

Patent Litigation Strategies Handbook

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Chapter 28: Patent Defenses

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Section of Intellectual Property Law
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I. INTRODUCTION

Typical defenses found in a patent case are noninfringement, invalidity, unenforceability, fraud, laches, estoppel, and violations of the antitrust laws. Defending against a charge of infringement involves rebutting evidence, because the burden of proof to establish liability rests on the patent holder. In contrast, raising a defense of invalidity, unenforceability, fraud, laches, or estoppel or making an antitrust claim places the burden of proof on the accused infringer.

According to the patent statute, a defendant can plead the following defenses in any action involving the infringement or validity of a patent:

- (1) Noninfringement, absence of liability for infringement or unenforceability,
- (2) Invalidity of the patent or any claim in suit on any ground specified in part II of this title as a condition of patentability,
- (3) Invalidity of the patent or any claim in suit for failure to comply with any requirement of Sections 112 or 251 of this title,
- (4) Any other fact or act made a defense by this title.¹

¹35 U.S.C. §282.

Furthermore, the Federal Rules of Civil Procedure require a party to affirmatively set forth laches, estoppel, fraud, license, and any other matter constituting an avoidance or affirmative defense in the pleading.²

A defendant can claim that a patent is invalid by demonstrating it does not meet the conditions for patentability as specified under Part II of the patent statute. This part of the patent statute contains Sections 100 through 212, but only two of these specify conditions for patentability. Section 102 sets forth the conditions of novelty and loss of right, and 103 sets out the condition of nonobviousness. The patent statute further defines the inventions for which one may obtain a patent—in 101 as any new and useful process, machine, manufacture, or composition of matter; in 161 as any distinct or new variety of plant; and in 171 as any new, original, and ornamental design for an article of manufacture. This chapter will generally focus on inventions under Section 101, the so-called utility patents, even though much of the material also applies to plant and design patents.

Alternatively, a defendant can also claim that a patent is invalid by showing that it does not meet the requirements of Section 112 or Section 251 of the title. Section 112 sets forth the contents of the specification and the requirements for the patent claim. Section 251 sets out the conditions for reissue of a patent and states (with one exception immaterial to this chapter) that the “provisions of this title relating to applications for patent shall be applicable to applications for reissue of a patent.” The effect of a reissue, however, which is also specified in 251, is not within the scope of this chapter.

The defenses of unenforceability, fraud, laches, and estoppel consider the conduct of the patentee during the procurement or enforcement of the patent. A defendant can prove that a patent is unenforceable by demonstrating that the patentee engaged in inequitable conduct while procuring the patent. Fraud, however, can include actions of the patentee either while procuring or enforcing the patent and is a threshold element for certain antitrust counterclaims. Finally, the equitable defenses of laches and estoppel preclude liability partially or completely as a result of the conduct of the patentee. These latter two defenses, however, also consider the conduct of the accused infringer.

This chapter will explain these defenses and discuss how they can be used to resolve the litigation in an efficient and effective manner.

II. NONINFRINGEMENT

A. Infringement

Actions that give rise to infringement are set forth in 35 U.S.C. §271. A patent is infringed when someone, 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.³ This conduct has been called direct infringement, because it is the accused infringer who is making, using, or selling the patented invention.⁴

²FED. R. CIV. P. 8(c).

³35 U.S.C. §271(a).

⁴*Hilton Davis Chem. Co. v. Warner-Jenkinson Co.*, 62 F.3d 1512, 1527, 35 USPQ2d 1641, 1652–53 (Fed. Cir. 1995) (en banc), *rev’d & remanded*, 520 U.S. 17, 41 USPQ2d 1865 (1997).

One can also commit infringement by actively inducing, or contributing to, infringement of a patent.⁵ Here, the accused infringer is not actually practicing the claimed invention but, rather, is engaged in conduct that is somehow connected with a direct infringement by another. Contributing to or inducing infringement cannot occur unless there is direct infringement by another.⁶

To establish active inducement of infringement, the patent owner must prove that the seller had the specific intent to encourage another to infringe the patent.⁷ A case, therefore, can be brought to resolution quickly if it is shown that the party accused of inducing infringement had no specific intent to encourage an infringing use.

To prove contributory infringement under 271(c), the patent owner must show the following elements: (1) the seller sold a product for use in practicing the claimed invention; (2) the use of the product constituted a material part of the invention; and (3) the seller knew that the product was especially made or adapted for use in infringing the method claim.⁸ One form of activity, however, is exempt from contributory infringement. If the product is a staple article or commodity of commerce suitable for substantial noninfringing uses, then there can be no contributory infringement.⁹ Thus, if the defendant finds itself accused of infringing by supplying a product to another, it should investigate whether the product is one which can be considered a staple article or commodity of commerce.

One can also infringe a patent by

- (1) filing an application for a pharmaceutical or veterinary composition under certain sections of the Federal Food, Drug, and Cosmetic Act or the Act of March 4, 1913;¹⁰
- (2) supplying or causing to be supplied 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 the United States in a manner that would infringe the patent if such combination occurred within the United States;¹¹ and
- (3) importing into the United States, or offering to sell, selling, or using within the United States, a product that is made by a process patented in the United States, if the importation, offer to sell, sale, or use of the product occurs during the term of the process patent.¹²

Infringement is determined by first construing the patent claims in light of the patent specification and prosecution history, and then applying the properly interpreted claims to the accused product or process.¹³ The terms in a patent

⁵35 U.S.C. §§271(b) and (c).

⁶*Kendall Co. v. Progressive Med. Tech., Inc.*, 85 F.3d 1570, 1573, 38 USPQ2d 1917, 1919 (Fed. Cir. 1996).

⁷*DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1305 (Fed. Cir. 2006).

⁸*Golden Blount, Inc. v. Robert H. Peterson Co.*, 365 F.3d 1054, 1061 (Fed. Cir. 2004).

⁹*Id.*

¹⁰35 U.S.C. §271(e).

¹¹*Id.* §271(f).

¹²*Id.* §271(g).

¹³*Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976, 34 USPQ2d 1321, 1326 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370, 38 USPQ2d 1461 (1996).

claim are given the interpretation that one having ordinary skill in the art would gather reading the claim term in light of the entire patent, including the specification.¹⁴ All sources of evidence should be considered in interpreting the meaning of a claim term including the claim, the specification, prosecution history, and extrinsic evidence regarding the meaning of technical terms.¹⁵ However, the specification is the single best guide to interpreting a claim term.¹⁶ The prosecution history also may limit the interpretation of the claim terms to exclude any interpretation disclaimed during prosecution.¹⁷

Thus, regardless of the statutory basis for infringement, an excellent opportunity for achieving an early resolution to a dispute is to seek a hearing before the court on the meaning of the claims. An understanding of what the claims cover may lead to the filing of motions for summary judgment early in the discovery phase or may possibly limit the scope of discovery. Unfortunately, because there is no nationwide standard for conducting a *Markman* hearing, the timing and format can vary widely. Some courts hold hearings early in discovery, while others hold hearings just prior to or during a trial. Still other courts may not make a *Markman* ruling until a party has sought summary judgment on infringement or invalidity. As to format, some courts may hold a hearing whereas others decide the issue of claim construction solely on written briefs. Whatever the case, the conduct of *Markman* hearings has been left to the urgings of the parties and, ultimately, the discretion of the court.

Properly construed patent claims may be infringed literally or by equivalents. To find literal infringement, every element of the claim in question must be found in the accused composition or method.¹⁸ Moreover, each limitation of a claim is material and essential.¹⁹ A patent claim may use the transitional term “comprising,” which means that the claim is open-ended and may encompass all the limitations following the term “comprising,” and for purposes of determining infringement, it does not exclude additional unrecited elements or method steps. For purposes of determining infringement, the word “containing” is also interpreted in an open-ended manner.²⁰

If literal infringement is not found, the trier of fact must also consider infringement under the doctrine of equivalents.²¹ The doctrine of equivalents applies if, and only if, a claimed element and an element of the accused product or process are equivalent. Moreover, 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.²²

¹⁴Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005).

¹⁵*Id.* at 1314.

¹⁶*Id.* at 1315.

¹⁷*Id.* at 1317.

¹⁸Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1217, 36 USPQ2d 1225, 1228 (Fed. Cir. 1995).

¹⁹*See, e.g.,* Hughes Aircraft Co. v. United States, 86 F.3d 1566, 1576, 39 USPQ2d 1065, 1072 (Fed. Cir. 1996), *overruled in part by* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 56 USPQ2d 1865 (Fed. Cir. 2000), *vacated*, 535 U.S. 722, 62 USPQ2d 1705 (2002).

²⁰Mars, Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1377 (Fed. Cir. 2004).

²¹Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 41 USPQ2d 1865, 1875 (1997); Pennwalt Corp. v. Durand-Wayland, Inc., 833 F.2d 931, 934–35, 4 USPQ2d 1737, 1739–40 (Fed. Cir. 1987).

²²*Warner-Jenkinson*, 520 U.S. at 29.

The test of equivalency may be worded in several ways, including: (1) whether the differences between the claimed element and accused products or processes are insubstantial, assessed according to an objective standard; and (2) whether an element of the accused product or process (a) performs substantially the same function (b) in substantially the same way (c) to achieve the same result as the element of the claimed apparatus or method.²³ In some cases, other factors may also be pertinent to determining infringement by equivalency, including the known interchangeability of claimed and accused elements.²⁴ However, with respect to any individual element of a claim, the doctrine of equivalents is not allowed such breadth as to effectively eliminate that element in its entirety.²⁵

For example, if application of the doctrine of equivalents has the effect of entirely vitiating a claim limitation, then a finding of infringement will be overturned.²⁶ In one instance, the district court found on summary judgment that an accused seat support member, which was fixed in place and rotatably mounted, met a limitation of “slidably mounted.” In reversing, the Federal Circuit held that such a finding completely vitiated the claim limitation that the support member be “slidably” mounted.²⁷ According to the panel, this is the precise type of overextension of the doctrine of equivalents that the claim vitiation doctrine is intended to protect.²⁸

Both prosecution history estoppel and the prior art may also limit the range of any available equivalence.²⁹ First, there is no infringement if the range of equivalence required to find infringement would encompass the prior art.³⁰ Second, a patentee cannot use the doctrine of equivalents to recapture subject matter relinquished during prosecution of the patent.³¹ Whenever prosecution history estoppel is invoked, an examination must be made of not only what was surrendered but also the reasons for the surrender.³²

The patentee must prove infringement by a preponderance of the evidence.³³ Thus, noninfringement is actually not a defense, even though it is listed in the statute as one. Indeed, the defendant will prevail on infringement even if it does not offer any evidence on noninfringement at trial as long as the patentee fails to meet its burden.

Nonetheless, it is helpful to the defendant to present its case to the jury by showing that no infringement occurred. Rather than merely denying the patentee’s evidence, the defendant should more persuasively present the reasons for developing its product or process. The accused infringer also earns credibility

²³*Id.* See also *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608, 85 USPQ 328, 330 (1950).

²⁴*Warner-Jenkinson*, 520 U.S. at 37.

²⁵*Id.*

²⁶*Freedman Seating Co. v. American Seating Co.*, 420 F.3d 1350, 1361 (Fed. Cir. 2005).

²⁷*Id.* at 1361–62.

²⁸*Id.* at 1362 (citing *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1160 (Fed. Cir. 1998)).

²⁹*Id.*

³⁰*Wilson Sporting Goods Co. v. David Geoffrey & Assocs.*, 904 F.2d 677, 684, 14 USPQ2d 1942, 1948 (Fed. Cir.), *cert. denied*, 498 U.S. 992 (1990), *overruled in part by* *Cardinal Chem. Co. v. Morton Int’l*, 508 U.S. 83 (1993).

³¹*Athletic Alternatives, Inc. v. Prince Mfg., Inc.*, 73 F.3d 1573, 1582, 37 USPQ2d 1365, 1373 (Fed. Cir. 1996).

³²*Warner-Jenkinson*, 520 U.S. at 33.

³³*Bene v. Jeantet*, 129 U.S. 683 (1889); *Wilson Sporting Goods*, 904 F.2d at 685, 14 USPQ2d at 1949.

when the judge and jury see that it established a legitimate reason for the accused infringing activity.

For example, a defendant is often accused of copying the plaintiff's patent or product. The accused infringer might explain its independent development of the product through engineers, scientists, and marketing and sales personnel. These witnesses will assist in explaining not only the origin of the product but also why the accused design is different from the patented invention.

Rarely is a charge of patent infringement defended only by denying infringement. More commonly, the accused infringer also asserts one or several of the many defenses of invalidity and unenforceability. These defenses, however, may be more difficult to establish because the burden of proof is higher than for infringement and is carried by the one asserting the defense.

Of course, if an infringement defendant admits that every limitation of a claim is present in the accused product, even a jury verdict of noninfringement will be overturned as a matter of law on the grounds that there is no basis for such a finding.³⁴ Particularly, this will occur, if the defendant agreed with, and did not appeal, the claim construction in the district court.³⁵

1. Section 271(e): Limited Safe Harbor

The Hatch-Waxman Act provides to generic manufacturers a defense to patent infringement via Section 271(e)(1). Congress enacted the Hatch-Waxman Act to address two hurdles to generic drug development resulting from the pre-market approval process required by the Federal Food Drug and Cosmetic Act: (1) the reduction of effective patent life caused by FDA-delayed market entry, and (2) the extension of patent life at the end of the patent term, also resulting from FDA premarket approval requirements.³⁶ Pre-Hatch-Waxman, a manufacturer's premarket activities, such as developing competitive products and obtaining FDA regulatory approval, constituted an act of patent infringement.³⁷

Section 271 (e)(1) states:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely 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.

This statute provides generic manufacturers with a "safe harbor" from claims of patent infringement based on FDA-approval related activities. Two terms of the statute have been further clarified by the courts, "reasonably related" and "patented invention."

In *Merck KGaA v. Integra Lifesciences I, Ltd.*, the Supreme Court vacated a decision by the Federal Circuit and expanded the safe harbor from liability for infringement of 35 U.S.C. §271(e)(1).³⁸ This section provides that there shall be no infringement of a U.S. patent if the alleged infringer uses the patented

³⁴*Callicrate v. Wadsworth Mfg., Inc.*, 427 F.3d 1361, 1372 (Fed. Cir. 2005).

³⁵*Id.*

³⁶*Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1260–61 (Fed. Cir. 2008).

³⁷*Id.* at 1261.

³⁸*Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372 (2005).

invention “solely for uses reasonably related to the development and submission of information” for the FDA. Integra owned several patents relating to RGD peptides, useful in promoting cell adhesion and at least theoretically an improvement in wound healing and the bio-compatibility of prosthetic devices, and in angiogenesis, the growth of new branches of blood vessels. A scientist at the Scripps Research Institute recognized that inhibiting angiogenesis could be very helpful in preventing the growth of tumors. Merck hired the scientist and Scripps to research and identify potential drug candidates that could inhibit angiogenesis.³⁹ Subsequent in vivo and in vitro experiments ultimately led to a candidate for clinical drug development.

Integra learned of the Merck research and sued for infringement. A jury found Merck liable for patent infringement and on appeal the Federal Circuit affirmed, finding only a limited safe harbor from infringement in Section 271(e) because the work was not clinical testing to supply information to the FDA, but only general biomedical research to identify new pharmaceutical compounds.⁴⁰ The Supreme Court vacated and remanded the case to the district court for further evidence. The Supreme Court agreed that the Section 271(e) safe harbor does not globally embrace all experimental activity that at some point, however attenuated, may lead to an FDA approval process. For instance, basic scientific research on a particular compound, performed without the intent to develop a particular drug or without a reasonable belief that the compound will have the desired physiological effect, is surely not “reasonably related to the development and submission of information” to the FDA.⁴¹

The Court, however, found that the Section 271(e) safe harbor did not necessarily exclude experimentation on drugs that are not ultimately the subject of a submission to the FDA or the use of a patented compound in experiments that are not ultimately submitted to the FDA.⁴² Scientific testing is conducted because drug makers do not know at the outset whether a promising candidate will work or not. It is only possible to know that a particular compound will be the subject of an eventual application to the FDA if the compound is identical to that in a drug that has already been approved.⁴³ A drug maker may have a reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a particular physiological effect. Under a properly construed Section 271(e), if the drug maker uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA, that use is “reasonably related” to the development and submission under Federal law.⁴⁴

a. “Reasonably Related”. After vacatur by the Supreme Court, the Federal Circuit applied the Supreme Court’s construction of Section 271(e) to the *Merck* facts.⁴⁵ The Federal Circuit explained that, under the Supreme Court’s construction, an experimental use is “reasonably related” to the development of a submission to the FDA where the biological process and physiological effect

³⁹*Id.* at 2377.

⁴⁰*Id.* at 2380.

⁴¹*Id.* at 2382.

⁴²*Id.*

⁴³*Id.* at 2383.

⁴⁴*Id.*

⁴⁵*Integra Lifesciences I, Ltd. v. Merck KGaA*, 496 F.3d 1334 (Fed. Cir. 2007).

of a compound have been identified and targeted for investigation.⁴⁶ Once the investigator has a reasonable basis to believe that a compound or class of related compounds will have a certain effect, the experiments necessary to determine the optimum candidate for commercial development are protected by the safe harbor, regardless of the content of any resulting FDA submission.⁴⁷ Applying this rule, the court held that the challenged experiments were reasonably related to research that, if successful, would have been appropriate for submission to the FDA, and therefore fell within the safe harbor.⁴⁸ The judgment of infringement was therefore reversed.⁴⁹

The Federal Circuit's broad interpretation of "reasonably related" does have limits. Section 271(e)(1) is limited to patented inventions that are themselves subject to the FDA premarket approval process.⁵⁰ The safe harbor does not immunize parties for the use in the premarket approval process of research tools and other laboratory equipment and devices not subject to FDA premarket approval.⁵¹

b. "Patented Invention". In *Eli Lilly & Co. v. Medtronic, Inc.*, the Supreme Court addressed the scope of "patented invention" in the context of a medical device case.⁵² The Court interpreted the phrase "patented invention" to encompass all products listed in Section 156, a complementary Hatch-Waxman provision.⁵³ Section 156 provides patent term extension to all products subject to regulatory delays caused by the FDA premarket approval process.⁵⁴ This interpretation extends the safe harbor beyond drug products to, among other things, food additives and medical devices.⁵⁵

In *Proveris Scientific Corp. v. Innovasystems, Inc.*, the Federal Circuit addressed the limits of the phrase "patented invention."⁵⁶ Proveris owned a patent directed to a system and apparatus for characterizing drug delivery aerosol sprays.⁵⁷ Innova manufactured and sold a device that was used to measure spray plume characteristics for compliance with FDA standards.⁵⁸ The device, though used exclusively in connection with FDA regulatory submissions, was not subject to FDA approval.⁵⁹ Proveris filed suit against Innova alleging infringement of its patent direct to drug delivery aerosol sprays. Innova raised the Section 271(e)(1) defense, arguing that the safe harbor immunized its activities because third parties used its device solely for the development and submission of information to the FDA.⁶⁰ The Federal Circuit held Section 271(e)(1) inapplicable because (1) Proveris's patent product was not eligible for Section 156(f) patent term extension, therefore it was not a "patented product" for the purposes of that Section

⁴⁶*Id.* at 1339.

⁴⁷*Id.* at 1340.

⁴⁸*Id.* at 1348.

⁴⁹*Id.*

⁵⁰*Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1265 (Fed. Cir. 2008).

⁵¹*Id.*

⁵²496 U.S. 661 (1990).

⁵³*Id.* at 672.

⁵⁴35 U.S.C. §156(f)(1)(B).

⁵⁵*Id.*

⁵⁶536 F.3d 1256 (Fed. Cir. 2008).

⁵⁷*Id.* at 1258.

⁵⁸*Id.* at 1264.

⁵⁹*Id.* at 1265.

⁶⁰*Id.* at 1266.

and (2) Innova's device was not subject to a required FDCA approval process and did not need safe harbor protection.⁶¹

2. *Section 271(f): Acts Within the United States*

Patents are territorial, effective only in the country in which they are issued and having no extraterritorial effect. Several recent cases show the limits of enforcement of U.S. patents. Pellegrini sued Analog Devices for infringing his patent for brushless motor drive circuits.⁶² It was undisputed that the circuits were manufactured exclusively outside the United States and that almost all the circuits were sold and shipped to customers outside the United States (except for a few that were imported into the United States for testing purposes).⁶³ The patentee alleged infringement on the grounds that the circuits were designed within the United States and that instructions for their manufacture and disposition were transmitted from within the United States, and that this violated Section 271(f)(1), which states:

Whoever without authority supplies or causes to be supplied 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 a manner as to actively induce the combination of such components outside the United States in a manner that would infringe the patent if such combination occurred within the United States shall be liable as an infringer.⁶⁴

The district court granted summary judgment of noninfringement on the grounds that U.S. patent laws do not have extraterritorial effect.⁶⁵ Pellegrini appealed to the Federal Circuit, arguing that Analog Devices was wholly based in the United States and that many of its actions concerning the allegedly infringing circuits took place in the United States, including conception and design. He also argued that Analog Design employees in the United States were responsible for fabrication, assembly, testing, subcontracting, selling, setting production levels, and receiving payment for the circuits.⁶⁶ Pellegrini pointed out that Analog exported the circuits from the United States, as indicated by Analog's commercial invoices. The Federal Circuit affirmed noninfringement, holding that Section 271(f)(1) applies only where components of a patented invention were physically present in the United States and then exported outside the United States in such a manner as to infringe a patent; the words "supplies or causes to be supplied" refer to physical supply of components, not to instructions or corporate oversight.⁶⁷ Infringement took place wholly outside the United States and thus did not infringe a U.S. patent.

In another case, the decision on infringement also turned on whether infringement occurred outside the U.S. or within the U.S., and on whether the alleged infringement concerned system claims or method claims. NTP sued Research In Motion (RIM) for patent infringement on the grounds that RIM's BlackBerry™

⁶¹*Id.* at 1265–66.

⁶²*Pellegrini v. Analog Devices, Inc.*, 375 F.3d 1113, 1114 (Fed. Cir. 2004).

⁶³*Id.*

⁶⁴*Id.* at 1115–16.

⁶⁵*Id.* at 1115.

⁶⁶*Id.* at 1116.

⁶⁷*Id.* at 1117–18.

system infringed NTP patents for a wireless e-mail system.⁶⁸ It was undisputed that an essential part of RIM's e-mail system was a BlackBerry relay which was located in Canada, and RIM argued, therefore, that there was no infringement under §271(a), which requires that infringement occur within the U.S.⁶⁹ The district court found infringement of both system and method claims.⁷⁰

On appeal, RIM argued that for infringement, the entire accused system and method must be contained or conducted within the territorial bounds of the U.S.⁷¹ The Federal Circuit noted that in *Deepsouth Packing Co. v. Laitram Corp.*, the infringement took place wholly outside the U.S., while the present case involves a system that is partly within and partly outside the U.S. and involves acts that may be occurring within or outside the U.S.⁷² The court held that when users manipulate their BlackBerry handheld units in the U.S., the location of the use of the communication system as a whole occurs in the U.S., with a resulting infringement of system claims under Section 271(a).⁷³ The Federal Circuit, however, found no infringement of the method claims because at least one step of each claim took place in Canada, the location of the relay.⁷⁴

NTP argued that RIM also infringed its patents under Section 271(f) because RIM supplied components for use in the U.S. The Federal Circuit reviewed *Deepsouth Packing Co. v. Laitram Corp.* and other precedential cases, including *Eolas Techs., Inc. v. Microsoft Corp.*, and concluded that Section 271(f) could apply to both system and method claims.⁷⁵ In the present case, infringement of the system claims was found under Section 271(a), so the court considered only method claims under Section 271(f). As noted, the method claims were not infringed because at least one step of the method of using BlackBerry handhelds took place in Canada. The court found no infringement of the method claims under Section 271(f) because RIM's handheld devices could not be the supply of "component" steps for combining into NTP's patented methods.⁷⁶

In a recent Supreme Court case, the Court held that software code is not a "component" amenable to a "combination" for purposes of Section 271(f).⁷⁷ Furthermore, foreign-made copies of components supplied from the United States do not trigger Section 271(f) liability.⁷⁸ AT&T sued Microsoft for infringement of a patent used to digitally encode and compress recorded speech.⁷⁹ Microsoft conceded that its Windows operating system, when installed on a computer in the United States, has the potential to infringe AT&T's patent directly and by inducement.⁸⁰ Microsoft denied liability for transmitting master

⁶⁸NTP, Inc. v. Research in Motion, Ltd., 418 F.3d 1282 (Fed. Cir. 2005).

⁶⁹*Id.* at 1289–90, 1313.

⁷⁰*Id.* at 1314.

⁷¹*Id.*

⁷²*Id.* at 1315.

⁷³*Id.* at 1314.

⁷⁴*Id.* at 1318.

⁷⁵*Id.* at 1322, *citing* *Deepsouth Packing Co. v. Laitram Corp.* 406 U.S. 518 (1972) and *Eolas Techs., Inc. v. Microsoft Corp.*, 399 F.3d 1325, 1338–41 (Fed. Cir. 2005).

⁷⁶*Id.* at 1322, *citing* *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 953 F.2d 1360, 1374 (Fed. Cir. 1991) (holding that the sale in the U.S. of an apparatus for carrying out a claimed process did not infringe the process claim under §271(f) where the customer practiced the process abroad).

⁷⁷*Microsoft Corp. v. AT&T Corp.*, 127 S. Ct. 1746 (2007).

⁷⁸*Id.* at 1748.

⁷⁹*Id.*

⁸⁰*Id.* at 1753.

disks and electronic transmission of Windows to foreign manufacturers.⁸¹ The district court held Microsoft liable for contributory infringement under Section 271(f).⁸² The Court of Appeals for the Federal Circuit affirmed.

On appeal, Microsoft argued that unincorporated software is intangible information that cannot be a “component” under Section 271(f) and that the foreign-generated copies of Windows that were installed on computers abroad were not “supplie[d] . . . from the United States.”⁸³ Microsoft sends foreign manufacturers copies of Windows either by master disk or electronic transmission.⁸⁴ The foreign manufacturer uses the master disk or transmission to generate copies of Windows.⁸⁵ Those copies, not the master version sent by Microsoft, are installed onto computers abroad, which are then sold abroad.⁸⁶

The Supreme Court defined two issues: (1) When, or in what form does software qualify as a “component” under Section 271(f), and (2) were “components” of the foreign-made computers involved in this case “supplied” by Microsoft from the United States.⁸⁷ The Court answered both questions in the negative.

Considering the first question, the Court recited that software is “a set of instructions, known as code, which directs a computer to perform specified functions or operations.”⁸⁸ The Court agreed with Microsoft that software code is intangible and therefore does not fit Section 271(f)’s concept of a “component” that is amenable to “combination.”⁸⁹

Similarly, copies of Windows, rather than the Microsoft-supplied master disks, were the medium actually installed on the computers.⁹⁰ Those copies were made abroad and therefore were not “supplied” from the United States.⁹¹ Section 271(f) attaches liability for combining the very components supplied from the United States, not copies of the components.⁹² Therefore, Microsoft was not liable under Section 271(f) for supplying Windows to be copied and installed on computers abroad.⁹³

Drawing on the Supreme Court’s holding in *Microsoft*, which the Federal Circuit framed as “sending a clear message that the territorial limits of patents should not be lightly breached,” the Federal Circuit revisited en banc the issue of whether Section 271(f) applies to method claims.⁹⁴ In *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, the en banc court overruled the panel decision in *Union Carbide Chemicals & Plastics Technology Corp. v. Shell Oil Co.*,⁹⁵ and

⁸¹*Id.*

⁸²*Id.*

⁸³*Id.* at 1748.

⁸⁴*Id.*

⁸⁵*Id.*

⁸⁶*Id.*

⁸⁷*Id.* at 1753–54.

⁸⁸*Id.* at 1754 (citing *Fantasy Sports Props., Inc. v. Sportsline.com, Inc.*, 287 F.3d 1108, 1118 (Fed. Cir. 2002)).

⁸⁹*Id.* at 1755.

⁹⁰*Id.*

⁹¹*Id.*

⁹²*Id.* at 1757.

⁹³*Id.*

⁹⁴*Union Carbide Chemicals & Plastics Technology Corp. v. Shell Oil Co.*, 425 F.3d 1366, 1361 (Fed. Cir. 2005).

⁹⁵425 F.3d 1366 (Fed. Cir. 2005).

held that Section 271(f) does not cover method claims.⁹⁶ The Federal Circuit extended its holding to overrule “any implication in *Eolas* or other decisions that Section 271(f) applies to method patents.”⁹⁷

3. Section 271(g): Defense Not Available in Section 1337 (ITC) Actions

A defense against patent infringers is available under the Tariff Act, known generally as a Section 1337 action. A patentee may file a complaint with the United States International Trade Commission (ITC) against one who imports an infringing article into the United States. In *Kinik Co. v. International Trade Commission*,⁹⁸ 3M brought such a complaint against Kinik, alleging that Kinik was importing certain abrasives. Kinik asserted a defense under the Patent Act, 35 U.S.C. §271(g). Part of this section provides that if one imports into the United States a product made by a patented process, a product which is made by a patented process will, for purposes of this title, not be considered to be so made after it is materially changed by a subsequent process or it becomes a trivial and nonessential component of another product.⁹⁹ Kinik asserted that even if it did infringe the 3M patent, the product of these steps was materially changed by subsequent processes and thus an affirmative defense was available under Section 271(g).¹⁰⁰

The ITC held that this defense does not apply to a proceeding under Section 1337 and found infringement. The ITC cited the Process Patents Amendments Act of 1988, which added the new Section 271(g) defense. The Act stated that the new defenses shall not deprive a patent owner of any remedies available under Section 1337 of the Tariff Act and under any other provision of law.¹⁰¹ This clause was inserted in order to prevent conflict between the Tariff Act and the Patent Act. Section 271(g) was enacted as part of the Omnibus Trade and Competitiveness Act of 1988 and was intended to provide rights for patent owners to sue for damages and to seek an injunction when someone imports into the United States a product made by their patented process.¹⁰² Accordingly, defenses under Section 271(g) are not available in actions under Section 1337 before the ITC. On appeal to the Federal Circuit, the ruling that the defense was not available in Section 271(g) actions was affirmed, but the judgment of infringement was reversed. In another recent case, the Federal Circuit affirmed that an array of defenses to infringement are available to 1337 defendants, including invalidity defenses.¹⁰³

4. Section 271(b): Inducement of Infringement

“Whoever actively induces infringement of a patent shall be liable as an infringer.”¹⁰⁴ The Federal Circuit addressed inducement in *Cross Medical*

⁹⁶*Union Carbide Chemicals & Plastics Technology Corp. v. Shell Oil Co.*, 425 F.3d 1348, 1365 (Fed. Cir. 2009).

⁹⁷*Id.*

⁹⁸362 F.3d 1359 (Fed. Cir. 2004).

⁹⁹*Id.* at 1361–62 (citing 35 U.S.C. §271(g)(1) and (g)(2)).

¹⁰⁰*Id.* at 1361.

¹⁰¹*Id.* at 1362 (citing Pub. L. No. 100-418, §90006(c)).

¹⁰²*Id.*

¹⁰³*Vastfame Camera, Inc., v. International Trade Comm’n*, 386 F.3d 1108, 1115 (Fed. Cir. 2004).

¹⁰⁴35 U.S.C. §271(b).

*Products, Inc. v. Medtronic Sofamor Danek, Inc.*¹⁰⁵ Cross sued Medtronic for direct and indirect infringement of a patent for an orthopedic surgical implant. The apparatus claim at issue contained a limitation that was construed to require a lower bone interface operatively joined to a bone segment such that the device could perform posterior stabilization when the interface and the bone segment were connected and in contact.¹⁰⁶ The district court granted partial summary judgment for validity and infringement.

On appeal, the Federal Circuit noted that to prove that a party induces infringement, there must be proof of direct infringement, that the alleged infringer knowingly induced infringement, and that the alleged infringer possessed a specific intent to encourage another's infringement.¹⁰⁷ Medtronic provided representatives to accompany surgeons in the operating room and illustrate the assembly of the Medtronic product.¹⁰⁸ The representatives appeared in the operating room and identified instruments used by the surgeons.¹⁰⁹ Cross Medical argued that, by being present and participating in the use of the accused device, Medtronic was a direct infringer.¹¹⁰ The court found that Medtronic's representatives did appear in the operating room and identified instruments used by the surgeons. However, the court found that Medtronic's kit did not directly infringe because the anchor seat did not contact bone until the surgeon implanted the anchor seat. Therefore, Medtronic was not a direct infringer.¹¹¹

B. Limits on Infringement

1. Claim Interpretation and Correction of Errors

In *Chef America, Inc. v. Lamb-Weston, Inc.*,¹¹² Chef America sued Lamb-Weston for infringement of its patent for baking dough products. The two independent claims of the patent included a step of heating batter-covered dough to a temperature in the range of about 400°F to about 850°F for a period of time. The district court construed the claims as requiring heating the dough, not the oven, to the prescribed temperatures and granted Lamb-Weston's motion for summary judgment of noninfringement, on the grounds that Lamb-Weston did not heat its dough products to the temperature range specified.¹¹³ The court noted that nothing in the patent or the prosecution history suggested that the temperature referred to was anything other than the dough temperature, and that courts were not permitted to rewrite the claims. On appeal, Chef America pointed out that at such temperatures, the dough would be burned to a crisp, instead of having the desired light, flaky, crispy texture, which was intended by the patented process.¹¹⁴ The claims as written, however, unambiguously required that the dough, not the

¹⁰⁵424 F.3d 1293 (Fed. Cir. 2005).

¹⁰⁶*Id.* at 1306.

¹⁰⁷*Id.* at 1312 (citing *MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp.*, 420 F.3d 1369, 1378 (Fed. Cir. 2005)).

¹⁰⁸*Id.* at 1311.

¹⁰⁹*Id.*

¹¹⁰*Id.*

¹¹¹*Id.* at 1311–12.

¹¹²358 F.3d 1371 (Fed. Cir. 2004).

¹¹³*Id.* at 1372, 1373.

¹¹⁴*Id.* at 1373.

oven, be heated to a temperature range of 400°F to about 850°F. The Federal Circuit noted that courts have repeatedly and consistently recognized that they may not redraft claims, whether to make them operable or to sustain their validity. In accord with settled practice, claims are construed as they are written, not as patentees wish they had written them.¹¹⁵

The Federal Circuit distinguished *Chef America, Inc.* in *Ecolab v. FMC Corp.*¹¹⁶ In that case, the issue was, in a claim for directed to a “method for sanitizing fowl,” the definition of the term “sanitize.”¹¹⁷

*Novo Industries L.P. v. Micro Molds Corp.*¹¹⁸ is another case that hinged on whether a district court could correct an error in a claim. The patent issued with the phrase “stop means formed on a rotatable with said support finger,” rather than the intended phrase “stop means formed on *and* rotatable with said support finger.”¹¹⁹ The district court allowed the correction and a jury found infringement. The Federal Circuit reversed, noting that Congress did not intend for district courts to correct any and all errors that the Patent and Trademark Office (PTO) would be authorized to correct under 35 U.S.C. §§254 and 255.¹²⁰ Courts can correct a patent if only (1) the correction is not subject to reasonable debate based on consideration of the claim language and the specification; and (2) the prosecution history does not suggest a different interpretation of the claims.¹²¹ Furthermore, facially obvious clerical errors by the USPTO which are not contradicted by the prosecution history of a patent can be corrected by a court.¹²²

In *Alloc, Inc. v. International Trade Commission*,¹²³ Alloc, owner of a patent for flooring products, filed a complaint with the ITC alleging that Pergo was importing and selling flooring materials, infringing the patent and in violation of 19 U.S.C. §1337 (Section 337 of the trade laws). The ITC conducted a hearing to construe the claims of the patent and compare them with the allegedly infringing articles. In construing the claims, the administrative law judge held that the claims included a space or “play” between a locking groove on a first panel and the locking element of a panel adjacent to the first panel. The judge also construed the claim terms “locking means,” “locking element,” and “locking member” in view of 35 U.S.C. §112, ¶6, to have structures requiring play.¹²⁴ With this construction, the imported products did not literally infringe, and the initial determination was that there was no violation of Section 337.

Alloc and the investigative staff of the ITC filed petitions for review, but the final determination agreed with the initial determination of no infringement. Alloc then appealed to the Federal Circuit. The court studied the specification, which taught that play was important in assembly of the panels and also criticized prior art floor systems without play.¹²⁵ In addition, the court studied the Patent

¹¹⁵*Id.* at 1374.

¹¹⁶569 F.3d 1335 (Fed. Cir. 2009).

¹¹⁷*Id.* at 1344.

¹¹⁸350 F.3d 1348 (Fed. Cir. 2003).

¹¹⁹*Id.* at 1352 (emphasis added).

¹²⁰*Id.* at 1356.

¹²¹*Id.* at 1357.

¹²²*Mobile Hi Tech Wheels v. CIA Wheel Group*, 514 F. Supp. 2d 1172, 1181 (C.D. Cal. 2007).

¹²³342 F.3d 1361 (Fed. Cir. 2003).

¹²⁴*Id.* at 1367.

¹²⁵*Id.* at 1369.

Cooperation Treaty (PCT) priority application for the U.S. patent, noting that the claims of the PCT application included a limitation of play. The court also noted that the International Preliminary Examination Report (IPER) stated that none of the documents in the IPER described a system “where a play exists between the locking groove (14) and the locking element (8), where the connection allows mutual displacement of the panels.”¹²⁶

During prosecution of the patent, Alloc had emphasized that play is “important” because it enables displacement and disassembly of connected panels.¹²⁷ The examiner allowed the claims of the patent because the prior art of record did not show paneling in which the panels were interconnected so as to allow displacement of the panels in a direction toward a joint to allow the panels to be disassembled.¹²⁸ The Federal Circuit held that the patentee had disavowed systems without play during prosecution of the patent and had emphasized the importance of play in the specification. Thus, the claims were interpreted to require play.¹²⁹ The court also noted factual similarity to another case in which a claim was interpreted to include a limitation from the specification because of the manner in which the product was described in the specification.¹³⁰

In construing claims, intrinsic evidence—that is, evidence already in the record of a patent—is preferred over extrinsic evidence. Intrinsic evidence includes the patent itself, its file history, the claims, the specification, and the drawings. All evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises, is considered extrinsic evidence.¹³¹ Extrinsic evidence may not be used to contradict the meaning of a claim term that has an unambiguous meaning in light of the intrinsic evidence.¹³²

Playtex sued Procter & Gamble for infringing its patent for a tampon applicator, which included a tubular barrel comprising two diametrically opposed, substantially flattened surfaces. The term “substantially flattened surfaces” was not specifically defined, but during prosecution, Playtex distinguished its claimed surfaces from the cylindrical surfaces of the prior art.¹³³ During trial, the court acknowledged that the plain and ordinary meaning of the term “substantially flattened surfaces” was “two opposing surfaces with a curvature less than either the barrel or the transitional portion of the prior art.” However, the court reasoned that this interpretation excluded the preferred embodiment, in which the thumb and finger holding surfaces were flat.

A claim construction that excludes the preferred embodiment is rarely, if ever, correct, and the court thus found that the term “substantially flattened surfaces” was ambiguous.¹³⁴ The court therefore accepted an expert witness’s

¹²⁶*Id.* at 1371.

¹²⁷*Id.*

¹²⁸*Id.*

¹²⁹*Id.* at 1372, 1373.

¹³⁰*Id.* at 1370 (citing *SciMed Life Sys., Inc., v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1345 (Fed. Cir. 2001)).

¹³¹*Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff’d*, 517 U.S. 370 (1996).

¹³²*Playtex Prods., Inc., v. Procter & Gamble Distrib. Co.*, 400 F.3d, 901, 908–09 (Fed. Cir. 2005).

¹³³*Id.* at 903.

¹³⁴*Id.* at 904 (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996)).

determination that the device should have two surfaces that were flat within a manufacturing tolerance. Since the finger grip area of the accused applicator was elliptical, the court found that it could not fall within a manufacturing tolerance for flatness, and granted summary judgment of noninfringement.¹³⁵

On appeal, the Federal Circuit vacated and remanded. The plain language of the claim “substantially flattened” did not require a flat surface, or one within a manufacturing tolerance. The term “substantial” was a meaningful modifier implying “approximate” rather than perfect.¹³⁶ Neither the specification nor the drawings, intrinsic evidence, required the opposed surfaces to be flat rather than substantially flattened. The claim term was a comparative term, requiring that the surfaces be flattened in comparison with the only antecedent basis in the claim, the tubular barrel. The claim was therefore for something flatter than a tubular barrel, but not necessarily flat.¹³⁷ Extrinsic evidence, such as an expert witness, cannot be used to contradict the unambiguous meaning of a claim term.¹³⁸ Expert testimony can be helpful in interpreting a claim term, especially when the intrinsic evidence is unclear.¹³⁹ However, extrinsic evidence is always given less weight than intrinsic evidence.¹⁴⁰

2. Prosecution History Estoppel

The Supreme Court, emphasizing the importance of continuity and consistency in the law, overruled the Federal Circuit in a long-awaited case concerning the doctrine of equivalents.¹⁴¹ *Festo* sued Shoketsu Kinzoku Kogyo Kabushiki for infringing two patents, and the defendants appealed from a summary judgment of infringement of one patent and from a jury verdict of infringement on a second patent. After several rounds of appeals, the Federal Circuit issued an en banc ruling reversing the district court’s judgment of infringement under the doctrine of equivalents.¹⁴² The Supreme Court subsequently granted certiorari. The en banc decision of the Federal Circuit was that prosecution history estoppel arises from any amendment that narrows a claim to comply with the Patent Act, not merely from amendments made to avoid the prior art.¹⁴³ Previous decisions from the Federal Circuit had held that prosecution history estoppel constituted a flexible bar, foreclosing some but not all claims of equivalence. The en banc decision, however, held that when estoppel applies, it stands as a complete bar against any claims of equivalence for the element that was amended.¹⁴⁴ The Supreme Court vacated the Federal Circuit decision.

¹³⁵*Id.* at 905.

¹³⁶*Id.* at 907.

¹³⁷*Id.* at 908–09.

¹³⁸*Id.* at 908. *See also* On-Line Techs., Inc., v. Bodenseewerk Perkin-Elmer GmbH, 386 F.3d 1133, 1140 (Fed. Cir. 2004) (vacating a district court’s finding of noninfringement based on the use of extrinsic evidence to improperly interpret a claim in which the preferred embodiment was excluded).

¹³⁹*Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1382 (Fed. Cir. 2008).

¹⁴⁰*Kara Tech. Inc. v. Stamps.com Inc.*, 582 F.3d 1341, 1348 (Fed. Cir. 2009).

¹⁴¹*Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 62 USPQ2d 1705 (2002) (*Festo VIII*).

¹⁴²*Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558, 56 USPQ2d 1865 (2000) (en banc), *overruled*, 535 U.S. 722, 62 USPQ2d 1705 (2002) (*Festo VIII*).

¹⁴³*Festo VIII*, 535 U.S. at 729–30, 62 USPQ2d at 1709.

¹⁴⁴*Id.* at 730, 62 USPQ2d at 1709.

The Court ruled that prosecution history estoppel requires that the claims of a patent be interpreted in light of the proceedings in the PTO during the application process. The doctrine of equivalents allows the patentee to claim those insubstantial alterations that were not captured in drafting the original patent claim but could be created through trivial changes.¹⁴⁵ Prosecution history estoppel ensures that the doctrine of equivalents remains tied to its underlying purpose. Where the original application once embraced the purported equivalent, but the patentee narrowed the claim to obtain a patent or to protect its validity, the patentee cannot assert that he or she lacked the words to describe the subject matter in question. In such a case, the prosecution history establishes that the inventor focused on the subject matter in question, knew the words for the broader and narrower claim, and affirmatively chose the latter.¹⁴⁶

A narrowing amendment made to satisfy any requirement of the Patent Act may give rise to an estoppel. A patentee who narrows a claim as a condition for obtaining a patent disavows a claim to the broader subject matter, whether the amendment was made to avoid the prior art or to comply with Section 112.¹⁴⁷ However, there is no reason why a narrow amendment should be deemed to relinquish equivalents unforeseeable at the time of the amendment and beyond a fair interpretation of what was surrendered. Nor is there any call to foreclose claims of equivalents for aspects of the invention that have only a peripheral relation to the reason the amendment was submitted.¹⁴⁸

The doctrine of equivalents and prosecution history are established law, and a balance between them is struck by requiring a patentee to show that an amendment was not for purposes of patentability: where no explanation is established, the court should presume that the patent application had a substantial reason related to patentability for including the limiting element added by amendment. In those circumstances, prosecution history estoppel would bar the application of the doctrine of equivalents as to that element.¹⁴⁹ *Warner-Jenkinson* held that the patentee bears the burden of proving that an amendment was not made for a reason that would give rise to estoppel; the Court held in *Festo* that the patentee should also bear the burden of showing that the amendment does not surrender the particular equivalent in question. If a court is unable to determine the purpose underlying a narrowing amendment, and hence a rationale for limiting the estoppel to the surrender of particular equivalents, the court should not presume a complete bar, but rather a surrender of all subject matter between the broader and the narrow language.¹⁵⁰

After reversal by the Supreme Court for several points relating to the range of equivalents available when a claim has been narrowed, the Federal Circuit remanded this case to the district court of Massachusetts. In *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*,¹⁵¹ the Federal Circuit discussed application of the doctrine of equivalents to claims in which there has been a narrowing

¹⁴⁵*Id.* at 733, 62 USPQ2d at 1710–11.

¹⁴⁶*Id.* at 734–35, 62 USPQ2d at 1711.

