United States of America

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United States of America

(1) APPLICABLE LAWS

1 The authority for the patent laws of the United States arises from Article I, section 8 of the Constitution of the United States, which grants the legislature the power to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." The first United States Patent Act was enacted in 1790. The current patent laws are listed in Title 35 of the United States Code (U.S.C.).

2 Title 35 of the United States Code has recently been amended in part by the Leahy-Smith America Invents Act (AIA), which was enacted on September 16, 2011. Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011). The AIA's various provisions have different effective dates, with most changes effective by at least March 16, 2013. The United States Patent and Trademark Office (USPTO) has published a table that summarizes the AIA's effective dates. *See* USPTO, *America Invents Act: Effective Dates* (October 5, 2011) (*available at* http://www.uspto.gov/aia_implementation/aia-effective-dates.pdf). For at least the next 20 years, the U.S. patent system will function under two regimes: the AIA system, which applies to patent claims with an effective filing date of March 16, 2013 or later; and the pre-AIA system, which generally applies to patent claims with an effective filing date before March 16, 2013.

3 The executive branch of the United States government administers the patent system through the USPTO. Title 37 of the Code of Federal Regulations (C.F.R.) governs the patent system's administration. In addition, the USPTO promulgates the Manual of Patent Examining Procedure (MPEP), which provides USPTO patent examiners, applicants, attorneys, agents, and representatives of applicants with guidance on prosecution of patent applications before the USPTO. *See generally* USPTO, MPEP, *available at* http://www.uspto.gov/web/offices/pac//html

4 The district courts of the United States have original jurisdiction over cases arising under the patent laws. *See* 28 U.S.C. §§1331, 1338. Under 28 U.S.C. §1295(a), the Court of Appeals for the Federal Circuit has exclusive jurisdiction over appeals of decisions from the district courts arising under the patent laws. Appeals of Federal Circuit cases are decided by the Supreme Court of the United States, but only if the Supreme Court first grants a petition to review the case. Venue in patent cases is governed by 28 U.S.C. §1400.

5 The United States customs laws provide another venue for pursuing an infringement action in some circumstances. Under 19 U.S.C. §1337(a)(1)(B)(i), it is an unlawful act to import, sell for importation, or sell within the United States after importation articles that are covered by the claims of a valid, enforceable U.S. patent. Similarly, 19 U.S.C. §1337(a)(1)(B)(ii) makes it an unlawful act to import, sell for importation, or sell within the United States after importation articles that are made abroad by means of a process covered by the claims of a U.S. patent. The enforcement of these provisions by the U.S. International Trade Commission (ITC) forum is further described below. *See infra* § 8.3.2, Administrative Enforcement.

(2) ENTITLEMENT

(2.1) COMPENSATION

6 "[A]n invention presumptively belongs to its creator." *Teets v. Chromalloy Gas Turbine Corp.*, 83 F.3d 403, 407 (Fed. Cir. 1996). Consistent with this presumption, an employee may own the rights to a patent even though the invention was conceived and/or reduced to practice during the course of employment, but an employee's rights depend on the relationship between the employee-inventor and his or her employer. *Id.; see infra* §§ 2.3, Applicant, 2.4, Employee. The patent laws of the United States do not contain special compensation provisions for employee-inventors who conduct research for a university or educational institution. *See infra* § 2.5, Education/Research. The United States has promulgated laws governing patent rights for inventions obtained with federal funding. *See infra* § 2.7.3, Federally Funded Inventions.

(2.2) DERIVATION

6.1 Derivation involves a claim that a named inventor did not invent the claimed invention but instead derived the invention from another. A person is not entitled to a patent if "he did not himself invent the subject matter sought to be patented." 35 U.S.C. §102(f) (pre-AIA) (hereinafter, sections of United States Code Section 35 in effect prior to the effective date of the Leahy-Smith America Invents Act (AIA) are referred to as "pre-AIA"). For patent applications filed before March 16, 2013, under the first-to-invent system, derivation is a ground for invalidity and defense to infringement and is also litigated in interference proceedings at the U.S. Patent & Trademark Office (USPTO).

7 To prove derivation, the challenging party must provide clear and convincing evidence "both prior conception of the invention by another and communication of that conception to the patentee." *Eaton Corp. v. Rockwell Int'l Corp.*, 323 F.3d 1332, 1344 (Fed. Cir. 2003); *see also Brand v. Miller*, 487 F.3d 862, 869–870 (Fed. Cir. 2007) (similar standard applied in interference proceedings at the UPSTO). The communication to the patentee must be "sufficient to enable one of ordinary skill in the art to make the patented invention." *Eaton Corp.*, 323 F.3d at 1344. The courts consider derivation as a question of fact. *Id.*

8 "To meet the clear and convincing burden of proof, alleged co-inventors must prove their contribution to the conception with more than their own testimony respecting the facts surrounding a claim of derivation or priority of invention." *Trovan, Ltd. v. Sokymat SA*, 299 F.3d 1292, 1302 (Fed. Cir. 2002). "Whether the inventor's testimony has been sufficiently corroborated is evaluated under a 'rule of reason' analysis." *Id.* "Under this analysis, an evaluation of all pertinent evidence must be made so that a sound determination of the credibility of the alleged inventor's story may be reached." *Id.* (alterations, quotations, and citation omitted). Although corroborating evidence may take many forms, "[r]eliable evidence of corroboration preferably comes in the form of physical records that were made contemporaneously with the alleged prior invention." *Id.* Circumstantial evidence about the inventive process, or oral testimony of someone other than the alleged inventor, may also corroborate. *See id.* at 1302–1303.

9 For patent applications filed on or after March 16, 2013, section 3 of the Leahy-Smith America Invents Act, 125 Stat. 284, 285–293 (2011), includes amendments to 35 U.S.C. §§103, 134, 135, and 146 directed to the issue of derivation. These amendments provide details and identify requirements regarding the institution of derivation proceedings at the USPTO. A civil action based on a claim of derivation is also available under 35 U.S.C. §291

under limited circumstances. For patent applications filed on or after March 16, 2013, derivation is no longer a defense to infringement. *See* AIA, section 3, 125 Stat. 284, 285–293 (2011).

(2.3) APPLICANT

10 Pursuant to 35 U.S.C. §101, "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor," subject to the other requirements and conditions of Title 35 of the United States Code.

11 "[A]n invention presumptively belongs to its creator." *Teets v. Chromalloy Gas Turbine Corp.*, 83 F.3d 403, 407 (Fed. Cir. 1996). The touchstone of inventorship is conception, which is "the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention." *Univ. of Pittsburgh of the Commonwealth Sys. of Higher Educ. v. Hedrick*, 573 F.3d 1290, 1297–1298 (Fed. Cir. 2009) (citation and quotations omitted). Effective March 16, 2013, however, the Leahy-Smith America Invents Act moved the United States from a first-to-invent system, which focuses on the date of invention, to a first-to-file system, which focuses on the effective filing date of a patent application on the invention. *See* AIA § 3, 125 Stat. 284, 285–293 (2011); *see infra* § 5.1 (vii)–(viii), Invalidity (Novelty and Anticipation, Obviousness).

12 Only natural persons can be inventors. *Beech Aircraft Corp. v. Edo Corp.*, 990 F.2d 1237, 1248 (Fed. Cir. 1993). Patents must be "applied for in the name or names of the actual inventor or inventors," 37 C.F.R. §1.41, and inventors must submit an oath attesting to their belief that they are the "original" inventor of the claimed invention, 35 U.S.C. §115. For patent applications filed before September 16, 2012, inventors were required to submit oaths attesting to their belief that they also were the "first" inventor of the claimed invention. 35 U.S.C. §115 (pre-AIA). Before September 16, 2012, the governing statutes required all inventors to be properly identified, but they also contain provisions to correct errors in inventorship made without deceptive intent. *See* 35 U.S.C. §116(c) (pre-AIA); 35 U.S.C. § 256 (pre-AIA). Effective September 16, 2012, correction of inventorship no longer requires that the error occurred without deceptive intent, AIA, § 20, 125 Stat. 284, 333 (2011), and improperly designated inventorship is no longer grounds for finding a patent unenforceable. *See* 35 U.S.C. §115(h).

13 Patents may be obtained when an inventor is unable or unwilling to apply for a patent on his or her own behalf. For example, 35 U.S.C. §117 allows legal representatives of deceased or incapacitated inventors to apply for patents. Before September 16, 2012, 35 U.S.C. §118 (pre-AIA) allowed a party with sufficient proprietary interest in an invention, under certain circumstances, to file and obtain a patent on behalf of the inventor if the inventor refused to file an application or could not be reached. Effective September 16, 2012, the America Invents Act changed the definition of a patent applicant to allow an entity other than an inventor—such as a corporation to whom the inventor has assigned rights to the invention—to apply for a patent: "A person to whom the inventor has assigned or is under an obligation to assign the invention may make an application for a patent." AIA § 4, 125 Stat. 284, 296–297 (2011); 35 U.S.C. §118; *see also* 37 C.F.R. §1.42.

(2.4) EMPLOYEE

14 Consistent with the presumption that the inventor owns his invention, an individual owns the rights to a patent even though the invention was conceived and/or reduced to practice during the course of employment. At the same time, however, the law recognizes

that employers may have an interest in the creative products of their employees. *Teets v. Chromalloy Gas Turbine Corp.*, 83 F.3d 403, 407 (Fed. Cir. 1996). For example, an employee may enter into a contract whereby all of her inventive ideas are expressly assigned to her employer. *Id.*; *see also infra* §7.1, Assignment.

15 Even without an express assignment, employers may still claim ownership of an employee's inventive work where the employer specifically hires or directs the employee to exercise inventive faculties. *Teets*, 83 F.3d at 407. In applying this principle, courts examine the employment relationship at the time of the inventive work to determine if the parties entered an implied-in-fact contract to assign patent rights. *Id.* This inquiry is governed by state common law, as opposed to federal statutory authority. *Id.*

16 Employers that contribute to the development of an invention (e.g., by providing resources such as time, materials, equipment, etc.) may also, under certain circumstances, obtain "shop rights" to an employee's invention. *McElmurry v. Arkansas Power & Light Co.*, 995 F.2d 1576, 1580 (Fed. Cir. 1993). "A 'shop right' is generally accepted as being a right that is created at common law… entitling an employer to use without charge an invention patented by one or more of its employees without liability for infringement." *Id.* A shop right may entitle an employer to procure an invention from outside contractors. *See Beriont v. GTE Labs., Inc.*, 535 Fed. App'x 919, 924 (Fed. Cir. 2013) (non-precedential opinion) (citing *McElmurry*, 995 F.2d at 1583–1584).

17 Shop rights are not ownership rights. Courts have alternatively characterized them as a type of implied license, a form of equitable estoppel, or simply as a right based on principles of equity and fairness. In discussing the doctrine's application, the Federal Circuit has stated that:

> [T]he proper methodology for determining whether an employer has acquired a "shop right" in a patented invention is to look to the totality of the circumstances on a case by case basis and determine whether the facts of a particular case demand, under principles of equity and fairness, a finding that a "shop right" exists. In such an analysis, one should look to such factors as the circumstances surrounding the development of the patented invention and the inventor's activities respecting that invention, once developed, to determine whether equity and fairness demand that the employer be allowed to use that invention in his business. A factually driven analysis such as this ensures that the principles of equity and fairness underlying the "shop rights" rule are considered.

18 *McElmurry*, 995 F.2d at 1581–1582. Some relevant factors to consider when determining whether a shop right exists include the extent to which an employer has financed an employee's inventions, the contractual relationship between the employer and employee, and the extent to which the employee consented to or assisted employer's use of the invention.

(2.5) EDUCATION/RESEARCH

19 The United States' patent laws do not contain any special compensation provisions for employee-inventors who conduct research for a university or educational institution. As set forth above, *see supra* § 2.4, Employee, an employee's rights depend on the relationship between the employee-inventor and his or her employer.

20 It is important to note, however, that a significant portion of university research is funded by the United States government. As explained below, the United States has laws

that govern patent rights for inventions obtained with federal funding. *See infra* §2.7.3, Federally Funded Inventions.

(2.6) TEAMWORK

21 "When an invention is made by two or more persons jointly, they shall apply for patent jointly." 35 U.S.C. §116(a). "In the absence of any agreement to the contrary, each of the joint owners of a patent may make, use, offer to sell, or sell the patented invention within the United States, or import the patented invention into the United States, without the consent of and without accounting to the other owners." 35 U.S.C. § 262.

22 "Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent." 35 U.S.C. §116(a). To determine whether a person made a contribution to the conception of the subject matter of a claim, courts must determine what the person's contribution was and then whether that contribution appears in the claimed invention. *Frank's Casing Crew & Rental Tools, Inc. v. PMR Techs., Inc.*, 292 F.3d 1363, 1373 (Fed. Cir. 2002).

23 If a joint inventor refuses to join in a patent application, or cannot be reached, the USPTO may permit an application to be made by the other inventor(s) on behalf of themselves and the omitted inventor. 35 U.S.C. §116(b).

(2.7) ENTITLEMENT CLAIMS

(2.7.1) Interference Proceedings and Interfering Patents

24 Until the Leahy-Smith America Invents Act (AIA) was enacted in 2011, United States patent laws rewarded the party who invented first, as opposed to the party who filed a patent application first. *See Bruning v. Hirose*, 161 F.3d 681, 685 (Fed. Cir. 1998). For patent applications or patents with an effective filing date prior to March 16, 2013 where two or more parties claim substantially the same or the same subject matter (i.e., claims "interfere" with one another), the USPTO may initiate an interference proceeding to determine which party invented first and also to address the issue of originality. The USPTO may initiate interference proceedings as to two pending applications or a pending application and an issued U.S. patent if they have effective filing dates prior to March 16, 2013, subject to certain limitations associated with application publication dates and patent issue dates. *See* 35 U.S.C. §135 (pre-AIA); MPEP §2304.02(c) (9th ed. March 2014) ("If an application claim interferes with a claim of a patent or published application, and the claim was added to the application by an amendment filed more than 1 year after issuance of the patent, or the application was not filed until more than 1 year after issuance of the patent (but the patent is not a statutory bar), then under the provisions of 35 U.S.C. 135(b), an interference will not be declared unless at least one of the claims which were in the application, or in a parent application, prior to expiration of the one-year period was for 'substantially the same subject matter' as at least one of the claims of the patent.")

25 Under 35 U.S.C. §291, on the other hand, the owner of an interfering patent with an effective filing date prior to March 16, 2013 may bring a civil action to establish the priority of its patent over that of another patent and to invalidate the other patent. And 35 U.S.C. §256 also provides a party with a private cause of action to challenge inventorship of a patent issued or applied for before March 16, 2013. *HIF Bio, Inc. v. Yung Shin Pharms. Indus. Co.*, 600 F.3d 1347, 1354 (Fed. Cir. 2010) ("Once a patent issues . . . 35 U.S.C. §256 provides a private right of action to challenge inventorship, and such a challenge arises under §1338(a).").

26 As to the interference inquiry itself, the pre-AIA version of 35 U.S.C. §102(g) explains that a party is not entitled to a patent if:

> (1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

27 Section 3 of the AIA, 125 Stat. 284, 285–293 (2011), amends 35 U.S.C. §§100, 102, 103, 134, 135, 146, and 291 to, among other things, replace the United States' current first-to-invent system with a first-to-file system and replace interference proceedings with derivation proceedings. *See supra* §2.2, Derivation. These provisions took effect on March 16, 2013.

(2.7.2) Rights of Third Parties in Good Faith

28 Patent assignments must be duly recorded with the USPTO in order for the assignee to be protected from subsequent bona fide purchasers who lack notice of the assignment. Under 35 U.S.C. §261, "[a]n assignment, grant, or conveyance shall be void as against any subsequent purchaser or mortgagee for a valuable consideration, without notice, unless it is recorded in the USPTO within 3 months from its date or prior to the date of such subsequent purchase or mortgage."

(2.7.3) Federally Funded Inventions

29 The provisions of 35 U.S.C. §§200–212, commonly referred to as the Bayh-Dole Act, govern patent rights for inventions made with federal assistance. The Bayh-Dole Act applies to federally funded inventions by a contractor (e.g., a research institution) that receives federal funds, including inventions by an employee of the contractor, the rights to which have been assigned to the contractor. *See Bd. of Trs. of the Leland Stanford Jr. Univ. v. Roche Molecular Sys.*, 131 S. Ct. 2188 (2011).

(3) SCOPE OF PROTECTION

(3.1) CLAIM, DESCRIPTION AND DRAWINGS

30 35 U.S.C. §112(b) requires a patent specification to "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention." It is a "bedrock principle" of United States patent law that "the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (citations omitted).

31 Courts interpret patent claims, and hence their scope, as a matter of law in a process commonly referred to as claim construction. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977–979 (Fed. Cir. 1995) (en banc). Claim terms are generally given their ordinary and customary meaning, which is "the meaning that the term[s] would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips*, 415 F.3d at 1312–1313. In determining the ordinary and customary meaning of claim terms, the courts consider intrinsic evidence such as the claim language itself, the remainder of the specification, and the file history, and may also consider extrinsic evidence such as expert and inventor testimony, dictionaries and learned treatises, as further explained below. *See id.* at 1317; *infra* §3.4, Criterion for Scope of Protection. "Extrinsic evidence . . . is less significant than the intrinsic record in determining the legally operative meaning of claim language." *Phillips*, 415 F.3d at 1312–1313 (quotations and citation omitted).

32 The Supreme Court recently held that the Federal Circuit must review factual findings underlying claim construction for clear error, although interpretation of intrinsic evidence (including the specification and prosecution history) and the ultimate issue of claim construction is reviewed de novo. *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, 574 U.S. ____ (2015); *see infra* §8.11, Appeals.

(3.2) PATENT AS GRANTED

Nature of the Patent Right

33 United States patents provide:

> the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by that process, referring to the specification for the particulars thereof.

35 U.S.C. § 154(a)(1). In other words, United States patents are exclusionary in nature and "do not create any affirmative right to make, use, or sell anything." *Leatherman Tool Grp. v. Cooper Indus.*, 131 F.3d 1011, 1015 (Fed. Cir. 1997). Consequently, it is possible for a party to practice the claims of a patent to which it has been granted rights and nonetheless infringe the claims of another patent to which it has not. *See,* e.g., *Glaxo Wellcome, Inc. v.*

Andrx Pharm., Inc., 344 F.3d 1226, 1233–1234 (Fed. Cir. 2003); *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1580–1581 (Fed. Cir. 1984).

Temporal Scope

34 For United States patents (other than design patents, *see* 35 U.S.C. §173) that were filed on or after June 8, 1995, the term of the patent begins on its issue date and extends to 20 years from the filing date of the earliest referenced application under 35 U.S.C. §§120, 121 or 365(c) from which priority is claimed. *See* 35 U.S.C. §154(a)(2). For patents that were either in force or based on an application that was pending on June 8, 1995, the patent term is the longer of 17 years from the issue date of the patent or the previously described 20 year term. *See* 35 U.S.C. §154(c)(1); Uruguay Round Agreements Act, Pub. L. No. 103-465, §532, 108 Stat. 4809 (1994).

35 Under 35 U.S.C. §154(b), adjustment of the patent term is available to compensate patent holders for certain delays at the Patent and Trademark Office and for derivation proceedings, secrecy orders, and appeals. *See also* 37 C.F.R. §§1.701–1.705; *Novartis AG v. Lee*, 740 F.3d 593, 602 (Fed. Cir. 2014) (holding that patent term extension should include delays occurring between the time of a patent's notice of allowance and the patent's issuance). Under 35 U.S.C. §156, term extensions are available to compensate patent holders for the time required to comply with federal regulatory requirements associated with, for example, certain drugs, food additives, and medical devices. *See also* MPEP §2750 (9th ed. March 2014).

36 In contrast, under certain circumstances, patentees or patent applicants may file "terminal disclaimers" limiting the term of an issued patent for "obviousness-type double patenting," i.e., where a second, commonly-owned patent contains claims that are not patentably distinct from another patent, whether or not that patent would qualify as invalidating art under 35 U.S.C. §103. *See* 37 C.F.R. §1.321; *Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280, 1297–1298 (Fed. Cir. 2012); *see also Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1217 (Fed. Cir. 2014).

Territorial Scope

37 Territorial application of United States patent law generally is coextensive with the geographic boundaries of the United States and its territories and possessions. *See* 35 U.S.C. §§100(c), 154(a)(1). Extraterritorial impact is felt through importation bars or border seizures of infringing goods. Also, in some instances, United States patents can reach goods manufactured abroad if the essential components are exported from the United States and intended for assembly overseas. *See* 35 U.S.C. § 271(f). Further, goods manufactured overseas using a process patented in the United States can give rise to patent infringement if those goods are imported into the United States or sold or used in the United States. *See* 35 U.S.C. § 271(g).

(3.3) INTERPRETATION OF STATE OF THE ART

38 Claim terms are generally given their "ordinary and customary meaning," that is, the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–1313 (Fed. Cir. 2005) (en banc). The "person of ordinary skill in the art" is a theoretical construct who 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. *Id.* at 1313. And such a person is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification. *Id.*

39 With respect to validity determinations, the hypothetical person of skill in the art is presumed to be aware of all pertinent prior art. *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1363 (Fed. Cir. 2007). "Whether prior art invalidates a patent claim as obvious is determined from the perspective of one of ordinary skill in the art." *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 655 F.3d 1364, 1374 (Fed. Cir. 2011). When considering a reference under 35 U.S.C. §103 (obviousness), the person of ordinary skill will be presumed to possess "ordinary creativity." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

40 In practice, parties to litigation generally define the level of a person of ordinary skill in terms of their education and relevant work or research experience.

(3.4) CRITERION FOR SCOPE OF PROTECTION

Claim Language

41 "The claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (citations omitted). The starting point for claim construction or interpretation is the claim language itself. Courts cannot rewrite claim language and cannot broaden or narrow claims to give the patent holder something different than what the claims sets forth. *See Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1383–1384 (Fed. Cir. 2008); *Phillips*, 415 F.3d at 1312 ("Because the patentee is required to define precisely what his invention is . . . it is unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms." (quotations and citation omitted)).

42 Claim language is not, however, interpreted in a vacuum. Instead, a "person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Phillips*, 415 F.3d at 1313. As such, the "context in which a term is used in the asserted claim can be highly instructive" to its proper construction. *Id.* at 1314–1315. And other claims of the patent in question "can also be valuable sources of enlightenment as to the meaning of a claim term." *Id.* at 1315. And, as explained below, a patent holder may expressly define a claim term to have a particular meaning and may limit the scope of claims or claim terms in the specification or in the prosecution history.

43 Notably, 35 U.S.C. §112(f) (paragraph 6) provides:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

44 Claim limitations such as those described in 35 U.S.C. §112(f) are generally known as "means-plus-function" or "step-plus-function" limitations. "Through the use of means-plus-function limitations, patent applicants are allowed to claim an element of a combination functionally, without reciting structures for performing those functions." *Apex Inc. v. Raritan Computer, Inc.*, 325 F.3d 1364, 1371 (Fed. Cir. 2003). "A claim limitation that actually uses

the word 'means' invokes a rebuttable presumption that § 112, ¶ 6 applies. By contrast, a claim term that does not use 'means' will trigger the rebuttable presumption that §112, ¶ 6 does not apply." *Id.* (quotations, alterations, and citations omitted). "Means-plus-function claiming applies only to purely functional limitations that do not provide the structure that performs the recited function." *Welker Bearing Co. v. PHD, Inc.*, 550 F.3d 1090, 1095 (Fed. Cir. 2008) (quotations and citations omitted). A means-plus-function limitation "must be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." *Commonwealth Scientific and Indus. Research Org. v. Buffalo Tech. (USA)*, 542 F.3d 1363, 1383 (Fed. Cir. 2008) (quotations and citations omitted). Where a patentee fails to provide a description of the structure or means for performing the claimed function in the specification, the claim is invalid. *See Function Media, LLC v. Google, Inc.*, 708 F.3d 1310, 1318–1319 (Fed. Cir. 2013).

Specification

45 Patent claims must be read in view of the specification, of which they are a part. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). The specification is always highly relevant to claim construction, and has been called the "single best guide to the meaning of a disputed term." *Id.* at 1321 (quotations and citations omitted). The specification provides the context from which the claims arose and "necessarily informs the proper construction of the claims." *Id.* at 1316.

46 That said, "a construing court's reliance on the specification must not go so far as to import limitations into claims from examples or embodiments appearing only in a patent's written description unless . . . the specification makes clear that the patentee . . . intends for the claims and the embodiments in the specification to be strictly coextensive." *Silicon Graphics, Inc. v. ATI Techs., Inc.*, 607 F.3d 784, 792 (Fed. Cir. 2010) (quotations and citations omitted). In some cases, there may be a fine line between reading a claim in light of the specification and improperly importing a limitation into the claim from the specification. *See Phillips*, 415 F.3d at 1313. And in practice, the extent to which the specification affects the construction of a particular claim or claim term is often the subject of vigorous dispute.

47 "A patentee may act as its own lexicographer and assign to a term a unique definition that is different from its ordinary and customary meaning" by "clearly express[ing] that intent in the written description." *See Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1381 (Fed. Cir. 2008). "When a patentee defines a claim term, the patentee's definition governs, even if it is contrary to the conventional meaning of the term." *Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp.*, 493 F.3d 1358, 1361 (Fed. Cir. 2007). A patentee may define a claim term in the specification either expressly or by implication. *See Phillips*, 415 F.3d at 1321.

48 In addition to defining a claim term, "the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor." *Id.* at 1316. To avoid improperly importing limitations into the claims from the specification, disavowals of claim scope must be "expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." *Epistar Corp. v. ITC*, 566 F.3d 1321, 1335 (Fed. Cir. 2009) (quotations and citation omitted). But the Federal Circuit has rejected the notion that rigid formalism is required for a disavowal. Disclaimer does not require a patentee to expressly state, for example, that "my invention does not include ____." *Astrazeneca AB v. Mut. Pharm. Co.*, 384 F.3d 1333, 1340 (Fed. Cir. 2004). "Where the general summary or description of the invention describes a feature of the invention . . . and criticizes other products . . . that lack that same feature, this operates as a clear disavowal of these other products." *Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1333 (Fed. Cir. 2009) (quotations and citation omitted). "To

disavow claim scope, the specification must contain 'expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope.' In general, statements about the difficulties and failures in the prior art, without more, do not act to disclaim claim scope." *Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296, 1306 (Fed. Cir. 2011) (quoting *Epistar Corp. v. ITC*, 566 F.3d 1321, 1335 (Fed. Cir. 2009)).

Prosecution History

49 The prosecution history, which consists of the complete record of prosecution before the U.S. Patent and Trademark Office, is considered "intrinsic evidence" for claim construction. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005) (en banc). "It can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.* But because the prosecution file represents an ongoing negotiation between the patent applicant and the U.S. Patent and Trademark Office, it often lacks the clarity of the specification and is considered somewhat less useful for claim construction purposes. *Id.* The role of the prosecution history in claim construction is further detailed below. *See infra* §3.5, Role of Prosecution History.

Extrinsic Evidence

50 The Federal Circuit considers extrinsic evidence, which includes all evidence external to the patent and prosecution history, to be "less significant than the intrinsic record in determining the legally operative meaning of claim language." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005) (en banc) (quotations and citation omitted). Extrinsic evidence cannot therefore be used to contradict the meaning of a claim term that is otherwise apparent from the intrinsic evidence. *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1382 (Fed. Cir. 2008). The Supreme Court recently held that the Federal Circuit must review factual findings underlying claim construction for clear error, although interpretation of intrinsic evidence (including the specification and prosecution history) and the ultimate issue of claim construction is reviewed de novo. *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, 574 U.S. ___ (2015).

51 Extrinsic evidence such as dictionaries and treatises has nonetheless been "properly recognized as among the many tools that can assist the court in determining the meaning of particular terminology to those of skill in the art of the invention." *Phillips*, 415 F.3d at 1318. But courts "must ensure that any reliance on dictionaries accords with the intrinsic evidence." *Free Motion Fitness, Inc. v. Cybex Int'l*, 423 F.3d 1343, 1348 (Fed. Cir. 2005). "[T]he rule that a court will give a claim term the full range of its ordinary meaning does not mean that the term will presumptively receive its broadest dictionary definition or the aggregate of multiple dictionary definitions." *Id.* (quotations and citations omitted). Instead, where reliance on dictionaries is necessary, "the task is to scrutinize the intrinsic evidence in order to determine the most appropriate definition." *Id.* at 134849. To do otherwise risks improperly focusing the claim construction "inquiry on the abstract meaning of words rather than on the meaning of claim terms within the context of the patent." *Phillips*, 415 F.3d at 1321.

52 Like dictionaries, "expert testimony may be useful in claim construction, but it should be considered in the context of the intrinsic evidence". *Biagro Western Sales, Inc. v. Grow More, Inc.*, 423 F.3d 1296, 1302 (Fed. Cir. 2005). "[C]onclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court, [and] a court should discount any expert testimony that is clearly at odds" with the intrinsic evidence. *Phillips*, 415 F.3d at 1318 (quotations and citations omitted).

(3.5) ROLE OF PROSECUTION HISTORY

53 "Under the doctrine of prosecution disclaimer, a patentee may limit the meaning of a claim term by making a clear and unmistakable disavowal of scope during prosecution." *Purdue Pharma L.P. v. Endo Pharms., Inc.*, 438 F.3d 1123, 1136 (Fed. Cir. 2006). "A patentee could do so, for example, by clearly characterizing the invention in a way to try to overcome rejections based on prior art." *Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1375 (Fed. Cir. 2008). Prosecution disclaimer may also arise from an applicant's statements in the course of prosecuting a related patent application if the "statements … relat[e] to the same subject matter as the claim language at issue in the patent being construed." *See Ormco Corp. v. Align Tech., Inc.*, 498 F.3d 1307, 1314 (Fed. Cir. 2007).

54 "Prosecution disclaimer does not apply to an ambiguous disavowal," however. *See Computer Docking Station Corp.*, 519 F.3d at 1374. "And if the specification expressly defines a claim term and remarks made to distinguish claims from the prior art are broader than necessary to distinguish the prior art, the full breadth of the remark is not a clear and unambiguous disavowal of claim scope as required to depart from the meaning of the term provided in the written description." *Computer Docking Station Corp.*, 519 F.3d at 1375 (quotations omitted).

