such as those relating to the Patent Act. For example, in a patent infringement lawsuit, a party who is dissatisfied with the judgment of a court of first instance (the Tokyo District Court or the Osaka District Court) can appeal to the court of second instance (the IP High Court), and a party who is dissatisfied with that decision can appeal to the court of third instance (the Supreme Court).

¹¹³ JPO, *Annual Report*, main vol. pt 2, ch. 2.17, www.jpo.go.jp/resources/report/nenji/2022/index.html (in Japanese), at 125.

¹¹⁴ JPO, *Annual Report*

Figure 7.8 The judicial administration structure in Japan

Source: Judicial Administration Structure for IP Disputes provided by the Supreme Court of Japan, available at www.wipo.int/wipolex/en/judgments/j-admin/jp.html.

The Court Act, the Code of Civil Procedure and other related laws determine which court has jurisdiction over each case.¹¹⁵

7.3.2 Tokyo District Court and Osaka District Court

7.3.2.1 Jurisdiction

A patentee may file a civil lawsuit seeking an injunction against, or damages for, an alleged infringement of a patent.

Patent infringement lawsuits handled by a district court are under the exclusive jurisdiction of the Tokyo District Court or the Osaka District Court. One or both of these courts will have jurisdiction depending on the location of the defendant, the plaintiff (if damages are sought) and where the infringement occurred. The Tokyo District Court has jurisdiction if this location is in the northern or eastern parts of Japan, and the Osaka District Court has jurisdiction if the location is in the southern or western parts of Japan.¹¹⁶

For the period from 2014 to 2021, approximately 30 percent of patent infringement cases that came before the Tokyo District Court and Osaka District Court were settled. Of the remainder,

¹¹⁵ Saibanshohō (Court Act), Act No. 59 of April 16, 1947; Code of Civil Procedure.

¹¹⁶ Code of Civil Procedure, art. 6(1). See Section 7.6 of this chapter for information on the patent infringement court process.

21 percent had the claim upheld, 44 percent were dismissed, 2 percent were dismissed without prejudice, and 2 percent upheld confirmation of the nonexistence of obligation. In 2021, the average duration of an IP case handled by the Tokyo District Court or Osaka District Court (from commencement to a final decision) was 15.2 months.¹¹⁷

The Tokyo District Court has made the following documents available in English (via the IP High Court website):

- *Guideline for Proceedings of Patent Infringement Suit*; and
- *Guide to IP Conciliation Proceedings*.¹¹⁸

The Osaka District Court has made the following documents available in English (via the IP High Court website):

- *Flow of Procedures for a Patent / Utility Model Right Infringement Suit*;
- *Instructions for Proceedings of the Stage for Examination on Damages*;
- *Guidelines for IP Conciliation Proceedings at the Osaka District Court*; and
- *Explanation of the New IP Conciliation at the Osaka District Court*.¹¹⁹

See Section 7.6 for more information about the district court process in relation to patent infringement lawsuits.

7.3.2.2 Key personnel

7.3.2.2.1 District court judges

As of April 1, 2021, the Tokyo District Court had 12 judges in four divisions that specialize in IP-related cases, and the Osaka District Court had 5 judges in two divisions. District court judges are appointed by the Cabinet from lists of candidates nominated by the Supreme Court. Most district court judges start their careers as assistant judges. Assistant judges are allowed to serve on the bench but are not authorized to deliver a judgment as a single-judge panel; they usually sit as a member of a three-judge panel. In certain circumstances, the Supreme Court may appoint an assistant judge to hear a case as a single-judge panel.¹²⁰

7.3.2.2.2 Conciliators

The IP divisions of the Tokyo District Court and Osaka District Court provide IP conciliation services. Part-time judicial officers called “conciliators” settle civil disputes through conciliation proceedings in which they have the same level of authority as a judge. They are generally appointed from among attorneys with at least five years’ experience in practice.¹²¹

7.3.2.2.3 Expert court officials

The Tokyo District Court, Osaka District Court and the IP High Court employ technical advisors and judicial research officials to help ensure the efficiency of court proceedings and the accuracy of decisions that involve highly specialized technical issues. The role of these expert court officials – in both the district courts and the IP High Court – is discussed in Sections 7.3.3.3 and 7.3.3.4.¹²²

7.3.3 Intellectual Property High Court

The IP High Court plays a very important role in setting the rules in relation to patent validity and patent infringement. It exercises jurisdiction over both administrative lawsuits against decisions made by the TAD of the JPO and patent infringement lawsuits. If the IP High Court finds an error in the decision of the TAD of the JPO or a district court, it may correct it and also establish the proper interpretation of patent law.

¹¹⁷ IP High Court, *Statistics* [hereinafter IP High Court, *Statistics*], www.ip.courts.go.jp/eng/documents/statistics/index.html

¹¹⁸ See IP High Court, *Rules of Practice* [hereinafter IP High Court, *Rules of Practice*], www.ip.courts.go.jp/eng/Guidelines_for_Proceedings/index.html

¹¹⁹ See IP High Court, *Rules of Practice*.

¹²⁰ Supreme Court of Japan, *Courts in Japan* at 31 (2020), [hereinafter Supreme Court of Japan, *Courts in Japan*], www.courts.go.jp/english/vc-files/courts-en/file/2020_Courts_in_Japan.pdf

¹²¹ Supreme Court of Japan, *Courts in Japan* at 32.

¹²² See Section 7.6 for further information on the role of experts in explanatory sessions (technical briefing sessions).

7.3.3.1 Jurisdiction over administrative lawsuits in relation to Japan Patent

Office decisions

As noted in Section 7.2.3.4, a person may file a revocation action (an administrative lawsuit) with the IP High Court against the following TAD decisions:

- an appeal decision to refuse an invention in an appeal against an examiner’s decision of refusal;
- a decision to revoke a patent in an opposition to the grant of patent;¹²³ or
- a trial decision in either a trial for invalidation or a trial for correction.¹²⁴

Each of these lawsuits is under the exclusive jurisdiction of the IP High Court, as the court in charge of the first instance.¹²⁵ In an *ex parte* case, such as a trial against an examiner’s decision of refusal, the JPO Commissioner will be the defendant. In the case of an *inter partes* case, such as a patent invalidation trial, the party unsuccessful at the JPO will be the plaintiff.

In 2021, the average duration of an administrative lawsuit in relation to a decision of the TAD, handled by the IP High Court (from commencement to a final decision), was 9.8 months.¹²⁶

The IP High Court is required to determine whether a TAD decision is legally correct. If it reverses the decision, it will remand the case to the JPO for further proceedings. The TAD will then conduct the proceedings again and make another decision that a patent right is either granted, corrected or revoked. If the IP High Court finds that the JPO decision in relation to an examiner’s decision of refusal is legally incorrect, it can only revoke the JPO decision. The IP High Court has no authority to grant a patent.

The IP High Court has made a number of documents available in English, including:

- *Proceedings of Suits against Appeal/Trial Decision Made by the JPO (For Patent/Utility Model)*, which provides information for parties regarding preparation; and
- *Flow of Procedures in the Intellectual Property High Court of Suits against Appeal/Trial Decision Made by the JPO (Patent/Utility Model)*, which sets out the process.¹²⁷

See Section 7.4 for a detailed description of the IP High Court process for administrative lawsuits in relation to JPO decisions.

7.3.3.2 Jurisdiction over patent infringement lawsuits

Any appeal against a patent infringement decision of the district courts is under the exclusive jurisdiction of the IP High Court.¹²⁸ The scope of the review of the IP High Court is not limited to legal issues. The court may decide on factual as well as legal issues.

In 2021, the average duration of an IP case handled by the IP High Court (from commencement to a final decision) was 7.0 months. Section 7.6 provides more information about the IP High Court process in relation to patent infringement lawsuits.

7.3.3.3 Key personnel

7.3.3.3.1 Intellectual Property High Court judges

The IP High Court consists of four divisions. Each division consists of several judges, including a presiding judge. The Chief Judge of the IP High Court is usually a presiding judge of the First Division. As of April 1, 2021, the IP High Court had 15 judges in four divisions, and the Osaka High Court had 4 judges in one division that handled IP-related cases as well as general civil cases.

Each division generally handles cases by forming panels of three judges for each case. The same panel will handle administrative lawsuits against a JPO decision in a trial for invalidity and appeals against a district court decision in a patent infringement lawsuit, including in relation to the same patent.

123 Opponents may not file a revocation action against a decision to maintain a patent. Patent Act, art. 114(5).

124 There is no appeal to the court in relation to the Hantei process.

125 Patent Act, art. 178.

126 IP High Court, *Statistics*.

127 See IP High Court, *Rules of Practice*.

128 Code of Civil Procedure, art. 6(3); Act for Establishment of the IP High Court, art. 2(1).

7.3.3.3.2 Grand Panel

In exceptional cases, the IP High Court may handle patent cases by forming a panel of five judges. Such a formation is called a Special Division or, more commonly, a Grand Panel. The Chief Judge of the IP High Court will set up the Grand Panel, and the four presiding judges from each of the four divisions serve as members of the Grand Panel. The Grand Panel conducts proceedings that require highly specialized technical knowledge and when the outcome may have a significant impact on business activities and the economy. Grand Panels help maintain consistent decision-making and interpretation of IP law.

A Grand Panel judgment has been delivered every year since 2012. As of June 2022, the latest judgment was rendered in February 2020. In this Grand Panel case, the IP High Court made a ruling on the calculation of the amount of lost profit of a patentee under the Patent Act in a case where the feature of a patented invention that was worked was only a part of the product.¹²⁹

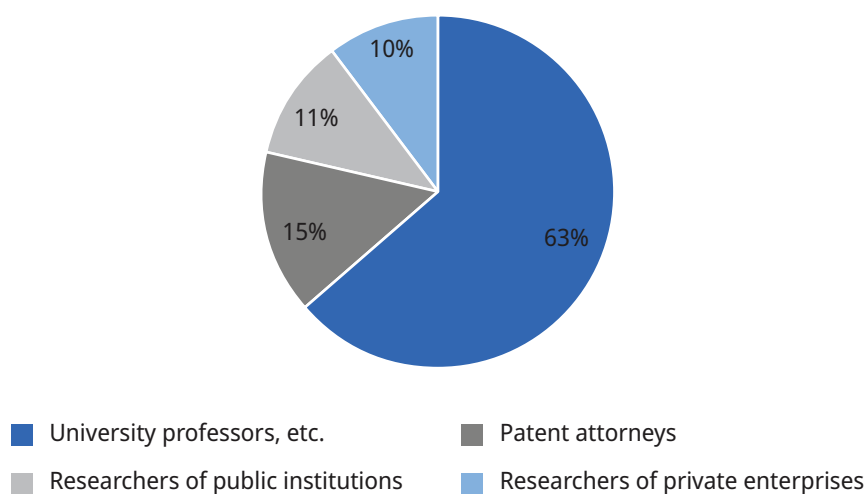
7.3.3.3.3 Technical advisors

In 2003, the Code of Civil Procedure was amended to introduce a technical advisor system to ensure high-quality decisions in proceedings in which specialized and technical matters are at issue, such as IP proceedings. Article 92-2(1) of the Code of Civil Procedure provides the following:

If the court finds that it will need to have a technical [advisor] participate during deliberations on the necessary particulars involved in the arrangement of issues and evidence or the progress of litigation proceedings in order to clarify a matter related to the litigation or create a framework for smooth progress in the litigation proceedings, the court, after hearing the opinions of the parties, may rule to have a technical [advisor] participate in the proceedings so as to hear an explanation based on the technical [advisor's] expert knowledge. In such a case, the presiding judge shall have the technical [advisor] give an explanation in writing or orally on a date for oral arguments or preparatory proceedings.

The IP High Court, Tokyo District Court and Osaka District Court maintain lists of persons with relevant knowledge and experience in a technical field, such as university researchers and patent attorneys (see Figure 7.9). Technical advisors are selected from these lists.

Figure 7.9 Technical advisors involved in intellectual property proceedings as of September 1, 2021



Source: Reprinted from IP High Court (2022).¹³⁰

¹²⁹ Chiteki Zaisan Kōtō Saibansho (Intellectual Prop. High Ct) Feb. 28, 2020, Reiwa 2 (ne) no. 10003, Chiteki Zaisan Kōtō Saibansho saibanrei kensaku (Chizai kōsai web) (*MTG Co. Ltd v. Five Stars Co. Ltd*) (*Beauty Instrument Case*).

¹³⁰ IP High Court, *Guidebook of the Intellectual Property High Court* (2022) [hereinafter IP High Court, *Guidebook*], at 27 www.ip.courts.go.jp/eng/documents/thesis/141006_setuguusiryo/index.html

A court may select a technical advisor for a certain case to clarify the matters related to the litigation or to ensure the smooth progress of court proceedings.¹³¹ Technical advisors will also be involved in explanatory sessions (see Section 7.6).

A technical advisor must provide a fair and neutral opinion on highly specialized and technical matters based on their expertise. However, the expert advisors' explanations are not to be treated as evidence. It is the judge's role to deliver a judgment after clarifying the issues. It is not the technical advisor's role to present evidence to a judge as to whether a patent is valid, invalid or infringed.

To date, approximately 200 technical advisors have been appointed in Japan. As of April 1, 2019, more than 2,100 expert advisors had been involved in IP proceedings.

7.3.3.4 Judicial research officials

Judicial research officials are full-time court staff members of the IP High Court and the divisions of the Tokyo District Court and the Osaka District Court. There are 11 judicial research officials for proceedings in the IP High Court, seven in the Tokyo District Court and three in the Osaka District Court. They include former JPO trial examiners and patent attorneys who have specialized knowledge in technical fields such as machinery, chemistry and electric equipment, as well as knowledge about the Patent Act and related matters.

In principle, judicial research officials are engaged in all technology-based IP-related litigation, such as those related to patents or utility models. They conduct research on technical matters relevant to the proceedings and the judicial decision for a case.

If the court finds it necessary, a judicial research official may, on the date of oral argument or during other similar proceedings:

- ask the parties questions or urge them to offer proof with regard to factual or legal matters;
- ask witnesses, the parties themselves or party-appointed experts questions;
- give an explanation based on expert knowledge; or
- state an opinion about the case to a judge.¹³²

7.3.3.4 English versions of judgments and case summaries

The IP High Court website includes English translations of selected IP judgments and case summaries of its own decisions and those of the Supreme Court and the district courts.¹³³

7.3.4 Supreme Court

Under the Constitution of Japan, the Supreme Court is the highest court in Japan, and judicial power is vested in it and in such lower courts as are established by law.¹³⁴ In the context of IP law, the Supreme Court's role is to correct or modify the interpretation of IP laws of the IP High Court. In the past, the Supreme Court has delivered a limited number of judgments that have reversed decisions of the IP High Court.

The most recent decision of the Supreme Court that reversed an IP High Court decision was handed down in August 2019. In that case, the Supreme Court ruled in favor of the patentee, finding that the claimed invention satisfied the inventive step requirement as the invention could not be easily conceived by a person having ordinary skill in the art.¹³⁵

7.3.4.1 Jurisdiction

A party that is dissatisfied with the IP High Court's decision may file a final appeal or a petition for the acceptance of a final appeal to the Supreme Court within two weeks from the date when an

¹³¹ Code of Civil Procedure, art. 92-2.

¹³² Code of Civil Procedure, art. 92-8.

¹³³ See IP High Court, *IP Judgments in Japan*, www.ip.courts.go.jp/eng/hanrei/index.html; see also Courts in Japan, *Judgments of the Supreme Court*, www.courts.go.jp/app/hanrei_en/search

¹³⁴ Nihon-koku kenpō (Constitution of Japan), art. 76.

¹³⁵ Saikō Saibansho (Sup. Ct) Aug. 27, 2019, Heisei 30 (gyo-hi) 69, 262 Saikō Saibansho Saibanshū Minji (Shūmin) 51 (*Anonymous v. Alcon Research Ltd and Kyōwa Hakkō Kirin Co. Ltd.*)

authenticated copy of the written decision is served.¹³⁶ If the party is located in a foreign country, 30 days is generally designated as an additional period.¹³⁷

The Supreme Court may accept a final appeal against a judgment issued by the IP High Court:

- as the court of first instance with respect to an administrative suit against a decision made by the TAD of the JPO; and
- as the court of second instance with respect to a patent infringement suit.¹³⁸

The grounds for final appeal to the Supreme Court are limited under the Code of Civil Procedure. Article 312 of the Code of Civil Procedure provides that a final appeal may be filed on a number of grounds, including on the grounds that:

- a judgment reflects an error in the interpretation of the Constitution; and
- a violation of law or regulations has clearly influenced the judgment.¹³⁹

For example, the Supreme Court may accept a final appeal if a judgment of the IP High Court involves a ruling that conflicts with Supreme Court precedent (or, if there is no Supreme Court precedent, a ruling that conflicts with IP High Court precedent). If the Supreme Court determines that there are no grounds for a final appeal, it will dismiss the petition without a hearing. Conversely, if it determines that there are grounds for a final appeal, it will hear oral arguments and then deliver a decision.

The Supreme Court only decides questions of law, and so questions of fact of a prior instance decision may not be contested at the Supreme Court.¹⁴⁰ The Supreme Court examines questions of law based only on the records of the lower courts concerned.

7.3.4.2 Justices and other personnel

The Supreme Court is composed of a Chief Justice and 14 other Justices. It is divided into three petty benches. Most cases are adjudicated by one of the benches. Three Justices constitute a quorum for deciding a case within a petty bench. However, if a final appeal involves an issue of constitutional interpretation, the Grand Bench, composed of the Chief Justice and all 14 other Justices, adjudicates the case.

A number of elite career judges are assigned to assist the Justices of the Supreme Court as judicial research officials, including in IP-related cases.

7.4 Patent validity and scope: review of Japan Patent Office decisions by the Intellectual Property High Court

This section describes the procedure and the standard of review applied by the IP High Court when reviewing decisions of the TAD of the JPO. These decisions include an appeal decision to refuse to grant a patent, a decision to revoke a patent in an opposition, and a trial decision in a trial for invalidation or in a trial for correction.¹⁴¹

The section first outlines the decisions that may be the subject of review in a revocation action (an administrative lawsuit). It then considers who may commence such actions, the IP High Court procedure and the various grounds that the IP High Court will consider when reviewing a JPO decision, including possible procedural and substantive law defects. These defects may include those related to the eligibility of an invention; novelty and inventive step; and description, support, enablement, clarity and correction requirements.

¹³⁶ Code of Civil Procedure, arts 285, 313.

¹³⁷ Code of Civil Procedure, art. 96(2).

¹³⁸ Code of Civil Procedure, art. 311(1); Act for Establishment of the IP High Court, art. 2(1)(ii).

¹³⁹ Code of Civil Procedure, art. 312(1), (3).

¹⁴⁰ Code of Civil Procedure, art. 321(1).

¹⁴¹ As noted in Section 7.2.4.6, there is no appeal to the IP High Court in relation to Hantei (advisory opinion).

7.4.1 Overview

When a JPO trial or appeal processes have been finalized, and a decision has been delivered, a demandant or demandee may file an action to revoke certain trial or appeal decisions, including:

- an *ex parte* appeal decision to refuse to grant a patent;
- a decision to revoke a patent in an *ex parte* opposition;
- a trial decision in an *inter partes* trial for invalidation; and
- an *ex parte* decision to refuse to grant a correction.

Each of these revocation actions falls under the exclusive jurisdiction of the Tokyo High Court and is handled by the IP High Court.¹⁴² If the court finds that a JPO decision is incorrect, the decision will be overturned, and the case will be remitted to the JPO. For example, if the IP High Court decides to overturn a decision by the TAD to affirm an examiner's decision of refusal, it may only set aside the TAD decision and remit it to the JPO. The IP High Court does not have the authority to grant a patent. A person who is dissatisfied with a judgment of the IP High Court may file a final appeal with the Supreme Court.¹⁴³

7.4.2 Parties

The plaintiff in an action for revocation of a trial or appeal decision¹⁴⁴ is limited to:

- parties and intervenors in the case; and
- any person whose application to intervene in the proceedings of the opposition to the grant of a patent, in a trial or a TAD retrial, is refused.¹⁴⁵

In the case of a request to revoke an *ex parte* JPO ruling to revoke or not to grant a patent or to refuse to grant a correction, the Commissioner of the JPO becomes the defendant. However, in the case of a request to revoke a decision following a trial for invalidation, the demandant or the demandee (patentee) from the JPO trial will become the defendant.¹⁴⁶

An action for revocation of a trial or appeal decision may be instituted within 30 days of the date that a certified copy of the decision is served.¹⁴⁷ In the case of a trial or appeal decision unfavorable to a foreign party, 90 days may generally be added.¹⁴⁸

In relation to an action for revocation of a decision in a trial for invalidation, there is an issue concerning whether the action for revocation must be instituted by all joint owners if the patent right or the right to the grant of a patent is jointly owned. While Article 132(2) and (3) of the Patent Act provide that the *request for a JPO trial* must be filed by or against all joint owners regardless of whether the joint owners serve as the demandant or demandee, there is no such stipulation for an *action for revocation of a trial decision*.

The Supreme Court has held that, when the right to the grant of a patent is shared, an action for the revocation of an appeal decision to refuse an invention in an appeal against an examiner's decision of refusal is an inherently mandatory joint suit to be filed by all joint owners serving as the plaintiff.¹⁴⁹

In contrast, in an action for the revocation of a trial decision in a trial for invalidation in which a jointly owned patent right was invalidated, one of the joint owners may file an action for revocation of the trial decision. It is understood that this action is intended to achieve the

¹⁴² Patent Act, art. 178.

¹⁴³ See Section 7.3 for further information on the IP High Court and the Supreme Court.

¹⁴⁴ In this section, "trial or appeal decision" is used to refer collectively to the following decisions: an *ex parte* appeal decision to refuse to grant a patent; a decision to revoke a patent in an *ex parte* opposition; a trial decision in an *inter partes* trial for invalidation; and an *ex parte* decision to refuse to grant a correction.

¹⁴⁵ Patent Act, art. 178(2).

¹⁴⁶ Patent Act, art. 179.

¹⁴⁷ Patent Act, art. 178(3).

¹⁴⁸ Patent Act, art. 178(5).

¹⁴⁹ Saikō Saibansho (Sup. Ct) March 7, 1995, Heisei 6 (gyō tsu) no. 83, 49(3) Saikō Saibansho minji hanreishū (Minshū) 944 (*Commissioner of the Japan Patent Office v. Nihon Kenkō Zōshin Kenkyū-kai Co., Ltd.*).

protection of a right as “an act of preservation” in light of each joint owner’s right to an already-established right.¹⁵⁰ This is despite the view that the rights of joint owners should be determined “as a unified matter” before the establishment of a patent right.¹⁵¹

7.4.3 Procedure

The IP High Court makes available on its website *Guidelines for the Proceedings of Suits Against Appeal/Trial Decision Made by the JPO* in which it requests parties to make the following preparations:¹⁵²

1. Designation of the first date for preparatory proceedings
The Intellectual Property High Court [...] shall designate the first date for preparatory proceedings prior to the first date for oral argument. The Court will send a written inquiry to both parties prior to the designation. Please respond to the inquiry by indicating your opinions for referring your case to preparatory proceedings and candidate dates for the proceedings.
2. Preparations by the parties before the first date for preparatory proceedings
 - (1) Submission of the first brief and evidence by the Plaintiff
 - A. Submission of basic documentary evidence
The Plaintiff should submit basic documentary evidence within about two weeks from the filing of the complaint (the specific date is indicated in the above-mentioned inquiry) along with the description of evidence. Regarding the manner of offering documentary evidence and the type of basic documentary evidence, please refer to “Submission of Documentary Evidence/Evidence in Electromagnetic Data” in the *Guidelines and Formats for Proceedings of Suits against Appeal/Trial Decision made by the JPO*.
 - B. Submission of the first brief and evidence other than basic documentary evidence
 - a. The Plaintiff should submit the first brief no later than ten days before the first date for preparatory proceedings except in cases when the Court designates a specific submission date.
In this first brief, the plaintiff should state concrete statements of admission and/or denial in the appeal/trial decision and state the grounds for rescission of the decision. All grounds for rescission should be stated in this first brief.
 - b. All evidence other than basic documentary evidence should be submitted by this point in time. The description of evidence should also be submitted at the same time.
 - (2) Submission of a written answer by the Defendant
When the Defendant receives a complaint, the Defendant should promptly submit a written answer that includes statements of the answers to the objects of the claim described in the complaint, and admission and/or denial of each of the fact described in the statements of the claims.
3. The first date for preparatory proceedings
On the first date for preparatory proceedings, points at issue shall be clarified, and the schedule for the proceeding shall be coordinated considering the deadlines of the Defendant’s brief for rebuttal and the Plaintiff’s brief for re-rebuttal, as well as whether to schedule an explanatory session.
4. Preparations by the parties before the second date for preparatory proceedings
 - (1) Submission of a brief and evidence by the Defendant
 - A. The Defendant should submit a brief describing rebuttal to the Plaintiff’s allegation of the grounds for rescission by the deadline set by the Court on the first date for preparatory proceedings (approximately within one month from the first date for preparatory proceedings). All the Defendant’s arguments should be stated in this brief.

¹⁵⁰ Saikō Saibansho (Sup. Ct) Feb. 22, 2002, Heisei 13 (gyō hi) no. 142, 56(2) Minshū 348 (*Komaryo Co., Ltd v. Pierre Andre Senizergues*).

¹⁵¹ Makiko Takabe, *Jitsumushyōsetsu Tokkyōkankeisoshyō (Practical and Detailed Explanation on Patent-Related Litigation)* 340 (3rd ed. 2016) [hereinafter Takabe, *Practical and Detailed Explanation on Patent-Related Litigation*].

¹⁵² IP High Court, *Guidelines for Proceedings of Suits against Appeal/Trial Decision Made by the JPO*, www.ip.courts.go.jp/eng/vc-files/eng/file/GuidelinesForProceedings.pdf

- B. All necessary evidence should be submitted at this point in time. The description of evidence should also be submitted at the same time.
- (2) Submission of the second brief by the Plaintiff
 - A. Upon receipt of the Defendant's brief referred to above, the Plaintiff should submit the second brief if there is any re-rebuttal or matter to supplement the argument by the deadline set by the Court on the first date for preparatory proceedings (approximately within one month from the date specified in (1) A. above).
 - B. Any additional or supplemental evidence in connection with the above should be submitted with the description of evidence.
- 5. The second date for preparatory proceedings

The second date for preparatory proceedings, which was designated on the first date for preparatory proceedings, is about one to two weeks from the deadline of submission of the second brief by the Plaintiff as stipulated in 4 (2) above.

 - (1) Clarification of the points at issue and submission of evidence shall be substantially completed on this date. However, the Court may designate the third date for preparatory proceedings (and more) to continue allegations and submission of evidence as necessary.
 - (2) Upon substantial completion of the clarification of points at issue and submission of evidence, the Court shall conclude preparatory proceedings and give a notice of the scheduled date for oral argument, in which the outcome of preparatory proceedings shall be stated. (See 7. *infra*)
 - (3) Explanatory session may be conducted on the second or third date for preparatory proceedings, or on the first date for oral argument. (See 6. *infra*)
- 6. Explanatory session
 - (1) Explanatory session may be conducted on the second or third date for preparatory proceedings, or on the first date for oral argument. Technical advisors attend the session in general.
 - (2) Please prepare the following materials for explanatory session:
 - A. Copies of the submitted briefs and documentary evidence for the technical advisors when involved; and
 - B. Materials to be used in the explanatory session (submit them as documentary evidence).
- 7. Oral argument

Oral argument will be conducted in the courtroom on the designated date. In oral argument, the outcome of preparatory proceedings shall be stated. The Court may request both parties to present five-minute explanation of the points in dispute. Thereafter, the argument shall be concluded and the date for rendition of judgment shall be designated.
- 8. Rendition of judgment
 - (1) Judgment shall be rendered on the designated date in the courtroom. The parties are not required to appear in the courtroom on the date for rendition of judgment.
 - (2) The parties may receive the service of an authenticated copy of the judgment document after its rendition at the office of the court clerk who administers the case. Service by postal mail is also available.

7.4.4 Subject of examination and grounds for overturning a trial or appeal decision

A party who is dissatisfied with the decision may claim that the trial or appeal decision made by the TAD of the JPO – as an administrative agency – is incorrect because of either procedural or substantive law defects (or both) and demand the decision's revocation. Each of these defects must have had, by itself or together with other defects, an effect on the conclusion of the trial or appeal decision.

Appeals against JPO decisions are administrative lawsuits. In principle, parties to administrative lawsuits can claim and prove any new fact regarding the administrative decision. However, raising new facts or evidence must be limited in proceedings against the JPO so that the parties may receive the benefit of an effective trial by the JPO as a specialized administrative agency before any administrative litigation.

In the *Knitting Machine Case*,¹⁵³ the Supreme Court ruled that, in suits against JPO decisions, parties could not raise new facts that had not been raised in the trial before the JPO, even if they related to the novelty of the invention or if the same provision of the Patent Act was cited in the earlier proceedings. In other words, in court proceedings challenging a JPO decision, no documents for establishing a new factual basis for the invalidity grounds may be introduced, even for grounds for invalidation under the same provision of the Patent Act.

For example, under the *Knitting Machine* rule, if a plaintiff claims lack of novelty citing prior art references A, B and C, and the JPO revokes the patent based on the prior art reference A without referring to the prior art references B and C, the IP High Court can only consider prior art reference A when determining the grounds for lack of novelty.

The court will examine issues – such as novelty and inventive step – considered in trials and appeals by the TAD of the JPO. Parties should be given the opportunity to have their case heard both before the JPO and the IP High Court, particularly given that:

- these cases usually involve highly technical matters; and
- the JPO and the court have different expertise and are expected to examine the issues individually.

The JPO is likely to be more experienced than the IP High Court on highly technical matters, although the IP High Court does have judicial research officials with specialized knowledge who support judges in patent cases.¹⁵⁴ The judges of the IP High Court review and decide the validity of the JPO's decision based on their experience and with the assistance of judicial research officials on the technical aspects of the case.

From this perspective, the 1976 decision of the Supreme Court in the *Knitting Machine Case* remains applicable today. Furthermore, according to the Supreme Court in the *Structure of Food Packaging Containers Case*, parties can add new evidence to reinforce their argument based on prior art reference A in an appeal against a JPO decision.¹⁵⁵ If the court finds that the JPO decision regarding prior art reference A is incorrect and must be set aside, the case will be remitted for a new trial before the JPO, and the JPO may then examine prior art references B and C.

7.4.5 Procedural defects and substantive law defects

If a trial or appeal decision is revoked by the IP High Court, the JPO will commence further trial proceedings to issue a new trial or appeal decision.¹⁵⁶

7.4.5.1 Procedural defects

Procedural defects that have been found to affect the conclusion of a trial or appeal decision include, for example:

- serving a copy of a request for a trial to an old (and no longer current) address of the demandee;¹⁵⁷
- a change of proceedings – which should have been oral proceedings – to documentary proceedings, which was unfair and beyond the reasonable discretion of the panel of administrative patent judges;¹⁵⁸ and
- rejecting an amendment without providing an opportunity for the submission of further amendments and opinions on the basis of a notice of reasons for refusal that included new well-known art corresponding to a secondary reference that was not provided in the initial notice of reasons for refusal.¹⁵⁹

153 Saikō Saibansho (Sup. Ct) March 10, 1976, Shōwa 42 (gyō tsu) no. 28, 30(2) Minshū 79 (*Speed Amiki Co., Ltd v. Bunji Okumura*) (*Knitting Machine Case*).

154 See Section 7.3 for further information on judicial research officials.

155 Saikō Saibansho (Sup. Ct) Jan. 24, 1980, Shōwa 54 (gyō tsu) no. 2, 34(1) Minshū 80 (*Kyōdō Giken Co., Ltd v. Nihon Kōkan Co., Ltd*) (*Structure of Food Packaging Containers Case*).

156 Patent Act, art. 181(2).

157 Chiteki Zaisan Kōtō Saibansho (Intellectual Prop. High Ct) Sep. 30, 2010, Heisei 22 (gyō ke) no. 10078, Chizai kōsai web (*Irs Australia Pty Ltd v. Ozdare Academy Pty Ltd*).

158 Chiteki Zaisan Kōtō Saibansho (Intellectual Prop. High Ct) June 29, 2009, Heisei 20 (gyō ke) 10427, 101 Hanrei jihō (Hanji) 2104 (*Tokyo Electron Ltd v. Y.*).

159 Chiteki Zaisan Kōtō Saibansho (Intellectual Prop. High Ct) Oct. 4, 2011, Heisei 22 (gyō ke) 10298, 77 Hanji 2139 (*Haier Group Corporation v. Commissioner of the Japan Patent Office*).

7.4.5.2 Substantive law defect

A substantive law defect is deemed to be a ground for revocation because a trial or appeal decision is not correct. A summary of the main grounds for revocation due to a substantive defect is provided in this section.

7.4.5.2.1 Eligibility of invention

The subject to which a patent right is granted is an “invention.” The Patent Act defines an “invention” as a “highly advanced creation of technical ideas utilizing the laws of nature.”¹⁶⁰ To be regarded as an invention, a creation must utilize laws of nature excluding, for example, mere mental activities, purely academic laws or artificial arrangements. Even if an act resulting from a human mental activity is an invention, the eligibility of this “invention” for patent rights is based on the essence of it being directed to providing a technical means for supporting or replacing a human mental activity.¹⁶¹

7.4.5.2.2 Novelty and inventive step

The presence or absence of an inventive step is often used as a ground for the revocation of a trial or appeal decision.¹⁶²

Identification of the presence or absence of inventive step is determined by the JPO in a trial or appeal decision, usually in the following order:

1. identification of the gist of the invention (present invention);
2. identification of the primary cited invention;
3. comparison of the present invention and the primary cited invention;
4. identification of correspondence and difference; and
5. determination of whether the present invention could be easily conceived.

Accordingly, the ground for revocation argued by a plaintiff is usually that some or all of the above five steps have been incorrectly determined by the TAD. If the first four steps have been incorrectly determined, but no error is found in the ultimate decision (Step 5), this will not serve as an effective ground for revocation of a trial or appeal decision.

Step 1 – identification of the gist of the invention. The gist of the invention of a patent is to be understood from the statement in the scope of claims.¹⁶³ In the *Lipase Case*, the Supreme Court clarified that the gist of the invention – serving as the basis for the examination of the existence of novelty and inventive step – should be determined based on the statement in the scope of claims unless:

- there are “special circumstances” whereby it is not possible to unambiguously and clearly understand the technical meaning of the statement in the scope of claims;
- the statement has an obvious error in light of the statement in the detailed description of the invention in the specification; or
- for certain other reasons.¹⁶⁴

However, when identifying the gist of the invention, it is acceptable to read through the statement in the detailed description of the invention and the drawings to clarify technical details relating to the invention. The *Lipase Case* presents a theory that elements described only in the detailed description of the invention and the drawings should not be added beyond the statement in the scope of claims.¹⁶⁵ That is, the elements described only in the detailed description of the invention and the drawings should not be considered if they extend beyond the scope of claims outlined in the statement.

Step 2 – identification of the primary cited invention. The primary cited invention is an invention that:

¹⁶⁰ Patent Act, art. 2(1).

¹⁶¹ Chiteki Zaisan Kōtō Saibansho (Intellectual Prop. High Ct) June 24, 2008, Heisei 19 (gyō ke) 10369, 123 Hanji 2026 (*Shade Analyzing Technologies, Inc. v. Commissioner of the Japan Patent Office*).

¹⁶² Patent Act, art. 29(2).

¹⁶³ Patent Act, art. 36(5).

¹⁶⁴ Saikō Saibansho (Sup. Ct) March 8, 1991, Shōwa 62 (gyō tsu) no. 3, 45(3) Minshū 123 (*Commissioner of the Japan Patent Office v. Boehringer Mannheim GmbH*) (*Lipase Case*).

¹⁶⁵ Shuhei Shiotsuki, *Saikosaibansho hanreikaisetsu minjihei 3 nendo* (Explanation of the Supreme Court Precedents, Civil Procedure Part for 1991) 39 (1994).

- is common knowledge within Japan or in a foreign country prior to the filing of the patent application;
- has been publicly worked; or
- is described in a distributed publication or made available online for public use.¹⁶⁶

Step 3 – comparison of the present invention and the primary cited invention. For identification of correspondence and difference, the most suitable reference is typically selected as a principal reference to compare with the present invention.

Step 4 – identification of correspondence and difference. The IP High Court will compare the present invention with the primary cited invention to investigate:

- whether there is any error in correspondence or difference as identified in a trial or appeal decision; and
- whether any further correspondences or differences that were not identified in the trial or appeal decision exist.

Step 5 – determination of whether the present invention could be easily conceived. It is often disputed whether a difference identified by comparing the present invention and the primary cited invention would have been easily conceived by persons having ordinary skill in the art at the time of the filing of the application.

The court usually investigates whether the differences identified in Step 3 would have been easily conceivable by those having ordinary skill in the art by combining one or more references (a secondary reference) or well-known technology with the primary cited invention.

The existence of circumstances that may have prevented a person having ordinary skill in the art from easily conceiving the present invention and the advantageous effects of the present invention also affect a decision concerning the requirement of an inventive step.

7.4.5.2.3 Description requirement

Article 36 of the Patent Act stipulates matters that must be included in a patent application. The patent system grants an exclusive right for a certain period to a patented invention in exchange for publication of the invention. Therefore, a defect in the disclosure at the time of the filing of a patent application will prevent the grant of an exclusive right.

7.4.5.2.4 Support requirement

The statement in the scope of claims must comply with the requirement that the invention for which the patent is sought is stated in the detailed description of the invention under Article 36(6)(i) of the Patent Act. This is called the “support requirement.” The support requirement is necessary because

the specification to be attached to the application by a person who seeks a patent granted for an invention primarily has the role of disclosing technical details of the invention to the public and clarifying the scope of effect of the invention after establishment of a patent right (technical scope of patented invention) and therefore, in order to obtain a patent based on the description of the invention in the scope of claims, the statement in the detailed description of the invention in the specification must enable those having ordinary skill in the art to solve the problem of the invention.¹⁶⁷

The support requirement should be determined

by comparing the statement in the scope of claims and the statement in the detailed description of the invention, and investigating whether the invention described in the scope of claims corresponds to the invention described in the detailed description of

¹⁶⁶ Patent Act, art. 29(1)(i)–(iii).

¹⁶⁷ Chiteki Zaisan Kōtō Saibansho (Intellectual Prop. High Ct) Nov. 11, 2005, Heisei 17 (gyō ke) no. 10042, 164 Hanrei taimusu (Hanta) 1192 (*The Nippon Synthetic Chemical Industry Co., Ltd v. Commissioner of the Japan Patent Office*) (Parameter Patent Case). An unofficial English translation of this judgment is available via the IP High Court website at www.ip.courts.go.jp/app/files/hanrei_en/309/000309.pdf

the invention, and falls within the scope that can be recognized as enabling those having ordinary skill in the art to solve the problem of the invention based on the statement in the detailed description of the invention or not, and whether the invention described in the scope of the claims falls within the scope that is recognized as enabling those having ordinary skill in the art to solve the problem of the invention in light of the common technical knowledge at the time of filing of the application.¹⁶⁸

7.4.5.2.5 Enablement requirement

The Patent Act provides that the statement in the detailed description of the invention must be clear and sufficient in order to enable those having ordinary skill in the art of the invention to work the invention.¹⁶⁹

To determine whether the enablement requirement is satisfied, not only the statement in the specification and the drawings but also common technical knowledge at the time of the filing of the application can be taken into consideration.¹⁷⁰

7.4.5.2.6 Clarity requirement

The invention for which a patent is sought must be clear from the statement in the scope of claims.¹⁷¹ This is called the “clarity requirement.”

In the *Pravastatin Sodium Case*, the Supreme Court ruled that a product-by-process claim can meet the clarity requirement in exceptional circumstances, such as when it is impossible to specify the product directly from its structure or features at the time of the filing of the application and where excessive expenditure or time is required to identify the product’s structure or features.¹⁷²

7.4.5.2.7 Correction requirement

A patentee may file a request for a *trial* for correction to correct the specifications, the scope of the claims or the drawings of a patented invention for which a patent right was granted.¹⁷³ However, to prevent any delay if a trial for invalidation is pending, a *request* for correction is allowed within certain periods in relation to:

- restricting the scope of claims;
- correcting errors or mistranslations;
- clarifying ambiguous statements;¹⁷⁴ and
- rewriting a claim that cites another claim into a claim that does not cite that other claim.¹⁷⁵

Furthermore, due to the so-called prohibition of the addition of new matters, the correction must remain within the scope of matters described in the specification, scope of claims or drawings of the patent.¹⁷⁶ Whether a correction involves the addition of new matters is determined from the perspective of a person having ordinary skill in the art in relation to technical matters derived from the comprehensive interpretation of the specification and drawings. Prohibiting the addition of new matters is intended to prevent unexpected loss by third parties and to ensure that the interests of the patentee and third parties are balanced.¹⁷⁷

A party who is dissatisfied with a decision of correction in a trial decision – that is, an appellant or a patentee whose correction was not granted – may contest the matter in an action for revocation of a trial decision before the court.

168 *Parameter Patent Case*.

169 Patent Act, art. 36(4)(i).

170 Chiteki Zaisan Kōtō Saibansho (Intellectual Prop. High Ct) April 14, 2011, Heisei 22 (gyō ke) no. 10247, Chizai kōsai web (*Applied Nanotech Holdings Inc. v. Commissioner of the Japan Patent Office*).

171 Patent Act, art. 36(6)(i).

172 Saikō Saibansho (Sup. Ct) June 5, 2015, Heisei 24 (ju) no. 1204, 69(4) Minshū 700 (*TEVA Gyogyszergyar Zartkoruen Mukodo Reszvenytársaság v. Kyowa Hakko Kirin Co., Ltd*) (*Pravastatin Sodium Case*) (final appellate instance).

173 Patent Act, art. 126. See Section 7.2 for further information on the trial for correction.

174 Patent Act, art. 134-2(1).

175 Patent Act, art. 126(1)(iv).

176 Patent Act, arts 126(5), 134-2(9).

177 Chiteki Zaisan Kōtō Saibansho (Intellectual Prop. High Ct) May 30, 2008, Heisei 18 (gyō ke) no. 10563, 224 Hanta 1290 (*Tamura Chemical Corporation v. Taiyo Ink Mfg. Co., Ltd*) (*Solder Resist Case*).

When contesting whether a correction was appropriate in an action for the revocation of a trial decision, identification of the gist of the invention before and after the correction needs to be argued by considering the possibility of either the grant or rejection of the correction by the court. Additionally, when a defendant contests the determination of the appropriateness of a correction in the trial decision, the plaintiff must argue against this based on the gist of the invention before or after the correction (or both), taking into consideration the possibility of the court either granting or rejecting the correction.

7.4.6 Effect of judgment

A judgment in an action for the revocation of a trial or appeal decision has the effect of *res judicata*.¹⁷⁸ This means the court is not allowed to change its final judgment rendered in the action in a possible separate future action. Furthermore, the parties are also prohibited from contesting the judgment in any subsequent action.¹⁷⁹

Where the court finds for the plaintiff in an action for the revocation of a trial or appeal decision, it must revoke the decision.¹⁸⁰ When the court's decision has become final and binding, the trial or appeal decision is revoked. The final and binding judgment to revoke a trial or appeal decision has an effect on third parties, and the administrative patent judges of the JPO must carry out further proceedings and issue a new trial or appeal decision.¹⁸¹

Under Article 33(1) of the Administrative Case Litigation Act, a judgment of revocation is binding on the administrative agency that made the original administrative disposition or administrative disposition on appeal and any other relevant administrative agency with regard to the case. Accordingly, a decision of revocation is binding on the JPO decision, including any findings of fact and legal interpretation or analysis.¹⁸² Administrative patent judges of the JPO who carry out further proceedings and issue a new trial or appeal decision are prohibited from making a determination in conflict with the determination in the judgment of revocation.

7.5 Patent infringement: claim construction, doctrine of equivalents and defenses

This section outlines some key concepts that are relevant to the enforcement of patent rights in a civil lawsuit for an alleged infringement of a patent right. The following concepts are addressed: claim construction, including which materials may be used to interpret a claim, product-by-process claims and functional claims; the doctrine of equivalents; the defense of invalidity; and correction as a defense against patent invalidity.

7.5.1 Claim construction

The principles of claim construction derive from the purpose of the patent system.¹⁸³ The Supreme Court has stated that

[t]he purpose of the patent system shall be to encourage inventions and thereby to contribute to the development of the industry by granting exclusive rights (patents) to applicants who disclose their inventions. On the one hand, the patent system can protect inventions which patentees have developed. On the other hand, it facilitates the utilization of inventions by third parties through their disclosure (Patent Act, Article 1).¹⁸⁴

¹⁷⁸ Code of Civil Procedure, art. 114.

¹⁷⁹ Code of Civil Procedure, art. 115(1).

¹⁸⁰ Patent Act, art. 181(1).

¹⁸¹ Gyōsei jiken soshōhō (Administrative Case Litigation Act), Act No. 139 of May 16, 1962, arts 32(1), 33(1); Patent Act, art. 181(2).

¹⁸² Saikō Saibansho (Sup. Ct) April 28, 1992, Shōwa 63 (gyō tsu) no. 10, 46(4) Minshū 245 (*Tipton Corp. v. Toho Koki Co. Ltd.*).

¹⁸³ See Section 7.4 for information on claim construction in the context of the JPO opposition to the grant of a patent process.

¹⁸⁴ Saikō Saibansho (Sup. Ct) March 24, 2017, Hei 28 (ju) no. 1242, 71(3) Minshū 359 (*DKSH Japan Co., Ltd v. Chugai Pharmaceuticals Co., Ltd*), at 363. An unofficial English translation of this judgment is available via the *Courts in Japan* website at www.courts.go.jp/app/hanrei_en/detail?id=1516

In this way, the patent system grants an exclusive right in exchange for the applicant's disclosure of a patent to the public.¹⁸⁵

In patent infringement lawsuits, it is important to determine the scope of this exclusive right while balancing the protection of the patented invention and the interest of third parties to freely operate outside the scope of the patented invention.

7.5.1.1 Claim wording

Taking the purpose of the patent system into consideration, Article 70(1) of the Patent Act provides that “[t]he technical scope of a patented invention shall be determined on the basis of the statements of the patent claims attached to the application.” There is a similar principle in both U.S. and European patent law.¹⁸⁶

According to this principle, all the elements and limitations stated in the claims must be present in the defendant's product to establish infringement. It is only when this principle is satisfied that a defendant's product will fall within the technical scope of a patented invention. Therefore, these claims have a special status compared to other sources for interpretation. It is not possible to use elements that are not mentioned in the claims – such as from the specification and other sources – to interpret a claim more narrowly than was originally intended.¹⁸⁷ In other words, patent law provides that claims are to be interpreted according to the wording of the claims and that the wording is both the starting point and the goal.

Article 36(5) of the Patent Act provides that the applicant must state in the claims all the matters necessary for specifying the invention for which a patent right is sought. Such claims have the function of providing a third party with the most important tools to understand the content of the patented invention.

7.5.1.2 Interpreting the claims

When interpreting the wording of the claims, the standard applied is usually the natural meaning from the point of view of a person having ordinary skill in the art. The technical scope of the patented invention must be established based on the claim terms without any broadening or narrowing of their meaning.

Article 24 of the Patent Law Enforcement Regulation provides that the technical terms in the specification should be academic terms that are used in their usual sense and uniformly throughout the specification. Furthermore, the terms must be defined if they are used to indicate a specific meaning.¹⁸⁸ However, claim terms are abstract when compared to, for example, the certainty provided by a boundary line in real property. They are not defined as a particular tangible object and can be esoteric. Therefore, other materials are usually required for claim construction.

7.5.1.3 Sources for claim construction

According to Article 70(2) of the Patent Act, “the meaning of the claim terms shall be interpreted in light of specifications and the drawings.” Therefore, the detailed description of the invention in the specification and the drawings is prescribed by statute as a source for interpreting patent claims.

The prosecution file history of the patent, publicly known art, as well as common knowledge of the art can also be relevant sources for claim interpretation. Even though those sources are not provided for in statute, they are legitimate sources similar to specifications and drawings.¹⁸⁹

The key rationale for allowing non-statutory sources such as publicly known art to be used to interpret claims is disclosure to third parties: specifications and drawings are disclosed to a third party in the one document with the claims. Additionally, according to Article 186 of the Patent Act,

185 Takabe, *Practical and Detailed Explanation on Patent-Related Litigation* at 163.

186 Convention on the Grant of European Patents (European Patent Convention), Oct. 5, 1973, 1065 UNTS 255, art. 69 (as revised by the Act revising Article 63, Dec. 17, 1991, and the Act revising the European Patent Convention, Nov. 29, 2000).

187 *Lipase Case*, Shōwa 62 (gyō tsu) no. 3.

188 Tokkyohō sekōhō (Japanese Patent Law Enforcement Regulation), Ordinance of the Ministry of International Trade and Industry No. 10 of March 8, 1959.

189 Tōkyō Chihō Saibansho (Tokyo Dist. Ct) March 3, 2015, Hesei 16 (wa) no.10402, Saikō Saibansho web (Saibansho web); Osaka Chihō Saibansho (Osaka Dist. Ct) Sep. 12, 2006, Heisei 16 (wa), Hanta, 942, 238.

the prosecution file history can be viewed by any third party. Further, publicly known art and common knowledge of the art is technical information that is naturally possessed by a person having ordinary skill in the art.

7.5.1.4 How to use sources

One issue in patent litigation is how all this information should be taken into consideration to properly construe the claim terms. As is the case for specifications and drawings, it is not possible to introduce elements that are not mentioned in the claims and thus to interpret the claim terms more narrowly than originally intended. However, in patent infringement lawsuits, the file history, publicly known art or common knowledge of the art can sometimes be a deciding factor when the claim construction is disputed. Establishing publicly known art and common knowledge in the art are also very important. These matters are supposed to be already possessed by persons having ordinary skill in the art, who are readers of the claims and specifications.

7.5.1.5 Product-by-process claims

Product-by-process claims can be defined as claims for inventions of products that recite the manufacturing processes of the products. The Supreme Court has stated, in a case involving this type of claim, that "[e]ven in such a case, the technical scope of the patented invention is determined as a product having the same structures and properties, which is manufactured by the described processes."¹⁹⁰ In the same case, the Supreme Court ruled that the patents were invalid because they were contrary to the principle of claim clarity under Article 36(6)(ii) of the Patent Act and stated that such claims will conform to the principle of claim clarity only when there are circumstances where it is impossible or almost impractical to request the applicant to directly identify the product by its structure or properties. For instance, when it is technically impossible for the applicant to directly identify the object by its structure or properties, or it takes excessive economic expenditure or time to perform the identification work.¹⁹¹

Conversely, if these requirements are met, the specifications will disclose the invention of a product and not a process. In that case, it is an insufficient defense to argue that the product has been manufactured by a different process. However, in the absence of impossible or impractical circumstances, as outlined by Supreme Court above, a product-by-process claim is invalid because it runs counter to the principle of claim clarity.

Therefore, with regard to the claim wording of a manufacturing process, it cannot be assumed that all claims that contain any steps as part of a process fall within product-by-process claims. This is to be determined from a substantive and practical point of view in order not to invalidate patented inventions that have not yet been identified as product-by-process claims. In this context, it has been pointed out that, in practice, it is important to appropriately limit the scope of the application of the Supreme Court decision.¹⁹²

When the claims are determined not to be a product-by-process claim – even though they contain a manufacturing process – those processes must constitute elements or limitations in the claims so that, in accordance with the basic principle of claim interpretation, a product manufactured with a different process is not covered by the technical scope of the patented invention.

7.5.1.6 Functional claims

Functional claims are defined as claims that "are described by not concrete structures but absolute functions of the structures."¹⁹³ An example would be when the function of glue, rather than its chemical structure, is described in the claims, using words such as "adhesive means." As stated above, Article 36(5) of the Patent Act provides that an applicant must state in the claims all the matters necessary for specifying the invention for which a patent right is sought. Functional claims comply with this requirement and are well established in practice.

The technical scope of functional claims must be determined based on the technical idea embodied in the specific structures disclosed in the specification. This does not mean that the

¹⁹⁰ *Pravastatin Sodium Case*, Heisei 24 (ju) no. 1204, 69(4) Minshū 700 at 704-705. An unofficial English translation of this judgment is available via the *IP High Court* website at www.ip.courts.go.jp/app/files/hanrei_en/918/001918.pdf

¹⁹¹ *Pravastatin Sodium Case*, at 704-705.

¹⁹² Ryuichi Shitara, "PBP Saikōsaibansho no hanketsu to jissai-tekina mondaï" ("PBP Supreme Court Decision and Practical Issues"), 73 *Law and Technology* 36, 45 (Oct. 2016).

¹⁹³ Takabe, *Practical and Detailed Explanation on Patent-Related Litigation*, at 192.

scope of the claims is limited to the embodiments. A structure that is not described in the embodiments but that a person having ordinary skill in the art can determine from the structure disclosed in the specification or from the detailed description of the invention is to be included in the technical scope of the invention.

It can be difficult to understand to what extent identifying particular features of embodiments is allowed. Establishing publicly known art and common knowledge in the art can help deal with this issue. These are matters that are supposed to be possessed by persons having ordinary skill in the art, who are readers of the claims and the specifications, and whose understanding is deemed to show the technical scope of the patented invention.

7.5.2 Doctrine of equivalents

There are no Japanese statutes that refer to finding patent infringement under the doctrine of equivalents. However, case law has introduced the concept of equivalence into Japanese patent law.

7.5.2.1 Five requirements of the *Ball Spline Bearing Case*

In the *Ball Spline Bearing Case*,¹⁹⁴ the Supreme Court stated that a patent can be found to have been infringed not only by a product or process that falls within the literal scope of a patent claim but also under the doctrine of equivalents. The Supreme Court set out five requirements for finding patent infringement under the doctrine of equivalents:

1. The claim elements that are lacking in an allegedly infringing product or process are not essential parts of the patented invention.
2. The purpose of the patented invention can be achieved, and the same function and effect can be obtained, if the lacking claim elements are replaced with corresponding parts in the allegedly infringing product or process.
3. It would have been easy for a person having ordinary skill in the art to conceive of the idea of replacing the lacking claim elements with the corresponding parts in the allegedly infringing product or process at the time of the act of infringement.
4. The allegedly infringing product or process was neither identical to nor easily conceived from prior art at the time the application for the patent was filed.
5. No special circumstances preclude the doctrine of equivalents, such as where the allegedly infringing product or process was intentionally excluded from the scope of the claim during patent prosecution before the JPO.

The Supreme Court explained the grounds for finding patent infringement under the doctrine of equivalents in relation to these five requirements as follows:

It is extremely difficult to foresee all the types of infringements which may occur in the future and to formulate the scope of the patent claim in the specifications, and it will greatly reduce the incentive for invention in society in general if persons are able to easily avoid becoming subject to grants of injunctive relief and other exercises of rights by the patent holder by merely replacing part of the claim elements with the substance or technology which came to be known after the patent application. This would not only be contrary to the purposes of Patent Act – to the promotion of the development of industry through the protection and encouragement of invention – but would also be contrary to the principle of social justice and the idea of fairness.

Taking this into account, the substantive value of the patented invention extends to the technology which a third party can easily conceive as substantially equivalent to the construction as indicated in the scope of the patent claim in the specification, and third parties should be expected to foresee this.

On the other hand, technologies which were already in the public domain, or which a person having an average knowledge in the area of the technology used in this invention could easily have conceived at the time of the patent application, since no one could in any case have obtained a patent therefor (Patent Act, Article 29), cannot be found to fall within the technical scope of the patented invention.

¹⁹⁴ Saikō Saibansho (Sup. Ct) Feb. 24, 1998, Hei 6 (o) no. 1083, 52(1) Minshū 114 (*Tsubakimoto Seiko Co., Ltd v. THK Co., Ltd*) (*Ball Spline Bearing Case*). An unofficial English translation of this judgment is available via the Courts in Japan website at www.courts.go.jp/app/hanrei_en/detail?id=374

Furthermore, if a patent holder has acknowledged that technology is not within the technical scope of the patent claim, or their behaviour has indicated this to be the case, for example, by intentionally excluding the technology from the scope of the patent claim during patent prosecution, the patent holder is not entitled to claim otherwise afterwards, since this is against the doctrine of estoppel.

7.5.2.2 Burden of proof

According to decisions of the lower courts that have followed the *Ball Spline Bearing Case* and the Grand Panel of the IP High Court in the *Maxacalcitol Case* (see below):

- A patentee bears the burden of proof regarding Requirements 1–3 as prescribed in the *Ball Spline Bearing Case* to establish patent infringement under the doctrine of equivalents.
- An alleged infringer bears the burden of proof in relation to Requirements 4–5 for denying patent infringement under the doctrine of equivalents.¹⁹⁵

7.5.2.3 Requirement 1: nonessential part

The criteria used to determine whether claim elements are essential have been the subject of case law. In the *Maxacalcitol Case*, the Grand Panel of the IP High Court opined as follows:

The substantial value of an invention which the Patent Act intends to protect exists in the disclosure to society of a means with a specific structure for solving a technical problem that could not have been solved by prior art, which is based on a unique technical idea that is not seen in prior art. Therefore, the essential part of a patented invention should be understood as the characteristic part which constitutes a unique technical idea that is not seen in prior art in the statements in the scope of claims of the patented invention. The aforementioned essential part should be found by first understanding the problem to be solved and the means for solving the problem of the patented invention [...] and its effects [...] based on the statements in the scope of claims and the specification and then determining the characteristic part that constitutes a unique technical idea that is not seen in prior art in the statements in the scope of claims of the patented invention.

The above opinion aligns with the majority of lower court decisions that have followed the *Ball Spline Bearing Case*.¹⁹⁶ However, this formula was not enough to resolve the issue in the *Maxacalcitol Case*, where the enforced patent claim required that the starting material and intermediate for producing maxacalcitol were cis-form vitamin D structures, while those used in the allegedly infringing process had trans-form vitamin D structures that were geometric isomers. That is, even after finding that the claim element was a part of the patented invention, there remained the question as to whether the cis-form was essential or not. As to this question, the Grand Panel of the IP High Court found that the cis-form was not essential, on the following grounds:

That is, taking into account that the substantial value of a patented invention is defined depending on the degree of contribution in comparison with prior art in the relevant technical field, the essential part of a patented invention should be found, based on the statements in the scope of the claim and the specification and, in particular, through comparison with prior art stated in the specification, to be in accordance with the following principle: (i) If the degree of contribution of the patented invention is considered to be large in comparison to the prior art, an essential part of the patented invention is found to be a superior concept in relation to part of the statements in the scope of claims.[...] (ii) If the degree of the contribution of the patented invention is evaluated as not much more than prior art, an essential part of the patented invention is found to be the same as literally stated in the scope of claims.

However, if the statement of the problem in the specification, which is described as one that prior art could not solve, is objectively insufficient in light of prior art as of the filing date [...] prior art that is not stated in the specification should also be taken into

¹⁹⁵ Chiteki Zaisan Kōtō Saibansho (Intellectual Prop. High Ct) March 25, 2016, Hei 27 (ne) no. 10014, 1430 Hanta 152 (*DKSH Japan Co., Ltd v. Chugai Pharmaceuticals Co., Ltd*) (*Maxacalcitol Case*). An unofficial English translation of this judgment is available via the IP High Court website at www.ip.courts.go.jp/app/files/hanrei_en/003/002003.pdf

¹⁹⁶ E.g., Tōkyō Chihō Saibansho (Tokyo Dist. Ct) March 23, 2000, Hei 10 (wa) no. 11453, Saibansho web (*Shinwa Seisaku-jyō Co. Ltd v. Furuta Denki Co. Ltd*).

consideration for the purpose of finding a characteristic part which constitutes a unique technical idea of the patented invention that is not seen in prior art. In such cases, the essential part of the patented invention is found to be closer to the statements in the scope of claims compared to cases where it is found only based on the statements in the scope of claims and the specification, and the scope of application of the doctrine of equivalents is considered to be narrower.

In addition, in determining the fulfillment of the first requirement, that is, whether an element which is different from the allegedly infringing product, etc., is a non-essential part, it is not appropriate to first divide the claim elements stated in the scope of claims into essential parts and non-essential parts, and then consider that the doctrine of equivalents is not applicable to all of the claim elements that fall under essential parts, but it is necessary to first determine whether the allegedly infringing product, etc., commonly has the essential part of the patented invention as mentioned above, and then consider a difference not to be an essential part if the subject product, etc., is recognized as having said essential part. Even if the allegedly infringing product, etc., has a difference which is not the characteristic part that constitutes a unique technical idea that was not seen in prior art, this fact does not become a reason for denying the fulfillment of the first requirement.¹⁹⁷

7.5.2.4 Requirement 2: possibility of replacement

The second requirement of the doctrine of equivalents is often referred to as the “possibility of replacement.” It is not always clear how or whether the function and effect of the allegedly infringing product or process can be judged to be the “same” as those of the patented invention when only allegedly trivial or immaterial differences exist. The courts have not provided any clear guidance on this issue.¹⁹⁸

7.5.2.5 Requirement 3: ease of replacement

Regarding the third requirement, such judgment needs to be made in light of the level of technology at the time of the act of infringement. Therefore, for example, if an alleged infringer’s manufacturing and distribution of an allegedly infringing product continue despite pending court proceedings, a judgment should be made based on the level of technology at the time of the closing of the oral hearings.

7.5.2.6 Requirement 4: difficulty of conception

As stated above, an alleged infringer bears the burden of proof when arguing its defense under the fourth requirement. The alleged infringer’s argument under this requirement may overlap, to some extent, with a defense based on patent invalidity due to a lack of novelty or inventive step. Under this requirement, the alleged infringer needs to establish that the allegedly infringing product or process was neither identical to nor easily conceived from the prior art while also establishing patent invalidity, which requires that the patented invention was identical to or easily conceived from the prior art.

7.5.2.7 Requirement 5: no special circumstances

The fifth requirement is that there are no special circumstances that might preclude the application of the doctrine of equivalents. A typical “special circumstance” which the Supreme Court referred to in the *Ball Spline Bearing Case* is where the allegedly infringing product or process was intentionally excluded from the scope of the claim during patent prosecution before the JPO. This is similar to prosecution history estoppel, which can be raised by an alleged infringer as a defense against literal infringement.

In the *Maxacalcitol Case*, the alleged infringer argued that there was a special circumstance preventing patent infringement from being found based on the doctrine of equivalents. The applicant had not crafted the patent claim so that it included the process where the starting material and intermediate for producing maxacalcitol had trans-form vitamin D structures, even though ordinary persons having ordinary skill in the art could have easily conceived using such a material at the time of patent filing. The Supreme Court accepted the appeal of the alleged infringer on this issue but ultimately rejected the argument:

¹⁹⁷ *Maxacalcitol Case*, Hei 27 (ne) no. 10014.

¹⁹⁸ However, the decision regarding Requirement 2 in the *Maxacalcitol Case* by the Grand Panel of the IP High Court is an interesting approach to this issue and will be a reference for future court decisions.

- (1) [...] even in a situation where the scope of patent claims written by the patent applicant do not mention the structure for allegedly infringing products or processes different in part from the structure stated in the scope of claims while the applicant was able to easily conceive the structure for such allegedly infringing products or processes at the time of filing the application, the mere fact of such omission in the scope of the patent claims does not constitute a special circumstance such as where the allegedly infringing products or processes were intentionally excluded from the scope of patent claims in the course of filling the patent application.
- (2) [...] in cases where the applicant has failed to describe the structure of allegedly infringing products or processes that are different from corresponding elements of the structure stated in the patent claims, the existence of special circumstances, such as the intentional exclusion of allegedly infringing products or processes from the scope of patent claims in the course of filing an application for a patent, should be found if the applicant is objectively and visibly determined to have indicated their intention of omitting statements concerning allegedly infringing products or processes in the scope of the patent claims while recognizing that the structure for the allegedly infringing products or processes could substitute for the structure stated in the scope of the patent claims.

In light of the facts explained in the above, nothing contained in the application for the patent indicates objectively and visibly the applicant's intention of omitting to mention the structure for the applicant's process in the scope of claims while recognizing that the structure adopted by the applicant, which was different in part from the structure stated in the scope of claims, could substitute for said structure.¹⁹⁹

7.5.2.8 Other relevant cases

In an early equivalence case delivered shortly after the judgment in the *Ball Spline Bearing Case* and prior to the establishment of the IP High Court, the Osaka High Court found indirect infringement under Article 101 of the Patent Act with respect to a product that was used exclusively for the exploitation of the allegedly infringing process. The court decided that the process for which the product was exclusively used was equivalent to the process that fell within the literal scope of the patented claim.²⁰⁰ In another, more recent case, a patentee's right to seek compensation for the unauthorized use of a patented invention – after the publication of an unexamined application but prior to registration of the patent right under Article 65 of the Patent Act – was found to extend to the unauthorized use of products or processes equivalent to those falling within the literal scope of the patented claim.²⁰¹

7.5.3 Defense of invalidity

The defense of invalidity of a patent involves an alleged infringer asserting that a plaintiff's patent should be invalidated.²⁰² Alleged infringers assert the defense of invalidity in about 80 percent of patent infringement cases.²⁰³ An alleged infringer may also request a JPO trial for invalidation (see Section 7.4). These trials are often conducted in parallel with a court's determination of invalidity, and sometimes conflicting decisions are reached (see below).

Alleged infringers will sometimes adopt a strategy of not filing for a trial for invalidation because they think that a court is more likely to find invalidity than the JPO, particularly in cases in which matters of fact are contested, such as fraud, violation of the rules relating to joint applications, or publicly worked inventions. Like any other claim, the defense of invalidity of a patent will be

199 Saikō Saibansho (Sup. Ct) March 24, 2017, Hei 28 (ju) no. 1242, 71(3) Minshū 359 (*DKSH Japan Co., Ltd v. Chugai Pharmaceuticals Co., Ltd*) aff'g *Maxacalcitol Case*, Hei 27 (ne) no. 10014. An unofficial English translation of this judgment is available via the *Courts in Japan* website at www.courts.go.jp/app/hanrei_en/detail?id=1516

200 Osaka Kōtō Saibansho (Osaka High Ct) April 1, 2001, Hei 11 (ne) no. 2198, Saibansho web (*Nippon Eli Lilly Co., Ltd v. Pharmacia AB*).

201 Chiteki Zaisan Kōtō Saibansho (Intellectual Prop. High Ct) May 27, 2010, Hei 21 (ne) no. 10006, Chizai kōsai web (*Yokohama Rubber Co., Ltd v. Yonex Co., Ltd*).

202 Patent Act, art. 104-3(1).

203 JPO, "Nihon tokkyo mukō shinpanshin" ("Patent Invalidation Trials in Japan"), in Symposium, *Patent Litigation in Europe and Japan 2016*, slide 6 (Nov. 18, 2016), www.jpo.go.jp/news/kokusai/seminar/document/nichi_oh_symposium_2016/04_keynote3_jp.pdf

dismissed if the assertion is not made in a timely manner or if the case would be unduly delayed.²⁰⁴

The statutory basis for the defense of invalidity was introduced by an amendment of the Patent Act in 2004 in response to a decision by the Supreme Court (*Kilby Case*), which held that the defense of abuse of rights could be asserted even before a trial for invalidation by the JPO becomes final and binding.²⁰⁵ While the Supreme Court's decision in *Kilby* suggested that a patent would have to be invalid due to lack of inventive step to allow the defense to be raised, Article 104-3(1) of the Patent Act did not include such a restriction. However, there is no substantive difference between the level of "obviousness" required as set out in the Supreme Court decision and Article 104-3(1).

7.5.3.1 Grounds for invalidity

The grounds for invalidity that can be claimed in a defense of invalidity are violations of the following patent requirements:

- amendment requirement (addition of new matter; Patent Act, Article 17-2(3));
- novelty (Patent Act, Article 29(1));
- inventive step (Patent Act, Article 29(2));
- prior art effect (Patent Act, Article 29-2);
- enablement requirement (Patent Act, Article 36(4)(i));
- support requirement (Patent Act, Article 36(6)(i));
- clarity requirement (Patent Act, Article 36(6)(ii)); and
- usurpation (Patent Act, Article 49(7)).

Various court decisions that have addressed these grounds for invalidity are outlined below.

7.5.3.1.1 Amendment requirement (addition of new matter; Patent Act, Article 17-2(3))

In the *Solder Resist Case*, a Grand Panel of the IP High Court stated that

[t]he "matters described in the description or drawings" are technical matters derived by a person having ordinary skill in the art putting together all statements in the specification or drawing. *If a correction introduces no new technical matter in relation to those thus derived, the correction may be deemed to be within the scope of matters described in the description or drawings.*²⁰⁶

The patentee who amended the patent bears the burden of proof for this ground for invalidity.²⁰⁷

7.5.3.1.2 Novelty (Patent Act, Article 29(1))

The IP High Court has held that

[i]n order for an "invention of a product" to be described in a "publication," *it is necessary to first disclose the structure of the invention in the publication, and as the invention is a creation of technical ideas (see Patent Act, Article 2(1)), it is necessary not only to disclose the structure of the invention but also to disclose the technical ideas of the invention to the extent that a person having ordinary skill in the art who has access to the "publication" can easily work the technical ideas.*²⁰⁸

The alleged infringer bears the burden of proof for this ground for invalidity.

²⁰⁴ Code of Civil Procedure, art. 157; Patent Act, art. 104-3(1).

²⁰⁵ Saikō Saibansho (Supreme Ct) April 11, 2000, Hei 10 (o) no. 364, 54(4) Minshū 1368 (*Texas Instruments Inc. v. Fujitsu Co., Ltd*) (*Kilby Case*).

²⁰⁶ *Solder Resist Case*, Heisei 18 (gyō ke) no. 10563 (emphasis added). An unofficial English translation of this judgment is available via the IP High Court website at www.ip.courts.go.jp/app/files/hanrei_en/064/000064.pdf

²⁰⁷ On the burden of proof in relation to the defense of invalidity, see Yasuyuki Echi, "Shinsa/shinpan/shinketsu torikeshi soshō mukō no kōben o meguru tokkyō-hō no kihan kōzō to 'shuchō risshō sekinin'" ("The Normative Structure of the Patent Law and the 'Burden of Proof' of Claims Concerning Examination/Trial/Trial Decision Cancellation Litigation/Invalid Defense"), 71(4) Patentō (Patent) 126 (2018).

²⁰⁸ Chiteki Zaisan Kōtō Saibansho (Intellectual Prop. High Ct) June 30, 2008, Hei 19 (gyō ke) no. 10378, Chizai kōsai web (*Shiono Chemical Co., Ltd v. Pfizer Inc.*) (emphasis added).

7.5.3.1.3 Inventive step (Patent Act, Article 29(2))

In *Bridgestone Co., Ltd v. Commissioner of the Patent Office*, the IP High Court found that

*[t]he invention of this application arranges a surface rubber layer having a low elastic modulus so that the tire can exhibit the performance on ice even in the initial stage of use, whereas the cited invention enables the body layer to exhibit the specified performance quickly by removing the surface layer by peeling easily. Therefore, the concrete problem for enabling the body layer to exhibit the performance even in the initial stage of use is different, and the technical idea of each invention's surface layer conflicts with each other.*²⁰⁹

When problems solved by the invention and a cited invention are different, such a difference is considered to support a finding of inventive step. The alleged infringer bears the burden of proof for this ground for invalidity.

7.5.3.1.4 Prior art effect (Patent Act, Article 29-2)

Requirements for this ground are:

- another application (the other application) was filed on a day earlier than the filing date of the application concerned;
- the publication of the other application occurred after the filing date of the application concerned;
- the inventor of the invention in the other application was not the same as the inventor of the invention claimed in the application concerned; and
- the applicant for the other application was not the same as the applicant for the application concerned as of the filing date of the application concerned.

The Tokyo High Court has held that

[w]here the invention claimed in the application concerned and the cited invention are different but share substantial identity, it is deemed "identity" regarding the prior art effect.

Substantial identity referred to herein means a case where a difference between the invention claimed in the application concerned and the cited invention is a very minor difference (an addition, deletion, conversion, etc., of common general knowledge or commonly used art which does not yield any new effect) in embodying means for resolving a problem.²¹⁰

The IP High Court has stated that

*[e]ven if there is no particular statement in the description etc. of the prior application, the invention of the prior application can be found taking into consideration the common general technical knowledge of a person having ordinary skill in the art in order to understand the invention of the prior application. On the other hand, in the case where an invention is abstract, or technical content of an invention is insufficiently disclosed even taking into consideration the common general technical knowledge of a person having ordinary skill in the art, such invention does not fall under the "invention" mentioned above and does not have the effect of excluding the later application provided for in this Article. Further, created technical content which is not configured to the extent that any person having ordinary knowledge and experience in the art can repeatedly work the technical content to achieve an intended technical effect is not yet an "invention" and it should not be deemed that such technical content falls under "invention" as referred to in Article 29-2 of the Patent Act.*²¹¹

The alleged infringer bears the burden of proof for this ground for invalidity.

209 Chiteki Zaisan Kōtō Saibansho (Intellectual Prop. High Ct) Nov. 16, 2016, Hei 28 (gyō ke) no. 10079, Chizai kōsai web (*Bridgestone Co., Ltd v. Commissioner of the Patent Office*) (emphasis added).

210 Tōkyō Kōtō Saibansho (Tokyo High Ct) Feb. 19, 2004, Hei 13 (gyō ke) no. 533, Saibansho web (*Koninklijke Philips N.V. v. Commissioner of the Patent Office*).

211 Chiteki Zaisan Kōtō Saibansho (Intellectual Prop. High Ct) Nov. 10, 2020, Reiwa 2 (gyō ke) no. 10005, Chizai kōsai web (*Tokushu Tokai Paper Co., Ltd v. Commissioner of the Patent Office*) (emphasis added). An unofficial English translation of this judgment is available via the IP High Court website at www.ip.courts.go.jp/app/files/hanrei_en/871/002871.pdf

7.5.3.1.5 Enablement requirement (Patent Act, Article 36(1)(i))

The IP High Court has held that

[i]n order to satisfy the enablement requirement for a *process*, the detailed description of the invention is required to have a description to such a degree that a person having ordinary skill in the art can use the process without requiring excessive trial and error on the basis of the contents described in the detailed description of the invention and the common general technical knowledge as at the time of filing, and the presence of the description to such a degree is sufficient.

In order to satisfy the enablement requirement for a *product*, the detailed description of the invention is required to have a description to such a degree that a person having ordinary skill in the art can make the product without requiring excessive trial and error on the basis of the contents described in the detailed description of the Invention and the common general technical knowledge as of the time of the filing.²¹²

The IP High Court has also held that

[i]n order to fulfil the enablement requirement for a *process for producing the product*, the detailed description of the invention is required to have a description to such a degree that a person having ordinary skill in the art can use the process and also can use the product produced by the process without requiring excessive trial and error on the basis of the contents described in the detailed description of the invention and the common general technical knowledge as of the time of the filing.²¹³

The patentee bears the burden of proof for this ground for invalidity (as long as it is the same patent that is the subject of an invalidation trial before the JPO (common view)).

7.5.3.1.6 Support requirement (Patent Act, Article 36(6)(i))

In the *Polarizing Film Manufacturing Process Case*, a Grand Panel of the IP High Court held that

[c]laim recitations are first compared with the detailed description of the invention; then the fulfillment of the Support Requirement is determined according to *whether the claimed invention was described in the detailed description of the invention*, whether a person having ordinary skill in the art could have solved the problem of the claimed invention based on its recitations, or a person having ordinary skill in the art could have solved the problem of the claimed invention based on common technical knowledge at the filing date given that the recitations were not included nor suggested in the detailed description of the invention.²¹⁴

The patentee bears the burden of proof for this ground for invalidity (as long as it is the same patent that is the subject of an invalidation trial before the JPO (common view)).

7.5.3.1.7 Clarity requirement (Patent Act, Article 36(6)(ii))

The IP High Court has held that

[Article 36(6)(ii) of the Patent Act] was established in view of the fact that, if the invention presented in the claims is not clear enough, the technical scope of the invention protected by the patent would be unclear and could cause unexpected disadvantage to third parties. The objective of this provision is to prevent such inconvenience. A determination as to whether or not the invention claimed in a patent application is clear should be determined based not only on the information presented in the claims but also on the information presented in the description and drawings attached to the patent application. Moreover, that determination should be made from the perspective of *whether the information presented in the claims can be considered to*

212 Chiteki Zaisan Kōtō Saibansho (Intellectual Prop. High Ct) Sep. 15, 2011, Hei 22 (gyō ke) no. 10348, Chizai kōsai web (*Oriental Giken Co., Ltd v. Tosoh Co., Ltd*) (emphasis added).

213 Chiteki Zaisan Kōtō Saibansho (Intellectual Prop. High Ct) Sep. 18, 2019, Hei 30 (gyō ke) no. 10150, Chizai kōsai web (*Towa Corporation Co., Ltd v. Ansell Healthcare Products LLC*) (emphasis added). An unofficial English translation of this judgment is available via the IP High Court website at www.ip.courts.go.jp/app/files/hanrei_en/665/002665.pdf

214 *Parameter Patent Case*, Heisei 17 (gyō ke) no. 10042, Chizai kōsai web (emphasis added). An unofficial English translation of this judgment is available via the IP High Court website at www.ip.courts.go.jp/app/files/hanrei_en/309/000309.pdf

*be so unclear that it would make third parties suffer unexpected disadvantages in light of the common general technical knowledge of persons having ordinary skill in the art as of the time of the filing of the application.*²¹⁵

However, the IP High Court has also held that

*[e]ven if a process for manufacturing a product is described in the scope of claims for a product, if it is clear from the scope of claims, description, drawings, and common general knowledge that the structure or properties of the product are represented by the process, the benefit of a third party is not unreasonably harmed, and therefore, it does not constitute a violation of the clarity requirement.*²¹⁶

The patentee bears the burden of proof for this ground for invalidity (as long as it is the same patent that is the subject of an invalidation trial before the JPO (common view)).

7.5.3.1.8 Usurpation (Patent Act, Article 49(7))

The IP High Court has held that

*[i]n a trial for patent invalidation requested on the grounds of a usurped application, it is the patentee that bears the burden of allegation and proof in relation to the fact that “the patent application was filed by the inventor of the invention for which a patent was sought or by a person to whom the right to obtain a patent was assigned from the inventor.” Even if such interpretation is adopted, it would not mean that the patentee of an invention who faces such a trial is always required to present independent, specific, concrete, and detailed allegations and proof with regard to how the invention was made. The required breadth and depth of the patentee’s allegations and proof should be determined based on the nature of the specific grounds that allege that the patent was granted based on a usurped application and also based on the breadth and depth of the allegations and proof of the person who requested a trial for invalidation, and also that, if the person who requested a trial for invalidation fails to provide any specific grounds to allege that the patent was granted based on a usurped application and also fails to provide any evidence for such allegation, the patentee is merely required to provide relatively simple allegations and proof. Whereas, if the person who requested a trial for invalidation provides specific grounds to allege that the patent was granted based on a usurped application and also provides evidence for such allegation, the patentee cannot be considered to have fulfilled the burden of allegation and proof unless the patentee provides allegations and proof that outweigh the allegations and proof provided by the former person.*²¹⁷

The alleged infringer bears the burden of proof for this ground for invalidity. However, for this ground, the burden of proof will pass to the patentee if the appellant of a trial for invalidation identifies circumstances in support of usurpation.²¹⁸

7.5.3.2 Parallel Japan Patent Office trial for invalidation

As noted above, an alleged infringer may request a JPO trial for invalidation in addition to asserting the defense of invalidity in a patent infringement lawsuit. JPO trials are frequently conducted in parallel to a court’s proceedings, and conflicting decisions are sometimes reached. However, an invalidity determination by the court affects only the parties and therefore does not invalidate the patent with respect to third parties. Only the JPO can invalidate a patent with *erga omnes* effect.

215 Chiteki Zaisan Kōtō Saibansho (Intellectual Prop. High Ct) Nov. 26, 2015, Hei 26 (gyō ke) no. 10254, Chizai kōsai web (*Bellegreenwise Co., Ltd v. Sumitomo Bakelite Co., Ltd*) (emphasis added). An unofficial English translation of this judgment is available via the *IP High Court* website at www.ip.courts.go.jp/app/files/hanrei_en/925/001925.pdf

216 Chiteki Zaisan Kōtō Saibansho (Intellectual Prop. High Ct) Dec. 21, 2017, Hei 29 (gyō ke) no. 10083, Chizai kōsai web (*Toyoko Rice Co., Ltd v. Kohnan Shokuryo Co., Ltd*). An unofficial English translation of this judgment is available via the *IP High Court* website at www.ip.courts.go.jp/app/files/hanrei_en/252/002252.pdf

217 Chiteki Zaisan Kōtō Saibansho (Intellectual Prop. High Ct) Jan. 25, 2017, Hei 27 (gyō ke) no. 10230, Chizai kōsai web (emphasis added). An unofficial English translation of this judgment is available via the *IP High Court* website at www.ip.courts.go.jp/app/files/hanrei_en/153/002153.pdf. See Section 7.2 of this chapter for further information on the JPO trial for invalidation.

218 In 2011, the Patent Act was amended by the Tokkyo-ho no Ichibu wo Kaisei suru Houritsu (Act to Partially Amend the Patent Act, etc.), Act No. 63 of June 8, 2011 to provide that the true owner of the right shall also have the right to claim recovery. Patent Act, art. 74.

When a JPO trial for invalidation results in a decision that a patent is invalid, and that decision become final and binding, the patent is invalid for the parties and any third parties. Therefore, the patent will also be invalid for the purpose of a patent infringement lawsuit, and so the case will be decided against the patentee.

When a JPO trial for invalidation results in a decision that a patent is valid and should be maintained, and the decision becomes final and binding – and the defendant does not appeal the JPO decision to the IP High Court – it will be impossible to assert a defense of invalidity on the same grounds in a patent infringement lawsuit. This is because it would be a violation of the doctrine of good faith and fair dealing.²¹⁹ Therefore, if an alleged infringer in a patent infringement lawsuit is not successful in a parallel JPO trial for invalidation, the alleged infringer must appeal to the IP High Court.²²⁰

7.5.3.3 Limitations on assertions in retrials

In patent infringement proceedings, a defendant may assert a defense of invalidity, and a plaintiff may assert a defense of correction, and both parties will present their views as to the validity and scope of the allegedly infringed patent. However, there is the potential that a JPO decision in a trial for invalidation or a trial for correction – that differs from the judgment in a patent infringement lawsuit in relation to the validity and scope of a patent – becomes final and binding after the judgment in the patent infringement lawsuit becomes final and binding, thereby reversing that judgment. Thus, in 2011, the Patent Act was amended to impose certain limitations on the assertions that may be made in a retrial under Article 338(1)(viii) of the Code of Civil Procedure (when a civil judgment has been modified by a subsequent administrative decision).

Article 104-4 of the Patent Act provides that if a JPO trial or appeal decision – that a patent is to be invalidated or corrected – becomes final and binding after a final judgment in a patent infringement lawsuit becomes final and binding, a person that was a party to the patent infringement lawsuit may not assert that JPO trial or appeal in a retrial of the final decision in the patent infringement lawsuit, including in any action claiming compensation for damages and restitution for unjust enrichment.

For example, a person who has been found liable for infringement in a patent infringement lawsuit cannot, in a retrial of the lawsuit, demand the return of compensation for damages or restitution paid if the JPO later finds the patent to be invalid. In these circumstances, an injunction order issued in a patent infringement lawsuit would no longer be effective because the basis for infringement would have disappeared. Any compensation or restitution already paid cannot be reclaimed.

In addition, although not originally envisaged by Article 104-4, the IP High Court has held that

because the Patent Act provides that an alleged infringing item that does not fall within the technical scope of the patent invention before a correction does not fall within the technical scope of the patented invention after a correction, an allegation by a patentee in a retrial that an alleged infringing item falls within the technical scope of the patent invention as a result of a JPO decision upholding a correction but after a judgment that dismissed the request on the grounds that the alleged infringing item did not fall within the technical scope of the patent invention, is not envisaged by the Patent Act.²²¹

Therefore, an alleged infringer must strongly argue the defense of invalidity, and a patentee must strongly argue the defense of correction in patent litigation proceedings. Otherwise, even if a favorable JPO trial decision becomes final and binding after the judgment of a court in a patent infringement lawsuit becomes final and binding, the judgment of the latter may not be reversed in a retrial.

219 Chiteki Zaisan Kōtō Saibansho (Intellectual Prop. High Ct) Dec. 18, 2018, Hei 29 (ne) no. 10086, Chizai kōsai web (*MTG Co., Ltd v. Benoa Japan Co., Ltd*); Chiteki Zaisan Kōtō Saibansho (Intellectual Prop. High Ct) June 27, 2020, Hei 31 (ne) no. 10009, Chizai kōsai web (*Nissin Iryouki Co., Ltd v. Yuyama Seisakujiyo Co., Ltd*).

220 See Section 7.2 for further information on JPO trials for invalidation.

221 Chiteki Zaisan Kōtō Saibansho (Intellectual Prop. High Ct) Sep. 18, 2018, Hei 30 (mu) no. 10003, Chizai kōsai web (*HousekinoAngel Ltd v. Ishihuku Jewelry Parts Co., Ltd*). An unofficial English translation of this judgment is available via the IP High Court website at www.ip.courts.go.jp/app/files/hanrei_en/325/002325.pdf

7.5.4 Defense of correction

When a defense of invalidity is asserted by a defendant in patent infringement proceedings, the plaintiff (the patentee) may be able to avoid invalidity by asserting a defense of correction – that the grounds for invalidity can be addressed by either a final and binding JPO correction decision or a request for a correction. Therefore, in parallel with this, the alleged infringer can assert the effect of the correction in a suit for infringement of a patent.

7.5.4.1 Four requirements and an exception

The following four requirements must be satisfied for a defense of correction:

- The request for correction (where a trial for invalidation is pending) or the request for a trial of correction by the JPO (where a trial for invalidation is not pending) must be lawful.²²²
- The correction meets the correction requirements – that is, no new matter has been added.
- The reason for invalidation alleged in the defense of invalidity is resolved by the correction.
- The defendant's product (or process) falls within the technical scope of the patented invention after correction.

However, in relation to the first requirement, under the Patent Act, there is period in which a request for neither a correction nor for a trial for correction can be made, and so the IP High Court has ruled that

when it is legally difficult for a patentee to file a request for correction etc., such circumstances should be taken into consideration on a case-by-case basis from the standpoint of fairness, and when there are special circumstances that do not require the filing of a legal request for correction etc., the patentee may be allowed to make an allegation of defense of correction without satisfying such requirement.²²³

In this regard, the IP High Court has held that

if such request cannot be made because the patentee's right to request correction or request a trial for correction is restricted, a declaration to the effect that such request for correction (or a request for a trial for correction) will be made when it "becomes possible" is sufficient.²²⁴

In addition, the IP High Court has also held that

the appellant could request neither a correction nor a trial for correction until receiving a notice of the trial decision from the JPO under Article 126, paragraph (2), Article 134-2, paragraph (1) of the Patent Act. Under such circumstances, the appellant does not need to make these requests to the JPO in order to assert the defense of correction.²²⁵

Accordingly, it is still possible to assert the defense of correction even during the term when it is not possible to request a correction or a trial for correction under the Patent Act. However, the patentee will need to request a correction or trial for correction at the JPO when it becomes possible to do so under the Patent Act.

A patentee is required to assert a defense of correction before the conclusion of the oral hearing of the IP High Court at the latest so as not to cause a delay, irrespective of the progress of the hearing proceedings before the JPO. Otherwise, it will be impossible to assert a defense of correction when a correction or a trial for correction may be requested under the Patent Act.²²⁶ A patentee should be mindful of this timing issue.

²²² See Section 7.2 for a discussion of the JPO trial for correction and a request for correction.

²²³ Chiteki Zaisan Kōtō Saibansho (Intellectual Prop. High Ct) Sep. 17, 2014, Hei 25 (ne) no. 10090, Chizai kōsai web (*Renishaw Public Limited Company v. Nanophoton Co., Ltd.*). An unofficial English translation of this judgment is available via the IP High Court website at www.ip.courts.go.jp/app/files/hanrei_en/429/001429.pdf

²²⁴ Chiteki Zaisan Kōtō Saibansho (Intellectual Prop. High Ct) March 14, 2017, Hei 28 (ne) no. 10100, Chizai kōsai web (*Globeride Co., Ltd v. Shimano Co., Ltd.*). An unofficial English translation of this judgment is available via the IP High Court website at www.ip.courts.go.jp/app/files/hanrei_en/159/002159.pdf

²²⁵ Chiteki Zaisan Kōtō Saibansho (Intellectual Prop. High Ct) Sep. 26, 2018, Hei 30 (ne) no. 10015, Chizai kōsai web (*Denso Wave Co., Ltd v. Casio Computer Co., Ltd*) (citing Saikō Saibansho (Sup. Ct) July 10, 2017, Hei 28 (ju) no. 632, 71(6) Minshū 861).

²²⁶ Saikō Saibansho (Sup. Ct) July 10, 2017, Hei 28 (ju) no. 632, 71(6) Minshū 861.

7.5.4.2 When to assert the defense

The defense of correction will be dismissed if it is late or if it will unduly delay the proceedings.²²⁷ For example, the IP High Court has dismissed a defense of correction submitted four days before the first hearing date of an appeal trial because “it was possible to the assert the defense of correction by the due date of the first brief before the IP High Court.”²²⁸

7.5.4.3 Consent of joint owner and exclusive licensee

Under the Patent Act, a patentee may only request a trial for correction with the consent of any joint owners and exclusive licensees.²²⁹ Further, the Tokyo District Court has also rejected a patentee’s defense of correction assertion to which a nonexclusive licensee did not consent.²³⁰

7.5.4.4 Patentee failure to request correction or trial for correction

As noted above, the defense of correction usually requires that a lawful request for correction or a trial of correction has been made with the JPO.²³¹ However, the IP High Court has indicated that this is not necessary during the period when neither a correction nor a trial for correction may be requested under the Patent Act. In these circumstances, the patentee is required to file a request for correction or a trial for correction at the JPO when it becomes possible to do so under the Patent Act.

However, there is a risk that this could lead to complexity and undesirable outcomes. For example, it could lead to a situation wherein a patentee asserts the defense of correction (without first requesting a correction or a trial for correction) and is successful in a patent infringement lawsuit as a result of asserting this defense but does not request a correction or a trial for correction with different claim wording with the JPO, even when it becomes possible to do so under the Patent Act.

There is some debate as to the type of penalty that could be imposed on the patentee in such a situation and whether a defendant could seek a retrial of a patent infringement lawsuit that has already become final and binding. However, there are no court cases that consider this point, and the debate is still developing.

7.6 Judicial patent proceedings and case management

This section sets out the process for seeking an injunction against, or damages for, an alleged infringement of a patent right, with a particular focus on the district court process. It addresses jurisdiction and case assignment; conciliation; the two-stage district court process for assessing infringement and damages; provisional dispositions (preliminary injunctions); and discovery and appeal. This section also outlines the remedies a patentee may seek when a person infringes or is likely to infringe a patent right, including an injunction, damages, measures to restore credibility and the return of unjust enrichment.

The IP divisions of the Tokyo District Court and the Osaka District Court adopt the following two-stage process for patent infringement lawsuits:

1. infringement determination stage – the court determines whether a patent has been infringed (including the validity of a patent); and
2. damages determination stage – if the court finds that infringement has occurred, a second stage is conducted to determine the amount of damages.

²²⁷ Code of Civil Procedure, art. 157.

²²⁸ Chiteki Zaisan Kōtō Saibansho (Intellectual Prop. High Ct) Sep. 26, 2018, Hei 30 (ne) no. 10044, Chizai kōsai web (*Denso Wave Co., Ltd v. Zebra Technologies Japan Co., Ltd*).

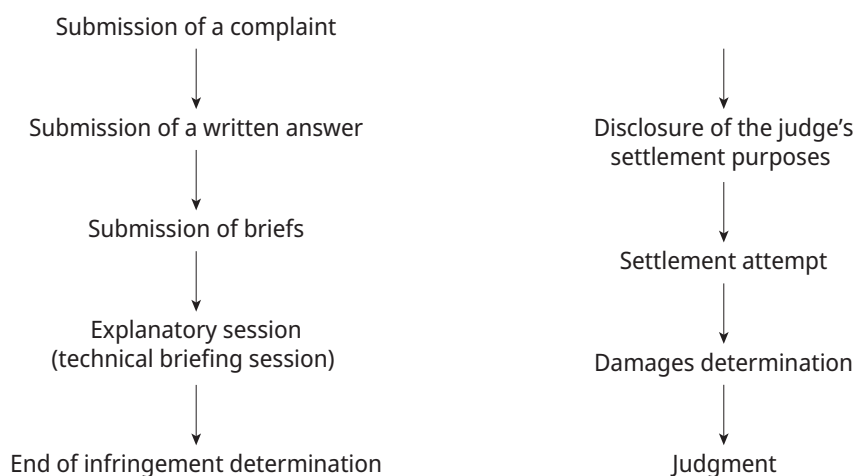
²²⁹ Patent Act, art. 127.

²³⁰ Tōkyō Chihō Saibansho (Tokyo Dist. Ct) July 13, 2016, Hei 25 (wa) no. 19418, Saibansho web (*EHS Lens Philippines, Inc. v. Nikon Essilor Co., Ltd*).

²³¹ See Section 7.2 for a discussion of requests for correction in the context of oppositions to the grant of a patent and trials for invalidation, as well as the JPO process for a trial for correction. See Section 7.4 for a discussion of appeals to the IP High Court against JPO trials for correction, as well as the “correction requirement” as a ground the IP High Court will consider when reviewing a JPO decision.

Figure 7.10 provides an overview of the patent infringement lawsuit litigation process.

Figure 7.10 First-instance patent litigation



The IP divisions of the Tokyo District Court and the Osaka District Court have published the following guidelines on the two-stage infringement lawsuit process in English:

- *Proceedings Model for Patent Infringement Suit (Stage for Examination on Infringement)* (Tokyo District Court);
- *Proceedings Model for Patent Infringement Suit (Stage for Examination on Damages)* (Tokyo District Court);
- *Flow of Procedures for a Patent/Utility Model Right Infringement Suit* (Osaka District Court); and
- *Instructions for Proceedings of the Stage for Examination on Damages* (Osaka District Court).²³²

7.6.1 Jurisdiction and case assignment

As noted in Section 7.3, the Tokyo District Court or the Osaka District Court handles first instances of civil lawsuits for an alleged infringement of a patent.²³³ Patent infringement cases are assigned to panels of the IP divisions of the district courts according to the order in which they are filed. Civil Divisions 29, 40, 46 and 47 of the Tokyo District Court and Civil Divisions 21 and 26 of the Osaka District Court specialize in IP infringement proceedings.

A panel of three judges will usually hear patent infringement cases. Fact-finding does not involve jurors and is conducted by judges. However, judicial research officials – examiners seconded from the JPO, or patent attorneys – are assigned to assist district court judges with technical matters.

Any appeal against a district court decision in a patent infringement lawsuit is under the exclusive jurisdiction of the IP High Court.²³⁴ A party that is dissatisfied with a decision of the IP High Court may file a final appeal or a petition for the acceptance of a final appeal to the Supreme Court.²³⁵

²³² Tokyo District Court, *Proceedings Model for Patent Infringement Suit (Stage for Examination on Infringement)*, Intellectual Property High Court, www.ip.courts.go.jp/eng/vc-files/eng/file/tokyo_district_court_attachment1.pdf; Tokyo District Court, *Proceedings Model for Patent Infringement Suit (Stage for Examination on Damages)*, Intellectual Property High Court, www.ip.courts.go.jp/eng/vc-files/eng/file/tokyo_district_court_attachment2.pdf; Osaka District Court, *Flow of Procedures for a Patent/Utility Model Right Infringement Suit*, Intellectual Property High Court, www.ip.courts.go.jp/eng/vc-files/eng/file/osaka_district_court_2.pdf; Osaka District Court, *Instructions for Proceedings of the Stage for Examination on Damages*, Intellectual Property High Court www.ip.courts.go.jp/eng/vc-files/eng/file/osaka_district_court_1.pdf

²³³ Code of Civil Procedure, art. 6(1).

²³⁴ Code of Civil Procedure, art. 6(3); Act for Establishment of the IP High Court, art. 2(1). See Section 7.3 of this chapter for further information on the IP High Court.

²³⁵ Code of Civil Procedure, arts 285, 313. The appeal of district court patent infringement decisions to the IP High Court and the Supreme Court is discussed below. See Section 7.3 for further information on the Supreme Court.

7.6.2 Statements of case (complaint and answer)

On the first date for oral argument, the plaintiff will present the complaint, and the defendant will present an answer. The answer should outline the arguments that the defendant intends to present, including:

- identification of the alleged infringing product or process and a description of its composition;
- admission or denial of the assertions made in the complaint; and
- the defense of patent invalidity.²³⁶

The parties should submit basic documentary evidence – for example, the patent register, the patent gazette or a pamphlet describing the defendant's product – along with a description of the evidence.

7.6.3 Early case management (preparatory proceedings)

In most cases, after the first date for oral argument, the court refers the case to preparatory proceedings to identify and organize the issues and evidence. The presiding judge and another judge from the three-judge panel will conduct the preparatory proceedings during which the parties will present their detailed arguments.

On the first or second date of the preparatory proceedings, the court and the parties will confirm the issues in dispute and may decide a schedule for the proceedings. Depending on the arguments made on each date of the proceedings, the court and the parties may adjust the schedule or discuss what the parties should prepare for the next date for proceedings.

During preparatory proceedings, according to Article 104-2 of Patent Act, when the defendant denies the description of the allegedly infringing products or process described by the plaintiff in the complaint, the defendant should present a description of those products or process prepared by the defendant. Based on this description, the defendant will present a brief that includes arguments as to whether the alleged infringing product or process falls within the technical scope of the patented invention. If the defendant argues a defense of patent invalidity, the defendant will present a brief outlining the defense based on an investigation of publicly known prior art documents and should also submit any other relevant and necessary documentary evidence in its possession.

The plaintiff will also present a brief that outlines the plaintiff's arguments against the defendant's denial of infringement in terms of the technical scope of the patented invention, as well as any defense of patent invalidity (including the defense of correction), and will also submit any necessary documentary evidence to support its assertions.

On the third date of preparatory proceedings, the defendant will present another brief to counter the plaintiff's allegation made at the previous day of preparatory proceedings regarding the technical scope of the patented invention. The defendant may also provide supplementary material relevant to the defense of patent invalidity.

On the fourth date of preparatory proceedings, the plaintiff will present briefs that outline any supplementary arguments with respect to the defense of patent invalidity. At this stage, the key arguments on infringement, including the validity of the patent and their proof, will be completed.

7.6.4 Provisional measures (preliminary injunction against patent infringement)

Article 23(2) of the Civil Provisional Remedies Act provides for a provisional disposition (preliminary injunction) to prohibit the supply of goods or services that infringe a patent right, in addition to a permanent injunction issued in an infringement action based on the merits.²³⁷ Article 23(2) provides that a preliminary injunction may be issued "when such status is necessary

²³⁶ Patent Act, art. 104-3(1).

²³⁷ Minji hozenhō (Civil Provisional Remedies Act), Act No. 91 of Dec. 22, 1989 (Civil Provisional Remedies Act).

in order to avoid any substantial damage or imminent danger that would occur to” the patentee with respect to “the relationship of rights in dispute.”

If a patentee is successful in an infringement action on the merits, the court will permit the patentee to exercise the right to:

- stop the infringing activities;²³⁸
- demand the disposal of infringing products;²³⁹
- demand compensation for damages;²⁴⁰ and
- demand measures to restore the patentee’s reputation.²⁴¹

However, in the case of a preliminary injunction against patent infringement, only the following remedies are permitted:

- an injunction against the infringing activities; and
- the retention of the infringing products by the court enforcement officer for the purpose of ensuring the disposal of the infringing products upon obtaining a final judgment.²⁴²

Article 24 of the Civil Provisional Remedies Act provides the following:

In order to achieve the objective of a petition for an order of provisional disposition, the court may issue a disposition ordering the [respondent (alleged infringer)] to take or prohibit from taking certain actions, ordering the [respondent] to tender performance, or causing the object to be placed in the custody of a custodian, or issue any other necessary disposition.