¹⁴⁷*Id.* at 737, 62 USPQ2d at 1712.

¹⁴⁸*Id.* at 738, 62 USPQ2d at 1712.

¹⁴⁹*Id.* at 739–40, 62 USPQ2d at 1713 (citing *Warner-Jenkinson v. Hilton-Davis Chem. Co.*, 520 U.S. 17, 33, 41 USPQ2d 1865, 1873 (1997)).

¹⁵⁰*Id.* at 740, 62 USPQ2d at 1713.

¹⁵¹344 F.3d 1359 (Fed. Cir. 2003) (en banc) (*Festo IX*).

amendment. The threshold requirement is that a narrowing amendment that is made to comply with any provision of the Patent Act is subject to prosecution history estoppel.¹⁵² Also undisturbed is the holding that “voluntary” amendments may give rise to estoppel. If the reason for a narrowing amendment is not given, there is a presumption that the amendment was made for a reason substantially related to patentability.¹⁵³ When the court is unable to determine the purpose of a narrowing amendment, and thus a rationale for limiting the estoppel to the surrender of a particular equivalent, the court should presume that the patentee surrendered all subject matter between the broader and narrower language.¹⁵⁴ A patentee may now rebut the presumption that an unexplained amendment surrendered all equivalents, i.e., the entire territory between the original and the amended claim limitations.

The court then outlined the three ways in which the presumption of surrender may be rebutted. One way is by showing that a particular equivalent may have been unforeseeable at the time of the amendment, in which case the equivalent is beyond a fair interpretation of what was surrendered.¹⁵⁵ If the alleged equivalent was known at the time of the amendment, it certainly should have been foreseeable at the time of the amendment.¹⁵⁶ A second rebuttal may arise if the patentee can demonstrate that the rationale underlying the narrowing amendment bore no more than a tangential relation to the equivalent in question.¹⁵⁷ The question may be posed as to whether the amendment was merely peripheral or directly relevant to the alleged equivalent. An amendment made to avoid prior art that contains the equivalent is not tangential but is central to the allowance of the claim. A third rebuttal may arise if a patentee can establish some other reason suggesting that the patentee could not reasonably have been expected to have described the insubstantial substitute in question.¹⁵⁸ Examples may be the shortcomings of language which prevented the patentee from describing the alleged equivalent when it narrowed the claim. Determination of this third rebuttal criterion should be limited to the prosecution history record. For example, if the alleged equivalent is in the prior art, there can be no reason the patentee could not have described the equivalent in question, and he may not rely on the third rebuttal criterion. The court also noted that this decision applies to all granted patents and to all pending litigation that has not been concluded with a final judgment, including appeals.¹⁵⁹

In *Glaxo Wellcome, Inc. v. Impax Laboratories, Inc.*,¹⁶⁰ Glaxo Wellcome developed a time-release formula for an antidepressant, bupropion hydrochloride, and patented the formula. The key to the time-release feature was the addition of hydroxypropyl methylcellulose (HPMC), which transforms into a gel that swells upon ingestion. During prosecution of the patent, Glaxo submitted

¹⁵²*Id.* at 1366.

¹⁵³*Id.* (citing *Warner-Jenkinson*, 520 U.S. at 33).

¹⁵⁴*Id.* at 1367 (citing *Festo VIII*, 535 U.S. at 740).

¹⁵⁵*Id.* at 1369 (citing *Festo VIII*, 535 U.S. at 738).

¹⁵⁶*Id.* (citing *Pioneer Magnetics, Inc. v. Micro Linear Corp.*, 330 F.3d 1352, 1357 (Fed. Cir. 2003) (issued before *Festo IX*)).

¹⁵⁷*Id.*

¹⁵⁸*Id.* at 1370.

¹⁵⁹*Id.* at 1370 & n.4.

¹⁶⁰356 F.3d 1348 (Fed. Cir. 2004).

claims that did not recite HPMC. When some claims were rejected for lack of enablement under 35 U.S.C. §112, ¶1, the claims, but not claim 1, which originally recited HPMC, were amended to add the HPMC limitation. Impax later prepared two Abbreviated New Drug Applications (ANDAs) for the FDA, for products corresponding to Glaxo's. The ANDAs certified that Impax's products did not infringe the Glaxo patent because they used hydroxylpropyl cellulose (HPC), another gel-forming compound. Glaxo sued for infringement and for a preliminary injunction.¹⁶¹

Impax moved for summary judgment of noninfringement on the grounds that HPC did not infringe the patent because of prosecution history estoppel. The district court granted the summary judgment on the grounds that the amendments narrowed the patent and that the use of HPC did not infringe the patents via the doctrine of equivalents.¹⁶² On appeal, Glaxo argued that Claim 1, filed with the HPMC limitation, had not been amended, and that HPMC and HPC were equivalents. The court noted, in a section entitled "Infectious Estoppel," that subject matter surrendered via claim amendments during prosecution is also relinquished for other claims containing the same limitation.¹⁶³ This rule ensures consistent interpretation of the same claim terms in the same patent. Thus, even though Claim 1 was not amended to add the HPMC limitation, it must receive the same treatment as the amended claims, i.e., a very limited range of equivalents, such as those unforeseeable at the time of the application.¹⁶⁴

The Federal Circuit noted that HPMC was the only release mechanism in the specification and that Glaxo could not have added other release mechanisms without violating the new-matter prohibition.¹⁶⁵ While HPC was known at the time as a sustained-release compound, Glaxo did not add it to the application or to the claims, and thus could not claim that HPC was an equivalent to HPMC under the Supreme Court's *Festo VIII* decision.¹⁶⁶ The Federal Circuit also cited *Festo IX*, subsequent to the Supreme Court's decision, concerning the foreseeability of equivalents: "[I]f the alleged equivalent were known in the prior art, it certainly should have been foreseeable at the time of the amendment."¹⁶⁷ In other words, if the equivalents were foreseeable, they should have been written into the claim. The district court observed, and the Federal Circuit agreed, that "anyone skilled in the art would have known that HPC and HPMC were substantially equivalent."¹⁶⁸ Thus, Glaxo could not rebut the *Festo* presumption that prosecution history estoppel bars a finding of infringement under the doctrine of equivalents.

¹⁶¹*Id.* at 1351.

¹⁶²*Id.*

¹⁶³*Id.* at 1356 (citing *Builders Concrete, Inc. v. Bremerton Concrete Prods. Inc.*, 757 F.2d 255, 260 (Fed. Cir. 1985)).

¹⁶⁴*Id.* at 1353 (citing *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 740–41 (2002) (*Festo VIII*)).

¹⁶⁵*Id.* at 1352–54.

¹⁶⁶*Id.* at 1354 (citing *Festo VIII*, 535 U.S. at 741, for the proposition that the patentee must show that at the time of the amendment one skilled in the art could not have reasonably expected to have drafted a claim that would have literally encompassed the alleged equivalent).

¹⁶⁷*Id.* at 1353–54 (citing *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1369 (Fed. Cir. 2003) (en banc) (*Festo IX*)).

¹⁶⁸*Id.* at 1351, 1356.

In *Microsoft Corp. v. Multitech Systems, Inc.*,¹⁶⁹ Microsoft sued Multitech for a declaratory judgment of invalidity, noninfringement, and unenforceability of several Multitech patents that concerned personal computer systems and methods for simultaneously transmitting voice and/or computer data to a remote site over a computer line. These cases included a common specification and, in particular, three patents that were prosecuted sequentially from the common parent application.¹⁷⁰ In a *Markman* hearing, the district court held that Multitech had disclaimed the transmission of information through a packet-switch network during prosecution of the second of the three cases, and applied this disclaimer to all the cases, including the earlier-prosecuted case and the later-prosecuted case.¹⁷¹ Under this claim construction, Multitech stipulated to noninfringement and appealed.

The Federal Circuit affirmed. In previous cases, the court had held that the prosecution history of one patent is relevant to an understanding of the scope of a term common to a second patent stemming from the same parent application.¹⁷² In this instance, the court held statements made during the prosecution of the second application were relevant to an understanding of both the earlier and later applications. The court noted that the three had a common specification and that the parent application had many inventions. Multitech's statement to the PTO was thus not limited to the invention disclosed in the second application but was a representation of its own understanding of the inventions disclosed in all three patents.¹⁷³ A statement from the prosecution history of an application is pertinent to an interpretation of a related, later-prosecuted application, and the court held that it was not unsound to apply the same interpretation to a related patent that had already issued.¹⁷⁴

Multitech argued that statements made during the later-prosecuted application should not be applied to the issued patent because the examiner could not have relied on those statements in allowing the issued patent. The court noted, however, that a patentee's statements, whether or not the examiner relies on them, are relevant to claim interpretation.¹⁷⁵ The court also noted that any statement of a patentee in the prosecution of a related application as to the scope of the invention is relevant to claim construction, and that the relevance in this case was enhanced because "it was made in an official proceeding in which the patentee had every incentive to exercise care in characterizing the scope of its invention."¹⁷⁶ Thus, statements made during prosecution of an application with regard to the scope of its inventions as disclosed in the common specification are relevant to the application itself, a later-prosecuted application, and any earlier-prosecuted patent. Another recent case held that prior art cited by the patentee in

¹⁶⁹357 F.3d 1340, 1344 (Fed. Cir. 2004).

¹⁷⁰*Id.* at 1342, 1344.

¹⁷¹*Id.* at 1344–45.

¹⁷²*Id.* at 1349 (citing *Jonsson v. Stanley Works*, 903 F.2d 812 (Fed. Cir. 1990), and *Laitram Corp. v. Morehouse Indus., Inc.*, 143 F.3d 1456 (Fed. Cir. 1998) (applying the prosecution histories of two sibling patents which shared a common written description)).

¹⁷³*Id.* at 1350.

¹⁷⁴*Id.*

¹⁷⁵*Id.* (citing *Laitram*, 143 F.3d at 1462 (stating that the fact that an examiner placed no reliance on an applicant's statement distinguishing prior art does not mean that the statement is inconsequential for purposes of claim construction)).

¹⁷⁶*Id.*

an Information Disclosure Statement (IDS) during prosecution of an application may constitute intrinsic evidence, the primary tool used to supply context for the interpretation of disputed claim terms, if the evidence can shed light on the meaning of a term.¹⁷⁷

In *Honeywell International, Inc. v. Hamilton-Sundstrand Corp.*,¹⁷⁸ Honeywell sued Hamilton-Sundstrand for infringing its patents for inlet guide vanes for an aircraft auxiliary power unit. During prosecution of the patents, several independent claims were rejected, but the examiner indicated that certain dependent claims would be allowable if they were rewritten in independent format. Honeywell responded by rewriting these dependent claims in independent format, and the patents issued.¹⁷⁹ Hamilton-Sundstrand argued that the amendments narrowed the scope of the claims, in accordance with the *Festo* principle that “[e]stoppel arises when an amendment is made to secure the patent and the amendment narrows the patent’s scope.”¹⁸⁰ The Federal Circuit looked closely at *Festo*, in which the Supreme Court gave examples of presumptive surrender of subject matter required by the PTO during prosecution. These examples included requiring applicants to clarify an ambiguous term, to improve the translation of a foreign word, or to rewrite a dependent claim as an independent one.¹⁸¹ The court noted that even if the scope of a rewritten claim is unchanged, the subject matter of the patent may have been narrowed if an original independent claim was canceled. The court concluded that prosecution history estoppel might apply because the subject matter of the original independent claim was narrowed to secure the patent.¹⁸² Thus, the court ruled that Honeywell presumptively surrendered all the equivalents to the inlet guide vane limitations in dependent claims that were added to the original independent claims.¹⁸³ The court vacated the judgment of infringement and remanded for a determination of whether Honeywell could overcome the presumption of surrender it invoked in making these amendments.

In another case concerning prosecution history estoppel, the meaning of the claim term “solubilizer” was disputed.¹⁸⁴ The application and the patent discussed the need for a drug with low solubility to enhance the long-term effectiveness of the drug. The discussion stated that “the solubilizers suitable according to the invention are defined below.”¹⁸⁵ The specification then described solubilizers in terms normally used for surfactants, and also stated that solubilizers included semi-solid or liquid nonionic surface active agents.¹⁸⁶ The specification then gave five examples of drug formulations, using surfactants in each.¹⁸⁷

The issue at the district court was whether a solubilizer included only surfactants or also included co-solvents and complexation agents. The district court rejected arguments that the prosecution history limited solubilizers to

¹⁷⁷V-Formation, Inc., v. Benetton Group Spa, 401 F.3d 1307, 1311 (Fed. Cir. 2005).

¹⁷⁸370 F.3d 1131 (Fed. Cir. 2004).

¹⁷⁹*Id.* at 1137.

¹⁸⁰*Id.* at 1139 (citing *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002)).

¹⁸¹*Id.* at 1142 (citing *Festo*, 535 U.S. at 736–37).

¹⁸²*Id.*

¹⁸³*Id.* at 1144.

¹⁸⁴*AstraZeneca AB v. Mutual Pharm. Co.*, 384 F.3d 1333 (Fed. Cir. 2004).

¹⁸⁵*Id.* at 1339.

¹⁸⁶*Id.*

¹⁸⁷*Id.* at 1339, 1341.

surfactants and found the patent valid and infringed.¹⁸⁸ On appeal, the Federal Circuit reversed this claim construction and remanded for entry of a judgment of noninfringement.¹⁸⁹

The intrinsic evidence in the case, the specification and the prosecution history, acted as a clear disavowal of the scope of the claim term.¹⁹⁰ The specification described a feature of the invention that pertained only to surfactants (micelles formed by the solubilizer) and criticized other products that lacked that same feature (other solubilizers, including co-solvents). This description acted as a clear disavowal of these other products and processes using these products.¹⁹¹ In addition, during prosecution, the patentees made remarks referring to the above “definition” of solubilizer in the specification, implying that the patentees acted as their own lexicographer, and used the term “surfactant” as a substitute for solubilizer. A statement of the form “I define _____ to mean _____” is not required for a definition of a claim term.¹⁹² Thus, the term “solubilizer” was limited to surfactants.

When an amendment is made, the scope of surrender of subject matter is not limited to the minimum necessary to overcome the prior art but instead includes what was actually surrendered.¹⁹³ In *Norian Corp. v. Stryker Corp.*, a patentee sued an alleged infringer over a patent that claimed a kit for preparing a bone cement. The claim recited “a solution consisting of water and a sodium phosphate,” with further limitations on the concentration and pH of the solution.¹⁹⁴ The allegedly infringing kit included a solution that was made from two different sodium phosphates.

During prosecution, the preamble of the claim, which originally contained the phrase “comprising,” first was amended to state “consisting essentially of,” and later was amended to state “consisting of” certain limitations. One important limitation also was changed from “a sodium phosphate solution” to “a solution consisting of water and a sodium phosphate.”¹⁹⁵ The attorney prosecuting the application had argued that the amendment limited the claimed kit to one in which the solution is made of water and a single solute, in which the solute is completely dissolved in water. The amendment was made to overcome a reference that taught a colloidal setting solution, rather than a pure solution containing no suspended particles (such as a colloid).¹⁹⁶

The parties agreed that the allegedly infringing kit contained two sodium phosphates. The district court and the Federal Circuit found no infringement, because with the preamble “consisting of,” the term “a” must be interpreted to mean that the solution consists only of water and a single solute, a single type of

¹⁸⁸*Id.* at 1336.

¹⁸⁹*Id.* at 1342.

¹⁹⁰*Id.* at 1340 (citing *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1340–45 (Fed. Cir. 2001)).

¹⁹¹*Id.*

¹⁹²*Id.* at 1339. As a general principle, claim interpretation is limited by definitions given in the specification and during prosecution of the patent. *C.R. Bard, Inc., v. United States Surgical Corp.*, 388 F.3d 858 (Fed. Cir. 2004) (affirming judgment of noninfringement of a patent by interpreting a claim term based on the patent disclosure and arguments made during the prosecution history of the patent).

¹⁹³*Norian Corp. v. Stryker Corp.*, 432 F.3d 1356 (Fed. Cir. 2005).

¹⁹⁴*Id.* at 1357.

¹⁹⁵*Id.* at 1360.

¹⁹⁶*Id.* at 1361.

sodium phosphate, not multiple types.¹⁹⁷ There was support for this interpretation in the specification.

The patentee had argued that because the amendment was made to overcome a reference which disclosed a colloidal suspension, rather than a solution of more than one solute, the prosecution history should not be interpreted as disclaiming solutions that are made from more than one solute.¹⁹⁸ The court noted that patent applicants frequently surrender more than is needed to overcome a reference. Further, the court stated that patentees are held to the scope of what they claim, consistent with their arguments, and they are not allowed to assert interpretations of the claims as if they had surrendered only what they had to.¹⁹⁹

3. *Material Disclosed but Not Claimed*

Material disclosed in a patent application but not claimed should be reviewed as a basis for a noninfringement defense, because such material may be dedicated to the public if distinct from the claimed subject matter.²⁰⁰ A patent owned by Johnson & Johnston (“‘050 patent”) claimed thin sheets of copper laminated to aluminum for use in manufacturing printed circuit boards. The specification of the patent stated that aluminum was a preferred material, and other materials, such as stainless steel and nickel, could be used with the thin copper sheets. Johnson accused R.E. Service Co. (RES) of infringing the patent by using laminates of steel instead of aluminum.

On cross-motions for summary judgment, the district court ruled that the ‘050 patent did not dedicate the steel substrate to the public, and found RES liable for willful infringement under the doctrine of equivalents. Relying upon *Maxwell v. J. Baker, Inc.*,²⁰¹ RES argued that Johnson did not claim steel substrates, but limited its patent scope to aluminum substrates, thus dedicating to the public this unclaimed subject matter. Johnson countered that there was no dedication to the public under *YBM Magnex, Inc., v. International Trade Commission*,²⁰² a decision in which a Federal Circuit panel noted that *Maxwell* was limited to situations where a patent discloses an unclaimed alternative distinct from the claimed invention.

On appeal, the Federal Circuit affirmed, first noting that the claims of a patent define the scope of patent protection and also give notice to the public of the scope of patent protection.²⁰³ The court reiterated that the doctrine of equivalents extends the right to exclude beyond the literal scope of the claims. An equivalent may include matter that is not disclosed or suggested but equivalent to the claims of the patent.²⁰⁴ Discussing *Maxwell*, the court noted that a number of alternative shoe attachment systems were disclosed but not claimed, thereby avoiding examination of the claims during prosecution. The court explained

¹⁹⁷*Id.* at 1358.

¹⁹⁸*Id.* at 1361.

¹⁹⁹*Id.* at 1361–62.

²⁰⁰*Johnson & Johnston Assocs., Inc. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002) (en banc).

²⁰¹86 F.3d 1098, 1106 (Fed. Cir. 1996).

²⁰²145 F.3d 1317, 1320 (Fed. Cir. 1998), *overruled by Johnson*, 285 F.3d 1046.

²⁰³*Johnson*, 285 F.3d at 1052.

²⁰⁴*Johnson*, 285 F.3d at 1054 (citing *Warner-Jenkinson Co. v. Hilton-Davis Chem. Co.*, 520 U.S. 17 (1997)).

that the Patent and Trademark Office examiner was deprived of an opportunity to consider whether the alternatives were patentable, and therefore a reasonable person would conclude that since the alternative systems were disclosed but not claimed, the patentee had dedicated the use of such systems to the public.²⁰⁵ In *YBM*, however, the patent claimed a permanent magnet alloy comprising certain elements, including 6,000 to 36,000 ppm (parts per million) oxygen. The accused infringer used similar magnet alloys with an oxygen content between 5,450 and 6,000 ppm and alleged that this range was disclosed but not claimed in the *YBM* patent.²⁰⁶ The *YBM* panel found that the patentee had not dedicated alloys with oxygen content between 5,450 and 6,000 ppm under these circumstances and distinguished *Maxwell*, emphasizing that claimed subject matter must be distinct from the alternatives in the specification in order for those alternatives to be dedicated to the public.²⁰⁷ Finally, to temper possible confusion, the Federal Circuit specifically overruled *YBM* to the extent that it conflicted with its en banc holding in *Johnson*.²⁰⁸

The Federal Circuit used *PSC Computer Products, Inc. v. Foxconn International, Inc.*²⁰⁹ to resolve the question of how specific a disclosure in the specification must be in order for matter not claimed to be dedicated to the public. PSC received a patent for an invention for securing a heat sink to an electronic chip using a cam-type retainer clip. PSC sued Foxconn for infringement. Foxconn's defense was that it did not infringe literally because it used plastic straps rather than the metal straps claimed, and that it did not infringe under the doctrine of equivalents because plastic straps were disclosed but not claimed, and therefore dedicated to the public.²¹⁰ The court granted summary judgment of noninfringement, both literally and under the doctrine of equivalents.

On appeal, the Federal Circuit noted that one limitation of claim 1 of the patent was for "an elongated, resilient metal strap." The specification had both general and specific disclosures of other materials. A generic disclosure stated that "other resilient materials may be suitable for the strap," while a more specific disclosure stated that "other prior art devices use molded plastic and/or metal parts."²¹¹ A reader of ordinary skill in the art could reasonably conclude from this language in the specification that plastic clip parts could be substituted for metal clip parts. Thus, PSC was obliged either to claim plastic parts in addition to metal parts, and to submit this broader claim for examination, or to not claim them and dedicate the use of plastic parts to the public.²¹² The court held that if one of ordinary skill in the art can understand the unclaimed, disclosed teaching upon reading the written description, the alternative matter disclosed has been dedicated to the public. The disclosure must be of such specificity that one of ordinary skill in the art can identify the subject matter that has been disclosed and not claimed.²¹³ Intent is not part of the *Johnson*

²⁰⁵*Johnson*, 285 F.3d at 1051 (citing *Maxwell*, 86 F.3d at 1106).

²⁰⁶*Johnson*, 285 F.3d at 1052. (citing *YBM*, 145 F.3d at 1321, overruled by *Johnson*, 285 F.3d 1046).

²⁰⁷*Id.*

²⁰⁸*Johnson*, 285 F.3d at 1055.

²⁰⁹355 F.3d 1353, 1358 (Fed. Cir. 2004).

²¹⁰*Id.* at 1355.

²¹¹*Id.* at 1360.

²¹²*Id.*

²¹³*Id.*

& *Johnston* disclosure-dedication analysis; the patentee's subjective intent is irrelevant to determining whether unclaimed subject matter has been disclosed and therefore dedicated to the public.²¹⁴

The Federal Circuit may have placed a limit on this defense. In *Pfizer, Inc. v. Teva Pharmaceutical USA, Inc.*, the court noted that its preceding dedication to the public/disclosure cases dealt with patents in which subject matter was disclosed as an alternative to the relevant claim limitation.²¹⁵ In *Pfizer*, there were generic and specific disclosures of subject matter, but there was no disclosure of subject matter specifically identified as being an alternative to the subject matter in a claim limitation. Thus, even if the district court had construed the relevant claim limitation in a way favorable to the defendant, the defendant had not pointed to a portion of the patent in which the inventors had identified the subject matter in dispute as an unclaimed alternative that would function in the prescribed manner.²¹⁶ The decision suggests that before unclaimed subject matter is dedicated to the public, the patent must present it as an alternative to the claimed subject matter.

C. Section 272

Specific statutory provisions may provide an exception to what otherwise would seem to be a clear case of infringement. Section 272 of U.S. patent law provides a unique defense to patent infringement:

The use of any invention in any vessel, aircraft or vehicle of any country which affords similar privileges to vessels, aircraft, or vehicles of the United States, entering the United States temporarily or accidentally, shall not constitute infringement of any patent, if the invention is used exclusively for the needs of the vessel, aircraft, or vehicle and is not offered for sale or sold in or used for the manufacture of anything to be sold in or exported from the United States.

National Steel Car, Ltd. sued Canadian Pacific Railway, Ltd., for infringing its patents for railway cars.²¹⁷ It was undisputed that the railway cars spent a majority of their useful lifetime within the United States delivering lumber from Canada to the United States.²¹⁸ Without granting a *Markman* hearing, the district court found that the possible defenses of anticipation, obviousness, and Section 272 were not sufficiently substantial to preclude entry of a preliminary injunction, and it granted a preliminary injunction against Canadian Pacific's using its railway cars in the United States.²¹⁹

On appeal, the Federal Circuit noted that this was its first opportunity to address Section 272. The district court had held that for purposes of entering the United States, the relevant vehicle was the train of which the railway car was a part, rather than the railway car itself.²²⁰ The Federal Circuit considered the several definitions of the word "vehicle," as used in the statute, and decided that

²¹⁴*Toro Co. v. White Consol. Indus., Inc.*, 383 F.3d 1326, 1333 (Fed. Cir. 2004) (citing *Johnson & Johnston Assocs., Inc.*, 285 F.3d at 1053 n.1).

²¹⁵429 F.3d 1364, 1379 (Fed. Cir. 2005).

²¹⁶*Id.*

²¹⁷*National Steel Car, Ltd. v. Canadian Pac. Ry., Ltd.*, 357 F.3d 1319 (Fed. Cir. 2004).

²¹⁸*Id.* at 1323–24.

²¹⁹*Id.* at 1324, 1335.

²²⁰*Id.* at 1328.

the definition was sufficiently broad to encompass a railway car rather than the entire train. The court also considered the meaning of the word “temporarily.” Even though the railcars might have spent more than 50 percent of their useful lives in the United States, they were present for the purposes of engaging in international commerce, unloading foreign goods, or loading domestic goods for foreign markets.²²¹ The Federal Circuit also found that the cars were used “exclusively for the need of the . . . vehicle” as required, holding that “need” could encompass both “propulsive” and “structural” needs.²²² The preliminary injunction was reversed.

D. Section 273: First-Inventor Defense to Business Method Patent

When Congress passed the American Inventors Protection Act in November 1999, it created a defense for those accused of infringing patent claims covering a method of doing or conducting business. Although it is entitled the “first-inventor defense,”²²³ the party asserting it need not be the actual first person to invent the patented business method in the sense of 35 U.S.C. §§102 and 103 to benefit from the defense. Instead, a successful assertion requires establishing two essential acts: (1) an actual reduction to practice of the accused method one year before the effective filing date of the patent and (2) commercial use of the accused method at any time before the same date.²²⁴ It appears, moreover, that the actual first inventor need not be identified, but the accused business method must not have been derived from the patentee or persons in privity with the patentee.²²⁵

The defense, however, has limited use; it is available to the party that conducted the prior activity and a few others. The defense is assignable or transferable from one entity to another, but only upon sale of the business to which the defense relates.²²⁶ If transferred, the defense applies only to prior uses carried out at certain sites.²²⁷ It also protects purchasers of products produced by an accused method. According to the statute, the sale or disposition of a useful end product produced by a patented method, by a person entitled to assert the defense to that useful end result, shall exhaust the patent owner’s rights under the patent to the extent such rights would have been exhausted had such sale or other disposition been made by the patent owner.²²⁸

Significantly, a successfully asserted first-inventor defense does not invalidate a business method patent, as would, for example, another’s prior invention under 35 U.S.C. §102(g). Instead, if demonstrated, the defense frees the prevailing party from liability for infringing the patent but leaves the patent intact for enforcement against others.²²⁹

²²¹*Id.* at 1331. The Federal Circuit noted that if certain of these cars were taken from the trains and used for domestic-only traffic, that would be an infringing use. *Id.* at 1332.

²²²*Id.* at 1332–33.

²²³*See* Pub. L. No. 106-113, subtit. C (codified at 35 U.S.C. §273).

²²⁴35 U.S.C. §273(b)(1).

²²⁵*Id.* §273(b)(3)(B).

²²⁶*Id.* §273(6).

²²⁷*Id.* §273(7).

²²⁸*Id.* §273(b)(2).

²²⁹*Id.* §273(9).

Finally, the defense contains a few provisions that may deter its use. First, the burden of proof is high, requiring clear and convincing evidence.²³⁰ Also, if the defense fails and a reasonable basis for asserting it cannot be demonstrated, the court shall find the case exceptional as a basis for awarding attorney's fees to the patent owner.²³¹

Certainly, there will be issues for litigation when the defense is asserted. For example, it is limited to the infringement of method claims; it may not apply to patent claims covering a composition, article of manufacture, or a method that does not conduct business.²³² However, the statute provides no guidance on the meaning of "a method of doing or conducting business."

Unfortunately, no reported case law was available when this chapter was submitted for publication. Thus, although the effect and application of the defense are uncertain, businesses will benefit from documenting how and when they obtained and used their internal business procedures.

E. Advice-of-Counsel Defense to Willful Infringement

The patent statute allows the court, at its discretion, to award up to treble damages in a patent infringement case.²³³ The Federal Circuit developed the requirement that willful infringement be shown as a prerequisite for enhanced damages.²³⁴ However, an award of enhanced damages is not required when willfulness is found.²³⁵ A finding of willfulness just merely permits the awarding of treble damages.²³⁶ Litigants accused of willful infringement typically assert the "advice-of-counsel defense."²³⁷ Historically, the advice-of-counsel defense has presented accused infringers with a dilemma of choosing between preserving attorney-client privilege and waiving that privilege in a willfulness defense.²³⁸

In *In re Seagate Tech., LLC*,²³⁹ the en banc Federal Circuit reevaluated and clarified the standard for evaluating willful infringement.²⁴⁰ The court also addressed the appropriate scope of attorney-client privilege waiver resulting from the advice-of-counsel defense.²⁴¹

Prior to *Seagate*, the Federal Circuit opinion in *Underwater Devices v. Morrison-Knudsen Co.*²⁴² controlled the willfulness determination.²⁴³ The *Underwater Devices* standard allowed recovery of treble damages on a showing of negligence.²⁴⁴ In *Seagate*, the Federal Circuit overruled *Underwater Devices* and held that "proof of willful infringement permitting enhanced damages requires at least a showing of objective recklessness" and "reemphasize[d] that

²³⁰*Id.* §273(4).

²³¹*Id.* §273(8).

²³²*Id.* §§273(1)(3) and (b)(3)(A).

²³³ 35 U.S.C. §284 (2000).

²³⁴ *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 858 (Fed. Cir. 2010).

²³⁵ *In re Seagate Tech., LLC*, 497 F.3d 1360, 1368 (Fed. Cir. 2007).

²³⁶*Id.*

²³⁷*Id.* at 1369.

²³⁸*Id.*

²³⁹ 497 F.3d 1360 (Fed. Cir. 2007).

²⁴⁰*Id.* at 1370.

²⁴¹*Id.* at 1372.

²⁴² 717 F.2d 1380 (Fed. Cir. 1983).

²⁴³ *Seagate*, 497 F.3d at 1371.

²⁴⁴*Id.*

there is no affirmative obligation to obtain opinion of counsel.”²⁴⁵ Citing the Supreme Court, the en banc court stated that “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.”²⁴⁶ Finally, the Federal Circuit held that “[i]f 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.”²⁴⁷ In a later opinion, a panel of the Federal Circuit commented in dicta that under the objective standard set out in *Seagate*, “both legitimate defenses to infringement claims and credible invalidity arguments demonstrate the lack of an objectively high likelihood that a party took actions constituting infringement of a valid patent.”²⁴⁸

As to the extent of waiver, the Federal Circuit held that a litigant asserting the advice-of-counsel defense only waives its privilege as to opinion counsel.²⁴⁹ That waiver does not extend to trial counsel.²⁵⁰ Similarly, “rel[iance] on opinion counsel’s work product does not waive work product immunity with respect to trial counsel.”²⁵¹ Finally, the Federal Circuit emphasized that the willfulness inquiry is only concerned with an accused infringer’s prelitigation conduct.²⁵²

III. INVALIDITY

A patent is presumed valid.²⁵³ It will be found invalid, however, if it fails to satisfy the conditions of patentability or any requirement in the statute. Thus, a patent may be invalid under Section 101 for lack of patentable subject matter; Section 102 for lack of novelty, various statutory bars, or derivation from another; Section 103 for obviousness; Section 112 for deficiencies in the specification and claims; or Section 251 for failing to comply with the requirements of reissue. The Patent Statute does not provide a defense of invalidity for procedural irregularities.²⁵⁴ For example, improper revival of an abandoned patent application may not be asserted as a defense to patent infringement.²⁵⁵

All invalidity defenses require the patent challenger to prove its case by clear and convincing evidence.²⁵⁶ The most common invalidity defenses are those based on the prior art. Under these defenses, the patent challenger must

²⁴⁵*Id.*

²⁴⁶*Id.* (citing *Safeco Ins. Co. v. Burr*, 127 S. Ct. 2201, 2215 (2007)).

²⁴⁷*Id.*

²⁴⁸*Black & Decker, Inc. v. Robert Bosch Tool Corp.*, 260 Fed. App’x 284, 291 (Fed. Cir. 2008).

²⁴⁹*Seagate*, 497 F.3d at 1373.

²⁵⁰*Id.*

²⁵¹*Id.* at 1376.

²⁵²*Id.* at 1374.

²⁵³35 U.S.C. §282.

²⁵⁴*Magnivision, Inc. v. Bonneau Co.*, 115 F.3d 956, 960 (Fed. Cir. 1997).

²⁵⁵*Aristocrat Tech. Australia Pty, Ltd. v. International Game Tech*, 543 F.3d 657, 661 (Fed. Cir. 2008) (reversing lower court which held patent invalid due to improper revival based upon “unintentional” rather than “unavoidable” delay).

²⁵⁶*Trans-World Mfg. Corp. v. Al Nyman & Sons, Inc.*, 750 F.2d 1552, 1560, 224 USPQ 259, 263 (Fed. Cir. 1984); *Railroad Dynamics, Inc. v. A. Stucki Co.*, 727 F.2d 1506, 1517, 220 USPQ 929, 939 (Fed. Cir.), *cert. denied*, 469 U.S. 871, 224 USPQ 520 (1984).

prove that the claims of the patent are either anticipated by or obvious in view of the prior art.

A. Invalidity Based on the Prior Art

The claims of a patent are anticipated under 35 U.S.C. §102 when a single prior art reference discloses every limitation of the claimed invention, either explicitly or inherently.²⁵⁷ To establish anticipation, one must identify the elements of the claims and determine their meaning in light of the specification and prosecution history. It is an axiom of patent law that, whether for purposes of infringement or validity, the claims of a patent must be construed the same.²⁵⁸

1. Anticipation

Several sections may be invoked in an anticipation defense. Section 102(a) bars a patent if 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. Thus, a *prima facie* case is made under Section 102(a) if the invention or an obvious variant is described in a printed publication whose authorship differs from the inventive entity, unless the publication itself states that the publication describes the applicant's work.²⁵⁹ If anticipation by another can be proven, a patent will be held invalid under Section 102(a).²⁶⁰ A judgment of invalidity under Section 102(a) of an item supposedly known or used by others in this country will not be sustained unless there is clear and convincing evidence of prior knowledge or use by others.²⁶¹

Similarly, Section 102(b) bars a patent if the invention was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States. A key distinction between these two sections is that the prior art applied under them may be different. Under Section 102(a), applicable prior art is determined in part by the date of the invention of the patent at issue, because this section involves activity occurring before the "invention thereof by the applicant." Under Section 102(b), applicable prior art is determined in part by the date on which the patent in question was filed in the United States. Thus, Section 102(a) invokes prior activity occurring before the date of invention, and Section 102(b) invokes activity occurring before the date a patent application is filed.

Section 102(e) bars a patent if the invention was described in an application for a patent published under Section 122(b) by another before the invention by the applicant, or if the invention was described in a patent granted on an application by another filed in the United States before the invention by the applicant, except that an international application shall be effective for purposes of Section

²⁵⁷*In re Schreiber*, 128 F.3d 1473, 1477–78, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997); *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771, 218 USPQ 781, 789 (Fed. Cir. 1983), *overruled in part by* *SRI Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 227 USPQ 577 (Fed. Cir. 1985).

²⁵⁸*Quantum Corp. v. Mountain Computer Inc.*, 5 USPQ2d 1103, 1107 (N.D. Calif.), *aff'd*, 818 F.2d 977 (Fed. Cir. 1987).

²⁵⁹*In re Katz*, 687 F.2d 450, 215 USPQ2d 14 (C.C.P.A. 1982).

²⁶⁰*New Idea Farm Equip. Corp. v. Sperry Corp.*, 916 F.2d 1561, 16 USPQ2d 1424 (Fed. Cir. 1990).

²⁶¹*Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1373, 47 USPQ2d 1363, 1368 (Fed. Cir. 1998).

102(e) only if the international application designated the United States and was published in English. Section 102(e) was amended by the American Inventors Protection Act of 1999²⁶² and by the Intellectual Property and High Technology Technical Amendments Act of 2002.²⁶³ The amended law became effective on November 29, 2000, and applies to patent and patent applications pending on that date. Significant case law has not yet developed under the revised section. Of course, if a reference was described in a printed publication, such as a patent, more than one year prior to an application, Section 102(b) will apply. Therefore, Section 102(e) will continue to be useful in patent defense where a reference is less than one year prior to the application for patent. By requiring that international applications designate the United States and be published in English, the amended Section 102(e) continues to limit references to U.S. patent applications.²⁶⁴

Section 102(f) denies an applicant a patent if the applicant did not invent the subject matter sought to be patented. Most determinations of invalidity under this section involve derivation of the invention from another.²⁶⁵ While Sections 102(a), (b), (e), and (g) apply primarily to public prior art and use, Section 102(f) may apply more often to other activities, such as private communications between an inventor and another, which communications may never become public.²⁶⁶ Prior art under Section 102(f) may be combined with other prior art to render a patent obvious under Section 103(a).²⁶⁷ Section 102(f) may also be used to invalidate a patent for incorrect inventorship if the named inventor did not invent the patented invention.²⁶⁸

Section 102(g) may be used to deny an applicant a patent as a result of an interference if another can prove invention to the extent provided for in Section 104 (under NAFTA and WTO inclusions) prior to the applicant's without suppression, abandonment, or concealment of the invention. An inventor may also be denied a patent if the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed the invention. Section 102(g) may also be used as a basis for invalidating a patent in a defense to an infringement suit.²⁶⁹

The standard for enablement of a prior art reference under Section 102 is different from the enablement standard under Section 112.²⁷⁰ While Section 112 provides that the specification must enable one having skill in the art to use the invention, there is no such requirement under Section 102 as to an anticipatory disclosure. The Federal Circuit has held that there is a presumption that both the claimed and the unclaimed disclosures in a prior art patent are enabled,

²⁶²Pub. L. No. 106-113, 113 Stat. 1501 (1999).

²⁶³Pub. L. No. 107-273, 116 Stat. 1758 (2002).

²⁶⁴*In re Hilmer*, 359 F.2d 859, 149 USPQ 480 (C.C.P.A. 1966).

²⁶⁵*Ex parte Kusko*, 215 USPQ 972, 974 (BPAI 1981).

²⁶⁶*OddzOn Prods., Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1401-02, 43 USPQ2d 1641, 1644 (Fed. Cir. 1997) (involving confidential disclosures made to the inventor and not submitted to the PTO during patent prosecution); *superseded by* CREATE Act, Pub. L. No. 108-453, 118 Stat. 3596 (2004) (codified in 35 U.S.C. §103(c)).

²⁶⁷*Id.* at 1403-04, 43 USPQ2d at 1646.

²⁶⁸*Pannu v. Iolab Corp.*, 155 F.3d 1344, 47 USPQ2d 1657 (Fed. Cir. 1998) (remanding for a determination of inventorship).

²⁶⁹*Checkpoint Sys. v. United States Int'l Trade Comm'n*, 54 F.3d 756, 761, 35 USPQ2d 1042, 1047 (Fed. Cir. 1995).

²⁷⁰*Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1325 (Fed. Cir. 2005).

but the court had not decided whether the presumption applied to non-patent publications.²⁷¹

In *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*,²⁷² an alleged infringer of a patent directed to production of human growth hormone asserted the defense of anticipation based on an article in a scientific journal. The patentee argued that the article did not anticipate because two limitations of an important claim were not disclosed.²⁷³ The patentee asserted that the test results disclosed in the article did not demonstrate conclusively that the human growth hormone produced from a nonhuman secretion process (hGH1) was identical to that derived from human pituitary glands (hGH).

The Federal Circuit noted that the standard for an enabling disclosure for purposes of anticipation does not require actual performance of suggestions in a disclosure; it requires only that those suggestions be enabled to one of skill in the art.²⁷⁴ The article described numerous tests to show that the hGH1 was identical to hGH with full biological activity and with identical amino acid sequences. Furthermore, the Federal Circuit noted that the district court did not rely solely on the presumption that the disclosure was enabling, but rather that the defendant had affirmatively demonstrated enablement of the article.²⁷⁵ Accordingly, the article was an enabling disclosure which anticipated the claim.

A prior inventor need not realize that he is an inventor to achieve a Section 102(g) priority.²⁷⁶ Employees at Astro-Valcour experimented with an issued patent and devised a new foam that was later patented by Dow.²⁷⁷ When Dow sued Astro-Valcour, and Astro raised a Section 102(g) defense, Dow countered that no one at Astro qualified as an inventor because no one believed they had invented anything. Dow argued that the alleged Astro inventors believed they were simply working on a patent they had previously licensed.²⁷⁸ The court found that the Astro employees clearly recognized and appreciated the products they had made and that it was immaterial whether they understood that they had produced a legally patentable invention.²⁷⁹

The language “in this country” applies to where the invention was made, not where any concealment, abandonment, or suppression took place.²⁸⁰ Apotex sued Merck for infringement of two patents for a process for making a medication for high blood pressure. Merck mounted a Section 102(g) defense of invalidity of the patents-in-suit, claiming that Merck had invented the subject matter of the patents-in-suit within the United States, and that it had not abandoned, concealed, or suppressed the invention.²⁸¹ Merck had disclosed details of the ingredients in a French pharmaceutical dictionary and in thousands of copies of a Canadian product brochure.²⁸² Apotex contested the grant of summary judgment of inva-

²⁷¹*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1355 n.22 (Fed. Cir. 2003).

²⁷²314 F.3d 1313 (Fed. Cir. 2003).

²⁷³*Id.* at 1354.

²⁷⁴*Id.* at 1355–56.

²⁷⁵*Id.* at 1356.

²⁷⁶*Dow Chem. Co. v. Astro-Valcour, Inc.*, 267 F.3d 1334, 60 USPQ2d 1519 (Fed. Cir. 2001).

²⁷⁷*Id.* at 1336–37, 60 USPQ2d at 1520.

²⁷⁸*Id.* at 1340, 60 USPQ2d at 1522–23.

²⁷⁹*Id.* at 1341, 60 USPQ2d at 1523–24.

²⁸⁰*Apotex USA, Inc. v. Merck & Co.*, 254 F.3d 1031, 59 USPQ2d 1139 (Fed. Cir. 2001).

²⁸¹*Id.* at 1034, 59 USPQ2d at 1141.

²⁸²*Id.*

lidity on the grounds that Merck's disclosures were not made within the United States, and that Merck had failed to file a U.S. patent application for the product. The court held that the language "in this country" applied to the country where the invention was made, and that proof negating suppression and concealment was not limited to activities occurring within the United States.²⁸³

2. *Inherent Anticipation*

In *Schering Corp. v. Geneva Pharmaceuticals, Inc.*,²⁸⁴ Schering Corp. owned U.S. Pat. No. 4,282,233, for loratadine, an antihistamine that does not cause drowsiness. More than two years after the '233 patent issued, Schering applied for another patent, U.S. Pat. No. 4,659,716, for a metabolite of loratadine, DCL (descarboethoxy-loratadine), which was also useful as an antihistamine that did not cause drowsiness. A metabolite is the compound formed in the patient's body upon ingestion of a drug. The ingested pharmaceutical undergoes a chemical conversion in the digestion process to form a new metabolite. The earlier patent did not disclose DCL and did not refer to metabolites of loratadine. When others, including Geneva, applied to the FDA for regulatory approval of generic versions to be sold when the '233 patent expired, their applications claimed that the '716 patent was invalid.²⁸⁵

Schering sued for infringement and the parties agreed that the claims of the '716 patent covered DCL in all its forms, including forms metabolized in the human body and synthetically produced in a purified and isolated form. The district court then found that DCL was necessarily formed as a metabolite by carrying out the process of the earlier '233 patent, which inherently anticipated the '716 patent.²⁸⁶ The '716 patent was thus invalid for anticipation by the '233 patent. Inherent anticipation does not require that those skilled in the art appreciate or would have recognized the inherent disclosure.²⁸⁷ In this case, the record showed that DCL necessarily and inevitably formed when loratadine was ingested under normal conditions; DCL was a necessary consequence of administering loratadine to patients, even though a skilled artisan might not have recognized this from the earlier patent.²⁸⁸ The '233 patent did not disclose any compound that was identifiable as DCL; nevertheless, patent law requires only that a prior art reference expressly or inherently contain each and every limitation of the claimed subject matter in order to anticipate and invalidate.²⁸⁹ The court distinguished the normal, readily detectable presence of DCL in the human body from situations in which only a minuscule amount might be formed that might be undetectable.²⁹⁰ Anticipation does not require actual creation or reduction to practice of the prior art subject matter but only an enabling disclosure.²⁹¹ The prior art sufficed as

²⁸³*Id.* at 1036, 59 USPQ2d at 1142.

²⁸⁴339 F.3d 1373 (Fed. Cir. 2003).

²⁸⁵*Id.* at 1376.

²⁸⁶*Id.*

²⁸⁷*Id.* at 1377 (citing *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1351 (Fed. Cir. 2002)).

²⁸⁸*Id.* at 1378.

²⁸⁹*Id.* at 1378–79 (citing *EMI Group N. Am., Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1350 (Fed. Cir. 2001)).

²⁹⁰*Id.* at 1379 (citing *In re Seaborg*, 328 F.2d 996 (C.C.P.A. 1964) (stating that an isotope of americium was not anticipated by the possibility that only one-billionth of a gram might be present in 40 tons of material)).

