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 Jam. 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" claiming[14] – 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 2011[19] 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 relief[29] 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.

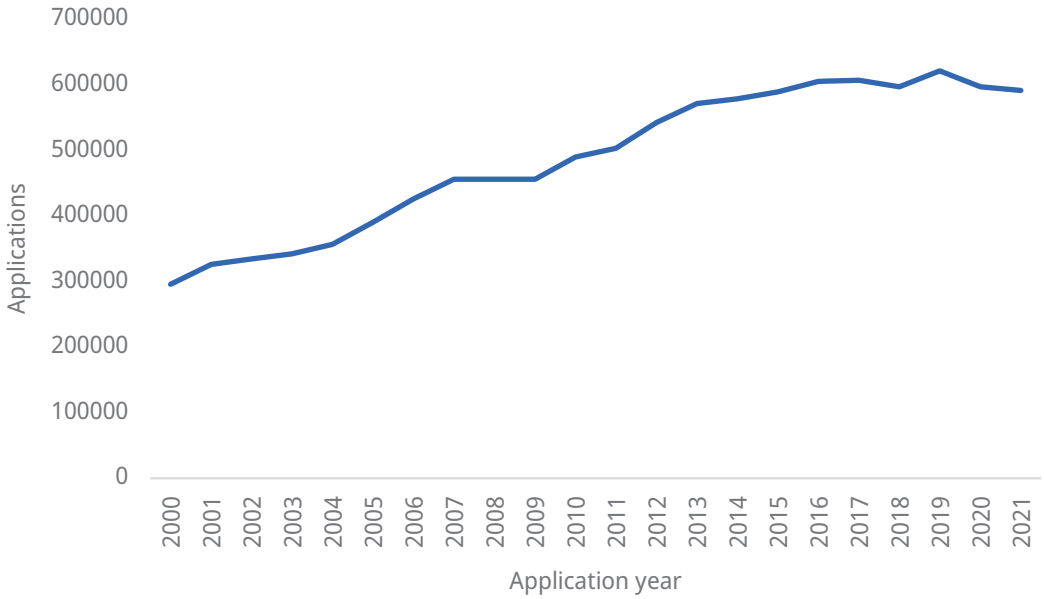
Although the U.S. patent system has authorized the USPTO to correct defects and adjust patent scope through a reissuance process,[33] Congress did not authorize the USPTO to reexamine or revoke patents until 1980. As a result of the AIA, administrative patent review is now a robust and commonly used 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 patent[40] – 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 PTAB[51] 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)