The case for a preliminary injunction may be filed at the same time as the main action. When the same counsel represents each party in both matters, the case for a preliminary injunction and the main case will often be considered by the court at the same time.

7.6.4.1 Requirements for a preliminary injunction order

The requirements for a preliminary injunction are a likelihood of success on the merits and the necessity to preserve the patentee’s position pending the final determination. Article 13(1) of the Civil Provisional Remedies Act provides: “A petition for an order for a provisional remedy must clarify the purpose thereof and the rights or relationship of rights that must be preserved and the necessity of preserving it.”

To show that there is a likelihood of success on the merits, it is necessary to demonstrate that a patent right is infringed – that is, that the other party’s goods or services fall within the technical scope of the patented invention. The respondent (alleged infringer) may deny this by showing that the right should be invalidated in a trial for invalidation before the JPO or that the right is not infringed.²⁴³

The necessity of the preliminary injunction must be established by *prima facie* evidence that shows serious damage or imminent danger to the petitioner (patentee).

7.6.4.2 Proof in a preliminary injunction case

The proof required for a preliminary injunction is a *prima facie* case. Article 13(2) of the Civil Provisional Remedies Act provides that a *prima facie* case must show “the right or the relationship of rights to be preserved and the necessity to preserve it.” *Prima facie* evidence is evidence that can be assessed immediately by the court.²⁴⁴ Documentary evidence is generally provided, and hearing of a witness who is not present in court is not permitted. A court will accept *prima facie* evidence that is above factual doubt.

238 Patent Act, art. 100(1).

239 Patent Act, art. 100(2).

240 Minpō (Civil Code), Act No. 89 of April 27, 1896, art. 709 (Civil Code).

241 Patent Act, art. 106.

242 Civil Provisional Remedies Act, art. 24.

243 See Section 7.2 for further information on JPO trials for invalidation.

244 Code of Civil Procedure, art. 188.

The proof required in an action on the merits is “certainty beyond a reasonable doubt.” The burden of proof is lower for a *prima facie* case. However, in practice, the proof required for a preliminary injunction is often closer to that required in an action on the merits, particularly when the impact on the respondent (alleged infringer) will be significant and if the possibility of the preliminary injunction being suspended is low.

7.6.4.3 Proceedings of preliminary injunction cases

The Tokyo District Court and the Osaka District Court have jurisdiction over preliminary injunction cases.²⁴⁵ In principle, the court deciding a preliminary injunction case must hold oral proceedings or a hearing date at which the respondent (alleged infringer) may be present. However, Article 23(4) of the Civil Provisional Remedies Act provides that this does not apply when the objective of the petition for an order of preliminary injunction cannot be achieved if such proceedings are held. The time required for a hearing depends on the complexity of the case, but it usually takes several months from the filing of the petition to the handing down of the decision if the case involves issues of infringement or invalidity.

7.6.4.4 Preliminary injunction cases and necessity of security deposit

A respondent (alleged infringer) may incur damage if a preliminary injunction is incorrectly issued. Therefore, it is usual for a court to require a security deposit when issuing a preliminary injunction. Under the Civil Provisional Remedies Act, whether a security deposit is required is left to the discretion of the court. Article 14(1) of the Civil Provisional Remedies Act provides the following:

An order for a provisional remedy may be issued while requiring provision of security or requiring provision of security within a certain period of time that is found to be reasonable as a condition for implementing the execution of the provisional remedy, or not requiring the provision of security.

The court determines the amount of the security deposit after reviewing materials submitted by the parties and taking various circumstances into account. The amount of the security deposit may be high if the sales generated by the alleged infringing goods or services are large. In addition, the security deposit will not be refunded until the dispute is resolved.

7.6.4.5 Execution of an order for a preliminary injunction

A permanent injunction is not enforceable until a declaration allowing the execution is issued or a judgment becomes final and binding. Conversely, a preliminary injunction order can be executed immediately.

A preliminary injunction is a provisional disposition prohibiting the respondent from performing an action (an alleged infringement) that comes into effect when a preliminary injunction order is served on the respondent (the alleged infringer). When a respondent is in violation of a preliminary injunction, the petitioner (patentee) can seek enforcement by filing a petition for substitute execution or indirect compulsory execution with the execution court based on an authenticated copy of the preliminary injunction order.²⁴⁶

To enforce an indirect compulsory execution, a petitioner must prove that the respondent is likely to breach their obligation not to act, but it is not necessary to prove that the respondent is actually in breach of their obligation not to act.²⁴⁷

A preliminary injunction order must be executed within two weeks from the day on which the preliminary injunction order is served on the respondent.²⁴⁸

7.6.4.6 Appeal against a preliminary injunction case

If a petition for a preliminary injunction order is dismissed, the petitioner (the patentee) may file an immediate appeal within two weeks from the day on which it is notified of the decision.²⁴⁹

²⁴⁵ Civil Provisional Remedies Act, art. 12(2); Code of Civil Procedure, art. 6(1).

²⁴⁶ Minji shikkōhō (Civil Execution Act), Act No. 4 of March 30, 1979, arts 171–172.

²⁴⁷ Saikō Saibansho (Sup. Ct) Dec. 9, 2005, 59(10) Minshū 2889.

²⁴⁸ Civil Provisional Remedies Act, art. 43(2).

²⁴⁹ Civil Provisional Remedies Act, art. 19(1).

When a preliminary injunction order is issued, the respondent (the alleged infringer) may file an objection to the preliminary injunction with the court that issued the order.²⁵⁰

An objection to a preliminary injunction order establishes a forum for reassessing the right to be preserved and the necessity of preservation. Although a petition for the stay of the execution of a preliminary injunction may be filed at the same time as an objection to a preliminary injunction order, it is practically impossible to obtain a stay of the execution of a preliminary injunction order. This is because a *prima facie* case is required to demonstrate the grounds for revocation of the order, and the execution of the preliminary injunction is likely to cause damage for which compensation cannot be made.²⁵¹ Therefore, the hurdle for seeking a stay is high.

The respondent may file a petition for an order against the petitioner to file a suit on the merits. If the petitioner does not file a suit on the merits despite the issuance of the order, the respondent may file a petition for revocation of the preliminary injunction. Article 37 of the Civil Provisional Remedies Act provides:

- (1) At the petition of the [respondent], the court that issued the order for a provisional remedy must order the [petitioner] to, within a certain period of time that it finds to be reasonable, file an action on the merits and submit a document certifying such filing, or, if the [petitioner] has already filed an action on the merits, to submit a document certifying that such action is pending before a court.
- (2) The period referred to in the preceding paragraph must be two weeks or more.
- (3) The court must revoke the order for a provisional remedy at the petition of the [respondent] if the [petitioner] fails to submit the document set forth in paragraph (1) within the period set forth in said paragraph.

7.6.4.7 Claim for damages against an erroneous order for a preliminary injunction

If, after a preliminary injunction order against infringement has been issued, it becomes clear in a judgment on the merits – as a result of a successful invalidity defense or a non-infringement argument – that there is no right to be preserved, and the judgment becomes final and binding, the petitioner (the patentee) who has executed the preliminary injunction order is liable to compensate the respondent for damage suffered as a result of the execution of the preliminary injunction if the petitioner was willful or negligent when enforcing the illegal preliminary injunction. Unless there are special circumstances, it is generally presumed that the petitioner was negligent when executing an illegal preliminary injunction.²⁵²

7.6.5 Discovery (limited) and gathering of information

Commentators have noted that the law relating to evidence collection in Japan needs amendment because it favors infringers.²⁵³ Attorney–client privilege is rarely an issue in patent infringement suits in Japan as discovery is limited.

The process for evidence collection under the Patent Act includes special provisions that were based on and supplement the Code of Civil Procedure.

7.6.5.1 Order to produce documents

One of the traditional methods for collecting evidence under Article 105 of the Patent Act is an order to submit documents.²⁵⁴ Article 105, which is a special provision that supplements Article 220 of the Code of Civil Procedure, aims to reduce the burden of the plaintiff to prove the act of infringement and the amount of damage. The exceptions to the obligation to submit documents are more limited in the Patent Act compared to the Code of Civil Procedure. Article 105(1) of the Patent Act stipulates the exception as “reasonable grounds,” whereas Article 220 of the Code of Civil Procedure stipulates a list of specific situations in which a person may not refuse to submit a document.

²⁵⁰ Civil Provisional Remedies Act, art. 26.

²⁵¹ Civil Provisional Remedies Act, art. 27(1).

²⁵² Tōkyō Chihō Saibansho (Tokyo Dist. Ct) Dec. 3, 2020, Rei 1 (wa) no. 21183, Saibansho web (the defendants in this case were Microsoft Corp. and Nihon Microsoft Kabushiki Kaisha (or, Microsoft Japan Co., Ltd)).

²⁵³ Nobuhiro Nakayama, *Tokkyohō (Patent Law)* 420 (4th ed., 2019).

²⁵⁴ Patent Act, art. 105.

7.6.5.1.1 Requirements

Article 105(1) stipulates that, in litigation concerning the infringement of a patent right or exclusive license, the court may, upon a motion of a party, order the other party to produce documents that are required to prove the act of infringement or to calculate the damage arising from the act of infringement. It also stipulates that this shall not apply where there are reasonable grounds for the person possessing the documents to refuse production of the documents. For example, it may be reasonable grounds to refuse the production of a document if it contains trade secrets. However, the courts have found that reasonable grounds are not found merely because a document contains trade secrets. A confidentiality protective order under Article 105-4 of the Patent Act can reduce the disadvantage to a person possessing such a document and is a relevant factor when denying reasonable grounds.²⁵⁵

7.6.5.1.2 Determination of reasonable grounds

Article 105(2) of the Patent Act stipulates that, if a court finds it necessary to decide whether there are reasonable grounds, the court may cause the person possessing documents to present such documents. In such a case, no person may request the disclosure of the documents.

It is not always easy for the court to decide whether there are reasonable grounds. However, generally speaking:

- when the documents would prove infringement, reasonable grounds will often be denied under the protection of a protective order; and
- when the documents would not prove infringement, reasonable grounds will often be found.

It is not appropriate for a court to decide this issue based solely on the assertion of the person possessing the documents. Therefore, Article 105(3) of the Patent Act provides that a court may disclose the documents to the parties or their attorneys when it is necessary to make a decision concerning the existence of reasonable grounds. In addition, under Article 105(4), a court may disclose the documents to a technical advisor with the consent of the parties when it is necessary to hear an explanation based on technical knowledge or acquire technical advice from the technical advisor.²⁵⁶

The inspection of evidence relating to infringing objects such as manufacturing equipment is indispensable to proving infringement in some patent litigation cases. Therefore, under Article 105(5) of the Patent Act, the same rules outlined above in relation to document production apply *mutatis mutandis* to the production of an infringing object.

7.6.5.1.3 Effect of a party's noncompliance with an order to produce a document

According to Article 224 of the Code of Civil Procedure, a court may find an adverse party's allegations concerning the details of a document to be true if a party:

- does not comply with an order to produce a document; or
- has caused a document to be lost or otherwise unusable for the purpose of preventing the adverse party from using it.

This provision ensures the effectiveness of the system of production of documents.

7.6.5.2 On-site examination by an expert (inspection system)

Article 105-2 of the Patent Act provides for an inspection system, in which a neutral technical expert (inspector) enters the facility of an alleged infringer, conducts an investigation when there is a possibility of patent infringement, and submits a report to a court. The inspection system is thought to be an effective measure for collecting evidence in cases where the production method is unclear or where infringement cannot be determined by physically taking the product apart.

The inspection system can only be used in limited circumstances. The term "in litigation" under Article 105-2(1) of the Patent Act implies that the system can only be used after a patent infringement suit has been filed. Accordingly, a party cannot use the inspection system when filing a preliminary injunction action (see above).

²⁵⁵ Takabe, *Practical and Detailed Explanation on Patent-Related Litigation*, at 85, 94.

²⁵⁶ Code of Civil Procedure, pt 1(V)(2)(1).

7.6.5.2.1 Requirements to issue an inspection order

According to Article 105-2(1), the court, after hearing the opinions of the parties, may issue the inspection order after considering the following:

- whether the evidence is necessary to prove the infringement;
- the probability that the evidence will prove the infringement. This is required to prevent abuse of the inspection system. The level of the “probability” required is not as high as for the proof of infringement;²⁵⁷
- whether there is no alternative. This requirement will not be satisfied when an alleged infringer’s product can be easily acquired on the open market; and
- whether it is not too burdensome for the party subject to the inspection. A typical example of such a burden is that the party is forced to shut down its factory for a while.

7.6.5.2.2 Inspector

Under Article 105-2(2), the court designates neutral and appropriate experts as inspectors. These inspectors may include lawyers, patent attorneys or university professors. Under Article 105-2-4(2), designated inspectors may enter a defendant’s factories, office or other place and demand the production of documents, inspect equipment or conduct experiments. Depending on the case, two or more experts may be designated as inspectors.

7.6.5.2.3 Disclosure of the inspection report to the plaintiff

Article 105-2-4(1) provides that, after conducting the inspection, inspectors must summarize the results and submit a report to the court. The report will be disclosed to the inspected defendant but not to the plaintiff at this stage. The defendant may petition the court not to disclose the report for the protection of a trade secret.²⁵⁸ The court will then decide whether to disclose the whole or a part of the report to the plaintiff.²⁵⁹ The defendant’s petition will be allowed if reasonable grounds not to disclose the report are found. Otherwise, the report will be disclosed to the plaintiff, and the plaintiff may submit it to the court as evidence.

7.6.5.2.4 Effect of noncompliance with an inspection order

Under Article 105-2-5, if a party does not comply with an inspection order, the court may find the adverse party’s allegations concerning the facts to be proved to be true, as is the case when a party does not comply with a document production order.

7.6.6 Infringement determination

7.6.6.1 Explanatory session

The court will usually not hear parties or witnesses in patent infringement lawsuit proceedings. Rather, the court determines the scope of the patented invention and patent infringement using documentary evidence, such as patent specifications, technical documents of prior art and specifications of the allegedly infringing products. It is also rare for an expert witness to be used to prove the technical background of a patented invention.

However, as the last substantive step of the stage for assessing infringement, the court will usually preside over an explanatory session (technical briefing session).²⁶⁰ These sessions are held not only for cases involving cutting-edge technology or highly specialized technology but also to establish the general understanding of persons having ordinary skill in the art in the technical field in question, or where general technical knowledge in the art is at issue.

Explanatory sessions may take various forms. For example, an explanatory session may be conducted as an official oral court hearing or as part of the preparatory proceedings. An explanatory session conducted as an oral court hearing will be attended by the judges, the judicial research official in charge of the case, a court clerk and three technical advisors selected from among the experts in the technical field in question.²⁶¹

257 Ryuichi Shitara, “Reiwa-gannen tokkyohō kaisei niyoru sashyō-seido no kaisetsu to sono igi” (“Commentary on the Inspection System Established by the Revision of Patent Act in 2019”), 89 Law and Technology 45, 48 (2020).

258 Patent Act, art. 105-2-6(2).

259 Patent Act, art. 105-2-6(3).

260 See Code of Civil Procedure, art. 92-2 to 92-7.

261 See Section 7.3 for further information on judicial research officials and technical advisors.

At the beginning of the session, each party will make a presentation lasting approximately 30 minutes summarizing their arguments and covering technical matters, such as the details of the invention, prior art and common general technical knowledge available at the time when the application was filed. The parties may provide an explanation by using the products produced by working a patented invention and the allegedly infringing products and may use diagrams, presentation software or videos to indicate correlations between the patented invention and the allegedly infringing product.

After the presentation, the participants engage in a discussion that allows both parties, the technical advisors, judges and the judicial research official to ask questions about the content of the presentation or to clarify points in the arguments or evidence. The technical advisors may also present explanations about technical matters. These sessions allow all participants to identify issues and deepen their understanding of technical matters.

7.6.6.2 Preliminary view and settlement

Following the explanatory session, the court will prepare a preliminary view on infringement, taking into account the arguments and evidence, including the technical explanations given by the parties.

If the court finds non-infringement, the court closes the proceedings and delivers a judgment. In some cases, the court may recommend the parties compromise and designate a date for settlement. There are a number of reasons why the court may still recommend settlement in these circumstances, including that the case is not strong and the successful party is not sure if they will be successful in IP High Court proceedings, or that the settlement agreement includes a licensing clause.

If the court finds infringement, the court will express its preliminary view, then proceed to the stage for assessing damages. In some cases, the court may recommend the parties settle at this stage and designate a date for settlement. The court expresses this view on the premise that both parties have completed their arguments and the introduction of evidence regarding infringement.

A large number of cases resolved through court settlement tend to favor the patent holder, including cases where a large amount of damages is claimed.²⁶² In Japan, court settlement is widely recognized as an efficient and speedy way to reach an appropriate resolution.

7.6.7 Damages determination

When the court proceeds to the stage for assessing damages, the plaintiff should clarify the allegations regarding the amount of damage, including the relevant statutory provision that constitutes the basis for the plaintiff's claim for damages.²⁶³ If the plaintiff does not make any change to the statement of the claim written in the original complaint, the plaintiff should state so on this date.

The plaintiff or the defendant presents their arguments on price, quantities, costs and other matters relating to the allegedly infringing product or process that are necessary to determine the amount of damage, depending on the nature of the damages claim.²⁶⁴

The plaintiff will then present a document that clarifies their arguments regarding the amount of damages based on the quantities and values introduced by the plaintiff and the defendant, which could include an amendment of the amount claimed in the written complaint.²⁶⁵ Following this, the defendant will present a document that either acknowledges or denies the amount of damages claimed by the plaintiff. If the defendant denies the damages claim, the document has to state appropriate reasons for that denial.

²⁶² IP High Court, *Guidebook*, at 46–47.

²⁶³ For example, whether it is a claim based on Patent Act, art. 102(1), (2) or (3).

²⁶⁴ The calculation of damages is discussed in Section 7.7.2.

²⁶⁵ Code of Civil Procedure, art. 143(1).

If disputes remain between the parties, the court may order that an opinion of a neutral expert (to be appointed by the court) be obtained for the calculation of damages. In such a case, the parties are obliged to assist the expert witness in their calculation of damages.²⁶⁶

The plaintiff may then counterargue and provide supplementary evidence, and the defendant may do the same. Following this, the stage for determining damages is complete. The court will prepare its final view regarding the amount of damages. It will then conclude the preparatory proceeding and oral argument and deliver a judgment. In some cases, the court may disclose its opinion to the parties and advise them to compromise.

The methods for calculating damages are outlined below in Section 7.7.2.

7.6.8 Conciliation

IP conciliation is designed to provide simple and speedy resolution of IP rights disputes. IP conciliation is suited to patent infringement cases when the issues in dispute are clear but have not been able to be resolved through negotiations between the parties.

The IP divisions of the Tokyo District Court and Osaka District Court provide IP conciliation services.²⁶⁷ While summary courts have general jurisdiction over conciliation cases, the Tokyo District Court and the Osaka District Court handle IP-specific conciliation cases. A case is handled by the district court agreed to by the parties.²⁶⁸

The Osaka District Court has published information on its IP conciliation process in English:

- *Explanation of the New IP Conciliation at the Osaka District Court*; and
- *Guidelines for IP Conciliation Proceedings at the Osaka District Court*.²⁶⁹

IP conciliation is conducted by a conciliation committee composed of three members: a judge of the IP division of the district court and two experts, such as a patent attorney or a lawyer with extensive experience in IP cases. In cases that involve technical matters, a judicial research official may administer some matters during a conciliation process.²⁷⁰

The parties to an IP conciliation are required to submit their allegations and related evidence by the first day of proceedings, and the conciliation committee is required to provide its opinion verbally by the third date of the proceedings. The committee's opinion includes not only its determination on the issues but also its view on whether the case would be more suited to litigation, given the difficulties of proof and the complexity of the case.

The parties may then choose to either continue or terminate the conciliation (due to an unsuccessful conciliation process or the withdrawal of the petition). If the conciliation is terminated, the case may return to out-of-court negotiations, or a party may file a lawsuit or request a preliminary injunction. If the parties reach agreement during conciliation, and the agreement is recorded, this record will have the same effect as a judicial settlement.²⁷¹

If a lawsuit is filed in relation to the same claim as a terminated conciliation, judges of any of the IP divisions other than the division of the judge who served as a member of the conciliation committee will conduct the lawsuit proceedings.

266 Patent Act, art. 105-2-11.

267 See Section 7.3 for information on the role of conciliators in the Tokyo District Court and the Osaka District Court.

268 Minji chōteihō (Civil Conciliation Act), Act No. 222 of June 9, 1951, art. 3(1) (Civil Conciliation Act).

269 Osaka District Court, *Explanation of the New IP Conciliation at the Osaka District Court*, Intellectual Property High Court (Sep. 1, 2019), www.ip.courts.go.jp/eng/vc-files/eng/file/Explanation_of_the_New_IP_Conciliation_at_the_Osaka_District_Court.pdf; Osaka District Court, *Guidelines for IP Conciliation Proceedings at the Osaka District Court*, Intellectual Property High Court (Sep. 1, 2019), www.ip.courts.go.jp/eng/vc-files/eng/file/Guidelines_for_IP_Conciliation_Proceedings_at_the_Osaka_District_Court.pdf

270 A technical advisor may also administer some matters. Civil Conciliation Act, art. 22. However, this is rare. See Section 7.3 of this chapter for further information about judicial research officials and technical advisors.

271 Civil Conciliation Act, art. 16. See above for a further discussion of settlement in the context of the two-stage district court process.

7.7 Civil remedies

This section outlines the remedies a patentee may seek when a person infringes or is found to be likely to infringe a patent right. Remedies discussed include injunctive relief, damages, measures to restore credibility and the return of unjust enrichment.

7.7.1 Injunction

A patentee may demand a person who infringes or is likely to infringe a patent right to stop or to prevent such infringement.²⁷² In other words, injunctive relief is available when a patentee can prove that the patent right is being infringed or it is highly probable that the patent right will be infringed in the future. When the patent is jointly owned, each owner has the right to seek an injunction.

The required infringement includes both direct infringement and indirect infringement – that is, the acts deemed to constitute infringement in Article 101 of the Patent Act. The acts deemed to constitute infringement do not include all acts of aiding and abetting and are limited to the acts stipulated in Article 101. Injunctive relief does not require any intention or negligence by the infringer.

The patentee may demand measures necessary for the prevention of such infringement, including the disposal of products that are infringing, as well as the removal of facilities used for the act of infringement.²⁷³ The scope of such measures must be limited to those necessary for the prevention of infringement and must always be accompanied by a demand to stop infringement.

7.7.2 Damages

The act of intentionally or negligently infringing the patent right of another person is deemed to be a tort. Accordingly, a patentee may claim damages under Article 709 of the Civil Code. The requirements for a finding of a claim for tort damages include:

1. an infringement of any right or legally protected interest;
2. an intentional or negligent act;
3. a causal relationship between (1) and (2);
4. damage; and
5. a causal relationship between (1) and (4).²⁷⁴

Article 103 of the Patent Act provides that an infringer of a patent right of another person is presumed to be negligent in the commission of the act of infringement. A person may reverse this presumption if they can prove there was no negligence. However, it is quite rare that the court finds that an infringer was not negligent. For example, relying on an outside counsel's opinion erroneously concluding non-infringement or invalidity is not enough to prove there was no negligence.²⁷⁵

Given the complexity in proving patent infringement and resulting damage, once a patentee proves that damage has occurred, the Patent Act sets out a number of presumptions for the calculation of damages. Amounts for damages can only be compensatory. Japanese courts do not award punitive damages.²⁷⁶ Article 102 sets out three formulas to calculate the amount of compensatory damages: lost profits, infringer's profits and reasonable royalty.

7.7.2.1 Lost profits

Article 102(1) provides that, if an infringer assigned products that constitute the act of infringement, the amount of damages may be presumed to be the total of the following two amounts:

- (i) the amount of profit per unit of the product(s) which *would have been sold* by the patentee [...] if there had been no infringement, multiplied by the portion not

²⁷² Patent Act, art. 100(1).

²⁷³ Patent Act, art. 100(2).

²⁷⁴ Civil Code, art. 709.

²⁷⁵ Osaka Chihō Saibansho (Osaka Dist. Ct) Oct. 30, 1984, no. 263 Hanta 543 (wa).

²⁷⁶ A court may award attorney fees, but the amount would usually be limited to approximately 10 percent of the damage.

- exceeding the quantity (minus any quantity of products, circumstances due to which the patentee would have been unable to sell ("specified quantity")) proportionate to the ability of the patentee [...] to work the products ("working equivalent quantity") within the quantity of products assigned by the infringer ("assigned quantity"); [and]
- (ii) the amount equivalent to the amount of money to be received *for the working of the patented invention* relating to the patent right [...] according to the quantity in the case where there is a quantity that exceeds the working equivalent quantity within the assigned quantity, or a specified quantity (except when the patentee [...] would have been able to establish an exclusive license or grant a non-exclusive license on the patent right [...]). (emphasis added)

Article 102(1) had originally only included the lost profit formula set out in Article 102(1)(i) above. However, in a case where a patentee does not have the ability to work the products within the quantity of products assigned by an infringer, the patentee would not be able to recover damages in relation to that quantity. The infringer could thus enjoy the profit of such quantity. Such a situation was regarded as undesirable from the perspective of protecting patents by awarding reasonable compensation. Therefore, the provision was amended in 2019 (and came into force on April 1, 2020) to include Article 102(1)(ii), which effectively enables a patentee to claim lost profits for any infringing sales up to the patentee's production capacity, and a reasonable royalty for any remaining infringing sales (see Section 7.7.2.3).

A Grand Panel of the IP High Court has clarified certain key terminology of Article 102(1)(i):

- The "product(s) which would have been sold by the patentee if there had been no infringement" only needs to be a product of the patentee whose sales were affected by the infringement – that is, a product of the patentee having a competitive relationship with the infringing product in the market.
- The "amount of profit per unit" is an amount of marginal profit obtained by deducting the cost additionally required in direct relation with the manufacture and sales of the aforementioned product for the patentee from the sales of the product of the patentee, and the burden of proof resides with the patentee.
- Even if the patented invention is characterized only in a part of the patentee's product that worked the patented invention, it is factually presumed that the total amount of the marginal profit obtained by the sales of the patentee's product is the lost profit of the patentee. However, in circumstances where the portion of a product that is attractive to customers cannot be considered to contribute to all the profit earned by sales of the product by the patentee, the contribution rate may be reduced and deducted from the marginal profit.
- The "ability (of the patentee) to work" by supplying the product that embodies the invention only needs to be a potential ability. If the patentee is able to supply the quantity of the patentee's product corresponding to the sales quantity of the infringing product by means such as outsourcing its production, it is reasonable to construe that the patentee has the capability to work the invention. The burden of proof for showing such potential ability resides with the patentee.
- The "circumstances due to which the patentee would have been unable to sell" prescribed in the provision to Article 102(1) of the Patent Act refers to circumstances that rebut a reasonable causal relationship between the infringement and the decrease in sales of the patentee's product, and circumstances such as (i) the presence of differences in the business models or prices between the patentee and the infringer (difference of the subject market); (ii) the presence of competitive products in the market; (iii) the marketing efforts of the infringer (brand power and promotion activities); and (iv) the presence of differences in performance of the infringing product and the patentee's product (functions, design and other features different from those of the patented invention). The burden of proof to demonstrate such aforementioned circumstances resides with the infringer.²⁷⁷

7.7.2.2 Infringer's profits

Article 102(2) of the Patent Act provides that, if the infringer earned profits from the act of infringement, the amount of profits earned by the infringer is presumed to constitute the amount of damage sustained by the patentee or exclusive licensee.

²⁷⁷ *Beauty Instrument Case*, Reiwa 1 (ne) no. 10003.

A Grand Panel of the IP High Court found that “there should be a presumption under the paragraph for a total amount of profit (made by the infringer)” and that the “expenses which may be deducted from the sales of infringing products in order to calculate marginal profit are only any additional costs that were necessitated in direct relation to manufacture and sales of infringing products by an infringer.”²⁷⁸

Furthermore, the IP High Court has indicated that the following circumstances could either “rebut a reasonable causal relationship between profit gained by the infringer and damage caused to the patentee” or overturn the presumption:

- the presence of differences in the business models between the patentee and the infringer (difference of the subject market);
- presence of competitive products in the market;
- marketing efforts of the infringer (brand power and promotion activities);
- the performance of infringing products (functions, design and other features different from those of the patented invention); and
- when “a patented invention is implemented for only a part of the infringing products.”²⁷⁹

7.7.2.3 Reasonable royalty

Article 102(3) of the Patent Act provides that a patentee may claim compensation for damage sustained as a result of a negligent infringement of a patent, by regarding the amount the patentee would have been entitled to receive for the working of the patented invention, that is, an amount equal to a hypothetical reasonable royalty, as the amount of damage sustained.

A Grand Panel of the IP High Court held that a reasonable royalty rate for an infringement should be determined by taking into account a number of circumstances such as:

- the royalty rate set in license agreements for the patented invention, or if there are no license agreements, a comparable royalty rate in the industry;
- the value of the patent, that is, the technical contribution or significance of the patented invention, and whether it may be substituted with alternative technology;
- contributions to sales and profit when the patented invention is used for products, and the manner of the infringement; and
- the competitive relationship between a patentee and an infringer, as well as the business policy of the patentee.²⁸⁰

7.7.2.4 Matters the court may take into consideration

Article 102(4), which was amended in 2019,²⁸¹ provides that, when a court is determining a reasonable royalty as provided for in Article 102(1) and (3), the court “may take into consideration compensation which the patentee would obtain if the patentee agreed on the compensation of the working of the patented invention relating to the patent right with the infringer on the premise that the patent right had been infringed.”

In both of the Grand Panel cases cited in the two previous sections, the IP High Court used a framework that allowed the amount of damages to be reduced in two steps by taking into account:

- the degree of contribution of the patent to the infringing product's value; and
- other circumstances, in relation to both Article 102(1) and (2).

Under Article 102(5), when an infringer has infringed a patent right without intention or gross negligence, the court may also take these circumstances into consideration when determining the amount of damages. Further, a patentee may claim attorney's fees as damages under Article 709 of the Civil Code.

²⁷⁸ Chiteki Zaisan Kōtō Saibansho (Intellectual Prop. High Ct) June 7, 2019, Hei 30 (ne) no. 10063, Chizai kōsai web at 33. An unofficial English translation of this judgment is available via the *IP High Court* website at www.ip.courts.go.jp/app/files/hanrei_en/472/002472.pdf

²⁷⁹ Chiteki Zaisan Kōtō Saibansho (Intellectual Prop. High Ct) June 7, 2019, Hei 30 (ne) no. 10063.

²⁸⁰ Chiteki Zaisan Kōtō Saibansho (Intellectual Prop. High Ct) June 7, 2019, Hei 30 (ne) no. 10063.

²⁸¹ Tokkyohō no Ichibu wo Kaisei suru Hōritsu (Act to Partially Amend the Patent Act and Other Acts), Act No. 3 on May 17, 2019.

7.7.3 Other remedies

7.7.3.1 Measures to restore credibility

Article 106 of the Patent Act provides that, on the request of a patentee, the court may order the person(s) who harmed the business credibility of the patentee by intentionally or negligently infringing the patent right to take measures necessary to restore the business credibility of the patentee in lieu of or in addition to compensation for damages. However, the court rarely grants such requests.²⁸²

7.7.3.2 Return of unjust enrichment

A patentee may claim the return of unjust enrichment under civil law against a person who has “benefited” from the patentee’s patent right “without legal cause” and “thereby caused loss” to the patentee.²⁸³ For example, when a person works a patented invention without obtaining a license, the patentee may claim the return of an amount equivalent to a hypothetical license fee. A patentee typically claims unjust enrichment when the three-year statute of limitations has run against a claim for damages.²⁸⁴

7.8 Appellate review

As noted in Section 7.3, Japan has adopted a three-tier court system in relation to civil matters, including those relating to patents. A party who is dissatisfied with the patent judgment of a court of first instance (the Tokyo District Court or the Osaka District Court) can appeal to the court of second instance (the IP High Court), and a party who is dissatisfied with that decision can appeal to the court of third instance (the Supreme Court). Any appeal against a patent infringement decision of the district courts is under the exclusive jurisdiction of the IP High Court.²⁸⁵

The IP High Court consists of four divisions. A panel of three judges will usually hear patent infringement cases. The IP High Court may also convene a Grand Panel of five judges for particular matters.²⁸⁶ Article 310-2 of the Code of Civil Procedure provides the following:

In the Tokyo High Court, if an appeal is filed against a final judgment that any of the courts specified in the items of Article 6, paragraph (1) enters as the court of first instance in an Action Involving a Patent Right, etc., a panel of five judges may rule for the panel to conduct a trial and reach a judicial decision on that case; provided, however, that this does not apply to a case that involves an appeal to the court of second instance, against a final judgment in an action for litigation that has been transferred pursuant to the provision of Article 20-2, paragraph (1).

When reviewing district court decisions, the IP High Court may consider both factual and legal issues. The IP High Court’s patent infringement lawsuit process is carried out in accordance with the Code of Civil Procedure and the special provisions of the Patent Act outlined above. The IP High Court will generally focus on the judgment rendered by the district court and the grounds of the appeal, but the court may review all the evidence already submitted by the parties in the district court and new evidence submitted (subject to certain restrictions) by the appellant and respondent in the appeal court process.

The IP High Court renders a judgment revoking the judgment of the district courts or dismissing the appeal after examining the fact-finding and the application of law by the judgment of the district courts. A dissatisfied party may file a final appeal or a petition for the acceptance of a final appeal with the Supreme Court on a question of law against the judgment of the IP High Court.²⁸⁷

282 There has been one decision. However, it relates to trade mark infringement (Article 106 of Patent Act applies *mutatis mutandis* to trade mark infringement. Shōhyōhō (Trade Mark Act), Act No. 127 of April 13, 1959, art. 39). In this case, the court ordered the infringer to publish an apology in a newspaper as a measure necessary to restore the business credibility of the trade mark owner. Osaka Chihō Saibansho (Osaka Dist. Ct) March 11, 2008, no. 1288 Hanta 242 (*Daks Simpson Group Public Limited Company v. Steilar C. K. M. Co. Ltd.*).

283 Civil Code, art. 703.

284 The statute of limitations is counted from the time when the patentee becomes aware of the infringement.

285 Code of Civil Procedure, art. 6(3); Act for Establishment of the IP High Court, art. 2(1).

286 Code of Civil Procedure, art. 310-2. See Section 7.3 for further information on the Special Division (Grand Panel) of the IP High Court.

287 Code of Civil Procedure, arts 285, 313. See Section 7.3 for further information on the Supreme Court.

7.9 Border measures

A patentee may commence customs proceedings in relation to the importation of allegedly infringing products. When a patentee files a petition for cessation of importation, the Customs office appoints three outside experts from a pool of Japanese patent law experts to decide whether to accept the petition. Requirements for acceptance are that (1) the patent has been infringed, (2) the infringement can be confirmed, (3) the infringing product can be identified at Customs, (4) the petitioner is the owner of the patent and (5) the patent is in effect. The importer is given an opportunity to present an invalidity defense as well as a non-infringement defense.

This process moves very quickly. Once a petition is accepted, it will be difficult to import an allegedly infringing product into Japan because every shipment of the product will need to go through a certification process, which takes some time. If a product is found to infringe a patent, it will be destroyed.

The speed and the potential for a harsh outcome impose significant pressure on alleged infringers. However, in contrast to International Trade Commission proceedings in the United States, the Japan Customs office will often decide to put a petition on hold if parallel court proceedings are pending.

Chapter 8

Republic of Korea

Authors:

Judge Kyuhong Lee, Sang-Wook Han, Judge Kwangnam Kim and Unjung Park

8.1 Overview of the patent system

8.1.1 Evolution of the patent system

The Patent Act states its purpose in Article 1 as being “to promote technical development by protecting and encouraging inventions and promoting their use in order to contribute to industrial growth.” It was enacted with the aim of protecting the interests of both inventors and the users of inventions.¹ With the ultimate goal of industrial growth, a balance between public and private interests has been the overarching theme in the continuous evolvement of patent law and the patent system. Patent law protects inventions that contribute to the technical development of society by compensating for the time, effort and costs incurred in their production. By contrast, inventions lacking an inventive step or otherwise falling short of the criteria for being a protectable invention are put into the public domain for everyone’s use.

A patent right is a property right and is thus protected under the general provision of the Constitution guaranteeing property rights,² as is often seen in the constitutions of other countries. In addition, Article 22(2) of the Constitution specifically sets forth that “the rights of authors, inventors, scientists, engineers and artists shall be protected by the law,” focusing on the implied notion that a patent right, as a property right, should be exercised to the degree that corresponds to its actual value and in a manner that promotes justice and fairness.³ In search of the right balance, the patent litigation system has contributed in many ways to realizing the purpose of Article 1 of the Patent Act. For example, it has worked to determine whether a specific invention is worth protecting, defined the scope of patent rights to decide what remains in the public domain and has held those who have infringed others’ patent rights liable.

The first Patent Act of the Republic of Korea was enacted on October 5, 1946, pursuant to Order No. 91 of US martial law. The 1946 Patent Act installed the Patent Bureau within the Ministry of Commerce and Industry and launched the Tribunal and the Appellate Tribunal under the Patent Bureau. The Tribunal took charge of *inter partes* cases, such as the scope of rights confirmation and invalidation cases, while the Appellate Tribunal took charge of appeals against the *inter partes* decisions of the Tribunal and of cases filed against rejections of patent applications. The decisions of the Appellate Tribunal were appealable to the Supreme Court only when statutory violations were at issue. While the Patent Act had been amended numerous times since then, and the Patent Bureau was reestablished as the Korean Intellectual Property Office (KIPO) in 1977, the patent trial system – starting with the Tribunal, leading to the Appellate Tribunal and then to the Supreme Court – survived up until the Patent Court opened.

8.1.2 Patent application trends

Figure 8.1 shows the total number of patent applications (direct and Patent Cooperation Treaty (PCT) national phase entry) filed in the Republic of Korea from 2000 to 2021.

8.2 Korean Intellectual Property Office and administrative review proceedings

8.2.1 Korean Intellectual Property Office and the Intellectual Property Trial and Appeal Board

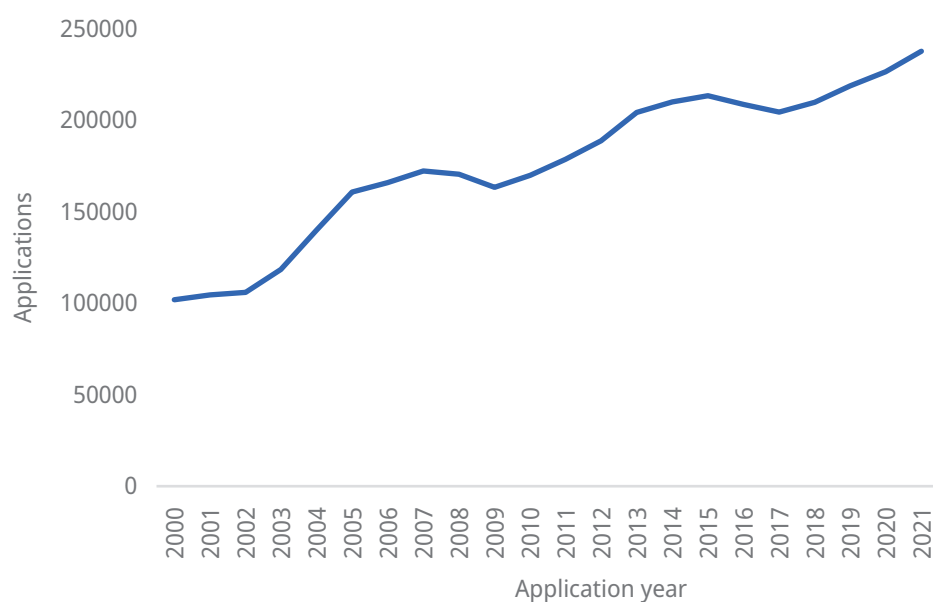
The KIPO is under the management of the Minister of Trade, Industry and Energy and is responsible for handling administrative affairs regarding patents, utility models, designs and trademarks and conducting examinations and trials thereon.⁴ It also revises laws and establishes policies relating to industrial property rights. The KIPO was initially established as the Patent Bureau on May 23, 1949, and was renamed the KIPO on March 12, 1977, along with the launch of the Tribunal and the Appellate Tribunal under its management. Subsequently, in March 1998, the Tribunal and the Appellate Tribunal were integrated into the Intellectual Property Trial and Appeal Board (IPTAB).

1 Daebeobwon (Sup. Ct), Jan. 19, 2012, 2010Da95390.

2 Daehanminkuk Hunbeob (Constitution of the Republic of Korea), art. 23.

3 Daebeobwon (Sup. Ct), Jan. 19, 2012, 2010Da95390.

4 Jeongbujojikbeob (Government Organization Act), art. 37(4).

Figure 8.1 Patent applications filed in the Republic of Korea, 2000–2021

Source: WIPO IP Statistics Data Center, available at www3.wipo.int/ipstats/index.htm?tab=patent

The IPTAB is a special administrative appeals institution established to address disputes over the creation, change, extinguishment and scope confirmation of industrial property rights (i.e., patents, utility models, designs and trademarks). It is largely responsible for trials against rejections of applications, trials to invalidate registrations and trials to confirm the scope of rights. As will be discussed later in Section 8.3.1.4, administrative appeal procedures were simplified into a single-step process with the establishment of the Patent Court and as the Tribunal and Appellate Tribunal were integrated into the newly installed IPTAB. The IPTAB has three divisions: Appeals boards, a Litigation division and a Trial Policy division. The Appeals boards handle various trials and appeals related to the rejection of applications, the invalidation and cancellation of registrations, corrections, and the confirmation of the scope of industrial property rights granted in connection with patents, utility models, designs and trademarks. Consisting of a panel of three administrative judges, each board is in charge of a specific area. The Litigation division represents the Commissioner of the KIPO in revocation suits in the Patent Court. The Trial Policy division oversees general affairs relating to the operation of the IPTAB.

8.2.2 Administrative review proceedings

There are two types of IPTAB proceedings: *ex parte* and *inter partes* proceedings. An *ex parte* case is an appeal against an examiner's decision to reject an application and involves only the petitioner. From March 2017, the IPTAB has also started hearing "patent opposition" challenges *ex parte*. In *inter partes* cases, a petitioner and a defendant dispute over a granted right. *Ex parte* and *inter partes* trial cases include the following trials:

- *ex parte* proceedings:
 - appeal against a decision to reject an application;
 - trial for correction;
 - patent opposition;
- *inter partes* proceedings:
 - trial for invalidation; and
 - trial to confirm the scope of rights.

The majority of IPTAB patent proceedings can be classified into the following categories based on their subject matter:

- appeal against a decision to reject an application – when an applicant receives a decision of rejection from an examiner, they may pursue an appeal within 30 days of the date of receipt of the certified copy of the decision (Article 132-17 of the Patent Act);
- trial for correction – a patent holder may pursue a petition for the correction of a granted patent or utility model for the reasons of narrowing a claim, correcting a clerical error, or clarifying an ambiguous description (Article 136 of the Patent Act);
- trial for invalidation – an interested party may seek a trial to retroactively invalidate the granted patent right based on statutory invalidation grounds (Article 133 of the Patent Act);
- trial to confirm the scope of rights – an interested party may seek a trial to confirm whether a technology that is being practiced or will be practiced by a third party falls within the scope of a granted patent (Article 135 of the Patent Act); and
- patent opposition – any person may request a patent opposition, within six months of the publication of the grant of the patent, to revoke the patent based on prior art (Article 132-2 of the Patent Act).

8.2.2.1 Patent trial procedures

Hearings may be held orally or in writing. Unless requested otherwise, hearings are conducted generally in writing. An oral hearing is held upon request from the parties or if the presiding administrative judge finds it necessary.⁵

A panel of three or five administrative judges hears a case and participates in deliberations to reach a conclusion by a majority vote before rendering the final decision.⁶ An applicant who is dissatisfied with the final decision of the IPTAB may appeal to the Patent Court. A Patent Court decision is appealed to the Supreme Court.

8.2.2.2 Effects of Intellectual Property Trial and Appeal Board decisions: *non bis in idem*

If an IPTAB decision on a case becomes final and conclusive, no person may demand a retrial based on the same facts or evidence. However, this requirement does not apply where the final and conclusive ruling is a rejection.⁷ The term “same facts” means certain facts that stem from the same cause with respect to the same right. Thus, although causes such as lack of novelty, inventive step or industrial usability would all result in the same outcome of patent invalidity, they all constitute separate facts. The term “same evidence” includes not only the evidence submitted before a previously confirmed IPTAB decision but also any supplementary evidence that is not compelling enough to overturn the confirmed decision. Therefore, if new evidence is submitted, but it is compelling enough to overturn the confirmed decision, it is not in breach of the *non bis in idem* principle.⁸

8.2.2.3 Relationship between revocation suits and administrative patent trials

Litigation for the revocation of an IPTAB decision is a judicial process carried out by the Patent Court under the judicial branch of the government prioritizing the adversarial system and the principle of pleadings that the parties are responsible for making arguments and submitting materials for the court to consider to reach its conclusion. Administrative patent trials are administrative appeal procedures handled by the IPTAB under the executive branch of the government and operate under the inquisitorial system. In this regard, revocation suits and administrative trials are fundamentally different.⁹

An IPTAB trial has some similarities to a (judicial) appellate proceeding in that an IPTAB decision is the subject matter of a revocation suit, as a district court decision is the subject matter of an appeal. However, it should be noted that IPTAB trials are fundamentally different from appellate trials in general due to the aforementioned aspect. They are not linked to each other in terms of instance, such as the courts of the first and second instance. This means that arguments or materials presented in an IPTAB trial cannot be automatically treated as presented in a revocation suit in a court because the latter requires arguments and materials to be newly presented or submitted for the court to consider them.

⁵ Teukheobeob (Patent Act), art. 154(1).

⁶ Patent Act, art. 146.

⁷ Patent Act, art. 163.

⁸ Daebeobwon (Sup. Ct), March 11, 2005, 2004Hu42.

⁹ IP Litigation Research Committee of the Patent Court of Korea, *Intellectual Property Law Theory and Practice* 14 (4th ed. 2019) [hereinafter IP Litigation Research Committee, *Intellectual Property Law Theory and Practice*].

8.3 Judicial institutions

8.3.1 Judicial administration

8.3.1.1 Overview of Korean courts

The Republic of Korea has a three-level court system consisting of district courts, high courts and the Supreme Court. By type, there is the Supreme Court, high courts, district courts, the Patent Court, family courts, the administrative court and the bankruptcy court. Among the courts exercising specialized functions, the Patent Court is at the level of the high courts, while the family, administrative and bankruptcy courts are at the level of district courts. By level and region, courts are classified as follows: the Supreme Court is the court of last resort, located in Seoul; high courts handle appeals filed against judgments rendered by panels of district courts and are located in the six major cities, Seoul, Daejeon, Daegu, Busan, Gwangju and Suwon; and there are 18 district courts across the country, which hear cases of first instance (by a single judge or a panel) as well as appeals filed against decisions rendered by single judges. District courts may have branch courts within their respective jurisdictions. There are currently 42 branch courts nationwide.¹⁰

Each trial is presided over by either a single judge or a panel of three judges. The judicial power of a high court, the Patent Court or an administrative court must be exercised by a panel of three judges (Article 7(3) of the Court Organization Act). The judicial power of a district court, family court or bankruptcy court is exercised by a single judge by default. However, certain district court cases are adjudicated by three-judge panels: any civil case where the value of the subject of the lawsuit exceeds KRW 500 million and any criminal case subject to capital punishment or imprisonment, with or without labor, for an indefinite term or for not less than one year in the short term (Article 32(1) of the Court Organization Act; such cases are referred to as “civil panel cases” and “criminal panel cases,” respectively).

Every court case in the Republic of Korea is presided by a judge, and no jury trial system is in place. Some criminal panel cases are eligible for public participation upon the request of the parties.¹¹ However, a public participation trial is different from a jury trial under Anglo-American laws in that the verdict and sentencing opinions that the jurors may offer in a public participation trial do not bind the court.¹² As explained later in Section 8.9.2.2., all criminal patent cases are single-judge cases and, therefore, not eligible for public participation. Figure 8.2 shows the judicial structure of the Republic of Korea.

8.3.1.2 Types of patent cases

Patent lawsuits are broadly classified into civil, administrative and criminal lawsuits. Civil patent lawsuits are further divided into cases on the merits and preliminary injunction cases. Merits cases involve infringement;¹³ the transfer, grant or extinguishment of patent rights; compensation for employee inventions; royalty payments; and so on. Administrative patent lawsuits are generally cases seeking the revocation of IPTAB decisions such as decisions upholding the examiner's rejection to grant a patent or decisions ruling that a patent is invalid. Criminal patent lawsuits involve the acts punishable under Chapter XII of the Patent Act.¹⁴

8.3.1.3 Enforcement of concentrated jurisdiction over patent cases

Until 2015, the Patent Court had exclusive jurisdiction only over cases seeking the revocation of IPTAB decisions. Civil patent cases, such as infringement suits, like any other civil cases, were heard by district courts nationwide in the first instance and then appealed to the high courts or to the appellate divisions of district courts.¹⁵ This bifurcated system sent revocation cases for rejections and invalidations to the Patent Court and sent infringement and other civil cases to general civil courts. This two-track framework left room for contradictory outcomes in the Patent

10 For an organizational chart of the judiciary, see <https://eng.scourt.go.kr/eng/judiciary/organization/organizational.jsp>

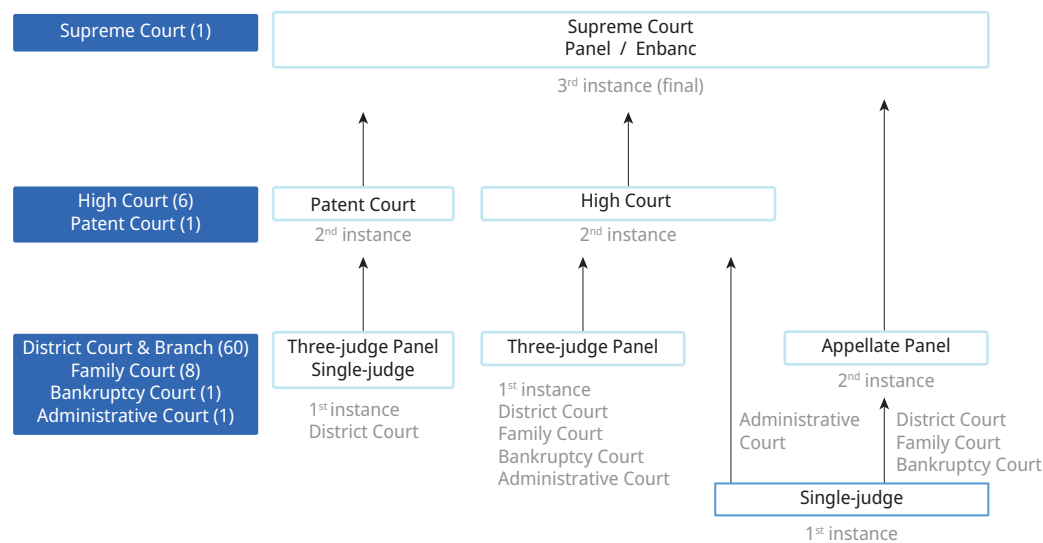
11 Gugminui Hyeongsajapan Chamyoe Gwanhan Beobryul (Act on Citizen Participation in Criminal Trials), art. 5(1).

12 Act on Citizen Participation in Criminal Trials, art. 46(5).

13 Typical examples are claims for permanent injunction, claims for compensatory damages and claims for reinstatement of the reputation of patentees (Articles 126, 128 and 131 of the Patent Act, respectively).

14 A typical example is the offense of patent right infringement (Article 225 of the Patent Act).

15 International Intellectual Property Law Research Center, *Comparative Research on Exclusive Jurisdiction over IP Litigation* 6 (2019) [hereinafter International Intellectual Property Law Research Center, *Comparative Research on Exclusive Jurisdiction*].

Figure 8.2 Judicial structure of the Republic of Korea

Source: Prepared by authors.

Court and general civil courts over the same patent. A civil court's attempt to wait for the disposition of the IPTAB on invalidation or of the Patent Court on revocation to prevent inconsistency often led to prolonged dispute resolution.¹⁶

In response, the Court Organization Act and Civil Procedure Act were amended to enforce a concentrated jurisdiction system, effective from January 1, 2016, with the original jurisdiction of civil patent cases limited to a number of civil courts, and appeals in patent infringement suits under the exclusive jurisdiction of the Patent Court. District courts located where the high courts were seated were conferred with original and exclusive jurisdiction of civil actions in the first instance concerning patent, utility model, design, trademark and plant variety rights [hereinafter, "patent and other listed IP rights"], with the Seoul Central District Court having concurrent jurisdiction. As for appellate jurisdiction, the exclusive jurisdiction of the Patent Court was enlarged and now covered all civil appeals concerning patent and other listed IP rights, in addition to lawsuits seeking the revocation of IPTAB decisions. Figure 8.3 summarizes the current intellectual property (IP) jurisdiction in the Republic of Korea.

8.3.1.4 The Patent Court

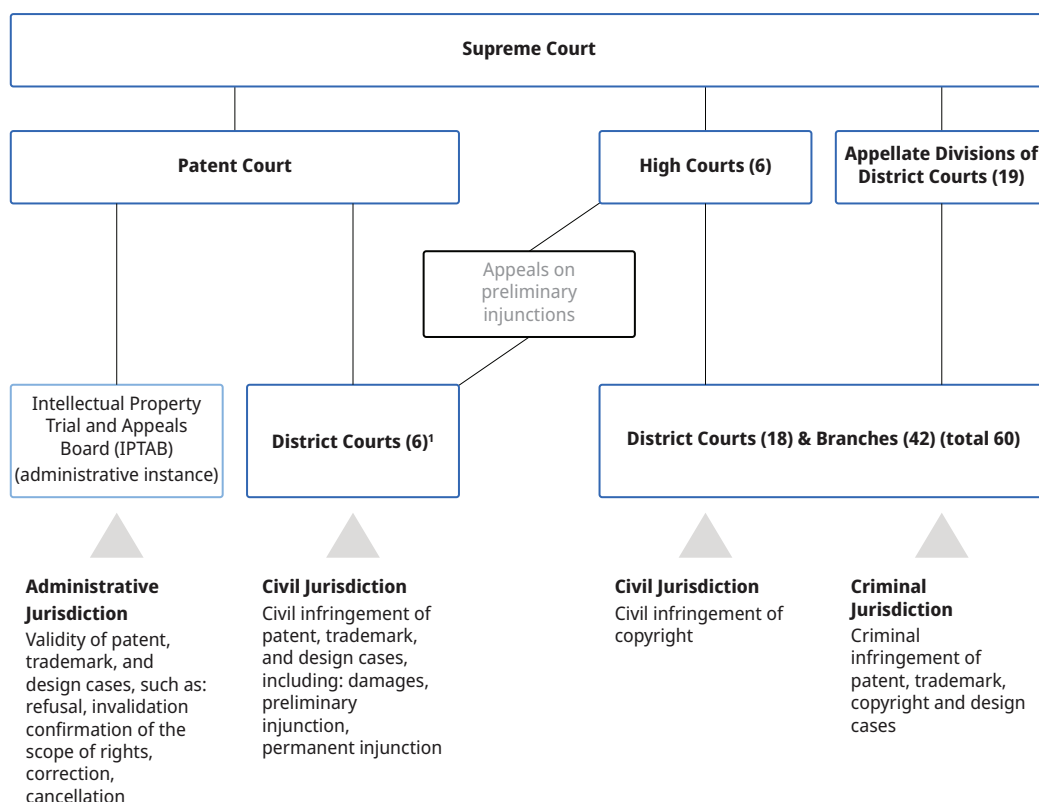
The Patent Court opened on March 1, 1998, as a specialized court at the high court level, having jurisdiction over the entire country. Article 186(1) of the old Patent Act (prior to its amendment on January 5, 1995, under Law No. 4892) provided that, with regard to administrative patent suits (e.g., a revocation action against government agency decisions upon quasi-judicial trials), a party served with a decision of the Appellate Tribunal could appeal to the Supreme Court only on the ground that the decision was in violation of statute. This framework faced criticism for infringing upon the basic constitutional right of a person to trial by a judge.¹⁷ In response, the Supreme Court requested the Constitutional Court, on August 25, 1993, to find the above provision unconstitutional. The Constitutional Court consequently ruled it inconsistent with the Constitution.¹⁸

To implement the ruling, the Court Organization Act was amended to incorporate the two-step administrative trial process of the Tribunal and the Appellate Tribunal into one before the newly installed IPTAB. As for the judicial branch, the Patent Court was established at the high court level. Under this new system, lawsuits in objection to IPTAB decisions fell under the

16 International Intellectual Property Law Research Center, *Comparative Research on Exclusive Jurisdiction*, at 8.

17 Constitution, art. 27(1) ("All citizens shall have the right to be tried in conformity with the law by judges qualified under the Constitution and the law").

18 Hunbeobjaepanso (Const. Ct), Sep. 28, 1995, 92HeonGa11.

Figure 8.3 Judicial administration structure for IP disputes in the Republic of Korea

¹ District Courts with exclusive jurisdiction: Daejeon, Busan, Daegu, Gwangju, Suwon and Seoul Central (concurrent jurisdiction). Source: Judicial Administration Structure for IP Disputes provided by the International IP Law Research Center of the Patent Court, available at www.wipo.int/wipolex/en/judgments/j-admin/kr.html

exclusive jurisdiction of the Patent Court, and appeals from the Patent Court went to the Supreme Court, allowing for the full adjudication of the factual and legal issues by the judiciary.¹⁹

The Patent Court first opened in Seoul but relocated on March 1, 2000, to Daejeon, the home of the KIPO and the Daedeok Science Town, where government-funded research institutes and laboratories of private companies, as well as educational institutions, such as the Korea Advanced Institute of Science and Technology, were concentrated.²⁰ The court shared a building with the Daejeon High Court and the Daejeon District Court at the time of the relocation but later moved to the current Patent Court building on September 1, 2003, in response to the constant rise in the number of IP disputes, preparing itself for broader jurisdiction, more cases and more judges.

The Patent Court consists of the Chief Judge, judges, judicial technical examiners, judicial technical researchers, the International Intellectual Property Law Research Center and the Administration Bureau. The Chief Judge is in charge of the overall management of judicial administrative affairs, leading and supervising court officials, and serves as the presiding judge for trials of the special division.

The Patent Court currently has five general divisions, each consisting of three judges. Cases are randomly assigned to one of the five divisions. However, a special division may be formed – consisting of the Chief Judge and two judges from general divisions – to preside over certain cases: cases that could possibly become important precedent or call for further research, cases that carry great weight and are thus expected to significantly influence society, and cases that lack sufficient precedents for reference but with those of a similar nature pending in several

¹⁹ IP Litigation Research Committee, *Intellectual Property Law Theory and Practice*, at 3.

²⁰ Woosoo Kim et al., *Reflection on the Past 20 Years and Future of Patent Court* (2018), at 5-6.

divisions. A case meeting any of these criteria in a general division may be reallocated to the special division.²¹

Judicial technical examiners and judicial technical researchers provide support for adjudication, focusing on technical issues in the cases assigned to them based on their respective fields of technical expertise. Their roles and responsibilities are explained in greater detail in Section 8.6.7.6.2.

The International Intellectual Property Law Research Center consists of judicial researchers (judges) and nonjudge, full-time researchers. It conducts long-term research projects on major subjects that call for comparative studies as well as ad hoc projects for specific issues in ongoing cases. It also takes charge of the court's international exchanges and cooperation.

8.3.2 Specialized intellectual property judiciary

8.3.2.1 Specialized patent courts and divisions

In relation to patent trials, the Republic of Korea operates both a specialized court system and a specialized division system. As discussed in Section 8.3.1.4, the Patent Court serves as the specialized patent court of the Republic of Korea. It is at the level of a high court and has jurisdiction over the entire country, exercising exclusive jurisdiction over civil appeals and revocation cases.²²

The six district courts that came to have jurisdiction over first-instance civil patent cases after the enforcement of the jurisdictional concentration – namely the Seoul Central District Court, Daejeon District Court, Daegu District Court, Busan District Court, Gwangju District Court and Suwon District Court – all have specialized IP divisions. Preliminary injunctions go to the IP divisions in the case of the Seoul Central District Court, whereas a separate division for preservative dispositions is in charge of preliminary injunctions in the five other district courts.²³ For criminal patent cases, there is no separate specialized court or division.

To summarize by case type, civil patent cases are heard by the specialized divisions in the district courts in the first instance and by the specialized court (Patent Court) in the second instance. Administrative patent cases, or revocation cases, go to the Patent Court. In the case of criminal patent cases, no particular specialized court or division is in charge.

8.3.2.2 International divisions

More and more foreign parties are litigating their patent cases in the Republic of Korea. Comprising a third of all patent cases, such cases created a need for better language access for foreign parties. In response, the Patent Court and the Seoul Central District Court established International divisions to handle certain IP cases with the goal of providing equal judicial access to all parties, effective as of June 13, 2018 (Article 62-2 of the Court Organization Act). As a result, parties can now make oral arguments or submit documents in a foreign language in these courts if permission is given to handle the case as an “international case.”

A case may be handled as an international case when a party to the lawsuit is a foreigner or a foreign company, there is a need to examine material evidence in a foreign language, or there are other circumstances that make the case “international” in nature.²⁴ Consent of the adverse party is required. The court may also refuse to permit to proceed as an international case if significant delay is expected.²⁵ Application and consent are made in writing before the first trial date, either in the Seoul Central District Court or in the Patent Court, barring exceptional circumstances.²⁶ The effect of the permission is limited to the level of the court.²⁷

21 Patent Court Bylaws on Case Assignment, art. 6.

22 In addition to patent cases, the Patent Court has exclusive jurisdiction over revocation cases and civil appeals relating to trademark and design rights. However, it does not have exclusive jurisdiction over copyright cases, meaning that a civil appeal in a copyright case will go to one of the high courts or the appellate division of a district court.

23 Courts generally have a division exclusively responsible for preservative dispositions, such as provisional attachment and garnishment. In the case of the Seoul Central District Court, which takes many patent cases for preservative disposition, an IP division is reserved for preservative dispositions for patents (60th Civil Division). Preservative dispositions for patents are handled by the division in charge of general civil cases in other courts.

24 Supreme Court Regulations on Establishment and Operation of the International Division, art. 5 (Supreme Court Regulations).

25 Supreme Court Regulations, art. 5.

26 Supreme Court Regulations, art. 6.

27 Supreme Court Regulations, art. 7.

In an international case, parties may make oral arguments in a permitted foreign language or file briefs or exhibits in the foreign language without translation.²⁸ Interpretation is provided by the court on the trial date.²⁹ Due to practical considerations regarding actual demands, the permitted foreign language is currently limited to English under the current Supreme Court regulations, but other languages may also be permitted upon petition by the party.³⁰ Decisions are rendered in Korean, and the decision in Korean is the basis for calculating the appeal period or the effect of the judgment.³¹ Parties will be given a translation of the decision in the foreign language after the service of the authentic copy of the decision.³² In case of an appeal, the notice of appeal may be filed in the permitted foreign language.³³

8.3.2.3 Specialized patent judges

Korean judges rotate between courts. Most judges are assigned to different courts every three to four years and to different roles every one to two years. There are no express requirements to qualify as a judge in the specialized court or division. However, it is understood that securing specialized judges is crucial for the efficient and fair management of patent cases. The Patent Court has thus worked to bring in judges who have majored in science, engineering or IP; judges who have exclusively handled IP matters in other courts; or judges who have served as attorneys or patent attorneys in the field for many years. In addition, it has been making progressive efforts to secure them for longer periods. The term of service of patent court judges tends to be longer than that of general courts.

8.3.3 Judicial education on intellectual property

The Judicial Research and Training Institute offers an annual IP Litigation Training Program for judges who are handling patent cases for the first time and provides an Advanced IP Litigation Training Program every two years on particularly interesting subjects in IP practice. In addition, judges dealing with patent cases also actively share their academic and practical insights through an online community of the judges currently working on or interested in patent cases, practice research committees in the Patent Court, and joint seminars between the Patent Court and the Seoul Central District Court.

8.4 Patent invalidity

8.4.1 Revocation cases

Revocation actions refer to those seeking judicial review and subsequent revocation of IPTAB decisions. The IPTAB decides on the invalidity of patent registration, confirms the scope of patent rights and reviews the examiners' rejections of patent applications. Given that IPTAB decisions are administrative dispositions and that revocation actions are administrative lawsuits filed to contest such dispositions, the Administrative Procedure Act is applicable to revocation actions, and the Civil Procedure Act also applies *mutatis mutandis* to those actions pursuant to Article 8(2) of the Administrative Procedure Act.³⁴

8.4.1.1 Territorial jurisdiction

While Article 8(1) of the Administrative Procedure Act stipulates that "[e]xcept as otherwise provided for in other Acts, administrative suits shall be governed by this Act," Article 186(1) of the Patent Act sets forth that the Patent Court has exclusive jurisdiction over revocation actions.³⁵ Revocation actions were the only type of cases that fell under the exclusive jurisdiction of the Patent Court before the jurisdictional concentration.

28 Supreme Court Regulations, art. 12.

29 Supreme Court Regulations, art. 11.

30 Supreme Court Regulations, art. 9.

31 Supreme Court Regulations, art. 16.

32 Supreme Court Regulations, art. 17.

33 Supreme Court Regulations, art. 18.

34 Daebeobwon (Sup. Ct), Sep. 13, 2012, 2012KaHeo15.

35 The court of first instance in revocation actions, among all other administrative actions in general, must be an "administrative court having jurisdiction over the location of the defendant." Where a revocation action is filed against a defendant who is a central administrative agency or its head, it may be instituted with an administrative court having jurisdiction over the location of the Supreme Court. Haengjeongsosongbeob (Administrative Litigation Act), art. 9.

8.4.1.2 Jurisdiction by court level

The Patent Court's decision on a revocation case may be appealed to the Supreme Court (Article 186(8) of the Patent Act). In the Patent Act and other applicable laws, there is no special provision regarding the appeal procedure, so the procedures in general civil actions apply *mutatis mutandis* to the appeals in revocation cases (Article 8(2) of the Administrative Procedure Act).

8.4.2 Administrative patent lawsuits

Administrative litigation, as a type of judicial process, is a procedure wherein a court judges a dispute over legal relations under public law. Administrative litigation associated with patents is classified into (i) legal proceedings seeking the revocation of decisions rendered by the IPTAB as prescribed in Article 186 of the Patent Act, (ii) administrative lawsuits against administrative dispositions (other than the IPTAB decisions) imposed by the government or the Commissioner of the KIPO,³⁶ and (iii) legal proceedings against IPTAB decisions, rulings or adjudications on compensation or considerations prescribed in Article 190 of the Patent Act.³⁷ For administrative litigation falling under the first category, the Patent Court has exclusive jurisdiction. For administrative litigation falling under the second and third categories, the administrative court with jurisdiction over the location of the defendant's administrative agency, or the Seoul Administrative Court, has jurisdiction pursuant to Article 9 of the Administrative Litigation Act. Accordingly, legal proceedings against dispositions of the Korea Trade Commission, which serves the equivalent role as the United States International Trade Commission, should also be filed with the Seoul Administrative Court or any other competent court, not with the Patent Court. Administrative litigation falling under the first category always requires the IPTAB's decision before lodging a lawsuit with the Patent Court.³⁸ However, administrative litigation falling under the other two categories may be instituted without going through the adjudication process.³⁹

Among the three types of administrative litigation concerning patents, legal proceedings falling under the first category – namely, litigation for the revocation of IPTAB decisions, or revocation suits – are most frequently used to contest the invalidation of patents. Thus, in the following paragraphs, we focus only on revocation suits.

8.4.2.1 Characteristics of revocation suits and applicable laws

As explained above, litigation for the revocation of IPTAB decisions is a type of administrative litigation, filed against dispositions or omissions of an administrative agency as prescribed in Article 3(i) of the Administrative Litigation Act. The Supreme Court has ruled that appeals suits include *ex parte* cases filed against the Commissioner of the KIPO and *inter partes* cases filed against patent holders or parties interested.⁴⁰

The Patent Act is first applicable to revocation suits. For matters not prescribed in the Patent Act, the provisions of the Administrative Litigation Act apply *mutatis mutandis* because lawsuits seeking the revocation of IPTAB decisions basically have the characteristics of administrative litigation. At the same time, matters not specifically stipulated in the Administrative Litigation Act are governed by the Civil Procedure Act.⁴¹ Therefore, the litigation and evidence collection procedures explained later in Section 8.6 are also generally applicable to revocation suits.

8.4.2.2 Scope of revocation suits

For appeals suits in general, a revocation suit can only be filed against the original disposition (namely, the principle of original dispositions), with the exception of cases where the adjudication itself is legally flawed (namely, the principle of exceptional adjudication).⁴² It should be noted that the Patent Act only allows the filing of a suit against the adjudication on an administrative appeal when it comes to litigation for the revocation of IPTAB decisions.⁴³ A decision to reject a patent

36 This includes legal proceedings seeking the revocation of written rejections or the revocation of various correction recommendations pursuant to art. 203 of the Patent Act.

37 This includes legal proceedings against prohibitions on the filing of patent applications in a foreign country for inventions necessary for national defense (art. 41 of the Patent Act) and against compensation payable upon expropriation of patents (art. 106 of the Patent Act).

38 Patent Act, art. 186(6).

39 Administrative Litigation Act, art. 18(1).

40 See, e.g., Daebeobwon (Sup. Ct), May 28, 2009, 2007Hu4410.

41 Administrative Litigation Act, art. 8(2).

42 Administrative Litigation Act, art. 19(1).

43 For legal proceedings falling under the categories (ii) and (iii) in Section 8.4.2, a suit can only be lodged against the original disposition, not the adjudication thereon.

application or to allow patent registration cannot be the subject matter of a revocation suit. If the applicant opposes any such decision, they must go through the IPTAB trial process before filing a suit against the IPTAB decision. Accordingly, the plaintiff must state in the complaint that their demand is to “revoke the decision of the IPTAB rendered on [date] with respect to [administrative trial case number],” not as “[patent number] shall become null and void.”

8.4.2.3 Litigants to a revocation suit

In ordinary administrative litigation, a person with legal interests to seek revocation of a disposition has the standing to sue⁴⁴ so that the person subject to the disposition or a third party all have standing as the plaintiff. However, a revocation suit may only be instituted by a party to the IPTAB trial, an intervenor in the IPTAB trial or a person who sought to intervene in the IPTAB trial but was denied.⁴⁵

In *ex parte* revocation suits, such as those concerning an examiner’s rejection, the Commissioner of the KIPO is named as the defendant. However, in *inter partes* revocation suits seeking invalidation of patents or confirmation of the scope of patent rights, the petitioners or respondents in the IPTAB proceeding have standing as the defendant.⁴⁶ In other words, in an *inter partes* revocation suit, the party who has received an unfavorable ruling in the *inter partes* administrative proceeding becomes the plaintiff, and the other party becomes the defendant. In a revocation suit against an IPTAB decision affirming the petitioner’s request, the petitioner is named as the defendant. If the petitioner’s request was denied at the IPTAB, the defendant in the revocation suit is the respondent in the IPTAB proceeding.

8.4.2.4 Period of filing a revocation suit

A revocation suit must be filed within 30 days from the date when a certified copy of the relevant IPTAB decision or ruling was served.⁴⁷ Any revocation suit filed after this period is considered unlawful and is dismissed.⁴⁸ The 30-day period can never be extended or shortened by the court, unlike other adjustable periods.⁴⁹ However, the presiding judge of the IPTAB may, *ex officio*, grant an additional period for the benefit of a person living in a remote area or in an area with poor access to transportation.⁵⁰ In practice, an additional period of 20 to 30 days is granted to foreigners overseas. Where the presiding judge of the IPTAB grants an additional period after the lapse of the initial 30 days, the revocation suit will still be dismissed because of the lapse of the initial period even if the application for extension had been filed with the IPTAB prior to the lapse of the initial period.⁵¹

8.4.2.5 Scope of examination in a revocation suit

According to the majority view and judicial precedent, the subject matter of a revocation suit is usually the unlawfulness of a disposition.⁵² Thus, the unlawfulness objectively present at the time of disposition, in any facet of the administrative disposition, including the procedure and elements thereof, becomes the subject matter of a revocation suit. As with other lawsuits seeking the revocation of administrative dispositions, litigation for the revocation of IPTAB decisions also goes through an examination of unlawfulness from both substantive and procedural perspectives. However, there is an issue as to whether the scope of examination in revocation suits against IPTAB decisions is limited to the grounds and evidence claimed in the IPTAB trial. There are two conflicting theories regarding this issue: the limitation theory and the nonlimitation theory.

For *inter partes* cases, the Supreme Court has upheld the nonlimitation theory on the following grounds: first, a revocation suit is classified as an appeals suit because it is filed against the IPTAB’s decision, which is an administrative disposition; therefore, the subject matter of the revocation suit is substantive or procedural unlawfulness in the decision; second, the litigant may

44 Administrative Litigation Act, art. 12.

45 Patent Act, art. 154(1).

46 Patent Act, art. 187.

47 Patent Act, art. 186(3).

48 When it is clear that the period for filing a lawsuit has lapsed, the court may reject the relevant lawsuit without designating a date for hearing – in accordance with art. 8(2) of the Administrative Litigation Act and art. 219 of the Civil Procedure Act – by finding that the lawsuit is unjustifiable and has defects that are not rectifiable.

49 Patent Act, art. 186(4).

50 Patent Act, art. 186(5).

51 Teukheobeobwon (Pat. Ct), April 25, 2007, 2006Heo11572.

52 Daebeobwon (Sup. Ct) May 28, 2009, 2007Hu4410.

argue and prove, in the process of the revocation suit, the reasons for the unlawfulness of the decision even if it did not rule on such reasons, and the court presiding the revocation suit may examine and judge on such reasons and take them as the basis for its decision unless there are special circumstances not to do so.⁵³

For *ex parte* cases, an administrative agency's disposition limiting a party's right without prior notice or an opportunity to submit opinion is unlawful and shall be revoked unless an exception applies, according to the Supreme Court.⁵⁴ The Supreme Court has taken the same position in patent rejection cases. In a suit seeking revocation of an IPTAB decision upholding a patent rejection, it held that the Commissioner of the KIPO may not raise a new ground of rejection that was not raised before the examiner or the IPTAB because the plaintiff was not given an opportunity to submit opinion disputing the new ground.⁵⁵ Nonetheless, this limitation is only applicable to the Commissioner of the KIPO (the defendant) and not to the patent applicant (the plaintiff). In light of the foregoing, the Supreme Court's decision is generally viewed as having intended to protect the procedural rights of the applicant rather than having been based on the limitation theory.

Further, if the Commissioner of the KIPO claims new grounds in a revocation suit in line with the essence of the grounds for rejection and for which the applicant was given an opportunity to submit their opinion in the examination or IPTAB trial phase (and are thus just supplementary to the already notified grounds for rejection), such grounds may be admitted and serve as the basis for judging whether the IPTAB decision should be revoked.⁵⁶

8.4.2.6 Litigation procedures for revocation suits

8.4.2.6.1 Submission of a complaint

A revocation suit is initiated when the plaintiff submits a complaint to the competent court. The plaintiff must describe the following matters on its complaint in detail.⁵⁷

- the procedural background on the IPTAB trial;
- a summary of the administrative decision (the arguments of the parties and the decision thereon by the IPTAB at the trial stage);
- parts admitted and not admitted among the grounds for the decision;
- all arguments relating to the grounds for revoking the decision;
- a notice of related cases (e.g., pending IPTAB trial or lawsuit on the same patent); and
- the plaintiff's opinion on the overall litigation proceedings, including any plan to request evidence.

Additionally, the plaintiff must be careful not to overlook the following basic evidentiary documents and requisite attachments, along with a power of attorney for litigation, a corporate register or a certificate of corporate nationality (if the party is a foreign corporation), and a certificate of service of the administrative decision.⁵⁸

- for a revocation case on rejection – the IPTAB decision, patent application, examiner's preliminary rejection, amendment, opinion and final rejection;
- for a revocation case on invalidation – the IPTAB decision, original register, publication of registration and evidence relating to prior art; and
- for a revocation case on the scope of rights – the IPTAB decision, original register, publication of registration, explanatory documents and the drawings of the invention for review in the scope of rights confirmation action.

Once a revocation suit is lodged (upon submission of a complaint), the IPTAB decision subject to the revocation is prevented from being treated as final and conclusive. For this, the Patent Court requires that the purpose of a revocation suit, or an appeal against the revocation suit, be notified to the President of the IPTAB without delay.⁵⁹

53 See, e.g., Daebeobwon (Sup. Ct), Oct. 24, 2003, 2002Hu1102.

54 Daebeobwon (Sup. Ct), Oct. 27, 2016, 2016Du41811.

55 See, e.g., Daebeobwon (Sup. Ct), Feb. 26, 2003, 2001Hu1617.

56 See, e.g., Daebeobwon (Sup. Ct), Feb. 26, 2003, 2001Hu1617.

57 Patent Court, *Practice Directions for Revocation Trial in the Patent Court of Korea*, ch. II(1)(A) [hereinafter Patent Court, *Practice Directions for Revocation Trial*].

58 Patent Court, *Practice Directions for Revocation Trial*, ch. II(1)(B).

59 Patent Act, art. 188(1).

8.4.2.6.2 Submission of answer

No later than three weeks from the service of the plaintiff's complaint or brief containing the specific cause of action, the defendant must submit an answer, including the following matters, together with evidence cited in the answer and explanatory documents for evidence:

- an answer to the plaintiff's demand;
- the parts admitted and not admitted among the plaintiff's arguments;
- detailed rebuttal arguments on the parts not admitted among the plaintiff's arguments;
- other arguments relating to the grounds necessary to maintain the decision;
- a notice of related cases;
- acceptance or denial of evidentiary documents submitted by the plaintiff; and
- the defendant's opinion on the overall litigation proceedings, including a plan to request evidence.

8.4.2.6.3 Preparatory hearing

As in a civil patent suit, once key issues of a revocation suit are specified through the presentation of written arguments between the parties, a hearing date is immediately designated, and sometimes a date for a preparatory hearing as well. Preparatory hearings are usually conducted via conference call and supervised by a presiding judge serving as a commissioned judge. The following matters are generally discussed in the course of a preparatory hearing:⁶⁰

- the dates and number of trials and the matters to be addressed in each;
- deadlines for the submission of arguments and evidence (including deadlines for the submission of comprehensive briefs and an affidavit of an expert witness, and the number of submissions and length of briefs);
- whether to request evidentiary methods requiring a substantial amount of time, such as verification, appraisal and expert witness, and the deadlines for such requests;
- whether to designate a technical advisor;
- whether to hold a technical explanatory session by the parties;
- whether to first hold a hearing for claim construction;
- how to proceed the trial if a trial for correction or petition for correction is pending;
- whether to hold a parallel hearing if relevant cases, such as invalidation, confirmation of the scope of rights and infringement, are pending; and
- confirmation and summary of disputed issues.

8.4.2.6.4 Internal technical explanatory session

Once a date for the hearing is determined in a revocation suit, an internal technical explanatory session is held before the hearing date to increase the court's understanding of technical issues. During the session, a technical examiner explains the background of relevant technology, along with other technical issues relating to the invention at issue and prior arts. Unlike civil patent cases, where internal technical explanatory sessions may be omitted because there are no technical issues, an internal technical explanatory session is held in almost all revocation suits.

8.4.2.6.5 Hearing

As in civil patent suits, during a hearing of a revocation suit, the examination of evidence, documentary evidence and so on are conducted in connection with the arguments of both parties, along with the identification and sharing of key issues, presentation of oral arguments regarding the key issues, and filing of applications by both parties for further evidence. Revocation suits often involve professional knowledge and complex issues relating to patents, so it usually takes a significant amount of time for parties to prepare their arguments. Accordingly, revocation suits are given sufficiently more time than for civil suits in general. For a civil patent case of first instance, hearings are conducted on multiple occasions, with an interval of about one month, before closing arguments. For a revocation suit, the court usually closes arguments after the first round of intensive or concentrated examination of each issue. This is because revocation suits rarely involve a dispute over relevant facts and instead focus only on the judgment of technical issues such as inventive step. Moreover, in most cases, the first hearing is often arranged as a technical explanatory session. Arguments in a revocation suit may also be presented in a foreign language so long as both parties consent and the court permits.

60 See Patent Court, *Practice Directions for Revocation Trial*, ch. III(3)(C).

8.4.2.6.6 Relationship between invalidity and infringement proceedings

The Civil Procedure Act also applies *mutatis mutandis* to revocation suits (administrative patent lawsuits), except as otherwise provided for in the Patent Act and the Administrative Litigation Act.⁶¹ Therefore, revocation suits and civil patent suits have almost the same litigation and evidence collection procedures. Moreover, patent infringement suits and revocation suits are also very similar in terms of the key issues, considering that the grounds for invalidation of a patent may also be contended in a patent infringement suit. The difference is that a patent infringement suit deals with various issues concurrently, including whether the product of the other party falls within the scope of protection of the patent at issue, whether there are grounds for invalidation of the patent, and the assessment of damages. In a revocation suit, by contrast, only some of those key issues are contested, and such suits thereby progress more quickly.⁶²

8.4.2.7 Examination in parallel with an infringement suit

Related cases with the same registration number of IP rights are, in principle, allocated to the same judicial panel. If the parties to a case are the same, and the same or similar IP rights are assigned to different judicial panels, they may be allocated to the same judicial panel through a reallocation procedure. The parties must notify the judicial panels of such circumstances if related cases are allocated to or pending before different judicial panels.⁶³

When an infringement case and a revocation case of IPTAB decision involving the same patent right are pending concurrently before the same judicial panel and are litigated by the same parties – and when the need for a parallel hearing is recognized – the court will, in principle, hold the trial on both cases in parallel.⁶⁴

8.4.2.8 Evidence collection procedures

In revocation suits, the types of evidence and the process of requesting for evidence and conducting evidence examination are similar to those in civil litigation.⁶⁵ The difference is that, in a revocation case, the court may examine evidence *ex officio* if necessary.⁶⁶ However, this does not mean that the “doctrine of *ex officio* detection of facts” is adopted for the court to collect evidence on an *ex officio* basis. The principle of pleadings remains the governing rule, and the “doctrine of *ex officio* examination of facts” is adopted to allow the court to examine evidence and acknowledge facts by its own authority to the extent that its examination is supplementary and performed on the evidence available on record.⁶⁷

8.4.2.9 Appeal

The Patent Court’s decision in a revocation case may be appealed to the Supreme Court.⁶⁸ The appeal procedure in revocation cases is the same as that of civil cases, as discussed in Section 8.8.⁶⁹

8.4.2.10 Effect of a decision revoking an Intellectual Property Trial and Appeal Board decision

Once a court decision revoking an IPTAB decision becomes final and conclusive, the revoked decision becomes void without having the need for any action to be taken by the IPTAB. Additionally, administrative judges of the IPTAB must review the case and render another decision.⁷⁰ The grounds on which revocation was rendered are binding upon the IPTAB with respect to the case.⁷¹ For example, if a patent application of the plaintiff (the applicant) was rejected, followed by the IPTAB’s ruling to dismiss the application, and subsequently the Patent Court’s decision revoking the IPTAB’s ruling became final and conclusive in a revocation suit, the patent will be registered by the following process:

61 See Section 8.4.2.1.

62 E.g., the key issue in a patent invalidation case is likely to be whether there are grounds for invalidation of the patented invention, whereas the key issue in a case seeking confirmation of the scope of protected rights will be whether the invention at issue falls within the scope of protection of the patented invention.

63 See Patent Court, *Practice Directions for Revocation Trial*, ch. IV(3)(C).

64 See Patent Court, *Practice Directions for Revocation Trial*, ch. IV(3)(A).

65 See Section 8.6.7 for more details.

66 Administrative Litigation Act, art. 26.

67 IP Litigation Research Committee, *Intellectual Property Law Theory and Practice*, at 96.

68 Patent Act, art. 186(8).

69 See Section 8.8.2 for a discussion of the Supreme Court.

70 Patent Act, art. 189(2).

71 Patent Act, art. 189(3).

1. The patent application is submitted.
2. An examiner rejects the patent application.
3. The IPTAB dismisses the applicant's appeal.
4. The Patent Court revokes the IPTAB's decision.
5. The decision is appealed to the Supreme Court, which affirms the appellate court's (the Patent Court's) revocation.
6. The IPTAB revokes the rejection of the patent application, granting the appeal pursuant to the binding force of the judicial decision.
7. The examiner grants the patent.

8.5 Patent infringement

A patentee enjoys the exclusive right to practice their patented invention for business purposes.⁷² Therefore, any person who is neither a patentee nor an exclusive licensee and who practices a patented invention for business purposes without permission from the patentee or the exclusive licensee is committing an act of infringement.

A patentee can grant exclusive license of the patent right to others⁷³ and an exclusive licensee enjoys the monopoly on the right to exploit the patented invention within the scope of the exclusive license granted by the patentee.⁷⁴ The grant of exclusive license must be registered to take effect.⁷⁵ A patentee can grant nonexclusive license as well.⁷⁶ A nonexclusive license is different from an exclusive license in that a nonexclusive licensee does not enjoy monopoly and nonexclusive licenses can be granted to multiple licensees. Registration is not needed for a nonexclusive license to be effective between the parties but is necessary to be effective against a third party.⁷⁷

Because a nonexclusive licensee does not have the power to exclude others from exploiting the patent, they may not seek damages or injunction for patent infringement. In contrast, an exclusive licensee has the power to exclude others, and can seek damages or injunction on their own as such. In case exclusive license is granted over the entire scope of the patent right, the common view is that the patentee retains the authority to file for injunction nonetheless, because the patentee has an interest in preventing infringing acts to remove obstacles in exploiting the patent right for their own purpose upon expiration of the exclusive license.⁷⁸ Meanwhile, the same does not apply to damages. The patentee may not independently seek damages arising from infringement of the patent right for which an exclusive license is granted without joining the exclusive licensee.^{79,80}

Once patent infringement is established, the patentee may seek compensation for damages against the infringer (Article 750 of the Civil Act; Article 128(1) of the Patent Act) or file a claim for restitution of unjust enrichment (Article 741 of the Civil Act). Further, they may also seek a preliminary or permanent injunction against the infringer (Article 126 of the Patent Act) or the recovery of reputation in certain circumstances (Article 131 of the Patent Act). Patent infringement may also incur criminal liability (Article 225 of the Patent Act).

To establish patent infringement, the patentee should contend and prove that they are the owner of the patent and that the defendant has practiced⁸¹ the patent, and the defendant's products or methods must be found as falling within the scope of protection of the patentee's patent right.

⁷² Patent Act, art. 94.

⁷³ Patent Act, art. 100(1).

⁷⁴ Patent Act, art. 100(2).

⁷⁵ Patent Act, art. 101.

⁷⁶ Patent Act, art. 102(1).

⁷⁷ Patent Act, art. 118(2), (3).

⁷⁸ IP Litigation Research Committee, *Intellectual Property Law Theory and Practice*, at 484, 485.

⁷⁹ Daebeobwon (Sup. Ct), Oct. 11, 2002, 2002Da33175. The case concerns trademark rights but the rationale is equally applicable to patent rights.

⁸⁰ The patentee and the exclusive licensee are hereinafter collectively referred to as the patentee in the context of the protection a right holder is entitled to. Likewise, a patent and an exclusive license are collectively referred to as the patent, unless specified otherwise.

⁸¹ The defendant's "practice" of a patent means any of the following for business purposes: (i) manufacturing, using, assigning, leasing or importing the patented product, or offering to assign or lease the product (including displaying the product for the purpose of assigning or leasing); (ii) using or offering to use the patented process; or (iii) otherwise being about to commit any of these acts.

8.5.1 Claim construction

8.5.1.1 Relationship between claims and scope of protection

The scope of protection of a patented invention is the objective scope that the effects of the patent reach and is determined by what is stated in the claims.⁸² Accordingly, the scope of protection should be determined before the issue of infringement, and such a determination involves claim construction. Claim construction is also done before deciding whether the invention at issue lacks novelty or an inventive step. It is a matter of legal decision or evaluation, not of fact-finding, and thus may not be done via confession.

8.5.1.2 Principles of claim construction

Claims state the scope of the patented invention for which the applicant seeks to receive protection. The scope of the claims must be determined based on what is stated in the claims and cannot be broadened or narrowed based on other statements (e.g., detailed descriptions or drawings). Nevertheless, reference to the descriptions or drawings of the invention is necessary to accurately understand the technical meaning of the claims. Thus, claims should be construed in an objective and reasonable manner based on contemplation of the technical meaning sought to be expressed by the wording of the claims, on the basis of the general meaning of the wording used in the claims but also in reference to the detailed description and drawings.⁸³ In other words, one should mainly look to the wording of the claims for claim construction (the principle of literal interpretation), but the descriptions or drawings of the invention, as well as the general technical knowledge at the time of filing, should also be given weight (the principle of reference to description).

Further, one may also refer to other documents containing the applicant's arguments in the prosecution history, such as specifications, amendments and written arguments presented by the applicant in the course of filing, as well as opinions presented by the KIPO examiner (the principle of reference to prosecution history). However, reference to these documents should never be used to broaden or narrow the meaning of the wordings used in the claims.

8.5.2 Infringement analysis

8.5.2.1 Comparison of the patented invention with the infringing product or process

A defendant's product or process infringes the patent only if it falls within the protected scope of the patent. In practice, the plaintiff breaks down the disputed claim into elements and compares them with the corresponding elements of the defendant's product or process. The defendant provides their answer on whether the elements are appropriately identified and compared, and the court subsequently intervenes to ensure that both parties have the same understanding of the matter. A one-to-one comparison chart is often produced to compare the elements. The elements must be as confirmed in the claim construction process.

For the defendant's product or process to fall within the scope of protection of the patented invention, every element stated in the claims, and their organic combination, must be included in the defendant's product or process. If any of the elements is missing, the defendant's product or process does not fall under the protected scope of the patented invention (all elements rule).

8.5.2.2 Literal infringement

Literal infringement is the most basic type of infringement. It is established when all of the elements and the way the elements are organically combined (as specified by a literal interpretation of the claims) are found in the defendant's product or process.

8.5.2.3 Infringement by equivalence

Infringement by equivalence is established when the elements of the defendant's product or process are not literally identical but are equivalent to the corresponding elements of the patented invention.

Infringement by equivalence has positive and negative requirements. In terms of positive requirements, (i) both inventions must have adopted the same principle to solve the problem

⁸² Patent Act, art. 97.

⁸³ See, e.g., Daebeobwon (Sup. Ct), Oct. 25, 2007, 2006Hu3625.

(identity of solution principles); (ii) in spite of any replacement, the defendant's product or process must have a substantially identical effect as the patented invention (substantial identity of effects); and (iii) the replacement must be self-evident to the extent that any person of ordinary skill in the art would have easily conceived of it (easiness of replacement). In terms of negative requirements, (iv) the defendant's product or process must not be a free-to-practice technology that is in the public domain; and (v) the replaced element in the defendant's product or process must not have been purposefully excluded from the scope of claims in the prosecution process. The patentee has the burden of proof as to the positive requirements, whereas the infringer has the burden of proof as to the negative requirements.

To determine whether the patented invention and the defendant's product or process use the same principle to solve the problem, the superficial deduction of features recited in the claims does not suffice. Instead, the essence of the technical idea underlying the solution that is unique to the patented invention, in comparison with prior arts, should be identified in reference to the detailed description of the invention along with known technologies at the time of filing and be put under substantive review.⁸⁴

8.5.2.4 Indirect infringement

In addition to direct infringement, the Patent Act regulates certain indirect acts as constructively constituting infringement. Under Article 127(1) and (2), the manufacturing, assigning, leasing, importing or offering to assign or lease a product exclusively used for manufacturing a patented product or for practicing a patented process, if done so for business purposes, are also deemed infringement.⁸⁵ The purpose of this provision is to deem acts that are yet to reach the stage of practicing all elements of the patented invention as constituting infringement under certain circumstances if it is highly plausible that such acts would lead to the practice of all elements of the patented invention. The provision thereby offers effective relief against foreseeable future infringement.⁸⁶

The patentee has the burden of proof. To prove indirect infringement, the patentee must show that the alleged good is used in practicing the patented invention (the use requirement), that the alleged good is exclusively used in practicing the patented invention (the exclusivity requirement) and that the alleged good is made for business purposes.

8.5.3 Defenses

When the patentee argues and proves all required elements to show infringement under each claim for injunction or damages and so on, the defendant should contend and prove contradicting facts to defeat the claim. The means of defense available to the defendant are classified into "denials,"⁸⁷ for which the burden of proof lies with the plaintiff, and "defenses," for which the burden of proof is on the defendant. The following sections focus on defenses.

The accused patent infringer denying infringement must disclose the product or process actually used. Under the amended Patent Act, the defendant denying infringement in spite of a *prima facie* showing by the plaintiff that the defendant is using the patented product or process must provide details regarding the product or process the defendant is actually using. If the defendant refuses to provide such details without adequate justification, the court may presume that the defendant actually committed the infringing act as claimed by the plaintiff.⁸⁸

8.5.3.1 Abuse of rights

Whether the issue of inventive step of a patented invention can be examined and determined in an infringement case was subject to dispute until a Supreme Court decision in 2012. Ruling *en banc* in its 2010Da95390 decision on January 19, 2012, the Supreme Court expressly upheld the so-called defense of abuse of rights, forbidding the exercise of patent rights in an infringement suit when the patented invention lacks an inventive step, stating that

84 See, e.g., Daebeobwon (Sup. Ct), Jan. 31, 2019, 2017Hu424.

85 Patent Act, art. 127.

86 See, e.g., Daebeobwon (Sup. Ct), July 23, 2015, 2014Da42110.

87 E.g., denial is a defendant's argument that the plaintiff's patent right does not exist or that the defendant's implementation of the disputed technology does not fall within the scope of the plaintiff's patent right. Likewise, a refutation against the plaintiff's argument on infringement by equivalence also constitutes denial.

88 Patent Act, art. 126-2.

Even before when the administrative decision invalidating the patent is finalized, claims for damages or injunctions based on the patent may constitute an abuse of the rights and be impermissible when it is clear the patented invention lacks an inventive step and will be invalidated by the administrative invalidation proceeding. When the defense is raised that the patentee's claim for damages or injunction constitutes an abuse of rights, the court handling the infringement suit is entitled to review and determine the inventive step issue in order to decide whether the defense is well-grounded.⁸⁹

Deciding when a lack of an inventive step is "clear" may be an issue, but, in practice, the clarity requirement is considered met and is not independently examined so long as the judge finds the patented invention lacks an inventive step in the infringement suit.⁹⁰

This Supreme Court decision dealt with a case where the inventive step of the patented invention was denied, but it is also considered equally applicable to cases where a patented invention lacks novelty or sufficient description so as to be invalid or is in violation of the first-to-file rule. However, the Supreme Court had held that a patented invention lacking novelty or sufficient description had no protectable scope of right even before the 2010Da95390 decision.⁹¹

The plaintiff may submit a reply of correction of the patented invention in response to the defendant's defense of abuse of rights. It is possible to "correct" a patent to narrow the claims, correct typographical errors or clarify ambiguous language, either during an IPTAB invalidation proceeding or by filing a separate correction petition at the IPTAB, provided that the correction does not substantially alter the nature of what is claimed.

8.5.3.2 Free-to-exploit technology

The defendant may raise a defense of free-to-exploit technology to argue that the defendant's product or process only implemented technology that was publicly known or could be easily derived from what was publicly known. The Supreme Court has held as follows:

In determining whether the technology the defendant exploits falls within the scope of rights of the patented invention, the comparison between the two is unnecessary to conclude that the exploited technology does not fall within the patented scope if the defendant's product only consists of publicly known technologies or can be easily practiced by any person of ordinary skill in the pertinent art from publicly known technologies.⁹²

This analysis resembles that given for inventive step but is different in that what is compared with the prior art or publicly known technology is the defendant's infringing product, not the patented invention. In practice, the defense of free-to-exploit technology is rarely seen in infringement cases because the defendant can use the defense of abuse of rights to argue that the patented invention lacks an inventive step.⁹³

8.5.3.3 Known technology

As discussed above, the Supreme Court has held that patent rights may not be exercised when the invention consists only of technologies that were already publicly known or in public use at the time of the filing, whether or not the IPTAB has ruled on the invalidity of the patented invention. The defendant bears the burden of contention and proof to demonstrate that the patented invention is a publicly known technology. Such a defense of known technology may be asserted in addition to the defense of free-to-exploit technology, but, in practice, it is less frequently asserted than the defenses of abuse of rights or of free-to-exploit technology.⁹⁴

89 Daebeobwon (Sup. Ct), Jan. 19, 2012, 2010Da95390 (*en banc*).

90 The judge in a patent infringement lawsuit may determine whether the invention lacks an inventive step, irrespective of whether an administrative trial to invalidate the patent or a lawsuit to revoke the decision therefrom is filed or whether a decision has been rendered in such proceedings.

91 Daebeobwon (Sup. Ct), Jul. 26, 1983, 81Hu56 (*en banc*); Daebeobwon (Sup. Ct), Dec. 27, 2001, 99Hu1973.

92 Daebeobwon (Sup. Ct), Sep. 23, 2004, 2002Da60610.

93 However, the defense of free-to-exploit technology is very frequently raised in lawsuits seeking the revocation of administrative confirmations of the scope of rights where the inventive step may not have been disputed.

94 IP Litigation Research Committee, *Intellectual Property Law Theory and Practice*, at 499.

8.5.3.4 Patent exhaustion

Even though it is not expressly stipulated in the Patent Act, reselling or using a patented product is generally deemed acceptable and does not constitute patent infringement so long as the product is lawfully transferred from the patentee. This is called the “exhaustion doctrine” or “first sale doctrine.” A defendant may raise the defense of patent exhaustion in a patent infringement lawsuit.

The Supreme Court has acknowledged the doctrine of patent exhaustion as applicable to product inventions by ruling as follows:

When a patentee or licensee of a product patent lawfully sells the product implementing the patented invention in the territory of the Republic of Korea, the effects of the patent right shall not extend to the acts of using, assigning or leasing the product by the assignee or buyer with regard to the assigned product because the patent right on that product has achieved its purpose and is thus exhausted.⁹⁵

8.5.3.5 Limited effect or lawful practice of patent right

In addition to the above defenses, the defendant may also assert defenses such as that:

- the effect of the patent is limited (Articles 96 and 181 of the Patent Act);
- the defendant has an exclusive or nonexclusive license granted by the patentee;
- the defendant has a statutory license granted under Articles 103, 104, 105, 122, 182 or 183 of the Patent Act, or
- the defendant is granted a compulsory license under Articles 98, 106, 107 and 138 of the Patent Act.⁹⁶

8.6 Judicial patent proceedings and case management

8.6.1 Key features in patent proceedings

Though civil patent litigation typically refers to patent infringement suits, it also encompasses the transfer, grant and extinguishment of patent rights; compensation for employee invention; and royalty payments. When a third party without a lawful title practices a person's patented invention, the patentee may seek an injunction and compensatory damages through an infringement lawsuit. Challenges in infringement suits often come from the fundamental problem that evidence is concentrated on the defendant's possession, which generally makes it difficult to prove the infringement and consequential damages. Taking this into account, the Patent Act shifts the burden of proof or constructively deems certain acts to be patent infringement to protect patentees – shown, for example, in Article 129 (presumption of manufacturing process), Article 130 (presumption of negligence) and Article 127 (acts deemed to be infringement). In addition, the Patent Act also has special provisions to further relieve the burden of proof, such as Article 126-2 (obligation to disclose the actual product or process in use), Article 132 (order to submit materials) and Article 128-2 (obligation to explain matters for appraisal). In response, the defendant may dispute the accused infringement on the ground that there are circumstances restricting the exercise of the patent right, such as that its effect is limited under Article 96 of the Patent Act or that the exercise of the right would be abusive because the patent was exhausted or lacked an inventive step, or they may argue that exploiting the patent is justified because there is a license or simply that the technology adopted by the alleged infringer is a free-to-practice technology.⁹⁷

In the absence of any justifying cause or upon the failure of justification, a patentee may obtain civil relief from the patent infringement. A patentee may seek the prevention or prohibition of infringement via an injunction against the party that has infringed or is likely to infringe the patent (Article 126(1) of the Patent Act) and, additionally, seek disposal of the means by which the infringement has been committed (Article 126(2) of the Patent Act) and seek measures to recover the patentee's reputation (Article 131 of the Patent Act). A patentee may also claim for damages or restitution of unjust enrichment against the infringer with respect to the damage or loss

⁹⁵ Daebeobwon (Sup. Ct), April 11, 2003, 2002Do3445.

