
CHAMBERS GLOBAL PRACTICE GUIDES

Life Sciences & Pharma IP Litigation 2026

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USA: Law & Practice

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Law and Practice

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Gemini Law LLP is a new kind of life sciences law firm that brings together some of the most experienced attorneys in an innovative, low-overhead model that allows the firm to offer “big law” service at half the cost or less. The team has decades of law firm, in-house, and Patent Office experience to provide a full range of services including high-stakes, complex IP litigation and appeals; post-grant proceedings; strategic patent prosecution and opinion work; IP transactions and diligence; and biotech counselling ser-

vices. As one example, the combined Gemini team has participated in the BPCIA “patent dance” dozens of times since the law was enacted. It has worked on IP transactions and diligence on deals worth tens of millions of dollars. The firm has tried dozens of cases at the district court, PTAB, and appellate level, and brings in-depth experience across small-molecule pharmaceuticals, biologics, medical devices, chemical and industrial products, and other technologies.

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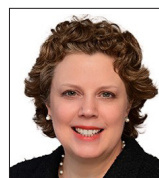
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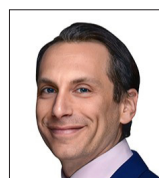
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1. Life Sciences and Pharma/ Biopharma Patent Litigation

1.1 Claimants/Plaintiffs to an Action

Standing to assert rights in US courts comes from Article III of the US Constitution. The Federal Circuit has recognised three categories of parties with rights in a patent that can be considered in the standing analysis: (i) those that have standing to sue in their own name, (ii) those that have standing to sue if joined with the patent owner; and (iii) those that do not have standing to sue at all. *Rite-Hite Corp. v Kelley Co.*, 56 F.3d 1538, 1551-52 (Fed. Cir. 1995) (en banc); *Lone Star Silicon Innovations LLC v Nanya Tech. Corp.*, 925 F.3d 1225, 1228 (Fed. Cir. 2019).

The first category includes the patent owner or an exclusive licensee that has “all substantial rights” in the patent. *Lone Star*, 925 F.3d at 1229. The second category includes exclusive licensees or others with “exclusionary rights” that have standing to assert patents if they join the patent owner. *Id.* The third category covers non-exclusive or “bare” licensees, who never have standing to sue, even if a contract purports to give them that right. *Textile Productions, Inc. v Mead Corp.*, 134 F.3d 1481, 1485 (Fed. Cir. 1998), cert. denied, 525 US 826 (1998).

A party may seek a declaration of invalidity, unenforceability, or non-infringement of a patent under the Declaratory Judgment Act, 28 USC 2201. To have standing, the party must establish a live case or controversy between the parties. However, a patent licensee is not required to break or terminate its licence before seeking a declaratory judgment. *MedImmune, Inc. v Genentech, Inc.*, 549 US 118, 137 (2007).

A party can also challenge a patent before the US Patent and Trademark Office (USPTO) in an inter partes review (IPR), post-grant review (PGR), or business method review. Because these are conducted before the USPTO rather than an Article III court, there is no standing requirement. Any person or entity may file an IPR to challenge the validity of a patent. 35 USCS. 311 (a). However, because appeals from USPTO proceedings are heard at the US Court of Appeals for the Federal Circuit, which is an Article III court, the challenger must have standing to appeal an adverse decision if necessary. *JTEKT Corp. v GKN Auto. Ltd.*, 898 F.3d 1217, 1219 (Fed. Cir. 2018). The appellant must show that it is engaged or will likely engage in some activity that would give rise to a possible infringement suit. *Id.* at 1220.

Finally, a party may seek an exclusion order at the International Trade Commission (ITC) by bringing an action under Section 337 of the Tariff Act. 19 USC 337. The party must allege an unlawful act of trade, such as patent infringement, and satisfy a “domestic industry” requirement. This requires the complainant to show “an industry” as defined by Section 337 (a)(3) (commonly called the “economic prong”) and relation to the patented article (commonly called the “technical prong”). *Lashify, Inc. v Int’l Trade Comm’n*, 130 F.4th 948, 951 (Fed. Cir. 2025).

1.2 Defendants/Other Parties to an Action

In general, the defendants named in life sciences lawsuits include those that submit US Food and Drug Administration (FDA) filings such as New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), abbreviated Biologics Licence Applications (aBLAs), and Biologics Licence Applications (BLAs).

In Hatch-Waxman and Biologics Price Competition and Innovation Act (BPCIA) litigations, patentees are required under 35 USC 271 (e)(2) to sue at least the party that submits the ANDA or aBLA, respectively, because it is the submission that can constitute an artificial act of infringement. In at least one litigation, however, a district court adopted an expansive definition of what it meant to submit an application and permitted a patentee to bring infringement claims against a foreign parent company where the US subsidiary, not the parent, was the named sponsor of the aBLA. See *AbbVie Inc. v Alvotect hf.*, No 1:21-cv-02258, Doc. 51 (N.D. Ill. 23 August 2021). Referring to an earlier Federal Circuit case, the district court stated that an entity “submits” a regulatory file where it “intends to benefit directly” from approval and “by participating in the manufacture, importation, distribution and/or sale” of the drug product.

Unless it impacts a patentee’s preference for venue, a patentee may also sue other affiliates/parties involved in the development, submission, and/or commercialisation of the accused drug product. Often the patentee will stipulate to dismissal of the dispensable parties in exchange for an agreement that they will be bound by the outcome of the case and co-operate with discovery.

Whether any other entities will be sued is fact-dependent, but rare. In one instance, an insurance company was sued for inducing infringement of a method of treatment patent that had been allegedly carved out from the generic applicant’s product. Those infringement allegations survived a motion to dismiss. *Amarin Pharma, Inc. v Hikma Pharms. USA Inc.*, 578 F. Supp. 3d 642 (D. Del. 2022).

Third parties who supply components of a drug product or manufacturing services are less likely to be sued but may be the subject of subpoenas for discovery. See *In Re Subpoena to FujiFilm Irvine Scientific*, Civil No 24-8830 (CPO/EAP) (ECF No 18). Distributors (apart from commercial partners) and doctors are rarely sued in typical Hatch-Waxman or BPCIA cases.

1.3 Preliminary Injunction Proceedings

Preliminary injunctions (PIs) are available in life sciences patent cases in district court. PIs are ordered

if a four-factor test is met, where the plaintiff must establish:

- it is likely to succeed on the merits on a granted patent;
- it is likely to suffer irreparable harm in the absence of relief;
- the balance of equities tips in the plaintiff’s favour; and
- an injunction is in the public interest.

