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2007 Patent Law Decisions of the Federal Circuit

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2007 Patent Law Decisions of the Federal Circuit

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AREA SUMMARIES

2007 PATENT LAW DECISIONS OF THE FEDERAL CIRCUIT*

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I. Introduction

In the pages that follow, we initially review and summarize the evolving landscape of U.S. patent law as interpreted, expounded upon, and altered by each of the three branches of the U.S. government. We then follow with summaries of the patent decisions of the United States Court of Appeals for the Federal Circuit ("Federal Circuit") for the calendar year 2007. We conclude with an appendix presenting statistical data regarding the 2007 decisions of the Federal Circuit and its judges.

One important note is that the Federal Rules of Appellate Procedure, and similarly the Federal Circuit's rules, have been changed so as to remove the prohibition on a party's citation of nonprecedential opinions issued after January 1, 2007. An opinion may be designated nonprecedential because it does "not add[] significantly to the body of law." The Federal Circuit "may look to a nonprecedential disposition for guidance or persuasive reasoning, but will not give one of its own nonprecedential dispositions the effect of binding precedent." Because of the non-binding nature of these cases, our case summaries address only the Federal Circuit's 2007 precedential decisions. Our statistical data in the appendix, however, include details on both precedential and nonprecedential decisions.

A. Twenty-Five Years of the Federal Circuit

This year marks the twenty-fifth anniversary of the establishment of the Federal Circuit. One of the primary goals in creating the court was to foster uniformity in the application of the patent laws in order

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^{1.} See FED. R. APP. P. 32.1(a) ("A court may not prohibit or restrict the citation of federal judicial opinions, orders, judgments, or other written dispositions that have been: (i) designated as 'unpublished,' 'not for publication,' 'non-precedential,' 'not precedent,' or the like; and (ii) issued on or after January 1, 2007.").

^{2.} See FED. CIR. R. 32.1(c) ("Parties are not prohibited or restricted from citing nonprecedential dispositions issued after January 1, 2007. This rule does not preclude assertion of claim preclusion, issue preclusion, judicial estoppel, law of the case, and the like based on a nonprecedential disposition issued before that date.").

^{3.} *Id.* 32.1(b). 4. *Id.* 32.1(d).

to promote innovation and further technology.⁵ "National uniformity in the application of the patent laws was perceived as a way of reducing uncertainty regarding the validity of patents[,]" thereby increasing their value and the incentives to invent and disclose, ultimately enhancing technological innovation in the United States.⁶ Such innovation would "benefit[] consumers through the development of new and improved goods, services, and processes." "An economy's capacity for invention and innovation helps drive its economic growth and the degree to which standards of living increase."8 "Competition and patents stand out among the federal policies that influence innovation."

The idea of granting exclusive rights to inventors in order to stimulate innovation was well-established when the Constitution was drafted in 1789. Indeed, among the explicit powers granted to Congress by the Constitution is the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." 10 "The Patent Clause itself reflects a balance between the need to encourage innovation and [to avoid] monopolies which stifle competition without any concomitant advance in the 'Progress of Science and useful Arts. The same balance has been embodied in the federal patent laws since their inception, for they reward innovation while recognizing that imitation and refinement of those innovations are also necessary both to "invention itself and to the very lifeblood of a competitive economy."¹²

The establishment of a national court for all patent appeals is an idea that also dates back over 100 years, 13 but it was finally achieved

^{5.} See S. REP. No. 97-275, at 5 (1981) (noting that the uniformity in patent law resulting from the creation of the Federal Circuit will prevent the forum-shopping that is so prevalent in patent litigation and, in turn, decrease the "number of appeals resulting from attempts to obtain different rulings on disputed legal points").

^{6.} Herbert Schwartz, Patent Law and Practice 5 (5th ed. 2006).

^{7.} FEDERAL TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 1 (2003).

^{8.} Id. (citing Roger W. Ferguson, Jr., Vice Chairman, Fed. Reserve Bd., Patent Policy in a Broader Context, Remarks at the 2003 Financial Markets Conference of the Federal Reserve Bank of Atlanta (Apr. 5, 2003)).

^{9.} *Id*.

^{10.} U.S. CONST. art. I, § 8.

^{11.} Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 147, 9 U.S.P.Q.2d (BNA) 1847, 1850 (1989).

^{12.} Id., 9 U.S.P.Q.2d (BNA) at 1850.

^{13.} MARGARET M. CONWAY, STUDY OF THE SUBCOMMITTEE ON PATENTS, TRADEMARKS. AND COPYRIGHTS OF THE S. COMM. ON THE JUDICIARY, 85TH CONG., SINGLE COURT OF PATENT APPEALS—A LEGISLATIVE HISTORY 1 (Comm. Print 1959) (explaining that in the nineteenth century, the Supreme Court had exclusive jurisdiction over patent

on April 2, 1982, when President Ronald Reagan signed into law the Federal Courts Improvements Act of 1982.¹⁴ The intent of the Federal Courts Improvements Act was to revitalize the American economy and ensure continued economic growth and development by correcting perceived defects in the federal appellate court structure.¹⁵ Contrary to the perceptions of some, the Federal Circuit is not fairly characterized as a "specialized" court. The jurisdiction of the Federal Circuit includes appeals from final decisions of the federal district courts on patent matters, as well as final decisions of the United States Court of Federal Claims, the United States Court of International Trade, the United States International Trade Commission, and the United States Court of Appeals for Veteran Claims.¹⁶

Unlike other appellate courts, the Federal Circuit's jurisdiction is based on subject matter and not on geography. Prior to the creation of the Federal Circuit, the regional courts of appeals were individually charged with the task of hearing patent appeals from their respective district courts.¹⁷ However, because the decision of one appellate court is not binding on another appellate court, layers of ambiguity and inconsistency overshadowed the patent laws, inconsistencies that could only be resolved by the United States Supreme Court. 18 Yet only rarely did the Supreme Court interject itself into patent issues. 19 The Federal Circuit was thus created to provide a level of certainty, predictability, and stability to the patent system, to restore the integrity of the patent system, and to provide the basis for

appeals, but after 1891, when the U.S. circuit courts of appeals obtained jurisdiction over patent issues, the "section of patent, trademark and copyright law of the American Bar Association consistently supported the establishment of a special court of patent appeals with jurisdiction throughout the United States").

14. Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25

^{(1982) (}codified as amended in scattered sections of 28 U.S.C.).

^{15.} See Frank P. Cihlar, The Court American Business Wanted and Got: The United States Court of Appeals for the Federal Circuit 11 (1982) (describing how important the integrity of the patent system is to technological growth and industrial innovation).

^{16.} See 28 U.S.C. § 1295 (2000) (setting forth the jurisdiction of the United States Court of Appeals for the Federal Circuit).

^{17.} See Charles W. Adams, The Court of Appeals for the Federal Circuit: More than a National Patent Court, 49 Mo. L. REV. 43, 61 (1984) (noting that many federal appeals judges do not regret losing jurisdiction over patent cases).

^{18.} See id. at 50 (stating that intercircuit conflicts in patent law made the enforcement of patents unpredictable and thus public confidence in the patent system waned).

^{19.} See John F. Duffy, The Festo Decision and the Return of the Supreme Court to the Bar of Patents, 2002 SUP. CT. REV. 273, 275-76 (2002) (observing that by the middle of the twentieth century, the Supreme Court's patent docket declined drastically, hearing on average only one patent case per year, which was significantly less than during the nineteenth and early twentieth centuries).

reasoned business judgments about the risks and rewards associated with the development of a patented invention.²⁰

The creation of the Federal Circuit has had an enormous impact on the development of the patent laws of the United States. The Federal Circuit, in attempting to create a uniform understanding of patent law, has focused and refined the law on every important issue of patent law, not the least of which has been the implementation of holdings by the Supreme Court in such landmark patent cases as Markman v. Westview Instruments, Inc., 21 Warner-Jenkinson Co. v. Hilton Davis Chemical Co.,²² Pfaff v. Wells Electronics, Inc.,²³ Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.,24 Holmes Group, Inc. v. Vornado Air Circulation Systems, Inc., 25 and Merck KGaA v. Integra Lifesciences I, Ltd., 26 to name a few. The Federal Circuit continues to reexamine many areas of patent law, including claim construction, written description, jurisdiction, remedies, declaratory judgments, and the doctrine of equivalents.

While the importance of the Federal Circuit is indisputable, its effectiveness in achieving Congress's primary goal of increasing uniformity of patent law has been the subject of debate.²⁷ Many people believe that Federal Circuit jurisprudence has increased patent law certainty and consistency compared to what existed before its creation.²⁸ Others, however, have "questioned the extent to which the Federal Circuit has succeeded in achieving this goal,"29 while still others believe the Federal Circuit has "conformed [certain areas of] patent law, but in unhelpful ways."30

No matter what one thinks of the Federal Circuit's success in achieving its seminal purpose, one thing is clear—the Federal Cir-

^{20.} See CIHLAR, supra note 15, at 11 (discussing how detrimental uncertainty and forum shopping are to patent law, where stability and predictability provide the basis for reasoned business judgments).

^{21. 517} U.S. 370, 38 U.S.P.Q.2d (BNA) 1461 (1996). 22. 520 U.S. 17, 41 U.S.P.Q.2d (BNA) 1865 (1997).

^{23. 525} U.S. 55, 48 U.S.P.Q.2d (BNA) 1641 (1998). 24. 535 U.S. 722, 62 U.S.P.Q.2d (BNA) 1705 (2002).

^{25. 535} U.S. 826, 62 U.S.P.Q.2d (BNA) 1801 (2002). 26. 545 U.S. 193, 74 U.S.P.Q.2d (BNA) 1801 (2005).

^{27.} See FEDERAL TRADE COMM'N, supra note 7, at 15 (describing how some panelists view the Federal Circuit's jurisprudence as bringing "certainty and consistency" to patent law, while others continue to question whether the Federal Circuit has been successful).

^{28.} Id.; see also id. at 15 n.89 (noting that the President of the Industrial Research Institutes, Ross Armbrecht, felt that the IRI members thought that the Federal Circuit brought more stability and predictability to the patent process).

^{29.} FEDERAL TRADE COMM'N, supra note 7, at 15; see also id. at 15 n.90 (listing several commentators who express doubt as to the Federal Circuit's success).

^{30.} FEDERAL TRADE COMM'N, supra note 7, at 15.

cuit's twenty-fifth anniversary was marked by one of the most active years in the history of U.S. patent law. All three branches of the U.S. government were actively involved in 2007 in shaping and revising or attempting to revise several areas of patent law. For example, the Executive Branch, through the U.S. Patent and Trademark Office ("PTO"), attempted to promulgate new rules of practice before the office (but is presently enjoined from enacting the rules), which would dramatically affect patent prosecution and continuation practices. The U.S. House of Representatives passed significant patent reform legislation, which, at the time of this writing, is still awaiting action by the U.S. Senate. The U.S. Supreme Court has stepped up its involvement in patent law by reviewing, and often dramatically altering, the Federal Circuit's interpretation of existing patent laws. The following sections provide a brief overview of the actions taken by each of the branches of government in the sphere of patent law.

B. The Executive Branch: The Rules Promulgated by the U.S. Patent and Trademark Office

On August 21, 2007, the PTO published new rules regarding continuation filings and examination of claims ("new rules"). The new rules limit the number of continuation applications that can be filed from a patent application without justification, as well as the number of claims an applicant can include in a patent application without including an examination support document. The new rules also require applicants to disclose related patents and patent applications, as well as to distinguish between claims in related patents and/or applications. The new rules apply to: (1) any new applications filed after November 1, 2007, and (2) any applications that were pending

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^{31.} See infra Part I.B (discussing in detail the new rules and the current injunction on enforcing those rules).

^{32.} See infra Part I.C (comparing and contrasting in detail the proposed legislation from both the House and the Senate).

^{33.} See infra Part I.D (surveying some of the Supreme Court's most important patent decisions of the year).

^{34.} Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46,716 (Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1) [hereinafter Changes to Practice].

^{35.} See id. (outlining the new revisions to the rules of practice for continued examination practices and for the examination of claims in patent applications).

^{36.} See id. at 46,721–22 (providing that applicants must identify other pending applications that have been filed within the previous two months, as well as rebut the presumption that the multiple filings are indistinct by explaining how the various applications have distinct claims).

as of November 1, 2007, but had not received a first office action on the merits as of that date.³⁷

The new rules contain several marked changes from the status quo. While the current rules permit applicants to file an unlimited number of continuation applications, the new rules limit applicants to only two continuation applications, including continuation-in-part ("CIP") applications, from a single patent application, and only one request for continued examination ("RCE") without justification. These rules would apply to any application filed after November 1, 2007, including those claiming priority to an earlier filed non-provisional application. In order to file more than two continuations or more than one RCE, an applicant has to explain why the request, amendment, argument, or evidence could not have been previously submitted.

The new rules also limit an applicant's right to file continuation applications from pending applications with an existing priority claim under 35 U.S.C. §§ 120, 121, or 365(c) that were filed before August 21, 2007. In such a case, the applicant can file only "one more" continuation application without justification and without regard to the number of continuations previously filed in that application family. Specifically, the rules limit an applicant who filed more than two continuation or CIP applications of an initial application before August 21, 2007, to the filing of only "one more" continuing application on or after November 1, 2007, without a petition and showing, provided no other application was filed on or after August 21, 2007, that claims the benefit of the prior-filed application.

The new rules require an applicant to identify support for all claims in the parent of a CIP application.⁴⁴ Any claims for which such support is not identified would be entitled only to the filing date of the CIP and would be subject to prior art based on the actual later filing date.⁴⁵ Moreover, because a CIP application is included in the definition of "continuation application," only two CIP applications

^{37.} Id. at 46,716–17.

^{38.} Id. at 46,716.

^{39.} *Id.* at 46,716–17.

^{40.} Id. at 46,716.

^{41.} *Id.* at 46,717.

^{42.} *Id.* at 46,717, 46,733.

^{43.} *Id.* at 46,717.

^{44.} *Id.* at 46,723.

^{45.} Id.

can be filed in an application family. ⁴⁶ In an October 10, 2007, clarification, the PTO waived this identification requirement for applications in which an office action on the merits was received before November 1, 2007. ⁴⁷ In applications in which a first office action on the merits was not mailed by November 1, 2007, the PTO delayed the requirement for identification until February 1, 2008. ⁴⁸

The rules also restrict the number of claims that can be filed in a single patent application in the absence of additional information. For example, applications that included more than twenty-five claims or more than five independent claims (the so-called "5/25 rule") would have to include an examination support document and prior art search report with an explanation as to how each claim differs from the prior art.

For applications filed on or after November 1, 2007, applicants also have to identify by application number and patent number (if applicable) each other pending application or patent, in which: (1) the application has a filing date or priority claim that is the same as the filing date of the other pending or patented application; (2) "the application names at least one inventor in common with the other pending or patented application; and (3) the application is owned by the same person, or subject to an obligation of assignment to the same person, as the other pending or patented application." Applicants would have to identify the other applications or patents by the later of four months from the filing date of the non-provisional application (or national phase application) or February 1, 2008. 52

Under the new rules, the PTO takes the position that there is a rebuttable presumption that a non-provisional application contains at least one claim that is not patentably distinct from at least one of the

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^{46.} See id. at 46,716 (grouping together "continuation application" and "continuation-in-part application" in all references, thus treating them as equivalents for the purposes of the new rules).

^{47.} See John Love, Deputy Comm'r for Patent Examination Policy, U.S. Patent and Trademark Office, Clarification of the Transitional Provisions Relating to Continuing Applications and Applications Containing Patentably Indistinct Claims 2 (Oct. 10, 2007), http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/cl mcontclarification.pdf ("[F]or any continuation-in-part application in which a first Coffice action on the merits has been mailed before November 1, 2007, the requirement . . . that an applicant must identify the claim . . . in the continuation-in-part application for which the subject matter is disclosed . . . in the prior-filed application is hereby waived.").

^{48.} Id. at 3.

^{49.} Changes to Practice, *supra* note 34, at 46,721.

^{50.} See Love, supra note 47, at 3 (waiving the "or within two months of" requirement, previously required by this part of the new rules, in certain instances for applications filed on or after November 1, 2007).

^{51.} Changes to Practice, *supra* note 34, at 46,734.

^{52.} *Id.* at 46,717.

claims in another patent application if: (1) the application has a filing date and/or priority date that is the same as the filing date of the other application; (2) the two applications have at least one common inventor; (3) the two applications are owned by the same entity or subject to an obligation of assignment to the same entity; and (4) the applications contain substantially overlapping subject matter.⁵³

The applicant could rebut this presumption by explaining how all the claims are patentably distinct or by submitting a terminal disclaimer. Where patentably indistinct claims are identified, the applicant would have to submit good and sufficient reasons for having multiple applications. The PTO could require elimination of the indistinct claims from one of the applications without such a showing. The properties of the applications without such a showing.

It is noteworthy that the final rules provide that if multiple applications, including applications having a continuity relationship, contain patentably indistinct claims, the PTO would treat the multiple applications as a single application for purposes of determining whether each of the multiple applications exceeds the threshold of five independent claims or twenty-five total claims (the "5/25" limitation). ⁵⁷

The final rules also allow an applicant to file a divisional application if the application was subject to a restriction requirement.⁵⁸ Multiple divisional applications can be prosecuted in series or in parallel.⁵⁹ An applicant can file two continuation applications (but not a CIP) for each divisional application plus one RCE without justification.⁶⁰

Alternatively, an applicant can "suggest" a restriction requirement and elect a group of claims that meets the 5/25 claim requirement. ⁶¹ If accepted by the examiner, this would permit the applicant to pursue the remaining nonelected claims in one or more divisional applications. ⁶² If the examiner refused the suggestion, the applicant would be given two months in which to reduce the number of claims or to file an examination support document. ⁶³

^{53.} Id. at 46,735.

^{54.} *Id*.

^{55.} *Id*.

^{56.} *Id*.

^{57.} *Id*.

^{58.} *Id.* at 46,745.

^{59.} *Id.* at 46,718.

^{60.} *Id*.

^{61.} Id. at 46,726.

^{62.} *Id.* at 46,726–27.

^{63.} Id.

On October 31, 2007, the United States District Court for the Eastern District of Virginia granted a preliminary injunction in favor of plaintiffs Triantafyllos Tafas and SmithKline Beecham Corporation, enjoining the PTO from implementing the changes to the patent rules on November 1, 2007. In a detailed opinion, the district court found in favor of the plaintiffs on all four prongs of the legal test for granting a preliminary injunction. Eastern District Court for October 31, 2007.

First, the court found that the plaintiffs had demonstrated a likelihood of success on the merits on its allegations that the rules exceed the Patent Office's statutory authority. The court concluded that the rules are contrary to the Patent Act, the PTO's application of the rules to pending applications implicates the prohibition on retroactive application of agency regulations, and the standards for submitting an examination support document are impermissibly vague.⁶⁶ Second, the district court found that plaintiffs would be irreparably harmed by implementation of the new rules due to the uncertainty that the regulations would create and the negative impact on investment to file future patent applications.⁶⁷ The district court found the third prong, "balance of the hardships," to be in favor of the plaintiffs, stating that "the uncertainty and loss of investment suffered immediately by [the plaintiffs] tilts the balance of hardships in their favor."68 Finally, the court found "the public interest [was] most served by continuing the status quo and granting the TRO."69

On April 1, 2008, the U.S. District Court for the Eastern District of Virginia issued an order permanently enjoining the U.S. Patent and Trademark Office from implementation and enforcement of the new rules related to claims and continuation practice in patent applications. The ruling held that the PTO exceeded its rule-making authority in attempting to implement what the district court deemed to be substantive rules. The rules are the properties of the Eastern District of Virginia issued an order permanently enjoining the U.S. Patent and Trademark Office from implementation and enforcement of the new rules related to claims and continuation practice in patent applications.

^{64.} Tafas v. Dudas, 511 F. Supp. 2d 652, 671 (E.D. Va. 2007).

^{65.} Id. at 670.

^{66.} Id. at 663-68.

^{67.} Id. at 668-69.

^{68.} Id. at 670.

^{69.} Id.

^{70.} Tafas v. Dudas, No. 1:07CV846, 2008 WL 859467, at *10 (E.D. Va. Apr. 1, 2008).

^{71.} *Id*.

The Legislative Branch: The Patent Reform Act of 2007

The Patent Reform Act of 2007 is currently being considered for passage by the United States Congress.⁷² As amended, H.R. 1908 was passed by the House on September 7, 2007, by a vote of 220 (ayes) to 175 (nays).⁷³ The Senate version, S. 1145, was reported out of the Senate Judiciary Committee on July 19, 2007, and is presently pending in the Senate.74

Regarded as the most significant piece of patent legislation since the 1952 Patent Act, 75 the Patent Reform Act of 2007 would affect many fundamental and long-established patent law provisions, including the loss of right provisions in § 102, 76 the best mode requirement,⁷⁷ inequitable conduct, injunctive relief, damages, and willful infringement.78

Most dramatically, the House-passed bill would change the U.S. patent system from a first-to-invent system to a first-to-file system, contingent upon a finding that major patenting authorities have adopted a grace period having substantially the same effect as that in the bill." The Senate bill contains a similar first-to-file provision, but it is not contingent upon such a finding.⁸⁰

The House bill would also change the apportionment of damages in infringement cases. In particular, H.R. 1908 would allow judges to select the method of calculating a reasonable royalty from: (1) the economic value attributable to the patent's specific contribution over prior art; (2) its entire market value; or (3) if neither (1) nor (2) is appropriate, the terms of any nonexclusive marketplace licensing of the invention and other relevant factors, such as the fifteen factors set forth in Georgia Pacific Corp. v. United States Plywood Corp. 81 The Senate

^{72.} Patent Reform Act of 2007, H.R. 1908, 110th Cong. (2007); S. 1145, 110th Cong. (2007).

THOMAS (The Library of Congress), http://thomas.loc.gov/cgi-bin/bdquer y/z?d110:HR01908:@@@L&summ2=m& (last visited Feb. 14, 2008).

^{74.} THOMAS (The Library of Congress), http://thomas.loc.gov/cgi-bin/bdquer

y/z?d110:SN01145:@@@L&summ2=m& (last visited Feb. 14, 2008).
75. 1952 Patent Act, Pub. L. No. 82-593, 66 Stat. 792 (1952) (codified as amended in scattered sections of 35 U.S.C.).

^{76. 35} U.S.C. § 102 (2000).

^{77.} *Id.* § 112(1)

^{78.} Id. §§ 284, 298.