⁹⁶ IP Litigation Research Committee, *Intellectual Property Law Theory and Practice*, at 504.

⁹⁷ See Section 8.5.3 for a discussion of defenses.

caused by the infringement.⁹⁸ Preliminary injunctions are a useful tool when the decision of the main lawsuit is yet to be finalized: a patentee may ask the court to grant, in advance, the relief that would be awarded at the disposition of the main lawsuit based on the patentee's right to seek an injunction against infringement.

A lawsuit seeking compensation for employee inventions is often where patent law, civil law and labor law cross paths. An employee is entitled to fair compensation when the employer succeeds from them a patent, utility model or design right arising out of the employee invention – or the rights to acquire them – or is granted an exclusive license in the respective right under the contract or employment regulations (Article 15(1) of the Invention Promotion Act). In such cases, the employee may file a claim seeking compensation for their invention when they believe that the employer did not pay them fair compensation.

This section focuses on the procedural matters that are common among civil patent lawsuits.⁹⁹

8.6.1.1 Procedure

A civil action is generally initiated by filing a complaint with the court having jurisdiction over the district where the defendant maintains its residence or place of business. As will be discussed in Section 8.6.2.1, a civil patent case over patent and other listed IP rights goes to one of the six district courts, with the Seoul Central District Court having concurrent jurisdiction. Service of process is conducted exclusively by the court. The defendant is typically served with the complaint by mail or through other means of delivery at the defendant's domicile, place of residence or place of business. If all such locations of the defendant are unknown, the court may conduct service by public notice.

Unlike in the United States, where trials in a civil proceeding generally refer to a single event that may last days or weeks depending on the complexity of the case, a civil action in the Republic of Korea may consist of several trials, each of which takes place only for the day, three to five weeks apart, with the first trial ordinarily scheduled two or three months from the filing of the complaint. At each trial, the parties typically submit briefs and evidence in support of their cases, and trials in most civil actions tend to be short unless a witness is called. However, patent infringement trials are significantly longer than other types of civil cases because they often involve presentations on the relevant technologies, and more substantive oral arguments are exchanged by the parties.

Generally, trials continue to be held until the court and parties believe that sufficient arguments and evidence have been presented for a decision to be rendered. In a main action seeking only a permanent injunction (without damages), a district court typically renders a decision within about 8–12 months from the initiation of the lawsuit. Cases in which both an injunction and damages are claimed generally require additional corroboration and a brief submission and usually take longer than cases in which no claim for damages is made – about 12–18 months.

The IP divisions of the Seoul Central District Court, which are in charge of most civil patent cases, as well as the Patent Court, which has exclusive jurisdiction over appeals of such civil cases, provide practice directions for parties to follow in the litigation at each level.¹⁰⁰

8.6.1.2 Electronic litigation system

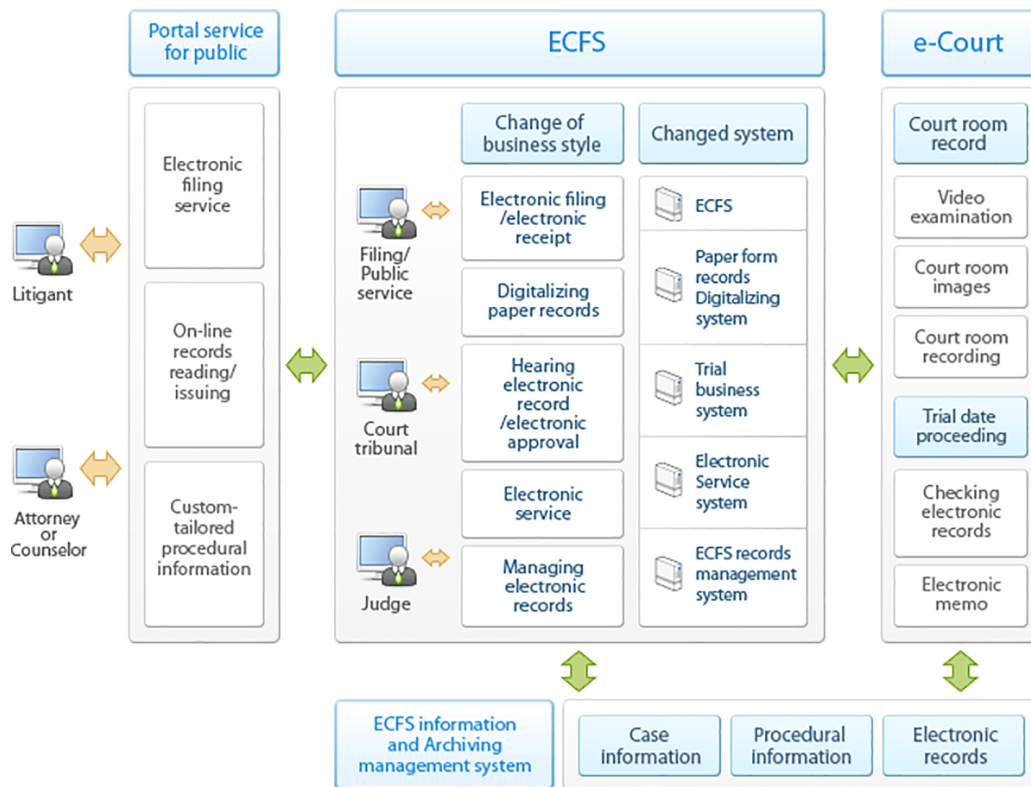
The Electronic Case Filing System (ECFS, <http://ecfs.scourt.go.kr>) is the Korean judiciary's electronic litigation system, which enables the paperless processing of civil actions. While not mandatory, it is often used in civil proceedings. Most civil patent lawsuits are processed through the ECFS, reflecting the high rate of attorney representation in patent cases. Figure 8.4 maps the ECFS.

Litigants and their attorneys can file and manage cases and access court information and procedures electronically through the system. All court documents, briefs, documentary

⁹⁸ See Section 8.7 for a discussion of civil remedies.

⁹⁹ See Sections 8.5, 8.7.2 and 8.6.6 for discussions of patent infringement lawsuits, lawsuits seeking compensation for employee inventions and lawsuits seeking preliminary injunctions, respectively.

¹⁰⁰ Seoul Central District Court, *Procedural Guidelines for Intellectual Property Litigation in the Seoul Central District Court* (Jan. 6, 2020), https://seoul.scourt.go.kr/seoul/info/Procedural_Guidelines_eng.pdf; Patent Court of Korea, *Practice Directions for Civil Appellate Trial in the Patent Court of Korea* (June 14, 2016), [hereinafter Patent Court, *Practice Directions for Civil Appellate Trial*] <https://patent.scourt.go.kr/dcboard/new/EngDcNewsListAction.work?gubun=547>

Figure 8.4 Map of the Electronic Case Filing System

Note: ECFS = Electronic Case Filing System.

Source: Computer Data Management Bureau, Supreme Court of Korea

evidence and digital evidence can be uploaded to the system without mailing them or physically visiting the court. After filing a case via the electronic system, the plaintiff or petitioner receives email and text message notifications when the other party submits documents to the court. If the defendant or respondent consents to e-filing, they may also receive electronic notices of the plaintiff's or petitioner's filings. These notifications and electronic access to case records allow all parties using the ECFS to promptly check the current status of the proceedings.

The ECFS also allows judges and court officials to manage cases much more efficiently by electronically viewing the case records and checking the case statuses in a speedy manner. The ECFS has rapidly replaced the conventional paper-based process. During trials and hearings, all case records can be retrieved from the central database and displayed on monitors and larger screens in courtrooms. The electronic files are closed to the public, and only the litigants, their attorneys and the court can access them, for privacy and security reasons. However, the public may access published court decisions online via the judiciary's online decision search service.

8.6.2 Venue, jurisdiction and case assignment rules

8.6.2.1 Territorial jurisdiction

8.6.2.1.1 Interpretation of relevant laws

Article 24 of the Civil Procedure Act and Article 28-4 of the Court Organization Act provide territorial jurisdiction over IP rights, following the enforcement of jurisdictional concentration, as follows:

– Civil Procedure Act:

Article 24 (Special Forum for Intellectual Property and Other Rights)

- (1) A lawsuit concerning an international transaction and an intellectual property right, excluding a patent, utility model, design, trademark, and plant variety rights [hereinafter referred to as "patent and other listed IP rights"] may be brought to a district court in the jurisdictional area of a high court which has

jurisdiction over the location of a competent court pursuant to Arts. 2 through 23: Provided, That the district court in the jurisdictional area of Seoul High Court shall be limited to the Seoul Central District Court. <Amended by Act No. 10629, May 19, 2011; Act No. 13521, Dec. 1, 2015>

- (2) A lawsuit concerning patent and other listed IP rights shall be under the exclusive jurisdiction of the district court in the jurisdictional area of a high court which has jurisdiction over the location of a competent court pursuant to Arts. 2 through 23: Provided, That the district court in the jurisdictional area of Seoul High Court shall be limited to the Seoul Central District Court. <Newly Inserted by Act No. 13521, Dec. 1, 2015>
- (3) Notwithstanding paragraph (2), a party may bring a lawsuit concerning patent and other listed IP rights to the Seoul Central District Court. <Newly Inserted by Act No. 13521, Dec. 1, 2015>

– Court Organization Act:

Article 28-4 (Judicial Power)

The Patent Court shall judge the following cases: <Amended by Act No. 13522, Dec. 1, 2015; Act No. 14033, Feb. 29, 2016>

1. Cases of first instance provided in Art. 186 (1) of the Patent Act, Art. 33 of the Utility Model Act, Art. 166 (1) of the Design Protection Act, and Art. 162 of the Trademark Act;
2. Appeals of the cases under Art. 24 (2) and (3) of the Civil Procedure Act;
3. Cases falling under the jurisdiction of the Patent Court under other Acts. [Wholly Amended by Act No. 12886, Dec. 30, 2014].

In sum, lawsuits concerning patent and other listed IP rights fall under the exclusive jurisdiction of the district court that is located where a high court is seated (Article 24(2) of the Civil Procedure Act),¹⁰¹ with concurrent original jurisdiction to the Seoul Central District Court over all lawsuits concerning patent and other listed IP rights (Article 24(3) of the Civil Procedure Act).¹⁰² As Article 24 sets forth exclusive jurisdiction, any agreement to the contrary is void, and a court without jurisdiction will not become competent by the party arguing on the merits of the case, waiving the jurisdictional defense.¹⁰³ Meanwhile, the Patent Court has exclusive jurisdiction over appeals of lawsuits concerning patent and other listed IP rights (Article 28-4(2) of the Court Organization Act). This exclusive jurisdiction is enforceable irrespective of subject matter jurisdiction – that is, regardless of whether it is a small claims case or whether it was heard by a single judge or a panel in the first instance. Therefore, an appeal of a small claims case concerning patent or other listed IP rights falls under the exclusive jurisdiction of the Patent Court, notwithstanding that such an appeal usually goes to an appellate division of a district court in other types of cases.¹⁰⁴

Notably, the exclusive jurisdiction provision does not apply to a civil patent case, in a broad sense, so long as the case is considered a “lawsuit concerning IP rights *excluding* patent and other listed IP rights.”¹⁰⁵ For such cases, jurisdiction will be determined in accordance with Articles 2 to 23 of the Civil Procedure Act, with a chance of the special forum under Article 24(1) of that Act. As such, whether a case is considered a “lawsuit concerning patent and other listed IP rights” is critical in determining jurisdiction over civil patent actions. In the sections that follow, the meanings of “patent and other listed IP rights” and “concerning” are explored in further detail.

Exclusive jurisdiction is particularly reserved for lawsuits concerning patent and other listed IP rights because adjudication of these lawsuits often requires expert knowledge and technical understanding. Concentrating the cases to specific courts is an effort toward the appropriate protection of IP rights that allows judges specialized to handle such cases, equipped with

101 Such courts are the Seoul Central District Court, Daejeon District Court, Daegu District Court, Busan District Court, Gwangju District Court and Suwon District Court. The Seoul Eastern District Court, Seoul Southern District Court, Seoul Northern District Court and Seoul Western District Court – in addition to the Seoul Central District Court – are all located where the Seoul High Court is seated. However, exclusive jurisdiction has been conferred only on the Seoul Central District Court (Minsasosongbeob [Civil Procedure Act], art. 24(2) proviso).

102 In practice, this is also called “concurrent jurisdiction” or “selective exclusive jurisdiction.”

103 IP Litigation Research Committee, *Intellectual Property Law Theory and Practice*, at 8.

104 See Daebeobwon (Sup. Ct), Feb. 27, 2020, 2019Da284186.

105 Because “patent and other listed IP rights” is defined as patent, utility model, trademark, design and plant variety rights, a typical example of an IP right *excluding* these rights would be a copyright.

appropriate experience and a tailored system, to thoroughly and promptly review these challenging cases.¹⁰⁶

By type of lawsuit (i.e., which cases are lawsuits “concerning” patent or other listed IP rights), patent infringement lawsuits are exemplary of those that require expert knowledge or technical understanding. Thus, the cases subject to exclusive jurisdiction include those seeking an injunction against infringement, disposal and destruction, recovery of reputation, and damages. Likewise, claims to transfer or extinguish patent registration due to assignment or termination thereof, claims to establish or extinguish exclusive or nonexclusive license due to license agreement or termination thereof and claims for remuneration from employee invention also fall under this exclusive jurisdiction. It is the same with royalty claims, as they often involve disputes over whether the technology implemented by the defendant is subject to the license agreement, demanding expert knowledge or technical understanding for resolution. In addition, cases seeking confirmation as to the attribution of patent or other listed IP rights are also subject to exclusive jurisdiction, since issues of attribution should be resolved before the above issues.

8.6.2.1.2 Transfer

A court lacking jurisdiction over a lawsuit concerning patent and other listed IP rights should transfer the case to a competent court. A competent court may also decide to transfer a case to another that has jurisdiction under Articles 2 to 23 of the Civil Procedure Act – either *ex officio* or by granting the request of a party – when the transfer is necessary to avoid significant damage or delay (Article 36(3) of the Civil Procedure Act).

However, the literal interpretation of Article 36(3) of the Civil Procedure Act suggests that it is not applicable to appeals. There has, therefore, been a demand for the insertion of a provision similar to Article 24(3) of the Civil Procedure Act to allow the discretionary transfer to a court of general appellate jurisdiction when significant damage or delay is expected.¹⁰⁷

8.6.2.1.3 Preliminary injunction cases

Article 303 of the Civil Execution Act stipulates that “[t]he court having jurisdiction over the merits, or the district court having jurisdiction over the location of disputed subject matter, shall exercise jurisdiction over preliminary injunction trials.” Accordingly, preliminary injunction cases may be brought to any district court having jurisdiction over the location of the disputed subject matter, in addition to the six district courts prescribed in Article 24(2)–(3) of the Civil Procedure Act that award exclusive jurisdiction. However, Article 28-4(ii) of the Court Organization Act only sets forth that the Patent Court will hear “appeals among cases under Article 24(2) and (3) of the Civil Procedure Act,” meaning that the Patent Court is not competent to hear appeals of preliminary injunction cases. Thus, it should be noted that preliminary injunction cases were left out of the jurisdictional concentration. Such appeals go to the high court that is competent to hear the appeal from the district court that handled the first-instance case.

8.6.2.2 Subject matter jurisdiction

8.6.2.2.1 Definition

The Court Organization Act requires that the judicial power of a district court be exercised by a single judge in principle but, exceptionally, allows cases defined in Article 32(1) to be heard by a three-judge panel (Articles 7(4)–(5) and 32(1) of the Court Organization Act). The term “subject matter jurisdiction” under Korean law refers to the allocation of cases of first instance between single judges and three-judge panels in district courts.

8.6.2.2.2 Claims for monetary awards (e.g., compensatory damages)

A claim for monetary awards (e.g., compensatory damages) with the value of the subject of the lawsuit exceeding KRW 500 million is brought to a three-judge panel in the district court, while a claim with the value of the subject being KRW 500 million or less is brought to a single-judge bench.¹⁰⁸ The value of the subject of a lawsuit is calculated on the basis of the benefits as claimed by the lawsuit (Article 26(1) of the Civil Procedure Act). If multiple claims are joined in one lawsuit,

¹⁰⁶ Daebeobwon (Sup. Ct), April 10, 2019, 2017Ma6337.

¹⁰⁷ Seoul National University R&DB Foundation, *A Study on Countermeasures to Prevent Abuse of Litigation Resulting from Strengthened Protection of Patent Rights* 75–76 (Dec. 2015).

¹⁰⁸ Rules on the Subject-Matter Jurisdiction in Civil and Family Litigation, art. 2. The amount is raised from KRW 200 million to 500 million on March 1, 2022.

the value of the subject of the lawsuit is determined by summing the values of all claims (Article 27(1) of the Civil Procedure Act). A case that originally belongs to a single-judge bench may be handled by a panel court upon its decision to take the case (Article 32(1)(i) of the Court Organization Act). On such occasions, the Seoul Central District Court assigns the cases to panel courts via panel decisions, regardless of the value of the subject of the lawsuit.¹⁰⁹

8.6.2.2.3 Cases on injunction, registration of transfer and extinguishment of registration

Cases seeking an injunction against patent infringement or the transfer or extinguishment of patent registration are lawsuits over property rights for which the value of the lawsuit cannot be calculated. Such lawsuits fall under the jurisdiction of district court panels.¹¹⁰ Thus, a case seeking an injunction along with damages not exceeding KRW 500 million also goes to a district court panel.

8.6.2.3 Jurisdiction by court level

In civil patent cases, for lawsuits concerning patent and other listed IP rights, the Patent Court has exclusive appellate jurisdiction, irrespective of the subject matter jurisdiction in the first instance (Article 28-4(ii) of the Court Organization Act).

For an appeal of a lawsuit concerning IP rights other than patent and other listed IP rights, judicial power is vested in either a panel of a district court, if the lower court's decision was rendered by a single judge of the district court (Article 32(2) of the Court Organization Act), or the high court, if the lower court's decision was rendered by a panel of a district court (Article 28(i) of the Court Organization Act).

The Supreme Court is the court of last resort for all types of civil patent cases.

8.6.3 Statements of case

Parties must submit written briefs in advance in order for the trial to proceed in a focused manner.¹¹¹ Briefs should be filed in due time to give the other party a chance to prepare their response.¹¹² A brief containing a new offensive or defensive method should be filed at an appropriate time for it to be served to the other party at least seven days before the trial or preparatory hearing.¹¹³ The following lists a few points of caution per issue in preparing briefs.¹¹⁴

- Contention on the inventive step – the brief should contain an element-by-element chart identifying the elements in the prior art and comparing them with the corresponding elements of the patented invention. To argue that the patented invention lacks an inventive step based on a combination of multiple prior arts, the brief should specify the primary prior art and provide a detailed explanation of how the prior arts are combined and the reasons why such a combination can be easily obtained by a person having ordinary skill in the art.
- Contention on infringement – the brief should specify, in detail and both individually and graphically, the product or process practiced by the defendant by listing the product name and product type number and attaching drawings or pictures so that the enforcing authority can identify them without further deliberation. The defendant's product or process should be described in detail so that it can be compared with the patented invention by element and graphically described to maintain identity with the actual product or process practiced by the defendant. The brief should contain an element-by-element chart comparing the patented invention and the defendant's product or process.
- Contention on damages – a claimant seeking compensatory damages should specify the legal provisions serving as the basis for calculating the amount of damages and identify the exhibit number associated with each legal element set forth in the provisions. To dispute the facts

¹⁰⁹ It varies by district courts whether cases belonging to a single judge bench can be assigned to a panel upon the panel's decision on adjudication. For example, the Daegu District Court has both three-judge and single-judge IP divisions, so the subject matter jurisdiction is determined based on the value of the subject of the lawsuit.

¹¹⁰ Minsasosong deung injibeob (Act on the Stamps Attached for Civil Litigation and Others), art. 2(4); Rules of the Stamps Attached for Civil Litigation and Others, art. 18; Rules on the Subject Matter Jurisdiction in Civil and Family Litigation, art. 2.

¹¹¹ Civil Procedure Act, art. 272(1).

¹¹² Civil Procedure Act, art. 273.

¹¹³ Civil Procedure Rules, art. 69-3.

¹¹⁴ IP Litigation Research Committee, *Intellectual Property Law Theory and Practice*, at 187-88.

alleged by the claimant, the other party should provide a detailed answer rather than a simple denial.

8.6.4 Early case management

Unless the case is to be decided without a trial, the presiding judge must set the trial date without delay and usually fixes a date as soon as the defendant files an answer disputing the complaint.¹¹⁵ The judge will evaluate how hotly the case is disputed, how complex it is, whether it is well suited for mediation or whether there is a particularly urgent need for adjudication and sets the earliest practical date for a trial as the first trial date. Where early mediation is likely to settle the case, the case may be referred to the mediation court or mediation center before the first trial date is set.

8.6.5 Preparatory hearings

A preparatory hearing is an opportunity to sort out the arguments and evidence of the parties to enable an effective and focused trial.¹¹⁶ In most cases, issues are trimmed via the exchange of briefs, and the process advances straight to trial. Preparatory hearings are held only in exceptional cases, where arguments and evidence need to be sorted out in advance. In civil patent lawsuits, a preparatory hearing will be scheduled only in complex cases to coordinate case management and primarily in the form of a video conference. The following matters are often discussed at a preparatory hearing:

- trial date and time, as well as the issues to be addressed in the trial;
- deadlines to state contentions and submit evidence (including deadlines for the submission of comprehensive briefs and expert witness affidavits, the maximum number of submissions and the length of briefs);
- whether to use an evidence production method that requires a substantial amount of time, such as inspection, appraisal and expert witnesses, and the deadlines for such methods;
- whether to designate a technical advisor;
- whether to hold a technology review session by the parties;
- whether to hold separate hearings by legal issue, such as infringement, invalidity, assessment of damages and so on;
- how to proceed litigation procedures if a related case is pending before the IPTAB; and
- whether to refer the case to a mediation procedure.

8.6.6 Provisional measures

Two types of civil actions are available to enforce IP rights: a main suit, where both a permanent injunction and damages may be sought, and a petition for provisional disposition, where only a preliminary injunction may be sought, and damages are not recoverable. A preliminary injunction proceeding is a relatively quick method for enforcing IP rights.

A plaintiff may petition a district court to issue a preliminary injunction to prevent further infringement by an accused infringer before the infringement issue is decided in the main suit. Unlike permanent injunctions in the main suit, a preliminary injunction will not be granted merely because the patent is shown to be valid and infringed; the plaintiff must demonstrate the likelihood of infringement and the necessity for provisional relief. In determining the latter, courts will balance the irreparable harm to the plaintiff arising from the ongoing infringement with the economic harm to the defendant if the injunction is granted.

Courts will also consider the adequacy of the form of relief to redress the injury to the plaintiff by the infringement and the likelihood that the patent will be invalidated. Absent exceptional circumstances, preliminary injunction actions are generally *inter partes* proceedings conducted through a series of mandatory hearings. The initial hearing is typically scheduled within two to three weeks from the date the petition is filed.

During the court's review, the plaintiff must submit evidence of infringement, such as brochures and samples of infringing products. Witness testimony is usually limited to affidavits because

¹¹⁵ Civil Procedure Act, art. 258(1).

¹¹⁶ Civil Procedure Act, art. 279(1).

witnesses are generally not permitted to take the stand during hearings. Typically, very little discovery is allowed in a preliminary injunction action, so the claimant should make all efforts to gather sufficient evidence of infringement before initiating the action. Courts are often reluctant to grant preliminary injunctions if expert testimony or tests are required to establish infringement. Therefore, the primary form of evidence used in preliminary injunction actions is documentary evidence.

Once the plaintiff has established the likelihood of infringement and the necessity for provisional relief, the defendant is given an opportunity to introduce arguments and evidence in rebuttal. A defendant can raise a defense of abuse of right to avoid enforcement of the patent, which would be based on the likely invalidity of the asserted patent, although the patent cannot be formally invalidated in a preliminary injunction proceeding. The court has discretion to grant additional hearings for further arguments and evidence upon the parties' request.

When the court determines that it is ready to resolve the case, it will close the hearings and render a decision. Granting a preliminary injunction, the court may prohibit the defendant from continuing the manufacture or sale of the infringing goods, order that the infringing articles or other articles used to infringe be transferred to the custody of a court bailiff, or instruct the court bailiff to post an appropriate public notice of the order on the premises of the defendant.

Due to the provisional nature of such proceedings, the court generally requires the plaintiff to post a security deposit or bond for the purpose of compensating the enjoined party for damages resulting from the injunction in the event the injunction is later overturned or revoked. A deposit posted by the plaintiff upon the issuance of a preliminary injunctive order will be returned when the injunction becomes final upon any appeals.

However, if a preliminary injunctive order is later found to have been improperly issued, the right holder that petitioned for the injunction may be liable for tort under Korean law. The right holder will be held liable for ordinary damages suffered by the defendant due to the preliminary injunction, as well as any extraordinary damages that were reasonably foreseeable to the right holder at the time of execution. If a preliminary injunction executed by an IP right holder has been improperly issued, the right holder is rebuttably presumed to have been negligent in enforcing the injunction.

The district court's decision on a preliminary injunction may be appealed to the high court.¹¹⁷ Alternatively, the plaintiff may file an action for a permanent injunction or other relief at the district court. A defendant subject to a preliminary injunction may challenge the order by filing a request for reconsideration with the same court that issued the injunction. A preliminary injunction may be enforced while an appeal or challenge is pending. As an alternative, and in addition to the above proceedings, the defendant may request that the court compel the plaintiff to institute the main suit for a permanent injunction or damages in connection with the enjoined activities. If such a request is made, the court will instruct the plaintiff to file a main complaint within a certain timeframe. If the complaint is not filed by the specified deadline, the court will revoke the preliminary injunction.

8.6.7 Evidence

In general, the Civil Procedure Act does not provide pre-trial discovery processes like depositions and interrogatories in the United States. Instead, evidence is produced during trials. In exceptional cases where certain evidence may not be available during the trial unless it is timely preserved, a party may request a court order to examine evidence prior to filing the lawsuit. All requests for evidence production are made by petition to the court, and the court will exercise its discretion in granting or dismissing the petition, balancing the need for the evidence and any delay or harm that may be caused by the production of the evidence. Any party that submits documentary evidence or files requests for witnesses, inquiry of facts, entrustment to send a certified and authenticated copy, order to submit documents, inspection, appraisal and so on must specify, in detail, the matters to be substantiated by the evidence.

¹¹⁷ See Section 8.6.2.1.3 for a discussion of jurisdiction.

8.6.7.1 Documentary evidence

Documentary evidence submitted in civil patent cases includes patent specifications, general books (technical literature), published materials, patent gazettes or laid-open gazettes, and patent registers. Any product, model, photograph, video or other material capturing or using the patent can also be submitted as evidence to help in the understanding of technical aspects of the patent. In principle, documentary evidence must be submitted in its original copy. However, in practice, it is acceptable to submit a scanned version of the original copy unless the other party disputes the existence or authenticity of the original copy, in which case the nonconverted original copy must be made available for examination on the trial date. Any document written in a foreign language must be submitted along with a translated version,¹¹⁸ the exception being for documents written in the permitted language in an international case.¹¹⁹

8.6.7.2 Inspection

Either party may ask the court to inspect samples of the other party's products (e.g., the accused's infringing articles) or conduct an on-site inspection of the other party's property (e.g., the defendant's manufacturing facility). The petitioner may also request that the court order the other party or a third party to submit the product to be inspected, if the petitioner does not already have a sample of the product in its possession. Upon submission, the court may choose to inspect it directly or may appoint an expert to inspect the product and submit an opinion based on relevant findings.

A party seeking an on-site inspection must persuade the court that the inspection is necessary. For example, an on-site inspection of the defendant's premise may be necessary to prove infringement in a case involving a manufacturing process. If a petition for an on-site inspection is granted in such a manufacturing process case, the court will usually appoint an expert witness to accompany the judges to help perform the inspection and identify the relevant manufacturing process.

8.6.7.3 Court-appointed expert evaluation

The court can also appoint independent experts to provide testimony on complex technical issues that require input from experts (Article 335 of the Civil Procedure Act). The court may appoint an expert at the request of one of the parties or at its own discretion. Further, the court may ask public institutions, schools, organizations that have appropriate facilities, or foreign public institutions to provide their expert opinion (Article 341 of the Civil Procedure Act).

The court may appoint one or more experts to conduct testing or to submit an opinion on disputed issues that require special knowledge or experimentation, usually upon petition by one of the parties. In rare cases, the court may appoint one or more experts at its discretion. A party may petition the court to seek the opinion of a specific expert, in which case the other party may object to the recommended expert by presenting evidence of bias or other disqualifying grounds. The court has broad discretion regarding the selection of its own expert or in denying a petition for an expert.

Each party may petition to disqualify a potential expert by indicating that the person is incapable of providing a fair and true opinion (e.g., the expert was granted research funds by a party or its affiliates) or that they are not properly qualified. The Civil Procedure Act does not limit court-appointed experts based on their nationality or residence; the sole requirement is that the person has the necessary knowledge and experience to provide the expert opinion.

Court-appointed experts, like witnesses, are required to take an oath before the court that they will provide their opinion based upon what they believe to be true and correct and be subject to criminal punishment for perjury. Further, if necessary, a court-appointed expert may enter a party's premise with the court's approval. This is an exercise of the court's power by the court-appointed expert.

8.6.7.4 Orders promoting evidence production

In civil cases, a party seeking to file documentary evidence possessed by the opposing party or a third party may request that the court order the holder of the document to submit the document

¹¹⁸ Civil Procedure Act, art. 277.

¹¹⁹ See Section 8.3.2.2 for more details.

(a “document submission order”).¹²⁰ If the respondent does not comply with an order under the Civil Procedure Act, the court may find what is alleged by the petitioner as to the contents of the document to be true.

Taking into account the distinct nature of patent cases, where evidence is often concentrated in the other party’s possession, the Patent Act expands the scope from documents specifically to materials more broadly and has enhanced the disadvantage to the noncompliant party (a “material submission order”). Failure to comply with a material submission order may result in the court admitting not only the petitioner’s contention about what is in the material but also the contention about the fact sought to be established by the materials as valid under certain conditions. The following sections discuss the document submission order under the Civil Procedure Act and the material submission order under the Patent Act.

8.6.7.4.1 Document submission order

Under Article 343 of the Civil Procedure Act, a party may petition the court to order the other party or a third party to submit a document known to be relevant to the merits of the case. Under Article 345 of the Act, a petition requesting the court to order document submission must clearly indicate the document title, its purpose, the person holding the document, the facts the document proves and the basis for the obligation to produce the document. The holder of the document has the obligation to produce the document under Article 344 if (i) they are a party and have referred to the document in the lawsuit, (ii) the petitioner is legally entitled to demand delivery or perusal of the document from the holder, or (iii) the document has been made for the benefit of the petitioner or concerns the legal relationship between the petitioner and the document holder, with some exceptions as prescribed in the provision.

Beginning July 9, 2019, accused patent or utility model infringers must also respond to credible infringement claims with evidence rather than with simple denials (which have been common where the evidence of infringement is entirely within the defendant’s premises and therefore difficult for the plaintiff to obtain through court orders). If a *prima facie* showing of likely infringement is made, an accused infringer denying infringement must present evidence of the actual process or product it is practicing or else risk the court presuming that the accused infringing activity has actually taken place.

8.6.7.4.2 Material submission order

The Patent Act has been amended (partial amendment by Law No. 14112, effective June 30, 2016) to expand the scope of submission orders from “documents” to “materials,” which may also include electronic files, video clips or any other nondocumentary form of data. The Act was amended to also prevent parties from refusing to comply on the basis that the materials contain trade secrets. Under the amended law, the petitioning party should first establish, via an *in camera* proceeding if necessary, that the materials actually contain trade secrets. Even if successful, the material holder cannot simply refuse to comply with the order if such evidence is deemed necessary to prove infringement. Instead, the holder may request that the court limit the scope of disclosure or the persons who can access the materials.

If a requested material is withheld without justification, the amended law permits the court to presume that the other party’s claim based on the facts sought to be proved through the material is true. These changes were designed to make it easier for patent litigants in the Republic of Korea to obtain the necessary evidence regarding infringement and damages. The amendment applies to all infringement actions filed on or after June 30, 2016. The court preserves broad discretion in granting requests for submission orders.

8.6.7.5 Evidence preservation (before or during an infringement action)

Evidence preservation is a tool used to obtain evidence that is otherwise difficult to secure. Petitions to preserve evidence have been granted in some patent infringement cases. To be successful, the petitioner should establish that there is a likelihood or reasonable probability of patent infringement and establish the necessity for evidence preservation. If successful, the court will issue a ruling that states to the effect of “(1) evidence examination shall be conducted with regards to this case and (2) the respondent is hereby ordered to submit materials.” In the annex

120 Civil Procedure Act, art. 343.

to the ruling, the subject¹²¹ the place¹²² and date of examination will be specified for evidence examination, as well as the facts to be proven and the subject materials¹²³ for material submission.¹²⁴

A petition for evidence preservation can be filed either before or during an infringement action. Before filing an infringement action, the petition for evidence preservation should be submitted to the district court having jurisdiction over the place of residence of the party possessing the alleged evidence or the location of the evidence intended for inspection, and the case will be heard by a single judge. After filing a lawsuit, the petition can be submitted to the court where the lawsuit has been filed, and the case will usually be heard by the same panel reviewing the lawsuit.

8.6.7.6 Experts

8.6.7.6.1 Witnesses (including expert witnesses)

Although documentary evidence is the most frequently used form of corroboration in civil patent litigation, the use of witness examination to prove factual background has been gradually increasing. It is particularly common in civil patent cases to conduct expert witness examinations of people who are acknowledged to have expertise in the particular technology. Expert witness examination is different from other witness examination in that the latter focuses on the facts that the witness has actually experienced in person, whereas an expert witness in a patent case is mostly called upon to testify on matters such as (i) the technical level of a person having ordinary skill in the art at the time of filing of the patent, (ii) the disclosure of the prior art, (iii) analysis and comparison of the infringing goods, (iv) the amount of loss caused by the infringement and (v) the reasonable amount of royalty, among others. To call an expert witness to the stand, the petitioner must submit a “Basic Statement for Expert Witness” to the court. This form is available in the practice directions of the Patent Court and the IP divisions of the Seoul Central District Court.¹²⁵

The Civil Procedure Act prescribes several ways that experts may provide their opinions to the court. Expert testimony may be submitted either through a declaration or through direct testimony before the court. Declarations are the more commonly used method. Either party to the litigation may introduce independent expert declarations as evidence in support of its case, and such declarations may be based on the expert’s own testing and knowledge or on other evidence reviewed by the expert.

Expert witnesses may also be called to testify at the trial, usually upon a request by a party. The questions to be asked must be submitted to the court in writing prior to the trial. Direct examination usually requires only a very brief answer. Whether to allow expert testimony is at the court’s discretion, and, if it is allowed, the other party will have the opportunity to cross-examine the witness. Questions for cross-examination and redirect examination need not be presented to the court in advance. The court may also appoint experts to evaluate the disputed technologies or damages-related facts.¹²⁶

8.6.7.6.2 Technical expert support

8.6.7.6.2.1 Judicial technical examiners

The Patent Court has judicial technical examiners providing full-time expeditious and effective support in dispute resolution through the specialized examination of issues surrounding technical matters in patent or utility model cases.¹²⁷ The judicial technical examiners in the Patent Court have expert knowledge and experience in scientific and technical fields, such as machinery, communications, electrics and electronics, chemistry, drugs, agriculture, and construction. They come from a variety of backgrounds: for example, KIPO examiners, patent

121 Typically the accused product (final or semi-final product).

122 Typically where the infringing act took place, such as the respondent’s factory.

123 The same as the subject of evidence examination in most cases.

124 See e.g., Seouljoongangjibangbeobwon (Seoul Central Dist. Ct), Aug. 24, 2017, 2017KaGi50496; Seouljoongangjibangbeobwon (Seoul Central Dist. Ct), April 4, 2019, 2019KaGi50261.

125 See IP Divisions of the Seoul Central District Court, *Procedural Guidelines for IP Litigation*, ch. IV(2); Patent Court, *Practice Directions for Civil Appellate Trial*, ch. V.

126 See Section 8.6.7.3 for a discussion of court-appointed evaluators.

127 Beobwonjojikbeob (Court Organization Act), art. 54-2(1). Technical expert support in the Patent Court mainly comes from judicial technical examiners and judicial technical researchers. The main difference between the positions is that judicial technical examiners are dispatched from the KIPO, and judicial technical researchers are directly hired by the court. However, since their roles are practically very similar, both are hereinafter collectively referred to as judicial technical examiners.

attorneys and researchers in the relevant fields, often with Master of Science or PhD degrees. The KIPO also dispatches its division heads to the Patent Court as judicial technical examiners.

Upon the request of the judicial panel, judicial technical examiners provide opinions on technical matters in suits involving patents and utility models and, if deemed necessary by the panel, participate in preparatory hearings and trials and ask questions to the parties with the permission of the presiding judge.¹²⁸ In principle, each patent case of the Patent Court has a judicial technical examiner having expertise in the field assigned to the case, and the judicial panel holds a technical explanatory session before the trial, during which the judicial technical examiner helps the judges to understand the technical issues of the case.¹²⁹ The IP divisions of the Seoul Central District Court, in charge of most of the first-instance patent cases, and the Supreme Court, in charge of the final trials of all patent cases, have judicial technical examiners as well.

8.6.7.6.2.2 *Technical advisors*

In addition to judicial technical examiners, the court may choose to appoint a technical advisor to provide expert opinion on a particular issue of the case. Technical advisors are selected from a pool of registered experts in a wide variety of technical fields, including machinery, communications, electrics and electronics, chemistry, drugs, agriculture, and construction. Most of them are researchers of national research institutes or professors teaching in graduate schools.

Technical advisors participate in the litigation by either submitting written opinions or attending on the trial date to provide explanations or opinions on technical matters and, with the permission of the presiding judge, to ask questions to the parties or witnesses. These experts are bound by confidentiality obligations in connection with the cases in which they participate and are deemed government employees for the purpose of the bribery provision under the Criminal Act.¹³⁰

Technical advisors are distinguished from judicial technical examiners in that they are outside professionals appointed on a case-by-case basis, whereas judicial technical examiners work full-time at the court.

8.6.8 Technology tutorials and technical briefing sessions

8.6.8.1 Pre-trial internal technical explanatory session

Judicial panels of the Patent Court hold technical explanatory sessions in the preparation of trials concerning patents or utility models to better understand the relevant technologies. At these sessions, technical experts, such as judicial technical examiners, explain the relevant technologies in the context of the party's argument by using drawings, products, miniatures, computer graphics and video equipment.

8.6.8.2 Technology review session on the date of trial

On the trial date, the court hears the arguments stated by the parties, examines the relevant evidence and identifies the issues with the parties. The parties present their oral arguments and produce further evidence. In cases involving complex technical issues, technology review sessions are often held on the trial date. Each party or its legal counsel prepares presentation materials and explains the relevant technology by, for example, showing video clips, photographs or drawings in the session. The parties are advised to submit their materials for technology review prior to the trial date. The materials are often filed in PDF or slideshow format and become a part of the court record once filed. Since most civil patent cases are processed via the electronic system, the parties electronically submit video files and other materials before the trial date. In cases where the parties' consent and the court's approval are obtained, trials may be conducted

128 Regulations on Judicial Technical Examiners, art. 4(1).

129 The function of the technology explanatory session is similar to that of technical tutorials in the US in that both are aimed at enhancing the technical understanding of the judges. The two are different, however, in that technology explanatory sessions are held within the court with no participation of the parties or their counsels. The judicial panel will first educate themselves with the technical issues of the case with the help of the judicial technical examiner (a court employee with a neutral standpoint) before they hear the arguments from counsels. Counsels will have their opportunities to explain the disputed technologies from their viewpoints in a technology review session during the trial.

130 Civil Procedure Act, art. 164-8 (constructive treatment as government employee in imposing criminal punishment). Technical advisors are treated as government employees in imposing criminal punishment under art. 129 through art. 132 of the Criminal Act.

in a foreign language.¹³¹ Another important process that takes place on the date of trial is evidence examination.

8.6.9 Protecting trade secrets in litigation

8.6.9.1 Limited access to trade secrets

Access to trade secrets may be restricted by court orders. Upon a party's request, the court can order that only the parties to the lawsuit may access or copy the portions containing trade secrets in the court record or request delivery of the authentic copy, certified copy or abstract of the portions containing trade secrets in the court decision or trial record.¹³² However, this restriction cannot regulate a party's divulgence to others of trade secrets learned in the course of litigation, which may instead be prevented by a confidentiality protective order.

8.6.9.2 Confidentiality protective order

A party may refuse to produce a document on the grounds that it contains confidential information (e.g., a trade secret). In that case, the court may order the party to present the document to the court for an *in camera* review. Neither the parties nor their counsels can participate in such review.

Where it is necessary for a party to disclose a trade secret in litigation alleging violation of the Unfair Competition Prevention and Trade Secret Protection Act, then, under Article 14-4 of the Act, the party may petition the court to issue a confidentiality protective order to prevent any unauthorized disclosure of the trade secret thereafter. Under the Act, a "trade secret" is defined as information of a technical or business nature that can be used in business activities and is generally unknown to the public and possesses independent economic value, the secrecy of which is maintained through substantial efforts.

The Act protects trade secrets disclosed in litigation using confidentiality protective orders, a violation of which may be subject to criminal punishment. Upon a party's request, the court may issue an order prohibiting the opposing party, its counsel or any other person who becomes aware of the trade secret through the litigation from using the trade secret for purposes other than conducting the litigation and from disclosing the trade secret to anyone other than the persons to whom the confidentiality protective order was issued.

A party petitioning for a confidentiality protective order must establish that a brief or evidence already submitted or to be submitted contains trade secrets and that any use or disclosure of the trade secret for purposes other than conducting the litigation would likely impede the business operation of the relevant party. The petition must specify the facts to support that these criteria are met, the person(s) who should be subject to the order and the facts sufficient to identify the trade secrets to be protected by the order.

Once the order is issued, the persons subject to the order are prohibited from using or disclosing the trade secret for purposes other than the particular lawsuit. Such prohibition includes the cross-use of the relevant materials or information in other lawsuits domestic or foreign. Any party violating the confidentiality protective order in the Republic of Korea or overseas without justification may be imprisoned for up to five years or fined up to KRW 50,000,000. Such violations may be penalized only after a complaint is filed by the party that requested the confidentiality protective order.

8.6.9.3 Protecting trade secrets by orders to submit documents and materials

When the court orders the submission of a document to decide whether it is subject to the obligation to produce documents, the court must take measures to protect the document from disclosure to others.¹³³ The document should be reviewed *in camera* so that it remains sealed from the other party or third parties. Likewise, when a party refuses to submit materials upon a court order, the court may order the submission of the materials to decide whether the party has a good reason to refuse submission, but only with proper measures to prevent others from accessing the materials.¹³⁴

¹³¹ See Section 8.3.2.2 for more details.

¹³² Civil Procedure Act, art. 163(1).

¹³³ Patent Act, art. 347(4).

¹³⁴ Patent Act, art. 132(2).

8.6.10 Trial

A civil lawsuit typically involves a series of trial dates for oral arguments that are three to five weeks apart from each other. The court will render its decision in three to four weeks after the trial is closed (see Section 8.6.1.1). On the first trial date, the court will identify the disputed issues of the case and hold technology review session (see Section 8.6.8.2). The court will then visit any remaining issues and hold evidence examination or witness examination in subsequent trial dates. At the end of each date, the court will schedule the next trial date and notify the parties what issues should be addressed on that date. Before the next trial, parties will submit briefs and evidence on the issues for the court's review in advance. Upon going through the issues on the next trial date, the court will decide whether it has heard enough from the parties to render a decision.

8.6.11 Alternative dispute resolution

8.6.11.1 Meaning and scope

Alternative dispute resolution (ADR) refers to any legal means of resolving disputes without litigation and trial. ADR is classified into judicial, administrative and private ADR according to the characteristics of the responsible institution. In terms of the method of settling disputes, ADR can also be classified into settlement, mediation and arbitration. The salient features of litigation and ADR are compared in Table 8.1.

Table 8.1 Comparison of litigation and alternative dispute resolution

Feature	Litigation	Alternative dispute resolution		
		Settlement	Mediation	Arbitration
Participation	Involuntary	Voluntary	Voluntary	Voluntary
Effect of adjudication	Claim preclusion, executory power	Agreement ¹	Agreement ¹	Same as a final and conclusive judgment
Scope of effect	National	International	International	International
Presider	Judge	—	Selected by the parties	Selected by the parties
Procedural formalities	Conducted according to the Civil Procedure Act etc.	Informal	Informal	Involves less formality ²
Outcome	Written reasoned judgment	Agreement	Agreement	Reasoned arbitration award
Disclosure	Disclosure required	Nondisclosure	Nondisclosure	Nondisclosure

¹ Settlement and mediation by the court both have the same effect as a judgment.

² Except those contrary to the mandatory provisions, parties may agree on the arbitral proceedings. However, if they fail to reach an agreement, the arbitral proceedings will be conducted in accordance with the Arbitration Act.¹³⁵

In the following sections, we discuss the systems both of settlement in litigation and of mediation falling under the category of judicial ADR. The judicial ADR systems discussed below are only applicable to civil patent lawsuits and not to administrative or criminal patent lawsuits.

8.6.11.2 Settlement in litigation

The term “settlement in litigation” refers to an agreement that parties to an ongoing lawsuit can reach before the judge through mutual concessions on their claims for the rights or legal relationships at issue. Any settlement reached between the parties out of court is only considered a settlement agreement in private law and does not have the same effect as a settlement in litigation.¹³⁶

8.6.11.2.1 Process

Settlement in litigation may be reached at any time while the lawsuit is pending. Thus, a case may be settled in litigation at the appellate court or the Supreme Court, even after the argument is closed and the judgment is rendered, so long as the judgment is not confirmed as final and conclusive.

¹³⁵ Joongjaebeob (Arbitration Act), art. 20(1)–(2).

¹³⁶ Minbeob (Civil Code), art. 731.

In principle, any settlement in litigation can only be reached by the parties' verbal statement in court on the date of hearing. If the parties make a statement regarding the settlement agreement, this will be written down in the court record for trial to have the same effect as a final and conclusive judgment. This may be done on a date of hearing, preparatory hearing or examination of evidence, or a separate hearing date for settlement may be scheduled. In addition, a settlement is considered as reached if either party has expressed the intent of settlement in their brief, authenticated by a notarial office, and the other party has appeared in court on the hearing date and accepted such intent to settle.¹³⁷

8.6.11.2.2 Effect

When a settlement in litigation is stated in the court record for trial, such protocol has the same effect as a final and conclusive judgment.¹³⁸ Therefore, the settlement closes the lawsuit, and the settlement record serves as the source of executory force for compulsory execution.¹³⁹ Given the fact that a record of settlement in litigation has the same effect as a final and conclusive judgment and thus has the effect of *res judicata*, neither party may assert the nullity of the settlement between themselves even if its content is in violation of mandatory provisions unless the record is revoked by a quasi-retrial.¹⁴⁰

8.6.11.2.3 Recommendation of a settlement

A court, commissioned judge or entrusted judge may, on the case during the pendency of action, render *ex officio* a ruling of settlement recommendation to fairly settle the case by taking account of the parties' interests and all other circumstances, within the boundary of the gist of the claim.¹⁴¹ A ruling of settlement recommendation has the same effect as a judicial settlement when neither party raises an objection within two weeks of the date of receiving the ruling from the court or when such an objection is withdrawn or waived.¹⁴²

As explained in Section 8.6.11.2, a settlement agreement in private law, which is reached between the parties out of court, does not have the same effect as a settlement in litigation. In private settlements, the parties may resort to the settlement recommendation system. In some cases, the court may render a ruling of settlement recommendation after the closing of argument but before pronouncing a judgment, based on its review of the case records in their entirety.

8.6.11.3 Mediation

The civil mediation system is a dispute resolution method wherein a neutral third party (or a mediator) intervenes in the negotiation process, with the consent of the parties, to help them easily settle the dispute. It is similar to a settlement in litigation in that an agreement should be reached between the parties but different in that the mediator more actively recommends and facilitates an agreement between the parties.

8.6.11.3.1 Institutions

Mediation cases may be dealt with by either a mediation judge, standing commissioner, mediation council or a court handling the lawsuit serving as a mediation institution.¹⁴³ These are, respectively, called mediation by a mediation judge, mediation by a standing commissioner, mediation by a mediation council and mediation by a court of the lawsuit.

Courts also operate a mediation system with external institutions, entrusting them with the handling of mediation cases through memorandums of understanding. Some courts operate all of the mediation institutions, and others have only some of them, as each court sees fit.

8.6.11.3.2 Proceedings

Mediation proceedings may be initiated by either party's filing of a request for mediation with a court or by a court of the lawsuit's referral to mediation.¹⁴⁴ Thus, a case could first start with

¹³⁷ Civil Procedure Act, art. 148(3).

¹³⁸ Civil Procedure Act, art. 220.

¹³⁹ Minsajiphaengbeob (Civil Execution Act), art. 56.

¹⁴⁰ Daebeobwon (Sup. Ct), Oct. 8, 1999, 98Da38760.

¹⁴¹ Civil Procedure Act, art. 225.

¹⁴² Civil Procedure Act, art. 231.

¹⁴³ Minsajojeongbeob (Judicial Conciliation of Civil Disputes Act), art. 7.

¹⁴⁴ Judicial Conciliation of Civil Disputes Act, arts 2, 6.

mediation but return to litigation after the mediation fails;¹⁴⁵ or it could start with litigation, be referred to mediation, and then return to litigation after mediation fails.

Mediation proceedings usually take place in a court's mediation chamber on a scheduled date but may also be conducted in any other appropriate venue other than the courthouse.¹⁴⁶ Mediation proceedings may be sealed from the public; however, a mediation judge may allow nonparties to attend the sealed proceedings where appropriate.¹⁴⁷

8.6.11.3.3 Completion and effect of mediation

Mediation is duly reached by putting the matters agreed upon between the parties into the record.¹⁴⁸ Accordingly, once mediation is reached at the mediation hearing, authentic copies of the mediation record are sent to the parties, and the mediation has the same effect as a judicial settlement in litigation.¹⁴⁹

With respect to cases where agreement has not been reached or where the terms of the agreement are deemed inappropriate, a mediation judge or judge at the court of the lawsuit in charge of mediation may render a ruling to ensure a fair resolution of the case, taking into account *ex officio* the interests of the parties and all other relevant circumstances to the extent not contrary to the purpose of the request for mediation.¹⁵⁰ This is called a "ruling in lieu of mediation" or "mandatory mediation ruling." As with a ruling of settlement recommendation, a mandatory mediation ruling has the same effect as a judicial settlement if neither party files an objection against the decision within two weeks from the date on which they received an authentic copy of the decision.¹⁵¹

Mediation proceedings are closed when mediation is not constituted or when an objection is filed against a mandatory mediation ruling. In such cases, the case is shifted to litigation if a lawsuit was filed before the mediation proceedings; if mediation was sought without filing any lawsuit, a lawsuit is regarded to have been filed at the time the request for mediation was made.

8.6.11.3.4 Current mediation systems of the Patent Court

Since January 1, 2016, the Patent Court has had exclusive jurisdiction over appellate cases involving patent infringement. On March 10, 2016, the Patent Court established the Internal Regulations on Patent Court Mediation Commissioners. The Patent Court has taken these regulations as the basis for operating a mediation council consisting of legal professionals (e.g., former judges with profound experience in patent litigation) and technical experts (e.g., those from research institutions and university professors). Furthermore, a mediation judge system has been in place since February 27, 2017, to manage mediation cases in a systematic manner and to facilitate early mediation.¹⁵² The Patent Court also operates a mediation system whereby it may entrust external institutions, such as the Korean Commercial Arbitration Board, with the handling of mediation cases through memorandums of understanding.

8.6.11.4 Arbitration

Arbitration refers to a procedure to settle a dispute that the parties can resolve through reconciliation – not by a judgment of a court but by an award of an arbitrator.¹⁵³ Given that arbitration is determined by an award of an arbitrator, it is fundamentally different from settlement and mediation reached by an agreement between the parties. In this respect, arbitration has a lot in common with the general litigation system but is still different in that arbitration is not disclosed to the public in principle, allows more flexibility in terms of procedural formalities and usually relies on a single-instance resolution.

145 In such cases where the complainant files a lawsuit, they must supplement the amount of the stamp to reflect the amount of the stamp to be affixed to the complaint less the amount of the stamp affixed to the written request for mediation. Judicial Conciliation of Civil Disputes Act, art. 36(2).

146 Judicial Conciliation of Civil Disputes Act, art. 9. For instance, even though mediation by the Patent Court should be conducted within the Patent Court, it may also take place in the mediation chamber in the Seoul Central District Court, and, in some cases, hearings for mediation are held in the office of a commissioner for the convenience of the parties.

147 Judicial Conciliation of Civil Disputes Act, art. 20.

148 Judicial Conciliation of Civil Disputes Act, art. 28.

149 Judicial Conciliation of Civil Disputes Act, art. 29.

150 Judicial Conciliation of Civil Disputes Act, art. 30.

151 Judicial Conciliation of Civil Disputes Act, art. 34(4).

152 The use of mediation judges has gradually gained momentum, thereby increasing the number of applications and the success rate. In 2019, 45.8 percent of cases were successfully mediated, and this included not only patent cases but also trademark and design cases.

153 Arbitration Act, art. 3(1).

For mediation cases pursuant to the Judicial Conciliation of Civil Disputes Act, a case may be freely referred to mediation during the course of litigation or may be returned to the litigation procedure. For arbitration cases, however, a court should dismiss the action that has been brought in a matter that is the subject of an arbitration agreement when the defendant raises, as a defense, the existence of an arbitration agreement, provided that the court does not find the arbitration agreement null and void, inoperative or incapable of being performed.¹⁵⁴

An arbitration agreement takes effect when the parties agree in writing to settle by arbitration – not by a judgment of a court – all or part of the dispute that has already arisen or might arise in the future in respect of legal relationships under private law. The effectiveness of an arbitration clause as an arbitration agreement is determined based on an overall consideration of the meaning of arbitration as defined in the Arbitration Act, the nature and form of the arbitration agreement, and specific circumstances, including the content of the relevant arbitration clauses and the background to the parties' decision to have the arbitration clause. Optional arbitration clauses only take effect when either party opts for an arbitration procedure, not a judgment of a court, and pursues dispute resolution via arbitration, and the other party participates in the arbitration procedure without objection.¹⁵⁵

Given that arbitral proceedings are conducted for an award, it is difficult to link them with litigation proceedings, unlike mediation, which relies on an agreement between the parties. Therefore, even though it is technically possible, there have been very few cases wherein arbitration proceedings were initiated after withdrawing the lawsuit in the course of litigation proceedings due to reasons such as having an *ex post* arbitration agreement.

8.7 Civil remedies

A right holder is mainly entitled to two forms of relief from patent infringement – injunction and damages. They may be sought together or separately.¹⁵⁶ Other forms of remedies include measures necessary to reinstate the goodwill or reputation of the right holder. For employee inventions, the employee may seek compensation for employee invention for what they invented in relation to the duties of the employment.

8.7.1 Recovery of goodwill and reputation

When the plaintiff in a patent infringement lawsuit (i.e., the patentee or exclusive licensee) demands that the defendant put up advertisements in newspapers or any other periodical publications for explanatory purposes and as measures necessary to reinstate the plaintiff's goodwill or reputation – in lieu of or in addition to compensatory damages – the plaintiff should specify in their demand in the complaint the specifics of such advertisements, such as the contents, size, font size and so on.

8.7.2 Compensation for employee inventions

8.7.2.1 Overview

An employee invention refers to an invention, utility model or creation protected under the Patent Act, Utility Model Act or Design Protection Act, respectively [hereinafter collectively referred to as an "invention" unless otherwise specified], that an employee, executive officer of a corporation or government employee [hereinafter collectively referred to as an "employee" unless otherwise specified] makes in connection with their duties, where it falls within the scope of the business of the employer, the corporation, or the national or local government, and where the activities that have led to the invention fall within the present or past duties of the employee (Article 2(ii) of the Invention Promotion Act). An employer is automatically entitled to a free nonexclusive license to an employee's invention (Article 10(1) of the Invention Promotion Act). Where the employer succeeds, under a contract or employment regulations, the patent, utility model or design rights related to the employee's invention – or the right to acquire them – or is to be granted an exclusive license to the right, the employee is entitled to fair compensation (Article 15(1) of the Invention Promotion Act).

¹⁵⁴ Arbitration Act, art. 9(1).

¹⁵⁵ See Daebeobwon (Sup. Ct), Aug. 22, 2003, 2003Da318.

¹⁵⁶ Parties often seek injunction only because significant time will be spent on assessing damages award if the injunction claim is consolidated with claim for damages.

Provisions concerning compensation for employee inventions fall within the sphere governed jointly by civil law, labor law and patent law. Such provisions are regarded as compulsory provisions intended to protect employees, who are often in the weaker position at the negotiation table, so that the distinct legal nature of the employee invention is acknowledged, and the employee enjoys compensation for the invention separately from the wages compensating them for their service. Typical defenses against the claim for compensation are that the statute of limitations has run (10 years, as in general credit cases) or that a certain amount was already paid to the employee and should be deducted accordingly.

8.7.2.2 Elements

The plaintiff should contend and prove (i) that they invented the employee invention; (ii) that the defendant, who is the employer, succeeded from the plaintiff the patent, utility model or design right – or the rights to acquire them – for the employee invention; (iii) that the employer earned sole and exclusive profits generated by the employee invention; and (iv) the scope of compensation for the employee invention.

First, to prove the fact that the plaintiff is the inventor of the employee invention, it must be established that (i) they are an employee; (ii) the invention falls within the scope of business of the employer; and (iii) the invention falls within the present or past duties of the employee. More importantly, the plaintiff must have contributed to the completion of the invention. The advancements of science and technology in modern society often require a group of departments or multiple parties to cooperate for inventions, raising the issue of inventorship. An employee can be a co-inventor only if they have had a mutually cooperative relationship with others for the completion of the invention. More specifically, the employee must have contributed to the actual creation of a technical idea by, for example, (i) suggesting, adding or supplementing a concrete idea to solve technical problems of the invention; (ii) embodying a new idea through experiments; (iii) providing a specific means or method to achieve the purpose and effects of the invention; or (iv) providing detailed advice or guidance to enable the creation of the invention.¹⁵⁷

Second, considering that the employer is entitled to a nonexclusive license for free even if they do not succeed the right relating to the employee invention (Article 10(1) of the Invention Promotion Act), the term “employer’s profits,” when calculating the amount of compensation for the employee, refers to the profits the employer is expected to earn by acquiring a sole and exclusive position to practice the employee invention that surpasses a nonexclusive license.¹⁵⁸

Third and most importantly, all these elements must be taken into consideration to reach a fair sum for compensation. The Invention Promotion Act sets forth the following factors for calculation:

- A. the profits the employer anticipates obtaining with the employee invention. This is calculated by product sales revenue × hypothetical royalty rate × contribution ratio of the exclusivity of the right;
- B. the employee’s ratio of contribution, with respect to the employer’s contribution, to the completion of the invention. This is calculated by (1 – the employer’s contribution ratio) (Article 15(6) of the Invention Promotion Act);
- C. if the employee invention is a joint invention, the employee’s ratio of contribution with respect to co-inventors; and
- D. if the product that embodies the invention is a part or component of a multicomponent final product, the employee’s ratio of contribution to the final product. In this case, the sales revenue of the final product should be used for (A).

The resulting formula calculation for the amount of compensation is $A \times B \times C \times D$: the amount of the employer’s profits × the ratio of the employee’s contribution with respect to the employer’s contribution × the ratio of the employee’s contribution with respect to co-inventors (for joint inventions) × the ratio of the employee’s contribution to the final product (for inventions that form a part or component of a multicomponent final product).

157 See Daebeobwon (Sup. Ct), July 28, 2011, 2009Da75178.

158 See Daebeobwon (Sup. Ct), Sep. 8, 2011, 2009Da91507.

8.7.3 Permanent injunction

Once patent infringement is established, as discussed in Section 8.5, the patentee may seek a court order preventing the defendant from manufacturing, using or assigning the defendant's products or using its processes.¹⁵⁹ The patentee may also seek an order for the defendant to take actions, for example, to destroy the products by which the infringement had been committed.¹⁶⁰ These are different forms of permanent injunctions. In this section, we focus on the issues arising in relation to injunctions.

8.7.3.1 Elements

There are five elements to a permanent injunction.

The person seeking an injunction against infringement (i.e., the patentee). The plaintiff must be registered as the patentee when argument at the fact-finding trial is closed. A nonexclusive licensee is not entitled to file a claim for an injunction against infringement because they do not have the exclusive rights to practice the patent. If a group of persons jointly own the patent right, one of them may independently file for an injunction because the exercise of the claim is an act of preservation.

The party subject to the injunctive order (i.e., the person committing infringement). The patentee may seek an injunction against a person who infringes or is likely to infringe on their patent right by practicing the patented invention without legitimate authority to do so. Nonetheless, a request for disposal or other actions under Article 126(2) of the Patent Act should be made to the person who owns or has the right to dispose of the infringing product or facilities subject to the destruction order.¹⁶¹ In cases where a group of persons has practiced the patented invention, and such acts individually constitute patent infringement,¹⁶² the patentee may seek an injunction on each act against each of the infringers.

Practicing the patented invention for business purposes. To constitute patent infringement, the infringing party must have exploited the patented invention for business purposes. Practicing the invention for personal or household purposes does not constitute infringement. As long as the patented invention was practiced for business purposes, the number and scale of the practice, as well as whether any profit was derived therefrom, are irrelevant. Implementation for nonprofit business operations is still a practice for business purposes.

Specification of the infringing act and the defendant's duty to disclose the specific act. The plaintiff should specify each infringing act committed by the defendant. When the defendant disputes the specified infringing act, the burden of proof rests on the plaintiff. The Patent Act requires the defendant to disclose their actual conduct, and, where they fail to present the specific conduct without any justifiable reason, the court may deem the specific infringing conduct as alleged by the plaintiff to be true.

Infringement or likelihood of infringement. The patentee may seek an injunction against the implementation of the patented invention by the other party if the other party is currently committing an infringing act or, even if not, is likely to commit the infringing act in the future.

8.7.3.2 Scope

There are three elements to the scope of a permanent injunction.

Claim for an injunction. Once the aforementioned requirements for patent infringement are met, the court's default move is to automatically issue a permanent injunction as per the plaintiff's claim, usually to prohibit the practices of the other party that amount to patent infringement. If the patented invention pertains to a part or component of the defendant's product, issues may arise as to what extent the permanent injunction covers the whole product and whether the plaintiff may also claim for destruction of the whole product in addition to the injunction. The law on this issue is unsettled. Some lower courts have issued injunctions only against the infringing

¹⁵⁹ Patent Act, art. 126(1).

¹⁶⁰ Patent Act, art. 126(2).

¹⁶¹ See *Daebeobwon* (Sup. Ct), Dec. 23, 1996, 96Da16605.

¹⁶² E.g., where person A manufactures the infringing products while person B sells and person C uses those products.

part and have ordered the destruction of the manufacturing equipment on the ground that the infringing part could be detached and separately traded from the rest of the product.¹⁶³

Claim for disposal of infringing products. The patentee may demand the disposal of the products that constituted infringement (including the products obtained by the infringement if the relevant invention is a product by process invention), the removal of the facilities used for the infringing act, and other measures necessary to prevent infringement.¹⁶⁴ A claim for the disposal of such products must accompany a claim for injunction and may not be independently sought. The products to be disposed of should be clearly specified in an appendix. The court will dismiss a claim for any unspecified part in the plaintiff's demand in the complaint.

Other measures necessary to prevent infringement. The Patent Act allows the patentee to claim for "other measures necessary to prevent infringement." However, a far-fetched and unlimited interpretation of the term may cause an excessive burden to the other party beyond the protectable scope of the patent right. The need for such measures should be determined after balancing the potential disadvantage to the other party if the measure is issued and the potential disadvantage to the patentee if the claim is dismissed.¹⁶⁵

An example of a court order for an injunction against infringement is as follows:

- A. The defendant shall not produce, use, assign, lease, import, offer to assign or lease, or display to assign or lease each product described in [Appendix 1] PRODUCTS practiced by the defendant.
- B. The defendant shall discard finished goods and semi-finished goods (articles that have the structure of finished goods but are not yet completed) of each product described in [Appendix 1] PRODUCTS practiced by the defendant in the head office, branch office, office, business office, plant, or warehouse of the defendant. The defendant shall also discard all equipment used solely for the production of the goods.

8.7.4 Damages

The Patent Act articulates its own provision for the patentee's right to seek compensatory damages from infringement in Article 128(1) as follows: "[a] patentee or exclusive licensee may claim for compensation for the damages caused by a person who has willfully or negligently infringed the patent or exclusive license." Nonetheless, patent infringement is generally viewed as a type of tort under the Civil Act. Accordingly, as in cases of a tort, the plaintiff in a lawsuit seeking compensatory damages has to contend and prove that (i) the plaintiff is the patentee, (ii) the infringer has willfully or negligently infringed the patentee's patent right, (iii) the infringer's patent infringement is unlawful, (iv) the infringer was capable of assuming liability at the time of the infringement, (v) the patentee suffered damages, and (vi) there is proximate causation between the infringement on the patent right and the damages suffered by the plaintiff.¹⁶⁶

8.7.4.1 Elements

Damages may be awarded only upon the showing of infringement. As the criteria for establishing infringement have been discussed in detail above, the following discussion focuses on other elements for receiving damages.

Claimant (i.e., the patentee). The claimant seeking damages must be the patentee or exclusive licensee. For a jointly owned patent, it is the judicial practice to award damages only in proportion to each right holder's percentage of ownership. A nonexclusive licensee does not have standing, as the right has no exclusive effect, but a sole nonexclusive licensee may be successful in a tort claim based on infringement of credit.

The party responding to the claim for damages (i.e., the infringer). In most cases, the defendant in a lawsuit seeking damages for patent infringement is the direct infringer. Where indirect

¹⁶³ IP Litigation Research Committee, *Intellectual Property Law Theory and Practice*, at 492.

¹⁶⁴ Patent Act, art. 126(2).

¹⁶⁵ IP Litigation Research Committee, *Intellectual Property Law Theory and Practice*, at 494.

¹⁶⁶ *Intellectual Property Law Theory and Practice* at 528.

infringement is established under Article 127 of the Patent Act, the indirect infringer is also liable to compensate for the damages. Further, as in cases of tort under the Civil Act, any person who has aided or abetted patent infringement is also held liable for damages jointly with the patent infringer. In cases where patent infringement is divided among multiple parties,¹⁶⁷ joint tort prescribed in Article 760 of the Civil Act may be established. Views are split on whether the objective element that each tortfeasor's act jointly occurred is sufficient to establish joint tort (objective joint tort theory) or whether the subject element of the tortfeasors' knowledge of acting jointly or conspiring to act should also be met (subjective joint tort theory).

Willfulness or negligence. A damages claim requires willfulness or negligence to succeed. However, the intent element is rarely disputed in practice because the Patent Act sets forth that "a person who infringes a patent or exclusive license of any third person shall be presumed negligent regarding such infringement."¹⁶⁸ The amended Patent Act effective on January 8, 2019, added a provision allowing the court to enhance damages up to three times the actual damages if the infringement of the patent or exclusive license of another person is deemed to be willful. This new provision is expected to be one of the key issues that draw attention in practice.

8.7.4.2 Calculation of damages

The patentee may seek compensation for any damages sustained as a result of the infringement from any person who has willfully or negligently infringed the patent or exclusive license. The Patent Act provides that an infringer is presumed to have infringed with negligence. The Patent Act recognizes four grounds in assessing damages: (i) loss suffered by the patentee, (ii) the profits earned by the infringer (which is presumed to be the amount of damages suffered by the plaintiff), (iii) reasonable royalty (at the minimum) and (iv) damages determined at the court's discretion based on an examination of the evidence and a review of overall arguments. Discretionary damages may be awarded if the nature of the case makes it difficult to produce evidence proving the actual damages incurred.

An action for damages resulting from infringement must be filed within three years from the date the plaintiff became aware of the damages caused by the infringement or within 10 years from the date of the infringement, whichever is earlier. The plaintiff must identify the alleged infringer. An action for damages based on an infringer's unjust enrichment may be filed within 10 years.

8.7.4.2.1 Lost profits

The patentee's lost profits as the basis for the award of damages is stipulated in Article 128(2) of the Patent Act. This provision was recently amended to ensure fair compensation by clarifying that, on top of lost profits, the patentee may also recover reasonable royalties for the infringing goods that were transferred in excess of the right holder's production capacity (partial amendment by Law No. 17422, effective from December 10, 2020).

For units that were within the patentee's production capacity, lost profits may be awarded for the number of units that the patentee would have sold but for the infringement. For these units, the damages may be calculated by multiplying the number of units of the infringer's transferred articles by the profit per unit that the patentee could have sold in the absence of the infringement (Article 128(2)(i) of the Patent Act). This excludes the number of units the patentee could not sell due to reasons other than the infringement (if any) and the number of units that were outside of the right holder's production capacity.

While the lost profit approach had been around before the amendment to the Patent Act, the pre-amendment statute did not answer the lingering question as to whether the patentee could also recover damages for the number of units that were outside of their production capacity. In response, the amended Patent Act effective on December 10, 2020, added a provision that, if the transferred amount of the infringer's articles exceeds the patentee's own production capacity, the patentee can recover reasonable royalty for the excess (Article 128(2)(ii) of the Patent Act).

This new provision clarified that an amount equivalent to the royalty prescribed in Article 128(5) of the Patent Act can be awarded as damages for the infringing products transferred to third

¹⁶⁷ This refers to cases where none of the parties practice all of the elements of a patented claim severally, but, when taken together, their joint act implements all elements of the claim.

¹⁶⁸ Patent Act, art. 130.

parties that (i) exceed the quantity calculated by deducting the number of units actually sold from the number of units that could have been produced by the patentee or (ii) could not be sold due to any reason other than the infringement. The amendment clarified that a reasonable royalty for practicing the patented invention may be recovered for the above units (except for those for which the patentee could not have earned royalties even without the infringement: e.g., any number of units for which the patentee could not have granted an exclusive or nonexclusive license on the patent or for which the exclusive licensee could not have granted a nonexclusive license on the exclusive license).

8.7.4.2.2 Infringer's profits

As it is relatively easier to establish the amount of profits gained by the infringer than the actual loss incurred to the patentee from the patent infringement, the infringer's profit is often presumed to be the patentee's lost profit. The "profit" here includes all types of profits earned by the infringer through the infringement on the patent right without specific limits. In practice, the net profit theory (i.e., profit = sales revenue – [fixed costs + variable costs]) and the marginal profit theory (profit = sales revenue – variable costs. Unlike the net profit theory, fixed costs are not deducted) are commonly adopted. While less challenging than proving lost profits, an infringer's profits may also be difficult to prove without proper evidence. This has led courts to resort to awarding discretionary damages, as discussed below in Section 8.7.4.2.5.

8.7.4.2.3 Reasonable royalties

A patentee can recover reasonable royalties that they would have ordinarily received. The patentee should contend and prove (i) the infringement on the patent right, (ii) the sales revenue or quantity of the products manufactured and sold, and (iii) the reasonable amount of royalty that would have been received by the patentee. The patentee is not required to contend and prove specific occurrences of loss.

To determine the reasonable royalty for a particular patent, the following may be considered:

- the objective technical value of the patented invention;
- license agreements with third parties for the patented invention, if any;
- license agreements with the defendant in the past, if any;
- royalties that may be received for similar inventions in the same technical field;
- the remaining term of the patent;
- the type of the patentee's use of the patent;
- the existence of substitute technologies for the patented invention; and
- the infringer's profits from the infringement.¹⁶⁹

The reasonable royalty provision does not set forth a ceiling for damages. Therefore, when the amount of loss exceeds the reasonable royalty, the patentee may also seek compensatory damages for the excess amount in accordance with the principle of compensation for actual harm.

8.7.4.2.4 Reduced damages

For balanced protection of both sides, the Patent Act protects the patentee by presuming the infringer's negligence in Article 130 and prescribing the method of calculating damages in Article 128(2)–(5) while providing a protective measure for the infringer in Article 128(6). Article 128(6) prescribes that the court may consider the lack of willfulness or lack of gross negligence by the infringer when awarding damages, so the infringer should contend and prove as such to argue that an award should be reduced. However, even if the amount of damages is reduced accordingly, the reduced amount may not be lower than a reasonable royalty.

8.7.4.2.5 Calculation at the court's discretion

When the nature of the relevant facts makes it extremely difficult to prove the underlying facts for establishing the amount of damages under any of the preceding grounds, even though the occurrence of harm itself has been acknowledged, the Patent Act allows the court to determine a reasonable amount of damages by taking into account the overall purport of the arguments and other relevant circumstances found based on the evidence, notwithstanding the provisions of

¹⁶⁹ See *Daebeobwon* (Sup. Ct), April 27, 2006, 2003Da15006.

Article 128(2)–(6). However, discretionary awards are by no means arbitrary, and most court decisions clearly state the calculation basis even when the amount of damages has been determined at the court's discretion.

8.7.4.2.6 Enhanced (treble) damages

The amendment to the Patent Act effective on July 9, 2019, included provisions for an enhanced damages system that provides compensation up to three times the amount of damages when an infringement was willful. The term “willful” means that the infringer committed the act while being aware of the fact that the act would result in patent infringement. Under the amended Patent Act, in determining willfulness, the court should comprehensively consider the following factors: (i) whether the infringer is in a superior position to the patentee, (ii) willfulness or how well the infringer was aware of the likelihood that the infringing act would cause harm, (iii) the significance of the harm to the patentee, (iv) the economic benefits to the infringer resulting from the infringement, (v) the frequency and length of the infringing act, (vi) the criminal penalty for the infringing act, (vii) the financial status of the infringer, and (viii) the level of effort the infringer exerted to provide relief.

8.8 Appellate review

8.8.1 Appellate-level courts

A party in a civil infringement action involving patent or other listed IP rights may appeal the decision of the district court to the Patent Court. Other IP infringement cases generally must be appealed to one of the high courts (or to an appellate panel of the district court in some cases).¹⁷⁰ Unless dismissed on procedural grounds, appellate proceedings are conducted on a substantially *de novo* basis. In other words, while the appellate court will generally rely heavily on the record of the lower court, it is typical for the court to admit new evidence and arguments from the parties.

If a party requests to introduce new evidence in the appellate proceeding, the party must provide a detailed explanation for the failure to submit the evidence in the lower court. The court will then determine whether to admit the evidence in consideration of the circumstances, including whether significant harm to the other party is expected from a delay in court proceedings or whether an expedited proceeding is necessary.¹⁷¹

Unlike in the court of first instance, where hearings are often held multiple times, the appellate court usually closes the hearing after the first issue-by-issue review unless a new piece of evidence is introduced. In most cases, each party holds a technology review session explaining the technology from its viewpoint, followed by oral arguments for about 20 minutes.¹⁷² After both parties have presented their cases, the judicial panel asks questions by issue.¹⁷³

When an infringement case and a revocation case of IPTAB decision involving the same patent or other listed IP rights are pending concurrently before the same judicial panel and are litigated by the same parties, and when the need for parallel hearing is recognized, the court will, in principle, hold the trial on both cases in parallel.¹⁷⁴

The appellate court will generally try to render a decision within six months to one year from the filing of the appeal. However, this timeframe may be significantly longer for complex cases.

8.8.2 Supreme Court

A decision by the appellate court may be appealed to the Supreme Court (the highest court in the Republic of Korea). The Supreme Court generally only hears cases dealing with legal issues of material importance, such as legal issues of first impression. Otherwise, the appeal will be summarily dismissed without a review of the merits of the case, typically within four months from the date of transfer of litigation records to the Supreme Court.

¹⁷⁰ See Section 8.6.2.1 for a discussion of jurisdiction.

¹⁷¹ Patent Court, *Practice Directions for Civil Appellate Trial*, ch. V(1)(A).

¹⁷² See Section 8.6.8.2 regarding these technology review sessions.

¹⁷³ Patent Court, *Practice Directions for Civil Appellate Trial*, ch. IV(1)(A).

¹⁷⁴ Patent Court, *Practice Directions for Civil Appellate Trial*, ch. IV(3).

If the case is accepted for substantive review, the Supreme Court will decide the case in view of the evidence presented to the lower courts and will typically render a decision within one to two years from the date of appeal. These appeals are usually handled by a panel of four justices. However, the Supreme Court may choose to review the appeal *en banc* when the usual four-justice panel seems insufficient, such as when there is a need to overrule precedents.

8.9 Criminal proceedings

Chapter XII (penalty provisions) of the Patent Act provides for criminal punishment for certain acts related to patent rights – lawsuits related thereto are called criminal patent lawsuits. Such acts include patent infringement,¹⁷⁵ the divulgence of confidential information,¹⁷⁶ perjury,¹⁷⁷ false indication,¹⁷⁸ fraud¹⁷⁹ and a breach of orders to maintain confidentiality.¹⁸⁰ Of these, we will mainly discuss patent infringement in this section because it is the most common in practice.

8.9.1 Offense not punishable against the victim's will

Previously, patent infringement was an offense subject to prosecution only upon complaint, meaning that it could not be prosecuted without the victim's complaint. However, with the amendment of Article 225(2) of the Patent Act on October 20, 2020 (partial amendment by Law No. 17536), patent infringements committed thereafter became an offense that cannot be prosecuted against the express will of the victim but are prosecutable without the victim's official complaint.

8.9.2 Jurisdiction

8.9.2.1 Territorial jurisdiction

Unlike civil patent cases, there is no provision on territorial jurisdiction specifically carved out for criminal patent cases. Thus, like in any criminal case, the court having jurisdiction over the place of the offense, the place of domicile or residence of the defendant, or the place where the defendant is presently located has territorial jurisdiction over the criminal patent case.¹⁸¹

8.9.2.2 Subject matter jurisdiction

For civil cases, the judicial power of a district court is exercised by a single judge, in principle, while the cases defined in Article 32(1) of the Court Organization Act may exceptionally be judged by a panel of the district court (Articles 7(4)–(5) and 32(1) of the Court Organization Act). Article 32(1)(iii) of the Court Organization Act dictates that, except for certain types of cases, a panel should preside over cases that may result in “capital punishment, imprisonment with or without labor for an indefinite term or for not less than one year in the short term.” However, such punishments are not applicable to the patent crimes defined in Chapter XII of the Patent Act. Therefore, all criminal patent cases are handled by a single-judge bench.

175 Patent Act, art. 225 (“(1) Any person who infringes a patent or an exclusive license shall be punished by imprisonment with labor for not more than seven years or by a fine not exceeding 100 million won. (2) No person shall be prosecuted for committing an offense under paragraph (1) against the victim's express will”).

176 Patent Act, Art. 226 (“Any current or former employee of the Korean Intellectual Property Office or the Korean Intellectual Property Trial and Appeal Board who divulges or pirates confidential information that he/she has become aware of regarding an invention claimed in a pending patent (including an invention claimed in a pending international patent application) in the course of performing his/her duties shall be punished by imprisonment with labor for not more than five years or by a fine not exceeding 50 million won”).

177 Patent Act, 227(1) (“Any witness, expert witness, or interpreter who makes a false statement under oath taken under this Act in his/her testimony, expert opinion, or interpretation before the Korean Intellectual Property Trial and Appeal Board shall be punished by imprisonment with labor for not more than five years or by a fine not exceeding 50 million won”).

178 Patent Act, 228 (“Any person who violates Article 224 shall be punished by imprisonment with labor for not more than three years, or by a fine not exceeding 30 million won”).

179 Patent Act, 229 (“Any person who obtains a patent, the registration of an extension of the valid term of a patent, or an administrative ruling or decision on a request for cancellation of a granted patent in his/her favor by fraud or other improper means shall be punished by imprisonment with labor for not more than three years or by a fine not exceeding 30 million won”).

180 Patent Act, 229-2(1) (“Any person who breaches an order to maintain confidentiality issued under Article 224-3(1), inside or outside of the Republic of Korea, without just grounds shall be punished by imprisonment with labor for not more than five years or by a fine not exceeding 50 million won”).

181 Hyeongsasosongbeob (Criminal Procedure Act), art. 4(1). Jurisdiction of each court is determined in accordance with Annex 3 of the Gagegub Beobwonui Seolchiwa Gwanhalguyeoge Gwanhan Beobryul (Act on the Establishment and Jurisdiction of Courts of Various Levels) as prescribed in art. 4(i) of the same Act.

8.9.2.3 Jurisdiction by court level

As stated above, criminal patent cases go to single judges in district courts or their branches and are appealed to panels of district courts (Article 32(2) of the Court Organization Act). Appeals thereof are heard by the Supreme Court.

8.9.3 Investigation

8.9.3.1 Investigators and initiation of investigation

The Criminal Procedure Act amended on January 1, 2021 has excluded violation of the Patent Act from the offenses subject to initiation of investigation by a prosecutor. As a result, the primary investigators of patent infringement in the Republic of Korea were divided into general judicial police officers and special judicial police officers of the KIPO.

At the same time, the provision that required a patentee to file a complaint within six months from the date on which they became aware of the infringer was no longer applicable. Patent infringement was changed from an offense subject to prosecution only upon complaint to an offense not punishable against the victim's will, and a special judicial police officer may recognize patent infringement if they discover it. However, in practice, patent infringement is brought as a criminal case after the patentee has analyzed whether the infringer's act constitutes infringement. Therefore, the primary investigation into most patent infringement is still initiated upon a patentee's complaint.

As described above, a two-track investigation system is in place for criminal patent infringement – by general judicial police officers and special judicial police officers. After the primary investigation by them, the case may be transferred to the prosecutors' office from each but in different manners. A general judicial police officer transfers the case to the prosecutors' office if they decide to acknowledge the allegation or, even when they decide not to acknowledge the allegation, if there is an objection by the patentee (Articles 245-5(1) and 245-7(2) of the Criminal Procedure Act). When a special judicial police officer conducts a primary investigation, they express their opinion on whether to acknowledge the allegation and transfer all cases to the prosecution (Article 245-10(5) and (6) of the Criminal Procedure Act).

The prosecution may directly conduct a supplementary investigation into the transferred patent infringement case, request a judicial police officer to conduct the supplementary investigation (Article 197-2(1) of the Criminal Procedure Act) or direct a special judicial police officer to reinvestigate the case (Article 245-10(2) of the Criminal Procedure Act). If the prosecution finds an offense directly related to the transferred offense in its direct supplementary investigation, it may additionally recognize and investigate the offense (Article 4(1)(c) of the Prosecutors' Office Act).

8.9.3.2 Designation of a focal prosecutors' office and establishment of a specialized investigation department

Since 2014, the prosecution has been responding to criminal cases that require professional and technical backgrounds by designating focal prosecutors' offices and establishing specialized departments. In relation to patent offenses, in November 2015, the Daejeon District Prosecutors' Office, which is situated close to the Patent Court and the KIPO, was designated as a focal prosecutors' office for patent offenses. In February 2018, the Patent Offense Investigation department was established. In March 2018, the Suwon District Prosecutors' Office was designated as a focal prosecutors' office for advanced industry protection. Finally, in February 2019, the Industrial Technology Offense Investigation department was established (its scope of work was expanded when it became the National Defense Business and Industrial Technology Offense Criminal department).

8.9.3.3 Patent investigation advisor system

A patent investigation advisor system is in place under the prosecution to provide focal prosecutors' offices and specialized investigation departments with technical advice on new patent infringement, trade secret and other such cases. Patent investigation advisors are appointed via two procedures: three patent investigation advisors (experienced patent attorneys) are directly hired by the Supreme Prosecutors' Office, and six patent investigation advisors are

dispatched from the KIPO (Grade IV officials at the KIPO).¹⁸² Patent investigation advisors provide advice not only on the cases of the prosecutors' office to which they belong but also on the cases of other district prosecutors' offices through transfer.¹⁸³ However, even if the suspect is investigated by the Daejeon District Prosecutors' Office (where patent investigation advisors are located) through the transfer procedure, the actual trial is held by the court having territorial jurisdiction over the criminal case (i.e., the court having jurisdiction over the place of domicile or residence of the suspect, the place where the suspect is presently located or the place of offense).

8.9.3.4 Disposition by prosecutor

With respect to transferred cases, a prosecutor directly renders a nonindictment decision if the allegation is not proved or if the authority to indict is not vested. However, for a specialized case transferred to the Daejeon District Prosecutors' Office, the prosecutor of the Daejeon District Prosecutors' Office may either directly render a nonindictment decision or, after the necessary investigation at the Daejeon District Prosecutors' Office, return the case to the prosecutor of the district having territorial jurisdiction over the case for the final disposition. If the prosecutor of the Daejeon District Prosecutors' Office decides not to indict, the appeal process will be handled by the Daejeon High Prosecutors' Office.

In 2020, a total of 212 cases were filed with the prosecution in relation to criminal violations of the Patent Act, including patent infringement, accounting for only about 1.1 percent of the 18,943 cases concerning IP-related offenses that year.¹⁸⁴ The total number of cases processed in 2020 was 385. Of these 385 cases, indictment decisions were made for only 33 cases; a majority of the remaining cases were closed with "allegation not proved" or "no authority to indict."¹⁸⁵

8.9.4 Trial and hearing

For criminal patent infringement to be established, (i) a valid patent right should exist, (ii) the product or process practicing the patent right should be within the protective scope of the patent right, (iii) the alleged infringer's practice of the patent right should be unlawful, (iv) the alleged infringer should have the ability to fulfill their legal responsibility, and (v) the alleged infringer should have intent. We will mainly discuss requirement (ii) below, as it is most challenged in practice.

8.9.4.1 Whether the practiced product or process falls within the protected scope of the patent right

As in a civil patent lawsuit, the protective scope of a patented invention should be defined first to determine patent infringement. Thus, an interpretation of the scope of claims is required first, with a focus on the language and text stated in the scope of claims (principle of literal interpretation), while also taking into account the descriptions and drawings of the invention and common technical knowledge at the time the application was filed (principle of reference to the descriptions of the invention).¹⁸⁶

Additionally, to determine patent infringement, the elements stated in the patented invention's scope of claims and the elements of the infringing product or process should be compared based on claim construction, and the elements that are stated only in the descriptions of the invention should not be compared. To fall within the protective scope of a patented invention, the

¹⁸² Patent investigation advisors hired by the Supreme Prosecutors' Office through the first procedure are dispatched to the criminal division of the Seoul Central District Prosecutors' Office exclusively for IP right- and culture/art-related cases (Criminal Division VI) and provide advisory services there. Of the patent investigation advisors dispatched through the second procedure, four work at the Daejeon District Prosecutors' Office (focal prosecutors' office for patent offenses) while two serve at the Suwon District Prosecutors' Office (focal prosecutors' office for industrial technology offense), providing advisory services there.

¹⁸³ E.g., cases with IP issues, such as patent infringement, are transferred from prosecutors' offices across the country (except Seoul) to the Daejeon District Prosecutors' Office – the focal prosecutors' office for patent offenses – for investigation.

¹⁸⁴ Institute of Justice, *2021 Offense White Paper* (2022), at 125. This figure includes all violations of the Trademark Act; Copyright Act; Unfair Competition Prevention and Trade Secret Protection Act; Music, Video and Game Act; Game Industry Promotion Act; Music Industry Promotion Act; Promotion of the Motion Pictures and Video Products Act; Design Protection Act; Patent Act; and Utility Model Act.

¹⁸⁵ Institute of Justice, *2021 Offense White Paper* at 281. Of the 33 cases with indictment decisions, two were brought to formal trials, and thirty one were closed with summary indictments. Of the remaining cases filed with the prosecution in relation to Patent Act violations, 250 were closed with "allegation not proved," and 66 were closed with "no authority to indict." Because patent infringement is an offense not punishable against the victim's will, there is "no authority to indict" if the victim and the suspect settle during the investigation.

¹⁸⁶ See Section 8.5.1 for more details.

defendant's product or process must include all elements of the patented invention. If only some of the elements of the patented invention are included, with the rest missing, then the product or process does not fall within the protective scope of the patented invention in principle.¹⁸⁷

Patent infringement includes both literal infringement and infringement under the doctrine of equivalents. Therefore, patent infringement may be established in a case where the elements of the defendant's product or process are not literally identical but instead equivalent to the corresponding elements of the plaintiff's patented invention.

However, whether indirect infringement can constitute patent infringement is an issue. Court precedent takes the position that indirect infringement is fundamentally a preparatory act of infringement, and, since the punishment of a preparatory act of a criminal act requires a specific provision therefor, the provision to punish patent infringement cannot itself be used in punishing indirect infringement, a preparatory act of infringement.¹⁸⁸

8.9.4.2 Grounds for patent invalidation in criminal patent infringement cases

In cases where the elements of a patented invention are identical to those of the prior art known at the time of patent application and thus lack novelty, the patented invention has no scope of the right worth protecting regardless of the absence of an invalidation decision, and, thus, patent infringement is not established.¹⁸⁹

Whether a lack of inventive step can be reviewed in a criminal patent lawsuit is an issue. As discussed above, in a civil patent lawsuit, the defendant typically argues against the plaintiff's patent infringement claim to the effect that it is an abuse of rights based on a clearly invalid patent right that lacks an inventive step, and such a defense has been upheld as valid.¹⁹⁰ Although there has not yet been explicit precedent in a criminal lawsuit, it is a common view that no criminal infringement will be found if the patented invention is found to be lacking an inventive step upon review. However, in practice, if a lack of an inventive step is alleged, the trial will generally proceed in consideration of the progress of the related judicial and administrative trials.

8.9.4.3 Intent and unlawfulness

Criminal patent infringement requires the infringer's intent. The term "intent" here refers to the awareness and acceptance of patent infringement;¹⁹¹ it cannot be readily concluded that an infringer has criminal intent on the sole basis of a registered patent. Where a right holder becomes aware of another person's act of infringement, they may secure evidence of intent by sending a warning letter to the infringer.

However, the Criminal Act provides that "[w]hen a person commits a crime mistakenly believing that his or her act does not constitute a crime under the laws and regulations, he or she shall not be punishable if the misunderstanding is based on reasonable grounds."¹⁹² In this regard, an issue arises as to whether this provision applies when a defendant has been advised, for example, by a patent attorney on patent infringement. Courts tend to take a strict view as to whether such advice may be construed as a justifiable ground for the misunderstanding of law: the mere fact of receiving advice is not enough to escape punishment.

8.9.4.4 Number of offenses

As the legal interest sought in a patent infringement lawsuit is to protect the patent right, then even if one person has committed multiple infringements, a single comprehensive offense may be established if the unity and continuity of their criminal intent is recognized.¹⁹³ In other words, in such cases, multiple infringements are treated as one offense. In addition, regardless of whether the right holder is the same, only one offense of infringement is established for each patent right.

¹⁸⁷ Daebeobwon (Sup. Ct), Jan. 12, 2006, 2004Hu1564.

¹⁸⁸ Daebeobwon (Sup. Ct), Feb. 23, 1993, 92Do3350.

¹⁸⁹ Daebeobwon (Sup. Ct), Feb. 27, 2004, 2003Do6283. Additionally, if there is a description defect in the scope of claims of a patented invention, the scope of right cannot be acknowledged even before a decision invalidating the patent is finalized, and practicing an invention in the same or equivalent relationship with a patented invention whose scope of right is not acknowledged as above does not constitute patent infringement (Daebeobwon (Sup. Ct), Oct. 14, 2005, 2005Do1262).

¹⁹⁰ Daebeobwon (Sup. Ct), Jan. 19, 2012, 2010Da95390 (*en banc*).

¹⁹¹ Daebeobwon (Sup. Ct), Jan. 14, 2010, 2008Do639.

¹⁹² Hyoungbeob (Criminal Act), art. 16.

¹⁹³ Daebeobwon (Sup. Ct), Feb. 14, 2008, 2007Do9659.

8.9.5 Sentencing

The statutory punishment for patent infringement is imprisonment with labor for not more than seven years or a fine not exceeding KRW 100 million. In general, factors to be considered in sentencing include whether the patented invention is actually practiced by the patentee, whether the defendant is in a competitive relationship with the patentee, whether the infringement is literal infringement or infringement under the doctrine of equivalents, the degree of infringement, the degree of damage inflicted on the victim by the infringing act, whether an agreement was reached, and the degree of intent to infringe.

As seen in Section 8.9.3.4, there has been a very limited number of cases where a person has actually been indicted and subjected to a criminal patent lawsuit. Most of these indicted cases were closed by an agreement between the defendant and the victim in criminal proceedings, and guilty decisions were rarely made. Even if a person were to be found guilty, they are, in practice, rarely sentenced to imprisonment; instead, they are mostly sentenced to a fine and probation.

8.9.5.1 Forfeiture and joint penal provision

Any article created by patent infringement or obtained by such infringement can be confiscated or ordered to be delivered to the injured party upon the injured party's request.¹⁹⁴

If a representative of a corporation or an agent, employee or other worker of a corporation or individual commits patent infringement in connection with the business of the corporation or individual, then not only will the offender be punished by a fine, but also the corporation or individual. However, this does not apply where the corporation or individual has not been negligent in giving due attention and supervision concerning the relevant business to prevent such an offense.¹⁹⁵

8.9.6 Appeals

As a criminal patent case is a single-judge case at the district and branch courts, an appeal from the decision is judged by the three-judge panel of the district court (Article 32(2) of the Court Organization Act), and an appeal from the panel's decision is judged by the Supreme Court.

¹⁹⁴ Patent Act, art. 231(1).

¹⁹⁵ Patent Act, art. 230.

Chapter 9

United Kingdom

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9.1 Overview of the patent system

9.1.1 Evolution of the patent system

9.1.1.1 Characteristics of the system

Patent litigation in the United Kingdom includes the following features:

- Litigation is according to a common law system, with a public trial before a specialist judge, involving oral and written submissions, the cross-examination of witnesses and disclosure of relevant documents, leading to a fully reasoned judgment.
- Litigation follows procedural code that has an overriding objective to do justice at proportionate cost. Case management is conducted by judges from the same pool as would hear the trial. Docketing occurs in some cases. The court aims to bring cases to trial within 12 months of issue if possible.
- The parties are able to call expert witnesses and cross-examine the other party's expert witnesses.
- Validity and infringement are generally tried together before the same court at the same time. Bifurcation is possible if appropriate but is rare.
- The United Kingdom has a large and experienced body of specialist legal practitioners, mostly with scientific training.
- The trend is toward streamlining cases, having regard to their value and importance, to focus only on that which is necessary and proportionate for their fair disposal.
- There are specific courts and procedures for cases of lower value or those that can be dealt with more speedily – the Intellectual Property Enterprise Court (IPEC) and the Shorter Trials Scheme.
- The courts are able and willing to develop remedies (interim and final) to meet the circumstances of the case.
- The losing party is required to pay a substantial share of the costs (i.e., legal expenses) of the winning party.
- Appeals, with leave, are to the second instance (Court of Appeal) and third instance (Supreme Court). These higher courts also have judges who are experienced in patent cases on the panels. New facts or evidence are not generally admissible on appeal.

9.1.1.2 Sources of law

The principal statutory source of patent law in the United Kingdom, applicable both to U.K. patents granted by the U.K. Intellectual Property Office (UKIPO) and to European patents (UK) granted by the European Patent Office (EPO), is the Patents Act 1977 ("the Act"),¹ though some substantive law is found in other legislative instruments.² The substantive law of supplementary protection certificates is found in the relevant European Union regulations³ as amended by the United Kingdom on its withdrawal from the European Union⁴ and in Section 128B and Schedule 4A of the Act.

The United Kingdom is divided into three jurisdictions: England and Wales, Scotland, and Northern Ireland. Allocation of proceedings between these jurisdictions is governed by Schedule 4 of the Civil Jurisdiction and Judgments Act 1982. The basic rule is that persons domiciled in one part of the United Kingdom shall be sued in the courts of that part.⁵ However, they may instead be sued for patent infringement in the courts of the part of the United Kingdom where the infringement took place.⁶ They may also be sued in the courts of another part of the United Kingdom if they are one of a number of defendants, one of which is domiciled in that other part, and the claims "are so closely connected that it is expedient to hear and determine

1 The Act has been amended several times since it was first passed. The text of the Act can be found at www.legislation.gov.uk (note that recent amendments to the Act may not have been incorporated into that text). An unofficial consolidation of the Act, taking account of amendments, is produced periodically by the UKIPO and can be found at www.gov.uk/government/publications/the-patents-act-1977

2 E.g., The Intellectual Property (Enforcement, etc.) Regulations 2006, SI 2006/1028.

3 Regulation (EC) 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the Supplementary Protection Certificate for Medicinal Products, 2009 OJ (L 152) 1 (for medicinal products); Regulation (EC) 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the Creation of a Supplementary Protection Certificate for Plant Protection Products, 1996 OJ (L 198) 30 (for plant protection products).

4 Patents (Amendment) (EU Exit) Regulations 2019, SI 2019/801, pts 6, 8.

5 Civil Jurisdiction and Judgments Act 1982, sch. 4 para. 1.

6 Civil Jurisdiction and Judgments Act 1982, sch. 4 para. 3(c).

them together to avoid the risk of irreconcilable judgments resulting from separate proceedings.⁷ The vast majority of U.K. patents cases take place in England and Wales rather than in Scotland or Northern Ireland, and, accordingly, this chapter is focused on the procedure of the courts of England and Wales.

In England and Wales, the primary source of procedural law is the Civil Procedure Rules (CPR),⁸ which consists of a series of rules of court and associated practice directions governing procedure in the courts in which patent litigation is conducted. Within the CPR, there is a specific rule (Part 63) and associated practice direction (Practice Direction 63) concerned with patent litigation. These address some matters specific to patent litigation and explain how some of the general rules in the CPR are modified in the case of patent litigation. Practice Direction 63 also sets out procedural differences between proceedings in the Patents Court and in IPEC. In addition, the *Patents Court Guide*⁹ provides guidance as to the conduct of proceedings before the Patents Court, while similar guidance relating to IPEC is provided in the *Intellectual Property Enterprise Court Guide (IPEC Guide)*.¹⁰

Scotland and Northern Ireland have different procedural rules, summarized in Sections 9.3.1.4 and 9.3.1.5, respectively. Certain patents proceedings can be brought before the Comptroller-General of Patents, Designs and Trade Marks ("the Comptroller," who is the head of the UKIPO) as explained in Section 9.2 below; these proceedings are governed by the Patents Rules 2007.¹¹

The legislative provisions referred to above (both substantive and procedural) have been interpreted in numerous judgments of the first-instance and appeal courts of the United Kingdom.¹² The courts of the United Kingdom operate under a system of *stare decisis*: first-instance courts are bound by the *ratio decidendi* (the reasoning necessary to the decision) of the appeal courts. The High Court (which, in England and Wales, includes the Patents Court and IPEC) will only depart from the *ratio decidendi* of a decision of another High Court judge if convinced that it is wrong. Further, the Court of Appeal¹³ is (save in certain circumstances) bound by the *ratio decidendi* of its previous decisions, as well as by previous decisions of the Supreme Court (or its predecessor, the House of Lords). The Supreme Court will depart from its previous decisions (or those of the House of Lords) only "if it appears right to do so."¹⁴

9.1.1.3 The relationship with the European Patent Convention and the European Patent Office

The Act is intended to comply with the United Kingdom's obligations under the European Patent Convention (EPC). Section 130(7) provides that certain provisions of the Act, including those concerned with patentability, the contents of an application for a patent, infringement, invalidity and the definition of an invention,¹⁵ "are so framed as to have, as nearly as practicable, the same effects in the United Kingdom as the corresponding provisions" of the EPC, the Community Patent Convention and the Patent Cooperation Treaty.