²⁹¹*Id.* at 1380 (citing *In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985)).

anticipatory prior art if it disclosed in an enabling manner the administration of loratadine to patients.

3. *Obviousness*

The Supreme Court's first significant discussion of the obviousness defense was in *Hotchkiss v. Greenwood*.²⁹² That case addressed the patentability of the mechanical combination of a doorknob, shank, and spindle. The patentee claimed novelty in that the doorknob was formed of porcelain rather than wood or metal (which led to improved durability). The court invalidated the patent, finding no invention in the substitution of materials. From this case emerged the "Hotchkiss Test": to be patentable, an invention must evidence more ingenuity and skill than that possessed by an ordinary mechanic acquainted with the business. Nearly 100 years later, Congress embraced the obviousness concept in Section 103 of the Patent Act of 1953.

*Graham v. John Deere Co. of Kansas City*²⁹³ was the first opportunity for the Supreme Court to apply Section 103. In that case, the Court preserved *Hotchkiss*, but provided an analytical framework for analyzing Section 103 obviousness. That framework has come to be referred to as the "Graham Test." Under that test, four factors are essential to the nonobviousness analysis: (1) level of ordinary skill in the art; (2) scope and content of the prior art; (3) differences between the claimed invention and the prior art; and (4) secondary considerations (i.e., objective indicia of nonobviousness). These "secondary considerations" include failure of others to solve the problem addressed by the invention, the commercial success of the invention, the existence of a long-felt need for the invention, the licensing and acquiescence of others to the patent at issue, and copying of the invention.

Over time, the Federal Circuit, drawing on precedent from the Court of Customs and Patent Appeals, ostensibly established an additional requirement for demonstrating obviousness: a teaching, suggestion, or motivation to combine known elements in order to show that the combination is obvious.²⁹⁴

The Supreme Court's unanimous decision in *KSR International Co. v. Teleflex, Inc.*²⁹⁵ instructed the Federal Circuit to retreat from a strict application of the "teaching, motivation, or suggestion" (TSM) test. While crediting the Federal Circuit for its attempt to "resolve the obviousness question with more uniformity and consistency," the Court held that, in the case of *KSR*, the TSM test's reliance on express teachings in the art was too rigid.²⁹⁶ The Court further criticized the Federal Circuit's "problem that the patentee was trying to solve" test.²⁹⁷

In *KSR*, the technology at issue was a position-adjustable pedal assembly with an electronic pedal position sensor attached at a fixed pivot point (disclosed

²⁹²52 U.S. (11 How.) 248, 13 L. Ed. 683 (1851).

²⁹³383 U.S. 1, 17–18 (1966).

²⁹⁴*See, e.g.,* Winner Int'l Royalty Corp. v. Wang, 202 F.3d 1340, 1348 (Fed. Cir. 2000) ("When an obviousness determination is based on multiple prior art references, there must be a showing of some 'teaching, suggestion, or reason' to combine the references.")

²⁹⁵550 U.S. 398, 400 (2007).

²⁹⁶*Id.* at 402.

²⁹⁷*Id.*

in claim 4 of the Engelgau patent).²⁹⁸ KSR had developed and patented an adjustable pedal for cars with cable-actuated throttles.²⁹⁹ General Motors Corporation (GMC) contracted with KSR to supply GMC with adjustable pedal systems for trucks using computer controlled throttles.³⁰⁰ In response to the supply contract, KSR adapted its pedals by adding a modular sensor to its design, bringing the KSR pedal within the scope of claim 4 of the Engelgau patent.³⁰¹ Teleflex, the exclusive licensee of the Engelgau patent, sued KSR for patent infringement. KSR counterclaimed that asserted claim 4 was invalid as obvious under Section 103 of the Patent Act.³⁰² KSR combined several prior-art references including patents and existing products that had been before the Examiner of the Engelgau patent, with a reference that was not before the Examiner—the “Asano” patent.³⁰³ The district court found claim 4 obvious over the combination of the Asano patent, which disclosed a pedal assembly without the electronic control, with any of three patents disclosing (1) an assembly with a sensor located in the pedal housing, (2) an assembly with an electronic control located on the support bracket, or (3) an assembly with a non-constant pedal point during adjustment.³⁰⁴ The Federal Circuit reversed, holding that the Asano patent did not address the “same problem” as the Engelgau patent.³⁰⁵ The Asano pedal was designed so that the force necessary to depress the pedal remained constant regardless of the pedal’s adjustment setting, whereas the Engelgau patent sought to provide a simpler, smaller, cheaper adjustable pedal.³⁰⁶ The Federal Circuit reasoned that, absent prior-art references addressing the precise problem that the patentee was trying to solve, there is no teaching, suggestion, or motivation to combine.³⁰⁷

The Supreme Court reversed. In reaffirming *Graham v. John Deere Co. of Kansas City*, the Court clarified that teaching, suggestion, or motivation to combine prior art to meet the claimed subject matter is sufficient, but not necessary, to determine whether subject matter is obvious.³⁰⁸ The Court noted a distinction between the necessity of a court’s articulating the “rational underpinnings” of a legal conclusion of obviousness and a rigid requirement that a court rely only on an explicitly published teaching, suggestion, or motivation.³⁰⁹ The Court accordingly instructed that Section 103 requires an “expansive and flexible” approach to the obviousness question whether raised as a defense or a counterclaim.³¹⁰

The Court provided guidance in several areas explored previously by the Federal Circuit. Concerning the “problem to be solved” test, the Court instructed the Federal Circuit to widen its view beyond the problem that the patentee was trying to solve.³¹¹ Rather, “[u]nder the correct analysis, any need or problem

²⁹⁸*Id.* at 399.

²⁹⁹*Id.*

³⁰⁰*Id.*

³⁰¹*Id.*

³⁰²*Id.*

³⁰³*Teleflex, Inc. v. KSR Int’l Co.*, 298 F. Supp. 2d 581 (E.D. Mich. 2003).

³⁰⁴*Id.*

³⁰⁵*Teleflex, Inc. v. KSR Int’l Co.*, 119 Fed. App’x 282, 288 (Fed. Cir. 2005).

³⁰⁶*Id.*

³⁰⁷*Id.*

³⁰⁸550 U.S. at 419.

³⁰⁹*Id.* at 418.

³¹⁰*Id.* at 401.

³¹¹*Id.* at 402.

known in the field and addressed by the patent can provide a reason for combining the elements in the manner claimed.”³¹² Addressing the Federal Circuit’s rejection of the “obvious to try” defense, the Court stated that “[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions . . . the fact that a combination was obvious to try might show that it was obvious under §103.”³¹³ Finally, the Court cautioned against allowing rigid rules devised to prevent “hindsight bias” to deny fact finders recourse to common sense.³¹⁴

The Court also instructed that while a Section 103(a) rejection must explicitly identify the reasons a person of ordinary skill would have combined the prior-art elements in the manner claimed, the reasoning does not have to be found explicitly in a published reference.³¹⁵ The Court articulated several questions that a proper obviousness analysis should address:

- Is the improvement more than the predictable use of prior-art elements according to their established functions?
- Did there exist at the time of invention a known problem for which there was an obvious solution encompassed by the patent’s claims?
- Was the combination obvious to a person with ordinary skill in the art (as opposed to the patentee)?
- Aside from the “secondary considerations” articulated by *Graham*, were there design needs and market pressures, coupled with a finite number of identified predictable solutions, that would lead a person of ordinary skill in the art to pursue the combination in question?³¹⁶

Leapfrog Enterprises, Inc. v. Fisher-Price, Inc. and *Takeda Chemical Industries v. Alphapharm* were the first two cases in which the Federal Circuit applied *KSR*. In *Leapfrog Enterprises, Inc. v. Fisher-Price, Inc.*, the Federal Circuit affirmed a finding of obviousness.³¹⁷ Leapfrog filed suit against Fisher-Price and Mattel, Inc. alleging infringement of Leapfrog’s patent for a learning device to help children learn to read phonetically.³¹⁸ The asserted claim recited a toy with switches, processors, memory, and a reader. Each processor was associated with a letter of the alphabet such that by pressing a letter (switch) the processor was signaled to produce the corresponding phoneme. The “reader” communicated the identity of the letter to the processor.³¹⁹

Fisher-Price and Mattel defended on the grounds that the patent was invalid as obvious in view of a prior-art patent and a Texas Instrument product.³²⁰ The patent relied upon disclosed a mechanical learning device featuring letter-imprinted puzzle pieces that when pressed into the mechanical device caused the device to play the associated phoneme.³²¹ The second piece of prior art relied upon was a

³¹²*Id.*

³¹³*Id.* at 421.

³¹⁴*Id.*

³¹⁵*Id.*

³¹⁶*Id.* at 415–22.

³¹⁷485 F.3d 1157 (2007).

³¹⁸*Id.* at 1158.

³¹⁹*Id.*

³²⁰*Id.* at 1161.

³²¹*Id.*

product that held a book and could detect when a child pressed on different areas of the book and then, through a processor and memory, produce the associated phoneme.³²²

The trial court found obvious the automation of a mechanical device in order to gain the benefit of adaptation, decreased size, simplification, and reduced cost.³²³ The Federal Circuit agreed with the district court and concluded that Leapfrog's asserted claim was obvious and thus invalid.³²⁴ Taking into consideration that the goal of the asserted claim was to allow a child to press a switch associated with a letter in a word and hear the associated phoneme, the court held that applying modern electronics to an older mechanical device would have been obvious to one of ordinary skill in designing children's learning tools.³²⁵ The "reader" was the only element missing in the prior art relied upon.³²⁶ The court held that the readers were well-known in the art at the time of the invention and that it would be obvious to add the reader to the prior-art devices for the same reason as it was added to other children's toys—to provide the benefit of simplicity of use.³²⁷

In *Takeda Chemical Industries v. Alphapharm Pty., Ltd.*, the Federal Circuit held that, "in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound."³²⁸

Takeda owned a patent directed to thiazolidinedione derivatives useful for the treatment of diabetes.³²⁹ Takeda sued Alphapharm, a generic drug manufacturer, alleging infringement of the patent in response to Alphapharm's ANDA filing.³³⁰ Alphapharm argued that the patent was invalid as obvious over a prior-art compound that was referenced in Takeda's patent.³³¹ Alphapharm asserted that it would have been obvious to make the claimed compound using techniques known in the art.³³² Also, relying on *KSR*, Alphapharm argued that it would have been "obvious to try" the modifications employed to convert the prior-art compound into the claimed compound.³³³

The Federal Circuit affirmed the district court's judgment that a patent which related to thiazolidinedione derivatives and their use to treat Type 2 diabetes was not invalid for obviousness. The Federal Circuit acknowledged the Supreme Court's recent rejection of a rigid application of the teaching, suggestion, or motivation test in an obviousness inquiry.³³⁴ However, the court held that cases involving chemical compounds were cases in which the teaching, suggestion, or motivation test could provide "helpful insight" and thus

³²²*Id.*

³²³*Id.* at 1162.

³²⁴*Id.* at 1161.

³²⁵*Id.*

³²⁶*Id.* at 1162.

³²⁷*Id.*

³²⁸492 F.3d 1350, 1357 (Fed. Cir. 2007).

³²⁹*Id.* at 1353.

³³⁰*Id.* at 1354.

³³¹*Id.*

³³²*Id.* at 1355.

³³³*Id.* at 1359.

³³⁴*Id.* at 1356.

necessitated identification of “some reason” that would have led a chemist to modify a known compound in a particular manner.³³⁵

The Federal Circuit distinguished the facts in *KSR* and held that the modifications in Takeda’s patent were not “obvious to try.” The court held that this was not a case involving predictable solutions for antidiabetic treatment; rather, the prior art disclosed a broad spectrum of potential antidiabetic compounds.³³⁶ The court, relying on this broad spectrum of choices and on the fact that the compound chosen by Takeda exhibited negative properties that taught away from its use as an antidiabetic, held that it was not “obvious to try” the compound and/or the modifications selected by Takeda.³³⁷

In addition to anticipation, a patent may be invalid as obvious even if the subject matter of the patent is not identical to prior art under Section 102, if the difference between the subject matter and the prior art is such that the subject matter as a whole would have been obvious to a person having ordinary skill in the art to which the subject matter pertains.³³⁸

Assertion of the defense typically involves the combination of two prior art references. For example, in *Merck & Co. v. Teva Pharmaceutical USA, Inc.*,³³⁹ the patentee sued Teva, a manufacturer of generic drugs, alleging that the filing of an ANDA was an act of infringement of its Fosamax patent. The claims in dispute recited weekly dosage levels of about 70 mg of alendronate monosodium trihydrate, on an alendronic acid basis, for treatment of osteoporosis, and about 35 mg for preventing osteoporosis. The accused defended on the grounds that the patent was invalid as anticipated or obvious in view of two magazine articles which were prior art under Section 102(a).³⁴⁰ One magazine article disclosed treatment of a once-weekly dose, while the other recommended doses at 80 mg for treatment and 40 mg for prevention.³⁴¹ The district court concluded that the magazine articles did not anticipate the claims of the patent because there was no evidence that the higher doses in the magazine articles contained the same number of alendronate core molecules as those in the claims; the district court found that the articles did not make the claims of the patent obvious because it would not have been obvious to recommend a higher weekly dose, rather than the previous smaller daily doses, in light of gastrointestinal side effects associated with the daily dose.³⁴²

On appeal, the Federal Circuit reversed. The principal issue on appeal was the meaning of the claim term “about.” The rulings of the district court made it clear that it used the term “about” to account for variations in the molecular weight of the different derivatives of alendronic acid, so that the dose would deliver exactly 70 or 35 mg of alendronic acid.³⁴³ During prosecution, however, the patentee did not set out any particular definition of “about,” which must

³³⁵*Id.*

³³⁶*Id.* at 1359.

³³⁷*Id.*

³³⁸35 U.S.C. §103(a).

³³⁹395 F.3d 1364, 1367 (Fed. Cir. 2005).

³⁴⁰*Id.*

³⁴¹*Id.* at 1366–67, 1368.

³⁴²*Id.* at 1368.

³⁴³*Id.* at 1369.

therefore be given its ordinary meaning of “approximately.”³⁴⁴ In light of this interpretation, the Federal Circuit reversed, finding that there was sufficient motivation to combine the articles and to find the claims of the patent obvious in light of these articles to one of ordinary skill in the art.³⁴⁵ The patent was therefore invalid and not infringed.

B. Reliance on Art Already Cited by the PTO

It may be difficult, but not impossible, to invalidate a patent with art cited during prosecution of the patent. If a reference discloses all the limitations of a claim, that reference will anticipate and invalidate the claim, even if the reference was cited by the Examiner during prosecution of the patent.³⁴⁶ The Federal Circuit considered a district court summary judgment invalidating three patents directed to growing and eating sprouts.³⁴⁷ Johns Hopkins University sued a number of producers of sprouts for infringing three patents claiming methods of producing food products made from sprouts of certain plants. Sprouts of the plants in question were rich in glucosinolates, having a high enzyme-producing potential. The enzymes are part of the human body’s mechanism for detoxifying potential carcinogens and thus have a chemoprotective effect against cancer.³⁴⁸

The patentees did not invent the plants, such as broccoli and cauliflower, but rather discovered a new and significant property of certain types of sprouts of these plants.³⁴⁹ The district court studied the claims of the patent and the prior art, including art that had been cited during prosecution of the patents. The court noted that the references disclosed high glucosinolate content and the enzyme-producing potential of sprouts, and that these references identified the same sprouts as suitable for eating.³⁵⁰ While the patentees may have found a new benefit from eating sprouts, the prior art inherently contained all the claim limitations the patentees relied upon to distinguish their inventions from the prior art.³⁵¹ The Federal Circuit upheld summary judgment of invalidity, stating that the public remains free to make, use, or sell prior art compositions, regardless of whether they understand their complete makeup or the underlying scientific principles that allow them to operate.³⁵²

In *Elan Pharmaceuticals, Inc. v. Mayo Foundation*,³⁵³ Elan owned two patents for transgenic mice. When Elan sued the Mayo Foundation, the district court found that the patents were invalid for inherent anticipation by one of the references that had been before the PTO during prosecution, the Mullan patent. On appeal, the Federal Circuit reversed, finding that the arguments were more

³⁴⁴*Id.* at 1371–72.

³⁴⁵*Id.* at 1373–74, 1376.

³⁴⁶ *IPXL Holdings, LLC v. Amazon.com*, 430 F.3d 1377, 1381, 1383 (Fed. Cir. 2005).

³⁴⁷ *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 64 USPQ2d 1202 (Fed. Cir. 2002).

³⁴⁸*Id.* at 1345, 64 USPQ2d at 1203.

³⁴⁹*Id.* at 1346, 64 USPQ2d at 1204.

³⁵⁰*Id.* at 1350–52, 64 USPQ2d at 1206–08 (listing three references from one of the patents-in-suit).

³⁵¹*Id.* at 1351–52, 64 USPQ2d (BNA) at 1208.

³⁵²*Id.* at 1351, 64 USPQ2d at 1208, (citing *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1348, 51 U.S.P.Q.2d (BNA) 1943, 1947 (Fed. Cir. 1999)).

³⁵³ 346 F.3d 1051, 1054 (Fed. Cir. 2003).

properly characterized as enablement arguments than inherency arguments.³⁵⁴ The court found that the district court did not address the issue of whether the reference was an enabling disclosure, i.e., a disclosure that enabled one to produce the transgenic mouse without undue experimentation.³⁵⁵ The Federal Circuit noted without comment that the Mullan patent was a reference during prosecution and that the patent had amended claims to distinguish over the Mullan patent.³⁵⁶

In *Abbott Laboratories v. Syntron Bioresearch, Inc.*,³⁵⁷ Abbott sued Syntron for infringement of its patent for chemical analysis, and a jury found the claims valid and not infringed. In considering Syntron's appeal of the jury's finding of validity, and affirming the trial court's decision,³⁵⁸ the Federal Circuit noted that there was substantial evidence, including prior art that had been before the examiner at the Patent Office, to support the jury's finding of validity of the patent on a question of whether there was a sufficient written description.³⁵⁹

The court also noted that there is a presumption that all issued patents are valid.³⁶⁰ The presumption of validity remains the same whether or not the art relied upon at trial was before the examiner.³⁶¹ While allowing the use of the prior art reference at trial, the court noted that the fact that a skilled examiner passed upon that very reference during prosecution may be a factor in determining whether the challenger has met the burden of proving invalidity by clear and convincing evidence.

Anticipation, therefore, is a somewhat difficult defense to establish. Its premise is that the invention is not novel because each limitation that appears in the patent claims is disclosed by one piece of prior art. If one limitation is missing, the defense fails. The accused infringer must then turn to a combination of prior art references and assert that the claims are obvious in view of the prior art.³⁶²

Like anticipation, the question of obviousness is assessed by first determining the scope of the patent claims. But more complex than anticipation, obviousness also requires, as stated by the Supreme Court in *Graham v. John Deere Co.*,³⁶³ determining the scope of the prior art that is pertinent to the patent claims, determining the level of one ordinarily skilled in the art, and assessing whether the differences between the scope of the claims and the prior art would have been obvious to one skilled in the art at the time the invention was made.

But the inquiry is not over because the defense also involves the so-called secondary considerations.³⁶⁴ The secondary considerations generally include

³⁵⁴*Id.* at 1054, 1056.

³⁵⁵*Id.* at 1056.

³⁵⁶*Id.* at 1054.

³⁵⁷334 F. 3d 1343, 1346 (Fed. Cir. 2003).

³⁵⁸*Id.* at 1357.

³⁵⁹*Id.* at 1356–57.

³⁶⁰*Id.* at 1357 (citing 35 U.S.C. §282 (2000)).

³⁶¹*Id.* (citing *SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1355–56 (Fed. Cir. 2000)).

³⁶²Sections 102(f) and (g) provide similar defenses. Under 102(f), a person is not entitled to a patent if that person did not invent the subject matter sought to be patented. Under 102(g), a patent may be invalid as anticipated as a result of the prior conception and reduction to practice by another of the claimed invention. *Texas Instruments, Inc. v. ITC*, 988 F.2d 1165, 1077, 26 USPQ2d 1018, 1028 (Fed. Cir. 1993).

³⁶³383 U.S. 1, 15, 148 USPQ 459, 467 (1966).

³⁶⁴*Id.* at 17–18, 148 USPQ at 467.

commercial success, long-felt need for the invention, acceptance of the invention by those skilled in the art, and failures of others.³⁶⁵ Evidence of secondary considerations, including evidence of unexpected results and commercial success, is part of the “totality of the evidence” that must be considered to reach the ultimate conclusion of obviousness.³⁶⁶ While all the *Graham* factors must be considered, the weight of the secondary considerations may be insufficient to override a determination of obviousness based on primary considerations.³⁶⁷

The obviousness defense, therefore, is a fact-intensive examination that generally involves a greater amount of evidence than the typical anticipation defense. To bring about an efficient resolution, the accused infringer should expect to rely upon documentary evidence showing the prior art and upon the testimony of expert and fact witnesses not employed by the litigating parties.

In support of both defenses, one or more technical experts most likely will testify about the background of the pertinent technology and the application of the prior art to the patent claims. The evidence on anticipation usually ends here.³⁶⁸ But in presenting an obviousness defense, the technical experts may also provide testimony that will aid in determining the level of one skilled in the art. Such testimony would include the expert’s understanding of the typical education and experience of those who worked in the area of the invention. Fact testimony may also prove useful in determining the level of skill in the art. The level of skill in the art is determined at the time the invention was made, and it is conceivable that testimony from those who actually worked and published in the pertinent field is relevant to this question.

Both technical experts and fact witnesses may also provide testimony relevant to many of the secondary considerations. It is not uncommon, for instance, for evidence to be introduced through either type of witness about the acceptance of, or skepticism toward, the invention, the long-time need for the invention, or the commercial success of the invention. It has been held that while evidence of secondary considerations can support validity of the challenged patent, evidence of lack of secondary considerations cannot support a defense of invalidity.³⁶⁹

C. Invalidity Based on Loss of Right

There are three statutory provisions under 35 U.S.C. §102 that result in a loss of a right to a patent: the on-sale bar, abandonment, and a prior foreign patent. Under *LaBounty Manufacturing, Inc. v. United States International Trade Commission*,³⁷⁰ the general purpose behind these statutory bars is to require

³⁶⁵*Id.*

³⁶⁶*Richardson-Vicks, Inc. v. Upjohn Co.*, 122 F.3d 1476, 1483, 44 USPQ2d 1181, 1187 (Fed. Cir. 1997).

³⁶⁷*Id.*; *Rothman v. Target Corp.*, 556 F.3d 1310, 1322 (Fed. Cir. 2009).

³⁶⁸*See, e.g., Motorola, Inc. v. Interdigital Technology Corp.*, 121 F.3d 1461, 1473 (Fed. Cir. 1997) (“An expert’s conclusory testimony, unsupported by the documentary evidence, cannot supplant the requirement of anticipatory disclosure in the prior art reference itself.”).

³⁶⁹*Medtronic, Inc. v. Intermedics, Inc.*, 799 F.2d 734, 739, 230 USPQ 641 (Fed. Cir. 1986); *Penn Int’l Indus. v. Pennington Corp.*, 583 F.2d 1078 (9th Cir. 1978) (“Consideration of secondary factors will often assist in ascertaining whether the alleged invention is obvious, but neither their presence nor absence is alone determinative of the question.”); *Penda Corp. v. United States*, 29 Fed. Cl. 533, 567 (1993) (“[L]ack of commercial success does not in and of itself tend to show obviousness.”).

³⁷⁰958 F.2d 1066, 1071, 22 USPQ2d 1025, 1028–29 (Fed. Cir. 1992).

inventors to assert with due diligence their right to a patent through the prompt filing of a patent application.

Section 102(b) bars a patent if the invention was in public use or on sale in the United States more than one year prior to the application date of the patent. The on-sale bar of 102(b) balances the policies of allowing the inventor a reasonable amount of time to ascertain the commercial value of an invention and requiring prompt entry into the patent system after sales activity has begun. Thus, the statute limits the period of commercial sale or offers for sale of an invention to one year before the patent application is filed.³⁷¹

The on-sale bar applies when two conditions are satisfied before the critical one-year date. First, a product covered by the invention must be the subject of a commercial offer for sale. Second, the invention must be ready for patenting. The latter condition may be satisfied in at least two ways: by proof of reduction to practice before the critical date or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention.³⁷²

A patentee, however, may escape the 102(b) bar if the use for sale was experimental. “A use or sale is experimental for purposes of section 102(b) if it represents a bona fide effort to perfect the invention or to ascertain whether it will answer its intended purpose. If any commercial exploitation does occur, it must be merely incidental to the primary purpose of experimentation to perfect the invention.”³⁷³ An inventor should not be able to sell his or her invention for commercial purposes but avoid the on-sale bar by separately conducting tests on the invention.³⁷⁴ The overriding concern of 102(b) is preventing the inventor from expanding the period of commercial protection beyond the statutory limit.

For summary judgment consideration, once an alleged infringer presents facts sufficient to establish a prima facie case of public use or sale, it falls to the patent owner to come forward with some evidence raising a genuine issue of material fact to the contrary.³⁷⁵ Public uses that are nonexperimental include:

- (1) any use of the invention by a person other than the inventor who is under no limitation restriction or obligation of secrecy to the inventor;³⁷⁶
- (2) use in laboratory without confidentiality requirement;³⁷⁷ and
- (3) loss of control by the inventor of the claimed equipment while it is in the hands of a purchaser.³⁷⁸

³⁷¹*Seal-Flex, Inc. v. Athletic Track & Court Constr.*, 98 F.3d 1318, 1322, 40 USPQ2d 1450, 1452–53 (Fed. Cir. 1996).

³⁷²*Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67–68, 48 USPQ2d 1641, 1646–47 (1998).

³⁷³*LaBounty*, 958 F.2d at 1071, 22 USPQ2d at 1029; *Pennwalt Corp. v. Akzona, Inc.*, 740 F.2d 1573, 1580–81, 222 USPQ 833, 838 (Fed. Cir. 1984), *superseded on other grounds by* *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 62 USPQ2d 1705 (2002).

³⁷⁴*Seal-Flex*, 98 F.3d at 1325, 40 USPQ2d at 1454–55.

³⁷⁵*Petrolite Corp. v. Baker Hughes, Inc.*, 96 F.3d 1423, 1426, 40 USPQ2d 1201, 1203 (Fed. Cir. 1996).

³⁷⁶*Lough v. Brunswick Corp.*, 86 F.3d 1113, 39 USPQ2d 1100 (Fed. Cir. 1996), *reh'g denied*, 103 F.3d 1517, 41 USPQ2d 1385 (Fed. Cir.), *cert. denied*, 522 U.S. 806 (1997).

³⁷⁷*Baxter Int'l, Inc. v. Cobe Labs., Inc.*, 88 F.3d 1054, 39 USPQ2d 1437 (Fed. Cir. 1996).

³⁷⁸*Baker Oil Tools v. Geo Vann, Inc.*, 828 F.2d 1558, 4 USPQ2d 1210 (Fed. Cir. 1987).

“Public use” means use of the product or process in its natural and intended way even though the invention may in fact be hidden from public view with such use.³⁷⁹

A secret, hidden use of the product before the critical date will not establish a bar date if the patentee neither sold, nor offered for sale, the claimed process or any product derived from the process, nor otherwise placed either the process or any product derived from it into the public domain.³⁸⁰ In *Invitrogen Corp. v. Biocrest Manufacturing, LP*, Invitrogen, the patentee, secretly used a process for making E. coli cells in its own labs to develop new products. It maintained the process as a secret until it later prepared a patent application more than a year after it began to use the cells in its own labs.³⁸¹

After Invitrogen sued a competitor for patent infringement, Biocrest raised the defense of a Section 102(b) public use bar. The district court favored that argument and ruled on summary judgment that the Invitrogen patent was invalid. The Federal Circuit reversed. The court noted that, in this case, the product was not given to another for secret experimentation or use and that the patentee did not receive compensation for exploiting its cells internally.³⁸² Thus, the invention was not “on sale” and does not meet the “on sale” prong of the *Pfaff v. Wells* test.³⁸³

The burden of proving an instance of use or sale prior to the critical date rests upon the person challenging the validity of the patent³⁸⁴ and must be shown by clear and convincing evidence.³⁸⁵

Section 102(b) may create a bar to patentability either alone, if the device used in public is an anticipation of the later claimed invention, or in conjunction with 35 U.S.C. §103, if the claimed invention would have been obvious from the on-sale device in conjunction with the prior art.³⁸⁶ A 102(b)/103 bar, accordingly, involves a device that is not a reduction to practice of the claimed invention but is nevertheless prior art.³⁸⁷

A recent case turned on whether there had been public use of the invention more than one year prior to the filing of the patent application, and thus whether there was a statutory bar to the patent under Section 102(b).³⁸⁸ Eolas sued Microsoft for infringement of its Web browser patent, and Microsoft defended on grounds that the claims were invalid for anticipation and obviousness, as well as inequitable conduct on the part of Eolas. Eolas demonstrated one early version (DX34) to two Sun Microsystems engineers on May 7, 1993, without a confidentiality agreement, or other agreement or limitation, and later, on May 31,

³⁷⁹*FMC Corp. v. F.E. Myers & Bros.*, 384 F.2d 4, 9, 155 USPQ 299, 303 (6th Cir. 1967), *cert. denied*, 390 U.S. 988 (1968).

³⁸⁰*Invitrogen Corp. v. Biocrest Mfg., LP*, 424 F.3d 1374, 1380 (Fed. Cir. 2005).

³⁸¹*Id.* at 1379.

³⁸²*Id.* at 1383.

³⁸³*Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67–68, 48 USPQ2d 1641, 1646–47 (1998).

³⁸⁴*Dart Indus., Inc. v. E.I. du Pont de Nemours & Co.*, 489 F.2d 1359, 1364, 179 USPQ 392, 396 (7th Cir. 1973), *cert. denied*, 417 U.S. 933, 182 USPQ 1 (1974).

³⁸⁵*Atlantic Thermoplastics Co. v. Faytex Corp.*, 974 F.2d 1299, 24 USPQ2d 1138 (Fed. Cir. 1992), *appeal after remand*, 5 F.3d 1477, 1479–80, 28 USPQ2d 1343, 1344 (Fed. Cir. 1993).

³⁸⁶*Lough v. Brunswick Corp.*, 86 F.3d 1113, 1122 n.5, 39 USPQ2d 1100, 1107 n.5 (Fed. Cir. 1996), *reh'g denied*, 103 F.3d 1517, 41 USPQ2d 1385 (Fed. Cir.), *cert. denied*, 118 S. Ct. 43 (1997).

³⁸⁷*LaBounty Mfg., Inc. v. United States Int'l Trade Comm'n*, 958 F.2d 1066, 1071 n.3, 22 USPQ2d 1025, 1028 n.3 (Fed. Cir. 1992).

³⁸⁸*Eolas Tech., Inc. v. Microsoft Corp.*, 399 F.3d 1325 (Fed. Cir. 2005).

1993, posted another version (DX37) on a publicly accessible Internet site and notified a Sun Microsystems engineer that DX37 was available for downloading.³⁸⁹ The patent application was filed on October 17, 1994.

The district court found that since Eolas had changed the browser, the early version, DX34, had been abandoned within the meaning of Section 102(g), and its demonstration could not constitute a public use under 102(b).³⁹⁰ The court also decided that since DX34 had been abandoned, there was no inequitable conduct in Eolas's failure to bring DX34 or DX37 to the attention of the PTO during prosecution. The court prevented Microsoft from presenting any further evidence concerning DX34 to the jury and, after hearing from Microsoft's expert witness, granted a Rule 50 motion for judgment as a matter of law (JMOL) that neither anticipation nor obviousness defenses could be presented to the jury, including evidence concerning DX37.³⁹¹

On appeal, the Federal Circuit vacated the JMOL and also vacated the district court's decisions on abandonment, anticipation, obviousness, and inequitable conduct, and remanded.³⁹² The Federal Circuit noted that improvements to an invention do not cause the earlier version to be "abandoned," especially in this case, in which the later version, DX37, included the same contested features as the earlier version, DX34.³⁹³ The court also vacated the finding that there had been no public use in the demonstration to the Sun Microsystems engineers because DX34 had been "abandoned," especially in light of remarks by the engineers that they intended to share DX34 with other people at Sun. A public use under Section 102(b) cannot be undone by subsequent actions, and an inquiry of public use under 102(b) is independent of any inquiry of abandonment under Section 102(g).³⁹⁴

Section 102(c) provides that a person shall be entitled to a patent unless he or she has abandoned the invention. The policy behind 102(c) is that if the first inventor does not patent the invention so that the public may benefit, that inventor loses the right to patent protection. The Federal Circuit found in *Maxwell v. J. Baker, Inc.*³⁹⁵ that subject matter disclosed in the specification, but not claimed, is dedicated to the public and cannot be deemed an infringement under the doctrine of equivalents. In that case, Maxwell disclosed in the specification an alternate system for attaching shoes together for sale. This alternate method, however, was not claimed specifically. At trial, Maxwell argued the doctrine of equivalents permitted the inclusion of the alternative description in the specification. The court found that such a result would merely encourage a patent applicant to present a broad disclosure in the specification of the application and file narrow claims, avoiding examination of broader claims that the applicant could have filed consistent with the specification.³⁹⁶

³⁸⁹*Id.* at 1329, 1333, 1334.

³⁹⁰*Id.* at 1329–30.

³⁹¹*Id.* at 1330, 1335.

³⁹²*Id.* at 1335.

³⁹³*Id.* at 1333.

³⁹⁴*Id.* at 1334.

³⁹⁵86 F.3d 1098, 1106, 39 USPQ2d 1001, 1006 (Fed. Cir. 1996).

³⁹⁶*See* Genentech, Inc. v. Wellcome Found., Ltd., 29 F.3d 1555, 1564, 31 USPQ2d 1161, 1167 (Fed. Cir. 1994).

Section 102(d) forbids a U.S. patent if a foreign counterpart patent issues before the U.S. version on a foreign application filed more than one year prior to the filing date in the United States. The general purpose of this section is to require applicants for patent in the United States to exercise reasonable promptness in filing their applications after they have filed and obtained foreign patents.³⁹⁷ This section, however, is not to be confused with Section 119, which relates to foreign priority. Thus, if a U.S. application claims foreign priority rights under Section 119, its effective filing date in the United States under Section 102(d) is the actual date of the filing in the United States.³⁹⁸

It is possible to remove certain prior art by establishing that the invention was made before the effective date of the prior art. One way to show a prior invention is by relying upon a patent application filed prior to the effective date of the prior art. Case law is beginning to develop around the assertion that a provisional patent application establishes such priority.

For example, a provisional application will not support a claim for priority if the invention is not described in sufficient detail. *New Railhead Manufacturing Co. v. Vermeer Manufacturing Co.* for infringement of a patent covering a drill bit.³⁹⁹ The patents asserted by New Railhead were continuations-in-part of a provisional application that had been previously filed on February 5, 1997. Commercial embodiments of the drill bit were sold during the summer and fall of 1996, within one year of the date of filing of the provisional application. Nonprovisional patent applications that matured into the patents-in-suit were filed on November 12, 1997, claiming priority to the provisional application. These applications were filed more than one year after commercial sales had taken place. Vermeer claimed that the patents were invalid under Section 102(b) because of the on-sale bar occurring more than one year prior to the conventional filing date of the patent application.⁴⁰⁰ New Railhead claimed that the commercial sales did not qualify as prior art because the provisional patent application established a timely filing date within the one-year period allowed by Section 102(b).

The issue was whether the provisional application covered the commercial embodiments that were sold. An important feature of the patents was an angle between the drill bit and a housing that holds the bit during operation. The provisional application depicted the drill bit in an exploded view that did not show the bit attached to the housing. The provisional application also did not describe the bit as being angled with respect to the housing.⁴⁰¹ The patentee claimed that certain portions of the specification of the provisional application adequately described the required angle. The cited portions required a “high angle of attack” of the bit on the materials to be drilled, described an “asymmetrical geometry” for the drill rack, and noted that the drill had an offset drill point.⁴⁰²

The Federal Circuit was not impressed. The court noted that the provisional application did not specifically describe the angled relationship between the bit and its housing. In contrast, the nonprovisional application specifically pointed

³⁹⁷*In re Kathawala*, 9 F.3d 942, 946, 28 USPQ2d 1785, 1788 (Fed. Cir. 1993).

³⁹⁸*Bayer AG v. Barr Labs., Inc.*, 39 USPQ2d 1862, 1863–64 (S.D.N.Y. 1996).

³⁹⁹*New Railhead Mfg., LLC v. Vermeer Mfg. Co.*, 298 F.3d 1290, 63 USPQ2d 1843 (Fed. Cir. 2002).

⁴⁰⁰*Id.* at 1293, 63 USPQ2d at 1845.

⁴⁰¹*Id.* at 1293, 1295, 63 USPQ2d at 1845, 1846.

⁴⁰²*Id.* at 1296, 63 USPQ2d at 1847–48.

out that the bit body was angled with respect to the housing and depicted this relationship in the figures.⁴⁰³ The court found that the patent was not entitled to the filing date of the provisional application because the disclosure in the provisional application did not adequately support the invention claimed in the patent. The court held that the patent was invalid under 35 U.S.C. §102(b) because it was supported by the nonprovisional utility patent that was filed over a year after the commercial offers for sale.⁴⁰⁴

D. Invalidity Based on Inadequacies in the Specification or Claims

Several defenses under Section 112 deal with deficiencies in the patent specification or the claims. Their focus is different from the prior art defenses in that the novelty and obviousness of the claims are not germane. Instead, these invalidity defenses are established by showing that the specification fails to provide the best mode or an enabling description of the invention or that the claims fail to clearly point out the invention. Though not discussed here, additional defenses in this category include invalidity because the claims contain new matter under Section 132 and invalidity resulting from double patenting. Like the prior art and loss-of-right defenses, these defenses must be proven by clear and convincing evidence.⁴⁰⁵

1. The Enablement Requirement

The specification defenses generally require the patent challenger to show that the disclosures of the specification are inadequate when viewed by one skilled in the art. The determination of lack of enablement is viewed as a question of law.⁴⁰⁶ A decision on the issue of enablement, however, requires determination of whether a person skilled in the pertinent art, using the knowledge available and the disclosure in the patent document, could make and use the invention without undue experimentation.⁴⁰⁷ The trier of fact, therefore, must first determine the level of skill in the art and then, from this viewpoint, determine whether the claimed invention is enabled.

It is not required that the specification disclose every piece of information necessary to make and use the invention. For example, the amount of disclosure that will enable practice of an invention that utilizes a computer program may vary according to the nature of the invention, the role of the program in carrying it out, and the complexity of the contemplated programming, all from the viewpoint of the skilled programmer.⁴⁰⁸ Thus, the inventor is given latitude to rely upon the knowledge of one skilled in the art at the time of the invention. In the end, it is the claimed invention for which enablement is required, and a patent applicant is not required to predict every possible variation, improvement, or commercial

⁴⁰³*Id.* at 1296–97, 63 USPQ2d at 1848.

⁴⁰⁴*Id.* at 1297, 63 USPQ2d at 1848.

⁴⁰⁵*See, e.g.,* Nobelpharma AB v. Implant Innovations, Inc., 46 USPQ2d 1097, 1102 (Fed. Cir. 1998).

⁴⁰⁶*Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1469, 28 USPQ2d 1190, 1194 (Fed. Cir.), *on remand from* 503 U.S. 83, 26 USPQ2d 1721 (1993).

⁴⁰⁷*Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 941, 15 USPQ2d 1321, 1329 (Fed. Cir.), *cert. denied*, 498 U.S. 920 (1990).

⁴⁰⁸*Id.* at 941.

embodiment of the invention.⁴⁰⁹ The court, accordingly, may accept evidence on the teachings of the specification, as well as what was known to one skilled in the art, often through expert testimony.⁴¹⁰ Indeed, the courts will consider evidence, presented by an inventor, that details were omitted from the patent because they are standard in the industry.⁴¹¹

A patent specification may sufficiently enable a feature even if only the background section of the specification provides the enabling disclosure.⁴¹² Even if that section includes remarks that disparage the prior art as ineffective, this does not remove those disclosures as enabling references.⁴¹³ The Federal Circuit has concluded that such a discussion may enable one reading it to know how to make and use the invention.⁴¹⁴

Moreover, it is not fatal if some experimentation is needed, for the patent document is not intended to be a production specification.⁴¹⁵ The amount of experimentation, however, must not be unduly extensive.⁴¹⁶ According to the Federal Circuit, whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations.⁴¹⁷

2. *The Written-Description Requirement*

The first paragraph of Section 112 provides that the “specification shall contain a written description of the invention.” This requirement is different from the enablement requirement.⁴¹⁸ The purpose behind the written-description requirement is to ensure the applicant was in possession of claimed subject matter at the application date and to allow subsequent inventors to benefit from the applicant’s teachings. Thus, the specification must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, the inventor was in possession of whatever is now being claimed.⁴¹⁹

The written-description requirement may be viewed as a check on whether the inventor actually made the invention claimed. Thus, while it is not required that an inventor make a prototype of the invention, it is required that the invention be described with particularity in the body of the patent.⁴²⁰ Like enablement, the written-description requirement is judged from the viewpoint of one skilled in the art.⁴²¹ Determination of the requirement, however, is a question of fact.⁴²²

⁴⁰⁹*Phillips Petroleum Co. v. U.S. Steel Corp.*, 673 F. Supp. 1278, 1292, 6 USPQ2d 1065, 1074 (D. Del. 1987), *aff’d*, 865 F.2d 1247, 9 USPQ2d 1461 (Fed. Cir. 1989).

⁴¹⁰*Northern Telecom*, 908 F.2d at 941–42.

⁴¹¹*Koito Mfg. Co., Ltd., v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1148, 1155–56 (Fed. Cir. 2004).

⁴¹²*Callicrate v. Wadsworth Mfg., Inc.*, 427 F.3d 1361, 1374 (Fed. Cir. 2005) (citing *United States v. Teletronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988)).

⁴¹³*Id.*

⁴¹⁴*Id.*

⁴¹⁵*Northern Telecom*, 908 F.2d at 940.

⁴¹⁶*Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991).

⁴¹⁷*In re Wands*, 858 F.2d 731, 736–37, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

⁴¹⁸*Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991).

⁴¹⁹*Id.*

⁴²⁰*Fiers v. Revel*, 984 F.2d 1164, 1169, 25 USPQ2d 1601, 1605 (Fed. Cir. 1993).

⁴²¹*Wang Labs., Inc. v. Toshiba Corp.*, 993 F.2d 858, 865, 26 USPQ2d 1767, 1774 (Fed. Cir. 1993).

⁴²²*Vas-Cath*, 935 F.2d at 1563.

The written-description defense should be explored if support for claimed subject matter is alleged to be found in an earlier-filed application. In such an instance, the scope of the earlier disclosure should be considered. For example, the Federal Circuit held that a disclosure of a range of 45 percent to 55 percent in an earlier-filed application was not sufficient to support a range of “about 50% to about 60%” claimed in a later-filed application.⁴²³ The defense also should be investigated when claims are first presented after the patent application was filed or when they are amended during prosecution to the extent that it appears that they are encompassing a new invention. While a claim may not be limited to a preferred embodiment, the scope of the right to exclude may be limited by a narrow disclosure.⁴²⁴ The testimony of the inventor may be relevant to, though not dispositive of, the supporting disclosure inquiry.⁴²⁵

The use of a specification as anticipating prior art should not be confused with its use under the written-description requirement. The Federal Circuit has noted that a description of a single embodiment of broadly claimed subject matter constitutes a description of the invention for anticipation purposes. On the other hand, the same description in a specification may not alone be enough to provide a description of the invention for purposes of adequate disclosure.⁴²⁶

In *Lizardtech, Inc. v. Earth Resource Mapping, Inc.*, the Federal Circuit found that the written description was not sufficiently detailed to support a very broad claim for a method of compressing digital images.⁴²⁷ Lizardtech obtained a patent for methods of compressing digital images, the method (algorithm) including a step of maintaining updated sums, while performing the compression, to create “seamless” discrete wavelet transformation (DWT) coefficients.⁴²⁸ However, one of the claims did not include the steps of “maintaining updated sums”; using “periodically compressing said sums”; and the “seamless” limitation. Accordingly, the district court found that the claim was invalid because the specification did not describe a seamless method.⁴²⁹

During prosecution, the patentee had argued that the claims recited algorithms that resulted in a seamless DWT, and that the invention was to “provide a seamless stored array of compressed DWT coefficients.”⁴³⁰ The Examiner stated as a reason for allowance that the method of these claims formed a seamless DWT of the image. The specification, however, only provided one method for forming a seamless DWT—namely, to maintain updated sums of the DWT coefficients—and did not provide support for a claim that does not include the “seamless” limitation.

On appeal, the Federal Circuit noted that the written description must enable a person of ordinary skill in the art to make and use the full scope of the invention without undue experimentation. It must also describe the invention sufficiently to convey to a person of skill in the art that the patentee had possession of the

⁴²³Eiselstein v. Frank, 52 F.3d 1035, 1040, 34 USPQ2d 1467, 1471 (Fed. Cir. 1995).

⁴²⁴Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 1479, 45 USPQ2d 1498, 1503 (Fed. Cir. 1998).

⁴²⁵*Id.* at 1479, 45 USPQ2d at 1503.

⁴²⁶*Vas-Cath*, 935 F.2d at 1562.

⁴²⁷424 F.3d 1336 (Fed. Cir. 2005).

⁴²⁸*Id.* at 1342.

⁴²⁹*Id.* at 1343.

⁴³⁰*Id.* at 1344.

claimed invention at the time of the application, that is, that the patentee had invented what is claimed.