^{79.} See H.R. 1908, 110th Cong. § 3(a) (2007) ("The effective filing date of a claimed invention is: (1) the filing date of the patent or application for patent containing the claim to the invention")

^{80.} S. 1145, 110th Cong. § 2(a) (2007). 81. H.R. 1908 § 5(a) (3); see Georgia-Pacific Corp. v. U.S. Plywood Corp., 318 F. Supp. 1116, 1120, 166 U.S.P.Q. (BNA) 235, 238 (S.D.N.Y. 1970) (listing fifteen factors to consider when determining the amount of a reasonable royalty for a patent license).

bill would allow the court to select the method of calculating a reasonable royalty from: (1) the "entire market value"; (2) "an established royalty based on marketplace licensing"; or (3) if neither (1) nor (2) is appropriate, "the economic value of the infringing product or process properly attributable to the claimed invention's specific contribution over prior art[,]" with special rules for combination inventions.⁸²

Both H.R. 1908 and S. 1145 would heighten the standard for willful infringement. Both bills would also provide for a post-grant opposition proceeding in the PTO. The House version would establish a first window post-grant review proceeding but no second window.⁸³ For the purpose of such a proceeding, the patent would not be entitled to a presumption of validity, and the burden of proof would be lessened to a preponderance of evidence.84 The Senate version, in contrast, would establish both first and second window post-grant review proceedings, with different presumptions and burdens of proof. 85 To trigger a second window, a petition would have to be filed within twelve months of notice alleging infringement and would have to show that "the continued existence of the challenged claim... causes or is likely to cause the petitioner significant economic harm."86 Under the Senate bill, a patent would be entitled to a presumption of validity in the second window but not in the first window.87 The burden of proof of invalidity in the first window would be by the preponderance of evidence, but a showing of invalidity in the second window would require clear and convincing evidence.8

The House bill would expand *inter partes* reexamination in lieu of second window in post-grant and require that an administrative patent judge hear petitions rather than an examiner. The Senate version would abolish *inter partes* reexamination entirely. Description

The House and Senate versions would both allow pre-issuance prior art submissions for at least six months after publication, a provision which would become effective one year after enactment. The House bill also includes defendant-based venue provisions and carve-out provisions for certain plaintiffs, such as universities, inventors,

^{82.} S. 1145 § 4(a).

^{83.} H.R. 1908 § 6(a) (1).

^{84.} *Id.* § 6(f) (1).

^{85.} S. $1145 \pm 5(c)(1)$.

^{86.} Id.

^{87.} Id.

^{88.} Id.

^{89.} H.R. 1908 § 6(c)(1).

^{90.} S. 1145 § 5(b) (1).

^{91.} H.R. 1908 § 9(b); S. 1145 § 7(b).

and companies engaged in substantial research and development activities. ⁹² Venue for declaratory judgment actions would be the same as for infringement actions.93 In cases involving foreign defendants with a U.S. subsidiary, venue would be based on the location of incorporation or primary subsidiary; for foreign defendants without a U.S. subsidiary, venue would be proper in any district.⁹⁴ The Senate version is similar to the House version on these points but does not address foreign corporations without a U.S. subsidiary. 95 Both the House and Senate versions would require that the Federal Circuit hear an interlocutory appeal on claim construction upon certification by the district court. 96

H.R. 1908 would also codify a materiality standard similar to existing PTO Rule 1.56 of whether "a reasonable examiner would have made a prima facie finding of unpatentability." The Senate version would codify the "important" to a "reasonable examiner" standard for materiality.9

The House bill would also prohibit the use of "best mode" as a basis for invalidity in either litigation or post-grant proceedings. 99 The House bill also provides more flexibility in completing the oath requirements, particularly when it is difficult to reach an inventor. 100 The Senate bill is similar but specifically allows the assignee to apply for the patent.¹⁰¹ Other provisions of the Patent Reform Act would require mandatory search reports submitted by patent applicants and provide the PTO with advanced rule-making authority. 10

D. The Judicial Branch: Supreme Court Patent Cases in 2007

The Supreme Court has also continued to take an unusually active role in patent law, handing down three significant decisions in 2007 alone. These cases are discussed below. The Supreme Court also granted certiorari to review a case on the first-sale doctrine, Quanta Computer, Inc. v. LG Electronics, Inc. 103

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92. H.R. 1908 § 11(a).
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^{93.} *Id*.

^{94.} *Id*.

^{95.} S. 1145 § 8(a).

^{96.} H.R. 1908 § 11(b); S. 1145 § 8(b).

^{97.} H.R. 1908 § 12(b) (4).

^{98.} S. 1145 § 12.

^{99.} H.R. 1908 § 13.

^{100.} *Id.* § $4(a)(\bar{1})$.

^{101.} S. 1145 § 3. 102. *Id.* § 11.

^{103.} LG Elec., Inc. v. Bizcom Elec., Inc., 453 F.3d 1364, 79 U.S.P.Q.2d (BNA) 1443 (Fed. Cir. 2006), cert. granted, 128 S. Ct. 28 (2007).

1. Declaratory judgments—the MedImmune decision

In MedImmune, Inc. v. Genentech, Inc., 104 the U.S. Supreme Court held that a patent licensee in good standing need not terminate or breach its license before filing a declaratory judgment action seeking patent invalidity, unenforceability, or non-infringement. 105 The decision thus allows patent licensees to challenge the patent while putting nothing more at risk than the royalties they would have paid during the pendency of the litigation.

In 1997, MedImmune licensed a patent and then-pending patent application from Genentech. 106 In 2001, after the patent application had matured into a U.S. patent, Genentech notified MedImmune that MedImmune's drug was covered by the newly issued patent and that MedImmune would be responsible for paying royalties on that drug in accordance with the license agreement. 107 MedImmune believed that no royalties were due because the patent was invalid, unenforceable, and not infringed by the subject drug. 108 MedImmune thereafter paid the demanded royalties under protest and with reservation of all its rights but filed an action in the United States District Court for the Central District of California for declaratory judgment that the newly issued patent was invalid or unenforceable.

The district court dismissed MedImmune's declaratory judgment claims for lack of subject matter jurisdiction in accordance with Gen-Probe Inc. v. Vysis, Inc., 110 which held that a patent licensee in good standing cannot establish the requisite "case or controversy" with regard to the validity, enforceability, or scope of a patent because the license agreement "obliterate[s] any reasonable apprehension" that the licensee would be sued for infringement.¹¹¹ The Federal Circuit affirmed the lower court's dismissal of MedImmune's declaratory judgment claims.¹¹²

On certiorari, the Supreme Court reversed the Federal Circuit's ruling.¹¹³ Justice Scalia authored the majority opinion, while Justice Thomas was the lone dissenter. The Court held that Article III of the U.S. Constitution does not require a patent licensee to terminate or

^{104. 127} S. Ct. 764, 81 U.S.P.Q.2d (BNA) 1225 (2007).

^{105.} Id. at 777, 81 U.S.P.Q.2d (BNA) at 1234.

^{106.} Id. at 767–68, 81 U.S.P.Q.2d (BNA) at 1227.

^{107.} *Id.* at 768, 81 U.S.P.Q.2d (BNA) at 1227. 108. *Id.*, 81 U.S.P.Q.2d (BNA) at 1227.

^{109.} Id., 81 U.S.P.Q.2d (BNA) at 1227. 110. 359 F.3d 1376, 70 U.S.P.Q.2d (BNA) 1087 (Fed. Cir. 2004). 111. MedImmune, 127 S. Ct. at 768, 81 U.S.P.Q.2d (BNA) at 1227 (alterations in original) (citing Gen-Probe, 359 F.3d at 1381, 70 U.S.P.Q.2d (BNA) at 1091).

^{112.} Id., 81 U.S.P.Q.2d (BNA) at 1227.

^{113.} Id. at 777, 81 U.S.P.Q.2d (BNA) at 1234.

breach its "license agreement before seeking a declaratory judgment of invalid[ity], unenforceab[ility], or [non]-infringe[ment]. The Court analogized this situation to a suit challenging the basis for a governmental action, wherein the plaintiff need not expose itself to liability before contesting the constitutionality of the law threatened to be enforced. 115 The Court also cited its decision in Altvater v. Freeman, 116 in which it held that Article III's requirements were satisfied where a licensee brought a declaratory judgment action seeking invalidity of two patents arguably covered by a license agreement while continuing to pay royalties under protest. 117 The Federal Circuit's Gen-Probe decision had distinguished Altvater because it concerned a privately obtained injunction. The Supreme Court dismissed this distinction because the coercive actions in Altvater were not governmental but those of a private party.¹¹⁹

The Supreme Court also rejected Genentech's argument that the parties' license agreement had effectively settled their dispute and that permitting MedImmune to contest the validity of the patent without terminating the agreement would alter the parties' bargain. 120 While the license did obligate MedImmune to pay royalties on patents that have not been held invalid, the Court found that such a promise "does not amount to a promise not to seek a holding of their invalidity." Thus, there was no contractual prohibition against challenging the validity of the patents. 122

The *MedImmune* decision, which effectively overrules the Federal Circuit's Gen-Probe decision, has implications for patent licensees and licensors alike. Patent licensees may now simultaneously bring declaratory judgment claims to challenge licensed patents while continuing to pay contractual royalties, thereby risking nothing more than the royalties paid during the pendency of the litigation. Licensors must thus consider whether to press for the inclusion of express prohibitions on future patent challenges and must draft any such potential prohibitions with an eye to MedImmune and other court decisions evaluating such provisions.

^{114.} Id., 81 U.S.P.Q.2d (BNA) at 1234.

^{115.} Id. at 772, 81 U.S.P.Q.2d (BNA) at 1230.

^{116. 319} U.S. 359, 57 U.S.P.Q. (BNA) 285 (1943).

^{117.} MedImmune, 127 S. Ct. at 773, 81 U.S.P.Q.2d (BNA) at 1231.

^{118.} Gen-Probe Inc. v. Vysis, Inc., 359 F.3d 1376, 1381–82, 70 U.S.P.Q.2d (BNA) 1087, 1091 (Fed. Cir. 2004).

MedImmune, 127 S. Ct. at 774, 81 U.S.P.Q.2d (BNA) at 1231–32.
 Id. at 775–76, 81 U.S.P.Q.2d (BNA) at 1233.

^{121.} Id. at 776, 81 U.S.P.Q.2d (BNA) at 1233.

^{122.} Id., 81 U.S.P.Q.2d (BNA) at 1233.

Exportation and infringement—the Microsoft decision

In Microsoft Corp. v. AT&T Corp., 123 the Supreme Court analyzed "the applicability of § 271(f) [of the Patent Act] to computer software first sent from the United States to a foreign manufacturer on a master disk, or by electronic transmission, then copied by the foreign recipient for installation on computers made and sold abroad."¹²⁴ The Court concluded that defendant Microsoft was not liable for infringement because it was not exporting copies of Windows and thus was not supplying "components" from the United States for installation on foreign-made computers, as that term is used in § 271(f). 125

Section 271(f), adopted in 1984, is an exception to the territorial limitations of U.S. patents, which generally cannot be infringed when a patented product is made and sold outside of the United States. 126 In pertinent part, § 271(f)(1) provides that infringement occurs whenever one

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 manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States ¹²⁷

In this case, AT&T sued Microsoft under § 271(f) for selling abroad a software "component" that was being used to make computers that allegedly infringed AT&T's patent on speech-processing devices. 128 Microsoft argued it did not infringe AT&T's patent because intangible information like software is not a "component" under § 271(f). 129 Microsoft also argued that it does not actually sell copies of Windows, or "components," abroad for installation on foreign-made computers. 130 Rather, Microsoft sends a foreign manufacturer a master version of Windows, either on a disk or via an encrypted electronic transmission, from which the manufacturer generates the copies it installs on the computer products it sells abroad. 131 The district court rejected these arguments and found Mi-

^{123.} Microsoft Corp. v. AT&T Corp., 127 S. Ct. 1746, 82 U.S.P.Q.2d (BNA) 1400 (2007).

^{124.} *Id.* at 1750, 82 U.S.P.Q.2d (BNA) at 1404. 125. *Id.* at 1756–57, 82 U.S.P.Q.2d (BNA) at 1404. 126. 35 U.S.C. § 271 (f) (2000).

^{127.} *Id.* § 271(f)(1). 128. *Microsoft*, 127 S. Ct. at 1750–51, 82 U.S.P.Q.2d (BNA) at 1406.

^{129.} Id. at 1753, 82 U.S.P.Q.2d (BNA) at 1406.

^{130.} Id., 82 U.S.P.Q.2d (BNA) at 1406.

^{131.} Id., 82 U.S.P.Q.2d (BNA) at 1406.

crosoft liable under § 271(f).132 A divided Federal Circuit panel affirmed.133

The Supreme Court reversed, finding that an actual "copy of Windows, not Windows in the abstract, qualifies as a 'component' under § 271(f)":134

The provision thus applies only to "such components" as are combined to form the "patented invention" at issue. The patented invention here is AT&T's speech-processing computer.

Until it is expressed as a computer-readable "copy," e.g., on a CD-ROM, Windows software—indeed any software detached from an activating medium—remains uncombinable. It cannot be inserted into a CD-ROM drive or downloaded from the Internet; it cannot be installed or executed on a computer. Abstract software code is an idea without physical embodiment, and as such, it does not match § 271(f)'s categorization: "components" amenable to "combination." Windows abstracted from a tangible copy no doubt is information—a detailed set of instructions—and thus might be compared to a blueprint (or anything containing design information . . .). A blueprint may contain precise instructions for the construction and combination of the components of a patented device, but it is not itself a combinable component of that device. 135

Whether or not encoding software onto a computer-readable medium is easy, the answer remains the same. 136 The copy-producing step is "what renders the software a usable, combinable part of a computer."137 According to the Court, regardless of whether that extra copying step is easy or not, it is essential to liability. ¹³⁸ Section 271(f) also contains no indication that if duplication is easy or cheap enough, the copy made abroad is deemed to have been "supplie[d] ... from the United States." Many tools, in fact, "may be used easily and inexpensively to generate the parts of a device[,]" but inclusion of those parts does not render the tools "components" of the device, "at least not under any ordinary understanding of the term 'component.'"140 Congress, moreover, declined to expand

^{132.} Id., 82 U.S.P.Q.2d (BNA) at 1406.

^{133.} Id., 82 U.S.P.Q.2d (BNA) at 1406.

Id. at 1756, 82 U.S.P.Q.2d (BNA) at 1408.

^{135.} *Id.* at 1755, 82 U.S.P.Q.2d (BNA) at 1407–08 (footnote omitted).

^{136.} See id. at 1756, 82 U.S.P.Q.2d (BNA) at 1408 (declining to accept AT&T's argument that "[b]ecause it is so easy to encode software's instructions onto a medium that can be read by a computer . . . [the copy-producing] step should not play a decisive role under $\S 271(f)$ ").

^{137.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1408. 138. *Id.*, 82 U.S.P.Q.2d (BNA) at 1408.

^{139.} *Id.* at 1757, 82 U.S.P.Q.2d (BNA) at 1409 (alteration in original).

^{140.} Id. at 1756, 82 U.S.P.Q.2d (BNA) at 1408.

§ 271(f)'s scope beyond supplying a patented invention's "components" to also include "information, instructions, or tools from which those components readily may be generated."¹⁴¹

The Supreme Court further held that under a conventional reading of § 271(f), those copies must be supplied from the United States. 142 Thus, Microsoft did not infringe AT&T's patent because it did not "suppl[y]... from the United States" the foreign-made copies of Windows that were installed on the accused computers. ¹⁴³ In so holding, the Supreme Court rejected the majority opinion of the Federal Circuit panel, which had concluded that "in the case of software the act of copying is subsumed in the act of supplying" because the master is identical to the copies, which are generated quickly, cheaply, and easily from the master. 144 Judge Rader had similarly dissented from that majority opinion on the basis that "'supplying' is ordinarily understood to mean an activity separate and distinct from any subsequent 'copying, replicating, reproducing—in effect manufacturing." "[N]othing in § 271(f)'s text, Judge Rader maintained, renders ease of copying a relevant, no less decisive, factor in triggering liability for infringement."146 The Supreme Court agreed, finding that liability is triggered only when the actual "components [are] supplied from the United States, and not foreign-made copies thereof," and "combined abroad to form the patented invention at issue."147 "The absence of anything addressing copying in the statutory text weighs against a judicial determination that replication abroad of a master dispatched from the United States 'supplies' the foreign-made copies from the United States "148

The Court added that "[a]ny doubt that Microsoft's conduct falls outside § 271(f)'s compass would be resolved by the presumption against extraterritoriality." Foreign conduct, explained the Court, "is [generally] the domain of foreign law," which in the context of patent law "may embody different policy judgments about the relative rights of inventors, competitors, and the public in patented inven-

^{141.} Id., 82 U.S.P.Q.2d (BNA) at 1408.

^{142.} Id., 82 U.S.P.Q.2d (BNA) at 1408-09.

^{143.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1408. 144. *Id.*, 82 U.S.P.Q.2d (BNA) at 1408–09. 145. *Id.*, 82 U.S.P.Q.2d (BNA) at 1409 (citing AT&T Corp. v. Microsoft Corp., 414 F.3d 1366, 1372–73, 75 U.S.P.Q.2d (BNA) 1506, 1510 (Fed. Cir. 2005)).

^{146.} *Id.* at 1757, 82 U.S.P.Q.2d (BNA) at 1409 (citing *AT&T*, 414 F.3d at 1374, 75 U.S.P.Q.2d (BNA) at 1511).

^{147.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1409. 148. *Id.*, 82 U.S.P.Q.2d (BNA) at 1409.

^{149.} *Id.* at 1758, 82 U.S.P.Q.2d (BNA) at 1410.

tions."150 In short, the Court stated that "foreign law alone, not United States law, currently governs the manufacture and sale of components of patented inventions in foreign countries." Thus, "the presumption tugs strongly against construction of § 271(f) to encompass as a 'component' not only a physical copy of software, but also software's intangible code, and to render 'supplie[d] ... from the United States' not only exported copies of software, but also duplicates made abroad." The Court admonished that "[i]f AT&T desires to prevent copying in foreign countries, its remedy today lies in obtaining and enforcing foreign patents."153

Although the Court acknowledged AT&T's argument that "reading § 271(f) to cover only those copies of software actually dispatched from the United States creates a 'loophole' for software makers[,]" the Court was "not persuaded that dynamic judicial interpretation of § 271(f) [was] in order." Rather, the Court noted that any "loophole" is properly within the province of Congress to consider and close, if it deems it warranted. Section 271 (f), the Supreme Court noted.

was a direct response to a gap in [U.S.] patent law revealed by [Deepsouth Packing Co. v. Laitram Corp., 156 where] . . . the items exported were kits containing all the physical, readily assemblable parts of a . . . machine (not an intangible set of instructions), and those parts themselves (not foreign-made copies of them) would be combined abroad by foreign buyers. 157

In contrast, the Court found that Congress has not addressed other arguable gaps or taken into account the ease by which electronic media such as software can be copied. ¹⁵⁸ Any adjustments in the patent law to account for the realities of software distribution should be made only after focused legislative consideration and not by the judiciary, the Court explained, especially in view of the extraterritorial implications of this issue.¹⁵⁹

^{150.} Id., 82 U.S.P.Q.2d (BNA) at 1410 (internal citation omitted) (alteration in original).

^{151.} *Id.* at 1759, 82 U.S.P.Q.2d (BNA) at 1410.

^{152.} *Id.* at 1758, 82 U.S.P.Q.2d (BNA) at 1410 (alteration in original). 153. *Id.* at 1759, 82 U.S.P.Q.2d (BNA) at 1410.

^{154.} Id., 82 U.S.P.Q.2d (BNA) at 1410–11. 155. Id., 82 U.S.P.Q.2d (BNA) at 1411. 156. 406 U.S. 518, 173 U.S.P.Q. (BNA) 769 (1972). 157. Microsoft, 127 S. Ct. at 1759, 82 U.S.P.Q.2d (BNA) at 1411.

^{158.} *Id.* at 1759–60, 82 U.S.P.Q.2d (BNA) at 1411.

^{159.} *Id.* at 1760, 82 U.S.P.Q.2d (BNA) at 1411; *cf.* Sony Corp. of Am. v. Universal City Studios, Inc., 464 U.S. 417, 431, 220 U.S.P.Q. (BNA) 665, 673 (1984) (noting that as new technology comes about, Congress is the entity that creates the appropriate and necessary new rules).

Obviousness—The KSR decision

Overshadowing the Microsoft decision was the U.S. Supreme Court's April 30, 2007, ruling in KSR International v. Teleflex Inc. 160 In KSR, the Supreme Court did not just reverse another Federal Circuit decision but overturned the lower court's supposedly "rigid" application of the "teaching, suggestion, or motivation" ("TSM") 161 test for evaluating combinations of references in an obviousness analysis.¹⁶² The Supreme Court clarified that an obviousness analysis "need not seek out precise teachings"¹⁶³ but rather must take account of "the inferences and creative steps that a person of ordinary skill in the art would employ."164

Teleflex, the exclusive licensee under the patent-in-suit, sued KSR for infringement of the claimed invention, which was "a mechanism for combining an electronic sensor with an adjustable automobile pedal" in order to transmit the pedal's position to a computer that controls the throttle in the vehicle's engine. 165 KSR counterclaimed that claim 4 of the patent was invalid as obvious. 166 The district court granted summary judgment in KSR's favor by applying a Graham¹⁶⁷ analysis as well as the Federal Circuit's TSM test. 168 The Federal Circuit reversed the lower court's grant of summary judgment of invalidity because "the District Court had not been strict enough in applying the test." According to the Federal Circuit, the lower court failed to make "finding[s] as to the specific understanding or principle within the knowledge of a skilled artisan that would have motivated one with no knowledge of [the] invention'... to attach an electronic control to the support bracket of the [prior art] assembly."¹⁷⁰

The Supreme Court began its analysis by rejecting the "rigid approach" of the Federal Circuit in applying its TSM test.¹⁷¹ Justice Kennedy, writing for a unanimous Court, stated, "[t]hroughout this Court's engagement with the question of obviousness, our cases have

^{160. 127} S. Ct. 1727, 82 U.S.P.Q.2d (BNA) 1385 (2007).

^{161.} *Id.* at 1734, 82 U.S.P.Q.2d (BNA) at 1391.

^{162.} Id. at 1739, 82 U.S.P.Q.2d (BNA) at 1395.

^{163.} Id. at 1741, 82 U.S.P.Q.2d (BNA) at 1396.

^{164.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1396. 165. *Id.* at 1734, 82 U.S.P.Q.2d (BNA) at 1391.

^{166.} Id., 82 U.S.P.Q.2d (BNA) at 1391.

^{167.} Graham v. John Deere Co. of Kan. City, 383 U.S. 1, 148 U.S.P.Q. (BNA) 459 (1966).

^{168.} KSR, 127 S. Ct. at 1737-38, 82 U.S.P.Q.2d (BNA) at 1393-94.

^{169.} *Id.* at 1738, 82 U.S.P.Q.2d (BNA) at 1394.

^{170.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1394 (quoting Teleflex, Inc. v. KSR Int'l Co., 119 F. App'x 282, 288 (Fed. Cir. 2007), *rev'd KSR*, 127 S. Ct. 1727, 82 U.S.P.Q.2d (BNA) 1385 (2007)).