Winter v Natural Resources Defense Council, Inc., 555 U.S. 7 (2008).

The Court may deny relief if the plaintiff fails to prove any one of the four factors, especially either of the first two. See, eg, *Jack Guttman, Inc. v KopyKake Enters., Inc.*, 302 F.3d 1352, 1356 (Fed. Cir. 2002). A PI, if granted, will enjoin allegedly infringing activities, eg, sales of the defendant’s products, until patent expiration or a district court decision on the merits. Ex parte preliminary injunctions are not available. The defendant always has an opportunity to oppose a request for a PI.

A temporary restraining order (TRO) may also be available and can be requested ex parte. The standards for granting TROs and PIs are generally the same, but TROs are more limited in time, as they only last for a short, specified period and are a first-line, emergency relief that a patentee may seek if infringement/harm is imminent.

Demonstrating irreparable harm entails showing a likelihood of substantial and immediate irreparable injury. *Apple, Inc. v Samsung Elecs. Co.*, 678 F.3d 1314, 1325 (Fed. Cir. 2012). In general, demonstrating irreparable harm is more straightforward where the defendant is directly taking, and the only party directly taking, market share away from the patentee. See, eg, *Abbott Labs. v Sandoz*, 544 F.3d 1341, 1361-62 (Fed Cir 2008). Additionally, although there is no true deadline for seeking a PI, where a patentee fails to show urgency and delays seeking a PI once a launch is imminent or infringement is recently discovered, that weighs in favour of denying the request for the PI. See, eg, *Pfizer, Inc. v Teva Pharms., USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005); *Genentech*,

Inc. v Amgen Inc., 2019 WL 3290167 at *2–3 (D. Del. 18 July 2019).

PIs rarely rise or fall solely based on balancing hardships or public interest. With respect to the former, courts generally consider potential harm to the patentee, including potential loss of market exclusivity, price erosion, and downstream financial impacts on, eg, R&D, and compare that to harm that an injunction would impose on the defendant, including potential loss of investment in manufacturing and marketing. In evaluating public interest, courts often weigh, eg, the importance of protecting patent rights, the public's interest in patients being afforded access to lower cost medicines, and whether the accused product provides a patient population with a unique role that cannot be replaced even by the brand.

Courts may issue PIs only after notice has been provided under Federal Rule of Civil Procedure (FRCP) 65. Motions for PIs are filed as part of a federal patent case, either with a complaint or later in litigation. The defendant is immediately provided notice of the request and, pursuant to any applicable local rules and/or court order, can submit an opposition. The opposition, like the motion itself, generally includes expert declarations and other evidence. Often, PI proceedings will amount to “mini trials,” with depositions, live testimony, and oral argument. The court will weigh the evidence and decide whether a PI is warranted.

Although they are available in the Hatch-Waxman context, requests for PIs are not common. Under the ANDA framework, a 30-month stay ensues if a brand product patent owner files an infringement suit against generic applicants within 45 days of receiving an ANDA notification. 21 USC 355 (j)(5)(B). Because of the 30-month stay, the parties usually have time to litigate any patent disputes before the ANDA filer can receive final approval and be able to launch. That said, PI motions are possible after the expiration of the 30-month stay and final approval, depending on what patent disputes are outstanding at that point and whether the defendant threatens to “launch at risk.”

Requests for PIs are more common in biosimilar cases under the BPCIA. In BPCIA cases there are no automatic 30-month stays of approval or automatic stays

of approval after a finding of patent infringement (but see 35 USC 271 (e)(4)(D)). Requests for PIs are normally triggered by a notice of commercial marketing (NCM) by the aBLA applicant to the reference sponsor, which must be given no less than 180 days before commercial marketing begins. The notice gives the patentee time to seek a PI and for the court to preside over PI proceedings, if requested by the sponsor, before a product launch.

1.4 Structure of Main Proceedings on Infringement/Validity

In the United States, infringement and validity proceedings are generally handled together. For example, a patent holder may sue a defendant for infringement, and the defendant may raise affirmative defences or counterclaims related to non-infringement and invalidity. The defendant may also raise equitable defences such as laches, estoppel, or patent misuse. These defences are typically tried together although it is possible that certain equitable defences may be bifurcated at the discretion of the court.

If damages are at issue, a defendant generally has a constitutional right to a jury trial under the Seventh Amendment to the US Constitution. However, most cases brought under the Hatch-Waxman act are instituted before a product has been launched during a 30-month stay of approval, and thus damages are not at issue. These cases are typically tried to the court rather than a jury (which is referred to as a “bench trial”). When damages are at issue, they may be handled at the same time as other issues or in a bifurcated manner, either upon request of the parties or by sua sponte order of a court.

It is possible to file patent actions while the Patent Office is conducting an IPR, in which the court may decide whether to stay the case. The impact of a potential IPR will be discussed below in **1.16 Requirements to Bring Infringement Action**.

1.5 Timing for Main Proceedings on Infringement/Validity

There is no formal statute of limitations for patent infringement actions in the United States, although a patent holder may only recover for damages going back six years from the filing of the complaint. 35 USC

286. A patent holder does not have to sue as soon as a patent issues or infringement is expected, although if the patent holder waits too long, the defence of laches may come into play. Laches cannot bar a claim for damages if it is brought within the time period set by 35 USC 286. *SCA Hygiene Prods Aktiebolag v First Quality Baby Prods, LLC*, 137 S. Ct. 954, 121 USP.Q. 2d 1873 (2017).

Parties in patent proceedings are notified of the action by service. Service is governed by FRCP 4 and 5, as well as local rules of the district in which the case is filed.

Under FRCP 4 (m), a defendant must be served within 90 days after the complaint is filed, and the remainder of the deadlines in the case do not run until service is effected. A party can waive formal service in return for an automatic extension of the deadline to answer the complaint. FRCP 4 (d).

The usual time to a final decision varies greatly by district and the nature of the case. The median time to trial can range from just over a year in some of the faster “rocket dockets” (E.D. Va.) to three to four years in other district courts.

1.6 Requirements to Bring Infringement Action

Patent infringement suits can only be based on granted patents, not pending patent applications or allowed applications soon to grant. For a plaintiff to file a patent infringement suit, it must have standing, as discussed in 1.1 Claimants/Plaintiffs to an Action.