(3.6) EQUIVALENTS

55 Protection granted under a patent is not necessarily limited to the devices and processes covered by the literal meaning of the claims. Under the doctrine of equivalents, infringement may be found even if the accused device or process does not literally meet each limitation of the asserted claim, but rather constitutes an "equivalent" of the claimed device or process. There are two tests for determining if an accused device or process is equivalent. Under the "primary" test, the accused product or process will be deemed equivalent if it "[1] performs substantially the same function, [2] in substantially the same way, [3] to achieve substantially the same result" as the claimed invention. *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1296 (Fed. Cir. 2009). And under the second test, a device or process will be deemed equivalent if only an "insubstantial" difference exists between each of the features of the accused device or process and the corresponding element of the claimed invention. *Id.* at 1297; *see also Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997) (holding that the different tests "may be more suitable to different cases, depending on their particular facts"). Under either test, however, "[i]nfringement analysis under the doctrine of equivalents proceeds element-by-element; a generalized showing of equivalency between the claim as a whole and the allegedly infringing product or process is not sufficient to show infringement." *Abbott Labs.*, 566 F.3d at 1296; *see also Warner-Jenkinson Co.*, 520 U.S. at 40 ("[T]he particular linguistic framework used is less important than whether the test is probative of the essential inquiry: Does the accused product or process contain elements identical or equivalent to each claimed element of the patented invention?"). If this standard is satisfied, the fact that an equivalent would have been foreseeable at the time of the patent application does not by itself bar the application of the doctrine of equivalents. *Ring & Pinion Serv. Inc. v. ARB Corp., Ltd.*, 743 F.3d 831, 833–834 (Fed. Cir. 2014).

56 Prosecution history estoppel may limit application of the doctrine of equivalents. "Whether prosecution history estoppel applies to a particular argument . . . is a question of law." *Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282, 1290–1291 (Fed. Cir. 2010). "Where an amendment narrows the scope of the claims, and that amendment is adopted for a substantial reason related to patentability, the amendment gives rise to a presumption of surrender for all equivalents that reside in 'the territory between the original claim and the amended claim.'" *Id.* at 1291 (quoting *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 740 (2002)).

57 "This presumption can be overcome by showing that 'at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent.'" *Id.* (quoting *Festo Corp.*, 535 U.S. at 741). "The equivalent may have been unforeseeable at the time of the application; the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question; or there may be some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question. In those cases the patentee can overcome the presumption that prosecution history estoppel bars a finding of equivalence." *Festo Corp.*, 535 U.S. at 741. The burden of overcoming the presumption that the equivalent has been surrendered rests squarely on the patentee. *Id.* at 740.

(3.7) NON-INVENTIVE APPLICATION OF THE STATE OF THE ART

58 The Federal Circuit does not recognize a "practicing the prior art" defense to literal infringement, and "there is no requirement that the accused device be non-obvious in light of the prior art, or otherwise be itself patentable." *Tate Access Floors, Inc. v. Interface Architectural Res., Inc.*, 279 F.3d 1357, 1365–1366 (Fed. Cir. 2002); *Baxter Healthcare Corp. v. Spectramed, Inc.*, 49 F.3d 1575, 1583 (Fed. Cir. 1995)). "Literal infringement exists if each of the limitations of the asserted claim(s) read on, that is, are found in, the accused device. Questions of obviousness in light of the prior art go to validity of the claims, not to whether an accused device infringes." *Baxter Healthcare Corp.*, 49 F.3d at 1583.

(3.8) TRANSLATIONS

59 Not applicable in this jurisdiction.

(3.9) NATIONAL (NON-EUROPEAN) PATENT

60 Not applicable in this jurisdiction.

(4) INFRINGEMENT

(4.1) DIRECT INFRINGEMENT

61 A direct infringer is one 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." 35 U.S.C. § 271(a). Infringement may also be indirect by inducing others or contributing to the infringement of others (§ 271(b), (c)) (*see infra* § 4.2, Indirect Infringement):

(a) Except as otherwise provided in this title, 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, infringes the patent.
(b) Whoever actively induces infringement of a patent shall be liable as an infringer.
(c) 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, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

35 U.S.C. §271.

62 Direct infringement may be literal or may arise under the doctrine of equivalents. "Actions predicated on direct patent infringement . . . do not require any showing of intent to infringe." *Fla. Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank*, 527 U.S. 627, 645 (1999); *see also Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 35 (1997) ("[N]either [literal or equivalent infringement] requires proof of intent."). *But see infra* §8.2, Limitations Period (discussing the relationship between patent marking and recovery of damages).

Literal Infringement

63 In order to infringe literally, an accused device must fall within the literal scope of each limitation of a construed patent claim. The Federal Circuit has articulated a two-step analysis for determining infringement: first, a court must construe the claims; and second, the court must then compare the construed claims to the accused device or process to determine whether all elements of the claims are present in the accused device or process. *See Mars, Inc. v. H.J. Heinz Co., L.P.*, 377 F.3d 1369, 1373, 1379 (Fed. Cir. 2004). "To establish literal infringement, all of the elements of the claim, as correctly construed, must be present in the accused system." *TechSearch L.L.C. v. Intel Corp.*, 286 F.3d 1360, 1371 (Fed. Cir. 2002).

Infringement Pursuant to the Doctrine of Equivalents

64 "[T]o permit imitation of a patented invention which does not copy every literal detail would be to convert the protection of the patent grant into a hollow and useless thing."

Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 607 (1950). The doctrine of equivalents thus allows a finding of infringement when claim limitations are not literally met so long as "only insubstantial differences distinguish [each] missing claim element from the corresponding aspects of the accused device." *Sage Prods. Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1423 (Fed. Cir. 1997) (quotations omitted). Thus, "[t]he doctrine of equivalents allows the patentee to claim those insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 733 (2002)

65 As discussed *supra* in §3.6, there are two tests for determining whether an accused device or process infringes under the doctrine of equivalents. Under the "primary" test, the accused product or process is deemed equivalent if it "[1] performs substantially the same function, [2] in substantially the same way, [3] to achieve substantially the same result" as the claimed invention. *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1296 (Fed. Cir. 2009). Under the second test, a device or process is equivalent if only an "insubstantial" difference exists between each of the features of the accused device or process and the corresponding element of the claimed invention. *Id.* at 1297; *see also Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997) (holding that the different tests "may be more suitable to different cases, depending on their particular facts"). Under either test, however, "[i]nfringement analysis under the doctrine of equivalents proceeds element-by-element; a generalized showing of equivalency between the claim as a whole and the allegedly infringing product or process is not sufficient to show infringement." *Abbott Labs.*, 566 F.3d at 1296; *see also Warner-Jenkinson Co.*, 520 U.S. at 40 ("[T]he particular linguistic framework used is less important than whether the test is probative of the essential inquiry: Does the accused product or process contain elements identical or equivalent to each claimed element of the patented invention?"). If this standard is satisfied, the fact that an equivalent would have been foreseeable at the time of the patent application does not by itself bar the application of the doctrine of equivalents. *Ring & Pinion Serv. Inc. v. ARB Corp., Ltd.*, 743 F.3d 831, 833–834 (Fed. Cir. 2014).

66 An accused device infringes under the doctrine of equivalents only if every element in the claim is present in the accused device, either literally or equivalently. *See Abbott Labs.*, 566 F.3d at 1296; *TechSearch L.L.C.*, 286 F.3d at 1372 (Fed. Cir. 2002). "Each element contained in a patent claim is deemed material to defining the scope of the patented invention, and thus the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole." *Warner-Jenkinson Co.*, 520 U.S. at 29.

67 Importantly, application of the doctrine of equivalents may be precluded by prosecution history estoppel. "Where an amendment [made during a patent's prosecution] narrows the scope of the claims, and that amendment is adopted for a substantial reason related to patentability, the amendment gives rise to a presumption of surrender for all equivalents that reside in 'the territory between the original claim and the amended claim.'" *Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282, 1291 (Fed. Cir. 2010) (quoting *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 740 (2002)). A patentee may be able to overcome or circumvent this presumption, however, by showing that "at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent"—for example, because "[t]he equivalent [was] unforeseeable at the time of the application" or because "the rationale underlying the amendment [bears] no more than a tangential relation to the equivalent in question." *Festo Corp.*, 535 U.S. at 740–741.

Infringement and Invalidity

68 "It is axiomatic that one cannot infringe an invalid patent." *Commil USA, LLC v. Cisco Systems, Inc.*, 720 F.3d 1361, 1368 (Fed. Cir. 2013), *cert. granted* (U.S. Dec. 5, 2014) (No. 13-896). *See infra* § 5.1, Invalidity.

(4.1.1) Products

Offers for Sale

69 Offering a patented product for sale within the United States is infringement. 35 U.S.C. §271(a); *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc.*, 617 F.3d 1296, 1309 (Fed. Cir. 2010); *3D Systems, Inc. v. Aarotech Laboratories, Inc.*, 160 F.3d 1373, 1378 (Fed. Cir. 1998). An offer for sale constitutes direct infringement if the offer is for a product that meets every element of a patent claim. *See FieldTurf Int'l, Inc. v. Sprinturf, Inc.*, 433 F.3d 1366, 1369–1370 (Fed. Cir. 2006).

Components Supplied in or from the United States

70 35 U.S.C. §271(f) addresses the situation wherein products are assembled outside the United States from components supplied in or from the United States. One who supplies "in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States," in a way that would infringe the patent if the components were combined in the United States, "shall be liable as an infringer." 35 U.S.C. §271(f)(1); *see also Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437, 452 (2007); *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 576 F.3d 1348, 1362 (Fed. Cir. 2009) (en banc). Similar language in 35 U.S.C. §271(f)(2) is relevant to components that are "especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use," and for which the alleged infringer knows the component is "so made or adapted" and intends that the components "will be combined outside of the United States in a manner that would infringe" if they were so combined within the United States. 35 U.S.C. §271(f)(2). Section 271(f) does not apply to method patents. *Cardiac Pacemakers*, 576 F.3d at 1365.

FDA Research

71 Under 35 U.S.C. §271(e)(1), the use of an invention does not qualify as infringement if that use is "reasonably related" to obtaining regulatory approval (such as from the U.S. Food and Drug Administration (FDA)) to market pharmaceutical or veterinary products. 35 U.S.C. §271(e)(1); *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202–203, 208 (2005); *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d 1348, 1357–1359 (Fed. Cir. 2012); *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011); *see also infra* §§5.2, Research Exemption, 5.3, Bolar Exemption. The §271(e)(1) "safe harbor" also applies to medical devices requiring FDA approval. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990).

Improvements to Patented Inventions

72 Even if an improvement to a patented invention is itself patentable, the improvement may still infringe the patented invention. Separate patentability of the improvement "presents no legal or evidentiary presumption of noninfringement." *Hoechst Celanese Corp. v.*

BP Chemicals Ltd., 78 F.3d 1575, 1582 (Fed. Cir. 1996); *Cantrell v. Wallick*, 117 U.S. 689, 694 (1886) (stating "[t]wo patents may both be valid when the second is an improvement on the first, in which event, if the second includes the first, neither of the two patentees can lawfully use the invention of the other without the other's consent."). "Whether improvement or modification avoids infringement depends on the particular facts." *Glaxo Wellcome, Inc. v. Andrx Pharms., Inc.*, 344 F.3d 1226, 1233–1234 (Fed. Cir. 2003); *Nat'l Presto Indus., Inc. v. West Bend Co.*, 76 F.3d 1185, 1191–1192 (Fed. Cir. 1996); *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1580 (Fed. Cir. 1984) (stating that an improvement of a step of a patented process did not avoid infringement under the doctrine of equivalents, even though the improvement was separately patentable).

73 An accused embodiment "cannot escape infringement by merely adding features, if it otherwise has adopted the basic features of the patent." *Amstar Corp. v. Envirotech Corp.*, 730 F.2d 1476, 1482 (Fed. Cir. 1984) (quoting *Acme Highway Prods. Corp. v. D.S. Brown Co.*, 473 F.2d 849, 855 (6th Cir. 1973)). "Modification by mere *addition* of elements of functions, whenever made, cannot negate infringement without disregard of the long-established, hornbook law." *Amstar Corp.*, 730 F.2d at 1482. "It is fundamental that one cannot avoid infringement merely by adding elements if each element recited in the claims is found in the accused device." *A.B. Dick Co. v. Burroughs Corp.*, 713 F.2d 700, 703 (Fed. Cir. 1983) (citing *Temco Elec. Motor Co. v. Apco Mfg. Co.*, 275 U.S. 319, 328 (1928)). The Federal Circuit illustrated this principle with the example of a claim to a pencil that is infringed when the pencil is incorporated into a complex machine: "a pencil structurally infringing a patent claim would not become noninfringing when incorporated into a complex machine that limits or controls what the pencil can write," and "[n]either would infringement be negated simply because the patentee failed to contemplate use of the pencil in that environment." *A.B. Dick Co.*, 713 F.2d at 703. This same principle has been applied in cases involving accused chemical compositions and biological compounds. *Mars, Inc. v. H.J. Heinz Co., L.P.*, 377 F.3d 1369, 1376-77 (Fed. Cir. 2004) (holding that the claim term "containing a mixture of lipid and solid ingredients" did not exclude the presence of "additional, unnamed ingredients"); *Amgen Inc. v. F. Hoffmann-La Roche Ltd.*, 580 F.3d 1340, 1376 (Fed. Cir. 2009) (affirming that attaching a certain molecule to a patented biological compound was "the addition of an element, which cannot negate infringement, as opposed to a fundamental chemical transformation, which might save [the accused product] from infringement").

(4.1.2) Processes

74 To prove infringement of a process patent, the patent holder must not only show that each of the claimed steps was performed, but also that each of the claimed steps was performed by a single party or that a single party "exercises 'control or direction' over the entire process such that every step is attributable to the controlling party." *Muniauction, Inc. v. Thompson Corp.*, 532 F.3d 1318, 1329 (Fed. Cir. 2008). This same rule applies to claims for induced infringement; unless a single actor performs each of the claimed process steps such that the actor would be liable for direct infringement under §271(a), no claim for induced infringement under §271(b) can exist. *See Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111, 2118 (2014).

75 The exclusive rights of the patentee in relation to a patented process are not necessarily restricted to use of the steps of the patented process alone. A patented process "comprising" certain steps will be infringed by a process using those steps and others. "An accused

method does not avoid literally infringing a method claim simply because it employs *additional* steps," when the patent claim at issue "comprises" a series of steps (rather than limiting the process to those steps). *Dow Chem. Co. v. Sumitomo Chem. Co.*, 257 F.3d 1364, 1380 (Fed. Cir. 2001) (alteration and citation omitted). "[W]hen all the steps of a claimed process are practiced in the same way and for the same purpose as shown in the patent, the addition of further steps generally does not avoid infringement." *Kinik Co. v. ITC*, 362 F.3d 1359, 1366 (Fed. Cir. 2004); *see also Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1178 (Fed. Cir. 1991).

76 Under 35 U.S.C. §271(a), the use of a process cannot qualify as infringement unless each of its steps is performed "within the United States." *See NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1318 (Fed. Cir. 2005). Although use of a patented process outside the U.S. may avoid infringement under 35 U.S.C. §271(a), one may nevertheless infringe under 35 U.S.C. §271(g), which provides that importation into the United States of a product made by a process patented in the United States is an act of infringement. *See* 35 U.S.C. §271(g); *see also Amgen Inc. v. F. Hoffmann-La Roche, Ltd.*, 580 F.3d 1340, 1377 (Fed. Cir. 2009). In addition, "in order for a product to have been made by a process patented in the United States" under §271(g), it must have been a physical article that was "manufactured"; "the production of information is not covered" by §271(g). *Bayer AG v. Housey Pharms., Inc.*, 340 F.3d 1367, 1377 (Fed. Cir. 2003) (quotations and citations omitted). If, however, the product made by the patented process is "materially changed by subsequent processes" prior to importation or "becomes a trivial and nonessential component of another product," then importation of that product does not constitute infringement. *Id.* at 1372–1373; 35 U.S.C. §271(g). "Where the specification or asserted claims recite a structure or function for the product of the processes, then significant variations from the recited structure and function are material. What makes a variation significant enough to be a 'material change,' however, is a question of degree." *Amgen*, 580 F.3d at 1379. A material change typically involves change to "a physical or chemical property which is an important feature of the product produced by the patented process" or to "physical or chemical properties of the product in a manner which changes the basic utility of the product produced by the patented process," but "infringement can be found, even in the case of a significant change in the imported product, if it would not have been possible or commercially viable to make the different product but for the patented process." *Eli Lilly & Co. v. Am. Cyanamid Co.*, 82 F.3d 1568, 1575, 1577 (Fed. Cir. 1996) (alterations and citations omitted).

77 In many instances, particularly those involving § 271(g), it may not be possible for the patent holder to determine the process used to make the allegedly infringing product during the course of litigation. This situation may arise, for example, where a U.S.-based defendant imports an allegedly infringing product made by a foreign third-party supplier. In such cases, the patentee-plaintiff may be able to shift the burden to the accused infringer-defendant under 35 U.S.C. §295 to establish that its product was not made by the patented process. Invoking § 295's burden shifting requires the patent holder to satisfy two requirements: (1) a substantial likelihood must exist that the product was made by the patented process, and (2) the patent holder must show that it has made a reasonable effort to determine the process actually used in production of the product and was unable to so determine. *See* 35 U.S.C. §295; *Nutinova Nutrition Specialties & Food Ingredients GmbH v. ITC*, 224 F.3d 1356, 1359–1360 (Fed. Cir. 2000). To meet the first prong of §295, a patent holder must make a showing that is greater than speculation but not as high as the "more likely than not" standard necessary to prove infringement. *See*, e.g., *Creative Compounds, LLC v. Starmark Labs.*, 651 F.3d 1303, 1314–1315 (Fed. Cir. 2011). Proper evidence to make this

showing may include, for example, expert testimony concerning the commercially feasible options for manufacturing the product along with an evaluation of the likelihood that the defendant is using any non-infringing alternatives, if such alternatives exist. *See,* e.g., *Aventis Pharms., Inc. v. Barr Labs., Inc.*, 411 F. Supp. 2d 490, 509–514 (D.N.J. 2006). With respect to the second prong of § 295, courts have required plaintiffs to use reasonable available options to determine the defendant's manufacturing process. *See,* e.g., *Creative Compounds*, 651 F.3d at 1314–1315. This may include subpoenas for documents and samples, third-party depositions, and, if the entities are foreign, letters rogatory seeking documents or foreign depositions under the Hague Convention. If the patent holder is able to obtain samples of the allegedly infringing product, this element of § 295 may also require testing to look for indications of the manufacturing process used (e.g., specific process-related impurities in chemical compounds). *See,* e.g., *West v. Jewelry Innovations Inc.*, No. 07-cv-1812 (N.D. Cal. July 17, 2007) (non-precedential).

Product-by-Process Infringement

78 Product-by-process claims ultimately claim a product, but define that product by how it is made. Although product-by-process claims are typically used when "an inventor invents a product whose structure is either not fully known or too complex to analyze," *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1294 (Fed. Cir. 2009), an inventor is free to use the product-by-process claim structure "even if the invention could have been described independent of the process." *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1315 (Fed. Cir. 2006). The process steps of a product-by-process claim are treated as limitations when determining infringement. *Abbott Labs.*, 566 F.3d at 1293. An accused end product therefore does not infringe a product-by-process claim unless the end product results from a process in which each of the claimed steps are performed. *Id.* Yet, because product-by-process claims "are always to a product, not a process," the claim's validity "is based on the product itself [and] does not depend on [the product's] method of production." *SmithKline Beecham Corp.*, 439 F.3d at 1317; *see also* MPEP §2113 (9th ed. March 2014).

(4.1.3) Absolute Product Protection

79 Infringement of a product claim focuses solely on whether the accused product meets the claim limitations. As a result, the uses to which the product is put are largely irrelevant to the analysis of whether a product claim is infringed. One cannot avoid infringement of a product claim by using the product solely in a way never contemplated by the inventor, or never discussed in the patent specification. "[A]pparatus claims cover what a device *is*, not what a device *does*." *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 909 F.2d 1464, 1468 (Fed. Cir. 1990); *Roberts v. Ryer*, 91 U.S. 150, 157 (1875) ("The inventor of a machine is entitled to the benefit of all the uses to which it can be put, no matter whether he had conceived the idea of the use or not."); *Catalina Marketing Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed. Cir. 2002) ("[A] patent grants the right to exclude others from making, using, selling, offering to sale, or importing the claimed apparatus or composition for any use of that apparatus or composition, whether or not the patentee envisioned such use.").

80 To claim an invention by reference to how someone uses the invention, and thereby limit the scope of the claim to particular uses, the patent must claim a method of use. U.S. law generally does not permit a patent claim to simultaneously claim a product and a specific use of the product in the same claim. *IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377, 1384 (Fed. Cir. 2005) (holding that a claim was invalid as indefinite under 35

U.S.C. §112, because it claimed simultaneously a system and a method of using the system). Patent applicants can avoid this problem by seeking separate product claims and method of use claims. Although method claims may recite physical structures, and product claims may include functional language, the language of such claims must unambiguously limit the claim either to practicing the claimed method or to a product having the claimed structure. *Microprocessor Enhancement Corp. v. Texas Instruments Inc.*, 520 F.3d 1367, 1374–1375 (Fed. Cir. 2008).

(4.1.4) *De Minimis*

81 Under the patent statute, any use of the patented invention constitutes infringement. *See* 35 U.S.C. §271. The common law has recognized a limited *de minimis* infringement exception for non-commercial experimental usage for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry. *Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002); *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984), *superseded on other grounds by* 35 U.S.C. §271(e)(1); *see also Pitcairn v. United States*, 547 F.2d 1106 (1976). The exception does not apply if the use has any commercial or business purpose. *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002). *See also infra* §5.2 (Research Exemption).

(4.1.5) Biological Material

82 The protection conferred by a patent on a biological material will likely extend to any copies of that biological material derived from that biological material through propagation or multiplication. *Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1336 (Fed. Cir. 2006) ("The fact that a patented technology can replicate itself does not give a purchaser the right to use replicated copies of the technology. Applying the first sale doctrine to subsequent generations of self-replicating technology would eviscerate the rights of the patent holder."); *Monsanto Co. v. McFarling*, 302 F.3d 1291, 1298–1299 (Fed. Cir. 2002). Exhaustion applies only to the items sold and not reproductions. *Bowman v. Monsanto Co.*, 133 S. Ct. 1761, 1768 (U.S. 2013).

83 The protection conferred by a patent on a process for producing a biological material does not necessarily extend to that biological material if it is produced by a different process. *See,* e.g., *Novo Nordisk of North America, Inc. v. Genentech, Inc.*, 77 F.3d 1364, 1371 (Fed. Cir. 1996) (concluding that there was no literal infringement of a claim for a "process for the direct expression" of a protein, where the accused infringer "does not directly express" the protein and instead used a different process to produce the protein).

(4.1.6) Products Containing or Consisting of Genetic Information

84 The protection conferred by a patent on a product containing or consisting of genetic information has been limited by the Supreme Court's decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013). "[A] naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated," but "synthetically created DNA known as complementary DNA (cDNA), which contains the same protein-coding information found in a segment of natural DNA but omits portions within the DNA segment that do not code for proteins . . . is patent eligible because it is not naturally occurring." *Id.* at 2111. Similarly, a claim involving "a transformed cell, which is made by man, in contrast to a natural material" also has been

found to be patent eligible. *Ass'n for Molecular Pathology v. U.S. PTO*, 689 F.3d 1303, 1333–1335 (Fed. Cir. 2012) (invalidating claims drawn to comparing genetic sequences), *aff'd in part and rev'd in part on other grounds*, *Myriad*, 133 S. Ct. 2107.

(4.2) INDIRECT INFRINGEMENT

85 Indirect infringement occurs where a party induces another party to infringe or contributes to an infringement in violation of 35 U.S.C. §§271(b) or (c). In order for indirect infringement to exist, there must be a predicate finding of direct infringement. *BMC Res., Inc. v. Paymentech, L.*P., 498 F.3d 1373, 1379 (Fed. Cir. 2007); *Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1272 (Fed. Cir. 2004). "Absent direct infringement of the patent claims, there can be neither contributory infringement, nor inducement of infringement." *Met-Coil Sys. Corp. v. Korners Unlimited, Inc.*, 803 F.2d 684, 687 (Fed. Cir. 1986) (citations omitted); *see also ACCO Brands, Inc. v. ABA Locks Mfr. Co., Ltd.*, 501 F.3d 1307, 1312 (Fed. Cir. 2007). Accordingly, a patent holder must either point to specific instances of direct infringement or show that the accused device necessarily infringes the patent in suit. *ACCO Brands*, 501 F.3d at 1313; *see also Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1334 (Fed. Cir. 2003).

(4.2.1) Inducement of Infringement

86 Pursuant to 35 U.S.C. §271(b), whoever actively induces infringement of a patent shall be liable as an infringer. To establish liability under section 271(b), a patent holder must prove that once the accused infringer knew of the patent, it actively and knowingly aided and abetted another's direct infringement. *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1305 (Fed. Cir. 2006) (en banc in relevant part). With respect to the knowledge requirement, the Supreme Court has explained that a willfully blind defendant will meet the requirement while a merely reckless or negligent defendant will not. *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2068–2070 (2011). A willfully blind defendant is one who "takes deliberate actions to avoid confirming a high probability of wrongdoing and who can almost be said to have actually known the critical facts." *Id.* at 2071. By contrast, "a reckless defendant is one who merely knows of a substantial and unjustified risk of such wrongdoing, and a negligent defendant is one who should have known of a similar risk but, in fact, did not." *Id.* (citations omitted). Induced infringement can only be found if direct infringement can be attributed to a single party. *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111, 2117 (2014). Evidence of an accused inducer's "good-faith belief" that a patent is invalid "may negate the requisite intent for induced infringement." *Commil USA, LLC v. Cisco Systems, Inc.*, 720 F.3d 1361, 1367 (Fed. Cir. 2013), *cert. granted* (U.S. Dec. 5, 2014) (No. 13-896).

(4.2.2) Contributory Infringement

87 Under 35 U.S.C. §271(c), a party that sells a component of a patented invention or a material or apparatus for use in a patented process that constitutes a material part of the invention and knows it to be especially made or adapted for use in an infringement of the patent, and is not a staple article of commerce suitable for substantial non-infringing use, is liable as a contributory infringer. 35 U.S.C. §271(c); *see also Wordtech Sys. v. Integrated Networks Solutions, Inc.*, 609 F.3d 1308, 1316 (Fed. Cir. 2010). To establish contributory infringement, a patent holder must show: "1) that there is direct infringement, 2) that the accused infringer had knowledge of the patent, 3) that the component has no substantial

noninfringing uses, and 4) that the component is a material part of the invention." *Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1326 (Fed. Cir. 2010). "[N]on-infringing uses are substantial when they are not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental." *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1327 (Fed. Cir. 2009). A determination of whether a possible non-infringing use is substantial cannot be "evaluated in a vacuum," and instead may involve evaluation of "not only the use's frequency, but also the use's practicality, the invention's intended purpose, and the intended market." *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 851 (Fed. Cir. 2010). An accused infringer cannot escape liability under §271(c) by merely embedding an infringing component into a larger product that has additional features capable of substantial non-infringing uses. *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1320 (Fed. Cir. 2009); *Ricoh Co. v. Quanta Computer Inc.*, 550 F.3d 1325, 1337–1338 (Fed. Cir. 2008).

(4.2.3) Joint Infringement

88 Direct infringement of a method claim requires a party to perform each and every step of the claim. *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1378 (Fed. Cir. 2007).

89 This requirement raises questions regarding joint infringement when the limitations of a claim are met only through the combined actions of, for example, an entity and that entity's customers. In *BMC Resources* and *Muniauction*, the Federal Circuit held that when more than one party performs the steps of a claimed method, there can be no infringement unless one party exercises "control or direction" over the entire process such that every step is attributable to the controlling party. *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1329 (Fed. Cir. 2008), citing *BMC Res.*, 498 F.3d at 1380–1381. The Supreme Court has "assum[ed] without deciding that the Federal Circuit's holding in *Muniauction* is correct," and has held that there is also no induced infringement of a method claim under 35 U.S.C. §271(b) unless performance of all of the method's steps are attributable to a single entity. *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111, 2117 (2014).

90 With respect to system claims, the Federal Circuit has held that "use" of a system, for the purposes of infringement, requires a party to "put the invention into service, i.e., control the system as a whole and obtain benefit from it." *Centillion Data Sys., LLC v. Qwest Communs. Int'l, Inc.* 631 F.3d 1279, 1284 (Fed. Cir. 2011). "Use" may also be established through the actions of another party for which the allegedly using party is vicariously liable. *Id.* at 1286. When a defendant participates in or encourages infringement but does not directly infringe a patent, the normal recourse under the law is for the court to apply the standards for liability under indirect infringement. Indirect infringement requires, as a predicate, a finding that some party amongst the accused actors has committed the entire act of direct infringement. *Limelight Networks*, 134 S. Ct. at 2117.

(4.3) UNFAIR COMPETITION

91 Section 337 of the Tariff Act of 1930 prohibits "unfair methods of competition and unfair acts in the importation of articles . . . into the United States." Smoot-Hawley Tariff Act of 1930, 19 U.S.C. §1337(a)(1)(A). As amended, section 337 prohibits "[t]he importation into the United States, the sale for importation, or the sale within the United States after importation" of articles that (i) "infringe a valid and enforceable United States patent" or (ii) that "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." 19 U.S.C.

§1337(a)(1)(B). Section 337 is administered by the U.S. International Trade Commission (ITC). Although the ITC cannot award damages for patent infringement, "[w]hen the ITC determines that a defendant has engaged in unfair practices in import trade, it may direct that the articles at issue be excluded from entry into the United States, 19 U.S.C. §1337(d), issue a cease and desist order, 19 U.S.C. §1337(f), and/or issue an order providing that the articles in violation be seized and forfeited to the United States, 19 U.S.C. §1337(i)." *Bio-Tech. Gen. Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1564 (Fed. Cir. 1996).

92 Patent infringement generally does not give rise to a claim for unfair competition under state law. Pursuant to case law governing conflicts between state and federal law relating to the same subject matter, federal patent law preempts state unfair competition law unless the state law claim contains a qualitatively different extra element distinguishing it from federal patent protection. *Summit Mach. Tool Mfg. Corp. v. Victor CNC Sys., Inc.*, 7 F.3d 1434, 1439–1440 (9th Cir. 1993). For example, "principles of patent law preemption do not override potential causes of action based on unfair commercial practices." *Hall v. Bed Bath & Beyond, Inc.*, 705 F.3d 1357, 1372 (Fed. Cir. 2013).