The Supreme Court has held that U.K. courts, "although not bound to do so, should normally follow the jurisprudence of the EPO (especially decisions of its Enlarged Board of Appeal) on the

7 Civil Jurisdiction and Judgments Act 1982, sch. 4 para. 5(a).

8 This can be found at www.gov.uk/guidance/the-civil-procedure-rules

9 See Courts and Tribunals Judiciary, *Patents Court Guide* (Feb. 2022), www.judiciary.uk/wp-content/uploads/2022/06/Patents-Court-Guide-Feb-2022.pdf. It should be read in conjunction with HM Courts and Tribunals Service, *Chancery Guide 2022*, <https://www.judiciary.uk/courts-and-tribunals/business-and-property-courts/chancery-division/litigating-in-the-chancery-division/the-chancery-guide/>

10 See HM Courts and Tribunals Service, *Intellectual Property Enterprise Court Guide* (Oct. 2022), www.judiciary.uk/wp-content/uploads/2022/11/IPEC_Guide_revised_2022-1.pdf

11 SI 2007/3291. In particular, Parts 7 and 8.

12 Most judgments delivered in recent decades are available through the British and Irish Legal Information Institute at www.bailii.org, as well as the National Archive's *Find case law* at <https://caselaw.nationalarchives.gov.uk>. In England and Wales, since about 2000, judgments have been given a so-called neutral citation. In the High Court these take the form [] EWHC <starting page>; in the Court of Appeal, [] EWCA (Civ.) <starting page>; and in the House of Lords and Supreme Court, [] UKHL/UKSC <starting page>. In this chapter we mainly give only these neutral citations. Some judgments are also reported, with headnotes, in either the Reports of Patent, Design and Trade Mark Cases (RPC) or the Fleet Street Reports (FSR). For cases before about 2000, we cite the RPC or FSR. Some older cases are not available on Bailii and may only be found in the RPC or the FSR.

13 In England and Wales or in Northern Ireland; the Inner House of the Court of Session in Scotland.

14 See the House of Lords' practice statement of 26 July 1966, which still applies in the Supreme Court. *Austin v. London Borough of Southwark* [2010] UKSC 28, [24]–[25]. The same applies if the Supreme Court is to depart from previous retained European Union case law. European Union (Withdrawal) Act 2018, §6(4)–(5).

15 Sections 1–6, 14(3), 14(5), 60, 72(1)–(2) and 125 of the Act, respectively.

interpretation of [the EPC] in the interests of uniformity, especially where the question is one of principle.”¹⁶ To promote such uniformity, the Court of Appeal has recognized an exception to the general rule that it is bound by the *ratio decidendi* of its own previous decisions in a case where “it is satisfied that the EPO Boards of Appeal have formed a settled view of European patent law which is inconsistent with that earlier decision.”¹⁷ However, U.K. courts are not bound to follow the settled jurisprudence of the EPO Boards of Appeal: “In the unlikely event that we are convinced that the commodore is steering the convoy towards the rocks we can steer our ship away.”¹⁸

Further, U.K. courts do not regard themselves as being bound by the reasoning in any particular decision of the Boards of Appeal; they may regard that decision as taking the law in an inappropriate direction or as misapplying previous EPO jurisprudence.¹⁹ Moreover, in any particular case, U.K. courts may reach different conclusions to those reached in EPO opposition proceedings on the same patent “because they have different evidence or arguments, or because they assess the same competing arguments and factual or expert evidence differently, or, particularly in a borderline case, because they form different judgments on the same view of the expert and factual evidence.”²⁰

U.K. proceedings concerning the validity or infringement of the U.K. designation of a European patent can proceed in parallel with (though will generally be out of step with) opposition proceedings in the EPO relating to that European patent. If a final decision in EPO opposition proceedings leads to the patent being revoked or amended, that decision will automatically affect the U.K. designation of the patent. Accordingly, the existence of parallel EPO opposition proceedings has the potential to affect the basis on which proceedings in the United Kingdom are being or have been conducted. If an injunction has been granted in the United Kingdom on the basis of claims that are later held to have been invalid, then the injunction will be discharged; if the claims are later narrowed, then the injunction will be correspondingly narrowed. If an assessment of financial relief has been ordered on the basis of infringement of claims that are later revoked or narrowed in EPO opposition proceedings, then the party held to have infringed can rely on the subsequent revocation or amendment as an answer to the claim for financial relief, though it remains doubtful whether a sum paid over can be recovered.²¹

The potential for the final decision in EPO opposition proceedings to affect the U.K. litigation is an argument for staying the U.K. proceedings until the EPO opposition proceedings have concluded. However, in many cases, EPO opposition proceedings take a long time to conclude, and staying U.K. proceedings commenced at a similar time to EPO opposition proceedings may lead to a patent proprietor being denied any remedy, and to the parties being denied any degree of commercial certainty, for many years. U.K. courts therefore approach applications to stay U.K. proceedings pending the final outcome of parallel EPO opposition proceedings by seeking to achieve the balance of justice between the parties having regard to all the relevant circumstances of the particular case, including factors such as:

- whether there is a risk that the patentee might be able to obtain financial compensation that would not be repayable if the patent were to be revoked in the EPO proceedings (a factor that can be mitigated by suitable undertakings to repay);
- whether some commercial certainty would be achieved at a considerably earlier date in the U.K. proceedings than those in the EPO;
- whether the resolution of the national proceedings may promote settlement;
- the length of time that it will take the U.K. proceedings and those in the EPO to reach a conclusion (which affects any prejudice to the parties from delay);
- the public interest in removing the uncertainty surrounding the validity of the patent; and
- the risk of wasted costs of the U.K. proceedings.²²

16 *Actavis Group PTC EHf v. Icos Corp.* [2019] UKSC 15, [56].

17 *Actavis U.K. Ltd v. Merck & Co., Inc.* [2008] EWCA Civ 444, [85]–[107].

18 *Actavis U.K. Ltd* [2008] EWCA Civ 444.

19 *Human Genome Sciences, Inc. v. Eli Lilly & Co.* [2011] UKSC 51, [87].

20 *Human Genome Sciences* [2011] UKSC 51, [85].

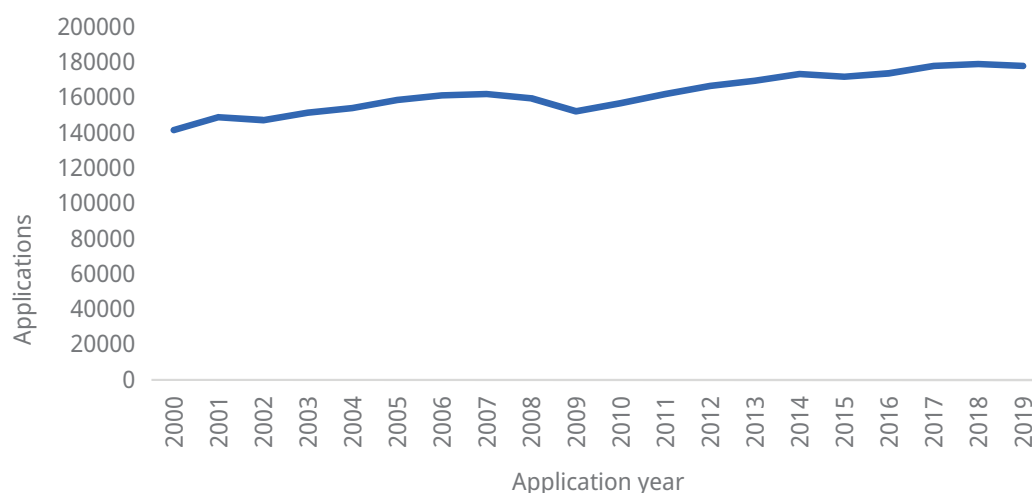
21 *Virgin Atlantic Airways Ltd v. Zodiac Seats U.K. Ltd* [2013] UKSC 46, [35]–[36].

22 *IPCom GmbH & Co. KG v. HTC Europe Co. Ltd* [2013] EWCA Civ 1496, [68].

9.1.2 Patent application trends

Figure 9.1 shows the total number of patent applications (direct, Patent Cooperation Treaty (PCT) national phase entry and European patent UK designation) filed in the United Kingdom from 2000 to 2019.

Figure 9.1 Patent applications filed in the United Kingdom, 2000–2019



Source: WIPO IP Statistics Data Center, available at www3.wipo.int/ipstats/index.htm?tab=patent and EPO PATSTAT, available at www.epo.org/searching-for-patents/business/patstat.html

9.2 The U.K. Intellectual Property Office and the Comptroller-General of Patents, Designs and Trade Marks

The United Kingdom's Intellectual Property Office (UKIPO) is the government body with responsibility for all intellectual property rights, including patents.

As noted above, the Comptroller is head of the UKIPO. In addition to their role in examining patent applications and granting patents, the Comptroller has jurisdiction to hear and determine:

- applications to revoke patents;²³
- applications for declarations of non-infringement;²⁴
- with the agreement of the parties, claims of infringement;²⁵
- references regarding entitlement to patents;²⁶
- applications for compensation by employees;²⁷ and
- applications in relation to licenses of right and compulsory licenses.²⁸

In such proceedings, the Comptroller is required to seek to give effect to the same overriding objective – of dealing with a case justly – that governs proceedings in the court.²⁹ The Patents Rules 2007 set out a procedural code for matters such as statements of the parties' cases, the filing of evidence, case management and hearings.³⁰ Appeals from decisions of the Comptroller in such matters can be made as of right to the Patents Court.³¹ According to the UKIPO website,

²³ Patents Act 1977, §72(1); also applications for declarations of invalidity of supplementary protection certificates.

²⁴ Patents Act 1977, §71.

²⁵ Patents Act 1977, §61(3).

²⁶ Patents Act 1977, §8 (entitlement to U.K. patents, before grant); Patents Act 1977, §12 (entitlement to foreign patents, before grant); Patents Act 1977, §37 (entitlement to U.K. patents, after grant).

²⁷ Patents Act 1977, §40.

²⁸ Patents Act 1977, §§46–48.

²⁹ Patents Rules 2007, r. 74.

³⁰ Patents Rules 2007, rr. 76–87.

³¹ Patents Act 1977, §97(1). A further appeal to the Court of Appeal requires permission and can only be made in specified circumstances. Patents Act 1977, §97(3).

the Comptroller issued only two decisions in contested disputes in the above areas in 2020 and in 2021.

The Comptroller also operates an opinion scheme, under which any person may request the Comptroller to issue a nonbinding opinion on any of the following matters:

- whether a particular act constitutes or would constitute an infringement of a patent;
- whether or to what extent an invention for which a patent has been granted is patentable;
- whether a patent is insufficient;
- whether a patent discloses matter not disclosed in the application therefor, or whether protection has been extended by an amendment; and
- whether a supplementary protection certificate is invalid.³²

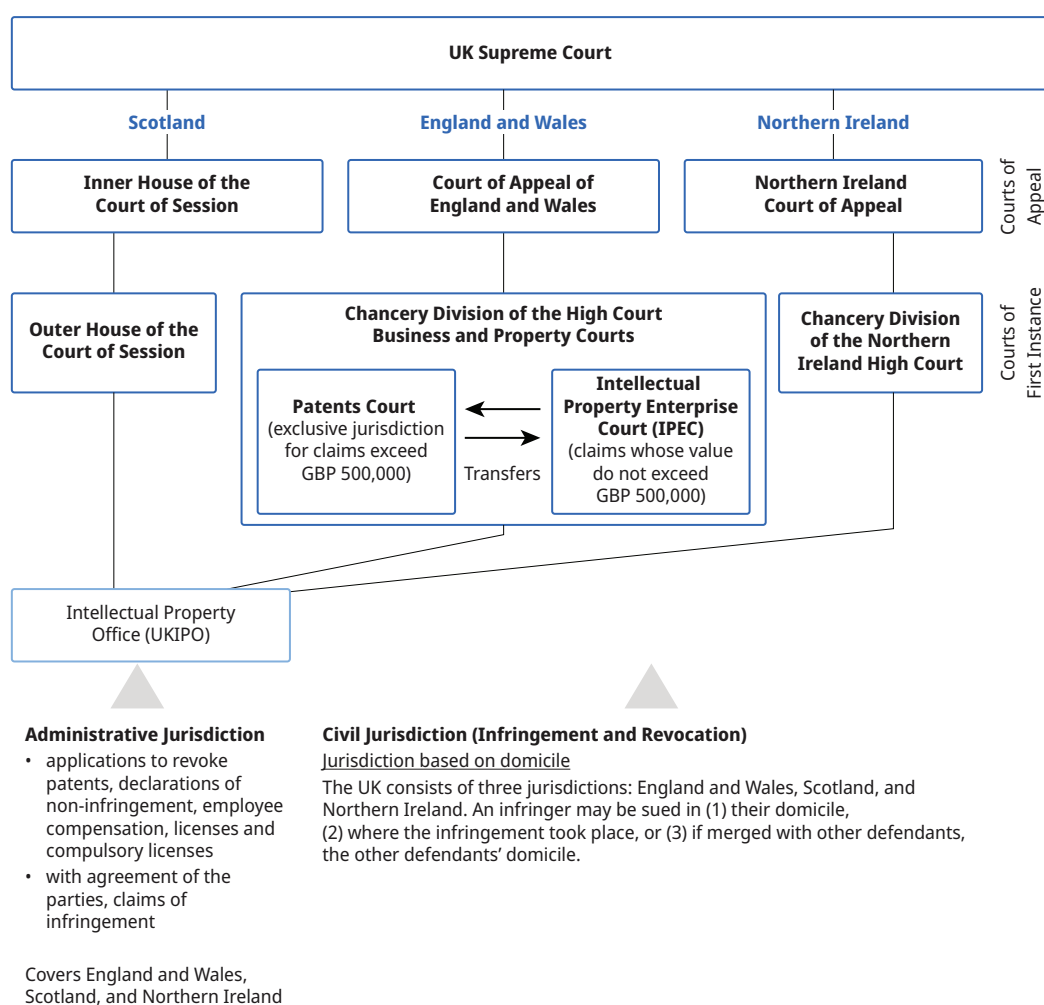
The Patents Rules 2007 prescribe the procedure to be followed if such an opinion is requested, including allowing for observations by any other person and for a review of the opinion by the Comptroller on request.³³ According to the UKIPO website, 26 requests were received for opinions in 2020, and 24 requests in 2021, all but one of which led to an opinion being issued.

9.3 Judicial institutions

9.3.1 Judicial administration structure

Figure 9.2 shows the judicial administration structure in the United Kingdom.

Figure 9.2 The judicial administration structure in the United Kingdom



32 Patents Act 1977, §74A; Patents Rules 2007, r. 93(6).

33 Patents Rules 2007, rr. 94–100.

9.3.1.1 The civil courts and judges of England and Wales

The jurisdiction of England and Wales has two first-instance civil courts: a set of local county courts, which are located in larger towns and cities throughout the jurisdiction, and a national High Court, with its principal seat in London and a series of district registries in major cities. Cases of high value and importance are heard in the High Court.

In all civil first-instance courts, trials are conducted by a single judge sitting alone. The judge is the tribunal of fact and law. Case management is also undertaken by a single judge. In some courts, trials are conducted by judges of a different grade from that of judges who hear trials; in other courts, the judges who hear trials also carry out case management. All patents cases are heard in courts of the latter sort.

Appeals go to the next court in the hierarchy. Appeals from the High Court are to the Court of Appeal, which sits as a panel of three judges. Appeals from the Court of Appeal are to the U.K. Supreme Court.

Judges are recruited from the ranks of qualified lawyers who have been in practice for a substantial time. When a lawyer is appointed as a full-time “salaried” judge, they leave their legal practice. It is also possible for a lawyer to act as a deputy judge as a part-time fee-paid appointment while continuing to work as a lawyer. Today deputy judge appointments are for a limited time so as to allow the lawyer to get a taste of work as a judge and decide if they wish to apply for a full-time post. Full-time judges are only appointed from the ranks of lawyers who have sat as deputies.

Judicial training is conducted at the Judicial College.

9.3.1.2 The Patents Court

The Patents Court is part of the Chancery Division of the High Court and is now organized as part of the Business and Property Courts of England and Wales. It handles most of the patents cases that are brought in the United Kingdom. In England and Wales, it has exclusive jurisdiction over patents cases³⁴ where the value is over GBP 500,000 and shares jurisdiction with IPEC in cases of a value between GBP 50,000 and GBP 500,000 (or more, if the parties agree).³⁵

The principal judges of the Patents Court always have extensive experience in patent litigation. The principal judges of the Patents Court, Mr Justice Meade and Mr Justice Mellor, were each in practice at the patent bar for about 30 years before their appointment, handling cases relating to a wide range of technologies. They are supported by five to eight other judges of the Chancery Division who are able to hear patents cases, by the judge in charge of IPEC (currently His Honour Judge Hacon) and by a number of deputy High Court judges (experienced practicing barristers or solicitors who have been appointed to sit as part-time judges).³⁶

The Patents Court operates a system in which the technical difficulty of the case is rated between one and five, with five representing the most technically complex cases. Only Mr Justice Meade, Mr Justice Mellor, His Honour Judge Hacon or suitably qualified deputy High Court judges are able to hear trials of cases with a technical complexity of four or five. Trials of cases of lower technical complexity and interim applications can be heard by any judge permitted to sit in the Patents Court.

Under Section 70(3) of the Senior Courts Act 1981, the Patents Court has the discretion to appoint scientific advisers. The role of a scientific adviser is to assist the court in understanding the technology and the technical evidence, not to assist the judge in deciding the case.³⁷ In most cases, the judges of the Patents Court sit without a scientific adviser; it is rarely necessary given

³⁴ It also has exclusive jurisdiction over registered design cases. See CPR 63.2. Claims relating to registered trademarks, copyright, unregistered design rights, passing off and various other intellectual property rights can be brought in the Chancery division or in IPEC. See CPR 63.13, PD63 para. 16.1.

³⁵ CPR 63.17A.

³⁶ The information in this paragraph is accurate as of October 2022. The official list of judges of the Patents Court can be found at www.judiciary.uk/you-and-the-judiciary/going-to-court/high-court/courts-of-the-chancery-division/patents-court/judges/ and of IPEC at www.judiciary.uk/you-and-the-judiciary/going-to-court/high-court/courts-of-the-chancery-division/intellectual-property-enterprise-court/judges/

³⁷ *Halliburton Energy Services Inc. v. Smith International (North Sea) Ltd* [2006] EWCA Civ 1599; see also *Halliburton v. Smith* [2006] EWCA Civ 1715, [5]–[7].

their background and the fact that they have the assistance of expert witnesses called by the parties. However, in some cases, scientific advisers have been appointed to assist the trial judge,³⁸ the Court of Appeal and the Supreme Court (or its predecessor, the House of Lords).³⁹

The English legal profession is divided into barristers and solicitors. Parties are generally represented before the Patents Court by specialist patent barristers instructed by specialist patent solicitors. There are about 119 members of the Intellectual Property Bar Association of England and Wales, many of whom practice extensively in the Patents Court. There are about 60 members of the Intellectual Property Lawyers' Association, which principally represents solicitors practicing in intellectual property law in England and Wales; of these, a substantial number are experienced in patent litigation, and some have rights of audience before the Patents Court as solicitor advocates. Parties can also be represented by patent attorneys, either instructing barristers or exercising their own rights of audience.

An individual may also represent themselves as a "litigant in person", and a company or other corporation may be represented by an employee, provided that the employee has been authorized by the company and the court gives permission.⁴⁰

The Patents Court, like the rest of the High Court, operates according to the "overriding objective" of the CPR – namely, that of "enabling the court to deal with cases justly and at proportionate cost."⁴¹ The CPR explains that

Dealing with a case justly and at proportionate cost includes, so far as practicable:

- (a) ensuring that the parties are on an equal footing and can participate fully in proceedings, and that parties and witnesses can give their best evidence;
- (b) saving expense;
- (c) dealing with the case in ways which are proportionate –
 - (i) to the amount of money involved;
 - (ii) to the importance of the case;
 - (iii) to the complexity of the issues; and
 - (iv) to the financial position of each party;
- (d) ensuring that it is dealt with expeditiously and fairly;
- (e) allotting to it an appropriate share of the court's resources, while taking into account the need to allot resources to other cases; and
- (f) enforcing compliance with rules, practice directions and orders.⁴²

This overriding objective has fueled many developments in case management in the Patents Court, and the High Court more generally, aimed at streamlining patent litigation while retaining the core features of the system that enable proper scrutiny of parties' cases. We address these in more detail in subsequent parts of this chapter, but examples include:

- providing the option for parties accused of infringement to provide a full and accurate product and process description of the alleged infringing product or process, rather than requiring the disclosure of documents;⁴³
- limiting the disclosure of internal documents that might be said to bear upon issues of obviousness or insufficiency to cases in which such disclosure is necessary to deal with the case justly and proportionately;⁴⁴
- introduction of a streamlined procedure (no disclosure or experiments, cross-examination on written evidence only on topics where it is necessary)⁴⁵ and the Shorter Trials Scheme (trials to be concluded within four days, disclosure subject to restrictions, evidence and cross-examination restricted to identified issues);⁴⁶ and

38 See, e.g., *Genentech Inc. v. The Wellcome Foundation Ltd* [1989] RPC 147; *Chiron Corp. v. Murex Diagnostics Ltd* [1996] RPC 535.

39 See, e.g., *Biogen Inc. v. Medeva plc* [1995] RPC 25 (CA); [1997] RPC 1 (HL); *Kirin-Amgen Inc. v. Hoechst Marion Roussel Ltd* [2004] UKHL 46; *Halliburton Energy Services Inc. v. Smith International (North Sea) Ltd.* [2006] EWCA Civ 1715.

40 CPR 39.6.

41 CPR 1.1(1).

42 CPR 1.1(2).

43 CPR PD63 para. 6.1(1).

44 *Positec Power Tools (Europe) Ltd v. Husqvarna AB* [2016] EWHC 1061 (Pat).

45 Courts and Tribunals Judiciary, *Patents Court Guide*, para. 7.6 (Feb. 2022).

46 CPR PD57AB §2.

- expedition of cases where merited,⁴⁷ as well as a general intention to bring cases on for trial within 12 months where possible.⁴⁸

Appeals from the Patents Court are not available as of right. A party wishing to appeal must seek and obtain permission to appeal, as discussed further in Section 9.8.1 below.

If permission is granted, appeals from decisions of the Patents Court will normally be heard by a panel of three judges of the Court of Appeal. The panel is likely to include at least one of the patent specialists in the Court of Appeal, currently Lords Justices Arnold and Birss, each of whom sat as a judge of the Patents Court for many years following lengthy periods of practice at the patent bar.

If permission to appeal to the Supreme Court is granted (discussed below in Section 9.8.3.2), then the case is likely to be heard by five Supreme Court justices, which is likely to include Lord Kitchin, who practiced at the patent bar before his appointment to the Patents Court, then the Court of Appeal and finally the Supreme Court.

In a case in which, while an appeal against the revocation of a patent is pending, the patent proprietor reaches a settlement with its opponent so that the appeal is unopposed, the appeal court will not simply allow the appeal. It will need to be persuaded that the decision to revoke the patent was wrong. In such cases, it is the practice to invite the Comptroller to make such submissions as they think fit to assist the court.⁴⁹

9.3.1.3 The Intellectual Property Enterprise Court

Like the Patents Court, IPEC is part of the Business and Property Courts of the High Court of England and Wales. It (and its predecessor, the Patents County Court) was established to improve access to justice in patents cases for small and medium-sized enterprises by providing a forum with streamlined litigation in which a party's potential liability for the costs of the other party is limited to GBP 60,000.⁵⁰ The presiding judge of IPEC is His Honour Judge Hacon, who is a specialist circuit judge.⁵¹ His Honour Judge Hacon is assisted by a number of deputy judges (comprising nominated barristers and solicitors who specialize in intellectual property law). All judges who sit in the Patents Court can also sit in IPEC. IPEC is covered in greater detail in Section 9.9 of this chapter.

9.3.1.4 Scotland

In Scotland, the Court of Session has exclusive jurisdiction in proceedings relating primarily to patents.⁵² Chapter 55 of the Act of Sederunt (Rules of the Court of Session 1994) 1994⁵³ contains specific rules governing the procedure for and case management of all intellectual property cases, including those involving patents.⁵⁴ Patents cases are heard by designated intellectual property judges,⁵⁵ who are frequently also judges in the Commercial Court. The court aims to ensure, as far as possible, that the same judge is responsible for the management of a case from commencement to conclusion.

Cases are put out at an early stage for a preliminary hearing.⁵⁶ At this hearing, the intellectual property judge can make orders that are “fit for the speedy determination of the cause,” such as ordering the disclosure of witnesses or documents or the lodging of expert reports or affidavits.⁵⁷ The intellectual property judges also have available to them extended powers that are peculiar to intellectual property cases, such as the power to order the disclosure of information relating to infringement of an intellectual property right.⁵⁸

47 See, e.g., *WL Gore & Associates GmbH v. Geox SpA* [2008] EWCA (Civ.) 622.

48 Patents Court, *Patents Court Guide, Annex D: Practice Statement: Listing of cases for trial in the Patents Court*.

49 *Halliburton Energy Services Inc. v. Smith International (North Sea) Ltd* [2006] EWCA Civ 185; see also *Halliburton v. Smith* [2006] EWCA Civ 1715, [3]–[4]; *Conor Medsystems Inc. v. Angiotech Pharmaceuticals Inc.* [2008] UKHL 49, [2].

50 This information is accurate as of October 2022. See footnote 36 above.

51 This was increased on 1 October, 2022 from GBP 50,000.

52 With the exception of proceedings before the Comptroller of Patents. See Civil Jurisdiction and Judgments Act 1982, sch. 8 para. 2(n); Patents Act 1977, §98(1). In addition, the Sheriff Court has a very limited jurisdiction in respect of certain incidental patent matters.

53 SI 1994/1443.

54 SI 1994/1443, r. 55.1.

55 SI 1994/1443, r. 55.2; though other judges can deal with the cases where required.

56 SI 1994/1443, r. 55.2E(1).

57 SI 1994/1443, r. 55.2E(2).

58 Intellectual Property (Enforcement, etc.) Regulations 2006, SI 2006/1028, reg. 4.

Thereafter, a case is usually set down for a procedural hearing.⁵⁹ At this hearing, the judge will decide which issues are to be determined at the substantive hearing of the case, how they will be addressed and may order, for example, the lodging of witness statements, the lodging of documentary and other evidence, and the carrying out of experiments.⁶⁰ The breadth of the orders and discretion available to the judges at each stage enables them to achieve both the specific procedure and the type of hearing that are best suited to the resolution of each individual case.

9.3.1.5 Northern Ireland

In Northern Ireland, patents cases are brought before the Chancery Division of the High Court of Northern Ireland. They are case-managed in the same way as other chancery cases. Once pleadings are complete, the case is set down, and it then comes before the chancery judge for case management. Case management involves the legal representatives completing a questionnaire: this deals with interlocutory matters, experts' reports and meetings, statements of law and fact, details of any alternative dispute resolution, and trial details (e.g., the number of witnesses, estimated length of trial, timetable for skeletons etc.). The judge then reviews the case with legal representatives present, and it is usually listed for hearing after two to three review hearings, depending on how matters progress. Patents cases in Northern Ireland are rare.

9.3.2 Relationship between invalidity and infringement proceedings

U.K. courts do not generally bifurcate the determination of the issues of patent infringement and validity; the issues are heard together. Consequently, a patentee cannot attempt to apply a different, narrower interpretation of the patent and its scope when the court is considering the issue of validity and an expansive interpretation when considering the issue of infringement. As it was once said by Lord Justice Jacob in the Court of Appeal:

Professor Mario Franzosi likens a patentee to an Angora cat. When validity is challenged, the patentee says his patent is very small: the cat with its fur smoothed down, cuddly and sleepy. But when the patentee goes on the attack, the fur bristles, the cat is twice the size with teeth bared and eyes ablaze.⁶¹

This also gives rise to so-called squeezes on the patentee, such as where the claimant contends that, if the claim is construed widely enough to cover the defendant's product, then it is also wide enough to cover the prior art and so must, accordingly, be invalid. Alternatively, if it is construed narrowly enough to avoid the prior art, then it does not cover the defendant's product, and so there can be no infringement.

9.4 Patent invalidity

Section 72(1) of the Act provides that any person⁶² may bring a claim before the court (again, that is to say, the High Court in England and Wales)⁶³ or the Comptroller for revocation of a patent⁶⁴ on the following grounds:

- (a) the invention is not a patentable invention;
[...]
- (c) the specification of the patent does not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art;
- (d) the matter disclosed in the specification of the patent extends beyond that disclosed in the application for the patent, as filed [...];
- (e) the protection conferred by the patent has been extended by an amendment which should not have been allowed.⁶⁵

59 Act of Sederunt (Rules of the Court of Session 1994) 1994, SI 1994/1443, r. 55.2E(4).

60 SI 1994/1443, r. 55.3(2).

61 *European Central Bank v. Document Security Systems* [2008] EWCA Civ 192, [5].

62 This does mean *any* person; no interest or standing need be shown to bring invalidity proceedings. See, e.g., *Oystertec plc v. Edwards Evans Barker* [2002] EWHC 2324 (Pat).

63 Or the Court of Session in Scotland, or the High Court in Northern Ireland.

64 In the case of a supplementary protection certificates, the remedy if invalidity is established is a declaration of invalidity rather than revocation.

65 The additional ground in Patents Act 1977, §72(1)(b) (nonentitlement) is only available in very specific circumstances. Patents Act 1977, §72(2).

Grounds (a), (c) and (d) correspond to those available in EPO opposition proceedings under Article 100(a)–(c) of the EPC.

The same grounds of invalidity may also be raised in response to a claim for infringement (either only by way of a defense or also in a counterclaim for revocation), in a claim for a declaration of non-infringement under Section 71 of the Act (see Section 9.5.4 below) and in threats proceedings (see Section 9.5.5 below).⁶⁶ However, threats proceedings can only be brought before the court, and claims for infringement may only be brought before the Comptroller with the consent of the parties.

In response to a claim for revocation (whether before the court or the Comptroller), a patent proprietor may apply for permission to amend the patent under Section 75 of the Act. The amendment will not be allowed if it results in the patent disclosing additional matter or extends the protection conferred by the patent⁶⁷ or if it introduces a lack of clarity to the claims.⁶⁸ The procedure for applying for permission to amend a patent is addressed in Section 9.6.6 below.

If the grounds of invalidity are established, the order for revocation may be unconditional or, where the court or the Comptroller determines that the patent is invalid only in part, an order that the patent should be revoked unless amended to its satisfaction.⁶⁹

Conversely, if the patent is held to be wholly or partially valid, the court or the Comptroller may grant a certificate of contested validity. The effect of such a certificate is that, in any subsequent proceedings for infringement or revocation of the patent in which a final order is made in favor of the party relying on the validity of the patent, that party is entitled to their costs at first instance (but not on any appeal) on an indemnity basis.⁷⁰

9.5 Patent infringement

9.5.1 Acts of infringement

Section 60(1) of the Act provides that a person infringes⁷¹ a patent if they do any of the following acts in the United Kingdom without the consent of the patent proprietor while the patent is in force:

- (a) where the invention is a product, he makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise;
- (b) where the invention is a process, he uses the process or he offers it for use in the United Kingdom when he knows, or it is obvious to a reasonable person in the circumstances, that its use there without the consent of the proprietor would be an infringement of the patent;
- (c) where the invention is a process, he disposes of, offers to dispose of, uses or imports any product obtained directly by means of that process or keeps any such product whether for disposal or otherwise.

Section 60(2) provides that a person also infringes⁷² a patent if, while the patent is in force and without the consent of the patent proprietor:

he supplies or offers to supply in the United Kingdom a person other than a licensee or other person entitled to work the invention with any of the means, relating to an essential element of the invention, for putting the invention into effect when he knows, or it is obvious to a reasonable person in the circumstances, that those means are suitable for putting, and are intended to put, the invention into effect in the United Kingdom.

⁶⁶ Patents Act 1977, §74(1)–(3).

⁶⁷ Patents Act 1977, §76(3).

⁶⁸ Patents Act 1977, §14(5)(b), 75(5); European Patent Convention, Article 84.

⁶⁹ Patents Act 1977, §74(4).

⁷⁰ Patents Act 1977, §65; *SmithKline Beecham plc v. Apotex Europe Ltd* [2004] EWCA Civ 1703, [8]–[18]. As to the meaning of costs on an indemnity basis, see Section 9.7.4 below.

⁷¹ Subject to various defenses set out in the Patents Act 1977, §60(5), as elaborated in §60(6A), (6G) and (7).

⁷² Again, subject to the same defenses – with the qualifications explained in Patents Act 1977, §60(6) and to that in §60(3).

These provisions are intended to reflect the corresponding provisions (Articles 25 and 26) of the Community Patent Convention (even though that convention never came into force).⁷³ Accordingly, U.K. courts have had reference to the decisions of courts of other states that were parties to that convention in interpreting these provisions.⁷⁴

English law also recognizes accessory liability of persons who either procure others to commit acts or have formed a common design with others to do acts, which amounts to infringement.⁷⁵

Section 61 of the Act provides the right of a patent proprietor to bring proceedings in the court (e.g., the High Court in England and Wales)⁷⁶ in respect of any act alleged to infringe the patent. An exclusive licensee⁷⁷ of the patent also has the right to bring proceedings in respect of any infringement committed after the date of the license.⁷⁸ The patent proprietor or an exclusive licensee also has the right to bring proceedings, after grant of the patent, in respect of acts committed after the publication of the application for the patent if they would have infringed the patent had it been granted.⁷⁹

Claims may also be brought in respect of threats to commit acts of infringement when no act of infringement has yet been committed – so-called *quia timet* actions. Such claims will only succeed if, at the date proceedings are issued, there was a sufficiently strong probability – a concrete, strong and tangible risk – that an injunction would be required to prevent the defendant from infringing.⁸⁰

9.5.2 Claim construction

The provisions of Section 60 of the Act refer to “the invention.” Section 125 defines an invention as follows:

(1) For the purposes of this Act an invention for a patent for which an application has been made or for which a patent has been granted shall, unless the context otherwise requires, be taken to be that specified in a claim of the specification of the application or patent, as the case may be, as interpreted by the description and any drawings contained in that specification, and the extent of the protection conferred by a patent or application for a patent shall be determined accordingly.

[...]

(3) The Protocol on the Interpretation of Article 69 of the European Patent Convention (which Article contains a provision corresponding to subsection (1) above) shall, as for the time being in force, apply for the purposes of subsection (1) above as it applies for the purposes of that Article.

The “Protocol on the Interpretation of Article 69 EPC” in the EPC provides as follows:

Article 69 should not be interpreted as meaning that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Nor should it be taken to mean that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patent proprietor has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties.

73 Patents Act 1977, §130(7).

74 See, e.g., *Grimme Maschinenfabrik GmbH v. Scott* [2010] EWCA Civ 1110, [79]–[132] (regarding the knowledge requirement in Patents Act 1977, §60(2)); *Pioneer Electronics Capital Inc. v. Warner Music Manufacturing Europe GmbH* [1997] RPC 757 (regarding “obtained directly by means of that process” in Patents Act 1977, §60(1)(c)); *Warner-Lambert Company LLC v. Generics (U.K.) Ltd* [2018] UKSC 56 (regarding second medical use or “Swiss-style” claims).

75 See, e.g., *Sea Shepherd U.K. v. Fish & Fish Ltd* [2015] UKSC 10.

76 Or the Court of Session in Scotland, or the High Court in Northern Ireland.

77 That is to say, a license from the proprietor conferring any right in the invention to the exclusion of all other persons. Patents Act 1977, §130(1).

78 Patents Act 1977, §67.

79 Patents Act 1977, §69 (subject to the caveats provided for in that section).

80 *Merck Sharp Dohme Corp. v. Teva Pharma BV* [2013] EWHC 1958 (Pat), [39]–[59].

For the purpose of determining the extent of protection conferred by a European patent, due account shall be taken of any element which is equivalent to an element specified in the claims.⁸¹

Until 2017, U.K. courts did not recognize a doctrine of equivalents. Instead, U.K. courts have determined the extent of protection of a patent by applying “purposive construction.” This involved determining what the skilled person would have understood the patentee to be using the language of the claims to mean, and, in that process, account could be taken of equivalents. A person could only infringe a patent if the product or process fell within the claims on a purposive construction.⁸² In 2017, the Supreme Court held that the interpretation of the language of the claims was only the first stage in determining whether there was infringement. The court also held that a product or process that did not fall within the claims on a normal interpretation could nevertheless infringe if it differed in a way that was immaterial, and proposed questions to assist in determining whether the variation was immaterial.⁸³

9.5.3 Remedies for infringement

Certain remedies for infringement that may be claimed are specified by Section 61 of the Act:

- (a) an injunction restraining the defendant from any apprehended act of infringement;
- (b) an order for him to deliver up or destroy any patented product in relation to which the patent is infringed or any article in which that product is inextricably comprised;
- (c) damages in respect of the infringement;
- (d) an account of the profits derived by him from the infringement;
- (e) a declaration that the patent is valid and has been infringed by him.⁸⁴

However, these remedies are said in Section 61 to be “without prejudice to any other jurisdiction of the court.” Remedies are dealt with in more detail in Section 9.7 below.

9.5.4 Claims for declaratory relief

As mentioned above, Section 61 of the Act makes it clear that, on a claim by the patent proprietor or an exclusive licensee, the court has the power to grant a declaration that a patent is valid and has been infringed. Conversely, Section 71 provides a route by which a person can obtain a declaration that a patent is not, or would not be, infringed:

Without prejudice to the court’s jurisdiction to make a declaration apart from this section, a declaration that an act does not, or a proposed act would not, constitute an infringement of a patent may be made by the court or the comptroller in proceedings between the person doing or proposing to do the act and the proprietor of the patent, notwithstanding that no assertion to the contrary has been made by the proprietor, if it is shown –

- (a) that that person has applied in writing to the proprietor for a written acknowledgment to the effect of the declaration claimed, and has furnished him with full particulars in writing of the act in question; and
- (b) that the proprietor has refused or failed to give any such acknowledgment.⁸⁵

A party seeking a declaration of noninfringement, prior to serving proceedings on the patentee, must first send a notice to the patentee containing a description of their product or process to give the patentee the opportunity before proceedings are issued to agree that that product or process is not an infringement.⁸⁶

However, as both Sections 61 and 71 make clear, that is not the limit of the court’s declaratory jurisdiction. CPR 40.20 provides that “[t]he court may make binding declarations whether or not

⁸¹ The Protocol can be found at www.epo.org/law-practice/legal-texts/html/epc/2020/e/ma2a.html

⁸² *Kirin-Amgen Inc. v. Hoechst Marion Roussel Ltd* [2004] UKHL 46, [27]–[52].

⁸³ *Actavis U.K. Ltd v. Eli Lilly & Co.* [2017] UKSC 48, [53]–[66].

⁸⁴ Using the language appropriate to England and Wales.

⁸⁵ Using the language appropriate to proceedings in England and Wales.

⁸⁶ Patents Act 1977, §71(1).

any other remedy is claimed.” This provides the court with a discretionary power to grant declaratory relief, which it will normally exercise only if there is a sufficiently well defined issue between the parties and if granting the declaration would serve a useful purpose. The court should also take into account justice to the parties and any other special reasons.⁸⁷

This jurisdiction has been used to grant declarations that a specified product was old or obvious at a particular date.⁸⁸ The practical effect of such a declaration is that the patent proprietor cannot then assert, against that product, any patents it obtained with that (or a later) priority date. This form of declaration (sometimes called an *Arrow* declaration, after the first case in which it was recognized)⁸⁹ is of particular use where a patent proprietor has divisional applications in prosecution that a party justifiably fears may be asserted against it if and when they are granted. It allows such a party to gain commercial certainty without having to wait until the patents are granted and then apply to revoke them. However, it is always necessary to demonstrate that the declaration would serve a useful purpose.⁹⁰

9.5.5 Threats actions

Threats to bring proceedings for infringement of a patent can have a chilling effect on trade, particularly when made to a trader’s customers or potential customers. The Act therefore makes provision to allow persons aggrieved by such threats to bring proceedings and seek relief. Such actions:

- can only be brought in respect of communications from which a reasonable person in the position of a recipient would understand that a patent exists and that a person intends to bring proceedings against another for infringement of the patent by an act done, or to be done, in the United Kingdom;⁹¹
- cannot be brought if the alleged infringement consists of making or importing a product for disposal or using a process, or consists of any other act in respect of that product or process by a person who has made or imported the product or used the process (or intends to do so);⁹²
- cannot be brought if the threat is not express and is made in a “permitted communication” (in essence, one that contains only information necessary to give notice of a patent proprietor’s rights or to seek information about the manufacture or importation of a product or the use of a process);⁹³ and
- cannot be brought against professional advisers acting on the instructions of another identified person.⁹⁴

The relief that can be sought in threats actions is:

- a declaration that the threats are unjustified;
- an injunction against the continuance of the threats; or
- damages in respect of any loss sustained by the person aggrieved by reason of the threats.⁹⁵

It is a defense for the person who made the threat to show that the act in respect of which proceedings were threatened constitutes (or, if done, would constitute) an infringement of the patent.⁹⁶ Most threats actions will therefore lead to such a defense being raised, together with a counterclaim for infringement, to which the claimant will respond with a defense of invalidity and a counterclaim for revocation.

87 See, e.g., *Fujifilm Kyowa Kirin Biologics Co. Ltd. v. AbbVie Biotechnology Ltd* [2017] EWCA Civ 1, [58]–[63].

88 This jurisdiction has also been used, e.g., to grant declarations that specified patents are not essential to specified telecommunications standards (see, e.g., *Nokia Corp. v. Interdigital Technology Corp.* [2006] EWCA Civ 1618. In this context “essential” has the meaning given to it by the Intellectual Property Rights Policy of the European Telecommunication Standards Institute) and that certain licensing terms are FRAND (see, e.g., *Unwired Planet International Ltd v. Huawei Technologies Co. Ltd* [2018] EWCA Civ 2344).

89 *Arrow Generics Ltd v. Merck & Co. Inc.* [2007] EWHC 1900 (Pat).

90 *Compare Fujifilm Kyowa Kirin Biologics Co. Ltd. v. AbbVie Biotechnology Ltd* [2017] EWHC 395 (Pat) (where there was a useful purpose) and *Pfizer Ltd v. F. Hoffmann-La Roche AG* [2019] EWHC 1520 (Pat) (where there was not).

91 Patents Act 1977, §70.

92 Patents Act 1977, §70A(2)–(4).

93 Patents Act 1977, §§70A(5), 70B.

94 Patents Act 1977, §70D.

95 Patents Act 1977, §70C(1).

96 Patents Act 1977, §70C(3). It is also a defense to show that, despite having taken reasonable steps, which were notified to the recipient, the person had not identified anyone who had made or imported the product or used the process. Patents Act 1977, §70C(4).

9.6 Judicial patents proceedings and case management

9.6.1 Pre-action

Parties' conduct before a patent action has begun is governed by the CPR. There is no specific pre-action protocol for litigation in the Patents Court, although the "Pre-Action Conduct and Protocols" practice direction applies.⁹⁷ Paragraph 6 of this practice direction requires a claimant to write a "letter before action" to the defendant with concise details of the claim, including the nature of the acts complained of and the relief they seek. The defendant should be given a reasonable period of time to respond, typically 14 days but sometimes longer, before the claimant commences proceedings. This is so that the defendant has an opportunity to decide whether or not to contest the claim and also to enable both parties to explore whether or not settlement of the dispute is possible before proceedings are commenced.

If the claimant fails to send a letter before action in this way, it is open to the court to regard their conduct as unreasonable and to make an adverse costs award against them, especially if the defendant, when served with proceedings, indicates that they will in fact not contest them.

However, the court will take into account that, in some circumstances, it is undesirable for the claimant to give the defendant notice of proceedings. This is particularly the case where there is a race to the court between the two parties in the United Kingdom and another in another country in order for the relevant court to be first seized of jurisdiction.

Owing to the actionable threats provisions in the Act, as set out in Section 9.5.5 above, care must be taken in writing a letter before action to anyone other than the manufacturer or importer of a product or user of a process.

Before an action is started, the court can order that a party to a dispute gives disclosure of a specific class of documents in their power or possession. This will typically happen where the disclosure is either likely to promote settlement of the dispute, where it is likely to resolve the dispute or where it will result in the saving of costs.⁹⁸ For example, where a patentee has granted a number of licenses under their patent, and the prospective defendant has indicated a willingness to take a license under the patent on similar terms to those already granted by the patentee, the patentee could be ordered to give disclosure of those licenses so that the defendant can see what might be similar terms of a license that they can agree to.

9.6.2 Venue, jurisdiction and case assignment rules

9.6.2.1 Jurisdiction, standing and service

All of the courts in England and Wales that handle patent litigation have jurisdiction over anyone carrying out one or more infringing acts occurring in their countries and can grant remedies covering the whole of the United Kingdom. They also have jurisdiction over anyone who is assisting the infringer to carry out infringing acts in that country, such as a parent company that runs a website directed to the United Kingdom. However, the courts no longer have jurisdiction over infringements of the equivalent European patent occurring in other European countries since the United Kingdom is no longer a party to the Convention on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (Lugano Convention) or other similar treaty for the mutual recognition and enforcement of judgments in Europe.

The patentee and the exclusive licensee have standing to bring proceedings for infringement of a patent in the United Kingdom.⁹⁹ If the defendant is domiciled outside the jurisdiction, the claimant will have to seek permission from the court to serve the proceedings out of the jurisdiction (on the basis of infringing acts in the jurisdiction) and serve in accordance with the rules of the Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters (HCCH Service Convention).¹⁰⁰

⁹⁷ CPR, Practice Direction – Pre-Action Conduct and Protocols, www.justice.gov.uk/courts/procedure-rules/civil/rules/pd_pre-action_conduct

⁹⁸ CPR 31.16(3)(d).

⁹⁹ Patents Act 1977, §§61, 67.

¹⁰⁰ CPR 6.36, PD6B.

Anyone has standing to bring proceedings for revocation of a patent and can serve such proceedings in the United Kingdom on the address for service registered against the patent at the UKIPO. Where the patentee is domiciled outside the United Kingdom, this makes service swift and straightforward and requires no translations or other Hague Convention requirements.

A claimant must bring all related claims in one set of proceedings in the United Kingdom. So, for example, if the patentee considers that a product infringes several of its patents, and if it starts proceedings for patent infringement, it must assert all of the patents it believes are infringed. The court will not permit the patentee to bring separate new proceedings later based on another of the patents in its portfolio that it alleges is infringed by the same product unless, for example, the facts giving rise to that infringement only came to light later. Bringing patents proceedings piecemeal in this fashion can be regarded by the court as an abuse of process.

A claimant must choose whether to issue their claim in the Patents Court or IPEC; see Section 9.9.1.1 below.

9.6.2.2 Court fees

To start proceedings, the claimant must pay the court an issue fee. The fee for cases with a value over GBP 200,000 is GBP 10,000. For lower-value cases, the fee is lower: five percent of the value of the claim for cases between GBP 10,000 and GBP 200,000 in value. For the very lowest value cases (under GBP 300), the issue fee is GBP 35. Individuals without the means to pay the issue fee can obtain a fee exemption known as “help with fees.”

There are only two other fees that usually need to be paid in a patents case at first instance. There is a GBP 255 fee for applications to the court, and a trial fee of GBP 1,090 is due when the date for trial is fixed. The court fees paid by a party are recoverable as part of that party's costs (see Section 9.7.4 below).

9.6.3 Statements of case

9.6.3.1 Formal pleadings

Proceedings are commenced by the issue of a claim form with the court.¹⁰¹ The claim form is a short document, no more than around three pages in length, in a format specified by the rules of procedure of the court. It sets out the identities of the claimant and defendant and the relief sought by the claimant. The claim form is issued by electronically filing it with the court.

The claimant must serve the claim form on the defendant within four months of it being issued if the defendant is within the jurisdiction, or within six months if the defendant is outside the jurisdiction.¹⁰² Either at the same time as serving the claim form or within 14 days of its service, the claimant must also serve on the defendant the particulars of claim.¹⁰³ It is best practice for a claimant to serve their particulars of claim with the claim form. The particulars of claim are typically relatively short and give brief details of the parties in the proceedings, the patent in issue, the relief sought and why that relief is justified.

If the claimant is the patentee alleging infringement of its patent(s), the particulars of claim will be accompanied by a particulars of infringement, which sets out the specific acts of infringement complained of and at least one specific example of an infringing act, including when and where it occurred.¹⁰⁴ If the claimant is a party seeking to revoke a patent, the particulars of claim will be accompanied by a grounds of invalidity, which specifies and particularizes the grounds on which the validity of the patent(s) is challenged.¹⁰⁵

For a lack of novelty or lack of inventive step plea (or both), the grounds of invalidity must identify the item(s) of prior art relied upon, and a copy of each prior art document, with an English translation if necessary, must accompany it.¹⁰⁶ No further details need to be provided as to the basis upon which a patent is said to be anticipated or obvious over that item of prior art. Normally,

¹⁰¹ CPR 7.2(1).

¹⁰² CPR 7.5(1)–(2).

¹⁰³ CPR 7.4(1)(b).

¹⁰⁴ CPR PD63 para. 4.1.

¹⁰⁵ CPR PD63 para. 4.2(2).

¹⁰⁶ CPR PD63 paras 4.2(3), 4.3(1), 4.4(1).

it is advisable to limit the number of items of prior art relied upon to no more than three or four per patent. If a prior use is alleged, details must be given, including the name of the persons making such use, where and when it took place, and how it was made available to the public.¹⁰⁷

More detail is generally required for pleas of added matter and insufficiency. An added matter plea should set out the details of the attack being made, with reference to what is said to be disclosed in the patent but not in the application as filed. An insufficiency plea should set out details as to the basis upon which it is said that the patent specification is insufficient, particularly which examples of the invention cannot be made to work and in which respects they do not work or do not work as described in the specification.¹⁰⁸

Following service of the particulars of claim, the defendant has 14 days within which to file a defense to the claim or to file an acknowledgment of service indicating if it challenges the jurisdiction of the court and if it intends to contest the claim.¹⁰⁹ If an acknowledgment of service is filed, the defendant is given additional time to serve a defense to the claim and must so do within 42 days of service of the particulars of claim.¹¹⁰

In its defense, the defendant will indicate which aspects of the particulars of claim (and, in the particular case, the particulars of infringement or the grounds of invalidity) the defendant admits, denies or requires the claimant to prove. The defendant may also include a counterclaim in its defense. This should follow on from the defense in the same document and should be headed "counterclaim."¹¹¹ The defense (and counterclaim) must be served on every other party.¹¹² In the case of an allegation of infringement, the counterclaim will almost always comprise a challenge to the patent's validity (and therefore be accompanied by the grounds of invalidity, as discussed above).

Where the defendant has included a counterclaim in their defense, the claimant must serve a reply and defense to counterclaim within 14 days of service of the defense and counterclaim. The defense to counterclaim should follow on from the reply in the same document and should be headed "defense to counterclaim."¹¹³ The defense to counterclaim component will indicate which aspects of the counterclaim the claimant admits, denies or requires the defendant to prove. The reply component will additionally provide the claimant an opportunity to respond to any points made in the defendant's defense to the claimant's claim.

The defendant will then, should they wish, have the opportunity to file a reply to defense to counterclaim, which will provide the defendant an opportunity to respond to any points made in the claimant's defense to counterclaim.

9.6.3.2 Requests for further information

Where either party considers that they need additional information or details about one or more aspects of the other party's case, or require clarification of any matter in dispute in the case, they can serve on the opposing party a request for further information (sometimes called a "Part 18 Request").¹¹⁴ Such requests should be strictly confined to matters that are reasonably necessary and proportionate to enable a party to prepare their own case or to understand the case they have to meet.¹¹⁵ A request for further information should set out – concisely and in the manner specified in Practice Direction 18 of the CPR – the further information, detail or clarification requested, often by reference to paragraphs of a party's statement of case.¹¹⁶

The receiving party will typically then respond to that request in the manner specified in the practice direction. However, the receiving party may refuse to respond, for example, on the basis that the information is not necessary or proportionate. If no response is received, the requesting party may seek an order from the court requiring a response by a certain date.

¹⁰⁷ CPR PD63 para. 4.4(2).

¹⁰⁸ CPR PD63 para. 4.3(2).

¹⁰⁹ CPR 10.3(1), 15.4(1)(a).

¹¹⁰ CPR 15.4(1)(b), 63.7(a).

¹¹¹ CPR PD20 para. 6.1.

¹¹² CPR 15.6.

¹¹³ CPR PD20 para. 6.2.

¹¹⁴ CPR 18.1.

¹¹⁵ CPR PD18 para. 1.2.

¹¹⁶ CPR PD18 paras 1.1–1.7.

9.6.3.3 Further statements of case

Besides the statements of case (including requests for further information and their responses) referred to above, there can be certain other formal pleadings ordered by the court at the discretion of the court, often at the request of the parties. Examples include statements of case on discrete aspects of a party's pleaded case, such as a statement of case on infringement by equivalents, a statement of case on priority, a statement of case on plausibility or a statement of case on essentiality or nonessentiality.

9.6.4 Early case management

9.6.4.1 Case management conference

Following service of the defense (with or without a counterclaim), the claimant can make an application to the court for a case management conference (CMC). This is a hearing wherein the timetable (i.e., directions) to trial is ordered by the court if the parties cannot agree to a timetable in advance. This timetable will deal with matters such as the following:

- time for service of any further statements of case, or an order that a party respond to a request for further information;
- time for service of any notices to admit facts, which are documents requiring a party to admit facts or admit a part of the opposing party's case. For example, the patentee might seek admissions as to whether the allegedly infringing product contains each element of the claim of the patent asserted. Suitable admissions will allow both parties to understand which elements of the claim are uncontested and which will be subject to argument at trial;
- time for the patentee to identify which of the claims of the patent it will rely upon at trial as being independently valid. This allows the court to focus only on a handful of claims at trial;
- a timetable for disclosure or time for service (or both), by the allegedly infringing party, of a product and process description (discussed in more detail below in Section 9.6.7.1);
- where a party wishes to establish any fact by experiment(s), the time for service of any notice of experiments setting out particulars of the experiments proposed to establish which facts;
- whether the parties have permission to call expert evidence and, if so, how many experts and in which field(s);
- whether a scientific adviser is to be appointed;
- timetable for the production of a technical primer or statement of agreed common general knowledge by the parties (discussed in more detail below in Section 9.6.9);
- time for the exchange of written fact evidence and expert evidence (both the first round of evidence (evidence in chief) and evidence in reply);
- the estimated length of the trial and the window within which it is to be listed; and
- the category of Patents Court judge required to hear the trial.

A typical order for directions made at a patents CMC can be found appended to the *Patents Court Guide*.¹¹⁷

It is often possible for the parties to agree the order for directions and ask the court to approve it on paper without a hearing. Even if this is not possible, in most cases, a large amount of the order can be agreed between the parties, and any outstanding issues are dealt with at the CMC hearing.

9.6.4.2 Time to trial and expedition

The stated ambition of the Patents Court in England and Wales is that the trial of a patent infringement claim should occur within 12 months of commencement of proceedings. In practice, the court issues a judgment at first instance within 12 to 15 months.

However, where necessary, the court can bring the issue to trial more quickly. For this to happen, one of the parties must seek an order that the proceedings be expedited. The most common situation in which this occurs is where the patentee seeks an interim injunction or, alternatively, an order for expedition on the basis that they will suffer irreparable harm if the infringement continues for 12 or more months before judgment at first instance. A straightforward way to resolve or at least mitigate the harm suffered by either party as a result of granting or not granting an interim injunction is to make the time to judgment as short as practicable. With an order for expedition, it can be the case that a trial will occur in as little as three months after the

117 Courts and Tribunals Judiciary, *Patents Court Guide*, annex B (Feb. 2022).

proceedings are started. This, of course, is incredibly quick and involves significantly shortening the normal timetable to trial and either partially or wholly removing certain steps in the proceedings with the permission of the court.

9.6.5 Interim orders and directions

9.6.5.1 Interim applications

In the run-up to trial, there can be various interim applications made by the parties. Some such applications are case management hearings, or akin to case management hearings, and involve sorting out aspects of the management of proceedings and the directions to trial that the parties cannot agree on between themselves. Other such applications, of which there are many, arise where a party seeks, for example:

- to strike out a particular part of the opposing party's case on the basis that it cannot succeed on its face in any event (the wording of the CPR being that it discloses no reasonable grounds for bringing or defending the claim);¹¹⁸
- summary judgment on the basis that the opposing party has no real prospect of succeeding on the claim (claimant) or successfully defending the claim (defendant);¹¹⁹
- interim injunctive relief;
- security for costs (discussed further below in Section 9.6.5.3.2);
- for a preliminary point to be decided that will either dispose of the claim or make the proceedings significantly shorter and more efficient;
- an order requiring the defendant to disclose a specific category of documents;
- an order requiring the defendant to provide samples of an allegedly infringing product;
- an order freezing the defendant's assets (in a case where there is evidence that persuades the court that it is likely that they will be dissipated);
- an order requiring the defendant to allow the claimant's representatives access to property for the purpose of searching for and seizing specified items or documents – an *Anton Piller* order – (in a case where there is evidence that persuades the court that otherwise the defendant will be likely to hide or destroy those materials).

The most common and often commercially significant interim relief sought in patent proceedings is an interim injunction (sometimes called a preliminary injunction).

The principles governing applications for interim injunctions derive from the case of *American Cyanamid Co. v. Ethicon Ltd* [1975] AC 396 and are, in summary, whether there is a serious question to be tried, whether damages are an adequate remedy (first to the claimant if relief is refused, and then to the defendant if relief is granted), whether either party would suffer irreparable and/or unquantifiable harm should the injunction be or not be granted and whether there are any special factors specific to the particular case in favour one way or the other.

In patents cases, it is often the case that the patentee can be compensated in damages for any infringement that occurs up until trial and therefore, an interim injunction is not normally granted (nor indeed applied for). The most common exception to this is where generic pharmaceutical products are or are at risk of coming onto the market, which will result in rapid price depression such that the patentee will never be able to recover its original price levels for the patented reference product if it is successful at trial. Even then, the court must be satisfied that the facts of the case, as borne out in the evidence, establish that damages are not an adequate remedy for the patentee.¹²⁰

The party in whose favor an interim injunction is granted pending trial will typically be required to provide a cross undertaking in damages to the court to the effect that, if it turns out the injunction is wrongly granted (in the sense that that party is unsuccessful at trial), then they will compensate the allegedly infringing party in damages for loss suffered by reason of the injunction.

¹¹⁸ CPR 3.4.

¹¹⁹ CPR 24.2.

¹²⁰ See *Neurim Pharmaceuticals (1991) Ltd v. Generics U.K. Ltd* [2020] EWHC 1362 (Pat) (where the court found that that was not the case on the facts), *aff'd* [2020] EWCA Civ 793.

9.6.5.2 Dividing a large case into multiple trials

If a dispute involves a number of patents, the court may divide the case into a series of distinct trials so that the liability issues relating to one patent (or a related family of patents) are addressed at one trial, and then one or more further separate trials are scheduled to deal with further patents. In telecommunications and FRAND (fair, reasonable and nondiscriminatory) license cases, the court may also schedule a distinct FRAND trial to take place, commonly after one or more of the earlier trials. In this case, those earlier trials are called “technical trials” because they deal with the technology issues relating to the patent, as opposed to the FRAND trial, which deals with licensing and potentially with competition issues.

9.6.5.3 Issues relating to costs

As discussed further below in Section 9.7.4, costs are generally awarded in patents cases against the losing party. Costs cover legal expenses incurred by the party, which include the fees charged by the legal representatives, those by experts and any court fees. As such, costs are an integral part of court procedure and are a weapon in the court’s armory that it can use both to encourage parties to behave reasonably and effectively, to encourage settlement out of court, and not to waste the court’s time and resources.

9.6.5.3.1 Costs budgeting

If, on the claim form, the claimant does not declare that their claim is worth more than GBP 10 million, then the parties both have to perform a costs budgeting exercise, governed by Part 3 of the CPR.¹²¹ Claims declared to be worth more than GBP 10 million, as many patents cases are, are exempt.¹²²

Costs budgeting requires the parties to fill out a form known as “Precedent H,” in which they set out how much they consider each stage of the proceedings will cost by reference to the hourly rates and time to be spent by the various members of the legal (solicitor or patent attorney) team, the costs of barristers instructed, the costs of experts to be instructed and other allowable disbursements. These Precedent H budgets then must either be agreed upon between the parties or approved at a hearing before the court. For each individual stage of the proceedings, the sum specified in the Precedent H for that party is the maximum level of costs recoverable from the other side by the winning party. Once agreed upon or approved, the Precedent H form can only be amended by application to the court on the basis of a significant change in circumstances.

9.6.5.3.2 Security for costs

If the claimant is impecunious or does not have any significant assets in the United Kingdom, the defendant can seek security for costs – namely, an order requiring that the claimant pay a sum upfront as security for the defendant’s litigation costs.¹²³ Such security can be given either by payment of the full sum of security into court, or by banker’s bond or banker’s guarantee. If the parties cannot agree that security for costs should be given by the claimant or agree upon the amount of security that should be provided, the defendant can make an application to the court for a determination. When making such an application, the defendant will often rely on its Precedent H as setting out its anticipated costs of the proceedings.

9.6.5.3.3 Costs for interim hearings

For interim hearings, especially for those of half a day or less, the court will make a summary assessment of the costs to be paid for that hearing by the party who lost the application. This summary assessment is made based on a schedule of costs for that hearing produced by the relevant party that summarizes the costs expended on the application and on the hearing itself. The court will make the summary assessment immediately after the court has told the parties of its decision.

Except in exceptional circumstances, each party bears its own costs of a case management hearing.

¹²¹ CPR 3.12 et seq., PD3E.

¹²² CPR 3.12(1)(a).

¹²³ CPR 25.12 et seq.

9.6.6 Amendment of the patent

During the course of patent infringement proceedings, it is possible for the patentee to make an application to amend the patent and, in particular, the claims of the patent, pursuant to Section 75 of the Act. To do so, the patentee must serve on the opposing party and the UKIPO an application to amend the patent, identifying the amendments it is seeking to make and the reasons for making the amendment (e.g., so as to avoid a specific passage in an item of prior art). The UKIPO will advertise the application to amend the patent so that third parties have the opportunity to intervene if they object to the amendment being made.

Amendment applications are almost always heard at the trial. However, where such an application is made close to the time of the trial, there may be ancillary consequences, not least because the court's power under Section 75 of the Act is discretionary:

(1) In any proceedings before the court or the comptroller in which the validity of a patent may be put in issue the court or, as the case may be, the comptroller *may*, subject to section 76 below, allow the proprietor of the patent to amend the specification of the patent in such manner, and subject to such terms as to advertising the proposed amendment and as to costs, expenses or otherwise, as the court or comptroller thinks fit. (emphasis added)

Any delay in making an application to amend the patent claims may affect the chances of the court allowing the application. In particular, the court will consider whether the application is procedurally fair to the other party. If the application is likely to necessitate another trial, this may result in it being refused. For example, in *Nokia GmbH v. IPCOM GmbH*,¹²⁴ the Court of Appeal confirmed the principles of patent claim amendment and duly rejected IPCOM's amendment application brought three days before trial on the grounds of procedural unfairness:

The main purpose of Art. 138 [of EPC 2000] as compared with the unamended Art. 138 was to provide that national authorities should have an amendment procedure at all. For prior to the amendment of the Treaty the laws of some countries did not allow patent amendment post-grant at all. Now they must. Art.138 was not intended to govern national rules of procedure concerning patent amendment, still less to require national courts to conduct them in a manner which national law regarded as an abuse of process.¹²⁵

Indeed, late-filed amendment applications may be considered to be an abuse of the court's process. This is particularly the case when the application is made after the trial has taken place.¹²⁶

In practical terms, this means that a patentee that wishes to make an amendment application should make that application as soon as practicable. To wait until the judgment is available will almost certainly be too late. Occasionally, a provision will be made in the order for directions at the CMC for the patentee to make any application to amend the patent-in-suit by a certain date.

9.6.7 Disclosure

In most patents proceedings, the discovery available – referred to as “disclosure” in the United Kingdom – is fairly limited.

9.6.7.1 Product and process descriptions

In place of disclosure on the issue of infringement, a defendant can and – particularly to avoid the costs and burden associated with documentary disclosure – often will opt to provide a product and process description. A product and process description is a detailed document describing the product or process alleged to be an infringement by reference to the disclosure of the patent and, in particular, the claims of the patent that the product or process is said to infringe.

¹²⁴ [2011] EWCA Civ 6.

¹²⁵ [2011] EWCA Civ 6 [127].

¹²⁶ See *Warner-Lambert Co. LLC v. Generics (U.K.) Ltd* [2018] UKSC 56.

9.6.7.2 Disclosure on validity

In many patents cases, provision is not made for disclosure on any question of patent validity. However, an alleged infringer may seek disclosure from the patentee in relation to, for example, insufficiency or obviousness, such as where the patentee seeks to run a case of commercial success to defeat a case of lack of inventive step.

When disclosure is sought on a question of validity, only documents relevant to a pleaded ground of invalidity that a party has in its power or possession and that came into existence no more than two years before or after the earliest claimed priority date of the patent are to be disclosed, unless the court orders otherwise. If, for some reason, one of the parties has a good reason to advance that there are relevant documents that they should see outside this narrow time window, then they will need to make an application for specific disclosure to the court and satisfy the court that there are very likely such relevant and important documents in the possession of the opposing party that will help to progress the case.

Disclosure in the Business and Property Courts is governed by the procedure under Practice Direction 57AD of the CPR.¹²⁷ This scheme requires parties to discuss and jointly complete a document known as a “disclosure review document,” which identifies the issues in dispute on which disclosure should be given, which level of disclosure is sought (by reference to the five models discussed below), what documents are likely to exist, and the individuals in the relevant organizations who are likely to be custodians of those documents. Keywords should also be provided in most instances to enable electronic disclosure (i.e., keyword searches).

The five models of disclosure are as follows:

- Model A – disclosure confined to known adverse documents;
- Model B – limited disclosure;
- Model C – request-led search-based disclosure;
- Model D – narrow search-based disclosure; and
- Model E – wide search-based disclosure (said to be exceptional).

If a party seeks Model C disclosure, it must set out in the disclosure review document its detailed requests for particular documents or narrow classes of documents sought in relation to the issue for disclosure. There is no presumption that any party is entitled to disclosure. The party seeking disclosure must justify to the court that the model sought is appropriate, reasonable and proportionate.

In practice, the disclosure review document is rarely agreed upon between the parties and can be the subject of significant argument at a hearing, often the CMC. The court will then make an order reflecting its determination of the issues. Even where the parties agree upon the contents of the disclosure review document, the court will still be required to approve it and make the order it sees fit.

9.6.8 Evidence

9.6.8.1 Evidence of fact

The typical issues of fact in a patents case are:

- whether an item of prior art was made available to the public before the priority date, particularly if the prior art involves a prior use of something rather than a publication; and
- the precise details of how the alleged infringing article or process operates.

In many cases, these questions will have been resolved before trial by the processes of disclosure and by admissions. If the matters are in issue, then evidence will be needed.

Evidence of fact can be admitted in patents proceedings by way of witness statements accompanied by any relevant documents as exhibits. The provision of trial witness statements is governed by Practice Direction 57AC of the CPR. Where a witness statement is being relied upon

¹²⁷ Between 1 January 2019 and 1 October 2022, this procedure was the subject of a mandatory pilot scheme governed by Practice Direction 51U.

at trial, the evidence should be within the direct knowledge of the witness, who must be willing to be cross-examined on the contents of that witness statement or anything else about the case about which they have knowledge. The witness will be required to sign their witness statement with a clear statement that its contents are true. They will then be asked to reaffirm this under oath if they are called to give evidence at trial. Their written witness statement will generally stand as their evidence in chief at trial, so they will not be required to repeat it orally. As such, a witness' oral evidence will be limited to cross-examination by the opposing party's legal representative(s) followed by, if necessary, reexamination.

9.6.8.2 Expert evidence

The provision of expert evidence in civil proceedings is governed by Part 35 of the CPR, supplemented by the *Guidance for the Instruction of Experts in Civil Claims*.¹²⁸ As noted above, the court's permission is always required to adduce expert evidence. Expert evidence is restricted to that which is reasonably required to resolve the proceedings.¹²⁹

Patents cases are cases in which technical expert evidence is nearly always a critical part. In most cases, the parties will each call an expert or experts in the relevant discipline or disciplines. An expert's duty is to help the court on matters within their expertise, and their role is to assist the court by providing objective, unbiased opinions on such matters.¹³⁰ This typically involves the expert putting themselves into the shoes of the skilled person in the relevant art at the relevant date of the patent. An expert must be independent, and their duty to the court overrides any obligation to the party instructing them, despite the fact that that party may be responsible for their remuneration.¹³¹

To protect the expert witnesses – particularly from criticisms of lack of objectivity in approaching a piece of prior art with hindsight (i.e., with the invention in mind) – lawyers instructing experts typically provide instructions to the experts in a fairly regimented manner, following guidance from the courts.¹³² Expert reports are thus prepared carefully and in a sequential way so that the expert comments first on the common general knowledge and the prior art before they have sight of the patent in issue.

Expert evidence is provided in detailed written expert reports. An expert report must comply with the requirements set out in the Practice Direction 35 of the CPR at paragraphs 3.1–3.3. This includes the expert confirming in writing that they understand their duty to the court and have complied with it and that the expert is aware of CPR Part 35, its corresponding practice direction and the *Guidance for the Instruction of Experts in Civil Claims*.¹³³

As with evidence of fact, an expert's written report stands as their evidence in chief at trial, and they do not need to repeat it orally. At trial, the experts will nearly always be cross-examined at length by the opposing party's legal representative(s) on the contents of their report and, if necessary, reexamined.

Besides technical evidence on the subject matter of the invention in the patent, expert evidence can also be provided, if needed, on other aspects of a case, such as the laws of other countries (by expert lawyers in the relevant jurisdiction).

9.6.9 Technical primers and statements of agreed common general knowledge

9.6.9.1 Technical primers

For anything other than the simplest technology or subject matter, the court will normally make provision at the CMC for the parties to provide an agreed technical primer. This is designed to be an introduction to the technology for the benefit of the trial judge and contain the basic undisputed technology relevant to the case. The parties typically identify which parts of the primer they agree form part of the common general knowledge of the skilled person in the art at the relevant date.

¹²⁸ Civil Justice Council, *Guidance for the Instruction of Experts in Civil Claims* (Aug. 2014), www.judiciary.uk/wp-content/uploads/2014/08/experts-guidance-cjc-aug-2014-amended-dec-8.pdf

¹²⁹ CPR 35.1.

¹³⁰ CPR 35.3(1), PD35 paras 2.1–2.2.

¹³¹ CPR 35.3(2).

¹³² See, e.g., *Medimmune Ltd v. Novartis Pharmaceuticals U.K. Ltd* [2011] EWHC 1669 (Pat), [98]–[114] (Arnold, J).

¹³³ CPR PD35 para. 3.2(9)(a)–(b).

The technical primer is produced sufficiently in advance of the parties preparing their expert evidence so as to avoid the experts unnecessarily repeating the same material in their reports as is covered in the primer. Generally, the claimant will produce a first draft of the primer, on which the defendant will provide comments, including any additions or deletions, before the parties agree on the contents of the final document. Parties will often ask their instructed experts to assist in preparing the technical primer.

9.6.9.2 Statements of agreed common general knowledge

More recently, practice in the Patents Court has been moving away from the provision of technical primers and toward what have become known as statements of agreed common general knowledge. These are intended to set out where the parties (or, typically, their respective experts) agree on aspects of the common general knowledge. Consequently, statements of agreed common general knowledge tend to be produced after the parties have exchanged expert evidence.

Once the contents of the statement have been agreed upon between the parties, it will typically be provided to the judge at the same time as the parties provide to the court their skeleton arguments for trial (see Section 9.6.13.2.1 below). The parties will also, at that stage, be required to provide an agreed list of disputed common general knowledge, which is intended to indicate the areas of dispute that remain between the parties on the common general knowledge that the judge may wish to decide. The judge may ask the parties to revise this list after trial to reflect any issues that have fallen away.

9.6.10 Confidentiality

It is very common in patents actions for parties to rely upon or to seek disclosure of documents that a party (or a third party) considers to be confidential (in whole or in part). For example, product and process descriptions often contain confidential information. However, when evidence or a document has been read to or by the court or referred to at a hearing that has been held in public, the restrictions on that document only being used for the purpose of the proceedings are lifted.¹³⁴ Further, interested parties may request access to the evidence or document, and any confidentiality in it may be lost. How these documents are addressed at trial is therefore important, as they must be appropriately managed.

The usual practice in the English courts is for the parties to agree to a “confidentiality club” (whether inter-parties or under the terms of a court order). These regimes usually provide that the parties’ lawyers, experts and certain individuals giving instructions may see the confidential material. The parties will therefore provide both confidential and non-confidential versions of any documents prepared or disclosed. In some cases, this is done by including any confidential information in an annex to the main document, but, more frequently, it is achieved through the use of redactions. The *Patents Court Guide* contains “confidentiality club” precedent documents.

At trial, if a confidential document is to be discussed, there are usually minor practical ways to address this. For example, the parties’ lawyers may refrain from orally mentioning any confidential information, instead asking the judge to read the relevant information to themselves from a document. Alternatively, where a more significant discussion is required, the court may sit in private (known as sitting *in camera*), but only when a good case can be made that it is necessary in the interests of justice to do so. In patents cases, this is only likely to be when evidence about technical trade secrets is to be given.

Where this happens, any recording or transcript of the proceedings will also be kept separate such that only people allowed access to the confidential information may view it. Given the principle of open justice, the court is generally reluctant to sit in private, particularly if the relevant confidential details do not have to be read out. When the court sits in private, members of the public and those outside any confidentiality club will be asked to leave the courtroom. Once the confidential evidence has been given, the court will again sit in public.

Once the trial is concluded, the parties must then seek an order from the court to restrict or prohibit the further use of any document, thus preventing the information from becoming public

134 CPR 31.22, 32.12.

for the reasons outlined above.¹³⁵ Such orders are known as “31.22 Orders,” after the provision in the CPR that governs the subsequent use of disclosed documents. The judge will need to be persuaded as to why the relevant material is truly confidential. Where such an order is made, the general rule regarding documents read to or by the court or referred to at a hearing that has been held in public is overridden, and the confidentiality of the documents is maintained. Where judgment is to be reserved to be delivered at a later date (as is common in patents cases), a 31.22 Order will be sought orally on a *pro tem* basis pending the further hearing on the consequential issues to be addressed after judgment.

9.6.11 Pre-trial review

A few weeks, typically three to five weeks, before the trial, the court will hold a hearing called a pre-trial review to carry out any case management required to ensure the trial runs smoothly. This provides the opportunity for any procedural matters outstanding to be sorted out and arrangements made for trial, such as arranging for witness evidence to be given remotely or for the court to sit late to accommodate a witness's availability.

9.6.12 Alternative procedures

It is worth noting for completeness that, in addition to that described above, there are a variety of alternative procedures that the court can be asked to adopt in patents proceedings, including:

- the Shorter Trials Scheme;
- the Flexible Trials Scheme; and
- a streamlined procedure.

All of these variously remove certain aspects of the standard procedure, such as disclosure or cross-examination of all witnesses and experts, reducing the time to trial and the overall cost of proceedings.

9.6.13 Trial

9.6.13.1 Types of trial

Historically, all patent trials took place in person, though dispensation could be obtained for one or more witnesses to appear via video link where it was not possible – or it was desirable – for them to appear in person. Interim hearings could be conducted remotely, for example, by telephone, but such an approach was rare in patents cases. However, the COVID-19 pandemic led to the rapid adoption of remote-trial techniques, and one of its legacies insofar as the court system is concerned is likely to be the increased use of remote technology in hearings and trials.

Trials generally do not take place during the court vacations (e.g., in August).

9.6.13.1.1 In-person trials

A trial in person – that is, a trial where everyone appears in the courtroom – is the most common form of trial in England and Wales.

The attendees from the court will be the judge and the court clerks. The parties will be represented by their barrister(s) and solicitor(s) and may also send one or more representatives. (While most trials involve two parties – a claimant and a defendant – it is reasonably common to have multiple parties in a single trial on the same claim if convenient: for example, where there are multiple defendants.)

Witnesses will also attend on the days on which they are due to give oral evidence and may choose to attend the entire trial. Indeed, witnesses (including experts) are generally entitled to listen to the cross-examination of their opposite numbers. There usually will be a transcript writer present. Finally, English court proceedings take place in public unless the court decides it needs to sit for a (short) time in private, so there are often members of the public and press present in the public galleries. Indeed, the Patents Court judges have traditionally had a strong preference for trials to take place in open court.

¹³⁵ CPR 31.22(2).

9.6.13.1.2 Hybrid trials

Hybrid trials are trials that take place partly in person and partly remotely. The most common aspect conducted remotely is the giving of witness oral evidence. Historically, a witness needed some special and justifiable reason to give evidence remotely. However, following the COVID-19 pandemic, the use of hybrid trials has increased significantly, not least because witnesses resident in foreign jurisdictions are often unable to travel to the United Kingdom.

Detailed guidance on hybrid trials is set out in Annex 3 to the Practice Direction 32 of the CPR. Importantly, despite the use of this trial format increasing, the court's permission is required for it. The party requesting the use of videoconferencing facilities at trial must also take care in its organization for two reasons. First, there are certain practicalities that must be considered. For example, relative time zones may mean a witness is giving evidence in the middle of the night where they are based. Second, there are often local rules governing the procedure by which a person must give evidence in one jurisdiction for use in another (as is happening where the witness is based outside of the United Kingdom). Any such local rules and requirements will need to be brought to the court's attention by the time of the pretrial review hearing and be complied with.

The increased use of remote videoconferencing in trials has also encouraged the adoption of other technologies designed to facilitate this form of trial: for example, court-specific online video platforms and software to enable the electronic sharing of bundles of documents.

9.6.13.1.3 Fully remote trials

Fully remote trials are trials where no part of the trial takes place in person (though the judge may base themselves at the court and sit in a courtroom or in their chambers). It is likely that such trials will be rarer in the future – absent a further pandemic – and may take place only where the specific circumstances of a case mean that this approach should be preferred.

9.6.13.2 Order of events and trial timetable

Directions to trial were discussed in Section 9.6.4 above, and pre-trial reviews were discussed in Section 9.6.11 above. At the pre-trial review, the scope of the trial will have been discussed (by reference to the directions). This may have included a discussion with the court about the timetable for the trial. Trials are then managed to follow that agreed timetable, subject to the need to deviate for any reasonable reasons.

In general, each side presents its case in turn, with the claimant going first unless the court orders – or there is agreement – otherwise. For example, it is common in revocation actions where there is a counterclaim for infringement by the patentee for the patentee to go first unless infringement is admitted subject to the validity of the patent.

9.6.13.2.1 Opening written and oral submissions

Prior to the commencement of the trial, the parties will invariably prepare written skeleton arguments for their case. The purpose of these arguments is to set out the background to the parties and the case, to introduce the witnesses, to set out the issues of both fact and law that the court will be required to grapple with at trial, and to advance a party's arguments on those issues (e.g., so-called squeezes between noninfringement and invalidity). These are then exchanged between the parties and provided to the judge, who will hear the case several days before the trial begins.¹³⁶ Their importance cannot be underestimated:

As anyone who has drafted skeleton arguments knows, the task is not rocket science. It just requires a few minutes clear thought and planning before you start. A good skeleton argument (of which we receive many) is a real help to judges when they are pre-reading the (usually voluminous) bundles. A bad skeleton argument simply adds to the paper jungle through which judges must hack their way in an effort to identify the issues and the competing arguments. A good skeleton argument is a real aid to the court during and after the hearing.¹³⁷

¹³⁶ In the Patents Court, this must be done at least two working days before trial. Courts and Tribunals Judiciary, *Patents Court Guide*, para. 14.7(b) (Feb. 2022).

¹³⁷ *InPlayer Ltd v. Thorogood* [2014] EWCA Civ 1511, [55] (Jackson, LJ).

The trial then begins with short oral opening submissions from the party going first. The purpose of these submissions is to succinctly introduce the case and the live issues (which may have changed since the skeleton arguments were prepared). Opening submissions also provide the judge with the opportunity to ask questions, to clarify certain points based on the parties' written skeleton arguments and to give directions to the parties (if needed). Sometimes the other party (or parties) will respond to the opening submissions, but only if it is necessary to do so at this stage. Long opening submissions are actively discouraged (indeed, a purpose of written skeleton arguments is to minimize the amount that needs to be said in a party's opening submissions). Generally, opening submissions take no more than half a day, and they are often dispensed with entirely, the trial beginning with the first witness being called into the witness box.

9.6.13.2.2 Witness evidence

Opening submissions are followed by the giving of witness evidence for the party in question. The general rule is that a party's fact witnesses will go first, followed by their expert witnesses. However, this general rule is often disrupted by practicalities such as witness availability and is therefore frequently varied. Individuals who have signed a product and process description must also make themselves available at trial to be asked questions.

The provision of evidence at trial takes place in three steps: examination in chief, cross-examination and reexamination. However, not all witnesses are called to give evidence at trial. A witness will have given a witness statement (or prepared an expert report) that acts as that witness' evidence in chief. Any witness who has provided a written statement upon which a party wishes to rely must be called to give oral evidence at court, but the court may order otherwise (particularly where the other party has confirmed that they do not wish to cross-examine the witness). Prior to any witness giving evidence, they will be asked to swear or affirm (at the witness' option, and on a relevant holy text if desired) that their evidence will be true.

Fact evidence often relates to whether a particular prior use happened and was made available to the public. Such evidence should not stray into providing an opinion. Expert evidence is the primary evidence on many aspects of patent law, such as obviousness and insufficiency. If a witness is being cross-examined during a break in their evidence (e.g., over lunch), that witness is said to be in "purdah" and must not discuss the case with anyone during the break.

9.6.13.2.3 Examination in chief

Examination in chief is conducted by the legal team of the party calling the witness. It is almost always very brief, given that the witness has already provided a written statement. Its purpose is to confirm the identity of the witness and that they still agree with their written statement. If needed, a witness also may be asked to correct small errors in their written statement.

9.6.13.2.4 Cross-examination

Cross-examination is a key part of English proceedings and is where a witness (whether fact or expert) is questioned by the other party's legal team. Not all witnesses will be cross-examined; it will depend upon the evidence provided and its connection to the facts in issue in a particular case.

The barrister (or solicitor-advocate) will put questions to the witness that are designed to test the witness's written evidence. They will almost certainly be "leading questions," meaning questions that are designed to elicit a yes or no response. The witness will also be referred to documents related to their statement or to the statements of other witnesses giving evidence in the trial. It is also possible for a witness to be presented with documents not previously in the case. Where this is to occur, the other party should provide the documents to the witness in good time before they give evidence at the trial (usually at least 48 hours) to prevent witness ambushing.

For expert witnesses, who often provide the core evidence in patents cases, there is also an option under the CPR for the provision of concurrent expert evidence,¹³⁸ though it is not commonly used in the Patents Court. The process has been referred to as "hot-tubbing": both experts are sworn in at the same time, and the judge initiates discussions between the experts on the issues in dispute and asks questions. Each issue is taken in turn. Once one issue has been

138 CPR PD35 para. 11.1.

addressed by both witnesses, the parties' representatives can ask questions of the experts to clarify or test their opinions. At the end of the exercise, the judge can summarize the evidence given by both experts and ask if the summary is correct.

9.6.13.2.5 Reexamination

After cross-examination, it is possible for the witness to be asked a few questions by the barrister (or solicitor-advocate) acting for the party who called the witness. If this occurs, the questions tend to be short and may only relate to matters arising from the cross-examination of the witness. As with the evidence in chief, the questions on reexamination must be open and cannot be "leading."

9.6.13.2.6 Closing written and oral submissions

After the witness evidence is complete, the parties must make their closing arguments. In patents cases, the parties will usually have the opportunity to prepare written closing submissions. These act as a summary of the evidence (both written and oral) presented during the trial as against the issues in the case that the judge has to decide. In this regard, they frequently draw attention to particular points raised by the other party where the evidence was inconsistent with that party's case, and they also allow a party the opportunity to clarify that, in light of the evidence given at trial, a particular point is no longer be pursued. As well as addressing the evidence, written closing submissions will also address the issues of law in the case.

Written closing submissions can be very lengthy, even though, traditionally, they are written in a short period of time. In a similar way to opening skeleton arguments, written closing submissions are exchanged with the other party and lodged with the judge so that they may be read and considered. The trial timetable usually contains an adjournment of the hearing between the end of the witness evidence and the start of the oral closing to give time for the preparation of written submissions.

The parties will generally then make oral closing arguments. Usually, the party who opened the case will go last, meaning the other party presents their closing arguments first. The purpose of oral closing arguments is to supplement the written closing arguments and to present the final case that each party puts forward for the court to decide, based on the totality of the evidence presented. It is also an opportunity for the judge to ask any final questions and to clarify any issues they are considering.

The time required for the oral closing submissions is generally about one or two days but can be more in bigger cases.

9.6.14 Trial from the judge's point of view

The listing of cases and allocation of judges to a case are judicial functions. The day-to-day task of listing cases for hearing and managing the court's diary is undertaken by a listing officer operating under delegated authority from the judge overseeing the court. In the event of a dispute, listing decisions will be made by a judge. Day-to-day allocation decisions are made by the listing office under the supervision of the relevant leadership judge: in the Patents Court, this is the Judge in Charge of the Patents Court, in consultation with the Chancellor of the High Court.

The court's lists are managed well over a year in advance, and, for cases that require very substantial amounts of court time, the calendar can be managed two or even three years in advance. Unless a case is docketed to an individual judge, the allocation of a judge to hear a trial will not generally take place until one or two days before the scheduled start of the hearing, when the judge needs to start their preparation. This is to maintain flexibility in listing and efficient use of judicial resources. The technical difficulty rating system (described above in Section 9.3.1.2) is used to assist in judicial allocation.

In cases with a pre-trial review, the court tries to ensure that the judge conducting the review will be the trial judge, in which case allocation happens a few weeks before trial. For trials in the Patents Court, which typically take four to eight working days to be heard, the time available to the judge for preparatory reading will be the one or two working days before the start of the hearing.

In patents cases, the pre-trial review and the preparatory reading are opportunities for the judge to start to become familiar with the relevant technology. The experts' written reports will contain explanations of the technology, which are aimed at educating the court. During the trial process itself, the parties and the experts will explain the technology to the judge, and the judge is able to ask questions and clarify their understanding.

The hearing itself is conducted in public. Transparency and open justice are of paramount importance. The court can and will sit for periods in private where necessary, as discussed above in Section 9.6.10. Normally, the court sits for about five hours per day, with the rest of the working day spent on preparation and on judgment writing. The sitting times are flexible to accommodate international witnesses, but, subject to that, the normal sitting times are from 10 a.m. or 10.30 a.m. until 1 p.m., and 2 p.m. until 4.15 p.m. or 4.30 p.m.

The hearings are recorded by the court. The court's recording can be transcribed after the event, but, generally, the parties will pay a private firm of transcribers to make a contemporaneous transcript of the hearing.

At the end of a hearing, if the matter is short, such as for a case management hearing, the judge may give an oral judgment immediately. These *ex tempore* judgments are recorded, and a transcript can be produced later if needed. These oral judgments will only be transcribed if someone (a party or member of the public) asks for them. For more substantial cases, such as patent trials, judgment will be reserved. The judge will produce a written judgment.

First-instance judges will generally prepare the written judgment alone. There is no full-scale system of US-style law clerks to assist judges at first instance, although there is a Judicial Assistants Scheme for the High Court, which some judges use.

Judgments are quite lengthy. They address the applicable law, reasoning out any conclusions on disputed aspects. They will make any relevant findings of primary fact, summarizing the evidence called upon on those issues and giving reasons for the findings. In general, the judgment will address major alternative aspects of a case. Obviousness will generally always be considered even if, for example, the patent is found to lack novelty. This is because, unlike any appellate court, the trial judge will have had the benefit of hearing the expert witnesses. Both validity and infringement will usually be addressed.

9.6.15 Judgment

In the Patents Court, there is no set period of time by which the judgment must be due, but it is usual practice for judges to provide judgments within three months of the end of the trial, often much sooner.

The judgment is initially provided to the parties on a confidential basis in draft. The parties are invited to identify typographical errors as well as any omissions; however, it is not an opportunity to reargue the case or to put in further submissions. While the judgment remains in draft, it is subject to strict restrictions on its use and dissemination. In particular, it is confidential to the parties and their legal representatives, and neither the draft itself nor its substance may be disclosed to any other person or be used in the public domain. The parties are required to take all reasonable steps to ensure that the confidentiality of the draft judgment is preserved, so it is common for it to only be circulated among a limited group of individuals. Further, no action is permitted to be taken by a party (other than internally) in response to the draft before judgment has been formally handed down. A breach of any of these obligations may be treated as a contempt of court.

The formal hand down of the judgment usually takes place approximately one week after the draft is received by the parties, after the court has considered any proposed amendments. This is usually an administrative matter where no parties attend the court; a separate date will be set after the judgment is handed down to hear arguments on the form of order the court should make consequential upon the judgment.¹³⁹ This allows the parties some time to consider the

¹³⁹ Although, in IPEC, the date and time of the hand down of judgment is often used for the consequential hearing.

issues arising from the judgment and to prepare any necessary evidence, for example, on costs. If the consequential hearing is delayed to a later date, any party that is considering appealing the decision will need to ask the court to extend the time to file any appeal on a *pro tem* basis, since the time to file an appeal runs from the time the judgment is handed down.¹⁴⁰ At the same time, a party will request a 31.22 Order if relevant (see Section 9.6.10 above).

9.6.16 The consequential hearing

The consequential hearing (unless matters are agreed between the parties) takes place before the trial judge within 28 days following hand down of judgment to address the form of order that should follow the judgment.¹⁴¹

Until the final order following judgment is made, the judge is not *functus officio*, and so, strictly, any new matter that has a significant bearing on the case should be raised with the judge and not saved for appeal. Cases where something occurs in the interregnum between judgment and the final order that affects the outcome of the case are extremely rare. However, it is an important consideration, as the appellate courts prefer matters to have been raised with the judge at first instance where possible.

9.6.17 Alternative dispute resolution

Throughout any proceedings, including patents proceedings, the court expects the parties to investigate alternative dispute resolution (i.e., explore whether their dispute can be settled out of court). If a party in proceedings invites the opposing party to participate in alternative dispute resolution, and the opposing party either refuses to participate or greets the invitation with silence, the court may well consider this to be unreasonable and penalize the opposing party in costs in some way.

The most common method of alternative dispute resolution that occurs during proceedings is mediation. All settlement discussions between the parties, including proposing, setting up and conducting a mediation, should be “without prejudice save as to costs.” This means that they are confidential and cannot be disclosed to the court during the proceedings until the point is reached where the court is considering what award of costs to make.

Mediation in these circumstances is typically arranged for a day with the parties exchanging short written mediation statements beforehand, which, as well as setting out their position in relation to the proceedings, provides an offer of settlement that they would be prepared to accept – effectively, their opening offer. The mediator is selected and agreed to between the parties, and the mediator’s costs and any mediation venue costs are typically shared equally between the parties.

9.7 Civil remedies

9.7.1 Injunctive relief

Often, the principal reason why a patentee will have commenced infringement proceedings will have been to seek an injunction against the defendant to prevent it from infringing the patent. The courts of England and Wales have the power to grant injunctions “in all cases in which it appears to the court to be just and convenient to do so.”¹⁴²

The exact wording and scope of an injunction is usually considered by the trial judge at the consequential hearing. The normal form of the injunction is one in “general form,” restraining the defendant(s) from infringing the patent, as opposed to one limited to restraining the defendant(s) from performing the specific acts found by the court at trial to infringe the patent.

¹⁴⁰ CPR PD52A para. 4.1(a).

¹⁴¹ Courts and Tribunals Judiciary, *Patents Court Guide*, para. 19.1 (Feb. 2022).

¹⁴² Senior Courts Act 1981, §37(1).

The granting of a general form injunction is a matter of discretion. The important issue of whether and in what terms to grant an injunction was considered by Mr Justice Birss (as he then was) in *Evalve Inc. v. Edwards Lifesciences Ltd*,¹⁴³ who identified the following general principles:

- i) A general injunction to restrain future infringements is the normal remedy for the patentee.
- ii) The burden is on the defendant to give reasons why such an injunction should not be granted.
- iii) All the circumstances should be considered. The public interest, such as the impact on third parties, is a relevant consideration. [...]
- iv) In a proper case, the public interest may justify refusal of or carve out from injunction, and an award of damages in lieu. [...]
- v) The starting point of any consideration of the public interest in relation to a remedy after a patent trial is that the patent system as a whole is already criss-crossed with provisions which strike balances between different public interests.
- vi) The availability of an exclusionary injunction is an important manifestation of the monopolistic nature of a patent right. While monopolies in general are against the public interest, once a patent has been found valid and infringed, the patent monopoly is something which it is in the public interest to protect by an injunction in order to further the purposes of the system as a whole, such as to promote investment in innovation.
- vii) Therefore when [...] various public interests are engaged and pull in different directions, one should have in mind that the legislator is better equipped than the courts to examine these issues and draw the appropriate broad balance. The jurisdiction to refuse or qualify a patent injunction on public interest grounds is not there to redraw the broad balance of public interests set by Parliament in the patent system. The power should be used sparingly and in limited circumstances.¹⁴⁴

The courts have, in an appropriate case, been prepared to grant an injunction that extends beyond the lifetime of the patent in order to deprive the defendant of the “springboard” from which it had benefited by infringement during the patent’s lifetime.¹⁴⁵

The courts also have the ability to tailor injunctive relief to the nature of the case. For example, in cases where the patentee is under an obligation to grant licenses on FRAND terms, the injunction may be expressed to lapse if the defendant enters into a license on the terms that the court has held to be FRAND.¹⁴⁶ Conversely, because the grant of an injunction is an exercise of the court’s discretion, the courts have, in appropriate cases, been prepared to refuse or limit a final injunction following a finding of infringement and substitute an award of damages in lieu of the injunction.

9.7.2 Financial relief – damages and account of profits

The quantum phase of patent litigation is the proceeding in which the amount (i.e., the quantum) of financial relief is determined. This may be damages or, at the claimant’s election, an account of profits. This phase is usually bifurcated from and occurs after the liability phase.

Thus, if a patent is held valid and infringed, separate proceedings will need to be commenced to determine the amount of compensation payable to the patentee. Having contested liability for several years and often in many other jurisdictions besides England and Wales, the parties frequently become financially and emotionally exhausted by the litigation and the patentee may, having secured injunctive relief as appropriate, be reasonably content with its position. It is for these reasons that parties often settle their differences before the quantum proceedings are commenced or at least in the early stages of such proceedings. Consequently, this is why judicial decisions and judgments on the quantum of damages payable following patent infringement are comparatively rare.

¹⁴³ [2020] EWHC 513 (Pat).

¹⁴⁴ [2020] EWHC 513 (Pat) [73].

¹⁴⁵ *Dyson Appliances Ltd. v. Hoover Ltd* [2001] EWHC 30 (Pat), [16]–[29].

¹⁴⁶ See, e.g., *Unwired Planet International Ltd v. Huawei Technologies Co. Ltd* [2017] EWHC 1304 (Pat), [2]–[32].

While damages are usually compensatory in nature, pursuant to Article 13 of the Intellectual Property Enforcement Directive¹⁴⁷ as implemented into U.K. law by Article 3 of the Intellectual Property (Enforcement, etc.) Regulations 2006,¹⁴⁸ it is possible that some form of enhanced level of damages could be ordered.

The patentee is entitled to elect whether it seeks financial compensation by way of damages or an account of profits but not both. Before election, a patentee is entitled to a limited amount of disclosure from the infringing party pursuant to the principles laid down in *Island Records Ltd v. Tring International plc*.¹⁴⁹ It is more common for the patentee to opt for an assessment of damages, although commercial considerations may push the patentee toward an account of profits.

When calculating damages, the court will consider whether the patentee manufactures goods in accordance with the patent, grants licenses to exploit the invention or both. If the patentee grants licenses, then it will be entitled to receive damages as if the infringer had a license on the usual terms and conditions required by the patentee. If the patentee manufactures in accordance with the patent, then, although the principle remains the same – to put the patentee in the position it would have been in but for the infringement – the analysis is often more complicated. The court must assess numerous factors, such as the extent to which the patentee's and the infringer's goods compete with one another, the extent to which the presence of the infringer caused price depression in the market and the extent to which sales of the patented product would have resulted in sales of other goods by the patentee as well. If a patentee neither manufactures goods in accordance with its patent nor grants licenses, the court will usually assess the compensation payable to a patentee on the basis of a reasonable royalty.

The approach that the court will take to the assessment of compensation if the patentee opts for an account of profits is different. An account of profits is restitutionary in nature, designed to deprive the infringer of the unlawful profits it made by virtue of the infringement of the patent and to hand those profits over to the patentee. If the patented product or process forms only part of the product – as will almost inevitably be the case with a composite article such as a mobile phone or a car – then the court will be required to make an apportionment of the value attributable to the patented component.

9.7.3 Other remedies

9.7.3.1 Revocation and declarations of invalidity

If the court makes a finding that a patent is invalid, it will make an order for the revocation of the patent, which the UKIPO will execute. It will also make a declaration that the patent is invalid.

9.7.3.2 Certificates of contested validity

If the validity of the patent has been unsuccessfully challenged, the patentee may request a certificate of contested validity. This certificate will be entered on the register for the patent at the UKIPO, and, if a further unsuccessful challenge to the validity of the patent is subsequently made, the patentee is entitled to have its costs of defending the challenge made on an indemnity basis unless the court directs otherwise.

9.7.3.3 Publication and dissemination of the judgment

The court may order the dissemination and publication of its judgment at the losing party's expense.¹⁵⁰ This is a discretionary matter for the court, and whether it is appropriate to do so (and if so, where and for how long the judgment should be publicized) will depend on the circumstances. In the case of a successful rights owner, such an order should normally only be made to act as a deterrent to future infringers or to raise awareness among the public. In the case of a successful defendant, such an order should normally only be made where there is a real

147 Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the Enforcement of Intellectual Property Rights, 2004 OJ (L 157) 45, <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32004L0048>.

148 SI 2006/1028.

149 [1995] FSR 560.