^{171.} Id. at 1739, 82 U.S.P.Q.2d (BNA) at 1395.

set forth an expansive and flexible approach inconsistent with the way the Court of Appeals applied its TSM test here." The Supreme Court explicitly warned that there was a "need for caution in granting a patent based on the combination of elements found in the prior art" because "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." As a result, the Supreme Court insisted that when adjudicating an obviousness issue, particularly when the analysis centers on a combination patent, "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions."175 However, the Supreme Court cautioned that "[r]ejections on obviousness grounds cannot be sustained by mere conclusory statements."¹⁷⁶

Based on the reasoning above, the Supreme Court found that Teleflex's patent for an adjustable gas pedal was invalid due to obviousness. In so holding, the Supreme Court found that although "[t]here is no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis[,]"¹⁷⁷ a court errs when it "transforms the general principle [of the TSM test] into a rigid rule that limits the obviousness inquiry."178

The Supreme Court proceeded to broaden the application of the TSM test in several ways. The Supreme Court reiterated that "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed[,]"179 not just the problem the inventor was trying to solve. 180 Similarly, "in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle"—not just "those elements of prior art designed to solve the same problem" on which the inventor is working. Isi Finally, and in the context of "a finite number of identified, predictable solutions," the Supreme Court stated that "the fact that a

^{172.} Id., 82 U.S.P.Q.2d (BNA) at 1395.

^{173.} Id., 82 U.S.P.Q.2d (BNA) at 1395.

^{174.} Id., 82 U.S.P.Q.2d (BNA) at 1395.

^{175.} Id. at 1740, 82 U.S.P.Q.2d (BNA) at 1396.

^{176.} *Id.* at 1741, 82 U.S.P.Q.2d (BNA) at 1396 (quoting *In re* Kahn, 441 F.3d 977, 988, 78 U.S.P.Q.2d (BNA) 1329, 1336 (Fed. Cir. 2006)).

^{177.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1396. 178. *Id.*, 82 U.S.P.Q.2d (BNA) at 1396–97.

^{179.} Id. at 1742, 82 U.S.P.Q.2d (BNA) at 1397.

^{180.} See id., 82 U.S.P.Q.2d (BNA) at 1397 (asserting that the obviousness analysis is not conducted from the perspective of the patentee but from the perspective of any person with ordinary skill in the art).

^{181.} Id., 82 U.S.P.Q.2d (BNA) at 1397.

combination was obvious to try might show that it was obvious under [35 U.S.C.] § 103," which further blurred the line between invalidating obviousness and the non-invalidating "obvious to try" standard. 182

This "expansive" and "flexible" approach toward a defense of obviousness will potentially make it easier to find a patent invalid for obviousness in court challenges, or for Patent Office examiners to maintain claim rejections for obviousness. This is particularly true for those inventions that combine previously known elements without demonstrating any unexpected or synergistic results. Additionally, the Supreme Court has broadened the definition of the legal construct of a person of ordinary skill in the art by stating that "[a] person of ordinary skill is also a person of ordinary creativity," 183 who may rely on "common sense" to render an invention obvious. 184 The Supreme Court's rationale was that "[g]ranting patent protection to advances that would occur in the ordinary course without real innovation retards progress."185

It should be noted that one of the prior art references relied upon by the Supreme Court in rendering the patent-in-suit invalid was not mentioned in the patent's prosecution. While the Supreme Court did not address the question of whether the "failure to disclose" prior art during prosecution "voids the presumption of validity given to issued patents," it explicitly "note[d] that the rationale underlying the presumption . . . seems much diminished here." 186

II. PROCEDURAL ASPECTS

A. Appellate Jurisdiction

The Federal Circuit is charged with the duty of increasing doctrinal stability in the field of patent law. 187 To this end, Congress granted the Federal Circuit exclusive jurisdiction over appeals from a final decision of a federal district court when the subject matter jurisdiction of that court was based, in whole or in part, on 28 U.S.C.

^{182.} Id., 82 U.S.P.Q.2d (BNA) at 1397.

^{183.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1397. 184. *See id.*, 82 U.S.P.Q.2d (BNA) at 1397 (proposing that technological advances driven by design needs or market pressures are likely the result of common sense and not necessarily patent-worthy innovation).

^{185.} *Id.* at 1741, 82 U.S.P.Q.2d (BNA) at 1396.

^{186.} *Id.* at 1745, 82 U.S.P.Q.2d (BNA) at 1399. 187. *See generally* S. REP. No. 97-275, at 2–7 (1981), reprinted in 1982 U.S.C.C.A.N. 11, 12-17 (explaining the purpose and structure of the new Court of Appeals for the Federal Circuit).

§ 1338(a), 188 and the case was not based solely on a copyright or trademark claim.189

Congress indicated that its grant of exclusive jurisdiction should not be manipulated:

This measure is intended to alleviate the serious problems of forums [sic] shopping among the regional courts of appeals on patent claims by investing exclusive jurisdiction in one court of appeals. It is not intended to create forum shopping opportunities between the Federal Circuit and the regional courts of appeals on other claims. 190

Like all courts, the Federal Circuit "has inherent jurisdiction to determine its own jurisdiction." The court has strictly construed its jurisdiction in harmony with its congressional mandate. 192 Substance, not form, controls the determination, and jurisdiction "cannot be conferred [on the court] by waiver or acquiescence." Thus, implicit in the court's mandate is the authority to recharacterize pleadings that would improperly evade the intent of Congress. The following cases demonstrate the court's scrutiny of its jurisdiction.

In Biotechnology Industry Organization v. District of Columbia, 194 two drug industry groups challenged a District of Columbia statute that regulated the price of patented prescription drugs. 195 "Because this case [did] not pose the typical questions of patent lawinfringement, validity, enforceability, and the like[,]" the Federal Circuit "raised the issue of whether [its] statutory grant of jurisdiction encompasse[d] this case *sua sponte* at oral argument." The Federal Circuit concluded that it did have jurisdiction over the matter, pursuant to the Supreme Court's decision in Shaw v. Delta Air Lines, Inc. 197 In *Shaw*, the Supreme Court stated:

^{188.} See 28 U.S.C. § 1338(a) (2000) (providing original jurisdiction to federal district courts for all federal actions relating to patents, plant variety protection, copyrights, and trademarks).

^{189.} *Id.* § 1295(a).

^{190.} S. REP. No. 97-275, at 19–20, reprinted in 1982 U.S.C.C.A.N. 11, 29–30. 191. C.R. Bard, Inc. v. Schwartz, 716 F.2d 874, 877, 219 U.S.P.Q. (BNA) 197, 200 (Fed. Cir. 1983).

^{192.} See C.P.C. v. Nosco Plastics, Inc., 719 F.2d 400, 401 (Fed. Cir. 1983) (recognizing—in an order granting motion to dismiss and denying motion to assess damages, costs, and attorney's fees—that the Court of Appeals for the Federal Circuit is limited in its jurisdiction to certain appeals from district courts and that it does not have any supervisory authority over the district courts).

^{193.} Coastal Corp. v. United States, 713 F.2d 728, 730 (Fed. Cir. 1983).

^{194. 496} F.3d 1362, 83 U.S.P.Q.2d (BNA) 1639 (Fed. Cir. 2007).

^{194. 430} F.3d 1302, 03 U.S.P.Q.2d (BNA) at 1642. 195. *Id.* at 1366, 83 U.S.P.Q.2d (BNA) at 1642. 196. *Id.* at 1367, 83 U.S.P.Q.2d (BNA) at 1642. 197. *Id.* at 1368–69, 83 U.S.P.Q.2d (BNA) at 1644 (citing Shaw v. Delta Air Lines, Inc., 463 U.S. 85, 96 n.14 (1983)).

A plaintiff who seeks injunctive relief from state regulation, on the ground that such regulation is pre-empted by a federal statute which, by virtue of the Supremacy Clause of the Constitution, must prevail, thus presents a federal question which the federal courts have jurisdiction under 28 U.S.C. § 1331 to resolve. 195

The Federal Circuit determined that "[t]he phrase 'arising under' has the same meaning in § 1338 as it does in § 1331, the general federal-question provision."199

Therefore, the Federal Circuit concluded that the preemption action at issue arose under an Act of Congress relating to patents, that the district court had jurisdiction based in part on § 1338, and that this case fell within its exclusive jurisdiction under § 1295.²⁰⁰ Thus, it determined that the appeal was properly before the court and should not be transferred back to the D.C. Circuit.²⁰¹

In Immunocept, LLC v. Fulbright & Jaworski, LLP²⁰² and Air Measurement Technologies, Inc. v. Akin Gump Strauss Hauer & Feld, LLP, 203 the Federal Circuit concluded that federal jurisdiction can extend even to patent malpractice suits arising under state law. 204 As noted in Air *Measurement*, this was a question of first impression for the court. ²⁰⁵

The Federal Circuit relied on the Supreme Court's holding in Christianson v. Colt Industries Operating Corp. 2016 that federal district courts have jurisdiction, pursuant to 28 U.S.C. § 1338, over any case "in which a well-pleaded complaint establishes either that federal patent law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims."207

The "substantial question of federal patent law" in *Immunocept* and Air Measurement involved prosecution, claim construction, and litigation of the patents at issue. In Immunocept, the patentee claimed that

^{198.} *Id.* at 1368, 83 U.S.P.Q.2d (BNA) at 1644 (quoting *Shaw*, 463 U.S. at 96 n.14). 198. Id. at 1308, 83 U.S.P.Q.2d (BNA) at 1644 (quoting Snaw, 463 U.S. at 96 ii.14). 199. Id., 83 U.S.P.Q.2d (BNA) at 1644 (citing Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc., 535 U.S. 826, 829–30, 62 U.S.P.Q.2d 1801, 1801–02 (2002)). 200. Id. at 1369, 83 U.S.P.Q.2d (BNA) at 1644.

^{201.} Id., 83 U.S.P.Q.2d (BNA) at 1644.

^{202. 504} F.3d 1281, 85 U.S.P.Q.2d (BNA) 1085 (Fed. Cir. 2007). 203. 504 F.3d 1262, 84 U.S.P.Q.2d (BNA) 2002 (Fed. Cir. 2007).

^{204.} See Immunocept, 504 F.3d at 1285-86, 85 U.S.P.Q.2d (BNA) at 1087-88 (holding that the court has jurisdiction under § 1338 for determination of patent claim scope); Air Measurement, 504 F.3d at 1268–69, 84 U.S.P.Q.2d (BNA) at 2005–06 (holding that the court had jurisdiction under § 1338 because the malpractice claim involved substantial questions of federal patent law).
205. 504 F.3d at 1267, 84 U.S.P.Q.2d (BNA) at 2004–05.
206. 486 U.S. 800, 7 U.S.P.Q.2d (BNA) 1109 (1988).

^{207.} Immunocept, 504 F.3d at 1284, 85 U.S.P.Q.2d (BNA) at 1087 (quoting Christianson, 486 U.S. at 809, 7 U.S.P.Q.2d (BNA) at 1113).

the prosecuting attorney had made a "fatal flaw"²⁰⁸ by using the limiting phrase "consisting of," instead of "comprising," in the claim preambles.²⁰⁹ This flaw allegedly caused the collapse of Immunocept's and a Johnson & Johnson subsidiary's negotiations to conduct clinical trials and commercialize the invention.²¹⁰ In *Air Measurement*, the plaintiff alleged that it would have prevailed in an earlier litigation had it not been for certain errors committed by its attorneys during prosecution and litigation of the patent in question.²¹¹

In both cases the Federal Circuit found that the plaintiffs' state-law malpractice claims rested on substantial questions of patent law. In *Immunocept*, for example, the Federal Circuit found that the determination of claim scope is a "complex" issue due to its diverse claim construction doctrines and thus would "benefit from federal judges who are used to handling these complicated rules." In *Air Measurement*, the court found that the issue of damages, which is not unique to malpractice or patent law, also invokes federal jurisdiction because the plaintiff must prove that its patent was infringed in order to recover damages. Even the prior litigant's invalidity defenses may be taken into account for jurisdictional purposes because the plaintiff must show that it would have prevailed in that suit had it not been for its attorneys' alleged malpractice. Notably, the law firm's own patent-based defenses were not relevant to jurisdiction, which under § 1338 is limited to examining the "well-pleaded complaint."

In *Voda v. Cordis Corp.*, ²¹⁶ the Federal Circuit, in a split decision with Judge Newman dissenting, ²¹⁷ addressed whether it had supplemental jurisdiction over infringement claims based on foreign patents. ²¹⁸

^{208.} Id. at 1283, 85 U.S.P.Q.2d (BNA) at 1086.

^{209.} Id. at 1286, 1285 n.3, 85 U.S.P.Q.2d (BNA) at 1087 n.3, 1088.

^{210.} Id. at 1283, 85 U.S.P.Q.2d (BNA) at 1086.

^{211.} Air Measurement Tech., Inc. v. Akin Gump Strauss Hauer & Feld, LLP, 504 F.3d 1262, 1266, 84 U.S.P.Q.2d (BNA) 2002, 2003–04 (Fed. Cir. 2007).

^{212. 504} F.3d at 1285, 85 U.S.P.Q.2d (BNA) at 1088. Unfortunately for Immunocept, the court affirmed that the two-year statute of limitations had run because Immunocept's attorney knew or should have known of the limiting effects of the term "consisting of" when he examined the patents. The attorney's knowledge was imputed to Immunocept because he was acting within the scope of his authority when he reviewed the patents, even if he did not have the duty to communicate such knowledge to Immunocept. *Id.* at 1286–89, 85 U.S.P.Q.2d (BNA) at 1088–90.

^{213. 504} F.3d at 1270–71, 84 U.S.P.Q.2d (BNA) at 2007.

^{214.} Id. at 1268-69, 84 U.S.P.Q.2d (BNA) at 2006.

^{215.} See id. at 1268, 84 U.S.P.Q.2d (BNA) at 2005 (determining that under the well-pleaded complaint rule, jurisdiction arises only from statements appearing in the plaintiff's claim); see also Immunocept, 504 F.3d at 1284, 85 U.S.P.Q.2d (BNA) at 1087 (invoking the well-pleaded complaint rule to establish federal jurisdiction).

^{216. 476} F.3d 887, 81 U.S.P.Q.2d (BNA) 1769 (Fed. Cir. 2007).

^{217.} Id. at 905, 81 U.S.P.Q.2d (BNA) at 1782 (Newman, J., dissenting).

^{218.} *Id.* at 893, 81 U.S.P.Q.2d (BNA) at 1772 (majority opinion).

The district court, having jurisdiction over Voda's original patent infringement claims, had granted leave for Voda to amend his complaint to add infringement claims based on foreign patents. 219 The district court rested its jurisdiction on 28 U.S.C. § 1367, which grants federal district courts "supplemental jurisdiction over other claims within the same case or controversy, as long as the action is one in which the district courts would have original jurisdiction."²²⁰ Pursuant to 28 U.S.C. § 1292(b), the district court certified an order for interlocutory review to determine "whether the district court has supplemental subject matter jurisdiction over Dr. Voda's five foreign patents."221

The Federal Circuit answered in the negative. The court relied on the Supreme Court's interpretation of § 1367(a)'s requirement "that foreign claims be 'so related to claims in the action within such original jurisdiction that they form part of the same case or controversy.'"²²² The Federal Circuit explained that the Supreme Court had interpreted this provision as codification by Congress of the Court's

principles of pendent and ancillary jurisdiction by which the federal courts' original jurisdiction over federal questions carries with it jurisdiction over state law claims that "derive from a common nucleus of operative fact," such that "the relationship between [the federal] claim and the state claim permits the conclusion that the entire action before the court comprises but one constitutional 'case.'"223

Quoting Stein Associates, Inc. v. Heat & Control, Inc., 224 the Federal Circuit stated that "[w]ith regard to the relationship between foreign and U.S. patent infringement claims, . . . 'the issues are not the same' where 'one action involv[es] United States patents and the other involv[es] British patents." The court also cited Mars, Inc. v. Kabushiki-Kaisha Nippon Conlux, 226 in which the Federal Circuit had concluded that the district court did not have jurisdiction over Japanese patent claims because: "[1] [t]he respective patents [were] different, [2] the accused devices [were] different, [3] the alleged acts [were]

^{219.} Id. at 889, 81 U.S.P.Q.2d (BNA) at 1770.

^{220.} *Id.* at 893, 81 U.S.P.Q.2d (BNA) at 1772 (quoting Exxon Mobil Corp. v. Allapattah Servs., Inc., 545 U.S. 546, 558 (2005)).

^{221.} Id. at 890, 81 U.S.P.Q.2d (BNA) at 1770 (quoting Voda v. Cordis Corp., 122

Fed. App'x 515, 515 (Fed. Cir. 2005)).
222. *Id.* at 894, 81 U.S.P.Q.2d (BNA) at 1773.
223. *Id.*, 81 U.S.P.Q.2d (BNA) at 1773 (alteration in original) (quoting Chicago v. Int'l Coll. of Surgeons, 522 U.S. 156, 164–65 (1997)).

^{224. 748} F.2d 653, 223 U.S.P.Q. (BNA) 1277 (Fed. Cir. 1984). 225. *Voda*, 476 F.3d at 894, 81 U.S.P.Q.2d (BNA) at 1773 (alteration in original) (quoting Stein, 748 F.2d at 658, 223 U.S.P.Q. (BNA) at 1280).

^{226. 24} F.3d 1368, 30 U.S.P.Q.2d (BNA) 1621 (Fed. Cir. 1994).

different, and [4] the governing laws [were] different."227 However, "the district court did not articulate any findings regarding the Mars factors."228

The Federal Circuit thus found several reasons why the district court did not have subject matter jurisdiction over the foreign patent claims: (1) there was no "common nucleus of operative fact" because the foreign patent claims were different, the accused devices were different, the alleged acts were different, and the governing laws were different;²²⁹ (2) nothing in patent treaties contemplates or allows one jurisdiction to adjudicate the patents of another; 230 (3) Voda did not show that it would be more convenient for a U.S. court to assume supplemental jurisdiction;²³¹ (4) Voda did not show that the foreign courts would inadequately protect his foreign patent rights;²³² and (5) the act of state doctrine, which "requires that, in the process of deciding, the acts of foreign sovereigns taken within their own jurisdictions shall be deemed valid," given that the grant of a patent by a sovereign is an act of state.233

The Federal Circuit also compared the limits of rights granted by patents to those conferred by land grants and found that "adjudication of Voda's foreign patent infringement claims should be left to the sovereigns that create the property rights in the first instance."234 Supplemental jurisdiction over the foreign patent infringement claims would not further judicial economy due to the lack of institutional competence of the U.S. courts in foreign patent regimes, and "the likelihood of jury confusion in applying the different patent regimes could result in separate trials."23

Judge Newman dissented on the basis that U.S. courts routinely apply foreign law; 236 there were probably not any differences between patents beyond the understanding of a U.S. court;²³⁷ judges should not avoid cases on the basis of complexity; 238 granting a patent is not

^{227.} Voda, 476 F.3d at 895, 81 U.S.P.Q.2d (BNA) at 1773-74 (quoting Mars, 24 F.3d at 1375, 30 U.S.P.Q.2d (BNA) at 1625–26).

^{228.} Id. at 896, 81 U.S.P.Q.2d (BNA) at 1774

^{229.} Id. at 895–96, 81 U.S.P.Q.2d (BNA) at 1774.

^{230.} Id. at 899–901, 81 U.S.P.Q.2d (BNA) at 1777–79.

^{231.} Id. at 901, 81 U.S.P.Q.2d (BNA) at 1778.

^{232.} Id., 81 U.S.P.Q.2d (BNA) at 1778.

^{233.} *Id.* at 904, 81 U.S.P.Q.2d (BNA) at 1781 (quoting W.S. Kirkpatrick & Co. v. Envtl. Tectonics Corp., Int'l, 493 U.S. 400, 409 (1990)).

^{234.} Id. at 902, 81 U.S.P.Q.2d (BNA) at 1779.

^{235.} *Id.* at 903, 81 U.S.P.Q.2d (BNA) at 1780. 236. *Id.* at 906–10, 81 U.S.P.Q.2d (BNA) at 1782–85 (Newman, J., dissenting).

^{237.} Id. at 911, 81 U.S.P.Q.2d (BNA) at 1786.

^{238.} Id. at 912–13, 81 U.S.P.Q.2d (BNA) at 1786–88.

an act of state;²³⁹ and the case "does not raise issues of comity, treaty, and diplomacy, when judgments are sought to be enforced in another country."240

In HIF Bio, Inc. v. Yung Shin Pharmaceuticals Industrial Co., 241 the Federal Circuit was faced with an issue of first impression, namely, whether the district court's decision under 28 U.S.C. § 1367(c) to decline to exercise supplemental jurisdiction over state-law claims and to remand to the state court was within the class of remands set forth in 28 U.S.C. § 1447(c) and thus barred from appellate review under 28 U.S.C. § 1447(d). 242 In pertinent part, defendants successfully removed HIF's original complaint from a California state court to a federal district court.243 HIF filed an amended complaint, in which it asserted a federal claim under the federal Racketeer Influenced and Corrupt Organizations Act ("RICO") and eleven purported state-law claims, including claims for declaratory judgment of inventorship and ownership of various anti-cancer, anti-angiogenesis drugs.²⁴⁴ The district court dismissed the RICO claim, declined to exercise supplemental jurisdiction over the remaining state-law claims, and remanded the case to state court.²⁴⁵

On appeal, the Federal Circuit declined to consider whether HIF's remanded claims raised a substantial issue of federal patent law inventorship—but disposed of the appeal "on a threshold issue whether [the] court ha[d] appellate jurisdiction to review the district court's remand order."246 While acknowledging that it had not yet addressed this particular issue, the Federal Circuit noted that several other Courts of Appeals, relying on the U.S. Supreme Court's decision in Carnegie-Mellon University v. Cohill, 247 have held that § 1447(d) does not bar review of a remand order based on declining supple-

^{239.} *Id.* at 914–15, 81 U.S.P.Q.2d (BNA) at 1788–89. Newman explained:

the common thread [in determining whether a particular governmental action is an act of state] is whether the issue is one that is normally consigned to the executive branches, such that an international dispute is resolved by political negotiations between diplomats; or whether the issue is more suitable to the individual review that is given to litigants in judicial proceedings dealing with specific facts.

Id. at 914, 81 U.S.P.Q.2d (BNA) at 1788.

^{240.} *Id.* at 915, 81 U.S.P.Q.2d (BNA) at 1789. 241. 508 F.3d 659, 85 U.S.P.Q.2d (BNA) 1240 (Fed. Cir. 2007).

^{242.} Id. at 665, 85 U.S.P.Q.2d (BNA) at 1244.

^{243.} *Id.* at 661, 85 U.S.P.Q.2d (BNA) at 1241.

^{244.} *Id.* at 662, 85 U.S.P.Q.2d (BNA) at 1241. 245. *Id.*, 85 U.S.P.Q.2d (BNA) at 1242. 246. *Id.* at 663, 85 U.S.P.Q.2d (BNA) at 1242.