Absent the specialised regulatory frameworks governing small molecules and biologics, the filing of a regulatory file would not constitute patent infringement. See 35 USC 271 (a) (infringing acts include making, using, offering to sell, selling, or importing a patented invention within the United States without authority to do so). The Hatch-Waxman Act and BPCIA enable plaintiffs to bring infringement actions at certain points in the ANDA or aBLA regulatory process even if the applicant has not yet committed an act that would traditionally constitute patent infringement. The filing of an ANDA or aBLA in these contexts qualifies as an “artificial” act of infringement under 35 USC 271 (e).

Under the Hatch-Waxman Act, to file suit based on an ANDA filing, the plaintiff must have received notice of a Paragraph IV certification from the ANDA filer, asserting that one or more patents listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”) are invalid, unenforceable, and/or not infringed. The only patents that can be listed in the Orange Book are those that claim the drug substance (or active ingredient), the drug product (or the drug formulation), or an approved method of treatment using the drug substance or product. Patents for processes, packaging, metabolites, intermediates, or devices that do not otherwise claim the active ingredient cannot be listed. Courts may allow patentees to assert non-listed Orange Book patents once a litigation has commenced, but those patents cannot be the basis for automatic stays of FDA approval.

Under the BPCIA, to file suit based on an aBLA filing, at least one of the following acts must have occurred: (i) the aBLA filer provided an NCM (see 1.3 Preliminary Injunction Proceedings), (ii) the parties completed the patent dance, or (iii) the aBLA filer opted out of the patent dance. There are no limits to the types of patents that can form the basis of a BPCIA patent infringement action. In fact, the vast majority of patents asserted in BPCIA cases are process patents.

Generally, to maintain an action for patent infringement based on a process patent, the patentee must show that the process is performed in the United States under 35 USC 271 (a) or that the product of the patented process is sold in, or imported into, the United States under 35 USC 271 (g) unless the product of the patented process was “materially changed” prior to importation or becomes a “trivial and non-essential component” of the product being imported.

1.7 Pre-Action Discovery/Disclosure

There is generally no pre-action discovery for patent infringement cases in the United States except for pre-action information exchanges in Hatch-Waxman and BPCIA cases. Under the Hatch-Waxman Act, if the ANDA filer is relying on non-infringement positions in its Notice Letter, it must include an Offer of Confidential Access to produce at least relevant portions of the ANDA. If the parties agree on the terms

under which documents will be produced, then the ANDA filer can produce those documents so that the NDA holder can determine whether a lawsuit may be brought for infringement.

Under the BPCIA, an aBLA filer can – but is not required to – participate in an exchange of information colloquially referred to as the “patent dance.” 42 USC 262; *Sandoz Inc. v Amgen Inc.*, 137 S. Ct. 1664, 1675–76 (2017). If the aBLA filer elects to engage in the patent dance, it must produce the aBLA and “such other information that describes the [manufacturing] process” within 20 days of the FDA acceptance of the BLA for review. 42 USC 262 (l)(2). That production can be done pursuant to confidentiality terms set forth in the BPCIA or pursuant to the parties’ private agreement. The reference product sponsor (RPS) then provides a list of patents it believes are infringed within 60 days of receipt of the applicant’s information under 42 USC Section 262 (l)(3). The parties then exchange contentions on those patents to agree on a final set of patents to litigate in a BPCIA action. 42 USC 262 (l).

Pre-action discovery is otherwise not generally available in the United States, with the exception of asking for an order to depose someone to perpetuate his or her testimony under FRCP 27. FRCP 27 provides a means to preserve evidence, such as when an individual is terminally ill and may be deceased before an infringement suit is filed.

1.8 Search and Seizure Orders

Search and seizure orders are not available for patent infringement in the United States. Although the USA allows for robust discovery under the FRCP, those rules do not allow parties to search for or remove materials from an accused infringer in the same way that search and seizure orders are available in other countries. Instead, parties must submit discovery requests such as requests for production of documents and information (FRCP 34), interrogatories (FRCP 33), and requests for admission (FRCP 36). Parties may seek inspections of the accused infringer’s premises under FRCP 34 (a)(2), which can be used to inspect factory equipment or other machinery that cannot easily be produced.

As noted in 1.7 Pre-Action Discovery/Disclosure, there is generally no pre-action discovery in the United States except for pre-suit exchanges under the Hatch-Waxman Act and BPCIA. Other than that, a patentee must conduct its own investigation using the information that is available to it and ensure that it can satisfy the requirement of FRCP 11 that it has a valid claim formed after a reasonable inquiry under the circumstances.

When pre-action exchanges are made under the Hatch-Waxman Act or BPCIA, they generally cannot be used in other jurisdictions because they are governed by confidentiality agreements between the parties that restrict their dissemination and use.

1.9 Declaratory Relief

US federal courts may grant declaratory relief in patent disputes when there is an actual case or controversy within the meaning of Article III of the US Constitution. Declaratory relief is discretionary under the Declaratory Judgment Act and requires a real and immediate dispute between parties with adverse legal interests, rather than a hypothetical or speculative disagreement. *Aetna Life Ins. Co. v Haworth*, 300 US 227, 239–41 (1937).

A party seeking declaratory relief does not need to breach a licence or otherwise expose itself to liability before bringing suit. *MedImmune, Inc. v Genentech, Inc.*, 549 US 118, 127–29 (2007).

In life sciences patent litigation, declaratory relief commonly takes the form of declarations of non-infringement, invalidity, or unenforceability of specific patent claims. US law does not recognise “Arrow declarations”; declaratory relief must be tied to identified patent rights and an actual controversy.

In BPCIA litigation, statutory limits apply. For example, if a biosimilar applicant fails to comply with the information-exchange provisions of the patent dance, it may be barred from bringing certain declaratory judgment actions relating to patents that could have been identified during that process. 42 USC 262 (l)(9).

1.10 Doctrine of Equivalents

US patent law recognises the Doctrine of Equivalents (DoE), which permits a finding of infringement even where an accused product or process does not literally meet every claim limitation. *Warner-Jenkinson Co. v Hilton Davis Chem. Co.*, 520 US 17, 29–30 (1997).

Courts assess equivalence using the function–way–result test or the insubstantial differences test, and the analysis must be conducted on an element-by-element basis rather than by reference to the invention as a whole. *Graver Tank & Mfg. Co. v Linde Air Prods. Co.*, 339 US 605, 608–09 (1950).