The court found that Lizardtech failed to satisfy either of these requirements. A person reading the patent would not understand how to make a seamless DWT and would not understand that Lizardtech had invented a method for making a seamless DWT, except by maintaining updated sums of the DWT coefficients.⁴³¹ The court analogized the case to one in which a person who invents a fuel efficient engine and describes the engine in sufficient detail may be entitled to a patent for that engine, but not necessarily for every fuel-efficient engine, no matter how similar in structure to the inventor's engine.⁴³² In other words, a specification that describes one method for a process that achieves an objective does not entitle an inventor to claim any and all means for achieving that objective.

Two biotech cases illustrate the use of the written-description requirement in defending against patent infringement. In *University of Rochester v. G.D. Searle & Co.*,⁴³³ the University of Rochester obtained a patent for a method of treating inflammation without undesirable side effects and sued Searle and Pfizer for infringement. A typical claim of the patent recited a method for selectively inhibiting the activity of enzymes in the body by administering a nonsteroidal compound that selectively inhibits such activity in a human host in need of such treatment. It was undisputed that the patent did not disclose any compounds that could be used in the claimed methods.⁴³⁴ The court found that neither the patent nor the inventors themselves knew of any such compound at the time the application was filed.⁴³⁵ The patent was therefore held invalid on summary judgment for lack of a written description.

The Federal Circuit, on appeal, noted that a written description has long been required by patent law. The district court had found that the patent did not disclose the structure or even physical properties of the compounds required to practice the claimed methods.⁴³⁶ The Federal Circuit found that the patent disclosed no compounds that would perform the claimed methods, and that no evidence had been presented that such a compound was known.⁴³⁷ Interestingly, the accused infringer, Pfizer, had adduced no evidence other than the patent-in-suit to support the written-description defense. The Federal Circuit was not persuaded that the presumption of validity requires more evidence than the patent-in-suit, noting that although Section 282 of the Patent Act places the burden of proof on the party seeking to invalidate a patent, it does not foreclose the possibility of that party's demonstrating that the patent-in-suit proves its own invalidity.⁴³⁸

In an interference proceeding for a patent on chimeric genes to enhance an immune system response, the Board of Patent Appeals and Interferences (BPAI) found that the specification of neither party met the requirements for a written description.⁴³⁹ Both parties appealed, claiming that their inventions were fully and

⁴³¹*Id.* at 1345.

⁴³²*Id.* at 1346.

⁴³³358 F.3d 916 (Fed. Cir. 2004).

⁴³⁴*Id.* at 927.

⁴³⁵*Id.* at 919.

⁴³⁶*Id.* at 926.

⁴³⁷*Id.* at 927.

⁴³⁸*Id.* at 930.

⁴³⁹*Capon v. Eshar*, 76 USPQ2d 1078 (Fed. Cir. 2005).

fairly described. The Federal Circuit agreed that the BPAI had used the wrong standard when it required that the DNA nucleotide sequences of the chimeric genes be fully presented even though the sequences were known.⁴⁴⁰ Both parties agreed that their inventions were not in discovering which DNA sequences are related to the immune response, but in the novel combination of DNA sequences to achieve a novel result.

The court then considered whether the specifications adequately supported the scope of the claims asserted. The court noted that it is not necessary for every permutation within a generally operable invention to be effective in order to obtain a generic claim, provided that the effect is sufficiently demonstrated to characterize a generic invention.⁴⁴¹ According to the court, however, an assessment of whether the inventors demonstrated sufficient support must be determined claim by claim.⁴⁴² The case was remanded for further consideration by the BPAI.

In a different case, the Federal Circuit held that where the patent specification unequivocally identified a species as unique and different, it could not convey the knowledge that the overall genus had the same qualities, regardless of the knowledge of those skilled in the art.⁴⁴³ Curtis filed a patent application for a dental floss with a low coefficient of friction, claiming polytetrafluoroethylene (PTFE) filaments coated with microcrystalline wax (MCW). This application contained a statement that it was unexpected that MCW would stick to PTFE and that the coated PTFE had a coefficient of friction intermediate between prior art floss and uncoated PTFE. Curtis also filed a counterpart application in the European Patent Office (EPO), which was published. More than one year after publication of the EPO application, he filed a continuation-in-part (CIP) application with statements in the specification that were not found in the earlier application, to the effect that coating PTFE with wax increases the coefficient of friction and thus makes the floss easier to handle.⁴⁴⁴ The CIP application included statements that suitable friction-enhancing coatings could include water-soluble polyvinyl alcohol (PVA) or polyethylene oxide (PEO).

A competitor filed a request for reexamination of the CIP patent, arguing that the CIP was invalid in view of the published EPO application, which had not been submitted to the PTO during prosecution, and also because the written description did not support the claims.⁴⁴⁵ The PTO merged a reissue application for the CIP patent with the reexamination of the CIP patent and found the claims of the CIP were anticipated by the EP application and obvious in view of another reference. To overcome the anticipation rejections, Curtis attempted to claim the benefit of the earlier filing date of the application from which the EPO application arose.⁴⁴⁶

The examiner determined that Curtis was not entitled to the earlier filing date because the disclosure of the earlier application did not enable a person of ordinary skill in the art to practice the claims without undue experimentation. The

⁴⁴⁰*Id.* at 1084–85.

⁴⁴¹*Id.* at 1085.

⁴⁴²*Id.* at 1086.

⁴⁴³*In re Curtis*, 354 F.3d 1347, 1357 (Fed. Cir. 2004).

⁴⁴⁴*Id.* at 1349.

⁴⁴⁵*Id.* at 1349–50.

⁴⁴⁶*Id.* at 1350.

Board of Patent Appeals and Interferences (the Board) affirmed on the grounds that where there is unpredictability, possession of one species does not put one in possession of a genus, and that the earlier application, disclosing only wax, did not support claims for other materials, such as PVA and PEO.⁴⁴⁷ Curtis appealed to the Federal Circuit, which also affirmed. The earlier application clearly stated that the result of MCW adhering to PTFE was unexpected, and one of ordinary skill in the art would be hard-pressed to instantly recall any other species of friction-enhancing coatings that would adhere to PTFE.⁴⁴⁸

In *Bancorp Services, LLC v. Hartford Life Insurance Co.*,⁴⁴⁹ Bancorp Services sued Hartford Life Insurance Co. for infringing its patent for a system for administering and tracking the value of life insurance policies. The district court granted summary judgment of invalidity for each independent claim in the application because the claim term “surrender valued protected investment credits” was fatally indefinite. The court accepted Hartford’s expert’s testimony that the phrase would be indefinite to a person skilled in the art of life insurance administration. But the court refused to consider testimony from one of the inventors as to the meaning of the term and evidence from Bancorp’s internal documents using the term.⁴⁵⁰

Bancorp Services appealed to the Federal Circuit. The Federal Circuit reversed, noting that a claim term is not indefinite merely because it poses a difficult issue of claim construction; if the claim is not insolubly ambiguous, it is not invalid for indefiniteness.⁴⁵¹ The court studied the patent and concluded that based on intrinsic evidence alone, the claim term could be construed properly; in addition, the district court had disregarded important portions of the extrinsic evidence offered.⁴⁵² The court disregarded Bancorp Services’ expert because he was an expert in stable value investments but not in life insurance administration, while the subject matter of the patent, as mentioned in the abstract, included a method to “track, reconcile, and administer the values of life insurance policies in separate accounts, including Stable Value Protected Investment Funds.” However, the title of the patent, “System for Managing a Stable Value Protected Investment Plan,” made it clear that the patent also related to the field of stable value protected investments.⁴⁵³

In determining the relevant art for purposes of addressing patent validity, the court must also look to the nature of the problem confronting the inventor, in this case devising a system of administering variable life insurance policies that included stable value protected investments.⁴⁵⁴ The district court correctly stated that the test is not what the parties know but what a person of ordinary skill in the art would know. However, evidence of the patentee’s knowledge and use of the term prior to patenting is relevant to show that the term was in use and had a

⁴⁴⁷*Id.* at 1351.

⁴⁴⁸*Id.* at 1355, 1357.

⁴⁴⁹359 F.3d 1367, 1369 (Fed. Cir. 2004).

⁴⁵⁰*Id.* at 1370–71.

⁴⁵¹*Id.* at 1371 (citing *Honeywell Int’l, Inc. v. Int’l Trade Comm’n*, 341 F.3d 1332, 1338–39 (Fed. Cir. 2003)).

⁴⁵²*Id.* at 1374.

⁴⁵³*Id.* at 1375.

⁴⁵⁴*Id.* (citing *Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1009 (Fed. Cir. 1983)).

discernible meaning to at least some persons practicing in the field.⁴⁵⁵ The judgment of invalidity for indefiniteness was reversed and the case was remanded.

In *Ariad Pharmaceuticals v. Eli Lilly & Co.*, the Federal Circuit confirmed that the written description requirement is separate and distinct from the enablement requirement.⁴⁵⁶ The court established that this requirement exists beyond claims in a priority dispute and must be fulfilled by claims in newly filed applications as well.⁴⁵⁷ If the claims in a patent cover multiple species, the application may not fulfill the written description requirement if a “representative number of species falling within the scope of the genus or structural features common to the members of the genus” are not disclosed.⁴⁵⁸ The court clarified that “possession of the claimed invention” is not entirely the correct standard for fulfilling the written description requirement and should instead be “possession as shown in the disclosure.”⁴⁵⁹ An actual possession of the invention outside of the specification is not sufficient to meet the requirement.⁴⁶⁰

3. *The Best Mode Requirement*

The defense of failure to disclose the best mode is different from enablement and the written-description requirement in that it requires proof of the knowledge and beliefs of the inventor in addition to how the specification would be understood by one skilled in the art. Determining whether a patent fails to comply with the best mode requirement involves two factual components.⁴⁶¹

The first inquiry is subjective: the fact finder must determine whether at the time the patent application was filed, the inventor knew of a mode of practicing the claimed invention that he or she considered to be better than any other mode.⁴⁶² The testimony of the inventor, therefore, obviously is relevant to this prong of the defense. Contemporaneous documents written by the inventor and others with knowledge of the inventor’s work also may provide evidence of the inventor’s state of mind.

The second factor is an objective determination, comparing what the inventor knew to what was disclosed in the patent. If the inventor had a best mode of practicing the invention, the fact finder must determine whether the best mode was disclosed in sufficient detail to allow a skilled artisan to practice it without undue experimentation.⁴⁶³ Invalidation based on a best mode violation requires that the inventor knew of and intentionally concealed a better mode than was disclosed.⁴⁶⁴ The best mode requirement is not violated, however, by unintentional omission of information that would be readily known to persons in the field of the invention.⁴⁶⁵ As with the enablement and written-description defenses,

⁴⁵⁵*Id.* at 1376.

⁴⁵⁶*Ariad Pharms. V. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010).

⁴⁵⁷*Id.* at 1349.

⁴⁵⁸*Id.* at 1350.

⁴⁵⁹*Id.* at 1351.

⁴⁶⁰*Id.*

⁴⁶¹*Chemcast Corp. v. Arco Indus. Corp.*, 913 F.2d 923, 927, 16 USPQ2d 1033, 1036 (Fed. Cir. 1990).

⁴⁶²*Id.* at 1036.

⁴⁶³*Id.*

⁴⁶⁴*High Concrete Structures, Inc., v. New Enter. Stone & Lime Co.*, 377 F.3d 1379, 1383 (Fed. Cir. 2004).

⁴⁶⁵*Id.*

the testimony of expert and fact witnesses will assist in determining the level of skill in the art and also in concluding whether the best mode was adequately disclosed in the patent.

4. *The Requirements of Claim Definiteness*

The standard of definiteness is one of reasonableness under the circumstances: In light of the teachings of the prior art and of the particular invention, do the claims set out and circumscribe a particular area with a reasonable degree of precision and particularity?⁴⁶⁶ Definiteness and enablement are separate requirements even though both are contained in 35 U.S.C. §112. The Supreme Court explained that “[i]ndefiniteness is objectionable because the patent does not disclose to the public how the discovery, if there is one, can be made useful and how its infringement may be avoided.”⁴⁶⁷ Indefiniteness, therefore, should not be confused with enablement, because enablement concerns the written description of the invention and indefiniteness concerns the claims.⁴⁶⁸

Compliance with the definiteness requirement is a question of law.⁴⁶⁹ A decision as to whether a claim is invalid for indefiniteness requires a determination of whether those skilled in the art would understand what is claimed.⁴⁷⁰ The defense therefore depends on whether those skilled in the art would understand the scope of the claim when the claim is read in light of the specification.⁴⁷¹ For example, the Federal Circuit found that a claim was definite where a person of ordinary skill in the art of computer programming could determine the bounds of a software claim when the claim was read in light of the specification.⁴⁷²

Technical terms, which often appear in patents, are not per se indefinite when expressed in qualitative terms without numerical limits.⁴⁷³ It is difficult, however, to predict hard-and-fast rules for assessing the indefiniteness of terms of degree. When a term of degree is used in a claim, the specification must provide some standard for measuring that degree.⁴⁷⁴ Several decisions discuss the definiteness of terms such as “substantially equal to,” “close to,” “sufficient to,” and “about.” For example, the Federal Circuit in *Amgen, Inc. v. Chugai Pharm. Co.*⁴⁷⁵ held invalid for indefiniteness claims to a purified protein of “at least about” a numerically specific activity level. After reviewing the term in the context of the specification, prosecution history, and the prior art, the court recognized that it might be acceptable in appropriate fact situations but not here. It went on to warn that its holding should not be understood as ruling out any and all uses of the term “at least about” in patent claims.⁴⁷⁶

⁴⁶⁶*Energizer Holdings, Inc. v. United States Int’l Trade Comm’n*, 435 F.3d 1366, 1370 (Fed. Cir. 2006) (citing *In re Moore*, 439 F.2d 1232, 1235, (C.C.P.A. 1971)).

⁴⁶⁷*Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 65 (1923).

⁴⁶⁸*Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 453, 227 USPQ 293, 297 (Fed. Cir. 1985).

⁴⁶⁹*Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1348 (Fed. Cir. 2005).

⁴⁷⁰*Allvoice Computing PLC v. Nuance Commc’ns, Inc.*, 504 F.3d 1236, 1240-41 (Fed. Cir. 2007).

⁴⁷¹*Id.* at 1240.

⁴⁷²*Id.* at 1242.

⁴⁷³*Modine Mfg. Co. v. United States Int’l Trade Comm’n*, 75 F.3d 1545, 1557, 37 USPQ2d 1609, 1617 (Fed. Cir. 1996).

⁴⁷⁴*Star Sci., Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1372 (Fed. Cir. 2008).

⁴⁷⁵927 F.2d at 1218, 18 USPQ2d at 1031.

⁴⁷⁶*Id.*

Nontechnical terms appearing in a patent claim may also subject a claim to invalidity due to indefiniteness. In *Datamize, LLC v. Plumtree Software, Inc.*, a patentee claimed an electronic kiosk in which an aggregate layout of a plurality of elements on an interface screen was to be aesthetically pleasing and functionally operable.⁴⁷⁷ The phrase “aesthetically pleasing” was not defined in the patent or discussed during prosecution.⁴⁷⁸ Further, the term “aesthetically pleasing” was used in a related continuation application.⁴⁷⁹ In that application, the examiner rejected the limitation, and the phrase was deleted.⁴⁸⁰

When *Datamize* sued *Plumtree* for infringement of the patent, the district court found on summary judgment that the claim was indefinite because of the “aesthetically pleasing” limitation.⁴⁸¹ The court discounted expert testimony on the grounds that expert testimony is disfavored and cannot be used to vary or contradict the claim language.⁴⁸² The expert, moreover, admitted that the specification and other references did not disclose an objective measure of aesthetics.⁴⁸³ In addition, one article on which the expert relied was published after the filing date of the application that matured into the patent in question.⁴⁸⁴

On appeal, the Federal Circuit affirmed.⁴⁸⁵ The court first noted that there must be some objective standard in order to allow the public to determine the scope of the claimed invention.⁴⁸⁶ Even if a court were to adopt a completely subjective construction of the phrase “aesthetically pleasing,” the claim would be indefinite and the patent invalid.⁴⁸⁷ The court noted that the expert himself was unable to use his own proposed parameters to determine whether particular interface screens were “aesthetically pleasing.”⁴⁸⁸ Because the patent provided no objective way to determine whether the look and feel of an interface screen was “aesthetically pleasing,” the claim was indefinite.⁴⁸⁹

Indefiniteness should not be confused with inoperability. Indeed, an accused infringer’s argument that the claims of a patent do not describe a workable invention appears irrelevant to the defense of indefiniteness. According to the Federal Circuit, an invention’s operability may say nothing about a skilled artisan’s understanding of the bounds of the claim.⁴⁹⁰ The court did note that such an argument is possibly relevant to the enablement requirement of Section 112 or to the utility requirement under Section 101.⁴⁹¹

Nonstatutory subject matter under Section 101 has been considered with indefiniteness and enablement under Section 112.⁴⁹² In one instance, applicants prepared and filed a patent application for five purified nucleic acid sequences

⁴⁷⁷417 F.3d 1342, 1344–45 (Fed. Cir. 2005).

⁴⁷⁸*Id.* at 1345.

⁴⁷⁹*Id.*

⁴⁸⁰*Id.*

⁴⁸¹*Id.* at 1345–46.

⁴⁸²*Id.* at 1346.

⁴⁸³*Id.*

⁴⁸⁴*Id.* at 1346.

⁴⁸⁵*Id.* at 1356.

⁴⁸⁶*Id.* at 1347.

⁴⁸⁷*Id.* at 1350–51.

⁴⁸⁸*Id.* at 1354.

⁴⁸⁹*Id.* at 1356.

⁴⁹⁰*Exxon Research and Eng’g Co. v. United States*, 265 F.3d 1371, 1382 (Fed. Cir. 2001).

⁴⁹¹*Id.*

⁴⁹²*In re Fisher*, 421 F.3d 1365, 1365 (Fed. Cir. 2005).

that encoded proteins and protein fragments in maize plants. These sequences are commonly referred to as expressed sequence tags, or “ESTs.”⁴⁹³ The application listed seven general ways in which the invention could be used. The Examiner rejected the claims of the application for lack of utility and for indefiniteness.

The Board of Patent Appeals and Interferences affirmed the absence of utility on the grounds that the application did not teach any specific use for the ESTs. The BPAI also held that since the application did not disclose a specific and substantial utility, the specification did not teach how to use the invention and thus was not enabling under Section 112, first paragraph.⁴⁹⁴

On appeal, the Federal Circuit affirmed, noting that an application must show that it is useful to the public as disclosed in its current form, not useful at some future date after further research. To satisfy a requirement for substantial utility, an asserted use must show that the claimed invention has a significant and presently available benefit to the public.⁴⁹⁵ An asserted use must also show that the claimed invention can be used to provide a well-defined and particular benefit to the public. Previous case law held that if a claimed invention did not have utility, the specification could not teach one how to use it.⁴⁹⁶

Indefiniteness issues may arise for claims with means-plus-function limitations.⁴⁹⁷ An applicant for a patent may express an element in a claim as a means or step for performing a specified function without reciting structure, material, or acts. In such a case, the claim shall be construed to cover the corresponding structure, material, or acts described in the specification, and their equivalents.⁴⁹⁸ In order to meet the requirement of Section 112 for definiteness, a structure disclosed in the specification must be linked clearly to and capable of performing the function claimed by the means-plus-function limitation.⁴⁹⁹ In addition, claims may be rejected or held invalid for indefiniteness for failing to invoke a Section 112, paragraph 6 construction in the first place. Where a functional claim, not reciting any language for structure, also lacks the “means-plus-function” language such as “means for,” a rebuttable presumption applies that Section 112, paragraph 6 does not apply, and thus this “purely functional” claim will be found indefinite.⁵⁰⁰ During construction, this presumption may be rebutted where the function limitation at issue does not involve any structure whatsoever, at which point, the functional limitation may be construed as a “means-plus-function” for corresponding structure in the specification.⁵⁰¹ However, during examination, the lack of appropriate “means for” language in functional limitations may essentially operate as a conclusive presumption against examining it as a Section 112, paragraph 6 claim.⁵⁰²

⁴⁹³*Id.* at 1367.

⁴⁹⁴*Id.* at 1368–69.

⁴⁹⁵*Id.* 1371.

⁴⁹⁶*Id.* at 1378–79 (citing *In re Brana*, 51 F.3d 1560, 1564 (Fed. Cir. 1995)).

⁴⁹⁷35 U.S.C. §112, ¶6.

⁴⁹⁸*Id.*

⁴⁹⁹*Default Proof Credit Card Sys. v. Home Depot U.S.A., Inc.*, 412 F.3d 1291, 1299 (Fed. Cir. 2005).

⁵⁰⁰*Ex parte Miyazaki*, No. 2007-3300, at 25 (BPAI Nov. 19, 2008) (citing *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1, 8–13 (1946)).

⁵⁰¹*Id.* at 22–23, 27.

⁵⁰²*See id.* at 22–23 (declining to rebut the presumption that §112 ¶6 does not apply even after finding that the functional limitation completely lacked structure, by reasoning that purely functional claims can be

Ex parte Miyazaki signals the BPAI's adoption of a new pre-issuance standard for indefiniteness.⁵⁰³ The BPAI has rejected the Federal Circuit's "insolubly ambiguous" standard for finding a claim indefinite.⁵⁰⁴ Rather, the BPAI adopted the "plausibly indefinite" standard, allowing examiners to reject claims that are amenable to more than one construction. In departing from the "insolubly ambiguous" standard, BPAI reasoned that the presumption of validity doesn't apply pre-issuance, and the applicant is not unfairly prejudiced by an indefiniteness rejection (as the claims could be readily, and preferably should be, amended).⁵⁰⁵ Further, finding a claim indefinite if it is amenable to more than one meaning is more in line with the PTO's practice of giving pending claims their broadest reasonable interpretation consistent with the specification.⁵⁰⁶

The district court in *Default Proof Credit Card, Inc. v. Home Depot USA, Inc.* found a patent claim indefinite because the specification failed to disclose any structure corresponding to a "means for dispensing at least one debit card" limitation.⁵⁰⁷ On appeal, the patentee argued that the specification described point-of-sale (POS) terminals as part of the claimed system, and that they were the claimed "means."⁵⁰⁸ The Federal Circuit examined the specification and agreed with the district court that the POS terminals could not constitute the means for dispensing. The claim at issue recited a POS terminal and also a "means for dispensing." It also recited an additional limitation that the debit cards were dispensed only after a validation signal was received from the separate POS assembly.⁵⁰⁹ Thus, the POS terminal and the "means for dispensing" are separate elements.

The patentee also argued the "means" could be the merchant using the apparatus, that is, the means could be a human being. In support, an expert witness had testified that the "means" were well known in the art, supporting the argument that the "means" need not be expressly described. The Federal Circuit rejected the patentee's argument, concluding that a human being cannot constitute a "means."⁵¹⁰ Further, the court rejected arguments that (1) undisclosed "parts" of the POS system could be the corresponding structure; (2) the corresponding structure need not be specifically disclosed because it is well known in the art; and (3) the corresponding structure may be incorporated by reference from a prior art patent.⁵¹¹ The court also held that while a patentee need not disclose details of structures well known in the art, the specification must nonetheless disclose some structure. Expert testimony cannot supplant the total absence of structure from the specification, and the claim was therefore invalid as indefinite.⁵¹²

amended to properly invoke §112 ¶6 analysis rather than through a post-issuance type analysis to rebut the presumption).

⁵⁰³*Id.* at 27–28.

⁵⁰⁴*Id.* at 11–12 (citing *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1347 (Fed. Cir. 2005)).

⁵⁰⁵*Ex parte Miyazaki*, at 12 ("the patent drafter is in the best position to resolve the ambiguity in the patent claims, and it is highly desirable that patent examiners demand that applicants do so in appropriate circumstances so that the patent can be amended during prosecution") (quoting *Halliburton Energy Servs. v. M-ILLC*, 514 F.3d 1244, 1255 (Fed. Cir. 2008)).

⁵⁰⁶*Id.* at 13.

⁵⁰⁷389 F. Supp. 2d 1325 (S.D. Fla. 2004).

⁵⁰⁸412 F.3d at 1299.

⁵⁰⁹*Id.* at 1300.

⁵¹⁰*Id.* (citing *In re Prater*, 415 F.2d 1393, 1398 (C.C.P.A. 1969)).

⁵¹¹*Id.*

⁵¹²*Id.* at 1302.

A claim is also indefinite if it attempts to claim both a system and a method for using that system.⁵¹³ In *IPXL Holdings, LLC v. Amazon.com, Inc.*, one claim of the patent recited a system and included a limitation that required the user to perform one task or another.⁵¹⁴ The Federal Circuit held a claim reciting both a system and a method for using the system is invalid, because it is unclear whether infringement of the claim occurs when one creates a system that allows the user to perform the tasks, or whether infringement occurs when the user actually performs one of the tasks.⁵¹⁵

The court explained that Section 112, paragraph 2 requires that the claims of a patent particularly point out and distinctly claim the subject matter which the applicant regards as the invention. A claim is considered indefinite if it does not reasonably apprise those skilled in the art of its scope.⁵¹⁶ According to the court, previous cases before the BPAI have made it clear that reciting both an apparatus and a method of using that apparatus renders the claim indefinite under Section 112, paragraph 2.⁵¹⁷ The court concluded that such a claim would result in a combination of two statutory classes of invention.⁵¹⁸ A manufacturer of the apparatus would not know from the claim whether he or she would be liable for contributory infringement because a buyer of the apparatus later performed the claimed method of using the apparatus.⁵¹⁹ Because of this ambiguity, the court reassured that the claim would not be sufficiently precise to provide competitors with an accurate determination of the metes and bounds of patent protection.⁵²⁰

5. *The Subject Matter That the Applicant Regards as His Invention*

Patents may also be declared invalid if the claims do not claim the subject matter that the applicant regards as his invention, as required by Section 112, second paragraph. In *Allen Engineering Corp. v. Bartell Industries, Inc.*,⁵²¹ a patent was applied for and granted on a motorized riding trowel for finishing a concrete surface. The riding trowel contained rotating blades to finish and smooth the concrete. The specification described the motor, drive shafts, and steering boxes necessary to operate the machine.⁵²² One requirement was that a lever arm tilt the gearbox in a plane generally parallel with a biaxial plane defined by a pair of rotatable shafts.⁵²³

It was clear from an inspection of the specification and drawings that the machine would not work if the plane of the gearbox were perpendicular to the biaxial plane; the specification stated specifically that the gearbox could not pivot in a plane perpendicular to the biaxial plane.⁵²⁴ Nevertheless, several claims of the

⁵¹³*IPXL Holdings, LLC v. Amazon.com, Inc.*, 430 F.3d 1377 (Fed. Cir. 2005).

⁵¹⁴*Id.* at 1384.

⁵¹⁵*Id.*

⁵¹⁶*Id.* at 1383–84 (citing *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1217 (Fed. Cir. 1991)).

⁵¹⁷*Id.* at 1384 (citing *Ex parte Lyell*, 17 USPQ2d 1548 (BPAI Aug. 16, 1990)).

⁵¹⁸*See id.* (citing U.S. PAT. & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE §2173.05(p)(II) 1302.12 (1999)).

⁵¹⁹*Id.*

⁵²⁰*Id.*

⁵²¹299 F.3d 1336, 63 USPQ2d 1769 (Fed. Cir. 2002).

⁵²²*Id.* at 1349, 63 USPQ2d at 1776.

⁵²³*Id.* at 1343, 63 USPQ2d at 1771.

⁵²⁴*Id.* at 1349, 63 USPQ2d at 1776.

patent claimed this perpendicular arrangement, rather than the parallel arrangement which was clearly meant.⁵²⁵ The court found the claims invalid under Section 112, second paragraph, because it was apparent from a simple comparison of the claims with the specification that the inventor did not regard as his invention a trowel in which the second gearbox pivoted only in a plane perpendicular to the biaxial plane.⁵²⁶ It was of no moment that the contradiction was obvious; the semantic indefiniteness of the claims was not rendered unobjectionable merely because it could have been corrected.⁵²⁷

E. Invalidity Based on Nonstatutory Double Patenting

In *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline, PLC*,⁵²⁸ GlaxoSmithKline filed a patent application in 1975 for the antibiotic clavulanic acid and its salts. The Patent Office issued a restriction requirement, asking the applicants to choose one of eight inventions the PTO found in the application. This led to two patents from the 1975 applications and two further applications. Patents were issued for one of these in 1985 and for the other in 2000 and 2001. No terminal disclaimers were filed in any of the cases.⁵²⁹ Pharmaceutical companies seeking to market generic equivalents filed three lawsuits seeking declaratory judgments of invalidity. The suits resulted in rulings and summary judgments that seven patents which were prosecuted without further restriction requirements on the record were invalid for nonstatutory double patenting, and the suits were consolidated into a single appeal.⁵³⁰

The Federal Circuit noted that it took almost a quarter century, from the original 1975 application until the last issue dates in 2000 and 2001, to prosecute these patents, and that the record did not explain such long delays.⁵³¹ At least three of the patents had been reexamined by the PTO, which concluded that the patents were valid because they were shielded from their parent applications by 35 U.S.C. § 121, which bars the use of a patent as a reference against a subsequent divisional application.⁵³² The district court, however, could find no restriction requirement on the record that enabled shielding by Section 121.⁵³³

The protection of Section 121 is available only if the restriction requirement is imposed by the PTO and shows with sufficient clarity and detail that a particular claim falls within the scope of the distinct inventions that the PTO has restricted.⁵³⁴ In addition, the claims of some of the “divisional” applications had not been a part of their “parent” application, and thus these claims could not have been the subject of a restriction requirement. In one of the patents, it appears

⁵²⁵*Id.*

⁵²⁶*Id.*

⁵²⁷*Id.* (citing *In re Hammack*, 427 F.2d 1384, 1388 & n.5, 166 USPQ 209, 213 & n.5 (C.C.P.A. 1970)).

⁵²⁸349 F.3d 1373 (Fed. Cir. 2003).

⁵²⁹*Id.* at 1375.

⁵³⁰*Id.* at 1376.

⁵³¹*Id.* at 1382.

⁵³²*Id.* at 1378.

⁵³³*Id.*

⁵³⁴*Id.* at 1382. This point was emphasized in a subsequent case in which the Federal Circuit vacated a district court’s summary judgment of validity because the record of restriction requirements was not at all clear. *Bristol-Myers Squibb Co. v. Pharmachemie B.V.*, 361 F.3d 1343, 1350 (Fed. Cir. 2004).

that the examiner had not entered the claims, and therefore there had not been a restriction requirement.⁵³⁵ Thus, the earlier patents were available as references against the seven later patents because Section 121 was not available as a shield, and the patents were invalid for nonstatutory double patenting.

F. The Section 282 Notice

A party challenging patent validity must ensure that notice of the basis for certain defenses is provided in writing to the adverse party. Section 282 requires that the party asserting invalidity or noninfringement shall at least 30 days before the trial give notice in the pleadings or otherwise in writing to the adverse party of the country, number, date, and name of the patentee of any patent; the title, date, and page number of any publication to be relied upon as anticipation of the patent-in-suit or as showing the state of the art; and the name and address of any person who may be relied upon as the prior inventor or as having prior knowledge of, or as having previously used or offered for sale, the invention of the patent-in-suit. If such notice is not provided, proof of these matters may not be made at the trial without permission of the court.⁵³⁶

G. Pleading Invalidity

Resolution of an invalidity defense may depend on whether it was pled as an affirmative defense, in a counterclaim, or in an action for declaratory judgment. When reviewing infringement on appeal, the Federal Circuit must review the issue of validity when that issue was raised by counterclaim or declaratory judgment and was decided by the trial court.⁵³⁷ However, according to the Federal Circuit, the Supreme Court in *Cardinal Chemical Co. v. Morton International, Inc.*⁵³⁸ suggested that appellate review was unnecessary when the issue of validity was raised only as an affirmative defense. Accordingly, the district court has no obligation to decide the issue of validity when the dispute has been finally disposed on other grounds.⁵³⁹

A particular invalidity defense might not be clear to the parties at during the original pleading stages. The availability of certain prior art may only become clear after claim construction. If a claim construction, for example, expands claim scope making new art relevant to the claims, a defendant may amend its defenses to plead invalidity.⁵⁴⁰ Claim construction may “change the rules of the game” such that, even a ten year delay in bringing an invalidity claim may be held non-prejudicial.⁵⁴¹

⁵³⁵*Geneva Pharms., Inc.*, 349 F.3d at 1379–80.

⁵³⁶*Eaton Corp. v. Appliance Valves Corp.*, 790 F.2d 874, 879, 229 USPQ 668, 672 (Fed. Cir. 1986).

⁵³⁷*Multiform Desiccants, Inc. v. Medzan, Ltd.*, 133 F.3d 1473, 1481 (Fed. Cir. 1998); *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 26 USPQ2d 1721 (1993).

⁵³⁸*Cardinal Chem.*, 568 U.S. at 83, 26 USPQ2d at 1721.

⁵³⁹*Multiform*, 133 F.3d at 1481 (citing *Cardinal Chem.*, 508 U.S. 83, 26 USPQ2d 1721).

⁵⁴⁰*Asyst Techs., Inc. v. Emtrak, Inc.*, 544 F.3d 1310, 1317 (Fed. Cir. 2008); *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1357 (Fed. Cir. 1998).

⁵⁴¹*Asyst Techs.* at 1317.

IV. INEQUITABLE CONDUCT

An applicant for a patent is under a duty of candor in dealing with the PTO. Inequitable conduct is a breach of that duty. The doctrine arises from case law, and the PTO has set forth its view of an applicant's duty of candor.⁵⁴² The PTO has revised its applicable regulations over the years, and it is important to identify the rule that was in effect when the alleged inequitable conduct occurred. If inequitable conduct is proven, the patent is unenforceable.

The defense involves proving two threshold elements: (1) materiality of undisclosed information to the patent examiner and (2) intent to deceive the patent examiner.⁵⁴³ Once materiality and intent are established, the court performs a balancing test, considering all circumstances before deciding on inequitable conduct.⁵⁴⁴

A. Materiality

Information is "material" when there is a substantial likelihood that a reasonable examiner would have considered the information important in deciding whether to allow the application to issue as a patent.⁵⁴⁵ In *Purdue Pharma, LP v. Endo Pharmaceuticals, Inc.*, the Federal Circuit found materiality under Rule 56 even where a reasonable examiner would not have relied on the misrepresentation.⁵⁴⁶ Failure to inform the PTO that a "surprising discovery" was based on insight rather than experimental data becomes a material omission when repeatedly used to distinguish prior art.⁵⁴⁷ If the information allegedly withheld is not as pertinent as that considered by the examiner, or is merely cumulative to that considered by the examiner, such information is not material.⁵⁴⁸ The standard applied in determining whether a reference is material is not whether the particular examiner of the application at issue considered the reference to be important; rather, it is the opinion of a "reasonable examiner."⁵⁴⁹

⁵⁴²37 C.F.R. §1.56 (1992).

⁵⁴³*Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178, 33 USPQ2d 1823, 1826–27 (Fed. Cir. 1995); *Halliburton Co. v. Schlumberger Tech. Corp.*, 925 F.2d 1435, 1439, 17 USPQ2d 1834, 1838 (Fed. Cir. 1991).

⁵⁴⁴*Modine Mfg. Co. v. Allen Group, Inc.*, 917 F.2d 538, 542, 16 USPQ2d 1622, 1625 (Fed. Cir. 1990).

⁵⁴⁵*In re Jerabek*, 789 F.2d 886, 890, 229 USPQ 530, 533 (Fed. Cir. 1986).

⁵⁴⁶*Purdue Pharma, LP v. Endo Pharms., Inc.*, 438 F.3d 1123 (Fed. Cir. 2006).

⁵⁴⁷*Id.* at 1133–34.

⁵⁴⁸*Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1582, 18 USPQ2d 1001, 1014–15 (Fed. Cir. 1991).

⁵⁴⁹*Molins PLC*, 48 F.3d at 1178, 33 USPQ2d at 1828. The PTO revised 37 CFR §1.56 in 1992. The new PTO Rule 56, which became effective March 16, 1992, states that all individuals associated with the filing or prosecution of a patent application have "a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." The section defines material as follows:

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in: (i) Opposing and argument of unpatentability relied on by the Office, or (ii) Asserting an argument of patentability.

37 C.F.R. §1.56 (1992).

The Federal Circuit recently addressed whether the Rule 56 standard replaced the “reasonable examiner” standard, or, if it did not replace it, whether the narrowing of Rule 56 by the 1992 amendment narrowed the “reasonable examiner” standard.⁵⁵⁰ The court held that the Rule 56 standard does not replace the “reasonable examiner” standard; it merely provides an additional test of materiality.⁵⁵¹ A misstatement or omission is material if it satisfies any test of materiality—the “reasonable examiner” test, Rule 56, or any of the older tests.⁵⁵²

Materiality is often established through the testimony of experts, who may compare the withheld information to the information that was considered by the examiner of the patent. Admissions of materiality can also be found in the documents and actions of the patent holder.

B. Intent

Intent is an independent element of inequitable conduct in patent prosecution and must be separately established.⁵⁵³ Given the ease with which a relatively routine act of patent prosecution can be portrayed as intended to mislead or deceive, clear and convincing evidence of conduct sufficient to support an inference of culpable intent is required.⁵⁵⁴

Prophetic examples—examples not actually conducted but which describe the manner and process of making an embodiment of an invention—may give rise to an inequitable-conduct defense. In an infringement action, a patent related to the production of human growth hormone was declared unenforceable because the patentee failed to inform the examiner that examples in the specification were prophetic.⁵⁵⁵ The court found that it was intentionally misleading by the patentee to describe the use of human growth hormones in the past tense when the work had never been successfully performed.⁵⁵⁶

A finding of culpable intent requires consideration of all the evidence, “including evidence indicative of good faith.”⁵⁵⁷ Knowledge alone is not culpable intent.⁵⁵⁸ Moreover, an inference without any probative evidence is insufficient to show culpable intent.⁵⁵⁹ A finding that particular conduct amounts to “gross negligence” does not of itself justify an inference of intent to deceive. Instead,

The Federal Circuit has held that this version should not be treated as retroactive but rather should apply only to activities after March 16, 1992. The court, however, has not ruled on the impact of the 1992 version of the rule. *Molins PLC*, 48 F.3d at 1179 n.8, 33 USPQ2d at 1827 n.8.

⁵⁵⁰*Digital Control, Inc. v. Charles Machine Works*, 437 F.3d 1309 (Fed. Cir. Feb. 8, 2006).

⁵⁵¹*Id.* at 1314–15.

⁵⁵²*Id.*

⁵⁵³*Allied Colloids, Inc. v. American Cyanamid Co.*, 64 F.3d 1570, 1578, 35 USPQ2d 1840, 1845 (Fed. Cir. 1995).

⁵⁵⁴*Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 939, 15 USPQ2d 1321, 1327 (Fed. Cir.), *cert. denied*, 498 U.S. 920 (1990).

⁵⁵⁵*Novo Nordisk Pharms., Inc. v. Bio-Technology Gen. Corp.*, 424 F.3d 1348, 1352 (Fed. Cir. 2005).

⁵⁵⁶*Id.* at 1359–60.

⁵⁵⁷*Hupp v. Siroflex of Am., Inc.*, 122 F.3d 1456, 1465, 43 USPQ2d 1887, 1894 (Fed. Cir. 1997).

⁵⁵⁸*Allen Organ Co. v. Kimball Int'l, Inc.*, 839 F.2d 1556, 1568, 5 USPQ2d 1769, 1779 (Fed. Cir. 1988).

⁵⁵⁹*Multiform Desiccants, Inc. v. Medzan, Ltd.*, 133 F.3d 1473, 1482 (Fed. Cir. 1998).

the conduct, viewed in light of all the evidence, including evidence of good faith, must indicate sufficient culpability to require a finding of intent to deceive.⁵⁶⁰

Inequitable conduct is rarely proven with direct evidence. The “smoking gun” document rarely emerges from the patent owner’s files. Rather, intent may be sufficiently inferred from circumstantial evidence.⁵⁶¹

The Federal Circuit also has developed a balancing approach to materiality and intent. A greater showing of materiality may permit a lesser showing of facts from which intent can be inferred to justify holding the patent unenforceable.⁵⁶² Alternatively, a specific showing of wrongful intent can lower the standard of materiality. Thus efforts must be made to establish intent directly and to establish that the accused activity was highly material.

In *Ulead Systems, Inc. v. Lex Computer & Management Corp.*,⁵⁶³ Ulead Systems sued Lex Computer in a declaratory judgment action concerning one of Lex’s patents. One of the allegations was that the patent was unenforceable because Lex had paid the maintenance fee for a small entity, when in fact the patent was licensed to at least three large entities.⁵⁶⁴ While Lex had never had more than 20 employees, it was established that the patent in question had been licensed to Adobe Systems and two other large entities. After the suit was filed, Lex corrected its error by submitting the balance of the deficiency in accordance with the procedures for correcting erroneous underpayments. The PTO accepted payment and changed Lex’s status to large entity.⁵⁶⁵

The district court, however, granted summary judgment to Ulead on the grounds that Lex had misled the PTO by declaring small-entity status and that the patent had expired. The court also found Ulead had shown by clear and convincing evidence that Lex was guilty of inequitable conduct and bad faith, and it awarded attorney’s fees and costs.⁵⁶⁶

On appeal, the Federal Circuit focused on the allegation of inequitable conduct. In a case of this type, inequitable conduct requires evidence of affirmative misrepresentation of a material fact coupled with an intent to deceive.⁵⁶⁷ The appropriate rule for maintenance fees, 37 C.F.R. §1.28(d), states that improper payment of small-entity fees constitutes fraud on the PTO only when there is an intent to deceive. The testimony of Lex’s president (an attorney but not a patent attorney) established that he was unaware that licensing to a large entity would cause loss of small-entity status; the testimony of Lex’s patent attorney, who did not handle the licensing arrangements, established that he was unaware of the licenses to the large entities.⁵⁶⁸ Summary judgment on the issue of intent was

⁵⁶⁰*Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 876, 9 USPQ2d 1384, 1392 (Fed. Cir. 1988), *vacated on other grounds*, 866 F.2d 1398, 9 USPQ2d 1831 (Fed. Cir.), *cert. denied*, 490 U.S. 1067 (1989).

⁵⁶¹*Klein v. Peterson*, 866 F.2d 412, 415, 9 USPQ2d 1558, 1560 (Fed. Cir.), *cert. denied*, 490 U.S. 1091 (1989).

⁵⁶²*American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1363, 220 USPQ 763, 773 (Fed. Cir.), *cert. denied*, 469 U.S. 821, 224 USPQ 520 (1984).

⁵⁶³351 F.3d 1139 (Fed. Cir. 2003).

⁵⁶⁴*Id.* at 1142.

⁵⁶⁵*Id.* at 1143.

⁵⁶⁶*Id.*

⁵⁶⁷*Id.* at 1144 (citing *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1366 (Fed. Cir. 2001)). The court also noted that the previous standard had been gross negligence. *Id.* at 1148.

⁵⁶⁸*Id.* at 1147, 1148.

vacated, since a question of fact on intent remained. The court also held that when the PTO accepts deficiency payments in good faith and without investigation under Section 1.28, a district court has no obligation or authority to conduct an investigation into the patentee's good faith; the submission of the deficiency fee payment, when accepted by the PTO, is effective to correct the error.⁵⁶⁹

In *Nilssen v. Osram Sylvania, Inc.*,⁵⁷⁰ the Federal Circuit affirmed the district court's judgment that fifteen patents prosecuted pro se by the inventor were unenforceable due to inequitable conduct.⁵⁷¹ Mr. Nilssen was the inventor of a large number of electrical lighting patents, and decided to take over prosecuting his own patent applications because he felt that his understanding of the subject matter was better than that of any attorney.⁵⁷² His not-for-profit organization, Geo Foundation, was the exclusive licensee of the Nilssen patent portfolio.⁵⁷³ The Geo Foundation and Nilssen sued the lighting company Osram, alleging that products manufactured and sold by Osram infringed the Nilssen patents.⁵⁷⁴ Osram asserted inequitable-conduct defenses, among others, against Nilssen.⁵⁷⁵

After conducting a six-day bench trial on Osram's inequitable-conduct defenses, the court found that Nilssen had: (1) misrepresented small entity status to justify small entity payments; (2) submitted affidavits in support of patentability without informing the examiner of the affiant's relationship to the inventor and financial interest in the invention; (3) misclaimed priority dates; (4) failed to disclose relevant litigation; and (5) failed to disclose material prior art.⁵⁷⁶ Nilssen initially asserted fifteen patents.⁵⁷⁷ He withdrew four of the patents shortly before trial.⁵⁷⁸ However, the district court held all fifteen patents unenforceable under what it called the "doctrine of infectious unenforceability."⁵⁷⁹ Under that doctrine, "[i]nequitable conduct with respect to one or more patents in a family can infect related applications."⁵⁸⁰

The Federal Circuit affirmed on all counts. As to misrepresentations of small-entity status, the court commented that "[w]hile a misrepresentation of small entity status is not strictly speaking inequitable conduct in the prosecution of a patent, . . . it is not beyond the authority of a district court to hold a patent unenforceable for inequitable conduct in misrepresenting one's status as justifying small entity maintenance payments."⁵⁸¹ The district court had found clear and convincing evidence of "Nilssen's obvious intent to mislead" and found Nilssen's justifications "not credible."⁵⁸² Regarding the misclaimed priority dates, the Federal Circuit affirmed the district court's finding of inequitable conduct, even

⁵⁶⁹*Id.* at 1150.

⁵⁷⁰504 F.3d 1223 (Fed. Cir. 2007).

⁵⁷¹*Id.* at 1235–36.