(4.4) UNJUSTIFIED THREATS

93 Sham litigation, impermissible under American antitrust law, involves efforts to exclude a rival, raise its costs, constrain its output, or cause similar competitive harm by using baseless litigation. Sham litigation involves the pursuit of claims, including patent infringement claims, that are so baseless that no reasonable litigant could realistically expect to secure favorable relief. *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.* ("PRE"), 508 U.S. 49, 56 (1993) (discussing sham litigation as an exception to the principle that "[t]hose who petition government for redress are generally immune from antitrust liability," and citing the *Noerr* and *Pennington* cases (*E. R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U. S. 127 (1961); *Mine Workers v. Pennington*, 381 U. S. 657, 669 (1965))). By contrast, "[t]he existence of probable cause to institute legal proceedings precludes a finding that an antitrust defendant has engaged in sham litigation." *PRE*, 508 U.S. at 62. In other words, "[i]f an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome," then "an antitrust claim premised on the sham exception must fail." *PRE*, 508 U.S. at 60. To qualify as anticompetitive, the challenged litigation must not only be "objectively meritless," but must also "conceal[] an attempt to interfere *directly* with the business relationships of a competitor through the use of the governmental *process*" (i.e., the litigation), "as opposed to the *outcome* of that process" (i.e., victory in the litigation), "as an anticompetitive weapon." *PRE*, 508 U.S. at 60–61 (alterations and quotations omitted; emphasis in original). In analyzing, with the benefit of hindsight, whether an unsuccessful lawsuit is an anticompetitive sham, the court must resist the temptation to engage in post hoc reasoning by concluding that an ultimately unsuccessful lawsuit must have been unreasonable or without foundation when the lawsuit was initially filed. *PRE*, 508 U.S. at 60 n. 5.

94 These standards for sham litigation informed past evaluations of whether to award attorneys' fees under 35 U.S.C. §285 at the conclusion of a litigation. *See Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 682 F.3d 1003, 1007 (Fed. Cir. 2012) (en banc). Section 285 provides that "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party." *See infra* §8.10.8, Order for Costs. However, the Supreme Court's opinion in *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 134 S. Ct. 1749 (2014) rejected this reliance on *Professional Real Estate Investors,* and instead held that under 35

U.S.C. §285, "a district court may award fees in the rare case in which a party's unreasonable conduct—while not necessarily independently sanctionable—is nonetheless so 'exceptional' as to justify an award of fees," and that "a case presenting either subjective bad faith or exceptionally meritless claims may sufficiently set itself apart from mine-run cases to warrant a fee award." *Octane Fitness*, 134 S. Ct. 1757; *see also Highmark Inc. v. Allcare Health Mgmt. Sys. Inc.*, 134 S. Ct. 1744 (2014) (holding that appellate review of district court fee shifting decisions in patent cases should be only for abuse of discretion, rather than de novo or for clear error).

(4.5) ANTITRUST ISSUES

95 American antitrust law is a complex topic, and there are certain antitrust claims that are relevant to patents. For example, antitrust issues can arise when a defendant asserts antitrust counterclaims or defenses. Such claims or defenses may include unlawful acquisition or maintenance of monopoly under section 2 of the Sherman Antitrust Act, sham litigation, bad faith patent enforcement, or fraudulent patent procurement. *See also infra* §5.9(v), Patent Misuse.

96 Section 2 of the Sherman Act prohibits acquisition or maintenance of monopoly power through anticompetitive conduct. *See* 15 U.S.C. §2 ("[e]very person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony"). There are several hurdles for the alleged infringer/antitrust claimant who contends that the patentee has monopolized or attempted to monopolize in violation of section 2. To prove section 2 monopolization, the accused infringer must show that the patentee has monopoly power in the relevant market, and that the market power was acquired through anticompetitive behavior. *See Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1353 (Fed. Cir. 1999); *Brown Shoe Co. v. United States*, 370 U.S. 294, 324 (1962). Although a patent confers exclusivity and is often colloquially referred to as a government-conferred monopoly, owning a patent is not sufficient evidence of market power, because the antitrust law of market definition recognizes the possibility of non-infringing substitutes for the patented technology. *See Abbott Labs. v. Brennan*, 952 F.2d 1346, 1354–1355 (Fed. Cir. 1991). Additionally, if the accused infringer is not actively competing with the patentee, the accused infringer may not have a basis to assert an antitrust counterclaim. *Intergraph Corp.*, 195 F.3d at 1355.

97 To the extent that the patentee's use of the judicial process results in anticompetitive effects, the patentee's use of judicial process is immune from antitrust liability unless the accused infringer/antitrust claimant establishes either that (i) the patent was obtained from the U.S. Patent and Trademark Office (USPTO) through knowing and willful fraud, or (ii) the patent infringement lawsuit itself is a sham litigation. *See Q-Pharma, Inc. v. Andrew Jergens Co.*, 360 F.3d 1295, 1304–1305 (Fed. Cir. 2004) (citing *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177 (1965), and *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60–61 (1993)). For example, the defendant could allege the patentee is seeking to enforce the patent even though the patentee learned, after obtaining the patent, that the patent is invalid or unenforceable. *See Handgards, Inc. v. Ethicon, Inc.*, 601 F.2d 986 (9th Cir. 1979); *Bio Tech. Gen. Corp. v. Genentech, Inc.*, 267 F.3d 1325, 1332–1333 (Fed. Cir. 2001).

98 Section 2 counterclaims may also involve assertions that the patentee engaged in misconduct through deceptive participation in an industry standards-setting organization. For example, an alleged infringer may assert that the patentee engaged in deceptive conduct in the standards-setting process by incorporating its patented technology into the industry standard, without giving notice of its patent, and reserving the ability to assert that patent against anyone in the industry who practiced the standard. *See,* e.g., *Rambus, Inc. v. FTC,* 522 F.3d 456, 463 (D.C. Cir. 2008). Alternatively an alleged infringer may assert that the patentee reneged on a commitment to the standards organization and its members to license its patents on Fair, Reasonable, And Non-Discriminatory (FRAND) terms (also sometimes referred to as RAND or Reasonable And Non-Discriminatory). *See,* e.g., *Broadcom Corp. v. Qualcomm, Inc.*, 501 F.3d 297, 313–314 (3d Cir. 2007).

(4.6) WILLFUL INFRINGEMENT

99 In the United States, a finding of willful infringement, which may result in enhanced damages against an infringer, requires at least a showing of objective recklessness. *In re Seagate Tech. LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007) (en banc). To establish willful infringement, a patentee must show "by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent." *Id.* The state of mind of the accused infringer is not relevant to this objective inquiry. "If this threshold objective standard is satisfied, the patentee must also demonstrate that this objectively-defined risk (determined by the record developed in the infringement proceeding) was either known or so obvious that it should have been known to the accused infringer." *Id.*; *see also Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 682 F.3d 1003, 1007 (Fed. Cir. 2012) (en banc) (holding that the threshold objective determination of recklessness is to be decided by the judge as a question of law). "Where an accused infringer relies on a reasonable defense to a charge of infringement, the objective prong tends not to be met." *Powell v. Home Depot U.S.A., Inc.*, 663 F.3d 1221, 1236 (Fed. Cir. 2011) (quotations and citations omitted).

100 Although there is no obligation to obtain an opinion of counsel, if the infringer obtained an opinion of counsel that the patents were either not infringed, invalid, or unenforceable, that can provide "sufficient basis . . . to proceed without engaging in objectively reckless behavior." *Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1339 (Fed. Cir. 2008). The America Invents Act (AIA) provides that the failure of an accused infringer to have obtained the advice of counsel, or to present such advice to the court or jury during litigation, "may not be used to prove that the accused infringer willfully infringed the patent." 35 U.S.C. §298.

(5) FURTHER DEFENSES TO INFRINGEMENT

101 "Defenses to allegations of patent infringement fall into two broad groups: statutory and equitable." *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1331 (Fed. Cir. 2001). The statutory defenses are set forth in 35 U.S.C. §282(b), and include non-infringement, absence of liability for infringement (including license, *see infra* §5.4;, compulsory license, *see infra* §5.5; and exhaustion, *see infra* §5.7), unenforceability, and invalidity. 35 U.S.C. §282(b); *Mylan Pharms.*, 268 F.3d at 1331. "The equitable defenses include [but are not limited to] unclean hands, unenforceability of the patent for fraud and inequitable conduct, misuse, and delay in filing suit resulting in laches or estoppel." *Mylan Pharms.*, 268 F.3d at 1331.

102 The available defenses or exceptions to infringement are reflected in various sections of the Patent Act and in case law. The topics discussed in this section do not represent a complete list of defenses and exceptions to infringement. Notably, some limitations that might be categorized as defenses or exceptions are referenced in other sections. *See*, e.g., *supra* § 4, (regarding non-infringement), *infra* § 8.1 (regarding standing to bring an action), § 8.7.1.2 (regarding motions to dismiss under Federal Rule of Civil Procedure 12), §§ 8.10.6 (regarding limitations on damages).

103 Because the section regarding infringement addresses the issue of non-infringement, the following begins with a discussion of invalidity as a defense to infringement.

(5.1) INVALIDITY

104 Challenges to validity often occur in response to infringement lawsuits, in the form of affirmative defenses or counterclaims. A person under threat of being accused of patent infringement may also, under certain circumstances, bring a declaratory judgment claim for invalidity without first being sued by the patentee. *See MedImmune, Inc., v. Genetech, Inc.*, 549 U.S. 118 (2007); *see infra* §8.1.5, Other Declaratory Judgment Plaintiff.

105 Section 282(a) of the Patent Act provides that each claim in a patent "shall be presumed valid" and that "[t]he burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting invalidity." 35 U.S.C. §282(a). To prevail, a party challenging a patent must prove invalidity "by clear and convincing evidence." *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2242 (2011). Although "new evidence"—that is, evidence that was not considered by the Patent and Trademark Office during prosecution—"may carry more weight in an infringement action than evidence previously considered by the PTO," the nature of the evidence does not affect the standard of proof, which remains clear and convincing evidence. *Id.* at 2251 (quotations and citation omitted).

106 Validity is evaluated on a claim-by-claim basis. For courts, this evaluation is in view of the provision that "[e]ach claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims." *See* 35 U.S.C. §282(a). For the USPTO, evaluation is of each issued claim independently, but with no presumption of validity. A court's final judgment that a patent claim is invalid may prevent the patentee from undertaking further suits against other alleged infringers. *See In re Cygnus Telecommc'ns Tech., LLC, Patent Litig.*, 536 F.3d 1343, 1349 (Fed. Cir. 2008).

(5.1.1) Patentable Subject Matter and Utility

107 A party may challenge the validity of a patent claim on grounds that it is drawn to subject matter that is ineligible for patenting under 35 U.S.C. §101. Section 101 defines eligible subject matter as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. §101. Section 100(b) further explains that "[t]he term 'process' means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material." 35 U.S.C. §100(b). The Supreme Court has held that certain subject matter that falls within the literal scope of §101 is nonetheless ineligible for patenting: "Laws of nature, natural phenomena, and abstract ideas are not patentable." *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354 (2014) (quoting *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116 (2013)).

108 The Supreme Court has described a two-step "framework for distinguishing patents that claim [ineligible subject matter] from those that claim patent-eligible applications of" such subject matter. *Alice Corp.*, 134 S. Ct. at 2355. First, a court must determine, at a high level, "whether the claims at issue are directed to one of" the three categories of ineligible subject matter, i.e., laws of nature, natural phenomena, or abstract ideas. *Id.* Next, the court must "ask, '[w]hat else is there in the claims'" apart from the ineligible matter. *Id.* (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1297 (2012)). "To answer that question, [the court must] consider the elements of each claim both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application" of the ineligible matter. *Id.* (quoting *Prometheus*, 132 S. Ct. at 1297–1298). The Court has "described step two of this analysis as a search for an 'inventive concept'—i.e., an element or combination of elements that is 'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.'" *Id.* (quoting *Prometheus*, 132 S. Ct. at 1294). Although the Supreme Court has stated that the "machine or transformation" test for patent eligibility (which evaluates, for example, whether a claim is tied to a particular machine or transforms a particular article into a different state) is an "important and useful clue" to patentability, that test does not "trump[] the 'law of nature' exclusion." *Id.* (quoting *Prometheus*, 132 S. Ct. at 1303) (quoting *Bilski v. Kappos*, 561 U.S. 593 (2010)).

109 In *Myriad*, the Supreme Court held that isolated segments of naturally occurring DNA are unpatentable "product[s] of nature." *Myriad*, 133 S. Ct. at 2110–2111. In *Prometheus*, the Supreme Court held that claims drawn to the diagnostic use of certain naturally occurring relationships between drug doses and chemicals in the bloodstream were invalid because they claimed laws of nature. *Prometheus*, 132 S. Ct. at 1294. In *Alice Corp.*, the Supreme Court held that claims involving a method for exchanging financial obligations using a computer were unpatentable abstract ideas. *Alice Corp.*, 134 S. Ct. at 2351–2352.

110 Section 101 also contains a utility requirement. In order to be "useful" within the meaning of §101, the subject matter of the patent must have been "operable" at the time of patenting, and not merely a "research proposal" or an "object[] upon which scientific research could be performed with no assurance that anything useful will be discovered in the end." *See In re '318 Patent Infringement Litig.*, 583 F.3d 1317, 1323–1324 (Fed. Cir. 2009) (quotations and citations omitted); *In re Fisher*, 421 F.3d 1365, 1373 (Fed. Cir. 2005). As such, the utility requirement of §101 is closely related to the enablement requirement of 35 U.S.C. §112(a). *See In re '318 Patent Infringement Litig.*, 583 F.3d at 1323–1324.

111 FDA approval of a product is not required in order to satisfy the utility requirement of §101. For example, the USPTO instructs its examiners that "therapeutic utility sufficient under the patent laws is not to be confused with the requirements of the FDA with regard to safety and efficacy of drugs marketed in the United States." *See* MPEP §2107.3(IV) (9th ed. March 2014). Instead, "results from animal tests or in vitro experiments may be sufficient to satisfy the utility requirement." *'318 Patent Infringement Litig.*, 583 F.3d at 1324–1325.

(5.1.2) Disclosure and Enablement

112 A patent is also invalid if it fails to meet the requirements of 35 U.S.C. §112, which sets forth certain standards regarding the required form and substance of a patent's specification and claims. The relevant requirements are informally referred to as the written description, enablement, best mode, and definiteness requirements.

(5.1.3) Written Description

113 Subsection (a) of §112 (previously paragraph 1 of §112) requires that the "specification . . . contain a written description of the invention." 35 U.S.C. §112(a). The written description requirement "is part of the quid pro quo of a patent; one describes an invention, and, if the [Patent Act's] other requirements are met, one obtains a patent." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1345 (Fed. Cir. 2010) (en banc). The description "allows the [USPTO] to examine applications effectively; courts to understand the invention, determine compliance with the statute, and to construe the claims; and the public to understand and improve upon the invention and to avoid the claimed boundaries of the patentee's exclusive rights." *Id.* In practice, "the patent specification [must] set forth enough detail to allow a person of ordinary skill in the art to understand what is claimed and to recognize that the inventor invented what is claimed." *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 928 (Fed. Cir. 2004). This standard must be satisfied by means of "an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art"—a factual, contextual inquiry that takes into account "the nature and scope of the claims and . . . the complexity and predictability of the relevant technology." *Ariad Pharms.*, 598 F.3d at 1351. "[A]n adequate written description requires a precise definition, such as by structure, formula, chemical name, physical properties, or other properties." *GlaxoSmithKline LLC v. Banner Pharmacaps, Inc.*, 744 F.3d 725, 730 (Fed. Cir. 2014) (emphasis omitted). Although "the written description requirement does not demand either examples or an actual reduction to practice," the "specification must demonstrate constructive possession" so that "one of skill in the art can 'visualize or recognize' the claimed [invention] based on the specification's disclosure," rather than "merely recite a description of the problem to be solved while claiming all solutions to it." *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1352 (Fed. Cir. 2011) (quotations and citations omitted).

114 The written description requirement, together with the prohibition in 35 U.S.C. §132(a) on amendments during prosecution that "introduce new matter into the disclosure of the invention," also plays an important role with respect to patent priority. "To obtain the benefit of the filing date of a parent application, the claims of [a] later-filed application must be supported by the written description in the parent in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought." *Anascape, Ltd. v. Nintendo of Am., Inc.*, 601 F.3d 1333, 1335 (Fed. Cir.

2010) (quotations and citations omitted); *see also* 35 U.S.C. §120 ("An application for patent for an invention disclosed in the manner provided by section 112(a) . . . in an application previously filed in the United States [by the same inventor] shall have the same effect, as to such invention, as though filed on the date of the prior application . . . ."); *see also TurboCare Div. of Demag Delaval Turbomachinery Corp. v. Gen. Elec. Co.*, 264 F.3d 1111, 1118 (Fed. Cir. 2001).

(5.1.4) Enablement

115 Section 112(a) also requires that the patent specification describe "the manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the [invention]." 35 U.S.C. §112(a). This so-called enablement requirement is distinct from the requirement, also found in §112(a), that "the specification … contain a written description of the invention." *See Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1340 (Fed. Cir. 2010) (en banc). The enablement requirement is satisfied if "at the time of filing the application one skilled in the art, having read the specification, could [have] practice[d] the invention without undue experimentation." *Cephalon, Inc. v. Watson Pharms., Inc.*, 707 F.3d 1330, 1336 (Fed. Cir. 2013) (quotations and citations omitted). "Whether undue experimentation is required 'is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations,'" including the so-called *Wands* factors:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented [in the specification], (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Id. (citing *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1998)).

116 "[A] reasonable amount of routine experimentation required to practice a claimed invention does not violate the enablement requirement," and even "extensive experimentation does not necessarily render the experiments unduly extensive where the experiments involve repetition of known or commonly used techniques." *Id.* at 1336, 1338.

(5.1.5) Best Mode

117 Section 112(a) further requires that the specification "set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention." 35 U.S.C. §112(a). As of the enactment of the Leahy-Smith America Invents Act in 2011, however, an applicant's failure to disclose the best mode is no longer a defense in a patent infringement suit. *See* 35 U.S.C. §282(b)(3)(A) ("[T]he failure to disclose the best mode shall not be a basis on which any claim of a patent may be canceled or held invalid or otherwise unenforceable.").

(5.1.6) Definiteness

118 As a further disclosure requirement, 35 U.S.C. §112(b) states that a patent specification must "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or joint inventor regards as the invention." Because the claims of a patent define the invention, the Patent Act requires that

the scope of the claims be sufficiently definite to inform the public of the bounds of the protected invention. In this way, the patent claims should give notice to the Patent Examiner and the public at large, including potential competitors, of the scope of patent protection.

119 "[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments*, 134 S. Ct. 2120, 2124 (2014). "Definiteness is to be evaluated from the perspective of someone skilled in the relevant art," and "is measured from the viewpoint of a person skilled in [the] art at the time the patent was filed." *Id.* at 2128 (emphasis omitted).

(5.1.7) Novelty and Anticipation

120 To be patent-eligible, an invention must be "new." 35 U.S.C. §§101, 102. A finding of "anticipation" renders a patent invalid because it means that the subject matter of the invention was previously published, known, used, described or on sale. *See* 35 U.S.C. §102. Anticipation is a question of fact. *Brown v. 3M*, 265 F.3d 1349, 1351 (Fed. Cir. 2001).

121 The Leahy-Smith America Invents Act (AIA) reconfigured the conditions of patentability under 35 U.S.C. §102. Under the previous version of section 102, which applies to patent applications filed before March 16, 2013, specific limitations and bars to patentability were as follows.

122 "A person shall be entitled to a patent unless:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent; or
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than 1 year prior to the date of the application for patent in the United States; or
(c) he has abandoned the invention; or
(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than 12 months before the filing of the application in the United States; or
(e) the invention was described in—(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language; or
(f) he did not himself invent the subject matter sought to be patented; or
(g) (1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in

section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed; or

(2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other."

123 Under the current version of section 102, which applies to patent applications filed after March 15, 2013, specific limitations and bars to patentability are as follows:

(a) A person shall be entitled to a patent unless:

(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or

(2) the claimed invention was described in a patent issued under 35 U.S.C. §151, or in an application for patent published or deemed published under 35 U.S.C. §122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

(b) Exceptions:

(1) Disclosures made 1 year or less before the effective filing date of the claimed invention. A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if:

(i) the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or

(ii) the subject matter disclosed had, before such disclosure, been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.

(2) Disclosures appearing in applications and patents. A disclosure shall not be prior art to a claimed invention under subsection (a)(2) if:

(i) the subject matter disclosed was obtained directly or indirectly from the inventor or a joint inventor;

(ii) the subject matter disclosed had, before such subject matter was effectively filed under subsection (a)(2), been publicly disclosed by the inventor or a joint inventor or another who obtained the subject

matter disclosed directly or indirectly from the inventor or a joint inventor; or

(iii) the subject matter disclosed and the claimed invention, not later than the effective filing date of the claimed invention, were owned by the same person or subject to an obligation of assignment to the same person.

(c) Common ownership under joint research agreements. Subject matter disclosed and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person in applying the provisions of subsection (b)(2)(C) if:

(1) the subject matter disclosed was developed and the claimed invention was made by, or on behalf of, 1 or more parties to a joint research agreement that was in effect on or before the effective filing date of the claimed invention;
(2) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and
(3) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

(d) Patents and published applications effective as prior art. For purposes of determining whether a patent or application for patent is prior art to a claimed invention under subsection (a)(2), such patent or application shall be considered to have been effectively filed, with respect to any subject matter described in the patent or application:

(1) if paragraph (2) does not apply, as of the actual filing date of the patent or the application for patent; or
(2) if the patent or application for patent is entitled to claim a right of priority under 35 U.S.C. §§119, 365(a), or 365(b), or to claim the benefit of an earlier filing date under 35 U.S.C. §§120, 121, or 365(c), based upon 1 or more prior filed applications for patent, as of the filing date of the earliest such application that describes the subject matter.

124 Section 3 of the Leahy-Smith America Invents Act significantly amended §102. Consistent with the AIA's shift from a first-to-invent to a first-to-file system, the current provisions define prior art with respect to the "effective filing date of the claimed invention," instead of the date of invention. *See* Leahy-Smith America Invents Act, Pub. L. 112–129, §3(a), 125 Stat. 284, 285–286 (2011). The Act also removes the geographic limitation previously reflected in §§102(a)–(b) that certain prior art must be in public use, on sale, known, or used by others *in the United States*. *Id.*, 125 Stat. at 285–286. Furthermore, it limited the 1 year grace period of the previous §102(b) to disclosures made by the inventor, a joint inventor, or another who obtained the subject matter directly or indirectly from the inventor or joint inventor. *Id.* These and other changes to §102 went into effect on March 16, 2013. With the AIA's change from a first-to-invent to a first-to-file system, anticipation by prior disclosure of an invention is now measured from the effective date of filing the patent application rather than the date of invention. In addition, an anticipatory public use, sale, or offer for sale, or other public accessibility to the invention more than

1 year before the filing date may now have been anywhere in the world rather than only in the U.S. The AIA also removed the grace period for disclosures made after the date of invention but within 1 year before filing, and replaced it with a 1 year grace period for disclosures by or through an inventor.

125 Anticipation under §102 requires that every element and limitation of the claimed invention be found, either expressly or inherently, in a single prior art reference, arranged as in the claim. *Brown*, 265 F.3d at 1351; *see also King Pharms., Inc. v. Eon Labs., Inc.*, 616 F.3d 1267, 1274 (Fed. Cir. 2010). Anticipatory disclosures must also be enabling. *See Verizon Servs. Corp. v. Cox Fibernet Va., Inc.*, 602 F.3d 1325, 1337 (Fed. Cir. 2010). Inherent anticipation requires that the missing descriptive material is necessarily present, not merely probably or possibly present, in the prior art. *See Trintec Indus. v. Top-U.S.A., Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002).

126-127 The courts have created a large body of case law applying the provisions of 35 U.S.C. §102 to various factual scenarios. Although a meaningful summary of those cases lies beyond the scope of this chapter, at least the "on-sale bar" and "public use" provisions found in §102 warrant some additional explanation. Section 102's "on-sale bar" provision precludes patents for inventions that were ready to be patented and placed on sale more than 1 year before the patentee filed the patent application. *Hamilton Beach Brands, Inc. v. Sunbeam Products, Inc.*, 726 F.3d 1370, 1374–1375 (Fed. Cir. 2013). Section 102's "public use" bar precludes patents for inventions whose use, more than 1 year before the patentee filed the application, was accessible to the public or commercially exploited. *Dey, L.P. v. Sunovion Pharms., Inc.*, 715 F.3d 1351, 1355 (Fed. Cir. 2013).

(5.1.8) Obviousness

128 Until March 16, 2013, 35 U.S.C. §103 provided that an invention cannot be patented if the "subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. §103 (pre-AIA); *P&G v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009) (quotations and citation omitted):

> A party seeking to invalidate a patent based on obviousness must demonstrate by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.

P&G, 566 F.3d at 994 (quotations and citation omitted).

129 As a general matter, "the obviousness determination turns on underlying factual inquiries involving: (1) the scope and content of prior art, (2) differences between claims and prior art, (3) the level of ordinary skill in pertinent art, and (4) secondary considerations such as commercial success and satisfaction of a long-felt need." *Id.* (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)). "Relevant secondary considerations include commercial success, long-felt but unsolved needs, failure of others, and unexpected results." *Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286, 1291 (Fed. Cir. 2013). "[E]vidence rising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of obviousness." *High Point Design LLC v. Buyers Direct, Inc.*, 730 F.3d 1301, 1315 (Fed. Cir. 2013). However, "[e]vidence of commercial success, or other secondary

considerations, is only significant if there is a nexus between the claimed invention and the commercial success." *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311–1312 (Fed. Cir. 2006).

130 In *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418–419 (2007), the Supreme Court addressed the question of obviousness and, in particular, the kind of proof required to show motivation to combine teachings from the prior art. Before the Supreme Court's seminal decision in *KSR*, the Federal Circuit sometimes employed the "teaching, suggestion, or motivation" (TSM) test, under which a patent claim could be proved obvious only if some motivation or suggestion to combine could be found in the prior art, the nature of the problem addressed by the patent claim, or the knowledge of a person of ordinary skill in the Article *Id.* at 406. In *KSR*, the Supreme Court rejected the rigid application of the TSM test and made clear that courts should instead employ an "expansive and flexible" approach to the obviousness inquiry. *Id.* at 415; *see also Wyers v. Master Lock Co.*, 616 F.3d 1231, 1238 (Fed. Cir. 2010). Although it rejected a "rigid" application of the TSM test, the Supreme Court did recognize that the TSM test captures a "helpful insight," *KSR*, 550 U.S. at 418, and the Federal Circuit has since stated that "a flexible TSM test remains the primary guarantor against a non-statutory hindsight analysis." *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008).

131 After *KSR*, in an obviousness analysis, "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions." *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1351–1352 (Fed. Cir. 2008) (quoting *KSR*, 550 U.S. at 417). Obviousness "must be decided in its particular context, including the characteristics of the science or technology, its state of advance, the nature of the known choices, the specificity or generality of the prior art, and the predictability of results in the area of interest." *Id.* at 1352. "[I]n appropriate cases, the ultimate inference as to the existence of a motivation to combine references may boil down to a question of 'common sense.'" *Wyers*, 616 F.3d at 1245 (quotations and citation omitted). The Federal Circuit has held that a claimed invention was not obvious when the prior art "would have directed one of ordinary skill in the art away" from the claimed invention, distinguishing "obvious to try" circumstances in which "'there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions'" and "'the fact that a combination was obvious to try might show that it was obvious under §103.'" *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.* 492 F.3d 1350, 1359 (Fed. Cir. 2007) (quoting *KSR*, 550 U.S. at 421).

132 Section 3 of the Leahy-Smith America Invents Act amended 35 U.S.C. §103 in a number of ways. The most significant change is that §103 now requires, consistent with the AIA's shift from a first-to-invent to a first-to-file system, that the obviousness inquiry be determined with respect to the "effective filing date of the claimed invention," as opposed to the time of invention. AIA, §3(a), 125 Stat. at 288. This and the other changes to §103 went into effect on March 16, 2013.

(5.2) RESEARCH EXEMPTION

(5.2.1) Experimental Use

133 Experimental use may be exempt from patent infringement, but courts have sharply limited the experimental use exception. Only "pure" research use qualifies for this defense.

There is no fair use or research and development exception for a use that is "in any way commercial in nature." *Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002). Rather, the experimental use defense is "limited to actions performed for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." *Id.* (quotation and citation omitted). Once the use of the object rises to the level of commercial use, then the experimental use defense no longer is available to an alleged infringer. *See id.*

(5.2.2) Pharmaceuticals

134 Special provisions exist for the manufacture and distribution of products regulated by the U.S. FDA under the Hatch-Waxman Act, Pub. L. No. 98-417, §§101–106, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. §355), to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§301–399f. The purposes of the Hatch-Waxman Act were to increase the public availability of low cost generic drugs while simultaneously creating incentives for pharmaceutical companies to invest in drug research and development. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358 (Fed. Cir. 2003).

135 Generic drug manufacturers must file an Abbreviated New Drug Application (ANDA), which must demonstrate that the generic drug is the bioequivalent of a pioneer drug, often patented, that is already approved by the FDA. 21 U.S.C. §355(j)(2)(A)(iv). "[A] generic drug manufacturer is allowed to experiment with a patented drug to prove that its planned product is bioequivalent to one already approved" by the FDA. *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1357 n. 6 (Fed. Cir. 2005); *see also infra* §5.3, Bolar Exemption.

136 In order to protect the original patentee drug manufacturer, the generic manufacturer is required to certify that the generic drug will not infringe any valid patent that claims the original, previously approved drug. 21 U.S.C. §355(j)(2)(A)(vii). This certification typically takes the form of a so-called Paragraph IV certification that any such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted. *See* 21 C.F.R. §314.94(a)(12)(i). As the Supreme Court explained, "[f]iling a paragraph IV certification means provoking litigation. The patent statute treats such a filing as itself an act of infringement, which gives the innovator an immediate right to sue. Assuming the innovator does so, the FDA generally may not approve the ANDA until 30 months pass or the court finds the patent invalid or not infringed." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1677–1678 (2012) (citations omitted); *see* 21 U.S.C. §355(j)(5)(B)(iii).