^{247. 484} U.S. 343 (1988).

mental jurisdiction.²⁴⁸ Nonetheless, the Federal Circuit further observed that a concurring opinion by Justices Kennedy and Ginsberg in Things Remembered, Inc. v. Petrarca²⁴⁹ introduced a degree of uncertainty about this conclusion, when they explained that the Court in Cohill "did not find it necessary to decide whether [§ 1447](d) would bar review of a remand on these grounds."²⁵⁰

While there is "no decision that grapples with Justice Kennedy's Things Remembered concurrence,"251 the Federal Circuit found that the Supreme Court's recent decision in Powerex Corp. v. Reliant Energy Services, Inc.252 "made the uncertainty introduced by Justice Kennedy's . . . concurrence precedential."253 In particular, *Powerex* stated, "[i]t is far from clear... that when discretionary supplemental jurisdiction is declined the remand is not based on lack of subject-matter jurisdiction for purposes of § 1447(c) and § 1447(d)"²⁵⁴ and further that the Court has "never passed on whether Cohill remands are subject matter jurisdictional for purposes of post-1988 versions of § 1447(c) and § 1447(d)."255

Left to its own analysis, the Federal Circuit held that when a district court declines to exercise supplemental jurisdiction to claims "over which it has no independent basis of subject matter jurisdiction, i.e., state claims[,] . . . [it] strips the claims of the only basis on which they are within the jurisdiction of the court." The court concluded:

In short, because every § 1367(c) remand necessarily involves a predicate finding that the claims at issue lack an independent basis of subject matter jurisdiction, a remand based on declining supplemental jurisdiction can be colorably characterized as a remand based on lack of subject matter jurisdiction. Accordingly, a remand based on declining supplemental jurisdiction must be considered

^{248.} $HIF\ Bio,\ 508\ F.3d\ at\ 665,\ 85\ U.S.P.Q.2d\ (BNA)$ at 1244; $see,\ e.g.,\ Trans\ Penn$ Wax Corp. v. McCandless, 50 F.3d 217, 223-24 (3d Cir. 1995) (citing precedents in the Fourth, Fifth, Sixth, Seventh, Eighth, Ninth, Tenth, and Eleventh Circuits); see also 14C Charles Alan Wright, Arthur R. Miller & Edward H. Cooper, Federal PRACTICE & PROCEDURE § 3740 n.39 (3d ed. 1998) (listing examples of cases that discuss the appealability of removal orders by district courts on discretionary grounds).

^{249. 516} U.S. 124 (1995).

^{250.} HIF Bio, 508 F.3d at 665, 85 U.S.P.Q.2d (BNA) at 1244 (alteration in original) (quoting *Things Remembered*, 516 U.S. at 130 (Kennedy, J., concurring)).

^{251.} *Id.* at 665, 85 U.S.P.Q.2d (BNA) at 1244. 252. 127 S. Ct. 2411 (2007).

^{253.} HIF Bio, 508 F.3d at 666, 85 U.S.P.Q.2d (BNA) at 1244.

^{254.} Id., 85 U.S.P.Q.2d (BNA) at 1244 (alteration in original) (quoting Powerex, 127 S. Ct. at 2418-19).

^{255.} Id., 85 U.S.P.O.2d (BNA) at 1244 (quoting Powerex, 127 S. Ct. at 2419 n.4).

^{256.} Id. at 667, 85 U.S.P.Q.2d (BNA) at 1245.

within the class of remands described in § 1447(c) and thus barred from appellate review by § 1447(d).²⁵⁷

B. Final Judgment Rule

Appellate courts have historically disfavored piecemeal litigation and thus, with limited exceptions, have permitted appeals only from complete and final judgments.²⁵⁸ In the case of the Federal Circuit, the "final judgment rule" for patent disputes arising under 28 U.S.C. § 1338 is set forth at 28 U.S.C. § 1295, which states that parties may appeal only a "final decision of a district court." The Supreme Court has defined a final judgment as a decision by the district court that "ends the litigation on the merits and leaves nothing for the court to do but execute the judgment."260 By requiring parties to "raise all claims of error in a single appeal following final judgment on the merits,"²⁶¹ § 1295, like its counterpart § 1291, "forbid[s] piecemeal disposition on appeal of what for practical purposes is a single controversy."²⁶² Thus, there is no "final decision" under 28 U.S.C. § 1295(a)(1), and therefore no Federal Circuit jurisdiction, unless a case has been fully adjudicated as to all claims for all parties or there was an express determination that there is no just reason for delay or express direction for entry of judgment as to fewer than all of the parties or claims.²⁶³

The finality of the judgment was a central issue in SafeTCare Manufacturing, Inc. v. Tele-Made, Inc., 264 in which the district court had entered summary judgment of non-infringement in favor of appellee Burke and another defendant, and then proceeded to enter a "final judgment" and dismissed the action, even though it had not yet resolved the claims against the other defendants or their counterclaims.265

The Federal Circuit explained that a court of appeals has jurisdiction over a "final judgment" only "when it terminates the litigation

^{257.} Id., 85 U.S.P.Q.2d (BNA) at 1245.

^{258.} See Catlin v. United States, 324 U.S. 229, 233-34 (1945) (pointing to the conservation of judicial energy and the prevention of delays as policy reasons for limiting appellate review to final judgments).

^{259. 28} U.S.C. § 1295 (2000).

^{260.} Catlin, 324 U.S. at 233.

^{261.} Firestone Tire & Rubber Co. v. Risjord, 449 U.S. 368, 374 (1981). 262. Cobbledick v. United States, 309 U.S. 323, 325 (1940). 263. See Pandrol USA, LP v. Airboss Ry. Prod., Inc., 320 F.3d 1354, 1362, 65 U.S.P.Q.2d 1985, 1990-91 (Fed. Cir. 2003) (holding that determining whether a district court's order constitutes a final judgment is a function of pragmatic and not formalistic analysis).

^{264. 497} F.3d 1262, 83 U.S.P.Q.2d (BNA) 1618 (Fed. Cir. 2007).

^{265.} Id. at 1266, 83 U.S.P.Q.2d (BNA) at 1620.

between the parties on the merits of the case, and leaves nothing to be done but to enforce by execution what has been determined."266 The "final judgment" in this case was premature because it did not resolve SafeTCare's claims against the other defendants or their counterclaims.²⁶⁷ As a result, the district court's purported "final judgment" did not establish appellate subject matter jurisdiction, regardless of the district court's own description of its order or any belief, concession, or agreement by the parties.²⁶⁸

Nonetheless, this issue became moot once the district court belatedly entered a Rule 54(b) judgment nunc pro tunc, following the Federal Circuit's notification to the parties of the jurisdictional problem. 269 A Rule 54(b) judgment is an exception to the final judgment rule, for it ripened SafeTCare's appeal and vested the Federal Circuit with jurisdiction. 270

In Walter Kidde Portable Equipment, Inc. v. Universal Security Instruments, Inc.,271 the Federal Circuit rejected Kidde's argument that the court lacked jurisdiction because the district court's dismissal order was not a final and appealable judgment.²⁷² In limited circumstances, the court explained, it could also "entertain an appeal from an order deciding less than the entire case, such as . . . an interlocutory order certified by a district court pursuant to 28 U.S.C. § 1292(b)."273 In this case, the district court's order stated "that the 'action' was dismissed, not simply the complaint."274 The court interpreted the term "action" to encompass the entire proceeding, including termination of the defendant's counterclaims. Accordingly, [the Federal Circuit] construed the district court's order granting Kidde's motion for voluntary dismissal as disposing of the entire case, including [Universal's] counterclaims, and [asserted] jurisdiction over th[e] appeal, pursuant to 28 U.S.C. § 1295(a)(1)."²⁷⁶

^{266.} Id. at 1267, 83 U.S.P.Q.2d (BNA) at 1621 (quoting Parr v. United States, 351 U.S. 513, 518 (1956)).

^{267.} Id. at 1266, 83 U.S.P.Q.2d (BNA) at 1620.

^{268.} *Id.* at 1267, 83 U.S.P.Q.2d (BNA) at 1621.

^{269.} Id., 83 U.S.P.Q.2d (BNA) at 1621.

^{270.} Id., 83 U.S.P.Q.2d (BNA) at 1621.

^{271. 479} F.3d 1330, 81 U.S.P.Q.2d (BNA) 1929 (Fed. Cir. 2007). 272. *Id.* at 1334–35, 81 U.S.P.Q.2d (BNA) at 1932.

^{273.} Id. at 1335, 81 U.S.P.Q.2d (BNA) at 1932.

^{274.} Id., 81 U.S.P.Q.2d (BNA) at 1932.

^{275.} Id., 81 U.S.P.Q.2d (BNA) at 1932; cf. Local Union No. 38, Sheet Metal Workers' Int'l Ass'n v. Pelella, 350 F.3d 73, 81 (2d Cir. 2003) ("The word 'action,' without more, is arguably broad enough to encompass any type of judicial proceeding, including counterclaims.")

^{276.} Walter Kidde, 479 F.3d at 1335, 81 U.S.P.Q.2d (BNA) at 1933.

In International Electronic Technology Corp. v. Hughes Aircraft Co., 277 however, the Federal Circuit warned that "the parties and other members of the bar are hereby placed on notice that the court shall in the future begin to cite counsel for failure to determine whether or not the appealed judgment is final."²⁷⁸ The district court had granted summary judgment to Hughes, but Hughes had not dismissed its outstanding counterclaims before the plaintiff filed a notice of appeal.²⁷⁹ "A final decision, as defined by the Supreme Court, is a decision issued by the trial court which 'ends the litigation on the merits and leaves nothing for the court to do but execute the judgment."280 Under Rule 54(b) of the Federal Rules of Civil Procedure, however, a district court may "direct the entry of a final judgment as to one or more but fewer than all of the claims or parties only upon an express determination that there is no just reason for delay and upon an express direction for the entry of judgment."281 Since the parties had failed to obtain such a partial judgment, the court found that the appeal was premature.²⁸²

C. Interlocutory Appeals

Although the Federal Circuit has the authority to hear interlocutory appeals under 28 U.S.C. § 1292(c)(1), 283 interlocutory appeals have not been widely pursued, due to the court's reluctance to hear them. However, in Regents of the University of California v. Dako North America, Inc., 284 the Federal Circuit took the unusual step of granting a petition for an interlocutory appeal from a claim construction ruling. 285 The claim constructions at issue had already been put before the court in two pending appeals from the district court's denial of the appellant's motion for preliminary injunction.²⁸⁶ After those appeals had been filed, however, the district court revisited its claim construction rulings in light of new evidence.²⁸⁷ The Federal Circuit found that it would be "an efficient use of judicial resources and

^{277. 476} F.3d 1329, 81 U.S.P.Q.2d (BNA) 1543 (Fed. Cir. 2007).

^{278.} Id. at 1331, 81 U.S.P.Q.2d (BNA) at 1544.

^{279.} Id. at 1330, 81 U.S.P.Q.2d (BNA) at 1544.

^{280.} Id., 81 U.S.P.Q.2d (BNA) at 1543 (quoting Coopers & Lybrand v. Livesay, 437 U.S. 463, 467 (1978)).

^{281.} FED. R. CIV. P. 54(b).

^{282.} *Int'l Elec.*, 476 F.3d at 1331, 81 U.S.P.Q.2d (BNA) at 1544. 283. *See* 28 U.S.C. § 1292(c)(1) (2000) (authorizing the Federal Circuit's jurisdic-283. See 28 U.S.C. § 1292(c)(1) (2000) (authorizing the Federal Circuit s jurisdiction over "an appeal from an interlocutory order or decree . . . in any case over which the court would have jurisdiction of an appeal under section 1295 of this title").
284. 477 F.3d 1335, 81 U.S.P.Q.2d (BNA) 1926 (Fed. Cir. 2007).
285. Id. at 1337, 81 U.S.P.Q.2d (BNA) at 1927.
286. Id. at 1336, 81 U.S.P.Q.2d (BNA) at 1926.

^{287.} Id., 81 U.S.P.Q.2d (BNA) at 1927.

would facilitate resolution of all of the claim construction disputes" to grant the petition for interlocutory review and consider the district court's revised claim construction in conjunction with the pending appeals.²⁸⁸ Indeed, denial of the interlocutory appeals would have left the merits panel to review an admittedly outdated claim construction order.²⁸⁹ "Because the matters in the recent [claim construction] order [were] thus intertwined with the issues in the pending appeals, [the Federal Circuit] determine[d] that granting the petition in these unusual circumstances [was] warranted."²⁹⁰

The Federal Circuit declined to consider an interlocutory appeal of a civil contempt order in Entegris, Inc. v. Pall Corp. 291 The district court had initially granted Entegris's motion for a preliminary injunction but dissolved it after Pall had presented new evidence that challenged the validity of the patents at issue.²⁹² Nonetheless, the district court held Pall in civil contempt for violating the (now dissolved) preliminary injunction by continuing to sell the accused products after it had been ordered not to do so.²⁹³ Pall appealed the civil contempt order, while Entegris cross-appealed the dismissal of the preliminary injunction order.²⁹

The Federal Circuit concluded it did not have jurisdiction over the civil contempt order and dismissed Pall's appeal.²⁹⁵ Pursuant to 28 U.S.C. § 1292, the court's jurisdiction over interlocutory appeals extends only to interlocutory orders "granting, continuing, modifying, refusing or dissolving injunctions, or refusing to dissolve or modify injunctions, except where a direct review may be had in the Supreme Court."296 Since Pall's contempt order did not fall under any of these categories, and Pall did not allege that it would suffer "irreparable consequence" if it were unable to appeal the order, the Federal Circuit concluded that it did not have jurisdiction over Pall's interlocutory appeal.²⁹⁷

Neither did the court find jurisdiction under the "final judgment rule" of 28 U.S.C. § 1295(a). A contempt order against a party-

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288. Id., 81 U.S.P.Q.2d (BNA) at 1927.
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^{289.} Id. at 1337, 81 U.S.P.Q.2d (BNA) at 1927.

^{290.} Id., 81 U.S.P.Q.2d (BNA) at 1927.

^{291. 490} F.3d 1340, 83 U.S.P.Q.2d (BNA) 1001 (Fed. Cir. 2007). 292. *Id.* at 1341–42, 83 U.S.P.Q.2d (BNA) at 1003.

^{293.} *Id.* at 1342, 83 U.S.P.Q.2d (BNA) at 1003.

^{294.} *Id.*, 83 U.S.P.Q.2d (BNA) at 1003. 295. *Id.* at 1345–46, 83 U.S.P.Q.2d (BNA) at 1006.

^{296.} Id. at 1343, 83 U.S.P.Q.2d (BNA) at 1005 (quoting 28 U.S.C. § 1292(a) (2000)

^{297.} Id. at 1345-46, 83 U.S.P.Q.2d (BNA) at 1006.

^{298.} Id. at 1348, 83 U.S.P.Q.2d (BNA) at 1008.

litigant is appealable only from the final judgment in the litigation; in other words, it is not an appealable final judgment unless the party in contempt is not a party to the action.²⁹⁹ The Federal Circuit also found it would have been inappropriate to exercise pendent jurisdiction over the civil contempt order because the facts underlying that order were not "inextricably intertwined" with those underlying the preliminary injunction order. 300

The Federal Circuit then held that it did have jurisdiction over Entegris's cross-appeal of the order dissolving the preliminary injunction. That order, the court found, rested only on the alleged invalidity of patents in view of newly discovered prior art.³⁰² In so holding, the court rejected Pall's argument that non-infringement was a second, independent basis to support that order. Pall's assertion that its new product was not infringing instead went to the question of irreparable harm.³⁰⁴ Having satisfied itself of its jurisdiction over Entergis's cross-appeal, the Federal Circuit rejected that appeal on its merits, finding that the district court had not abused its discretion in dissolving the preliminary injunction because Pall's new invalidity defense had substantial merit.3

D. Declaratory Judgment

In the wake of the Supreme Court's decision in MedImmune, Inc. v. Genentech Inc., 306 which rejected the Federal Circuit's "reasonable apprehension of suit"307 test for declaratory judgment jurisdiction, the Federal Circuit has significantly lowered the bar for determining when "a case of actual controversy" exists within its jurisdiction. The following cases highlight the Federal Circuit's new standard for determining whether declaratory judgment jurisdiction will arise.

SanDisk Corp. v. STMicroelectronics, Inc. 308 was the Federal Circuit's first substantive examination of declaratory judgment jurisdiction after MedImmune. While MedImmune examined declaratory judgment

^{299.} See Doyle v. London Guarantee & Accident Co., 204 U.S. 599, 603 (1907) (holding that contempt orders were to be viewed as interlocutory and were only to be reviewed on appeal from a final judgment in the case); *see also* Fox v. Capital Co., 299 U.S. 105, 107 (1936) (restating the rule that civil contempt orders may only be reviewed on appeal from a final judgment).

^{300.} Entegris, 490 F.3d at 1349, 83 U.S.P.Q.2d (BNA) at 1009.

^{301.} *Id.* at 1350, 83 U.S.P.Q.2d (BNA) at 1009. 302. *Id.* at 1351, 83 U.S.P.Q.2d (BNA) at 1010.

^{303.} *Id.*, 83 U.S.P.Q.2d (BNA) at 1010. 304. *Id.* at 1350, 83 U.S.P.Q.2d (BNA) at 1010.

^{305.} Id. at 1352, 83 U.S.P.Q.2d (BNA) at 1011. 306. 127 S. Ct. 764, 81 U.S.P.Q.2d (BNA) 1225 (2007). 307. Id. at 774 n.11, 81 U.S.P.Q.2d (BNA) at 1232 n.11.

^{308. 480} F.3d 1372, 82 U.S.P.Q.2d (BNA) 1173 (Fed. Cir. 2007).

jurisdiction in the context of a signed license agreement, 309 SanDisk took those principles one step farther by applying them to conduct prior to the existence of a license. 310

STMicroelectronics ("ST") had contacted SanDisk in April 2004 to propose cross-licensing their patents on flash memory technology.³¹¹ Despite extensive discussions over the next six months, including representations that the parties would not sue each other, the parties were unable to reach an agreement.³¹² SanDisk finally brought a complaint against ST for infringement of one of its patents and declaratory judgment of non-infringement and invalidity with respect to fourteen ST patents.³¹³ The district court granted ST's motion to dismiss SanDisk's declaratory judgment claims because SanDisk did not have a reasonable apprehension of suit under the pre-MedImmune standard. SanDisk appealed. 315

The Federal Circuit vacated the district court's opinion and remanded for further proceedings. ³¹⁶ In *MedImmune*, the Supreme Court interpreted the Declaratory Judgment Act, in light of Article III, to require "a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." The dispute must be "'definite and concrete, touching the legal relations of parties having adverse legal interests'; and . . . be 'real and substantial' and 'admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts."318 A declaratory judgment plaintiff, however, is not required "to expose himself to liability before bringing suit to challenge the basis for the threat" because "the declaratory judgment procedure is an alternative to pursuit of the arguably illegal activity."319 "The dilemma posed by that coercion—putting the challenger to the choice between abandoning his rights or risking prose-

309. MedImmune, 127 S. Ct. at 767, 81 U.S.P.Q.2d (BNA) at 1227.

^{310.} See SanDisk, 480 F.3d at 1381, 82 U.S.P.Q.2d (BNA) at 1180 (holding that declaratory judgment jurisdiction can exist prior to the existence of a patent license).

^{311.} *Id.* at 1374, 82 U.S.P.Q.2d (BNA) at 1175. 312. *Id.* at 1374–76, 82 U.S.P.Q.2d (BNA) at 1175–76.

^{313.} Id. at 1376, 82 U.S.P.Q.2d (BNA) at 1176.

^{314.} *Id.* at 1376–77, 82 U.S.P.Q.2d (BNA) at 1176–77.

^{315.} Id. at 1377, 82 U.S.P.Q.2d (BNA) at 1177.

^{316.} *Id.* at 1383, 82 U.S.P.Q.2d (BNA) at 1181. 317. *Id.* at 1378, 82 U.S.P.Q.2d (BNA) at 1178 (quoting MedImmune Inc. v. Genentech Inc., 127 S. Ct. 764, 771, 81 U.S.P.Q.2d (BNA) 1225, 1229 (2007)).

^{318.} Id., 82 U.S.P.Q.2d (BNA) at 1178 (second alteration in original) (quoting MedImmune, 127 S. Ct. at 771, 81 U.S.P.Q.2d (BNA) at 1229).

^{319.} Id., 82 U.S.P.Q.2d (BNA) at 1178 (quoting MedImmune, 127 S. Ct. at 772, 81 U.S.P.Q.2d (BNA) at 1230).

cution—is a dilemma that it was the very purpose of the Declaratory Judgment Act to ameliorate."320

With those principles in mind, the Federal Circuit explained that "Article III jurisdiction may be met where the patentee takes a position that puts the declaratory judgment plaintiff in the position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do." While declining to set forth "the outer boundaries of declaratory judgment jurisdiction," the court stated:

We hold only that where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license, an Article III case or controversy will arise and the party need not risk a suit for infringement by engaging in the identified activity before seeking a declaration of its legal rights. 322

The Federal Circuit concluded that ST's pursuit of "a royalty under its patents based on specific, identified activity by SanDisk" gave rise to declaratory judgment jurisdiction.³²³ In particular, ST had made detailed infringement presentations to SanDisk, which included a "thorough infringement analysis . . . by seasoned litigation experts," 324 an "element-by-element" analysis of each of SanDisk's allegedly infringing products, 325 "liberal[] refer[ences] to SanDisk's present, ongoing infringement of ST's patents and the need for SanDisk to license those patents[,]"326 a 300-page "packet of materials" containing each of ST's fourteen allegedly infringed patents, 327 "reverse engineering reports for certain of SanDisk's products, and diagrams showing a detailed infringement analysis of SanDisk's products[,]"328 and related communications. 329 In response, SanDisk "maintained that it could proceed in its conduct without the payment of royalties to ST."330 Those facts were sufficient to evince the creation of "a substantial controversy, between parties having adverse legal interest, of sufficient immediacy and reality to warrant the issuance of a declara-

^{320.} Id. at 1378-79, 82 U.S.P.Q.2d (BNA) at 1178 (quoting MedImmune, 127 S. Ct. at 773, 81 U.S.P.Q.2d (BNA) at 1230).

^{321.} *Id.* at 1381, 82 U.S.P.Q.2d (BNA) at 1179–80. 322. *Id.*, 82 U.S.P.Q.2d (BNA) at 1180.

^{323.} Id. at 1382, 82 U.S.P.Q.2d (BNA) at 1180.

^{324.} Id., 82 U.S.P.Q.2d (BNA) at 1180.

^{325.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1180.

^{326.} *Id.* at 1382, 82 U.S.P.Q.2d (BNA) at 1180–81.

^{327.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1181.

^{328.} Id., 82 U.S.P.Q.2d (BNA) at 1181.

^{329.} See id., 82 U.S.P.Q.2d (BNA) at 1181 (relating that ST communicated to San-Disk its determination of infringement and its assertion of the right to royalties).