150 CPR PD63 para. 26.2 (implementing Article 15 of Directive 2004/48/EC on the Enforcement of Intellectual Property Rights, 2004 OJ (L 157) 45).

need to dispel commercial uncertainty.¹⁵¹ As such, such an order may be refused when the effect may be to cause embarrassment to the published party.¹⁵²

9.7.3.4 Delivery up and destruction

As Section 61 of the Act (see Section 9.5.3 above) makes clear, the court has the power to order delivery up or destruction of infringing articles in the infringer's control or, in some exceptional circumstances, that the defendant should recall infringing products from any parties to whom those products have been supplied. In general, such an order is regarded as ancillary to an injunction and made to render the injunction more effective. However, such an order may also be made in other circumstances, such as an order for delivery up made so as to prevent a defendant from selling after-expiry stock that had been obtained by acts of infringement.¹⁵³

9.7.4 Costs award and assessment

At the consequential hearing, the trial judge will usually be asked to determine how the costs of the proceedings are to be apportioned. The starting point for the judge will be to assess which party was the overall winner from a commercial perspective and to award that party its costs. However, an issue-by-issue approach is often applied, with the result that the overall winner may not be awarded its costs in relation to certain issues on which it fought but did not succeed and may even be required to pay the costs of the losing party in certain circumstances.¹⁵⁴ Thus, for example, a party may challenge the validity of a patent on grounds of anticipation (novelty), obviousness and insufficiency but may prevail only on the issue of obviousness. In these circumstances, the challenging party will have succeeded in its goal of invalidating the patent but may well not be awarded its costs of the anticipation and insufficiency issues. Further, if the judge considers that the challenger was unreasonable to have run such challenges, it may be that the challenger will be ordered to pay the patentee's costs of these challenges.

The trial judge will usually not determine the amount of costs payable from one side to the other. This will be held over to a detailed assessment (discussed further below in Section 9.7.5) if not agreed upon by the parties. However, the trial judge may order that the paying party should pay a set percentage of the receiving party's costs, taking a broad approach based on the principles described above and setting off the costs of one issue against another. This guidance from the judge is often helpful in encouraging the settlement of costs issues. The exception to this rule is where the parties have been required to prepare costs budgets (see Section 9.6.5.3.1 above). Assuming that the winning party has adhered to its costs budget, the trial judge may direct for all or substantially all of the costs of the winning party to be paid by the losing party.

In general, the court may award costs on what is known as a standard basis or on an indemnity basis. The standard basis excludes the costs of the lawyers advising their client and helping the client to understand the proceedings. Therefore, costs on a standard basis normally amount to about 65 percent to 75 percent of the actual costs incurred. Costs on an indemnity basis amount to around 90 percent of the actual costs but are awarded very rarely and only in circumstances where the court is satisfied that some sort of penalty ought to be imposed for some reason on the paying party (e.g., if they have behaved in a particularly egregious manner in relation to an issue or issues in the case).

Having determined which should be the receiving party and which should be the paying party, the trial judge will usually order an interim payment on account of costs to be paid by the paying party to the receiving party. This sum will be more than an irreducible minimum amount that the paying party is likely to recover, and the trial judge, again using a broad approach, may typically award approximately 60 percent of the expenses that the party has incurred.¹⁵⁵ Thus, if a party has, using an issue-by-issue approach, been awarded 70 percent of its costs, the trial judge may order that it should receive 60 percent of those costs by way of an interim payment. For example, if the receiving party had incurred costs of GBP 1 million, then the interim payment – 60 percent of 70 percent of 1 million – is GBP 420,000.

¹⁵¹ *Samsung Electronics (U.K.) Ltd v. Apple Inc.* [2012] EWCA Civ 1339, [64]–[77].

¹⁵² See *Regeneron Pharmaceuticals Inc. v. Kymab Ltd* [2018] EWCA Civ 1186.

¹⁵³ *Merck Canada Inc. v. Sigma Pharmaceuticals plc* [2013] EWCA Civ 326, [88]–[95].

¹⁵⁴ See a recent summary of the relevant principles in *Coloplast A/S v. Salts Healthcare Ltd* [2021] EWHC 107 (Pat), [4]–[5].

¹⁵⁵ See *Excalibur Ventures LLC v. Texas Keystone Inc.* [2015] EWHC (Comm) 566; *Wobben Properties GmbH v. Siemens plc* [2015] EWHC 2863 (Pat).

9.7.5 Detailed assessment of costs

As discussed above, at the consequential hearing, the trial judge will typically give two directions as to costs: (i) a decision on which party should receive its costs and the percentage of its costs that it should receive, and (ii) an order for an interim payment.

In many cases, the parties will reflect on the comments from the trial judge and negotiate a sum to be paid from one to the other in respect of costs. Invariably, if there is to be an appeal, the money will be paid subject to an undertaking to repay in the event of a successful appeal or will be held in escrow.

In the event that costs cannot be negotiated, the rules provide a framework for the detailed assessment of costs by a specialist costs judge in a procedure governed by CPR 47.

9.8 Appellate review

9.8.1 Permission to appeal

As noted above in Section 9.3.1.2, permission is required to appeal any decision of the English Patents Court. A party seeking to appeal the judgment of the trial judge will usually apply to that judge for permission to appeal as one of the issues to be considered at the consequential hearing. The trial judge will normally consider the submissions both in writing and orally and must give reasons for granting or refusing permission to appeal.

If the first-instance judge refuses to grant permission to appeal, then that party can make an application on paper to the Court of Appeal.¹⁵⁶ Applications to the Court of Appeal for permission to appeal are normally decided by a single appellate judge on paper without a hearing. If the appellate judge considering the application considers that it cannot be fairly determined without an oral hearing, then they will direct an oral hearing.

The test for granting permission to appeal, whether obtaining permission from the trial judge or the Court of Appeal, is whether the appeal has “a real prospect of success” (which means that there should be more than a fanciful chance that the appeal will succeed) or that there should be another compelling reason for the appeal to be heard.¹⁵⁷

Following the changes to the CPR, the Court of Appeal in *Teva U.K. Ltd v. Boehringer Ingelheim Pharma GmbH*¹⁵⁸ held that technical complexity is no longer a factor to be considered by the trial judge when deciding whether to grant permission to appeal. As a result, trial judges may be stricter when it comes to granting permission to appeal, especially in obviousness cases.¹⁵⁹

9.8.2 Stays pending appeal

If one or both parties are given permission to appeal parts of a decision, the question may arise as to whether the enforcement of a decision or a part thereof should be stayed pending the outcome of the appeal. Generally speaking, the existence of an appeal may lead to the stay of an injunction but is unlikely to stay an inquiry as to damages or account of profits or as to the assessment of costs unless this is agreed to by the parties. If the parties wish to stay a detailed assessment of costs pending appeal, they will need to make an application to the court whose order is being appealed or the appeal court.¹⁶⁰

In deciding whether to grant a stay of an injunction, the court must consider the balance of convenience.¹⁶¹ The object is to arrange matters so that, when the appeal is heard, the appellate

¹⁵⁶ CPR 52.3.

¹⁵⁷ CPR 52.6.

¹⁵⁸ [2016] EWCA Civ 1296.

¹⁵⁹ See, e.g., *Hospira U.K. Ltd v. Cubist Pharmaceuticals* [2016] EWHC 2661 (Pat), [27] (Carr, J) (“I bear in mind that there are a number of well-known cases where the Court of Appeal has referred to the difficulties of challenging a decision on obviousness, which is a multifactorial value judgment. It is important to consider the draft grounds of appeal, and to check whether the unsuccessful party is seeking to re-argue the trial in the Court of Appeal rather than to identify real errors of law or principle which are material to the judgment”).

¹⁶⁰ CPR 47.2.

¹⁶¹ See *Evalve Inc. v. Edwards Lifesciences Ltd* [2020] EWHC 1524 (Pat).

court can do justice between the parties. Where the potentially adverse consequences of granting the stay are relatively evenly balanced, the court will probably maintain the status quo pending the outcome of appeal.¹⁶² The party seeking the stay is likely to be required to give a cross undertaking in damages.

The commencement of an appeal by an unsuccessful patentee on validity will lead to a stay of any order for revocation pending the outcome of the appeal.

9.8.3 Appeals to the Court of Appeal and the Supreme Court

9.8.3.1 Appeals to the Court of Appeal

If permission to appeal is granted either by the trial judge or by the Court of Appeal, an appeal to the Court of Appeal is likely to be heard within 9 to 15 months of the permission being given.

On appeal to the Court of Appeal, it is not possible to adduce fresh evidence other than in exceptional circumstances. An appeal is a review – the Court of Appeal will be reluctant to interfere with the first-instance decision unless the appellant can show that the trial judge erred as a matter of principle or misinterpreted the law.

Normally, on appeal, the only new documents in the case are the formal documents and the skeleton arguments. All the other documents are copies of the documents from the first instance. The formal documents are an appellant's notice, including the brief grounds of appeal and, in some cases, a respondent's notice, which is required when a respondent to the appeal wishes to support the conclusion reached by the court below but for reasons other than those given by the first-instance judge. In practice, the parties' skeleton arguments are full written submissions. In advance of the oral hearing, the appeal court judges will each have read at least the skeleton arguments and the judgment of the court below. They will also read other documents in the case as directed by the skeleton arguments. The oral hearing typically takes one or two days. Rarely will a patent appeal require more than two days. Judgment is usually reserved.

As noted above in Section 9.3.1.2, at least one of the three judges on the panel will be a specialist in patent law. Each of the three judges is independent, and it is open to each of them to write their own substantive decision. If the three judges do not agree, then the decision is that of the majority. However, it is usual for one judge, often the patent specialist, to write a decision with which the others agree. It is not uncommon for one or more of the other judges to make a few written observations to say why they agreed with one or more aspects of the main judgments.

9.8.3.2 Appeals to the Supreme Court

A party can only appeal to the Supreme Court against a decision of the Court of Appeal if it can demonstrate that the appeal raises an arguable point of law of general public importance that ought to be considered by the Supreme Court at that time.¹⁶³ Permission must be obtained from either the Court of Appeal or the Supreme Court. Unlike with appeals at first instance, the Supreme Court will only consider an application for permission to appeal if the Court of Appeal has declined to give permission to appeal. In practice, permission to appeal to the Supreme Court in patents cases is only granted by the Supreme Court itself. The Supreme Court hears about one patents case every one to two years.

9.9 The Intellectual Property Enterprise Court

Reference was made in Section 9.3.1.3 above to the specialist list in the Chancery division of the High Court known as IPEC. This section is focused on the differences in procedure between IPEC and the Patents Court.

IPEC was created on October 1, 2013, reforming the preexisting Patents County Court system. IPEC was established to handle smaller, shorter, less-complex or lower-value intellectual property actions, including patents cases.¹⁶⁴ It aims to provide cheaper, speedier and more informal

¹⁶² *HTC Corp. v. Nokia Corp. (No. 2)* [2013] EWCA Civ 1759.

¹⁶³ U.K. Supreme Court, *Practice Direction 3*, para. 3.3.3.

¹⁶⁴ *IPEC Guide*, §1.1.

procedures than the Patents Court and to safeguard parties from the risk of paying large sums in costs to the opposing party at the conclusion of the proceedings.

A key feature of litigation in IPEC is active judicial case management, which is carried out using a cost-benefit approach. Parties are required to identify the issues to be determined and the steps necessary to resolve them at an early stage in the proceedings.

IPEC has a “multi-track” and a “small claims track” to differentiate claims based on their value and complexity. Only the multi-track is suitable for patents cases, and, therefore, unless expressly stated otherwise, references to IPEC in this section are to the IPEC multi-track.

The active case management of litigation in IPEC (including disclosure, evidence and trials) is managed so as to ensure that the shorter trial lengths are achieved and that the litigation can be conducted at a more proportionate cost.

9.9.1 General

9.9.1.1 Jurisdiction

IPEC only hears cases relating to intellectual property. This includes disputes, such as contractual claims, that involve matters other than intellectual property, but only if associated with an intellectual property claim. Trials in IPEC should last no more than two days (or, at the most, three days).

In IPEC, any claim for damages (or an account of profits) cannot exceed GBP 500,000,¹⁶⁵ although this limit can be waived by agreement between the parties.¹⁶⁶ As explained in more detail below in Section 9.9.12, proceedings in IPEC are subject to a costs cap of GBP 60,000 (with very limited exceptions).

All the remedies (including interim remedies) available in the Patents Court are available in IPEC. As in the Patents Court, procedure in IPEC is governed by the CPR. Part 63(V) and Practice Direction 63 relate to all proceedings started in (or transferred into) IPEC. The costs provisions are set out in Part 45(IV) and Practice Direction 45.

As noted earlier, IPEC has its own dedicated court guide, the *IPEC Guide*, which, as with the *Patents Court Guide*, is to be read in conjunction with the *Chancery Guide*.¹⁶⁷

9.9.1.2 Judges

The majority of cases in IPEC are managed and heard by the presiding judge of IPEC. This de facto docketing of cases facilitates the active case management of the proceedings by the court.

9.9.1.3 Location and type of hearing

IPEC is located in the Rolls Building, London. IPEC trials can be heard outside London, particularly where this would save costs and is agreed between the parties. Prior to the COVID-19 pandemic, all other hearings (including CMCs) would not be heard outside London, as this would typically have been impractical for a short hearing. However, following feedback from IPEC users in respect of the use of videoconferences for all hearings (including trials) during the pandemic, it is anticipated that the default position will be for all hearings (other than trials) to take place by videoconference and for trials to take place as in-person hearings.

9.9.1.4 Representation

Solicitors and patent attorneys are entitled to represent clients in IPEC. They can do this themselves or additionally instruct barristers to help prepare and argue the case in court. Parties may also appear as litigants in person.

¹⁶⁵ CPR 63.17(1).

¹⁶⁶ CPR 63.17(3).

¹⁶⁷ See HM Courts and Tribunals Service, *Chancery Guide 2022*, <https://www.judiciary.uk/courts-and-tribunals/business-and-property-courts/chancery-division/litigating-in-the-chancery-division/the-chancery-guide/>

9.9.2 Pre-action

As in the Patents Court, there is no specific pre-action protocol for litigation in IPEC, and the “Pre-action Conduct and Protocols” practice direction¹⁶⁸ applies. Defendants in an IPEC case are expected to respond within 14 days, except in exceptional circumstances.

The claimant will choose whether it issues its claim in the Patents Court or IPEC, and this will be specified in the claim form.

9.9.3 Transfer

A defendant sued in the Patents Court is entitled to apply to have the case transferred to IPEC and vice versa.¹⁶⁹ If the parties agree that the case should be transferred, it still requires the approval of a judge in the court in which the case is currently listed, but it is likely to be granted. If there is no agreement, an application to transfer must be made. This should be done, at the latest, at the CMC.

The following factors are relevant in determining whether a claim should be transferred into or out of IPEC:

- the financial resources of the parties;
- the overall complexity of the claim;
- the nature of the evidence; and
- the value of the claim.¹⁷⁰

9.9.4 Statements of case

9.9.4.1 The pleadings

Statements of case in IPEC are more detailed than those in the Patents Court. IPEC statements of case must set out concisely all the facts and arguments upon which the party serving the statement relies.¹⁷¹ This requires all relevant facts and arguments to be included in the statement of the case but concisely and at an appropriate level of detail. The CMC in IPEC (see Section 9.9.5.3) is conducted on an issue-by-issue basis, and the parties and court need to know all of the issues for the conference. This is explained in the *IPEC Guide* in the following terms:

Part 63 rule 20(1) requires that a statement of case in IPEC must set out concisely all the facts and arguments upon which the party serving the statement relies. This is sometimes misunderstood. All relevant facts and arguments must be stated. But they should not be set out in a manner which includes every detail. There will be an opportunity by the time of the trial to explain to the court everything that matters. A good approach is to make the statement of case as concise as is possible, while considering whether any argument proposed to be run at trial and the basis for it will come as a surprise to an opponent who has read the statement of case. If not, the statement of case has probably been drafted in sufficient detail.

[...]

- A statement of case alleging infringement of a patent must (a) state which of the claims are alleged to be infringed and (b) give at least one example of the defendant’s infringing product or process.
- A statement of case alleging that a patent is invalid must specify the grounds on which the validity of the patent is challenged, including any challenge to a priority date. All prior art relied on must be specified and a copy of each item of prior art must be attached to the pleading. If it is alleged that a patent does not disclose the invention clearly and completely enough for it to be performed, the pleading must state which aspects of the invention cannot be made to work and in which respects the invention cannot be made to work.

¹⁶⁸ CPR, Practice Direction – Pre-action Conduct and Protocols, www.justice.gov.uk/courts/procedure-rules/civil/rules/pd_pre-action_conduct

¹⁶⁹ CPR pt 30. In particular, PD30 paragraphs 9.1 and 9.2. These apply to the transfer of proceedings to and from IPEC. CPR 30.5, when applied to IPEC transfers, is modified by CPR 63.18.

¹⁷⁰ CPR 63.18, PD30 paras 9.1–9.2. For a summary of the approach, see *77M Ltd v. Ordnance Survey Ltd* [2017] EWHC (IPEC) 1501.

¹⁷¹ CPR 63.20(1).

- A statement of case served in response to an allegation that the patent is invalid must state which claims are said to be independently valid.¹⁷²

The active case management of litigation in IPEC requires the parties to identify, before the CMC (insofar as these have not already been articulated in the parties' statements of case), (i) which claims are in issue, (ii) what they understand to be the inventive concept of those claims, (iii) the facts that are said to be relevant common general knowledge and (iv) the nature and characteristics of the skilled person should be identified.

The parties should bear in mind that, at the CMC, the court may require the number of claims in issue to be reduced, so consideration should be given to which claim is or which claims are most important to the party's case. In most cases, the court will not allow a patentee to rely on more than three claims that are alleged to be independently valid and infringed. The patentee should create a suitable chart, diagram or other document stating which integers of the claim are embodied in the allegedly infringing product or are incorporated in the allegedly infringing process. Similarly, a party alleging that a patent is invalid because it lacks novelty or inventive step over prior art should create an appropriate document identifying which integers of the claim are present in the pleaded prior art. A party alleging invalidity is unlikely to be permitted to rely on more than three prior art citations. Insofar as these documents have not been produced as part of the statements of case, they must be produced before the CMC at the latest.

Statements of case in IPEC must be verified with a statement of truth signed by a person with knowledge of the facts alleged or, if no one person has knowledge of all the facts, by persons who between them have knowledge of all the facts alleged.¹⁷³

9.9.4.2 Timing

Given the additional content to be included in statements of case, the timelines for filing a defense and subsequent statements of case are slightly different in IPEC. There is an additional requirement in IPEC that the particulars of claim must confirm whether or not paragraph 6 of the "Pre-action Conduct and Protocols" practice direction has been complied with.¹⁷⁴

If no acknowledgment of service has been filed, the period for filing the defense is 14 days after service of the particulars of claim.¹⁷⁵ If an acknowledgment of service has been filed, then the time limit for filing the defense is 42 days (if the particulars of claim confirm that paragraph 6 of the "Pre-action Conduct and Protocols" practice direction has been complied with)¹⁷⁶ or 72 days (if it does not).¹⁷⁷

A party's defense (and counterclaim) must be served on every other party. The CPR does not specify a time limit for serving the counterclaim, but the *IPEC Guide* states that this should be done at the same time as filing the defense, and undue delay may carry adverse consequences in costs.¹⁷⁸

A party's reply (and reply and defense to counterclaim) must be filed and served on all other parties within 28 days of the service of the defense.¹⁷⁹ If a party chooses to serve a reply to the defense to counterclaim, this must be both filed and served 14 days from the service of the defense to counterclaim.¹⁸⁰

The time limits for service of statements of case in IPEC cannot be extended without the prior consent of the court.¹⁸¹ An application for an extension of time must be made before the expiry of the relevant period and should set out good reasons why the extension is required. Such applications are typically dealt with without a hearing.

¹⁷² *IPEC Guide*, §4.5(a), (c).

¹⁷³ CPR 63.21.

¹⁷⁴ CPR 63.20(2).

¹⁷⁵ CPR 15.4(1)(a).

¹⁷⁶ CPR 63.22(2).

¹⁷⁷ CPR 63.22(3).

¹⁷⁸ *IPEC Guide*, §4.5(b).

¹⁷⁹ CPR 63.22(4).

¹⁸⁰ CPR 63.22(5).

¹⁸¹ CPR 63.22(6).

9.9.5 Early case management and preliminary measures

9.9.5.1 Interim applications

All interim remedies available in the Patents Court (interim injunctions, search and seizure and asset-freezing orders, security for costs etc.) are available in IPEC.

An application to the court, including an application for judgment in default, is made according to the procedure set out in CPR 63.25.¹⁸² Once served with an application, the respondent must file and serve its response on all relevant parties within five working days.¹⁸³ If the parties cannot resolve the application by agreement, having seen the respondent's response, the applicant will contact the court and arrange a hearing.

If five working days elapse and the respondent has done nothing, the applicant is entitled to ask the court to make the order sought without further delay.

Applications for urgent relief (including interim injunctions) should be made by filing an application notice in the usual way. Once served, the applicant should contact the judge's clerk, who will find a date for the hearing that is appropriate to the urgency of the matter and, if possible, is convenient to all parties. In cases of extreme urgency, an application may be made without an application notice. This is done by contacting the clerk to IPEC. No such application will be entertained unless the judge is given very good reason why the matter is extremely urgent.

The court will always fix a date and time for hearings appropriate to the urgency of the application, which may mean that the application will be heard by a judge other than the presiding judge. The convenience of the parties and their advisers will be taken into account but will not be of paramount importance. As explained above in Section 9.9.1.3, post-COVID-19, the default position will be that all applications will be heard by videoconference unless there are good reasons why an in-person hearing is necessary.

Costs of applications are subject to a stage cap and assessed at the end of the trial unless a party has behaved unreasonably, in which case the costs can be assessed at the conclusion of the hearing¹⁸⁴ and will not count to the overall cap.¹⁸⁵

9.9.5.2 Expression of a preliminary, nonbinding opinion on the merits

In appropriate circumstances, and where all parties agree, IPEC can express a preliminary and nonbinding opinion on the merits of the case (an "early neutral evaluation"). A request for such an opinion should be made in advance of the CMC so that the court may consider whether it is appropriate.

9.9.5.3 Case management

The CMC is an important hearing at which the court will determine how to progress the matter to trial in an efficient and proportionate manner. The court will identify the issues of law and fact to be resolved at the trial¹⁸⁶ and the extent to which disclosure (including the provision of a product and process description), experiments, evidence (factual and expert), cross-examination and written submissions are necessary for the fair determination of the dispute.¹⁸⁷ Any order permitting one or more of these steps will only be made in relation to specific and identified issues¹⁸⁸ and only where the court is satisfied that the benefit of the step (in terms of its value in resolving the relevant issue) appears likely to justify the cost of producing and dealing with it.¹⁸⁹

9.9.6 Disclosure

Only specific disclosure (i.e., disclosure of particular documents or classes of documents) is available in IPEC and will typically be limited to one or more of the issues identified at the CMC.

¹⁸² CPR 63.25 applies CPR Part 23 with modifications.

¹⁸³ CPR 63.25 (2).

¹⁸⁴ CPR 63.26(2).

¹⁸⁵ CPR 46.22.

¹⁸⁶ CPR 63.23(1).

¹⁸⁷ CPR PD63 para. 29.1. Note that material other than that identified in this paragraph will only be permitted in exceptional circumstances. CPR 63.23(2).

¹⁸⁸ CPR PD63 para. 29.2(1).

¹⁸⁹ CPR PD63 para. 29.2(2).

The procedure for disclosure under Practice Direction 57AD of the CPR does not apply in IPEC, although litigants will be expected to disclose all known adverse documents, whether or not an order for disclosure is made at the CMC.¹⁹⁰

9.9.7 Evidence

A party's statement of case can stand as evidence at trial. If it is necessary, additional evidence in the form of witness statements can be directed at the CMC. The court will typically seek to control fact evidence by limiting the issues to which it can be directed, the number of witnesses and the length of their statements.

Similar case management applies to expert evidence. If expert evidence is permitted at all, only where it is clearly shown that different and distinct areas of expertise are relevant to the issues at trial will more than one expert per party be allowed. Experts in IPEC are subject to the same obligations as those in the Patents Court. Although "in-house" experts are more common to satisfy the cost-benefit test, those experts are still required to act independently and in compliance with their obligations and duties as an expert.

9.9.8 Pretrial review

Pretrial reviews do not usually take place in IPEC.

9.9.9 Trial

9.9.9.1 Trial length, format and timetable

IPEC trials should last no more than two days (or at the most three days). As explained above in Section 9.9.1.3, it is anticipated that, post-COVID-19, trials will take place in person.

The court controls the conduct of the trials to ensure that the trial estimate is achieved. The parties are required to file a timetable for the conduct of the trial in advance, and, once approved by the court, this timetable is likely to be enforced strictly. Unless there is good reason not to, the court will allocate equal time to the parties.

Opening speeches, if necessary at all, are likely to be short, and, if the parties have prepared written skeleton arguments in advance of trial, it is not uncommon to proceed straight to the evidence. Unlike in the Patents Court, parties are usually not permitted to put documents to the witnesses (including expert witnesses) that are not already in the case.¹⁹¹ Also unlike in the Patents Court, trials in IPEC do not usually allow for time to prepare written submissions after the evidence, and closing arguments will usually follow immediately after the conclusion of the evidence.

In an appropriate case, and if the parties consent, the trial may be conducted on paper (i.e., there is no hearing). The judgment is delivered in the usual way once the judge has read the papers.

9.9.10 Judgment

As in the Patents Court, many trial judgments will be reserved and handed down at a later date. The parties' legal representatives (or litigants in person) will be provided with a copy of the draft judgment in advance of the date of handing down so that they may notify the court of typographical and obvious errors (if any). The judgment following a trial on the papers is delivered in the usual way once the judge has read the papers.

The text may be shown, in confidence, to the parties, but only for the purpose of obtaining instructions and on the strict understanding that the judgment, and its effect, are not to be disclosed to any other person or used in the public domain and that no action is to be taken (other than internally) in response to the judgment. If the parties prefer not to be shown the draft judgment on this basis, they should inform the court at the time the judgment is reserved.

¹⁹⁰ *IPEC Guide*, §4.6(c).

¹⁹¹ A party needs to permission to submit material in addition to that ordered at the CMC, permission for which will only be granted in exceptional circumstances. CPR 63.23(2).

9.9.11 The consequential hearing

There will often be a hearing after the judgment has been handed down to finalize the order to be made in consequence of the judgment. This may be immediately after the judgment is handed down or may be at a later date.

Where the parties are agreed as to the consequential order and have supplied to the judge a copy signed by all parties or their representatives, no hearing will be necessary.

9.9.12 Costs

Subject to some very limited exceptions¹⁹² costs orders in IPEC are subject to a costs cap. The court will not order a party to pay total costs of more than GBP 60,000 on the final determination of a claim in relation to liability¹⁹³ and no more than GBP 25,000 on an inquiry as to damages or an account of profits.¹⁹⁴ In addition to these overall caps, various stage caps are also applied, capping the costs recoverable for each stage of the litigation.¹⁹⁵

In IPEC, all costs (other than the costs of an interim hearing in which a party is held to have behaved unreasonably)¹⁹⁶ are summarily assessed after trial. The party seeking its costs will submit a detailed summary of its costs broken down into the relevant stages. The court assesses the parties' actual costs for each stage and applies any appropriate deduction at this stage. The resulting figure is compared with the cap for that stage, and the party receives the lower of the two. The various subtotals for each stage are summed, and the party will receive that sum subject to the overall cap.¹⁹⁷ As costs are assessed summarily, there is no need to award an interim payment on account. There is no requirement for costs budgets in IPEC.

9.9.13 Remedies

All the remedies available in the Patents Court following trial are available in IPEC (final injunctions, declarations of noninfringement, certificates of contested validity, orders for the payment of damages or an account of profits, orders requiring the dissemination of a judgment, *Arrow* declarations etc.).

9.9.14 Appeals

An order of IPEC (whether made following an application or trial) may be appealed. All appeals go to the Court of Appeal.¹⁹⁸ No party has an absolute right to appeal; permission must be obtained. Permission to appeal may (and generally should) be sought from the judge who made the order. If the judge refuses to give permission, the party may instead seek permission from the Court of Appeal.

There is no automatic capping of costs in the Court of Appeal. An appellant who wishes to have the appeal costs capped should apply to the Court of Appeal as soon as is practicable. The Court of Appeal has the discretion to make an order limiting the costs that a successful party may recover from the unsuccessful party on appeal.¹⁹⁹ The discretion will be exercised with regard to the means of both parties, all the circumstances of the case and the need to facilitate access to justice.

¹⁹² Court fees, costs relating to enforcement of an order and wasted costs are excluded. CPR 46.21(5). Costs of any interim hearing where a party has behaved unreasonably can be awarded in addition to the overall cap. CPR 46.22. Any recoverable value-added tax is not included in the capped costs. CPR 46.21(6). Also, the caps do not apply where a party has behaved in a manner which amounts to an abuse of the court's process. CPR 46.20(2)(a).

¹⁹³ CPR 46.21(a).

¹⁹⁴ CPR 46.21(1)(b).

¹⁹⁵ These caps are set out in Tables A and B of Practice Direction 46 of the CPR.

¹⁹⁶ CPR 63.26(2).

¹⁹⁷ *BOS GmbH v. Cobra U.K. Automotive Products Division Ltd* [2012] EWPCC 44.

¹⁹⁸ CPR PD52A tbl. 1. Note that all appeals from the IPEC small claims track go to an enterprise judge (i.e., a judge of the IPEC multi-track). See CPR 63.19(3).

¹⁹⁹ CPR 59.19.

Chapter 10

United States of America

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10.1 Overview of the patent system

The landscape of modern U.S. patent institutions reflects the common-law and constitutional foundations of U.S. legal institutions. It comprises three principal adjudication institutions: (1) U.S. district courts, which adjudicate patent infringement actions and resolve invalidity disputes; (2) the United States International Trade Commission (USITC), which investigates complaints alleging patent infringement with respect to imported goods; and (3) the Patent Office, which prosecutes patents and now features a Patent Trial and Appeal Board (PTAB) that reviews patent validity. These institutions vary in their level of specialization, procedures and role within the overall patent system.

A summary of the various features of these institutions is available in the Appendix (Section 10.15) to this chapter.

10.1.1 Evolution of the patent system

10.1.1.1 Federal governmental and judicial structure

Several distinctive and key features of modern U.S. patent law and case management grow out of the colonial and formative period of U.S. history, including national or federal (as opposed to state) protection for patents, jurisdiction over nearly all legal disputes (including patent cases) in general (nonspecialized) courts, the common-law character of U.S. courts, the availability of jury trials for patent cases and the combination of patent validity and enforcement adjudication in federal courts.

The U.S. judiciary emerged from English law and practices, including the common-law legal tradition. The U.S. patent system grew out of the early English Statute of Monopolies (1623), which prohibited the Crown from arbitrarily issuing letters patent “to court favorites in goods or businesses” while authorizing grants of exclusive rights to the “working or making of any manner of new Manufacture.”¹ State patents were granted in most of the original 13 American colonies. Even after the Revolution, under the Articles of Confederation and prior to ratification of the U.S. Constitution, the individual states continued to issue patents.

Conflicts began to arise among the states over steamboat patents, which were issued to two different inventors during this period. With this problem (among others) in mind, the Constitutional Convention of 1789 resolved to create a national patent system rooted in the U.S. Constitution itself. Thus, the provision of Article I, Section 8, Clause 8 authorizes Congress “to promote the Progress of [. . .] useful Arts, by securing for limited Times to [. . .] Inventors the exclusive Right to their [. . .] Discoveries.”

The U.S. Constitution separated federal powers among the legislature (Article I), the executive (Article II), and the judiciary (Article III). It also divided power between the federal government and states through several compromises. Federalists advocated a substantial national government and a strong lower federal judiciary. Anti-Federalists sought to weaken federal power, including judicial authority, however. The latter advocated the passage of a Bill of Rights to protect citizens against the tyranny of national government and preferred judicial power to reside with the states. The clash of perspectives played out in the First Congress in 1789, resulting in a grand compromise that produced the Bill of Rights and a limited system of lower federal courts tied to state boundaries. The Bill of Rights includes the right to a jury trial in the Seventh Amendment to the U.S. Constitution.

10.1.1.2 U.S. patent system history

The first Patent Act, passed in 1790, set forth terse general standards for protection, duration, rights, and remedies, but provided few details. This original institutional structure of the U.S. patent system was, however, short-lived for several reasons. It called upon the Secretary of State (Thomas Jefferson), the Secretary for the Department of War, and the Attorney General to examine patents, which, in light of these officers’ other responsibilities, proved untenable. Second, inventors were displeased with the high and vague threshold for protection: that inventions be deemed “sufficiently useful and important.”

1 21 Jan. 1, ch. 3, §§1, 6 (1623).

As a result, in 1793, Congress removed the requirement that inventions be “sufficiently useful and important” and replaced the examination process with a registration system, leaving the evaluation of patentability entirely to the courts. The Patent Act of 1793 retained a terse standard for patentability: an inventor could patent “any new and useful art, machine, manufacture or composition of matter, or any new and useful improvement on any art, machine, manufacture or composition of matter, not known or used before the application.”² The inventor was still required to provide a written description of the invention and the manner of use:

in such full, clear and exact terms, as to distinguish the same from all other things before known, and to enable any person skilled in the art or science, of which it is a branch, or with which it is most nearly connected, to make, compound, and use the same.³

The courts fleshed out this lean statute. Justice Joseph Story, who would emerge as the leading patent jurist of the first half of the nineteenth century, immediately came to see the problems with vague and conclusory descriptions of inventions. Sitting on his first patent case (and the first case to focus on the question of distinguishing a patented invention from the prior art), he noted the “intrinsic difficulty [...] to ascertain [...] the exact boundaries between what was known and used before, and what [was] new.”⁴ Consequently, patent drafters began to include formal patent claims at the end of their applications for the purpose of avoiding invalidation on the ground of defective specification. The early judicial focus on patent clarity was directed to the question of patent validity – whether the specification adequately described the invention “in such full, clear and exact terms, as to distinguish the same from all other things before known” – as opposed to patent infringement.⁵

The lack of an examination system eroded faith in the patent system due to the proliferation of “unrestrained and promiscuous grants of patent privileges.”⁶ The Senate report accompanying the Patent Act of 1836 lamented that “[a] considerable portion of all the patents granted are worthless and void, as conflicting with, and infringing upon one another,” the country had become “flooded with patent monopolies, embarrassing to bona fide patentees, whose rights are thus invaded on all sides,” and that the “interference and collision of patents and privileges” had produced ruinous vexatious litigation.⁷

In response, the Patent Act of 1836 instituted examination in a newly constituted Patent Office and introduced other procedural and institutional reforms.⁸ In the decades following the 1836 Act, the Supreme Court and lower federal courts established and explicated many of the key patent law doctrines: nonobviousness,⁹ limitations on patentable subject matter,¹⁰ written description,¹¹ and the doctrine of equivalents.¹²

Of particular relevance to patent case management, the Patent Act of 1836 encouraged claiming conventions reflected in jurisprudence by requiring applicants to “particularly specify and point out the part, improvement, or combination, which he claims as his own invention or discovery.”¹³ The form of patent claiming that emerged during this period – which came to be known as “central” claiming¹⁴ – gradually gave way to the “peripheral” format. Peripheral claims use linguistic formulations and claim restrictions, rather than references to specific improvements, to delineate the metes and bounds of the claimed invention.

Claims were not, however, used during this era as the basis for assessing patent infringement. The early infringement standard measured the accused device against the entirety of the patent,

2 Patent Act of Feb. 21, 1793, ch. 11, §1, 1 Stat. 318 (1793).

3 See Patent Act of Feb. 21, 1793, § 3.

4 *Whittemore v. Cutter*, 29 F Cas. 1123, 1124 (C.C.D. Mass 1813).

5 See William Redin Woodward, “Definiteness and Particularity in Patent Claims,” 46 Mich. L. Rev. 755, 760 (1948).

6 See John Ruggles, Select Committee Report on the State and Condition of the Patent Office, S. Doc. No. 24–338, at 4 (1836).

7 See *Senate Report Accompanying Senate Bill No. 239*, 24th Cong., 1st Sess. (April 28, 1836).

8 See Patent Act of July 4, 1836, ch. 357, 5 Stat. 117 (1836).

9 *Hotchkiss v. Greenwood*, 52 U.S. 248 (1850).

10 *Le Roy v. Tatham*, 55 U.S. (14 How.) 156 (1853).

11 *O'Reilly v. Morse*, 56 U.S. 62 (1853).

12 *Winans v. Denmead*, 56 U.S. 330 (1854).

13 Patent Act of July 4, 1836, ch. 357, §6, 5 Stat. 117, 119 (1836).

14 The early claiming format responded to the invalidation of overbroad claiming by using “reference characters” – alphanumeric labels for patent drawings – to specify particular structural components illustrating their improvement.

sometimes with reference to the patentee's actual device, using a substantial identity test: "whether that identity is described by the terms, 'same principle,' same *modus operandi*, or any other."¹⁵ Infringement focused on the operative principle of the invention as set forth in the specification and the patentee's device.

As claims became more significant parts of patents and became standardized, courts increasingly looked to the claim language in assessing infringement. Judges took on the task of interpreting claim language and "the custom developed of having the judge include in his charge to the jury a detailed interpretation of the patent coupled with instructions that his interpretation was binding on the jury."¹⁶

The Patent Act of 1870 formalized the use of patent claims by requiring applicants to "*particularly point out and distinctly claim* the part, improvement, or combination which he claims as his invention or discovery."¹⁷ Over the next several decades, peripheral claims became the norm in American patent practice. The patent claim quickly emerged as the defining feature of the patent. In his seminal 1890 treatise, William C. Robinson characterized it as "the office of the Claim to define the limits of that exclusive use which is secured to the inventor by the patent"; "[t]he Claim is thus the life of the patent so far as the rights of the inventor are concerned."¹⁸ This shift brought claim construction to a prominent role in patent litigation.

The modern Patent Act, passed in 1952, consolidated patent laws and codified the judge-made nonobviousness requirement in Title 35 of the U.S. Code. It was not until 1982 that Congress established the U.S. Court of Appeals for the Federal Circuit (Federal Circuit), with exclusive jurisdiction over all patent appeals from the United States Patent and Trademark Office (USPTO) and federal district courts. And, although Congress established *ex parte* patent reexamination in 1980 and *inter partes* reexamination in 1999 at the USPTO, it was not until the passage of the America Invents Act (AIA) of 2011¹⁹ that administrative patent review became a robust feature of the American patent system.

10.1.1.3 Growing concerns with economic power

By the late nineteenth century, the patent system was a well-accepted feature of the American economic landscape. Key patents on the light bulb, the telephone system, the basic design of the automobile, and the first airplanes symbolized the technical virtuosity and dynamism of the age. The last two decades of the nineteenth century, however, also saw periods of economic depression and increasing concern over the formation of corporate trusts in key transportation, manufacturing, and mining industries, resulting in the unprecedented concentration of economic power. Consequently, courts became more skeptical of patent protection.²⁰ These concerns contributed to judicial development of the exhaustion doctrine.

Congress passed the Sherman Antitrust Act of 1890,²¹ prohibiting monopolization and contracts in restraint of trade. Although the antitrust law did not override patent protection, it reflected a shift in attitudes toward monopoly power. Courts drew upon common-law restraints on property and contractual rights as well as emerging antitrust principles to curtail the scope of patent protection.²²

Following the stock market crash in 1929 and during the nadir of the Great Depression, Franklin Delano Roosevelt rode a platform of economic justice and combating corporate abuse to the

15 George Ticknor Curtis, *A Treatise on the Law of Patents for Useful Inventions in the United States of America* §220, at 262 (1849).

16 Karl B. Lutz, "Evolution of the Claims of U.S. Patents," 20 J. Pat. Off. Soc'y 134, 134 (1938).

17 Patent Act of 1870, ch. 230, §26, 16 Stat. 198, 201 (1870) (emphasis added).

18 2 William C. Robinson, *The Law of Patents for Useful Inventions* §504, at 110 (1890).

19 Leahy-Smith America Invents Act of 2011, Pub. L. No. 112-29, 125 Stat. 284 (2011).

20 See *Adams v. Burke*, 84 U.S. 453 (1873) (recognizing the patent exhaustion doctrine); *Atl. Works v. Brady*, 107 U.S. (17 Otto) 192, 200 (1883) (observing that "[i]t was never the object of those laws to grant a monopoly for every trifling device, every shadow of a shade of an idea, which would naturally and spontaneously occur to any skilled mechanic or operator in the ordinary progress of manufactures [. . . and that to do so] lay a heavy tax upon the industry of the country, without contributing anything to the real advancement of the art"); Lawrence M. Friedman, *A History of American Law* 380 (1973) (noting that, by the late nineteenth century, the courts seemed "to become keenly aware that a patent could be used to stifle competition [and] became stingy with preliminary injunctions against infringement").

21 Sherman Antitrust Act of 1890, 26 Stat. 209 (1890) (codified at 15 U.S.C. §§1-7).

22 See *Henry v. A.B. Dick Co.*, 224 U.S. 1 (1912) (limiting the scope of contributory patent liability to prevent leveraging of patent rights into markets for non-patented products); *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502 (1917) (recognizing the patent misuse doctrine).

White House in the 1932 presidential election. Roosevelt's administration brought in policymakers who distrusted corporate power and favored economic regulation and worker protections. In 1939, President Roosevelt appointed William O. Douglas, an idealistic skeptic of corporate power, to the Supreme Court. Justice Douglas's appointment reinforced the shifting balance of economic regulation and antitrust enforcement. In a series of decisions in the 1940s, Justice Douglas raised the judge-made standard of nonobviousness to require that patentable inventions reflect "a flash of creative genius."²³ He also authored a controversial decision questioning the eligibility of combinations of naturally occurring substances.²⁴ By the end of that decade, Justice Robert Jackson quipped that the Supreme Court's passion for striking down patents might lead observers to conclude that "the only patent that is valid is one which this Court has not been able to get its hands on."²⁵

10.1.1.4 Patent codification, revitalization, and compromise: the 1952 Patent Act

The tightening of patent law standards by the Supreme Court produced a concerted effort by the patent bar to loosen the "flash of genius" standard. This coincided with the legislative program of codifying U.S. laws into the U.S. Code. The 1952 Patent Act consolidated prior patent laws into the modern regime. For the first time, the Patent Act set forth the nonobviousness requirement using the more modest bar recognized by the courts prior to the 1940s: "[T]he manner in which the invention was made," whether "from long toil and experimentation or from a flash of genius," is immaterial to its patentability.²⁶ Although the Patent Act of 1952 simplified and fleshed out the patent law, it left many important doctrines free-floating in jurisprudence. Even after this codification, the formal patent law still contained no mention of limitations on patent eligibility (or patentable subject matter), the experimental use exception to the statutory bar, the doctrine of equivalents, the reverse doctrine of equivalents, the experimental use defense, the exhaustion doctrine, the patent misuse doctrine, the inequitable conduct doctrine, or equitable estoppel.

10.1.1.5 The U.S. Court of Appeals for the Federal Circuit

Concerns arose in the 1960s and 1970s about overloaded federal court dockets and patent forum shopping due to varying patent law standards among the regional circuit courts of appeals. In response to these concerns, Congress passed the Federal Courts Improvement Act in 1982,²⁷ establishing the Federal Circuit and conferring on this court exclusive jurisdiction over patent appeals. While the Federal Circuit was formed to harmonize patent law and eliminate forum shopping across regional appellate circuits, it has also strengthened the patent law in several ways.

10.1.1.6 The Hatch-Waxman Drug Price Competition and Patent Term Restoration Act of 1984

In 1984, Congress amended the Federal Food, Drug, and Cosmetic Act to encourage the release of low-cost generic versions of drugs on the market without undermining incentives to develop pioneering research or the development of new drugs. The law incentivized generic drug manufacturers to file Abbreviated New Drug Applications (ANDAs) by permitting the ANDA filer to rely on the pioneering drug company's clinical data and granting the generic filer a 180-day market exclusivity period following the ANDA's approval by the Food and Drug Administration (FDA) if it could successfully challenge the patent(s) on the pioneering company's drug. This legislation created a specialized form of patent litigation, which we summarize in Section 10.13.2.1.

10.1.1.7 The Digital Age: the bursting of the dot-com bubble, Supreme Court intervention, and the America Invents Act

Patent litigation ramped up in the United States during 1980s as the economy shifted increasingly from tangible to intangible assets, digital technology industries took off, and the value of patent assets grew. The increased stakes attracted more traditional litigators, who preferred jury trials to bench trials. Software patenting took off in the 1990s as companies sought to build defensive portfolios and attract venture capital. Reversing a longstanding view that business methods were not patentable, the Federal Circuit held in *State Street Bank & Trust Co. v.*

23 See, e.g., *Cuno Eng'g Corp. v. Automatic Devices Corp.*, 314 U.S. 84, 91 (1941).

24 See *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948).

25 *Jungersen v. Ostby & Barton Co.*, 335 U.S. 560, 572 (1949) (Jackson, J., dissenting).

26 See 35 U.S.C. §103; H.R. Rep. No. 82-1923, at 7, 18 (1952).

27 Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (1982).

*Signature Financial Group, Inc.*²⁸ that any method that produced a “useful, concrete and tangible result” is eligible for patent protection, including the transformation of data by a machine – in that case, a method for managing a financial portfolio.

This decision contributed to a growing rate of software patenting. Patents drove venture capital investing and the run-up of initial public offering valuations for internet-related start-ups, which peaked in early 2000.

The bursting of the dot-com bubble in March 2000 resulted in a massive sell-off, causing valuations to plummet, financing to dry up, and many start-ups to be driven into bankruptcy. The resulting auctioning of these start-up patents attracted a new breed of patent-assertion entities that used the often-vague software patents to extract settlements from established technology companies. In addition, Congress heard calls for addressing the large and growing backlog of patent applications and promoting international harmonization.

As Congress struggled to find common ground and balance divergent industry concerns, the Supreme Court and the Federal Circuit addressed much of the reform agenda through statutory interpretation and crafting of judicially-created doctrines. The Supreme Court tightened the standard for obtaining injunctive relief²⁹ and the nonobviousness requirement.³⁰ The Federal Circuit raised the bar for proving a reasonable royalty.³¹

Only after the courts had resolved the most controversial issues dividing interest groups was there sufficient consensus for Congress to pass the AIA in September 2011. The AIA contained two principal reforms: (1) it shifted the U.S. patent system to a modified first-to-file system (retaining a grace period for inventor disclosure), and (2) it established a far more robust system of administrative patent review. The latter reform dramatically altered the patent litigation landscape by creating a relatively fast and less expensive process for invalidating patents, as discussed in the next section.

10.2 Patent office and administrative review proceedings

10.2.1 United States Patent and Trademark Office

The USPTO examines patent applications and issues patents. The patent examination procedures are set forth in the Manual of Patent Examining Procedure.³²

Figure 10.1 shows the total number of patent applications (direct and Patent Cooperation Treaty national phase entry) filed with USPTO from 2000 to 2021. In 2021, the USPTO received 591,473 patent applications, a significant increase over the 425,966 applications filed in 2006.

Although the U.S. patent system has authorized the USPTO to correct defects and adjust patent scope through a reissuance process,³³ Congress did not authorize the USPTO to reexamine or revoke patents until 1980. As a result of the AIA, administrative patent review is now a robust and commonly used mechanism to challenge patent validity.

In 1980, Congress established an *ex parte* (one party) reexamination process that enabled patent owners or third parties to request the USPTO to review the validity of issued patents.³⁴ The review process was limited to the review of novelty and nonobviousness based on a limited range of prior art (patents and printed publications). The process was conducted *ex parte* – that is, only the patent owner participated in the proceeding with the USPTO.

For several reasons, the *ex parte* reexamination process was only rarely invoked. For example, it often took years to complete. As a result, district courts were reluctant to stay enforcement proceedings pending completion of reexamination. Furthermore, many potential challengers

28 149 F.3d 1368 (Fed. Cir. 1998).

29 *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388 (2006).

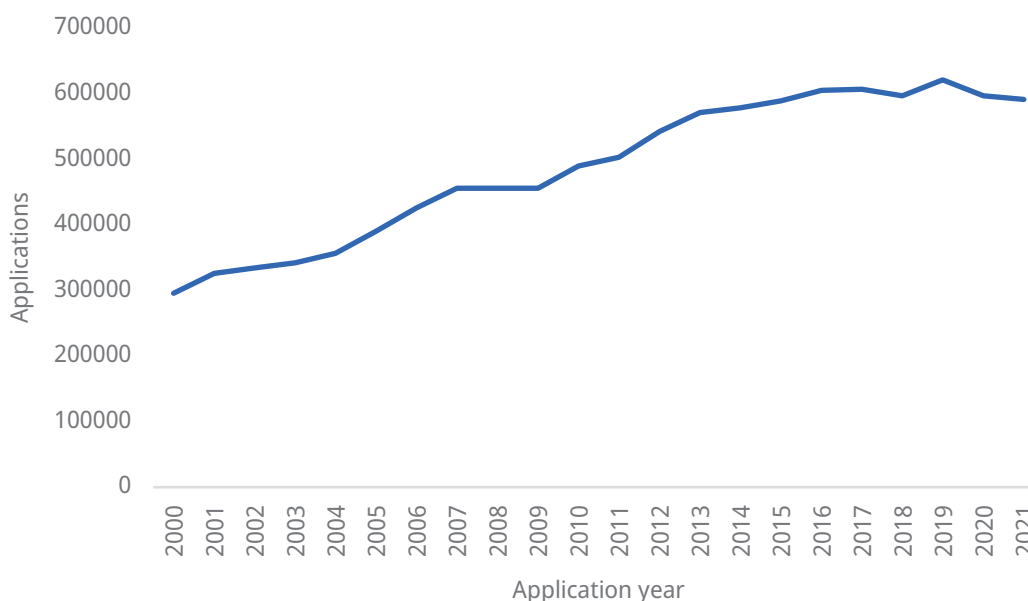
30 *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).

31 See *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292 (Fed. Cir. 2011); *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301 (Fed. Cir. 2009).

32 Available at www.uspto.gov/web/offices/pac/mpep/index.html

33 See 35 U.S.C. §§251–52.

34 See 35 U.S.C. §§301–07; USPTO Ex Parte Reexamination Rules, 37 C.F.R. §1.515(a).

Figure 10.1 Patent applications filed in the United States, 2000–2021

Source: WIPO IP Statistics Data Center, available at www3.wipo.int/ipstats/index.htm?tab=patent

perceived that the process was tilted toward upholding validity. Consequently, most accused infringers did not consider *ex parte* reexamination to be a viable alternative to litigation.

In 1999, Congress established a more balanced *inter partes* (between parties) reexamination procedure that allowed third-party challengers to comment on patent owner responses.³⁵ This process, however, also failed to gain much traction: it was slow and barred challengers from raising any ground that could have been raised during the reexamination in subsequent civil litigation.

The bursting of the dot-com bubble in March 2000 caused start-ups to declare bankruptcy, resulting in their software and internet-business-related patents being put up for auction. A new breed of patent-assertion entities scooped up these assets and pursued a wave of nonpracticing entity lawsuits. The havoc wrought by these cases, some of which threatened to enjoin substantial business units, spurred technology companies to pressure Congress to reform many aspects of the patent system. Amid this turmoil, in 2005 the USPTO established the Central Reexamination Unit (CRU), which expedited reexaminations and resulted in greater usage of the USPTO's reexamination processes. Nonetheless, district courts were still reluctant to stay parallel cases, leading to costly duplication of administrative and judicial resources.

Passing comprehensive patent reform proved difficult. As the Supreme Court and the Federal Circuit addressed some of the thornier issues, such as tightening the standard for obtaining injunctive relief and the nonobviousness standard, Congress focused its reform on a less controversial issue: administrative patent review. Following the logic of patent oppositions in the European Patent Office, Congress expanded and expedited administrative patent review as a key component of the AIA.

The AIA established three principal review procedures: (1) *inter partes* review (IPR) – which replaced *inter partes* reexamination with a streamlined and more robust review process;³⁶ (2) covered business method review – a transitional review proceeding focused on weeding out dubious business method patents;³⁷ and (3) post-grant review (PGR).³⁸ The AIA left *ex parte* reexamination in place.³⁹ It also established supplemental examination – an expedited procedure

35 See Intellectual Property and Communications Omnibus Reform Act of 1999, Pub. L. No. 106–113, §4608(a), 113 Stat. 1501A-521 (1999).

36 35 U.S.C. §§311–19.

37 AIA §18.

38 35 U.S.C. §§321–29.

39 See 35 U.S.C. §§301–07.

for the USPTO to consider, reconsider or correct information believed to be relevant to the patent⁴⁰ – and it added a special proceeding (derivation proceeding) for determining whether a patent application “derived” a claimed invention from another person or persons and whether it was therefore patentable by that applicant.⁴¹ Covered business method review expired in September 2020. The AIA left the CRU in place; it now handles patent reissuance, *ex parte* reexamination, and supplemental examination.

10.2.1.1 Representation at the United States Patent and Trademark Office

To represent parties at the USPTO – including in patent review proceedings – a practitioner must be a member of the Patent Bar.⁴² To qualify for membership, a person must possess the requisite scientific and technical training and pass the Patent Bar examination, which tests an applicant’s knowledge of patent law and procedures.

10.2.1.2 Central Reexamination Unit

As noted above, the USPTO established the CRU in 2005 to expedite and elevate the credibility of *ex parte* and *inter partes* reexaminations. The CRU is staffed with senior primary patent examiners and supervisory patent examiners, who have a wide range of technical expertise and advanced patent legal knowledge.

The AIA supplanted and augmented the prior administrative review processes. Most importantly, the AIA replaced *inter partes* reexamination with a streamlined and expeditious IPR, which is handled by the PTAB (see Section 10.2.2.4). The AIA retained *ex parte* reexamination with the CRU with modest adjustments. It also added supplemental examination, a post-grant proceeding that provided patent owners with a new process for requesting supplemental examination of an issued patent to “consider, reconsider, or correct information” believed to be relevant to the patent. In 2014, the USPTO transferred the responsibility and oversight for all reissue applications to the CRU.

10.2.1.3 The Patent Trial and Appeal Board

The AIA significantly expanded the USPTO’s patent review authority through its establishment of several review proceedings under the auspices of the PTAB, a new review authority within the USPTO. The PTAB is divided into an Appeals Division and a Trial Division. The Appeals Division handles appeals of patent examiner rejections, with specialized sections adjudicating different technology areas. The Trial Division handles contested cases such as IPRs, PGRs, and derivation proceedings. The PTAB employs approximately 200 Administrative Patent Judges (APJs), who have scientific or engineering technical training as well as legal training and patent litigation experience.

Most importantly, the AIA replaced *inter partes* reexamination with a streamlined, expeditious IPR trial proceeding that can be pursued at any time after nine months following the patent grant.⁴³ Within a few years of the AIA’s passage, IPRs reshaped the patent enforcement landscape. The IPR mechanism for challenging patent validity proved popular among accused infringers. In its first full year of operation (2012), the PTAB received over 1,000 petitions. The PTAB instituted reviews for over 80 percent of these petitions and invalidated many of the reviewed claims. The institution and invalidation rates have since leveled off. Of the 13,927 IPR petitions filed through October 2022, the PTAB instituted review of approximately 60% of the petitions challenging 8,578 patents. The PTAB has invalidated at least one claim in 2,749 of those patents and fully invalidated 890 patents.

The AIA also added PGR, a patent challenge that is available within nine months of patent issuance.⁴⁴ Although broader in scope than an IPR, PGR is not widely used due to its high cost and uncertain benefits. The IPR provides a more certain potential benefit: revoking a patent asserted against the challenger.

40 See 35 U.S.C. §257

41 AIA §135.

42 See United States Patent and Trademark Office, Office of Enrollment and Discipline, *General Requirements Bulletin for Admission to the Examination for Registration to Practice in Patent Cases before the United States Patent and Trademark Office* (Oct. 2021).

43 35 U.S.C. §§311–19.

44 35 U.S.C. §321.

With the shift to a modified first-to-file novelty standard, the AIA provided for derivation proceedings to adjudicate inventorship disputes.⁴⁵ These proceedings replaced interference proceedings, which more commonly arose when the United States used a first-to-invent novelty regime. Derivation proceedings have been relatively rare.

10.2.2 Administrative review proceedings

10.2.2.1 Patent reissuance

The patent reissue provision enables a patent owner to request the USPTO to reissue a patent that is “wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than they had a right to claim in the patent.”⁴⁶ The error must have been made without any deceptive intent, and the patent owner may not introduce new matter into the application for reissue.

10.2.2.2 *Ex parte* reexamination

The AIA retained and modestly reformed *ex parte* reexamination. Any person may, at any time, file a request for reexamination by the CRU of any patent claim on the basis of any:

prior art consisting of patents or printed publications which that person believes to have a bearing on the patentability of any claim of a particular patent; or [] statements of the patent owner filed in a proceeding before a Federal court or the [USPTO] in which the patent owner took a position on the scope of any claim of a particular patent.⁴⁷

Within three months following such a filing, the USPTO Director determines whether a substantial new question of patentability (SNQ) – which requires a showing that a reasonable examiner would consider the item of information important in determining the patentability of any claim – is raised by the request.⁴⁸ If the Director finds that an SNQ is raised, then the patent owner is given at least two months from the date of the determination to file a statement on the question, including any amendment to the patent.⁴⁹ If the patent owner files such a statement, the requester is provided a copy and may file a reply, after which the CRU conducts a prompt reexamination proceeding.⁵⁰ No proposed amended or new claim may expand the scope of the patent. Such reexamination decisions can be appealed to the PTAB⁵¹ and to the Federal Circuit with respect to any decision adverse to the patentability of any original or proposed amended or new claim of the patent.⁵²

10.2.2.3 Supplemental examination

Augmenting *ex parte* reexamination, supplemental examination affords a patent owner a three-month procedure during which the CRU may consider, reconsider or correct information believed to be relevant to the patent.⁵³ The patent owner may request consideration of any basis for patentability. Unlike *ex parte* reexamination, the information that forms the basis of the request is not limited to patents and printed publications, and may include other references (“offers for sale,” “public disclosures,” or “public uses”) and issues (such as eligibility, utility, and written description). The standard for granting the request is whether one or more items of information raises an SNQ.

10.2.2.4 *Inter partes* review

A patent challenger may pursue IPR to cancel as unpatentable one or more claims of a patent “only on a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications.”⁵⁴

45 35 U.S.C. §135.

46 35 U.S.C. §251(a).

47 See 35 U.S.C. §§301–02.

48 See 35 U.S.C. §303(a).

49 See 35 U.S.C. §304.

50 See 35 U.S.C. §305.

51 35 U.S.C. §134(b).

52 See 35 U.S.C. §306.

53 35 U.S.C. §257.

54 35 U.S.C. §311(b).

Figure 10.2 shows the number of IPR petitions filed each year, from fiscal year 2012 (the first year in which IPR proceedings were available) through May 2022.⁵⁵ These statistics reflect the rapid rise in IPRs filed after enactment of the AIA in 2011.

Figure 10.2 IPR petitions filed (2012 to 2022)

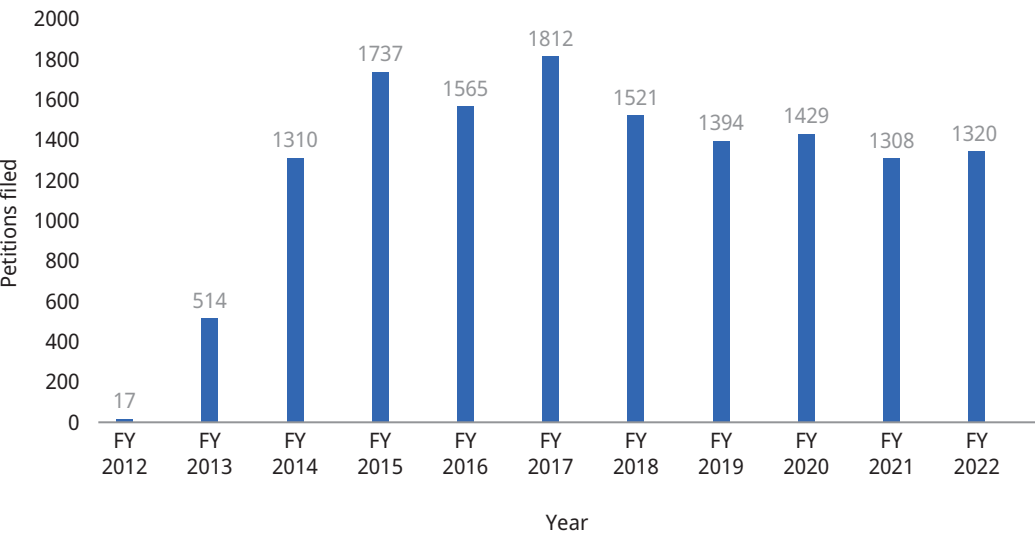
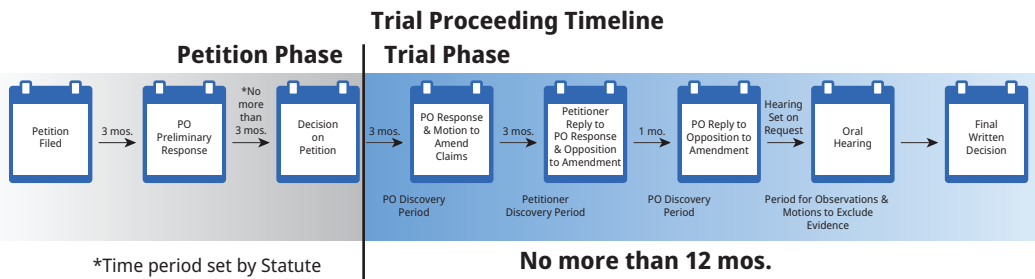


Figure 10.3 illustrates the IPR timeline, described in further detail below.⁵⁶

Figure 10.3 Inter partes review timeline



Note: PO = patent owner.

During the petition phase, the PTAB decides whether to institute an IPR. The patent owner may file a preliminary response to the petition prior to the institution decision, within three months of filing of the petition. The PTAB must decide whether to institute the IPR proceeding within three months of receiving the preliminary response (or three months from the last day on which such a response can be filed).⁵⁷

The threshold for institution – whether “there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition”⁵⁸ – is lower than the prior SNQ standard for initiating *inter partes* reexamination. The AIA requires the PTAB to make the institution decision within three months of the patent owner’s preliminary response (if any). The PTAB’s institution decision is not subject to appeal.⁵⁹ If the PTAB institutes review, the trial phase commences, and the PTAB provides the patent owner and the petitioner challenging the patent with a sequenced discovery process.

55 Data extracted from USPTO AIA Trial Statistics Archive, available at <https://www.uspto.gov/patents/ptab/statistics>

56 Available at www.uspto.gov/patents/ptab/trials/aia-trial-types

57 35 U.S.C. §314(b).

58 35 U.S.C. §314(a).

59 35 U.S.C. §314(d).

PTAB trials are administered by panels of three APJs. The USPTO established the rules for PTAB proceedings based on the AIA and the Administrative Procedure Act (APA). The USPTO has, from time to time, amended those rules.⁶⁰

10.2.2.4.1 Forum selection: inter partes review or declaratory relief

Unless a patent challenger has been sued for infringement, the challenger must elect between pursuing an IPR or a declaratory relief action in district court.⁶¹ If the challenger files an IPR after it has filed a declaratory relief action in district court, then the district court civil action will be automatically stayed until either: “(A) the patent owner moves the court to lift the stay; (B) the patent owner files a civil action or counterclaim alleging that the petitioner [...] has infringed the patent; or (C) the petitioner [...] moves the court to dismiss the civil action.”⁶² The rationale behind this rule is to spare the patent owner from having to defend both the declaratory relief action and the IPR simultaneously. The AIA further provides that an IPR may not be instituted if the petition requesting the proceeding is filed more than one year after the date on which the petitioner is served with a district court complaint alleging infringement of the patent.⁶³

10.2.2.4.2 Institution

The standard for instituting IPR is whether “there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.”⁶⁴ This standard is a “lower threshold than a ‘more likely than not’ requirement.”⁶⁵ Nonetheless, the PTAB has significant discretion in deciding whether to institute an IPR. It must, however, either allow review on all grounds raised or completely deny review. The petitioner must file a separate petition for each patent challenged.

10.2.2.4.3 Trial

The parties to an IPR may request a conference call within a month from the date of institution of the trial to discuss the scheduling order and any motions that the parties anticipate filing during the trial. The PTAB has developed rules and a standard scheduling order for sequenced discovery of information reasonably necessary for IPRs. The AIA provides that IPRs are generally open to the public, but a party may file a motion to seal confidential documents. The AIA also provides for protective orders to govern the exchange and submission of confidential information.

10.2.2.4.3.1 Claim amendments

The PTAB permits patentees to amend claims in IPR proceedings. Amendments may cancel any challenged patent claim, propose a reasonable number of substitute claims, or do both. Motions to amend must be filed no later than the filing of a patent owner response, three months after the institution decision.⁶⁶

10.2.2.4.3.2 Expert witnesses

Although the AIA limits the PTAB review to prior art patents and printed publications, the PTAB permits expert testimony in the form of a declaration to be submitted with the petition, with the preliminary response, and at other appropriate stages in a proceeding as ordered or allowed by the panel overseeing the trial. Expert opinion testimony is generally permitted where the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue.

10.2.2.4.3.3 Claim construction

As of 2018, the PTAB applies standards set forth in *Phillips v. AWH Corp.*⁶⁷ This policy harmonizes the PTAB’s claim construction framework for IPRs with the standards applied in district court cases.

60 The current rules as of the time of this publication can be found in USPTO, *Patent Trial and Appeal Board, Consolidated Trial Practice Guide* (Nov. 2019).

61 35 U.S.C. §315(a)(1).

62 35 U.S.C. §315(a)(2).

63 35 U.S.C. §315(b).

64 35 U.S.C. §314(a).

65 77 Fed. Reg. 48680, 48702 (Aug. 14, 2012).

66 37 C.F.R. §§42.121, 42.220.

67 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*).

10.2.2.4.3.4 Oral hearing

Each party has the right to request an oral hearing as part of an IPR. Such hearings, however, are far more streamlined and limited than district court or USITC patent trials. The PTAB expects to ordinarily provide for an hour of argument per side for a single proceeding. Oral hearings are set on request.

10.2.2.4.3.5 Standard of review

Petitioners bear the burden of proving that a patent is invalid by a preponderance of the evidence in the IPR.⁶⁸ Thus, unlike district court proceedings, the patent owner does not benefit from a presumption of validity in IPR proceedings.

10.2.2.4.3.6 Settlement

The PTAB promotes settlement of IPRs. The panel is available to facilitate settlement discussions and, where appropriate, may require a settlement discussion as part of the proceeding.

10.2.2.4.3.7 Final written decision

The panel will enter a final written decision not more than one year from the date a trial is instituted, except that the time may be extended up to six months for good cause shown.⁶⁹

10.2.2.4.4 Appeal

PTAB final trial decisions (but not institution decisions) can be appealed to the Federal Circuit.⁷⁰

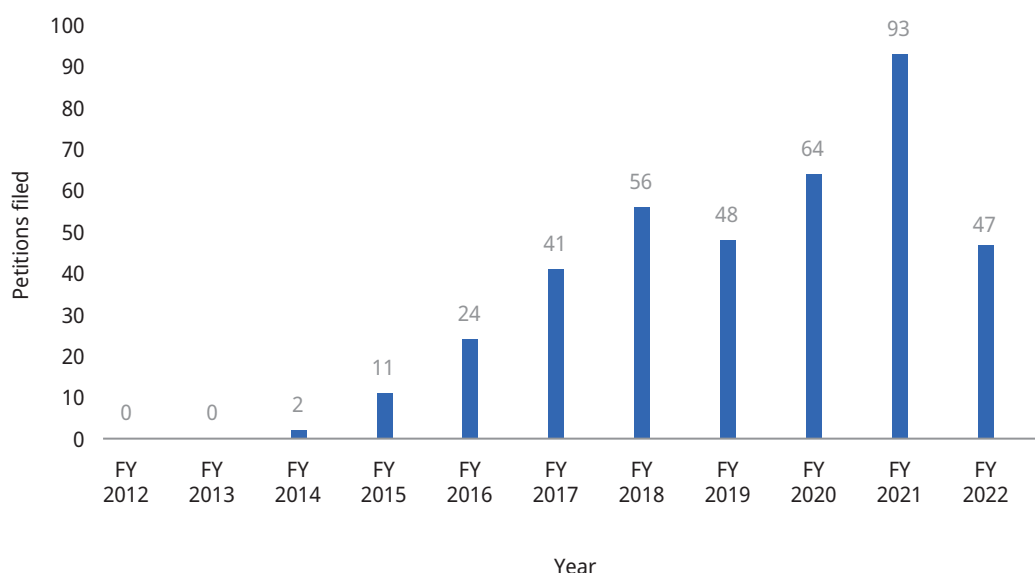
10.2.2.4.5 Estoppel

The AIA provides that the petitioner in an IPR is barred from raising “any ground that the petitioner raised or reasonably could have raised” during that IPR in district court or subsequent administrative proceedings.⁷¹

10.2.2.5 Post-grant review

Figure 10.4 shows the number of PGR petitions filed each year, from fiscal year 2012 through May 2022.⁷² Far fewer PGR petitions are filed than IPR petitions.

Figure 10.4 PGR petitions filed (2012 to 2022)



PGR petitions must be filed within nine months of patent issuance or reissuance and may seek invalidation of patent claims on any basis and without any limitations on prior art references.⁷³

68 35 U.S.C. §315(e).

69 35 U.S.C. §316(a)(11).

70 35 U.S.C. §141(c).

71 35 U.S.C. §315(e).

72 Data extracted from USPTO AIA Trial Statistics Archive, available at <https://www.uspto.gov/patents/ptab/statistics>

73 35 U.S.C. §321.

Any person who has not filed a civil action challenging the validity of a claim of a patent may file a PGR petition challenging the patent's validity. The standard for institution of a PGR is that the information presented in the petition would demonstrate that it is more likely than not that at least one of the claims challenged in the petition is unpatentable.⁷⁴ In addition, the PTAB may institute a PGR if the petition raises a novel or unsettled legal question that is important to other patents or patent applications.⁷⁵ In most other respects, the PGR trial process and ramifications parallel IPR proceedings. If the PGR is instituted and not dismissed, the PTAB will issue a final determination within one year (extendable for good cause by six months).

Table 10.1 compares the key characteristics of IPRs and PGRs.

Table 10.1 Administrative patent review proceedings

AIA review	Inter partes review	Post-grant review
Evidentiary standard	Petitioner to prove invalidity by preponderance of the evidence	
Grounds for review	35 U.S.C. §§ 102–03	Any defense relating to invalidity
Prior art limited to:	Patents and printed publications	No limits
Threshold to institute review	Reasonable likelihood that one or more claims are invalid	More likely than not that at least one claim is unpatentable, or petition raises a novel legal question of patentability
Time to file	More than 9 months after issue or reissue, or after post-grant review	Within 9 months of issue or reissue date
Time to decision	Maximum of 12–18 months from institution decision	
Claim amendments	Patent owner may cancel claims or propose a reasonable number of substitute claims; presumption that only one substitute claim will be required for each challenged claim	
Claim construction	“Ordinary and customary meaning” ¹	
Stay considerations	1) Will stay simplify issues and streamline trial? 2) Is discovery complete; trial date set? 3) Does stay tactically advantage moving party or unduly burden nonmoving party?	
Estoppel in subsequent civil action	Any ground raised or reasonably could have been raised	
Effect of settlement	Estoppel provisions do not apply	

¹ *Phillip v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*) standard.

10.2.2.6 Derivation proceedings

The AIA authorizes the PTAB to conduct derivation proceedings to determine whether (i) an inventor named in an earlier application derived the claimed invention from an inventor named in the petitioner's application and (ii) the earlier application claiming such invention was filed without authorization.⁷⁶ An applicant initiates a derivation proceeding by filing a petition setting forth the basis for finding that an inventor named in an earlier application derived the claimed invention from the petitioner. The petition must be filed within one year of the date of the first publication of a claim to an invention that is the same or substantially the same as the earlier application's claim to the invention.

Upon completion of the proceeding, the PTAB issues a written decision that states whether an inventor named in an earlier application derived the claimed invention from an inventor named in the petitioner's application without authorization. A party dissatisfied with the PTAB's final decision may appeal to the district court or the Federal Circuit.

10.2.3 Constitutionality

The constitutionality of PTAB trial proceedings and, in particular, IPR, has been challenged on multiple occasions and grounds. Parties have argued that these proceedings authorize the taking of private property rights without due process and that the appointment of PTAB judges does not comport with constitutional separation-of-powers requirements. In 2018, the Supreme Court held that the IPR process does not violate Article III or the Seventh Amendment of the U.S.

⁷⁴ 35 U.S.C. §324(a).

⁷⁵ 35 U.S.C. §324(b).

⁷⁶ 35 U.S.C. §135.

Constitution.⁷⁷ More recently, the Supreme Court determined that the APJs sitting on PTAB panels had been appointed in violation of the Appointments Clause in Article II of the Constitution.⁷⁸ To remedy this Constitutional violation, the Supreme Court rendered inoperative the portion of the governing statute⁷⁹ that prevented the USPTO Director from reviewing the final IPR decisions of APJs and made clear that the Director “may review final PTAB decisions and, upon review, may issue decisions himself on behalf of the Board.”⁸⁰ As the USPTO Director is appointed directly by the president, this “tailored solution” remedied the violation.

10.3 Judicial institutions

For most of U.S. history, federal district courts have been the exclusive tribunal for adjudicating patent cases and challenging the validity of patents. They remain a vital institution for both functions, although they now share the former with the USITC (with respect to imported goods) and the latter with the PTAB. It is not uncommon for patent disputes to play out in two or even all three institutions simultaneously, although there are rules and practices that stay or avoid overlapping proceedings. As noted above, there are also special sets of rules applicable to litigation over generic drugs (so-called ANDA cases) and biosimilars.

10.3.1 Federal judiciary structure

The U.S. federal judiciary has three levels for handling patent cases: (1) the district courts, which adjudicate disputes in the first instance; (2) the Federal Circuit, which has exclusive jurisdiction over patent appeals; and (3) the U.S. Supreme Court, which reviews appeals from the Federal Circuit on a discretionary basis.

Figure 10.5 shows the judicial administration structure in the U.S.

10.3.2 Specialized intellectual property judiciary

The U.S. federal judiciary has a mixed approach to patent specialization. Federal district courts have general jurisdiction. Therefore, federal district judges hear a full range of federal cases, ranging from criminal to civil matters. District judges are assisted by federal magistrate judges, law clerks and other court personnel, including general court clerks, administrative assistants and court reporters. Relatively few federal district judges or other district court personnel have scientific or technical backgrounds or patent litigation experience.

The Seventh Amendment to the U.S. Constitution affords either party the right to have patent cases heard by a jury. Since the mid-1990s, approximately 70 percent of patent cases have been tried to juries. Federal civil juries are randomly selected from lists of registered voters and people with a driver's license who live in the district in which the case is tried. Jurors rarely have specialized scientific, engineering, or patent law training. Federal Rule of Civil Procedure (FRCP) 48 provides that federal juries must contain between 6 and 12 jurors, verdicts must be returned by at least 6 jurors, and that verdicts must be unanimous unless the parties stipulate otherwise.

FRCP 53 and Federal Rule of Evidence (FRE) 706 authorize district judges to appoint special masters to hear evidence and argument from the parties and render an initial decision on substantive matters, such as claim construction or summary judgment. Special masters may also present testimony at trials. Relatively few courts use such advisors.

By contrast, the Federal Circuit has a specialized docket that includes patent appeals. The Federal Circuit was established to eliminate forum shopping among regional circuit courts and to develop a tribunal with particular expertise in patent law. Several of the 19 active and senior judges of the Federal Circuit have scientific or technical backgrounds, as do many of the law clerks.

The U.S. Supreme Court has general jurisdiction. The nine Justices do not have specialized training or experience in science or technology. At least four of the nine Justices must agree to grant review of cases, and all nine members hear cases as a single panel.

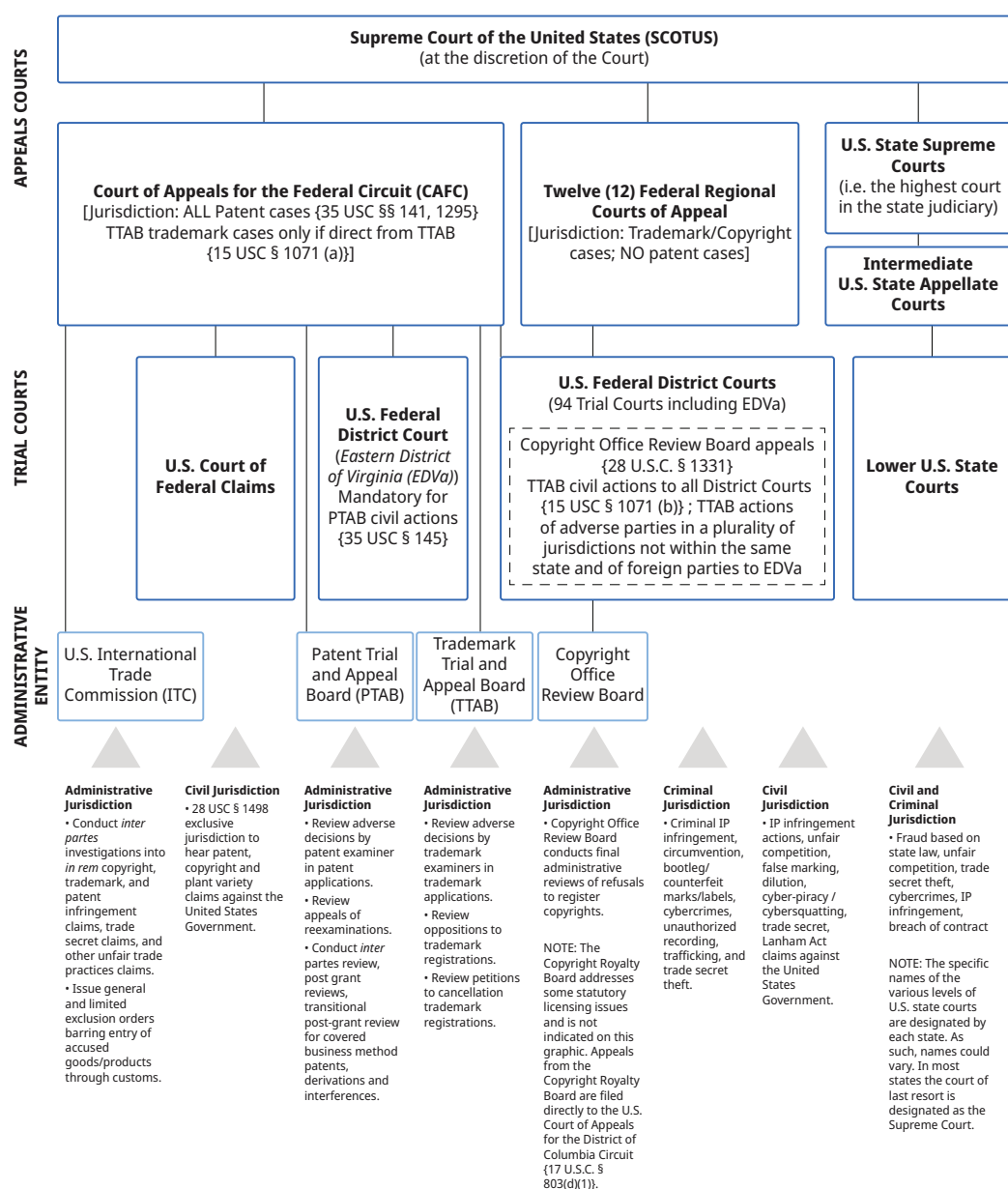
⁷⁷ *Oil States Energy Servs., LLC v. Greene's Energy Grp, LLC*, 138 S. Ct. 1365 (2018).

⁷⁸ *United States v. Arthrex, Inc.*, 141 S. Ct. 1970 (2021).

⁷⁹ 35 U.S.C. §6(c).

⁸⁰ *Arthrex*, 141 S. Ct. at 1987.

Figure 10.5 The judicial administration structure in the U.S.



Source: Judicial Administration Structure for IP Disputes provided by the USPTO, available at www.wipo.int/wipolex/en/judgments/j-admin/us.html

10.3.3 Relationship between invalidity and infringement proceedings

U.S. patent litigation often entails parallel proceedings with parties seeking to take advantage of the distinctive characteristics of different dispute resolution fora. The copendency of litigation involving the same patent can result in the duplicative expenditure of judicial resources and impose unnecessary burdens on parties. Various default rules and discretionary authority aim to avoid duplicative and wasteful litigation.

10.3.3.1 District court proceedings

It is not uncommon for patent holders to pursue infringement actions involving the same patent in different jurisdictions at the same time as a result of jurisdiction and venue considerations. Furthermore, copending litigation relating to the same patent can occur when a company under threat of patent enforcement pursues declaratory judgment of invalidity, noninfringement, or unenforceability in a jurisdiction other than where a patent holder is seeking to enforce the patent against that company or other entities. The public policy favoring expeditious

resolution of disputes is of particular weight when dealing with wasting assets such as patents.⁸¹ Nonetheless, when two actions involving nearly identical parties and closely related patent infringement questions are filed in separate districts, the general rule is that the case first filed takes priority. The first-to-file presumption applies to declaratory judgments as well.

The first-to-file rule, however, “is not rigidly or mechanically applied – an ample degree of discretion, appropriate for disciplined and experienced judges, must be left to the lower courts.”⁸² Courts occasionally make exceptions based on “considerations of judicial and litigant economy, and the just and effective disposition of disputes.”⁸³ In weighing venue transfer or stay motions, courts have looked to the status of the co-pending case, harm caused by delaying the stayed issues, whether the other forum lacks jurisdiction over all necessary or desirable parties, the possibility of consolidation, the convenience of the parties, and judicial economy.

Stays of co-pending patent litigation involving different parties have been most commonly granted in “customer suit” situations. Such litigation arises when the patent holder is engaged in one litigation against a provider of the accused technology and separate litigation against the purchaser of the accused technology. In some circumstances, courts have stayed patent litigation against such customers pending the outcome of the supplier suit, principally where resolution of liability with respect to the supplier will resolve liability with respect to the customer.

Cases involving the same patent and same parties (e.g., a declaratory judgment action brought by the accused infringer and a patent infringement action brought by the patent holder) are typically resolved by the first-to-file rule: the earlier-filed case takes precedence, and the later-filed case is transferred, stayed, or dismissed.

Even where one case or a group of cases clearly takes precedence based on the first-to-file principle, if the subsequent cases were filed soon after the case deemed to have precedence, the patent holder will likely argue that the stay will be prejudicial and that the possibility of case-narrowing is illusory – indeed, it may require the patent holder’s claims against some defendants to sit for years while other litigation is resolved. In addition, courts will also likely consider the possibility that the case(s) deemed to have precedence will not actually resolve issues that narrow the case sought to be stayed (because of settlement, because the patent holder prevails, or otherwise) and that, even when the same patent claims are asserted, the claim construction and invalidity issues may differ substantially (e.g., because the patent holder’s infringement allegations against the various defendants differ). For these reasons, where the request to stay is filed at the outset of the case, most courts will consider other options, such as multidistrict litigation, an important case management innovation that consolidates multiple complex related cases in a single district court.⁸⁴ The stage of the case deemed to have precedence can alter this analysis substantially. If, for example, a request seeks to stay a case in its infancy to await the resolution of a case that is on the eve of a trial at which invalidity is at issue, the factors may weigh strongly toward stay; likewise, if the case deemed to have precedence is pending in a venue with a short time to trial, that may also weigh strongly in favor of a stay.

10.3.3.2 United States International Trade Commission proceedings

Following the Supreme Court’s ruling in *eBay, Inc. v. MercExchange, L.L.C.*⁸⁵ (see Section 10.7.1) the USITC emerged as an active patent enforcement tribunal because it “is not required to apply the traditional four-factor test for injunctive relief.”⁸⁶ Where a USITC proceeding finds patent infringement, the USITC generally issues exclusion orders barring importation of the infringing articles into the United States.

Reflecting the USITC’s rapid adjudication timeline, Congress authorized parties to a district court patent case that are also respondents in a parallel USITC proceeding to move for a stay of the district court proceedings as a matter of right.⁸⁷ The stay remains in effect until the

81 See *Katz v. Lear Siegler, Inc.*, 909 F.2d 1459, 1464 (Fed. Cir. 1990).

82 *Merial Ltd v. Cipla Ltd.*, 681 F.3d 1283, 1299 (Fed. Cir. 2012) (further noting that the first-to-file rule “is a doctrine of federal comity, intended to avoid conflicting decisions and promote judicial efficiency, that generally favors pursuing only the first-filed action when multiple lawsuits involving the same claims are filed in different jurisdictions”).

83 *Futurewei Techs., Inc. v. Acacia Research Corp.*, 737 F.3d 704, 708 (Fed. Cir. 2013).

84 See 28 U.S.C. §1407.

85 547 U.S. 388 (2006).

86 See *Spansion, Inc. v. U.S. Int’l Trade Comm’n*, 629 F.3d 1331, 1359 (Fed. Cir. 2010).

87 28 U.S.C. §1659(a).

determination of the USITC becomes final. After the dissolution of the stay, 28 U.S.C. § 1659(b) allows the parties to use the USITC investigation record in the district court proceeding.

Although the § 1659(a) stay is mandatory, it only applies to “any claim that involves the same issues involved in the proceeding before the [USITC].” Nonetheless, in cases involving additional patents not at issue in a USITC proceeding, district courts are often asked to stay the entire proceeding. In deciding whether to grant such a stay, the district court will typically balance several factors, including possible damage that may result from the granting of a stay, the hardship or inequity that a party may suffer in being required to go forward and the orderly course of justice measured in terms of the simplifying or complicating of issues, proof and questions of law that could be expected to result from a stay.

Although district courts may consider the record from the USITC proceeding, USITC patent determinations – such as claim construction, validity, infringement, and defenses – do not have a preclusive effect on subsequent district court litigation.⁸⁸ The general intellectual property jurisdiction statute grants federal courts original and exclusive jurisdiction of civil actions “arising under any Act of Congress relating to patents.”⁸⁹ Nonetheless, district courts can and do consider USITC rulings in adjudicating cases involving the same patents considered by the USITC.

10.3.3.3 Patent Trial and Appeal Board proceedings

The AIA’s institution of IPR and PGR has invigorated the USPTO’s authority to invalidate patents. The AIA requires that these proceedings, conducted by the PTAB, proceed expeditiously in a streamlined process. In addition, patents reviewed in PTAB proceedings do not carry a presumption of validity. Thus, the challenger need only prove that it is more likely than not that the challenged patent claim is invalid; the challenger does not need to meet the higher “clear and convincing” evidentiary standard applicable in a district court proceeding. As a result, a high percentage of defendants in district court patent litigation seek administrative review of patents asserted against them.

USPTO processes principally affect district court patent case management through stays pending USPTO review. Many district judges have been receptive to staying proceedings involving the same patent claims subject to PTAB review pending resolution of the PTAB proceeding. The rate of stay grants, however, varies across districts and judges. Judges in the Northern District of California and the District of Delaware have granted a high percentage of stay motions, whereas judges in the Eastern and Western Districts of Texas have been reluctant to do so. This factor has a strong influence on where patentees file enforcement actions.

Most courts continue to evaluate stay motions according to the same three-factor test articulated prior to the passage of the AIA:

(1) whether discovery is complete and whether a trial date has been set; (2) whether a stay will simplify the issues in question and trial of the case; and (3) whether a stay would unduly prejudice or present a clear tactical disadvantage to the nonmoving party.⁹⁰

The decision remains based on the “totality of the circumstances,” and the inquiry is not limited to the three factors commonly cited.⁹¹ Because the PTAB has six months to decide whether to institute an IPR proceeding after a petition is filed,⁹² and the scope of the proceeding will not be known until it is instituted, many courts delay ruling on the stay motion until institution is granted.

One important issue in assessing a stay motion is whether the PTAB review would potentially resolve the full range of claims before the court. The stay motion presents the court with the opportunity to clarify the potential ramifications of the PTAB review. If a successful challenge would not resolve the outstanding questions, the court can explore the possibility of stipulations to streamline the district court litigation.

88 See *Tex. Instruments, Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1568–69 (Fed. Cir. 1996).

89 28 U.S.C. §1338.

90 *Telemac Corp. v. Teledigital, Inc.*, 450 F. Supp. 2d 1107, 1111 (N.D. Cal. 2006).

91 See *Universal Elecs., Inc. v. Universal Remote Control, Inc.*, 943 F. Supp. 2d 1028, 1030–31 (C.D. Cal. 2013).

92 35 U.S.C. §314(b).

PTAB decisions can also affect how a district court construes claim terms. Although the PTAB's claim construction is not binding on district courts, district judges can consider the PTAB's claim construction rulings as part of their claim construction process. Since 2018, the PTAB has applied the same standard as used by district courts – that set forth in *Phillips v. AWH Corp.*⁹³ – in construing patent claims.

10.3.4 Judicial education on intellectual property

The Federal Judicial Center, the education and research agency of the federal courts, provides new federal judges with general judicial training and continuing legal education, including a variety of judicial education programs in the patent area. In conjunction with Professor Peter Menell and the Berkeley Center for Law and Technology, the Center has conducted annual patent training programs since 1998. The *Patent Case Management Judicial Guide*,⁹⁴ now in its third edition, provides a comprehensive resource for managing patent cases.

10.4 Patent invalidity

Until 1980, U.S. district courts were the only institutions authorized to invalidate patents. They continue to play a central role in determining patent invalidity (see Section 10.5.3.1). In 1980, Congress augmented district court authority to review patents through patent reexamination at the USPTO (see Section 10.2.2.2). This process, however, proved cumbersome and slow, and hence was rarely used. The AIA established IPR, a robust and commonly used mechanism to challenge patent validity (see Section 10.2.2.4).

10.5 Patent infringement

Both district courts and the USITC adjudicate patent infringement. This section discusses the district court's role. Section 10.12 discusses the USITC's role and processes.

District court patent litigation begins with the filing of a civil complaint – either by a patent owner alleging patent infringement or a party that has been threatened with litigation seeking a declaration that a patent is invalid, not infringed, or not enforceable.⁹⁵ In the latter case, the patent owner defendant will typically file a counterclaim asserting patent infringement.

10.5.1 Claim construction

The construction of patent claims is central to the evaluation of infringement and validity and can affect or determine the outcome of other significant issues, such as unenforceability, enablement and remedies. The Supreme Court's decision in *Markman v. Westview Instruments*⁹⁶ laid the groundwork for modern U.S. claim construction practice. That decision, reinforced by *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*,⁹⁷ declared that “the construction of a patent, including terms of art within its claim, is exclusively within the province of the court.”⁹⁸

The Federal Circuit's decision in *Phillips v. AWH Corp.*⁹⁹ stands as the most authoritative synthesis of the claim construction doctrine. A “bedrock principle” of patent law is that “the claims of a patent define the invention to which the patentee is entitled the right to exclude.”¹⁰⁰ The “objective baseline” for construing patent claims is determining “how a person of ordinary skill in the art understands a claim term” “at the time of the invention, i.e., as of the effective filing date of the patent application.”¹⁰¹ “That starting point is based on the well-settled understanding that

93 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*).

94 Available at <https://www.fjc.gov/content/321534/patent-case-management-judicial-guide-third-edition>.

95 See 28 U.S.C. §2201(a) (“In a case of actual controversy within its jurisdiction [...] any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.”); *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (explaining that there must be “substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment”).

96 517 U.S. 370, 372 (1996).

97 574 U.S. 318 (2015).

98 *Markman*, 517 U.S. at 390.

99 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*).

100 415 F.3d at 1312.

101 415 F.3d at 1313.

inventors are typically persons skilled in the field of the invention and that patents are addressed to and intended to be read by others of skill in the pertinent art.”¹⁰² Often, other evidence will provide context for characterizing the person having ordinary skill in the art. The “effective filing date” is the earlier of the actual filing date or the filing date of an application from which priority is accorded. The skilled artisan “is deemed to read the words used in the patent documents with an understanding of their meaning in the field, and to have knowledge of any special meaning and usage in the field.”¹⁰³ Interpreting patent claims thus requires the court to consider “the same resources as would that person, viz., the patent specification and the prosecution history.”¹⁰⁴

The proper definition of a claim term is context-dependent. The patent and its prosecution history “usually provide the technological and temporal context to enable the court to ascertain the meaning of the claim to a person having ordinary skill in the art at the time of the invention.”¹⁰⁵ Thus, patent claims are to be interpreted in light of this “intrinsic” evidence (i.e., the patent specification and its prosecution history) as well as pertinent “extrinsic” evidence (i.e., evidence showing the usage of the terms in the field of art, such as in dictionaries, treatises, and inventor and expert testimony), but extrinsic evidence cannot contradict or override intrinsic evidence. The Federal Circuit explained why extrinsic evidence is inherently less reliable than intrinsic evidence:

First, extrinsic evidence by definition is not part of the patent and does not have the specification’s virtue of being created at the time of patent prosecution for the purpose of explaining the patent’s scope and meaning. Second, while claims are construed as they would be understood by a hypothetical person of skill in the art, extrinsic publications may not be written by or for skilled artisans and therefore may not reflect the understanding of a skilled artisan in the field of the patent. Third, extrinsic evidence consisting of expert reports and testimony is generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence [. . .] Fourth, there is a virtually unbounded universe of potential extrinsic evidence of some marginal relevance that could be brought to bear on any claim construction question [. . .] Finally, undue reliance on extrinsic evidence poses the risk that it will be used to change the meaning of claims in derogation of the “indisputable public records consisting of the claims, the specification and the prosecution history,” thereby undermining the public notice function of patents.¹⁰⁶

10.5.2 Infringement

U.S. patent law provides for liability for both direct and indirect infringement.

10.5.2.1 Direct infringement

Section 271(a) of the Patent Act imposes direct patent liability upon “whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor.” An accused product or process literally infringes a patent if it contains each and every limitation recited in a claim.

A defendant can also be held liable for nonliteral infringement where the accused product or process is close to the patented invention, but does not literally infringe. The doctrine of equivalents evolved in response to the concern that an “unscrupulous copyist” could avoid literal infringement of a patented invention by making insubstantial changes to the invention.¹⁰⁷ Under the function-way-result test, an accused element is equivalent to a claim limitation “if it performs substantially the same function in substantially the same way to obtain the same result.”¹⁰⁸ Under this test, a finding of equivalence requires that all three prongs be satisfied. The doctrine of equivalents determination is judged on the state of technology as of the time of the infringement, not (as in the case of means-plus-function claims) as of the time the patent issued.

¹⁰² 415 F.3d at 1313.

¹⁰³ 415 F.3d at 1313.

¹⁰⁴ 415 F.3d at 1313.

¹⁰⁵ 415 F.3d at 1313.

¹⁰⁶ 415 F.3d at 1318-19.

¹⁰⁷ *Graver Tank & Mfg Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 607-08 (1950).

¹⁰⁸ *Graver Tank*, 339 U.S. at 608 (quoting *Sanitary Refrigerator Co. v. Winters*, 280 U.S. 30, 42 (1929)).

The courts have limited the doctrine of equivalents in several ways. The all-elements rule provides that the test for equivalence under the doctrine of equivalents must be applied on an element-by-element (or limitation-by-limitation) basis. A finding of infringement therefore requires that the accused product or process contain each claim limitation or its equivalent.¹⁰⁹ Moreover, the doctrine of equivalents is not available where the patentee has narrowed a claim element during prosecution unless (1) the equivalent was unforeseeable to a person having ordinary skill in the art at the time of the amendment, (2) the rationale for the amendment was no more than tangentially related to the equivalent at issue, or (3) another reason suggesting that the patentee could not reasonably be expected to have described the alleged equivalent.¹¹⁰ Furthermore, under the public dedication rule, a patentee may not invoke the doctrine of equivalents to recapture subject matter disclosed but not claimed in a patent.¹¹¹

10.5.2.2 Indirect infringement

U.S. patent law also imposes liability upon those who actively induce or contribute to infringement by another person. Section 271(b) of the Patent Act provides that “[w]hoever actively induces infringement of a patent shall be liable as an infringer.” Induced infringement requires that the patentee prove that the defendant “actively and *knowingly* aid[ed] and abet[ted] another’s direct infringement.”¹¹² The knowledge requirement can be established by showing actual or constructive knowledge of the patent¹¹³ or that the defendant acted with “willful blindness.”¹¹⁴ Under the doctrine of “willful blindness,” the inducer must have (1) subjectively believed that there was a high probability of infringement and (2) taken deliberate actions to avoid learning of that fact.¹¹⁵

Section 271(c) imposes liability under the following circumstances:

[1] Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, [2] constituting a material part of the invention, [3] knowing the same to be especially made or especially adapted for use in an infringement of such patent, [4] and not a staple article or commodity of commerce suitable for substantial noninfringing use, [5] shall be liable as a contributory infringer.

The patentee must prove that the alleged contributory infringer had knowledge of the patent.¹¹⁶ Element [4] serves as an important defense, immunizing the sale of staple articles of commerce, that is, products that have substantial noninfringing uses. Thus, absent evidence of inducing conduct, sellers of non-patented goods are shielded from liability unless the good “has no commercial use except in connection with [. . . the] patented invention.”¹¹⁷

10.5.3 Defenses

Section 282 of the Patent Act provides for the following defenses: (1) noninfringement, absence of liability for infringement or unenforceability; (2) patent invalidity; and (3) any other fact or act made a defense.

10.5.3.1 Patent invalidity

Section 282(a) of the Patent Act provides that patents “shall be presumed valid.” Therefore, the patent owner does not need to prove validity in an infringement action. The challenger bears the burden to prove invalidity by “clear and convincing evidence.”¹¹⁸

10.5.3.2 Other defenses

An alleged infringer can defend on the ground that the patentee has consented to their use of the technology by, for example, granting a license.

109 See *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39 n.8 (1997).

110 See *Festo Corp. v. Shoketsu Kinzoku Kabushiki Co.*, 535 U.S. 722, 740–41 (2002) (applying prosecution history estoppel).

111 See *Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002) (*en banc*) (*per curiam*).

112 *Water Techs. Corp. v. Calco, Ltd.*, 850 F.2d 660, 668 (Fed. Cir. 1988) (emphasis in original).

113 See *Instituform Techs., Inc. v. Cat Contracting, Inc.*, 161 F.3d 688, 695 (Fed. Cir. 1998).

114 *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011).

115 See *Global-Tech Appliances, Inc.*, 563 U.S. at 769.

116 See *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 488 (1964).

117 *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 184 (1980).

118 See *Microsoft Corp. v. i4i Ltd P'ship*, 564 U.S. 91, 108–13 (2011).

Under the first-sale doctrine (sometimes referred to as the exhaustion principle), a form of implied license by operation of law, the first unrestricted sale of a patented product exhausts the patentee's control over that product, and it can be resold and repaired without implicating the patent owner's rights.¹¹⁹ The line between permitted repair and impermissible reconstruction is not easily determined, resulting in rather vague, context-specific rulings.¹²⁰ Such issues arise frequently in the context of contributory infringement claims, where the alleged infringer is providing specialized replacement parts.

Courts have long recognized a common-law defense of experimental use. The Federal Circuit has, however, interpreted this doctrine quite narrowly, limiting it to uses "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."¹²¹ In addition to the common-law doctrine of experimental use, § 271(e) creates a limited experimental use exception for submitting information for regulatory purposes.

Section 273 of the Patent Act provides for a prior-use right to a defendant who commercially used the invention in the United States at least one year before the earlier of either (1) the effective filing date or (2) the date of the first public disclosure of the claimed invention. The prior-use defense must be established by clear and convincing evidence.