(5.3) BOLAR EXCEPTION

137 The provisions of 35 U.S.C. §271(e)(1) link the Patent Act and the Hatch-Waxman Amendments, which are discussed in section 5.2 above. This section is sometimes referred to as the "Bolar exemption" or "Bolar amendment" because it effectively superseded *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858 (Fed. Cir. 1984), in which the Federal Circuit held that the manufacture, use, or sale of a patented invention during the term of the patent constituted an act of infringement, even if it was for the sole purpose of conducting tests and developing information necessary to apply for regulatory approval. *See id.* at 863. Section §271(e)(1) provides a safe harbor for "uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." *See Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202–203, 208 (2005); *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d

1348, 1357–1359 (Fed. Cir. 2012); *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011). The §271(e)(1) safe harbor also applies to medical devices requiring regulatory approval. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990).

(5.4) LICENSE

138 An express or implied license provides a complete defense to patent infringement assuming the scope of the license is the same as the alleged infringement. *See Met-Coil Sys. Corp. v. Korners Unlimited, Inc.*, 803 F.2d 684, 687 (Fed. Cir. 1986). Express licenses may be exclusive or non-exclusive. Exclusive licensees may grant the right to sublicense the patent. In any event, a patentee cannot recover against its licensees, whether exclusive or non-exclusive, and sub-licensees also obtain a license defense by virtue of the sublicense. An implied license arises where the course of conduct of the parties indicates that a license should be inferred. *See*, e.g., *Anton/Bauer, Inc. v. PAG, Ltd.*, 329 F.3d 1343, 1350 (Fed. Cir. 2003); *Wang Labs., Inc. v. Mitsubishi Elecs. Am., Inc.*, 103 F.3d 1571, 1578–1582 (Fed. Cir. 1997).

(5.5) COMPULSORY LICENSE

139 Compulsory licenses do not per se exist within the United States with respect to patent law. In some cases, courts have not awarded a permanent injunction to a prevailing patentee, citing public policy, and public health interests, including circumstances in which the patentee does not practice the invention and is not in direct competition with the accused infringer. Under these circumstances, the awarding of monetary compensation but not equitable remedies amounts to a de facto compulsory license. *See*, e.g., *Paice LLC v. Toyota Motor Corp.*, 504 F.3d 1293, 1313–1315 (Fed. Cir. 2007); *Foster v. Am. Mach. & Foundry Co.*, 492 F.2d 1317, 1324 (2d Cir. 1974). Under 35 U.S.C. §203, as part of the Bayh-Dole Act (*see supra* §2.7.3, Federally Funded Inventions), the government has reserved "march-in" rights to inventions made with federal funding. This provision gives the "Federal agency under whose funding agreement the subject invention was made" the right to "grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances" if, for example, "action is necessary to alleviate health or safety needs." 35 U.S.C. §203.

(5.6) PRIVATE PRIOR USE

140 For patents that issued before September 16, 2011, 35 U.S.C. §273 provides a defense against infringement for an earlier user of a business method that later falls within the scope of a business method patent. Subject to a number of limitations and qualifications, the defense exists for persons who, acting in good faith, at least 1 year before the effective filing date of such patent, commercially used the subject matter of the patent. Consol. Appropriations Act of 2000, Pub. L. No. 106-113, §4302, 113 Stat. 1501 (1999) (codified as amended at 35 U.S.C. §273 (pre-AIA)).

141 For patents issued on or after September 16, 2011, 35 U.S.C. §273 is available, not only for business methods, but also for subject matter consisting of a process, or consisting of a machine, manufacture, or composition of matter used in a manufacturing or other

commercial process if the alleged infringer's prior commercial use occurred in the United States more than 1 year before the earlier of "the effective filing date of the claimed invention" or the date upon which the prior use was disclosed to the public "in a manner that qualified for the exception from prior art under section 102(b)." *See* 35 U.S.C. §273(a); Leahy-Smith America Invents Act, Pub. L. No. 112-29, §5, 125 Stat. 284, 297–299 (2011). The defense "may be asserted only by the person who performed or directed the performance of the commercial use . . ., or by an entity that controls, is controlled by, or is under common control with such person." 35 U.S.C. §273(e)(1)(A). The defense must be established by clear and convincing evidence, 35 U.S.C. §273(b), and it does not apply to, among other things, (1) infringing activity occurring after the relied upon commercial use has been abandoned, or (2) patents "owned or subject to an obligation of assignment to either an institution of higher education . . . or a technology transfer organization whose primary purpose is to facilitate the commercialization of technologies developed by one or more such institutions of higher education." 35 U.S.C. §273(e)(4)–(5). In addition, it may only be asserted for uses at sites "where the subject matter that would otherwise infringe a claimed invention is in use before the later of the effective filing date of the claimed invention or the date of the assignment or transfer of such enterprise or line of business." 35 U.S.C. §273(e)(1)(C). For additional limitations regarding this defense, *see generally* 35 U.S.C. §273(e).

(5.7) EXHAUSTION

142 Under the first sale doctrine, or exhaustion, "the initial authorized sale of a patented item terminates all patent rights to that item." *Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617, 625 (2008). "The rationale underlying the doctrine rests upon the theory that an unconditional sale of a patented device exhausts the patentee's right to control the purchaser's use of that item thereafter because the patentee has bargained for and received full value for the goods." *Keurig, Inc. v. Sturm Foods, Inc.*, 732 F.3d 1370, 1373 (Fed. Cir. 2013). The doctrine "appl[ies] equally to all authorized transfers of title in property," regardless of whether the transfer is a gift or a sale. *LifeScan Scotland, Ltd. v. Shasta Techs., LLC*, 734 F.3d 1361, 1377 (Fed. Cir. 2013). The doctrine is limited to the particular item sold—it does not permit the recipient of the item to replicate or make new versions of the item. *See Bowman v. Monsanto Co.*, 133 S. Ct. 1761, 1766–1769 (2013).

143 The Supreme Court has held that the exhaustion doctrine extends to sales even when license agreements explicitly exclude the customers of the licensee and exclude the combination of licensed products with non-licensed products. *Quanta Computer*, 553 U.S. at 637. The Supreme Court also clarified that the exhaustion doctrine extends to method claims, *id.* at 628–630, and that sales of products that do not fully practice the invention can still trigger exhaustion when the item "substantially embodies the method . . . (1) has no reasonable noninfringing use and (2) includes all inventive aspects of the claimed method." *Keurig*, 732 F.3d at 1373 (citing *Quanta*, 553 U.S. at 638). Even if such an item has a reasonable non-infringing use, it can still trigger exhaustion if non-infringing uses were "plainly not intended." *LifeScan*, 734 F.3d at 1369. The Federal Circuit has additionally held that exhaustion is not adjudicated on a claim-by-claim basis, but rather focuses on "the exhaustion of the patents at issue in their entirety." *Keurig*, 732 F.3d at 1374. *See also infra* §6.1.2, Enforcement of Exclusive Licenses against Third Parties.

(5.8) FARMER'S PRIVILEGE

144 The Plant Variety Protection Act ("PVPA"), as set forth in 7 U.S.C. §2321 et seq., protects the rights of the breeder of a protected plant variety from certain enumerated infringing acts. The PVPA applies to "[t]he breeder of any sexually reproduced or tuber propagated plant variety (other than fungi or bacteria) who has so reproduced the variety . . . ." 7 U.S.C. §2402(a). Among its exemptions, the PVPA includes a limited exemption for saving seed: a farmer who legally purchases and plants a protected variety may save the seed from these plants for replanting on his or her own farm (but may not save seed for the purpose of selling it to other growers). *See* 7 U.S.C. §2543 ("[I]t shall not infringe any right hereunder for a person to save seed produced by the person from seed obtained, or descended from seed obtained, by authority of the owner of the variety for seeding purposes and use such saved seed in the production of a crop for use on the farm of the person, or for sale as provided in this section."); *Asgrow Seed Co v. Winterboer*, 513 U.S. 179 (1995).

145 Although different in scope, courts have found that the PVPA and the Patent Act are "complementary forms of statutory protection of plant 'breeders' rights.'" *Monsanto Co. v. McFarling*, 302 F.3d 1291, 1299 (Fed. Cir. 2002). Utility patents are available to plants and seeds that meet the (more stringent) requirements of patentability, independent of and in addition to rights under the PVPA. *See J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 141–143 (2001). Notably, the right to save seed of plants registered under the PVPA does not impart the right to save seed of plants patented under the Patent Act. *See id.* at 140 ("The utility patent statute does not contain similar exemptions [as those provided for by the PVPA].").

(5.9) FURTHER EXCEPTIONS TO INFRINGEMENT

(5.9.1) Inequitable Conduct before the Patent Office

146 Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1285 (Fed. Cir. 2011) (en banc). To prevail, the accused infringer must prove that the applicant misrepresented or omitted material information with the specific intent to deceive the U.S. Patent and Trademark Office (USPTO or PTO). The accused infringer must prove both elements—intent and materiality—by clear and convincing evidence. *Id.* at 1287. In conducting this analysis, courts must weigh the evidence of intent to deceive independent of materiality. It should not apply a "sliding scale" approach, "where a weak showing of intent may be found sufficient based on a strong showing of materiality, and vice versa." *Id.* at 1290. "If the accused infringer meets its burden of proving intent and materiality, then the district court must weigh the equities to determine whether the applicant's conduct before the PTO warrants rendering the entire patent unenforceable." *Id.* at 1287.

147 With respect to intent, as stated above, an accused infringer must prove that the patentee acted with the specific intent to deceive the USPTO. A misrepresentation or omission made through gross negligence or negligence—i.e., the patentee "should have known" —does not satisfy the intent requirement. *Id.* at 1290. Rather, clear and convincing evidence must show, for example, that the "applicant *made a deliberate decision* to withhold a *known* material reference." *See id.* (emphasis in original). "In other words, the accused

infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it." *Id.*

148 Direct evidence of deceptive intent is rare; a district court thus may infer intent from indirect and circumstantial evidence. To meet the clear and convincing evidence standard, however, "the specific intent to deceive must be the single most reasonable inference to be drawn from the evidence." *Id.* Intent to deceive cannot be found when multiple reasonable inferences may be drawn. *Id.* at 1290–1291.

149 The materiality required to establish inequitable conduct is generally "but-for" materiality. *Id.* at 1291. Prior art that an applicant fails to disclose is but-for material "if the PTO would not have allowed a claim had it been aware of the undisclosed prior art." *Id.* at 1291. Hence, in evaluating materiality, courts "must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference." *Id.* "In making this patentability determination, the court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction." *Id.* at 1291–1292.

150 The Federal Circuit recognizes an exception to but-for materiality in cases of "affirmative egregious misconduct." *Id.* at 1292. "When the patentee has engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit," the misconduct satisfies the materiality prong of inequitable conduct. *Id.* Neither mere nondisclosure of prior art references to the USPTO nor failure to mention prior art references in an affidavit constitutes affirmative egregious misconduct; claims of inequitable conduct that are based on such omissions require proof of but-for materiality. *Id.* at 1292–1293.

151 As a general rule, the doctrine of inequitable conduct should only be applied in instances where "the patentee's misconduct resulted in the unfair benefit of receiving an unwarranted claim." *Id.* at 1292. The Federal Circuit has noted that enforcement of an otherwise valid patent does not otherwise injure the public merely because of misconduct that was immaterial to the patent's issuance. *Id.*

(5.9.2) Unclean Hands

152 The doctrine of unclean hands is an equitable defense to a charge of patent infringement, under the familiar equitable maxim, "he who comes into equity must come with clean hands." The doctrine is rooted in the historical concept of a court of equity as a vehicle for affirmatively enforcing the requirements of conscience and good faith. As the Supreme Court has recognized, the doors of a court of equity should be closed to a litigant who is "tainted with inequitableness or bad faith relative to the matter in which he seeks relief, however improper may have been the behavior of the defendant." *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945). Although litigants need not have led "blameless lives," the doctrine of unclean hand does require that litigant seeking the aid of a court of equity "shall have acted fairly and without fraud or deceit as to the controversy in issue." *Id.* at 814–815.

153 The doctrine of unclean hands gives the equity court discretion in refusing to aid the unclean litigant. The trial court has broad discretion under the doctrine, and it is "not bound by formula or restrained by any limitation that tends to trammel the free and just exercise of discretion." *Id.* (quotations and citation omitted). For example, misconduct during the prosecution of one patent application may give rise to a finding of unclean hands as to other, related patent applications when the misconduct had an "immediate and necessary relation" to the equity being sought. *Consol. Aluminum Corp. v. Foseco Int'l, Ltd.*, 910

F.2d 804, 809–812 (Fed. Cir. 1990) (discussing *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933) and *Precision Instrument Mfg. Co.*, 324 U.S. 806 (1945)). As another example of the application of this doctrine, litigation misconduct may also result in a finding of unclean hands and dismissal of the underlying complaint. *See Aptix Corp. v. Quickturn Design Sys.*, 269 F.3d 1369, 1374–1375 (Fed. Cir. 2001). The doctrine may also preclude application of a defense, if the defendant is shown to be "guilty of misdeeds towards the [plaintiff]." *Pei-Herng Hor v. Ching-Wu Chu*, 699 F.3d 1331, 1337 (Fed. Cir. 2012) (quotations and citations omitted) (holding that a laches defense would not apply if plaintiff could "show not only that the defendant engaged in misconduct, but moreover that the defendant's misconduct was responsible for the plaintiff's delay in bringing suit" (quotations and citations omitted)).

(5.9.3) Laches and Equitable Estoppel

154 Laches is an equitable defense to patent infringement. It is "the neglect or delay in bringing suit to remedy an alleged wrong, which taken together with lapse of time and other circumstances, causes prejudice to the adverse party and operates as an equitable bar." *A. C. Aukerman Co. v. R. L. Chaides Constr. Co.*, 960 F.2d 1020, 1028–1029 (Fed. Cir. 1992) (en banc). The alleged infringer must show (1) that the patentee's delay in bringing suit was "for unreasonable and inexcusable length of time from the time the [patentee] knew or reasonably should have known of its claim against [the alleged infringer]", and (2) the alleged infringer suffered material prejudice or injury attributable to the delay. *Id.* at 1032. A presumption of laches arises where a patentee delays bringing suit for more than 6 years after the date the patentee knew or should have known of the alleged infringer's activity. *Id.* at 1035–1036. Once a presumption of laches arises, the patentee may offer proof directed to rebutting the laches factors. *Id.* at 1038.

155 A defense of equitable estoppel is sometimes raised with a defense of laches. To establish equitable estoppel, an accused infringer must prove that (1) the patentee, who usually must have knowledge of the true facts, communicates something in a misleading way, either by words, conduct or silence; (2) the other relies upon that communication; and (3) due to its reliance, the other would be harmed materially if the actor is later permitted to assert any claim inconsistent with his earlier conduct. *Aspex Eyewear, Inc. v. Clariti Eyewear, Inc.*, 605 F.3d 1305, 1310 (Fed. Cir. 2010). Unlike laches, no presumption adheres to an equitable estoppel defense. Despite a six-year delay in suit being filed, a defendant must prove each of the factual elements of estoppel on which the discretionary power of the court rests.

156 While the two defenses are similar, "reliance[] is not a requirement of laches but is essential to equitable estoppel." *Aukerman*, 960 F.2d at 1042. "To show reliance, the infringer must have had a relationship or communication with the plaintiff which lulls the infringer into a sense of security in going ahead with" his or her activity. *Id.* at 1043.

(5.9.4) Prosecution Laches

157 Prosecution laches is another equitable defense to patent infringement. The doctrine "may render a patent unenforceable when it has issued only after an unreasonable and unexplained delay in prosecution." *Symbol Techs., Inc. v. Lemelson Med. Educ. & Research Found., LP*, 422 F.3d 1378, 1385 (Fed. Cir. 2005). The requirement of an unreasonable and unexplained delay "includes a finding of prejudice, as does any laches defense." *Cancer Research Tech. Ltd. v. Barr Labs., Inc.*, 625 F.3d 724, 729 (Fed. Cir. 2010). Thus, to prevail on

a prosecution laches defense, 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." *Id.*

158 In addition, because there may be legitimate grounds for refiling a patent application, the Federal Circuit has recognized that "the doctrine should be used sparingly lest statutory provisions be unjustifiably vitiated." *Symbol Techs., Inc.*, 422 F.3d at 1385. The doctrine of prosecution laches does not stem from procedural lapses or irregularity during patent prosecution. *See Aristocrat Techs. Austl. Pty Ltd. v. Int'l Game Tech.*, 543 F.3d 657, 663 n. 4 (Fed. Cir. 2008). Instead, prosecution laches should be applied "only in egregious cases of misuse of the statutory patent system." *Symbol Techs., Inc.*, 422 F.3d at 1385 ("refiling an application solely containing previously-allowed claims for the business purpose of delaying their issuance can be considered an abuse of the patent system.").

(5.9.5) Patent Misuse

159 Patent misuse is an equitable defense to patent infringement that arises when the patentee has imposed on licensees a condition that "impermissibly broaden[s] the physical or temporal scope of the patent grant [with] anticompetitive effects." *Princo Corp. v. ITC*, 616 F.3d 1318, 1328 (Fed. Cir. 2010) (en banc). The defense arises in equity, and a holding of misuse "may render a patent unenforceable until the misconduct can be purged," but "it does not render the patent unenforceable for all time." *Qualcomm Inc. v. Broadcom Corp.*, 548 F.3d 1004, 1025 (Fed. Cir. 2008). "The doctrine of patent misuse is … grounded in the policy-based desire to prevent a patentee from using the patent to obtain market benefit beyond that which inheres in the statutory patent right." *Princo Corp.*, 616 F.3d at 1328 (quotations and citation omitted).

160 The courts have identified certain specific practices as typical examples of patent misuse, including so-called tying arrangements in which a patentee conditions a license for the use of a patent on the purchase of a separate, unpatented product. *See id.* at 1326–1328, 1333. Recently, however, the Federal Circuit has observed that because "the patent grant entitles the patentee to impose a broad range of conditions in licensing the right to practice the patent, the doctrine of patent misuse has largely been confined to a handful of specific practices," and "is not available to a presumptive infringer simply because a patentee engages in some kind of wrongful commercial conduct, even conduct that may have anticompetitive effects." *Id.* at 1329 (quotations and citations omitted). In its en banc decision in *Princo Corp.*, the Federal Circuit articulated two basic requirements for a patent misuse defense: the patent owner must have "leverage[d] the power of [the] patent to exact concessions from a licensee that are not fairly within the ambit of the patent right," and the owner's actions must have "had anticompetitive effects." *Id.* at 1333–1334.

161 In 1988, Congress amended 35 U.S.C. §271(d) to provide that a tying arrangement does not constitute patent misuse if there is no market power. Under 35 U.S.C. §271(d)(5), even a patentee who has "conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product" has not committed patent misuse "unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned." 35 U.S.C. §271(d)(5). Section 271(d) also provides a list of specific practices that may not support a finding of patent misuse, including "deriv[ing] revenue from acts which if performed by another without [the patent owner's] consent would constitute contributory infringement of the patent," and "refus[ing] to license or use any rights to the patent." *See* 35 U.S.C. §271(d).

(5.9.6) Intervening Rights

162 Intervening rights may arise in the context of patents that are reissued or reexamined. In the case of a reissued patent, the existence and scope of intervening rights are governed by 35 U.S.C. §252. If "the claims of the original and reissued patents are substantially identical," the reissued patent "constitute[s] a continuation" of the original patent, and no intervening rights arise. *Id.* If the claims are not "substantially identical," however, §252 "provides for two separate and distinct defenses to patent infringement under the doctrine of intervening rights: 'absolute' intervening rights and 'equitable' intervening rights." *Shockley v. Arcan, Inc.*, 248 F.3d 1349, 1359 (Fed. Cir. 2001).

163 The first sentence of the second paragraph of 35 U.S.C. §252 defines absolute intervening rights:

> A reissued patent shall not abridge or affect the right of any person or that person's successors in business who, prior to the grant of a reissue, made, purchased, offered to sell, or used within the United States, or imported into the United States, anything patented by the reissued patent, to continue the use of, to offer to sell, or to sell to others to be used, offered for sale, or sold, the specific thing so made, purchased, offered for sale, used, or imported unless the making, using, offering for sale, or selling of such thing infringes a valid claim of the reissued patent which was in the original patent.

35 U.S.C. §252; *Shockley*, 248 F.3d at 1359.

164 "The statute uses the term 'the specific thing' to refer to the tangible article which qualifies for absolute intervening rights. This 'specific thing' terminology suggests that the tangible article was in existence before the reissue date." *Shockley*, 248 F.3d at 1360. Therefore, even if an "offer[] to sell" certain items was made before the reissue date, the offeror does not enjoy absolute intervening rights to consummate the sale unless the items themselves were manufactured before the reissue date. *Id.*

165 The second sentence of the paragraph, by contrast, defines equitable intervening rights:

> The court before which such matter is in question may provide for the continued manufacture, use, offer for sale, or sale of the thing made, purchased, offered for sale, used, or imported as specified, or for the manufacture, use, offer for sale, or sale in the United States of which substantial preparation was made before the grant of the reissue, and the court may also provide for the continued practice of any process patented by the reissue that is practiced, or for the practice of which substantial preparation was made, before the grant of the reissue, to the extent and under such terms as the court deems equitable for the protection of investments made or business commenced before the grant of the reissue.

35 U.S.C. §252.

166 Equitable intervening rights, by contrast to absolute intervening rights, "explicitly extend protections for continued manufacture, thus extending protection to articles not yet in existence at the time of the reissue." *Shockley*, 248 F.3d at 1360. "Under the equitable intervening rights [doctrine], a district court has discretion to grant broader rights for an accused infringer to: (1) continue the manufacture, use, offer for sale, and sale of additional articles made before the reissue; and (2) continue to manufacture, use, offer to sell, or sell articles for which substantial preparations for manufacture or use was made before the

grant of the reissue". *Id.* at 1361. Because equitable intervening rights are, as their name implies, an equitable defense, an accused infringer may be denied these rights on grounds of "unclean hands." *Id.*

167 Intervening rights for a reexamined patent are treated the same way as they are for a reissued patent. *See Predicate Logic, Inc. v. Distributive Software, Inc.*, 544 F.3d 1298, 1304 (Fed. Cir. 2008) ("[A] claim that is amended in reexamination has the same effect as a claim that is amended in reissue proceedings under 35 U.S.C. §252."). Pursuant to 35 U.S.C. §307(b):

> Any proposed amended or new claim determined to be patentable and incorporated into a patent following a reexamination proceeding will have the same effect as that specified in section 252 for reissued patents on the right of any person who made, purchased, or used within the United States, or imported into the United States, anything patented by such proposed amended or new claim, or who made substantial preparation for the same, prior to issuance of a certificate [of reexamination].

35 U.S.C. §307(b).

168 "[U]nder §307(b), the first question when assessing whether intervening rights arose from a reexamination is whether the asserted claim is 'amended or new'; if the answer is no, that ends the inquiry." *Marine Polymer Techs., Inc. v. HemCon, Inc.*, 672 F.3d 1350, 1363 (Fed. Cir. 2012) (en banc). "Only if the claim at issue is new or has been amended may the court proceed to the second step in the analysis and assess the substantive effect of any such change pursuant to §252." *Id.* (holding that arguments made to a patent examiner during reexamination, even if they affect the claims' effective scope, do not "amend" those claims for intervening rights purposes or make them "new" as required for intervening rights under §307(b)).

(6) LICENSING

(6.1) VOLUNTARY LICENSES

169 A valid U.S. patent provides the patentee, patent owner, or assignee "the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States[,] or importing the invention into the United States." 35 U.S.C. §154(a)(1); 35 U.S.C. §271(a). A patentee, patent owner, or assignee may grant an exclusive or non-exclusive license to all or part of their rights to practice the patented invention. *McCoy v. Mitsuboshi Cutlery, Inc.*, 67 F.3d 917, 920 (Fed. Cir. 1995). A patent license is a contract that may be express or implied, and that is governed by contract law—typically, state law. *Id.* A U.S. patent license may be limited by territory, field of use, or other limitations as agreed to by the licensee and licensor.

170 A licensor may not grant a licensee patent rights beyond the scope of its own rights. For example, a license for U.S. patent rights cannot give or limit patent rights outside of the United States, or license an invalid or expired patent. Moreover, the doctrine of patent misuse limits a licensor's ability to impose certain conditions on a licensee, such as forcing a licensee to purchase additional, non-patented goods as a condition of the patent license agreement. *See Princo Corp. v. ITC*, 616 F.3d 1318, 1328 (Fed. Cir. 2010) (en banc); *supra* §5.9(v), Further Exceptions to Infringement (Patent Misuse).

171 Licensees typically exchange ongoing royalty-based payments and/or an upfront lump sum for the right to make, use, or sell the patented invention within the United States. A licensee may also negotiate for the right to sublicense the patented invention to others. Cross-licensing provisions are also common.

(6.1.1) Exclusive Licenses

172 An exclusive patent license guarantees, at a minimum, that the licensor will not grant licenses to third parties for the same subject matter as the exclusive licensee. Unless reserved by the language of the license, an exclusive patent license may prevent the licensor from practicing the claimed invention within the scope of the license granted to the licensee. *See,* e.g., *U.S. Valves, Inc. v. Dray*, 212 F.3d 1368, 1372 (Fed. Cir. 2000) ("The license agreement between Dray and U.S. Valves gives U.S. Valves 'an exclusive right to manufacture, use, sell, advertise, and distribute the Licensed Product.' To show that Dray sold valves in contravention of U.S. Valves' exclusive rights to such sales, U.S. Valves must show that Dray sold valves that were covered by the licensed patents.").

(6.1.2) Enforcement of Licenses against Third Parties

173 If a license agreement transfers "all substantial rights" to the licensee, the licensee has standing to bring suit against third parties for infringement in its own name. *See Propat Int'l Corp. v. RPost, Inc.* 473 F.3d 1187, 1189 (Fed. Cir. 2007). Courts have determined that by possessing "all substantial rights" the licensee has a sufficient "case or controversy" with the accused infringer to meet the threshold standing requirement of Article III of the U.S. Constitution. *See Ortho Pharm. Corp v. Genetics Inst., Inc.*, 52 F.3d 1026, 1030–1033 (Fed. Cir. 1995).

174 If, however, the licensor patentee has retained substantial rights, only the licensor patentee has standing to bring suit in its own name. *Prima Tek II, L.L.C. v. A-Roo Co.*, 222 F.3d 1372, 1378 (Fed. Cir. 2000). Whether the licensor patentee retained sufficient rights to prevent a licensee from having standing, or intended to do so, is a fact-specific question. *See,* e.g., *Aspex Eyewear, Inc. v. Miracle Optics, Inc.* 434 F.3d 1336, 1340 (Fed. Cir. 2006); *Mentor H/S, Inc. v. Medical Device Alliance, Inc.*, 240 F.3d 1016 (Fed. Cir. 2001). For example, if the licensor retains rights to use the patented invention, or control over how the licensee uses the patented invention, the licensor has not conveyed "all substantial rights." *See Mentor H/S, Inc.*, 240 F.3d at 1018. Importantly, to have standing to bring suit in his own name, the licensee must have the right to exclude others. *Id.* In addition, an exclusive license conveying rights sufficient to give the licensee standing to sue in its own name must be in writing. *See Enzo APA & Son v. Geapag A.G.*, 134 F.3d 1090, 1093 (Fed. Cir. 1998).

175 An exclusive licensee without "all substantial rights" can, however, bring an infringement suit against a third-party for monetary damages or injunctive relief by joining the patentee as a party plaintiff. *See* Fed. R. Civ. P. 19; *see also* 35 U.S.C.§§154, 271 (a) & (g); 281. By joining the patentee, the licensee cures its lack of standing. *Prima Tek II*, 222 F.3d at 1381. A non-exclusive licensee has no standing to bring a lawsuit against an accused infringer in its own name, and has no right to join a suit of the patentee or compel joinder of the patentee. *See Ortho Pharm.*, 52 F.3d at 1031.

(6.1.3) Licensee Challenge to the Validity of the Licensed Patent

176 Long-standing precedent holds that a licensee may challenge the validity of a licensed patent by ceasing royalty payments and bringing a declaratory judgment action challenging the validity of the patent. *See Lear, Inc. v. Adkins*, 395 U.S. 653, 674 (1969). A licensee may also challenge the validity of a licensed patent by stopping royalty payments and defending against a licensor's infringement suit with an invalidity defense. *See id.* More recent case law also allows a licensee to bring a declaratory judgment action for invalidity or unenforceability without repudiating the license contract. *See Medimmune, Inc. v. Genentech Inc.,* 549 U.S. 118 (2007). Under *Medimmune*, a licensee bears less risk in challenging the licensed patent because it can still enjoy the benefits of the license during the pendency of the invalidity action.

(6.1.4) Non-exclusive Licenses

177 A non-exclusive, or bare, license typically gives the licensee only the right to make, use, sell, offer for sale, or import a patented invention in the United States. A bare licensee does not have the right to exclude others and the licensor may grant non-exclusive licenses to other third parties. A non-exclusive license amounts to an agreement between the licensor and the licensee that the licensor will not sue the licensee for making, using, offering for sale, selling, or importing the patented invention in the United States. *See Ortho Pharm. Corp v. Genetics Inst., Inc.*, 52 F.3d 1026, 1031 (Fed. Cir. 1995).

(6.1.5) Implied Licenses

178 Under certain circumstances, a non-exclusive license to a patent may be implied. When the parties fail to spell out in writing all of the rights that were understood or intended to be included as indicated by the overall tenor of an agreement, a court may

augment the license agreement with an implied license. *See Endo Pharms. Inc. v. Actavis, Inc.*, 746 F.3d 1371, 1376–1378 (Fed. Cir. 2014). The two main types of implied licenses are licenses implied by estoppel and licenses implied by law; the former is comparable to contracts formed by promissory estoppel, whereas the latter are comparable to "quasi-contracts." An implied license, therefore, arises out of the conduct of parties from which a reasonable person would understand that an agreement had been reached. Accordingly, the conduct of the parties, applicable provisions of any existing written agreement between the parties, the expectations of the parties, and equity considerations all bear on whether an implied license was formed. For example, absent specific reservations to the contrary, the sale of a patented device usually includes with it an implied license to use the device even though its use would infringe. Implied license issues also may arise in situations where an inventor is employed and invents something in the course of work duties or when an inventor uses an employer's shop (or other assets) to create an invention, each of which may result in the employer having an implied license as to the invention. *See supra* §2.4, Employee.