⁵⁷²*Id.* at 1226–27.

⁵⁷³*Id.* at 1227.

⁵⁷⁴*Id.*

⁵⁷⁵*Id.*

⁵⁷⁶*Id.* at 1229–36.

⁵⁷⁷*Id.* at 1266.

⁵⁷⁸*Id.*

⁵⁷⁹*Id.* at 1230.

⁵⁸⁰*Id.*

⁵⁸¹*Id.* at 1231.

⁵⁸²*Id.* Among Nilssen's justifications were that he was not aware of the rule change in 2000 regarding large entity fees because he had continued to rely on a pre-2000 version of the MPEP. *Id.* at 1232.

though the examiner did not rely on the claim for priority for patentability.⁵⁸³ The Federal Circuit stated that “[a] claim for priority is inherently material to patentability because a priority date may determine validity, whether an issue arises in prosecution or later in court challenges to validity. . . . [A] misrepresentation that would not have immediately affected patentability is still material.”⁵⁸⁴ Failure to disclose relevant litigation was held material because litigation “signals the examiner that other material information relevant to patentability may become available through litigation proceedings.”⁵⁸⁵ Finally, the Federal Circuit affirmed the district court’s inference of intent with respect to the references Nilssen withheld.⁵⁸⁶ The district court based its inference on the fact that each of the references was repeatedly cited to Nilssen by the PTO examiners during the prosecution of his patents.⁵⁸⁷ In closing, the Federal Circuit commented that each of the five issues met with defenses by Nilssen that were not unreasonable when viewed in isolation; however, in combination the “repeated attempts to avoid playing fair and square with the patent system” constituted inequitable conduct.⁵⁸⁸

C. Pleading Inequitable Conduct

Inequitable conduct may be pled as an affirmative defense or in a counterclaim for declaratory judgment. As with the pleading of invalidity, the differences between an affirmative defense and a declaratory judgment counterclaim should be kept in mind.⁵⁸⁹

The accused infringer also should consider when to plead the inequitable conduct defense. Since all pleadings are subject to Rule 11 of the Federal Rules of Civil Procedure, inequitable conduct should not be pled without the proper basis. Moreover, the excessive assertion of the inequitable conduct defense in patent litigation has been criticized. But, since much of the relevant evidence is often under the patentee’s control, facts underlying inequitable conduct often are unearthed through discovery. Accordingly, one approach to pleading is to assert that the patentee may have committed inequitable conduct and to supplement discovery, as necessary, as the defense is developed.

In a recent case, Bruno sued Acorn for allegedly infringing its patent for “stairlifts,” devices that allow a person with mobility impairments to ascend and descend stairways on a chair that travels along a rail.⁵⁹⁰ During discovery, numerous documents were found that had not been submitted by Bruno to the examiner during prosecution of the patent. These documents included submissions to the Food and Drug Administration (FDA) of several prior-art stairlifts when Bruno sought approval to sell stairlifts covered by the patent.⁵⁹¹ Acorn then asked the district court to find inequitable conduct on Bruno’s part and to declare the case

⁵⁸³*Id.* at 1233.

⁵⁸⁴*Id.*

⁵⁸⁵*Id.* at 1234.

⁵⁸⁶*Id.* at 1235.

⁵⁸⁷*Id.*

⁵⁸⁸*Id.*

⁵⁸⁹*See* *MultiForm Desiccants, Inc. v. Medzan, Ltd.*, 133 F.3d 1473, 1481 (Fed. Cir. 1998); *Cardinal Chem. Co. v. Morton Int’l, Inc.*, 508 U.S. 83, 26 USPQ2d 1721 (1993). While these cases involved an invalidity defense, their holdings can be applied to the inequitable conduct defense.

⁵⁹⁰*Bruno Indep. Living Aids, Inc., v. Acorn Mobility Svcs., Ltd.*, 394 F.3d 1348 (Fed. Cir. 2005).

⁵⁹¹*Id.* at 1350.

exceptional for the purpose of awarding attorney's fees under Section 285. The district court agreed and awarded attorney's fees to Acorn.

On appeal, Bruno argued that it did not have a duty to disclose because it did not appreciate the materiality of at least one item of the prior art. However, the Federal Circuit found that Bruno possessed actual knowledge of this item and knew or should have known of its materiality.⁵⁹² One standard of materiality under 37 C.F.R. §1.56 is whether the information refutes, or is inconsistent with, a position the applicant takes in asserting an argument of patentability. During prosecution, one claim of the application was amended to recite a front offset swivel, and arguments were made that this amendment distinguished over the prior art.⁵⁹³ The district court found, and the Federal Circuit agreed, that if the examiner had known of the prior art, he would not have agreed with Bruno's arguments concerning novelty. Thus the prior art was material.⁵⁹⁴ Intent was inferred, primarily because Bruno disclosed prior art to the FDA, but not to the PTO, and offered no credible explanation for nondisclosure to the PTO.⁵⁹⁵

V. ANTITRUST

The patent statute requires that nothing in it "shall be deemed to convey to any person immunity from civil or criminal liability, or to create any defense to actions, under any antitrust law."⁵⁹⁶ Thus, if the patentee violates the antitrust laws in connection with the use of its patent, an accused infringer may assert an antitrust counterclaim. Conduct that may violate the antitrust laws includes enforcing a patent known to have been obtained through fraud or to be invalid, tying the purchase of an unpatented good to a license under a patent, or using the patent to violate the antitrust laws in any other way.⁵⁹⁷

The Federal Circuit decided that all antitrust claims premised on the bringing of a patent infringement suit are to be decided according to Federal Circuit law.⁵⁹⁸ However, the Federal Circuit will continue to apply the law of the appropriate regional circuit to issues involving other elements of antitrust law such as relevant market, market power, and damages, because those issues are not unique to patent law.⁵⁹⁹

Section 1 of the Sherman Antitrust Act forbids contracts or conspiracies in restraint of trade, while Section 2 forbids monopolizing, or attempts to monopolize, a trade.⁶⁰⁰ In general, under Section 2 of the Sherman Act, a monopoly may be proven by showing (1) the possession of monopoly power in the relevant market, and (2) the willful acquisition or maintenance of that power as opposed to growth or development as a consequence of a superior

⁵⁹²*Id.* at 1352.

⁵⁹³*Id.* at 1353.

⁵⁹⁴*Id.* at 1354.

⁵⁹⁵*Id.*

⁵⁹⁶35 U.S.C. §211.

⁵⁹⁷*Atari Games Corp. v. Nintendo of Am., Inc.*, 897 F.2d 1572, 1577–78, 14 USPQ2d 1034, 1037 (Fed. Cir. 1990).

⁵⁹⁸*Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068, 46 USPQ2d 1097, 1104 (Fed. Cir. 1998) (en banc in relevant portion).

⁵⁹⁹*Id.* at 1068, 46 USPQ2d 1097 at 1104.

⁶⁰⁰15 U.S.C. §§1 and 2 (1994).

product, business acumen, or historic accident.⁶⁰¹ An attempt to monopolize, also prohibited by Section 2, is proven when the following elements are established: (1) a specific intent to monopolize, (2) anticompetitive conduct, and (3) a dangerous probability of success.⁶⁰²

A. *Walker Process Claim*

A patentee's attempt to enforce its patent with the knowledge that the patent was obtained by fraud, constitutes an antitrust violation where the elements of a Sherman Act violation are established.⁶⁰³ In *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*,⁶⁰⁴ the Supreme Court held that in an antitrust plaintiff must prove that the patentee obtained the asserted patent by knowingly and willfully misrepresenting facts to the Patent Office. *Walker Process* fraud is a variant of common law fraud and requires the elements of (1) a representation of a material fact, (2) the falsity of that representation, (3) an intent to deceive (scienter), (4) justifiable reliance upon the misrepresentation by the party deceived which induces him to act thereon, and (5) injury to the party deceived as a result of his reliance on the misrepresentation.⁶⁰⁵ Exemplary cases of fraudulent procurement of a patent include *Precision Instrument Manufacturing v. Automotive Maintenance Machinery Co.*⁶⁰⁶ and *Hazel-Atlas Glass Co. v. Hartford Empire Co.*⁶⁰⁷

A claim of *Walker Process* fraud is distinct from the defense of inequitable conduct, which is a broader, more inclusive concept. In *Nobelpharma, AB v. Implant Innovations, Inc.*,⁶⁰⁸ the Federal Circuit explained that inequitable conduct may be based on evidence of a lesser misrepresentation or omission, such as omission of a reference that a reasonable examiner would consider important to the patentability of a claim. In contrast, a finding of *Walker Process* fraud requires greater showings of both intent and materiality than does a finding of inequitable conduct. Moreover, unlike a finding of inequitable conduct, the court does not apply equitable balancing of lesser degrees of materiality and intent in a finding of *Walker Process* fraud. Rather, the plaintiff must provide independent and clear evidence of deceptive intent together with a clear showing of reliance, i.e., that the reasonable examiner, but for the misrepresentation or omission, would deny the patent. Therefore, for an omission such as a failure to cite a piece of prior art

⁶⁰¹United States Philips Corp. v. Windmere Corp., 861 F.2d 695, 703, 8 USPQ2d 1885, 1891 (Fed. Cir. 1988).

⁶⁰²Abbott Labs v. Brennan, 952 F.2d 1346, 1354, 21 USPQ2d 1192, 1198 (Fed. Cir. 1992); Loctite Corp. v. Ultraseal, Ltd., 781 F.2d 861, 875, 228 USPQ 90, 100 (Fed. Cir. 1985), *overruled on other grounds by Nobelpharma AB*, 141 F.3d 1059, 46 USPQ2d 1097.

⁶⁰³Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 177, 147 USPQ 404, 406 (1965); Argus Chem. Corp. v. Fibre Glass-Evercoat Co., 812 F.2d 1381, 1385, 1 USPQ2d 1971, 1973 (Fed. Cir. 1987); Litton Indus. Prods., Inc. v. Solid State Sys. Corp., 755 F.2d 158, 166, 225 USPQ 34, 39–40 (Fed. Cir. 1985).

⁶⁰⁴Walker Process, 382 U.S. at 177.

⁶⁰⁵Unitherm Food Sys., Inc., v. Swift-Eckrich, Inc., 375 F.3d 1341, 1358 (Fed. Cir. 2004).

⁶⁰⁶Precision Instrument Mfg. v. Automotive Maint. Mach. Co., 324 U.S. 806, 65 USPQ 133 (1945) (patentee submitted false dates of conception and reduction to practice and fabricated evidence in support of these dates).

⁶⁰⁷Hazel-Atlas Glass Co. v. Hartford Empire Co., 322 U.S. 238, 64 USPQ 18 (1944) (patentee's attorney obtained issuance of a patent by falsely stating that an article he had authored praising the invention was actually written by a well-known expert in the field).

⁶⁰⁸141 F.3d 1059, 1106–07, 46 USPQ2d 1097 (Fed. Cir. 1998) (en banc in relevant portion).

to support a finding of *Walker Process* fraud, the withholding of the reference must show evidence of fraudulent intent. A mere failure to cite a reference to the Patent Office will not suffice.

But *Walker Process* fraud is only the beginning for an antitrust counterclaim. In addition, in order to find the patentee liable, the defendant must prove the elements of the applicable antitrust laws.⁶⁰⁹ Thus, the party asserting an antitrust counterclaim must be prepared for a complex and fact-intensive litigation.

In *Unitherm Food Systems, Inc. v. Swift-Eckrich, Inc.*,⁶¹⁰ Jennie-O successfully proved a *Walker Process* fraud but ultimately failed on its antitrust claim because it was unable to prove an acceptable market definition and injury. In *Unitherm*, Swift, doing business as ConAgra, obtained a patent for a method for browning meat products and wrote letters to equipment sellers informing them that it intended to enforce its patent and offering a license. Jennie-O Foods, a customer of an equipment manufacturer, Unitherm, received one of the letters and, upon investigation, determined that the patent covered the same equipment and process used by Jennie-O, and provided by Unitherm, since at least 1993.⁶¹¹ Jennie-O and Unitherm filed a declaratory judgment action against Swift, alleging that the patent was invalid and unenforceable and that Swift had committed a *Walker Process* violation. The district court in Oklahoma granted a summary judgment motion that the patent was invalid on the grounds that it had been on sale and in public use more than one year before the application for patent.⁶¹²

At trial, a jury found that Swift committed fraud by failing to disclose numerous demonstrations of the invention by Unitherm to ConAgra employees and other documents sent from Jennie-O to the named inventor, a ConAgra employee.⁶¹³ The jury further determined that the examiner, if presented with the evidence (including videotapes), would not have granted a patent.⁶¹⁴ Finally, the jury awarded damages upon a finding of injury to the PTO and the public.⁶¹⁵

On appeal, the Federal Circuit affirmed the finding of *Walker Process* fraud, and accordingly, the patentee was susceptible to antitrust liability if Jennie-O could show antitrust standing and all the elements of a claim under Section 2 of the Sherman Antitrust Act.⁶¹⁶ The court held that Jennie-O had antitrust standing because it met all the requirements under Tenth Circuit law. The court vacated the judgment of antitrust liability, however, because Jennie-O did not present any facts that would allow a reasonable jury to accept its proposed market definition or to demonstrate antitrust injury.⁶¹⁷ The court recognized that evidence of a relevant product market in the Tenth Circuit must include economic evidence of an antitrust injury.⁶¹⁸ Since there was no economic evidence to support an antitrust

⁶⁰⁹*Id.* at 1106.

⁶¹⁰375 F.3d 1341 (Fed. Cir. 2004).

⁶¹¹*Id.* at 1344–45, 1348.

⁶¹²*Id.* at 1347, 1354.

⁶¹³*Id.* at 1360–61.

⁶¹⁴*Id.*

⁶¹⁵*Id.* at 1361.

⁶¹⁶*Id.* at 1362.

⁶¹⁷*Id.* at 1365.

⁶¹⁸*Id.* at 1363, 1365.

market or other aspects of the Section 2 claim, the Federal Circuit vacated the judgment and the award of damages.⁶¹⁹

The Supreme Court reversed the ruling of the Federal Circuit on appeal.⁶²⁰ At trial, before the case was submitted to the jury, defendant Swift-Eckrich (Con-Agra) moved for a directed verdict under Rule 50(a) of the Federal Rules of Civil Procedure on the basis of the legal insufficiency of the evidence. After an unfavorable jury verdict, it failed to renew its motion for judgment as a matter of law under Rule 50(b), and did not file a motion for a new trial. The Supreme Court found that, by the text of Rule 50(b) itself, as well as supporting Supreme Court case law, failure to file or renew a motion under Rule 50(b) deprives an appellate court—and a district court—of the power to rule for that party. Therefore, the defendant had no basis to challenge the sufficiency of the evidence on appeal, and the holding of the Federal Circuit was reversed.⁶²¹

In *Abbott Laboratories v. Baxter Pharmaceutical Products, Inc.*,⁶²² Abbott Labs patented a method for protecting the shelf life of a sevoflurane anesthetic and sued Baxter for infringement when Baxter prepared and filed an ANDA with the FDA. The claims of the patent were for a quantity of sevoflurane and a Lewis acid inhibitor “in an amount effective to prevent degradation” of the compound. Baxter pointed out that Abbott had filed an IDS in which one reference noted that Abbott had sold sevoflurane, more than one year prior to the application for a patent, in glass bottles with up to 131 ppm water. Baxter then asserted that its generic sevoflurane contained no more than 130 ppm water and therefore did not infringe the patent.⁶²³ The district court agreed, construed the term “effective amount” to mean a water content above 131 ppm, and granted summary judgment of noninfringement.⁶²⁴

On appeal, Abbott noted that its IDS and prosecution history did not limit the scope of the claims to having a water content less than 131 ppm. The specification made it clear that the amount of inhibitor needed depended on many environmental considerations.⁶²⁵ Abbott made no express representation concerning the relevance of the prior sales to the claims of the patent and noted that the examiner did not reject the claims over the disclosed sales.⁶²⁶ Thus, the district court incorrectly relied on the IDS disclosure to limit the claim term “effective amount.” Abbott also relied on the specification, which stated that certain preferred embodiments included at least 150 ppm water, to about 10 times this amount.⁶²⁷ The court vacated the decision, noting that the disclosure of a reference to the PTO is not an admission that the reference is material prior art.⁶²⁸

⁶¹⁹*Id.* at 1365.

⁶²⁰ *Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 126 S. Ct. 980 (2006).

⁶²¹*Id.* at 987.

⁶²² 334 F.3d 1274, 1276 (Fed. Cir. 2003).

⁶²³*Id.* at 1277.

⁶²⁴*Id.*

⁶²⁵*Id.* at 1278.

⁶²⁶*Id.* at 1279.

⁶²⁷*Id.*

⁶²⁸*Id.* at 1282–83.

B. Sham Litigation

Under *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*,⁶²⁹ a patentee who brings an infringement suit may be subject to antitrust liability if the infringement suit is a mere sham to conceal an attempt to interfere directly with the business relationships of a competitor. The Supreme Court has not resolved *Noerr* immunity as it applies to the ex parte patent application process, and in particular, to the *Walker Process* claim.⁶³⁰ The panel in *Nobelpharma, AB v. Implant Innovations, Inc.*,⁶³¹ however, said that *Professional Real Estate Investors, Inc. v. Columbia Picture Industries, Inc.*⁶³² and *Walker Process* provide alternative legal grounds on which a patentee may be stripped of its immunity from the antitrust laws. Thus, both legal theories may be applied to the same conduct.

If the above-described elements of *Walker Process* fraud, as well as the other criteria for antitrust liability, are met, such liability can be imposed without an additional sham inquiry because *Walker Process* antitrust liability is based on the knowing assertion of a patent procured by fraud on the PTO. On the other hand, irrespective of the patent applicant's conduct before the PTO, an antitrust claim can be based on an allegation that a suit is baseless. In order to prove that a suit is within *Noerr*'s "sham" exception to immunity, an antitrust plaintiff must prove that the suit was both objectively baseless and subjectively motivated by a desire to impose collateral, anticompetitive injury to obtain a justifiable legal remedy.⁶³³

Thus, according to the *Nobelpharma* panel, a sham suit must be both subjectively brought in bad faith and based on an objectively baseless theory of either infringement or validity. If a suit is not objectively baseless, an antitrust defendant's subjective motivation is immaterial. In contrast with a *Walker Process* claim, a patentee's activities in procuring the patent are not necessarily at issue. It is the bringing of a subjectively and objectively baseless lawsuit that must be proved.⁶³⁴

C. Tying Arrangements

The patent statute states that no person otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of a patent by reason of his having 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, 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."⁶³⁵

⁶²⁹365 U.S. 127, 144 (1961).

⁶³⁰*Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1071, 46 USPQ2d 1097, 1107 (Fed. Cir. 1998) (en banc in relevant portion).

⁶³¹*Id.* at 1071, 46 USPQ2d at 1107.

⁶³²*Professional Real Estate Invs., Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 26 USPQ2d 1641 (1993).

⁶³³*Nobelpharma AB*, 141 F.3d at 1071.

⁶³⁴*Id.* at 1072.

⁶³⁵35 U.S.C. §271(d) (1994).

Independent Ink sued Trident, Inc., seeking a declaratory judgment of noninfringement, invalidity, and that Trident was engaged in illegal tying and monopolization in violation of Section 1 and Section 2 of the Sherman Antitrust Act.⁶³⁶ Trident sold ink jet cartridges for bar-code imprinting and required its ink jet cartridge customers to also purchase ink for the cartridges.⁶³⁷ The district court held that for patent tying to constitute a violation of the antitrust laws, market power must be affirmatively proven, and that Independent had submitted no evidence defining the relevant market or proving Trident's power within that market.⁶³⁸ The district court then granted summary judgment for Trident on both antitrust claims.

The Federal Circuit reversed on appeal. It first noted that where an antitrust claim or an antitrust patent misuse claim is based on procuring or defending a patent, the appeal is governed by Federal Circuit law rather than the law of the regional circuit.⁶³⁹ In Section 2 antitrust attempted monopolization claims, the antitrust plaintiff must define the relevant market and prove the defendant's power in that market, along with a dangerous probability of success.⁶⁴⁰ Since Independent had only made conclusory allegations of a geographic market with no economic evidence, the district court was correct to grant summary judgment as to the Section 2 claim.

With Section 1 antitrust claims, however, the court stated that market power is presumed in a tying case involving patents or copyrights.⁶⁴¹ The court noted that a patent case was the first in which tying was found to violate Section 1 of the Sherman Antitrust Act.⁶⁴² According to the court, subsequent cases made it clear that where the tying product is patented or copyrighted, market power may be presumed rather than proven.⁶⁴³ The Federal Circuit also noted that while there had been a dissent in the *Jefferson Parish* case, along with a number of academic articles critical of the Supreme Court, it is the duty of courts to follow Supreme Court precedent until the Supreme Court itself expressly overrules them.⁶⁴⁴

The Supreme Court granted certiorari to consider its previous tying rulings.⁶⁴⁵ The court has historically disfavored tying arrangements because of the assumption that a seller's exploitation of its control over the tying product might force the buyer into the purchase of a tied product that the buyer did not want or might prefer to purchase elsewhere on different terms.⁶⁴⁶ Over the years, however, the Court's strong disapproval of tying arrangements has substantially diminished, and more recent opinions have required a showing of market power in the tying product.

⁶³⁶Independent Ink, Inc. v. Illinois Tool Works, Inc., 396 F.3d 1342 (Fed. Cir. 2005).

⁶³⁷*Id.* at 1345.

⁶³⁸*Id.* The district court declined to follow several "vintage" Supreme Court cases, and also dismissed as dictum the ruling in a more recent Supreme Court case that the sale or lease of a patented item on condition that the buyer make all his purchases of a separate tied product from the patentee is unlawful (citing *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 16 (1984)).

⁶³⁹*Id.* at 1346.

⁶⁴⁰*Id.* at 1353 (citing *Spectrum Sports, Inc., v. McQuillan*, 506 U.S. 447, 455 (1993)).

⁶⁴¹*Id.* at 1348, 1354.

⁶⁴²*Id.* at 1346 (citing *International Salt Co. v. United States*, 332 U.S. 392 (1947)).

⁶⁴³*Id.* at 1348 (citing *United States v. Lowe's, Inc.*, 371 U.S. 38 (1962)).

⁶⁴⁴396 F.3d at 1351.

⁶⁴⁵*Illinois Tool Works, Inc. v. Independent Ink*, 126 S. Ct. 1281, 1287 (2006).

⁶⁴⁶*Id.* at 1285 (citing *Henry v. A.B. Dick Co.*, 224 U.S. 1 (1912)).

A plaintiff's failure to provide proof of market power by the defendant was fatal in a 1977 case in which the defendant provided cheap financing to sell expensive homes.⁶⁴⁷ In *United States Steel Corp. v. Fortner Enterprises, Inc.*, the Court rejected an earlier position that tying arrangements are anticompetitive, and this assumption has not been endorsed since.⁶⁴⁸ In another case concerning the Sherman Antitrust Act, a hospital offered a tied product (anesthesiologist services) to those who purchased a tying product (hospital services).⁶⁴⁹ The court ruled against the plaintiff patients, finding that they had failed to prove sufficient power in hospital services.

The presumption that a patent confers market power was upheld and extended to antitrust law in a 1947 case.⁶⁵⁰ This case was interpreted for the proposition that tying arrangements were a restraint of trade and were unlawful on their face under the Sherman Act. In 1988, Congress amended 35 U.S.C. §271(d) to state that a patentee may not be denied relief because of patent misuse, such as conditioning the sale of a patented product on the purchase of another product, 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."⁶⁵¹ While this change did not address antitrust law, the present court considered it an invitation to reconsider its antitrust precedent. Accordingly, tying arrangements involving patented products must now be supported by a proof of power in the relevant market rather than a mere presumption.⁶⁵²

Section 271(d)(5) was cited as a defense in another tying case, *U.S. Philips Corp. v. United States International Trade Commission*.⁶⁵³ In that case, patentee Philips was found to have market power. Philips offered several "pools" of patents to potential licensees for manufacturing recordable and rewritable compact discs. The same royalty was due for each disc manufactured using patents in the package, regardless of how many patents were actually used.⁶⁵⁴ Several licensees later ceased paying royalties and sued Philips before the International Trade Commission (ITC). The ITC held the patents unenforceable because of patent misuse.

Philips appealed on the grounds that its licensing arrangements were not a clearly anticompetitive practice, and that the ITC erred in concluding that its arrangements reflected the use of market power in one market to foreclose competition in a separate market. The Federal Circuit agreed and reversed. The court distinguished Philips' package patent licenses from product-to-patent and group patent licenses. Philips's nonexclusive license packages did not require the licensee to do anything, and the licensee was not required to practice any of the patents in a package that the licensee consider "non-essential." Philips

⁶⁴⁷*Id.* at 1287 (citing *United States Steel Corp. v. Fortner Enters., Inc.*, 429 U.S. 610 (1977)).

⁶⁴⁸*United States Steel Corp. v. Fortner Enters., Inc.*, 429 U.S. 610 (1977).

⁶⁴⁹*Illinois Tool*, 126 S. Ct. at 1284 (citing *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2 (1984)).

⁶⁵⁰*Id.* at 1289 (citing *International Salt Co. v. United States*, 332 U.S. 392 (1947)).

⁶⁵¹*Id.* at 1290 (citing 35 U.S.C. §271(d)(5)).

⁶⁵²*Id.* at 1291.

⁶⁵³424 F.3d 1179 (Fed. Cir 2005).

⁶⁵⁴*Id.* at 1182.

charged the same fee for each disc, regardless of how many patents were used in the licensee's manufacturing process.⁶⁵⁵

Philips introduced evidence that its license packages had lower transaction costs, and there was no evidence that Philips would have charged a lower price if its patents were offered individually. The Federal Circuit found that the ITC's application of the rule of per se illegality was legally flawed and failed to appreciate the efficiencies of package patent licensing.⁶⁵⁶ The Federal Circuit also reversed the ITC on the grounds of patent misuse to foreclose competition in an unrelated market. There was no showing of an anticompetitive effect from also licensing the "non-essential" patents in the license packages.⁶⁵⁷ Finally, the "rule of reason" analysis of the ITC was flawed because there was no evidence that any of the "unwilling" licensees of the nonessential patents had considered alternatives to the technology licensed by those patents, or that there were any commercially viable alternatives.⁶⁵⁸

VI. PATENT MISUSE

Patent misuse is an affirmative defense to a suit for patent infringement and requires that the accused infringer show that the patentee has impermissibly broadened the physical or temporal scope of the patent grant with anticompetitive effect.⁶⁵⁹ The result is that enforcement of the patent is barred.⁶⁶⁰ A successful patent misuse defense results in rendering the patent unenforceable until the misuse is purged.⁶⁶¹

The concept of patent misuse arose to restrain practices that did not in themselves violate any law but that drew anticompetitive strength from the patent right and thus were deemed to be contrary to public policy. The public policy purpose was to prevent a patentee from using the patent to obtain market benefit beyond that which is inherent in the statutory patent right.⁶⁶²

Misuse must be pleaded in any action involving validity or infringement. However, misuse often accompanies an antitrust claim. Even so, a patentee's act may constitute patent misuse without rising to the level of an antitrust violation.⁶⁶³

In the context of licensing, the Federal Circuit noted that the law of patent misuse need look only to the nature of the claimed invention as a basis for determining whether a product is a necessary concomitant of the invention or an entirely separate product. On the other hand, the law of antitrust violation, tailored to situations that may or may not involve a patent, looks to a consumer demand test for determining product separability.⁶⁶⁴

⁶⁵⁵*Id.* at 1188.

⁶⁵⁶*Id.* at 1193.

⁶⁵⁷*Id.* at 1195.

⁶⁵⁸*Id.* at 1198.

⁶⁵⁹*Windsurfing Int'l v. AMF, Inc.*, 782 F.2d 995, 1001, 228 USPQ 562, 566 (Fed. Cir. 1986), *vacated on other grounds*, 828 F.2d 755, 4 USPQ2d 1052 (Fed. Cir. 1987).

⁶⁶⁰*Id.*

⁶⁶¹*Senza-Gel Corp. v. Seiffhart*, 803 F.2d 661, 668 n.10, 231 USPQ 363, 368 n.10 (Fed. Cir. 1986).

⁶⁶²*Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 704, 24 USPQ2d 1173, 1176 (Fed. Cir. 1992).

⁶⁶³*Senza-Gel Corp.*, 803 F.2d at 668, 231 USPQ at 368.

⁶⁶⁴*Id.* at 670, 231 USPQ at 369–70.

Whether restrictions on use of a patented product constitute misuse is judged in terms of their relation to the patentee's right to exclude from all or part of the patent grant. Where an anticompetitive effect is asserted, the rule of reason is the basis of determining the legality of the provision.⁶⁶⁵

A. Patent Misuse and the First Sale Doctrine

The basic principle of the first sale doctrine is that an unconditional sale of a patented device exhausts the patentee's right to control the purchaser's use of the device.⁶⁶⁶ The Supreme Court reaffirmed the validity of the patent exhaustion doctrine in *Quanta Computer, Inc. v. LG Electronics, Inc.*⁶⁶⁷ In that case, the Court held that the exhaustion doctrine applies to an authorized sale of a component when it must be combined with additional components in order to practice the patented methods, and the component substantially embodies the inventive features of the patented invention.⁶⁶⁸ The Court also held that the exhaustion doctrine applies to method patents.⁶⁶⁹

LG Electronics owned a portfolio of computer technology patents on methods and systems for processing information.⁶⁷⁰ LG licensed to Intel the patent portfolio.⁶⁷¹ The license was stated in two agreements, a License Agreement and a Master Agreement.⁶⁷² In the License Agreement, LG authorized Intel to manufacture and sell microprocessor products that use the LG patents.⁶⁷³ In the Master Agreement, LG required Intel to give its customers notice that the patent license does not extend to any product made by combining a licensed Intel microprocessor with non-Intel components.⁶⁷⁴ Quanta purchased microprocessors and chipsets from Intel and received the notice required by the Master Agreement.⁶⁷⁵ Despite the notice, Quanta manufactured computers containing both Intel and non-Intel components.⁶⁷⁶ In so doing, Quanta followed Intel's specifications to incorporate the Intel parts into its own systems.⁶⁷⁷ LG filed a complaint against Quanta asserting that the combination of the Intel products with the non-Intel components infringed the LG patents.

Quanta prevailed in the district court under the exhaustion doctrine, but the Federal Circuit affirmed in part and reversed in part.⁶⁷⁸ The Federal Circuit held that the doctrine of patent exhaustion does not apply to method claims and that, in the alternative, the Master Agreement prohibited the sale of combination

⁶⁶⁵*Mallinckrodt, Inc.*, 976 F.2d at 706.

⁶⁶⁶*Intel Corp. v. ULSI Sys. Tech., Inc.*, 995 F.2d 1566, 1568, 27 USPQ2d 1136, 1138 (Fed. Cir. 1993), cert. denied, 510 U.S. 1092 (1994).

⁶⁶⁷128 S. Ct. 2109 (2008).

⁶⁶⁸*Id.* at 2119–20.

⁶⁶⁹*Id.* at 2117–18.

⁶⁷⁰*Id.* at 2113.

⁶⁷¹*Id.* at 2114.

⁶⁷²*Id.*

⁶⁷³*Id.*

⁶⁷⁴*Id.*

⁶⁷⁵*Id.*

⁶⁷⁶*Id.*

⁶⁷⁷*Id.*

⁶⁷⁸*Id.*

products.⁶⁷⁹ The Federal Circuit relied upon its 1992 ruling in *Mallinckrodt, Inc. v. Medipart, Inc.*, which held that a seller of patent goods could impose a post-sale restraint on its customer's use of the goods and that the exhaustion doctrine did not apply to method patents.⁶⁸⁰

The Supreme Court unanimously reversed the Federal Circuit. The Court first held that the patent exhaustion doctrine applies equally to method and product claims.⁶⁸¹ “[A] patented method may not be sold in the same way as an article or device, but methods nonetheless may be embodied in a product, the sale of which exhausts patent rights.”⁶⁸²

The Court cited its opinion in *United States v. Univis Lens Co.*,⁶⁸³ to examine what extent, if any, to which exhaustion of the patent rights on the products exhausted patent rights to the combinations. *Univis* involved the sale of an unpatented semifinished lens blank, which was further processed into a patented finished lens.⁶⁸⁴ The Court held that *Univis* governs this case.⁶⁸⁵ As in this case, in *Univis* “exhaustion was triggered by the sale of the lens blanks because their only reasonable and intended use was to practice the patent and because they ‘embodie[d] essential features of [the] patented inventions.’”⁶⁸⁶

The Court also held that the sales of the microprocessors exhausted LG's patent rights because “everything inventive about each patent was embodied in” the licensed Intel products, and the microprocessors “all but completely practice the patent.”⁶⁸⁷

LG, relying upon *General Talking Pictures Corp. v. Western Electric Co.*,⁶⁸⁸ argued that it had licensed Intel only in the field of manufacturing microprocessor products for combination with specified products and not with other products. The Court held that the LG license agreement included no such explicit limitations on the Field of Use. Rather the LG agreement broadly granted Intel the right to make, use, or sell products free of the patent claims. Although the LG agreement explicitly stated that it did not provide to third parties a right to practice the patents, the Court found “the question whether third parties received implied licenses was irrelevant because Quanta asserts its right to practice the patents based not on implied license but on exhaustion. And exhaustion turns only on Intel's own license to sell products practicing the . . . patents.”⁶⁸⁹

Furthermore, the LG agreements stated: “Notwithstanding anything to the contrary contained in this Agreement, the parties agree that nothing herein shall in any way limit or alter the effect of patent exhaustion that would otherwise apply when a party hereto sells any of its Licensed Products.”⁶⁹⁰ Thus, the exhaustion doctrine governed what Quanta could lawfully do with what it bought from Intel. The attempt to restrict from third parties a license to combine Intel microprocessor

⁶⁷⁹*Id.* at 2115.

⁶⁸⁰976 F.2d 700 (Fed. Cir. 1992).

⁶⁸¹*Quanta Comp.*, 128 S. Ct. at 2117.

⁶⁸²*Id.*

⁶⁸³316 U.S. 241 (1942).

⁶⁸⁴*Quanta Comp.*, 128 S. Ct. at 2116.

⁶⁸⁵*Id.* at 2119.

⁶⁸⁶*Id.* (quoting *Univis*, 316 U.S. at 249–51).

⁶⁸⁷*Id.* at 2120.

⁶⁸⁸304 U.S. 175 (1938).

⁶⁸⁹*Quanta Comp.*, 128 S. Ct. at 2122.

⁶⁹⁰*Id.* at 2114.

product with non-Intel products had no legal significance, because the exhaustion doctrine obviated any need for such a license. Having bought the products from an authorized seller, Quanta did not need a license.⁶⁹¹

B. Patent Misuse and Contributory Infringement

Patent misuse is intertwined with the contributory infringement provision of 35 U.S.C. §271(d), which prescribes that certain actions by the patentee are not patent misuse.⁶⁹² In *Milton Hodosh v. Block Drug Co.*,⁶⁹³ the patent that was asserted to be unenforceable for misuse related to a method for desensitizing teeth with potassium nitrate. Hodosh's alleged misuse was its derivation of revenue from sales of nontoxic paste containing potassium nitrate for use in desensitizing teeth. It was not disputed that potassium nitrate was a staple article of commerce.

The case came to the Federal Circuit on a certified question. The court noted that the contributory infringement and misuse inquiries require analysis of the actions of different entities. In considering a plaintiff's claim of contributory infringement under Section 271(c), a court must review the defendant's acts. In considering a defense of patent misuse, a court must review the plaintiff's actions in light of 271(d). To determine whether exception (1) or (2) of 271(d) applies, the court decides whether the patentee's action was performed by another without his or her consent, which would constitute contributory infringement.⁶⁹⁴ The answer to the certified question in *Hodosh*, therefore, was that "in determining the misuse issue presented in this case the proper focus is on Hodosh's effort to control the toothpaste containing potassium nitrate actually sold and not on the potassium nitrate ingredient alone."⁶⁹⁵

C. Patent Misuse and License Agreements

In *MedImmune, Inc. v. Genentech, Inc.*,⁶⁹⁶ the Supreme Court held that a licensee does not have to breach or terminate its licensing agreement to challenge the validity of the licensor's patent.⁶⁹⁷ Genentech, the owner of a then-pending patent application, and drug manufacturer MedImmune entered into a license

⁶⁹¹*Id.* at 2120–22.

⁶⁹²Section 271(d) states:

No patent owner otherwise entitled to relief for infringement of contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: (1) derived revenue from acts which if performed by another without his consent would constitute contributory infringement; (2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent; (3) sought to enforce his patent rights against infringement or contributory infringement; (4) refused to license or use any rights in another patent; or (5) 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, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent of patented product on which the license or sale is conditioned.

⁶⁹³833 F.2d 1575, 4 USPQ2d 1935 (Fed. Cir. 1987), *cert. denied*, 485 U.S. 1007 (1988).

⁶⁹⁴*Id.* at 1577.

⁶⁹⁵*Id.* at 1580.

⁶⁹⁶549 U.S. 118, 127 S. Ct. 764 (2007).

⁶⁹⁷*Id.*

agreement.⁶⁹⁸ Under that agreement, payment of royalties would come due after the grant of any claim which read upon a MedImmune product.⁶⁹⁹ After the patent office granted the patent, Genentech sent MedImmune a letter informing MedImmune that its manufacture of the drug Synagis was covered by the Genentech patent and that, under the agreement, MedImmune owed royalties.⁷⁰⁰ MedImmune paid the royalties despite its position that the patent was not valid and that Synagis did not infringe a valid claim.⁷⁰¹ MedImmune determined that nonpayment would incite Genentech to enforce the patent, terminate the license agreement, and bring a patent infringement action.⁷⁰² MedImmune did not want to assume the economic risk of defending an infringement action (including treble damages, an injunction resulting in lost market share, and attorney's fees).⁷⁰³

After paying the royalties "under protest," MedImmune filed an action in the district court for declaratory judgment on its contractual rights and obligations under the license agreement, in view of their noninfringement and patent invalidity.⁷⁰⁴ The district court dismissed the declaratory judgment claims for lack of subject matter jurisdiction because, under Federal Circuit precedent, a patent licensee in good standing cannot establish an Article III case or controversy with regard to the patent's validity, enforceability, or scope.⁷⁰⁵ The Federal Circuit affirmed.⁷⁰⁶

Genentech asserted that the license agreement was effectively an agreement that MedImmune would pay royalties and would not challenge patent validity and, in return, Genentech would not sue MedImmune for patent infringement.⁷⁰⁷ The Supreme Court, finding that the covenant not to challenge the patent had no basis in the express terms of the license agreement, noted that "[p]romising to pay royalties on patents that have not been held invalid does not amount to a promise *not to seek* a holding of their invalidity."⁷⁰⁸

Genentech argued that the covenant not to challenge derived from the common-law rule that a party to a contract cannot challenge the validity of a contract and continue to reap its benefits.⁷⁰⁹ The Supreme Court reasoned that MedImmune was not repudiating and reaping benefits at the same time; therefore the common-law rule had no application and did not affect the courts' Article III jurisdiction.⁷¹⁰ Rather, the Court stated that MedImmune was asserting that, if properly interpreted, the contract did not require royalties nor prevent it from challenging the patent.⁷¹¹

⁶⁹⁸*Id.* at 768.

⁶⁹⁹*Id.*

⁷⁰⁰*Id.* at 769.

⁷⁰¹*Id.*

⁷⁰²*Id.*

⁷⁰³*Id.*

⁷⁰⁴*Id.* at 769.

⁷⁰⁵*MedImmune, Inc. v. Genentech, Inc.*, No. 03–02567, 2004 U.S. Dist. LEXIS 28681 (C.D. Cal. Feb. 17, 2004).

⁷⁰⁶*MedImmune, Inc. v. Genentech, Inc.*, 427 F.3d 958 (Fed. Cir. 2005).

⁷⁰⁷*MedImmune*, 127 S. Ct. at 775–76.

⁷⁰⁸*Id.* at 776.

⁷⁰⁹*Id.*

⁷¹⁰*Id.*

⁷¹¹*Id.*

The Supreme Court finally held that the federal courts had Article III jurisdiction even where MedImmune did not break or terminate its contract.⁷¹² A party to a patent license may seek declaratory judgment in a federal court that the licensed patent is invalid, unenforceable, or not infringed without risking the damages that might accrue from breaching a license agreement.⁷¹³

Licensing practices may also constitute a form of patent misuse. The Federal Circuit articulated a three-step analysis for determining misuse in a tying context: (1) determine whether there are two things tied, i.e., whether there are separable or inseparable items; (2) if there are, determine whether the “thing” that is assertedly tied to the patented item is a staple or nonstaple item in commerce; and (3) if it is a staple item, determine whether in fact the two things are tied.⁷¹⁴

An agreement between an assignee of a patent and its competitor-licensee that prohibits further licenses under the patent primarily and impermissibly benefits the licensee rather than the patentee and has been held to be a violation of the Sherman Act. Such conditions, while not illegal per se, cannot be justified as necessary to the enjoyment of, or ancillary to, the patent rights conveyed.⁷¹⁵

In *United States v. Besser Mfg. Co.*,⁷¹⁶ the two inventors licensed their respective patents to Stearns, one of the two dominant firms in the industry, and later sued a customer of Besser, the other dominant firm in the industry. To settle the suit, the inventors agreed to license both Stearns and Besser under the patent. The license agreements, however, prohibited the inventors, as well as Stearns and Besser, from giving anyone else a license without the consent of Stearns and Besser. Thus, the patentees had joined hands with the two largest competitors in the industry and by the terms of their agreement had virtually made it impossible for others to obtain rights under those patents. Because the contract gave Stearns and Besser the power to restrict competition, the agreement was held to be invalid.⁷¹⁷

Since *Besser* and *United States v. Krasnov*⁷¹⁸ held that such agreements are violations of the Sherman Act, one could well argue that such a restriction also constitutes patent misuse. However, in *Moraine Products v. ICI America, Inc.*,⁷¹⁹ the Seventh Circuit held that an agreement that restricted further licensing under the patent unless the two signatories agreed was not a per se violation of Section 1 of the Sherman Act. The court did not address the question of whether the agreement constituted patent misuse but instead remanded for a determination of its lawfulness under the “rule of reason.”⁷²⁰

⁷¹²*Id.* at 777.

⁷¹³*Id.*

⁷¹⁴*Senza-Gel Corp. v. Seiffhart*, 803 F.2d 661, 665, 231 USPQ 363, 366 (Fed. Cir. 1986).

⁷¹⁵*United States v. Besser Mfg. Co.*, 96 F. Supp. 304, 311, 88 USPQ 421, 426 (E.D. Mich. 1951), *aff'd*, 343 U.S. 444, 93 USPQ 321 (1952); *United States v. Krasnov*, 143 F. Supp. 184, 198–99, 110 USPQ 411, 420 (E.D. Pa. 1956), *aff'd per curiam*, 355 U.S. 5, 115 USPQ 70 (1957) (affirming grant of summary judgment of violation of Sherman Act). *See also* *Polysius Corp. v. Fuller Co.*, 709 F. Supp. 560, 578–79, 10 USPQ2d 1417, 1431 (E.D. Pa.), *aff'd*, 889 F.2d 1100 (Fed. Cir. 1989) (noting *Besser* and *Krasnov* with approval).

⁷¹⁶96 F. Supp. 304, 88 USPQ 421.

⁷¹⁷*Id.* at 311, 88 USPQ at 426.

⁷¹⁸143 F. Supp. 184, 110 USPQ 411.

⁷¹⁹538 F.2d 134, 191 USPQ 65 (7th Cir.), *cert. denied*, 429 U.S. 941, 191 USPQ 717 (1976).

⁷²⁰*Id.* at 145.

In *Senza-Gel Corp. v. Seiffhart*,⁷²¹ the Federal Circuit considered and rejected the argument that recent economic theory would put into question the rationale behind holding any licensing practice per se anticompetitive. The court reasoned that it was bound to adhere to existing Supreme Court guidance.

Thus, it is not clear whether this type of license restriction should be analyzed under patent misuse law or antitrust law. The patent misuse approach would require fewer elements of proof and presumably would be tried in less time. A patent that has been misused, however, can be rendered enforceable by curing the wrongful conduct—for example, by deleting the anticompetitive license restriction. Thus, while a finding of patent misuse may not provide a permanent legal resolution, it may induce a settlement of the matter.

D. Bad Faith by Patentee

In *Globetrotter Software, Inc. v. Elan Computer Group, Inc.*,⁷²² Globetrotter sued Elan for infringement of three software patents. Elan countered with defenses of noninfringement and patent misuse. Elan alleged that Globetrotter had sent e-mails and letters alleging infringement to third parties that were negotiating to purchase Elan. As a result, Elan claimed, the third parties ceased negotiations to purchase Elan and later purchased it for a much lower price and refused to enter a planned agreement with another. These third parties then countered Globetrotter's patent infringement claims with claims for tortious interference with prospective economic advantage and unfair competition.⁷²³ The counterclaims also alleged bad-faith conduct by Globetrotter, on the grounds that the e-mails and letters were timed only to interfere with the negotiations of the accused infringers.⁷²⁴ The district court granted summary judgment for Globetrotter on the claim of tortious interference while granting summary judgment of noninfringement for Elan.