DoE is subject to important limitations. Prosecution history estoppel prevents a patentee from recapturing subject matter surrendered during prosecution. *Festo Corp. v Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 US 722, 733–34 (2002). Ensnarement bars a patentee from asserting equivalents that would encompass the prior art. *Jang v Boston Sci. Corp.*, 872 F.3d 1275, 1285–86 (Fed. Cir. 2017). Claim vitiation precludes application of DoE where it would effectively eliminate a claim limitation. *Edgewell Pers. Care Brands, LLC v Munchkin, Inc.*, 998 F.3d 917, 923–25 (Fed. Cir. 2021).

1.11 Clearing the Way

There is no obligation to “clear the way” ahead of a new product launch. Freedom to operate (FTO) analyses, however, are often conducted before launches by obtaining opinions from outside counsel. Accused infringers may rely on those opinions later in litigation to defend against allegations of wilful infringement – although such use will typically result in waiver of attorney–client privilege. A finding that a defendant wilfully infringed a patent can result in enhanced (eg, treble) damages. Producing an opinion of counsel can mitigate the risk of a wilful infringement finding by showing that the accused infringer acted reasonably, not recklessly or intentionally, after getting notice of the patent at issue.

Additionally, a party can petition for IPR or PGR of a patent at the USPTO, alleging that one or more claims of the patent is unpatentable. A party can bring such challenges before launching to help clear the way for a product launch, although it is not obligated to do so.

1.12 Experts

The use of experts is common in US life sciences patent litigation, which may involve several technical experts and economists. When a case is presented to a jury (or to the court in a bench trial), the court acts as “gatekeeper” to ensure that the expert’s opinion is based on scientific knowledge and a reliable methodology, which is referred to as the Daubert standard. *Daubert v Merrell Dow Pharmaceuticals Inc.*, 509 US 579 (1993).

In addition to satisfying Daubert, expert opinions are governed by the disclosure requirements of FRCP 26 (a)(2), which require testifying experts to submit written reports disclosing certain information.

Most patent cases in the life sciences include expert discovery, in which experts submit competing reports on infringement, invalidity, unenforceability, secondary considerations of non-obviousness (such as commercial success), and damages, if at issue. The experts are deposed by the opposing party. Experts often testify at trial using demonstratives or other ways of explaining technical or economic issues. Parties often make “Daubert motions” during the pre-trial period, particularly before jury trials, seeking to exclude the other side’s experts based on providing unreliable opinions.

1.13 Use of Experiments

In the United States, experts can engage in experimental testing and present their results in their written reports and/or at trial. These may cover infringement issues, such as testing the accused product to see if it meets certain patent claims, or invalidity issues, such as recreating the prior art to show inherency.

Sometimes parties hire non-testifying, consulting experts to conduct testing that is not used in litigation and does not have to be disclosed. For example, this may be done to test out an infringement or invalidity theory before having a testifying expert conduct such tests, since that testifying expert is required to disclose, and may be deposed about, their own testing.

1.14 Discovery/Disclosure

In the USA, the scope of discovery is broad. Parties may obtain discovery for any non-privileged matter

that is relevant to any party's claims or defences and is proportional to the needs of the case taking into consideration factors such as whether the burden or expense of the proposed discovery outweighs its likely benefits. FRCP 26 (b)(1).

In life sciences cases, discovery commonly includes technical descriptions of accused products or processes, inventor lab notebooks, batch records, regulatory submissions, internal research and development documents, and related communications. Parties typically use requests for production (FRCP 34), interrogatories (FRCP 33), requests for admission (FRCP 36), and fact witness depositions, including corporate designees under FRCP 30 (b)(6). Expert discovery proceeds through written reports and depositions under FRCP 26 (b)(2).

Many districts with significant patent dockets require early exchange of infringement and invalidity contentions under local patent rules, which structure the scope and sequencing of discovery. Discovery is commonly governed by protective orders due to the sensitivity of proprietary scientific and regulatory information.

1.15 Defences and Exceptions to Patent Infringement

A defendant has several categories of defences and statutory exemptions available, which can potentially defeat liability altogether, limit available remedies, or render the patent unenforceable.

At the most basic level, a defendant may establish non-infringement. Patent infringement is assessed on a claim-by-claim basis, and the patentee bears the burden of proving that every limitation of an asserted claim is met by the accused product or process. If one claim element is missing, either literally or under DoE, the claim is not infringed.

1.16 Stays and Relevance of Parallel Proceedings

US district court litigation may be stayed in view of an IPR or PGR proceeding either pursuant to statute or under the court's inherent discretionary authority to manage its docket.

For PGRs, Congress provided a statutory mechanism favouring stays. Once a PGR is instituted, a district court is required to consider a stay upon motion by the accused infringer, with a presumption that litigation should be stayed during the PTAB proceeding. The court considers whether a stay will simplify the issues in the case, whether discovery is complete and a trial date has been set, whether a stay would unduly prejudice the non-moving party or present a clear tactical disadvantage, and whether a stay will reduce the burden of litigation on the parties and the court.

By contrast, there is no statutory right to a stay during an IPR. When an IPR is filed or instituted, district courts rely on their inherent authority to control their dockets and decide whether a stay is appropriate. In exercising that discretion, courts typically apply a multi-factor balancing test. The most important considerations are the stage of the district court litigation, the likelihood that the IPR will simplify the issues, and whether a stay would cause undue prejudice to the patent owner or provide an unfair tactical advantage to the accused infringer.

District court proceedings can also be impacted if a proceeding is instituted in the ITC. Pursuant to 28 USC 1659, district courts must stay litigation at the request of any respondent to an ITC proceeding until a final decision, so long as the request is made within 30 days of the district court action's filing or after a party is named as a respondent in the ITC proceeding.

When IPR or PGR proceedings result in a final written decision, 35 USC 315 (e)(2) and 325 (e)(2) preclude petitioners from raising invalidity grounds in district court litigation that they raised or reasonably could have raised during that review. *California Inst of Tech v Broadcom Ltd*, 25 F.4th 976, 989 (Fed. Cir. 2022). ITC decisions have no preclusive effect on district courts but may have persuasive value. *Texas Instruments Inc v Cypress Semiconductor Corp*, 90 F.3d 1558, 1569 (Fed Cir 1996).

1.17 Patent Amendment

A federal court does not have the authority to amend patent claims in litigation, but it can correct an error when the following factors are met: (i) the error must be evident from the patent's face to a skilled artisan;

(ii) the correction cannot be subject to reasonable debate based on the claim language, specification, and prosecution history; and (iii) the correction must involve only obvious minor typographical or clerical errors. *Canatex Completion Solutions, Inc. v Wellmat-ics, LLC*, No 24-1466 (Fed. Cir. 12 November 2025).