179 Implied licenses may also arise out of the sale of components used to construct a patented device whereby the act of combining the components would infringe the patent on the device. If the components have no non-infringing use, were the subject of an unrestricted sale, and the sale was made under the express or implied authority of the patent owner, a court may find an implied license. *See Carborundum Co. v. Molten Metal Equip. Innovations, Inc.*, 72 F.3d 872, 878 (Fed. Cir. 1995); *see also LG Elecs., Inc. v. Bizcom Elecs., Inc.*, 453 F.3d 1364, 1368 (Fed. Cir. 2006), *rev'd on other grounds*, *Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617 (2008).

(6.1.6) Licensing by Patent Co-owners

180 When a patent is co-owned, any of the co-owners may make, use, import, offer to sell, or sell the patented invention without the consent or an accounting to the other patent owners. 35 U.S.C. §262. A co-owner may also grant non-exclusive licenses to the patent without the consent or knowledge of the other co-owner(s). *Id.* A co-owner may only grant a prospective license, however, and cannot unilaterally release a potential licensee from past infringement. *See Schering Corp. v. Roussel-UCLAF S.A.*, 104 F.3d 341, 345 (Fed. Cir. 1997).

(6.1.7) Recordation of a License

181 A patent license, either exclusive or non-exclusive, does not need to be recorded with the USPTO. *See* 35 U.S.C. §261. The grant of a license, however, may be recorded with the USPTO should a licensee wish to declare his or her rights. *See* 37 C.F.R §3.11(a).

(6.2) COMPULSORY LICENSES

182 Compulsory licenses do not per se exist within the United States. In some cases, courts have not awarded a permanent injunction to a prevailing patentee, citing public policy, and public health interests, including limited circumstances in which the patentee does not practice the invention and is not in direct competition with the accused infringer. Under these circumstances, the awarding of monetary compensation but not equitable remedies amounts to a de facto compulsory license. *See*, e.g., *Paice LLC v. Toyota Motor Corp.*,

504 F.3d 1293 (Fed. Cir. 2007); *Foster v. Am. Machine & Foundry Co.*, 492 F.2d 1317 (2d Cir. 1974); *Vitamin Technologists, Inc. v. Wis. Alumni Research Found.*, 146 F.2d 941 (9th Cir. 1944).

183 Under 35 U.S.C. §203, as part of the Bayh-Dole Act (*see supra* §2.7.3, Federally Funded Inventions), the government has reserved "march-in" rights to inventions made with federal funding. This provision gives the "Federal agency under whose funding agreement the subject invention was made" the right to "grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances" if, for example, "action is necessary to alleviate health or safety needs." 35 U.S.C. §203.

(7) PATENTS AS PART OF ASSETS

(7.1) ASSIGNMENT

184 A patentee may convey legal title of the entire patent, an undivided interest in the patent or share of the entire patent, or all rights under the patent in a specified geographic region. *Rite-Hite Corp. v. Kelley Co., Inc.*, 56 F.3d 1538, 1551 (Fed. Cir. 1995) (en banc). Transferring these rights constitutes an assignment and subsequently vests the assignee with title in the patent, and a right to sue infringers. *Id.*

185 Patents, patent applications, or any interests therein, are assignable by an instrument in writing. 35 U.S.C. §261. The writing must be executed by the patentee or by the patentee's assigns or legal representatives. *See United States v. Solomon*, 825 F.2d 1292, 1296 (9th Cir. 1987); *Gaia Techs., Inc. v. Reconversion Techs., Inc.*, 93 F.3d 774, 777 (Fed. Cir. 1996).

186 Although transfer of patent ownership through an assignment must be in writing, ownership of a patent can also be changed by operation of law. *Akazawa v. Link New Tech. Int'l, Inc.*, 520 F.3d 1354 (Fed. Cir. 2008).

(7.2) CO-OWNERSHIP

187 According to 35 U.S.C. §262, two or more persons may own an undivided percent of a patent. *See supra* §2.1, Inventor/Applicant; §8.1.2, Co-owner. "All co-owners must consent [in order] to join as plaintiffs in an infringement suit." *Ethicon, Inc. v. United States Surgical Corp.*, 135 F.3d 1456, 1468 (Fed. Cir. 1998). If by agreement, a co-owner waives his right to refuse to join a suit, his co-owners may subsequently force him to join in a suit. *Schering Corp. v. Roussel-UCLAF SA*, 104 F.3d 341, 345 (Fed. Cir. 1997).

(7.3) SURRENDER

188 In circumstances where a patent is issued with a mistake, but without any deceptive intent on the part of the applicant, one way a mistake can be corrected is to apply for reissuance of the patent to correct the mistake in the original patent application. 35 U.S.C. §251. To be eligible for reissue, the patent must be "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 he had a right to claim in the patent." *Id.* The act of applying for reissuance is considered an offer to surrender the patent that was the subject of the original application. 37 C.F.R. §1.178. The surrender is effective once the reissue application is granted; the original patent remains in effect until the reissue application is granted. *Id.*

(7.4) SECURITY RIGHTS

189 The Uniform Commercial Code (UCC), which has been adopted as state law in most states, governs the creation and treatment of security interests. "A security interest attaches to collateral when it becomes enforceable against the debtor with respect to the collateral,

unless an agreement expressly postpones the time of attachment." U.C.C. §9-203. A security interest in a patent is "enforceable against the debtor . . . only if: (1) value has been given; (2) the debtor has rights in the collateral or the power to transfer rights in the collateral to a secured party; and (3) . . . the debtor has authenticated a security agreement that provides a description of the collateral." *Id.*

190 After it is created, the security interest can be perfected. A perfected security interest gives a party priority in bankruptcy proceedings against subsequent lien holders. *In re Cybernetic Servs., Inc.*, 239 B.R. 917, 923 (B.A.P. 9th Cir. 1999). To "perfect" a security interest, the secured party must—under certain circumstances—provide public notice of the existence of such an interest by filing a lien notice or financing statement with the applicable local, state, or federal agency. U.C.C. §9-310.

191 A common practice to perfect security interests in a patent is to file a transfer of title with the USPTO. *Waterman v. McKenzie*, 138 U.S. 252 (1891). While filing with the USPTO is commonplace, it is not required in order to properly perfect; rather, one can separately utilize the public notice procedures under the U.C.C. state contract law governing perfection and priority of a security interest. *See*, e.g., *Cybernetic Servs.*, 239 B.R. at 923 (finding a security interest in a patent perfected by filing a UCC-1 Financing Statement with the California Secretary of State). However, to avoid any doubt, the fail safe approach for perfection is to do two filings: one under the U.C.C. procedures and one at the USPTO.

(7.5) ATTACHMENT

192 A patent can be attached as security for a claim. *Cybernetic Servs.*, 239 B.R. at 918.

(8) PATENT LITIGATION

(8.1) PLAINTIFF

(8.1.1) Owner

193 Section 281 of Title 35 authorizes a "patentee" to bring a civil action for patent infringement. 35 U.S.C. §281. Depending upon who holds legal title to the patent, the word "patentee" may mean the person to whom the patent was issued or the valid successor in title to the patent. 35 U.S.C. §100(d).

194 Patent owners may assign or transfer their ownership interests in a patent as personal property. *Isr. Bio-Eng'g Project v. Amgen Inc.*, 475 F.3d 1256, 1264 (Fed. Cir. 2007). A patentee may convey legal title of the "entire patent, an undivided part or share of the entire patent, or all rights under the patent in a specified geographical region of the United States." *Rite-Hite Corp. v. Kelley Co., Inc.*, 56 F.3d 1538, 1551 (Fed. Cir. 1995) (en banc). Transferring these rights constitutes an assignment (rather than a license) and subsequently "vests the assignee with title in the patent, and a right to sue infringers." *Id.* Transferring "less than one of these three interests is a license, not an assignment of legal title, and it gives the licensee no right to sue for infringement at law in the licensee's own name." *Id.* at 1552. A patent owner who conveys all interests in the patent relinquishes standing to sue for infringement. *See Beam Laser Sys., Inc. v. Cox Communs., Inc.*, 117 F. Supp. 2d 515, 520 (E.D. Va. 2000). Infringements that occurred prior to conveyance may still be actionable if the right to sue for past infringement is not conveyed.

(8.1.2) Co-owner

195 The general rule is that all co-owners of a patent must join as plaintiffs to a patent infringement action. *See Ethicon, Inc. v. United States Surgical Corp.*, 135 F.3d 1456, 1467 (Fed. Cir. 1998). Moreover, one co-owner cannot normally force another co-owner to join in an infringement action. *Id.* at 1468; *see also*, *Isr. Bio-Eng'g Project*, 475 F.3d at 1264 (stating that a "co-owner has the right to limit the other co-owner's ability to sue infringers by refusing to join voluntarily in the patent infringement suit"). This is consistent with 35 U.S.C. §262, which permits joint owners to, in the absence of an agreement to the contrary, make full use of the invention "without the consent of and without accounting to the other owners."

(8.1.3) Exclusive Licensee

196 An exclusive licensee that holds "all substantial rights" in a patent has standing to sue for infringement of the patent. *See Mentor H/S, Inc. v. Med. Device Alliance, Inc.*, 240 F.3d 1016, 1017–1018 (Fed. Cir. 2001). An exclusive licensee that does not have all substantial rights in a patent has standing "to sue third parties only as a co-plaintiff with the patentee." *Id.* at 1017 (quotations and citation omitted); *Abbott Labs. v. Diamedix Corp.* 47 F.3d 1128, 1131 (Fed. Cir. 1995); *Weinar v. Rollform Inc.*, 744 F.2d 797, 806–807 (Fed. Cir. 1984). An exclusive license, for standing purposes, includes the right to practice the invention within a given territory and the patentee's express or implied promise that others shall be excluded from practicing the invention within that territory as well. *See Independent Wireless Tel. Co. v. Radio Corp. Am.*, 269 U.S. 459, 468–469 (1926); *Rite-Hite Corp. v. Kelley Co., Inc.*, 56

F.3d 1538, 1552 (Fed. Cir. 1995) ("To be an exclusive licensee for standing purposes, a party must have received, not only the right to practice the invention within a given territory, but also the patentee's express or implied promise that others shall be excluded from practicing the invention within that territory as well.").

(8.1.4) Non-exclusive Licensee

197 Some licenses, on the other hand, "may amount to no more than a covenant by the patentee not to sue the licensee for making, using or selling the patented invention, [wherein] the patentee reserve[s] the right to grant other licensees the same right." *Ortho Pharm.*, 52 F.3d at 1031. Such a non-exclusive licensee has no standing to bring suit or even join in a suit brought by the patentee, because she suffers no legal injury from infringement. *Id.*; *see also Morrow v. Microsoft Corp.*, 499 F.3d 1332, 1339 (Fed. Cir. 2007); *Rite-Hite Corp.*, 56 F.3d at 1552.

(8.1.5) Declaratory Judgment Plaintiff

198 The Declaratory Judgment Act, 28 U.S.C. §2201, et seq., permits a party to, under certain circumstances, bring suit to obtain a ruling regarding patent non-infringement, invalidity, and/or unenforceability against a patent holder. In determining whether such a suit is permitted, the critical question is whether the case presents a "case or controversy" under Article III of the U.S. Constitution.

199 Defendants in patent infringement cases may, and commonly do, bring counterclaims against the patentee for declaratory judgment of non-infringement, invalidity, and unenforceability. More generally, though, there is no bright-line rule for determining whether a situation satisfies the case or controversy requirement of Article III. *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1336 (Fed. Cir. 2008) (citing *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 126 (2007)). The proper analysis "must be calibrated to the particular facts of each case, with the basic standard being whether the facts alleged . . . show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Id.* (quotations and citations omitted).

200 Before *MedImmune*, the Federal Circuit generally required that a declaratory judgment plaintiff in a patent dispute show: "(1) conduct by the patentee that created a 'reasonable apprehension' of suit on the part of the declaratory judgment plaintiff and (2) present activity by the declaratory judgment plaintiff that could constitute infringement or 'meaningful preparation' to conduct potentially infringing activity." *Id.* In *MedImmune*, however, "the Supreme Court rejected the reasonable apprehension of suit test as the sole test for jurisdiction." *Id.* The reasonable apprehension test is now regarded as "one the multiple ways that a declaratory judgment plaintiff can satisfy the more general totality of the circumstances test." *Id.*

201 Where no licensor-licensee relationship exists between parties, declaratory judgment jurisdiction does not generally arise "without some affirmative act by the patentee," even where a party is aware of a patent and perceives a potential risk of infringement. *SanDisk Corp. v. STMicroelecs., Inc.*, 480 F.3d 1372, 1380–1381 (Fed. Cir. 2007). But jurisdiction may arise "where the patentee takes a position that puts the declaratory judgment plaintiff in the position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do." *Id.*

202 Where a potential infringer is already under a license, the Supreme Court has held that Article III does not require a licensee to break or terminate its license agreement before seeking a declaratory judgment in federal court. *MedImmune*, 549 U.S. at 137; *see also Cummins, Inc. v. TAS Distrib. Co., Inc.*, 700 F.3d 1329, 1336 (Fed. Cir. 2012) ("[A] licensee's failure to cease its payment of royalties d[oes] not render nonjusticiable a dispute over the validity of the patent." (quoting *MedImmune*, 549 U.S. at 130)); *Powertech Tech. Inc. v. Tessera, Inc.*, 660 F.3d 1301, 1308 (Fed. Cir. 2011) (holding that a licensee "need not repudiate its license agreement" in order to "define its rights and obligations under its contract," where there is "no provision in the license agreement in which [the licensee] has agreed not to argue non-infringement or invalidity" (citing *MedImmune*, 549 U.S. at 135)).

(8.2) LIMITATIONS PERIOD

203 There is no applicable statute of limitations per se under the Patent Act. *See A.C. Aukerman Co. v. R.L. Chaides Const. Co.*, 960 F.2d 1020, 1032 (Fed. Cir. 1992) (en banc) ("there is no statute from which to determine the timeliness of an infringement action" (citation omitted)). Nevertheless, "no recovery shall be had for any infringement committed more than 6 years prior to the filing of the complaint or counterclaim for infringement in the action." 35 U.S.C. §286. Section 286 is not a statute of limitations in the sense that it defeats the right to bring suit; it only limits the period for recovery of damages. *See Standard Oil Co. v. Nippon Shokubai K.K. Co.*, 754 F.2d 345, 348 (Fed. Cir. 1985).

204 In addition, the Federal Circuit has recognized that the doctrines of laches and equitable estoppel may operate to bar relief to a patent holder "even though there is no applicable statute of limitations." *Blue & Gold, Fleet, L.P. v. United States*, 492 F.3d 1308, 1314–1315 (Fed. Cir. 2007); *see supra* §5.9(iii), Further Exceptions to Infringement (Laches and Equitable Estoppel).

205 The Patent Act also limits damages based on lack of notice, in the event of failure to mark a patented article as patented. 35 U.S.C. §287(a). In the event of failure to mark, "no damages shall be recovered by the patentee in any action for infringement, except on proof that the infringer was notified of the infringement and continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such notice. Filing of an action for infringement shall constitute such notice." *Id.* No marking or actual notice, however, is required if the patented invention is not made or sold by the patentee or someone acting under its authority. *See Texas Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1219–1220 (Fed. Cir. 2002). Further, neither actual nor constructive notice is required where the patent claims only a process or method. *See Crown Packaging Tech., Inc. v. Rexam Beverage Can Co.*, 559 F.3d 1308, 1316 (Fed. Cir. 2009) ("The law is clear that the notice provisions of §287 do not apply where the patent is directed to a process or method.").

(8.3) COMPETENT COURT/VENUE

(8.3.1) Federal Courts

206 Under 28 U.S.C. §1338(a), United States district courts have original jurisdiction over cases arising under patent law. For a case to arise under patent law, the patent law issue must either create the cause of action asserted, or raise a substantial question of federal

patent law significant to the federal patent system as a whole that is necessary to decide in order to resolve one of the claims at issue. *See Gunn v. Minton*, 133 S. Ct. 1059, 1064–1068 (2013); *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 807–809 (1988).

207 The applicable venue statute for patent infringement suits, 28 U.S.C. §1400, provides that "[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." And 28 U.S.C. §1391(c)(2) provides that a corporation "shall be deemed to reside, if a defendant, in any judicial district in which [it] is subject to the court's personal jurisdiction with respect to the civil action in question." When a case is brought for declaratory judgment, the case's venue is controlled by the general venue provisions of 28 U.S.C. §1391(b). *See VE Holding Corp. v. Johnson Gas Appliance Co.*, 917 F.2d 1574, 1583 (Fed. Cir. 1990) ("It has long been held that a declaratory judgment action alleging that a patent is invalid and not infringed—the mirror image of a suit for patent infringement—is governed by the general venue statutes, not by §1400(b)").

208 Under 28 U.S.C. §1404, a court may, "[f]or the convenience of parties and witnesses, in the interest of justice," transfer a case to a different district court. *See also* 28 U.S.C. §1406 (regarding cases filed in an improper venue). In addition, "[w]hen civil actions involving one or more common questions of fact are pending in different districts, such actions may be transferred to any district for coordinated or consolidated pretrial proceedings." 28 U.S.C. §1407(a); *see also* 35 U.S.C. §299 (providing that accused infringers may be joined in one action as defendants or have their actions consolidated for trial only if the allegations of infringement "aris[e] out of the same transaction, occurrence, or series 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"). If a district court denies a motion to sever and transfer a patent case, the movant may file a petition for a writ of mandamus with the Federal Circuit seeking an order directing the district court to grant the motion. *See In re EMC Corp.*, 677 F.3d 1351, 1354–1355 (Fed. Cir. 2012) (vacating denial of transfer from Eastern District of Texas to District of Utah); *see In re Toyota Motor Corp.*, 747 F.3d 1338 (Fed. Cir. 2014) (vacating denial of transfer from Eastern District of Texas to Eastern District of Michigan).

209 In the United States, a party may demand trial by jury as provided for in the Seventh Amendment to the Constitution in accordance with the procedures set forth in Fed. R. Civ. P. 38. Not all patent-related cases, however, are tried to a jury. Whether the right to a jury attaches to a particular case "turns on whether the case 'is more similar to cases that were tried in courts of law than to suits tried in courts of equity or admiralty' in 1791." *Tegal Corp. v. Tokyo Electron Am., Inc.*, 257 F.3d 1331, 1339 (Fed. Cir. 2001) (quoting *Tull v. United States*, 481 U.S. 412, 417 (1987)). "A right to a jury attaches only to cases more similar to those that were tried in courts of law," particularly with respect to the remedy sought. *Id.* Consequently, a party who seeks only injunctive relief, as opposed to damages, has no right to a jury trial. *Id.* at 1341. And even in cases involving juries, judges must determine questions of law. If parties disagree about what the law is on a particular point, then the judge must decide what law applies. *See Panther Pumps & Equip. Co. v. Hydrocraft, Inc.*, 468 F.2d 225, 227 (7th Cir. 1972) ("In a patent case, as in any other case tried to a jury, questions of law are for the court and questions of fact are for the jury.").

(8.3.2) Administrative Enforcement

210 The United States ITC may also enforce a patentee's right to exclude. Although a patentee cannot obtain damages in the International Trade Commission (ITC), *see* 19

U.S.C. §1337(d)–(f) (providing for exclusion orders and cease and desist orders), these proceedings have the advantage of being much faster than district court actions, and the threat of an exclusion order barring importation of infringing goods may lead to settlement. A patentee may seek an exclusion order from the ITC under section 337 (19 U.S.C. §1337) prohibiting further importation of infringing articles. An ITC exclusion order is enforced by Customs at the border and applies broadly to all infringing products from the named respondents (defendants). Personal jurisdiction over an accused manufacturer is not needed, because jurisdiction is based on importation of an accused product. In order to prevail and obtain an exclusion order from the ITC, the patentee must prove infringement as well as the existence of a domestic industry relating to the patented article. 19 U.S.C. §§1337(a)(1)(B), (2). Before the ITC provides relief for a violation of section 337, it must consider the impact of the relief on "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 consumers." 19 U.S.C. §§1337(d)(1), 1337(f).

211 Discovery in section 337 actions is compressed as compared to district court proceedings due to the shorter time between the filing of the complaint and the hearing on the merits. The ITC sets a specific target date for completion of each investigation, typically 16–18 months from institution, while district court litigation may take years to complete. Moreover, discovery is generally more intense in ITC actions due to the greater breadth of discovery permitted. For example, while the ITC rules permit each party to propound 175 interrogatories and take up to 20 fact depositions, 19 C.F.R. §§210.28(a). 210.29(a), the district court rules (Fed. R. Civ. P. 30 and 33) provide an initial default limit of only 25 interrogatories and 10 depositions per side.

212 ITC proceedings under 19 U.S.C. §1337 occur before an Administrative Law Judge without a jury. *See* 19 C.F.R. §§210.3, 210.36(e). Section 337 investigations are conducted in conformity with the adjudicative provisions of the Administrative Procedure Act (5 U.S.C. §§551–559) and pursuant to the ITC Rules (19 C.F.R. Part 210, modeled on the Federal Rules of Civil Procedure) and to Ground Rules issued by the presiding Administrative Law Judge. The judge's Ground Rules govern such matters as the time for responding to motions and to discovery, the conduct of any *Markman* hearing, the requirements for pre- and post-hearing briefs, the submission of proposed evidentiary exhibits, and the procedure for arranging a telephone conference between the parties and the Administrative Law Judge. In addition, the ITC assigns a staff investigator to these actions. The investigator participates in discovery and trial, and may also provide the Administrative Law Judge with advisory recommendations on issues in the case. The Administrative Law Judge makes an initial determination, including findings of fact and conclusions of law, regarding whether there has been a violation of 19 U.S.C. §1337. *See* 19 C.F.R. §210.42(a)–(f). The ITC then has an opportunity to review the initial determination, either at its own motion or upon petition by one of the parties. *See* 19 C.F.R. §§210.43-44. If the ITC does not elect to review the initial determination, it becomes the official determination of the ITC by default, generally after 45 days. 19 C.F.R. §210.42(h)(1); *but see* 19 C.F.R. §210.42(h)(2)–(6) (describing alternate procedures and timelines for specific types of determinations). If the ITC does decide to review the initial determination, it may "affirm, reverse, modify, set aside or remand for further proceedings, in whole or in part," the initial determination. 19 C.F.R. §210.45(c).

213 After an initial determination becomes the determination of the ITC, it is sent to the President of the United States for final review. 19 U.S.C. §1337(j)(1). The presidential review process lasts for 60 days. 19 U.S.C. §1337(j)(2). In that time, the President may reject

the ITC's determination for public policy reasons; otherwise, the determination will become final after the 60 day period expires. 19 U.S.C. §1337(j)(2), (4). In 2005, these presidential duties were assigned to the United States Trade Representative. Assignment of Certain Functions Under section 337 of the Tariff Act of 1930, 70 Fed. Reg. 43251 (July 21, 2005).

214 Final determinations of the ITC may be appealed to the Federal Circuit. 19 U.S.C. §1337(c).

(8.4) PATENT OFFICE

215 The USPTO is an administrative agency of the United States Federal Government. 35 U.S.C. §1(a). The USPTO has the sole authority to issue patents, *see* 35 U.S.C. §2, and does so through a patent prosecution process to determine the validity of the claims in the patent application, *see* 35 U.S.C. §131; 37 C.F.R. §1.104. The USPTO can conduct interference proceedings (for patent applications before March 16, 2013) or derivation proceedings (for patent applications on or after March 16, 2013) when more than one inventor seeks a patent for the same invention. *See supra* §2.7.1, Interference Proceedings & Interfering Patents; §2.2, Derivation. In addition, the USPTO can re-examine a patent's validity if a party presents a "substantial new question of patentability" regarding one or more existing patent claims based on prior art patents or printed publications. 35 U.S.C. §§303–304; *see also* 35 U.S.C. §§301–307; *In re NTP, Inc.*, 654 F.3d 1268, 1279 (Fed. Cir. 2011) ("a reference relied on in the original prosecution could create a substantial new question of patentability where the reference was used for a different purpose during reexamination"); *In re Swanson*, 540 F.3d 1368, 1375–1379 (Fed. Cir. 2008) (substantial new questions are those that have not yet been considered by the USPTO regardless of whether they were considered by a federal court).

216 Under the Leahy-Smith America Invents Act, the USPTO also has the authority to institute an *Inter Partes* Review (IPR) of a patent based on a petitioner's request to cancel one or more claims of the patent as anticipated or obvious in light of prior art patents or printed publications. 35 U.S.C. §311; *see also* 35 U.S.C. §§312–319. The USPTO may so institute an IPR if it finds that there is "a reasonable likelihood that the petitioner would prevail . . . ." 35 U.S.C. §314(a); *see also St. Jude Med., Cardiology Div., Inc. v. Volcano Corp.*, 749 F.3d 1373 (Fed. Cir. 2014) (holding that the Federal Circuit may not hear an appeal of a decision not to institute IPR). Additionally, the USPTO has the authority to undertake a Post-Grant Review (PGR) in response to a petitioner's request to cancel patent claims based on invalidity. 35 U.S.C. §321; *see also* 35 U.S.C. §§322–329. In this case, the USPTO may institute a PGR if it finds that the information in the petition, if not rebutted, would render it "more likely than not that at least 1 of the claims challenged in the petition is unpatentable." 35 U.S.C. §324(a). For PGR, the petition must be filed within 9 months of the date of grant of the patent. 35 U.S.C. §321(c). For IPR, the petition cannot be filed until after the later of 9 months after the grant of the patent or the termination of any PGR, and cannot be filed more than 1 year after the petitioner or certain related parties is served with a complaint alleging infringement of the patent. 35 U.S.C. §§311(c)(1), 315(b).

217 The USPTO does not determine patent infringement.

(8.5) PROVISIONAL MEASURES

(8.5.1) Attachment

(8.5.1.1) General Comments

218 The Federal Rules of Civil Procedure grant federal courts access to all remedies that provide for "seizing a person or property to secure satisfaction of the potential judgment" that are available under the law of the state where the court is located. Fed. R. Civ. P. 64(a). These remedies include attachment. Fed. R. Civ. P. 64(b).

(8.5.1.2) Assets

219 Once the trial court has entered a final monetary judgment against a party, that party has a right to a stay of the final judgment pending appeal, if they post a *supersedeas* bond (a form of surety bond) as security for payment of the judgment. Fed. R. Civ. P. 62(d); *see also Hebert v. Exxon Corp.*, 953 F.2d 936, 938 (5th Cir. 1992) ("This provision of Rule 62 entitles a party appealing a money judgment to an automatic stay upon posting a *supersedeas* bond."). This bond remains in place until the defendant has exhausted its appeal rights, and relieves the accused infringer from having to pay judgment before the accused infringer has exhausted its appeal rights. As the Fifth Circuit has said, "[t]he purpose of a *supersedeas* bond is to preserve the status quo while protecting the non-appealing party's rights pending appeal. A judgment debtor who wishes to appeal may use the bond to avoid the risk of satisfying the judgment only to find that restitution is impossible after reversal on appeal. At the same time, the bond secures the prevailing party against any loss sustained as a result of being forced to forgo execution on a judgment during the course of an ineffectual appeal." *Poplar Grove Planting & Ref. Co. v. Bache Halsey Stuart, Inc.*, 600 F.2d 1189, 1190–1191 (5th Cir. 1979).

220 Unlike the Copyright Act, 17 U.S.C. §503(a), which authorizes the court to order the impounding of all copies infringing the plaintiff's copyright along with any means for reproducing these infringing copies, the Patent Act is silent on the issue of impoundment. Nevertheless the Court may have authority to issue an impoundment order as part of a preliminary injunction order pursuant to Fed. R. Civ. P. 65 and 35 U.S.C. §283. *See*, e.g., *Giantceutical, Inc. v. Ken Mable, Inc.*, 356 F. Supp. 2d 374 (S.D.N.Y. 2005) (motion for preliminary injunction and impoundment of goods based on alleged patent infringement denied due to lack of standing and failure to demonstrate reasonable likelihood of success, irreparable harm, balance of equities, and public interest).

(8.5.1.3) Evidence

221 *See infra* §8.6.1, Preservation/Spoliation of Evidence.

(8.5.2) Preliminary Injunction Proceedings

222 The two most common provisional measures in U.S. patent litigation are the Temporary Restraining Order (TRO) and the preliminary injunction. These are discussed below. With respect to both provisional measures, under Fed. R. Civ. P. 65(c), a "court may issue a preliminary injunction or a TRO only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained."

(8.5.2.1) Ex Parte Proceedings: Temporary Restraining Orders

223 Under the Federal Rules of Civil Procedure, a patentee can obtain an ex parte TRO without notice to the party to be restrained. Fed. R. Civ. P. 65(b). However, an ex parte TRO is only available in extreme circumstances where the requesting party can "clearly show that immediate and irreparable injury, loss, or damage will result to the movant before the adverse party can be heard in opposition." Fed. R. Civ. P. 65(b)(1)(A); *see also Reno Air Racing Ass'n., Inc. v. McCord*, 452 F.3d 1126, 1131 (9th Cir. 2006) ("courts have recognized very few circumstances justifying the issuance of an ex parte TRO"); *First Tech. Safety Sys., Inc. v. Depinet*, 11 F.3d 641, 650 (6th Cir. 1993) (ex parte TRO is only appropriate where notice is "impossible" or where notice would "render fruitless further prosecution of the action"). As a result, a patentee will typically provide notice to the accused infringer when seeking provisional relief through a motion for a TRO or motion for preliminary injunction.

(8.5.2.2) Inter Partes Proceedings: Preliminary Injunctions and Temporary Restraining Orders

224 35 U.S.C. §283 authorizes district courts to issue injunctive relief, including a preliminary injunction. *See also* Fed. R. Civ. P. 65 (procedure for obtaining a preliminary injunction). However, "[a] preliminary injunction is an extraordinary remedy never awarded as of right." *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). Therefore, "[a] plaintiff seeking a preliminary injunction must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1375–1376 (Fed. Cir. 2009) (quoting *Winter*, 555 U.S. at 20). Of these four factors, the first two carry greater weight. *Qingdao Taifa Grp. Co., Ltd. v. United States*, 581 F.3d 1375, 1382 (Fed. Cir. 2009). This standard is "essentially the same as for a permanent injunction with the exception that the plaintiff must show a likelihood of success on the merits rather than actual success." *Amoco Prod. Co. v. Vill. of Gambell, AK*, 480 U.S. 531, 546 n. 12 (1987); *see also infra* §8.10.1, Injunction. Courts have broad discretion as to whether a preliminary injunction should be granted. *See Titan Tire,* 566 F.3d at 1375 ("On appeal, a trial court's decision to grant or deny a preliminary injunction, made after taking into account the relevant factors, will be overturned only upon a showing that the court abused its discretion.").