^{330.} Id., 82 U.S.P.Q.2d (BNA) at 1181.

tory judgment."331 Furthermore, borrowing language from MedImmune, the court concluded that "SanDisk need not 'bet the farm,' so to speak, and risk a suit for infringement by cutting off licensing discussions and continuing in the identified activity before seeking a declaration of its legal rights."332

Declaratory judgment jurisdiction was not defeated by SanDisk's assertions that it would not sue ST

because ST has engaged in a course of conduct that shows a preparedness and willingness to enforce its patent rights despite [this] statement. Having approached SanDisk, having made a studied and considered determination of infringement by SanDisk, having communicated that determination to SanDisk, and then saying that it does not intend to sue, ST is engaging in the kinds of "extrajudicial patent enforcement with scare-the-customer-and-run tactics" that the Declaratory Judgment Act was intended to obviate. 333

The Supreme Court, moreover, has rejected the "reasonable apprehension" test, which had provided the only "sound basis" for the district court's refusal to adjudicate SanDisk's declaratory judgment claims.334 Accordingly, the Federal Circuit vacated that decision and remanded the case.3

SanDisk figured prominently in the Federal Circuit's decision in Sony Electronics, Inc. v. Guardian Media Technologies, Ltd. 336 Defendantpatentee Guardian had contacted a number of companies about allegedly infringing its patents on "methods and apparatuses for blocking the viewing of certain television programs."337 Guardian provided each company with detailed claim charts setting forth its infringement contentions and engaged in protracted discussions and correspondence.338 None of the companies accepted Guardian's offer of a license, however, and instead filed separate actions for declaratory judgment of non-infringement, invalidity, and unenforceability. 339 The complaints were consolidated and dismissed by the district court

^{331.} Id., 82 U.S.P.Q.2d (BNA) at 1181 (quoting Md. Cas. Co. v. Pac. Coal & Oil Co., 312 U.S. 270, 273 (1941)).

^{332.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1181 (quoting MedImmune Inc. v. Genentech Inc., 127 S. Ct. 764, 774 n.11, 81 U.S.P.Q.2d (BNA) 1225, 1232 n.11 (2007)).

^{333.} Id. at 1383, 82 U.S.P.Q.2d (BNA) at 1181 (quoting Arrowhead Indus. Water, Inc. v. Ecolochem, Inc., 846 F.2d 731, 735, 6 U.S.P.Q.2d (BNA) 1685, 1688 (1988)).

^{334.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1181. 335. *Id.*, 82 U.S.P.Q.2d (BNA) at 1181. 336. 497 F.3d 1271, 83 U.S.P.Q.2d (BNA) 1798 (Fed. Cir. 2007).

^{337.} See id. at 1274-81, 83 U.S.P.Q.2d (BNA) at 1800-06 (documenting the correspondence between Guardian and Sony, Matsushita, JVC, and Mitsubishi).

^{338.} *Id.*, 83 U.S.P.Q.2d (BNA) at 1800–06.

^{339.} Id., 83 U.S.P.Q.2d (BNA) at 1800-06.

for lack of subject matter jurisdiction. 340 As in SanDisk, the Federal Circuit vacated the district court's dismissals because the parties' conduct and adverse positions demonstrated the presence of an "actual controversy," which was ripe for judicial determination. 341

In so holding, the Federal Circuit found no affirmative evidence to support Guardian's allegations that the declaratory judgment plaintiffs had filed their complaints as an "intimidation tactic to gain leverage in the licensing negotiations."³⁴² Even if the lawsuits did place the plaintiffs in a more favorable negotiating position, "that effect is not a sufficient reason to decline to hear the suit," the court wrote. 343 Nonetheless, the court instructed the district court to reconsider on remand whether to exercise its discretion to dismiss or stay the claims, particularly in light of the fact that the patents were undergoing reexamination.344

SanDisk was also followed by Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp., 345 in which the Federal Circuit examined declaratory judgment jurisdiction in the context of Abbreviated New Drug Applications ("ANDAs") and 21 U.S.C. § 355(j). 346 In 2004, Teva filed an ANDA for generic famciclovir tablets, in which it certified that the five Novartis Famvir Orange Book patents were either invalid or not infringed by Teva's proposed drug. 347 When Novartis sued for infringement of one of its five patents under 35 U.S.C. § 271(e)(1), Teva brought a declaratory judgment suit on the four remaining patents under 35 U.S.C. § 271(e)(5) and 21 U.S.C. § 355(j)(5)(C), which entitles an ANDA applicant to bring a declaratory judgment action "to obtain patent certainty" on any patent identified in the paragraph IV certification but not included in an infringement suit.³⁴⁸ On Novartis's motion, the district court dismissed Teva's declaratory judgment complaint because Teva had no reasonable apprehension of being sued on the four patents Novartis had not asserted in its complaint. Teva appealed. 351

^{340.} Id. at 1281, 83 U.S.P.Q.2d (BNA) at 1806.

^{341.} *Id.* at 1285–87, 83 U.S.P.Q.2d (BNA) at 1809–10. 342. *Id.* at 1289, 83 U.S.P.Q.2d (BNA) at 1811.

^{343.} Id., 83 U.S.P.Q.2d (BNA) at 1812.

^{344.} *Id.*, 83 U.S.P.Q.2d (BNA) at 1812.

^{345. 482} F.3d 1330, 82 U.S.P.Q.2d (BNA) 1225 (Fed. Cir. 2007). 346. *Id.* at 1334–35, 82 U.S.P.Q.2d (BNA) at 1226–27.

^{347.} Id. at 1334, 82 U.S.P.Q.2d (BNA) at 1226–27.

Id. at 1334-35, 82 U.S.P.Q.2d (BNA) at 1227 (quoting 21 U.S.C. § 355(j)(5)(c) (2000))

^{349.} Id. at 1335, 82 U.S.P.Q.2d (BNA) at 1227.

^{350.} Id., 82 U.S.P.Q.2d (BNA) at 1227.

The Federal Circuit reversed the district court's dismissal of Teva's declaratory judgment action.³⁵¹ As in SanDisk, the Federal Circuit recounted in detail the Supreme Court's analysis of the "actual controversy" requirements of the Declaratory Judgment Act and 35 U.S.C. § 271(e)(5). Since With that framework in mind, the court proceeded to find that Teva had an "injury-in-fact" and thus a justiciable controversy under Article III. 353

The court explained that Novartis had created a present and actual controversy by suing Teva under 35 U.S.C. § 271(e)(2)(A) for filing an ANDA. Since an ANDA is a "single act of infringement," regardless of the number of patents it identified, it did not matter that Novartis had elected to sue on only one of the five patents, or that Teva had filed a separate declaratory judgment action on the other four patents.³⁵⁶ Those complaints all arose from the same "controversy" created when Novartis listed its Famvir patents in the Orange Book. 357

The Federal Circuit then found that other actions by the parties collectively established a "justiciable controversy," which could be resolved by allowing Teva to bring a declaratory judgment action against Novartis.³⁵⁸ For example, Novartis's listing of its Famvir patents in the Orange Book meant that it could reasonably assert a claim of infringement against an unlicensed party making, using, or selling its claimed inventions.³⁵⁹ Second, Teva's submission of an ANDA gave rise to Novartis's infringement suit as well as Teva's "justiciable declaratory judgment controversy."360 Third, the statutory "civil action to obtain patent certainty,"361 the ANDA declaratory judgment provision, 362 and the Hatch-Waxman Act 363 combine to prevent patentees like Novartis from "gaming" the system by bringing suit on only one of the five patents Teva named in its ANDA in order to invoke the statute's thirty-month stay on Teva's ANDA while shielding the other

351. Id. at 1334, 82 U.S.P.Q.2d (BNA) at 1226.

^{352.} Id. at 1336-39, 82 U.S.P.Q.2d (BNA) at 1227-30.

^{353.} Id. at 1340, 82 U.S.P.Q.2d (BNA) at 1230.

^{354.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1231. 355. *Id.*, 82 U.S.P.Q.2d (BNA) at 1230.

^{356.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1230–31. 357. *Id.*, 82 U.S.P.Q.2d (BNA) at 1231.

^{358.} *Id.* at 1341, 82 U.S.P.Q.2d (BNA) at 1231.

^{359.} Id., 82 U.S.P.Q.2d (BNA) at 1231.

^{360.} Id. at 1342, 82 U.S.P.Q.2d (BNA) at 1232.

^{361. 21} U.S.C. § 355(j) (5) (C) (2000). 362. 35 U.S.C. § 271(e) (5) (2000).

^{363.} Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271(E)).

patents from a validity challenge. 364 Fourth, Novartis's infringement suit against Teva on one patent was sufficient to create "an actual declaratory judgment controversy as to all the paragraph IV certified patents."365 Finally, there was a "present and real harm" that Novartis could bring a future litigation against Teva on its other four Famvir patents if Teva was not allowed to bring a declaratory judgment action against Novartis on those patents.³⁶⁶

The Federal Circuit concluded that these factors demonstrated that "Teva has an injury-in-fact and a justiciable controversy that can be fully resolved by a declaratory judgment." Since "Teva's injuries are traceable to Novartis' conduct and those injuries can be redressed by a favorable judicial decision[,]" the Federal Circuit concluded that "Teva has established standing and an actual controversy . . . to confer jurisdiction under the Declaratory Judgment Act."368

In Adenta GmbH v. OrthoArm, Inc., 369 OrthoArm argued that the district court lacked subject matter jurisdiction to decide the case. 370 According to OrthoArm, "the court itself stated that it lacked adequate information to decide the jurisdictional issue, but then proceeded to deny OrthoArm's motion, thereby improperly assuming jurisdiction."371 OrthoArm further argued that "the court lacked subject matter jurisdiction to decide the case" because the "reasonable apprehension of an imminent infringement suit" was absent. 372 particular, according to OrthoArm, a letter threatening Adenta, stating that Orthoarm would "pursue its available legal remedies" in the event of a breach of the License Agreement, did not create in Adenta the reasonable apprehension that it would be sued.³⁷³

The Federal Circuit quoted its earlier holding in SanDisk, stating that "where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party," and where that party asserts its "right to engage in the accused activity without a license under the patent," a case or controversy will arise and the

^{364.} Teva, 482 F.3d at 1342, 82 U.S.P.Q.2d (BNA) at 1232.

^{365.} *Id.* at 1344, 82 U.S.P.O.2d (BNA) at 1234. 366. *Id.* at 1345, 82 U.S.P.O.2d (BNA) at 1234. 367. *Id.* at 1346, 82 U.S.P.O.2d (BNA) at 1235.

^{368.} Id., 82 U.S.P.Q.2d (BNA) at 1235.

^{369. 501} F.3d 1364, 84 U.S.P.Q.2d (BNA) 1428 (Fed. Cir. 2007).

^{370.} Id. at 1369, 84 U.S.P.Q.2d (BNA) at 1432.

^{371.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1432. 372. *Id.*, 84 U.S.P.Q.2d (BNA) at 1432.

^{373.} Id., 84 U.S.P.Q.2d (BNA) at 1432.

party does not have to risk an infringement suit "by engaging in the identified activity before seeking a declaration of its legal rights." ³⁷⁴

While *SanDisk*, *Sony*, *Teva*, and *Adenta* all examined when prelitigation activities may *create* declaratory judgment jurisdiction, at the other end of the spectrum is *Benitec Australia*, *Ltd. v. Nucleonics*, *Inc.*, ³⁷⁵ which examined when post-litigation conduct may *remove* declaratory judgment jurisdiction. ³⁷⁶

In pertinent part, Benitec's original infringement case was rendered moot by the Supreme Court's broad interpretation of the safe harbor provision of 35 U.S.C. § 271(e)(1) in its *Merck KGaA v. Integra Life Sciences*³⁷⁷ decision.³⁷⁸ After Benitec voluntarily dismissed its claims, the district court dismissed Nucleonics's counterclaims of patent invalidity for lack of declaratory judgment jurisdiction.³⁷⁹ Benitec, however, covenanted not to sue Nucleonics only with respect to Nucleonics's prior activities but not with respect to its ongoing and future research activities.³⁸⁰ Nucleonics argued that these potential claims for infringement were sufficient to support jurisdiction for a declaratory judgment.³⁸¹ The Federal Circuit rejected that argument, finding that Nucleonics had failed to show that it was "engaged in any present activity that could subject it to a claim of infringement by Benitec" and had further failed to show a claim of "sufficient immediacy and reality' to support declaratory judgment jurisdiction."³⁸²

Judge Dyk dissented, citing the Supreme Court's holding in *Cardinal Chemical Co. v. Morton International, Inc.*³⁸³ that once declaratory jurisdiction has been established, jurisdiction continues unless the party seeking to divest the court of jurisdiction can prove that there is no longer a current case or controversy.³⁸⁴ Thus, even if the patentee's infringement claim becomes moot, "a counterclaim for invalidity should not be dismissed unless the patentee demonstrates that there is no possibility of a future controversy with respect to invalidity." *Cardinal Chemical* reversed the Federal Circuit's initial holding

^{374.} *Id.* at 1370, 84 U.S.P.Q.2d (BNA) at 1432 (quoting SanDisk Corp. v. STMicroelectronics, Inc., 480 F.3d 1372, 1381, 82 U.S.P.Q.2d (BNA) 1173, 1180 (Fed Cir 2007))

^{375. 495} F.3d 1340, 83 U.S.P.Q.2d (BNA) 1449 (Fed. Cir. 2007).

^{376.} *Id.* at 1345, 83 U.S.P.Q.2d (BNA) at 1453.

^{377. 545} U.S. 193, 74 U.S.P.Q.2d 1801 (2005).

^{378.} Benitec, 495 F.3d at 1342–43, 83 U.S.P.Q.2d (BNA) at 1451.

^{379.} *Id.* at 1343, 83 U.S.P.Q.2d (BNA) at 1451.

^{380.} Id., 83 U.S.P.Q.2d (BNA) at 1451.

^{381.} Id., 83 U.S.P.Q.2d (BNA) at 1451.

^{382.} Id. at 1348-49, 83 U.S.P.Q.2d (BNA) at 1456.

^{383. 508} U.S. 83, 26 U.S.P.Q.2d (BNA) 1721 (1993).

^{384.} Benitec, 495 F.3d at 1352, 83 U.S.P.Q.2d (BNA) at 1458 (Dyk, J., dissenting).

^{385.} Id. at 1350, 83 U.S.P.Q.D.2d (BNA) at 1456.

"that a finding of non-infringement moots a declaratory counterclaim for invalidity," according to Judge Dyk. 386

E. Motion to Dismiss

A motion to dismiss for failure to state a claim upon which relief can be granted is a purely procedural question not pertaining to patent law. Thus, on review the Federal Circuit applies the law of the regional circuit.387

In McZeal v. Sprint Nextel Corp., 388 the Federal Circuit reversed the district court's dismissal of a pro se plaintiff's complaint for failure to adequately state a claim for patent and trademark infringement.³⁸⁹ The court, relying on the law of the regional circuit, noted that the bar for pro se litigants may be lower than that for litigants represented by an attorney.³⁹⁰ McZeal met this low bar, according to the majority, by pleading that he owned the patent and trademark in question and that they were infringed by the defendants' Motorola i930 and related cell phone products. 991 It was not necessary for McZeal to know how the accused devices worked for the purpose of satisfying Rule 12(b)(6). 392 Nor was it proper for the district court at the pleading stage to determine that McZeal's trademark is invalid as generic, which is a question of fact.393

Judge Dyk dissented with respect to the majority's vacatur of the dismissal of the patent infringement claim.³⁹⁴ Since the claim was predicated on the doctrine of equivalents, Judge Dyk argued that even a pro se plaintiff was required to plead with more specificity regarding which limitations were infringed literally or by equivalents and how the accused product was insubstantially different from the claims. 395

In RFR Industries, Inc. v. Century Steps, Inc., 396 the Federal Circuit affirmed the district court's dismissal of the action pursuant to Rule 41(a)(1)(i) of the Federal Rules of Civil Procedure, which authorizes a plaintiff to dismiss the action without a court order by filing a no-

^{386.} Id. at 1352, 83 U.S.P.Q.D.2d (BNA) at 1458.

^{387.} See, e.g., C&F Packing Co. v. IBP, Inc., 224 F.3d 1296, 1306, 55 U.S.P.Q.2d (BNA) 1865, 1872 (Fed. Cir. 2000) (applying Seventh Circuit jurisprudence to a motion to dismiss in a patent law case)

^{388. 501} F.3d 1354, 84 U.S.P.Q.2d (BNA) 1315 (Fed. Cir. 2007).

^{389.} *Id.* at 1355, 84 U.S.P.Q.2d (BNA) at 1316.

^{390.} *Id.* at 1356, 84 U.S.P.Q.2d (BNA) at 1317. 391. *Id.* at 1358, 84 U.S.P.Q.2d (BNA) at 1318.

^{392.} *Id.* at 1357–58, 84 U.S.P.Q.2d (BNA) at 1317–18. 393. Id. at 1358, 84 U.S.P.Q.2d (BNA) at 1318.

^{394.} *Id.* at 1359–61, 84 U.S.P.Q.2d (BNA) at 1319–21 (Dyk, J., dissenting).

^{395.} Id., 84 U.S.P.Q.2d (BNA) at 1319–21.

^{396. 477} F.3d 1348, 81 U.S.P.Q.2d (BNA) 1915 (Fed. Cir. 2007).

tice before the defendant serves its answer. 397 In this case, Century claimed Rule 41(a)(1)(i) did not apply because it had faxed its answer to the complaint before RFR voluntarily dismissed the action.³⁹⁸ The Federal Circuit disagreed, finding there was no "exceptional good cause" exception to Rule 5(b)(2)'s requirement that service by fax be consented to in writing.³⁹⁹ The court further noted that, according to the advisory committee notes for Rule 5, consent to service by fax "must be express, and cannot be implied from conduct." 400

The Federal Circuit also affirmed the district court's order granting the plaintiff's motion for voluntary dismissal in Walter Kidde Portable Equipment, Inc. v. Universal Security Instruments, Inc., 401 despite certain harmless legal errors. In what the court described as a "tortuous procedural history," Kidde filed a complaint ("Kidde I"), which Defendant Universal Security Instruments ("USI") moved to dismiss for improper venue and lack of standing because Kidde allegedly did not own the patent at the time it filed suit. 402 The district court denied the motion without addressing the standing issue, and the parties proceeded to litigate Kidde I.403 However, Kidde eventually moved to dismiss the action after the court granted USI's motion to exclude Kidde's expert reports as untimely and began to examine Kidde's standing more closely.404 On the same day, Kidde filed a new action ("Kidde II") in which it sought to resolve the standing issue by pointing to a corrected assignment of the patent at issue. 405 The district court dismissed Kidde I without prejudice or conditions, and USI appealed.406

The Federal Circuit concluded that the district court had acted within its discretion in dismissing *Kidde I* without prejudice or conditions.407 USI had not shown any severe prejudice, the court found, because USI could rely on the same factual and legal resources in Kidde II that it had developed in Kidde I. Furthermore, the in limine ruling excluding Kidde's expert reports was due to the timing of trial, and thus did not convey any rights to USI that were improp-

^{397.} Id. at 1349, 81 U.S.P.Q.2d (BNA) at 1916–17.

^{398.} *Id.* at 1350–51, 81 U.S.P.Q.2d (BNA) at 1917. 399. *Id.* at 1351–52, 81 U.S.P.Q.2d (BNA) at 1918.

^{400.} Id. at 1352, 81 U.S.P.Q.2d (BNA) at 1918.

^{401. 479} F.3d 1330, 81 U.S.P.Q.2d (BNA) 1929 (Fed. Cir. 2007). 402. *Id.* at 1332–33, 81 U.S.P.Q.2d (BNA) at 1930. 403. *Id.* at 1333–34, 81 U.S.P.Q.2d (BNA) at 1931–32.

^{404.} *Id.* at 1334, 81 U.S.P.Q.2d (BNA) at 1931–32.

^{405.} *Id.*, 81 U.S.P.Q.2d (BNA) at 1931–32. 406. *Id.*, 81 U.S.P.Q.2d (BNA) at 1931–32.

^{407.} *Id.* at 1337–38, 81 U.S.P.Q.2d (BNA) at 1934–35.

^{408.} Id. at 1337, 81 U.S.P.Q.2d (BNA) at 1934.

erly taken away when $Kidde\ I$ was dismissed. However, the Federal Circuit found the district court had erred in dismissing USI's counterclaims and failing to resolve the standing issue when it dismissed Kidde I.410 Nonetheless, these were harmless errors, which did not warrant a remand, because USI could reassert its counterclaims in Kidde II, and Kidde resolved the standing question before filing Kidde $II.^{411}$

In General Mills, Inc. v. Kraft Foods Global, Inc. 412 (General Mills II), the Federal Circuit initially affirmed the district court's decision that Kraft did not have a counterclaim pending at the time judgment was entered.413 Although Kraft responded to General Mills' original complaint with a counterclaim, Kraft later secured the dismissal of General Mills' subsequently filed amended complaint. The Federal Circuit held that Kraft did not "toll its deadline to answer the amended complaint and reassert its counterclaim" by filing its motion to dismiss. 415 "Accordingly, [the Federal Circuit] concluded that the district court did not abuse its discretion in refusing to permit Kraft to reassert the counterclaim after the motion to dismiss was granted."416 Kraft subsequently petitioned for rehearing, arguing that the Federal Circuit "misapprehended Rule 12 of the Federal Rules of Civil Procedure."417

The Federal Circuit did not agree, stating "[o]ur holding is narrower than Kraft's petition suggests. We did not and do not hold that the tolling provision of Rule 12(a)(4)(A) never applies to responses to amended pleadings."418 According to the court,

Rule 15(a), which sets the deadline for answering an amended pleading, has two prongs: "A party shall plead in response to an amended pleading [(1)] within the time remaining for response to the original pleading or [(2)] within 10 days after service of the amended pleading, whichever period may be the longer." Ordinarily, the time remaining for response to the original pleading" will be defined by one of the periods of time enumerated in Rule 12(a) and tolled by Rule 12(a)(4)(A). Thus, when there is time remaining for response to the original pleading-for example,

^{409.} *Id.* at 1338, 81 U.S.P.Q.2d (BNA) at 1935. 410. *Id.* at 1339–43, 81 U.S.P.Q.2d (BNA) at 1934–36.

^{411.} Id., 81 U.S.P.Q.2d (BNA) at 1934-36.

^{411.} *Id.*, 61 U.S.F.Q.2d (BNA) at 1534–50. 412. 495 F.3d 1378, 83 U.S.P.Q.2d (BNA) 1606 (Fed. Cir. 2007). 413. Gen. Mills, Inc. v. Kraft Foods Global, Inc. (*Gen. Mills I*), 487 F.3d 1368, 1376–77, 82 U.S.P.Q.2d (BNA) 1773, 1778 (Fed. Cir. 2007).

^{414.} Gen. Mills II, 495 F.3d at 1378–79, 83 U.S.P.Q.2d (BNA) at 1607.

^{415.} *Id.* at 1379, 83 U.S.P.Q.2d (BNA) at 1607. 416. *Id.*, 83 U.S.P.Q.2d (BNA) at 1607. 417. *Id.*, 83 U.S.P.Q.2d (BNA) at 1607.