Even where a defendant cannot prove that the patent has not been infringed or is invalid, it may avoid liability by showing that the patentee engaged in inequitable conduct or patent misuse or by proving another equitable defense (equitable estoppel or prosecution laches). Inequitable conduct may "arise from an affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive or mislead the [US]PTO."¹²² A determination that inequitable conduct occurred in relation to one or more claims will render the entire patent unenforceable.¹²³

Inequitable conduct claims must be pled with particularity under FRCP 9(b), and these claims "require[] identification of the specific who, what, when, where, and how of the material misrepresentation or omission committed before the [US]PTO."¹²⁴ The accused infringer must prove both materiality and intent by clear and convincing evidence.¹²⁵ Once these threshold findings are established, the court "must weigh them to determine whether the equities warrant a conclusion that inequitable conduct occurred."¹²⁶ "Intent and materiality are separate requirements. A district court should not use a 'sliding scale,' where a weak showing of intent may be found sufficient based on a strong showing of materiality and vice versa."¹²⁷

The affirmative defense of patent misuse exists to prevent harm to the market caused by a patentee extending a patent's right to exclude beyond its legal scope.¹²⁸ The underlying principle of misuse is that an alleged infringer must prove by clear and convincing evidence that a patentee has both "impermissibly broadened the physical or temporal scope of the patent grant" and caused some "anticompetitive effect."¹²⁹ Where the patentee's behavior remains within the grant of the patent right to exclude, however, there can never be patent misuse.¹³⁰ In response to concerns that this judge-made doctrine was vague, unpredictable, and overbroad, Congress exempted several specific behaviors from the doctrine by adding § 271(d): for example, enforcing a patent or refusing to license cannot constitute patent misuse.¹³¹

Equitable estoppel arises when a patentee misleads an alleged infringer into believing that it would not be sued for using the patented technology. The defense may bar all relief on an infringement claim.¹³² Prosecution laches renders a patent unenforceable where the patentee

119 See *Aro*, 377 U.S. at 484 (stating that "it is fundamental that sale of a patented article by the patentee [. . .] carries with it an 'implied license to use'").

120 See, e.g., *Hewlett-Packard Co. v. Repeat-O-Type Stencil Mfg. Co.*, 123 F.3d 1445 (Fed. Cir. 1997).

121 See *Madey v. Duke Univ.*, 307 F.3d 1351, 1361–62 (Fed. Cir. 2002).

122 *Purdue Pharma L.P. v. Endo Pharm. Inc.*, 410 F.3d 690, 695 (Fed. Cir. 2005).

123 *Kingsdown Med. Consultants, Ltd v. Hollister, Inc.*, 863 F.2d 867, 877 (Fed. Cir. 1988) (*en banc* in relevant part).

124 *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 (Fed. Cir. 2009).

125 See *Purdue Pharma L.P.*, 410 F.3d at 695.

126 See *Purdue Pharma L.P.*, 410 F.3d at 696.

127 *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (*en banc*) (internal citation omitted).

128 See *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502 (1917).

129 See *Va. Panel Corp. v. MAC Panel Co.*, 133 F.3d 860 (Fed. Cir. 1997).

130 See *Monsanto Co. v. McFarling*, 363 F.3d 1336, 1341 (Fed. Cir. 2004).

131 See 35 U.S.C. §271(d)(3)–(4).

132 See *A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020, 1041 (Fed. Cir. 1992) (*en banc*).

unreasonably delayed in prosecuting the patent, and the accused infringer or others suffered prejudice by the delay.¹³³

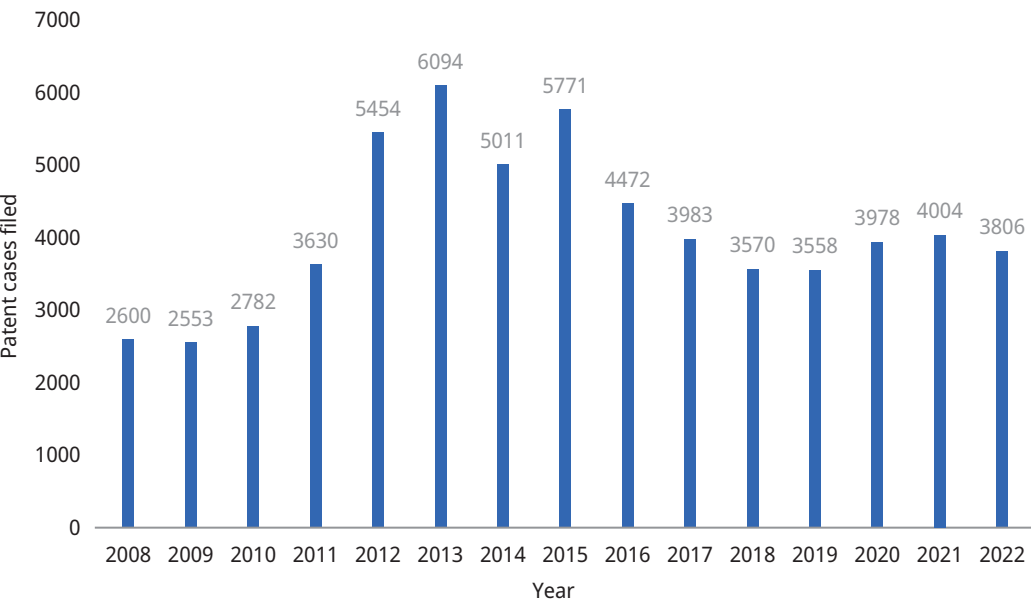
10.6 Judicial patent proceedings and case management

Prior to the mid-1990s, U.S. patent case management practices varied significantly across federal district courts. Busy federal judges improvised patent case management, leading to confusing and costly proceedings. In many respects, federal district judges operated as silos across a wide landscape.¹³⁴

Moreover, the growing use of juries complicated both patent trials and appellate review. In most jury trials, the district judges did not construe the patents themselves but rather instructed the juries to resolve claim construction disputes as part of their deliberations. Since juries did not explain their claim construction in rendering their verdicts, this practice shrouded the jury's claim construction determinations, making jury patent decisions especially difficult to review. This problem precipitated major changes in patent case management.

Figures 10.6 and 10.7 show the total number of patent cases filed across all U.S. district courts from 2008 to 2022, and the number of patent cases filed in certain U.S. district courts with a significant number of patent cases during this same time period (Northern District of California (N.D. Cal.), Central District of California (C.D. Cal.), Delaware (D. Del.), Eastern District of Texas (E.D. Tex.), and Western District of Texas (W.D. Tex.)).¹³⁵ These statistics reflect the growth of patent case filings nationwide during this time period, as well as the concentration of a large number of these cases in the jurisdictions shown.

Figure 10.6 Total U.S. district court patent case filings (2008 to 2022)



10.6.1 Key features in patent proceedings

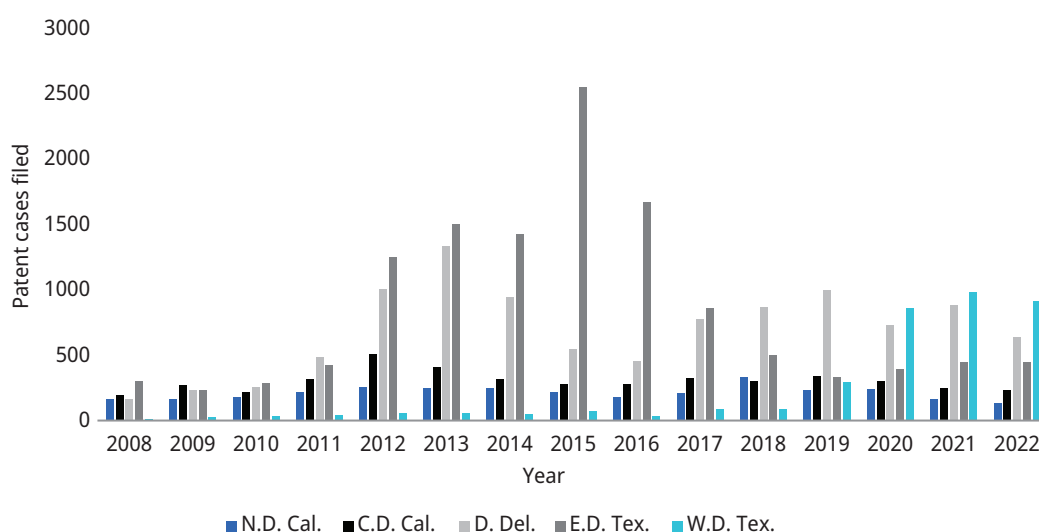
In 1996, the Supreme Court held that “the construction of a patent, including terms of art within its claim, is exclusively within the province of the court.”¹³⁶ This decision ushered in a new patent

133 See *Cancer Research Tech. Ltd v. Barr Labs., Inc.*, 625 F.3d 724, 729 (Fed. Cir. 2010) (holding that “to establish prejudice[,] an accused infringer must show evidence of intervening rights, i.e., that either the accused infringer or others invested in, worked on, or used the claimed technology during the period of delay”).

134 This section is based on Peter S. Menell, Lynn H. Pasahow, James Pooley, Matthew D. Powers, Steven C. Carlson, Jeffrey G. Homrig, George F. Pappas, Carolyn Chang, Colette Reiner Mayer, and Mark David Peters, *Patent Case Management Judicial Guide* (Federal Judicial Center 3rd edition 2016), available at <https://www.fjc.gov/content/321534/patent-case-management-judicial-guide-third-edition>.

135 Data extracted from Docket Navigator Omnibus Report (2008 to present), available at <https://search.docketnavigator.com/patent/binder/0/0>

136 *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996).

Figure 10.7 Patent case filings in certain U.S. district courts (2008 to 2022)

case management era, elevating claim construction to a critical and central role in patent litigation. In the aftermath of this decision, Judge Ronald Whyte promulgated “patent local rules” (PLRs) in collaboration with patent litigators for the Northern District of California in 1998. These voluntary case management schedules structured discovery, specified deadlines for infringement and invalidity contentions, and prioritized claim construction. Many other district courts adopted these or similar patent case management rules, leading to more streamlined and consistent practices. The following sections explain these and other district court patent case management practices in nonpharmaceutical patent cases. Section 10.13.2 discusses patent case management in pharmaceutical patent cases.

10.6.2 Pre-trial

A patent case is, in many ways, like other civil cases. In most patent cases, the plaintiff files a complaint alleging infringement. The defendant answers the complaint, alleging noninfringement and asserting various defenses, and potentially makes counterclaims of its own. The parties proceed to fact and expert discovery, motion practice, pre-trial briefing, and trial.

As in any litigation, the time necessary for each pre-trial phase varies with the complexity and potential consequences of the issues presented. There are, however, various unique aspects of patent litigation for which case characteristics and management approaches significantly affect the pre-trial timeline. Key among these are the complexity of the legal issues, the intricacy of the technology at issue, and the volume of highly sensitive technical documents, source code and other information exchanged during discovery.

Due to the many challenges posed by patent cases, many district courts and district judges have developed specialized PLRs to streamline discovery, require parties to disclose and narrow contentions, and facilitate claim construction. These rules produce joint, sequenced, staged, and timely disclosure of critical information without the need for significant judicial oversight.

10.6.3 Venue, jurisdiction and case assignment rules

Many patent litigants place tremendous significance on the choice of venue due to the range of patent case management practices, judicial assignment procedures, speed of case processing, geographical convenience for evidence and witnesses, and composition of jury pools. Most district courts assign cases randomly to judges within the district, but a few district courts allow cases to be filed in a particular courthouse. Where only one district judge sits in that courthouse, plaintiffs can effectively select not only a particular district but also a particular judge. This has led to controversy over the large number of cases brought in just a few district courts outside of the defendants’ state of incorporation and principal locations of operations.

Federal law provides “[a]ny civil action for patent infringement may be brought in the judicial district where the defendant resides, or where the defendant has committed acts of infringement and has a regular and established place of business.”¹³⁷ Regarding the first prong of the venue statute, the Supreme Court has clarified that a corporation “resides” only in its state of incorporation.¹³⁸ The Federal Circuit interprets the second prong of the venue statute to require three elements: (1) there must be a physical place in the district, (2) it must be a regular and established place of business, and (3) it must be the place of the defendant.¹³⁹

Even where venue is authorized, defendants can seek a change in venue by filing a motion early in the litigation process based on “the convenience of parties and witnesses, in the interest of justice.”¹⁴⁰ FRCP 72(a) requires that district courts “promptly conduct” venue transfer proceedings.¹⁴¹ In determining whether to transfer venue, courts balance the convenience of the litigants and the public interest in the fair and efficient administration of justice. The convenience factors include (1) the relative ease of access to sources of proof, (2) the availability of the compulsory process to secure witnesses’ attendance, (3) the willing witnesses’ cost of attendance and (4) all other practical problems that may interfere with the litigation being relatively easy, expeditious and inexpensive.¹⁴² The public factors include (1) the administrative difficulties flowing from court congestion, (2) the local interest in having local issues decided at home, (3) the forum’s familiarity with the governing law, and (4) the avoidance of unnecessary conflict-of-law problems involving the application of foreign law.¹⁴³ The Federal Circuit may grant a writ of mandamus ordering a district court to transfer a case to a different venue to correct “a patently erroneous denial of transfer.”¹⁴⁴

10.6.4 Alternative dispute resolution

The vast majority of patent cases (about 95 percent) settle prior to trial, but often not until late in the case. In the meantime, the litigation can be extremely expensive for the parties. Each side can expect to spend several million dollars in fees through the close of discovery, and between double or triple that amount in total through trial.¹⁴⁵

Most parties to patent litigation recognize the high economic stakes, uncertainty, and legal costs involved. Nevertheless, various impediments to settlement – ranging from the relationships between the particular parties to institutional issues arising out of the nature of some patent litigation – often prevent parties from settling cases without some outside assistance. Consequently, district judges seek to motivate the parties to settle patent cases. Early judicial intervention, usually at the initial case management conference, can be a critical factor in bringing about settlement. Such initiative by the court emphasizes to the parties that the court wants them to actively consider settlement strategies as well as litigation strategies throughout the case.

Effective judicial encouragement of settlement involves several considerations: (1) appropriate initiation of mediation, (2) selection of the mediator, (3) scheduling of mediation, (4) delineating the powers of the mediator, (5) confidentiality of the mediation process, and (6) the relationship between mediation and litigation activities. Additional considerations come into play in multiparty and multijurisdictional cases.¹⁴⁶

Many courts require, either by local rules or standardized order, that counsel for the parties discuss how they will attempt to mediate the case before the initial first case management conference and that they report either their agreed plan or differing positions to the court at the conference. District judges can order the parties to participate in mediation.¹⁴⁷ By requiring this early discussion, the court eliminates any concern that the party first raising the possibility of

137 28 U.S.C. §1400(b).

138 See *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514 (2017).

139 *In re Cray Inc.*, 871 F.3d 1355 (Fed. Cir. 2017).

140 28 U.S.C. §1404(a).

141 See *In re EMC Corp.*, 501 F. App’x 973, 975–76 (Fed. Cir. 2013).

142 *In re TS Tech USA Corp.*, 551 F.3d 1315, 1319 (Fed. Cir. 2008).

143 551 F.3d at 1319.

144 *In re Acer Am. Corp.*, 626 F.3d 1252, 1254 (Fed. Cir. 2010).

145 See American Intellectual Property Law Association, *Report of the Economic Survey* (2021).

146 See Kathi Vidal, Leeron G. Kalay, Peter S. Menell, Matthew Powers, and Sarita Venkat, *Patent Mediation Guide* (Federal Judicial Center 2019), available at <https://www.fjc.gov/content/337086/patent-mediation-guide>.

147 See 28 U.S.C. §562(a).

settlement appears weak. This can be particularly important at the outset of a case when attitudes may be especially rigid, posturing can be most severe, and counsel may know little about the merits of their clients' positions.

Courts can identify successful mediators for patent cases from a variety of sources: other judges and magistrate judges, retired judges, professional mediators and practicing lawyers. In some courts, the trial judge serves as mediator, but this requires the express consent of the parties.¹⁴⁸ Many judges decline to act in this role for their own cases because they believe that it is difficult to have the requisite candid discussion with parties and their counsel and later objectively rule on the many issues the court must decide. In some district courts, magistrate judges serve as mediators.

To maximize open communication and candor, most district courts treat everything submitted, said, or done during the mediation as confidential and not available for use for any other purpose. Confidentiality is usually required by agreement of the parties or by court order or rule.¹⁴⁹ Generally, the confidentiality requirements go beyond the evidentiary exclusion of FRE 408 to ensure that the parties, their counsel, and the mediator can candidly discuss the facts and merits of the litigation without concern that statements might be used in the litigation or publicized. This same concern for confidentiality usually precludes reports to the trial judge of anything other than procedural details about the mediation, such as the dates of mediation sessions, or a party's violation of court rules or orders requiring participation. In addition to being confidential, briefing and communications relating to mediation may be privileged against discovery in future litigation.

10.6.5 Statements of case (pleading)

Under the liberal federal pleading rules in the United States, patent infringement complaints typically provide a statement of ownership of the asserted patent(s), identify the accused infringer(s), provide a brief statement of alleged infringing acts, and (if applicable) provide a statement regarding the patent owner's marking of a product with the patent number under 35 U.S.C. § 287 (which affects potential monetary damages). The fleshing out of the allegations typically occurs as fact discovery unfolds and PLRs dictate.¹⁵⁰ After that early disclosure, the asserted claims and accused products may not be amended without leave of court for good cause.¹⁵¹

Like the plaintiff's allegations of infringement, the defendant's allegations of invalidity need not be pled with particularity. Defendants typically recite only that the patent is invalid and may identify sections of the Patent Act related to their invalidity allegations. Although this sort of notice-pleading has usually been held to satisfy the FRCP, in practice, it gives little notice to a patent holder about what grounds for invalidity a defendant will actually assert. Consequently, some district judges require that defendants disclose the specific grounds on which they assert invalidity early in a case, just as they require specific infringement contentions from a patent owner. Courts can require defendants to identify specific prior art references they intend to assert as invalidating and to disclose invalidity claims based on written description, indefiniteness or enablement.¹⁵² Following a specified period for making these disclosures, they may be amended only upon a showing of good cause.¹⁵³

With the exception of inequitable conduct, unenforceability allegations need not be pled with particularity. By contrast, inequitable conduct is seen as a species of fraud and must therefore be pled with particularity.¹⁵⁴ Inequitable conduct must rest on specific allegations of intentional, material omissions or misrepresentations by the patentee during the application process for a patent.

148 Committee on Codes of Conduct, Judicial Conference of the United States, *Code of Conduct for United States Judges* Canon 3A(4) (1999).

149 See, e.g., N.D. Cal. ADR L. R. 6–12 (broadly prohibiting disclosure or use outside the mediation of anything said or done in the mediation).

150 See, e.g., N.D. Cal. Pat. L.R. 3–1 (requiring early disclosure of asserted claims and accused products).

151 See N.D. Cal. Pat. L.R. 3–6.

152 See, e.g., N.D. Cal. Pat. L.R. 3–3.

153 See N.D. Cal. Pat. L.R. 3–6.

154 See FRCP 9(b).

The defendant typically asserts an array of counterclaims. In nearly every case, it seeks a declaratory judgment that the asserted patents are not infringed, invalid, and/or unenforceable. The defendant may also assert infringement of its own patents in a counterclaim. Under FRCP 13(a), a counterclaim is compulsory if it arises out of the same transaction or occurrence as the opposing party's claim. A counterclaim for infringement is compulsory in an action for declaration of noninfringement. Similarly, counterclaims for declaratory judgment of noninfringement or invalidity are compulsory with respect to a claim of infringement.

10.6.6 Early case management

After the complaint is served and the case is assigned to a district judge, the parties and the court prepare for the initial case management conference.¹⁵⁵ Since patent cases typically involve proprietary information, the court typically issues a protective order if the parties have not already agreed to one.¹⁵⁶ Pursuant to FRCP 26(f), the parties must confer as soon as practicable – and, in any event, at least 21 days before a scheduling conference – to discuss:

- the nature and basis of their claims and defenses and the possibilities for promptly settling or resolving the case;
- making or arranging for mandatory initial disclosures (contact information for individuals with discoverable information, a copy of or description by category and location of all documents that support claims or defenses, a computation of each category of damages, and any insurance agreements covering possible judgment)¹⁵⁷ and
- a discovery plan.

Based on these discussions, the parties prepare and submit a Joint Case Management Statement to the court within 14 days of their meeting.

At the initial case management conference, the court and parties identify issues relating to the substance of the case and any business considerations that influence the dispute. In many districts, the conference is held off the record, with only counsel in attendance. Informality can promote more productive discussion and compromise. In particularly complex or contentious cases, some judges conduct the proceeding on the record.

In advance of the initial conference, many courts will issue a form of standing order that applies to patent cases, addressing the matters to be covered in the joint case management statement, the agenda for the initial case management conference, PLRs and attendant disclosures, and presumptive limitations on discovery. Some courts have found it helpful in patent cases to distribute a very brief “advisory” document to address some of the special aspects of patent litigation, as well as expectations for the conduct of the case, beyond what might be found in a typical standing order or in local rules. This advisory document may be distributed at, or in advance of, the initial case management conference.

Table 10.2 identifies subjects for initial and subsequent case management conferences that guide preparations for discussing the case. Exploring these issues provides insight into how counsel might be expected to conduct the litigation and whether the case is amenable to early settlement or summary judgment.

Table 10.2 Case management conference checklist

Technological, market, and litigation background

- Informal description of the technology
 - Identity of the accused products
 - Whether the primary basis for asserted liability is direct or indirect infringement
 - Whether there are any third parties from which the parties expect to obtain substantial discovery
 - Scope of accused products relative to the defendant's business
 - Scope of the patented/embodied technology relative to the patentee's business
 - Whether the parties are competitors
 - Whether the patent(s)-in-suit have been, or are likely to be, the subject of reexamination proceedings
-

¹⁵⁵ See FRCP 16.

¹⁵⁶ See FRCP 26(c); Section 10.6.12.

¹⁵⁷ See FRCP 26(a)(1).

- Potential for parallel litigation and/or *inter partes* review
 - Will a party seek a stay, consolidation, coordination or transfer?
- Identify patent eligibility (35 U.S.C. § 101) issues and discuss when they should be addressed
- What type of relief is being sought?
 - What damage theory(ies) will be pursued? How will they be proven?
 - Will injunctive relief be sought, and what kind?
 - What are the estimated damages?
 - What do the parties contend is the “smallest saleable patent practicing unit”? (relevant to damages)
 - Is the patentee licensing the technology and when will it produce licensing information?
 - Are any technology standards implicated? (relevant to standard-essential patents (SEP) and fair, reasonable and nondiscriminatory agreements (FRAND))

Protective order

- Is a protective order needed?
- Will a standard protective order suffice, or will any party seek special requirements?
- Discuss known points of contention (e.g., prosecution bar, levels of confidentiality, and access by in-house lawyers) and, if applicable, convey the court’s general perspective on such issues

Willfulness

- Does the patentee intend to assert willful patent infringement? (relevant to enhanced damages)
- Timing of the assertion of the claim
- Timing of the reliance on any opinion of counsel
- Possibility of bifurcation
- Possibility of disqualification of counsel

Alternative dispute resolution

- Usefulness
- Timing
- Mediation, arbitration, or other form

Electronic discovery and limitations on discovery

- Format(s) for production of electronic discovery
- Limits on the scope of electronic discovery
- Source code – how will it be produced?
- Limits on the number of custodians
- Number of total hours for fact witnesses or number of depositions

Contention disclosures and schedule

- In patent local rule jurisdictions, discuss whether variance from the standard disclosure timelines is appropriate
- In jurisdictions without patent local rules, discuss whether the parties should exchange infringement, invalidity, unenforceability, and damages contentions and the appropriate schedule for such disclosures

Timing and procedures for claim construction and dispositive motions

- Determine the timing of summary judgment relative to claim construction
- If not addressed by local rule(s), set a schedule for exchanges of claim terms, proposed constructions, and supporting evidence
- Discuss whether a tutorial would be appropriate
- How is it conducted: by counsel? by experts? submissions (e.g., videos)?
 - Number of patents and patent claims that would be tried and possible ways of winnowing (reducing number of claims)
 - Limits on the number of claim terms submitted for construction
 - Require an explanation of the significance of the term (e.g., effect on infringement/validity)
 - Ask parties to rank the disputed claim terms based on their significance for resolving the case
- Logistics
 - Identify disputed subsidiary factual issues
 - Whether live witnesses should be called
 - Use of graphics, animations or other visual displays to aid in understanding the technology and disputed claim terms
 - Schedule a pre-claim construction conference to finalize the logistics for the hearing (held after the parties’ positions on claim construction have crystallized)
- Whether any summary judgment issues depend on claim construction or can otherwise be resolved with little or no discovery, including
 - Is there a dispute about the structure and/or function of the accused products?
 - Is there any claim term or claim construction issue that, once decided, will compel infringement or noninfringement?
 - Are there territorial issues (e.g., location of allegedly infringing acts) that affect infringement?
 - Are there any claims or defenses that are purely legal in nature?

Summary judgment

- Whether any limits on the number of summary judgment motions (or number of pages of briefing) should be imposed or modified

Limits on prior art references

- Whether any limits on the number of prior art references (per patent or overall) proffered by the defendant(s) should be imposed
- Timing for any planned reduction of the number of prior art references in the case

Expert witness and *in limine* (limiting evidence) motions

- Schedule expert witness exclusion (*Daubert*) motions well in advance of the pre-trial conference
- Scope of *in limine* motion practice
- Damages
 - Whether it would be appropriate to require damages contentions, an expedited damages discovery schedule, and/or both, or to take other steps to facilitate the early resolution of challenges to damages-related theories or expert testimony

Following the initial case management conference, the court issues a scheduling order setting time limits for joining other parties, amending the pleadings, carrying out discovery, and filing motions.

10.6.6.1 Patent local rules

Early case management focuses on the winnowing of patent claims, the revelation of invalidity contentions, and the timing of claim construction. The Northern District of California developed a set of PLRs in the late 1990s to streamline the process for focusing the litigation. Although the

Table 10.3 Northern District of California's patent local rules timetable¹

Stage	Patent local rule	Action	Timing
1		Federal Rule of Civil Procedure 26(a) case management conference	Set by the court
2	3-1, 3-2	Disclosure of asserted claims and infringement contentions	Within 14 days of Stage 1
3	3-3, 3-4	Invalidity contentions	Within 45 days of Stage 2
4	4-1	Identify claim terms to be construed	Within 14 days of Stage 3
5	4-2	Preliminary claim constructions	Within 21 days of Stage 4
6	3-8	Damages contentions	Within 50 days of Stage 3
7	3-9	Responsive damages contentions	Within 30 days of Stage 6
8	4-3	Joint claim construction and prehearing statement	Within 60 days of Stage 3
9	4-4	Close of claim construction discovery	Within 30 days of Stage 8
10	4-5(a)	Opening claim construction brief	Within 45 days of Stage 8
11	4-5(b)	Responsive claim construction brief	Within 14 days of Stage 10
12	4-5(c)	Reply claim construction brief	Within 7 days of Stage 11
13	4-6	Claim construction hearing	Subject to convenience of court, 14 days after Stage 12
14		Claim construction order	Determined by the court
15	3-7	Produce advice of counsel, if any	Within 30 days of Stage 14

¹ Available at cand.uscourts.gov/wp-content/uploads/local-rules/patent-local-rules/Patent_Local_Rules_11-2020.pdf.

rules were initially intended as guidelines, patent litigants and judges came to appreciate having default rules and the PLRs came to set case management into motion without objection in many patent cases. Many other courts have adopted these procedures. As a result, most U.S. patent cases are guided, if not governed, by a specialized set of procedural rules that supplement the FRCP.

PLRs require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed. Neither litigant can engage in a strategic game of saying it will not disclose its contentions until the other side reveals its arguments. By requiring parties to disclose contentions in an orderly, sequenced manner, PLRs counter the “shifting sands” tendencies of patent litigation, and provide more certainty for litigants and the court. In discussing the Northern District of California's PLRs, the Federal Circuit explained:

[T]hey are designed to require both the plaintiff and the defendant in patent cases to provide early notice of their infringement and invalidity contentions, and to proceed with diligence in amending those contentions when new information comes to light in the course of discovery. The rules thus seek to balance the right to develop new information in discovery with the need for certainty as to the legal theories.¹⁵⁸

PLRs focus on framing the court's claim construction decision. As reflected in Table 10.3, the Northern District of California's PLRs set forth a detailed timetable structuring the disclosure of asserted claims and infringement contentions, invalidity contentions, disputed claim terms, and damages contentions.¹⁵⁹ These disclosures are made in conjunction with a concise claim construction discovery period and followed by a claim construction briefing schedule. These PLRs are designed to enable the court to conduct a claim construction hearing (often called a “*Markman*” hearing)¹⁶⁰ seven months after the initial case management conference.

An accelerated timeline may be appropriate for less complex cases: for example, where the technology is simple or where there is little dispute as to the structure, function, or operation of accused devices. Under a particularly streamlined plan, the parties would not make patent-specific initial disclosures or file joint claim construction statements.

¹⁵⁸ *O2 Micro Int'l Ltd v. Monolithic Power Sys.*, 467 F.3d 1355, 1365–66 (Fed. Cir. 2006).

¹⁵⁹ The damages contentions serve primarily to promote settlement and surface economic expert theory and witness qualification exclusion issues early in case management.

¹⁶⁰ *Markman v. Westview Instruments*, 517 U.S. 370 (1996).

District courts have wide discretion to limit the number of claim terms at issue, at least provisionally. Restricting the scope of the claim construction hearing focuses the court's attention on the key issues (which may dispose of the case) and allows a more prompt and well-reasoned ruling on the central matters in the case. Allowing the parties wide discretion to brief all claim terms that are potentially at issue invites false or inconsequential disputes. Parties reflexively seek to avoid the risk of a waiver finding if they refrain from raising all potential disputes.

10.6.6.1.1 *Winnowing claim terms*

To focus patent litigation on the most salient issues, many courts have established a presumptive limit on the number of claim terms – typically 10 – that can be presented at the claim construction hearing.¹⁶¹ The default 10-term limit can be increased or decreased depending on the circumstances of the case. In addition, some courts require parties to explain why particular terms are case-dispositive or otherwise significant so as to provide the court with context for the claim construction dispute as well as the basis for deciding whether early construction of particular claim terms is warranted. The 10-term limit does not fix the total number of terms that can be construed before trial; parties can seek to construe additional terms at later phases in the case. However, for purposes of the principal claim construction hearing, selecting the most significant terms allows courts to resolve the key disputes in the case most efficiently.

10.6.6.1.2 *Winnowing prior art references*

Just as the assertion of myriad patent claims unduly complicates patent litigation for the defense, the assertion of myriad prior art references – many of which will not be pursued – can impose undue costs on the patentee and the court. A court can, within its discretion, propose a phased process for winnowing the number of asserted prior art references in a matter.

10.6.6.2 *Claim construction*

Most courts conduct a half-day or full-day claim construction hearing at which the attorneys present tutorials and their proposed constructions and the judge can question them. Some judges will issue a tentative ruling prior to the hearing to signal their inclination and to focus the argument. Such tentative rulings are less feasible where the patented invention involves complex science and technology.

The Supreme Court's ruling in *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*¹⁶² established that district courts may conduct evidentiary fact-finding to support their claim construction rulings. There is no requirement, however, for district courts to do so; they may base their rulings on evidence intrinsic to the patent, in which case the claim construction process is a question of law. District courts may also base their rulings on extrinsic evidence – such as documentary evidence that is not part of the patent file history; inventor or expert testimony; dictionaries; or treatises – in which case the subsidiary basis or bases are entitled to deference on appeal.

Most courts conduct claim construction hearings in an informal manner, applying the FRE loosely. Courts are generally circumspect about hearsay and allow the use of depositions instead of live testimony (so long as there has been an opportunity for cross-examination) and freer use of documents without a foundational witness (so long as there is no dispute about the document's authenticity). This approach reduces the cost and burden of the hearing. District judges should, however, apply more careful procedures to the extent they intend to make factual findings so that their determination rests on a sound evidentiary record.

District judges must construe claim terms from the perspective of a person having ordinary skill in the art as of the time the invention was made. Since few, if any, district judges have such training and experience, the parties need to educate the court about the science and technology, and the perspective of a person having ordinary skill in the art as of the time of the invention. The most common vehicle for accomplishing this task is the use of technology tutorials either preceding or in connection with a claim construction hearing. Most claim construction hearings proceed with lawyer argument on a term-by-term basis. This can be presented by the attorneys or technical experts hired by the parties.

¹⁶¹ See N.D. Cal. Pat. L.R. 4-1(b), 4-3(c); see also N.D. Ill. LPR 4.1(b) (requiring parties to limit terms submitted for construction to 10, absent a showing of good cause).

¹⁶² 574 U.S. 318 (2015).

Some judges take a significant further step and appoint a technical advisor, special master, or expert for the court. The Federal Circuit expressly approved appointing a technical advisor for claim construction proceedings in *TechSearch LLP v. Intel Corp.*,¹⁶³ although the court emphasized the need to establish “safeguards to prevent the technical advisor from introducing new evidence and to assure that the technical advisor does not influence the district court’s review of the factual disputes.”¹⁶⁴ The technical advisor’s proper role is that of a sounding board or tutor who aids the judge’s understanding of the technology. This includes explaining the jargon used in the field, the underlying theory or science of the invention, or other technical aspects of the evidence being presented by the parties.

Some courts, pursuant to FRCP 53, have delegated initial consideration of claim construction to a special master. Such special masters often have general legal training as well as experience with patent law. They might also be familiar with the technical field in question. The special master will typically conduct a claim construction process with briefing and argument. The special master will then prepare a formal report with recommendations regarding the construction of disputed claim terms. After the parties have had an opportunity to object to that report, the court will often conduct a hearing at which the court may receive additional evidence and then adopt, reject, or modify the recommended claim constructions.

10.6.6.2.1 The claim construction ruling

The claim construction ruling becomes the basis for the court’s jury instructions and ultimate appellate review. In view of the jury’s lack of scientific and technical expertise, judges should require the parties to propose constructions in language that can be readily understood by juries. Courts should draft their claim construction rulings with an eye toward making the claim terms understandable to the jury. Moreover, the court is free to devise its own construction of claim terms rather than adopt a construction proposed by either of the parties. However, the consequence of the court issuing its own construction is that it may upset the foundations of the parties’ expert reports and any pending motions before the court. This problem may be particularly acute in late-stage claim construction hearings where the parties’ experts have already rendered reports based on the particular wording of the parties’ proposed constructions. In such circumstances, departing from the parties’ proposed constructions may throw a case off track by requiring new expert reports and a redrafting of case-dispositive motions.

There is no requirement that a court construe a claim term when there is no genuine dispute about its meaning.¹⁶⁵ Claim construction aims to define the proper scope of the invention and to give meaning to claim language when the jury might otherwise misunderstand a claim term in the context of the patent and its file history. If a claim term is nontechnical, is in plain English, and derives no special meaning from the patent or its prosecution history, then the court need not function as a thesaurus. The “ordinary” meaning of such terms speaks for itself, and the court should avoid merely paraphrasing claim language with less accurate terminology.

10.6.6.3 Early case management motion practice

The FRCP authorize district courts to dismiss lawsuits for lack of personal jurisdiction¹⁶⁶ or failure to state a claim on which relief can be granted.¹⁶⁷ The district court may also grant judgment on the pleadings.¹⁶⁸ In the aftermath of the Supreme Court’s decisions tightening patent eligibility (35 U.S.C. § 101) standards,¹⁶⁹ some district courts have dismissed patent cases based on a pre-trial finding that the claims at issue were too abstract or lacked sufficient inventive application of laws of nature or natural phenomena. Two key questions in deciding whether to dismiss a patent case for failing to satisfy § 101 are (1) whether the determination that a claim element or combination of elements is well understood, routine and conventional to a skilled artisan in the relevant field is a question of fact, and (2) whether the patent eligibility determination requires claim construction.¹⁷⁰

¹⁶³ 286 F.3d 1360 (Fed. Cir. 2002).

¹⁶⁴ 286 F.3d at 1377.

¹⁶⁵ See *O2 Micro Int’l Ltd v. Beyond Innovation Tech. Co., Ltd*, 521 F.3d 1351, 1362 (Fed. Cir. 2008).

¹⁶⁶ FRCP 12(b)(2).

¹⁶⁷ FRCP 12(b)(6).

¹⁶⁸ FRCP 12(c).

¹⁶⁹ *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012); *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013); *Alice Corp. v. CLS Bank Int’l*, 573 U.S. 208 (2014).

¹⁷⁰ See *Berkheimer v. HP Inc.*, 881 F.3d 1360 (Fed. Cir. 2018); *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 882 F.3d 1121, 1125 (Fed. Cir. 2018).

District courts can also dismiss patent lawsuits or requests for enhanced damages early in the litigation process where a critical element of the patent cause of action is absent. Indirect infringement and willful infringement (a key issue in damage enhancement) both require that the accused infringer knew of the asserted patents prior to the litigation. Indirect infringement is also predicated on an act of direct infringement. Therefore, claims of indirect infringement and willfulness are susceptible to early determination.

Indirect infringement claims frequently arise in cases involving patents with method claims. In these cases, a patentee's only practical cause of action will often be for indirect infringement against the manufacturer of a product alleged to practice the method claim. In these circumstances, there are numerous ways in which a court can surface early case-dispositive weaknesses. For example, if no single entity is responsible for the performance of each step of the claim, it may be fatal to the patentee's case.¹⁷¹ Alternatively, if the accused product is capable of many noninfringing uses and the manufacturer exerts no control over its customers, the claim will likely fail.¹⁷²

10.6.7 Preliminary relief

Patentees may seek preliminary relief early in the litigation, although the burden is high. Section 283 of the Patent Act provides that courts "may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable." Such preliminary relief can come in two forms: (1) a preliminary injunction, or (2) a temporary restraining order (TRO).

Preliminary injunction applications in patent matters present special challenges. Proving the likelihood of success on the merits typically calls for analysis of nearly every substantive issue that ultimately will be presented at trial. To address the merits, the court must at least preliminarily construe patent claim terms, and invalidity, infringement, and enforceability must be addressed based on those constructions. The patent holder has the burden of proof to demonstrate the predicates for a preliminary injunction. This includes the burden of showing that the asserted patents are likely infringed and the absence of any substantial question that the asserted patent claims are valid or that the patent is enforceable. The validity and enforceability determinations are made in light of the presumption of patent validity and that the accused infringer has the ultimate burden of proof on these issues at trial. To address harm, the parties often present complicated market analyses. These issues typically require both fact and expert discovery, undertaken on a compressed preliminary injunction schedule.

FRCP 65 sets forth the procedures governing preliminary injunction motions, and Federal Circuit law governs the analysis. While:

the grant of a preliminary injunction [is] a matter of procedural law not unique to the exclusive jurisdiction of the Federal Circuit, and on appellate review [...] procedural law of the regional circuit in which the case was brought [applies], [...] the general considerations underlying the grant or denial of a preliminary injunction do not vary significantly among the circuits.¹⁷³

Consequently, the Federal Circuit has "built a body of precedent applying these general considerations to a large number of factually variant patent cases, and [it] give[s] dominant effect to Federal Circuit precedent insofar as it reflects considerations specific to patent issues."¹⁷⁴

While a preliminary injunction application places a weighty burden on a court's limited resources, it also presents opportunities for prioritizing case management. Aggressive use of expedited discovery strategies enhances these opportunities. Effectively managing the parties' expedited discovery demands can put the court in a good position to promote early settlement, summary judgment through revelation of case-dispositive issues, and possibly a consolidated trial under FRCP 65(a)(2).

¹⁷¹ See *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 572 U.S. 915 (2014).

¹⁷² 35 U.S.C. §271(c) (excluding indirect infringement liability for staple articles of commerce).

¹⁷³ *Mikohn Gaming Corp. v. Acres Gaming, Inc.*, 165 F.3d 891, 894 (Fed. Cir. 1998).

¹⁷⁴ *Mikohn Gaming Corp.*, 165 F.3d at 894. (footnote omitted).

10.6.7.1 Preliminary injunction

To evaluate a preliminary injunction application, the court uses the traditional four-factor test: the court weighs the applicant's likelihood of success on the merits, the likelihood of irreparable harm to the applicant, the balance of harm between the parties, and the public interest.¹⁷⁵ This standard is essentially the same as that for a permanent injunction, except that the applicant must prove a likelihood of success on the merits rather than actual success.¹⁷⁶

After the Supreme Court's *eBay* decision, patent owners who demonstrate a likelihood of success on the merits no longer enjoy a presumption of irreparable injury if the preliminary injunction is not granted.¹⁷⁷ Nonetheless, even though the usual economic consequences of competition – price and market erosion – would likely be calculable and thus “reparable” through a damages award, courts might still conclude that a preliminary injunction is warranted.¹⁷⁸

The grant or denial of a preliminary injunction is within the sound discretion of the district court.¹⁷⁹ Abuse of discretion in granting or denying a preliminary injunction requires a “showing that the court made a clear error of judgment in weighing relevant factors or exercised its discretion based upon an error of law or clearly erroneous factual findings.”¹⁸⁰ The trial court must provide sufficient factual findings to enable a meaningful review of the merits of its order. This requirement does not, however, extend to the denial of a preliminary injunction, which may be based on a party's failure to make a showing on any one of the four factors, particularly the first two – likelihood of success on the merits and of irreparable harm.

10.6.7.1.1 Discovery

Discovery relating to a preliminary injunction application can touch on nearly every substantive issue in a patent case. Claim construction is usually required, which may in turn require expert discovery if certain terms have special meaning in the art. The plaintiff may require fact and expert testimony as to the defendant's products, including their development, structure, and operation. The plaintiff's irreparable harm allegations may require fact and expert discovery as to market conditions and the defendant's financial condition. The defendant's invalidity and unenforceability allegations may require discovery into the prosecution of the plaintiff's patents (especially where the defendant asserts inequitable conduct) and sales by the plaintiff of products covered by the patent (as relevant to a potential on-sale bar argument). The defendant might also seek financial data relevant to the amount of bond necessary should a TRO or preliminary injunction issue.

The initial challenge for a court confronting a preliminary injunction application in a patent case is balancing (1) the need to resolve the application based on a reasonably full record against (2) the twin considerations that (a) a preliminary injunction proceeding needs to be resolved expeditiously, and (b) the parties need to conduct their business in the interim. Where a preliminary injunction application is filed prior to the initiation of discovery, the court can order expedited discovery upon motion or stipulation. Because much of the business information in a patent case is highly confidential, it will likely be necessary for the court to enter a protective order before preliminary injunction discovery can proceed (see Section 10.6.12). In view of these considerations, courts should consider strictly limiting the number of patent claims and prior art references that may be asserted, the number of claim terms that will be construed, the number of depositions that may be taken, the number and nature of document requests, and the issues to be considered.

10.6.7.1.2 Hearing or trial

A court has considerable discretion as to the handling of a hearing for a TRO or preliminary injunction application. FRCP 65 is not explicit about whether the court must have a hearing to consider a preliminary injunction. Given the complexity of patent TRO and preliminary injunction applications, however, courts generally hear arguments. Evidence received on a preliminary injunction motion that would be admissible at trial “becomes part of the trial record and need not be repeated at trial.”¹⁸¹

175 See *eBay, Inc. v. MercExchange, LLC*, 547 U.S. 388, 391–92 (2006).

176 *Apple Inc. v. Samsung Elecs. Co.*, 735 F.3d 1372, 1381 (Fed. Cir. 2013) (a permanent injunction case).

177 *Robert Bosch LLC v. Pylon Mfg Corp.*, 659 F.3d 1142, 1152–54 (Fed. Cir. 2011).

178 See *Aria Diagnostics, Inc. v. Sequenom, Inc.*, 726 F.3d 1296, 1304 (Fed. Cir. 2013) (vacating denial of preliminary injunction).

179 See *Abbott Labs. v. Andrx Pharm., Inc.*, 452 F.3d 1331, 1334 (Fed. Cir. 2006).

180 *Abbott Labs.*, 452 F.3d at 1335 (quoting *Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 973 (Fed. Cir. 1996)).

181 FRCP 65(a)(2).

Since the bulk of the substance of a patent case will be in play in deciding a preliminary injunction, one or more issues may be ripe for final disposition, even at this early stage. For example, a defendant might argue that its product is noninfringing because it is clear that a particular claim element is not in its revised product and that the plaintiff is using patent litigation as a tactic to disrupt or destroy the defendant's business. In such a case, FRCP 65 presents the court and the litigation "victim" with an opportunity to resolve the issue efficiently in the form of an early trial on the merits, through consolidation with the preliminary injunction hearing.¹⁸² A district court may order advancement of trial and consolidation with a preliminary injunction hearing on its own motion.¹⁸³ Of course, the decision to do so must be tempered by due process considerations.

10.6.7.1.3 Bond

As a result of the potential hardship of a preliminary relief on a defendant, FRCP 65(c) requires the patentee to post a security bond "in such sum as the court deems proper, for the payment of such costs and damages as may be incurred or suffered by any party who is found to have been wrongfully enjoined or restrained." Because the amount of the security bond is a procedural issue not unique to patent law, the amount is determined according to the law of the district court's regional circuit. The amount of a bond rests within the sound discretion of a trial court.

10.6.7.1.4 Order

FRCP 65(d)(1)(A) requires that the court address the factors considered in granting or denying the injunction. It must also specifically describe the infringing actions enjoined with reference to particular products.¹⁸⁴ An order granting an injunction must explain how the court assessed the four factors, providing the court's reasoning and conclusion. The order should also address the technology at issue as well as the scope of the injunction and the amount of the bond. Depending on the facts of the case, the court may also need to address the persons bound by the order. Denial of an injunction may be based on a finding that the movant has failed to demonstrate the likelihood of success on the merits or of irreparable harm.

10.6.7.1.5 Appellate review

A district court's decision on a motion for preliminary injunction is usually immediately appealable, whether it has decided to grant or deny the injunction.¹⁸⁵ "A decision to grant or deny a preliminary injunction pursuant to 35 U.S.C. § 283 is within the sound discretion of the district court," reviewed for abuse of discretion.¹⁸⁶ "[A] decision granting a preliminary injunction will be overturned on appeal only if it is established 'that the court made a clear error of judgment in weighing relevant factors or exercised its discretion based upon an error of law or clearly erroneous factual findings.'"¹⁸⁷ However, to the extent a district court's decision is based upon an issue of law, that issue is reviewed *de novo*.¹⁸⁸

Instead of appealing, a party may seek a writ of mandamus from the Federal Circuit ordering imposition or dissolution of a preliminary injunction:

The remedy of mandamus is available only in extraordinary situations to correct a clear abuse of discretion or usurpation of judicial power. A party seeking a writ bears the burden of proving that it has no other means of attaining the relief desired, and that the right to issuance of the writ is clear and indisputable.¹⁸⁹

Accordingly, a party dissatisfied with the outcome of a motion for preliminary injunction should first seek to stay the result and file a notice of appeal.¹⁹⁰

¹⁸² See FRCP 65(a)(2).

¹⁸³ FRCP 65(a)(2).

¹⁸⁴ See FRCP 65(d)(1)(C).

¹⁸⁵ 28 U.S.C. §1292(a)(1).

¹⁸⁶ *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1374 (Fed. Cir. 2006).

¹⁸⁷ *Sanofi-Synthelabo*, 470 F.3d at 1374 (quoting *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1364 (Fed. Cir. 1997)).

¹⁸⁸ *Sanofi-Synthelabo*, 470 F.3d at 1374.

¹⁸⁹ *Razor USA LLC v. ASA Prods., Inc.*, Nos. 01-1080, 636, 637, 638, 2000 WL 1819400, 2000 U.S. App. LEXIS 33182, at *4-5 (Fed. Cir. Nov. 22, 2000) (unpublished opinion) (citations omitted).

¹⁹⁰ *In re Lumenis, Inc.*, 89 F. App'x 255, 256 (Fed. Cir. 2004) ("The proper procedure for seeking to stay or vacate an injunction is to file a notice of appeal and a motion in the district court for a stay of the injunction, pending appeal.") (unpublished opinion).

A party subjected to a preliminary injunction may ask the district court to stay the injunction pending appeal: “While an appeal is pending [...] from an order [...] that grants, dissolves or denies an injunction, the court may suspend, [or] modify” the injunction.¹⁹¹ Whether to issue a stay of enforcement of a preliminary injunction is within the sound discretion of the district court.¹⁹²

10.6.7.2 Temporary restraining order

A TRO “is available under [FRCP] 65 to a [patent] litigant facing a threat of irreparable harm before a preliminary injunction hearing can be held.”¹⁹³ Courts assess the same four factors as for a preliminary injunction in evaluating an *ex parte* TRO application.

The Supreme Court has explained that “[e]x parte temporary restraining orders are no doubt necessary in certain circumstances, but under federal law they should be restricted to serving their underlying purpose of preserving the status quo and preventing irreparable harm just so long as is necessary to hold a hearing, and no longer.”¹⁹⁴ Consequently, TROs are exceedingly rare in patent cases. Entering a TRO enjoining the practice of a given technology can have extreme consequences, including the complete shutdown of a competitor’s business. Further, the factual and legal complexity of patent cases makes it difficult – if not impossible – for a court to make the sort of hair-trigger decisions necessary to grant a TRO application.

While a preliminary injunction may be issued only on notice to the adverse party, a TRO may issue without such notice.¹⁹⁵ Nonetheless, where an adverse party has adequate notice of an application for a TRO such that a meaningful adversarial hearing on the issues may be held, the court may treat an application for TRO as a motion for a preliminary injunction. Courts have discretion to handle the hearing, scheduling, and expedited discovery associated with TRO applications in a manner that best suits the circumstances of the case. The court may grant or deny the *ex parte* application without a hearing. Alternatively, the court may decline to rule on the TRO application until the adverse party has had an opportunity to respond.

A decision to grant or deny a TRO is not usually appealable.¹⁹⁶

10.6.8 Discovery

The FRCP provide the overarching framework for pre-trial discovery. These rules authorize broad and extensive pre-trial discovery in civil cases.¹⁹⁷ The goal of discovery is to enable the parties to obtain full knowledge of the critical facts and issues bearing on the litigation. By reducing asymmetric information, discovery ideally reduces the range of dispute and facilitates settlement.

The breadth of U.S. civil discovery, in conjunction with the wide range of claims and defenses, high stakes, trade secret sensitivity, and extensive use of electronic record-keeping by technology companies, makes discovery in patent cases especially complex. As a result, discovery can become a strategic battlefield, with better-skilled and -financed parties able to use discovery maneuvers to influence the litigation process. Thus, district judges are often called upon to supervise and balance the discovery process.

Discovery typically commences after the complaint has been filed and the parties have met and conferred. FRCP 26(f) requires the parties to confer as soon as practicable – and, in any event, at least 21 days before a Rule 16 scheduling conference. Due to the fact that many parties and counsel in patent litigation are repeat players, and patent cases are typically filed in a limited set of districts, many aspects of pre-trial patent discovery have been routinized, at least in the early stages of litigation. As noted in Section 10.6.6.1, many district courts and district judges have augmented those rules with PLRs and standing orders that provide detailed disclosure timetables.

FRCP 26(b) provides that, unless otherwise limited by court order:

¹⁹¹ FRCP 62(c).

¹⁹² *Abbott Labs. v. Sandoz, Inc.*, 500 F. Supp. 2d 846, 849 (N.D. Ill. 2007).

¹⁹³ *Fairchild Semiconductor Corp. v. Third Dimension (3D) Semiconductor, Inc.*, 564 F. Supp. 2d 63, 66 (D. Me. 2008).

¹⁹⁴ *Granny Goose Foods, Inc. v. Bhd. of Teamsters Local 70*, 415 U.S. 423, 439 (1974) (citation omitted).

¹⁹⁵ FRCP 65(a)(1), (b)(1).

¹⁹⁶ FRCP 65.

¹⁹⁷ See FRCP 26.

[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit. Information within this scope of discovery need not be admissible in evidence to be discoverable.

The "proportionality" requirement aims to focus courts and litigants on the expected contribution of discovery to the resolution of the case. This requirement provides district judges with a framework for moderating the extent and costs of discovery based on the nature and scope of the case, the amount of any damages sought and how the case compares to other patent cases.

10.6.8.1 Initial disclosures

Although FRCP 26(a)(1) requires early disclosure of "all documents, electronically stored information, and tangible things that the disclosing party has in its possession, custody, or control and may use to support its claims or defenses," and "a computation of each category of damages claimed," a patentee will rarely have access to this information in advance of discovery. Patent damages are based on profits lost by the patentee or, at a minimum, the reasonable royalty that the infringer would have paid to license the patented technology, both of which depend on the sales and offers made by the accused infringer. Thus, much of the evidence as to the patentee's damages resides in the hands of the accused infringer. Accordingly, initial disclosures as to damages typically only describe the types of damages sought (rather than providing a rough computation of the amount of damages sought) and necessarily defer disclosure of documents and other evidence to a date after discovery has been completed.

10.6.8.2 Document production

Reflecting the broad scope of activities relevant to patent cases, it is common for litigants to propound 100 or more document requests. Document requests typically reach into nearly every facet of a party's business, including product research and development, customer service and support, sales, marketing, accounting, and legal affairs. The documents must be collected in hard copy from custodians in nearly every department and in electronic form from both the company's active computer files and all readily accessible archives.

In addition, patent litigation often requires the production of technical information that is highly sensitive and difficult to reproduce for production. Some technical information, such as semiconductor schematics, can only be reviewed in native format using proprietary software that is itself valuable and sensitive. Such information may need to be reviewed on-site on the producing parties' computers. Computer source code is also highly sensitive and may need to be reviewed in native format. Often, it is produced on a stand-alone computer, unconnected to the internet and in a secure location, and with limitations imposed on the number of pages that may be printed.

Financial information related to damages is also viewed as highly sensitive and can be difficult to produce. Often, in lieu of the underlying financial documents (such as numerous invoices), companies produce reports from their financial databases. They must agree on which categories of information will be produced from these databases or come to terms with the fact that some categories of information cannot be generated by such systems.

Third-party confidential documents, such as patent licenses, are also usually relevant to the damages case, and third-party technical documents can be relevant to the liability case (e.g., if a third party makes the accused chip). The production of these documents often requires permission from third parties, the negotiation of protective orders, or even compulsory process and motions practice.

Document requests in patent cases usually generate multiple motions to compel, motions for protective orders or both. Courts can facilitate more effective document collection and production processes by:

- reviewing the parties' electronic discovery plan at the case management conference, as required by FRCP 26;

- requiring the parties to meet and confer to narrow document requests and to document their efforts in any motion to compel;
- requiring the parties to file a letter brief seeking permission to file a motion to compel or requiring a pre-motion telephonic conference with the Court, a magistrate or a special master prior to the filing of a motion to compel; and
- placing a limitation on the number of document requests permitted per side.

10.6.8.3 Interrogatories

FRCP 33(a) has a default limit of 25 interrogatories per party. In their joint case management statement, parties often make a joint request for additional interrogatories. These requests are typically granted because the scope of subject matter in patent litigation is quite broad. Because patent litigation often includes multiple plaintiffs and defendants, however, courts should consider imposing an interrogatory limit per side, rather than per party.

10.6.8.4 Depositions

FRCP 30(a)(2)(A) limits to 10 the number of depositions that may be taken by a party without leave of court. As a result of the breadth of discovery in patent cases, and in spite of the more extensive mandatory disclosure requirements imposed by PLRs, litigants often seek to take in excess of 20 depositions to develop their case, and may legitimately need more than the presumptive 10 depositions. The court should strongly encourage parties to reach mutual agreement in their Rule 26(f) proposed discovery plan regarding the number of depositions or cumulative hours that will be allowed without court order. Absent agreement, a limit should be set to promote the parties' efficient use of the depositions. A limit of 15 to 20 depositions per side, or about 100 hours, typically provides parties with plenty of opportunity to cover the major issues in a case. Many judges set significantly lower presumptive limits (e.g., 40 hours per side), allowing the parties to petition for more time where justified. The most common practice is to apply these limits to fact discovery, since expert depositions tend to be self-regulating and do not involve inconvenience to the parties themselves.

FRCP 30(d)(1) imposes a one-day (7 hour) limitation on the deposition of fact deponents that should presumptively apply in the absence of a showing of a real need for more time (e.g., if an inventor also has a role in the business). The 30(b)(6) depositions of parties' organizational officers in patent litigation are, however, often critical to the case. Typically, these depositions can encompass highly technical or detailed information spanning the course of years or even decades. It is often effective to allow 30(b)(6) depositions to continue for more than a single day. However, to prevent runaway 30(b)(6) depositions, the court can also require that each day of a 30(b)(6) deposition counts as a separate deposition for the purposes of the per-side deposition limit. Alternatively, a limit on the total number of deposition hours also helps avoid disputes over how many "depositions" a 30(b)(6) deposition constitutes, when it encompasses more than one topic.

10.6.8.5 Electronic records

A significant portion of discovery in patent litigation is electronic discovery. Although electronic discovery in patent litigation presents similar issues as electronic discovery in other complex litigation, certain challenges arise more frequently in patent cases.

Pursuant to FRCP 26(f)(2), the parties must "discuss any issues about preserving discoverable information; and develop a proposed discovery plan." The discovery plan produced under Rule 26 must address "any issues about disclosure or discovery of electronically stored information, including the form or forms in which it should be produced."¹⁹⁸ Additionally, each party's initial disclosures under Rule 26(a) must identify any electronically stored information (ESI) that it intends to use to support its case.

The nature of ESI is such that some types of documents are more accessible than others, ranging from active, online data to nearline data, offline storage and archives, backup tapes, and erased, fragmented, or damaged data.¹⁹⁹ Inasmuch as the last two categories contain "inaccessible" data, classification of data can be important in cost-shifting analysis. Under the federal rules, ESI is presumptively not discoverable if it comes from a source that is "not reasonably accessible

¹⁹⁸ FRCP 26(f)(3)(C).

¹⁹⁹ See *Zubulake v. UBS Warburg, LLC*, 217 F.R.D. 309 (S.D.N.Y. 2003).

because of undue burden or cost.” To raise the presumption, the responding party to a discovery request must identify the sources that are “not reasonably accessible” that it will not search or produce. In response, the requesting party may challenge the designation by moving to compel, whereupon the burden shifts to the responding party to show that the information is not reasonably accessible. The court may then hold that the information is not reasonably accessible and so is presumptively not discoverable. Even if the requesting party shows “good cause” to obtain production, the court may specify conditions on the production, such as cost-shifting.

Although there is much wisdom in this effort to reduce the costs of e-discovery, there is no one-size-fits-all solution, and greater experience in managing the scope of electronic discovery will likely result in further evolution and explication of the various guidelines. For example, in many cases, the most expensive ESI to collect is not email, which is often stored on relatively accessible central servers, but rather the contents of the computer hard drives of individual users, which must be individually copied or “imaged” to collect and produce the users’ working documents. Parties often look to their FRCP 26(a) initial disclosures to determine whose computers should be imaged.

10.6.8.6 Management of discovery disputes

District judges vary in how they deal with discovery disputes. Some judges refer discovery management to magistrate judges so as to reduce their need to deal with what can be frequent skirmishes. By contrast, some judges find that handling discovery disputes keeps them abreast of developments in the case and enables them to coordinate discovery and scheduling issues. Moreover, there can be an *in terrorem* effect at work when the district judge hears discovery disputes – litigants may be less likely to raise as many disputes and will likely be more conciliatory if the judge deciding the case has a greater opportunity to assess whether counsel have been unreasonable. Where referral is the common practice, experienced counsel soon learn the tendencies of the magistrate judges on particular issues, resulting in fewer motions. If this does not happen, or if the case otherwise appears likely to generate a disproportionate level of discovery controversy, courts can require the parties to engage a special master under FRCP 53. When the special master possesses substantial experience with patent litigation, the resulting process, although sometimes costly, can be substantially more efficient and effective.

10.6.9 Summary proceedings

District courts “shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.”²⁰⁰ Effective utilization of the summary judgment process is especially important in patent cases because such cases present so many complex issues. Summary judgment can play a critical role in resolving the case or narrowing or simplifying the issues, thereby promoting settlement or simplifying the trial. Conversely, the summary judgment process in a patent case can put a significant burden on the court, particularly if the parties file numerous, voluminous motions.

Effective management of the summary judgment process in patent cases requires an understanding of the types of issues that drive most patent cases, how they typically unfold over the life of a case, and if and when they are amenable for summary adjudication. The timing of summary judgment motions can be critical: if summary judgment proceedings are held too early for a given case, questions of fact that would have been resolved at a later stage preclude summary judgment. However, deferring summary judgment too long risks wasting the time and resources of the parties and the court on issues that limited discovery could have resolved.

10.6.9.1 Distinguishing questions of law from questions of fact

FRCP 56(a) authorizes summary adjudication of issues of law, where there is no disputed question of fact. That is, a court may only entertain summary judgment of pure questions of law, mixed questions of law and fact on which there is no genuine dispute as to any material fact, and undisputed questions of fact. These distinctions are especially subtle in patent litigation, reflecting the complex interplay of fact and law. Furthermore, even though the ultimate claim construction determination is a question of law potentially based on subsidiary questions of fact, the subsidiary facts are within the province of the court, thereby expanding the range of issues

200 FRCP 56(a).

that can be resolved on summary judgment. The common issues in most patent litigation – novelty, nonobviousness, and adequacy of written description – involve factual questions or are questions of law based on underlying questions of fact.

The issues least amenable to summary judgment are typically those that have the following characteristics: (1) require a high burden of proof, (2) are questions of fact, (3) are broad issues requiring the movant to establish a wide range of facts, and (4) involve subjects about which the underlying facts are typically disputed. One of the most vexing questions in U.S. patent law today is the extent to which patent eligibility can be resolved at the motion to dismiss or summary judgment stage of litigation.²⁰¹

10.6.9.2 Multi-track approach

The information necessary for assessing summary judgment emerges during discovery, case management conferences, claim construction, and other pre-trial processes. It is useful, therefore, to approach summary judgment case management as a multi-track process: (1) claim construction-related, (2) non-claim construction-related, and (3) off-track. Notwithstanding the caution about diverting judicial resources from claim construction, there may be an issue that arises early in the litigation that does not require claim construction and that can either resolve the entirety of the case or substantially streamline the case.

For example, Section 271(a) of the Patent Act imposes infringement liability on persons who “without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent.” Whether an allegedly infringing act occurred within, or outside of, the United States is a question of law, whereas whether an act occurring within the United States is sufficient to constitute a sale, offer to sell, use, manufacture, or importation is a question of fact. Typically, the parties agree that a certain set of events took place in certain locations, but dispute the conclusions to be drawn from these events as they relate to infringement. As a result, both questions – the locus and the characterization of the acts – are often amenable to summary judgment. Such a decision does not implicate claim construction and, therefore, might usefully be addressed early in the litigation process.

10.6.9.3 The summary judgment process and hearing

Notwithstanding the usefulness of summary adjudication in streamlining and resolving some patent cases, the potential exists for parties to inundate the court with summary judgment motions that can disrupt orderly and efficient case management. Consequently, courts have developed a variety of case management techniques for streamlining the summary judgment process, including (1) pre-screening – requiring the parties to file concise letter briefs requesting permission to file summary judgment followed by a telephone hearing to discuss the strengths and weaknesses of the proposed motion(s); (2) quantitative limitations, such as restricting the number of summary judgment motions and the total number of briefing pages, or consolidating motions into a single briefing; and (3) multiple rounds of summary judgment motions. These approaches are not mutually exclusive, and each has advantages and disadvantages based on the nature of the case and contentiousness of the parties. The first approach enables the judge to screen cases more efficiently: competent counsel can usually convey enough information to the court in two to three pages and five minutes of oral argument to enable the court to evaluate whether the substance of a proposed motion justifies a full briefing. The second approach motivates the parties to prioritize their motions. The third approach promotes efficient staging.

Most judges opt for an oral hearing on summary judgment motions. There is rarely any need for live testimony because the court cannot resolve factual disputes through summary adjudication. Live testimony can, however, be useful where declarations submitted by the parties do not squarely address each other and create the perception of a question of material fact when, in reality, one might not exist. The court might want to have a technology tutorial focused on the particular issues presented by the summary judgment motion(s), especially if the claim construction technology tutorial did not cover these areas. The length of time needed for a

201 See *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1368 (Fed. Cir. 2018) (observing that “[t]he question of whether a claim element or combination of elements is well-understood, routine and conventional to a skilled artisan in the relevant field is a question of fact,” but noting that “not every §101 determination contains genuine disputes over the underlying facts material to the §101 inquiry” (citations omitted)).

summary judgment motion varies widely depending on the court's preferences and the scope and nature of the issues at stake.

10.6.10 Evidence

Patent cases are characterized by motions – often many – directed at excluding or limiting the use of evidence, including motions attacking expert opinions.²⁰² It is common practice to resolve such issues substantially in advance of trial so that the parties return with their presentations appropriately honed in accordance with the court's limiting orders.

10.6.10.1 Technical and economic expert witnesses

Daubert sets forth a nonexclusive checklist for trial courts to use in assessing the reliability of scientific expert testimony: (1) whether the expert's technique or theory can be or has been tested – that is, whether the expert's theory can be challenged in some objective sense, or whether it is instead simply a subjective, conclusory approach that cannot reasonably be assessed for reliability; (2) whether the technique or theory has been subject to peer review and publication; (3) the known or potential rate of error of the technique or theory when applied; (4) the existence and maintenance of standards and controls; and (5) whether the technique or theory has been generally accepted in the scientific community.

Apart from the subject matter distinction between scientific or technical and economic (damages) experts, patent cases involve two distinct types of expert testimony. The first, common to most other types of litigation, involves applying an accepted technical, scientific, or economic methodology to facts established during the trial to reach conclusions about factual issues. An expert might testify, for example, about the results of their analysis to determine the chemical composition of the accused product. Because this type of testimony is directed to an analysis that the expert regularly performs outside of a litigation context, it falls squarely within the FRE 702 and *Daubert* frameworks. Consequently, it presents few novel issues.

The second type of testimony presents more challenges. In patent cases, an expert is often asked to use their scientific, technical, or specialized knowledge to evaluate a hypothetical legal construct. Examples include:

- Who is a “person having ordinary skill in the art”?
- Would a “person having ordinary skill in the art” believe at the time of alleged infringement that differences between the patent claim and the accused product are “insubstantial”?
- At the time the patent application was originally filed, would a “person having ordinary skill in the art” have had a motivation to combine known ideas to create the claimed invention?
- What royalty rate would the patentee and the infringer have agreed upon had they participated in a negotiation at the time of first infringement knowing that the patent was valid and infringed?

The court's gatekeeping function is more nuanced in these areas. Because it reflects a hypothetical legal construct, it necessarily departs from the type of generally accepted, peer-reviewed methodology contemplated by FRE 702 and *Daubert*.

Courts have wide discretion to determine the process and timing for resolving the admissibility of expert testimony. Although they can address *Daubert* challenges in conjunction with summary judgment or motions *in limine*, these approaches tend to give short shrift to the *Daubert* inquiry. Thus, many judges consider the admissibility of expert testimony through a specific *Daubert* briefing or hearing schedule for *Daubert* motions in the case management order.

The optimal time for scheduling such motions is after experts are deposed on their reports, but well before the pre-trial conference. Timing the briefing and hearing this way will ensure that a full record is available, but also give the court adequate time to consider the merits of each challenge. In addition, early consideration of *Daubert* challenges prevents the risk of a party being denied any expert at trial, which in some circumstances can be a harsh sanction for a

202 See *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993) (“If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.” (citation omitted)); FRE 702 (similar).

correctable error. For example, a common *Daubert* challenge to a damages expert is based on an alleged incorrect date for the hypothetical negotiation for the determination of a reasonable royalty. Determining this date can be challenging: not only because it depends on technical information related to infringement that is usually beyond the purview of damages experts, but also because the trial court's summary judgment rulings can affect that date. In this circumstance, even if a damages expert's methodology is adequate, the factual basis for the analysis may be incorrect as a matter of law. Once informed by the court's summary judgment rulings, the expert can revise their analysis to include the correct information – so if the question is raised through an *in limine* motion on the eve of trial, it would be unjust to grant the motion and strike the expert. Consequently, many courts hear *Daubert* challenges at the same time as, but separate from, summary judgment motions.

10.6.10.2 Patent law expert witnesses

Parties sometimes propose presenting expert testimony regarding patent law, procedures of the USPTO, patent terminology, prosecution history, or specific substantive (e.g., anticipation) and procedural (e.g., what a “reasonable patent examiner” would find material) issues through a patent attorney or former USPTO employee. In support of this testimony, parties often point out that the evidence rules specifically permit opinions on ultimate issues²⁰³ and the presentation of testimony without first specifying underlying facts or data.²⁰⁴

Testimony on issues of law by a patent law expert – as contrasted with a general description of how the patent process works – is usually inadmissible. Just as in any other field, it is exclusively for the court, not an expert, to instruct the jury regarding the underlying law. Conversely, testimony regarding the procedures and terminology used in patents and file histories, on the other hand, is often allowed. In many cases, however, this testimony might be redundant in light of a preliminary jury instruction explaining those procedures. Because a jury instruction is likely to be more neutral, it will usually be a preferable means of providing this information to the jury. A jury instruction, however, may lack sufficient specificity to explain a USPTO procedural event relevant in a particular case, and in that circumstance, expert testimony is more likely to be appropriate and helpful to the jury.

The admissibility of proffered patent expert testimony on ultimate issues will often depend on whether the expert is doing anything more than applying patent law to a presumed set of facts, essentially making the jury's determination. This is particularly true if the proffered patent expert has no relevant technical expertise. Thus, a patent expert's opinion regarding matters such as infringement, obviousness, and anticipation based on technical conclusions that are assumed or provided by a different expert is usually improper. Similarly, testimony applying patent law to issues intertwined with patent procedure, but dependent on technical conclusions supplied by others, such as the appropriate priority date of a claim in a continuation application, is usually inappropriate. Conversely, if the patent expert also has relevant technical expertise, she should be equally able to provide expert testimony within that expertise as would be any nonlegal expert with similar technical expertise.

In trials to the court, when there is no concern regarding jurors' overreliance on expert testimony, courts more freely admit the testimony of patent law experts. This includes, for example, testimony regarding whether a reasonable patent examiner would deem particular prior art or statements important in an inequitable conduct determination. Courts have found such testimony helpful and allowed it.²⁰⁵

Testimony is sometimes offered regarding the abilities of patent examiners, their workloads, time spent on applications, or similar matters. This testimony, which is meant to bolster or undermine the statutory presumption of validity, is improper.²⁰⁶ The deference the jury should give to the actions of the patent examiners is an issue of law like any other.

10.6.10.3 Inventor and technical employee witnesses

Inventors and other technical employee witnesses often testify at trial regarding the invention and other technical matters. These witnesses frequently would qualify as experts and, if properly

²⁰³ FRE 704.

²⁰⁴ FRE 705.

²⁰⁵ See, e.g., *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1238 (Fed. Cir. 2003).

²⁰⁶ See 35 U.S.C. §282; *Applied Materials, Inc. v. Advanced Semiconductors Materials Am., Inc.*, No. 92-20643, 1995 U.S. Dist. LEXIS 22335, 1995 WL 261407 (N.D. Cal. April 25, 1995).

disclosed as testifying experts, appropriately may provide expert testimony. Because their duties likely do not “regularly involve giving expert testimony,” no expert report is required by such employees absent special order; however, ordering such a report usually is appropriate and is a provision that might be included in the case management conference order.²⁰⁷

If inventors and other technical employees are not disclosed as experts, difficult line-drawing questions can arise regarding their testimony. For example, when an inventor or co-employee testifies regarding the invention to a jury, it is usually necessary to accompany the testimony regarding historical acts with an explanation of the technology involved. These explanations are sometimes challenged as undisclosed expert testimony. Other testimony that often draws a challenge is inventor or employee testimony regarding the nature of the prior art at the time the invention was made. While testimony about the invention and prior art may be highly technical, it may involve the description of historical facts without the expression of opinion. In that event, the non-opinion testimony is proper without expert disclosure. Such testimony, however, is sometimes employed in an attempt to introduce undisclosed opinion into evidence. Courts have discretion to admit into evidence demonstratives that summarize admissible evidence.²⁰⁸

10.6.10.4 Motions *in limine*

Motions *in limine* provide the court with an opportunity to establish procedures and substantive limitations that will streamline the evidence, shorten the trial, and reduce jury confusion. Although substantive to some degree, these motions largely implicate procedural requirements and the evidentiary basis for expert testimony. For this reason, some courts choose to hear motions *in limine* at the outset of a trial so that they are better acquainted with the disputes that are likely to arise, and then continue some portion of them until the issues are fleshed out during the course of the proceeding. Deferring these issues to trial can extend and interrupt the proceedings.

Motions *in limine* can cover a broad range of issues of concerns. Examples include:

- a motion to bar a comparison between the accused product and an embodying product sold by the patentee (out of concern that the jury will focus on the patentee’s product as opposed to the claimed invention);
- a motion to preclude undisclosed prior art (35 U.S.C. § 282(c) requires such disclosure at least 30 days before trial);
- a motion to preclude a claim or defense based on a failure of proof;
- a motion to preclude an expert from testifying about issues that were not identified in the expert’s report;
- a motion to bar reference to related proceedings in the Patent Office; and
- a motion to preclude the use of “patent troll” or other pejorative terms in referring to nonpracticing entities.

The resolution of these motions can involve legal questions as well as the facts and litigation process of the particular case.

The range of potential *in limine* motions can inundate judges as they are preparing for trial. In addition, some *in limine* motions might be disguised summary judgment or *Daubert* motions. Consequently, several judges implement rules to consolidate, streamline, and prioritize such motions, including requiring that:

- all motions *in limine* and responses shall be filed together in the proposed pre-trial order;
- each side shall be limited to three *in limine* requests, unless otherwise permitted by the court;
- the *in limine* request and any response shall contain the authorities relied upon; and
- each *in limine* request may be supported by a maximum of three pages of argument and may be opposed by a maximum of three pages of argument, and that the side making the *in limine* request may add a maximum of one additional page in reply in support of its request.
- Additionally, if more than one party is supporting or opposing an *in limine* request, such support or opposition shall be combined in a single three-page submission (and, if the moving party, a single one-page reply), unless otherwise ordered by the court.

207 See FRCP 26(a)(2)(B).

208 FRE 1006.

10.6.11 Technology tutorials

As noted earlier, courts have inherent discretionary authority as well as authority under FRCP 53 and FRE 706 to use technical advisors, special masters, and court-appointed experts to aid the court in understanding complex technology at the claim construction stage. When it comes to trial, the judge has the option of appointing an expert pursuant to FRE 706. After completing an analysis, the expert provides findings to the parties and the court, much like any expert's report. Any party may then depose the expert. Finally, the expert provides the court and, if present, the jury with the results in the form of expert testimony, subject to the same cross-examination as for party experts.

The Federal Circuit affirmed a district court's use of a court-appointed expert pursuant to FRE 706 in *Monolithic Power Sys., Inc. v. O2 Micro Int'l Ltd.*²⁰⁹ The Federal Circuit noted, however, that the "predicament inherent in court appointment of an independent expert and revelations to the jury about the expert's neutral status trouble [the] court to some extent," and admonished that the use of court-appointed experts should be limited to rare and exceptional cases. For similar reasons, parties usually will not favor allowing a court-appointed expert to testify to a jury and, if the expert does testify, will not favor identifying the expert as "court-appointed" or "neutral."

A technical advisor advises the judge on technical matters in a manner often analogized to a law clerk, although case law views the analogy as imperfect. The advisor is appointed pursuant to the court's inherent power. This is a power to be used "sparingly," but appointment is proper in any highly technical case where the science or technology is well beyond the experience of the judge. Importantly, if the advisor provides no evidence to the court, FRE 706 does not apply, and, as a result, the parties have no right to a deposition or other disclosure of the advisor's opinions or communications with the court. Alternatively, a person can be appointed as both a court expert and an advisor, in which case FRE 706 applies.

Best practices for the use of technical advisors are set out in several appellate court cases: *FTC v. Enforma Natural Products, Inc.*,²¹⁰ *TechSearch LLC v. Intel Corp.*,²¹¹ *Association of Mexican-American Educators v. California*,²¹² and *Reilly v. United States*.²¹³ These cases focus on several procedural aspects of the technical advisor process aimed at ensuring that the technical advisor does not improperly introduce new evidence unknown to the parties or influence the court's resolution of factual disputes. First, the court should assure a fair and open procedure for appointing a neutral advisor. Second, the advisor should explicitly be given a clearly defined, proper role that ensures there is no impingement on the court's role as fact finder. Third, the court should provide some assurance that the advisor remains within that proper role. The use of these procedures also facilitates appellate review of the propriety of the technical advisor's role.

To ensure fairness in the appointment, the court should identify the proposed advisor to the parties in advance of the appointment. This process can involve inviting the parties to propose advisors, either separately or together, after consultation. If the parties are asked to provide potential advisors, the court should establish, in advance, limits on the contact the parties may have with prospective advisors. Alternatively, the court can identify a proposed advisor to the parties – potentially, an advisor the judge worked with previously – without prior consultation. In either case, the parties should be allowed to challenge the advisor's bias, partiality, or lack of qualification. If any challenge is raised, the court should address it on the record.

The proper role of the advisor is to be a sounding board or tutor who aids the judge's understanding of the technology. This includes an explanation of the jargon used in the field, the underlying theory or science of the invention, or other technical aspects of the evidence presented by the parties. The advisor can also assist the judge's analysis by helping think through critical technical problems. In this latter function, case law admonishes that the court must be careful to assure that the decision-making is not delegated to the advisor. Although in form, and much like the interaction between a judge and law clerk, the situation is different in that, because

209 558 F.3d 1341 (Fed. Cir. 2009).

210 362 F.3d 1204, 1213–15 (9th Cir. 2004).

211 286 F.3d 1360, 1378–79 (Fed. Cir. 2002) (applying Ninth Circuit law).

212 231 F.3d 572, 611–14 (9th Cir. 2000) (*en banc*) (Tashima, J., dissenting).

213 863 F.2d 149 (1st Cir. 1988).

of a judge's knowledge of law, a clerk cannot usurp the judicial role; in contrast, a technical advisor in an area of science unfamiliar to the judge potentially could.

Within these parameters, the advisor can properly aid the judge's understanding and analysis throughout a patent case. This can include helping the judge understand the patent specification and claims, expert affidavits and testimony provided by the parties, and scientific articles that may be offered as prior art. Proper subjects for consultation with the advisor include whether technical facts are in dispute in a summary judgment motion, claim interpretation, validity and infringement questions, the proper articulation of technical issues for jury instructions, and the admissibility of proffered scientific evidence under *Daubert*. The advisor, however, may not provide evidence, either documentary or testimony, without compliance with FRE 706. The advisor's advice, therefore, cannot be based on extra-record information (except the use of technology-specific knowledge and background used to educate the judge), and the advisor cannot conduct any independent investigation. Particularly in situations in which the advisor assists the judge's efforts to resolve factual conflicts, the judge and advisor should be vigilant to avoid the advisor unduly influencing the judge's decision-making. In no circumstance, of course, should the advisor become an advocate for any party or position.

The court or advisor should confirm that the advisor's work is done within the proper parameters for the benefit of both the parties and appellate review. There is no fixed requirement for how this should be accomplished. Proper parameters can include supplying a transcript of the advisor's communications with the judge, providing a report by the advisor of the work performed and any communications had with the judge, or obtaining an affidavit from the advisor at the outset of the work committing to perform within a description of a proper scope of work and procedures (as outlined above) and obtaining a second affidavit at the conclusion attesting to compliance with the job description in the initial affidavit.

10.6.12 Confidentiality

Due to the sensitive nature of information relevant to patent litigation, one of the first orders of business following the filing of a patent complaint is establishing a protective order. Many patent-heavy district courts have developed default protective orders that go into effect immediately upon the filing of a patent case or soon thereafter upon a motion of a party. These rules enable the discovery process to begin promptly. Most sophisticated parties will typically want to customize the protective order and will generally agree relatively quickly on an order best tailored to their particular circumstances. The expectation that the court will enter a default protective order often facilitates consensus among the parties.

Protective orders need to serve two opposing purposes. First, they must enable the litigators to access information needed to resolve the issues posed by the case, such as product engineering, internal communications, and strategic plans that are often trade secrets. Second, they must prevent disclosure of highly sensitive technical, financial, licensing, or business strategy information both to the public and to the parties' competitive decision-makers.

The Northern District of California's multi-tiered default protective order illustrates how courts have approached the task of balancing these clashing objectives. It distinguishes three tiers: (1) "confidential" information (information that qualifies for protection under FRCP 26(c)), (2) "highly confidential – attorneys' eyes only" information (information that is "extremely sensitive," disclosure of which "would create a substantial risk of serious harm that could not be avoided by less restrictive means"), and (3) "highly confidential – source code" information ("extremely sensitive" information "representing source code and associated comments and revision histories, formulas, engineering specifications, or schematics that define or otherwise describe in detail the algorithms or structure of software or hardware designs").²¹⁴ While "confidential" information may be disclosed to parties and their representatives who sign an acknowledgment of the protective order, so long as it is used only for the purposes of litigation, "highly confidential – attorneys' eyes only" information may be disclosed only to in-house attorneys who are not involved in competitive decision-making and whose identities are disclosed in advance. "Highly confidential – source code" information is made available for inspection

214 See N.D. Cal. Pat. L.R. 2–2, Interim Model Protective Order.

pursuant to a strict set of guidelines – rather than produced – and is restricted to the same two in-house attorneys, as well as outside counsel and approved experts.

In situations where an attorney represents a party both in litigation and in front of the Patent Office in prosecution or PTAB proceedings, the parties or the court will typically include a “prosecution bar” in the protective order. This provision limits the ability of those who have seen designated material to engage in prosecution activities for a certain amount of time.

In view of the large volume of discoverable materials in patent litigation, courts may be called upon to resolve disputes regarding over-designation of confidential information. Many district judges refer discovery matters to magistrate judges. In extreme cases, a party’s overzealous confidentiality designations may warrant sanctions.

Courts may also have to deal with clawing back privileged documents that were inadvertently produced. FRCP 26(b)(5)(B) addresses this situation, providing that a party that believes it has unintentionally produced privileged information may give notice to the receiving party, who must then “promptly return, sequester, or destroy the specified information and any copies it has” and “take reasonable steps to retrieve” any information it has already distributed or disclosed to others. The producing party is required to preserve the information, and the receiving party may not use or disclose it. Many protective orders include clawback provisions, which provide a process for retrieving documents that were inadvertently produced.

10.6.13 Trial

Although parties can consent to a bench trial of patent cases, which was the norm half a century ago, a substantial majority of patent owners today opt for jury trials. So long as they seek monetary damages, the U.S. Constitution secures them a jury trial. As previous sections have illustrated, the prospect of a jury trial greatly influences patent case management. The claim construction process, as well as many of the pre-trial processes, are designed with the jury trial in mind. The inherent complexity of patent law and technology can result in unsupportable or inconsistent findings of fact by a confused jury. For this reason, judges devote substantial time and effort to avoiding such a result. And, if unsupportable or inconsistent findings of fact occur, the court must devote substantial additional time and effort to unravel and remedy such findings. Thus, trial, like all other phases of a patent case, benefits from early and close judicial management to assist the fact finder in evaluating the merits.

As the Federal Circuit has remarked, a court’s “discretion is at its broadest on matters of trial management.”²¹⁵ Various procedural and substantive considerations factor into the exercise of the court’s discretion in facilitating the jury’s and the court’s fact-finding role.

10.6.13.1 Procedural issues

District judges have a range of options for setting the scope of trial and the ground rules, including bifurcation and trial logistics.

10.6.13.1.1 *Separate trials (bifurcation)*

FRCP 42(b) provides:

[f]or convenience, to avoid prejudice, or to expedite and economize, the court may order a separate trial of one or more separate issues, claims, crossclaims, counterclaims, or third-party claims. When ordering a separate trial, the court must preserve any federal right to a jury trial.

The district judge’s discretion, however, is not without limits. Section 299 of the Patent Act, relating to the joinder of parties, provides that, even if multiple actions involving the same or similar issues, such as infringement of the same patent, have been consolidated for pre-trial purposes, they nevertheless must be separately tried unless:

(1) any right to relief is asserted against the parties jointly, severally, or in the alternative with respect to or arising out of the same transaction, occurrence, or series

215 *Massachusetts Inst. of Tech. v. Abacus Software*, 462 F.3d 1344, 1367 (Fed. Cir. 2006).

of transactions or occurrences relating to the making, using, importing into the United States, offering for sale, or selling of the same accused product or process; and (2) questions of fact common to all defendants or counterclaim defendants will arise in the action.

More generally, when deciding whether issues should be separately tried, trial courts must ensure that a litigant's constitutional right to a jury is preserved.²¹⁶

In exercising discretion to structure trials, judges typically find it more efficient to have one trial and one appeal. Thus, bifurcation in patent cases is the exception, not the rule, and it is appropriate only if it will promote judicial economy and not be inconvenient or prejudicial to the parties.²¹⁷

Patent cases are often complex, however, and sometimes involve different technologies, non-patent claims with overlapping facts, various legal and equitable claims and defenses, complex damages issues, and multiple causes of action, including antitrust, trade secret, copyright, and trademark claims. Whether all these issues should be resolved in a single trial depends on the facts and circumstances of the particular case. Factors to be considered when deciding whether to bifurcate include whether the issues, and the evidence required for each issue, are significantly different; whether they are triable by jury or the court; whether discovery has been directed to a single trial of all issues; whether a party would be prejudiced by a single or by separate trials; and whether a single trial would create the potential for jury confusion.

Ultimately, considerations regarding the manageability and comprehensibility (particularly for jurors) of the various issues presented in the case govern the decision to bifurcate and hold separate trials. From a case management standpoint, bifurcation can assist the court in segregating from juror consideration evidence that may be integral for one issue in the case but irrelevant and prejudicial for another. Bifurcation can also assist jurors by focusing attention on one issue at a time, thereby avoiding overwhelming jurors with multiple complex issues at once. At the same time, there are efficiencies that result from resolving all issues in one proceeding that should not be disregarded when deciding whether to bifurcate or even trifurcate patent cases.

10.6.13.2 Pre-trial case management

The complexity of patent cases creates a particular need for pre-trial preparation to minimize jury downtime and promote jury comprehension. The pre-trial conference represents the final opportunity to anticipate and resolve problems that would otherwise interrupt and delay trial proceedings.

10.6.13.2.1 Pre-trial conference

The pre-trial conference should be held sufficiently in advance of trial, but long enough after claim construction and dispositive motion practice so that the court and counsel have a good idea of the boundaries of the trial and the interplay of issues that may need to be tried. Usually, the conference is set six to eight weeks before trial.

The objective of the pre-trial conference is to generate an order that will govern the issues for trial and establish the ground rules for the conduct of the trial. Many judges provide counsel with a draft form of order that leaves blanks where appropriate, effectively providing a checklist of issues to consider. The form reflects the court's typical view on many aspects of the trial. Judges afford counsel some leeway to tailor the case to the particular circumstances.

A typical pre-trial order for patent cases includes the following topics:

- trial counsel for the parties;
- jurisdiction;
- nature of the action;
- the parties' contentions;

²¹⁶ *Dimick v. Schiedt*, 293 U.S. 474, 486 (1935).

²¹⁷ See *F & G Scrolling Mouse L.L.C. v. IBM Corp.*, 190 F.R.D. 385 (M.D.N.C. 1999) (burden on moving party to show bifurcation will [1] promote greater convenience to parties, witnesses, jurors, and the court; [2] be conducive to expedition and economy; and [3] not result in undue prejudice to any party); *Spectra-Physics Lasers, Inc. v. Uniphase Corp.*, 144 F.R.D. 99, 101 (N.D. Cal. 1992) (denying motion to bifurcate trial into separate liability and damages phases where defendant failed to meet its burden).

- uncontested facts and stipulations;
- contested legal and factual issues;
- jury and non-jury issues;
- list of witnesses;
- objections to expert testimony;
- list of exhibits;
- bifurcated trial (indicating whether the parties desire a bifurcated trial and, if so, why);
- motions *in limine*;
- motions for judgment as a matter of law (indicating how the parties will make motions for judgment as a matter of law, whether it be immediately at the appropriate point during trial or at a subsequent break);
- amendments to the pleadings (including a statement of whether the proposed amendment is objected to and, if objected to, the grounds for the objection);
- jury instructions (indicating, where the parties disagree, whether the instruction was proposed by the plaintiff or defendant and a brief explanation of why the instruction should be adopted, including citations to relevant authorities);
- verdict form;
- trial length and logistics; and
- additional matters (including whether the parties anticipate requesting the courtroom be closed to the public for a portion of any specified witness' testimony).

10.6.13.2.2 Jury instructions

The court works with the parties in the lead-up to the trial to develop jury instructions. Since relatively few jurors called to service have much prior experience with or understanding of trial practice, the legal system or patent law, it is common to develop two sets of instructions – a preliminary set of instructions for the start of the trial and the final instructions given at the close of evidence.

10.6.13.2.2.1 Preliminary instructions

Preliminary instructions typically cover basic aspects of civil adjudication – the duty of the jury, what constitutes evidence, the varying burdens of proof in a civil trial, and the trial proceedings – as well as an overview of the patent system and a nonargumentative description of the technology involved, the accused products, and the patents. Some judges present a video developed by the Federal Judicial Center providing a basic primer on the patent system. This video, together with a sample mock patent, provides background information on what patents are, why they are needed, how inventors obtain them, the role of the USPTO, and why disputes over patents arise. The Center updated this video in 2013 to address changes in patent law, including the enactment and implementation of the AIA.²¹⁸ Preliminary instructions should set forth the court's construction of patent claim terms and explain that jurors must accept the court's constructions and are not allowed to construe terms on their own.

10.6.13.2.2.2 Final instructions

Several judicial and patent bar organizations have prepared model patent jury instructions, which typically serve as the starting point for parties in compiling proposed instructions. The parties will often seek to redline these instructions to reflect new developments in patent law and jurisprudence.

While the court has discretion to instruct the jury before or after closing arguments, it is usually preferred to give instructions beforehand.²¹⁹ This is especially true in a patent case: jurors are usually more focused and in a better position to listen to instructions before closing arguments. Jurors better understand the arguments advanced during the closings when they have been instructed on the law applicable to the case. Instructing the jury before closing arguments can also lead to more effective arguments by the parties. Closing arguments can be tailored to meet the specific language of the instructions, enabling the parties to highlight the significance of particular evidence.

218 This 2013 video, *The Patent Process: An Overview for Jurors*, can be found at www.youtube.com/watch?v=ax7QHQTbKQE

219 See FRCP 51, 1987 Advisory Committee Notes (delineating benefits of instructions before closing arguments).

10.6.13.2.3 Trial logistics

Effective management of patent trials includes establishing reasonable time limits, maintaining a daily trial schedule, and outlining the order of the parties' presentations. With an established protocol, the parties are better able to structure and streamline their presentations to fit the court's schedule, resulting in a more understandable and efficient dispute resolution process.

10.6.13.2.3.1 Time limits and trial length

A trial court's inherent power to control cases includes the broad authority to impose reasonable time limits during trial to focus the parties' presentation of evidence and prevent undue delay, waste of time, or needless presentation of cumulative evidence.²²⁰ Time limits have been recognized as a trial technique that enhances the quality of justice and improves the administrative aspects of any civil trial. These limits force the parties to evaluate what is and is not important to their case. Time limits are particularly appropriate in patent cases, where the issues are complex, and an unduly long trial would unnecessarily burden jurors and the court.

What constitutes a reasonable time for trial depends on the particulars of a case, including the number of patents and patent claims at issue, the complexity of the technology, the nature and number of any associated non-patent claims, and whether issues are being bifurcated. To account for all these factors, a court's limits on the length of trial should be set after an informed analysis based on a review of the parties' proposed witness lists and proffered testimony, as well as their estimates of trial time. Time limits that are reasonable are (1) established in consultation with the parties, (2) allocated evenhandedly, (3) allotted to whatever evidence the parties deem appropriate; and (4) applied flexibly.

Whatever the specifics of the case, a limit on the total amount of time for trial is advisable in almost every patent case. An open-ended case schedule can quickly become unmanageable in the face of so many complex issues, and it imposes an unnecessary and unreasonable burden on the jury impaneled to hear the case. Most patent cases can be fully tried within two weeks, allocating approximately 20 hours to each side, beginning with opening statements and continuing through closing arguments. Procedures conducted by the court, mainly *voir dire* and instructions, are typically not clocked.

10.6.13.2.3.2 Order of trial presentations

In typical cases, the plaintiffs go first because they bear the burden of proof. In patent cases, however, the burden of proof is shared by the parties. While plaintiffs bear the burden of proof on infringement, for example, defendants bear the burden of proof on invalidity.

In view of these burdens, most patent trials begin with the patentee's infringement case. If damages are not bifurcated or staged, the patentee would also present its damages case. The defendant then responds to the infringement evidence, presents its invalidity evidence, and responds to the damages evidence. The patentee then offers its rebuttal on infringement and damages and its response to the invalidity challenge. The defendant then has an opportunity to rebut the plaintiff's response to that invalidity challenge.

10.6.13.2.3.3 Jury selection and management

Like any other civil trial, patent jury trials are governed by the FRCP, which require that a jury be impaneled with a minimum of 6 and a maximum of 12 jurors.²²¹ As patent trials can take longer than other civil trials and are often more complex, it may prove difficult to find jurors able to commit the necessary time and attention. Such considerations weigh against impaneling a 12-member jury. Nonetheless, judges typically impanel more than the minimum 6 jurors to ensure a verdict can be taken if one or two jurors become unable to serve during trial.

The *voir dire* process in a patent trial is largely similar to that in other civil cases. Given the specialized nature of patent cases, however, it is appropriate to question prospective jurors on their experience with the technology underlying the patents, experience with the patent system, and their feelings regarding patent protection. Because both parties are likely to be interested in eliciting such information, the *voir dire* process can be streamlined by having the prospective jurors complete questionnaires ahead of time.

²²⁰ FRCP 16(c)(15).

²²¹ See FRCP 48.

10.6.13.3 Motion for judgment as a matter of law

Once a party has completed its case-in-chief as to an issue, the party's opponent can move for judgment as a matter of law as to the issue.²²² The usual standard of decision is that judgment will be denied if, "viewing the evidence in the light most favorable to the non-moving party, and giving the non-movant the benefit of all reasonable inferences, there is sufficient evidence of record to support a jury verdict in favor of the non-movant."²²³ These motions and their appellate implications, however, take on special significance in patent cases where each side has important claims and defenses for which it bears the burden of proof, and where claim construction issues often play a pivotal role.

Absent an FRCP 50 motion before the case is submitted to the jury, specifically addressed to an issue, no argument can be made in post-trial motions or on appeal that the evidence is insufficient to support the jury's verdict as to that issue.²²⁴ In the patent law context, this may require, for example, that a Rule 50 motion by an accused infringer specify the particular claim or claims as to which it asserts no infringement has been proven or the particular prior art references it contends render the patent obvious or anticipated, and that a motion by a patent owner specify the particular invalidity bases it asserts have not been proven.²²⁵ Circumstances in particular cases, however, may make much more cryptic motions sufficient if, in context, it is clear that the court and opposing party understood what was intended.²²⁶

10.6.13.4 Verdict forms

Due to the complexity of many determinations in a patent trial, many trials use special verdict forms and special interrogatories rather than simple general verdict forms. Special verdicts require a jury to make specific findings of fact from which the court applies the applicable law. A court can also use a general verdict form with special interrogatories.²²⁷ The use of special interrogatories differs from the use of special verdicts only in that the jury, rather than the court, makes the ultimate decision when general verdicts with special interrogatories are used. There is still a risk that the jury will make a decision inconsistent with its findings. In such cases, the federal rules permit the court to enter judgment consistent with the jury's findings notwithstanding the verdict.²²⁸ Where the findings are inconsistent and do not support the verdict, the court can recall the jury for further consideration or order a new trial.

10.6.13.5 Bench trials

A court may try a patent case without a jury where the parties have waived the right to a jury trial or when equitable issues have been bifurcated for the court's consideration. However, such waivers are rare. Most often, bench trials are held to try equitable defenses such as inequitable conduct and estoppel.

As the court is the fact finder in bench trials, there is less of a need for extensive judicial management. The court must make specific findings of facts and conclusions of law when rendering its decision.²²⁹ It can, however, be less stringent with issues of admissibility and evidentiary objections because it is both the arbiter of those issues and the ultimate fact finder. There is less of a concern that the court will be prejudiced by certain evidence.

Bench trials are the standard method for trying cases involving pharmaceutical patents under the Hatch-Waxman Act (ANDA cases) and the Biologics Price Competition and Innovation Act (BPCIA), where issues of damages are not implicated (see Section 10.13.2).

10.6.13.6 Post-trial

Patent trials, as with most trials, are usually followed by a series of post-trial motions. Where there is a finding of infringement, patent owners almost always seek a permanent injunction. In cases of willful infringement, the patent owner will also typically move for enhanced damages.

²²² FRCP 50.

²²³ *Honeywell Int'l Inc. v. Hamilton Sundstrand Corp.*, 370 F.3d 1131, 1139 (Fed. Cir. 2004) (*en banc*) (citation omitted).

²²⁴ See *Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 546 U.S. 394, 398 (2006) ("A post-trial motion for judgment can be granted only on grounds advanced in the pre-verdict motion").

²²⁵ See *Duro-Last, Inc. v. Custom Seal, Inc.*, 321 F.3d 1098, 1105–09 (Fed. Cir. 2003).

²²⁶ See *Western Union Co. v. MoneyGram Payment Sys.*, 626 F.3d 1361, 1367–68 (Fed. Cir. 2010).

²²⁷ See FRCP 49(b).

²²⁸ See FRCP 49(b).

²²⁹ See FRCP 52.

Because the patent statute authorizes the award of attorneys' fees in exceptional cases, post-trial motions often seek attorneys' fees. In addition, parties will likely bring motions for judgment as a matter of law, new trial motions on the liability issues or both.

10.6.13.6.1 Motion for a new trial

Within 28 days after entry of judgment in a jury or court trial, with or without a motion for judgment as a matter of law, a party can move for a new trial.²³⁰ As with FRCP 50(b) motions, the time limit is jurisdictional and may not be extended.²³¹ The motion is judged under the law of the regional circuit court of appeals and, in a patent case, the motion can be based on the same grounds as any trial. These grounds include (1) that the judgment is contrary to the weight of the evidence; (2) misconduct by an attorney or witness that denies an opponent fair consideration; (3) jury misconduct; (4) erroneous rulings regarding evidence, jury instructions, or trial conduct issues; (5) excessive (with or without a remittitur) or inadequate (with or without an additur) damages; and (6) new evidence that could not have been discovered during trial. To merit granting a new trial, the subject of the motion must have caused substantial prejudice and, in virtually all cases, have been the subject of a timely objection. In patent cases, a motion for a new trial is often used to challenge the claim construction provided in jury instructions.

10.6.13.6.2 Renewed motion for judgment as a matter of law

Provided that a motion for judgment as a matter of law was made at the close of presentation of all the evidence at trial, a party may renew that motion within 28 days after entry of judgment.²³² The rule's time limit for making the motion is jurisdictional and cannot be extended.²³³ A renewed motion must be based on the same claimed failure of proof as the initial motion and, in judging it, the court should apply the same standard. The motion may be, and often is, joined with a motion for a new trial.²³⁴ A joint motion permits the court to grant the new trial motion as an alternative, should the order granting judgment be reversed on appeal.²³⁵

10.6.13.6.3 Motion to vacate judgment in connection with settlement

Following the entry of final judgment, parties are sometimes able to settle before any appellate disposition. As part of the settlement agreement, the patentee and the accused infringer may agree to jointly ask the district court to vacate its judgment finding the patent invalid, not infringed, or unenforceable, as well as certain subsidiary rulings such as claim construction orders that limit the patent's scope. In some cases, the parties will even make the settlement contingent upon the grant of vacatur. The motivation of the patentee in seeking vacatur is to strip any potential preclusive effect (for collateral estoppel purposes) associated with an adverse ruling regarding the patent's validity, scope, or enforceability. For the accused infringer, conversely, this cost-free concession presumably helps it obtain monetary or other consideration from the patentee as part of the settlement. Vacatur allows it to share the anticompetitive benefits resulting from the deterrent effect of the restored patent, which could be asserted against its competitors.