While the timing of the communications might have suggested subjective bad faith, the issue was whether such bad faith could be proven. Federal patent law preempts state law tort liability for a patentee's good-faith conduct in communications asserting infringement of the patent and warning of potential litigation.⁷²⁵ Such state law claims can survive federal preemption only to the extent that the claims are based on proof of bad faith in asserting infringement.⁷²⁶ At trial, the defendants made no effort to establish that the claims asserted were objectively baseless either because the patents were obviously invalid or because they were plainly not infringed.⁷²⁷ The standard for objectively baseless claims in litigation was set forth in the 1993 Supreme Court case of *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.*,⁷²⁸ in which the court held that an objectively reasonable effort to litigate cannot be baseless regardless of subjective intent. The *Professional Real Estate* standard, however, had not

⁷²¹803 F.2d 661, 665 n.5, 231 USPQ 363, 366 n.5 (Fed. Cir. 1986).

⁷²²362 F.3d 1367, 1370 (Fed. Cir. 2004).

⁷²³*Id.*

⁷²⁴*Id.* at 1375.

⁷²⁵*Id.* at 1374 (citing *Zenith Elecs. Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1355 (Fed. Cir. 1999)).

⁷²⁶*Id.*

⁷²⁷*Id.* at 1375.

⁷²⁸508 U.S. 49, 57 (1993) (stating that “the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits”).

been applied outside the context of actual litigation, although other circuits have applied these protections to prelitigation communications.⁷²⁹ The Federal Circuit held that the objectively baseless standard of *Professional Real Estate* applies to state-law claims based on communications alleging patent infringement, and affirmed the district court's summary judgment on the tortious interference count.⁷³⁰ A plaintiff claiming that a patentee has engaged in wrongful conduct by asserting claims of patent infringement must establish that the claims were objectively baseless.⁷³¹

VII. LACHES AND EQUITABLE ESTOPPEL

The defenses of laches and estoppel are not found in the patent statute but grow out of equity. As with inequitable conduct, there is no right to a jury trial on such issues. In *Gardco Manufacturing, Inc. v. Herst Lighting Co.*,⁷³² the district court ordered separate trials: a nonjury trial for the equitable issues and then, if necessary, a jury trial on infringement and validity.

The en banc Federal Circuit decision of *A.C. Aukerman Co. v. R.L. Chaides Construction Co.*⁷³³ is the case most commonly cited for the application of these defenses in patent infringement cases. In *Aukerman*, the Federal Circuit explained that both laches and estoppel, not requiring the statutory presumption of validity, are established by a preponderance of the evidence.⁷³⁴ Moreover, both defenses inquire into the conduct of both the patentee and the accused infringer. But since the relief from liability that they provide is different, the elements of these defenses are different in scope.

A. Laches

The application of the defense of laches is subject to the sound discretion of the district court.⁷³⁵ The defense is personal to the particular party and equitable in nature.

To invoke the laches defense, a defendant must prove two factors: (1) the plaintiff delayed filing suit for an unreasonable and inexcusable length of time from the time the plaintiff knew or reasonably should have known of its claim against the defendant; and (2) the delay operated to the prejudice or injury of the defendant.⁷³⁶

Establishing laches bars the recovery of damages for any patent infringement occurring prior to the filing of the lawsuit.⁷³⁷

A presumption of laches arises where a patentee delays bringing suit for more than six years after the date the patentee knew or should have known of

⁷²⁹362 F.3d at 1376 (noting that other circuits have applied such protections to prelitigation communications).

⁷³⁰*Id.* at 1377.

⁷³¹*Id.*

⁷³²820 F.2d 1209, 2 USPQ2d 2015 (Fed. Cir. 1987).

⁷³³960 F.2d 1020, 22 USPQ2d 1321 (Fed. Cir. 1992) (en banc).

⁷³⁴*Id.* at 1045, 22 USPQ2d at 1338–39.

⁷³⁵*Id.* at 1028, 22 USPQ2d at 1325.

⁷³⁶*Id.* at 1032, 22 USPQ2d at 1328.

⁷³⁷*Adelberg Labs., Inc. v. Miles, Inc.*, 921 F.2d 1267, 1272, 17 USPQ2d 1111, 1115 (Fed. Cir. 1990).

the alleged infringer's activity.⁷³⁸ The presumption has the effect of shifting the burden of going forward with evidence; it does not alter the burden of persuasion. But the presumption disappears once the patentee introduces evidence sufficient to create a genuine issue that would rebut any laches factor, including the reasonableness of or an excuse for the delay, lack of prejudice, or egregious misconduct by the accused infringer.⁷³⁹

B. Estoppel

Equitable estoppel requires the defendant to prove by a preponderance of the evidence that: (1) the patent owner, through misleading conduct, led the alleged infringer to reasonably infer that the patent owner did not intend to enforce its patent against the alleged infringer; (2) the alleged infringer relied on this conduct; and (3) due to the reliance, the alleged infringer will be materially prejudiced if the patent owner is allowed to proceed on its claim.⁷⁴⁰ As with laches, egregious conduct must be considered as part of the equitable estoppel determination.⁷⁴¹

Both of these equitable defenses can be very effective in bringing about a quick and efficient resolution to a claim of infringement. Regardless of liability, laches serves to bar all damages up to the filing of the complaint, and estoppel bars a patentee's claim for infringement completely. Moreover, since these defenses often have little to do with the questions of infringement, validity, and unenforceability, the parties can agree that they should be investigated first. If the parties cannot agree, the accused infringer should consider seeking a stay of the action, except for the issues of laches and estoppel, and, under Federal Rule of Civil Procedure 42(b), should request a separate trial on these issues.

C. Prosecution Laches

In 2002, the Federal Circuit in *Symbol Technologies, Inc. v. Lemelson*⁷⁴² held that as a matter of law, the equitable doctrine of laches may be applied to bar enforcement of patent claims that issued after an unreasonable and unexplained delay in prosecution even though the applicant complied with pertinent statutes and rules. In *Symbol Technologies*, the patent owner, Lemelson Medical, was the assignee of approximately 185 unexpired patents and additional pending patent applications of Jerome H. Lemelson, deceased. The patents at issue related to machine vision and automatic identification technology and allegedly were entitled to the benefit of the filing date of two applications filed in 1954 and 1956. The plaintiffs, which included designers and manufacturers, sold and used bar-code scanners and related products. In 1998, Lemelson told the plaintiffs' customers that the use of the plaintiffs' products infringed various Lemelson patents. In response, the plaintiffs sought a declaratory judgment on several defenses, including that the patents were unenforceable on the grounds of prosecution laches.

⁷³⁸*A.C. Aukerman*, 960 F.2d at 1038.

⁷³⁹*Id.* at 1033–34.

⁷⁴⁰*Gasser Chair Co., Inc. v. Infanti Chair Mfg. Corp.*, 60 F.3d 770, 776, 34 USPQ2d 1822, 1826–27 (Fed. Cir. 1995), *vacated on other grounds*, 40 USPQ2d 1700 (Fed. Cir. 1996).

⁷⁴¹*Id.*

⁷⁴²277 F.3d 1361, 1363, 61 USPQ2d 1515 (Fed. Cir.), *cert. denied*, 537 U.S. 825 (2002).

Lemelson moved for dismissal, arguing that the plaintiffs' cause of action for prosecution laches failed to state a claim for relief under Federal Rule of Civil Procedure 12(b)(6). In holding that the defense of prosecution laches is recognizable as a matter of law, the Federal Circuit traced its origin to two 1920s Supreme Court decisions. The defense of prosecution laches was first applied in *Woodbridge v. United States*,⁷⁴³ in which the Court rendered a patent unenforceable where there had been an unexplained nine-year delay in prosecution. Pursuant to a statute in place at the time, the Patent Office agreed to delay the issuance of Woodbridge's patent for one year. The Patent Office, however, neglected to issue the patent when the time came up, and rather than inform the Office of its error, Woodbridge waited nine years before requesting that the patent be issued. At the time of issuance, Woodbridge sought to amend the specification and claims to encompass related innovations that had occurred in the intervening nine years. According to the Federal Circuit, the Court held that because of his delay, Woodbridge had forfeited his rights to the patent.⁷⁴⁴

The Supreme Court applied the doctrine a year later in *Webster Electric Co. v. Splitdorf Electrical Co.*,⁷⁴⁵ where it held that an unreasonable eight-year delay in prosecution rendered the claims at issue unenforceable. In that case, Kane filed a patent application in 1910 that ultimately issued in 1916. In 1915, while the original application was still pending, Kane filed a divisional application, copying nine claims of a recently issued patent for the purpose of provoking an interference. After losing the interference, Kane filed two additional claims, claims 7 and 8, which issued in 1918 and were the subject of the litigation. During all this time the subject matter of the claims was disclosed and in general use, and Kane, so far as claims 7 and 8 were concerned, stood by and awaited developments. The Federal Circuit noted that the Supreme Court held claims 7 and 8 unenforceable, and the circumstances shown by the record constituted laches, by which the petitioner lost any rights to which it might otherwise have been entitled.⁷⁴⁶

The Federal Circuit rejected Lemelson's arguments that the doctrine was limited to interferences and that the passage of the 1952 Patent Act foreclosed the application of the doctrine. The court first noted that claims at issue in *Webster* were not the subject of an interference, and that a later Supreme Court decision, *Crown Cork & Seal Co. v. Ferdinand Gutman Co.*,⁷⁴⁷ validated prosecution laches and did not limit *Webster* to cases involving interferences.⁷⁴⁸ As to the 1952 Patent Act, the Federal Circuit explained that the defense coexisted with continuation practice prior to 1952 and there was nothing in the legislative history of the statute to suggest that Congress did not intend to carry forward the defense of prosecution laches. To the contrary, the Federal Circuit noted that the defense of laches was incorporated into Section 282 of the 1952 Act.⁷⁴⁹ Finally, the court noted that one of its predecessor courts had since recognized the prosecution form of laches.⁷⁵⁰ The Federal Circuit reversed and remanded for further proceedings.

⁷⁴³263 U.S. 50 (1923).

⁷⁴⁴*Symbol Techs.*, 277 F.3d at 1364.

⁷⁴⁵264 U.S. 463 (1924).

⁷⁴⁶*Symbol Techs.*, 277 F.3d at 1364.

⁷⁴⁷304 U.S. 159, 37 USPQ 351 (1938).

⁷⁴⁸*Symbol Techs.*, 277 F.3d at 1365.

⁷⁴⁹*Id.* at 1366.

⁷⁵⁰*Id.* (citing *Pratt & Whitney Co. v. United States*, 345 F.2d 838 (Ct. Cl. 1965)).

The Patent Office also recognized laches in rejecting an application for unreasonable delay after the applicant delayed prosecution and issuance of a patent by filing a long series of continuations without substantive prosecution on the merits.⁷⁵¹ The Federal Circuit affirmed the rejection, noting that even though there is no specific sanction for “undue delay” in the patent law, a federal agency has the inherent authority to govern procedure before it, and the Office had given the applicant sufficient warning that an unreasonable delay could result in forfeiture.⁷⁵²

The Federal Circuit affirmed the defense of prosecution laches in the litigation involving the above-mentioned Lemelson patents.⁷⁵³ The Federal Circuit held that prosecution laches was a legally viable defense. In a previous appeal, the Federal Circuit had remanded the case to the district court for further proceedings to determine the relevant facts of the case. The district court found that the patents were invalid for lack of enablement and unenforceable due to prosecution laches; the district court further held that the claims of the patent were not infringed.⁷⁵⁴

On appeal, Lemelson argued that Symbol had not proven that Lemelson had intentionally delayed issuance of the patents, and that this fact should have been dispositive of the prosecution laches defense. The Federal Circuit held that since laches is an equitable defense, the standard for review is abuse of discretion.⁷⁵⁵ As such, there are no strict time limits, but the doctrine of prosecution laches may render a patent unenforceable when it has issued only after an unreasonable and unexplained delay in prosecution. The doctrine should be applied only in egregious cases of misuse of the statutory patent system.⁷⁵⁶

In dicta, the Federal Circuit distinguished prosecution laches from valid uses of the patent system. Filing a divisional application, resulting from a restriction requirement imposed by the PTO, and even filing the application just before issuance of the parent application, is expressly allowed by statute. One might legitimately refile an application containing rejected claims in order to present evidence of unexpected advantages of an invention when that evidence may not have existed at the time of an original rejection. One might refile an application to add subject matter to support broader claims. One may refile an application even in the absence of any of these reasons, provided that such filing is not unduly successive or repetitive.⁷⁵⁷ However, filing an application solely containing previously allowed claims for the business purpose of delaying their issuance can be considered an abuse of the system. Multiple examples of repetitive filings that demonstrate a pattern of unjustifiably delayed prosecution may be held to constitute laches.⁷⁵⁸ Taken singly, the delay in any one application is unlikely to merit equitable relief by the courts. A prosecution history of a series of related patents and an overall delay in issuing claims may trigger laches.

⁷⁵¹*In re Bogese*, 303 F.3d 1362, 64 USPQ2d 1448 (Fed. Cir. 2002).

⁷⁵²*Id.* at 1368, 64 USPQ2d at 1452–53.

⁷⁵³*Symbol Tech., Inc. v. Lemelson Med. Ed. & Res. Found.*, 422 F.3d 1378 (Fed. Cir. 2005).

⁷⁵⁴*Id.* at 1381–82.

⁷⁵⁵*Id.* at 1384.

⁷⁵⁶*Id.* at 1385.

⁷⁵⁷*Id.*

⁷⁵⁸*Id.*

VIII. OWNERSHIP AND LICENSES

Two types of licenses may provide a defense to patent infringement: express and implied. The express license may rise out of either a written or an oral agreement and generally involves a grant by the owner of the patent to practice the invention. Thus the accused infringer asserts that it has the contractual right to practice the invention and owes nothing to the patent holder except as required by the license agreement. The express license agreement is governed by state contract law.⁷⁵⁹

The existence of an express license is normally proven through oral testimony from one or both of the parties that made the agreement, and when background information is considered relevant, persons who have knowledge of the circumstances underlying the agreement may also testify. When the license is written, its existence obviously will also be proven by putting in evidence the license itself and other necessary documentary evidence.

Another basic principle of patent litigation is that an action for infringement must join as plaintiffs all co-owners.⁷⁶⁰ The following case illustrates a defense based upon ownership and the express license of patent rights.

Inventor Yoon, a medical doctor, and his exclusive licensee, Ethicon, sued U.S. Surgical Corp. for infringement of a patent for trocars, which are puncturing tools used to puncture skin in endoscopic surgery.⁷⁶¹ While the suit was pending, U.S. Surgical became aware of a second unnamed inventor, Choi, and obtained from him a retroactive license to any of his trocar-related inventions.⁷⁶² With this license in hand, U.S. Surgical asked the district court to correct inventorship under Section 256, claiming that Choi had contributed to at least four claims of the patent. After an extensive hearing, the court determined that Choi had contributed to at least two claims and granted the motion correcting inventorship.⁷⁶³ U.S. Surgical then moved for dismissal on the grounds that Choi, as a joint owner of the patent, had granted them a license, and the district court granted the motion and dismissed the suit.

Ethicon appealed to the Federal Circuit, arguing that there was insufficient corroboration of Choi's inventorship and insufficient evidence to show co-invention clearly and convincingly. Ethicon also argued that even if Choi was an inventor, he had contributed to only two claims and could license only his portion of the patent; and that even if Choi was a co-owner and could license the entire patent, he could not release U.S. Surgical from past infringement.⁷⁶⁴ The Federal Circuit noted that the standard for correcting inventorship is clear and convincing evidence. This standard was met by the evidence presented in district court, which included a series of sketches made by Choi depicting features of the two claims and a number of the sketches including sophisticated electronics that

⁷⁵⁹*Power Lift, Inc. v. Weatherford Nipple-Up Sys., Inc.*, 871 F.2d 1082, 1085, 10 USPQ2d 1464, 1466 (Fed. Cir. 1989).

⁷⁶⁰*Waterman v. Mackenzie*, 138 U.S. 252, 255 (1891).

⁷⁶¹*Ethicon, Inc., v. U.S. Surgical Corp.*, 135 F.3d 1456 (Fed. Cir. 1998).

⁷⁶²*Id.* at 1459.

⁷⁶³*Id.*

⁷⁶⁴*Id.* at 1460.

only an electrical engineer or technician would understand.⁷⁶⁵ The Federal Circuit affirmed the correction of inventorship, on the grounds that there was sufficient corroboration under the rule of reason, given the circumstances, the sketches, and Yoon's lack of credibility, as found by the district court.⁷⁶⁶

The court then studied the ownership and license issues. Under the 1984 changes to 35 U.S.C. § 116, the court noted that a joint inventor does not need to contribute to every claim of the patent. Thus, if an inventor contributes to only one claim, the inventor is a joint inventor and a co-owner of a patent that includes that claim. Therefore, the court found that Choi was a joint inventor and a co-owner of the entire patent with the power to license rights in the entire patent.⁷⁶⁷ Since Choi did not join Ethicon and Yoon in bringing suit, the principle that an action for infringement must join all the co-owners was violated.⁷⁶⁸ Therefore, the Federal Circuit affirmed the dismissal. The court also noted that had the suit not been dismissed, Choi had no power to release U.S. Surgical for past accrued damages to Ethicon, but only for damages to himself, since a co-owner has no right to grant a release of another co-owner's right to accrued damages.⁷⁶⁹

The Federal Circuit is continuously faced with unresolved standing issues relating to complex licensing situations. The court addressed a licensee's standing to sue for infringement in *Aspex Eyewear, Inc. v. Miracle Optics, Inc.*⁷⁷⁰ The case involved a comprehensive exclusive license with rights to sublicense between a patent holder, Contour, and a nonparty, Chic Optic. The license also gave Chic Optic the first right to commence infringement actions against third parties.⁷⁷¹ During the period after Chic Optic had agreed to sublicense its entire right and interest in the patent to Aspex, but before the sublicense was executed, Aspex and Contour filed a complaint against Miracle Optic alleging infringement of the patent in interest.⁷⁷² The district court granted defendant Miracle's motion to dismiss the action on the ground that neither Contour nor Aspex had standing to sue for infringement of the patent.⁷⁷³ The court held that Contour had no standing because it had transferred all its rights to Chic, and that Aspex had no standing because it was not an exclusive licensee at the time of filing the original complaint.⁷⁷⁴

On appeal, the Federal Circuit vacated the decision. As to Contour, the court held that even though the "license" transferred many ownership interests, it was not an assignment due to the dispositive fact that the term was a fixed period of years and was less than the entire patent term.⁷⁷⁵ The court distinguished this case from licensee standing cases which did not involve date-certain licenses, and thus were effectively considered assignments conveying standing to sue upon the licensee.⁷⁷⁶ The court remanded the case for a determination of the effective

⁷⁶⁵*Id.* at 1464.

⁷⁶⁶*Id.* at 1464–65.

⁷⁶⁷*Id.* at 1466.

⁷⁶⁸*Id.* at 1467–68.

⁷⁶⁹*Id.* at 1467.

⁷⁷⁰434 F.3d 1336 (Fed. Cir. 2006).

⁷⁷¹*Id.* at 1338.

⁷⁷²*Id.*

⁷⁷³*Id.* at 1338–39.

⁷⁷⁴*Id.* at 1339.

⁷⁷⁵*Id.* at 1342.

⁷⁷⁶*Id.* at 1343.

date of the license between Chic and Aspex, to determine whether all necessary parties, including an exclusive licensee, had been joined.⁷⁷⁷

Patent ownership was also the issue in another case, *Sicom Systems, Inc. v. Agilent Technologies, Inc.*⁷⁷⁸ A patent issued to the Canadian government, which licensed it to Sicom. However, the patentee retained rights to practice the patent, veto sublicenses, grant contracts to further develop the technology, sublicense any improvements or corrections developed by Sicom, and sue for infringement, except for “commercial infringement actions.”⁷⁷⁹ Sicom also was required to first notify Canada before bringing suits, and could not assign its rights without Canada’s approval. When Sicom brought suit against Agilent, Canada refused to join the action. The suit was dismissed on the grounds that Canada had retained substantial rights to a degree that was sufficient to bar Sicom from bringing an action without the Canadian government.⁷⁸⁰

Sicom and Canada then signed another agreement granting Sicom the exclusive right to “initiate commercial infringement actions,” and Sicom brought this suit against Agilent et al. The defendants again sought and obtained dismissal on the grounds that Sicom did not possess all of the substantial rights in the patent necessary for standing.⁷⁸¹ While the second agreement expanded Sicom’s rights, it did not include the right to assign or the right to sue for past infringement. Also, Canada still had the right to sue for noncommercial infringement, such as suits against governmental entities, the military, and universities. In addition, Sicom was still obligated to notify Canada before bringing suit, was required to consult with Canada for threatened or actual litigation, and could not admit liability or offer or conclude a settlement without the prior written permission of Canada.⁷⁸² The suit was dismissed with prejudice, on the grounds that plaintiff had tried twice, and failed, to establish standing.

On appeal, the Federal Circuit affirmed. Normally, a patentee may sue to enforce a patent. While a licensee normally does not have standing to sue without joinder of the patentee, to avoid multiplicity of litigation, an exclusive license may be treated like an assignment for purposes of creating standing if it conveys all substantial rights to the licensee.⁷⁸³ After a discussion of prior cases, the court decided that the agreement between Sicom and Canada transferred fewer than all substantial rights, citing in particular Canada’s right to permit infringement in certain cases, the requirement that Canada consent to certain actions and be consulted in others, and the limits on Sicom’s right to assign its interest in the patent.⁷⁸⁴ In addition, while dismissal of a suit for lack of standing is normally without prejudice, the Federal Circuit upheld the court below on this point also, because this was the second attempt to establish standing, and the dismissal without prejudice was not raised at the district court.

⁷⁷⁷*Id.* at 1344.

⁷⁷⁸427 F.3d 971 (Fed. Cir. 2005).

⁷⁷⁹*Id.* at 973.

⁷⁸⁰*Id.*

⁷⁸¹*Id.* at 974.

⁷⁸²*Id.*

⁷⁸³*Id.* at 976.

⁷⁸⁴*Id.* at 980.

In *International Gamco, Inc. v. Multimedia Games, Inc.*,⁷⁸⁵ the Federal Circuit, in a case of first impression, concluded that the holder of an exclusive field-of-use license does not hold all substantial rights in a licensed patent and therefore does not have standing to sue in its own name absent the patent owner.⁷⁸⁶ The plaintiff in that case was the licensee under an “exclusive enterprise license.”⁷⁸⁷ An enterprise license is a combination of an exclusive territorial license and an exclusive field-of-use license.⁷⁸⁸ In reaching its decision the Federal Circuit reasoned that, to have standing, the licensee must meet the standing requirements of both the geographic license and the field-of-use license.⁷⁸⁹ The court equated the exclusive field-of-use license to the claim-by-claim license at issue in *Pope Manufacturing Co. v. Gormully & Jeffery Manufacturing Co.*⁷⁹⁰ In that case, the Supreme Court reasoned that allowing standing to a licensee of only one claim opened up the potential for multiple litigation against any defendant and among licensees themselves.⁷⁹¹ The potential for multiple litigation similarly infects an exclusive field-of-use license.⁷⁹² The exclusive territorial license does not involve multiple litigation risks, and therefore the holder of an exclusive territorial license has standing by virtue of the license alone.⁷⁹³ However, “[t]he problem of a multiplicity of lawsuits arising from an exclusive field of use license is not cured by adding a geographic restriction.”⁷⁹⁴

In *Morrow v. Microsoft Corp.*,⁷⁹⁵ the Federal Circuit reversed a district court’s determination that a bankruptcy trustee had patent standing. The bankruptcy plan agent set up two bankruptcy trustees under its liquidation plan. The plan agent held legal title to all patents, but gave one of the bankruptcy trustees the right to bring suit on the intellectual property assets of the liquidated company. The trustee brought suit against Microsoft for infringement of estate patents. The Federal Circuit found that the trustee did not have standing because it was not the holder of an exclusionary right (i.e., to make, use, or sell). Furthermore, the trustee suffered no injury in fact, therefore joining the patent owner, the plan agent, did not cure the standing problem.⁷⁹⁶ *Central Admixture Pharmacy Services, Inc. v. Advanced Cardiac Solutions, PC*⁷⁹⁷ presented a new ownership defense in the context of a license relating to a patent originating from a university. The patent at issue claimed a chemical solution used during heart surgery. The patent holder was the inventor, who had gained rights in the patent under the Bayh-Dole Act⁷⁹⁸ after the university waived the patent rights back to the National Institutes of Health (NIH).⁷⁹⁹ When the inventor petitioned NIH for the rights under Section 202(c) of the Bayh-Dole Act, NIH granted him rights in the

⁷⁸⁵504 F.3d 1273 (Fed. Cir. 2007).

⁷⁸⁶*Id.* at 1280.

⁷⁸⁷*Id.* at 1273.

⁷⁸⁸*Id.*

⁷⁸⁹*Id.* at 1279.

⁷⁹⁰144 U.S. 24 (1892).

⁷⁹¹*International Gamco*, 504 F.3d at 1279.

⁷⁹²*Id.*

⁷⁹³*Id.* at 1278.

⁷⁹⁴*Id.* at 1279.

⁷⁹⁵499 F.3d 1332 (Fed. Cir. 2007).

⁷⁹⁶*Id.* at 1343–44.

⁷⁹⁷482 F.3d 1347 (Fed. Cir. 2007).

⁷⁹⁸35 U.S.C. §§200–212.

⁷⁹⁹482 F.3d at 1351.

invention on the condition that he execute to NIH a nonexclusive license to use the invention. The inventor failed to execute the license. After receiving rights in the patent, the inventor entered into an exclusive patent license with Central Admixture Pharmacy. Defendants argued that Central Admixture and the inventor both lacked standing to bring the action because the inventor had failed to execute the license required by NIH.⁸⁰⁰

The Federal Circuit held that a violation of the Bayh-Dole Act makes a patent voidable, but not void.⁸⁰¹ The government agency, in this case NIH, may choose to take action and void the title, but absent such action, title remains with the named inventors and their licensees.⁸⁰² Since NIH, in its discretion, did not take title to the patent rights, the inventor's and thus the licensees' rights, and thus their standing to sue, remained intact.⁸⁰³

An implied license is one that is imposed by law. Probably the most common implied license defense is that of the first sale doctrine or exhaustion of patent rights. In *United States v. Univis Lens Co.*,⁸⁰⁴ the Supreme Court held that the first authorized sale of an article embodying a patent invention exhausts the patent rights in that article. Thus, an unrestricted sale by the patentee gives the purchaser the right to use the article for its intended use without further authorization from the patentee.

A license may also be implied by estoppel due to the conduct of the patentee and by an earlier payment of damages to the patentee for infringement.⁸⁰⁵

In *Anton/Bauer, Inc. v. PAG, Ltd.*,⁸⁰⁶ Anton/Bauer produced and patented a battery pack connection for recharging a battery. The claims of the patent recited a combination of a female plate and a male plate, the female plate containing a plurality of keyholes or slots, and the male plate containing a plurality of projections corresponding to the female keyholes or slots. No claim in the patent separately covered the male plate or the female plate. Generally, the female plates were sold to the portable television video camera industry for attachment to portable video cameras. When Anton/Bauer sold battery packs, they typically had housings that contained the Anton/Bauer male plates.⁸⁰⁷ A competitor, PAG, also sold a battery pack, the pack containing a male plate which could be connected to the Anton/Bauer female plate. PAG sold no female plate meeting the limitations of any of the Anton/Bauer patent claims.⁸⁰⁸

Anton/Bauer sued PAG, alleging that PAG's battery packs infringed the patent, and requested an injunction barring PAG from making and selling the packs.⁸⁰⁹ The injunction was granted, and PAG appealed to the Federal Circuit.⁸¹⁰ The Federal Circuit reversed on the grounds that Anton/Bauer was not likely to succeed on the merits of its claims of patent infringement. PAG argued that

⁸⁰⁰*Id.*

⁸⁰¹*Id.* at 1352–53.

⁸⁰²*Id.*

⁸⁰³*Id.* at 1253.

⁸⁰⁴316 U.S. 241, 53 USPQ 404 (1942).

⁸⁰⁵*Bandag, Inc. v. Al Bosler's Tire Stores, Inc.*, 750 F.2d 903, 925–26, 223 USPQ 982, 998–99 (Fed. Cir. 1984).

⁸⁰⁶329 F.3d 1343, 1346 (Fed. Cir. 2003).

⁸⁰⁷*Id.* at 1347.

⁸⁰⁸*Id.*

⁸⁰⁹*Id.*

⁸¹⁰*Id.* at 1348.

Anton/Bauer's customers, having purchased a camera and a female plate, did not directly infringe the patent because the customers were protected by the doctrines of patent exhaustion and an implied license.⁸¹¹ The exhaustion doctrine is based upon the proposition that the unrestricted sale of a patented article, by or with the authority of the patentee, "exhausts" the patentee's right to control further sale and use of that article by enforcing the patent under which it was first sold.⁸¹² The court also stated that sale of an unpatented article exhausts the seller's right to control the future sale and use of that article, but only certain circumstances exhaust a seller's patent right and result in an implied license.⁸¹³

The court noted that a patentee grants an implied license to a purchaser when the patentee sells an article that has no noninfringing uses and the circumstances of the sale plainly indicate that the grant of a license should be inferred.⁸¹⁴ Thus, if Anton/Bauer's customers had an implied license, they could not infringe the patent, and without direct infringement, PAG could not be liable for contributory infringement or inducement of infringement. The parties agreed that there were no noninfringing uses of the female plate, and the court held that the sale of an unpatented female plate by Anton/Bauer was a complete transfer of the ownership of the plate.⁸¹⁵ Since there were no restrictions on the sale of the female plates, which were authorized sales to Anton/Bauer's customers, Anton/Bauer impliedly granted a license to its customers to employ the combination claimed in the patent, and therefore there was no direct or contributory infringement.⁸¹⁶ The court further held that a purchaser of the female plate from Anton/Bauer had an implied license to practice the patent during the lifetime of the female plate, and concluded that Anton/Bauer would not likely succeed on the merits for its claims of patent infringement.⁸¹⁷

The "noninfringing use" doctrine does not apply where there exists an express agreement authorizing a licensee to sell a product for infringing uses.⁸¹⁸ In *Jacobs v. Nintendo of America, Inc.*, Jacobs owned a patent relating to a tilt-sensitive video controller.⁸¹⁹ Jacobs asserted the patent against Analog Devices, a component manufacturer, claiming that Analog's accelerometer components infringed Jacobs' patent. The parties entered into a settlement agreement under which Jacobs granted Analog an irrevocable license "to take any actions set forth in 35 U.S.C. §271 which would, but for this license, constitute infringement or violation of Jacobs' patent rights."⁸²⁰ In a separate clause, the license stated: "Jacobs covenants not to sue Analog for any alleged infringement or violation of the '958 patent. This covenant not to sue extends to any cause of action having as an element the infringement of the '958 patent by Analog or any other party, whether occurring in the past, present or in the future."⁸²¹ Jacobs later filed a

⁸¹¹*Id.* at 1349.

⁸¹²*Id.* (citing *Jazz Photo Corp. v. International Trade Comm'n*, 264 F.3d 1094, 1105 (Fed. Cir. 2001)).

⁸¹³*Id.* at 1349–50 (citing *United States v. Univis Lens Co.*, 316 U.S. 241, 249 (1942)).

⁸¹⁴*Id.* at 1350 (citing *Met-Coil Sys. Corp. v. Korner Unlimited*, 803 F.2d 684, 687 (Fed. Cir. 1986)).

⁸¹⁵*Id.* at 1343, 1351.

⁸¹⁶*Id.*

⁸¹⁷*Id.* at 1343, 1352, 1353.

⁸¹⁸*Jacobs v. Nintendo of Am., Inc.*, 370 F.3d 1097, 1100 (Fed. Cir. 2004); *Zenith Elecs. Corp. v. PDI Comme's Sys., Inc.*, 522 F.3d 1348, 1360–61 (Fed. Cir. 2008).

⁸¹⁹*Jacobs*, 370 F.3d at 1100.

⁸²⁰*Id.* at 1098.

⁸²¹*Id.* at 1098–99.

claim of infringement against Nintendo alleging that Nintendo's Kirby Tilt'n Tumble game cartridge infringed the '958 patent. Nintendo asserted the implied license defense, stating that the settlement agreement between Jacobs and Analog protected Analog's customers, including Nintendo.⁸²² The district court agreed with Nintendo and the Federal Circuit affirmed. The district court stated that, by the settlement agreement, Jacobs expressly authorized Analog to sell the accelerometers for use in tilt-sensitive control boxes.⁸²³ That grant necessarily carried with it an implied license to Analog's customers to use the accelerometers in its tilt-sensitive control boxes as any other interpretation would undermine Analog's right to sell.⁸²⁴ *TransCore, LP v. Electronic Transaction Consultants Corp.* took the implied license and exhaustion doctrines a step further.⁸²⁵

In that case, the Federal Circuit addressed "whether an unconditional covenant not to sue authorizes sales by the covenantee for purposes of patent exhaustion."⁸²⁶ TransCore owned patents relating to automated toll collection systems. It brought an infringement action against Electronic Transaction Consultants Corp. (ETC), a toll collection service provider, for setting up and testing a toll-collection system purchased by the Illinois State Toll Highway Authority (ISTHA). ETC asserted that its activities were permitted under theories of patent exhaustion, implied license and legal estoppel, by a settlement agreement between TransCore and the toll collection system provider, Mark IV.⁸²⁷ In that agreement, TransCore granted Mark IV a covenant and release from any "demand, claim, lawsuit, or action against Mark IV for future infringement" under the patents covering the automated toll collection system technology.⁸²⁸ The Federal Circuit held that this was an unconditional covenant not to sue.⁸²⁹ TransCore argued that an unconditional covenant not to sue provided only a promise not to sue, not a license to sell.⁸³⁰ The Federal Circuit focused the issue not on the form of the agreement, but on the substance of the agreement; namely, what does the agreement authorize?⁸³¹ The unconditional covenant not to sue TransCore granted to Mark IV, bearing no apparent restrictions or limitations, "authorize[d] all acts that would otherwise be infringements: making, using, offering for sale, selling, or importing."⁸³² Since nothing in the license agreement between TransCore and Mark IV restricted Mark IV's right to sell products, the sales to ISTHA were authorized and TransCore's patent rights were exhausted.⁸³³

Litigation over licenses often involves the scope of authority that the patent holder has provided in the license. For instance, if the license of a patent specifically grants to the licensee the right to make, use, or sell components for a device specifically covered in the patent, the licensor is barred from interfering with the

⁸²²*Id.* at 1098.

⁸²³*Id.* at 1099.

⁸²⁴*Id.*

⁸²⁵*Transcore, LP v. Electronic Transaction Consultants Corp.*, 563 F.3d 1271 (Fed. Cir. 2009).

⁸²⁶*Id.* at 1274.

⁸²⁷*Id.* at 1274.

⁸²⁸*Id.* at 1273.

⁸²⁹*Id.*

⁸³⁰*Id.* at 1274.

⁸³¹*Id.* at 1276.

⁸³²*Id.* at 1276.

⁸³³*Id.*

licensee's customers using those devices.⁸³⁴ Thus, relevant evidence that will assist in the understanding and interpretation of the terms of the contract will be considered. But care should be taken to delineate the scope of the claims in the patent and to assess the exclusionary rights resulting from the patent grant.

The burden of proving a license is placed on the alleged infringer, who must establish it by a preponderance of the evidence.⁸³⁵ Ultimately, an implied license is a legal question and thus determined by the court.⁸³⁶

An ambiguity in the terms of a license will be construed against the drafter of the terms. Intel developed and promulgated a new standard for computer-chip specifications and granted a royalty-free license to all those interested in complying with its new standard.⁸³⁷ It drafted a one-page license agreement for an Accelerated Graphics Port (AGP) Interface Specification, which was "legally binding" on anyone whose authorized representative signed the agreement and delivered it to Intel at the address listed on the agreement. Via Technologies signed licenses for the AGP 1.0 and 2.0 specifications.⁸³⁸ The licenses stated that they did not extend to features of a product that were not required to comply with the AGP interfaces. AGP interfaces were defined as interfaces, specifications, and protocols disclosed in and required by the AGP interface specifications.⁸³⁹

Intel asserted a patent covering this subject matter against Via Technologies. The district court construed the license as covering any patent claims that must be infringed in order to comply with the electrical interfaces and bus control protocols disclosed in and required by the specifications recited in the documents describing the AGP protocols. The district court concluded that Via Technologies' product was covered by the license and granted summary judgment of noninfringement.⁸⁴⁰

On appeal, Intel asserted that the allegedly infringing product did not fall under the license because it used optional rather than required interfaces or protocols. Intel interpreted the license as not covering anything that was not required, and specifically excluding protocols identified in the specifications as optional.⁸⁴¹ Via Technologies interpreted the license as extending to all protocols in the AGP 2.0 specifications, whether labeled optional or not. The court noted that there were two meanings for the word "required." It analogized the situation to classes in school that are required or optional. In either case, books are required for each class. The court further noted that some features or mechanisms labeled as "optional" in the protocols were conceded by Intel to be "required."⁸⁴²

The Federal Circuit agreed with the district court that both interpretations of the license were reasonable, thus creating an ambiguity. The court applied the doctrine of contra preferentum, in which an ambiguity in a document is construed

⁸³⁴*Jacobs v. Nintendo of Am., Inc.*, 370 F.3d 1097, 1098, 1101 (Fed. Cir. 2004) (noting that allowing customers of the licensee to benefit from the license upholds the basic contract law principle that a party may not assign a right, receive consideration for it, and then takes steps that would render the right worthless).

⁸³⁵*Met-Coil Sys.*, 803 F.2d at 687, 231 USPQ at 476; *Bandag, Inc. v. Al Bosler's Tire Stores*, 750 F.2d 903, 924, 223 USPQ 982, 998 (Fed. Cir. 1984).

⁸³⁶*Met-Coil Sys.*, 803 F.2d at 687, 231 USPQ at 476.

⁸³⁷*Intel Corp. v. Via Techs., Inc.*, 319 F.3d 1357, 65 USPQ2d 1934 (Fed. Cir. 2003).

⁸³⁸*Id.* at 1360, 65 USPQ2d at 1936.

⁸³⁹*Id.* at 1359–60, 65 USPQ2d at 1935–36.

⁸⁴⁰*Id.* at 1360–61, 65 USPQ2d at 1936.

⁸⁴¹*Id.* at 1362, 65 USPQ2d at 1937.

⁸⁴²*Id.* at 1362, 65 USPQ2d at 1937.

against the drafter, who is solely responsible for its terms.⁸⁴³ Therefore, the court affirmed that Via Technologies was covered by the license and was not liable for infringement.

IX. CONTRACTUAL ESTOPPEL DEFENSE TO ENFORCEMENT OF A PATENT

The Federal Circuit noted in *Flex-Foot, Inc. v. CRP, Inc.*⁸⁴⁴ that, depending on terms in an agreement between a patentee and a licensee, there may be a defense of contractual estoppel, but not licensee estoppel, to the enforcement of a patent. In a settlement agreement, Flex-Foot had licensed several patents to CRP. CRP agreed not to challenge the validity or enforceability of the patents and agreed that any future infringement disagreements would be resolved by arbitration.⁸⁴⁵ The settlement agreement was part of a stipulation that the parties entered for dismissal of the action with prejudice.⁸⁴⁶ Flex-Foot later filed a complaint alleging infringement of one of the patents in the agreement, and in accordance with the settlement agreement, the complaint was sent to arbitration. The arbitration panel decided in favor of Flex-Foot, and CRP sued in federal court to vacate the award on the grounds that the patent in question was invalid.⁸⁴⁷ The district court upheld the arbitration panel's decision and entered a permanent injunction against CRP, concluding that CRP was collaterally estopped from challenging the validity and enforceability of the patent-in-suit.⁸⁴⁸

On appeal, the Federal Circuit held that, though it is not collateral estoppel, an agreement to a dismissal with prejudice that accompanies such a settlement agreement gives rise to contractual estoppel of CRP's challenge to validity.⁸⁴⁹ The court explained that contractual estoppel arises out of an agreement, while collateral estoppel is "an affirmative defense barring a party from relitigating an issue *determined against that party* in an earlier action, even if the second action differs significantly from the first one."⁸⁵⁰

The court also distinguished contractual estoppel from the older, discredited doctrine of "licensee estoppel," which was overruled when the Supreme Court held, in *Lear v. Adkins*,⁸⁵¹ that the important public interest in permitting full and free competition in the use of ideas that are in reality a part of the public domain trumps the technical requirements of contract doctrine.⁸⁵² The doctrine of licensee estoppel held that a licensee was denied the right to prove that the patentee-licensor was demanding royalties for the use of an idea that was in reality a part of the public domain.⁸⁵³ The theory underlying this doctrine was that a licensee should not be permitted to enjoy the benefits of the agreement

⁸⁴³*Id.* at 1367–68, 65 USPQ2d at 1942.

⁸⁴⁴238 F.3d 1362, 57 USPQ2d 1635 (Fed. Cir. 2001).

⁸⁴⁵*Id.* at 1363–64, 57 USPQ2d at 1636–37.

⁸⁴⁶*Id.* at 1364, 57 USPQ2d at 1637.

⁸⁴⁷*Id.*

⁸⁴⁸*Id.*

⁸⁴⁹*Id.* at 1367–68, 57 USPQ2d at 1639.

⁸⁵⁰*Id.* at 1367 & n.2, 57 USPQ2d at 1639 & n.2 (emphasis in original).

⁸⁵¹395 U.S. 653 (1969).

⁸⁵²*Flex-Foot*, 238 F.3d at 1368, 57 USPQ2d at 1639–40 (citing *Lear*, 395 U.S. at 670–71).

⁸⁵³*Lear*, 395 U.S. at 656.

while simultaneously urging that the patent forming the basis of the agreement was void.⁸⁵⁴

The Federal Circuit noted that in *Lear*, the license agreement was not accompanied by any promise by the licensee not to challenge the validity of the patent.⁸⁵⁵ The facts in *Flex-Foot* were distinguished because of the agreements and the important policy of enforcing agreements and *res judicata*.⁸⁵⁶ The court recalled other cases involving contracts and stipulations for dismissal from litigation that were distinguished from *Lear*.⁸⁵⁷ The court noted that such agreements, as well as suits settled via a consent decree, i.e., a decision by the court to which the parties have agreed, are subject to the strong public interest in settlement of patent litigation.⁸⁵⁸ Upholding terms of settlements fosters judicial economy by encouraging patent owners to agree to settlements.⁸⁵⁹ The court concluded that once an accused infringer has challenged patent validity, has had an opportunity to conduct discovery on validity issues, and has elected to voluntarily dismiss the litigation with prejudice under a settlement agreement containing a clear and unambiguous undertaking not to challenge validity and/or enforceability of the patent-in-suit, the accused infringer is contractually estopped from raising any such challenge in any subsequent proceeding.⁸⁶⁰

In *Unova, Inc. v. Acer, Inc.*,⁸⁶¹ Unova and Compaq entered into a settlement agreement with mutual releases from infringement, covenants not to sue, and licenses for Unova's patents for "smart battery" management technology used in notebook computers. About a year later, Hewlett-Packard acquired Compaq, and Unova sued Hewlett-Packard and several other computer manufacturers for infringing these same patents. Hewlett-Packard filed for summary judgment on the grounds that the settlement agreement released them from liability for infringement because the contract included Compaq's "parents" in its terms. A district court in California granted summary judgment for Hewlett-Packard, and Unova appealed to the Federal Circuit.⁸⁶²

On appeal, the issues were which law governed this contractual issue and whether the release included Hewlett-Packard, which became Compaq's parent after the agreement. The Federal Circuit noted that contract interpretation is ordinarily a question of state law.⁸⁶³ In addition, the agreement expressly provided that California law applied, so the Federal Circuit applied that law. Under California law, a contract must be interpreted to give effect to the mutual intention of the parties as it existed at the time of contracting.⁸⁶⁴ California courts have also held that a third party's rights under a release agreement are predicated upon the con-

⁸⁵⁴*Flex-Foot*, 238 F.3d at 1368, 57 USPQ2d at 1640.

⁸⁵⁵*Id.*

⁸⁵⁶*Id.*

⁸⁵⁷*Id.* at 1369, 57 USPQ2d at 1640 (citing *Hemstreet v. Spiegel, Inc.*, 851 F.2d 348, 7 USPQ2d 1502 (Fed. Cir. 1988), *rev'd on other grounds*, 861 F.2d 728 (Fed. Cir. 1988)).

⁸⁵⁸*Id.* at 1369, 57 USPQ2d at 1641 (citing *Foster v. Hallco*, 947 F.2d 469, 20 USPQ2d 1241 (Fed. Cir. 1991)).

⁸⁵⁹*Id.*

⁸⁶⁰*Id.* at 1370, 57 USPQ2d at 1641.

⁸⁶¹363 F.3d 1278 (Fed. Cir. 2004).

⁸⁶²*Id.* at 1280.

⁸⁶³*Id.* (citing *Volt Info. Scis., Inc. v. Board of Trs. of Leland Stanford Jr. Univ.*, 489 U.S. 468, 474 (1989)).

⁸⁶⁴*Id.* at 1281 (citing CAL. CIV. CODE §1336 (Deering, 2004)); *see also* *AIU Ins. Co. v. Superior Ct.*, 799 P.2d 1253, 1264 (Cal. 1990).

tracting parties' intent to benefit him and that the third party bears the burden of showing that the contracting parties intended to release him.