While a case is pending, a patentee can also request a certificate of correction from the USPTO under 35 USC 254 (USPTO's mistake) or 255 (Applicant error). A USPTO certificate of correction, however, is only effective for causes of action arising after it was issued (absent the federal court correcting an error, as discussed above). See *H-W Tech, LC v Overstock.com, Inc.*, 758 F.3d 1329, 1334 (Fed. Cir. 2014).

Patent claims can be substantively amended at the USPTO during a re-examination (under 35 USC 302), in a reissuance proceeding (under 35 USC 251), or during IPR or PGR proceedings (under 35 USC 311-319). But like a certificate of correction, the amended claims can only define the scope of future infringement. If they are substantially changed, infringers may have intervening rights, meaning that they cannot be held liable for infringement of the original claims before the amendment. Such amendments may result in dismissal of ongoing suits and the filing of new suits based on the newly amended claims. For that reason, ongoing litigations may be stayed during the pendency of the USPTO proceedings.

1.18 Court Arbiter

Life sciences patent cases are heard in the first instance in US federal district courts, which have exclusive jurisdiction over patent actions. 28 USC 1338 (a). Judges are generalist Article III judges rather than specialist patent judges.

Cases may be tried either to the bench or to a jury. Pre-launch Hatch-Waxman cases are typically bench trials because damages are not available prior to commercial launch. 35 USC 271 (e)(2). Jury trials are more common in post-launch pharmaceutical and biologics cases where damages are sought, consistent with the Seventh Amendment.

Venue and personal jurisdiction constrain forum selection in patent cases. Patent venue is governed by *TC*

Heartland LLC v Kraft Foods Grp. Brands LLC, 137 S. Ct. 1514, 1519–20 (2017), and personal jurisdiction must satisfy constitutional due-process requirements. Practical differences nevertheless remain between districts with established patent dockets, particularly in judicial experience and case management practices.

The ITC can also hear certain patent cases, in particular those relating to imported goods, focusing on whether those imports infringe on valid US patents and cause injury to a domestic industry.

2. Generic Market Entry

2.1 Infringing Acts

The Hatch-Waxman Act provides a framework for producers of brand-name and generic small-molecule drugs to resolve patent issues around their products. It requires an RPS to list patents for which a reasonable claim of infringement could be asserted if a generic producer made, used, or sold the drug in question in the Orange Book. As noted in **1.6 Stays and Relevance of Parallel Proceedings**, manufacturers are required to list patents covering the drug, formulations of the drug, and methods of using the drug, but not manufacturing patents.

If a company wants to sell a generic version of that drug, it must submit an ANDA that contains a certification to each patent in the Orange Book:

- Paragraph I: no patent information has been filed for the reference listed drug (RLD) under the Orange Book;
- Paragraph II: the listed patent has expired;
- Paragraph III: the applicant does not intend to market its ANDA product until after the expiration of the listed patent; or
- Paragraph IV: the ANDA product will not infringe or the listed patent is invalid or unenforceable.

ANDA applicants can also file “section viii” statements that they will leave a patented indication off their label (ie, they will “carve out” the patented indication). See *GlaxoSmithKline LLC v Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1327 (Fed. Cir. 2021); 21 USC 355 (j)(2)(A)(viii).

As explained in **1.2 Defendants/Other Parties to an Action** and **1.6 Requirements to Bring Infringement Action**, the Hatch-Waxman Act makes it an artificial act of infringement to submit an ANDA (or Section 505 (b)(2) NDA) seeking FDA approval of a drug or its use that is claimed in a patent. 35 USC 271 (e)(2). Thus, patent infringement suits can be brought after a Paragraph IV certification is submitted and before the drug is marketed. Indeed, there is a thirty-month stay of ANDA approval in Paragraph IV litigations so that the parties can resolve their patent infringement issues before launch.

Because a marketed accused product typically does not exist at the time of suit, infringement is based on “whether the probable ANDA product would infringe once it is made, used or sold.” *Par Pharm., Inc. v Eagle Pharms., Inc.*, 44 F.4th 1379, 1383 (Fed. Cir. 2022). Damages are typically not at issue and thus most Hatch-Waxman cases are decided by a court instead of a jury.

An ANDA applicant may also be liable for induced infringement under 35 USC 271 (b) if its ANDA product, proposed label, and the other circumstances would induce infringement. *Amarin Pharma, Inc. v Hikma Pharms. USA Inc.*, 104 F.4th 1370, 1377 (Fed. Cir. 2024).

An ANDA applicant may be liable for contributory infringement under 35 USC 271 (c) if it sells or offers to sell a material or apparatus for use in a patented combination or process where the ANDA product is a material part of the patented invention and has no substantial non-infringing uses. *Eli Lilly & Co. v Actavis Elizabeth LLC*, 435 F. App’x 917, 926 (Fed. Cir. 2011) (unpublished).

2.2 Regulatory Data and Market Exclusivity

The FD&C Act sets forth various exclusivities for small-molecule products, the most common of which are set forth below.

- NCE – five years; applies to small-molecule drugs with active moiety not previously approved by FDA; ANDAs and 505 (b)(2) applications can be filed with Paragraph IV certifications on the “NCE-1” date (21 USC 355 (c)(3)(E)(ii) and 355 (j)(5)(F)(ii)).

- ODE – seven years; orphan drug exclusivity for the same drug and the same condition (21 USC 360cc).
- PED – six months; paediatric extension of exclusivity and listed patents (21 USC 355a).
- Clinical – three years; exclusivity for new clinical investigations essential to approval (21 USC 355 (c)(3)(E)(iii) and 355 (j)(5)(F)(iii)).
- 180-day ANDA – 180-day exclusivity for the first ANDA(s) with Paragraph IV certification (21 USC 355 (j)(5)(B)(iv)).

2.3 Acceptable Pre-Launch Preparations

The Hatch-Waxman Act established a safe harbour provision providing that it “shall not be an act of infringement to make, use, offer to sell, or sell... a patented invention... solely for uses reasonably related to the development and submission of information under a federal law [that] regulates the manufacture, use, or sale of drugs.” 35 USC 271 (e)(1)). Such protection also extends to medical devices and biologics products. *Eli Lilly & Co. v Medtronic, Inc.*, 496 US 661, 663 (1990); *Amgen Inc. v Hospira, Inc.*, 944 F.3d 1327, 1337 (Fed. Cir. 2019).