^{418.} Id., 83 U.S.P.Q.2d (BNA) at 1607.

when a plaintiff amends her complaint as a matter of right before serving the defendant or before the defendant answers—the first prong of Rule 15(a) (which refers to a deadline that is tolled by Rule 12(a)(4)(A)) becomes the longer of the two prongs, and the extended deadline of Rule 12(a)(4) controls. 419

Kraft then argued in its petition that the Federal Circuit decision "undermines the 'clearly expressed intent' of Rule 12—to permit certain defenses, including failure to state a claim upon which relief can be granted, to be raised by motion instead of in a responsive pleading."420 The Federal Circuit again disagreed, stating "where the meaning of Rule 12 is unambiguous, we decline to ignore the text of the rule in service of a purported purpose."421 The court further stated that "[t]he language of the rule is unambiguous: Rule 12(a)(4) does not extend the time for filing an answer to an amended complaint when 'the time remaining for response to the original pleading' has elapsed."422

F. Standing

"The doctrine of standing limits federal judicial power and has both constitutional and prudential components."423 Constitutional standing requires only that a plaintiff have suffered an injury in fact, that there be a causal connection between the injury and a defendant's conduct, and that the injury be redressable by a favorable court decision. 424

The Federal Circuit addressed the issue of standing in MyMail, Ltd. v. America Online, Inc. 425 MyMail acquired the pending patent application that became the patent at issue ("the '290 patent") through an assignment from an individual, who had obtained it "through a state court foreclosure action on a promissory note secured by the application."426 Defendants asserted that the promissory note was fraudulent, which meant MyMail's chain of title was insufficient to establish ownership of the '290 patent or to create standing to bring an infringement action.427

^{419.} Id., 83 U.S.P.Q.2d (BNA) at 1607 (additional internal quotations omitted) (citing FED. R. CIV. P. 15(a)).

^{420.} Id., 83 U.S.P.Q.2d (BNA) at 1607.

^{421.} Id., 83 U.S.P.Q.2d (BNA) at 1607.

^{422.} *Id.*, 83 U.S.P.Q.2d (BNA) at 1607 (citing FED. R. CIV. P. 15(a)). 423. Media Techs. Licensing, LLC v. Upper Deck Co., 334 F.3d 1366, 1369, 67 U.S.P.Q.2d (BNA) 1374, 1376 (Fed. Cir. 2003).

^{424.} Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992).

^{425. 476} F.3d 1372, 81 U.S.P.Q.2d (BNA) 1832 (Fed. Cir. 2007).

^{426.} *Id.* at 1375, 81 U.S.P.Q.2d (BNA) at 1834.

^{427.} Id., 81 U.S.P.Q.2d (BNA) at 1834.

The Federal Circuit disagreed and affirmed the district court's finding that the state court judgment through which the individual had acquired the application was not subject to collateral attack in the federal case. 428 In so holding, the court rejected the defendants' reliance on cases involving inequitable conduct in their attempt to show that, "as a matter of law, anyone can assert fraud at any time." 429 The Federal Circuit explained that "[f]raud in the procurement bears on the enforceability of the patent and thus implicates the public's interest in ensuring that the grant of patent rights is legitimate."430 MyMail, on the other hand, dealt with patent ownership, a property matter dealt with by state law. 431

In PODS, Inc. v. Porta Stor, Inc., 432 the Federal Circuit determined that Porta Stor "lack[ed] standing to appeal the jury's finding of a violation of the Florida Deceptive and Unfair Trade Practices Act."433 There had been no award of damages, no injunction, and no award of attorney's fees, and PODS had not sought a declaratory judgment.434 Thus, Porta Stor was seeking no more than a "review of unfavorable findings," which was insufficient to create standing. 435 Pursuant to Penda Corp. v. United States, 436 "the law is well-settled that a party lacks standing to appeal from a judgment by which it is not aggrieved."437

The Federal Circuit also examined standing in the context of federal research grants in Central Admixture Pharmacy Services, Inc. v. Advanced Cardiac Solutions, P.C. 438 In that case, co-plaintiff Dr. Buckberg had performed research under a grant from the National Institutes of Health ("NIH"), which led to the '515 patent at issue. 439 The grant entitled the federal government to certain rights in the patent under the Bayh-Dole Act, 35 U.S.C. §§ 200–212. 440 Defendant Advanced Cardiac Solutions argued that Central Admixture Pharmacy Services ("CAPS") lacked standing because Dr. Buckberg had failed to exe-

^{428.} Id., 81 U.S.P.Q.2d (BNA) at 1834.

^{429.} Id. at 1375, 81 U.S.P.Q.2d (BNA) at 1834.

^{430.} *Id.* at 1375–76, 81 U.S.P.Q.2d (BNA) at 1834–35.

^{431.} *Id.* at 1376, 81 U.S.P.Q.2d (BNA) at 1835.

^{432. 484} F.3d 1359, 82 U.S.P.Q.2d (BNA) 1553 (Fed. Cir. 2007). 433. *Id.* at 1366, 82 U.S.P.Q.2d (BNA) at 1557.

^{434.} Id., 82 U.S.P.Q.2d (BNA) at 1557.

^{435.} Id., 82 U.S.P.Q.2d (BNA) at 1557 (citing Penda Corp. v. United States, 44 F.3d 967, 972, 33 U.S.P.Q.2d (BNA) 1200, 1203 (Fed. Cir. 1994)).

^{436. 44} F.3d 967, 33 Û.S.P.Q.2d (BNA) 1200 (Fed. Cir. 1994).

^{437.} Pods, 484 F.3d at 1366, 82 U.S.P.Q.2d (BNA) at 1557 (quoting Penda Corp., 44 F.3d at 971, 33 U.S.P.Q.2d (BNA) at 1203).

^{438. 482} F.3d 1347, 82 U.S.P.Q.2d (BNA) 1293 (Fed. Cir. 2007).

^{439.} *Id.* at 1351, 82 U.S.P.Q.2d (BNA) at 1295–96.

^{440.} Id., 82 U.S.P.Q.2d (BNA) at 1296.

cute a license, as required by the NIH. 441 The Federal Circuit rejected this argument, finding that the Bayh-Dole Act gives the government only discretionary authority to take title but does not mandate such a transfer.442 Because NIH had made no effort to take title to Dr. Buckberg's invention, the patent remained with Dr. Buckberg, which meant his exclusive license to CAPS was valid, and CAPS had sufficient standing to sue for infringement. 443 In so holding, the court distinguished Campbell Plastics Engineering & Manufacturing, Inc. v. Brownlee, 444 in which title to a patent had been forfeited to the federal government after it had demanded those rights from a contractor, who had failed to disclose the invention. 445

In Propat International Corp. v. RPost, Inc., 446 the plaintiff Propat had been granted responsibility by patentee Authentix to license its patent, enforce license agreements, and sue infringers.447 The district court found that Propat did not have standing to sue without joining Authentix because Propat was not the owner of the patent but only a bare licensee, lacking any proprietary or substantial rights in the patent. 448 Accordingly, the district court dismissed the case without prejudice and without ruling on Propat's motion to join Authentix. 449

The Federal Circuit affirmed. 450 Propat had not been assigned any right to make, use, and sell the patented invention but had received only a share of licensing royalties and any judgment or settlement resulting from litigation. 451 Authentix, on the other hand, retained "an economic interest in the patent and a substantial measure of control over decisions affecting the patent rights."452 Moreover, Propat was obligated to notify Authentix of targets for licensing or suit and obtain Authentix's consent before proceeding. 453 Authentix thus retained the "right to veto any transfer of Propat's rights under the agreement," even if it did so "arbitrarily," as well as the right to terminate the contract if Propat failed to meet certain conditions. 454 The Federal Circuit concluded that Authentix "retains sufficient

441. Id. at 1352, 82 U.S.P.Q.2d (BNA) at 1296.

^{442.} *Id.* at 1352–53, 82 U.S.P.Q.2d (BNA) at 1297.

^{443.} *Id.* at 1353, 82 U.S.P.Q.2d (BNA) at 1297.

^{444. 389} F.3d 1243, 73 U.S.P.Q.2d (BNA) 1357 (Fed. Cir. 2004).

^{445.} Central Admixture, 482 F.3d at 1352, 82 U.S.P.Q.2d (BNA) at 1296.

^{446. 473} F.3d 1187, 81 U.S.P.Q.2d (BNA) 1350 (Fed. Cir. 2007).

^{447.} Id. at 1189, 81 U.S.P.Q.2d (BNA) at 1352.

^{448.} *Id.* at 1188–89, 81 U.S.P.Q.2d (BNA) at 1351.

^{449.} Id., 81 U.S.P.Q.2d (BNA) at 1351.

^{450.} Id. at 1189, 81 U.S.P.Q.2d (BNA) at 1351.

^{451.} *Id.* at 1190–91, 81 U.S.P.Q.2d (BNA) at 1352–53. 452. *Id.* at 1191, 81 U.S.P.Q.2d (BNA) at 1353.

^{453.} Id., 81 U.S.P.Q.2d (BNA) at 1353.

^{454.} Id., 81 U.S.P.Q.2d (BNA) at 1353.

rights in the patent that it cannot be said to have assigned 'all substantial rights' in the patent to Propat."455

In Israeli Bio-Engineering Project v. Amgen Inc., 456 the Federal Circuit found that Israeli Bio-Engineering Project ("IBEP") lacked standing to sue in its own name because it did not have full ownership of the patent in dispute and could not voluntarily join the co-owner of the patent. 457 In particular, it was argued that certain inventors of claims two and three of the patent at issue had an ownership interest in those claims because work on the project that resulted in the invention described in those claims had not begun until after the contract assigning all patents to IBEP had expired. 458 The Federal Circuit affirmed the district court's summary judgment that IBEP lacked standing to sue for infringement. 459

Non-party standing was the issue in Nisus Corp. v. Perma-Chink Systems, Inc., 460 in which the parties settled their infringement dispute after the district court had found the patent unenforceable due to inequitable conduct. 461 An attorney involved in prosecution of the unenforceable patent moved to intervene to amend and reconsider the judgment. 462 The district court denied the motions. 463

The Federal Circuit affirmed. 464 Ordinarily, non-parties do not have standing to appeal from judgments of a district court, even when the non-party alleges that the judgment has an adverse impact on him. 465 Although there are rare exceptions when an attorney is sanctioned by the court in the course of litigation, those cases required some change in the legal rights of the non-party as a result of the court's action. 466 Critical remarks in the record about a non-party are not sufficient to confer standing upon that non-party. 467 The Federal Circuit further pointed out that allowing attorneys (or members of other professions) to appeal mere criticisms would stretch the concept of collateral proceedings into an unrecognizable form. 468 The court thus affirmed the district court's denial of the attorney's

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455. Id. at 1190-91, 81 U.S.P.Q.2d (BNA) at 1353.
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^{456. 475} F.3d 1256, 81 U.S.P.Q.2d (BNA) 1558 (Fed. Cir. 2007).

^{457.} Id. at 1258, 1268, 81 U.S.P.Q.2d (BNA) at 1560, 1568.

^{458.} *Id.* at 1261–62, 81 U.S.P.Q.2d (BNA) at 1562–63.

^{459.} *Id.* at 1268, 81 U.S.P.Q.2d (BNA) at 1568.

^{460. 497} F.3d 1316, 83 U.S.P.Q.2d (BNA) 1758 (Fed. Cir. 2007).

^{461.} *Id.* at 1318, 83 U.S.P.Q.2d (BNA) at 1758–59.

^{462.} *Id.*, 83 U.S.P.Q.2d (BNA) at 1758–59.

^{463.} *Id.*, 83 U.S.P.Q.2d (BNA) at 1758–59. 464. *Id.*, 83 U.S.P.Q.2d (BNA) at 1759.

^{465.} *Id.*, 83 U.S.P.Q.2d (BNA) at 1759. 466. *Id.* at 1319, 83 U.S.P.Q.2d (BNA) at 1759–60.

^{467.} *Id.* at 1319–21, 83 U.S.P.Q.2d (BNA) at 1760–61.

^{468.} Id. at 1320, 83 U.S.P.Q.2d (BNA) at 1760.

motion to intervene, although it noted that "[t]o the extent that an individual is harmed by the mere existence of a statement in an opinion, that individual 'is free to petition for a writ of mandamus, ... and request that offending commentary be expunged from the public record." 469

In Hydril Co. LP v. Grant Prideco LP, 470 the question was whether Hydril could state a Walker Process 471 fraud claim based on Grant Prideco's threat to bring infringement suits against Hydril's customers. 472 The district court dismissed Hydril's antitrust claim "[b]ecause Hydril ha[d] failed to allege enforcement activity by Grant Prideco which would create an objectively reasonable apprehension that Grant Prideco intended to enforce the '631 Patent against Hydril." 473 The district court also dismissed the patent claim on the ground that the parties had waived their right to sue for patent infringement in their merger agreement, which left breach of contract as the only available remedy for such claims. 474 Having dismissed Hydril's federal claims, "the district court declined to exercise 'supplemental jurisdiction' over the 'state law breach of contract claim.'"

The Federal Circuit reversed the district court's dismissal of the Walker Process fraud claim and its determination that the merger agreement barred a claim for patent infringement.476 The court noted that if Hydril could prove allegations that Grant Prideco had withheld material prior art, it could state a claim for a violation of § 2 of the Sherman Act. 477 The court also found that "a valid Walker Process claim may be based upon enforcement activity directed against the plaintiff's customers" because threatening to bring patent infringe-

^{469.} Id. at 1322, 83 U.S.P.Q.2d (BNA) at 1761 (quoting In re Williams, 156 F.3d 86, 92 (1st Cir. 1998))

^{470. 474} F.3d 1344, 81 U.S.P.Q.2d (BNA) 1507 (Fed. Cir. 2007).

^{471.} Walker Process Equipment, Inc. v. Food Machinery & Chemical Co., 382 U.S. 172, 147 U.S.P.Q. (BNA) 404 (1965), involved patent fraud under the Sherman Act. In essence, Walker Process fraud is common law fraud applied to a patentee's conduct in patent prosecution. It is more difficult to establish than inequitable conduct because the plaintiff must show that there was either fraudulent misrepresentation or fraudulent omission in the prosecution of a patent with a clear intent to deceive the examiner, resulting in an invalid patent. Id. at 177-78, 147 U.S.P.Q. (BNA) at 406-07. In addition, the patentee must have been aware of the fraud when bringing suit to enforce its patent. *Id.*, 147 U.S.P.Q. (BNA) at 406–07. Finally, there must also be a violation of the antitrust laws. *Id.*, 147 U.S.P.Q. (BNA) at 405–07.

^{472.} Hydril Co., 474 F.3d at 1346, 81 U.S.P.Q.2d (BNA) at 1509–10.

^{473.} *Id.* at 1348, 81 U.S.P.Q.2d (BNA) at 1511 (first alteration in original) (quoting Hydril Co., L.P. v. Grant Prideco L.P., 385 F. Supp. 2d 609, 612 (S.D. Tex. 2005)).

^{474.} *Id.*, 81 U.S.P.Q.2d (BNA) at 1511. 475. *Id.*, 81 U.S.P.Q.2d (BNA) at 1511.

^{476.} Id. at 1353, 81 U.S.P.Q.2d (BNA) at 1514–15.

^{477.} Id. at 1349, 81 U.S.P.Q.2d (BNA) at 1511.

ment suits against customers to cause them to stop dealing with their suppliers "is the kind of economic coercion that the antitrust laws are intended to prevent."478

As for the alleged waiver of the right to sue for patent infringement, the court determined that

[i]n view of the length and detail relating to all aspects of the merger set forth in the Merger Agreement, the text of which occupies [forty-seven] pages of the joint appendix, one would think that if the parties intended to preclude the patent infringement suits, they would have explicitly so provided. 479

Further, "[a]lthough in other contexts patent infringement sometimes has been referred to as a tort, the term 'tort' . . . cannot properly be read to cover a claim for patent infringement."480

Judge Mayer dissented with respect to the antitrust claim. Hydril had only alleged competing with Grant Prideco outside the United States, which ruled out standing to bring a Walker Process claim, he wrote. 482 Judge Mayer also would have affirmed the district court's determination that the parties had waived any patent infringement claims, finding that such claims were covered by the term "tort" in the parties' merger agreement. 483

In Biotechnology Industry Organization v. District of Columbia, 484 the Federal Circuit concluded that Biotechnology Industry Organization and another industry group had standing to challenge the constitutionality of the District of Columbia's Excessive Pricing Act. 485 The Act made it "unlawful for any drug manufacturer or licensee . . . to sell or supply for sale or impose minimum resale requirements for a patented prescription drug that results in the prescription drug being sold in the District for an excessive price."486 The plaintiffs alleged that the Act violated the Commerce Clause of the Constitution by seeking to control prices outside the District and was preempted by federal patent law. 487 The district court agreed with the industry groups and issued a permanent injunction preventing the enforcement of the act. 488 The District of Columbia appealed the lower

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478. Id. at 1350, 81 U.S.P.Q.2d (BNA) at 1512.
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^{479.} *Id.* at 1352, 81 U.S.P.Q.2d (BNA) 1514. 480. *Id.*, 81 U.S.P.Q.2d (BNA) at 1514 (citation omitted).

^{481.} *Id.* at 1353, 81 U.S.P.Q.2d (BNA) at 1515 (Mayer, C.J., dissenting).

^{482.} *Id.* at 1353–54, 81 U.S.P.Q.2d (BNA) at 1515.
483. *Id.* at 1355, 81 U.S.P.Q.2d (BNA) at 1515.
484. 496 F.3d 1362, 83 U.S.P.Q.2d (BNA) 1639 (Fed. Cir. 2007), *aff'g* Pharm. Res. & Mfrs. of Am. v. District of Columbia, 406 F. Supp. 2d 56 (D.D.C. 2005).

^{485.} *Id.* at 1371, 83 U.S.P.Q.2d (BNA) at 1646.

^{486.} D.C. Code § 28-4553 (2006)

^{487.} Biotechnology Indus. Org., 496 F.3d at 1366, 83 U.S.P.Q.2d (BNA) at 1642. 488. Id., 83 U.S.P.Q.2d (BNA) at 1642.

court's decision and challenged the standing of the industry organizations to bring the suit. 489 The Federal Circuit affirmed that the plaintiffs had standing because at least one member of the group had "some threatened or actual injury resulting from the putatively illegal action."490

In IpVenture, Inc. v. Prostar Computer, Inc., 491 the court considered whether an organization can have standing if the inventor failed to assign his invention to his previous employer, as directed by his employment agreement with that employer. 492 In particular, IpVenture owned and licensed the patent at issue and others on inventions relating to the management of personal computer systems. 493 The coinventors of the '235 patent included a part owner of IpVenture, who had been working as a patent attorney for Hewlett-Packard Company ("HP") at the time of the invention. 494

IpVenture sued two computer manufacturers, ProStar Computer and Midern Computer, for infringing its '235 patent. 495 The defendants moved to dismiss on the ground that IpVenture lacked standing to sue because one of the inventors had been obligated under his employment contract to assign his '235 patent to HP. 496 The district court agreed and dismissed the suit without prejudice. 497 IpVenture subsequently appealed the dismissal, and the ProStar cross-appealed for attorney fees. 498 The Federal Circuit found the dismissal was in error and vacated the lower court's decision. 499 The inventor's employment agreement with HP used the language "agree to assign," 500 which the Federal Circuit stated was not equivalent to a "does hereby grant" provision, as the district court had concluded. 501 In the absence of any actual written assignment to HP, the Federal Circuit concluded that HP had no immediate ownership interest in the patent, which meant IpVenture held the rights by virtue of an assignment from the inventor. 502

^{489.} Id., 83 U.S.P.Q.2d (BNA) at 1642.

^{490.} Id. at 1370, 83 U.S.P.Q.2d (BNA) at 1645 (quoting Virginia v. Am. Booksellers Ass'n, 484 U.S. 383, 392 (1988))

^{491. 503} F.3d 1324, 84 U.S.P.Q.2d (BNA) 1853 (Fed. Cir. 2007).

^{492.} Id. at 1326, 84 U.S.P.Q.2d (BNA) at 1854.

^{493.} Id. at 1325, 84 U.S.P.Q.2d (BNA) at 1853.

^{494.} Id., 84 U.S.P.Q.2d (BNA) at 1854.

^{495.} Id., 84 U.S.P.Q.2d (BNA) at 1854.

^{496.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1854. 497. *Id.*, 84 U.S.P.Q.2d (BNA) at 1854.

^{498.} Id., 84 U.S.P.Q.2d (BNA) at 1854. 499. Id. at 1327, 84 U.S.P.Q.2d (BNA) at 1855–56.

^{500.} Id., 84 U.S.P.Q.2d (BNA) at 1855.

^{501.} Id., 84 U.S.P.Q.2d (BNA) at 1855.

^{502.} Id., 84 U.S.P.Q.2d (BNA) at 1855.

Furthermore, HP had expressly disclaimed any interest in the patent in a 2005 agreement with IpVenture. 503 Even though HP had executed this agreement after IpVenture had filed the present lawsuit, the Federal Circuit found it was error to disregard it, as it removed any doubt that HP had no rights to the patent and had essentially acknowledged that it could not sue ProStar for infringement.⁵⁰⁴ Consequently, the court concluded that IpVenture had standing to assert the '254 patent on its own and without joining HP. 505

Schwarz Pharma, Inc. v. Paddock Labs., Inc. 506 was a case of first impression in which the Federal Circuit considered whether an exclusive licensee, Schwarz Pharma, had standing to appeal, when the patent owner, Warner-Lambert, which had participated in the original suit, declined to join the appeal.⁵⁰⁷ Paddock Labs argued that Schwarz Pharma lacked standing without Warner-Lambert. 508 Schwarz Pharma responded that joinder of the patent owner by an exclusive licensee is merely prudential and not constitutional. ⁵⁰⁹ The Federal Circuit concluded, "Warner-Lambert need not have joined in the appeal and Schwarz has standing to appeal on its own" because Warner-Lambert had already had an opportunity to protect its interests as a plaintiff in the original lawsuit. 510 Thus, this case satisfied the Supreme Court's directives in Independent Wireless Telegraph Co. v. Radio Corp. of America, 511 in which the Court held that a patent owner should be joined so that "a patent should not be placed at risk of invalidation by the licensee without the participation of the patentee."512 Warner-Lambert's presence in the original action also "enable[d] the alleged infringer to respond in one action to all claims of infringement for his act, and thus either to defeat all claims in the one action, or by satisfying one adverse decree to bar all subsequent actions."513 Thus, the Federal Circuit found no need to join Warner-Lambert in the appeal.

The Federal Circuit also addressed a question of first impression in Morrow v. Microsoft Corporation, 514 in which it considered "how bankruptcy or trust law relationships affect the standing analysis in a pat-

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503. Id., 84 U.S.P.Q.2d (BNA) at 1855.
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^{504.} *Id.* at 1326–27, 84 U.S.P.Q.2d (BNA) at 1855–56. 505. *Id.*, 84 U.S.P.Q.2d (BNA) at 1855.

^{506. 504} F.3d 1371, 84 U.S.P.Q.2d (BNA) 1900 (Fed. Cir. 2007).

^{507.} Id. at 1373, 84 U.S.P.Q.2d (BNA) at 1902.

^{508.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1902.

^{509.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1902.

^{510.} *Id.* at 1374, 84 U.S.P.Q.2d (BNA) at 1903.

^{511.} 269 U.S. 459 (1926).

^{512.} Schwarz Pharma, 504 F.3d at 1374, 84 U.S.P.Q.2d (BNA) at 1903.

^{513.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1903.