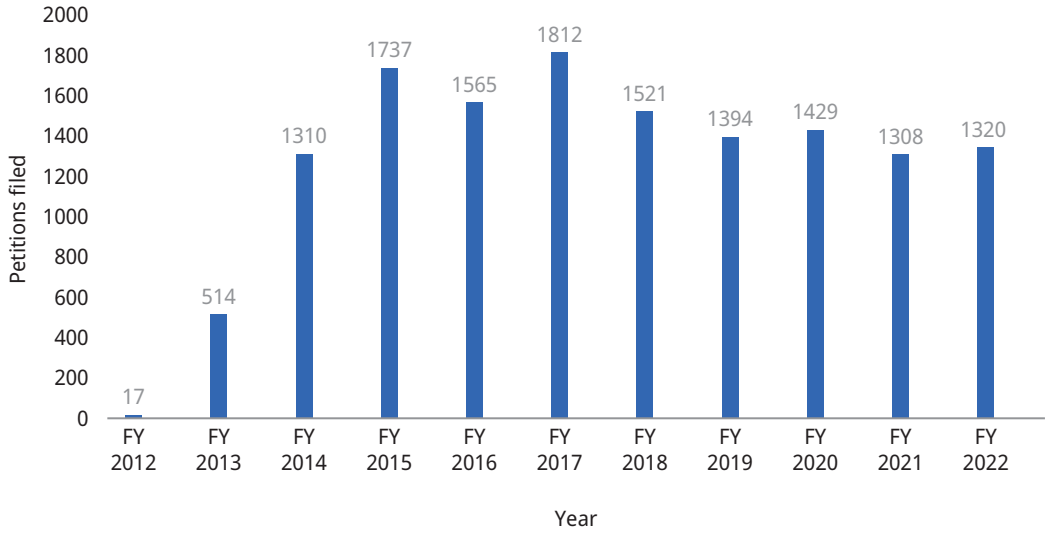
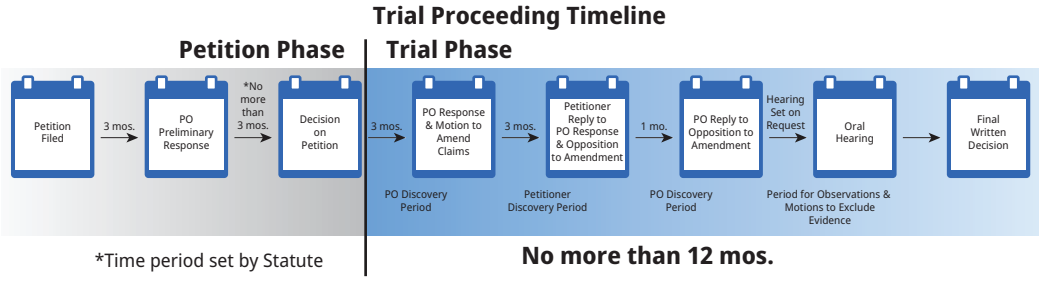


Figure 10.3 illustrates the IPR timeline, described in further detail below.[56]

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]

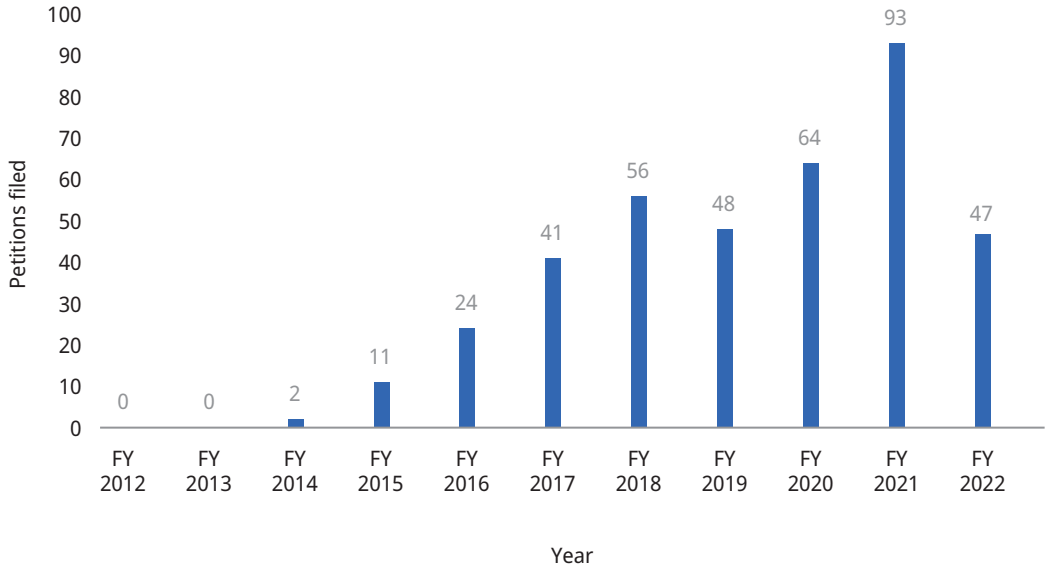
10.2.2.4.5 Estoppel

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 statute[79] 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.