The safe harbour “extends to all uses of patented inventions that are reasonably related to the development and submission of any information under the FDCA.” *Merck KGaA v Integra Lifesciences I, Ltd.*, 545 US 193, 202 (2005) (emphasis in original). The analysis of whether an activity is “reasonably related” to seeking approval depends on the type of patent. For example, in the *Amgen v Hospira* case, the “accused activity is Hospira’s use of Amgen’s claimed methods of manufacture. The relevant inquiry, therefore, is not how Hospira used each batch it manufactured, but whether each act of manufacture was for uses reasonably related to submitting information to the FDA.” *Amgen Inc.*, 944 F.3d at 1339. Thus, each infringing act (eg, the manufacture of each batch of drug) is analysed to see whether it was done solely for uses reasonably related to regulatory approval.

2.4 Publicly Available Drug and Patent Information

The Orange Book provides a list of all approved prescription drug products with therapeutic equivalence evaluations and patents identified by the reference

drug sponsors as covering those products under the Hatch-Waxman Act. As discussed in **2.1 Infringing Acts**, an ANDA applicant must provide a certification or label carve-out for each patent listed in the Orange Book. 21 USC 355 (j)(2)(A)(vii) and 355 (j)(2)(A)(viii).

If the applicant certifies that the patent will not be infringed or is invalid, the applicant must also give notice of such Paragraph IV certification to the patent owner and the holder of an approved NDA for that product. The recipient of the Paragraph IV certification has 45 days after receiving notice to file an action “for infringement of the patent that is the subject of the certification.” 21 USC 355 (c)(3) and 355 (j)(5)(B). If such action is brought, approval of the ANDA will not become effective before expiration of a 30-month period (the “30-month stay”) or upon a judicial decision that the patent is invalid or not infringed. Id.

2.5 Reimbursement and Pricing/Linkage Markets

In the USA, decisions on pricing and reimbursement are generally not linked to patent status.

3. Biosimilar Market Entry

3.1 Infringing Acts

Biologic applicants operate under the BPCIA, not the Hatch-Waxman Act. The BPCIA amended the Patent Act to provide that it “shall be an act of infringement to submit... an application seeking approval of a biological product” regarding patents that are or could be identified pursuant to Section 351 (l)(3) of the Public Health Service Act. 21 USC 271 (e)(2)(C).

The BPCIA provides for pre-litigation and litigation phases. As discussed in **1.7 Pre-Action Discovery/Disclosure**, the biosimilar applicant has the option of participating in the “patent dance” under 42 USC 262 (l)(2). During the patent dance, the biosimilar applicant provides certain technical information about its product (under confidentiality terms), the patentee provides a list of patents which it believes it could reasonably assert, the parties exchange contentions, and ultimately, the parties negotiate a list of patents that are subject to immediate litigation. Only listed patents at this stage are subject to a declaratory action of

infringement, validity, or enforceability until the applicant provides notice to the patent owner that it will begin commercial marketing of the biosimilar in not less than 180 days. 42 USC 262 (l)(9)(A).

Although an aBLA applicant cannot be forced to engage in the patent dance (*Amgen Inc v Sandoz Inc*, 137 S Ct 1664 (2017)), failure to do so bars the applicant from initiating a declaratory judgment action – whereas the patent owner may immediately bring a declaratory judgment action for any patent claiming the biosimilar. 42 USC 262 (l)(9)(C).

A second phase commences once the biosimilar applicant provides the NCM. At that point, a PI can be sought and all listed patents not in litigation can be asserted. If the NCM is given before a first wave litigation commences, both waves fold into one. 42 USC 262 (l) (3); 42 USC 262 (l)(8)(B). The RPS may assert any patents identified in the patent dance or that are subsequently granted.

3.2 Data and Regulatory Exclusivity

The BPCIA provides the following exclusivities.

- 12-year Biologic – 12-year reference product exclusivity for biologics; aBLAs can be filed 4 years after the reference product was first licenced. 42 USC 262 (k)(7)(B).
- Paediatric exclusivity – 12-year exclusivity may be extended by six months. Unlike the Hatch-Waxman Act, a six-month period is not added onto Orange-Book patent expiration.
- Orphan drug exclusivity (same as generics).
- Up to one-year Interchangeability Exclusivity – the first biosimilar deemed interchangeable to a reference product by the FDA can be awarded up to 12 months of exclusivity, during which time no other biosimilar may be deemed interchangeable. 42 USC 262 (k)(6)(A).

“Interchangeability” means that a biosimilar can be substituted for its reference product by a pharmacist without the intervention of the prescribing healthcare provider, provided it is expected to produce the same clinical result in any given patient and the risks of alternating or switching are not greater than using the reference product alone. Depending on various fac-

tors, there may be less exclusivity or none at all (eg, depending on launch delays), and during the exclusivity period, the FDA may still approve other biosimilars. It is only prohibited from deeming any others interchangeable.

3.3 Acceptable Pre-Launch Preparations

The safe harbour provision of 35 USC 271 (e)(1) also shelters activities of biosimilar applicants conducted solely for the purpose of developing and submitting information under federal law.

3.4 Publicly Available Drug and Patent Information

The FDA maintains the Purple Book, or List of Licensed Biological Products, which contains biological products regulated by the Centre for Drug Evaluation and Research. This includes not only reference products but also licensed biosimilars. The Purple Book includes the date of licensing for the product, the date of expiration for exclusivity periods, and certain patent information, as discussed further below.

Unlike the Orange Book, however, the RPS is not required to submit patent information upon approval or immediately after patent grant (if after approval). Instead, the sponsor need only submit to the FDA the patent lists that they serve on biosimilar applicants during the patent dance (within 30 days of providing the biosimilar applicant with the list) or that are asserted in litigation (also within 30 days). The FDA updates the Purple Book every 30 days. 42 USC 262 (k)(9)(A).

Additionally, there is no need for the biosimilar applicant to make any certifications with respect to Purple Book patents. Rather, the Purple Book merely provides notice as to which patents have already been listed or asserted with respect to previous applicants.

3.5 Reimbursement and Pricing/Linkage Markets

Unlike the Hatch-Waxman Act, the BPCIA:

- does not require any patent certifications, rather it provides for an optional information exchange (the patent dance);

- does not have the automatic 30-month stay tied to a patent certification, but it does require aBLA applicants to provide a six-month NCM;
- does not have an automatic stay of approval if there is a final finding of infringement, although 35 USC 271 (e)(4)(D) does provide for an automatic injunction until patent expiry if there is:
 - (a) a final finding of infringement from which no further appeal may be taken (apart from seeking certiorari at the Supreme Court); and
 - (b) the reference product's regulatory exclusivity has not yet expired; and
- has different exclusivities.