The court reversed, holding that the settlement agreement did not show that the parties intended to benefit Hewlett-Packard.⁸⁶⁵ Releases from liability for patent infringement typically immunize a party for liability for past acts of infringement; the agreement was written in the present tense and referred to acts of past infringement. The agreement referred to "Compaq, its parents, and its subsidiaries" (even though Compaq at the time had no parent), but did not refer to future parents of Compaq; elsewhere the agreement referred to "past, present, and future officers, directors, shareholders" of Compaq.⁸⁶⁶ The court concluded that there was no suggestion that the release provision encompassed Compaq's future parent, and thus it did not insulate Hewlett-Packard from liability for infringement.⁸⁶⁷

X. OBVIOUSNESS-TYPE DOUBLE PATENTING

The judicially created doctrine of double patenting is grounded in public policy to prevent the unjustified or improper timewise extension of the right to exclude granted by a patent.⁸⁶⁸ This doctrine prevents a patent term extension through claims in a second patent that are not patentably distinct from claims in a commonly owned earlier patent.⁸⁶⁹ Analysis of obviousness-type double patenting entails two steps. First, a court construes the claim in the earlier patent and the claim in the later patent and determines the differences.⁸⁷⁰ Second, the court determines whether the differences in subject matter between the two claims render the claims patentably distinct.⁸⁷¹ A later patent claim is not patentably distinct from an earlier claim if the later claim is obvious over, or anticipated by, the earlier claim.⁸⁷² That is, a later patent claim that fails to provide novel invention over an earlier claim is not patentably distinct from the earlier claim.⁸⁷³

During patent prosecution, two tests are applied to determine obviousness-type double patenting. If the application at issue is a later-filed application, or both applications were filed on the same day, a one-way obviousness test is applied, i.e., whether the invention defined in the (later or same-day) claim is an obvious variation of the invention defined in a claim of the patent.⁸⁷⁴ If the patent is the later-filed application, a two-way test is to be applied only when the applicant could not have filed the claims in a single application and there was administrative delay on the part of the Patent Office.⁸⁷⁵ Double-patenting

⁸⁶⁵*Unova*, 363 F.3d at 1282, 1284.

⁸⁶⁶*Id.* at 1282.

⁸⁶⁷*Id.*

⁸⁶⁸*In re Longi*, 759 F.2d 887, 892, 225 USPQ 645, 648 (Fed. Cir. 1985).

⁸⁶⁹*Id.*

⁸⁷⁰*Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968, 58 USPQ2d 1865, 1878 (Fed. Cir. 2001).

⁸⁷¹*Id.*

⁸⁷²*Id.*

⁸⁷³*Id.* at 970, 58 USPQ2d at 1880.

⁸⁷⁴MANUAL OF PATENT EXAMINING PROCEDURE ¶804(a) (8th ed. Aug. 2001) (citing *In re Berg*, 46 USPQ2d 1226 (Fed. Cir. 1998)).

⁸⁷⁵*Id.* In a two-way test, the test includes the one-way test described above and a second test with the patent (earlier) claims as the claims in issue. *Id.* ¶804(b).

rejections may be overcome by filing a terminal disclaimer in compliance with 37 C.F.R. §1.321(c), provided the conflicting application or patent is shown to be commonly owned with the present application.⁸⁷⁶ The terminal disclaimer must include a provision that any patent granted on the application (or on a patent subject to reexamination) shall be enforced only for and during such period that the patent is commonly owned with the application or patent that formed the basis for the rejection.⁸⁷⁷

In *Eli Lilly & Co. v. Barr Laboratories, Inc.*,⁸⁷⁸ the district court found that no double patenting existed between Lilly's earlier and later patents for an antidepressant drug and granted summary judgment for Lilly on this issue. On appeal, the Federal Circuit compared a claim from the later patent to a claim from the earlier patent, and under a one-way test found that they were not patentably distinct and thus invalid for obviousness-type double patenting.⁸⁷⁹ The court noted that a patent owner cannot avoid double patenting by disclaiming the earlier patent.⁸⁸⁰ Further, because Lilly had disclaimed the earlier patent, it could not now terminally disclaim the later patent to expire at the time the earlier patent would have expired had it not been disclaimed. The fact that the earlier patent had been disclaimed gave no help to Lilly because double patenting precluded a claim in the later patent from extending beyond the termination date of the earlier patent, whether that termination date was at the end of its normal term or, as was the case here, the date was terminated via disclaimer.⁸⁸¹

XI. SOVEREIGN IMMUNITY DEFENSE TO ENFORCEMENT OF A PATENT

The U.S. Supreme Court held in *Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank*⁸⁸² that the Eleventh Amendment to the Constitution provides states with immunity from patent infringement suits in federal court, despite the absence of other venues for recovery. In *Florida Prepaid*, College Savings sued Florida Prepaid under the Patent Remedy Act, 35 U.S.C. §§271(h) and 296(a), a statute passed by Congress in 1992 to remedy a finding in a previous suit that the patent laws failed to contain the requisite statement of intent to abrogate state sovereign immunity from infringement suits.⁸⁸³ The appropriate sections of the law stated:

As used in this section, the term "whoever" includes any State, any instrumentality of a State, and any officer or employee of a State or instrumentality of a State acting in his official capacity.⁸⁸⁴

Any State, any instrumentality of a State, and any officer or employee of a State or instrumentality of a State acting in his official capacity, shall not be immune, under the eleventh amendment of the Constitution of the United States, or under any other doctrine of sovereign immunity, from suit in Federal court by any person

⁸⁷⁶37 C.F.R. §1.130(b).

⁸⁷⁷*Id.*

⁸⁷⁸251 F.3d 955, 958, 58 USPQ2d 1865, 1870–71 (Fed. Cir. 2001).

⁸⁷⁹*Id.* at 972, 58 USPQ2d at 1881.

⁸⁸⁰*Id.* at 967 & n.5, 58 USPQ2d 1877–78 & n.5.

⁸⁸¹*Id.*

⁸⁸²527 U.S. 627, 647–48 (1999).

⁸⁸³*Id.* at 631–32 (citing *Atascadero State Hosp. v. Scanlon*, 473 U.S. 234, 242–43 (1985)).

⁸⁸⁴35 U.S.C. §271(h) (1994).

... for infringement of a patent under section 271, or for any other section of this title.⁸⁸⁵

Florida Prepaid was an entity created by the state of Florida to administer tuition prepayment contracts available to Florida residents and their children.⁸⁸⁶ When College Savings sued Florida Prepaid for infringing its patent, the district court concluded that for immunity purposes, Florida Prepaid was an arm of the state of Florida.⁸⁸⁷ The Supreme Court noted that one of the few ways to abrogate state sovereignty and the Eleventh Amendment was the Fourteenth Amendment, and that the Patent Remedy Act had invoked the Fourteenth Amendment.⁸⁸⁸ However, to properly invoke the Fourteenth Amendment, case law has held that legislation must be “appropriate” and “remedial” in nature, such as legislation that deters or remedies constitutional violations.⁸⁸⁹

The Supreme Court held that for Congress to invoke the Fourteenth Amendment and its enforcement provision, it must identify conduct transgressing the Fourteenth Amendment’s substantive provisions and must tailor its legislative scheme to remedying or preventing such conduct.⁸⁹⁰ In preparing for the Patent Remedy Act, however, Congress had identified no pattern of patent infringement by the states, let alone a pattern of constitutional violations, and had identified only eight patent infringement suits against states in the 110 years between 1880 and 1990.⁸⁹¹ The Supreme Court did not completely close the door to a future patent law that could abrogate state immunity, pointing out that the present statute did not respond to a history of widespread and persistent deprivation of constitutional rights and that the provisions of the present statute were so out of proportion to a supposed remedial or preventive object that they could not be understood as responsive to, or designed to prevent, unconstitutional behavior.⁸⁹²

A number of cases after *Florida Prepaid* have found that private companies administering state programs, such as Medicaid programs, are entitled to sovereign immunity under the Eleventh Amendment.⁸⁹³ Courts have found that a waiver of immunity must be unequivocal⁸⁹⁴ but that acceptance of a patent waives immunity under the Eleventh Amendment to a declaratory judgment for patent invalidity.⁸⁹⁵

Two recent cases involving inventorship of university patents demonstrate the application of Eleventh Amendment immunity. Xechem sued the University of Texas to correct inventorship by adding one of its employees as an inventor

⁸⁸⁵*Id.* §296(a) (1994).

⁸⁸⁶*Florida Prepaid*, 527 U.S. at 631.

⁸⁸⁷*Id.* at 632–33 & n.3.

⁸⁸⁸*Id.* at 637. The Patent Remedy Act had also referred to the Constitution’s Article I Patent and Interstate Commerce Clauses; however, Congress has insufficient authority to abrogate state sovereign immunity pursuant to an Article I power. *Id.* at 636 (citing *Seminole Tribe of Fla. v. Florida*, 517 U.S. 44 (1996)).

⁸⁸⁹*Id.* at 636–37 (citing *City of Boerne v. Flores*, 521 U.S. 507 (1997)); *id.* at 638.

⁸⁹⁰*Id.* at 639.

⁸⁹¹*Id.* at 640.

⁸⁹²*Id.* at 645–46.

⁸⁹³*See, e.g.,* *United States v. Mack*, 48 F. Supp. 2d 708 (S.D. Tex. 1999) (finding immunity for a state agency and an insurance company contracted with the state to process insurance claims).

⁸⁹⁴*State Contracting & Eng’g Corp. v. Florida*, 258 F.3d 1329, 59 USPQ2d 1498 (Fed. Cir. 2001).

⁸⁹⁵*New Star Lasers, Inc. v. Regents of the Univ. of Cal.*, 63 F. Supp. 2d 1240, 52 USPQ2d 1215 (E.D. Cal. 1999).

on two patents arising from collaboration between Xechem and the university.⁸⁹⁶ The university claimed immunity from suit under the Eleventh Amendment, and the district court granted the university's motion to dismiss on the proceedings. Xechem argued on appeal that by entering into a collaborative agreement, applying for a patent, and accepting the grant of a patent, the university had waived this immunity. The Federal Circuit held that waiver of immunity must be clear, express, and voluntary, and cannot be imposed on a state that has merely entered the patent system and not voluntarily entered federal jurisdiction.⁸⁹⁷ In closing, the court suggested that the proper forum for this dispute was in state court.⁸⁹⁸

A university may waive immunity if it files suit to correct ownership, thus voluntarily entering federal jurisdiction. In *Regents of the University of New Mexico v. Knight*,⁸⁹⁹ the University of New Mexico (UNM) sued two professors at the university, seeking to enforce employment agreements binding the professors to assign their inventions to UNM. The professors had invented compounds potentially useful in treating cancer and had assigned five patent applications to UNM. Later, when CIPs were prepared, the two inventors refused to assign their rights.⁹⁰⁰ UNM sued and the professors filed counterclaims for a variety of causes, including violations of the duty of care, good faith, and fair dealing; a determination of rights in the patents; royalties and lost wages; breach of contract; intentional interference with prospective economic advantage; abuse of process; slander; and breach of fiduciary duty.⁹⁰¹ A special master found no genuine issue of material fact concerning the assignment issues, which were resolved in favor of UNM. At that point, however, UNM sought to amend its complaint by withdrawing any request for money damages. While UNM enjoyed Eleventh Amendment immunity from suit as an arm of the state, it had waived its immunity from claims in recoupment arising out of the same transaction or occurrence. Therefore, when the court allowed the amendment, it also dismissed the professors' complaints as barred by the Eleventh Amendment.⁹⁰²

The professors appealed both the contractual issues and the counterclaim/immunity issues. One professor entered each year into a written contract with UNM, including UNM's Patent Policy and Co-Inventor Agreement, which required staff members to assign their inventions to UNM.⁹⁰³ The other professor had no employment contract but was also bound by these patent policies. The professors were obligated to assign the CIPs because they were bound by the Patent Policy and the Co-Inventor Agreement, they had previously acted in accordance with the Patent Policy, and the CIPs were related applications.⁹⁰⁴

While a state may waive immunity by filing suit and thus submitting to the jurisdiction of the court, dismissal without prejudice prevents the "carry over" of an earlier waiver to a subsequent lawsuit.⁹⁰⁵ In *Biomedical Patent Management*

⁸⁹⁶Xechem Int'l, Inc. v. University of Tex., 382 F.3d 1324 (Fed. Cir. 2004).

⁸⁹⁷*Id.* at 1331.

⁸⁹⁸*Id.* at 1332.

⁸⁹⁹321 F.3d 1111 (Fed. Cir. 2003).

⁹⁰⁰*Id.* at 1115.

⁹⁰¹*Id.* at 1116.

⁹⁰²*Id.* at 1116–17.

⁹⁰³*Id.* at 1118–19.

⁹⁰⁴*Id.* at 1120.

⁹⁰⁵*Biomedical Patent Mgmt. Corp. v. California Dept. of Health Servs.*, 505 F.3d 1328, 1341 (Fed. Cir. 2007).

Corp. v. California Department of Health Services, the patent owner alleged that the California Department of Health Services (DHS) infringed its patent for screening birth defects in pregnant women.⁹⁰⁶ The District Court for the Northern District of California dismissed the suit on the grounds of sovereign immunity under the Eleventh Amendment.⁹⁰⁷

The patent owner appealed, asserting that DHS had waived sovereign immunity by intervening in an earlier case involving the patent in suit.⁹⁰⁸ The earlier action was brought by a DHS subcontractor seeking a declaratory judgment that the DHS screening program did not infringe Biomedical's patent.⁹⁰⁹ DHS had moved to intervene in that case and submitted a complaint that also sought declaration of noninfringement and invalidity of plaintiff's patents.⁹¹⁰ Biomedical's compulsory counterclaim against DHS and its subcontractor in that action asserted the same four counts that Biomedical asserted in the instant action.⁹¹¹ Five days after the earlier action was dismissed on Biomedical's motion for improper venue, Biomedical filed the instant action against DHS for infringement of its patents.⁹¹² DHS answered asserting only sovereign immunity.⁹¹³ Plaintiff argued, among other things, that DHS's waiver in the earlier action carried over to the new lawsuit because the new lawsuit involved the same subject matter and the same parties.⁹¹⁴ The district court and the Federal Circuit disagreed. The Federal Circuit refused to diverge from the "general principles of waiver": "that a waiver generally does not extend to a separate lawsuit, and that any waiver, including one affected by litigation conduct, must be 'clear.'"⁹¹⁵

A state may waive immunity by expressly agreeing to federal jurisdiction in a patent license agreement.⁹¹⁶ In *Baum Research and Development v. University of Massachusetts*, an inventor brought an infringement and breach of contract action against the university licensee, which asserted immunity under the Eleventh Amendment.⁹¹⁷ The inventor argued waiver based on a clause in the license which stated: "This Agreement will be construed, interpreted and applied according to the laws of the State of Michigan and all parties agree to proper venue and hereby submit to jurisdiction in the appropriate State or Federal Courts of Record sitting in the State of Michigan."⁹¹⁸ The district court held that this clause was an "unequivocally expressed" waiver, as required by *Florida Prepaid*, and thus denied the university's motion to dismiss.⁹¹⁹ The Federal Circuit affirmed, pointing out that it was inconsistent for the university to assert its authority to enter into a contract and, at the same time, argue

⁹⁰⁶*Id.*

⁹⁰⁷*Id.* at 1331.

⁹⁰⁸*Id.* at 1333.

⁹⁰⁹*Id.*

⁹¹⁰*Id.* at 1331.

⁹¹¹*Id.*

⁹¹²*Id.*

⁹¹³*Id.* at 1332.

⁹¹⁴*Id.* at 1334.

⁹¹⁵*Id.* at 1341.

⁹¹⁶*Baum Research and Dev. v. University of Mass.*, 503 F.3d 1367, 1370 (Fed. Cir. 2007).

⁹¹⁷*Id.*

⁹¹⁸*Id.* at 1369.

⁹¹⁹*Id.* at 1370.

that the plaintiff inventor must prove it had authority to waive its Eleventh Amendment immunity.⁹²⁰

As for the immunity issues, the Federal Circuit decided that the law of the Federal Circuit rather than the Tenth Circuit applied in order to ensure uniformity when patent issues were decided.⁹²¹ Although UNM is an arm of the state of New Mexico and is immune under the Eleventh Amendment from suit in federal courts, it has long been established that a state waives such immunity when it consents to federal jurisdiction by voluntarily appearing in court.⁹²² The issue, then, was whether the court should allow only claims in recoupment by the other party, or whether all compulsory counterclaims should be allowed. The Federal Circuit held that there would be seriously unfair results if a state could appear in court to enforce a right to ownership of a patent, and still could claim immunity from liability for royalties or other compensation arising from those same contracts or conduct.⁹²³ Such counterclaims would include “claims in recoupment,” i.e., claims of the same kind or nature, but claims in recoupment would not include royalties. The Federal Circuit held that by filing suit for patent ownership based on contracts and conduct, UNM waived its rights to all compulsory counterclaims arising from those contracts and conduct.⁹²⁴

XII. NO “PRACTICING PRIOR ART” AND “REVERSE DOCTRINE OF EQUIVALENTS” DEFENSES

A. Practicing Prior Art

In *Tate Access Floors, Inc. v. Interface Architectural Resources, Inc.*,⁹²⁵ the Federal Circuit emphasized that there is no “practicing prior art” defense, and stated that it is highly unlikely that the court would ever affirm a finding of no infringement based on the reverse doctrine of equivalents. Under a so-called practicing-prior-art-defense, the alleged infringer challenged literal infringement because its devices “merely practice the prior art, or that which would have been obvious in light of the prior art.”⁹²⁶ The court noted that there is no such defense where an alleged infringer could attempt to avoid infringement under a less stringent preponderance-of-the-evidence standard. Instead, if claim language reads on the prior art, the patent is invalid, and the law requires patent challengers to prove invalidity by clear and convincing evidence.⁹²⁷

B. Reverse Doctrine of Equivalents

The court also noted that the Federal Circuit has never affirmed a decision finding no infringement based on the reverse doctrine of equivalents, primarily

⁹²⁰*Id.* at 1372.

⁹²¹*Id.* at 1124.

⁹²²*Id.* (citing *Clark v. Barnard*, 108 U.S. 436, 447 (1883)).

⁹²³*Id.* at 1125.

⁹²⁴*Id.* at 1126.

⁹²⁵279 F.3d 1357, 61 USPQ2d 1647 (Fed. Cir. 2002).

⁹²⁶*Id.* at 1369, 61 USPQ2d at 1653.

⁹²⁷*Id.* at 1367, 61 USPQ2d at 1654.

because of the adoption of 35 U.S.C. §112.⁹²⁸ Section 112 imposed requirements for the written description, enablement, indefiniteness, and means-plus-function claims that are coextensive with the broadest possible reach of the reverse doctrine of equivalents.⁹²⁹

XIII. SECTION 1498(A): GOVERNMENT CONTRACTOR DEFENSE

Section 1498(a) of 28 U.S.C. provides an affirmative defense against patent infringement for a government contractor under certain circumstances. The government itself may be sued only in the Court of Federal Claims, but the statute does not specifically mention government contractors. Section 1498(a) recites:

Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm or corporation for the Government and with the authorization and consent of the Government shall be construed as use or manufacture by the United States.

In *Toxgon Corp. v. BNFL, Inc.*,⁹³⁰ the Department of Energy contracted with BNFL to develop a process to treat and immobilize radioactive waste. Toxgon sued BNFL for infringement of its patent for the process. BNFL moved for a dismissal under Fed. R. Civ. P. 12(b)(1) for lack of subject matter jurisdiction on the grounds that any alleged infringement occurred under the authority of and for the sole benefit of the United States. BNFL asserted that the litigation must proceed in the Court of Federal Claims under 28 U.S.C. §1498(a), not in district court.⁹³¹ The district court agreed and granted the motion to dismiss.

Toxgon appealed to the Ninth Circuit Court of Appeals, which transferred the case to the Federal Circuit. The impact of Section 1498(a) differs according to whether the accused infringer is the government or a contractor. The settled law is that in cases between private parties, 1498(a) is an affirmative defense, while in cases involving the government it is a jurisdictional bar.⁹³² The Federal Circuit vacated the dismissal for lack of jurisdiction and noted that Rule 12(b)(6) for failure to state a claim is the only rule under which a court may treat a motion to dismiss as a summary judgment motion.⁹³³ Improperly entertaining a motion under Rule 12(b)(1) placed the burden on the plaintiff (Toxgon) to show that subject matter jurisdiction existed. An affirmative defense under 12(b)(6) and 1498(a) would require defendants (BNFL) to bear

⁹²⁸*Id.* at 1368, 61 USPQ2d at 1655. Section 112 was adopted after the decision in *Graver Tank & Manufacturing Co. v. Linde Air Products Co.*, 339 U.S. 605, 85 USPQ 328 (1950).

⁹²⁹*Id.*

⁹³⁰312 F.3d 1379, 65 USPQ2d 1146 (Fed. Cir. 2002).

⁹³¹*Id.* at 1380, 65 USPQ2d at 1147–48.

⁹³²*Id.* at 1381, 65 USPQ2d at 1148–49.

⁹³³*Id.* at 1382–83, 65 USPQ2d at 1149.

the burden of proof by showing the absence of any genuine issue of material fact to prevail on summary judgment.⁹³⁴

In *Zoltek Corp. v. United States*,⁹³⁵ the Court of Appeals for the Federal Circuit held that the United States is liable for the use of a method patent under Section 1498(a) only if all steps of the method are performed in the United States. In *Zoltek*, contractor Lockheed used two types of silicon carbide fibers in assembling the F-22 fighter aircraft; both were made in Japan and imported into the United States. Because at least some steps of the process for making the fibers were performed in Japan, the court of claims correctly found that the claims were barred by Section 1498(c).⁹³⁶

However, the appeals court ruled that the court of claims erred when it allowed the corporation to allege patent infringement as a “taking” under the Fifth Amendment to the U.S. Constitution, pursuant to Section 1292(d)(2).⁹³⁷

The Federal Circuit relied upon *Schillinger v. United States*⁹³⁸ when it held that a patentee cannot sue the government for patent infringement under the Fifth Amendment.⁹³⁹ After *Schillinger*, the Patent Act of 1910 was enacted, providing exclusive relief for patent infringement against the government in the court of claims. Even before the Patent Act, it was recognized that the government could only be sued for patent infringement in the court of claims under a contract or implied contract theory—not as a taking.⁹⁴⁰

Reversing the lower court’s ruling, the Federal Circuit found that the patent infringement claims were barred by the *Schillinger* precedent and under Section 1498(a).⁹⁴¹

XIV. EXCEPTION FOR EXPERIMENTAL USE

There is a narrow exception to patent infringement that could be called the experimental-use defense. A professor at Duke University, Dr. Madey, sued Duke in district court in North Carolina for infringement of his laser patents.⁹⁴² Equipment embodying the concepts of the patents was built under a contract from the Air Force Office of Scientific Research (AFOSR). The equipment was owned by another university but located at Duke.

Dr. Madey alleged that the equipment was used not only for government purposes pursuant to a research grant from the Office of Naval Research (ONR) but also for purposes unrelated to the ONR grant. Duke asserted an experimental-use defense. The district court acknowledged that the use was potentially mixed between uses related to the ONR contract and uses not related.⁹⁴³ The

⁹³⁴*Id.* at 1383, 65 USPQ2d at 1149–50.

⁹³⁵442 F.3d 1345 (Fed. Cir. 2006).

⁹³⁶28 U.S.C. §1498(c) (stating that “the provisions of this section shall not apply to any claim arising in a foreign country”).

⁹³⁷*Zoltek*, 442 F.3d at 1349.

⁹³⁸155 U.S. 163 (1884).

⁹³⁹*Zoltek*, 442 F.3d at 1350 (citing *Schillinger*).

⁹⁴⁰*Id.* at 1350–51 (citing *Crozier v. Fried. Krupp Aktiengesellschaft*, 224 U.S. 290 (1912)).

⁹⁴¹*Id.* at 1353.

⁹⁴²*Madey v. Duke Univ.*, 307 F.3d 1351, 64 USPQ2d 1737 (Fed. Cir. 2002), *cert. denied*, 539 U.S. 958 (2003).

⁹⁴³*Id.* at 1354, 64 USPQ2d 1740.

district court dismissed Madey's claims against Duke under the government research grant and granted summary judgment for Duke for noninfringement on one count and for an experimental-use defense on another. The court noted a common-law "exception" for patent infringement liability for uses that are solely for research, academic, or experimental purposes.⁹⁴⁴ The district court also cited a Federal Circuit case holding that the experimental-use defense was viable for experimental, nonprofit purposes.⁹⁴⁵

The Federal Circuit reversed on the experimental-use issue. The court noted that the experimental-use exception is very narrow and limited to actions performed for amusement, for satisfaction of idle curiosity, or for strictly philosophical inquiry.⁹⁴⁶ Uses do not qualify for the experimental-use exception when they are undertaken under the guise of scientific inquiry but have definite, cognizable, and not insubstantial commercial purposes.⁹⁴⁷ The court noted that major universities such as Duke often sanction and fund research projects with arguably no commercial application whatsoever. These projects, however, unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects, increasing the status of the university, and luring lucrative research grants, students, and faculty.⁹⁴⁸ The focus on an experimental-use exception should be whether the use was solely for amusement, satisfaction of idle curiosity, or strictly philosophical inquiry.

The Federal Circuit also reversed the dismissal under 28 U.S.C. §1498(a) and explained that if a 1498(a) defense is raised in a suit against the United States, it is a jurisdictional matter—that is, the question of whether the suit belongs in the Court of Federal Claims or elsewhere. If the 1498(a) defense is asserted by a private party as a defense, its use is not jurisdictional but rather an affirmative defense.⁹⁴⁹ To the extent that Section 1498(a) is procedural, it is unique to patent law, and Federal Circuit law applies. Therefore, the court found that it was error to require the plaintiff to prove subject matter jurisdiction as required by Fourth Circuit law.⁹⁵⁰

XV. DECLARATORY JUDGMENT

The declaratory judgment statute, 28 U.S.C. §2201, requires a "a case of actual controversy" to invoke jurisdiction by a court. A defense that becomes available to the patent owner drawn into such a suit is that there is no actual controversy between the parties and thus the court has no jurisdiction. A recent case studied whether the declaratory judgment plaintiff, potentially a patent infringer, had suf-

⁹⁴⁴*Id.* at 1355, 64 USPQ2d at 1740–41 (citing *Deuterium Corp. v. United States*, 19 Cl. Ct. 624, 631, 14 USPQ2d 1636, 1642 (1990)).

⁹⁴⁵*Id.* at 1355, 64 USPQ2d at 1741 (citing *Embrex, Inc. v. Service Eng'g Corp.*, 216 F.3d 1343, 1349, 55 USPQ2d 1161, 1163 (Fed. Cir. 2000) (noting that courts should not construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of scientific inquiry, when that inquiry has definite, cognizable, and not insubstantial commercial purposes)).

⁹⁴⁶*Id.* at 1362, 64 USPQ2d at 1746 (citing *Embrex*, 216 F.3d at 1349, 55 USPQ2d at 1163).

⁹⁴⁷*Id.* (citing *Roche Prods., Inc., v. Bolar Pharm. Co.*, 733 F.2d 858, 863, 221 USPQ2d 937, 940 (Fed. Cir. 1984), *superseded in part by* 35 U.S.C. §271(e)(1) (1984)).

⁹⁴⁸*Id.*

⁹⁴⁹*Id.* at 1359–60, 64 USPQ2d at 1744.

⁹⁵⁰*Id.* at 1359, 64 USPQ2d at 1744.

ficient apprehension of a suit for the statute to apply. PEAT developed and acquired a patent covering technology relating to a high-temperature thermal destruction and recovery waste processing system (TDR technology).⁹⁵¹ PEAT and Vanguard worked together for a period of time to develop and market the technology. The parties later had a falling out and PEAT filed suit in Alabama alleging breach of contract, misappropriation of trade secrets, unfair competition, breach of fiduciary duty, and other counts. PEAT did not allege patent infringement.⁹⁵²

The suit was later transferred to Virginia, where Vanguard filed for a declaratory judgment that PEAT's patent was invalid and unenforceable. Later, Vanguard filed a second Alabama suit on a number of nonpatent issues and included the same declaratory judgment action on the patents.⁹⁵³ PEAT moved to dismiss Vanguard's Alabama action on the grounds that Vanguard had no reasonable apprehension that PEAT would sue for patent infringement and that Vanguard's claims were compulsory counterclaims to PEAT's Alabama suit.⁹⁵⁴ The district court converted PEAT's motion to dismiss into a motion for summary judgment, dismissed the complaint with prejudice, and ordered Vanguard to pay costs and attorney's fees.⁹⁵⁵

The Federal Circuit reversed the Alabama district court's dismissal of Vanguard's declaratory judgment action, finding that there was an actual case or controversy between the parties, in spite of PEAT's assertion that it had never filed a patent claim against Vanguard and still had not indicated any intention of doing so.⁹⁵⁶ Vanguard's position was that PEAT had sought to enjoin Vanguard's use of the technology by filing suit against Vanguard on other grounds, by writing a letter to Vanguard indicating that Vanguard had no right to market the technology, and by repeatedly contacting government agencies and implying that Vanguard was using PEAT's technology without PEAT's permission. By filing a lawsuit on other issues and informing Vanguard's clients that Vanguard was using PEAT's technology, PEAT showed a willingness to protect the technology.⁹⁵⁷ The court noted that filing a lawsuit would be just another logical step in protecting the technology, and thus there was a reasonable apprehension on the part of Vanguard, the declaratory judgment plaintiff.

XVI. CONCLUSION

Numerous defenses are available to the accused patent infringer. These defenses are provided by the patent and antitrust statutes or arise from equity. Some defenses involve the noninfringement and invalidity of the patent, while others are grounded in the conduct of the patent holder. These defenses require different levels of proof—clear and convincing versus preponderance of the evidence—and yield different results. Each should be investigated to determine its effect on the efficient resolution of any litigation.

⁹⁵¹Vanguard Research, Inc. v. PEAT, Inc., 304 F.3d 1249, 64 USPQ2d 1370 (Fed. Cir. 2002).

⁹⁵²*Id.* at 1251, 64 USPQ2d at 1371.

⁹⁵³*Id.* at 1252–53, 64 USPQ2d at 1372.

⁹⁵⁴*Id.* at 1252, 64 USPQ2d at 1372.

⁹⁵⁵*Id.* at 1253, 64 USPQ2d at 1373.

⁹⁵⁶*Id.* at 1255, 64 USPQ2d at 1374.

⁹⁵⁷*Id.*

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Chapter 28: Patent Defenses

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CHAPTER 28

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II. NONINFRINGEMENT

A. Infringement

[Add the following after the first paragraph of the section.]

Under Section 271(a), a patent is infringed when someone, without authority, uses a patented invention within the United States or imports into the United States any patented invention during the term of the patent. When a patent claims a multi-component system, the Federal Circuit has held that “use” of a system requires an actor to “‘use each and every . . . element of a claimed [system].’”¹ In multi-step process claims, the Federal Circuit has stated that there is no direct infringement unless all elements are practiced (or controlled) by a single direct infringer.²

In *Akamai Technologies, Inc. v. Limelight Networks, Inc.*³ and *McKesson Technologies Inc. v. Epic Systems Corp.*,⁴ the Federal Circuit had further held that there can be joint infringement only if there is an agency or contractual relationship between the parties. But the Federal Circuit subsequently vacated the opinions in both cases and ordered further briefing for en banc reconsiderations.⁵

Combining the *Akamai* and *McKesson* cases, the en banc Federal Circuit held that all the steps of a claimed method must be performed in order to find induced infringement, but that it is not necessary to prove that all the steps were committed by a single entity.⁶

The court reached its decision by addressing two questions:

- 1) whether a defendant may be held liable for induced infringement if the defendant has performed some of the steps of a claimed method and has induced other parties to commit the remaining steps (as in *Akamai*), and
- 2) if the defendant has induced other parties to collectively perform all the steps of the claimed method, but no single party has performed all of the steps (as in *McKesson*).⁷

The court concluded that its recent precedents were wrong, as a matter of statutory construction, precedent, and sound patent policy, to interpret Section 271(b) to mean that unless the accused infringer directs or controls the action of the party or parties that are performing the claimed steps, the patentee has no remedy, even though the patentee’s rights are plainly being violated by the actors’ joint conduct.⁸ In specifically overruling *BMC Resources, Inc. v. Paymentech, L.P.*,⁹ the court noted that it decided the *Akamai* and *McKesson*

¹Centillion Data Sys., LLC v. Qwest Commc’ns Int’l, 631 F.3d 1279, 1284, 97 USPQ2d 1697 (Fed. Cir. 2011) (alterations in original) (citation omitted).

²*Id.* at 1287.

³629 F.3d 1311, 97 USPQ2d 1321 (Fed. Cir. 2010).

⁴No. 2010-1291, 2011 U.S. App. LEXIS 7531, 98 USPQ2d 1281 (Fed. Cir. Apr. 12, 2011).

⁵*Akamai Techs., Inc. v. Limelight Networks, Inc.*, 419 Fed. Appx. 989 (Fed. Cir. Apr. 20, 2011); *McKesson Techs. Inc. v. Epic Sys. Corp.*, 463 Fed. Appx. 906 (Fed. Cir. May 26, 2011).

⁶*Akamai Techs., Inc. v. Limelight Networks, Inc.*, and *McKesson Techs. Inc. v. Epic Sys. Corp.*, 692 F.3d 1301, 1305, 104 USPQ2d 1799 (Fed. Cir. 2012).

⁷*Id.*

⁸*Id.* at 1306.

⁹498 F.3d 1373, 84 USPQ2d 1545 (Fed. Cir. 2007).

cases through an application of the doctrine of induced infringement, and that it left unresolved the question whether direct infringement can be found when no single entity performs all of the claimed steps of the patent.¹⁰

On appeal, the Supreme Court reversed the Federal Circuit's ruling, finding no infringement under §271(b).¹¹ According to the Court, the Federal Circuit's analysis fundamentally misunderstands what it means to infringe a method patent. A method patent claims a number of steps; under the Court's case law, the patent is not infringed unless all the steps are carried out.

Turning to direct infringement under §271(a), the Court noted that the Federal Circuit had held in *Muniauction, Inc. v. Thomson Corp.*¹² that a method's steps have not all been performed as claimed by the patent unless they are all attributable to the same defendant, either because the defendant actually performed those steps or because he directed or controlled others who performed them.¹³ While assuming, but not deciding, that the Federal Circuit's holding in *Muniauction* was correct, the Court explained there was no infringement of the method claim under *Muniauction* because the performance of all the patent's steps was not attributable to any one person. The Court thus concluded that where there has been no direct infringement, there can be no inducement of infringement under §271(b).¹⁴

Significantly, the Court noted that a decision on the §271(b) question necessitated a remand to the Federal Circuit. On remand, the Court noted the Federal Circuit will have the opportunity to revisit the §271(a) question and thus its holding in *Muniauction* if it so chooses.¹⁵

1. Section 271(e): Limited Safe Harbor

a. "Reasonably Related".

[Add the following at the end of the section.]

In *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*,¹⁶ the Federal Circuit held that a patentee was unlikely to succeed on the merits of its infringement claim because the accused activity was within the scope of the Drug Price Competition and Patent Term Restoration Act's safe harbor provision.¹⁷ In *Momenta*, a generic drug manufacturer was alleged to have used the patented invention in tests conducted and submitted to the Food and Drug Administration (FDA). The generic drug manufacturer planned to continue to use the allegedly infringing test after receiving FDA approval to sell the generic drug in order to satisfy the FDA requirement that each batch of the generic drug be actually the same as the brand name drug.

Amphastar had gained approval from the FDA to sell enoxaparin, a generic version of Lovenox®, a low molecular weight version of the naturally occurring

¹⁰*Akamai Techs./McKesson Techs.*, 692 F.3d at 1306.

¹¹*Limelight Networks, Inc. v. Akamai Technologies, Inc.*, 134 S. Ct. 2111, 110 USPQ2d 1681 (U.S. 2014).

¹²532 F. 3d 1318 (Fed. Cir 2008).

¹³532 F. 3d. at 1329–30.

¹⁴*Id.*

¹⁵*Id.* at ____.

¹⁶686 F.3d 1348, 103 USPQ2d 1800 (Fed. Cir. 2012).

¹⁷*Id.* at 1361. The safe harbor provision is codified at 35 U.S.C. §271(e).

polysaccharide polymer, heparin.¹⁸ Enoxiparin is a diverse molecule produced by breaking the heparin into smaller pieces called oligosaccharaides.¹⁹ To conclude that generic enoxaparin has the same active ingredient as the reference drug, Lovenox®, the FDA required, among other things, equivalence in disaccharide building blocks, fragment mapping, and sequence of oligosaccharide species. The FDA noted that a number of techniques could be used to separate and quantify the disaccharides. It turned out that detecting the presence of a 1,6-anhydro ring structure was particularly important for proving equivalence.²⁰

Momenta owned a patent relating to methods for analyzing heterogeneous populations of sulfated polysaccharides, such as heparin. Momenta asserted that Amphastar infringed its patent by using a testing method to determine that the oligosaccharide chains that make up enoxaparin include a 1,6-anhydro ring structure. According to the court, Momenta alleged that Amphastar's infringing test was necessary because the FDA requires a generic manufacturer to include in its manufacturing process the analysis of each batch of its enoxaparin drug substance to confirm that it includes a 1,6-anhydro ring structure.²¹ Momenta obtained a temporary restraining order and preliminary injunction, which the Federal Circuit stayed and later vacated.²²

Guided by the principal that statutes are to be taken as they are found, the court noted that the broad language of Section 271(e)(1) unambiguously applies to submissions under any federal law, provided that the law regulates the manufacture, use, or sale of drugs.²³ To support its conclusion that Congress did not link the safe harbor provision to the submission of an application for approval under the Federal Food, Drug, and Cosmetic Act, the court contrasted the closely related Section 271(e)(2), which states that it is an act of infringement to submit an application.²⁴

4. Section 271(b): Inducement of Infringement

[Add the following at the end of the section.]

In *Global-Tech Appliances, Inc. v. SEB S.A.*,²⁵ the Supreme Court held that in order to establish active inducement of infringement, the patent owner must prove that the seller had “knowledge that the induced acts constitute patent infringement.”²⁶ If the actor acted with willful blindness, however, the actor cannot escape liability.²⁷ The requirements for willful blindness are that: “(1) the defendant must subjectively believe that there is a high probability that a fact exists and (2) the defendant must take deliberate actions to avoid learning of that fact.”²⁸ In *Global-Tech*, the Court found that the infringer's decision to copy an

¹⁸*Momenta*, 686 F.3d at 1349.

¹⁹*Id.* at 1350.

²⁰*Id.* at 1350–51.

²¹*Id.* at 1351–52.

²²*Id.* at 1352.

²³*Id.* at 1354.

²⁴*Id.* at 1355.

²⁵131 S. Ct. 2060, 179 L. Ed. 2d 1167, 98 USPQ2d 1665 (2011).

²⁶*Id.* at 2068, 179 L. Ed. 2d at 1177.

²⁷*Id.* at 2069, 179 L. Ed. 2d at 1178.

²⁸*Id.* at 2070, 179 L. Ed. 2d at 1179.

overseas model of a deep fryer and failure to disclose the knock-off to an attorney hired to write a right-to-use opinion rose to the level of willful blindness.²⁹

In *Commil USA, LLC v. Cisco Systems, Inc.*,³⁰ the court found that an accused infringer's evidence of a good-faith belief of invalidity may negate the requisite intent for induced infringement. Prior to the second trial at the district court, Cisco proffered evidence of its good-faith belief of invalidity to rebut Commil's allegations of induced infringement.³¹ Commil filed a motion in limine to exclude the evidence and the district court granted it without a written opinion.³² The court found the district court error because "evidence of an accused inducer's good-faith belief of invalidity may negate the requisite intent for induced infringement" and the evidence "should be considered by the fact-finder in determining whether an accused party knew 'that the induced acts constitute patent infringement.'"³³ The court noted that under its case law, evidence of a good-faith belief of noninfringement is relevant evidence that tends to demonstrate that an accused infringer lacked the requisite intent to induce infringement and that it sees no principled distinction between a good-faith belief of invalidity versus noninfringement for purpose of specific intent to induce infringement.³⁴ The court reasoned that "[i]t is axiomatic that one cannot infringe an invalid patent" and that "one could be aware of a patent and induce another to perform the steps of the patent claim, but have a good-faith belief that the patent is not valid."³⁵ According to the court, "[u]nder those circumstances, it can hardly be said that the alleged inducer intended to induce infringement" and therefore "a good-faith belief of invalidity is evidence that may negate the specific intent to encourage another's infringement, which is required for induced infringement."³⁶

The *Commil* court also vacated the district court's induced infringement verdict because the jury was not instructed that induced infringement requires knowledge that the induced acts constitute infringement.³⁷ Applying *Global-Tech*, the court stated that "[a] finding of inducement requires both knowledge of the existence of the patent and 'knowledge that the induced acts constitute patent infringement.'"³⁸ The jury was instructed that Cisco could be held liable if "Cisco knew or should have known that its actions would induce direct infringement," and the Federal Circuit found that this was erroneous and could have changed the result.³⁹ The court noted that "[f]acts sufficient to support a negligence finding are not necessarily sufficient to support a finding of knowledge."⁴⁰

In *Smith & Nephew, Inc. v. Arthrex, Inc.*,⁴¹ the court found no reason to disturb the jury finding of inducement even though the district court instructed the jury under both the "deliberate indifference" standard and the "wilful blindness"

²⁹*Id.* at 2071–72, 179 L. Ed. 2d at 1180.

³⁰720 F.3d 1361, 107 USPQ2d 1290 (Fed. Cir. 2013).

³¹*Id.* at 1367.

³²*Id.*

³³*Id.* at 1368–69 (footnote omitted) (quoting *Global-Tech*, 131 S. Ct. at 2068, 179 L. Ed. 2d at 1177).

³⁴*Id.* at 1368.

³⁵*Id.*

³⁶*Id.*

³⁷*Id.* at 1367.

³⁸*Id.* (quoting *Global-Tech*, 131 S. Ct. at 2068, 179 L. Ed. 2d at 1177).

³⁹*Id.*

⁴⁰*Id.*

⁴¹502 Fed. Appx. 945 (Fed. Cir. Jan. 16, 2013).

standard because the jury found inducement under both and thus the district court erred in granting judgment as a matter of law of no inducement. The court noted that the jury heard evidence that Arthrex “indisputably knew” of the patent prior to any infringement, that the president and owner of Arthrex as well as the chief engineer and group director for one of the accused products knew of the patent, that the group director, after learning of the patent, drafted instructions for use of the accused product that paralleled the patented method steps, and that Arthrex made no attempt to compare its product to the claims of the patent at issue.⁴² The court noted that the jury weighed the evidence, resolved the factual issue of knowledge against Arthrex, and concluded Arthrex had the required knowledge for induced and contributory infringement.⁴³

In *SynQor, Inc. v. Artesyn Technologies, Inc.*,⁴⁴ the court found that the record contained sufficient evidence from which a reasonable juror could infer that the defendants had actual knowledge of the patents. The court noted that SynQor had presented specific evidence for each defendant showing each “possessed SynQor datasheets or products marked with SynQor’s earlier patents, including” a patent to which the patents in suit claimed priority. Furthermore, SynQor’s expert had delivered an opinion that “‘there was a significant effort by the Defendants in this case to cross/imitate SynQor’s products,’ and that those efforts would have exposed Defendants to SynQor’s patents.”⁴⁵ Some defendants had also “admitted to monitoring SynQor’s patents and one was shown to have possessed the ’190 patent [one of the patents in suit] prior to the time this suit was filed.”⁴⁶

[Add the following new section.]

5. *Product by Process [New Topic]*

In *Abbott Laboratories v. Sandoz, Inc.*,⁴⁷ the court held that infringement of a product-by-process claim requires the alleged product to infringe the process described in the product-by-process claim because “process terms in product-by-process claims serve as limitations in determining infringement.” Therefore, if an alleged product is not made by the process described in the product-by-process claim, it cannot infringe the claim.⁴⁸

[Add the following new section.]

F. **Section 273: Prior Commercial Use [New Topic]**

When Congress passed the America Invents Act⁴⁹ in September 2011, it amended the prior commercial use defense of Section 273. Effective September 16, 2011, a defense exists if the person “commercially used the subject matter in the United States, either in connection with an internal commercial use of an

⁴²*Id.* at 950.

⁴³*Id.*

⁴⁴709 F.3d 1365, 106 USPQ2d 1052 (Fed. Cir. 2013).

⁴⁵*Id.* at 1380.

⁴⁶*Id.*

⁴⁷566 F.3d 1282, 1293, 90 USPQ2d 1769 (Fed. Cir. 2009).

⁴⁸*Id.*

⁴⁹Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (Sept. 16, 2011).

actual arm's length sale or other arm's length commercial transfer of a useful end result of such commercial use" at least one year before the earlier of the effective filing date or "the date on which the claimed invention was disclosed to the public in a manner that qualified for the exception from prior art under section 102(b)."⁵⁰ The person asserting this defense must establish it by clear and convincing evidence.⁵¹

Congress also recognized two additional commercial uses: premarketing regulatory review and nonprofit laboratory use.⁵² Premarketing regulatory review is a commercial use when "[s]ubject matter for which commercial marketing or use is subject to a premarketing regulatory review period during which the safety or efficacy of the subject matter is established."⁵³ Nonprofit laboratory use is deemed a commercial use when it involves the use of "subject matter by a nonprofit research laboratory or other nonprofit entity, such as a university or hospital, for which the public is the intended beneficiary."⁵⁴ This may be asserted only "for continued and noncommercial use by and in the laboratory or other nonprofit entity."⁵⁵ If a person abandons the commercial use of the subject matter, he or she may not rely on activities performed prior to that date of abandonment.⁵⁶ A university exception exists, prohibiting a person from asserting the defense when the "claimed invention with respect to which the defense is asserted was, at the time the invention was made, owned or subject to an obligation of assignment to either an institution of higher education . . . or a technology transfer organization"⁵⁷

III. INVALIDITY

²⁵⁶[Replace footnote 256 with the following.] The Supreme Court unanimously affirmed the Federal Circuit's interpretation of 35 U.S.C. §282 as establishing a "clear and convincing" burden to challenge patent validity. *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2252, 180 L. Ed. 2d 131, 98 USPQ2d 1857 (2011).