^{514. 499} F.3d 1332, 84 U.S.P.Q.2d (BNA) 1377 (Fed. Cir. 2007).

ent infringement case."515 After internet service provider At Home Corporation ("AHC") went bankrupt, the liquidation agreement created three separate trusts-the At Home Liquidating Trust ("AHLT"), the General Unsecured Creditors' Liquidating Trust ("GUCLT"), and the Bondholders Liquidating Trust ("BHLT"). 516 In pertinent part, AHLT was given ownership and liquidation rights in AHC's intellectual property, including the '647 patent at issue, but not the right to bring suit. 517 GUCLT, on the other hand, received the rights to all causes of action, including patent infringement, but did not receive any ownership or liquidation rights under the '647 or other patents.⁵¹⁸

GUCLT's trustee subsequently sued Microsoft for infringement of the ACH's '647 patent.⁵¹⁹ The district court denied Microsoft's motion to dismiss for lack of standing, citing GUCLT's status as trust beneficiary and other bankruptcy principles, but granted Microsoft's motion for summary judgment of non-infringement.⁵²⁰ The trustees for GUCLT and AHLT appealed the non-infringement ruling, while Microsoft cross-appealed the ruling on standing. 521

The Federal Circuit reversed the lower court's ruling on standing and vacated the non-infringement ruling as moot.⁵²² Although the parties' rights were granted through bankruptcy law, their standing must be determined according to the patent laws, which "govern the creation and protection of patent rights, how rights can be transferred, and the parties entitled to assert those rights[,]"523 including "when patent rights have been transferred as a result of bankruptcy or proceedings in equity" or "[w]here parties have contractually divided patent rights." 524 Of particular importance was the principle that the party holding the exclusionary rights to the patent is the one that suffers legal injury when another party infringes the patent. 525

Plaintiffs in patent infringement suits can be divided into three general categories for standing purposes.⁵²⁶ The first category consists of those who can sue in their own name alone because they hold

^{515.} Id. at 1336, 84 U.S.P.Q.2d (BNA) at 1380.

^{516.} Id. at 1335, 84 U.S.P.Q.2d (BNA) at 1379.

^{517.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1379.

^{518.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1379. 519. *Id.*, 84 U.S.P.Q.2d (BNA) at 1379.

^{520.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1379–80.

^{521.} *Id.* at 1336, 84 U.S.P.Q.2d (BNA) at 1380.

^{522.} Id. at 1344, 84 U.S.P.Q.2d (BNA) at 1385.

^{523.} *Id.* at 1336, 84 U.S.P.Q.2d (BNA) at 1380. 524. *Id.* at 1337, 84 U.S.P.Q.2d (BNA) at 1381.

^{525.} *Id.* at 1339, 84 U.S.P.Q.2d (BNA) at 1382.

^{526.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1382.

or have been assigned all rights or all substantial rights to the patent. 527 The second category consists of those who do not hold all the substantial rights to the patent but hold sufficient exclusionary rights and interests that they suffer injury by the infringing acts of another. 528 Accordingly, this category of plaintiffs, which includes exclusive licensees, can sue as long as the patent owner is joined in the suit. 529 The third and final category of patent plaintiffs consists of those who do not hold all substantial rights or sufficient exclusionary rights to meet the injury requirement for standing and thus cannot participate as a party to the infringement suit even if joined with another.51

In this case,

[t]he question is whether GUCLT's interests in the patent include sufficient exclusionary rights such that GUCLT suffers an injury in fact from infringing activities. If GUCLT holds all substantial rights, it can sue in its name alone. If GUCLT holds less than all substantial rights but sufficient exclusionary rights that it suffers injury in fact, it can sue as a co-party with legal title holder AHLT. If it lacks injury in fact, GUCLT lacks standing to be a party to this case.531

According to the majority, "[t]he problem for GUCLT and AHLT is that the exclusionary rights have been separated from the right to sue for infringement."532 Although GUCLT had the right to sue for patent infringement, that right was not unlimited, for GUCLT could not sue controlling shareholders or settle a lawsuit without AHLT's approval. Thus, GUCLT lacked sufficient exclusionary rights to suffer legal injury from infringement. 534 Those exclusionary rights belonged instead to AHLT, which held the title to the patent as well as the rights to sell, grant, transfer, or license any rights under the patent to another party. 535 Even though AHLT required the consent of GUCLT and BHLT to transfer its patent rights, the majority found this was not a substantial restriction and did not transfer any exclusionary rights to GUCLT. 536 Moreover, there was no restriction on the parties to whom AHLT could transfer its exclusionary rights or to

^{527.} Id., 84 U.S.P.Q.2d (BNA) at 1382.

^{528.} Id. at 1339-40, 84 U.S.P.Q.2d (BNA) at 1382-83.

^{529.} *Id.* at 1340, 84 U.S.P.Q.2d (BNA) at 1383. 530. *Id.* at 1339–41, 84 U.S.P.Q.2d (BNA) at 1382–83.

^{531.} *Id.* at 1341, 84 U.S.P.Q.2d (BNA) at 1383–84.

^{532.} *Id.* at 1342, 84 U.S.P.Q.2d (BNA) at 1384.

^{533.} Id., 84 U.S.P.Q.2d (BNA) at 1384.

^{534.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1384. 535. *Id.*, 84 U.S.P.Q.2d (BNA) at 1384.

^{536.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1384.

whom it could confer an exclusive license. 537 As a result, the majority concluded that GUCLT did not have standing to bring suit, even as a co-plaintiff with AHLT. 538

Judge Prost dissented, arguing that GUCLT held "a sufficient bundle of rights to support co-plaintiff standing" with AHLT because neither party could enforce the patent on its own. 539 GUCLT, he further argued, had suffered an injury in fact by virtue of its equitable title to the patent as beneficiary to AHLT, as well as its explicit right to sue as part of the bankruptcy agreement. 540

The lack of exclusionary rights was also the basis for finding that exclusive distributor Mitutoyo America Corporation ("MAC") lacked standing in Mitutoyo Corp. v. Central Purchasing, LLC.541 MAC had joined the patentee Mitutoyo in a suit against Central Purchasing ("Central") for infringement and breach of a 1994 settlement agreement. 542 The Federal Circuit concluded:

In order for a licensee to have co-plaintiff standing, it must hold at least some of the proprietary rights under the patent. Consequently, the pertinent question is whether MAC has the exclusive right to sell products made according to the '902 patent in the United States; the exclusive right to sell only Mitutoyo's products made according to the '902 patent, however, is not a sufficient basis for standing.543

In another question of first impression, the Federal Circuit found that the holder of an "exclusive enterprise license" lacked sufficient exclusionary rights to sue in its own name in International Gamco, Inc. v. Multimedia Games, Inc. 544 An "exclusive enterprise license," the court explained, is "an amalgam of an exclusive territorial license and an exclusive field of use license."545 Specifically, plaintiff Gamco assigned the patent at issue to International Game Technology ("IGT") as part of an asset purchase agreement but reserved to itself the exclusive right to sue for infringement within a particular territory, which was defined as "the lawful operation of lottery games authorized by the New York State Lottery in the state of New York."546 Since Gamco's license contained a field of use restriction ("lottery games"),

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537. Id., 84 U.S.P.Q.2d (BNA) at 1384.
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^{538.} *Id.* at 1343–44, 84 U.S.P.Q.2d (BNA) at 1385–86.

^{539.} *Id.* at 1344, 84 U.S.P.Q.2d (BNA) at 1386 (Prost, J., dissenting).

^{540.} *Id.* at 1344–48, 84 U.S.P.Q.2d (BNA) at 1386–89. 541. 499 F.3d 1284, 1291, 84 U.S.P.Q.2d (BNA) 1001, 1006 (Fed. Cir. 2007).

^{542.} Id. at 1287, 84 U.S.P.Q.2d (BNA) at 1003.

^{543.} *Id.* at 1291, 84 U.S.P.Q.2d (BNA) at 1006 (citation omitted). 544. 504 F.3d 1273, 1280, 84 U.S.P.Q.2d (BNA) 2017, 2022 (Fed. Cir. 2007).

^{545.} Id. at 1274, 84 U.S.P.Q.2d (BNA) at 2018.

^{546.} *Id.* at 1275, 84 U.S.P.Q.2d (BNA) at 2018–19.

the Federal Circuit found that it created the risk that an accused infringer could be subjected to a multiplicity of lawsuits by different persons holding different game-specific rights to the patent. 447 "The problem of a multiplicity of lawsuits arising from an exclusive field of use license is not cured by adding a geographic restriction[,]" the court stated.⁵⁴⁸ Accordingly, the Federal Circuit concluded that Gamco lacked substantial rights in the licensed patent within the licensed territory to sue in its own name, without joining IGT. Judge Friedman, in an opinion dubitante, doubted there was a serious danger of a multiplicity of lawsuits in this case and thus remained unconvinced that Gamco could not sue in its own name. 550

G. Collateral Estoppel

The Federal Circuit has held that issue preclusion (or collateral estoppel) has four prerequisites: (1) an identity of issues between the prior and present proceedings, (2) the issue in question was actually litigated in the prior proceeding, (3) the determination of the issue in the prior proceeding was necessary to the resulting judgment, and (4) the party defending against preclusion had a full and fair opportunity to litigate the issue in the prior proceeding.⁵⁵¹

The absence of the last prerequisite led the court to conclude that the PTO did not have to give preclusive effect to a district court's Markman opinion in In re Trans Texas Holdings Corp. 552 At Trans Texas's request, the PTO reexamined two of Trans Texas's patents on business methods for insulating deposit and loan accounts from inflation and providing stability to financial institutions.⁵⁵³ The PTO, however, refused to give preclusive effect to a claim construction opinion by a district court in an earlier infringement proceeding and eventually rejected all of the claims as obvious.⁵⁵⁴

The Federal Circuit affirmed that the PTO was not bound by the district court's Markman order, emphasizing that it had "never applied issue preclusion *against* a non-party to the first action." Since the PTO was not a party to the earlier litigation, it did not have a "full and fair opportunity to litigate" the claim construction issue, as re-

^{547.} Id. at 1279, 84 U.S.P.Q.2d (BNA) at 2022.

^{548.} Id., 84 U.S.P.Q.2d (BNA) at 2022.

^{549.} *Id.* at 1280, 84 U.S.P.Q.2d (BNA) at 2022.

^{550.} *Id.*, 84 U.S.P.Q.2d (BNA) at 2023 (Friedman, J., dubitante).

^{551.} In n Trans Texas Holdings Corp., 498 F.3d 1290, 1297, 83 U.S.P.Q.2d 1835, 1840 (Fed. Cir. 2007).

^{552.} *Id.*, 83 U.S.P.Q.2d at 1840. 553. *Id.* at 1294, 83 U.S.P.Q.2d at 1838.

^{554.} *Id.* at 1295–96, 83 U.S.P.Q.2d at 1839.

^{555.} Id. at 1297, 83 U.S.P.Q.2d at 1840.

quired for estoppel to apply.⁵⁵⁶ The Federal Circuit also rejected Trans Texas's argument that it had "somehow represented the PTO's interests in the district court action" by arguing against the construction that was ultimately adopted by the district court.⁵⁵⁷ The presumption that a non-party can be bound by a judgment in an earlier proceeding can be rebutted only in limited circumstances, e.g., "when the non-party [is] in privity with the party, has interests that are derivative from a party, or 'participated in an active and controlling way in the earlier litigation." Since none of those exceptions applied here, and the PTO was not a party, the Federal Circuit found that the PTO had properly declined to give preclusive effect to the district court's claim construction. 559

In Abbott Laboratories v. Andrx Pharmaceuticals, Inc., 560 Andrx asserted on appeal that Abbott was "collaterally estopped from seeking a preliminary injunction based on holdings in the preliminary injunction proceedings . . . that all of the asserted claims are invalid or unenforceable."561

The Federal Circuit concluded:

[T]he determinations made in proceedings against defendants Teva and Ranbaxy were not full litigation and decision on the merits for purposes of issue preclusion. Andrx argues that there has been a final resolution on the limited issue of whether there is a substantial question of invalidity of Abbott's patents, but Seventh Circuit law does not support this view. 565

However, the Federal Circuit stated that "[a] determination that there is merely a likelihood of proving invalidity is a determination made solely in terms of probabilities, not certainties and is therefore not full litigation and decision on the merits for purposes of issue preclusion."563 The Federal Circuit determined that "[i]n both the Teva and Ranbaxy cases, the district court judge did not intend to firmly and finally resolve the issue for which preclusion [was] asserted, the validity or enforceability of the Abbott patents, in its preliminary injunction proceedings."564

^{556.} Id., 83 U.S.P.Q.2d at 1840 (internal quotation marks omitted).

^{557.} *Id.*, 83 U.S.P.Q.2d at 1840.

^{558.} Id., 83 U.S.P.Q.2d at 1840 (quoting 18 CHARLES ALAN WRIGHT, ARTHUR R. MILLER, & EDWARD H. COOPER, FEDÊRAL PRACTICE & PROCEDURE § 4449 (2d ed. 2002)).

^{559.} Id. at 1297-98, 83 U.S.P.Q.2d at 1840.

^{560. 473} F.3d 1196, 81 U.S.P.Q.2d (BNA) 1289 (Fed. Cir. 2007).

^{561.} *Id.* at 1200, 81 U.S.P.Q.2d (BNA) at 1290. 562. *Id.* at 1206, 81 U.S.P.Q.2d (BNA) at 1296 (internal quotation marks omitted).

^{563.} Id., 81 U.S.P.Q.2d (BNA) at 1296 (internal quotation marks omitted).

^{564.} Id., 81 U.S.P.Q.2d (BNA) at 1296 (internal quotation marks omitted).

In Transclean Corp. v. Jiffy Lube International, Inc. (Transclean II), 565 "the district court granted summary judgment in favor of Jiffy Lube and ... other defendants ..., holding that under the doctrine of claim preclusion, a judgment against Bridgewood [in a prior litigation barred] Transclean from bringing a separate infringement action against Bridgewood's customers" (i.e., the defendants in the instant litigation). 566 In particular, the Federal Circuit in Transclean I 567 affirmed the judgment against Bridgewood that Bridgewood infringed claims one, two, three, four, and twelve of a patent to which Transclean was the exclusive licensee. 568 Transclean then filed the instant patent infringement suit against the defendants who had purchased the accused devices from Bridgewood. 569

"[T]he trial court granted Jiffy Lube's motion for summary judgment that Transclean was precluded from bringing infringement claims against Jiffy Lube[,]" concluding that Jiffy Lube had satisfied the elements of claim preclusion. 570

First, there was no dispute that the Bridgewood litigation ended in a final judgment on the merits or that the court properly exercised jurisdiction in that matter. Nor did Transclean dispute that Jiffy Lube was in privity with Bridgewood, the defendant in the prior litigation. Finally, Transclean did not dispute that during the first litigation it was aware of Jiffy Lube's use of T-Tech machines and could have brought claims against Jiffy Lube. 571

Transclean argued that its claim should not be precluded because "the law generally allows a patentee to sue manufacturers or sellers and users of an infringing device as joint tortfeasors, and that the law permits multiple suits, just not multiple (i.e., double) recoveries."572

According to the Federal Circuit, "the real question [was] whether the relationship between the defendants and Bridgewood was so close that they were in privity for claim preclusion purposes."⁵⁷³ "[A] manufacturer or seller of a product who is sued for patent infringement typically is not in privity with a party, otherwise unrelated, who does no more than purchase and use the product."574 Defendants argued that Transclean's admission that Bridgewood and its customers

⁴⁷⁴ F.3d 1298, 81 U.S.P.Q.2d (BNA) 1400 (Fed. Cir. 2007). $\emph{Id}.$ at 1301, 81 U.S.P.Q.2d (BNA) at 1401. 565.

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^{567.} Transclean Corp. v. Bridgewood Servs., Inc. (Transclean I), 290 F.3d 1364, 62 U.S.P.Q.2d (BNA) 1865 (Fed. Cir. 2002)

Transclean Corp., 474 F.3d at 1301, 81 U.S.P.Q.2d (BNA) at 1401.

^{569.} *Id.*, 81 U.S.P.Q.2d (BNA) at 1401.

^{570.} Id. at 1302, 81 U.S.P.Q.2d (BNA) at 1402.

^{571.} *Id.* at 1302–03, 81 U.S.P.Q.2d (BNA) at 1402. 572. *Id.* at 1303, 81 U.S.P.Q.2d (BNA) at 1403.

^{573.} Id. at 1305, 81 U.S.P.Q.2d (BNA) at 1404.

^{574.} *Id.* at 1306, 81 U.S.P.Q.2d (BNA) at 1405.

were in privity was "binding because privity is a question of fact that can be admitted." Transclean contended that "privity cannot be admitted because it is a question of law and [the Federal Circuit is] free to determine that Bridgewood and the Participating Defendants were not in privity if that conclusion is supported by the actual facts."

The Federal Circuit concluded that "even if Transclean is correct that the issue should be characterized as a legal conclusion, . . . Transclean should be bound by its concession under the doctrine of judicial estoppel." Thus, the court held that judicial estoppel bound Transclean to its repeated, prior concessions that competitor's customers were in privity with competitor, for claim preclusion purposes, and patentee's infringement claims against defaulting defendants were barred by claim preclusion. ⁵⁷⁸

Interestingly, "[t]he district court previously had entered default judgment in favor of Transclean against several other defendants ('Defaulting Defendants'), none of whom had answered the complaint." According to the Federal Circuit, however, preclusion issues may be raised by a court sua sponte even though the Defaulting Defendants had not pleaded claim preclusion as an affirmative defense. Halthough the general rule is that claim preclusion and issue preclusion must be pleaded, an exception exists where all relevant data and legal records are before the court and the demands of comity, continuity in the law, and essential justice mandate invocation of preclusion principles." As such, the court "believe[d] that as a matter of law and fairness, claim preclusion should bar Transclean's infringement claims against the Defaulting Defendants." The Federal Circuit therefore reversed the judgment against the Defaulting Defendants.

^{575.} Id., 81 U.S.P.Q.2d (BNA) at 1405.

^{576.} *Id.*, 81 U.S.P.Q.2d (BNA) at 1405.

^{577.} *Id.*, 81 U.S.P.Q.2d (BNA) at 1405.

^{578.} *Id.* at 1307, 81 U.S.P.Q.2d (BNA) at 1406.

^{579.} *Id.* at 1301, 81 U.S.P.Q.2d (BNA) at 1401.

^{580.} *Id.* at 1308, 81 U.S.P.Q.2d (BNA) at 1406. 581. *Id.*, 81 U.S.P.Q.2d (BNA) at 1406 (internal quotation marks omitted).

^{582.} *Id.*, 81 U.S.P.Q.2d (BNA) at 1406–07.

^{583.} *Id.*, 81 U.S.P.Q.2d (BNA) at 1407.

H. Trial Procedures

1. Right to a jury trial

The right to a jury trial was a central issue in Shum v. Intel Corp., 584 which stemmed from an unsuccessful venture between Plaintiff Frank Shum and co-defendant Jean-Marc Verdiell.⁵⁸⁵ After the partners had dissolved their joint corporation Radiance Design ("Radiance"), Shum sued Verdiell, his corporation LightLogic, and its purchaser Intel for fraud, unjust enrichment, and other state law claims and asserted a claim for improper inventorship of Verdiell's patents.⁵⁸⁶ In particular, Shum accused Verdill of forming LightLogic to file patent applications in Verdiell's name based on technology developed at Radiance, misrepresenting to the PTO and third parties that Verdiell was the sole inventor of a patent application by Shum, improperly causing the PTO to abandon Shum's application, transferring Radiance's funds to Verdiell's exclusive control, excluding Shum from meetings with Radiance investors, removing Shum as a "principal investigator" from government contracts, and engaging in other questionable activity.54

In pertinent part, the district court dismissed Shum's unjust enrichment claim and granted defendants' motion to bifurcate the trial, with Shum's inventorship claim to be tried before the court and the state law claims to be tried before the jury.⁵⁸⁸ The district court held a bench trial and concluded Shum had not met his burden of proving that he was the inventor of any of the patents at issue. Based on that result, the court granted defendants' motion for summary judgment on Shum's remaining state law claims and entered judgment in their favor. 590 Shum appealed. 591

The Federal Circuit concluded that the district court violated Shum's constitutional right to a jury by holding a bench trial on his inventorship claim before holding a jury trial. 592 The U.S. Supreme Court has held that "only under the most imperative circumstances . . . can the right to a jury trial of legal issues be lost through

^{584. 499} F.3d 1272, 83 U.S.P.Q.2d (BNA) 1933 (Fed. Cir. 2007). 585. *Id.* at 1274–75, 83 U.S.P.Q.2d (BNA) at 1934–35.

^{586.} *Id.* at 1275, 83 U.S.P.Q.2d (BNA) at 1935.

^{587.} *Id.*, 83 U.S.P.Q.2d (BNA) at 1935. 588. *Id.*, 83 U.S.P.Q.2d (BNA) at 1935.

^{589.} *Id.*, 83 U.S.P.Q.2d (BNA) at 1935. 590. *Id.* at 1275–76, 83 U.S.P.Q.2d (BNA) at 1935.

^{591.} Id. at 1276, 83 U.S.P.Q.2d (BNA) at 1935.

^{592.} Id. at 1279, 83 U.S.P.Q.2d (BNA) at 1938.

prior determination of equitable claims." 593 Although Shum's claim for correction of inventorship was an equitable claim with no right to a jury trial, it had common factual issues with his state law claims, including proofs that Shum conceived the invention, the degree of his inventive contribution, and the time and place of conception.⁵⁹⁴ Both the district court and the appellees implicitly recognized these facts were common to both sets of claims when they stated that Shum's state law claims would fail if he was not the inventor. 595 The Federal Circuit thus vacated the district court's determination on inventorship and its summary judgment on the state law claims, and remanded the case for further proceedings.⁵⁹⁶

The Federal Circuit also reversed the district court's dismissal of Shum's unjust enrichment claim because it rested on different elements and was not "merely duplicative and dependent" upon Shum's fraudulent concealment claim, as the lower court had found. 597 Moreover, under California law, unjust enrichment can exist as a separate cause of action where, as here, it is grounded in equitable principles of restitution. 598

Judge Friedman dissented on the Seventh Amendment issue, arguing that Shum had no common-law right to a jury trial on his improper inventorship claim, which was sufficiently different from his state law claims as to justify bifurcation. 599 Judge Friedman also found a "striking parallel" between this case and Markman v. Westview Instruments, Inc., 600 where the Supreme Court found that claim construction was a legal issue exclusively within the province of the court, even though it may be dispositive of the remaining issues to be tried before the jury. 601

In Paice LLC v. Toyota Motor Corp., 602 the Federal Circuit found that a patentee does not necessarily have a Seventh Amendment right to a trial by jury on the question of the reasonable royalty a court may impose on an infringer. 603 Although the court agreed with Paice that

^{593.} Id. at 1276, 83 U.S.P.Q.2d (BNA) at 1936 (quoting Beacon Theaters, Inc. v. Westover, 359 U.S. 500, 510–11 (1959)).

^{594.} *Id.* at 1277, 83 U.S.P.Q.2d (BNA) at 1937–38. 595. *Id.* at 1278, 83 U.S.P.Q.2d (BNA) at 1937.