225 With regard to the first factor, likelihood of success on the merits, a patentee "must show that it will likely prove infringement, and that it will likely withstand challenges, if any, to the validity of the patent." *Titan Tire*, 566 F.3d at 1376. In making this assessment, "the court views the matter in light of the burdens and presumptions that will inhere at trial," including those uniquely applicable to patent law. *Id.* "Thus, if a patentee moves for a preliminary injunction and the alleged infringer does not challenge validity, the very existence of the patent with its concomitant presumption of validity satisfies the patentee's burden of showing a likelihood of success on the validity issue." *Id.* at 1377. If, on the other hand, the alleged infringer responds to the preliminary injunction motion by coming forward with evidence of invalidity, the patentee must respond with "contrary evidence, which of course may include analysis and argument." *Id.* "A preliminary injunction should not issue if an alleged infringer raises a substantial question regarding either infringement or validity, i.e., the alleged infringer asserts an infringement or invalidity defense that the patentee has not shown lacks substantial merit." *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1050 (Fed. Cir. 2010).

226 The second factor, irreparable harm, has been demonstrated by, for example, the inability of an accused infringer to satisfy a monetary judgment (*see,* e.g., *Eli Lilly & Co. v. Premo Pharm. Labs., Inc.*, 630 F.2d 120, 137 (3d Cir. 1980)), loss of market share, loss of customers, and price erosion (*see,* e.g., *Hutzler Mfg. Co., Inc. v. Bradshaw Int'l, Inc.*, 11-CV-7211-PGG (S.D.N.Y. July 25, 2012)), or damage to reputation (*see,* e.g., *CVI/Beta Ventures, Inc. v. Custom Optical Frames, Inc.*, 893 F. Supp. 508, 524 (D. Md. 1995), *aff'd*, 92 F.3d 1203 (Fed. Cir. 1996)). On the other hand, "[E]vidence that a patent owner unduly delays in bringing suit against an alleged infringer negates the idea of irreparability." *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005); *see also Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 974 (Fed. Cir. 1996); *Nutrition 21 v. United States*, 930 F.2d 867, 872 (Fed. Cir. 1991). The degree of "causal nexus" between infringement and irreparable harm is an area of law that is in some tension and continues to evolve, and practitioners are advised to review the most recent authority available. *Compare,* e.g., *Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F.3d 1336, 1344–1345 (Fed. Cir. 2013) (reversing denial of permanent injunction due to harm patentee would suffer to its "reputation as an innovator," its "market exclusivity," and its "competitor's increasing share of the market," without discussing causal nexus) *with Apple Inc. v. Samsung Elecs. Co., Ltd.*, 695 F.3d 1370, 1374 (Fed. Cir. 2012) (requiring that "a sufficiently strong causal nexus relates the alleged harm to the alleged infringement") *and Apple, Inc. v. Samsung Elecs. Co., Ltd.*, 678 F.3d 1314, 1324 (Fed. Cir. 2012) ("To show irreparable harm, it is necessary to show that the infringement caused harm in the first place.").

227 Irreparable harm is no longer presumed. *See Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1149 (Fed. Cir. 2011) (in the context of a permanent injunction proceeding, confirming that "*eBay* [*v. MercExchange, L.L.C.*, 547 U.S. 388 (2006)] jettisoned the presumption of irreparable harm as it applies to determining the appropriateness of injunctive relief."); *Automated Merch. Sys., Inc. v. Crane Co.*, 357 F. App'x 297, 301 (Fed. Cir. 2009) (holding, in a non-precedential opinion, that the presumption of irreparable harm is "no longer the law" in the context of a preliminary injunction proceeding).

228 When evaluating the third factor, the balance of equities (also known as the balance of hardships), courts "must balance the harm that will occur to the moving party from the denial of the preliminary injunction with the harm that the non-moving party will incur if the injunction is granted." *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1457 (Fed. Cir. 1988). However, there is generally no requirement that the equities tip in favor of the movant if the other factors favor granting a preliminary injunction. *See id.* at 1457–1458.

229 Under the final factor, public interest, courts must determine whether the public interest will be harmed by entry of the preliminary injunction. *See Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312–313 (1982) ("where an injunction is asked which will adversely affect a public interest for whose impairment, even temporarily, an injunction bond cannot compensate, the court may in the public interest withhold relief until a final determination of the rights of the parties, though the postponement may be burdensome to the plaintiff"). On this ground, courts have refused to grant a preliminary injunction in part for public policy reasons, when the product to be enjoined offers an important medical benefit, *see Cordis Corp. v. Boston Scientific Corp.*, 99 F. App'x 928, 935–936 (Fed. Cir. 2004) (non-precedential opinion), or even when the injunction would lead to a significant loss of jobs during a tough economic period. *See Capital Mach. Co., Inc. v. Miller Veneers, Inc.*, 1:09-CV-00702-JMS-TAB (S.D. Ind. July 28, 2010).

230 For examples of courts issuing TROs, *see*, e.g., *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, No. 1-09-MD-02118-SLR (D. Del. May 24, 2011)

(TRO entered during appeal of district court's finding of patent invalidity); *BASF Agro B.V. v. Makhteshim Agan of N. Am., Inc.*, No. 1:10-CV-276-WLO (M.D.N.C. April 13, 2011) (granting TRO that was ultimately dissolved upon denial of preliminary injunction, *see* 1:10-CV-276-WLO (M.D.N.C. May 27, 2011); *see also BASF Agro B.V. v. Makhteshim Agan of N. Am., Inc.*, 519 Fed. App'x 1008 (Fed. Cir. 2013)); *Miche Bag, LLC v. Thirty One Gifts LLC*, No. 2:10-CV-781-TS (D. Utah September 13, 2010) (granting TRO that was ultimately dissolved upon denial of preliminary injunction, *see* No. 2:10-CV-781-TS, Dkt. No. 37 (D. Utah September 24, 2010)).

(8.5.2.3) Evidence

231 *See infra* §8.6.1, Preservation/Spoliation of Evidence.

(8.6) EVIDENCE

232 The United States has a comprehensive set of laws governing how and when various forms of evidence may be used in federal courts. The Federal Rules of Evidence address topics such as the relevancy of certain types of evidence, privileges that may protect evidence from disclosure, evidence and opinions provided through lay and expert witnesses, authentication of evidence, etc. Parties may obtain information from one another and from third parties pursuant to "discovery" rules set forth in the Federal Rules of Civil Procedure ("FRCP") 26–37 and 45.

233 In addition to the FRCP, judicial districts often adopt "local rules" that may provide further direction regarding discovery. Some districts, such as the Northern District of California and the Eastern District of Texas, have local patent rules that specifically address issues common to patent litigation cases.

(8.6.1) Preservation/Seizure of Evidence

234 In the United States, parties have a common law duty to preserve evidence relevant to anticipated litigation. *Micron Tech., Inc. v. Rambus, Inc.*, 645 F.3d 1311, 1319–1321 (Fed. Cir. 2011); *Hynix Semiconductor, Inc. v. Rambus, Inc.*, 645 F.3d 1336, 1345 (Fed. Cir. 2011). Once litigation is reasonably foreseeable, a party must suspend its routine document retention/destruction policy and put in place a "litigation hold" to ensure the preservation of relevant documents and things. *See Micron Tech., Inc.*, 645 F.3d at 1321; *Hynix Semiconductor, Inc.*, 645 F.3d at 1345–1347. Breach of the duty to preserve, and the resulting spoliation of evidence, may result in the imposition of sanctions. *Micron Tech., Inc.*, 645 F.3d at 1326–1329; *Hynix Semiconductor, Inc.*, 645 F.3d at 1347.

235 The determination of an appropriate sanction for spoliation, if any, is left to the sound discretion of the trial judge "exercising its inherent authority and in assuring the fairness of the proceedings before it." *Micron Tech., Inc.*, 645 F.3d at 1326. Sanctions may include further discovery from the offending party, cost-shifting, fines, special jury instructions, preclusion of evidence, and, in extreme cases involving clear and convincing evidence of bad faith, the entry of default judgment or dismissal (terminating sanctions). *Pension Comm. of the Univ. of Montreal Pension Plan v. Banc of Am. Sec.*, LLC, 685 F. Supp. 2d 456 (S.D.N.Y. 2010); *see also Micron Tech., Inc.*, 645 F.3d at 1326.

(8.6.2) Gathering Evidence

236 The FRCP allow for liberal discovery, and the parties to patent infringement cases typically engage in extensive discovery prior to trial. Pursuant to FRCP 26(b), "[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense—including the existence, description, nature, custody, condition, and location of any documents or other tangible things and the identity and location of persons who know of any discoverable matter." "Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." Fed. R. Civ. P. 26(b)(1).

237 These liberal discovery rules are not, however, without limitation. Parties may object to discovery requests that they believe are improper, and courts limit otherwise allowable discovery where the material sought is unreasonably cumulative or burdensome or could have been obtained from a more convenient, less burdensome, or less expensive source. *See* Fed. R. Civ. P. 26(b)(2)(C). In addition, evidence may be protected from discovery due to various privileges, such as the attorney-client privilege or the attorney work product doctrine. Furthermore, parties may also move for a "protective order," which may forbid, limit or specify how to conduct discovery in certain instances. *See* Fed. R. Civ. P. 26(c). In patent cases, the parties often enter into a protective order that limits the disclosure of sensitive or confidential information to only a specifically identified group of people such as outside legal counsel.

238 Various means are at a party's disposal to conduct discovery. These means include the use of informal methods such as requesting the patent application history from the USPTO and independent searches for prior art. More formal methods include oral depositions under FRCP 30, written interrogatories under FRCP 33, document requests under FRCP 34, and requests for admissions under FRCP 36. "The Federal Rules of Civil Procedure, as well as the local discovery rules and policies of a number of district courts, allow for liberal discovery, and it is not uncommon for an accused infringer to produce millions of pages of documents, collected from central repositories and numerous document custodians," and "[t]hose discovery costs are generally paid by the producing party." *Eon-Net LP v. Flagstar Bancorp*, 653 F.3d 1314, 1327 (Fed. Cir. 2011). Failure to cooperate with such discovery requests may result in court orders to comply with the requests under Rule 37(a), and in sanctions for failing to comply with such court orders under Rule 37(b). *See* Fed. R. Civ. P. 37.

239 Furthermore, FRCP 26 requires all parties to make automatic disclosures of certain information. For example, the parties must disclose the name and contact information of each individual likely to have discoverable information that the disclosing party may use to support its claims or defenses, within 14 days after a mandatory discovery conference. Fed. R. Civ. P. 26(a)(1).

240 FRCP 26 also requires the parties to disclose information related to expert witnesses and evidence that may be presented at trial. For example, FRCP 26(a)(3) requires each party to disclose witnesses and other evidence (e.g., documents and other exhibits) that it may present at trial. And FRCP 26(a)(2) requires each party to disclose the identity and qualifications of respective expert witnesses it may use at trial. The party generally must accompany this disclosure with an expert report that sets forth the opinions to which the expert will testify and the bases or reasons for such opinions. Absent a stipulation or court order to the contrary, these disclosures generally must be made at least 90 days before trial. Fed. R. Civ. P. 26(a)(2)(D).

(8.6.3) Experts

241 Federal Rule of Evidence ("FRE") 702 authorizes qualified expert witnesses to testify in patent and other cases if their "scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue," so long as the expert's testimony is based on sufficient facts and is the product of reliable principles and methods that the expert reliably applied to the facts of the case. In patent cases, the parties often employ the aid of technical experts to develop their cases, testify at trial, and testify during, or otherwise support, claim construction proceedings. Depending on the complexity of the relevant technology, expert testimony may be essential to a party's claims regarding infringement, validity and enforceability. Technical experts commonly testify as to the state of the relevant technological art and the attributes of a person of ordinary skill in the art at the time of invention.

242 In addition to technical experts, parties may also use a damages expert to aid in the determination of damages.

243 Pursuant to FRCP 26(a)(2), each party "must disclose to the other parties the identity of any witness it may use at trial to present evidence under Federal Rule of Evidence 702," among others. The Rule further requires that identified experts prepare a written, signed report that details the expert's opinions, the bases for those opinions, as well as information about the expert's qualifications and compensation for the study and testimony provided in the case. Fed. R. Civ. P. 26(a)(2)(B). Expert witnesses are also subject to deposition and cross-examination at trial.

244 FRE 706 also authorizes the court to also appoint its own expert. According to the rule, court-appointed experts may be deposed by any party, called upon to testify by the court or any party, and cross-examined by any party. Fed. R. Evid. 706. When appointed, such experts generally assist the court in understanding the relevant technology or assist in claim construction. But at least one district court judge has also permitted a court-appointed expert to testify at trial, along with the parties' respective experts. *See Monolithic Power Sys., Inc. v. O2 Micro Int'l Ltd.*, 558 F.3d 1341, 1346–1348 (Fed. Cir. 2009).

(8.6.4) Inspection

245 Under Federal Rule of Civil Procedure 34(a), a party may request that another party "produce and permit the requesting party or its representative to inspect, copy, test, or sample" documents, electronically stored information, or tangible things that are "in the responding party's possession, custody, or control." In addition, a party may request to be allowed to enter land or other property owned or controlled by the responding party and to "inspect, measure, survey, photograph, test, or sample the property or any designated object or operation on it." Fed. R. Civ. P. 34(a).

(8.7) PROCEEDINGS ON THE MERIT

(8.7.1) Infringement Proceedings: Patent Litigation Proceedings in District Courts

246 The procedure for patent infringement cases is governed in large part by the FRCP and the local rules and procedures adopted in the various district courts throughout the

United States. District court judges enjoy considerable discretion as to how they conduct and manage the cases before them, however, and different judges may employ substantially different approaches to managing patent cases. Their procedures may also vary case-to-case in view of different factual scenarios. Thus the description provided herein about litigation procedure should be understood to be general in nature.

(8.7.1.1) Pre-filing Activity

247 A prospective patent litigant must be mindful of its obligation to adequately investigate its allegations of infringement before filing its complaint. FRCP 11(b) requires an attorney to conduct a reasonable inquiry into the law and facts before filing a pleading in a court and to certify that the claims contained therein are not frivolous, legally unreasonable, without factual foundation, or asserted for an improper purpose. *Q-Pharma, Inc. v. Andrew Jergens Co.*, 360 F.3d 1295, 1300 (Fed. Cir. 2004). In the context of patent infringement actions, an attorney for the filing party must interpret the asserted patent claims and compare the accused device with those claims before filing a claim alleging infringement. *Id.* at 1300–1301. A party that fails to meet its pre-filing obligations may be subject to sanctions pursuant to FRCP 11(c). *Id.* at 1300.

248 A patent holder considering approaching another party about licensing a patent before filing a complaint for patent infringement with the court should also be mindful of the possibility that the other party may, after being approached, respond by a filing an action for declaratory judgment of non-infringement, invalidity, etc. in the venue of its choosing. *See supra* §8.1.5, Other Declaratory Judgment Plaintiff. A patent holder concerned about this possibility may want to consider filing its patent infringement complaint before approaching the potential licensee. FRCP 4(m) recognizes that a party may file a complaint with a court without immediately serving it on the defendant(s); rather, a plaintiff generally has 120 days from the filing of the complaint in which to serve defendant(s). *See* Fed. R. Civ. P. 4(m).

(8.7.1.2) Responding to the Complaint

249 Once a complaint has been filed and served, a defendant must file either an "answer" responsive to the complaint or a motion under FRCP 12 challenging jurisdiction, venue, service, or the adequacy of the complaint. *See* FRCP 8, 12. Filing a motion under FRCP 12 may delay the date upon which a defendant must file its answer to the complaint. FRCP 12(a)(4).

250 As set forth in FRCP 8, a party answering a complaint must "admit or deny the allegations asserted against it by [the] opposing party" and "must affirmatively state any avoidance or affirmative defense" to the claims asserted against it. FRCP 8(b)(1)(B),(c)(1).

251 In addition, FRCP 13 provides for the pleading of compulsory and permissive counterclaims against an opposing party, as well as cross-claims against a co-party, and FRCP 14 provides for the filing of a third-party complaint against "a nonparty who is or may be liable to [the defendant] for all or part of the claim against it." FRCP 13–14. FRCP 18–21 deal with the joinder of claims and parties.

(8.7.1.3) Case Management

252 Once pleadings have been filed, the parties' attorneys confer regarding discovery and related case management issues. FRCP 26(f). After conferring, the parties must submit to the court a proposed discovery plan, referred to as a Rule 26(f) report. *Id.* Although the rule

requires the parties to develop and submit a "proposed discovery plan," *id.*, parties may fail to agree on all or some issues, and submit competing plans.

253 After the Rule 26(f) conference has taken place, outside of court, and the Rule 26(f) report has been submitted, "the court may order the attorneys and any unrepresented parties to appear [in court] for one or more pretrial conferences," in which the court addresses case management concerns. FRCP 16(a). District and magistrate judges must also issue a scheduling order early in the course of the litigation that "limit[s] the time to join other parties, amend the pleadings, complete discovery, and file motions." FRCP 16(b). The scheduling order may also modify the extent or timing of discovery, "set dates for pretrial conferences and for trial," and address other relevant issues. FRCP 16(b)(3)(B).

254 In addition to a scheduling order, many of the deadlines and procedures for a case may be dictated by local court rules pertaining to civil cases and/or by local patent rules. For example, the Local Patent Rules for the Northern District of California require the parties to provide detailed disclosures of asserted patent claims and infringement contentions, invalidity contentions, and the parties' respective claim construction positions and supporting evidence, among other things. *See* N.D. Cal. Patent L.R. 3-1 to 4-2. Other jurisdictions with local patent rules include the District of New Jersey, the Western District of Washington, the Eastern District of Texas, and the Southern and Eastern Districts of New York.

(8.7.1.4) Claim Construction

255 Although a court must construe the claims in accordance with the applicable legal guidelines, "there is no requirement that the district court construe the claims at any particular time," or engage in any particular type of judicial procedure or hearing to perform claim construction. *See Network Commerce, Inc. v. Microsoft Corp.*, 422 F.3d 1353, 1363–1364 (Fed. Cir. 2005); *Ballard Med. Prods. v. Allegiance Healthcare Corp.*, 268 F.3d 1352, 1358 (Fed. Cir. 2001). Indeed, a court "may engage in a rolling claim construction, in which the court revisits and alters its interpretation of the claim terms as its understanding of the technology evolves." *Jack Guttman, Inc. v. Kopykake Enters., Inc.*, 302 F.3d 1352, 1361 (Fed. Cir. 2002).

256 District court judges, as opposed to jurors, interpret patent claims as a matter of law in a process commonly referred to as claim construction. *See supra* §3.4, Criterion for Scope of Protection. To facilitate their claim construction responsibilities, many courts have found it useful to hold hearings prior to construing contested claim terms. These claim construction hearings, referred to as *Markman* hearings (after *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996)), may include attorney argument and live witnesses. Courts may also allow attorneys or the parties' respective expert witnesses to present technology tutorials, and in some cases will employ a court-appointed expert to aid them in understanding the technology underlying the case.

(8.7.1.5) Summary Judgment

257 Summary judgment allows a court to rule on a patent infringement case without resorting to a trial by jury where "there is no genuine dispute as to any material fact." FRCP 56(a). The purpose of summary judgment is to avoid expensive and lengthy trials when the outcome can be determined as a matter of law on the basis of the undisputed evidentiary record created by pretrial discovery. FRCP 56 provides that "[t]he court 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." FRCP 56(a). A

favorable *Markman* ruling may provide the legal basis for a party to obtain summary judgment.

(8.7.1.6) The Trial Process

258 In accordance with the right to jury trial when damages are sought (*see supra* §8.3.1, Federal Courts), some patent infringement cases are tried to a jury. Other patent trials are instead bench trials, and do not involve a jury. A trial may address both liability and damages, or may be bifurcated to try liability and damages separately.

259 A patent trial commonly occurs as follows. First, each party presents its opening statement, which introduces the party's case and important issues.

260 The majority of the trial then consists of witness examination. Each party directly examines witnesses it calls, with the other party immediately following each direct examination with a cross-examination of the witness. If the rules of the court permit, the direct examining party may then re-examine its witness in order to address issues raised during the cross-examination. Counsel for the parties examine both expert and fact witnesses.

261 Trials often conclude with each party presenting a closing argument. The closing argument provides an opportunity to review the evidence presented and argue the case.

262 Following the closing arguments, the court provides instructions to the jury and sequesters the jury to allow it to make its decision. The jury's decision-making process may be lengthy. Upon reaching a decision, the jury reports back to the court with a verdict.

263 At any time during the course of the trial before the matter is submitted to the jury, either party may bring a motion for a judgment as a matter of law pursuant to FRCP 50(a). Judgment as a matter of law is proper where "a party has been fully heard on an issue . . . and the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue." FRCP 50(a)(1).

264 Following the jury's verdict, a party may move for judgment as a matter of law notwithstanding the jury's verdict, or for a new trial. *See* FRCP 50(b). Any decision regarding an injunction or other equitable relief must be made by the court, in the exercise of its discretion, rather than by the jury. *See eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 390–391 (2006).

(8.7.1.7) Suspension of Proceedings

265 "[D]istrict courts have broad discretion to manage their dockets, including the power to grant a stay of proceedings." *Procter & Gamble Co. v. Kraft Foods Global, Inc.*, 549 F.3d 842, 848–849 (Fed. Cir. 2008). This includes the discretion to grant stays in view of patent reexamination or review proceedings in the USPTO. *Id.*; *see,* e.g., *VirtualAgility Inc. v. Salesforce.com, Inc.*, No. 2014-1232 (Fed. Cir. July 10, 2014) (reversing district court's denial of the defendants' motion to stay pending covered business method patent review by the USPTO); *Universal Elecs., Inc. v. Universal Remote Control, Inc.*, 943 F. Supp. 2d 1028 (C.D. Cal. 2013) (denying defendant's motion to stay pending IPR by the USPTO). With the changes to patent reexamination and review proceedings introduced by the Leahy-Smith America Invents Act, this area of procedural law is rapidly evolving, and practitioners are advised to review the most recent authority available in their jurisdiction.

(8.7.2) Invalidity Proceedings

266 Generally, an accused infringer presents its invalidity case during the same trial in which infringement is tried. Bifurcation of trial into separate proceedings relating to invalidity and infringement is rare. The finder of fact is required to determine invalidity using the same claim construction applied to determine infringement. *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001) ("claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses."); *Polaroid Corp. v. Eastman Kodak Co.*, 789 F.2d 1556, 1573 (Fed. Cir. 1986) ("That which infringes if later anticipates if earlier."), *citing Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (1889); *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987).

267 There are no bright-line rules governing order of presentation. Although the party bearing the burden of proof on an issue often presents evidence first, a court has discretion under FRE 611(a) to structure the presentation of evidence.

268 Invalidity or enforceability issues requiring legal or equitable determination, such as obviousness-type double patenting and inequitable conduct, may be tried in a separate bench trial. *See*, e.g., *Amgen Inc. v. F. Hoffmann-La Roche Ltd.*, 580 F.3d 1340 (Fed. Cir. 2009) (upholding judgments that followed jury trial on claims of anticipation, obviousness, non-enablement, indefiniteness, and inadequate written description, and separate bench trial on claims of obviousness-type double patenting and inequitable conduct). Some courts instead have "submitted special interrogatories to the jury on the facts" required for these determinations, or have "instructed the jury to find and weigh the facts" and decide the ultimate determination at issue. *Hebert v. Lisle Corp.*, 99 F.3d 1109 (Fed. Cir. 1996); *see also Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1358 (Fed. Cir. 2012) ("[t]he term 'advisory jury' can also be used to denote a jury's resolution of a legal issue that the court can permissibly give to the jury to decide, but whose ultimate determination is reserved for the court").

269 Instead of or in addition to litigating the issue of validity in a trial, a party may also file petitions with the U.S. Patent and Trademark Office challenging a patent. Prior to the implementation of the Leahy-Smith America Invents Act (AIA), a party could challenge a patent through either an Ex Parte Reexamination or *Inter Partes* Reexamination. In order to challenge a patent using an *Ex Parte* Reexamination, the challenger may file a request for reexamination based on prior art or legal arguments that raise a substantial new question of patentability. 35 U.S.C. §§302, 303. The AIA eliminated the *Inter Partes* Reexamination procedure.

270 The enactment of the AIA created several new post-grant procedures that can be used to challenge the validity of U.S. patents at the U.S. Patent and Trademark Office (USPTO), as well as a procedure for challenging the inventorship of a pending application or recently issued patent. *See* AIA §§3, 6, 7, 18, 125 Stat. 284, 285–293, 299–315, 329–331 (2011); *see supra* §8.4, Patent Office. These procedures are designed so that the party (petitioner) seeking review of the validity or inventorship of patent claims is able to participate throughout the proceedings. The proceedings are instituted and conducted by the newly created Patent Trial and Appeal Board (PTAB), which consists of Administrative Patent Judges who have experience and training both in technology fields and in contentious patent matters. 35 U.S.C. §6.

271 The AIA authorized four new procedures (1) *inter partes* review (IPR), (2) post-grant review (PGR), (3) covered business methods (CBM) review and (4) derivation proceedings. *See* 35 U.S.C. §§135, 311–319, 321–329; AIA §18, 125 Stat. at 329–331. IPR, PGR and

CBM proceedings relate to validity challenges to issued patents. *See* 35 U.S.C. §§311, 321; AIA §18, 125 Stat. at 329–331. Derivation proceedings relate to situations in which a party asserts that someone has derived a claimed invention from another person, and is intended to replace interference proceedings. *See* 35 U.S.C. §135. Petitioners have the possibility of obtaining a stay of any district court litigation involving the challenged patent during the pendency of a PGR. *See,* e.g., AIA §18(b), 125 Stat. at 329–331. For the post-grant proceedings, the PTO aims to reach a final decision within 1 year from the institution of the proceeding. *See* 35 U.S.C. §§316(a)(11); 326(a)(11); AIA §18(a), 125 Stat. at 329–331. For "good cause" the PTAB can extend the time period for an additional 6 months. *See* 35 U.S.C. §§316(a)(11); 326(a)(11); AIA §18(a), 125 Stat. at 329–331.

272 The PTO reviews the validity of the challenged claims under the less deferential "preponderance of the evidence" standard and not the higher "clear and convincing evidence" standard used in validity challenges in civil actions in the district courts. *See* 35 U.S.C. §§316(e); 326(e); AIA §18(a); *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S.Ct. 2238 (2011). The PTO also interprets the claims using "the broadest reasonable interpretation" of the claim terms and not the "ordinary and customary meaning" claim construction standard used in the district courts. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–1318 (Fed. Cir. 2005) (en banc) (describing the claim construction standard in district court litigation); *see,* e.g., 37 C.F.R. §42.100(b) (providing the claim construction standard for IPRs).

273 Estoppel provisions in the AIA preclude a petitioner from raising any ground that was raised or could have been raised in the post-grant proceeding in another proceeding before the PTO, a district court or the ITC. *See* 35 U.S.C. §§315(e), 325(e); AIA §18(a), 125 Stat. at 329–331. The patent owner is estopped from taking any action inconsistent with an adverse judgment, including obtaining a claim that is patentably indistinct from a finally refused or canceled claim. *See* 37 C.F.R. §42.73(d). In AIA post-grant proceedings, estoppel attaches when the final written decision is issued from the PTAB. *See id.* This represents a change from the *inter partes* reexamination proceedings that were replaced by AIA post-grant proceedings, in which estoppel arose only after all appeals had been exhausted. *See* §315(c) (pre-AIA); *Bettcher Indus. v. Bunzl USA*, 661 F.3d 629, 642–643 (Fed. Cir. 2011). In addition, post-grant proceedings (unlike the prior ex parte reexamination proceedings) require disclosure of the real party-in-interest behind the petition. *See* 35 U.S.C. §§312(a); 322(a).

274 The IPR procedure became available on September 16, 2012. The procedure replaces *inter partes* reexamination, which after September 15, 2012 is no longer available. *See* AIA §6(c)(3)(B), 125 Stat. at 305. To initiate an IPR for a patent, the patent must have been issued for at least 9 months. *See* 35 U.S.C. §311(c). An IPR must also be filed within 1 year of when the petitioner has been served with a complaint alleging infringement of the patent. *See* 35 U.S.C. §311(b). A petitioner may challenge the validity of all or some of the claims of a patent using prior art patents and printed publications. *See id.* The PTAB will institute an IPR if it determines that there is a reasonable likelihood that the petitioner will prevail on at least one challenged claim. *See* 35 U.S.C. §314(a).

275 The PGR procedure is available for patents that issue from applications subject to the AIA first-inventor-to-file provisions, which apply to patent applications filed after March 16, 2013. *See* AIA §6(f)(2)(A), 125 Stat. at 311. Because patent applications typically remain pending for several years before a patent issues, PGR procedures will not be in widespread use for several years. A PGR petition may be filed when a patent issues and up to 9 months after issuance. *See* 35 U.S.C. §321(c). Additionally, the petitioner cannot have filed any civil action challenging the validity of a claim of the patent for which PGR is sought. *See* 35

U.S.C. §325(a). The grounds for challenging patent validity are broader than those available for IPR and can include challenges to the sufficiency and clarity of the disclosure (i.e., written description, enablement and indefiniteness). *See* 35 U.S.C. §321(b). The PTAB institutes a PGR if it determines that it is more likely than not that at least one of the claims challenged in the petition is unpatentable. *See* 35 U.S.C. §324(a).

276 The procedure for covered business method (CBM) patent review became available on September 16, 2012. *See* AIA §18(a), 125 Stat. at 329. The AIA provides that the CBM review provision sunsets 8 years from the effective date of the provision. *See* AIA §18(a)(3), 125 Stat. at 330–331. Accordingly, the USPTO will not accept new petitions for CBM review filed on or after September 16, 2020. A CBM review is available for any patent that claims a "covered business method." *See* AIA §18, 125 Stat. at 329–331. The AIA specifies that a covered business method patent is a patent that "claims a method or corresponding apparatus for performing data processing or other operations used in the practice, administration, or management of a financial product or service." AIA §18(d)(1), 125 Stat. at 331. In order to be eligible to file a CBM petition, a petitioner must either have been sued on the patent or charged with infringement. *See* AIA §18(a)(1)(B), 125 Stat. at 330. A CBM review may be requested any time except during the period in which a petition for PGR could be filed, e.g., 9 months after the issuance of a patent that is subject to the first inventor-to-file provisions. *See* AIA §18(a)(2), 125 Stat. at 330. CBM patent review is available for patents under the previous first-to-invent system, even within the first 9 months after the patent issues. *See id.* The AIA provides that patents eligible for CBM do not include patents for "technological inventions." AIA §18(d)(1), 125 Stat. at 331. The PTO will consider the following in determining whether a patent is for a technological invention and thus ineligible for CBM patent review: "whether the claimed subject matter as a whole recites a technological feature that is novel and unobvious over the prior art; and solves a technical problem using a technical solution." 37 C.F.R. §42.301. The petitioner bears the burden to show that the petitioner has standing to proceed by demonstrating that the challenged patent is a covered business method patent and that at least one claim of the challenged patent is not directed to a technological invention. *See* 37 C.F.R. §42.304(a).