4. Patent Term Extensions for Pharmaceutical Products

4.1 Supplementary Protection Certificates

There is no equivalent to a Supplementary Protection Certificates (SPC) in the United States. However, a patent term extension (PTE) is available for certain patents claiming drug products – and methods of use or manufacture of drug products – that are subject to regulatory review before commercial marketing or use. 35 USC 156 (a). To obtain a PTE, the BLA or NDA holder must submit an application for extension within 60 days of receiving permission from the FDA to market the product. Only one patent may receive a PTE per reference product. 35 USC 156 (c)(4).

The PTE determination is made by the FDA and USPTO together. The FDA is responsible for initially calculating the length of the regulatory review for the product, which is published in the Federal Register. 35 USC 156 (d)-(2)(A)(ii). After a chance for comment by interested parties, the USPTO calculates the final PTE length, which is capped at five years. 35 USC 156 (g)(6)(A).

4.2 Paediatric Extensions

The USA has paediatric exclusivity as indicated in 2.2 Regulatory Data and Market Exclusivity and 3.2 Data and Regulatory Exclusivity.

4.3 Paediatric-Use Marketing Authorisations

In the USA, there is no paediatric-use marketing authorisation exclusivity analogous to that available under the EU system.

4.4 Orphan Medicines Extensions

The USA has orphan drug exclusivity as indicated in 2.2 Regulatory Data and Market Exclusivity and 3.2 Data and Regulatory Exclusivity.

5. Relief Available for Patent Infringement

5.1 Preliminary Injunctive Relief

Section 1.3 Preliminary Injunction Proceedings discusses the availability of PIs, including under the Hatch-Waxman Act and the BPCIA.

As a condition of granting a PI, the court may require the movant to post a bond sufficient to cover costs and damages sustained by any party later found to have been wrongfully enjoined. FRCP 65 (c). The amount of the bond is within the court's discretion. A PI is enforceable upon issuance of the court's order, subject to satisfaction of any bond requirement, and is enforced through the court's contempt powers.

A stay of a PI pending appeal may be granted in the court's discretion, applying equitable considerations.

5.2 Final Injunctive Relief

A permanent injunction, if ordered upon a finding of infringement, is issued as part of a final judgment and is ordinarily effective upon entry, unless stayed. Unlike PIs, permanent injunctions generally do not require the posting of a bond. *eBay Inc. v MercExchange, L.L.C.*, 547 US 388, 391 (2006).

In general, in deciding whether to grant a permanent injunction, courts apply the traditional four-factor equitable test to determine whether a permanent injunction is appropriate. *Weinberger v Romero-Barcelo*, 456 US 305, 311–13 (1982); *eBay*, 547 US at 391. However, 35 USC 271 (e) has special considerations for drug products under the Hatch-Waxman Act and BPCIA.

Section 271 (e)(4)(A) specifies that, with respect to an infringing ANDA or 505 (b)(2) product that has yet to receive final approval, “the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed.” If an ANDA or 505 (b)(2) product has already received final approval and launched, however, the traditional four-factor test would apply instead.

Section 271 (e)(4)(D) specifies that, with respect to an infringing biosimilar, “the court shall order a permanent injunction prohibiting any infringement” until patent expiration, so long as the regulatory exclusivity of the reference product has yet to expire. If the exclusivity period has expired, however, the court would apply the four-factor test.

A permanent injunction is enforceable pending appeal unless stayed. Courts have discretion to grant a stay pending appeal and may condition a stay on the posting of a bond.

5.3 Discretion to Award Injunctive Relief (Final or Preliminary)

US courts have discretion to deny injunctive relief and award damages, even where infringement is established. Injunctive relief is not automatic and must satisfy equitable principles. *eBay Inc. v MercExchange, L.L.C.*, 547 US 388, 391 (2006).

Monetary damages and injunctive relief are not mutually exclusive. Courts may award damages for past infringement while denying or limiting injunctive relief for future conduct. In life sciences cases, public interest considerations may be particularly significant, including patient access to medicines, availability of alternative therapies, and public health considerations.

5.4 Damages

Under 35 USC 284, a court shall award the patent owner damages adequate to compensate for infringement, but not less than a reasonable royalty, plus interest and costs fixed by the court. The primary methods for calculating damages in US patent cases are lost profits and reasonable royalties.

To recover lost profits, a patent owner must demonstrate that, but for the infringement, it would have made the infringer's sales. The "Panduit" framework requires proof of (i) demand for the patented product, (ii) absence of acceptable non-infringing alternatives, (iii) the patentee's manufacturing and marketing capability to meet demand, and (iv) the amount of profit the patentee would have made. *Rite-Hite Corp. v Kelley Co.*, 56 F.3d 1538, 1545 (Fed. Cir. 1995) (en banc).

If lost profits cannot be established, damages are a reasonable royalty, which is the amount that would have been agreed upon in a hypothetical negotiation between a willing licensor and a willing licensee at the time infringement began. Courts determine such a royalty using the factors set out in *Georgia-Pacific Corp. v US Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970), including the nature of the patented invention, comparable licence agreements, and the commercial relationship between the parties. In pharmaceutical cases, courts frequently examine existing licence agreements covering similar technologies, considering regulatory risk and market exclusivity.

Enhanced damages may be awarded in egregious cases of wilful infringement. Under *Halo Elecs., Inc. v Pulse Elecs., Inc.*, 579 US 93, 102–04 (2016), district courts have discretion to award up to treble damages, but such awards are reserved for conduct that is wilful, wanton, or in bad faith.

Damages are generally limited to infringement occurring within six years prior to the filing of the complaint. 35 USC 286. Pre-judgment interest is ordinarily awarded to fully compensate the patent owner and typically accrues from the date of first infringement. Post-judgment interest is governed by statute and accrues from the date of judgment.

In Hatch-Waxman and BPCIA litigation, damages are unavailable absent a commercial launch. The filing of an ANDA with a Paragraph IV certification does not give rise to damages unless the accused product is commercially marketed. Similarly, under the BPCIA, damages may be limited to a reasonable royalty where a suit is not timely filed following an NCM. 42 USC 262 (l)(8)–(9).

Damages must be determined by a jury if requested, consistent with the Seventh Amendment to the US Constitution. Courts have discretion to bifurcate liability and damages or to try them together. Execution of a damages judgment is generally stayed for 30 days after entry unless the court orders otherwise. FRCP 62 (a).