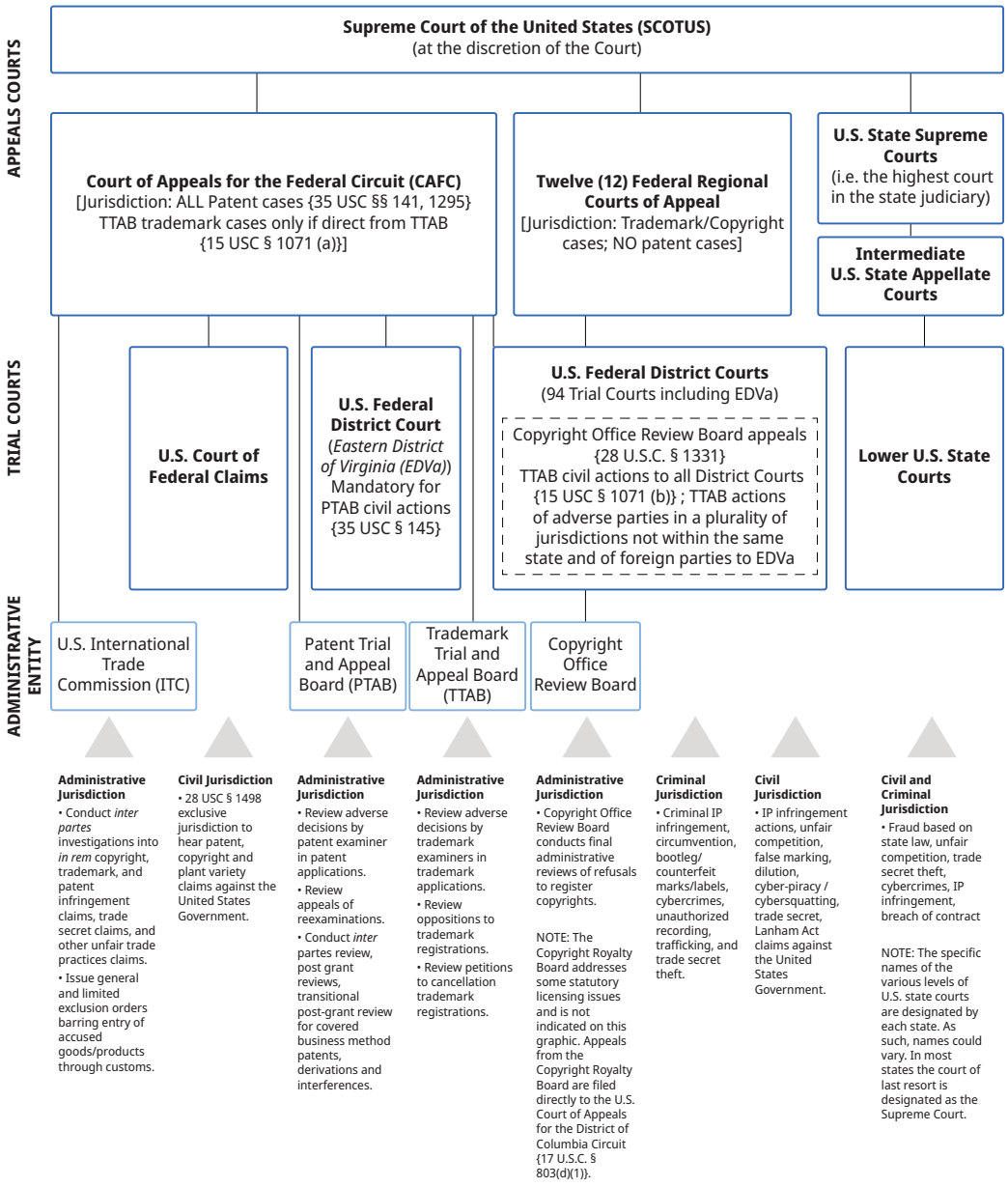
FRCP 53 and Federal Rule of Evidence (FRE) 706 authorize district judges to appoint special masters to hear evidence and argument from the parties and render an initial decision on substantive matters, such as claim construction or summary judgment. Special masters may also present testimony at trials. 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 patent[113] 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 *Insituform 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]