277 The effective date for the derivation provision in the AIA is March 16, 2013. *See* AIA §3(n), 125 Stat. at 293. A derivation proceeding requires that an applicant for a patent file a petition to institute the proceeding. *See* 35 U.S.C. §135(a). The petition must set forth with particularity the evidence showing that an inventor named in an earlier application instead derived the claimed invention from the petitioner. *See id.* The petition must be filed within 1 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. *See id.*; *see also supra* §2.2, Derivation.

(8.7.3) Entitlement Proceedings

278 Under the America Invents Act, the first party to file is entitled to the patent. 35 U.S.C. §102. In order to combat an unscrupulous filing of a first patent application, the America Invents Act establishes a derivation proceeding that allows a party to challenge the inventorship of an earlier-filed patent application. *See* 35 U.S.C. §§135, 291; *see also supra* §2.2, Derivation.

279 For those patents with an effective filing date before March 16, 2013, disputes as to who first invented and is therefore entitled to a patent (i.e., priority disputes) take place either in the USPTO or in district court, depending on whether the dispute involves a

patent application or issued patents. *See* 35 U.S.C. §135 (pre-AIA); 35 U.S.C. §291 (pre-AIA); 35 U.S.C. §256; *HIF Bio, Inc. v. Yung Shin Pharms. Indus. Co.*, 600 F.3d 1347, 1354 (Fed. Cir. 2010). The procedure for deciding such disputes in the USPTO are governed by provisions in the MPEP regarding interferences. *See* MPEP, Chapter 2300. And priority disputes in district courts are—like patent infringement disputes—governed by the FRCP, and local court rules.

(8.7.4) Suspension of Proceedings

280 *See supra* §8.7.1.7, Suspension of Proceedings.

(8.8) CUSTOMS SEIZURES

Border Detention Measures and International Trade Commission Proceedings

281 As explained above, a patentee may seek an exclusion order from the U.S. ITC under section 337 (19 U.S.C. §1337) prohibiting further importation of infringing articles. *See supra* §8.3.2, Administrative Enforcement. An ITC exclusion order is enforced by United States Customs at the border and applies broadly to all infringing products from the named respondents (defendants). Section 337 investigations are conducted in conformity with the adjudicative provisions of the Administrative Procedure Act (5 U.S.C. §§551–559) and pursuant to the ITC Rules (19 C.F.R. Part 210 (modeled on the FRCP)) and to Ground Rules issued by the presiding Administrative Law Judge. The judge's Ground Rules govern such matters as the time for responding to motions and to discovery, the conduct of any *Markman* hearing, the requirements for pre- and post-hearing briefs, the submission of proposed evidentiary exhibits, and the procedure for arranging a telephone conference between the parties and the Administrative Law Judge.

282 Discovery in section 337 actions is compressed as compared to district court proceedings due to the shorter time between the filing of the complaint and the hearing on the merits. The ITC sets a specific target date for completion of each investigation, typically 16–18 months from institution, while district court litigation may take years to complete. Moreover, discovery is generally more intense in ITC actions due to the greater breadth of discovery permitted. For example, while the ITC rules permit each party to propound 175 interrogatories and take up to 20 fact depositions, 19 C.F.R. §§210.28(a), 210.29(a), the district court rules, Fed. R. Civ. P. 30(a), 33(a), provide an initial default limit of only 25 interrogatories and 10 depositions per side.

283 Given the breadth of discovery, the compressed timeline, the need to respond to positions taken by the ITC's investigative attorney (who participates as a party, representing the public interest), and additional briefing requirements, section 337 actions may be expensive and demanding.

(8.9) REMEDIES

(8.9.1) Injunction

284 A permanent injunction is one form of relief a patent holder may obtain against a patent infringer. *See eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006). It is the plaintiff-patentee's burden to come forward with evidence demonstrating: "(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." *Id.* In *eBay*, the Supreme Court rejected the Federal Circuit's prior "'general rule,' unique to patent disputes, 'that a permanent injunction will issue once infringement and validity have been adjudged'" and "should be denied only in the 'unusual' case." *Id.* at 393–394. "The standard for a preliminary injunction is essentially the same as for a permanent injunction with the exception that the plaintiff must show a likelihood of success on the merits rather than actual success." *Amoco Prod. Co. v. Vill. of Gambell*, 480 U.S. 531, 546 n. 12 (1987). Moreover, "[e]very injunctive case must be considered according to its unique facts." *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1338 n. 6 (Fed. Cir. 2012).

285 The first factor, irreparable injury, essentially means that "unless an injunction is granted, the plaintiff will suffer harm which cannot be repaired." *Canadian Lumber Trade Alliance v. United States*, 441 F. Supp. 2d 1259, 1264 n. 4 (2006), *aff'd*, 517 F.3d 1319 (Fed. Cir. 2008) (quoting *Studebaker Corp. v. Gittlin*, 360 F.2d 692, 698 (2d Cir. 1966)). The degree of "causal nexus" between infringement and irreparable harm is an area of law that is in some tension and continues to evolve, and practitioners are advised to review the most recent authority available. *Compare*, e.g., *Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F.3d 1336, 1344–1345 (Fed. Cir. 2013) (reversing denial of permanent injunction due to harm patentee would suffer to its "reputation as an innovator," its "market exclusivity," and its "competitor's increasing share of the market," without discussing causal nexus) *with Apple Inc. v. Samsung Elecs. Co., Ltd.*, 735 F.3d 1352, 1363–1364 (Fed. Cir. 2013) (affirming need for "a showing of some causal nexus" between infringing conduct and alleged harm in injunction context, but holding that "certain of the standards arguably articulated by the district court go too far"). Examples of irreparable harm that may warrant injunctive relief include: a patentee's significant loss of market share, a sharp decline in revenue and lost goodwill. *See,* e.g., *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 861–862 (Fed. Cir. 2010), *aff'd*, 131 S. Ct. 2238 (2011); *Smith & Nephew, Inc. v. Synthes (U.S.A.)*, 466 F. Supp. 2d 978, 983 (W.D. Tenn. 2006); *Transocean Offshore Deepwater Drilling, Inc. v. GlobalSantaFe Corp.*, No. H-03-2910 (S.D. Tex. December 27, 2006); lost revenues and increased expenditures that will decrease funding for research and development. *See,* e.g., *Sanofi-Synthelabo v. Apotex, Inc.*, 492 F. Supp. 2d 353, 397 (S.D.N.Y. 2007); *Commonwealth Sci. & Indus. Research Org. v. Buffalo Tech. Inc.*, 492 F. Supp. 2d 600, 604 (E.D. Tex. 2007); deprivation of the patentee's right to decide who may practice its patents and on what terms. *See,* e.g., *Douglas Dynamics*, 717 F.3d at 1345; *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1456–1457 (Fed. Cir. 1985) (in the context of a preliminary injunction); loss of the patentee's reputation as an innovator. *See,* e.g., *Douglas Dynamics*, 717 F.3d at 1344–1345; *Muniauction, Inc. v. Thomson Corp.*, 502 F. Supp. 2d 477, 483 (W.D. Pa. 2007), *rev'd on other grounds*, 532 F.3d 1318 (Fed. Cir. 2008);

Wald v. Mudhopper Oilfield Servs., Inc., CIV-04-1693-C (W.D. Okla. July 27, 2006); or decreased ability to recruit top researchers. *See,* e.g., *Commonwealth Sci.*, 492 F. Supp. 2d at 604.

286 In the context of patent infringement, the second factor—inadequacy of remedies at law—is generally shown through a showing of the first factor—irreparable injury. Because a patentee usually shows irreparable injury by demonstrating the inadequacy of money damages, and money damages is the basic remedy at law, proof of the first factor generally constitutes proof of the second. *See,* e.g.*, Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1155 (Fed. Cir. 2011) (en banc) (finding inadequacy of money damages where the plaintiff "will continue to suffer irreparable harm due to lost market share, lost business opportunities, and price erosion" for which "money damages alone cannot fully compensate"). Although a party need not practice the asserted patent to obtain injunctive relief, a party who is a direct competitor is more likely to be able to show that money damages are not an adequate remedy. *See Trebro Manf., Inc. v. FireFly Equip., LLC*, 748 F.3d 1159, 1171 (Fed. Cir. 2014) ("[A] party that does not practice the asserted patent may still receive an injunction when it sells a competing product."); *High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc.*, 49 F.3d 1551, 1556–1557 (Fed. Cir. 1995) (reversing grant of preliminary injunction due to "lack of commercial activity by the patentee," but noting "a patentee's failure to practice an invention does not necessarily defeat the patentee's claim of irreparable harm").

287 In evaluating the balance of harms (the third factor), a court "assesses the relative effect of granting or denying an injunction on the parties." *i4i Ltd.*, 598 F.3d at 862. The court may consider many factors in its analysis, including the parties' "sizes, products, and revenue sources." *Id.* However, the court should not consider harm to an infringing party resulting from that party's infringement: an accused infringer "who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected." *Broadcom Corp. v. Qualcomm, Inc.*, 543 F.3d 683, 704 (Fed. Cir. 2008) (quoting *Windsurfing Int'l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1003 n. 12 (Fed. Cir. 1986)). The accused infringer "should not be permitted to prevail on a theory that successful exploitation of infringing technology shields a party from injunctive relief." *Id.* (quotations omitted).

288 When evaluating the fourth factor, public interest, "the touchstone . . . is whether an injunction, both in scope and effect, strikes a workable balance between protecting the patentee's rights and protecting the public from the injunction's adverse effects." *i4i Ltd.*, 598 F.3d at 863. Barring unusual circumstances, this factor generally tips in favor of the patentee. "In general, public policy favors the enforcement of patent rights," *Commonwealth Sci.*, 492 F. Supp. 2d at 607, and "[i]n order to outweigh the public interest in protecting patent rights, the harm should be of a unique or socially valuable type." *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 827 F. Supp. 2d 641, 652 (E.D. Va. 2011), *aff'd in relevant part, but rev'd on other grounds*, 694 F.3d 1312 (Fed. Cir. 2012). "[S]elling a lower priced product does not justify infringing a patent." *Payless Shoesource, Inc. v. Reebok Int'l Ltd.*, 998 F.2d 985, 991 (Fed. Cir. 1993) (in the context of a preliminary injunction). "While the general public certainly enjoys lower prices, cheap copies of patented inventions have the effect of inhibiting innovation and incentive." *Douglas Dynamics*, 717 F.3d at 1346 (Fed. Cir. 2013).

289 However, courts can exercise their discretion to deny injunctive relief when the harm to the public from granting the injunction is so severe that it outweighs the patentee's individual right to exclude. Therefore, courts have found "rare and limited circumstances" in which serious concerns such as public health and safety outweigh the public's interest in promoting and rewarding the inventive process. *Commonwealth Sci.*, 492 F. Supp. 2d at 607; *see also City of Milwaukee v. Activated Sludge, Inc.*, 69 F.2d 577, 593 (7th Cir. 1934) (refusing to enter a permanent injunction that would leave an entire community without sewage disposal); *Johnson & Johnson Vision Care, Inc., v. CIBA Vision Corp.*, 712 F. Supp. 2d 1285, 1292 (M.D. Fla. 2010) (denying a motion for permanent injunction of infringing contact lenses, in part because it would force "millions of innocent contact lens wearers" to be refitted for new lenses); *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, CV-03-0597-PHX-MHM (D. Ariz. March 31, 2009), *aff'd*, 670 F.3d 1171 (Fed. Cir. 2012), *vacated in part on other grounds on reconsideration*, 682 F.3d 1003 (Fed. Cir. 2012), *vacated in part other grounds on reh'g* en banc, 476 F. App'x 747 (Fed. Cir. 2012) (in a non-precedential opinion, refusing to enter a permanent injunction against infringing stents because it would "deny many sick patients a full range of clinically effective and potentially life saving treatments"). Nevertheless, absent compelling public concerns, courts commonly determine that the public interest will not be disserved by enjoining competing drug makers and medical device suppliers from infringing a direct competitor's patent. *See,* e.g., *A & L Tech. v. Resound Corp.*, No. 93-cv-00107-CW (N.D. Cal. 1995); *Johns Hopkins Univ. v. Datascope Corp.*, 513 F. Supp. 2d 578, 586 (D. Md. 2007), *rev'd on other grounds*, 543 F.3d 1342 (Fed. Cir. 2008); *Sanofi-Synthelabo*, 492 F. Supp. 2d at 397; *Smith & Nephew*, 466 F. Supp. 2d at 985; *ALM Surgical Equip. Inc. v. Kirschner Med. Corp.*, C.A. No. 6:89-1622-3 (D.S.C. April 23, 1990).

290 With respect to the content of the injunction itself, vague and overly broad injunctions are disallowed by both the FRCP and case law. Every injunction must "state its terms specifically" and "describe in reasonable detail—and not by referring to the complaint or other document—the act or acts restrained or required." Fed. R. Civ. P 65(d)(1). "[A]n injunction cannot impose unnecessary restraints on lawful activity." *Riles v. Shell Exploration & Prod. Co.*, 298 F.3d 1302, 1311 (Fed. Cir. 2002) (citing *Gemveto Jewelry Co. v. Jeff Cooper, Inc.*, 800 F.2d 256, 259 (Fed. Cir. 1986)). Moreover, the Supreme Court has rejected the use of "overly broad injunctions due to the threat of costly contempt proceedings for acts unrelated to those originally judged unlawful." *Additive Controls*, 986 F.2d at 479. For this reason, the Federal Circuit has vacated permanent injunctions on the basis of over breadth, vagueness, and violation of Fed. R. Civ. P 65(d)(1). *See,* e.g., *id.* at 477, 479 (reversing the district court's grant of an injunction that "forever barred" plaintiff from infringing a patent, because the injunction "[did] not use specific terms or describe in reasonable detail the acts sought to be restrained," and "[did] not state which acts of [the defendant] constitute[d] infringement" of the patent-in-suit); *Rocket Jewelry Box, Inc. v. Quality Int'l Packaging, Ltd.*, 90 F. App'x 543, 548 (Fed. Cir. 2004) (in a non-precedential opinion, vacating and remanding permanent injunction of products "similar" to the patented and trademarked products, on the grounds that the injunction did not describe "in reasonable detail the parameters for determining the extent of any such 'similarity'").

(8.9.2) Intermediaries

291 35 U.S.C. §271(a) states that "whoever without authority makes, uses, offers to sell, or sells any patented invention . . . infringes the patent." Accordingly, it not only constitutes infringement for a manufacturer to create and sell an infringing product to a third-party distributor, it also constitutes infringement for a third-party distributor to re-sell that product. Thus, third-party distributors can be enjoined from infringing re-sale activity.

292 One way to enjoin a third-party distributor from selling an infringing product is to name the third-party distributor as a defendant in a lawsuit. This way, the patent holder can obtain an injunction directly against the third-party distributor. However, if an injunction has already been entered against the manufacturer of infringing products, a third-party distributor may still be held in contempt under this injunction, even if it is not a party to the injunction. Under Fed. R. Civ. P. 65(d)(2), an injunction binds not only parties to it, but also "other persons who are in active concert or participation with" any parties to the injunction. Third parties are considered to be in "active concert" with an enjoined party if they "act with an enjoined party to bring about a result forbidden by the injunction . . . if they are aware of the injunction and know that their acts violate the injunction." *Merial Ltd. v. Cipla Ltd.*, 681 F.3d 1283, 1304–1305 (Fed. Cir. 2012) (quoting *Additive Controls*, 154 F.3d at 1353); *see also Aevoe Corp. v. AE Tech Co., Ltd.*, 727 F.3d 1375, 1384 (Fed. Cir. 2013) (finding that third-party distributors fell within the injunction of a company whose infringing products they sold, because the distributor "had notice of the injunction, had been apprised of which products were enjoined, and informed Aevoe that they obtained the barred products solely from" the directly enjoined company).

293 However, an injunction may not be obtained or enforced against a third-party distributor with respect to sales of infringing products purchased by that third-party distributor if the patent holder has already been fully compensated for those infringing product through a prior damages award. *See Odetics v. Storage Tech. Corp.*, 14 F. Supp. 2d 785, 788–789 (E.D. Va. 1998), *rev'd on other grounds*, 185 F.3d 1259, 1273 (Fed. Cir. 1999). Even if a defendant manufacturer is liable for damages and subject to an injunction, that injunction would not enjoin further use of the infringing product by those who previously bought the infringing product from the manufacturer. *Id.*

(8.9.3) Right to Information

294 Consistent with the FRCP, the parties to patent infringement cases are typically allowed extensive discovery prior to trial. Pursuant to Federal Rule of Civil Procedure 26(b)(1), "[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense—including the existence, description, nature, custody, condition, and location of any documents or other tangible things and the identity and location of person who know of any discoverable matter." "Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." Fed. R. Civ. P. 26(b)(1).

295 After a finding of infringement, an accounting of the infringer's profits and/or units of infringing product is sometimes awarded. *See*, e.g., *Robert Bosch, LLC v. Pylon Mfg. Corp.*, 719 F.3d 1305, 1309–1317 (Fed. Cir. 2013) (en banc); *TWM Mfg. Corp. v. Dura Corp.*, 722 F.2d 1261, 1264–1265, 1270 (6th Cir. 1983); *Floe Int'l Inc. v. Newmans' Mfg Inc.*, No. 04-5120, slip op. at 17–18 (D. Minn. August 23, 2006). As previously explained, such information is also generally discoverable during litigation. *See supra* §8.6, Evidence General Comments.

(8.9.4) Corrective Measures (Recall, Destruction, Etc)

296 If the Court decides that a patent is infringed, the patentee can in certain instances seek recall or destruction of each unit of the infringing product. *See*, e.g., *Proveris Scientific Corp. v. InnovaSystems, Inc.*, No. 1:05-cv-12424-RGS, slip op. at 3 (D. Mass. May 11, 2007) (requiring defendant to "destroy all inventory of its OSA product"); *TiVo Inc. v. Dish Network Corp.*, 640 F. Supp. 2d 853, 858 (E.D. Tex. 2009) (ordering injunctive relief requiring,

among other things, that the adjudged infringer "disable the DVR functionality (i.e., disable all storage to and playback from a hard disk drive of television data) in all but 192,708 units of the Infringing Products"), *aff'd in part and vacated in part*, 646 F.3d 869, 890 (Fed. Cir. 2011) (en banc); *but see Additive Controls & Measurement Sys., Inc. v. Flowdata, Inc.*, 154 F.3d 1345, 1356 (Fed. Cir. 1998) (stating that broad prophylactic injunction orders prohibiting any activity involving an entire class of device "should be used only in exceptional cases"). However, a request for destruction or disablement of infringing units may be more likely to be granted in circumstances where the defendant has violated an earlier form of injunction, and more severe remedies are sought to ensure cessation of further infringement. *See Additive Controls*, 154 F.3d at 1356. (upholding an injunction "prohibit[ing a party] and those found to have acted in active concert and participation with him from undertaking any activities with respect to positive displacement flow meters without first obtaining leave of court"); *Spindelfabrik Suessen-Schurr v. Shubert & Salzer Maschinenfabrik Aktiengesellschaft*, 903 F.2d 1568, 1574–1577 (Fed. Cir. 1990) (finding that "repeated and 'flagrant' violations of the district court's earlier injunction fully justified broad" injunction provisions prohibiting "directly or indirectly engaging in any activity which in any way relates to the manufacture, sale, use, servicing, exhibition, demonstration, promotion or commercialization of any automated rotor spinning machines, either in the United States or for use in the United States").

(8.9.5) Reasonable Compensation

297 *See infra* §8.9.6, Damages.

(8.9.6) Damages

(8.9.6.1) Reasonable Royalty

298 The patent owner is entitled to an award of "damages adequate to compensate for the infringement, but in no event less than a reasonable royalty" for the use the defendants made of the invention. *Nickson Indus. v. Rol Mfg. Co., Ltd.*, 847 F.2d 795, 798 (Fed. Cir. 1988) (quoting *Hanson v. Alpine Valley Ski Area, Inc.*, 718 F.2d 1075, 1079 (Fed. Cir. 1983)); *see also Smithkline Diagnostics, Inc. v. Helena Labs. Corp.*, 926 F.2d 1161, 1164 (Fed. Cir. 1991) ("A patentee may seek to recover actual damages or . . . a reasonable royalty.").

299 A "reasonable" royalty is the amount of money a willing patent owner and a willing licensee would have agreed upon—at the time the infringement first began—for the right to use the patented invention. *See Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1119–1120 (S.D.N.Y. 1970) (describing the construction of a "hypothetical negotiation" between the parties to determine a reasonable royalty); *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1324–1325 (Fed. Cir. 2009). The determination of the amount of a reasonable royalty focuses on the time period when the infringer first infringed the patent and the circumstances as they existed at that time, including what the parties' expectations would have been had they entered negotiations for royalties at the time of the infringing activity. *Georgia-Pacific*, 318 F. Supp. at 1122. The "*Georgia Pacific*" factors that may be considered in deciding a reasonable royalty are:

(1) Whether the patent holder had an established history of licensing the patented invention and, if so, what royalties were agreed upon in those licenses.

(2) The nature of the commercial relationship if any between the patent owner and the licensee, such as, whether they are competitors in the same territory in the same line of business, or whether they are inventor and promoter.
(3) The established profitability of the patented product, its commercial success, and its popularity at the time.
(4) Whether the patent owner had an established policy of granting licenses under its patents or retaining the exclusive right to practice its inventions.
(5) The size of the anticipated market for the invention at the time the infringement began.
(6) The duration of the patent and of the license as well as the terms and scope of the license, such as whether it is exclusive or non-exclusive or subject to territorial restrictions.
(7) The rates paid by the licensee for the use of the patents comparable to the plaintiffs' patents;
(8) Whether the licensee's infringing use of the patented invention promotes the sale of other non-infringing products, and whether the patentee's use of the patented invention generates sales of its non-patented items.
(9) The utility and advantage, if any, of the patented invention over prior products or practices used to perform similar functions.
(10) The nature of the patented invention, its character in the commercial embodiment owned and produced by the licensor, and the benefits to those who used it.
(11) The extent to which the infringer used the invention and any evidence probative of the value of such use.
(12) The portion of profits in the particular business that are customarily attributable to the use of the invention or analogous inventions.
(13) The portion of profits caused by the infringer's use of the patented invention as distinguished from the portion of profits caused by the infringer's use of non-patented elements, manufacturing processes, business prowess, or features or improvements added by the infringer.
(14) The opinion and testimony of qualified experts and of the patent holder.
(15) Any other factors which in your mind would have increased or decreased the royalty the infringer would have been willing to pay and the patent owner would have been willing to accept acting as normally prudent business people.

Id. at 1120 (noting that this list of factors is non-exclusive).

300 The claimed royalty rate should be appropriately adjusted to "separate or apportion the defendant's profits and the patentee's damages between the patented feature and the unpatented features." *Lucent Techs.*, 580 F.3d at 1337 (quoting *Garretson v. Clark*, 111 U.S. 120, 121 (1884)). In addition, a patentee claiming a reasonable royalty must prove that: (1) any licenses relied on as comparable were in fact "sufficiently comparable" to the circumstances of the hypothetical negotiation and license to sustain the jury's damages award; (2) the contribution of the patented invention to the defendant's accused sales supports the requested share of revenues or profits; and (3) the extent of expected demand for the infringing feature supports the jury's award. *Id.* at 1325, 1329, 1332–1335; *see also ActiveVideo*, 694 F.3d at 1333; *LaserDynamics, Inc. v. Quanta Computer, Inc.*, 694 F.3d 51, 79 (Fed. Cir. 2012). "[I]f it can be shown that the patented feature drives the demand for an entire multi-component product, a patentee may be awarded damages as a percentage of revenues or profits attributable to the entire product." *Id.* But "when claims are drawn to an individual component of a multi-component product, it is the exception, not the rule, that damages may be based upon the value of the multi-component product." *VirnetX, Inc. v. Cisco Systems, Inc.*, 767 F.3d 1308, 1326

(Fed. Cir. 2014); *see also Ericsson, Inc. v. D-Link Systems, Inc.*, --- F.3d ----, 2014 WL 6804864, at *19 (Fed. Cir. Dec. 4, 2014) ("[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.")

301 Until a patent issues, there is no valid patent that can be infringed. *Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352, 1359–1360 (Fed. Cir. 2007) ("[I]nfringement under §271(a) requires use 'without authority . . . during the patent term.'"); *Spectronics Corp. v. H.B. Fuller Co., Inc.*, 940 F.2d 631, 636 (Fed. Cir. 1991) ("Before a patent issues, and during the pendency of a patent application in the PTO, the courts have no claims by which to gauge an alleged infringer's conduct"). The patentee therefore has no standing to file suit against one who makes, uses, sells, offers for sale, or imports products within the scope of the claimed invention during the period between the publication of the application and the grant of the patent, and the potential infringer has no standing to seek declaratory judgment of non-infringement. *See Monsanto*, 503 F.3d at 1359–1360; *In re Dr. Reddy's Labs., Ltd.*, No. 1-cv-10102 (S.D.N.Y. September 13, 2002) ("It is axiomatic that DRL cannot obtain a declaratory judgment of invalidity and/or noninfringement on a patent that has not yet been issued by the PTO at the time the complaint was filed." (citing *Gaf Bldg. Materials Corp. v. Elk Corp.*, 90 F.3d 479, 482 (Fed. Cir. 1996))). However, under 35 U.S.C. §154(d), a patent owner, in specified circumstances, can obtain reasonable royalty damages from those who make, use, offer for sale, sell, or import an otherwise infringing products after the date of the application's publication but prior to the patent's date of issuance. 35 U.S.C. §154(d)(1). To obtain provisional damages, the patentee has the burden to show that (1) the infringing activities occurred after the publication of the patent application, (2) the asserted claims of the issued patent are substantially identical to the claims in the published application, and (3) the infringer had "actual notice" of the published patent application. *See*, e.g., *Stephens v. Tech Int'l, Inc.*, 393 F.3d 1269, 1275 (Fed. Cir. 2004); *Classen Immunotherapies, Inc. v. Shionogi, Inc.*, No. 13-cv-921 (D. Md. January 29, 2014) (dismissing complaint allegations where patent claims had changed significantly between publication of the application and final issuance and were therefore not "substantially identical").

(8.9.6.2) Payment of Profits Made

302 "Lost-profits damages are appropriate whenever there is a 'reasonable probability that, "but for" the infringement, [the patentee] would have made the sales that were made by the infringer.'" *Versata Software, Inc. v. SAP Am., Inc.*, 717 F.3d 1255, 1263–1264 (Fed. Cir. 2013) (quoting *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1545 (Fed. Cir. 1995) (en banc)). "To recover lost profits as opposed to royalties, a patent owner must prove a causal relation between the infringement and its loss of profits." *BIC Leisure Prods. v. Windsurfing Int'l*, 1 F.3d 1214, 1218 (Fed. Cir. 1993); *see also Crystal Semiconductor Corp. v. Tritech Microelecs. Int'l*, 246 F.3d 1336, 1353 (Fed. Cir. 2001); *Kearns v. Chrysler Corp.*, 32 F.3d 1541, 1551 (Fed. Cir. 1992); *King Instruments Corp. v. Perego*, 65 F.3d 941, 952 (Fed. Cir. 1995). "The showing of causation requires comparison between the breach and non-breach worlds," and the patentee "must show, by a preponderance of the evidence, that the alleged loss was the proximate result of the breach." *Nycal Offshore Dev. Corp. v. United States*, 743 F.3d 837, 843 (Fed. Cir. 2014) (quotations and citations omitted). "A patentee need not negate every possibility that the purchaser might not have purchased a product other than its own, absent the infringement. The patentee need only show that there was a reasonable probability that the sales would have been made 'but-for' the infringement." *Rite-Hite*, 56 F.3d at 1545(citation omitted).

303 U.S. patent law "does not require a patentee to make the patented invention to qualify for damages." *King Instruments Corp.*, 65 F.3d at 947. A patent owner who has suffered lost profits is entitled to lost profits damages regardless of whether the patent owner has made, used, or sold the patented device. *Id.* (citing *Rite-Hite*, 56 F.3d at 1546). Courts therefore may award lost profits on products that do not embody the claimed inventions as long as a patentee can prove but-for causation in the lost sales. *Id.*; *see also Am. Seating Co. v. USSC Grp. Inc.*, 514 F.3d 1262, 1270 (Fed. Cir. 2008).

304 *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.* sets forth a four-factor test that has proved a useful, but not exclusive, way of showing lost profits damages. 575 F.2d 1152, 1156 (6th Cir. 1978); *see also Rite-Hite*, 56 F.3d at 1545. The *Panduit* test requires that a patentee establish: "(1) demand for the patented product; (2) absence of acceptable non-infringing substitutes; (3) manufacturing and marketing capability to exploit the demand; and (4) the amount of the profit it would have made." *Rite-Hite*, 56 F.3d at 1545 (citing *Panduit*, 575 F.2d at 1156). "A showing under *Panduit* permits a court to reasonably infer that the lost profits claimed were in fact caused by the infringing sales, thus establishing a patentee's prima facie case with respect to 'but-for' causation." *Id.*

(8.9.6.3) Enhanced Damages: Willful Infringement

305 Pursuant to 35 U.S.C. §284, trial courts have statutory discretion to enhance damages for patent infringement up to three times the amount found or assessed. An award of enhanced damages requires a showing of willful infringement. *Beatrice Foods Co. v. New England Printing & Lithographing Co.*, 923 F.2d 1576, 1578 (Fed. Cir. 1991); *see also Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 508 (1964); *Jurgens v. CBK, Ltd.*, 80 F.3d 1566, 1570 (Fed. Cir. 1996). A finding of willfulness does not mandate an award of enhanced damages; it merely permits it. *See* 35 U.S.C. §284; *Odetics, Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1274 (Fed. Cir. 1999); *Jurgens*, 80 F.3d at 1570.