[Add the following new section before Section A.]

A'. Section 101: Invalidity Based on Patent Ineligibility [New Topic]

Laws of nature, mathematical equations, natural phenomena, and abstract ideas do not qualify as patentable subject matter under 35 U.S.C. §101. This principle is an exception to, or preemption of, the broad statement of patentable subject matter set forth in Section 101.⁵⁸ The Supreme Court recognizes that the

⁵⁰*Id.* §5, 125 Stat. at 297 (codified at 35 U.S.C. §273(a)).

⁵¹*Id.* (codified at 35 U.S.C. §273(b)).

⁵²*Id.* (codified at 35 U.S.C. §273(c)).

⁵³*Id.*

⁵⁴*Id.*

⁵⁵*Id.*

⁵⁶*Id.* §5, 125 Stat. at 298 (codified at 35 U.S.C. §273(e)(4)).

⁵⁷*Id.* (codified at 35 U.S.C. §273(e)(5)).

⁵⁸*Alice Corp. Pty. Ltd. v. CLS Bank International*, 573 U.S. ___, ___ (2014)(slip op. at 5, citing *Bilski v. Kappos*, 130 S. Ct. 3218, 177 L. Ed. 2d 792, 95 USPQ2d 1001 (2010)).

patent laws are designed to promote rather than impede innovation and that at some level, “all inventions . . . embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.”⁵⁹ Thus over the decades, the Court has been very careful to preclude patents that tie up the building blocks of human ingenuity and allow patents that use the building blocks to add something new and useful for society.

In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*,⁶⁰ the Supreme Court invalidated a method claim under 35 U.S.C. §101, and took the opportunity to explain several of its prior decisions on patent eligibility. In *Mayo*, the Supreme Court held that certain claims directed to methods of optimizing therapeutic efficacy for treatment of certain disorders were not patent-eligible because they recited a law of nature. The invention involved the use of thiopurine drugs to treat autoimmune diseases, such as Crohn’s disease and ulcerative colitis. The typical claim at issue covered a method of optimizing therapeutic efficacy for treating a gastrointestinal disorder, comprising administering a drug and determining the level of a certain metabolite of the drug, wherein a low level of the metabolite indicates a need to increase and a high level of the metabolite indicates a need to decrease the amount of drug subsequently administered.

The Court addressed the claim in terms of its individual elements and as a whole. The Court first noted that “the ‘administering’ step simply refers to the relevant audience, namely doctors who treat patients with certain diseases with thiopurine drugs.”⁶¹ Citing to its previous decisions in *Diamond v. Diehr*⁶² and *Bilski v. Kappos*,⁶³ the Court explained that the “prohibition against patenting abstract ideas ‘cannot be circumvented by attempting to limit the use of the formula to a particular technological environment.’”⁶⁴ Second, according to the Court, “the ‘wherein’ clauses simply tell a doctor about the relevant natural laws,” and at most add a suggestion that he or she “should take those laws into account” when treating a patient.⁶⁵ Third, “the ‘determining’ step tells the doctor to determine the level of the relevant metabolites in the blood, through whatever process the doctor or the laboratory wishes to use.”⁶⁶ Citing again to *Bilski* and further to *Parker v. Flook*,⁶⁷ the Court concluded that “[p]urely ‘conventional or obvious’ ‘[pre]-solution activity’ is normally not sufficient to transform an unpatentable law of nature into a patent eligible application of such a law.”⁶⁸ Taking the claim as a whole, the Court remarked that considering the three steps as an ordered combination adds nothing to the laws of nature that is not already present when the steps are considered separately.⁶⁹

⁵⁹*Id.* (citing *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, 182 L. Ed. 2d 321, 101 USPQ2d 1961 (2012)).

⁶⁰132 S. Ct. 1289, 182 L. Ed. 2d 321, 101 USPQ2d 1961 (2012).

⁶¹*Id.* at 1297, 182 L. Ed. 2d at 331.

⁶²450 U.S. 175, 209 USPQ 1 (1981).

⁶³130 S. Ct. 3218, 177 L. Ed. 2d 792, 95 USPQ2d 1001 (2010).

⁶⁴*Mayo*, 132 S. Ct. at 1297, 182 L. Ed. 2d at 331 (quoting *Bilski*, 130 S. Ct. at 3225, 177 L. Ed. 2d at 801 (quoting *Diehr*, 450 U.S. at 191–92)).

⁶⁵*Id.*

⁶⁶*Id.*

⁶⁷437 U.S. 584, 198 USPQ 193 (1978).

⁶⁸*Mayo*, 132 S. Ct. at 1298, 182 L. Ed. 2d at 332 (quoting *Flook*, 437 U.S. at 590).

⁶⁹*Id.*

Thus, the Court found that the patent claims informed a relevant audience about certain laws of nature, but that the additional steps consisted of well-understood, routine, conventional activity already engaged in by the scientific community. Since those steps added nothing significant, the Court found they were not sufficient to transform unpatentable natural correlations into patentable applications of those regularities.⁷⁰

The Court considered its two previous rulings in *Diehr* and *Flook* to be most directly on point in deciding *Mayo*. The Court explained that the claims in *Mayo* presented a case for patentability that was weaker than the (patent-eligible) claim in *Diehr* and no stronger than the (unpatentable) claim in *Flook*.⁷¹

The *Diehr* process, which the Court had held to be patent-eligible, set forth a method for molding raw, uncured rubber into various cured, molded products, where the Arrhenius equation (i.e., mathematical algorithm) was used to determine when to open the press. (The equation used the temperature inside the mold, the time the rubber had been in the mold, and the thickness of the rubber.) The *Mayo* Court noted that the *Diehr* Court had pointed out that the basic mathematical equation, like a law of nature, was not patentable, but that the overall process was patent-eligible because of the way the additional steps of the process integrated the equation into the process as a whole.⁷²

The *Flook* process, which the *Flook* Court had held was not patent-eligible, provided a method for adjusting alarm limits in the catalytic conversion of hydrocarbons by measuring variables (such as temperature, pressure, and flow rates), calculating current alarm limits with a novel algorithm, and adjusting the system for new alarm limit values.⁷³ Like the *Diehr* Court, the *Flook* Court pointed out that the basic mathematical equation, like a law of nature, was not patentable. But the *Flook* Court characterized the claimed process as doing nothing other than “‘provid[ing] a[n unpatentable] formula for computing an updated alarm limit.’”⁷⁴

The patent-ineligible *Flook* claim, unlike the patent-eligible claim in *Diehr*, did not “‘explain how the variables used in the formula were to be selected, nor did the [*Flook* claim] contain any disclosure relating to chemical processes at work or the means of setting off an alarm or adjusting the alarm limit.’”⁷⁵ Thus, the *Mayo* Court noted that the other steps in the *Flook* process did not limit the claim to a particular application.⁷⁶

The *Mayo* Court went on to emphasize that its decisions in *Bilski*, *Flook*, and *Gottschalk v. Benson*⁷⁷ made clear that Section 101 precludes patenting of abstract ideas, but allows patenting of a substantial practical application of scientific principles.⁷⁸ In *Bilski*, the Court had considered claims covering a process for hedging risks of price changes by, e.g., contracting to purchase commodities from sellers at a fixed price (reflecting the desire of sellers to hedge against a drop in prices)

⁷⁰*Id.*

⁷¹*Id.* at 1299, 182 L. Ed. 2d at 334.

⁷²*Id.* at 1298–99, 182 L. Ed. 2d at 333.

⁷³*Id.* at 1299, 182 L. Ed. 2d at 333.

⁷⁴*Id.* (quoting *Parker v. Flook*, 437 U.S. 584, 586 (1978)).

⁷⁵*Id.* (quoting *Diamond v. Diehr*, 450 U.S. at 192 n.14 (1981), and citing *Flook*, 437 U.S. at 586)).

⁷⁶*Id.*

⁷⁷409 U.S. 63, 175 USPQ 673 (1972).

⁷⁸*Mayo*, 132 S. Ct. at 1299–1302, 182 L. Ed. 2d at 334–37.

while selling commodities to consumers at a fixed price (reflecting the desire of consumers to hedge against a price increase). One claim described the process; another reduced the process to a mathematical formula.⁷⁹ The *Bilski* Court held that the described “concept of hedging” was “an unpatentable abstract idea.”⁸⁰ The *Bilski* Court explained that its conclusion was not undermined by claims that limited hedging to use in commodities and energy markets, and specified that “well-known random analysis techniques [could be used] to help establish some of the inputs into the equation,” because “*Flook* established that limiting an abstract idea to one field of use or adding token post solution components did not make the concept patentable.”⁸¹

In *Benson*, the Court considered the patentability of a mathematical process for converting binary-coded decimal numerals into pure binary numbers on a general-purpose digital computer. The *Benson* claims “purported to cover any use of the claimed method in a general-purpose digital computer of any type.”⁸² The *Benson* Court recognized that “‘a novel and useful structure created with the aid of knowledge of scientific truth’” might be patentable.⁸³ But it held that simply implementing a mathematical principle on a physical machine, namely a computer, was not a patentable application of that principle. According to the *Benson* Court, the mathematical formula had “no substantial practical application except in connection with a digital computer.”⁸⁴

The *Mayo* Court also stressed that patent law may not inhibit further discovery by improperly tying up the future use of laws of nature.⁸⁵ Returning to its prior decisions, the Court explained that it had set aside as unpatentable Samuel Morse’s general claim for “‘the use of the motive power of the electric or galvanic current . . . however developed, for making or printing intelligible characters, letters, or signs, at any distances.’”⁸⁶ The *Mayo* Court noted similar holdings in *Benson*, *Bilski*, and *Flook*. Thus, the *Benson* claims were “‘so abstract and sweeping as to cover both known and unknown uses of the [mathematical formula]’”⁸⁷; the *Bilski* Court pointed out that to allow “‘petitioners to patent risk hedging would preempt use of this approach in all fields,’”⁸⁸ and the *Flook* Court expressed concern that the claimed process was simply “‘a formula for computing an updated alarm limit,’ which might ‘cover a broad range of potential uses.’”⁸⁹ The *Mayo* Court therefore held the claims at issue unpatentable as effectively claiming the underlying laws of nature themselves, which is patent-ineligible subject matter under Section 101, *Bilski*, and other Supreme Court precedent.⁹⁰

In *Association for Molecular Pathology v. Myriad Genetics, Inc.*,⁹¹ the Supreme Court held that isolated DNA is unpatentable subject matter under

⁷⁹*Id.* at 1300, 182 L. Ed. 2d at 335.

⁸⁰*Bilski*, 130 S. Ct. at 3231, 177 L. Ed. at 807.

⁸¹*Id.*

⁸²*Benson*, 409 U.S. at 64.

⁸³*Id.* at 67 (quoting *Mackay Radio & Tel. Co. v. Radio Corp. of Am.*, 306 U.S. 86, 94, 40 USPQ 199 (1939)).

⁸⁴*Id.* at 71.

⁸⁵*Mayo*, at 132 S. Ct. at 1301, 182 L. Ed. 2d at 335.

⁸⁶*Id.* (quoting *O’Reilly v. Morse*, 56 U.S. 62, 129, 15 How. 62, 86 (1854)).

⁸⁷*Id.*, 182 L. Ed. 2d at 336 (quoting *Benson*, 409 U.S. at 67, 68).

⁸⁸*Id.* (quoting *Bilski*, 130 S. Ct. at 3231, 177 L. Ed. 2d at 807).

⁸⁹*Id.* (quoting *Flook*, 437 U.S. at 586).

⁹⁰*Id.* at 1304, 182 L. Ed. 2d at 338–39.

⁹¹133 S. Ct. 2107, 186 L. Ed. 2d 124, 106 USPQ2d 1972 (2013).

Section 101 as a product of nature, but that complementary DNA (cDNA) is patentable subject matter because it is not naturally occurring. Myriad discovered and obtained a number of patents based on the precise location and sequence of BRCA1 and BRCA2 genes, which allowed Myriad to create medical tests for detecting mutations in these genes, thereby providing an assessment of a patient’s risk of breast or ovarian cancer.⁹² Myriad’s patent also permitted Myriad to synthetically create BRCA cDNA, which is created in a laboratory from mRNA and contains only the exons that occur in the DNA sequence.⁹³

Petitioner Ostrer, along with others, sought a declaration that Myriad’s patents were invalid under Section 101.⁹⁴ The Federal Circuit had found that Ostrer had standing in view of “Myriad’s actions against him and his stated ability and willingness to begin BRCA1 and BRCA2 testing if Myriad’s patents were invalidated.”⁹⁵ The Federal Circuit then held that both isolated DNA and cDNA were patentable subject matter under Section 101.⁹⁶

The Supreme Court first noted that Myriad “did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes” and did not “create or alter the genetic structure of DNA;” instead, the Court noted that Myriad uncovered the “precise location and genetic sequence of the BRCA1 and BRCA2 genes within chromosomes 17 and 13.”⁹⁷ In rejecting isolated DNA, and endorsing cDNA, as patent-eligible subject matter, the Court revisited three prior decisions.

The Court noted that in *Diamond v. Chakrabarty*⁹⁸ the “bacterium was new ‘with markedly different characteristics’ due to the additional plasmids and resultant ‘capacity for degrading oil.’”⁹⁹ In contrast, the Court found that Myriad merely separated a useful and important gene from its surrounding genetic material, which “is not an act of invention.”¹⁰⁰

In *Funk Brothers Seed Co. v. Kalo Inoculant Co.*,¹⁰¹ the Court noted that the composition patent claiming “a mixture of naturally occurring strains of bacteria that helped leguminous plants take nitrogen from the air and fix it in the soil” was “not patent eligible because the patent holder did not alter the bacteria in any way.”¹⁰² The Court found that Myriad’s patents, like those in *Funk Brothers*, “fell squarely within the law of nature exception.”¹⁰³

Finally, the Court noted that in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*,¹⁰⁴ it had “held that new plant breeds were eligible for utility patents under §101 notwithstanding separate statutes providing special protections for plants” and that “the Board of Patent Appeals and Interferences

⁹²*Id.* at 2109, 186 L. Ed. 2d at 126.

⁹³*Id.* at 2113, 2119, 186 L. Ed. 2d at 130, 136–37.

⁹⁴*Id.* at 2114, 186 L. Ed. 2d at 131 (citing *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 81 USPQ2d 1225 (2007)). See also Section VI.C in the Main Volume.

⁹⁵*Myriad*, 133 S. Ct. at 2114, 186 L. Ed. 2d at 132.

⁹⁶*Id.*

⁹⁷*Id.* at 2116, 186 L. Ed. 2d at 134.

⁹⁸447 U.S. 303, 206 USPQ (1980).

⁹⁹*Myriad*, 133 S. Ct. at 2117, 186 L. Ed. 2d at 134 (quoting *Chakrabarty*, 447 U.S. at 305 n.1).

¹⁰⁰*Id.*

¹⁰¹333 U.S. 127, 76 USPQ 280 (1948).

¹⁰²*Myriad*, 133 S. Ct. at 2117, 186 L. Ed. 2d at 134–35 (citing *Funk Bros.*, 333 U.S. at 128–29, 132).

¹⁰³*Id.*, 186 L. Ed. 2d at 135.

¹⁰⁴534 U.S. 124, 60 USPQ2d 1865 (2001).

had determined that new plant breeds were patent eligible under §101 and that Congress had recognized and endorsed that position.”¹⁰⁵ The Court distinguished *Pioneer Hi-Bred*, stating that “Congress has not endorsed the views of the PTO in subsequent litigation.”¹⁰⁶

In *Myriad*, with regard to cDNA, however, the Court explained that “the lab technician unquestionably creates something new when cDNA is made,” noting that “cDNA retains the naturally occurring exons of DNA, but it is distinct from the DNA from which it was derived.”¹⁰⁷ For these reasons, the Court found that cDNA is not a product of nature and is eligible for patent protection under Section 101 “except insofar as very short series of DNA may have no intervening introns to remove when creating cDNA,” because in that instance “a short strand of cDNA may be indistinguishable from natural DNA.”¹⁰⁸

Importantly, the Court noted what its decision did not implicate: (1) *Myriad* did not have any method claims before the Court, but had it “created an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could possibly have sought a method patent”; (2) *Myriad*’s challenged claims did not involve patents on “new *applications* of knowledge about the BRCA1 and BRCA2 genes”; and (3) the Court did not “consider the patentability of DNA in which the order of the naturally occurring nucleotides has been altered,” stating that “[s]cientific alteration of the genetic code presents a different inquiry” and that the Court did not express an opinion on the application of Section 101 in that case.¹⁰⁹

In *Alice Corp. Pty. Ltd. v. CLS Bank International*,¹¹⁰ the Court continued integrating its patent eligibility decisions while unanimously affirming the Federal Circuit and holding that the claims at issue are drawn to the abstract idea of intermediated settlement, and that merely requiring generic computer implementation fails to transform that abstract idea into a patent-eligible invention.¹¹¹ Embracing *Myriad*, the Court first noted that laws of nature, natural phenomena, and abstract ideas are not patentable subject matter under Section 101 because “monopolization of those [basic] tools through the grant of a patent might tend to impede innovation more than it would tend to promote it.”¹¹² The Court noted, however, that “an invention is not rendered ineligible for patent simply because it involves an abstract concept.”¹¹³ Rather, the Court explained that “applications of such concepts to a new and useful end . . . remain eligible for patent protection.”¹¹⁴ Accordingly, in applying the Section 101 exception, the Court instructed the task is to “distinguish between patents that claim the building blocks of human ingenuity and those that integrate the building blocks into something more, thereby transforming them into a patent-eligible invention.”¹¹⁵

¹⁰⁵*Myriad*, 133 S. Ct. at 2118, 186 L. Ed. 2d at 136 (citing *J.E.M.*, 534 U.S. at 144–45).

¹⁰⁶*Id.*

¹⁰⁷*Id.* at 2119, 186 L. Ed. 2d at 137.

¹⁰⁸*Id.*

¹⁰⁹*Id.* at 2119–20, 186 L. Ed. 2d at 137 (emphasis in original).

¹¹⁰573 U.S. ____ (2014).

¹¹¹573 U.S. at ____ (slip op. at 1).

¹¹²*Id.* at ____ (slip op. at 4–5).

¹¹³*Id.* at ____ (slip op. at 5, citing *Diamond v. Diehr*, 450 U. S. 175, 187 (1981)).

¹¹⁴*Id.* (citing *Gottschalk v. Benson*, 409 U. S. 63, 67 (1972)).

¹¹⁵*Id.* (citing *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, ___, 182 L. Ed. 2d 321, ___, 101 USPQ2d 1961, ___, (2012)).

Finding the claim ineligible for patent, the Court explained and applied the two-part test set forth in *Mayo*: 1) determine whether the claims at issue are directed to one of those patent-ineligible concepts; and 2) if so, then search for the “inventive concept” by considering 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.¹¹⁶ For step 1, the Court found “intermediated settlement, like hedging, is an ‘abstract idea’ beyond the scope of §101.”¹¹⁷ For step 2, the Court found “introduction of a computer into the claims does not alter the analysis at Mayo step two.”¹¹⁸

D. Invalidity Based on Inadequacies in the Specification or Claims

2. The Written-Description Requirement

⁴¹⁸[Replace footnote 418 with the following.] *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1344, 94 USPQ2d 1161 (Fed. Cir. 2010) (en banc). This case is discussed at the end of this section in the Main Volume.

3. The Best Mode Requirement

[Add the following at the end of the section.]

In *Wellman, Inc. v. Eastman Chemical Co.*,¹¹⁹ the Federal Circuit affirmed a grant of summary judgment of invalidity for failure to disclose the best mode. The patents-in-suit disclosed polyethylene terephthalate (PET) resins for use in plastic beverage containers. Wellman had commercialized a slow-crystallizing, hot-fill PET resin called Ti818 by the time the applications leading to the Wellman patents were filed. The recipe for Ti818, along with the additive carbon black, was not disclosed in the patents; instead, Wellman provided ranges of concentrations for lists of possible ingredients and led away from the use of carbon black by characterizing it merely as “suitable.”¹²⁰ The district court found that at the time of filing “at least inventor Dr. Nichols viewed Ti818 as the best mode of practicing the invention”¹²¹ and that inventors knew carbon black had “clearly the best reheat rate.”¹²² The Federal Circuit found that “Wellman concealed the best mode by not disclosing the recipe for Ti818, by identifying preferred concentration ranges for certain ingredients that excluded those used in Ti818, and by identifying preferred particles sizes for the HUR additive [black carbon] other than that used in Ti818.”¹²³ The Federal Circuit held that concealment of the recipe for Ti818 and the use of carbon black was intentional, and, therefore, found those claims invalid for failure to disclose the best mode.¹²⁴

¹¹⁶*Id.* at __ (slip op. at 5-6).

¹¹⁷*Id.* at __ (slip op. at 7).

¹¹⁸*Id.* at __ (slip op. at 9).

¹¹⁹642 F.3d 1355, 98 USPQ2d 1505 (Fed. Cir. 2011).

¹²⁰*Id.* at 1364.

¹²¹*Id.* at 1359.

¹²²*Id.* at 1362.

¹²³*Id.* at 1364.

¹²⁴*Id.* at 1365.

When Congress passed the America Invents Act in September 2011, it amended the best mode requirement of Section 282 by replacing paragraph (3). Effective September 16, 2011, “the 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.”¹²⁵

4. *The Requirements of Claim Definiteness*

[Add the following at the end of the section.]

In *Nautilus, Inc. v. Biosig Instruments, Inc.*, the Supreme Court vacated and remanded¹²⁶ the “insolubly ambiguous” standard set by the Federal Circuit for patent claim indefiniteness, under 35 U.S.C. §112(b).¹²⁷ The Federal Circuit had held that the term “spaced relationship” was not indefinite because the proper meaning could be determined knowing the intended functionality of the claim by referring to the term in the context of the intrinsic evidence.¹²⁸ The term “spaced relationship” was amenable to construction.¹²⁹ However, the district court determined during a summary judgment hearing that the term was indefinite, stating that “a spaced relationship did not tell me or anyone what precisely the space should be. . . . Not even any parameters as to what the space should be Nor whether the spaced relationship on the left side should be the same as the spaced relationship on the right side.”¹³⁰

“A claim is indefinite only when it is ‘not amenable to construction’ or insolubly ambiguous.”¹³¹ According to the Federal Circuit, because the term was amenable to construction, it would be indefinite only if a person of ordinary skill in the art would find it insolubly ambiguous.¹³² Insolubly ambiguous means that the term fails to provide sufficient clarity, to one of skill in the art, as to the bounds of the claim.¹³³ The court found that “spaced relationship” was not indefinite because a person of skill in the art would find such boundaries in the intrinsic evidence.¹³⁴ In analogizing the case to *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*,¹³⁵ the court noted that the variables affecting the “spaced relationship” between the electrodes can be determined by those of skill in the art and thus the term cannot be insolubly ambiguous.¹³⁶

The court further noted that “this court’s jurisprudence does not proscribe drafting or defining claims in relation to their functions” and that “‘claims are not

¹²⁵Leahy-Smith America Invents Act, Pub. L. No. 112-29, §15, 125 Stat. 284, 328 (Sept. 16, 2011) (codified at 35 U.S.C. §282(3)(A)).

¹²⁶134 S. Ct. 2120, 189 L. Ed. 2d 37, 110 USPQ2d 1688, decided June 2, 2014 (as corrected June 10, 2014).

¹²⁷*See Nautilus, Inc. v. Biosig Instruments, Petition for a Writ of Certiorari (Sept. 19, 2013)*, available at <http://sblog.s3.amazonaws.com/wp-content/uploads/2013/12/13-PETITION-FOR-A-WRIT-OF-CERTIORARI.pdf>.

¹²⁸*Biosig Instruments, Inc. v. Nautilus, Inc.*, 715 F.3d 891, 904, 106 USPQ2d 1554 (Fed. Cir. 2013).

¹²⁹*Id.* at 898–89.

¹³⁰*Id.* at 899 (internal quotation marks and citation omitted).

¹³¹*Id.* at 898 (quoting *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1347, 75 USPQ2d 1801 (Fed. Cir. 2005)).

¹³²*Id.* at 898–99.

¹³³*Id.* at 899.

¹³⁴*Id.*

¹³⁵655 F.3d 1364, 99 USPQ2d 1924 (Fed. Cir. 2011).

¹³⁶*Biosig*, 715 F.3d at 903.

necessarily indefinite for using functional language.’”¹³⁷ The court disagreed with the district court’s finding of fault on the experts’ references to the function of the claim term only and its holding that “this is all a description of the desired result and not a description of any invention . . . and, therefore, violates the requirement of specificity in Section 112” because courts often refer to the context in which a patented invention is claimed to determine its scope.¹³⁸ The court stated that determining the meaning of “spaced relationship” requires referring to the term in the context of the intrinsic evidence, whereas the district court viewed the term in a vacuum.¹³⁹ “[W]ithout context, it would be impossible to ascertain ‘what the inventors actually invented and intended to envelop with the claim’” and to examine the patent from the perspective of one skilled in the art.¹⁴⁰ The court noted that the district court erred to the extent it failed to consider Biosig’s evidence based on reasoning that it spoke only to the “function of the claim.”¹⁴¹

But the Supreme Court concluded that the Federal Circuit’s formulation, which tolerates some ambiguous claims but not others, does not satisfy the statute’s definiteness requirement. In place of the “insolubly ambiguous” standard, the Court held that 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.¹⁴² Expressing no opinion on the validity of the patent-in-suit, the Court remanded, instructing the Federal Circuit to decide the case employing the standard it prescribed.¹⁴³

V. ANTITRUST

[Add the following new section.]

D. Reverse Payments [New Topic]

In *Federal Trade Commission v. Actavis, Inc.*,¹⁴⁴ the Supreme Court held that the FTC should have been permitted to prove its antitrust claim that an alleged reverse payment violated antitrust laws. In finding that some agreements can violate the antitrust laws, the Court endorsed a rule-of-reason approach and rejected the FTC’s position that reverse payment settlement agreements are presumptively unlawful, as well as the dissent’s view that reverse payment settle-

¹³⁷*Id.* (citing *Moore U.S.A., Inc. v. Standard Register Co.*, 229 F.3d 1091, 1111, 56 USPQ2d 1225 (Fed. Cir. 2000) and quoting *Microprocessor Enhancement Corp. v. Texas Instruments Inc.*, 520 F.3d 1367, 1375, 86 USPQ2d 1225 (Fed. Cir. 2008)).

¹³⁸*Id.* at 904.

¹³⁹*Id.*

¹⁴⁰*Id.* (quoting *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250, 48 USPQ2d 1117 (Fed. Cir. 1998)).

¹⁴¹*Id.*

¹⁴²134 S. Ct. 2120, 2124, 189 L. Ed. 2d 37, ___, 110 USPQ2d 1688, ___, decided June 2, 2014 (as corrected June 10, 2014).

¹⁴³*Id.*

¹⁴⁴133 S. Ct. 2223, 186 L. Ed. 2d 343, 106 USPQ2d 1953 (2013).

ments “should be viewed for antitrust purposes in the same light as” traditional settlement agreements.¹⁴⁵

The Court identified five sets of considerations that led it to conclude that the FTC should have been allowed to present its antitrust claim.¹⁴⁶ First, the Court said, “the specific restraint at issue has the ‘potential for genuine adverse effects on competition.’”¹⁴⁷ Given this, the rationale behind the payment must be considered: It may be that restricting competition is exactly what the patentee intends.¹⁴⁸ Second, it is possible that the “anticompetitive consequences will at least sometimes prove unjustified.”¹⁴⁹ The Court noted that “[w]here a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidity or a finding of noninfringement”; as such, a defendant may show a legitimate justification to explain the challenged term and demonstrate the lawfulness of that term under the rule-of-reason approach.¹⁵⁰ Third, the Court noted that “where a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice.”¹⁵¹ As a fourth consideration, the Court noted that “the size of the unexplained reverse payment can provide a workable surrogate for a patent’s weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself.”¹⁵² Finally, “the fact that a large, unjustified reverse payment risks antitrust liability does not prevent” parties from settling in other ways.¹⁵³ The Court concluded these considerations, taken together, outweigh the single strong consideration of the policy favoring settlements, which led the Eleventh Circuit to provide general immunity for reverse payment agreements.

VI. PATENT MISUSE

A. Patent Misuse and the First Sale Doctrine

[Add the following at the end of the section.]

One court has interpreted the *Quanta* ruling to apply to authorized foreign sales as well as authorized sales in the United States.¹⁵⁴ In support of its broad interpretation of the first sale doctrine, the U.S. District Court for the Northern District of California stated that “[d]rawing such a distinction between authorized domestic sales and authorized foreign sales would negate the Supreme Court’s stated intent in *Quanta* to eliminate the possibility of a patent holder doing an ‘end-run’ around the sale exhaustion doctrine by authorizing a sale, thereby

¹⁴⁵*Id.* at 2233, 186 L. Ed. 2d at 359.

¹⁴⁶*Id.* at 2234, 186 L. Ed. 2d at 360.

¹⁴⁷*Id.* (quoting *Federal Trade Comm’n v. Indiana Fed’n of Dentists*, 476 U.S. 447, 460–61 (1986)).

¹⁴⁸*Id.*, 186 L. Ed. 2d at 360–61.

¹⁴⁹*Id.* at 2235–36, 186 L. Ed. 2d at 362.

¹⁵⁰*Id.* at 2236, 186 L. Ed. 2d at 362.

¹⁵¹*Id.*

¹⁵²*Id.* at 2236–37, 186 L. Ed. 2d at 363.

¹⁵³*Id.* at 2237, 186 L. Ed. 2d at 363.

¹⁵⁴*LG Elecs., Inc. v. Hitachi, Ltd.*, 655 F. Supp. 2d 1036, 1047 (N.D. Cal. 2009).

reaping the benefit of its patent, then suing a downstream purchaser for patent infringement.”¹⁵⁵

When a patent holder authorizes its licensees to sell the licensed products on credit and pay later, the fact that some licensees may “subsequently renege or fall behind on their royalty payments does not convert a once authorized sale into a non-authorized sale.”¹⁵⁶

In *Bowman v. Monsanto Co.*,¹⁵⁷ the Supreme Court held that patent exhaustion does not permit a farmer to reproduce patented seeds he purchased from a grain elevator that included the patented seeds, which were typically sold directly to farmers under a license precluding seed reproduction. Roundup Ready seed contained Monsanto’s invention of a “genetic modification that enables soybean plants to survive exposure” to a herbicide used to kill weeds.¹⁵⁸ Monsanto sold the seed under a special licensing agreement that prohibited farmers from saving and replanting harvested soybeans or selling them for that purpose.¹⁵⁹ Instead of purchasing seeds from Monsanto, Bowman purchased soybeans from a grain elevator and planted them, anticipating that many of the soybeans contained Monsanto’s patented technology.¹⁶⁰ Bowman was correct, and each year he saved the seed from that crop to replant the next season.¹⁶¹

Monsanto sued Bowman for infringement and Bowman raised the defense of patent exhaustion.¹⁶² The doctrine of patent exhaustion limits a patentee’s control over what others can do with the patented article following its authorized sale.¹⁶³ Following that initial sale, a patentee’s patent rights in that item terminate.¹⁶⁴

The district court rejected Bowman’s defense and the Federal Circuit affirmed, reasoning that Bowman created a “newly infringing article” and that the right to use a patented article obtained from an authorized sale “‘does not include the right to construct an essentially new article on the template of the original, for the right to make the article remains with the patentee.’”¹⁶⁵ The Supreme Court affirmed, finding that “the exhaustion doctrine does not enable Bowman to make *additional* patented soybeans without Monsanto’s permission (either express or implied). And that is precisely what Bowman did.”¹⁶⁶

Specifically, Bowman, “[a]fter buying beans for a single harvest, . . . saved enough seed each year to reduce or eliminate the need for additional purchases. Monsanto still held its patent, but received no gain from Bowman’s annual production and sale of Roundup Ready soybeans.”¹⁶⁷ The Court noted that the “exhaustion doctrine is limited to the ‘particular item’ sold to avoid just such a

¹⁵⁵*Id.* at 1046. In contrast, in copyright cases the first sale doctrine “only applies to copies legally made . . . in the United States.” *Omega S.A. v. Costco Wholesale Corp.*, 541 F.3d 982, 990, 88 USPQ2d 1102 (9th Cir. 2008) (citing *BMG Music v. Perez*, 952 F.2d 318, 319, 21 USPQ2d 1315 (9th Cir. 1991)).

¹⁵⁶*Tessera, Inc. v. International Trade Comm’n*, 646 F.3d 1357, 1370, 98 USPQ2d 1868 (Fed. Cir. 2011).

¹⁵⁷133 S. Ct. 1761, 185 L. Ed. 2d 931, 106 USPQ2d 1593 (2013).

¹⁵⁸*Id.* at 1764, 185 L. Ed. 2d at 935.

¹⁵⁹*Id.*

¹⁶⁰*Id.* at 1765, 185 L. Ed. 2d at 935–36.

¹⁶¹*Id.*, 185 L. Ed. 2d at 936.

¹⁶²*Id.*

¹⁶³*Id.* at 1766, 185 L. Ed. 2d at 936.

¹⁶⁴*Id.*

¹⁶⁵*Id.* at 1765, 185 L. Ed. 2d at 936 (quoting *Monsanto Co. v. Bowman*, 657 F.3d 1341, 1348, 100 USPQ2d 1224 (Fed. Cir. 2011)).

¹⁶⁶*Id.* at 1766, 185 L. Ed. 2d at 937 (emphasis in original).

¹⁶⁷*Id.* at 1767, 185 L. Ed. 2d at 938.

mismatch between invention and reward.”¹⁶⁸ Hence, exhaustion does not apply to reproductions because “if simple copying were a protected use, a patent would plummet in value after the first sale of the first item containing the invention.”¹⁶⁹ The Court found that “Bowman planted Monsanto’s patented soybeans solely to make and market replicas of them, thus depriving the company of the reward patent law provides for the sale of each article” and held that “patent exhaustion provides no haven for [Bowman’s] conduct.”¹⁷⁰ The Court noted, however, that its holding is limited and may not apply to every case of a self-replicating product.¹⁷¹

Monsanto’s suits of infringement also resulted in declaratory judgment actions brought against Monsanto. In *Organic Seed Growers & Trade Ass’n v. Monsanto Co.*,¹⁷² the Federal Circuit affirmed a district court dismissal of a declaratory judgment action brought by farmers, seed sellers, and related agricultural organizations seeking a ruling that they did not infringe by growing Monsanto Roundup Ready seed that was blown into their fields, and that 23 Monsanto patents on that seed were invalid.¹⁷³ In holding that appellants lacked standing, the Federal Circuit found that “[t]aken together, Monsanto’s representations unequivocally disclaim any intent to sue appellant growers, seed sellers, or organizations for inadvertently using or selling ‘trace amounts’ of genetically modified seeds,” which statements have an effect similar to that of a covenant not to sue.¹⁷⁴ Furthermore, the court found that no appellant had made allegations placing it outside the scope of Monsanto’s disclaimer representations.¹⁷⁵ Thus, no Article III controversy existed because “[w]hen it is ‘uncertain when, if ever, the declaratory plaintiff would engage in potentially infringing activity, the dispute [does] not present a case or controversy of sufficient immediacy to support a declaratory judgment.’”¹⁷⁶

VIII. OWNERSHIP AND LICENSES

[Add the following after the fourteenth paragraph of the section (after footnote 803).]

The Supreme Court has held that the Bayh-Dole Act does not automatically vest title to federally funded inventions in federal contractors or authorize contractors to unilaterally take title to such inventions.¹⁷⁷

¹⁶⁸*Id.*

¹⁶⁹*Id.* at 1768, 185 L. Ed. 2d at 939.

¹⁷⁰*Id.* at 1769, 185 L. Ed. 2d at 940.

¹⁷¹*Id.*

¹⁷²718 F.3d 1350, 2013 WL 2460949, 107 USPQ2d 1067 (Fed. Cir. 2013).

¹⁷³*Id.*, 2013 WL 2460949, at *1. *See also* Section VI.C in the Main Volume.

¹⁷⁴*Organic Seed Growers*, 2013 WL 2460949, at *6.

¹⁷⁵*Id.* at *6–7.

¹⁷⁶*Id.* at *7 (quoting *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 881, 87 USPQ2d 1065 (Fed. Cir. 2008)).

¹⁷⁷*Board of Trs. of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, 131 S. Ct. 2188, 2197, 180 L. Ed. 2d 1, 98 USPQ2d 1761 (2011).

[Add the following at the end of the section.]

In *Medtronic, Inc. v. Mirowski Family Ventures, LLC*,¹⁷⁸ the Supreme Court held that a patent licensor bears the burden of proof to show that products newly introduced by its licensee are covered by the claims of the licensed patent in a declaratory judgment action. In reaching this holding, the Court considered three legal propositions which, taken together, indicate that, “in a licensee’s declaratory judgment action, the burden of proving infringement should remain with the patentee.”¹⁷⁹ First, the Court pointed to the well-established law that the patentee bears the burden of proving infringement.¹⁸⁰ Second, the Court noted that it has “long considered ‘the operation of the Declaratory Judgment Act’ to be only ‘procedural.’”¹⁸¹ And third, the Court pointed to its holding “that ‘the burden of proof’ is a ‘substantive aspect of a claim.’”¹⁸²

X. OBVIOUSNESS-TYPE DOUBLE PATENTING

[Add the following at the end of the section.]

In *Sun Pharmaceutical Industries, Ltd. v. Eli Lilly & Co.*,¹⁸³ the Federal Circuit affirmed a district court finding that claims in a patent were invalid for obviousness-type double patenting. The patents-in-suit involved the compound gemcitabine, used to treat various forms of cancer. The earlier patent claimed “gemcitabine, as well as a method of using gemcitabine for treating viral infections” and the specification explained gemcitabine’s anticancer utility.¹⁸⁴ The later patent claimed “a method of using gemcitabine for treating cancer.”¹⁸⁵ The court found that the later patent claims for the method of treating cancer were not patentably distinct from the specification of the earlier patent.¹⁸⁶ In its analysis, the Federal Circuit looked to *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*,¹⁸⁷ and *Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*,¹⁸⁸ and found that these cases apply in the “situation in which an earlier patent claims a compound, disclosing the utility of that compound in the specification, and a later patent claims a method of using that compound for a particular use described in the specification of the earlier patent.”¹⁸⁹

¹⁷⁸134 S. Ct. 843, 187 L. Ed. 2d 703, 109 USPQ2d 1341 (2014).

¹⁷⁹*Id.* at 849, 187 L. Ed. 2d at 711.

¹⁸⁰*Id.*

¹⁸¹*Id.* (citation omitted).

¹⁸²*Id.* (citations omitted).

¹⁸³611 F.3d 1381, 95 USPQ2d 1797 (Fed. Cir. 2010).

¹⁸⁴*Id.* at 1383.

¹⁸⁵*Id.*

¹⁸⁶*Id.* at 1389.

¹⁸⁷349 F.3d 1373, 68 USPQ2d 1865 (Fed. Cir. 2003).

¹⁸⁸518 F.3d 1353, 86 USPQ2d 1001 (Fed. Cir. 2008).

¹⁸⁹*Sun Pharm.*, 611 F.3d at 1389.

[Add the following new sections.]

XVA. REEXAMINATION PROCEEDINGS [NEW TOPIC]

The recently enacted America Invents Act could curtail the availability of invalidity defenses to a party that participates in the inter partes and post-grant review proceedings established under the Act. These new proceedings also create an opportunity for asserting the defense of intervening rights. The bases for each of these provisions and their impact on patent defenses are discussed below.

A. Inter Partes Review [New Topic]

In passing the America Invents Act, Congress amended Chapter 31 of Title 35 of the U.S. Code to replace inter partes reexamination with inter partes review.¹⁹⁰ Effective September 16, 2012, only requests for inter partes review will be accepted. The director must determine whether the petition or response “shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.”¹⁹¹ The Director shall determine whether to institute review within three months after (1) receiving a preliminary response to a petition, or (2) if a preliminary response is not filed, the last date on which a response may be filed.¹⁹² The determination by the Director is not appealable.¹⁹³ If a civil action challenging the validity of a claim of a patent is filed on or after the date of a petition for inter partes review, that civil action is automatically stayed.¹⁹⁴

A final determination in an inter partes review must be “issued not later than 1 year after the date on which the Director notices the institution of a review.”¹⁹⁵ If any proposed amended or new claims are determined to be patentable and are incorporated into a patent after an inter partes review, they “shall 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 . . . , anything patented by such proposed amended or new claim, or who made substantial preparation therefor, before the issuance of a certificate” cancelling any claim finally determined to be unpatentable or confirming the patentability of any claim and incorporating any patentable new or amended claim.¹⁹⁶ The petitioner receiving a final written decision may not assert in a civil action of the International Trade Commission arising in whole or part under 28 U.S.C. §1338 or §1337 “that the claim is invalid on any ground that the petitioner raised or reasonably could have raised during the inter partes review.”¹⁹⁷ This final written decision is appealable under 35 U.S.C. §§141 through 144 by any party to the inter partes review dissatisfied by the decision.¹⁹⁸ The burden of proof for inter

¹⁹⁰Leahy-Smith America Invents Act of 2011, Pub. L. No. 112-29, §6, 125 Stat. 284, 299 (Sept. 16, 2011).

¹⁹¹*Id.* at 300.

¹⁹²*Id.*

¹⁹³*Id.*

¹⁹⁴*Id.* at 301.

¹⁹⁵*Id.* at 302.

¹⁹⁶*Id.* at 304.

¹⁹⁷*Id.* at 301.

¹⁹⁸*Id.* at 304.

partes review has been changed from “a substantial new question of patentability” to “a reasonable likelihood that the requester will prevail with respect to at least 1 of the claims challenged by the requester.”¹⁹⁹ This burden became effective September 16, 2011, and applies to inter partes reexaminations filed prior to September 16, 2012.

B. Post-Grant Review [New Topic]

The America Invents Act also makes post-grant review available, effective September 16, 2012, by amending Part III of Title 35 of the U.S. Code.²⁰⁰ The Director must determine whether the petition demonstrates “that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable.”²⁰¹ Additionally, the determination “may also be satisfied by a showing that the petition raises a novel or unsettled legal question that is important to other patents or patent applications.”²⁰² As in inter partes review, the Director shall determine whether to institute post-grant review within three months after (1) receiving a preliminary response to a petition, or (2) if a preliminary response is not filed, the last date on which a response may be filed. The determination is final and nonappealable. If a civil action challenging the validity of a claim of a patent is filed on or after the date of a petition for post-grant review, that civil action is automatically stayed.²⁰³

A final determination in a post-grant review must be “issued not later than 1 year after the date on which the Director notices the institution of a proceeding.”²⁰⁴ The same intervening rights as in inter partes review apply to post-grant review proceedings.²⁰⁵ The petitioner receiving a final written decision may not assert in a civil action of the International Trade Commission arising in whole or part under 28 U.S.C. §1338 or §337 “that the claim is invalid on any ground that the petitioner raised or reasonably could have raised during the post-grant review.”²⁰⁶ This final written decision is appealable under 35 U.S.C. §§141 through 144 by any party to the post-grant review dissatisfied with the decision.²⁰⁷

XVB. DERIVATION PROCEEDINGS [NEW TOPIC]

The America Invents Act also amended 35 U.S.C. §291.²⁰⁸ Under Section 291, the owner of a patent may have a civil action against the owner of another patent claiming the same invention and having an earlier effective filing date if the invention was “derived from the inventor of the invention claimed in the patent owned by the person seeking relief under this section.”²⁰⁹ This action may

¹⁹⁹*Id.*

²⁰⁰Leahy-Smith America Invents Act, Pub. L. No. 112-29, §6, 125 Stat. 284, 305 (Sept. 16, 2011).

²⁰¹*Id.* at 306.

²⁰²*Id.* at 307.

²⁰³*Id.*

²⁰⁴*Id.* at 308.

²⁰⁵*Id.* at 310.

²⁰⁶*Id.* at 308.

²⁰⁷*Id.* at 311.

²⁰⁸Leahy-Smith America Invents Act, Pub. L. No. 112-29, §3, 125 Stat. 284, 288 (Sept. 16, 2011).

²⁰⁹*Id.*

be filed before the expiration of the one-year period “beginning on the date of issuance of the first patent containing a claim to the allegedly derived invention and naming an individual alleged to have derived such invention as the inventor or joint inventor.”²¹⁰

The derivation proceeding under 35 U.S.C. §135 was also amended by the America Invents Act.²¹¹ When an applicant for a patent institutes a derivation proceeding, “the Patent Trial and Appeal Board shall determine whether an inventor named in the earlier application derived the claimed invention from an inventor named in the petitioner’s application and, without authorization, the earlier application claiming such invention was filed.”²¹² In appropriate circumstances, the Board may correct the naming of the inventor in the application or patent at issue.²¹³ The Board may defer acting on a petition for a derivation proceeding until after the three-month period “beginning on the date on which the Director issues a patent that includes the claimed invention that is the subject of the petition.”²¹⁴ The Board’s final decision, if adverse to claims in a patent application, “shall constitute the final refusal by the Office on those claims.”²¹⁵ If the final decision is adverse to the claims in a patent, and if no appeal or other review is or can be taken, the decision shall constitute cancellation of those claims.²¹⁶ Notice of the cancellation shall be endorsed on copies of the patent distributed after the cancellation of those claims.²¹⁷

²¹⁰*Id.* at 289.

²¹¹*Id.*

²¹²*Id.*

²¹³*Id.*

²¹⁴*Id.*

²¹⁵*Id.*

²¹⁶*Id.*

²¹⁷*Id.* at 290.