Notwithstanding the fact that both parties to the litigation agree that a vacatur motion should be granted, the public interest and considerations of judicial economy often weigh against this outcome.²³⁶ The alleged benefit of approving the vacatur request is that it will buy peace and reduce the costs of further judicial proceedings, such as appeal. These benefits, however, are speculative at best and more likely illusory. Vacating any judgment based on the parties' settlement is an "extraordinary remedy" that should be granted only in "exceptional circumstances" that go beyond the parties' desire to include such a remedy in their settlement.²³⁷ Indeed, FRCP 60(b)(6), under which a settlement-related motion for vacatur is typically brought, requires a showing of such "extraordinary circumstances."

²³⁰ FRCP 59(b).

²³¹ FRCP 6(b)(2).

²³² See FRCP 50(b).

²³³ FRCP 6(b).

²³⁴ FRCP 50(b).

²³⁵ FRCP 50(c)(1).

²³⁶ See Jeremy W. Bock, "An Empirical Study of Certain Settlement-Related Motions for Vacatur in Patent Cases," 88 Ind. L. J. 919 (2013) (synthesizing case law and analyzing empirical data on settlement-related motions for vacatur in patent cases over a five-year period); cf. *Lear, Inc. v. Adkins*, 395 U.S. 653, 674 n.19 (1969) (noting "the public's interest in the elimination of specious patents").

²³⁷ *U.S. Bancorp Mortg. Co. v. Bonner Mall P'ship*, 513 U.S. 18, 26, 29 (1994).

10.7 Civil remedies

U.S. patent law provides a potent arsenal of remedies, including injunctive relief, damages (which can be enhanced based on an infringer's conduct), costs, pre-judgment interest and attorneys' fees.

10.7.1 Injunction

Section 283 of the Patent Act provides that a court "may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable." Historically, courts routinely entered injunctions as a matter of course following an infringement finding. The only hesitation arose when an issuance of an injunction could threaten public health.²³⁸

The Supreme Court's decision in *eBay Inc. v. MercExchange, LLC*²³⁹ raised the threshold for obtaining injunctive relief in patent cases. An injunction may be issued only if the patent holder demonstrates:

(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.²⁴⁰

The Federal Circuit has interpreted *eBay* to eliminate the long-recognized presumption of irreparable injury to a patent holder after a judgment of infringement and no invalidity.²⁴¹ The Federal Circuit also has held that there must be a "causal nexus" between any such irreparable injury and patent infringement.²⁴²

Although *eBay* generally forbids "broad classifications" of cases for purposes of determining when an injunction is proper or improper, courts generally find the *eBay* test satisfied and issue an injunction in cases between direct or indirect competitors or where, as a result of an infringing feature, the infringer's product supplants the market for the patent holder's product. Even if the patent owner does not practice the patent, but rather sells a competing product, an injunction against a competitor may be proper. Additionally, an injunction against a competitor may be proper even when the patent holder previously licensed the patent to another competitor or its customer, when other unlicensed competitors employ the patent, when the patented product is not core to the patent holder's business, or when the injunction may put an infringer out of business. In some cases, the court will include a "sunset provision" that allows continued sales of the infringing product pursuant to a royalty to allow the infringer time to eliminate the disputed features from its product.²⁴³ The broad use of injunctions in these competitor cases, when properly supported by other factors, stems from the fundamental nature of patents as a grant to the owner of the right to exclude.

In the aftermath of *eBay*, courts have denied permanent injunctions in cases where the patentee merely licensed its technology and did not offer its own commercial embodiment, where only the patentee's licensee competes with an infringer, where the scope of the requested injunction was overly broad, or where an injunction created important public health concerns.

In connection with standard-setting proceedings and otherwise, patent owners sometimes commit to provide a fair, reasonable and nondiscriminatory (FRAND) license to any potential licensee (see Section 10.13.1). While there is no per se rule precluding an injunction to such a patent owner, an injunction is unlikely. Establishing irreparable harm is difficult, and allowing the use of a standard resulting from a FRAND commitment better serves the public interest.²⁴⁴

238 See *City of Milwaukee v. Activated Sludge, Inc.*, 69 F.2d 577 (7th Cir. 1934) (declining injunctive relief where enjoining operation of a large city's sewage treatment plant would pose a serious public health risk).

239 547 U.S. 388 (2006).

240 547 U.S. at 391.

241 *Robert Bosch LLC v. Pylon Mfg Corp.*, 659 F.3d 1142, 1149 (Fed. Cir. 2011).

242 *Apple Inc. v. Samsung Elecs. Co.*, 735 F.3d 1352, 1360 (Fed. Cir. 2013).

243 See, e.g., *Broadcom Corp. v. Qualcomm Inc.*, 543 F.3d 683, 704 (Fed. Cir. 2008).

244 See *Apple Inc. v. Motorola, Inc.*, 757 F.3d 1286, 1331–32 (Fed. Cir. 2014) (noting that, absent unusual circumstances, such as an infringer refusing a FRAND royalty or unreasonably delaying negotiations, it will be difficult for a patent owner

10.7.2 Damages

Section 284 of the Patent Act provides:

Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court. When the damages are not found by a jury, the court shall assess them. In either event the court may increase the damages up to three times the amount found or assessed. Increased damages under this paragraph shall not apply to provisional rights under section 154(d) of this title. The court may receive expert testimony as an aid to the determination of damages or of what royalty would be reasonable under the circumstances.

Section 286 establishes a six-year statute of limitations, barring patentees from recovering damages for any infringing acts committed more than six years prior to the filing of the complaint or counterclaim for infringement.

10.7.2.1 Actual damages

Courts apply several approaches for measuring damages “adequate to compensate” for a defendant’s infringement. To recover lost profits, the patentee must prove a causal relation between the infringement and its lost profits.²⁴⁵ Accordingly, the patentee must show “a reasonable probability that ‘but for’ the infringing activity, the patentee would have made the infringer’s sales.”²⁴⁶ An accepted “but nonexclusive” method for establishing “but-for” causation is the four-factor “DAMP” test, under which the patentee must prove:

- (1) demand for the patented product,
- (2) absence of acceptable noninfringing substitutes,
- (3) manufacturing and marketing capability to exploit the demand, and
- (4) profit it would have made.²⁴⁷

Additionally, the patentee is required to show that the damages were or should have been reasonably foreseeable by an infringing competitor in the relevant market.²⁴⁸

In addition to lost profits, the patentee may recover convoyed sales and losses due to price erosion:

A “convoyed sale” refers to the relationship between the sale of a patented product and a functionally associated non-patented product. A patentee may recover lost profits on unpatented components sold with a patented item, a convoyed sale, if both the patented and unpatented products “together were considered to be components of a single assembly or parts of a complete machine, or they together constituted a functional unit.”²⁴⁹

To recover for price erosion, the patentee must prove that “but for” the infringement, they would have sold their patented invention at a higher price.²⁵⁰ Furthermore, patentees must prove the number of products they would have sold at this price. Accordingly, “the patentee’s price erosion theory must account for the nature, or definition, of the market, similarities between any benchmark market and the market in which price erosion is alleged, and the effect of the hypothetically increased price on the likely number of sales at that price in that market.”²⁵¹

subject to a FRAND commitment to establish irreparable harm or that damages are not an adequate remedy; and that, even when an infringer has refused to accept any license offer, that does not necessarily justify injunctive relief).

245 See *Crystal Semiconductor Corp. v. Tritech Microelectronics Int’l, Inc.*, 246 F.3d 1336, 1354 (Fed. Cir. 2001).

246 *Crystal Semiconductor Corp.*, 246 F.3d at 1354.

247 *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1545 (Fed. Cir. 1995) (*en banc*) (citing *Panduit Corp. v. Stahl Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1156 (6th Cir. 1978)).

248 See *Rite-Hite*, 56 F.3d at 1546.

249 *American Seating Co. v. USSC Grp, Inc.*, 514 F.3d 1262, 1268 (Fed. Cir. 2008) (quoting *Rite-Hite*, 56 F.3d at 1550).

250 See *Crystal Semiconductor*, 246 F.3d at 1357.

251 *Crystal Semiconductor*, 246 F.3d at 1357.

10.7.2.2 Reasonable royalty

Under 35 U.S.C. § 284, the patentee may recover no less than a reasonable royalty on the infringer's sales for which the patentee has not shown entitlement to lost profits.²⁵² A reasonable royalty may be derived from an established royalty (if one exists) or, more commonly, from a hypothetical negotiation between the patentee and the infringer when the infringement began.²⁵³

The hypothetical negotiation (during which the asserted patent claims are assumed to be valid and infringed) tries "to recreate the *ex ante* licensing negotiation scenario and to describe the resulting agreement."²⁵⁴ Evidence relevant to calculating the reasonable royalty may include not only factual developments before the date of the hypothetical negotiation but also events occurring after that date.²⁵⁵

Determining the reasonable royalty based on the hypothetical negotiation commonly involves an analysis of the factors set forth in *Georgia-Pacific Corp. v. U.S. Plywood Corp.*:²⁵⁶

- (1) The royalties received by the patentee for the licensing of the patent in suit, proving or tending to prove an established royalty.
- (2) The rates paid by the licensee for the use of other patents comparable to the patent in suit.
- (3) The nature and scope of the license, as exclusive or nonexclusive; or as restricted or non-restricted in terms of territory or with respect to whom the manufactured product may be sold.
- (4) The licensor's established policy and marketing program to maintain his patent monopoly by not licensing others to use the invention or by granting licenses under special conditions designed to preserve that monopoly.
- (5) The commercial relationship between the licensor and licensee, such as, whether they are competitors in the same territory in the same line of business; or whether they are inventor and promoter.
- (6) The effect of selling the patented specialty in promoting sales of other products of the licensee; the existing value of the invention to the licensor as a generator of sales of his non-patented items; and the extent of such derivative or convoyed sales.
- (7) The duration of the patent and the term of the license.
- (8) The established profitability of the product made under the patent; its commercial success; and its current popularity.
- (9) The utility and advantages of the patent property over the old modes or devices, if any, that had been used for working out similar results.
- (10) The nature of the patented invention; the character of the commercial embodiment of it as owned and produced by the licensor; and the benefits to those who have used the invention.
- (11) The extent to which the infringer has made use of the invention; and any evidence probative of the value of that use.
- (12) The portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the invention or analogous inventions.
- (13) The portion of the realizable profit that should be credited to the invention as distinguished from non-patented elements, the manufacturing process, business risks, or significant features or improvements added by the infringer.
- (14) The opinion testimony of qualified experts.
- (15) The amount that a licensor (such as the patentee) and a licensee (such as the infringer) would have agreed upon (at the time the infringement began) if both had been reasonably and voluntarily trying to reach an agreement; that is, the amount which a prudent licensee – who desired, as a business proposition, to obtain a license to manufacture and sell a particular article embodying the patented invention – would have been willing to pay as a royalty and yet be able to make a reasonable profit and which amount would have been acceptable by a prudent patentee who was willing to grant a license.²⁵⁷

252 See *Rite-Hite*, 56 F.3d at 1554.

253 See *Rite-Hite*, 56 F.3d at 1554.

254 *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1325 (Fed. Cir. 2009).

255 See *Lucent Techs., Inc.*, 580 F.3d at 1333–34.

256 318 F. Supp. 1116 (S.D.N.Y. 1970).

257 318 F. Supp. at 1120.

A reasonable royalty calculation will typically require determining the royalty base and the royalty rate. The determination is relatively straightforward where the demand for a final product comprises a single patented technology, such as a drug with a patented active ingredient. The most sensible royalty base would typically be the total sales revenue for the final product – what is often referred to as the entire market value.²⁵⁸ The royalty rate would account for alternative treatments (of which there may be few), marketing costs, and manufacturing costs.

Patent law has long struggled to deal with apportioning patent value where a patent covers only one component of a larger product.²⁵⁹ The problem has become particularly acute in modern patent litigation as a result of the growing use of juries called upon to apportion value based on complex and often widely divergent economic expert analyses.

In general, a patent holder seeking a reasonable royalty must provide substantial evidence supporting both its choice of royalty base and royalty rate. “[W]here multi-component products are involved, the governing rule is that the ultimate combination of royalty base and royalty rate must reflect the value attributable to the infringing features of the product, and no more.”²⁶⁰ The Federal Circuit has warned, “reliance on the entire market value might mislead the jury, who may be less equipped to understand the extent to which the royalty rate would need to do the work in such instances.”²⁶¹

To cabin the risk of outsize awards in multicomponent cases, the Federal Circuit has pushed the royalty base toward the smallest salable patent-practicing unit or “SSPPU.”²⁶² The Federal Circuit embraced this framework in *LaserDynamics Inc. v. Quanta Computer, Inc.*,²⁶³ holding that “it is generally required that royalties be based not on the entire product, but instead on the ‘smallest salable patent-practicing unit.’ [...] The entire market value rule is a narrow exception to this general rule.”²⁶⁴

10.7.2.2.1 Ongoing royalty after denial of a permanent injunction

Where a court determines that a permanent injunction is not warranted, it might determine an appropriate ongoing royalty for the infringer’s continued use of the patented invention (unless the jury explicitly awarded damages for future infringement). In the event the parties are unable to negotiate a mutually agreeable royalty agreement, the court can impose an ongoing royalty.²⁶⁵ There is no Seventh Amendment right to a jury to determine the issue of an ongoing royalty. Indeed, even a jury’s determination of a reasonable royalty does not bind the court in setting an ongoing royalty.²⁶⁶ This is because there is a difference between a reasonable royalty for pre-verdict infringement and damages for post-verdict infringement, given the change in the parties’ legal relationship and other economic factors.²⁶⁷ Where the jury’s royalty damage award is a lump sum that includes a royalty for future sales, however, the jury’s royalty determination precludes any further award.²⁶⁸ In any event, the court should provide a reasoned explanation for any ongoing royalty it imposes. In particular, the court may take additional evidence into account for any additional economic factors relevant to establishing a royalty for ongoing use of the patented invention post-verdict.

In determining the amount of an ongoing royalty, the district court should consider:

the change in the parties’ bargaining positions, and the resulting change in economic circumstances, resulting from the determination of liability – for example, the

258 See *Fonar Corp. v. Gen. Elec. Co.*, 107 F.3d 1543, 1552 (Fed. Cir. 1997).

259 See *Cincinnati Car Co. v. New York Rapid Transit Corp.*, 66 F.2d 592, 593 (2d Cir. 1933) (observing that the allocation of profits among multiple components “is in its nature unanswerable”).

260 *Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1226 (Fed. Cir. 2014) (citing *VirnetX, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308 (Fed. Cir. 2014)).

261 *Ericsson, Inc.*, 773 F.3d at 1227 (citing *Laser Dynamics, Inc. v. Quanta Computer, Inc.*, 694 F.3d 51, 67, 68 (Fed. Cir. 2012)) (barring the use of too high a royalty base – even if mathematically offset by a “low enough royalty rate” – because such a base “carries a considerable risk” of misleading a jury into overcompensating, stating that such a base “cannot help but skew the damages horizon for the jury” and “make a patentee’s proffered damages amount appear modest by comparison” (quoting *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1320 (Fed. Cir. 2011)).

262 See *Cornell Univ. v. Hewlett-Packard Co.*, 609 F. Supp. 2d 279 (N.D.N.Y. 2009) (Rader, J., sitting by designation).

263 694 F.3d 51 (Fed. Cir. 2012).

264 694 F.3d at 67.

265 *Telcordia Techs., Inv. v. Cisco Sys.*, 612 F.3d 1365, 1379 (Fed. Cir. 2010); *Paice LLC v. Toyota Motor Corp.*, 504 F.3d 1293, 1315 (Fed. Cir. 2007).

266 *Amado v. Microsoft Corp.*, 517 F.3d 1353, 1361–62 (Fed. Cir. 2008).

267 See *Amado*, 517 F.3d at 1361–62.

268 *Summit 6, LLC v. Samsung Elecs. Co.*, 802 F.3d 1283, 1300–01 (Fed. Cir. 2015).

infringer's likelihood of success on appeal, the infringer's ability to immediately comply with the injunction, [...] etc. – as well as the evidence and arguments found material to the granting of the injunction and the stay.²⁶⁹

The district courts have approached the determination of ongoing royalty in a variety of ways. Some have used the *Georgia-Pacific* factors,²⁷⁰ but have modified the factors to assume that the hypothetical negotiation occurred after the determination of the patent's validity and infringement, when the infringer must consider the possibility that the patent holder could force it off the market absent a license. In doing so, some courts have noted that, since the pre-verdict analysis assumed the patent's validity and infringement, this change will not alter the pre-judgment running royalty set by the verdict. Other courts, relying on the Federal Circuit's citation of the "change in the parties' bargaining positions, and the resulting change in economic circumstances, resulting from the determination of liability," have inferred that the hypothetical negotiation should be more favorable to the patentee. Finally, while recognizing that the ultimate determination of the ongoing royalty is a legal issue to be determined by the court, some courts nevertheless submit the question to the jury for an advisory verdict, citing the efficiency of doing so.

10.7.2.3 Enhanced damages

Section 284 of the Patent Act authorizes a court to increase the damages award up to three times. In *Halo Electronics, Inc. v. Pulse Electronics, Inc.*,²⁷¹ the Supreme Court interpreted this provision to afford district courts broad, although not unbounded, discretion to enhance damage awards up to the treble cap. *Halo* "eschew[ed] any rigid formula for awarding enhanced damages," but noted that "such punishment should generally be reserved for egregious cases typified by willful misconduct," such as "wanton and malicious" piracy, that goes beyond typical infringement.²⁷² The defendant's willfulness, a factual determination to be made by a jury, is a significant factor in the enhanced damages determination. Courts typically set a briefing schedule for a motion for enhanced damages, as well as other post-trial motions, following the jury's verdict.

10.7.2.4 Pre-judgment interest

Section 284 authorizes the patentee to recover pre-judgment interest. The Supreme Court has held that pre-judgment interest "should be awarded [...] absent some justification for withholding such an award."²⁷³ A court may award pre-judgment interest only on compensatory damages and not on enhanced damages.²⁷⁴ Interest is calculated from the time of infringement until the date judgment is rendered.²⁷⁵ The district court has substantial discretion to determine both the pre-judgment interest rate and the assessment of simple or compound interest to the damages.²⁷⁶

10.7.3 Costs

10.7.3.1 Court fees

The award of costs under § 284 refers to FRCP 54(d)(1), which provides that "costs other than attorneys' fees shall be allowed as of course to the prevailing party unless the court otherwise directs." Additionally, 28 U.S.C. § 1920 lists the types of costs the prevailing party may recover under FRCP 54(d)(1), including reporter fees, docket fees and compensation for court-appointed experts.

10.7.3.2 Attorneys' fees

Section 285 of the Patent Act authorizes the award of reasonable attorneys' fees in "exceptional cases." The purpose is to give the court the power to shift the burden of unnecessary and vexatious litigation onto the party responsible for it. Like enhanced damages, the award of attorneys' fees lies in the trial court's discretion.

²⁶⁹ *Amado*, 517 F.3d at 1362.

²⁷⁰ See *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116 (S.D.N.Y. 1970).

²⁷¹ 579 U.S. 93 (2016).

²⁷² 579 U.S. at 104, 106–07.

²⁷³ *General Motors Corp. v. Devex Corp.*, 461 U.S. 648, 657 (1983).

²⁷⁴ See *Underwater Devices Inc. v. Morrison-Knudsen Co.*, 717 F.2d 1380, 1389 (Fed. Cir. 1983), overruled on other grounds by *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337 (Fed. Cir. 2004) (*en banc*).

²⁷⁵ See *General Motors*, 461 U.S. at 656.

²⁷⁶ See *Gyromat Corp. v. Champion Spark Plug Co.*, 735 F.2d 549, 556–57 (Fed. Cir. 1984).

The Supreme Court has held that “an ‘exceptional’ case is simply one that stands out from others with respect to the substantive strength of a party’s litigating position (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated.”²⁷⁷ The court makes this determination in its discretion based on the “totality of the circumstances.”²⁷⁸ In making this assessment, it may consider, as a “‘nonexclusive’ list of ‘factors’”: “frivolousness, motivation, objective unreasonableness (both in the factual and legal components of the case) and the need in particular circumstances to advance considerations of compensation and deterrence” as well as “either subjective bad faith or exceptionally meritless claims.”²⁷⁹ The district court also has discretion to decline to award fees even in exceptional cases.²⁸⁰ The district court should, however, set forth its reasons for declining to award fees despite the finding of litigation misconduct and exceptional case status.²⁸¹

Attorneys’ fees motions can be brought before or after entry of judgment, but no later than 14 days after entry of judgment.²⁸² When brought by a patent holder, a motion for attorneys’ fees usually is brought in conjunction with a request for enhanced damages, as the same facts usually support both motions.

10.8 Other actions

U.S. law authorizes the USITC to exclude infringing products at the border (see Section 10.12).

10.9 Enforcement of judgments

Following entry of a permanent injunction, infringing parties often modify the infringing product or process in an effort to design around the claimed invention and begin marketing the modified product. If the patent owner believes that the redesigned product infringes, it can challenge the design-around by commencing a second patent infringement action. In limited circumstances, the patent owner can instead seek to have an enjoined party held in civil contempt for violating the injunction.

To prove contempt, the patent owner must provide clear and convincing evidence both that the newly accused product is not more than colorably different from the product found to infringe and that the newly accused product actually infringes.²⁸³ To resolve this first and “primary” element, the court must determine “whether the newly accused product is so different from the product previously found to infringe that it raises ‘a fair ground of doubt as to the wrongfulness of the defendant’s conduct.’”²⁸⁴ In making this determination, the court focuses on “those aspects of the accused product that were [...] a basis for the prior finding of infringement, and the modified features of the newly accused product.” If an element previously found to infringe has been modified or removed, the court should determine whether that modification is significant.²⁸⁵ If the change is nonobvious, it is usually found to be a significant difference.²⁸⁶ If the product’s modification does render it more than colorably different, whether or not it still infringes the patent, there is no contempt; instead, infringement must be proven in a new jury trial.²⁸⁷

The test’s second, independent element is that the accused product must still infringe. In making this assessment, the court must determine that each element of a claim is infringed based upon the claim construction applied in the liability case.²⁸⁸ It must, however, construe any additional claims necessary to determine the infringement issue.²⁸⁹ Finally, the court must determine whether there is clear and convincing evidence that the specific provisions of the injunction were violated. In making this determination, the injunction must be construed narrowly, with any

277 *Octane Fitness, LLC v. Icon Health & Fitness, Inc.*, 572 U.S. 545, 554 (2014).

278 *Octane Fitness*, 572 U.S. at 554.

279 *Octane Fitness*, 572 U.S. at 554 n.6.

280 See *Octane Fitness, LLC v. Icon Health & Fitness, Inc.*, 576 F. App’x 1002 (Fed. Cir. Aug. 26, 2014) (unpublished opinion).

281 See *Oplus Techs., Ltd v. Vizio, Inc.*, 782 F.3d 1371, 1375–76 (Fed. Cir. 2015).

282 FRCP 54(d)(2)(B).

283 See *TiVo Inc. v. EchoStar Corp.*, 646 F.3d 869, 882 (Fed. Cir. 2011) (*en banc*).

284 *TiVo*, 646 F.3d at 882 (quoting *California Artificial Stone Paving Co. v. Molitor*, 113 U.S. 609, 618 (1885)).

285 See *Proveris Sci. Corp. v. Innovasystems, Inc.*, 739 F.3d 1367, 1370–71 (Fed. Cir. 2014).

286 See *TiVo*, 646 F.3d at 883.

287 *TiVo*, 646 F.3d at 883.

288 See *TiVo*, 646 F.3d at 883.

289 See *Proveris Sci. Corp.*, 739 F.3d at 1372.

ambiguity resolved against the patent owner.²⁹⁰ The propriety of the injunction or its specific provisions, however, is not subject to challenge during the contempt proceeding.²⁹¹

In assessing the appropriate penalty for contempt, the court has wide discretion. In exercising this discretion, it may consider the infringer's "diligence and good faith efforts" to create a noninfringing product. While neither diligence nor good faith is a defense to contempt, these factors are relevant to the appropriate penalty.²⁹²

As part of or following a contempt proceeding, the court may be asked to modify its injunction to assure that similar future infringement does not take place by adding a provision requiring that any subsequent claimed design-around be submitted to the patent holder or the court before public distribution. Such an order is allowed if the court determines that it is reasonably necessary to obtain compliance with the prior injunction.²⁹³

10.10 Appellate review

Although most decisions from district courts are subject to appellate review within the general jurisdiction regional U.S. courts of appeals, in 1982, Congress consolidated jurisdiction over patent appeals in the Federal Circuit. Congress also vested exclusive appellate jurisdiction over USITC and USPTO decisions with the Federal Circuit. The Federal Circuit's decisions can be appealed to the U.S. Supreme Court.

10.10.1 The U.S. Court of Appeals for the Federal Circuit

The jurisdiction of the Federal Circuit is unique among the 13 U.S. circuit courts of appeals in that it has nationwide jurisdiction over a number of specialized subject matter areas, including appeals on patent claims and compulsory counterclaims from all federal district courts,²⁹⁴ appeals from the United States Court of Federal Claims, appeals from the PTAB, and appeals from the USITC.

The Federal Circuit currently comprises 12 active judges and 7 judges with senior status. Typically, appeals at the Federal Circuit are initially heard and decided by three-judge panels. In some cases, the full court reviews the panel decision *en banc*. This mechanism can be used to resolve intra-circuit splits on patent issues. The Federal Circuit occasionally orders *en banc* review *sua sponte* (without a request from the parties), and *amici curiae* are invited to file briefs and sometimes to participate in oral argument.

The Federal Circuit also receives petitions for writs of mandamus, which are "available in extraordinary situations to correct a clear abuse of discretion or usurpation of judicial power."²⁹⁵ As noted in Section 10.6.3, writs of mandamus may be used to order a district court to transfer a case to correct the erroneous denial of a transfer motion.

10.10.1.1 Stay of injunction pending appeal

When an injunction has been issued and an appeal taken, the defendant will often request that the injunction be stayed pending appeal. FRCP 62(c) authorizes a district court, in its discretion, to stay an injunction when an appeal is taken. Moving for a stay of injunction in the district court pursuant to the Federal Rules is a prerequisite to requesting a stay in the Federal Circuit.²⁹⁶ A court can, as a matter of judicial economy, consider a stay at the same time as the motion for permanent injunction.

In considering whether to grant a stay, the court must apply four factors:

- (1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits;

²⁹⁰ See *Abbott Labs. v. Torpharm, Inc.*, 503 F.3d 1372, 1382–83 (Fed. Cir. 2007).

²⁹¹ See *TiVo*, 646 F.3d at 886.

²⁹² *TiVo*, 646 F.3d at 800.

²⁹³ See *Additive Controls & Measurement Sys., Inc. v. Flowdata, Inc.*, 154 F.3d 1345, 1356 (Fed. Cir. 1998) ("Although such broad injunctions should be used only in exceptional cases, the district court reasonably concluded that such measures were necessary in this case to compel compliance with the court's orders").

²⁹⁴ Permissive counterclaims – in which the counterclaims are related to allegations separate from those made by the plaintiff – are reviewed by the regional circuit courts of appeal, not the Federal Circuit.

²⁹⁵ *In re Nintendo Co.*, 589 F.3d 1194, 1197–98 (Fed. Cir. 2009).

²⁹⁶ Fed. R. App. P. 8.

- (2) whether the applicant will be irreparably injured absent a stay;
- (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and
- (4) where the public interest lies.²⁹⁷

The requirement of showing irreparable injury to obtain a stay of an injunction is applied stringently because the court has already conducted an analysis finding an injunction appropriate. Thus, irreparable harm, for the purposes of a stay of injunction, is usually not found unless the injunction will put the defendant out of business in the period pending appeal. A stay of injunction may be more appropriate if the defendant has a design-around, particularly if the patented feature is but one component in a multicomponent product. Under those circumstances, a court may stay the injunction and impose an ongoing royalty for the interim period to allow the defendant to continue its business while transitioning to the release of its design-around. The ongoing royalty amount should expressly consider the fact that any ongoing use of the patented invention takes place following the grant of an injunction.²⁹⁸

In the event that the district court denies a stay pending appeal, a party likely will ask the Federal Circuit to grant the stay.²⁹⁹ In conjunction with the request to the Federal Circuit, the party may also request that the district court grant a short stay allowing time for the party to prepare and obtain a ruling on its request from the Federal Circuit. In the event the district court does not grant this request, the party likely also will seek an interim stay from the Federal Circuit.

10.10.1.2 Remands

Following review by the Federal Circuit, some cases return to the district court for further proceedings. Some matters are remanded with specific instructions; others are remanded for further unspecified proceedings consistent with the appellate court's mandate and opinion.

10.10.2 U.S. Supreme Court

Article III, Section 1 of the U.S. Constitution establishes the Supreme Court of the United States. Since 1869, the Court has had nine Justices. The Constitution provides that, among other things, the Supreme Court has appellate jurisdiction to review decisions of the lower courts.

A party seeking Supreme Court review of an appellate decision must petition the Court for a writ of certiorari, which is a request that the Supreme Court order a lower court (typically a U.S. court of appeals, such as the Federal Circuit, or the highest court in a U.S. state) to send the record of a case to the Supreme Court for review. The Supreme Court's review of cases on appeal from the Federal Circuit (or indeed, an appeal from any case heard in a lower court) is discretionary. Four of the nine Supreme Court justices must vote to accept a case for review from a lower court. In a typical year, the Court grants certiorari in about 80 of the more than 7,000 cases in which Supreme Court review is requested. The Supreme Court has heard approximately one to two patent cases per year over the past two decades.

10.11 Criminal proceedings

The United States does not provide for criminal liability relating to patent infringement.

10.12 Border measures

10.12.1 United States International Trade Commission

The USITC provides a forum for domestic industries to seek exclusion of goods that violate U.S. intellectual property rights.³⁰⁰ The USITC now conducts more full patent adjudications on an annual basis than any individual district court. Figure 10.8 shows the number of new, completed,

²⁹⁷ *Standard Haven Prods., Inc. v. Gencor Indus.*, 897 F.2d 511, 512 (Fed. Cir. 1990). (quoting *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987)).

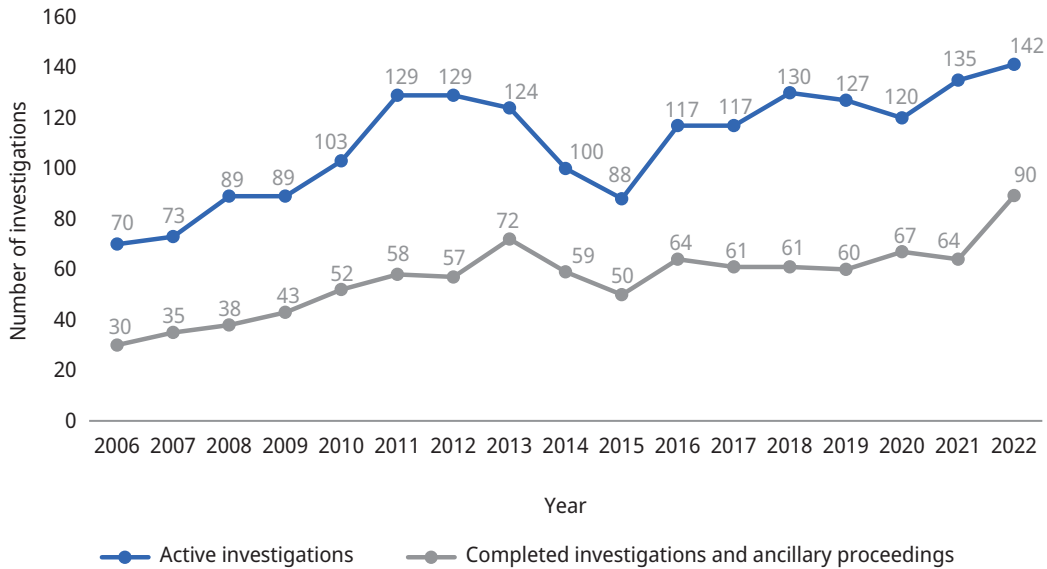
²⁹⁸ See *Amado v. Microsoft Corp.*, 517 F.3d 1353, 1362 (Fed. Cir. 2008).

²⁹⁹ See Fed. R. App. P. 8.

³⁰⁰ See generally Peter S. Menell, Colleen V. Chien, G. Brian Busey, Ruffin Cordell, Mark G. Davis, Matthew D. Powers, and Sturgis M. Sobin, *Section 337 Patent Investigation Management Guide* (Lexis 2012).

and active Section 337 investigations at the USITC from 2006 through 2022.³⁰¹ Since 2010, the USITC has generally had over 100 active investigations per year, and it has completed approximately 60 patent investigations per year.³⁰²

Figure 10.8 Section 337 investigations at the USITC (2006 to 2022)



The USITC's Section 337 Administrative Law Judges (ALJs) focus almost exclusively on patent investigations, making the USITC the nation's only specialized, trial-level patent-adjudication forum. The ALJs conduct an evidentiary hearing that resembles a bench trial. The ALJ's determinations are reviewed by the USITC's six Commissioners, and USITC decisions finding Section 337 violations are subject to review by the President.

Federal district court patent enforcement and USITC Section 337 patent investigations are closely interrelated, as approximately two-thirds of USITC patent cases have a district court counterpart. Over 90 percent of USITC intellectual property investigations initiated since the mid-1990s have involved allegations of patent infringement.

10.12.1.1 Section 337 authority

The USITC's authority to prohibit importation of infringing goods traces to Section 337 of the Tariff Act of 1930 (codified at 19 U.S.C. § 1337). The Trade Act of 1974 established the USITC as an independent agency and gave it authority to protect domestic industries against unfair practices. The USITC was granted authority to issue exclusion orders, cease and desist orders and civil penalties within the formal adjudication provisions of the APA. The Act required the USITC to conclude its investigations "at the earliest practicable time, but not later than one year (18 months in more complicated cases)" after commencement of the investigation and modernized the agency, bringing it within the formal adjudication provisions of the APA. These changes provided a more hospitable environment for patent owners and ushered in the modern era of USITC unfair import investigations.

Congress amended Section 337 in 1988 to further facilitate the use of USITC investigations in combating unfair trade practices.³⁰³ Among other changes, the 1988 Act eliminated the injury requirement for statutory intellectual property rights, thereby lowering the threshold for pursuing USITC investigations. The 1988 Act also removed the requirement of prior law that the domestic industry be "efficiently and economically operated," and expanded the scope of what constitutes a domestic industry. The 1988 Act provided that complainants could satisfy the

301 See *USITC, Section 337 Statistics: Number of New, Completed, and Active Investigations by Fiscal Year*, www.usitc.gov/intellectual_property/337_statistics_number_new_completed_and_active.htm

302 *USITC, Section 337 Statistics: Number of New, Completed, and Active Investigations by Fiscal Year*, www.usitc.gov/intellectual_property/337_statistics_number_new_completed_and_active.htm

303 See Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-418, §1342, 102 Stat. 1107, 1212-16 (1988) (codified at 19 U.S.C. §1337).

domestic industry requirement either by showing that domestic industries exist in the United States or “[are] in the process of being established.”³⁰⁴ The statute also added investment in the exploitation of intellectual property rights, including through “engineering, research and development, or licensing,” as a possible basis for showing the existence of a domestic industry.³⁰⁵ The 1988 Act also expedited enforcement remedies by requiring the USITC to issue temporary exclusion orders within 90 days (or 150 days in more complex cases) of the publication of the USITC’s notice of investigation in the Federal Register. Prior practice allowed ALJs four months to prepare the initial determination (ID) of requests for temporary relief, with no statutory requirement regarding when the USITC must act on the ID.

Congress passed legislation in 1994 to bring Section 337 into compliance with the General Agreement on Tariffs and Trade, including the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) added during the Uruguay Round.³⁰⁶ The principal changes were to (1) substitute a directive to complete USITC investigations “at the earliest practicable time” for the fixed 12- to 18-month limit for completing investigations; (2) permit respondents to lodge counterclaims, subject to the requirement that such counterclaims be removed immediately to a US district court with proper venue; (3) require district courts to stay their proceedings at the request of a party who is also a respondent in a Section 337 proceeding with respect to any claim that involves the same issues; and (4) limit the issuance of general exclusion orders to situations where such general exclusion from entry is necessary to prevent circumvention of the order or where a pattern of violation exists and the source of infringing products is difficult to identify.

10.12.1.2 Section 337 substantive requirements

USITC patent investigations arise under Section 337(a)(1)(B) of the Tariff Act, which prohibits:

- [t]he importation into the United States, the sale for importation, or the sale within the United States by the owner, importer, or consignee, of articles that –
- (i) infringe a valid and enforceable United States patent [...]; or
 - (ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent.

A complainant must establish three elements: (1) importation, (2) domestic industry, and (3) infringement of a valid U.S. patent (or other intellectual property).

10.12.1.2.1 Importation

The USITC interprets the importation requirement broadly to cover all commercial transactions that involve articles imported into the United States. The term “article” typically refers to an imported and allegedly infringing product that enters the United States through U.S. Customs and Border Protection. Section 337 also reaches software or data files that enter the country through physical media, but not if the importation of these items occurs through machine-readable form by electronic means.³⁰⁷ The USITC has stated that a “complainant need only prove importation of a single accused product to satisfy the importation element.”³⁰⁸ The purpose for which a respondent imports an infringing article is irrelevant with the exception of government use, which Section 337(l) exempts subject to the government compensating affected intellectual property owners the “reasonable and entire” value of the infringing articles in an action before the United States Court of Federal Claims. Consequently, the USITC has jurisdiction over foreign manufacturers, domestic companies that manufacture their products offshore and import them into the United States, and domestic companies that export products that are later re-imported.

In most USITC investigations, parties stipulate to importation, or the USITC decides the issue on summary determination. Thus, importation rarely presents a contested issue at the hearing. It is generally sufficient for the complainant to provide photographs of infringing products that are on sale within the United States or to include purchase orders that indicate prior importation.

304 19 U.S.C. §1337(a)(2).

305 19 U.S.C. §1337(a)(3)(C).

306 See Uruguay Round Amendments Act of 1994, Pub. L. 103–465, §321, 108 Stat. 4809 (1994).

307 See *ClearCorrect Operating LLC v. Int’l Trade Comm’n*, 810 F.3d 1283, 1293–99 (Fed. Cir. 2015), reh’g *en banc* denied, 819 F.3d 1334 (Fed. Cir. 2016).

308 *Certain Purple Protective Gloves*, No. 337-TA-500, Order No. 17 at 3 (U.S.I.T.C. Sept. 23, 2004).

10.12.1.2.2 Domestic industry

Complainants alleging violation of the infringing articles provisions must prove that a domestic industry “exists or is in the process of being established.”³⁰⁹ For purposes of this requirement, a domestic industry exists or is in the process of being established if:

there is in the United States, with respect to the articles protected by the patent [or other covered intellectual property right] –

- (A) significant investment in plant and equipment;
- (B) significant employment of labor or capital; or
- (C) substantial investment in its exploitation, including engineering, research and development, or licensing.³¹⁰

This domestic industry requirement has historically been relatively easy to meet. It does arise, however, where the complainant is not engaged in significant domestic production based on the patents at issue. The 1988 amendments to Section 337 clarified that substantial investment in the exploitation of the intellectual property right in the United States, including engineering, research and development, or licensing, satisfies the domestic industry requirement.

The domestic industry requirement has two elements: the economic prong and the technical prong. “The complainant in a patent-based 337 investigation must show that an industry exists or is being established (economic prong) and that the industry practices at least one claim of the patent at issue (technical prong).”³¹¹ As the language of the technical prong refers to articles protected by “the patent” (not just to claims found to infringe), the technical prong is satisfied if the complainant’s article practices any claim of the patent.³¹² The complainant’s patent claim used to satisfy the technical prong does not need to be the same patent claim(s) as those allegedly infringed by the respondent.³¹³

10.12.1.2.3 Infringement of a U.S. patent

The third element required to prove a Section 337 violation is infringement of a valid U.S. patent. This provision is based on the substantive federal patent law as interpreted by the federal courts. Section 337 patent investigations, however, do not permit defenses based on 35 U.S.C. § 271(g) or the award of monetary compensation.

10.12.1.3 Defenses to 35 U.S.C. § 271(g)

Section 271(g) extends patent liability to anyone who, without authority, “imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States.” Nonetheless, Congress excused “for purposes of this title,” products made by a patented process and that are “materially changed by subsequent processes” or “become[] a trivial and nonessential component of another product.”³¹⁴ Because Section 337 investigations arise under Title 19 (and not Title 35) of the U.S. Code, the Federal Circuit held that, although Section 337(c) of the Tariff Act states that “[a]ll legal and equitable defenses may be presented in all cases,” the safe harbors set forth in 35 U.S.C. § 271(g) cannot be asserted under Section 337 because Congress limited these defenses to “purposes under this title.”³¹⁵

10.12.1.4 Remedies

Section 337 does not provide a patent owner the authority to pursue monetary damages. Instead, the only type of remedy available at the USITC is injunctive relief stemming from the USITC’s jurisdiction over infringing articles, as the *eBay* factors do not apply.

309 19 U.S.C. §1337(a)(2).

310 19 U.S.C. §1337(a)(3).

311 *Certain Display Controllers and Products Containing Same and Certain Display Controllers with Upscaling Functionality and Products Containing Same*, Inv. Nos. 337-TA-491/481, Comm’n Op. at 52 (Feb. 4, 2005).

312 *Certain Microsphere Adhesives, Process for Making Same, and Products Containing Same, Including Self-Stick Repositionable Notes*, Inv. No. 337-TA-366, Comm’n Op. at 16 (Dec. 8, 1995).

313 *Certain Soft-Edged Trampolines and Components Thereof*, Inv. No. 337-TA-908, Comm’n Op. at 54 (May 1, 2015).

314 35 U.S.C. §271(g)(1)–(2).

315 See *Kinik v. U.S. Int’l Trade Comm’n*, 362 F.3d 1359, 1362–63 (Fed. Cir. 2004) (citing legislative history stating “[n]either is there any intention for these provisions to limit in any way the ability of process patent owners to obtain relief from the U.S. International Trade Commission.” (citing S. Rep. No. 100–83 at 60–61)).

10.12.2 United States International Trade Commission patent investigation process

USITC enforcement arises through an administrative process. Unlike district court patent enforcement, complaints are vetted by an investigatory body – the Office of Unfair Import Investigations (OUII) – whose recommendations are reviewed by the USITC before an investigation is instituted and assigned to an ALJ. OUII often (but not always) continues to participate in the adjudicatory process along with the complainant and the respondent after an investigation is launched. As noted above, the USITC is required to conclude its investigations “at the earliest practicable time” after commencement of the investigation. In view of this expedited process, and to avoid importers from being subjected to defend two proceedings in parallel, Congress requires district courts to stay parallel proceedings upon the timely request of a respondent (see Section 10.3.3.2).

The procedural requirements of a Section 337 investigation differ somewhat from the procedural requirements in federal district court litigation. While Section 337 investigations are quasi-judicial in nature, they typically follow a much faster timeline and are governed by a distinctive set of rules (see Table 10.4).

Table 10.4 Typical United States International Trade Commission investigation timeline

Timeline	Investigation stage
Filing of complaint	
Within 30 days	Institution decision. The USITC decides whether to institute an investigation.
Target date	Target date is set, typically at 16 months or sooner measured from the Notice of Investigation , but it can be extended for good cause. Investigations must be completed “at the earliest practicable time.”
Within 45 days of Notice of Investigation	The presiding ALJ sets a target date for completion of the investigation. Target dates of 16 months or sooner are set by the ALJ’s order. If the ALJ seeks to establish a later target date, the ALJ must issue an ID that is subject to review by the six Commissioners.
Within 35 days of filing a motion for temporary relief	The USITC determines whether to institute temporary exclusion order proceedings. The parties will conduct several weeks of targeted discovery followed by an evidentiary hearing on the merits of the motion.
Within 70 days (120 days in more complicated cases) of instituting a temporary exclusion order proceeding	Temporary exclusion order ID. ALJ issues an ID on the merits.
Within 90 days of Notice of Institution (150 days in more complicated cases)	The USITC determines whether to accept the ALJ’s ID and whether to grant temporary relief.
At least 20 days after institution and 60 days prior to hearing	Summary Determination motions are filed.
Typically 3–4 months after institution	Claim construction determination (depends on the case and presiding ALJ).
Typically 2–3 months prior to the deadline for ID	Evidentiary hearing (trial).
Within 45 days of issuance of an ID	The USITC determines whether to review the ID. If the USITC decides not to review, the ID becomes a Final Determination .
Within 60 days of Final Determination finding of no violation	Filing of Federal Circuit appeal. In investigations where no violation is found, an appeal must be filed by the complainant within 60 days at the Federal Circuit.
60 days following USITC review	Presidential review period. During this 60-day period, exclusion orders go into effect immediately, but excluded goods can continue to be imported upon posting of the bond set by the USITC. The bond is set at a level “sufficient to protect the complainant from any injury” during the Presidential review period.
After Presidential review period	Exclusion orders bar imports of excluded goods.
Within 60 days following Presidential review period	Federal Circuit appeal must be filed.

Note: USITC = United States International Trade Commission; ALJ = Administrative Law Judge; ID = initial determination; Federal Circuit = U.S. Court of Appeals for the Federal Circuit.

10.12.2.1 United States International Trade Commission personnel

The USITC staff comprises over 350 people, including international trade analysts (investigators and experts in particular industries), international economists, attorneys, and technical support personnel. Only a portion of the USITC staff, however, focuses on Section 337 investigations.

10.12.2.1.1 Commissioners

The USITC oversees all of the relevant staff and sets rules and policies governing Section 337 investigations. The USITC determines whether to institute an investigation based on complaints filed by private parties that allege violations of Section 337. Following the ID by the presiding ALJ, the USITC may review and adopt, modify, or reverse the ID, or it may decide not to review the ID. If the USITC declines to review an ID, it becomes the final determination of the USITC.

In the event that the USITC determines that Section 337 has been violated, the USITC may issue an exclusion order barring the products at issue from entry into the United States, as well as one or more cease and desist orders directing the violating parties to cease certain activities.

The USITC is headed by six Commissioners nominated by the President and confirmed by the U.S. Senate. No more than three Commissioners may be of any one political party. The Commissioners serve overlapping terms of nine years each, with a new term beginning every 18 months. The President designates the Chairman and Vice Chairman from among the current Commissioners for two-year terms. The Chairman and Vice Chairman must be from different political parties, and the Chairman cannot be from the same political party as the preceding Chairman.

10.12.2.1.2 Administrative law judges

After the USITC institutes an investigation under Section 337, the matter is referred to the Office of the Administrative Law Judges, where the Chief ALJ assigns an ALJ to the matter. USITC ALJs are selected from a pool of candidates with training and experience in administrative law. They are not required to have specific training in science, technology, or patent law, although some ALJs have such backgrounds. They typically will have served as ALJs in other administrative agencies, such as the Environmental Protection Agency, the Office of Medicare Hearings and Appeals, and the Social Security Administration. Once selected to serve at the USITC, the ALJs specialize in USITC investigations and typically handle approximately a dozen investigations at a time, far fewer matters than a typical district court judge.

The assigned ALJ conducts pre-hearing case management, resolves discovery matters, issues orders, considers summary determination motions, presides over a hearing, makes an ID regarding whether a violation has occurred, and recommends a remedy if appropriate. Section 337 investigations are conducted in accordance with procedural rules that are similar in many respects to the FRCP. These USITC procedural rules (found in 19 C.F.R. § 210) are always supplemented by a set of ground rules issued by the presiding ALJ, and a standard protective order (which the parties can supplement as needed).

The presiding ALJ conducts a formal evidentiary hearing on the merits of a Section 337 case in conformity with the adjudicative provisions of the APA.³¹⁶ Hence, parties have a right to adequate notice, cross-examination, presentation of evidence, objection, motion, argument, and other rights essential to a fair hearing. Following a hearing on the merits of the case, the presiding ALJ issues an ID that is certified to the USITC along with the evidentiary record. The USITC may review and adopt, modify, or reverse the ID, or it may decline to review the ID. If the USITC declines to review an ID, the ID becomes the final determination of the USITC.

10.12.2.1.3 Office of Unfair Import Investigations

OUII employs investigative attorneys and support staff. In addition to legal training, many OUII attorneys have engineering or science degrees and are registered to practice before the USPTO.

OUII serves various roles through the phases of Section 337 investigations. Prior to the filing of a complaint, OUII staff are available to consult with prospective complainants regarding the process for pursuing a Section 337 complaint. Once a complaint is filed, OUII reviews the matter and advises the USITC as to its sufficiency with regard to Section 337's procedural requirements and substantive elements.

If the USITC orders an investigation, the matter is assigned to an ALJ for discovery, hearing, and issuance of an ID on violation in accordance with the requirements of the APA. OUII will then staff an Investigative Attorney to the investigation, and OUII's role is to represent the public interest as an independent party to the proceeding. OUII's positions do not reflect the positions of the

³¹⁶ 5 U.S.C. §§551-59, 701-06.

USITC, and OUII's positions are not binding on the ALJs or the USITC. Under USITC rules, the OUII cannot communicate *ex parte* with the USITC, the USITC's Office of the General Counsel, or the ALJs regarding pending investigations.

During the course of the investigation, the OUII Investigative Attorney formulates an independent assessment on the issues and may take an active role in discovery (including depositions), motions practice, and the trial. Ultimately, the OUII Investigative Attorney will take positions on an issue-by-issue basis in the investigation and hence may side with different parties on the range of issues. The OUII Investigative Attorney may facilitate the investigation by discussing procedural and substantive issues with the private parties. It can be involved in settlement negotiations and comments on whether settlements and proposed consent decrees are in the public interest.

Following the rendering of an ID by the ALJ, the OUII Investigative Attorney typically participates in the final review process before the USITC. In investigations where the ALJ finds a violation of Section 337, the OUII Investigative Attorney typically contacts the Intellectual Property Branch of U.S. Customs and Border Protection when preparing a proposed exclusion order for submission to the USITC. In its remedy submission, the OUII Investigative Attorney may advise the USITC of any special concerns raised by U.S. Customs and Border Protection.

OUII and its investigative attorneys do not handle appeals to the Federal Circuit – those are handled by the Office of the General Counsel. The Office of the General Counsel represents the USITC's positions and, as discussed earlier, OUII's positions may diverge from those of an ALJ or the USITC. Moreover, in investigations in which OUII is a party, OUII lacks standing to participate in an appeal.

10.12.2.2 Procedural rules

Part 200 of Title 19 of the Code of Federal Regulations contains the rules that govern the USITC generally, and Part 210 of Title 19 of the Code of Federal Regulations contains the rules that govern USITC unfair trade practices investigations. In addition, the USITC's ALJs have their own "ground rules," analogous to the standing rules that district courts may have in their proceedings. These ground rules differ in various respects from the FRCP and the PLRs adopted by many of the district courts with the most active patent dockets.

10.12.2.3 Pleading

In contrast to the liberal notice-pleading requirements of the FRCP (see Section 10.6.5), the USITC requires that a Section 337 complaint allege sufficient pertinent facts to support the initiation of an investigation.³¹⁷ Such fact-pleading must include specific allegations of importation of the accused product, the patent(s) at issue, infringement (including a claim chart presentation), and the effects on the domestic industry.³¹⁸ In addition to identifying any patents at issue, the complaint must identify ownership, licensees, corresponding foreign patents and applications (with prosecution status), description of the patented invention(s), and designation of allegedly infringed claims.³¹⁹

10.12.2.4 Mechanisms for early disposition of investigation issues

Over the past few years, the USITC has piloted programs to allow for early resolution of issues that may be case-dispositive, or where disposition of an issue may facilitate settlement. These programs are outlined below.

10.12.2.4.1 100-day proceedings

In June 2013, the USITC launched a pilot program to facilitate early resolution of dispositive issues, such as domestic industry, standing, and importation requirements, through proceedings commonly known as "100-day proceedings." Under this program, the USITC is authorized to identify potentially dispositive issues at institution, and to direct the presiding ALJ to rule on those issues within 100 days of institution.³²⁰ The ALJ may expedite fact-finding on the designated issue(s), including holding an evidentiary hearing. The ALJ may also stay discovery on other issues

317 See 19 C.F.R. §210.12.

318 See 19 C.F.R. §210.12(a)(6), (a)(9).

319 See 19 C.F.R. §210.12(a)(9).

320 19 C.F.R. §210.10(b)(3).

in the investigation while the 100-day proceeding is pending. To date, 100-day proceedings have most commonly addressed the domestic industry issue.

100-day proceedings have been used less often than expected, due to the challenge of identifying potentially case-dispositive issues prior to institution, on a limited record. In addition, these proceedings can only be instituted by the USITC, not the ALJ, which decreases flexibility.

10.12.2.4.2 Pilot program: interim initial determinations

In May 2021, the USITC announced a new pilot program applying to all investigations instituted on or after May 12, 2021, allowing ALJs to issue interim IDs on fewer than all issues in an investigation. As with 100-day proceedings, the goal of this program is to facilitate the resolution of case-dispositive issues or significant issues that may facilitate settlement early in the investigation. This program improves upon the mechanism for 100-day proceedings in three important ways: (1) the presiding ALJ has discretion to designate an issue for accelerated determination after institution, and with the benefit of greater understanding of the issues in the investigation; (2) at the ALJ's discretion, the parties can move to have an issue receive an interim ID; and (3) the USITC will accelerate its processes for review of the interim ID.

Under this program, an ALJ is permitted to hold an evidentiary hearing and receive briefing on one or more discrete issues prior to the main evidentiary hearing. The presiding ALJ may elect to stay discovery on other issues during the interim ID process, and may place the remaining procedural schedule of an investigation on hold while an interim ID is before the USITC. Like 100-day proceedings, the ALJ may stay discovery during the interim ID process.

10.12.2.5 Early investigation management

Prior to the filing of a complaint, OUII staff are available to discuss the process for pursuing a Section 337 complaint, the requirements for filing a complaint, and the nature of remedies available. OUII does not form any position regarding the merits of a possible complaint at this stage, nor does it assess the strength of patents or evaluate infringement allegations. OUII may review a proposed complaint and may seek clarification or supplementation from the complainant.

Once a complaint is filed, an attorney within OUII reviews the matter and advises the USITC and the USITC's Office of the General Counsel as to its sufficiency with regard to Section 337's procedural requirements and substantive elements: (1) sale for importation, importation, or sale after importation of goods; (2) unfair acts or methods of competition, such as infringement of a U.S. patent; (3) presence of a domestic industry; and (4) proof of substantial or threatened injury in the case of non-statutory intellectual property rights complaints. The Office of the General Counsel may advise the USITC to disagree with OUII's recommendation. OUII does not assess the complainant's likelihood of success on the merits at this stage of the Section 337 investigation.

If the USITC orders an investigation, the matter is assigned to an ALJ for discovery, hearing, and issuance of an ID on violation in accordance with the requirements of the APA.

10.12.2.5.1 Protective orders

Complaints and associated exhibits nearly always contain confidential information. A complaint can be filed either as confidential with a public version or as a public complaint with confidential exhibits. Public versions of confidential exhibits must be filed. Proposed respondents do not have access to any of the confidential materials until after (1) the investigation has been instituted, (2) it has been assigned to an ALJ, (3) the ALJ has issued a protective order, and (4) respondent's counsel has subscribed to the protective order.³²¹ Protective orders are automatically issued by the ALJ.

There is no set form for a protective order in a Section 337 investigation. The provisions of a protective order governing a specific investigation may differ depending on the investigation and on the presiding ALJ. In practice, though, the provisions are similar (and similarly applied) by the various ALJs.³²²

³²¹ See Section 10.12.2.7.1.

³²² Summary of Commission Practice Relating to Administrative Protective Orders, 86 Fed. Reg. 71916, 71917-18 (Dec. 20, 2021).

10.12.2.5.2 Public interest submission

In conjunction with filing a complaint, complainants must submit a separate statement not more than five pages in length addressing how the requested relief may impact the public interest.³²³ As a means of gathering further information on the public interest issues, the USITC publishes a Notice in the Federal Register inviting comments from the public and proposed respondents on any public interest issue raised by the complaint and requested relief.

Based upon an evaluation of the public interest submissions made by the complainant, the public, and the respondent(s), the USITC may elect to delegate consideration of the public interest factors to the presiding ALJ in the notice of institution of investigation. In fiscal year 2021, the USITC delegated the development of a factual record on the public interest factors to the presiding ALJ in about 16 percent of total new investigations.³²⁴ In this scenario, the ALJ will hear evidence on the public interest factors by evaluating the impact that an exclusion order would have on (1) public health and welfare, (2) competitive conditions in the U.S. economy, (3) the production of like or directly competitive articles in the United States, and (4) U.S. consumers. If delegated, the ALJ will include findings on the public interest in their ID.

If the USITC does not delegate the public interest determination to the ALJ, the issue can be presented to the USITC as part of the briefing in the post-ID phase of the investigation.

10.12.2.5.3 Institution of investigation

Once the complaint is filed, the USITC has 30 days to review it for sufficiency relative to the requirements of the statute and regulations. The USITC has the authority to extend the 30-day deadline due to exceptional circumstances. Section 337 investigations are instituted by a majority or tie vote of the USITC.

Apart from evaluating the public interest issues raised in submissions, the USITC's role in this phase of the investigation is to determine whether a sufficient case has been pled under the statute and rules, not to evaluate claims substantively or to weigh the evidence. For this reason, the USITC does not encourage submissions or communications from other potentially interested parties, including proposed respondents.

An investigation is officially commenced by the issuance of a Notice of Institution of the investigation and its publication in the Federal Register. The Notice defines the scope of the investigation, including the parties, articles subject to investigation, alleged unfair acts (asserted patents and claims in a patent-based investigation), and alleged domestic industry. In most instances, the scope mirrors the complaint regarding these elements. The Notice of Investigation is served on all of the named parties, with additional copies to the embassy of each country of foreign named respondents.

10.12.2.5.4 Assignment of administrative law judges and Office of Unfair Import Investigations

The USITC delegates assignments of investigations to the Chief ALJ. Pursuant to the APA, the Chief ALJ assigns investigations to ALJs on a rotational basis, taking into consideration caseload balance, familiarity with the underlying technology, concerns about the potential for "judge-shopping," and the existence of related cases. OUII decides whether it will participate in each new investigation and, if so, with respect to what issues.

10.12.2.5.5 Response to the complaint

A respondent must file its response within 20 days of service.³²⁵ The USITC typically serves the complaint within a day or so of issuance of the notice of investigation by means of overnight delivery. Thus, respondents typically have only 21 days after the date of service to file a response. In many cases, respondents contend that the 21 days is not adequate time to compile the information and address the detailed allegations and, as a result, request an extension of this deadline. The complexities are even more substantial for foreign respondents, who may be unfamiliar with the U.S. legal process. Given both the practical realities facing respondents, who must hire counsel and begin a fast-track preparation for discovery and development of defenses,

323 19 C.F.R. §210.8(b).

324 USITC, 337 Statistics: Identification and Number of Cases Delegating Public Interest, available at https://www.usitc.gov/337_stats_delegating_public_interest

325 19 C.F.R. §210.13(a).

as well as the requirements for some specificity in pleading noted below, complainants rarely oppose requests for modest extensions of time to respond.

The USITC requires respondents to plead affirmative defenses with as much specificity as possible. Failure to comply with this rule may give rise to a motion, which can be styled in a variety of ways, seeking essentially to compel respondents to provide more detail regarding the alleged defense. Because of the speed of the litigation, it serves the interests of all litigants to identify as early as possible the issues expected to be litigated. In practice, a number of tools are available to assist in the elaboration of defenses as the discovery period progresses, including the discovery statement for the preliminary conference (see Section 10.12.2.5.7), contention interrogatories and other fact-based discovery (see Section 10.12.2.7), expert reports and the pre-hearing submissions (see Section 10.12.2.10.1). Given these additional tools, in most cases, the lack of extensive detail in a response can be addressed without a protracted adversarial process over the response itself. One exception to this approach is in the area of inequitable conduct. If a party asserts inequitable conduct, the USITC may well determine that pleading standards applicable in the district courts apply equally to the USITC.

Although USITC Rule 210.13(b)(1)³²⁶ “encourages” respondents to include noninfringement claim charts with their responses, in practice, many respondents do not do so because there has not been enough time to perform the analysis required to develop these detailed positions. Such claim charts would require respondents to construe claims as well as apply them to one or more products.

10.12.2.5.6 Setting the target date

Section 337 requires that the USITC complete investigations “at the earliest practicable time.” The USITC sets a fixed completion date, known as the “target date,” for each investigation pursuant to Rule 210.51(a).³²⁷ If the target date does not exceed 16 months from the date of institution of the investigation, the order of the ALJ is final and not subject to interlocutory review. If the target date exceeds 16 months, the order of the ALJ constitutes an ID. The USITC, however, typically does not review an ALJ’s ID to set target dates later than 16 months from the date of institution.

Once a target date has been set, it can be modified for good cause shown while the case is before the ALJ and by the USITC once the case has moved forward. Some intervening events that have provided a basis for modification include changes in parties, claims or defenses; problems in obtaining key discovery, including non-party discovery requiring enforcement of a USITC subpoena; and ancillary or related legal proceedings that directly affect the USITC’s investigation. At the USITC level, target dates can be extended for a variety of reasons, including complexity and number of issues reviewed, delays in the release of public versions of the ID enabling the public to provide comments on the proposed remedy and public interest issues, difficulty in reaching a decision by the USITC, and overall caseload.

10.12.2.5.7 Preliminary conference

ALJs have the discretion to, and normally do, schedule a preliminary conference within the first 30–60 days following institution of the investigation (typically by telephone). The agenda for these conferences usually includes a discussion of issues raised in discovery statements, the target date (if it has not already been set), procedural schedule, proposed modifications to the ground rules or protective order, prospects for settlement, and any significant issues raised with respect to discovery at that stage. In some cases, the conference is also used to explore in more detail the claims and defenses set out in the complaint and responses thereto. As a general proposition, the conference affords the ALJ an opportunity to provide some guidance that may facilitate expeditious adjudication. Although not required by USITC rules, ALJs generally establish a procedural schedule for each investigation.

10.12.2.5.8 Intervention

USITC Rule 210.19³²⁸ permits intervention by third parties in some situations, and the USITC looks to FCRP 24 for guidance. Intervention can arise where a complaint only names the downstream product manufacturer but not the manufacturer of the component that is critical to the

³²⁶ 19 C.F.R. §210.13(b)(1).

³²⁷ 19 C.F.R. §210.51(a).

³²⁸ 19 C.F.R. §210.19.

infringement claims. In some cases, the downstream respondent may simply seek the cooperation of the component supplier in developing defenses, while in others, the component supplier may feel it necessary to intervene in the case to protect its rights.

10.12.2.6 Temporary exclusion order

The USITC has authority to issue expedited relief in the form of temporary exclusion orders, cease and desist orders, or both.³²⁹ A complainant can file a motion for a temporary exclusion order simultaneously with a Section 337 complaint. The motion must contain a detailed statement of facts bearing on “whether the complainant should be required to post a bond” and “the appropriate amount of the bond.”³³⁰ If the USITC later determines that the respondent has not violated the provisions of Section 337, the bond may be forfeited to the respondent. The USITC also requires a detailed memorandum of facts and affidavits in support of the motion.³³¹

In deciding whether to grant temporary relief, “the [USITC] will apply the standards the [Federal Circuit] uses in determining to affirm lower court decisions granting preliminary injunctions.”³³² Therefore, in concert with Federal Circuit practice under 35 U.S.C. § 283, a complainant seeking temporary relief under Section 337 must establish (1) a reasonable likelihood of success on the merits, (2) irreparable harm if temporary relief is not granted, (3) a balance of hardships tipping in its favor, and (4) the temporary relief’s favorable impact on the public interest.

Motions for preliminary relief in Section 337 cases are rare because the expedited scheduling at the USITC already provides for a rapid resolution and the burden on the complainant is high. “As a general rule [...] such relief is an extraordinary remedy to be granted only where the right to relief is clear and unequivocal.”³³³

10.12.2.7 Discovery

Discovery in Section 337 investigations is often more challenging and onerous than discovery in district court cases due to the compressed time schedule and the addition of importation, domestic industry, and foreign discovery issues. That said, Section 337 investigations do not involve monetary damages, which reduces the scope of discovery to that extent. The most significant advantage of discovery in Section 337 investigations is the greater availability of the ALJ to resolve discovery disputes. ALJs at the USITC handle far fewer cases than do district judges, which affords them greater capacity to manage the USITC discovery process.

Discovery in a Section 337 investigation is governed by the USITC’s rules, particularly Rules 210.27–210.34,³³⁴ and by the ALJ’s ground rules. Although the USITC rules are similar in many ways to the FRCP, there are important differences. The FRCP serve as guidelines for the interpretation and application of parallel USITC rules. In consulting interpretation of the Federal Rules for guidance, where issues of patent law control disposition of a discovery dispute, Federal Circuit law applies.³³⁵

10.12.2.7.1 Protective order

Upon commencement of an investigation, the ALJ will typically begin the investigative process by issuing an administrative protective order governing the disclosure of confidential information over the course of the investigation. Such protective orders parallel those in district court litigation, including a prosecution bar that prohibits any attorney prosecuting patents for a party from viewing the confidential information of the party’s opponents (see Section 10.12.2.5.1).

10.12.2.7.2 Scope

The scope of discovery before the USITC is generally broader than that before district courts. The USITC rules provide that parties may obtain discovery regarding any matter, not privileged, that is reasonably calculated to lead to admissible evidence.³³⁶ Likewise, Section 337 investigations typically permit not only more discovery requests but also more and longer depositions.

329 See 19 U.S.C. §1337(e).

330 19 C.F.R. §210.52(b).

331 19 C.F.R. §210.52(b), (d).

332 19 C.F.R. §210.52(a).

333 *Vacuum Packaging Machines, Inv. No. 334-TA-496, Initial Determination Concerning Temporary Relief Proceeding* (Dec. 16, 2003).

334 19 C.F.R. §§210.27–34.

335 *Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356 (Fed. Cir. 1999).

336 19 C.F.R. §210.27(b).

As with district court litigation, discovery in USITC investigations extends to document production (including electronic records), interrogatories, contention interrogatories, depositions, requests for admission, third-party subpoenas, and the on-site inspection of documents and property. The USITC rules have higher default limits for fact depositions and interrogatories as compared to the FRCP. ALJs can adjust these limits.

10.12.2.7.3 Management of discovery disputes

Like district court litigation, parties in the high stakes of Section 337 investigations are frequently mired in contentious discovery battles. As with district court dispute resolution, ALJs begin by encouraging the resolution of disputes through the meet and confer process. A common procedure is to require the parties to have weekly calls to confer about discovery disputes. The ALJ can also require the participation of OUII staff attorneys as a way of encouraging participation of the principal attorneys; it also provides immediate feedback to the parties on the apparent reasonableness of their positions in disputes. Many ALJs require the parties and OUII attorneys to form a discovery committee to resolve disputes during the discovery phase. ALJs have wide discretion to impose sanctions, ranging up to issue and evidence preclusion or default, as a means of controlling discovery abuses.

10.12.2.8 Claim construction

Although *Markman v. Westview Instruments*³³⁷ had a profound effect on the role of judge and jury in district court patent litigation, it did not directly affect the USITC, where matters of fact and law are both decided by an ALJ. ALJs are not required to conduct claim construction hearings, but it has become standard practice for most ALJs to hold a *Markman* hearing, which may include a tutorial or live testimony. All ALJs have ground rules relating to claim construction, including requirements for identification of claim terms and the submission of claim construction briefing.

Some ALJs have adopted claim construction procedures commonly used by federal district judges, although on an accelerated schedule in line with the investigation target date. This entails a process by which the parties identify all claim terms requiring construction; exchange their constructions of terms identified along with supporting intrinsic and extrinsic evidence; meet and confer to discuss constructions and identify terms as to which there is a real dispute; and produce a joint statement of constructions, including terms as to which there is agreement and dispute. To ensure that the investigation stays on schedule, this process needs to be conducted in a period of two to three weeks and should be completed well before expert reports are completed to allow the experts to address and apply the respective positions. At a minimum, this process should occur at least three weeks prior to the initial expert reports.

10.12.2.9 Summary determination and interlocutory USITC review

As used in USITC parlance and the USITC's rules, the "summary judgment" standard is referred to as "summary determination" and is essentially viewed and defined in the same manner as the summary judgment standard used in district court:

The determination sought by the moving party shall be rendered if pleadings and any depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to summary determination as a matter of law.³³⁸

Summary determination under this rule is analogous to summary judgment and citation to both kinds of precedent is appropriate.³³⁹

As with summary judgment in district court litigation, summary determination at the USITC offers a path for early treatment of issues on which there is no genuine dispute as to the material facts and in which the party seeking relief is entitled to it as a matter of law. Tactically, some movants use summary determination as a lever to either "flush out" or defeat their opponents' arguments in advance of the hearing, or to provide the court with a preview of the arguments the movant believes are its most compelling. Unlike the judge in a jury trial, the ALJ is both the fact-finder and legal arbiter in the USITC's administrative proceedings. As a result, if the ALJ does not find a

³³⁷ 517 U.S. 370 (1996).

³³⁸ 19 C.F.R. §210.18(b).

³³⁹ *Certain Electronic Imaging Devices*, Inv. No. 337-TA-726, Order No. 18 (March 8, 2011).

movant's summary determination briefing compelling, the ALJ can require the parties to proceed to an evidentiary hearing without worrying about the impact on a lay jury. The OUII Investigative Attorney, upon occasion submits its own motion for summary determination.

As with district court litigation, the resolution of claim construction helps provide a foundation for addressing summary determination. In investigations featuring a separate claim construction phase, there has been a general willingness to permit summary determination practice following the claim construction order. Irrespective of these patent issues, it is common to have motions for summary determination on other issues, such as importation or on the economic prong of the domestic industry requirement.

10.12.2.10 Pre-hearing case management

As with district court litigation, the pre-hearing phase is an extremely important period in the life of a Section 337 case. The work in this period not only sets the stage for a successful hearing, but can also have a significant impact on the overall scope and outcome of the resulting case – for example, from potential issue waiver and preclusion of evidence.

10.12.2.10.1 Pre-hearing submissions

Prior to the evidentiary hearing, the parties submit both pre-hearing statements and pre-hearing briefs to the ALJ. These submissions are some of the most important filed in a Section 337 investigation, as they not only serve a pre-trial notice function regarding the arguments and evidence to be presented at trial, but also provide the final opportunity to raise issues to be considered in the investigation. Pursuant to each ALJ's ground rules, arguments not raised in the pre-hearing briefs are ordinarily deemed by rule to be abandoned or waived for purposes of the investigation and any appeal.

10.12.2.10.1.1 Contents of pre-hearing statements and briefs

Although ALJs vary in their rules governing the pre-hearing statement and brief, pre-hearing statements typically will include:

- the names of the witnesses, along with a brief outline of the proposed testimony and an estimated length for the testimony;
- a list of exhibits;
- a list of any stipulations to which the parties have agreed; and
- a proposed agenda for the pre-hearing conference, including any high-priority objections that the parties wish to resolve at the pre-hearing conference, as well as potential motions *in limine* that may be argued at the pre-hearing conference.

The pre-hearing brief lays out a party's contentions on the issues remaining to be litigated (and whether the party has the burden of proof on the issue). Each ALJ has detailed rules on the pre-hearing brief. Usually, the rules require the parties to agree to an outline for the brief and limit the length of the brief (or require a single brief from all complainants or all respondents in a multi-party case). All issues and contentions not addressed in the pre-hearing brief are waived.

10.12.2.10.1.2 Timing

Pre-hearing submissions are typically filed a few weeks before the hearing. The precise timing can depend on the overall length of the pre-hearing phase (i.e., the time between the close of discovery and the hearing). Further, there is usually a separate and later time set for the filing of OUII staff attorneys' pre-hearing statement. This allows OUII staff to have the benefit of reviewing the parties' briefs before filing their own. Although most ground rules make clear that all parties are expected to state a position on contested issues, in some cases, OUII staff have sought to "reserve" a final decision on an issue until after the hearing.

10.12.2.10.2 Witnesses, deposition designations, and exhibits

Pre-hearing case management is a significant challenge for USITC litigants given the relatively large number of witnesses and exhibits involved and the normally limited trial time. The ground rules for witness testimony and examination vary by ALJ – in particular, there are distinctions between ALJs as to whether direct testimony is to be presented live or via witness statement, and whether fact witnesses are sequestered by default or only if requested.

As a further streamlining technique, when depositions are admissible as substantive evidence – either by USITC rule or agreement of the parties – they take the form of specific line and page designations, rather than the entire deposition transcript.

The process of preparing, submitting, and objecting to exhibits is an area in which unproductive behavior – particularly with respect to objections – can create inefficiencies and risks of gaps in the record at trial. The process of lodging and resolving objections to exhibits can result in a prisoner’s dilemma in which counsel on each side lodge often rote technical objections to opposing counsel’s exhibits in anticipation that the other side’s counsel will act in a similar manner. But, in recent years, it has become common for the parties to agree to waive all but the highest priority objections. ALJs often must play an active role in resolving disputes over exhibits.

10.12.2.10.3 Motions in limine

Orders *in limine* are an important tool for managing the scope of hearings in Section 337 investigations. While potentially applicable to a broad range of pre-trial evidentiary disputes, they are most frequently granted in disputes involving the scope of expert testimony, whether arguments not disclosed in the pre-hearing brief may be heard, whether late-disclosed information (notably prior art references) may be introduced into evidence, and whether information that was shielded from discovery by a party may be relied upon by that party at trial.

10.12.2.10.4 Daubert motions

Motions to wholly preclude the testimony of a particular expert are rarely made or granted in Section 337 investigations. Instead, such challenges may result in a narrowing of the scope of an expert’s permitted testimony. More commonly, they expressly or implicitly trigger a post-trial determination that an expert’s testimony will be afforded less weight given weaknesses in their credentials or methodology. Even in such situations, however, the APA does not require the USITC to accept the ALJ’s weighing of credibility. Indeed, the USITC has at times relied upon the testimony of an expert to support its conclusions even though the ALJ determined following trial that the expert’s testimony should not receive less weight.

10.12.2.10.5 Tutorials

As in district court litigation, technology tutorials can be especially helpful in educating the ALJ about the underlying technology. While tutorials will always be shaped by the issues the parties are litigating, the goal of the tutorial should be to give the ALJ neutral, useful background information about the technology – not attorney argument about the merits of the investigation. Cases vary widely in the need for technology tutorials: some cases need little more than a brief introduction by the lawyers at the hearing, while others may benefit from a lengthy, separate presentation with animations and live fact or expert witnesses. There are no USITC rules either requiring technology tutorials, or establishing procedures to be used in the event one is included in the procedural schedule. Rather, whether to hold a tutorial, when to hold it and procedures therefor are left entirely to the discretion of the ALJ.

10.12.2.10.6 Pre-hearing conference

The pre-hearing conference provides a formal opportunity to identify and resolve pre-hearing issues in an orderly fashion. Pre-hearing conferences typically occur just before the evidentiary hearing (often on the same day). These conferences provide a forum to consolidate and address any remaining open matters that require rulings or clarification by the ALJ prior to the commencement of testimony. The pre-hearing conference also typically focuses on stipulations the parties have agreed to regarding trial logistics. As a general matter, pre-hearing conferences permit the aggregation of issues and fast resolution through rulings from the bench. They also help ensure that litigants and the ALJ have common expectations about how the hearing itself will proceed.

10.12.2.11 Hearing

Patent investigations often involve complex scientific and technological issues that color almost all aspects of the hearing (e.g., tutorials, exhibits, oral testimony, and attorney argument). This inherent complexity, especially when combined with misleading arguments, can result in unsupportable or inconsistent findings of fact by the ALJ. An inordinate amount of time and resources may be spent during the post-hearing or post-ID phases trying to unravel and remedy such findings.

Absent settlement, consent order, stipulated dismissal, or the grant of a dispositive motion, the USITC must provide the parties an opportunity for a hearing on the merits.³⁴⁰ At the violation hearing, the ALJ receives evidence and hears argument to make findings and recommendations for USITC action. Long before any hearing can begin, the ALJ must define the scope of the investigation and the ground rules governing its proceedings. These issues are of particular import in patent cases, which often involve numerous complex and technical claims and defenses.

10.12.2.11.1 Separate hearings (bifurcation)

USITC hearings are promptly “held at one place, continuing until completed” unless the ALJ orders otherwise in the procedural schedule or ground rules.³⁴¹ A preliminary question in any patent investigation is whether all the issues involved in a case should be resolved in a single hearing or bifurcated hearings. Bifurcation in Section 337 investigations is invoked rarely, and is appropriate only if it will promote judicial economy without causing inconvenience or prejudice to the parties. In recent years, the USITC has allowed for the resolution of certain case-dispositive issues in proceedings (including hearings) early in investigations under its 100-day program or interim ID pilot program, in effect allowing for bifurcated hearings in investigations (see Section 10.12.2.4).

Whether all of the issues raised in a USITC patent investigation – sometimes involving different technologies, non-patent claims with overlapping facts, and various legal and equitable claims, defenses, and remedies – should be resolved in a single hearing depends upon the facts and circumstances of the particular investigation. Factors to be considered in the bifurcation decision include whether the issues and the evidence required for each issue are significantly different, whether discovery has been directed to a single hearing of all issues, whether a party would be prejudiced by a single hearing or separate hearings, and whether a single hearing would create the potential for confusion.

10.12.2.11.2 Hearing logistics

Section 337 hearings are conducted under the APA and follow the USITC Rules of Practice and Procedure, which are generally consistent with the FRCP. An ALJ’s inherent power to control investigations includes the broad authority to impose reasonable time limits during hearings. Time limits have been recognized as a technique that enhances the quality of justice and improves the administrative aspects of any civil hearing. Such limits force the parties to evaluate what is and is not important to their case and prevent the undue burdens a long patent hearing would impose on the tribunal.

USITC hearings are usually public and may range from a few days to a week or so, depending on the complexity of the investigation. What is considered a reasonable length for a hearing depends upon the number of patents at issue, the number of named respondents, the complexity of the technology, and the nature and number of any associated non-patent claims.

The burden of presenting evidence in patent cases usually falls equally on the parties. In USITC hearings, a portion of the hearing time is allotted to OUII staff attorneys, with the remaining hearing time split evenly between the complainant and respondent(s). The presumed equal allocation of time between the complainant and respondent can, however, be adjusted for any demonstrable difference in the complexity of issues.

The length of hearing times and other time limits do not significantly change for investigations that involve multiple, rather than single, respondents. There may be hearings, however, when the ALJ should consider the number of respondents and redistribute hearing time accordingly (e.g., where multiple respondents have different interests and may wish to examine a witness separately). ALJs in patent hearings most often start with the complainant’s case-in-chief, followed by the respondent’s case-in-chief, the investigative staff attorney’s case-in-chief, and then the complainant’s rebuttal. At their discretion, ALJs often allocate time for the respondent to present a rebuttal case as well.

10.12.2.11.3 Evidentiary issues

ALJs follow the USITC’s rules at the evidentiary hearing and will apply the FRE more liberally than district court judges on evidentiary issues (e.g., hearsay may be allowed, and FRE 403 objections to relevance generally do not apply).

³⁴⁰ 19 C.F.R. §210.36(a).

³⁴¹ 19 C.F.R. §210.36(c).

10.12.2.11.3.1 *Patent law experts*

Parties sometimes propose the use of a patent attorney or former USPTO employee to present expert testimony regarding select patent law issues, USPTO procedures, or patent terminology. The use of patent law experts is strongly discouraged and, if allowed at all, should be limited to a non-biased explanation of USPTO procedures. Just as in any other field, it is exclusively for the ALJ – not a patent law expert – to interpret the underlying patent law and reach conclusions regarding the meaning and sufficiency of the evidence.

10.12.2.11.3.2 *Inventor and other technical party employee testimony*

The role of inventors and other technical party employee witnesses in USITC evidentiary hearings is largely the same as in district court (see Section 10.6.10.3).

10.12.2.11.4 *Post-hearing briefing and initial determination*

After the hearing, the parties have the opportunity to submit post-hearing briefs and proposed findings of fact, as well as rebuttal briefs and rebuttal proposed findings of fact. The parties should begin preparing the initial briefs and proposed findings of fact before the conclusion of the hearing because the post-hearing briefing schedule is severely compressed in most investigations. All issues in dispute must be discussed in the post-hearing briefing, or these issues are abandoned. Based on the hearing and post-hearing briefing, the ALJ will issue an ID as to whether there has been a violation and a recommended determination as to the proper remedy.

The ALJ is required to issue an ID on whether there is a violation of Section 337 no later than four months before the target date.³⁴² This ID is often referred to as a “final initial determination.” The final ID must contain “an opinion stating findings (with specific page references to principal supporting items of evidence in the record) and conclusions and the reasons or bases therefor necessary for the disposition of all material issues of fact, law, or discretion [...]”.³⁴³ Thus, the ALJ cannot limit the “final initial determination” to only to a single dispositive issue.

Within 14 days after issuing the final ID, the ALJ must issue a “[r]ecommended determination on issues concerning on issues concerning permanent relief and bonding.”³⁴⁴ Often, however, the ALJ issues recommendations on bonding and remedy in the same document as the final ID in a document entitled, “Final Initial and Recommended Determinations.” In the recommended determination, the ALJ will recommend the bond for the Presidential review period; whether an exclusion order, cease and desist order, or both should be entered; and the scope of any such orders.

10.12.3 Review

Section 337 ALJ decisions can potentially go through multiple levels of review: (1) USITC review, (2) Presidential review, and (3) Federal Circuit review.

10.12.3.1 USITC review

Parties have a right under the APA to petition the full USITC for review of an ALJ's ID. The OUII Investigative Attorney also has the right to petition for review. A petition for review may request relief on one or more of the following grounds: (1) that a finding or conclusion of material fact is clearly erroneous; (2) that a legal conclusion is erroneous, without governing precedent, rule or law, or constitutes an abuse of discretion; or (3) that the determination is one affecting USITC policy.³⁴⁵ Only one vote from any participating Commissioner is required to order a review of an ID.³⁴⁶

If the USITC decides to grant review, it issues a notice setting forth the scope and issues it will review. Although the USITC conducts *de novo* review, it generally defers to ALJs with regard to the credibility of witnesses, though it is not obligated under the APA to do so. The USITC also considers “the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States

³⁴² 19 C.F.R. §210.42(a)(1)(i).

³⁴³ 19 C.F.R. §210.42(d).

³⁴⁴ 19 C.F.R. §210.42(a)(1)(ii).

³⁴⁵ See 19 C.F.R. §210.43(b)(1).

³⁴⁶ See 19 C.F.R. §210.43(d)(3).

consumers” in deciding whether to exclude imported products.³⁴⁷ The USITC generally views the protection of intellectual property and grant of an exclusion order to be in the public interest.³⁴⁸

The USITC has the authority to affirm, set aside, or modify any portion of the ID under review. Because of the heavy evidentiary burden required to overturn the ALJ, the USITC usually upholds the ID.

10.12.3.2 Presidential review

If the USITC determines that a violation of Section 337 has occurred and adopts a remedy, then the case is passed to the President of the United States.³⁴⁹ Within a 60-day period, the President may disapprove the USITC order for “policy reasons.”³⁵⁰ In 2005, the President assigned this authority to the United States Trade Representative.³⁵¹ Presidential disapproval of a USITC order is extremely rare and has only occurred six times (most recently in 2013).

During the Presidential review period, respondents may continue to import and sell infringing articles provided the respondent posts a bond with U.S. Customs and Border Protection in an amount determined by the USITC. However, if the President does not disapprove of the USITC’s remedial order, the bond may be forfeited to the complainant.³⁵²

10.12.3.3 Federal Circuit review

A USITC decision “excluding or refusing to exclude articles from entry” that is not vacated by the President is appealable to the Federal Circuit by “[a]ny person adversely affected.”³⁵³ The Federal Circuit can, however, adjudicate USITC dismissals for lack of subject matter jurisdiction and interlocutory orders.³⁵⁴ The Federal Circuit can also review the USITC’s decision to decline to institute an investigation where the claims were precluded by statute (and thus a cognizable claim was not stated), as decisions of this type reach the merits of the complaint and decide whether the complainant can proceed in a Section 337 action.³⁵⁵

In appeals of USITC decisions under Section 337, the USITC is the appellee and defends its decision. Even so, prevailing parties commonly intervene to support the USITC’s final determination on appeal.

10.12.4 Post-final determination proceedings and enforcement of remedy orders

When the USITC issues a Final Determination, it will also order the appropriate remedy, if any, such as an exclusion order, a cease and desist order, or both. If a party has questions or concerns regarding the enforcement of such remedies, the party may pursue a post-final determination proceeding. Respondents in Section 337 proceedings can seek to avoid or circumvent the exclusion order by redesigning the excluded product.

Exclusion orders are implemented and enforced by U.S. Customs and Border Protection.³⁵⁶ The Exclusion Order Enforcement Branch of the Office of Regulations and Rulings within U.S. Customs and Border Protection is in charge of enforcing exclusion orders and disseminating information to enforce such orders to the ports of entry and field offices.

10.12.4.1 Enforcement proceedings

A complainant can seek redress through an enforcement proceeding at the USITC through formal or informal proceedings. Generally, formal proceedings are needed to address violations of exclusion orders. Formal proceedings are initiated by the filing of an enforcement complaint by the complainant, OUII, or the USITC on its own initiative.³⁵⁷ The development of the information

347 19 U.S.C. §1337(d)(1).

348 See *San Huan New Materials High Tech, Inc. v. U.S. Int’l Trade Comm’n*, 161 F.3d 1347 (Fed. Cir. 1998).

349 19 U.S.C. §1337(j)(1).

350 19 U.S.C. §1337(j)(2).

351 Memorandum for the United States Trade Representative: Assignment of Certain Functions Under Section 337 of the Tariff Act of 1930, 70 Fed. Reg. 43,251 (July 21, 2005).

352 19 U.S.C. §1337(j)(3).

353 19 U.S.C. §1337(c).

354 See *Amgen, Inc. v. U.S. Int’l Trade Comm’n*, 902 F.2d 1532, 1537 (Fed. Cir. 1990); see also 28 U.S.C. §1292(c)(1).

355 *Amarin Pharma, Inc. v. U.S. Int’l Trade Comm’n*, 923 F.3d 959, 963 (Fed. Cir. 2019).

356 19 U.S.C. §1337(d)(3).

357 19 C.F.R. §210.75.

and evidence for a formal complaint can require substantial investigation and resources. The formal enforcement proceeding generally will be assigned to an ALJ (usually the same ALJ that handled the original investigation).³⁵⁸ The presiding ALJ will issue an enforcement ID, which will become the decision of the USITC in 45 days if no review is ordered and the period for ordering review is not extended.³⁵⁹ Altogether, the process usually takes more than a year to complete.

As a result of its formal enforcement proceeding, the USITC may modify or revoke its original orders, order a seizure and forfeiture of goods involved in the violation, or, in the case of violations of cease and desist orders, impose monetary sanctions under Section 337(f).³⁶⁰ Further, the USITC may bring a civil action in federal district court, seeking civil penalties or the issuance of mandatory injunctions.³⁶¹

10.12.4.2 Cease and desist orders

Section 337(f)(1) grants the USITC the power to issue cease and desist orders, directed to U.S. companies to prevent the sale of articles that have already entered the United States, “in addition to, or in lieu of,” exclusion orders, subject to certain public interest factors. Final cease and desist orders are enforced by the USITC rather than U.S. Customs and Border Protection, which can assess civil penalties for violation of its orders and can file for injunctive relief in a district court.

If, as part of an enforcement proceeding, the USITC learns that respondents have violated a cease and desist order, the USITC can assess significant penalties (e.g., USD 100,000 or twice the value of the goods, whichever is greater, for each day an order is violated). The USITC may also bring a civil action in federal district court to request a civil penalty or issuance of an injunction. Any penalties for violations of cease and desist orders are payable to the U.S. Treasury, not the complainant.

Penalties for violations of cease and desist orders apply mainly to sales and imports of infringing goods after such orders issue. Although cease and desist orders often prohibit actions such as advertising or marketing infringing goods, relatively few enforcement cases have involved violations of such prohibitions.

10.12.4.3 Modification or revocation of exclusion orders

If changed conditions (in fact, law, or the public interest) require that a remedial order be set aside or modified, any person may file a motion with the USITC requesting such relief.³⁶² The USITC has the discretion to decide whether to rescind or modify previous orders.³⁶³ The petitioner must identify changed conditions of fact or law or changed public interest circumstances warranting rescission.³⁶⁴ Rescission orders typically address a change in the status of the intellectual property covered by a remedial order, changes in party relationships (such as settlement), or a case-dispositive reversal by the Federal Circuit.

If the petitioner was previously found to have violated Section 337 and is requesting either a determination that it is no longer in violation, or a modification or rescission of a remedial order issued pursuant to Section 337(d), (e), (f), (g), or (i), the burden of proof is on the petitioner.³⁶⁵

10.12.4.4 Advisory opinions

Any person can seek a ruling from the USITC as to whether a respondent’s new course of action (e.g., importation of a redesigned or new product) would violate a particular exclusion order. Prior to instituting such an advisory proceeding, the USITC will consider whether the issuance of such an advisory opinion would facilitate Section 337 enforcement, whether the opinion would be in the public interest, whether it would benefit consumers and competitive conditions in the United States, and whether the person has a compelling business need for the advice and has framed the request as fully and accurately as possible.³⁶⁶ The party asserting that a product is outside the scope of a limited exclusion order generally bears the burden of proving that the order does not cover its goods. Advisory proceedings are similar to formal enforcement proceedings, as they

³⁵⁸ See 19 C.F.R. §210.75(a)(3).

³⁵⁹ 19 C.F.R. §210.75(a)(3).

³⁶⁰ 19 U.S.C. §1337(f)(2).

³⁶¹ 19 C.F.R. §210.75(c).

³⁶² 19 U.S.C. §1337(k); 19 C.F.R. §210.76.

³⁶³ See 19 C.F.R. §210.76.

³⁶⁴ 19 C.F.R. §210.76(a)(1).

³⁶⁵ See 19 C.F.R. §210.76(a)(2).

³⁶⁶ 19 C.F.R. §210.79(a).

often involve further discovery and hearings and may be delegated by the USITC to an ALJ. It is not uncommon for enforcement proceedings (or modification and rescission proceedings) and advisory proceedings to be consolidated into a single proceeding. Advisory opinions are unusual and are not appealable.³⁶⁷

10.12.5 Interplay with district court enforcement

Patent holders often seek relief before the USITC and U.S. district courts simultaneously. Section 337 provides, at the request of a party who is a respondent at the USITC and a defendant in the district court, for an automatic stay of the district court proceeding with respect to any claim that involves the same issues. But even though that means that the USITC will typically resolve its handling of the patent claim before the district court proceeds, the USITC resolution is not binding on the district court in patent cases.³⁶⁸ Nonetheless, it can be and often is informative. Furthermore, the USITC litigation can lead to settlement of the parallel district court action. Conversely, prior district court determinations can affect USITC investigations, should the requirements for claim preclusion or issue preclusion be satisfied.

10.12.5.1 Stays

Under 28 U.S.C. § 1659(a), parties to a civil action that are also respondents in a parallel proceeding before the USITC can move for a stay of the district court action as a matter of right:

at the request of a party to the civil action that is also a respondent in the proceeding before the [USITC], the district court shall stay, until the determination of the [USITC] becomes final, proceedings in the civil action with respect to any claim that involves the same issues involved in the proceeding before the [USITC], but only if such request is made within –

- (1) 30 days after the party is named as a respondent in the proceeding before the [USITC], or
- (2) 30 days after the district court action is filed, whichever is later.

The stay remains in effect until the determination of the USITC becomes final. After the dissolution of the stay, 28 U.S.C. § 1659(b) allows the parties to use the USITC investigation record in the stayed district court proceeding. A district court must also decide whether to stay its proceedings as to all of the claims at issue, even if only a few of those claims are involved in a Section 337 investigation.

Thus, despite the statutory mandate of 28 U.S.C. § 1659(a), a respondent may still be required to make out a clear case of hardship or inequity before a stay will be entered. But, where the patent before the district court is a continuation of a patent before the USITC, a court might enter a stay to narrow complex issues and avoid duplicative discovery.

10.12.5.2 Effects of prior district court rulings and prior USITC determination

After the dissolution of a stay, a district court must still decide what deference to afford to a USITC determination. The ALJ and the USITC must similarly determine what standard of deference should be given to a prior district court ruling.

10.12.5.2.1 Claim preclusion at the United States International Trade Commission

The Federal Circuit has declared that, where a claim “which is the basis for the [Section 337] investigation is a claim which would be barred by a prior judgment if asserted in a second infringement suit, that infringement claim may also be barred in a § 1337 proceeding.”³⁶⁹ Thus, prior U.S. district court decisions have a preclusive effect on subsequent Section 337 investigations. That said, preclusion might not exist where the specific product at issue in the

³⁶⁷ *Allied Corp. v. U.S. Int'l Trade Comm'n*, 850 F.2d 1573, 1578 (Fed. Cir. 1988).

³⁶⁸ The USITC's non-patent findings may be entitled to preclusive effect. See, e.g., *Union Mfg Co., Inc. v. Han Baek Trading Co., Ltd*, 763 F.2d 42, 46 (2d Cir. 1985) (concluding that “ITC adjudications of unfair trade practice and trademark infringement causes of action are entitled to res judicata effect.”); *Manitowoc Cranes LLC v. Sany Am. Inc.*, Nos. 13-C-677, 15-C-647, 2017 WL 6327551, at *3 (E.D. Wisc. Dec. 11, 2017) (“[T]he court finds that ITC determinations regarding the unfair trade practices of trade secret misappropriation are entitled to preclusive effect”).

³⁶⁹ *Young Engineers, Inc. v. U.S. Int'l Trade Comm'n*, 721 F.2d 1305, 1316 (Fed. Cir. 1983).

investigation is materially different from the product at issue in the preceding district court litigation.³⁷⁰

10.12.5.2.2 Issue preclusion at the United States International Trade Commission

The general standard for issue preclusion requires the party seeking to foreclose relitigation of an issue to prove that (1) the issue sought to be precluded is identical to the issue decided in the prior action, (2) the issue was actually litigated in that action, (3) the party against whom collateral estoppel is sought had a full and fair opportunity to litigate the issue in the prior action, and (4) the determination was essential to the final judgment of the prior action.³⁷¹ Courts apply the collateral estoppel standard of the regional circuit because issue preclusion is a procedural matter.³⁷²

The AIA specifies several post-grant proceedings that have preclusive impacts on patents at the USITC. A final decision in PGR or IPR bars a petitioner from raising issues that it had raised or could have raised during subsequent USITC, district court, and USPTO proceedings. If the parties settle, however, there is no estoppel effect.

10.12.5.2.3 United States International Trade Commission patent determinations have no res judicata effect on district courts and do not invalidate patents

The Federal Circuit has established that the USITC's determinations on various patent issues (i.e., validity and infringement) are not entitled to preclusive effect in subsequent district court litigation.³⁷³ This holding also encompasses patent-based defenses. When authorizing the USITC to consider patent issues and defenses, Congress made clear that "any disposition of a [USITC] action by a Federal Court should not have a res judicata or collateral estoppel effect in [infringement] cases before such [district] courts."³⁷⁴ Accordingly, "Congress did not intend decisions of the [US]ITC on patent issues to have preclusive effect."³⁷⁵ In practice, however, USITC determinations are often given persuasive, if not binding, weight. If district courts reach different conclusions on the same facts as the USITC, the source of the difference generally must be explained. This may be why relitigation of the issues in district court after a full adjudication in the USITC – though perfectly legal – is rare.

10.13 Selected topics

10.13.1 Standard-essential patents and FRAND licensing enforcement

As a way of aiding the development, adoption, and advancement of a growing range of network technologies, standard-setting organizations (SSOs) bring together engineers from multiple enterprises and universities to develop industry-wide technical standards. Participants in the standard-setting processes commit to making their patented technologies available to others on FRAND terms. Such projects are commonly pursued in the digital technology industries, where they have facilitated joint innovation and product development. For antitrust and other business reasons, these consortia rarely establish licensing rates. In addition, they do not always specify which patents are covered. The emergence of standard-essential patents (SEPs) and related contractual commitments to license such patents on FRAND terms over the past decade has spawned a complex set of patent-related cases with distinctive case management aspects.

10.13.1.1 FRAND rate-setting litigation

Standards implementers who have not been able to work out a licensing agreement with SEP owners can file declaratory judgment breach of contract actions asserting that the SEP owners have breached their FRAND obligations by not offering the implementers FRAND licensing rates.³⁷⁶ The implementers have standing to bring such actions as third-party beneficiaries of the SEP consortium. The SEP owner will typically counterclaim for patent infringement. The

370 See *Foster v. Hallco Mfg. Co.*, 947 F.2d 469 (Fed. Cir. 1991).

371 See *Innovad Inc. v. Microsoft Corp.*, 260 F.3d 1326, 1334 (Fed. Cir. 2001) (citing *In re Freeman*, 30 F.3d 1459, 1465 (Fed. Cir. 1994)).

372 See *RF Del., Inc. v. Pacific Keystone Tech., Inc.*, 326 F.3d 1255, 1261 (Fed. Cir. 2003).

373 See *Texas Instruments, Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1568–69 (Fed. Cir. 1996).

374 S. Rep. No. 1298, 93rd Cong., 2d Sess. 196 (1974).

375 *Texas Instruments*, 90 F.3d at 1569.

376 See *Microsoft Corp. v. Motorola Inc.*, No. C10–1823-JLR, 2013 U.S. Dist. LEXIS 60233 (W.D. Wash. April 25, 2013), *aff'd*, 795 F.3d 1024 (9th Cir. 2015) (setting worldwide royalty rates for wireless and video compression SEPs); *In re Innovatio IP Ventures*, 2013 U.S. Dist. LEXIS 144061 (N.D. Ill. Sept 27, 2013).

counterclaim brings the litigation within the appellate purview of the Federal Circuit, although it is obliged to apply regional circuit contract law. If no patent counterclaim is asserted, the contract-based cause of action is reviewable in the regional circuit court covering the district court handling the litigation.

10.13.1.2 Anti-suit injunction litigation

Global battles over SEPs and FRAND rate-setting have international forum shopping. Companies have sought to establish global FRAND rates by seeking so-called anti-suit injunctions barring a defendant from commencing or requiring that they cease to pursue parallel litigation regarding the FRAND dispute.

Thus far, U.S. courts have resisted efforts to impose such restraints on U.S. litigation. Several months after Microsoft filed a declaratory relief action against Motorola seeking to set a worldwide FRAND rate for two SEPs, Motorola filed an action in Germany alleging that Microsoft infringed German patents covered by the same contractual FRAND commitments at issue in the U.S. case. After the German court issued an injunction prohibiting Microsoft from infringing Motorola's German patents, the U.S. district court prohibited Motorola from enforcing that injunction.³⁷⁷ The district court reasoned that the FRAND commitment required Motorola to license its SEPs on a "worldwide basis." Since the U.S. court was charged with determining the parties' worldwide rights, it was also responsible for deciding whether injunctive relief was allowed under the FRAND agreement. The court concluded that enforcing the German injunction would frustrate the district court's ability to adjudicate the issues properly before it.

In another controversy, a U.S. court repelled an effort by a foreign court to enjoin U.S. patent enforcement and rate-setting.³⁷⁸ After negotiations between Samsung and Ericsson over the renewal of their global patent cross-licensing agreement broke down in 2020, Samsung filed a suit in China asking the court to determine the global licensing terms in accordance with the applicable FRAND agreement. Samsung neglected to provide notice to Ericsson of the Chinese action. Upon learning of the filing, Ericsson filed a parallel action in the Eastern District of Texas on December 11, 2020. Three days later, Samsung requested the Chinese court to issue an anti-suit injunction, which the Chinese court granted on December 25, 2020. On December 28, 2020, Ericsson sought a TRO in the Eastern District of Texas prohibiting Samsung from enforcing the anti-suit injunction issued by the Chinese court. Concluding that the anti-suit injunction would be vexatious or oppressive, the Eastern District of Texas granted Ericsson's request for an anti-anti-suit (or anti-interference) injunction to prevent Samsung from attempting to enforce the Chinese anti-suit injunction and thereby interfering with the Eastern District of Texas's exercise of its own jurisdiction.³⁷⁹

10.13.2 Pharmaceutical patent case management

The interplay of the regulation of pharmaceutical products by the FDA and litigation related to those products creates a distinctive patent case management regime for pharmaceutical patent cases. The differences arise primarily from the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 (known as the Hatch-Waxman Act). In the Hatch-Waxman Act, Congress sought to streamline two related processes: (1) FDA marketing approval of generic small molecule pharmaceutical products, and (2) competition between generic drug manufacturers and pioneering drug manufacturers over the marketed small molecule drugs.