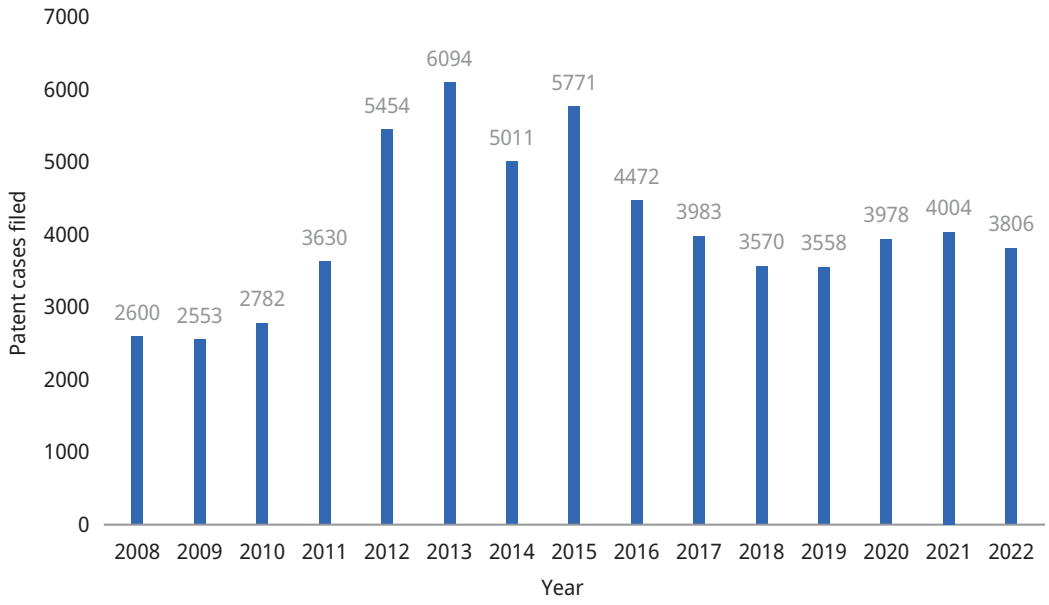
10.6 Judicial patent proceedings and case management

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

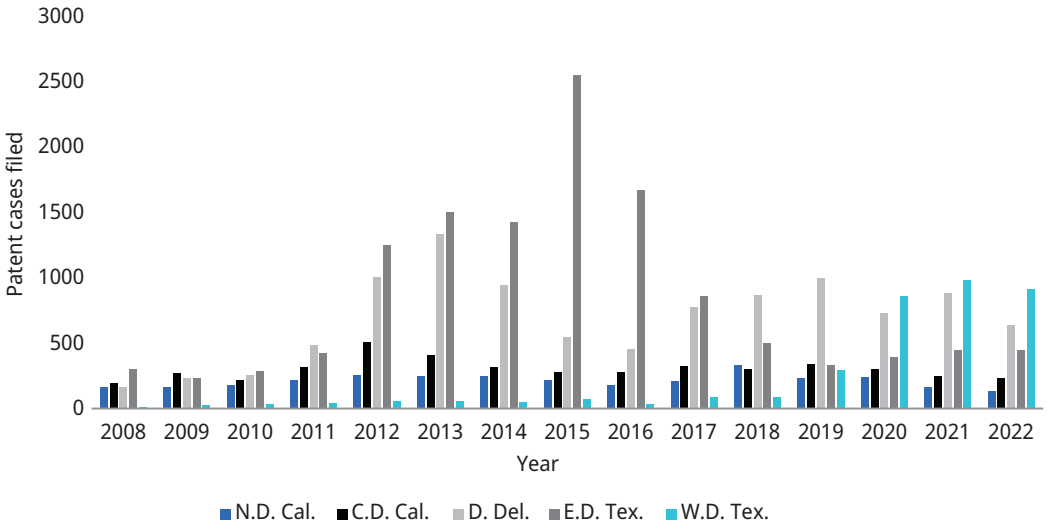
133 See *Cancer Research Tech. Ltd* v. *Barr Labs., Inc.*, 625 F.3d 724, 729 (Fed. Cir. 2010) (holding that "to establish prejudice[,] an accused infringer must show evidence of intervening rights, i.e., that either the accused infringer or others invested in, worked on, or used the claimed technology 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. §652(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/embodying 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 timetable[1]