If a party is wrongfully enjoined, recovery is typically limited to the amount of the injunction bond posted under FRCP 65 (c). Claims by third parties for patent damages are uncommon and generally limited to exclusive licensees that have standing to bring suit as discussed in **1.1 Claimants/Plaintiffs to an Action**.

5.5 Legal Costs

Under the American Rule, each party generally bears its own legal costs. However, courts may award reasonable attorneys' fees to the prevailing party in "exceptional cases" under 35 USC 285, as clarified by the Supreme Court in *Octane Fitness, LLC v ICON Health & Fitness, Inc.*, 572 US 545, 554 (2014).

An exceptional case is one that stands out based on the substantive strength of a party's litigating position or the unreasonable manner in which the case was litigated. Even where attorneys' fees are awarded, other costs such as expert fees are generally not recoverable absent specific statutory authority.

5.6 Relevance of Claimant/Plaintiff Conduct to Relief

US courts may withhold or limit relief based on inequitable conduct or other bad-faith behaviour by the patent owner. Inequitable conduct before the USPTO may render a patent unenforceable. *GS Cleantech Corp. v Adkins Energy LLC*, 951 F.3d 1310, 1325 (Fed. Cir. 2020).

Equitable relief may also be denied under the doctrine of unclean hands, which bars relief where a party has engaged in misconduct directly related to the asserted patent rights. *Precision Instrument Mfg. Co. v Automotive Maint. Mach. Co.*, 324 US 806, 814 (1945). In addition, unreasonable litigation conduct may support a finding that a case is exceptional, resulting in fee shifting under 35 USC 285. *Octane Fitness*, 572 US at 554.

6. Other IP Rights

6.1 Trade Marks

Trade mark disputes are not unheard of in the pharmaceutical industry. The core legal framework for trade mark disputes is the Lanham Act, but pharmaceutical product names are also regulated by the FDA. Pharmaceutical companies often trade mark their product names, logos, and trade dress, as well as non-functional aspects of product packaging and devices. Trade marks are occasionally asserted alongside patents. See *Glaxo Group Limited, et al. v Transpire Bio Inc.*, No. 25-cv-61939 (S.D. Fla. 25 September 2025).

6.2 Copyright

Copyright claims are not common in pharmaceutical cases. The Second Circuit Court of Appeals held that an ANDA filer cannot be liable for copyright infringement related to the reference product label because the Hatch-Waxman Act requires generic drug producers to use the same labelling. See *SmithKline Beecham Consumer Healthcare, LP v Watson Pharms, Inc.*, 211 F.3d 21, 23 (2d Cir. 2000)).

6.3 Trade Secrets

Trade secrets allegations have been raised in the pharmaceutical industry, particularly where employees have moved from one company to a competitor. For example, Amgen sued Coherus alleging a “massive conspiracy” of former employees who tried to “steal Amgen’s trade secrets and siphon off its talent” related to Amgen’s Neulasta product. The case later settled. See *Amgen Inc. et al. v Coherus Biosciences Inc. et al.*, California Superior Court, County of Ventura (3 March 2017).

7. Appeal

7.1 Timeframe to Appeal Decision

In federal court litigation between private parties, an appeal must be filed within 30 days after entry of the order or judgment being appealed from. Fed R App Proc 4 (a)(1). A patent holder obtaining a preliminary injunction is required to provide a bond in case the decision is reversed on appeal. FRCP 65 (c).

7.2 Appeal Court(s) Arbitrator

The Federal Circuit has nationwide and exclusive jurisdiction in a variety of subject areas, including patents, trade marks, and international trade. This means that the Federal Circuit handles all federal district court appeals regarding patent cases. The Federal Circuit also reviews certain administrative agency decisions, including those from the Patent Trial and Appeal Board (PTAB), the Trademark Trial and Appeal Board (TTAB) and the ITC.

The Federal Circuit’s work begins after the Clerk’s Office docketing a new appeal or petition and assigns a docket number. The parties to the cases prepare and file written briefs to present their arguments. The appeal is then randomly assigned to a panel comprising three randomly selected judges. There may be oral arguments, in which each side is typically allotted 15 minutes for argument. Parties may seek review of a Federal Circuit decision in the US Supreme Court.

7.3 Special Provisions

US district courts generally have broad discretion to manage their docket. Many district courts have local rules, including specific patent rules that govern the parties’ infringement and invalidity contentions, initial document production, claim construction, and other issues. In New Jersey, for example, the rules are reversed in Hatch-Waxman cases so that the Paragraph IV filer presents its contentions first. L Pat R 3.6.

8. Other Relevant Forums/Procedures

8.1 The UPC or Other Forums

Aside from US district courts, the most popular forum for pharmaceutical disputes has been the PTAB, which has heard many IPR petitions on pharmaceutical patents. However, since the middle of 2025 the Acting Director and current Director of the USPTO have denied more petitions for discretionary reasons than in the past, particularly if the patent owner has “settled expectations” that its patent has been in existence long enough that it is not likely to be challenged. Some have argued that this “settled expectations” doctrine is not appropriate for Hatch-Waxman and BPCIA cases because a party has no incentive to

challenge a patent until it is preparing for regulatory approval of a generic or biosimilar product.

9. Alternative Dispute Resolution

9.1 ADR Options

ADR processes are available for all types of cases in the US, including pharmaceutical cases. Many courts include a date in the schedule by which parties must report that they have engaged in settlement talks. Companies in the Hatch-Waxman and BPCIA space are typically sophisticated entities that have settlement experience, and they often negotiate settlements without the help of an arbitrator or mediator.

10. Settlement/Antitrust

10.1 Considerations and Scrutiny

Parties in Hatch-Waxman and BPCIA cases must file their settlements with the Federal Trade Commission. The US Supreme Court has held that patent settlements can violate the antitrust laws, particularly if they include “reverse payments” in the form of money or other consideration that exceeds litigation costs for the generic manufacturer to delay entry into the market. *FTC v Actavis, Inc.*, 570 U.S. 136, 159 (2013).

11. Collective Redress

11.1 Group Claims

Class action lawsuits brought by consumers in the pharmaceutical industry typically involve product liability claims and do not intersect with patent litigation. However, patent cases involving the same patents and products are sometimes consolidated for pre-trial proceedings either informally or through multidistrict litigation (MDL) under 28 USC Section 1407. See, for example, *In Re: Aflibercept Patent Litigation*, MDL No 1:24-md-03103 (NDWV).

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