The Hatch-Waxman Act covers drug products with small molecule active ingredients. In 2010, Congress supplemented this legislation with the BPCIA to provide a similar litigation scheme to expedite the entry of generic versions of larger molecule, "biologic" drug products (called "biosimilars").

10.13.2.1 Hatch-Waxman Act (ANDA) litigation

To understand pharmaceutical patent case management, it is important to begin with a description of the Hatch-Waxman statutory framework. We will then explore how this regime

³⁷⁷ *Microsoft Corp. v. Motorola, Inc.*, 871 F. Supp. 2d 1089 (W.D. Wash. 2012), *aff'd*, 696 F.3d 872 (9th Cir. 2012).

³⁷⁸ See *Ericsson, Inc. v. Samsung Elecs. Co.*, No. 2:20-CV-00380-JRG, 2021 WL 89980 (E.D. Tex. Jan. 11, 2021).

³⁷⁹ See *Ericsson, Inc.*, No. 2:20-CV-00380-JRG, 2021 WL 89980.

structures patent infringement litigation, the distinctive patent case management elements, and the unique competition issues that arise from settlement of such cases.

10.13.2.1.1 The Hatch-Waxman Act’s statutory framework

Prior to the passage of the Hatch-Waxman Act, a generic drug manufacturer had to obtain FDA marketing approval for its generic product before challenging patents encompassing a pioneering drug product. Obtaining this marketing approval required generic companies to generate data and complete clinical trials on their generic products, but there was little incentive for these companies to do so because, typically, they could not obtain patent protection for their products. The FDA approval process extended the effective term of patents encompassing a pioneering drug product for several years after the expiration of the patents, as generic companies had to manufacture or sell their generic drug products to create the basis for federal jurisdiction to adjudicate the validity, enforceability, and scope of the patents covering the pioneering drug.

The Hatch-Waxman Act established a framework to coordinate both FDA approval and adjudication of patent rights for generic versions of pioneering drugs covered by patents.³⁸⁰ In particular, the Hatch-Waxman Act provides a route for expediting litigation of patent validity and infringement issues related to generic drugs, thereby aiding generic drug manufacturers in marketing their noninfringing drug products sooner (and aiding consumers in obtaining cheaper drug products where patent protection does not block such marketing).

Table 10.5 shows the key dates and steps for Hatch-Waxman litigation.

Table 10.5 Key dates in Hatch-Waxman litigation

Timeline	Hatch-Waxman stage	Step
The FDA accepts generic’s ANDA for review	Trigger litigation	The generic company’s ANDA must be accepted for review before litigation can commence.
Within 20 days	Paragraph IV notice letter	Generic provides NDA holder with notice that it has filed a Paragraph IV certification, detailed statement(s). ¹
Within 45 days	Filing of complaint	NDA holder must file complaint within 45 days of receipt of Paragraph IV notice letter to receive an automatic 30-month stay of FDA approval for the generic product. ²
30 months after filing of complaint	30-month stay of FDA approval of ANDA expires	30-month stay of FDA approval expires if stay has not already been lifted due to completion of litigation. ³ If litigation is still pending, once ANDA is approved, generic can launch its product at risk.
After FDA approval of first filer’s ANDA	180-day marketing exclusivity	If patent challenge succeeds, first ANDA filer enjoys 180 days of marketing exclusivity.

Note: FDA = Food and Drug Administration; ANDA = Abbreviated New Drug Application; NDA = New Drug Application.

¹ 21 U.S.C. § 355(j)(2)(B)(iv)(II); see 21 C.F.R. 314.95(c)(6).

² 21 U.S.C. § 355(j)(5)(B)(iii).

³ 21 U.S.C. § 355(j)(5)(B)(iv).

10.13.2.1.2 Submission of NDAs (pioneering) and ANDAs (generic) to the FDA

Prior to marketing a new drug, a pioneering pharmaceutical company must submit a new drug application (NDA) to the FDA. The NDA must demonstrate the safety and efficacy of the proposed drug, usually through extensive testing data from a series of human clinical trials.³⁸¹

One of the key features of the Hatch-Waxman Act is that generic drug companies can enter the market at the earliest possible time through a potentially shortened and cheaper regulatory approval process for generic drugs. The ANDA applicant (i.e., the generic competitor) is not required to conduct independent human clinical trials or other testing to establish the safety and efficacy of its product; instead, it must demonstrate that its product is “bioequivalent” to the pioneering drug.³⁸² The testing required to demonstrate bioequivalence is usually significantly less onerous and expensive than that required to demonstrate safety and efficacy of a new drug.

380 See 21 U.S.C. §355(j).

381 21 U.S.C. §355(b).

382 21 U.S.C. §355(j)(2)(A).

10.13.2.1.3 Obtaining patent certainty: ANDAs and Paragraph IV certifications

Before the FDA will approve an ANDA, the ANDA filer must demonstrate that its generic drug will not infringe valid patents covering the equivalent pioneering drug. To facilitate this, the Hatch-Waxman Act requires that a pioneering drug company's NDA must disclose all patents that cover the drug or a method of using the drug in a manner encompassed by the NDA.³⁸³

Under the Hatch-Waxman Act, ANDA filers are required to make particular certifications with respect to each patent listed in the Orange Book that covers a pioneering drug product. Specifically, the ANDA filer must certify one of the following for each Orange Book-listed patent:

- (i) that the [NDA-required] patent information has not been filed;
- (ii) that such patent has expired;
- (iii) the date on which such patent will expire; or
- (iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the [ANDA] is submitted.³⁸⁴

The final certification listed above, that an Orange Book-listed patent is invalid or not infringed, is commonly known as a "Paragraph IV certification." To support a Paragraph IV certification, the ANDA filer must provide to the NDA holder "a detailed statement of the factual and legal basis for the opinion of the applicant that the patent is invalid or will not be infringed" or is unenforceable to both the patent owner and the NDA holder.³⁸⁵ A Paragraph IV certification is the only mechanism by which an ANDA filer can obtain FDA approval to market a generic version of a listed drug for a patented use prior to expiration or invalidation of an Orange Book-listed patent.³⁸⁶

10.13.2.1.4 Patent infringement suits under the Hatch-Waxman Act

One of the most important and innovative features of the Hatch-Waxman Act is the way that it facilitates resolution over patent rights of drug patents.

10.13.2.1.4.1 Filing of an ANDA that challenges an NDA holder's patent rights is a statutorily-created act of infringement conferring jurisdiction to sue

The Hatch-Waxman Act provides for the resolution of pioneering drug patent rights by treating the act of filing an ANDA that challenges an NDA holder's patent rights as a statutorily-created act of infringement that "enables the judicial adjudication" of claims for infringement and patent invalidity even though the generic company has not actually marketed its generic product.³⁸⁷

Filing of an ANDA with a Paragraph IV certification thus allows the NDA holder to initiate an infringement suit before the generic manufacturer sells its drug product.³⁸⁸

The filing of an ANDA establishes jurisdiction in district court for a patent litigation under 35 U.S.C. § 271(e), but the act of filing the ANDA itself does not mean that the generic product described in the ANDA will actually infringe one or more of the listed patents once sold. The NDA holder bears the burden to establish actual infringement of the patent claims at issue.³⁸⁹ In some cases, the drug described in the ANDA will meet every claim limitation at issue but, where the ANDA's description does not establish infringement, the Federal Circuit has endorsed the use of evidence such as testing of the final generic product that complies with the description in the ANDA (in *Ferring*, tests submitted to the FDA).³⁹⁰

10.13.2.1.4.2 Timing considerations for litigation and stays

Hatch-Waxman litigation differs from the other types of patent litigation previously discussed in that an action of the defendant to the suit – the filing of an ANDA by the generic drug company – triggers the litigation and dictates the timing of the lawsuit. To trigger this process, the ANDA filer is required to notify the NDA holder that it has filed a Paragraph IV certification within 20 days after the FDA accepts the ANDA for review. Typically, this notice takes the form of a letter (a Paragraph IV notice letter) in which the ANDA filer sets forth the detailed statement of the

383 21 U.S.C. §355(b)(1), (c)(2).

384 21 U.S.C. §355(j)(2)(A)(vii); see *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 677 (1990).

385 21 U.S.C. §355(j)(2)(B)(iv)(II); see 21 C.F.R. 314.95(c)(6).

386 *Eli Lilly*, 496 U.S. at 677.

387 *Eli Lilly*, 496 U.S. at 678; see also 35 U.S.C. §271(e)(2)(A).

388 35 U.S.C. §271(e)(2); *AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1377 (Fed. Cir. 2012); *Glaxo Grp. Ltd v. Apotex, Inc.*, 376 F.3d 1339, 1351 (Fed. Cir. 2004).

389 See *Ferring B.V. v. Watson Labs., Inc.*, 764 F.3d 1401 (Fed. Cir. 2014).

390 *Ferring B.V.*, 764 F.3d at 1408–09.

generic company's basis for believing that the Orange Book-listed patents are invalid or not infringed. The NDA holder's receipt of the Paragraph IV notice letter begins a 45-day period in which the NDA holder evaluates the claims and decides whether to file suit against the ANDA filer. If the NDA holder files an infringement action within this 45-day period, then the FDA may not grant final approval of the generic company's ANDA for 30 months, or until the case is finally resolved. The FDA may grant "tentative" approval of an ANDA during this 30-month stay period, but such approval does not become "final" (and thus allow for actual marketing of the generic drug) unless, prior to the end of the 30-month period, all relevant patents expire, the ANDA filer receives a favorable district court or Federal Circuit judgment, or the parties settle the lawsuit and agree that the ANDA filer's marketing of its generic drug product can begin.³⁹¹

When litigation extends beyond the 30-month stay, the ANDA holder may elect to launch their competing generic product "at-risk," even though it risks infringement of the drug patent(s). To prevent an at-risk launch, the NDA holder will often request a preliminary injunction. The prospect of launching at-risk changes the nature of an ANDA case, because post-launch damages will be available to the NDA holder, and the eventual trial could occur before a jury (as opposed to most ANDA cases, which are tried before a judge).

10.13.2.1.4.3 First ANDA filer's 180-day exclusive marketing period

The Hatch-Waxman Act provides a significant incentive to generic drug manufacturers to challenge applicable patents held by the NDA holder: if the patent challenge succeeds, the first ANDA filer receives a 180-day market exclusivity period following FDA approval of the ANDA. During this period, only the first ANDA filer, the NDA holder, and companies licensed by the NDA holder may market their competitor drugs, and later-filed ANDAs cannot be finally approved until this exclusivity period has ended.³⁹²

For ANDAs filed after December 8, 2003, the first Paragraph IV ANDA filer's marketing of its generic drug product is the only required trigger for the exclusivity period.³⁹³

10.13.2.1.4.4 Available remedies in ANDA litigation

Suits under the Hatch-Waxman Act usually do not involve damages.³⁹⁴ Thus, there is typically no right to a jury trial.³⁹⁵ Where an ANDA filer elects to launch at-risk after the 30-month stay has elapsed but before the litigation has concluded, damages may be available to the NDA holder (and the case can be tried before a jury).

In many circumstances, courts may only provide a declaratory judgment at the conclusion of a Hatch-Waxman litigation. Where the NDA holder wins and the patent is declared valid and infringed, the FDA will not grant final approval to the ANDA until the patent expires. If the district court judgment comes after the expiration of the 30-month stay and the ANDA filer has begun marketing its drug in an at-risk launch, the FDA will revoke its final approval, which precludes further sales. Although the FDA's revocation of the ANDA's final approval precludes the sale of the ANDA filer's drug, some courts will also grant an injunction.³⁹⁶

Where the ANDA applicant wins the district court case, the remaining portion of the 30-month stay is terminated upon entry of the judgment and, typically, the FDA will convert its tentative approval of the ANDA to a final approval, allowing the drug to be marketed.³⁹⁷ Where the ANDA filer begins marketing after receiving FDA approval at the end of a 30-month stay before a district court judgment has been rendered, and the district court subsequently finds infringement of a valid patent, injunctive relief and damages apply. The same is true where the Federal Circuit reverses the district court judgment after the ANDA filer has begun marketing its drug.

391 21 U.S.C. §355(j)(5)(B)(iii). If no infringement action is filed during the 45-day period after the ANDA filer provides notice of its filing, the FDA may approve the ANDA within 180 days after the ANDA was filed (a period which is often extended by agreement between FDA and ANDA filer), and the approval is immediately effective. 21 U.S.C. §355(j)(5)(A), (B)(iii).

392 21 U.S.C. §§355(j)(5)(B)(iv), (j)(5)(B)(iv)(II)(bb).

393 21 U.S.C. §355(j)(5)(B)(iv).

394 See 21 U.S.C. §271(e)(4)(C); §355(j)(5)(c)(iii).

395 See *Tegal Corp. v. Tokyo Electron Am. Inc.*, 257 F.3d 1331, 1339–41 (Fed. Cir. 2001).

396 See, e.g., *Sanofi-Synthelabo v. Apotex Inc.*, 294 F. Supp. 2d 353, 397 (S.D.N.Y. 2007), *aff'd*, 5590 F.3d 1075 (Fed. Cir. 2008), *cert. denied*, 130 S. Ct. 493 (2009).

397 21 U.S.C. §355(j)(5)(B)(iii)(I)(aa).

10.13.2.1.5 Case management considerations for Hatch-Waxman litigation

Beyond the distinctive posture and structuring of ANDA patent litigation, courts deal with a variety of case management decisions ranging from personal jurisdiction and venue to scheduling and trial management.

10.13.2.1.5.1 Personal jurisdiction and venue in Hatch-Waxman cases

The relevant personal jurisdiction and venue considerations in Hatch-Waxman cases differ from those present in other types of patent litigation, as the act of infringement that triggers the jurisdictional and venue question are tied to the *planned future acts* of the generic filer, not already-committed acts of infringement.

On personal jurisdiction, the Federal Circuit has ruled that submission of an ANDA with the intention to direct sales of a generic drug into a particular state provides sufficient minimum contacts to give rise to specific personal jurisdiction.³⁹⁸ Under this ruling, a generic drug manufacturer is subject to specific personal jurisdiction in any state in which it intends to market its generic drug.

The significance of this holding was restricted significantly in light of the Supreme Court's ruling in *TC Heartland LLC v. Kraft Foods Group Brands LLC*³⁹⁹ and later decisions from the Federal Circuit on venue in ANDA cases. *TC Heartland* reaffirmed that 28 U.S.C. § 1400(b) is the sole provision controlling venue in patent infringement actions. Thus, venue is proper for a generic drug manufacturer sued for patent infringement in two sets of judicial districts: (1) districts in the state of the generic manufacturer's incorporation, and (2) districts in which (a) the corporation has a regular and established place of business and (b) an act of infringement has occurred (see Section 10.6.3).

As the "act of infringement" in ANDA cases is the submission of the ANDA, which occurs before marketing or sale of the generic drug, the Federal Circuit has clarified that venue in ANDA cases "must be predicated on past acts of infringement – *i.e.*, acts that occurred before the action alleging infringement was filed [...]. It is the submission of the ANDA, and only the submission, that constitutes an act of infringement in this context."⁴⁰⁰ The Federal Circuit functionally limited the personal jurisdiction holding of *Acorda* by limiting the number of venues in which the suit could be brought under the venue analysis, making clear that venue does not extend to districts solely where the future marketing of the generic product described in the ANDA may be intended, which was permissible from a jurisdiction perspective under the earlier *Acorda* decision.⁴⁰¹ *Valeant* did not foreclose establishing venue at the generic filer's place of incorporation, nor did this decision disturb precedent as to establishing venue where a generic filer has its principal place of business.⁴⁰²

Historically, the majority of ANDA cases have been filed in New Jersey or Delaware, as a large number of generic manufacturers are incorporated in Delaware or have a regular and established place of business in New Jersey. Plaintiffs in multi-defendant ANDA cases often seek to consolidate the various cases into a single jurisdiction, largely for efficiency, the convenience of parties and witnesses, and judicial economy purposes. Plaintiffs often will file protective suits in multiple jurisdictions while attempting to consolidate the litigation. Plaintiffs may seek consolidation through several potential mechanisms, including where defendants consent to jurisdiction and venue in a district, and through the Judicial Panel on Multidistrict Litigation, which consolidates two or more cases for pre-trial proceedings where there are common questions of fact. Foreign ANDA filers may be sued in any judicial district.⁴⁰³

10.13.2.1.5.2 Scheduling considerations and timing of judgment

The parties to a Hatch-Waxman litigation usually have more information available to them at the start of a case than is typical in a patent suit because of the ANDA filer's required disclosures in

398 See *Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755, 760–64 (Fed. Cir. 2016).

399 137 S. Ct. 1514 (2017).

400 *Valeant Pharm. N. Am. LLC v. Mylan Pharms.*, 978 F.3d 1374, 1381 (Fed. Cir. 2020).

401 See *Valeant*, 978 F.3d. at 1381–83.

402 *Valeant* analyzes where "acts of infringement" occur in Hatch-Waxman litigation, based on filing of an ANDA before launch of the generic drug product. As the same type of statutorily-created act of infringement (filing of the biosimilar company's abbreviated biologics license application [aBLA]) triggers BPCIA litigation, the reasoning in this case may apply to venue determinations in BPCIA cases as well.

403 28 U.S.C. §1391(c)(3); see also *In re HTC Corp.*, 889 F.3d 1349, 1358 (Fed. Cir. 2018).

the Paragraph IV certification, which enumerate the factual and legal basis for its invalidity, unenforceability, and/or noninfringement opinions.⁴⁰⁴ Further, NDA holders have had notice of the ANDA holder's contentions, usually for 45 days before filing suit. Given these early disclosures and notice, courts can encourage quicker resolution of cases and issues by setting expedited case schedules and by requiring the early exchange of invalidity and noninfringement positions. This is important from a case management perspective because NDA holders have strong motivation to delay resolution until after the 30-month stay expires, to delay market entry of the first ANDA filer (as well as subsequent ANDA filers) and extend the NDA holder's monopoly. First ANDA filers may not oppose this delay in some situations, as the ANDA filer will want to delay the start of any exclusivity period it enjoys until it is prepared to market its drug. Subsequent ANDA filers, conversely, nearly always want a speedy resolution of litigation, so that they can enter the market more quickly. In a litigation between an NDA holder and the first ANDA filer, both parties may be uninterested in early resolution, and the court will need to manage the litigation accordingly.

Courts can also directly combat attempts by the parties to delay litigation. The Hatch-Waxman Act explicitly grants courts the discretion to adjust the 30-month stay period based on the parties' conduct during litigation, although this is uncommon.⁴⁰⁵

10.13.2.1.5.3 Order of case presentation at trial

Although the patent owner typically is the plaintiff in an ANDA case, the generic drug company defendant will often bear the burden of proof because ANDA cases typically focus on the invalidity or unenforceability of the patent owner's patents rather than the generic company's noninfringement of the patents in suit. As noted above, the ANDA applicant's generic drug and associated label must be identical to the NDA holder's drug and label and, thus, a patent that covers the NDA holder's drug likely also covers the ANDA drug product. In cases where invalidity, unenforceability, or both are the sole issues in a suit, courts typically reverse the order of proof at trial.

10.13.2.1.5.4 Local patent rules and scheduling orders in ANDA cases

As discussed in Section 10.6.6.1, numerous district courts with significant patent dockets have developed specialized local rules (i.e., PLRs) to facilitate early case management of patent cases. Several courts have adopted PLRs specific to Hatch-Waxman litigation.⁴⁰⁶ Generally, these rules recognize that Hatch-Waxman litigants possess different levels of knowledge early in the case, and therefore reverse the typical order and timing for the disclosure of infringement and invalidity contentions. The plaintiff in a Hatch-Waxman action may have very little knowledge about the defendant's generic drug, beyond what must be included in the Paragraph IV certification (the generic is bioequivalent, has the same dosage, and uses the same route of administration). Conversely, the defendant in a Hatch-Waxman case has controlled the timing and scope of litigation through its ANDA filing and has already prepared a "detailed statement of the factual and legal basis for the opinion of the applicant that the patent is invalid or will not be infringed" or is unenforceable, as part of its Paragraph IV certification.⁴⁰⁷ As such, ANDA local patent rules typically require the defendant to provide its invalidity contentions first.⁴⁰⁸ The local patent rules in New Jersey require the ANDA defendant to provide any noninfringement contentions at the same time as disclosure of the invalidity contentions;⁴⁰⁹ the plaintiff is required to provide its infringement contentions 45 days later.⁴¹⁰ In addition, New Jersey Local Patent Rule 3.6(j) amends the disclosure requirements for Hatch-Waxman cases. Parties with pending ANDAs that form the basis for a litigation must notify the FDA of motions for injunctive relief no later than three business days after filing the motion. These parties must also provide a copy of correspondence between the FDA and any party regarding the ANDA to each party bringing an infringement claim, or they must "set forth the basis of any claim of privilege" for the correspondence, no later than seven days after receiving or sending correspondence. This rule is intended to aid in the coordination of FDA proceedings and district court litigation, and to avoid discovery issues about the production of FDA correspondence during litigation proceedings.

⁴⁰⁴ 21 U.S.C. §355(j)(2)(B)(iv)(II); 21 C.F.R. §314.95(c)(6).

⁴⁰⁵ 21 U.S.C. §355(j)(5)(B)(iii).

⁴⁰⁶ See, e.g., D.N.J. L. Pat. R. 3.6; E.D. Tex. P. R. 3–8.

⁴⁰⁷ See 21 U.S.C. §355(j)(2)(B)(iv)(II); 21 C.F.R. §314.95(c)(6).

⁴⁰⁸ See D.N.J. L. Pat. R. 3.6.

⁴⁰⁹ D.N.J. L. Pat. R. 3.6.

⁴¹⁰ D.N.J. L. Pat. R. 3.6.

Apart from these changes in the disclosure order and times, ANDA cases are subject to the remaining local patent rules in New Jersey. The ANDA rules, for example, are silent with regard to the order of proof at trial.

The District of Delaware has not adopted district-wide local patent rules; instead, each judge has developed specific practices to manage patent cases, although some judges have ANDA-specific scheduling orders. Generally, in Delaware, plaintiffs file infringement contentions, while defendants file invalidity contentions. Responses to these contentions are issued through interrogatories. Summary judgment motions are generally not permitted in ANDA cases in Delaware absent agreement between the parties or leave from the court.

10.13.2.1.6 Settlement of Hatch-Waxman lawsuits: antitrust constraints

The relative risk assessment for parties engaged in Hatch-Waxman litigation differs significantly from that in other patent cases. Although the NDA holder benefits from the 30-month stay on FDA approval of the ANDA through litigation, the NDA holder faces the risk of having its patents invalidated in litigation, yet it usually cannot seek damages because the generic company has not sold a competing drug product. ANDA holders, conversely, can benefit greatly from litigation if they can enter the market before the expiration of the Orange Book-listed patents with a period of market exclusivity and, even in the worst-case scenario, are no worse off than they were before litigation (except for the cost of the litigation itself).

In addition, both NDA filers and first ANDA filers have economic incentives to settle litigation in ways that may delay consumer access to cheaper generic drugs. NDA filers may seek to avoid the first ANDA filer's market entry, both to delay market entry by all later-filing generics (by delaying the start of the first filer's 180-day exclusivity period) and to avoid the risk of a finding of patent invalidation or noninfringement in litigation. And, if a first ANDA filer is not prepared to market its proposed product, it may also favor delay of market entry so that it can take advantage of the full 180-day exclusivity period.

In light of these incentives, in the 1990s, NDA holders and first ANDA filers began entering into "reverse payment" or "pay for delay" settlements – in these settlements, the NDA filer makes a payment of cash or other incentives to the first ANDA filer, in exchange for the ANDA filer's promise to not enter the market for a negotiated period of time. Reverse payment settlements allow the NDA holder to guarantee market exclusivity for a period of time, regardless of the merits of the patents-in-suit. And, the first ANDA filer also wins, as it receives payment to delay its entry onto the market yet still retains the 180-day exclusivity period once it enters the market. Entry of later-filed ANDA holders onto the market is also delayed by these settlements, which in effect extend the period of exclusivity for the NDA holder.

In 2013, the Supreme Court found that reverse payment settlements were not always presumptively unlawful but may be anticompetitive in some circumstances.⁴¹¹ The Court ordered lower courts to apply a modified "rule-of-reason" antitrust analysis to determine whether specific settlements were, in fact, anticompetitive, where the plaintiff must show that the reverse payment settlement is intended to restrain or harm competition, that an actual injury to competition has occurred, and that the restraint or harm from the agreement is "unreasonable."⁴¹²

Since *Actavis*, both plaintiffs' groups and the U.S. Federal Trade Commission have actively challenged various reverse payment settlements as anticompetitive in the lower courts. In addition, the antitrust law of U.S. states can also be applied to analyze reverse payment settlements. California has been active in this space, passing Assembly Bill 824 in 2019, a law which explicitly prohibits reverse payment settlements. In December 2021, the Eastern District of California preliminarily enjoined the enforcement of Assembly Bill 824 on the ground that the legislation discriminates against or excessively burdens interstate commerce.⁴¹³

411 See *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

412 See *California Dental Ass'n v. FTC*, 224 F.3d 942, 947 (9th Cir. 2000).

413 *Ass'n for Accessible Meds. v. Bonta*, No. 2:20-cv-01708-TLN-DB, D.I. 42 (E.D. Cal. Dec. 9, 2021). Although we focus here on applications of antitrust law to Hatch-Waxman litigation, the antitrust laws may be implicated in settlements of litigation under the BPCIA. See, e.g., *In re Humira (Adalimumab) Antitrust Litig.*, 465 F. Supp. 3d 811 (N.D. Ill. 2020) aff'd, *Mayor & City Council of Baltimore v. Abbvie, Inc.*, 42 F.4th 709 (7th Cir. 2022) (affirming dismissal of purchaser's antitrust claims).

10.13.2.2 BPCIA litigation

The Hatch-Waxman Act governs the regulation and patent litigation related to small molecule drugs, typically synthesized from chemicals in a laboratory. Many drugs sold on the market today, however, are instead produced by living cells that have been genetically engineered to manufacture the drug or extracted from those cells. These drugs are called “biological products” or biologic drugs, and “generic” versions of these products are called “biosimilars.”⁴¹⁴ A “biosimilar” is a biological product that is “highly similar to the reference product notwithstanding minor differences in clinically inactive components” and for which “there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.”⁴¹⁵ A biosimilar product exists only in relation to a “reference product” (manufactured by a “reference product sponsor” [RPS]), an already-approved biological product against which the biosimilar is evaluated by the FDA.⁴¹⁶

The development of biosimilar products requires the investment of significantly more resources than the development of small molecule generic drug products. Biosimilar applicants typically must provide data from large clinical trials to compare the efficacy of the biosimilar product to the reference product. These trials typically cost orders of magnitude more to conduct than the bioequivalence trials required for ANDA applicants. In addition, the cost and technical difficulty associated with manufacturing biological drug products (and their biosimilar competitors) are also substantially greater than those for generic small molecule drugs.

Until 2010 and the passage of the BPCIA, there was no mechanism for the FDA to approve biosimilar drug products seeking to compete with reference products. The BPCIA provides “processes both for obtaining FDA approval of biosimilars and for resolving patent disputes between manufacturers of licensed biologics and manufacturers of biosimilars.”⁴¹⁷ The Supreme Court has recognized that this statutory scheme creating these regulatory and litigation processes is “complex.”⁴¹⁸

The expense and other technical challenges in developing biosimilar products shape U.S. biosimilar litigation in several ways. In particular, the costs involved in biosimilar development have meant that there are no “small” biosimilar cases – typically, only products that generate billions of dollars in sales are the subject of litigation. Given these stakes, the parties are heavily motivated to dispute all potential issues in the case, which heavily burdens the court’s resources.

10.13.2.2.1 Food and Drug Administration application pathway and exclusivities for biosimilars

As with regulatory approvals under the Hatch-Waxman Act, the regulatory pathway for approval of biosimilar applications under the BPCIA has a significant impact on the course of patent litigation that occur under the statute. To obtain marketing approval for a biologic drug product, a pioneering company submits a biologic license application (BLA) with the FDA, analogous to the filing of an NDA in the Hatch-Waxman context. The BLA typically contains extensive data demonstrating that the proposed product is “safe, pure, and potent,” among other requirements.⁴¹⁹ After approval of the pioneering company’s BLA, the approved drug is referred to as the “reference product” for purposes of subsequent biosimilar filings.

The BPCIA outlines an abbreviated route for FDA approval of biosimilar products. Under this route, the biosimilar manufacturer files an abbreviated biologic license application (aBLA) with the FDA. Applicants for aBLAs are permitted to rely on the approval of the reference product’s BLA (and the clinical trial data therein, demonstrating safety, purity, and potency), so long as the biosimilar manufacturer demonstrates that its product is “highly similar” to the reference product and that there are no “clinically meaningful differences” between the two in terms of safety, purity, and potency.⁴²⁰ Biosimilar manufacturers with products approved as “biosimilar” are not entitled to exclusivity as against other biosimilar manufacturers under the BPCIA.

414 42 U.S.C. §262(i)(1).

415 42 U.S.C. §262(i)(2).

416 See 42 U.S.C. §262(i)(4).

417 *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1669 (2017).

418 *Sandoz*, 137 S. Ct. at 1669.

419 42 U.S.C. §262(a)(2)(C)(i)(I).

420 42 U.S.C. §262(i)(2)(A), (B); see also 42 U.S.C. §262(k)(2)(A)(i)(I). The statutory scheme also contemplates the approval of biologic drugs that are “interchangeable” with the reference product. 42 U.S.C. §262(k)(4). An interchangeable biologic product must be (1) biosimilar and (2) expected to produce the same clinical result as the reference product in any given patient. In addition, if the product is to be administered more than once, there must be no greater risk in terms of safety or diminished efficacy in switching between the reference product and the product under examination than there is in

10.13.2.2.2 Overview of BPCIA litigation procedures

RPSs typically hold multiple patents covering the biologic drug itself, use of that drug for medical treatment, and the drug's manufacturing processes. The BPCIA provides a framework for patent litigation related to these patents prior to the biosimilar's FDA approval, even if the biosimilar applicant has not yet taken an action that would traditionally constitute patent infringement, by making the submission of the aBLA an act of infringement.⁴²¹

The BPCIA statute outlines several stages of pre-litigation exchanges (often called the "patent dance"), intended to force the parties to develop and test their contentions early, and to identify critical issues prior to litigation. First, the biosimilar applicant provides its application and information on its manufacturing process to the RPS (subject to default statutory confidentiality provisions). The parties then engage in detailed exchanges related to patents that may cover the biosimilar product, identifying the parties' contentions as to the infringement, validity, and enforceability of these patents. The parties then identify a set of patents for a first phase of litigation – any remaining patents may be litigated in a second phase of litigation. These exchanges dictate the timing of the litigation and, as explained further below, the remedies that the RPS may seek.

The Federal Circuit has held that the BPCIA's prelitigation procedures are not mandatory, however.⁴²² Therefore, the biosimilar applicant can decline to participate in these exchanges. If the biosimilar applicant declines to participate, however, the RPS may immediately bring an infringement suit against the biosimilar applicant.⁴²³

Tables 10.6–10.8 outline these steps of BPCIA patent litigation in further detail.

Table 10.6 Steps for the first phase of BPCIA litigation ("patent dance")

Timeline	Who acts?	Step(s)
	The FDA	The FDA accepts the biosimilar's aBLA for review.
Within 20 days	Biosimilar applicant	The biosimilar applicant provides the aBLA and manufacturing information to the RPS. ¹
Within 60 days	RPS	The RPS discloses a list of patents that it may assert in litigation to the biosimilar applicant and identifies which patents it is willing to license to the applicant. ²
Within 60 days	Biosimilar applicant	The biosimilar applicant discloses a list of other patents it believes should be included in litigation to the RPS, and identifies which patents it is willing to license. For each listed patent, the biosimilar applicant must provide a detailed statement or indicate it does not intend to market the biosimilar before expiration. ³
Within 60 days	RPS	The RPS responds to the biosimilar applicant's detailed statement(s). ⁴
	Both the RPS and the biosimilar applicant	Parties begin negotiation on a list of patents for immediate infringement action. ⁵

Note: FDA = Food and Drug Administration; aBLA = abbreviated biologic license application; RPS = reference product sponsor. Timeline is from the date the aBLA is accepted for review.

¹ 42 U.S.C. § 262(l)(2).

² 42 U.S.C. § 262(l)(3)(A). Throughout this process, the reference product sponsor shall supplement its patent list with any later-issued or licensed patents no later than 30 days from the issuance or licensing, or it may not assert those patents in the litigation proceeding. 42 U.S.C. § 262(l)(7).

³ 42 U.S.C. § 262(l)(3)(B).

⁴ 42 U.S.C. § 262(l)(3)(C).

⁵ 42 U.S.C. § 262(l)(4).

10.13.2.2.1 Remedies available in BPCIA litigation

Injunctive relief is available where a patent was included on any of the lists prepared to identify patents for the first stage of litigation, and the RPS filed suit on the patent within 30 days of the production of the lists. It is mandatory where there has been a final court decision on infringement and validity, and the exclusivity period for the reference product has not yet expired. If the patent owner fails to bring suit within 30 days on a patent included in the separate or agreed lists for litigation, the patent owner may only seek a reasonable royalty as to those

using the reference product without such a switch. As of December 2022, only two interchangeable biologic products have been approved by FDA. Interchangeable biological products are granted up to one year of exclusivity against subsequent interchangeable products. 42 U.S.C. § 262(k)(6).

421 35 U.S.C. § 271(e)(2)(C)(i), (ii).

422 *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1354–57 (Fed. Cir. 2015).

423 See *Amgen*, 794 F.3d at 1354–57.

Table 10.7 Steps for negotiation of the final patent list for the first phase of BPCIA litigation

Timeline	Who acts?	Step(s)
Within 15 days from the start of negotiation	Both the RPS and the biosimilar applicant	- If the parties cannot reach agreement after 15 days of negotiation, the parties exchange another set of lists. - The biosimilar applicant must disclose how many patents it will list.² If the parties reach agreement after 15 days of negotiation, the RPS must file complaint within 30 days.¹ First phase of patent litigation commences.
Within 5 days	Both the RPS and biosimilar applicant	Parties simultaneously exchange patent lists. ³ The RPS may not list more patents than the biosimilar applicant.
Within 30 days	RPS	The first phase of patent litigation commences upon filing of complaint against the biosimilar applicant, on patents listed by both parties. ⁴

Note: RPS = reference product sponsor.

¹ 42 U.S.C. § 262(l)(6).

² 42 U.S.C. § 262(l)(5).

³ 42 U.S.C. § 262(l)(5)(a).

⁴ 42 U.S.C. § 262(l)(6).

Table 10.8 Steps for the second phase of BPCIA litigation

Timeline	Who acts?	Step(s)
	The FDA	The FDA approves the abbreviated biologic license application (if RPS market exclusivity has expired).
At least 180 days before beginning marketing of the biosimilar drug product	Biosimilar applicant	The biosimilar applicant provides notice to the RPS no later than 180 days before the date of first commercial marketing. ¹ The biosimilar applicant does not need to wait until the FDA approves the biosimilar before providing notice. ²
Immediately (or within 6 months)	RPS	After receiving notice of commercial marketing, the RPS may seek a preliminary injunction on any patent listed on its initial § 262(l)(3) list exchanged during the patent dance (or any patent under § 262(l)(7) later) that was not included in the first phase of litigation. ³

Note: FDA = Food and Drug Administration; RPS = reference product sponsor.

¹ 42 U.S.C. § 262(l)(8)(A).

² *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1677 (2017).

³ 42 U.S.C. § 262(l)(8)(B).

patents, and injunctive relief is not available.⁴²⁴ Likewise, only a reasonable royalty may be recovered if an action on such patents was dismissed without prejudice or was not prosecuted in good faith.⁴²⁵ Where a biosimilar applicant has launched its biosimilar product at-risk prior to the conclusion of litigation, damages or other monetary relief may be available.⁴²⁶

To encourage the parties to a BPCIA dispute to comply with the statutorily-outlined exchanges and framework, the BPCIA includes consequences for each of the parties if they fail to engage with the procedural requirements. As discussed above, if the RPS fails to include a patent in its initial list, suit by the patent owner on that patent is barred.⁴²⁷ In addition, suit is barred on a later-issued or later-licensed patent if it is not added within 30 days.⁴²⁸ Where a biosimilar applicant fails to provide its aBLA and manufacturing information to the RPS, the parties do not engage in the exchanges outlined above. The RPS (but not the applicant) may immediately bring a declaratory judgment action, directed to infringement, validity, and/or enforceability of any patent that claims the biological product or a use of the product.⁴²⁹ And, where the biosimilar applicant provides its aBLA and manufacturing information but fails to complete a later exchange in the process, the RPS may bring a declaratory judgment action with respect to any patent listed on the RPS's initial list (and later-issued and later-acquired patents).⁴³⁰

424 35 U.S.C. §271(e)(6)(B).

425 35 U.S.C.

426 35 U.S.C. §271(e)(4)(C).

427 35 U.S.C. §271(e)(6)(C).

428 42 U.S.C. §262(l)(7).

429 42 U.S.C. §262(l)(9)(C).

430 42 U.S.C. §262(l)(9)(B).

10.14 Key challenges and efforts to improve patent case management

As the foregoing exploration of U.S. patent case management reveals, the U.S. patent review and enforcement system comprises a complex and overlapping patchwork of institutions, actors, and rules. The United States has been experimenting with a wide range of institutional and doctrinal mechanisms aimed at improving the functioning of the system. Although tremendous progress has been made in improving patent case management through procedural innovation, judicial education, and legislative reform, there remain significant challenges. Substantive law confusion (notably the patent eligibility requirement), district judge forum shopping, parallel proceedings, and gaps in scientific and technical expertise plague U.S. patent litigation, contributing to the high cost, complexity, and delay in resolving patent disputes.

10.15 Appendix

Table 10.A1 Comparison of U.S. district court patent adjudication, USITC patent investigations and Patent Trial and Appeal Board *inter partes* review

Characteristic	U.S. district courts	USITC patent investigation	PTAB IPR proceedings
General or specialized court?	General jurisdiction courts.	- Specialized court, presiding over alleged “unfair trade practices,” which includes importation of products that infringe U.S. intellectual property rights. - Patent investigations represent approximately 85% of the USITC docket.	Specialized court, presiding over disputes on validity (35 U.S.C. §§ 102, 103 grounds) of issued patents.
First-instance decision-maker	- District court judges rarely have science or technology backgrounds. - Few district judges have significant experience with patent cases, although most cases are filed in a handful of district courts (Delaware, Eastern and Western Texas, Northern California), where those judges have become experienced in patent matters.	USITC ALJs do not generally have science or technology backgrounds but do have specialized experience in unfair trade practices and patent investigations.	PTAB APJs have science or technology backgrounds and specialize in patent review.
Decision-maker: judge or jury?	- Jury trial if requested by either party. Jury members do not generally have science or technology backgrounds or patent expertise. - Pharmaceutical patent cases are typically heard by a judge, not a jury.	ALJ; no jury.	Three-APJ panel; no jury.
Initiation of action	Filing of a complaint.	- Filing of a complaint. - After a complaint is filed, the USITC determines whether to institute an investigation within 30 days.	- Filing of a petition by a patent challenger. - Parties must seek a proceeding within 12 months of being served with a complaint alleging infringement of the patent and are barred from seeking or maintaining an IPR if they file an action for a declaratory judgment that the patent is invalid.
Threshold for initiating proceeding	Low threshold (plausible claims of infringement and jurisdictional requirements of ownership).²	Complaint must be sufficient; Office of Unfair Imports reviews the matter and advises the USITC as to its sufficiency with regard to Section 337's procedural requirements and substantive elements: (1) sale for importation, importation or sale after importation of goods; (2) unfair acts or methods of competition, such as infringement of a U.S. patent; (3) presence of a domestic industry; and (4) proof of substantial or threatened injury in the case of non-statutory intellectual property rights complaints.	“Reasonable likelihood of success” based on the information presented in the petition and the patent owner's response to the petition.
Time frame for proceeding	- No designated time frame (varies significantly by district). - Often takes 3 years or more to reach trial.	16 months.	12–18 months.

Characteristic	U.S. district courts	USITC patent investigation	PTAB IPR proceedings
Parties	- In non-pharmaceutical cases: - patent owner (usually plaintiff) - alleged infringer (usually defendant, but can be plaintiff in a declaratory relief action). - In pharmaceutical cases: - Hatch-Waxman: - NDA holder (typically patent owner) usually plaintiff (but can be defendant in a declaratory relief action) - generic company (ANDA holder) typically defendant. - BPCIA: - BLA holder (typically patent owner) usually plaintiff (but can be defendant in a declaratory relief action) - aBLA holder or biosimilar manufacturer usually defendant.	- Complainant (patent owner seeking to protect domestic industry from unfair competition). - Respondent (importing allegedly infringing product). - Office of Unfair Imports and Investigations (USITC investigatory body).	- Petitioner (patent challenger). - Respondent (patent owner).
Intervention rules	- FRCP 24. - Consolidated in the same proceeding as the complaint.	Governed by a standard similar to FRCP 24.	- Joinder of additional parties possible. - PTAB will often deny “serial” petitions on the same patent, even if petitioners are different. “Parallel” petitions on the same patent are not favored by the PTAB.
Agency input	None.	Section 337 requires the USITC to consult with the U.S. Department of Justice, Federal Trade Commission, and other agencies it deems appropriate during the course of the investigation.	IPRs are administrative adjudications governed by the APA that occur within the USPTO.
Pleading standard	Notice pleading of a plausible claim of infringement.³	- Fact pleading - Must present infringement contentions (at least one patent claim and how it is infringed) and domestic industry contention.	- Higher than notice pleading standard in district court. - The PTAB has discretion in deciding whether to institute an IPR and strictly limits the petitioner to the patentability challenge grounds identified in the petition and the specific bases supporting those grounds. - Petition should identify the real party in interest and include all evidence supporting the patentability challenges, where each claim element is found in the prior art, how the PTAB should construe each disputed claim, and the specific relief requested. - Petitioner must file a separate petition for each patent challenged.
Filing fees	As of 2020, USD 402 to file a civil action in district court.	No fee.	- Request stage: USD 19,000 (basic fee) plus USD 375 (for each claim over 20). - Post-institution Stage: USD 22,500 (basic fee) plus USD 750 (for each claim over 20).
Counterclaims	- Consolidated in the same proceeding as the complaint. - In a declaratory judgment proceeding, the patentee (defendant) will typically file an infringement counterclaim.	- Permitted, but must request their immediate removal to district court. - Pending district court actions on common issues at the USITC can be stayed at the respondent's option; counterclaims are not stayed (although they are subject to the district court's case management determinations).	n.a.
Subject matter jurisdiction	Infringement of a U.S. intellectual property right.	Importation of products in violation of a U.S. intellectual property right where there is a domestic industry practicing the infringed intellectual property right.	Validity of issued patents on 35 U.S.C. § 102 (anticipation) and § 103 (obviousness) grounds.

Characteristic	U.S. district courts	USITC patent investigation	PTAB IPR proceedings
Personal jurisdiction	Whether the applicable state long-arm statute is satisfied and whether the exercise of personal jurisdiction is consistent with the Due Process Clause of the Constitution. Patent cases typically do not raise substantial issues of personal jurisdiction since the defendant is alleged to have sold or offered for sale infringing products within the district, which usually provides specific personal jurisdiction over the infringement dispute.	Not applicable; based on <i>in rem</i> jurisdiction.	
Subpoena power	Nationwide subpoena power.⁴	Nationwide subpoena power.	- The PTAB does not issue subpoenas directly. 35 U.S.C. § 24 authorizes a party to seek a subpoena (by motion) from the district court wherein testimony would be taken, for a contested matter before the USPTO.
<i>In rem</i> jurisdiction	Not available.	Available.	Available: "IPR is similarly an <i>in rem</i> proceeding – a proceeding to reevaluate the validity of an issued patent."⁵
Venue	"[W]here the defendant resides, or where the defendant has committed acts of infringement and has a regular and established place of business."⁶ - Subject to <i>forum non conveniens</i> doctrine that allows courts to transfer a case to a more convenient forum.	The USITC in Washington, D.C.	The USPTO in Alexandria, VA (or USPTO regional offices).
Effects on parallel proceedings	- Other district court proceedings: - generally first-filed district court case takes priority over later-filed cases, but courts have some discretion. - USITC investigation or decision: - USITC respondents are entitled to a motion for stay of district court proceedings on the same patents or issues as a matter of right.⁷ - A USITC decision does not have <i>res judicata</i> effect on district court proceedings, but decisions can be persuasive. - PTAB institution or decision: - Parties frequently seek stays of district court actions while PTAB proceedings are pending. - Challenger is estopped from raising any ground in district court that was already raised or that reasonably could have been raised at the PTAB. - PTAB decision does not have <i>res judicata</i> effect on district court proceedings unless affirmed by the Federal Circuit.	- PTAB institution or decision: - Challenger is estopped from raising any ground in USITC that was already raised or that reasonably could have been raised at the PTAB.	- USITC investigation or decision: - The PTAB will not discretionarily deny petitions for IPR based solely on a parallel USITC proceeding.⁸ - A USITC decision does not have <i>res judicata</i> effect on PTAB proceedings, but decisions can be persuasive. - Previous PTAB decision: - Challenger is estopped from raising any ground in district court that was already raised or that reasonably could have been raised at the PTAB in subsequent USPTO proceedings.
Procedural rules	- FRCP. - FRE. - Augmented in many of the most patent-intensive districts by "patent local rules" and standing orders.	- APA: formal adjudication. - USITC Rules of Practice and Procedure (which parallel the FRCP and FRE). - ALJ-specific "ground rules."	- USPTO regulations.⁹ - FRE (except as specified in USPTO regulations).
Discovery	Any nonprivileged information relevant to any party's claim or defense and proportional to the needs of the case.	- All information reasonably likely to lead to discovery of admissible evidence within the allowable period (usually limited to 6 months). - Responses to interrogatories and document requests typically limited to 10 days after service. - Nationwide subpoena power available against foreign respondents; sanctions available against foreign respondents who fail to comply with discovery.	Parties may depose witnesses submitting affidavits or declarations and seek such discovery as the USPTO determines is otherwise necessary in the interests of justice.

Characteristic	U.S. district courts	USITC patent investigation	PTAB IPR proceedings
Preliminary relief	Issuance of a preliminary injunction is based upon a balancing of the following equitable factors: (1) a reasonable likelihood of success on the merits, (2) irreparable harm if temporary relief is not granted, (3) a balance of hardships tipping in its favor, and (4) the temporary relief's favorable impact on the public interest.	- Two-part test in determining whether to issue a TEO: (1) whether there is "reason to believe" that there is a violation of Section 337, and (2) whether issuance of a TEO serves the public interest. - The USITC also applies the same standard as in a preliminary injunction.	No preliminary relief, but the decision process is completed within 12 months.
Claim construction	- Typically handled during the pre-trial phase. - Interpretation done by the trial judge applying the <i>Phillips</i> standard.	- Practices vary across cases and ALJs, but are increasingly done prior to trial. - Employs the <i>Phillips</i> standard.	Interpretation done by the PTAB panel applying the <i>Phillips</i> standard.
Summary adjudication	FRCP 56: no genuine issue of material fact.	Summary determination rules.	No summary determination.
Elements of proof	Infringement of intellectual property rights subject to all legal and equitable defenses.	- Importation requirement. - Domestic industry requirement (economic and technical prongs). - Infringement of intellectual property rights subject to most legal and equitable defenses.	The PTAB may invalidate patent claims on 35 U.S.C. § 102 (anticipation) and § 103 (obviousness) grounds based solely on patent and printed publication prior art.
Presumption of patent validity	Yes: clear and convincing evidence standard for invalidating patent claims.	Yes: clear and convincing evidence standard for invalidating patent claims.	No: preponderance of the evidence standard for invalidating patent claims.
Role of experts	- Experts must be qualified under FRE 702. - Experts used to apply scientific, technical, or economic methodology to facts of the case, and to evaluate hypothetical legal constructs. <i>Daubert</i> standard used by district courts to assess the reliability of scientific testimony (testing of methodology, peer review and acceptance in scientific community, rates of error, and standards and controls). <i>Daubert</i> motions can limit or exclude the testimony of expert witnesses.	- Experts must be qualified under FRE 702. - Motions to wholly preclude the testimony of experts rarely made in USITC proceedings; may limit portions of testimony.	The PTAB permits expert testimony in the form of a declaration to be submitted with the petition, preliminary response, and at other appropriate stages in a proceeding as ordered or allowed by the panel overseeing the trial.
Trial/hearing	- Judicial trial, subject to Seventh Amendment right to jury. - FRE. - Trial times vary, although judges are increasingly using time limits per side (e.g., 20 hours).	- APA: formal adjudication. - Similar to the FRE but sometimes less strictly applied (e.g., the hearsay rule might not be used). - ALJ-specific "ground rules." - Hearings usually last 1–2 weeks.	Each party has the right to request an oral hearing.
Record	Pleadings, rulings on motions, trial transcript and exhibits, and post-trial briefs.	Pleadings, final written decision, any findings or reports on which the final written decision is based, and the evidence and other parts of the proceeding before the USITC.	Pleadings, final written decision, any findings or reports on which the final written decision is based, and the evidence and other parts of the proceeding before the PTAB.
Remedies	- Invalidation of patent claims. - Monetary relief available. - Attorney fees and costs potentially available. - Injunctive relief subject to equitable balancing.	- No monetary relief. - Exclusion orders if infringement of valid patent found, unless public interest factors override. - Cease and desist orders.	- Invalidation of patent claims. - No monetary relief.
Effect of decision on patent	- Power to invalidate the patent. <i>Res judicata</i> effect.	- Initial determination by ALJ becomes final if not reviewed by the USITC within 45 days. - No <i>res judicata</i> effect: no effect on patent validity, only exclusion from the U.S. market.	Power to invalidate patent claims.
Enforcement	Contempt power.	Exclusion orders enforced by U.S. Customs & Border Protection.	Invalidation of patent claims.
Review by agency and/or Federal Circuit	- No administrative agency review. - Federal Circuit appeal.	- USITC review of ALJ initial determination. - Presidential review: the President has authority to disapprove USITC remedies on policy grounds (rarely invoked). - Federal Circuit appeal.	- USPTO Director may review all PTAB decisions.¹⁰ - Decisions of the PTAB can be appealed to the Federal Circuit.¹¹ - USPTO may intervene in Federal Circuit appeal to defend its decision.

Characteristic	U.S. district courts	USITC patent investigation	PTAB IPR proceedings
Standard(s) of review	- Hybrid standard of review of claim construction determinations underlying claim construction rulings are subject to the “clearly erroneous” (or “abuse of discretion”) standard of review, while the Federal Circuit exercises <i>de novo</i> review over the ultimate claim construction determination). - Substantial evidence or “clearly erroneous” standard for factual determinations. <i>De novo</i> review for legal determinations.	- Reviewed under standards of the APA. - Hybrid standard of review of claim construction determinations (factual determinations underlying claim construction rulings are subject to the “clearly erroneous” (or “abuse of discretion”) standard of review, while the Federal Circuit exercises <i>de novo</i> review over the ultimate claim construction determination). - Substantial evidence standard for factual determinations. <i>De novo</i> review for the USITC’s legal determinations.	- Reviewed under standards of the APA. - Substantial evidence standard for factual determinations. <i>De novo</i> review for the PTAB’s legal conclusions.

Note: aBLA = Abbreviated Biologic License Application; ALJ = Administrative Law Judge; ANDA = Abbreviated New Drug Application; APA = Administrative Procedure Act; APJ = Administrative Patent Judge; BLA = Biologic License Application; BPCIA = Biologics Price Competition and Innovation Act; Federal Circuit = U.S. Court of Appeals for the Federal Circuit; FRCP = Federal Rule(s) of Civil Procedure; FRE = Federal Rule(s) of Evidence; IPR = *inter partes* review; NDA = New Drug Application; PTAB = Patent Trial and Appeal Board; TEO = temporary exclusion order; U.S.C. = U.S. Code; USITC = United States International Trade Commission; USPTO = United States Patent and Trademark Office.

¹ 35 U.S.C. §§ 102, 103.

² FRCP 12(b)(6), 12(c).

³ See FRCP 12(b)(6); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007); *Ashcroft v. Iqbal*, 556 U.S. 662 (2009) (plausibility standard).

⁴ FRCP 45.

⁵ *Regents of the Univ. Of Minn. v. LSI Corp.*, 926 F.3d 1327, 1345 (Fed. Cir. 2019).

⁶ 28 U.S.C. § 1400(b).

⁷ 28 U.S.C. § 1659(a).

⁸ USPTO, Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation (June 21, 2022), available at https://www.uspto.gov/sites/default/files/documents/interim_proc_discretionary_denials_aia_parallel_district_court_litigation_memo_20220621_.pdf.

⁹ 37 C.F.R. § 42.

¹⁰ *United States v. Arthrex, Inc.*, 141 S. Ct. 1970 (2021).

¹¹ 35 U.S.C. § 141.

Chapter 11

The Boards of Appeal of the European Patent Office

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11.1 Overview of the patent system

11.1.1 Evolution of the European patent system

The European Patent Convention (EPC) was signed in 1973 and revised in 2000.¹ It is a special agreement under Article 19 of the Paris Convention and a regional patent treaty under Article 45(1) of the Patent Cooperation Treaty.² The EPC, however, goes significantly further than these treaties. What distinguishes the EPC is that it not only harmonizes substantive and procedural patent law but also creates a public authority with the power to grant patents completely independent from national patent offices – the European Patent Office (EPO). Patents granted by the EPO are called European patents.

Before the entry into force of the EPC, patent protection in multiple European countries could only be achieved by following the distinct grant procedures in each of those countries. The EPC now provides a single grant procedure in a single language (English, German or French, as the working languages of the EPO) for patent protection in up to 38 Contracting States.³

However, the procedure before the EPO does not supersede national grant procedures. When seeking patent protection in one or more Contracting States of the EPC, applicants have a choice between following national grant procedures before several national patent offices or taking the single European route before the EPO, which confers protection in all Contracting States designated by the applicant.

Once granted by the EPO, a European patent becomes a bundle of patents having equivalent effect to national patents, which must be validated in each of the selected Contracting States. The envisaged European patent with unitary effect removes the need for national validation procedures in the Contracting States participating in this system.⁴

11.1.2 Patent application trends

In 2021, 188,610 European patent applications were filed – a 4.5 percent increase over the filings in 2020. There was strong growth in digital technologies, such as digital communication, medical technology and computer technology.⁵ More information on patent application trends is available from the website of the EPO Statistics and Trends Centre.⁶

Figure 11.1 shows the total number of patent applications (direct and Patent Cooperation Treaty (PCT) national phase entry) filed with the EPO from 2000 to 2021.

11.2 Patent institutions and opposition proceedings

11.2.1 European Patent Organisation

The European Patent Organisation, instituted by the EPC, has two organs: the EPO and the Administrative Council.⁷ Executive powers are assigned to the EPO and its president, and supervisory powers are assigned to the Administrative Council.⁸ The Administrative Council consists of representatives of the Contracting States to the EPC.⁹ The Boards of Appeal, although not a separate organ of the European Patent Organisation but structurally a part of the EPO,¹⁰

1 Convention on the Grant of European Patents (European Patent Convention) (with Implementing Regulations), Oct. 5, 1973, 1065 UNTS 199, revised by the Act revising the EPC, Nov. 29, 2000 [hereinafter EPC], www.epo.org/law-practice/legal-texts/epc.html

2 See EPC, preamble.

3 In addition, the European Patent Organisation has an extension agreement with Bosnia and Herzegovina and validation agreements with Morocco, the Republic of Moldova, Tunisia and Cambodia.

4 EPC, art. 142. For further information, see www.epo.org/applying/european/unitary/unitary-patent.html

5 For a concise overview of the trends in 2021, see the infographic for the Patent Index 2021, accessible from www.epo.org/about-us/annual-reports-statistics/statistics/2021/statistics/patent-applications.html

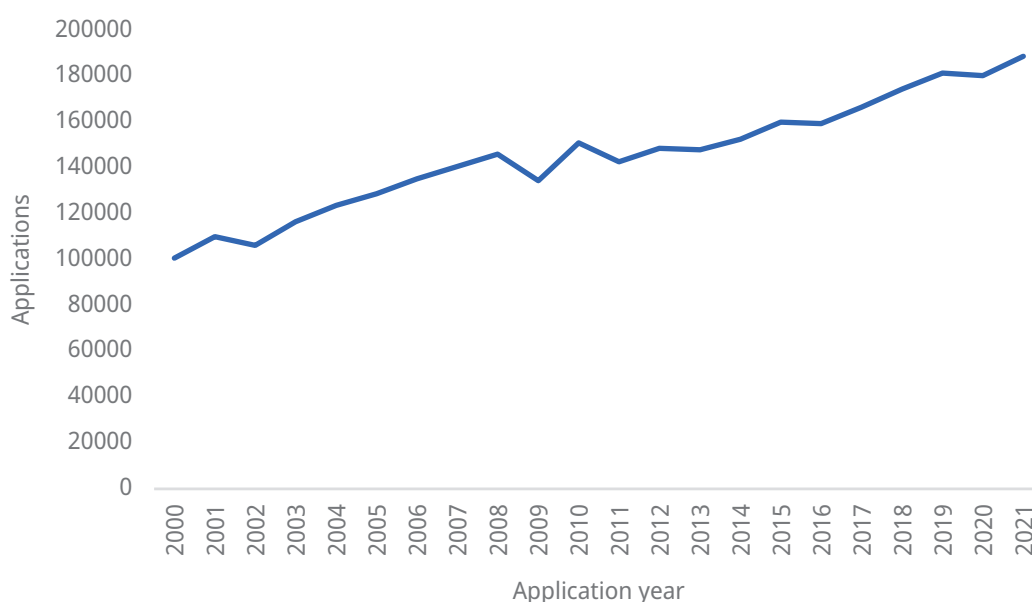
6 Accessible from <https://new.epo.org/en/statistics-centre>

7 EPC, art. 4(2).

8 EPC, arts 4(3), 10.

9 EPC, art. 26(1).

10 EPC, art. 15.

Figure 11.1 Patent applications filed with the EPO, 2000–2021

Source: WIPO IP Statistics Data Center, available at www3.wipo.int/ipstats/index.htm?tab=patent

are assigned the role of an independent judiciary in this patent system.¹¹ They provide an independent review of decisions taken by the EPO's Receiving Section, Examining Divisions, Opposition Divisions and the Legal Division.¹²

11.2.2 Opposition proceedings

The opposition procedure before the EPO is a contentious administrative procedure following the grant procedure. The relief sought by the opponent is not, as in pre-grant opposition, the refusal of the patent application but rather the revocation of the patent with retroactive effect in all designated Contracting States.¹³ Opposition proceedings thus allow, during a limited period, a request for the revocation of the entire European patent (i.e., encompassing all national parts) to be brought before and decided by the EPO in a centralized procedure.

Within nine months after publication of the mention that a European patent has been granted, anyone may give the EPO a notice of opposition.¹⁴ Opposition may only be filed on certain grounds – namely that:

- the patent's subject matter is not patentable (e.g., because the claimed subject matter is not novel, does not involve an inventive step or is excluded from patentability);
- the patent does not disclose the invention clearly and completely enough for it to be carried out by a person skilled in the art; or
- the patent's subject matter extends beyond the content of the (earlier) application as filed.¹⁵

In opposition proceedings, the Opposition Division examines whether the grounds for opposition prejudice the maintenance of the European patent.¹⁶ If necessary, the Opposition Division will

11 See e.g. German Federal Constitutional Court, consolidated cases BvR 2480/10, 2 BvR 421/13, 2 BvR 786/15, 2 BvR 756/16 and 2 BvR 561/18, 8 November 2022; High Court of Justice in the United Kingdom (Patents Court) in *Lenzing* [1997] R.P.C. 245, 22 May 1997; European Commission of Human Rights, *Lenzing AG v. U.K.* 9 September 1998 (in relation to Article 6 of the European Convention on Human Rights); see also the decisions of the Enlarged Board of Appeal and the Technical Boards summarized in Legal Research Service of the Boards of Appeal, *Case Law of the Boards of Appeal*, ch. VII sub-s. 1.2. "Boards of appeal as judicial authorities" (10th ed. 2022), http://www.epo.org/law-practice/legal-texts/html/caselaw/2022/e/clr_vii_1_2.htm

12 EPC, art. 106(1) first sentence.

13 EPC, art. 68.

14 EPC, art. 99(1).

15 EPC, art. 100.

16 EPC, art. 101(1) first sentence.

invite the parties to file written observations.¹⁷ The patent proprietor may file a description, claims and drawings in amended form.¹⁸ Proposals for amendment to the patent – in practice, these proposals are filed as (auxiliary) claim requests – might not be considered if they are late-filed.¹⁹ Oral proceedings before the Opposition Division must be arranged if requested by a party.²⁰ As a rule, oral proceedings in opposition proceedings are held by videoconference.²¹

At the conclusion of opposition proceedings, the Opposition Division may decide:

- to reject the opposition and maintain the patent as granted;
- maintain the patent in amended form; or
- revoke the patent.²²

Any party adversely affected by the Opposition Division's decision may lodge an appeal with the Boards of Appeal. Such an appeal has suspensive effect.²³

11.3 Judicial institutions

11.3.1 Judicial administration

The Boards of Appeal and the Enlarged Board of Appeal, including their registries and support services, are organized as a separate unit within the EPO. They are directed by the President of the Boards of Appeal, who is appointed by the Administrative Council of the European Patent Organisation. The President of the Boards of Appeal is solely responsible to the Administrative Council and exercises functions and powers delegated to them by the President of the EPO.²⁴

The President of the Boards of Appeal is advised by the Presidium of the Boards of Appeal. The Presidium consists of the President and 12 members of the Boards of Appeal elected by other members. It also adopts a Code of Conduct for the members of the Boards of Appeal²⁵ and, in an extended composition, the business distribution scheme.²⁶

11.3.2 Specialized intellectual property judiciary

11.3.2.1 Boards of Appeal as the first and final judicial instance

The Boards of Appeal are the first and final judicial instance in the procedures before the EPO. They have the task of reviewing contested decisions of the departments of first instance. In their decisions, they are not bound by any instructions and must comply only with the provisions of the EPC.²⁷ They are recognized as independent courts based on the rule of law.²⁸

11.3.2.2 Specialization

The Boards of Appeal deal exclusively with patent cases and are therefore a highly specialized intellectual property judiciary. They usually decide in a composition of two technically qualified members and one legally qualified member.²⁹ At the end of 2021, there were 196 board members and 28 Technical Boards of Appeal, each of which has a different technical specialization. The Boards of Appeal settled 3,395 patent cases in 2021.³⁰

As expert patent courts, the Boards of Appeal have a central role in the development of European patent law. Their decisions are final and not subject to any further appeal. Their case law and

¹⁷ EPC, art. 101(1) second sentence.

¹⁸ EPC, art. 123(1), r. 81(3).

¹⁹ EPC, arts 114(2), 123(1), r. 116.

²⁰ EPC, art. 116(1).

²¹ See Decision of the President of the European Patent Office dated 22 November 2022 concerning the format of oral proceedings before examining and opposition divisions, the Legal Division and the Receiving Section.

²² EPC, art. 101(2), (3)(a), (3)(b).

²³ EPC, arts 106(1), 107.

²⁴ EPC, r. 12a(1)–(2).

²⁵ For the text of the Code of Conduct and explanatory remarks thereto, see *Approval of the Code of Conduct for Members of the Boards of Appeal and of the Enlarged Board of Appeal*, EPO Doc. CA/68/21 (Nov. 26, 2021), www.epo.org/modules/epoweb/acdocument/epoweb2/530/en/CA-68-21_en.pdf

²⁶ EPC, r. 12b(1)–(4).

²⁷ EPC, art. 23(3).

²⁸ See Section 11.2.1.

²⁹ EPC, art. 21.

³⁰ For statistics and more information on the Boards of Appeal, see the annual reports, accessible from www.epo.org/law-practice/case-law-appeals/annual-report.html

interpretations of the EPC are not only the basis for the practices established by the EPO for examination and opposition proceedings but are also deemed highly persuasive in national court proceedings.³¹

The most important of the over 42,000 decisions that the Boards of Appeal have rendered from 1978 to 2021 are summarized in the book *Case Law of the Boards of Appeal* (in its 10th edition, published in 2022), which provides a compendious overview of their jurisprudence.³²

11.3.2.3 Enlarged Board of Appeal

The Enlarged Board of Appeal is mainly responsible for ensuring the uniform application of the EPC. It decides on points of law of fundamental importance referred to it either by a Board of Appeal or by the President of the EPO.

When a Board of Appeal refers a specific point of law to the Enlarged Board, the Enlarged Board decides only that point. The decision on the appeal itself is then taken by the referring Board, which is bound by the decision of the Enlarged Board in respect of the point of law that it referred.

The President of the EPO may also make a referral to the Enlarged Board, provided that two Boards of Appeal have given different decisions on a point of law of fundamental importance.³³ The Enlarged Board of Appeal will then give an opinion on this point of law.

If a Board of Appeal considers it necessary to deviate from an interpretation or explanation of the EPC contained in an earlier opinion or decision of the Enlarged Board of Appeal, it must refer the question (again) to the Enlarged Board of Appeal.³⁴

A further task of the Enlarged Board is a limited judicial review of decisions of the Boards of Appeal regarding possible fundamental procedural defects.³⁵ If a petition for such a review is successful, the decision is set aside, and the appeal proceedings are reopened before the Boards of Appeal.³⁶

11.3.3 Relationship between invalidity and infringement proceedings

The EPC created a patent litigation system in which an international court (i.e., the Boards of Appeal of the EPO), the national courts of the Contracting States to the EPC and the Unified Patent Court have concurrent jurisdiction on the validity of a European patent. The European patent as a whole – that is, the entire bundle of patents having equivalent effect to national patents – is subject to the centralized procedure before the EPO and its Boards of Appeal. At the same time, the individual national parts of a European patent are subject to national revocation proceedings (e.g., a German court may revoke the German part of a European patent; and a French court, the French part) and to revocation proceedings before the Unified Patent Court.³⁷

Appeal proceedings before the Boards of Appeal of the EPO and proceedings before national courts or the Unified Patent Court are formally independent of each other. However, a European patent revoked by the Boards of Appeal may not be reinstated by national courts or the Unified Patent Court, and a national part of a European patent revoked by a national court or the Unified Patent Court may not be reinstated by the Boards of Appeal.

31 See, e.g., *Merrell Dow Pharmaceuticals, Inc. v. HN Norton & Co. Ltd* [1996] R.P.C. 76 (HL), para. 12 (U.K.); *Human Genome Sciences v. Eli Lilly* [2011] UKSC 51, para. 84 (U.K.); Bundesgerichtshof (Federal Court of Justice), April 15, 2010, Xa ZB 10/09 (*Walzenformgebungsmaschine*), para. 14 (Ger).

32 *Case Law of the Boards of Appeal* can be accessed free of charge in English, French or German from www.epo.org/law-practice/case-law-appeals/case-law.html

33 EPC, art. 112.

34 Rules of Procedure of the Boards of Appeal, art. 21 (July 3, 2019) [hereinafter RPBA 2020].

35 EPC, art. 112a. See also the Enlarged Board of Appeal, July 15, 2008, R 1/08, which was the first case on a petition for review: “Under no circumstances should the petition for review be a means to review the application of substantive law.” [...] The Board therefore considers that Article 112a EPC provides an exceptional means of redress, which provisions have to be applied strictly. Thus, it is not the purpose of Article 112a EPC that a case be decided upon by a third instance, but rather, it provides the right for a judicial review founded on a limited number of grounds that have been exhaustively defined by the legislator.” *Id.* at 10.

36 EPC, art. 112a(5).

37 EPC, arts 99, 100, 138. See also Agreement on a Unified Patent Court, 2013 OJ (C 175) 1 [hereinafter Agreement on a Unified Patent Court], art. 65(2).

Infringement procedures on European patents fall under the competence of the national courts of the Contracting States to the EPC³⁸ and the Unified Patent Court.³⁹

11.3.4 Judicial education on intellectual property

The Boards of Appeal have a dedicated Professional Development Committee, which organizes comprehensive training programs for all board members – including lectures and interactive discussions on various patent-related topics – including with judges from other patent courts. The support services of the Boards of Appeal also include the Legal Research Service of the Boards of Appeal, which provides summaries of recent decisions and comparative studies on patent and procedural law. This ensures that board members are up to date with the latest developments in European patent law. Furthermore, newly appointed chairs and members receive extensive introductory training, and legal drafting and language courses are offered continuously to all board members.

11.4 Patent invalidity proceedings and invalidity grounds

As noted above in Section 11.2.2, the EPC provides an exhaustive list of grounds for opposition (i.e., grounds on which a European patent may be revoked). These are that:

- the patent's subject matter is not patentable (e.g., because the claimed subject matter is not novel, does not involve an inventive step or is excluded from patentability);
- the patent does not disclose the invention clearly and completely enough for it to be carried out by a person skilled in the art; or
- the patent's subject matter extends beyond the content of the (earlier) application as filed.⁴⁰

In opposition and opposition appeal proceedings, the patent proprietor may file amendments to the patent. The Opposition Division or the Board of Appeal will then assess whether the amended patent and the invention to which it relates meet the requirements of the EPC.⁴¹ An important requirement is that an amendment may not extend the protection conferred by the European patent.⁴² If it does, the European patent cannot be maintained on the basis of the amendment, and it may eventually be revoked.

The EPC also provides an exhaustive list of grounds for revocation of the national part of a European patent in national invalidity proceedings. These possible grounds for revocation correspond to the grounds for opposition mentioned above⁴³ and further include:

- that the protection conferred by the European patent has been extended (which must also be assessed by the EPO in case of amendments during opposition or opposition appeal proceedings); and
- that the proprietor is not entitled to the right to the European patent.⁴⁴

11.5 Patent infringement

As noted above in Section 11.3.3, infringement procedures regarding European patents fall under the competence of the national courts of the Contracting States to the EPC and the Unified Patent Court.

11.6 Judicial patent proceedings and case management

11.6.1 Key features in patent proceedings

The primary objective of proceedings before the Boards of Appeal is to review the decision under appeal in a judicial manner.⁴⁵ As mentioned above in Section 11.3.2.1, the Boards of Appeal

38 EPC, art. 64(3).

39 See Agreement on a Unified Patent Court, art. 32.

40 EPC, art. 100.

41 EPC, art. 101(3)(a).

42 EPC, art. 123(3).

43 EPC, art. 138(1)(a)–(c).

44 EPC, art. 138(1)(d) and (e).

45 RPBA 2020, art. 12(2).

constitute the first and final judicial instance in the procedures before the EPO. In this capacity, they review appealed decisions on points of law and fact.

Parties may amend their cases during appeal proceedings, which also includes the possibility for the applicant or patent proprietor to amend their patent application or patent. However, as appeal proceedings progress, the possibilities for parties to amend their cases become increasingly limited. This has been coined the “convergent approach” and is described in Section 11.6.4 below.

11.6.2 Venue, jurisdiction and case assignment rules

11.6.2.1 Venue and jurisdiction

The Boards of Appeal are located in Haar, near Munich, Germany. Their oral proceedings take place either at the Haar premises or at the EPO’s headquarters in Munich and may also be conducted by videoconference (see Section 11.6.8.4).

The Boards of Appeal have jurisdiction over the decisions taken by the Receiving Section, the Examining Divisions, the Opposition Divisions and the Legal Division of the EPO.⁴⁶ The Boards of Appeal deal only with patent validity, not with questions of patent infringement (see Section 11.3.3).

11.6.2.2 Case assignment

Technical cases are assigned to each Technical Board according to the business distribution scheme before the beginning of each working year.⁴⁷ Responsible for this allocation is the Presidium of the Boards of Appeal, extended to include all chairs of the Boards.⁴⁸ For technical cases, appeals are allocated to each Board based on the main International Patent Classification attributed to the application or patent at the time of the filing of the appeal.

Technical Boards may also share an International Patent Classification class. For Boards that share a class, cases are divided by year of appeal filing (e.g., appeals concerning a specific class filed in 2019 are allocated to one Board, and appeals of the same class but filed in 2020 are allocated to another Board).⁴⁹ If it is more appropriate to allocate a case to a different Board because of its technical content, the chairs of the two Boards may agree to change the allocation of the case.⁵⁰

A Technical Board usually consists of four to eight technically qualified members and two to four legally qualified board members. Technically qualified members are allocated to a single Technical Board; legally qualified board members are usually allocated to three different Technical Boards.⁵¹

The actual composition of a particular appeal is determined by the chair of the Board according to the criteria set out in the business distribution scheme. In particular, chairs take into account the technical and language requirements of the case and the workload of each member of their Board.⁵²

11.6.2.3 Party representation

As a rule, parties to proceedings before the Boards of Appeal (or to any proceedings before the EPO) are not obliged to be represented by a professional representative.⁵³ However, if parties do not have their residence or principal place of business in a Contracting State, they must be represented by professional representatives and act through them.⁵⁴ If, in such a case, a representative is not appointed, the procedural steps taken by the non-represented party are deemed not to have been taken.⁵⁵

⁴⁶ EPC, art. 21(1).

⁴⁷ The Legal Board of Appeal has a business distribution scheme, which is also adopted by the Presidium. The Enlarged Board of Appeal adopts its own business distribution scheme. Business distribution schemes can also be amended during the working year. See EPC, r. 12b(4) fourth sentence; RPBA 2020, art. 1(1) second sentence.

⁴⁸ EPC, r. 12b(4) first sentence.

⁴⁹ Presidium of the Boards of Appeal, *Business Distribution Scheme of the Technical Boards of Appeal for 2022* (Jan. 1, 2022) [hereinafter Business Distribution Scheme], see for example the allocation of appeals between Board 3.2.02 and Board 3.2.08 in art. 1(1).

⁵⁰ Business Distribution Scheme, art. 1(2).

⁵¹ Business Distribution Scheme, art. 2.

⁵² Business Distribution Scheme, art. 3(2).

⁵³ EPC, art. 133(1).

⁵⁴ EPC, art. 133(2).

⁵⁵ EPC, r. 152(6).

The EPO maintains a list of professional representatives who may represent parties in proceedings before the EPO. A professional representative must be a national of a Contracting State, have their place of business or employment in a Contracting State, and have passed the European Qualifying Examination.⁵⁶ The European Qualifying Examination is organized by the EPO and tests candidates' knowledge and aptitude to represent applicants in EPO proceedings.

Legal practitioners qualified in a Contracting State can also represent parties in EPO proceedings to the extent that they are entitled in that Contracting State to act as a professional representative in patent matters.⁵⁷

11.6.3 Statements of case

11.6.3.1 Appellant's statement setting out the grounds of appeal, and the respondent's reply thereto

An appellant who seeks to impugn the decision of the EPO's departments of first instance must file a notice of appeal within two months of the notification of the decision and, additionally, a statement setting out the grounds of appeal within four months of the notification of the decision.⁵⁸

The notice of appeal must contain the name and the address of the appellant, an indication of the decision impugned and a request defining the subject of the appeal, such as that the patent be revoked or that it be maintained in amended form.⁵⁹

The statement of grounds of appeal must contain the reasons for setting aside the decision being impugned – or state the extent to which it is to be amended (e.g., in which version the patent should be maintained, in particular with which set of claims) – and the facts and evidence on which the appeal is based.⁶⁰

The respondent (i.e., the non-appealing party in opposition-appeals proceedings) may file a reply to the appellant's grounds of appeal. The reply must be filed four months after the grounds of appeal are notified to the respondent.⁶¹

11.6.3.2 Parties' complete appeal cases

An appellant's statement of grounds of appeal and the respondent's reply thereto must contain each party's *complete* appeal case.⁶² This ensures a "front-loading" of the appeal proceedings so that the members of the Board, particularly the rapporteur responsible for the case, have all facts and requests on the table when they start examining the cases.

Since the first exchange of briefs must already contain a party's complete appeal case, the possibility of amending the appeal case later in the appeals proceedings is limited. During the later stages of the proceedings, opponents might attempt to attack the patent by submitting new facts or new evidence, and the patent proprietor might seek to defend the patent in an amended form by filing new auxiliary requests (i.e., new sets of claims). However, such amendments made by the parties to their respective initial pleadings may be admitted only at the discretion of the Board (see the following section).⁶³

11.6.4 Parties' amendments to their cases on appeal – the Boards of Appeal's convergent approach

The function of the Boards of Appeal is to review the appealed decision, not to merely continue the examination or opposition proceedings by reexamining the application or the revocation grounds against the patent. One of the consequences of this primary objective is that, as appeal proceedings progress, the possibilities for parties to amend their cases become increasingly

56 EPC, art. 134(1)–(2).

57 EPC, art. 134(8).

58 EPC, art. 108 first and third sentences.

59 EPC, r. 99(1).

60 EPC, r. 99(2).

61 RPBA 2020, art. 12(1)(c). The period for reply may exceptionally be extended at the Board's discretion by a maximum of two additional months for a total maximum of six months. RPBA 2020, art. 12(7).

62 RPBA 2020, art. 12(3).

63 RPBA 2020, art. 13(1).

limited. This has been coined the “convergent approach,” which consists of three levels, as regulated in the Rules of Procedure of the Boards of Appeal [hereinafter RPBA 2020].⁶⁴

Which of these provisions applies depends on the point in time at which a party changes its case:

- Article 12(4) applies when a party changes its case at the outset of the appeal proceedings (i.e., in its statement of case) with respect to what the party had filed before the Examining or Opposition Division, or with respect to what was decided by the division.
- Article 13(1) applies when a party changes its appeal case after the initial stage of the appeal proceedings but before a summons to oral proceedings has been notified.⁶⁵
- Article 13(2) applies when a party changes its appeal case after the summons to oral proceedings has been notified.⁶⁶

These three levels of convergence are explained in detail in the following sections.

11.6.4.1 First level of the convergent approach

In a party's statement of grounds or their reply, the case must be directed to the requests, facts, objections, arguments and evidence on which the decision under appeal was based.⁶⁷ This is in accordance with the primary objective of the appeal proceedings to review the decision under appeal.

If parts of a party's appeal case are not directed to the requests, facts, objections, arguments and evidence on which the decision under appeal was based, they are regarded as an “amendment.”⁶⁸ Two situations must be distinguished. In the first situation, the party presents, in its appeal, a case that is amended in comparison to what it had presented before the department of first instance. For example, a patent proprietor files a new claim request (i.e., a new set of claims) in its appeal, or the opponent submits a new prior art document, which had previously not been brought before the Opposition Division. In such a case, the filing of the new request or document is an amendment of the party's case and may be admitted only at the discretion of the Board.⁶⁹ The criteria that the Board may use in the exercise of its discretion are, *inter alia*, the complexity of the amendment, the suitability of the amendment to address the issues that led to the decision under appeal, and the need for procedural economy.⁷⁰

In the second situation, the appellant's case on appeal is not changed in comparison to the case it had presented during the first instance proceedings. However, the department of first instance did not base its decision on what was submitted by the party in the first instance proceedings. The submission on appeal is still regarded as an amendment under Article 12(4) of RPBA 2020. If, for example, the Opposition Division found the patent proprietor's main claim request to fulfill the patentability criteria of the EPC, it had no reason to address the patent proprietor's auxiliary requests in its decision. It is also possible that the Opposition Division found the disclosure of one prior art document to be novelty-destroying so that it had no reason to consider a second prior art document on which the opponent relied before the Opposition Division and still relies in its appeal. In such cases, the patent proprietor must demonstrate that the auxiliary requests – and the opponent must demonstrate that the second prior art document – were admissibly raised before the Opposition Division and maintained until the Opposition Division took its decision.⁷¹ If the party concerned complies with this obligation, the auxiliary requests and second prior art document will be part of the appeal proceedings and cannot be excluded by the Board.

In addition to these two situations, which are governed by Article 12(4) of RPBA 2020, Article 12(5) and (6) of the Rules regulate other typical situations in which a party submission may not be

64 RPBA 2020, arts 12(4), 13(1)–(2). See the explanatory remarks to the RPBA 2020 as contained in *Rules of Procedure of the Boards of Appeal*, EPO Doc. CA/3/19, 2020 OJ EPO Supp. 2 (Jan. 31, 2020) [Hereinafter *Rules of Procedure of the Boards of Appeal*]; see, in particular, the explanatory remarks to Articles 12(4), 13(1) and 13(2).

65 Or a period set in a communication under Rule 100(2) of the EPC has expired. However, these communications are sent sparingly by the Boards.

66 Or a period set in a communication under Rule 100(2) of the EPC has expired.

67 RPBA 2020, art. 12(2).

68 RPBA 2020, art. 12(4) first sentence.

69 RPBA 2020, art. 12(4) second sentence.

70 RPBA 2020, art. 12(4) fifth sentence.

71 RPBA 2020, art. 12(4) first sentence.

admitted into the appeal proceedings. For example, it is required that the statement of grounds of appeal and the reply thereto clearly and concisely set out the reasons why it is requested that the decision under appeal be reversed, amended or upheld, and it should specify expressly all the requests, facts, objections, arguments and evidence relied upon.⁷² Any part of the submission not meeting this requirement may not be admitted.⁷³ Moreover, the Board might not admit a request or document if the same request or document was already not admitted by the Opposition Division⁷⁴ or if a request or document should already have been submitted during the opposition proceedings (or, if they were submitted, no longer maintained).⁷⁵ Articles 12(5) and (6) of RPBA 2020 are applicable throughout the entire appeal proceedings – that is, they are also applicable at the later levels of the convergent approach.⁷⁶

11.6.4.2 Second level of the convergent approach

After the initial exchange of briefs (i.e., the appellant's statement of grounds of appeal and the respondent's reply thereto), the second level of the convergent approach commences. If parties amend their appeal case at this stage, they must provide reasons as to why their initial case has been amended and why this has been done only at this stage of the appeal proceedings. All amendments of a party's appeal case at this stage are subject to the Board's discretion alone.⁷⁷

The RPBA 2020 contains a list of possible criteria for applying that discretion. In general, the criteria for this stage are stricter than those at the first level of the convergent approach. The Board may consider, for example, whether the amendment is suitable for resolving the issues raised (at the first level of the convergent approach, it may be sufficient that the amendment "addresses" them) or whether the amendment is detrimental to procedural economy.⁷⁸

The RPBA 2020 also mentions specific requirements for when the patent or patent application is amended on appeal. In these situations, the applicant or patent proprietor must demonstrate why the amendment, *prima facie*, overcomes the objections raised so far and does not give rise to new objections (such as a new objection of lack of clarity or added subject matter).⁷⁹

11.6.4.3 Third level of the convergent approach

The third level of the convergent approach imposes the most stringent limitations on a party wishing to amend its appeal case. This level commences at an advanced stage of the proceedings, usually after a summons to oral proceedings has been notified.⁸⁰

At this late stage of the appeal proceedings, amendments to a party's appeal case are not to be taken into consideration. However, a limited exception is provided if there are "exceptional circumstances."⁸¹ For this exception to apply, a party must present compelling reasons ("cogent reasons") why the circumstances of the particular appeal exceptionally justify that the amendment be taken into account at this late stage of the proceedings. This may be the case, for example, if a party submits that the Board raised an objection for the first time in its communication that was sent in preparation for the oral proceedings (on this communication, see Section 11.6.8.2 below). The party must explain precisely why this objection is new and does not fall under objections previously raised by the Board or a party. The Board may then decide that there are exceptional circumstances and admit the amendment in the exercise of its discretion.

72 RPBA 2020, art. 12(3).

73 RPBA 2020, art. 12(5).

74 RPBA 2020, art. 12(6) first sentence.

75 RPBA 2020, art. 12(6) second sentence.

76 See RPBA 2020, art. 13(1) second sentence. See also the explanatory remarks to Article 12(4) of the RPBA 2020 as contained in *Rules of Procedure of the Boards of Appeal*.

77 RPBA 2020, art. 13(1).

78 RPBA 2020, art. 13(1) fourth sentence.

79 RPBA 2020, art. 13(1) fourth sentence.

80 RPBA 2020, art. 13(2). The third level also applies if the amendment to a party's appeal case is made after the expiry of a period specified by the Board in a communication under Rule 100(2) of the EPC; but, in practice, such a communication is rarely issued.

81 RPBA 2020, art. 13(2).

11.6.5 Early case management

11.6.5.1 Designation of rapporteur for the preliminary study of appeal

For the early management of a case, the chair of the Board may first designate only the rapporteur before determining the remaining composition of the Board.⁸² The rapporteur then carries out a preliminary study of the appeal.⁸³ The rapporteur also assesses whether the appeal should be given priority over other appeals – for example, if a remittal to the Examining or Opposition Division seems likely (e.g., because of a fundamental deficiency in the proceedings) or if the appeal appears to be inadmissible. The rapporteur can also suggest that the appeal be treated together with other appeals – for example, because they are clearly connected to each other (e.g., parent and divisional applications or applications based on the same priority application).⁸⁴

Only when the composition of the Board is complete may the rapporteur draft communications on behalf of the Board to the parties, make preparations for the oral proceedings and draft decisions.⁸⁵

11.6.5.2 Acceleration of the appeal proceedings

In general, cases are treated based on a first in, first out principle. However, a Board may accelerate the proceedings of its own motion.⁸⁶ This allows the Boards to give an appeal priority over other pending appeals. A case may, for example, be accelerated because the rapporteur has identified a fundamental deficiency in the proceedings at first instance, which renders the case highly likely to be remitted.

Parties may also request the acceleration of appeal proceedings.⁸⁷ The requesting party needs to provide reasons and, where appropriate, documentary evidence. Valid reasons for acceleration are, for example, that national infringement proceedings have been brought or are envisaged or that the decision of potential licensees of the patent-in-suit hinges on the outcome of the appeal.

Acceleration can be requested not only by parties but also by a national court. A court does not need to provide specific reasons for requesting acceleration. As a rule, Boards will grant a request for acceleration from a court. The Board will subsequently also promptly inform the court of when oral proceedings are likely to take place.⁸⁸

When the Board decides to accelerate proceedings, the case is given priority over other cases, and the Board may adopt a strict framework for the purpose of case management,⁸⁹ subject to the parties' right to be heard and the principle of fair proceedings. If the parties agree, the minimum notice of two months for summons to oral proceedings can be shortened as well.⁹⁰

11.6.5.3 Early exchange with the parties

No pre-hearings or case management hearings are organized before the Boards of Appeal. In the written phase of proceedings, the directions on matters of procedure are given by means of written communications.⁹¹ In practice, such early directions are rarely given.

The Board may also invite the parties, through a communication, to file observations on specific issues or in reaction to a preliminary view of the Board on patentability issues.⁹² Such a communication may be useful where parties have not requested oral proceedings. If such an invitation is accompanied by a time limit for reply, the applicant in *ex parte* proceedings must pay

82 RPBA 2020, art. 5(1).

83 RPBA 2020, art. 5(3).

84 See RPBA 2020, art. 10(2).

85 RPBA 2020, art. 5(1) fourth sentence, in conjunction with art. 5(4), (5).

86 RPBA 2020, art. 10(5).

87 RPBA 2020, art. 10(3).

88 RPBA 2020, art. 10(4).

89 RPBA 2020, art. 10(6).

90 EPC, r. 115(1) second sentence. The notice period for the summons can be shortened independently of an acceleration request.

91 RPBA 2020, art. 17(1).

92 EPC, art. 100(2).

special attention to the communication: if the applicant does not reply to the invitation within the period specified by the Board, the European patent application is deemed to be withdrawn.⁹³

In most cases, the first communication on substantive issues is issued to the parties once the date for the oral proceedings is set (see Section 11.6.8.2 below).

11.6.5.4 Annual list of cases

Before the start of a new calendar year, a list of cases is published, indicating for each Board all the cases that will likely be treated in the coming year, particularly cases where it is likely that oral proceedings will be held or a communication will be issued.⁹⁴ This advance planning of the expected workload for the coming year is done by the chair of each Board in October of the preceding year. It is intended to increase efficiency for the Boards and the parties and to make the work of the Boards more transparent and predictable. The annual list of cases is published on the Boards of Appeal website.⁹⁵

11.6.6 Evidence – experts

The EPC provides a nonexhaustive list of how evidence can be obtained and given, such as the production of documents, the hearing of witnesses, opinions by expert, inspection or sworn statements in writing.⁹⁶

Documents constitute the vast majority of evidence considered in proceedings before the Boards of Appeal. Sworn statements are, in practice, rare; instead, unsworn statements or affidavits are produced by the parties. Regarding the taking of evidence by way of an expert opinion, the Technical Boards of Appeal are composed of technical judges, who are well versed in the technical field of the case, so obtaining an expert opinion will almost never be necessary. The hearing of witnesses before the Boards of Appeal is very rare as well. Witnesses, who play a role in the proceedings particularly when an opponent alleged a public prior use, will normally have already been heard before the Opposition Division.

11.6.7 Confidentiality – public file inspection

Files relating to the proceedings before the Boards of Appeal may be inspected on request.⁹⁷ Parts of these files are excluded from public inspection, particularly the documents relating to the exclusion of or objections to members of the Boards of Appeal or of the Enlarged Board of Appeal; all draft decisions and notices and other internal preparatory documents;⁹⁸ and medical certificates filed by the parties.⁹⁹

Parties can request that documents be excluded from file inspection, particularly if their inspection would be prejudicial to the legitimate personal or economic interests of natural or legal persons.¹⁰⁰ Documents may also be excluded by the Board of its own motion for the same reasons, particularly to protect the interests of third parties (i.e., natural or legal persons not parties to the proceedings, or their representatives).¹⁰¹

The public part of the file can be accessed online via the European Patent Register.¹⁰²

93 EPC, art. 100(3). This consequence does not arise for the patent proprietor in opposition appeals proceedings.

94 RPBA 2020, art. 1(2).

95 Accessible from www.epo.org/law-practice/case-law-appeals/about-the-boards-of-appeal/annual-list-of-cases.html

96 EPC, art. 117.

97 EPC, art. 128(4).

98 EPC, r. 144.

99 See EPC, art. 144(d) together with the Decision of the President of the European Patent Office Dated 12 July 2007 concerning Documents Excluded from File Inspection, 2007 OJ EPO Spec. Ed. 3, ch. J.3.

100 See Decision of the President of the European Patent Office Dated 12 July 2007 concerning Documents Excluded from File Inspection, 2007 OJ EPO Spec. Ed. 3, ch. J.3, art. 1(2)(a).

101 Cf. Decision of the President of the European Patent Office Dated 12 July 2007 concerning Documents Excluded from File Inspection, 2007 OJ EPO Spec. Ed. 3, ch. J.3, art. 1(2)(b).

102 Accessible from www.epo.org/searching-for-patents/legal/register.html

11.6.8 Trial and hearing

11.6.8.1 Right to oral proceedings

Parties to proceedings before the Boards of Appeal have a right to oral proceedings.¹⁰³ If one party requests oral proceedings, a hearing must take place. If none of the parties requests oral proceedings (which is rather a rare occurrence), the Board may either summon the parties to oral proceedings on its own motion or decide the case in written proceedings.

Parties are usually summoned at least four months before the hearing is to take place.¹⁰⁴ They are summoned to the Boards of Appeal premises in Haar or to the EPO's headquarters in Munich. Oral proceedings may also be held by videoconference (see Section 11.6.8.4 below).¹⁰⁵

As a rule, oral proceedings before the Boards of Appeal are public.¹⁰⁶ In exceptional cases, a Board may decide to exclude the admission of the public where such admission could have serious and unjustified disadvantages (e.g., for a party to the proceedings).¹⁰⁷ It may also be the case, especially in proceedings before the Legal Board, that the European patent application has not yet been published; in this event, oral proceedings will not be public.¹⁰⁸

Parties may request a change of date of the oral proceedings.¹⁰⁹ However, parties must show serious reasons for such a request to be granted. Typical reasons that may justify a change of the date are the serious illness of the representatives or their firmly booked holiday or business trip, or if they had already been summoned to oral proceedings in other proceedings before the EPO or a national court.¹¹⁰ It is unlikely that reasons such as excessive work pressure or the appointment of a new professional representative will be accepted.¹¹¹

11.6.8.2 Communication issued by the Board of Appeal in preparation for oral proceedings

The Boards always issue a communication in preparation for oral proceedings.¹¹² This communication is based on a thorough analysis of the case and draws attention to matters that seem to be of particular significance for the decision to be taken. The communication should help the parties to concentrate on the essentials of the case in their preparation of oral proceedings and ensures that the oral proceedings are conducted efficiently. The Boards usually also give a preliminary opinion on the decisive points in their communications.¹¹³

These communications are normally issued at least four months in advance of the date of the oral proceedings.¹¹⁴ They may be issued together with the summons or later.

11.6.8.3 Conduct of oral proceedings and languages used

Oral proceedings are presided by the chair in the particular appeal. The chair ensures their fair, orderly and efficient conduct.¹¹⁵ If a party duly summoned to oral proceedings does not appear as summoned, the proceedings may continue without that party,¹¹⁶ and this party may then be treated as relying only on its written case.¹¹⁷

Each case before the EPO has a language of proceedings, which must be one of the official EPO languages (i.e., English, German or French). The language of proceedings is determined by the language in which the European patent application was filed.¹¹⁸ At the oral proceedings, however, parties may use any official language of the EPO.¹¹⁹ If a party chooses to deviate from the language of proceedings at the oral proceedings, they must give notice at least one month before

¹⁰³ EPC, art. 116(1).

¹⁰⁴ RPBA 2020, art. 15(1).

¹⁰⁵ RPBA 2020, art. 15a.

¹⁰⁶ EPC, art. 116(4).

¹⁰⁷ EPC, art. 116(4).

¹⁰⁸ See EPC, art. 116(4).

¹⁰⁹ RPBA 2020, art. 15(2).

¹¹⁰ See the list in RPBA 2020, art. 15(2)(b).

¹¹¹ See the list in RPBA 2020, art. 15(2)(c).

¹¹² RPBA 2020, art. 15(1).

¹¹³ RPBA 2020, art. 15(1) fifth sentence.

¹¹⁴ RPBA 2020, art. 15(1) sixth sentence.

¹¹⁵ RPBA 2020, art. 15(4).

¹¹⁶ EPC, r. 115(2).

¹¹⁷ RPBA 2020, art. 15(3).

¹¹⁸ EPC, art. 14(3).

¹¹⁹ EPC, r. 4(1).

the oral proceedings so that the EPO can organize and then pay for interpretation.¹²⁰ Parties can, of course, also provide for interpretation into the language of the proceedings at their own expense; at oral proceedings, they can also then use any official language of a Contracting State.¹²¹ In practice, oral proceedings before the Boards of Appeal with interpretation from and into one language – or even two or more languages – are quite frequent.

11.6.8.4 Oral proceedings by videoconference

The Boards of Appeal may hold oral proceedings by videoconference.¹²² Different setups are possible – for example:

- In “distributed oral proceedings,” all members, representatives and accompanying persons attend by videoconference.
- In “mixed-mode oral proceedings,” some parties, representatives and accompanying persons are physically present in the oral proceedings room with the board members, while others attend by videoconference.¹²³ Exceptionally, one or more of the board members may also attend by videoconference.¹²⁴

11.6.9 Decisions of the Board of Appeal

11.6.9.1 Decisions announced in oral proceedings

In the great majority of cases, the final decision of the Board is announced at the end of the oral proceedings.¹²⁵ After the chair closes the debate, they announce the order of the decision – for example, that the appeal is dismissed, that the patent is revoked, that the patent is maintained in a version different from the one granted or that the case is remitted for further prosecution. Once the decision is announced by the chair, it can no longer be changed by the Board.

11.6.9.2 Written decision within three months

The written decision, which includes the summary of the facts, the reasons and the order,¹²⁶ is issued in a timely manner.¹²⁷ For the usual case, where the decision is announced at the oral proceedings, this means that the Board must despatch it within three months of the date of the oral proceedings.¹²⁸

However, it may be that the Board is unable to meet this deadline: for example, because of the sickness of a member or because the case is particularly complex. In such cases, the Board should then inform the parties of the delay and when the decision is likely to be despatched.¹²⁹

The written decision is (electronically) signed by both the chair and the registrar of the Board.¹³⁰ It is notified to all parties.¹³¹

11.6.9.3 Reasons given for decision in abridged form

A Board may put the reasons for a decision, the order of which was announced in the oral proceedings, in an abridged form. However, this is possible only under the condition that the parties have given their consent.¹³² A Board cannot give the reasons in an abridged form if a third party or a court has informed the Board that it has a legitimate interest in the reasons for the decision not being in abridged form.¹³³

A Board may also decide to put the reasons for the decision in an abridged form if it agrees with all the findings and reasoning of the decision under appeal or with only the findings on one or

120 EPC, r. 4(5).

121 EPC, r. 4(1) second sentence.

122 RPBA 2020, art. 15a.

123 RPBA 2020, art. 15a(2).

124 See RPBA 2020, art. 15a(3).

125 RPBA 2020, art. 15(6).

126 EPC, r. 102, second sentence.

127 RPBA 2020, art. 15(9).

128 RPBA 2020, art. 15(9)(a).

129 RPBA 2020, art. 15(9)(a) second sentence.

130 EPC, r. 102 first sentence. For the role of the registrars, see RPBA 2020, art. 6.

131 EPC, r. 125. Decisions are notified by registered letter (EPC, r. 126) or by means of electronic communication (EPC, r. 127).

132 RPBA 2020, art. 15(7) first sentence.

133 RPBA 2020, art. 15(7) second sentence.

more specific issues.¹³⁴ In practice, however, written decisions rarely contain the reasons in an abridged form.

11.6.10 Costs

In *inter partes* proceedings before the Boards of Appeal (and in proceedings before the Opposition divisions), the rule is that each party (i.e., the patent proprietor and the opponent) must bear the costs it incurs.¹³⁵ An exception to this principle is if the Board, for reasons of equity, decides on a different apportionment of costs.¹³⁶

Before the Boards of Appeal, the party seeking a different apportionment of costs must file a request.¹³⁷ Eligible costs include those incurred because a party amended its appeal case at a late stage of the proceedings, because a party's behavior interfered with the timely and efficient conduct of oral proceedings, or because there has been an abuse of procedure.¹³⁸

The Board may decide on the apportionment of the costs by indicating a percentage of the costs to be borne or by expressing a specific sum.¹³⁹ If the total is not already fixed by the Board in the order of the decision as a specific sum, it is subsequently determined in a separate procedure for fixing the costs.¹⁴⁰ Eligible costs include, for example, those charged to a party by its professional representative and those of witnesses or experts paid by a party. However, such costs must always be necessarily and reasonably incurred.¹⁴¹

The final cost orders of the Boards of Appeal (or the EPO) are directly enforceable in the Contracting States. They are equivalent to final decisions given by a civil court of the state in which enforcement is to take place.¹⁴²

¹³⁴ RPBA 2020, art. 15(8).

¹³⁵ EPC, art. 104(1).

¹³⁶ EPC, art. 104(1).

¹³⁷ RPBA 2020, art. 16(1).

¹³⁸ See the nonexhaustive list in RPBA 2020, art. 16(1).

¹³⁹ RPBA 2020, art. 16(2) first sentence.

¹⁴⁰ See EPC, art. 104(2).

¹⁴¹ EPC, art. 16(2) third sentence.

¹⁴² EPC, art. 104(3). This also holds true in the event that the Board decides, directly in its decision on the appeal, to express the costs to be paid as a specific sum. See RPBA 2020, art. 16(2) second sentence.

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