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 jurisdiction[166] 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 issues[203] 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. *Stahlin 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

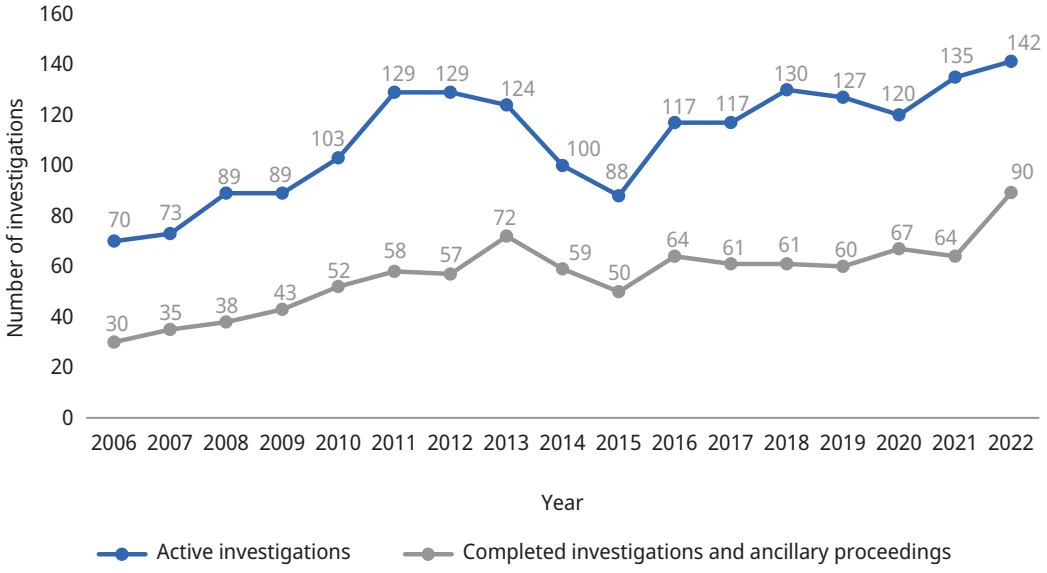
10.12.1 United States International Trade Commission

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 210.19[328] 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 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 [... I]t 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 *in rem* 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.
In rem jurisdiction	• Not available.	• Available.	• Available: "IPR is similarly an in rem 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 *forum non conveniens* 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 *res judicata* 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 *res judicata* 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 *res judicata* 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 *Phillips* standard.	• Practices vary across cases and ALJs, but are increasingly done prior to trial. • Employs the *Phillips* standard.	• Interpretation done by the PTAB panel applying the *Phillips* 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. • *Daubert* 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). • *Daubert* 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. • *Res judicata* effect.	• Initial determination by ALJ becomes final if not reviewed by the USITC within 45 days. • No *res judicata* 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 (factual determinations underlying claim construction rulings are subject to the "clearly erroneous" (or "abuse of discretion") standard of review, while the Federal Circuit exercises *de novo* review over the ultimate claim construction determination). • Substantial evidence or "clearly erroneous" standard for factual determinations. • *De novo* 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 *de novo* review over the ultimate claim construction determination). • Substantial evidence standard for factual determinations. • *De novo* review for the USITC's legal determinations.	• Reviewed under standards of the APA. • Substantial evidence standard for factual determinations. • *De novo* 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.