306 "Proof of willful infringement permitting enhanced damages requires at least a showing of objective recklessness." *In re Seagate Tech., LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007) (en banc):

> To establish willful infringement, a patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent. The state of mind of the accused infringer is not relevant to this objective inquiry. If this threshold objective standard is satisfied, the patentee must also demonstrate that this objectively-defined risk (determined by the record developed in the infringement proceeding) was either known or so obvious that it should have been known to the accused infringer.

Id. (citation omitted); *see also Powell v. Home Depot U.S.A., Inc.*, 663 F.3d 1221, 1236 (Fed. Cir. 2011) ("Since *Seagate*, this court has required patentees to prove the objective prong of the willful infringement inquiry by clear and convincing evidence as a predicate to the jury's consideration of the subjective prong. Where an accused infringer relies on a reasonable defense to a charge of infringement, the objective prong tends not to be met." (quotations and citations omitted)).

307-308 *Powell* clarified under what circumstances the court or the jury may consider the accused infringer's asserted reasonable defense under the objective prong: "Under the objective prong, the answer to whether an accused infringer's reliance on a particular issue or defense is reasonable is a question for the court when the resolution of that particular issue or defense is a matter of law. . . . When the resolution of a particular issue or defense is a factual

matter, however, whether reliance on that issue or defense was reasonable under the objective prong is properly considered by the jury." 663 F.3d at 1236–1237 (citations omitted).

(8.9.7) Disclosure of Judgment

309 Courts occasionally order a form of injunction requiring the adjudged infringer to provide a copy of the injunction order to the infringer's customers. *See,* e.g., *ePlus, Inc. v. Lawson Software, Inc.*, Civ. No. 3:09-cv-620, Dkt. No. 729 at 4 (E.D. Va. May 23, 2011).

(8.9.8) Order for Costs

310 In general, the prevailing party is entitled to costs. Fed. R. Civ. P. 54(d)(1). "Determination of the prevailing party is based on the relation of the litigation result to the overall objective of the litigation, and not on a count of the number of claims and defenses." *Brooks Furniture Mfg., Inc. v. Dutailier Int'l, Inc.*, 393 F.3d 1378, 1381 (Fed. Cir. 2005), *abrogated on other grounds by Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 134 S. Ct. 1749 (2014). A party that prevails on some of its patent claims is a prevailing party, even if the court did not find validity and infringement as to all of its claims. *Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro S.A. de C.V.*, 464 F.3d 1339, 1347–1348 (Fed. Cir. 2006). On the other hand, in cases involving split decisions concerning multiple controversies, the court can weigh the inequities that would result if the Court exercised its discretion to award costs.

311 The categories of costs allowable to the prevailing party are specifically enumerated at 28 U.S.C. §1920 and include clerk fees, marshal (i.e., service of process) fees, court reporter fees, printing and copying costs, witness fees, court-appointed expert fees, and docket fees. The Court is also empowered to require a party to pay special master costs. Fed. R. Civ. P. 53; *Aird v. Ford Motor Co.*, 86 F.3d 216, 221 (D.C. Cir. 1996). To obtain the statutorily enumerated costs, the prevailing party must itemize and document its costs, including providing an affidavit verifying that the items claimed in the bill of costs are correct, the costs have been necessarily incurred in the case, and the services for which fees have been charged were actually and necessarily performed.

312 Although the Court may, in its discretion, deny or reduce a prevailing party's request for costs, it should not without first articulating sound reasons for doing so. *See,* e.g., *Gochis v. Allstate Ins. Co.*, 162 F.R.D. 248, 250 (D. Mass. 1995); *Kalkowski v. Ronco, Inc.*, 424 F. Supp. 343, 354 (N.D. Ill. 1976).

Attorneys' Fees

313 Section 285 of Title 35 provides that "the court in exceptional cases may award reasonable attorney fees to the prevailing party." This provision is an exception to the so-called American Rule that each party bears its own attorney fees and expenses. Under §285, the Court can exercise its "inherent equitable power to make whole a party injured by an egregious abuse of the judicial process" in "exceptional cases." *Sun-Tek Indus. v. Kennedy Sky Lites, Inc.*, 929 F.2d 676, 678 (Fed. Cir. 1991).

314 The Supreme Court, rejecting a test that had been established by the Federal Circuit in *Brooks Furniture Mfg., Inc. v. Dutailier Int'l, Inc.*, 393 F.3d 1378, 1381 (Fed. Cir. 2005), recently 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. District courts may determine whether a case is 'exceptional' in the case-by-case exercise of their discretion, considering the totality of the circumstances." *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 134 S. Ct. 1749, 1756 (2014); *see also Classen Immunotherapies, Inc. v. Biogen Idec*, No. WDQ-04-2607 (D. Md. May 14, 2014) (awarding fees to defendant who had "defended against objectively baseless infringement claims for about nine years," after the date that the plaintiff "knew . . . that its claims were objectively baseless").

(8.10) CRIMINAL ENFORCEMENT

315 Patent infringement in the U.S. is regarded as a trespass on property, not a criminal act, and is therefore only subject to civil remedies. Acts giving rise to patent infringement may also constitute illegal use of trade secrets or violations of state unfair competition law. But the act of patent infringement by itself is not a crime. Nevertheless, failure to cease infringement in the face of an order from the Court enjoining the infringing acts may give rise to civil—or in some instances criminal—contempt proceedings. *Gunn v. Univ. Comm. to End the War in Vietnam*, 399 U.S. 383, 389 (1970); *Additive Controls & Measurement Sys., Inc. v. Flowdata, Inc.*, 154 F.3d 1345, 1356 (Fed. Cir. 1998); *Spindelfabrik Suessen-Schurr v. Shubert & Salzer Maschinenfabrik Aktiengesellschaft*, 903 F.2d 1568, 1577 (Fed. Cir. 1990).

(8.11) APPEALS

316 The Federal Circuit has jurisdiction over appeals from a final decision of a district court of the United States if the jurisdiction of the district court was based, in whole or in part, on 28 U.S.C. §1338, which provides district courts with exclusive jurisdiction over patent cases. *See* 28 U.S.C. §1295; 28 U.S.C. §1338.

317 The Supreme Court recently held that the Federal Circuit must review factual findings underlying claim construction for clear error, although interpretation of intrinsic evidence (including the specification and prosecution history) and the ultimate issue of claim construction is reviewed de novo. *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, 574 U.S. ___ (2015); *see supra* §3.1, Claim, Description and Drawings. When reviewing mixed questions of law and fact, such as obviousness, the Federal Circuit has "first presume[d] that the jury resolved the underlying factual disputes in favor of the verdict" and "le[ft] those presumed findings undisturbed if they are supported by substantial evidence," and then "examine[d] the [ultimate] legal conclusion . . . de novo to see whether it is correct in light of the presumed jury fact findings." *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1356–1357 (Fed. Cir. 2012). Factual determinations are reviewed, however, with deference to the district court's findings of fact because the appeals court is unable to make such findings of fact. But if the appeals court determines that the district court made such an egregious error that the factual findings resulted in an incorrect holding, then the appeals court will remand the decision to the district court to make new factual findings.

318 In addition to appeals from district courts, the Federal Circuit also has jurisdiction over appeals from final decisions issued by the ITC in section 337 actions (*see* 28 U.S.C. §1295; 19 U.S.C. §1337) and over appeals from decisions of the PTAB of the USPTO (*see* 28 U.S.C. §1295(a)(4)(A)).

(8.12) SUPREME COURT

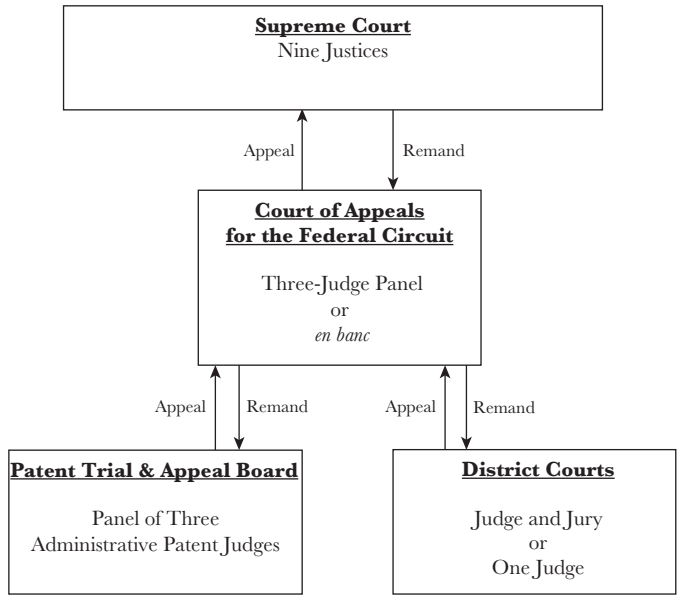
319 Federal Circuit decisions are subject to Supreme Court review, and the Supreme Court seems to have showed renewed interest in considering cases that raise important patent law issues. Nevertheless, the Supreme Court denies the vast majority of petitions for review it receives. Thus, as a practical matter, the Federal Circuit the de facto final, authoritative tribunal for most patent law cases.

(9) CONCLUSION

320 For at least the next 20 years, the United States will operate under two patent regimes: the system created by the 1952 Patent Act and its later amendments and judicial interpretations, and the system created by the 2011 America Invents Act. With the sustained interest in patents and patent litigation being shown by Congress and the Supreme Court, and with the development of the post-grant proceedings system at the U.S. Patent & Trademark Office, future amendments to and judicial interpretations of the U.S. patent statutes likely will continue to have significant impact on U.S. patent litigation.

(10) TABLES

Court Structure for Patent Infringement in the United States



Preliminary Injunction Proceedings: Ex Parte Injunctions (Temporary Restraining Orders)

(**NOTE:** The below rules are subject to and supplemented by the local rules of the district court and/or by the standing orders of the judge adjudicating the matter)

Introduction	Opposition	Oral Hearing	Judgment/ Appeal
Movant must clearly show "specific facts in an affidavit or a verified complaint . . . that immediate and irreparable injury, loss, or damage will result to the movant before the adverse party can be heard in opposition." Fed. R. Civ. P. 65(b)(1)(A).	There is no opposition for an ex parte petition for a Temporary Restraining Order. An ex parte temporary restraining order will generally not be granted unless notice to the opposing party is "impossible" or would "render fruitless further prosecution of the action." *First Technology Safety Systems, Inc. v. Depinet*, 11 F.3d 641, 650 (6th Cir. 1993). Movant's attorney must certify in writing "any efforts made to give notice and the reasons why it should not be required." Fed. R. Civ. P. 65(b)(1)(B).	May or may not occur.	District Court judge generally issues temporary restraining order. Any temporary restraining order is required to "state the date and hour it was issued; describe the injury and state why it is irreparable; state why the order was issued without notice; and be promptly filed in the clerk's office and entered in the record." Fed. R. Civ. P. 65(b)(2). A temporary restraining order must also: "(A) state the reasons why it issued; (B) state its terms specifically; and (C) describe in reasonable detail – and not by referring to the complaint or other document – the act or acts restrained or required." Fed. R. Civ. P. 65(d)(1).

Introduction	Opposition	Oral Hearing	Judgment/ Appeal
To obtain a temporary restraining order, movant must offer security "in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained." Fed. R. Civ. P. 65(c)	If a movant successfully obtains a temporary restraining order, the adverse party may move to modify or dissolve the order with 2 days' notice to the party who obtained the temporary restraining order. The court must "hear and decide the motion as promptly as justice requires." Fed. R. Civ. P. 65(b)(4).	If a temporary restraining order is entered, the court must hold a hearing on a preliminary injunction regarding the same matter "at the earliest possible time, taking precedence over all other matters except hearings on older matters of the same character." Fed. R. Civ. P. 65(b)(3).	The temporary restraining order expires at the time set by the court, not to exceed 14 days from entry of the order. The court may extend the time for good cause, "for a like period or the adverse party consents to a longer extension." Fed. R. Civ. P. 65(b)(2).
			In general, the denial of a temporary restraining order is not appealable. *See Office of Pers. Mgmt. v. Am. Fed'n of Gov't Emps., AFL-CIO*, 473 U.S. 1301, 1303-04 (1985)

Preliminary Injunction Proceedings: First Instance

(**NOTE:** The below rules are subject to and supplemented by the local rules of the district court and/or by the standing orders of the judge adjudicating the matter)

Introduction	Opposition	Oral Hearing	Judgment/ Appeal
"The court may issue a preliminary injunction only on notice to the adverse party." Fed. R. Civ. P. 65(a)(1).	Adverse party's right to notice of a preliminary injunction implies a right to a hearing to oppose the preliminary injunction, as well as a fair opportunity to prepare for such a hearing. *See Granny Goose Foods, Inc. v. Bhd. of Teamsters & Auto Truck Drivers Local No. 70 of Alameda Cnty*., 415 U.S. 423, 432 n. 7 (1974).	Where there are disputed factual issues, a district court generally must hold an evidentiary hearing, unless the disputed factual issues are resolved against the prevailing party. *See Warner Chilcott Labs. Ireland Ltd. v. Mylan Pharm. Inc.*, 451 F. App'x 935, 939 (Fed. Cir. 2011) (non-precedential opinion) (quoting *Elliott v. Kiesewetter*, 98 F.3d 47, 53 (3d Cir.1996)).	District Court judge issues preliminary injunction. An order granting a preliminary injunction must: "(A) state the reasons why it issued; (B) state its terms specifically; and (C) describe in reasonable detail – and not by referring to the complaint or other document – the act or acts restrained or required." Fed. R. Civ. P. 65(d)(1). Before granting or denying a preliminary injunction, a district court will generally make a finding regarding each of the four factors that a movant must show to obtain a preliminary

Introduction	Opposition	Oral Hearing	Judgment/ Appeal
			injunction: "(1) a reasonable likelihood of success on the merits; (2) irreparable harm; (3) a balance of hardships in its favor; and (4) a public interest in favor of the injunction." *Texas Instruments Inc. v. Tessera, Inc.*, 231 F.3d 1325, 1329 (Fed. Cir. 2000)
Movant will often file a request for expedited discovery along with a motion for preliminary injunction, in order to have sufficient evidence to demonstrate the allegations in the motion.		The court may consolidate the preliminary injunction motion with the trial on the merits of the case. Fed. R. Civ. P. 65(a)(2).	
To obtain a preliminary injunction, movant must offer security "in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained." Fed. R. Civ. P. 65(c)			Appeals of preliminary injunction motions may be made as a matter of right to the Federal Circuit. 28 U.S.C. §1292(a)(1), (c). The notice of appeal must be filed within 30 days after entry of the order. Fed. R. App. P. 4(a)(1)(A).

Preliminary Injunction Proceedings: Appeal (Expedited and Normal)

See also infra Proceedings on the Merits: Appeal

(**NOTE:** The below rules are subject to and supplemented by the local rules of the applicable Circuit Court)

Introduction	**Counterclaim**	**Oral Hearing**	**Judgment/ Appeal**
Appeals of preliminary injunction motions may be made as a matter of right, to the Federal Circuit when the conduct enjoined is allegedly infringing. 28 U.S.C. §1292(a)(1), (c)(1). The notice of appeal must be filed within 30 days after entry of the order. Fed. R. App. P. 4(a)(1)(A). A party may seek to have the district court stay the preliminary injunction pending appeal. Fed. R. Civ. P. 62(c). The appealing party may request that the appeal be expedited. *See* Fed. R. App. P. 2.			
Appellant must file and serve its brief within 40 days after the record on appeal is filed (or 60 days after	Appellee must file and serve its brief within 30 days after the appellant's brief is served (or 40 days	An oral argument "must be allowed in every case" unless every member of a three-judge panel	For preliminary injunctions of infringing conduct, case is heard and

Introduction	Counterclaim	Oral Hearing	Judgment/ Appeal
docketing if the appeal is before the Federal Circuit). Fed. R. App. P. 31(a)(1); Fed. Cir. R. 31(a)(1)(A).	if the appeal is before the Federal Circuit). Fed. R. App. P. 31(a)(1); Fed. Cir. R. 31(a)(2). Appellant may file a reply brief within 14 days after appellee's brief is served but no later than 7 days before oral argument. Fed. R. Civ. P. 31(a)(1).	agrees that it is unnecessary. Fed. R. App. P. 34(a)(2).	decided by three-judge panel of the Federal Circuit who are specialized in patent matters.
		A party may petition for a hearing or a rehearing en banc. Fed. R. App. P. 35(b). Case may be heard en banc (i.e., before all the circuit judges) if a majority of the active circuit judges determine it is necessary for uniformity or to decide a question of exceptional importance. Fed. R. App. P. 35(a).	Appeals court will not reverse a granting or denial of a preliminary injunction unless the moving party establishes that the trial court applied incorrect law, relied on clearly erroneous factual findings, or otherwise abused its discretion. *Texas Instruments Inc. v. Tessera, Inc.*, 231 F.3d 1325, 1328 (Fed. Cir. 2000)
			A party may appeal an appellate court judgment by filing a writ of certiorari with the Supreme Court within 90 days of entry of judgment. S. Ct. R. 13(1). The grant of a writ of certiorari is very rare.

Preliminary Injunction Proceedings: Appeal to Supreme Court

See infra Proceedings on the Merits: Appeal to the Supreme Court

Accelerated Proceedings on the Merits (Summary Judgment): First Instance

Introduction	Opposition	Oral Hearing	Judgment/Appeal
File motion in Court for summary judgment. Plaintiff may make motion for summary judgment at any time until 30 days after the close of discovery, unless a different time is set by local rule or court order. Fed. R. Civ. P. 56(b).	Respond by affidavit (prior to hearing) or otherwise set forth specific facts that would be admissible in evidence, showing that there is a genuine issue of material fact. Fed. R. Civ. P. 56(a), 56(c)(4).	Hearing not required but usually granted, especially if motion for summary judgment is to be granted.	Appeal of motion decided by three judges. A denial of summary judgment is not appealable. A party may not appeal a grant of summary judgment until a final judgment is entered.
Moving papers consist of (1) Notice of Motion and Motion; (2) Memorandum of Points and Authorities; and (3) Declarations or other evidence. Local districts may require the filing of separate 'Statement of Uncontroverted Facts and Conclusions of Law.'	Opposition papers may consist of: (1) declarations and other evidence; (2) Memorandum of Points and Authorities; (3) objection to the moving party's evidence; and (4) request for further discovery time, if appropriate.	Each side presents arguments. Time is generally determined by the Court.	
	Local rules dictate time by which opposition papers must be submitted.		

Introduction	Opposition	Oral Hearing	Judgment/Appeal
Judge sets hearing date for oral argument.	Opposition cannot rest upon mere allegations or denials of the pleadings. Must present admissible evidence showing there is a genuine issue for trial. Fed. R. Civ. P. 56(c)(1).		

Normal Proceedings on the Merits: First Instance

Introduction	Counterclaim	Trial	Judgment/Appeal
Plaintiff files a complaint. Fed. R. Civ. P. 3. A complaint includes a short and plain statement of the claim that the plaintiff is entitled to relief. A complaint must include a demand for the relief sought. Fed. R. Civ. P. 8.	Defendant must file answer and response, and counterclaim if appropriate, within 21 days of service of the complaint. Fed. R. Civ. P. 12, 13. The defendant must plead any affirmative defenses in the answer or waive them. Fed. R. Civ. P. 12. A counterclaim includes a short and plain statement of the claim that the party is entitled to relief. Must include a demand for the relief sought. Fed. R. Civ. P. 13.		At any time during trial before jury retires to decide outcome, a party may request judgment as a matter of law if no reasonable jury could conclude for the opposing side. Fed. R. Civ. P. 50.

Introduction	Counterclaim	Trial	Judgment/Appeal
		Each side generally makes an opening statement. Time determined by local and court rules. Each side directly examines witnesses it calls and cross-examines opposing witnesses. Time varies, depending on counsel's questioning. Each side generally presents closing arguments.	Jury decides outcome on issues submitted to it and may take considerable time.
Plaintiff has 21 days from the service of any counterclaim to reply. Fed. R. Civ. P. 12.	Must answer within 21 days. Fed. R. Civ. P. 12.		Judge may grant judgment notwithstanding the verdict if the evidence was not sufficient for the jury to make the decision that they did. Fed. R. Civ. P. 50.
	Must answer within 21 days of the service of the complaint. Fed. R. Civ. P. 12.		Losing party may file motion for new trial. Fed. R. Civ. P. 50, 59. Afterwards, may file motion to vacate or set aside a judgment. Fed. R. Civ. P. 60.
			Losing party may appeal after court issues final judgment. Fed. R. App. P. 4.

Normal Proceedings on the Merits: Appeal

Introduction	Defense/ Counterclaim	Oral Hearing	Judgment/ Appeal
In a civil case, except as provided in Rules 4(a)(1)(B), 4(a)(4), and 4(c), the notice of appeal required by Rule 3 must be filed with the district clerk within 30 days after the judgment or order appealed from is entered. Fed. R. App. P. 4(a)(1)(A).	A party may file an answer in opposition or a cross-petition to an appeal by permission under Fed. R. App. P. 5 within 10 days after the petition is served. Fed. R. App. P. 5(b)(2).	Any party may file, or a court may require by local rule, a statement explaining why oral argument should, or need not, be permitted. Fed. R. App. P. 34. Oral argument must be allowed unless a panel of three judges who have examined the briefs unanimously agree that oral argument is unnecessary. Fed. R. App. P. 34 (a)(2).	A petition for panel rehearing may be filed within 30 days after entry of judgment. Fed. Cir. R. 40(e). A party may opt to petition for an en banc hearing or rehearing. Fed. Cir. R. 35(c). A party may also opt to file a combined petition for panel rehearing and rehearing en banc. Fed. Cir. R. 35(d). Such petitions must comply with Fed. Cir. R. 35(e).
The petition must include the following: (A) the facts necessary to understand the question presented; (B) the question itself; (C) the relief sought; (D) the reasons why the appeal should be allowed and is authorized by a statute or rule; and (E) an attached		If the appellant declined to file a reply in anticipation of replying during oral argument, the appellant may file a reply within 14 days after the notice that the	A petition for a writ of certiorari to review a judgment of the Federal Circuit by the Supreme Court is timely

Introduction	Defense/ Counterclaim	Oral Hearing	Judgment/ Appeal
copy of: (i) the order, decree, or judgment complained of and any related opinion or memorandum, and (ii) any order stating the district court's permission to appeal or finding that the necessary conditions are met. Fed. R. App. P. 5(b)(1).		appeal will be submitted on the briefs. Fed. Cir. R. 34(a).	when it is filed within 90 days after entry of the final judgment. Sup. Ct. R. 13.
		The time allowed each side for oral argument will be determined by the court. The court may terminate the argument if it deems further argument unnecessary. Fed. Cir. R. 34(b).	

Normal Proceedings on the Merit: Appeal to the Supreme Court

Introduction	Defense/ Counterclaim	Oral Hearing	Judgment/ Appeal
A petition for a writ of certiorari to review a judgment of the Federal Circuit by the Supreme Court is timely when it is filed within 90 days after entry of the final judgment. Sup. Ct. R. 13. A petition for a writ of certiorari contains the questions presented for review; a list of all parties to the proceeding in the court whose judgment is sought to be reviewed; citations of the official and unofficial reports of the opinions and orders entered in the case by courts or the PTO; a concise statement of the basis for jurisdiction in the Court; the constitutional provisions, treaties, statutes, ordinances, and regulations involved in the case; a concise statement of the case setting out the facts material to consideration of the questions presented. Sup. Ct. R. 14.1.	Brief in opposition to a petition for a writ of certiorari may be filed by the respondent in any case. Sup. Ct. R. 15(3).	If the Supreme Court has granted the petition for writ of certiorari, the Court may place the case on the docket, order a summary disposition on the merits, or deny cert. Sup. Ct. R. 16.	Supreme Court decisions are final. Court may either affirm the Federal Circuit's holding or remand to the Federal Circuit to address the case based on the Supreme Court's holding.
	Any brief in opposition shall be filed within 30 days after the case is placed on the docket, unless the time is extended by the Court or a Justice, or the Clerk under Rule 30.4. Sup. Ct. R. 15.	If not disposed of summarily, the case stands for briefing and oral argument on the merits. Sup. Ct. R. 16.	

Introduction	Defense/ Counterclaim	Oral Hearing	Judgment/ Appeal
		Oral argument should emphasize and clarify the written arguments in the briefs on the merits. Sup. Ct. R. 28(1).	
		The petitioner opens and concludes the argument. Sup. Ct. R. 28(2).	
		Unless the Court directs otherwise, each side is allowed 30 minutes for argument. Sup. Ct. R. 28(3).	
		Additional time is rarely accorded. Sup. Ct. R. 28(3).	
		Only one attorney will be heard for each side, except by leave of the Court on motion. Sup. Ct. R. 28(4).	

Role of Experts

Party Experts	Experts Appointed by Court	Expert Opinion of the USPTO
Parties commonly use experts. Experts may, for example, testify at the *Markman* hearing and the trial.	Courts may appoint experts. *See* Fed. R. Evid. 706.	Courts do not ask the USPTO to render an opinion during trial. Instead, a USPTO-issued patent is presumed to be valid. *See* 35 U.S.C. §282(a). Any writings or materials produced during the prosecution of the patent (i.e., the prosecution history) are considered evidence.
Parties use expert declarations as well as expert testimony to support their position. Experts are usually industry-specific personnel with experience in the patent's field.		
Expert reports and testimony are governed by the Federal Rules of Civil Procedure. *See* Fed. R. Civ. P. 26(a)(2), 26(a)(4), 26(e)(2).		
Cross- and direct-examination of experts occurs during trial.		
Expert declarations and reports are available during the appeal as well, if they were made part of the record during trial.		

Duration of Preliminary Injunction Proceedings

First Instance	Court of Appeals	Appeal to the Supreme Court
The time for a district court to rule on a motion for a preliminary injunction varies. Some courts schedule hearings in addition to briefing on the motion.	A decision concerning a preliminary injunction may be appealed immediately to the Court of Appeals for the Federal Circuit. *See* 28 U.S.C. §1292(a)(1),(c)(1). Once an appeal has been noticed, the party that lost in the trial court may file a motion for an emergency injunction—or an emergency stay of an injunction—pending appeal. *See* FRAP 8; Fed. Cir. R. 8.[1]	A party challenging a decision of the Court of Appeals may seek to have the decision stayed pending the Supreme Court's decision on the petition for certiorari. *See* 28 U.S.C. §2101(f); Sup. Ct. R. 23. Note that only a small percentage of certiorari petitions are granted, and that the Supreme Court will hear a challenge to a decision on a preliminary injunction only in extraordinary circumstances.

[1] *See also Hilton v. Braunskill*, 481 U.S. 770, 776–777 (1987); *E.I. DuPont de Nemours & Co. v. Phillips Petroleum Co.*, 835 F.2d 277 (Fed. Cir. 1987).

Duration of Normal Proceedings (Infringement and/or Invalidity)

First Instance	Court of Appeals	Appeal to the Supreme Court
Median time from the complaint to the first day of trial is around two and one-half years, with considerable variation from court to court.[2] Trial and post-trial proceedings may then take days, weeks, or months. An appeal must generally be filed within 30 days of the entry of judgment in the district court or disposition of the last post-trial motion.[3]	Median time from docketing of the appeal to disposition by the Court of Appeals for the Federal Circuit is 1 year for cases appealed from district courts, and around 10 months for appeals from the PTO.[4] A petition for certiorari must be filed within 90 days after entry of judgment in the Court of Appeals.[5]	All cases argued during a term of the Supreme Court (annual terms begin in October) are decided before the Court's summer recess begins, usually by the end of June.

Costs of Infringement and Invalidity Proceedings

Preliminary Injunction	Normal Proceedings (Infringement)	Normal Proceedings (Validity)	Normal Proceedings (Infringement and invalidity)	Appeals
Plaintiff has to post a bond for securing any costs or damages that the defendant will suffer if the preliminary injunction is later found to be improperly granted.	The median cost to take a patent case through trial and appeal, with USD 1 million to USD 25 million at risk, was over USD 2.5 million in 2012.[6]		The median cost to try a patent case with USD 1 million to USD 25 million at risk was over USD 2.5 million in 2012.[7]	Varies; losing defendant must post supersedeas bond to stay money judgment[8]

[2] PricewaterhouseCoopers LLP, *2013 Patent Litigation Study: Big cases make headlines, while patent cases proliferate* 21–22 (2013).

[3] Fed. R. App. P. 4.

[4] United States Court of Appeals for the Federal Circuit, *Median Time to Disposition in Cases Terminated after Hearing or Submission* (2013).

[5] S. Ct. R. 13(1).

Preliminary Injunction	Normal Proceedings (Infringement)	Normal Proceedings (Validity)	Normal Proceedings (Infringement and invalidity)	Appeals
The bond amount depends on the facts of the case and is left to the court's discretion		The median cost in 2012 to request an *inter partes* reexamination[9] was USD 50,000[10] The filing fees for an inter partes review are significantly higher, but detailed practitioner's cost data for filing a request for an *inter partes* review is not yet available. The median cost in 2012 to complete an *inter partes* reexamination through appeal to the Patent Trial and Appeal Board was 130,000 USD.[11] The *inter partes* review estimated median cost is USD 300,000-500,000.[12]	Counterclaims of invalidity may increase litigation costs, depending on size of case and amount at risk.	

[6] American Intellectual Property Law Association (AIPLA) 2013 Survey at I-131 (containing 2012 data).
[7] *Ibid.*
[8] See Federal Rule of Civil Procedure 62(d); Federal Rule of Appellate Procedure.
[9] Inter Partes Reexamination is no longer available as of September 16, 2012.
[10] American Intellectual Property Law Association (AIPLA) 2013 Survey at I-189.
[11] *Ibid.* at I-190.

Preliminary Injunction	Normal Proceedings (Infringement)	Normal Proceedings (Validity)	Normal Proceedings (Infringement and invalidity)	Appeals
		Two party interference proceedings cost almost USD 300,000 in 2012.[13,14]		

[12] Comparison of Federal Court, ITC, and USPTO Proceedings in IP Disputes (AIPLA 2014), available at http://www.aipla.org/committees/committee_pages/IP-Practice-in-Japan/Committee%20Documents/2014%20MWI%20Presentations/Tom%20Engellenner%20-%20IP%20Dispute%20Cost%20Comparison.ppt.

[13] American Intellectual Property Law Association (AIPLA) 2013 Survey at I-188.

[14] Any patent application with an effective filing date of March 16, 2013, or thereafter will not be able to initiate an interference as a result of the Leahy-Smith America Invents Act. However, such applications may be eligible for derivation proceedings. See *supra* §2.2, Derivation.