^{596.} Id. at 1280, 83 U.S.P.Q.2d (BNA) at 1939.

^{597.} *Id.* at 1279–88, 83 U.S.P.Q.2d (BNA) at 1938–39.

^{598.} *Id.* at 1279, 83 U.S.P.Q.2d (BNA) at 1938.

^{599.} *Id.* at 1280, 83 U.S.P.Q.2d (BNA) at 1939 (Friedman, J., dissenting).

^{600. 517} U.S. 370, 38 U.S.P.Q.2d (BNA) 1461 (1996).

^{601.} Shum, 499 F.3d at 1284, 83 U.S.P.Q.2d (BNA) at 1942 (Friedman, J., dissent-

^{602. 504} F.3d 1293, 85 U.S.P.Q.2d (BNA) 1001 (Fed. Cir. 2007).

^{603.} Id. at 1316, 85 U.S.P.Q.2d (BNA) at 1017.

the determination of damages is generally a legal question that invokes the Seventh Amendment, it noted that "not all monetary relief is properly characterized as 'damages.'"604 The Federal Circuit concluded that "the fact that monetary relief is at issue in this case does not, standing alone, warrant a jury trial[,]" and rejected Paice's Seventh Amendment argument. 605

2. District court's interpretation of remand

In E-Pass Technologies, Inc. v. 3Com Corp. 606 (E-Pass II), E-Pass argued that the district court had erred in its interpretation of the previous Federal Circuit opinion, 607 in which the Federal Circuit had vacated and remanded the case to the district court to address the issue of infringement under the proper construction of the term "card." Epass's argument relied in substantial part on the Federal Circuit's statement in E-Pass I that "issues of material fact remain in dispute as to both literal and doctrine of equivalents infringement under the proper construction" of the term "card." However, the Federal Circuit stated that the district court's grant of summary judgment in E-Pass I was vacated and remanded for further proceedings, and by vacating the Federal Circuit signaled that, "although the district court's prior decision rested upon erroneous grounds, a proper claim construction might support a judgment (summary or otherwise) in favor of either party, depending on the evidence and argument submitted to the district court on remand and considered by the district court in the first instance."610

In E-Pass I, the Federal Circuit discussed in detail the claim construction of the term "card" and the district court's error in construing "card" to mean a card with the precise dimensions of a standard credit card. 611 At the conclusion of the discussion, the Federal Circuit emphasized that "under the correct construction of 'card' in this context . . . it may be or may not be that the accused Palm Pilot devices

^{604.} Id., 83 U.S.P.Q.2d (BNA) at 1017.

^{605.} *Id.*, 83 U.S.P.Q.2d (BNA) at 1017.

^{606. 473} F.3d 1213, 81 U.S.P.Q.2d (BNA) 1385 (Fed. Cir. 2007). 607. E-Pass Techs., Inc. v. 3Com Corp. (*E-Pass I*), 343 F.3d 1364, 1365, 67 U.S.P.Q.2d 1947, 1948–49 (BNA) (Fed. Cir. 2004).

^{608.} E-Pass II, 473 F.3d at 1218, 81 U.S.P.Q.2d (BNA) at 1388.

^{609.} E-Pass I, 343 F.3d at 1365, 67 U.S.P.Q.2d (BNA) at 1947. 610. E-Pass II, 473 F.3d at 1218, 81 U.S.P.Q.2d (BNA) at 1388; see id., 81 U.S.P.Q.2d at 1388 ("[W]hen the Supreme Court grants a writ of certiorari, vacates, and remands, it 'does not indicate, nor even suggest, that the lower court's decision was erroneous." (quoting Communities for Equity v. Mich. High Sch. Athletic Ass'n, 459 F.3d 676, 680 (6th Cir. 2006))).

^{611.} E-Pass I, 343 F.3d at 1367–71, 67 U.S.P.Q.2d (BNA) at 1948–52.

literally infringe."612 Indeed, in E-Pass II the Federal Circuit stated that it "could not have intended to foreclose a summary judgment of noninfringement because the record did not yet contain the evidence that the parties would put forward in support of their infringement and noninfringement contentions under the proper construction."613 "Accordingly, the district court correctly concluded that it had the authority to entertain the defendants' motions for summary judgment on remand."614

Summary judgment

The Federal Circuit reviews a district court's grant of summary judgment de novo, "reapplying the standard applicable at the district court."615 Summary judgment is appropriate "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law."616 In deciding such a motion, "[t]he evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor."617

In In re Gabapentin Patent Litigation, 618 the Federal Circuit noted that the district court had previously granted a motion for summary judgment of noninfringement based on Warner Lambert's failure to meet its burden of proof. 619 The district court "determined that Warner Lambert failed to adduce sufficient evidence to establish that the accused products meet the limitation that the anions of a mineral acid do not exceed 20 ppm ('the 20 ppm limitation')."620

The Federal Circuit reversed. The court explained that to prove infringement, Warner Lambert was required to demonstrate that the infringing party's samples contained less than 20 ppm of anions of a mineral acid, as recited in the claims. 622 Warner Lambert submitted pH tests performed by its analytical expert. 623 The Federal Circuit found that the "pH testing can indicate whether a sample contains

^{612.} Id. at 1371, 67 U.S.P.Q.2d (BNA) at 1951-52.

^{613.} E-Pass II, 473 F.3d at 1218, 81 U.S.P.Q.2d (BNA) at 1388.

^{614.} Id., 81 U.S.P.Q.2d (BNA) at 1388-89.

^{615.} Rodime PLC v. Seagate Tech., Inc., 174 F.3d 1294, 1301, 50 U.S.P.Q.2d (BNA) 1429, 1438 (Fed. Cir. 1999).

^{616.} FED. R. CIV. P. 56(c).

^{617.} Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986) (citing Adickes v. S.H. Kress & Co., 398 U.S. 144, 158–59 (1970))

^{618. 503} F.3d 1254, 84 U.S.P.Q.2d (BNA) 1651 (Fed. Cir. 2007).

^{619.} Id. at 1258, 84 U.S.P.Q.2d (BNA) at 1654.

^{620.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1654. 621. *Id.* at 1262, 84 U.S.P.Q.2d (BNA) at 1657.

^{622.} Id., 84 U.S.P.Q.2d (BNA) at 1657.

^{623.} Id. at 1260, 84 U.S.P.Q.2d (BNA) at 1655.

less than 20 ppm of acidic chloride by measuring the pH, or acidity, of the solution and comparing it against a sample with a known amount of acid." The court concluded that the district court erred in granting summary judgment of noninfringement based on Warner Lambert's purported failure to meet its burden of proof. The record showed that "Warner Lambert proffered sufficient evidence to create a genuine issue of material fact regarding whether the accused products met the 20 ppm claim limitation of the . . . patent."

I. United States Patent and Trademark Office Procedures

1. Reissue and recapture

The recapture rule limits the ability of patentees to broaden their patents after issuance. 627 Inventors may seek reissuance of their patent under 35 U.S.C. § 251. 628 If the reissue application is filed within two years of the patent's initial issuance and the patentee "through error without any deceptive intention . . . claim[ed] . . . less than he had a right to [,]" the reissue patent's claims may be broader than the original patent's claims. 629 Section 251 is "remedial in nature, based on fundamental principles of equity and fairness, and should be construed liberally."630 However, the remedial function of the statute is limited. Material that was surrendered in order to obtain issuance cannot be reclaimed via § 251, for "deliberate withdrawal or amendment... cannot be said to involve the inadvertence or mistake contemplated by 35 U.S.C. § 251."631 The Federal Circuit has mandated that "[i]t is critical to avoid allowing surrendered matter to creep back into the issued patent, since competitors and the public are on notice of the surrender and may have come to rely on the consequent

^{624.} Id. at 1262, 84 U.S.P.Q.2d (BNA) at 1657.

^{625.} Id., 84 U.S.P.Q.2d (BNA) at 1657.

^{626.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1657.

^{627.} See Pannu v. Štorz Instruments, Inc., 258 F.3d 1366, 1370–71, 59 U.S.P.Q.2d (BNA) 1597, 1600 (Fed. Cir. 2001) ("The recapture rule 'prevents a patentee from regaining through reissue the subject matter that he surrendered in an effort to obtain allowance of the original claims." (quoting In re Clement, 131 F.3d 1464, 1468, 45 U.S.P.Q.2d (BNA) 1161, 1164 (Fed. Cir. 1997))).

^{628. 35} U.S.C. § 251 (2000).

^{629.} *Id.*; see *In re* Handel, 312 F.2d 943, 948, 136 U.S.P.Q. (BNA) 460, 464 (Fed. Cir. 1963) ("[T]he whole purpose of the statute, so far as [reissue] claims are concerned, is to permit limitations . . . to be taken from claims that are too narrow.").

cerned, is to permit limitations... to be taken from claims that are too narrow."). 630. *In re* Weiler, 790 F.2d 1576, 1579, 229 U.S.P.Q. (BNA) 673, 675 (Fed. Cir. 1986) (citing *In re* Bennett, 766 F.2d 524, 528, 226 U.S.P.Q. (BNA) 413, 416 (Fed. Cir. 1985) (en banc)).

^{631.} *Clement*, 131 F.3d at 1468, 45 U.S.P.Q.2d (BNA) at 1164 (alteration in original) (quoting Haliczer v. United States, 356 F.2d 541, 545, 148 U.S.P.Q (BNA) 565, 569 (1966)).

limitations on claim scope."632 The recapture rule thus serves the same policy as the doctrine of prosecution history estoppel—both operate, albeit in different ways, to prevent a patentee from reclaiming territory that he had previously committed to the public. 633

In operation, the recapture rule excludes earlier deliberate withdrawals and amendments from the allowable scope of a reissue patent. "Under [the recapture] rule, claims that are 'broader than the original patent claims in a manner directly pertinent to the subject matter surrendered during prosecution' are impermissible." The Federal Circuit described the required analysis in a recapture case in depth in In re Clement. 635 First, the original and reissued claims are construed to ascertain "whether and in what 'aspect' the reissue claims are broader than the patent claims." If the reissue claims are broader in some way, the court must determine "whether the broader aspects of the reissue claims relate to surrendered subject matter."637 This is accomplished by reviewing the prosecution history to determine what has been surrendered and determining whether the additional coverage of the reissue claim reads on the surrendered matter. 638 If it does, the recapture rule bars the claim. 639

In MBO Laboratories, Inc. v. Becton, Dickinson & Co., 640 the Federal Circuit determined that MBO clearly sought in reissue to broaden the scope of its patent coverage by rewriting its claims directed to "providing a body slidably receiving the needle" to cover all relative movement, not just retraction. 641 MBO, in fact, had explicitly stated that such broadening was the purpose behind the reissue application. 642 In light of these "clear statements" in the prosecution history

^{632.} MBO Labs., Inc. v. Becton, Dickinson & Co., 474 F.3d 1323, 1331, 81 U.S.P.Q.2d (BNA) 1661, 1667 (Fed. Cir. 2007); see id. at 1331–32, 81 U.S.P.Q.2d (BNA) at 1667 ("[T]he recapture rule . . . ensur[es] the ability of the public to rely on a patent's public record." (quoting Vectra Fitness, Inc. v. TNWK Corp., 162 F.3d 1379, 1384, 49 U.S.P.Q.2d (BNA) 1144, 1148 (Fed. Cir. 1998))).

^{633.} See Hester Indus., Inc. v. Stein, Inc., 142 F.3d 1472, 1481, 46 U.S.P.Q.2d (BNA) 1641, 1649 (Fed. Cir. 1998) ("The recapture rule is based on principles of equity and therefore embodies the notion of estoppel . . . which prevents the application of the doctrine of equivalents in a manner contrary to the patent's prosecution

history."). 634. *Id.* at 1480, 46 U.S.P.Q.2d (BNA) at 1648 (citing *Clement*, 131 F.3d at 1468, 45 U.S.P.Q.2d (BNA) at 1164).

^{635. 131} F.3d at 1468-70, 45 U.S.P.Q.2d (BNA) at 1164-65.

^{636.} Id. at 1468, 45 U.S.P.Q.2d (BNA) at 1164.

^{637.} *Id.* at 1468–69, 45 U.S.P.Q.2d (BNA) at 1164. 638. *Id.* at 1469, 45 U.S.P.Q.2d (BNA) at 1164.

^{639.} *Id.* at 1469–70, 45 U.S.P.Q.2d (BNA) at 1164–65.

^{640. 474} F.3d 1323, 81 U.S.P.Q.2d (BNA) 1661 (Fed. Cir. 2007). 641. *Id.* at 1333, 81 U.S.P.Q.2d (BNA) at 1668.

^{642.} See id. at 1332, 81 U.S.P.Q.2d (BNA) at 1667 (noting MBO's statement in its Application for Reissue of its patent that the original claims "claim less than we had a

of the reissue patent, the court was "compelled to give effect to MBO's stated intent to broaden the coverage of its claims." ⁶⁴³ "The district court [thus] erred in the first instance by applying the recapture rule to rewrite the claims, essentially unmaking the change that the PTO had permitted."644 While determining that the recapture rule should not be used to rewrite claim language, claim construction should not, of course, be blind to validity issues: "claims should be so construed, if possible, as to sustain their validity."645 "A claim that is interpreted too broadly will run into validity issues, providing motivation for the construing court to choose a narrower interpretation if possible."646 However, according to the court, "validity construction should be used as a last resort, not a first principle." The court explained that it has "limited the maxim [that claims are to be construed to preserve validity] to cases in which the court concludes, after applying all the available tools of claim construction, that the claim is still ambiguous."648 The court stated, "[w]hether those broadened claims are invalidated by the recapture rule is an issue separate from construction."649

In *In Re Serenkin*, 650 the Federal Circuit affirmed the decision of the Board of Patent Appeals and Interferences that the error upon which Serenkin based his reissue application was not a correctable error under 35 U.S.C. § 251. 651 On January 29, 1997, Serenkin filed a U.S. provisional patent application in the PTO. 652 On January 28, 1998, one day less than a year after the filing of the provisional application, Serenkin "submitted an application to the PTO in its capacity as the United States Receiving Office ('USRO') under the Patent Cooperation Treaty ('the PCT application')."653 The PCT application claimed priority from the provisional application. 654 Although Serenkin's request form noted that the application contained eight pages of draw-

right to claim in that they fail to claim clearly that any relative movement . . . will achieve the desired result of preventing needlestick hazard, whether or not the needle moves toward the body and connected safety device").

^{643.} *Id.*, 81 U.S.P.Q.2d (BNA) at 1667. 644. *Id.*, 81 U.S.P.Q.2d (BNA) at 1667. 645. *Id.*, 81 U.S.P.Q.2d (BNA) at 1667 (internal quotation marks omitted) (quoting Rhine v. Casio, Inc., 183 F.3d 1342, 1345, 51 U.S.P.Q.2d 1377 (Fed. Cir. 1999)).

^{646.} *Id.*, 81 U.S.P.Q.2d (BNA) at 1667. 647. *Id.*, 81 U.S.P.Q.2d (BNA) at 1667. 648. *Id.*, 81 U.S.P.Q.2d (BNA) at 1667 (alteration in original) (quoting Phillips v. AWH Corp., 415 F.3d 1303, 1327, 75 U.S.P.Q.2d (BNA) 1321, 1336–37 (Fed. Cir. 2005)).

^{649.} Id., 81 U.S.P.Q.2d (BNA) at 1667.

^{650. 479} F.3d 1359, 81 U.S.P.Q.2d (BNA) 2011 (Fed. Cir. 2007).

^{651.} *Id.* at 1360, 81 U.S.P.Q.2d (BNA) at 2011. 652. *Id.*, 81 U.S.P.Q.2d (BNA) at 2011–12. 653. *Id.*, 81 U.S.P.Q.2d (BNA) at 2012.

^{654.} Id., 81 U.S.P.Q.2d (BNA) at 2012.

ings, and the PCT application referenced the eight figures, no drawings were actually included with the application. ⁶⁵⁵ Serenkin later received a postcard from the USRO notifying him of the receipt of the application and the missing drawings. 656

On March 24, 1998, the USRO issued a Petition Decision stating that "pursuant to PCT Rule 20.2(a) and PCT Administrative Instructions, sections 309(b) and 310, 'the filing date of an international application is the date when all the papers completing the international application are received." As such, Serenkin's drawings could not be treated as having been submitted on the original filing date. 658 Again, the USRO informed Serenkin that he must decide within fifteen days "whether he preferred to retain the original filing date of January 28, 1998, with the application as filed without drawings, or incorporate the drawings as part of the application and accept a new filing date of February 17, 1998."659 If Serenkin chose to incorporate his drawings, the USRO specifically stated that the priority date of January 29, 1997, would be lost. 660 On March 31, 1998, Serenkin's attorney filed a petition to the USRO accepting the later filing date of February 17, 1998. 661 A patent issued on August 29, 2000. 662

On April 30, 2002, through a new attorney, Serenkin sought reissue of the patent in order to obtain the benefit of the January 29, 1997, filing date for the provisional application. 663 "While admitting that the relief he [sought] is not available under PCT procedures, Serenkin argue[d] that such a procedural mistake is remediable under § 251, particularly in light of [Federal Circuit] case law authorizing the use of reissue to correct prosecution mistakes."664 The Federal Circuit affirmed the PTO's conclusion that it was not "permissible for Serenkin to claim the benefit of the earlier filing date through the reissue process."665

The Federal Circuit reasoned that while § 251 is "based on fundamental principles of equity and fairness, and should be construed

655.Id

^{., 81} U.S.P.Q.2d (BNA) at 2012. 656. Id., 81 U.S.P.Q.2d (BNA) at 2012.

^{657.} *Id.*, 81 U.S.P.Q.2d (BNA) at 2012. 658. *Id.*, 81 U.S.P.Q.2d (BNA) at 2012.

^{659.} Id. at 1360-61, 81 U.S.P.Q.2d (BNA) at 2012.

^{660.} Id. at 1361, 81 U.S.P.Q.2d (BNA) at 2012.

^{661.} Id., 81 U.S.P.Q.2d (BNA) at 2012.

^{662.} *Id.*, 81 U.S.P.Q.2d (BNA) at 2012. 663. *Id.*, 81 U.S.P.Q.2d (BNA) at 2012.

^{664.} *Id.* at 1362, 81 U.S.P.Q.2d (BNA) at 2013.

^{665.} Id., 81 U.S.P.Q.2d (BNA) at 2013.

liberally' . . . the remedial function is not without limits. 666 It went on to say, "[i]deed, 'the reissue statute was not enacted as a panacea for all patent prosecution problems, nor as a grant to the patentee of a second opportunity to prosecute de novo his original application." 667 As such, "not every event or circumstance that might be labeled 'error' is correctable by reissue."668

The court further pointed out that the reissue could be used to perfect a claim for priority but not in cases in which an applicant made a deliberate decision to accept a later priority date in exchange for including newly submitted material in the application. 669 Federal Circuit thus affirmed the PTO's determination that Serenkin's reissue was an improper attempt to change an error in judgment by the applicant during prosecution of the patent, which is not correctable by reissue under 35 U.S.C. § 251.670

In Forest Laboratories, Inc. v. Ivax Pharmaceuticals, 671 the question before the court was whether a change effected in the reissue application improperly broadened the scope of claim 11 of Forest's patent or merely clarified or corrected the original claim. 672 Defendants Ivax and Cipla argued that claim 11 was invalid because it had been improperly broadened during reissue two years after the original patent had issued.⁶⁷³ In particular, they argued that the change in the optical rotation sign of the diol intermediate in claim 11 during reissue broadened the claim because it now covered a process beginning with a different enantiomer. 674 Even if the change had been intended merely to correct a typographical error, the plaintiffs argued it may still be an improper broadening and that a "typographical error must be evident to the general public in order to serve the public notice function of patents."675

The Federal Circuit agreed with Forest that the change in the optical rotation sign for the diol intermediate in claim 11 did not broaden the scope of the claim. 676 The Federal Circuit relied on the

^{666.} Id., 81 U.S.P.Q.2d (BNA) at 2013 (quoting In re Weiler, 790 F.2d 1576, 1579, 229 U.S.P.Q (BNA) 673, 675 (Fed. Cir. 1986)).

²²⁹ U.S.F.Q (BNA) 073, 073 (Fed. Ch. 1300)).
667. Id., 81 U.S.P.Q.2d (BNA) at 2013 (internal quotations omitted) (quoting Weiler, 790 F.2d at 1582, 229 U.S.P.Q. (BNA) at 677).
668. Id., 81 U.S.P.Q.2d (BNA) at 2013–14 (quoting Weiler, 790 F.2d at 1579, 229

U.S.P.Q. (BNA) at 675).

^{669.} *Id.* at 1364, 81 U.S.P.Q.2d (BNA) at 2014–15. 670. *Id.* at 1365, 81 U.S.P.Q.2d (BNA) at 2015.

^{671. 501} F.3d 1263, 84 U.S.P.Q.2d (BNA) 1099 (Fed. Cir. 2007).

^{672.} Id. at 1270, 84 U.S.P.Q.2d (BNA) at 1105.

^{673.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1104. 674. *Id.*, 84 U.S.P.Q.2d (BNA) at 1105. 675. *Id.*, 84 U.S.P.Q.2d (BNA) at 1105.

^{676.} Id., 84 U.S.P.Q.2d (BNA) at 1105.

plain reading of the patent specification, which "supports, even compels, this conclusion."677 The court therefore agreed that "the change in the optical sign during reissue does not represent a change of claim scope but merely a correction of the claim to be consistent with the disclosure of the specification."678

2. Certificate of correction

A typographical error was also at issue in *Central Admixture Pharmacy* Services, Inc. v. Advanced Cardiac Solutions, 679 in which Advanced Cardiac Solutions and Charles Wall (collectively, "ACS") appealed from several summary judgment orders that found ACS liable to plaintiffs CAPS and Dr. Gerald Buckberg for willful infringement of U.S. Patent No. 4,988,515 ("the '515 patent").680

The Federal Circuit found that the certificate of correction CAPS obtained from the PTO to alter the asserted claims of the patent was invalid. 681 The court noted:

[T]he asserted patent claims initially required the solution to have an "osmolarity... of between about 400-500 mOsmol," but after the certificate issued, the claims required an "osmolality... of between about 400-500 mOsmol." For the solutions at issue here, the numerical figure for osmolarity will be less than the figure for osmolality by about one or two percent.⁶⁸²

Accordingly, the court vacated the finding of infringement and remanded for a "redetermination of infringement under the patent's original, uncorrected claims."683

The court explained that a patentee who has made "a mistake of a clerical or typographical nature, or of minor character" may apply to the PTO for a "certificate of correction, if the correction does not involve such changes in the patent as would constitute new matter or would require re-examination."684

"Invalidating a certificate of correction for impermissible broadening therefore requires proof of two elements: (1) the corrected claims are broader than the original claims; and (2) the presence of the clerical or typographical error, or how to correct that error, is not

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677. Id., 84 U.S.P.Q.2d (BNA) at 1105.
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^{678.} *Id.* at 1271, 84 U.S.P.Q.2d (BNA) at 1106. 679. 482 F.3d 1347, 82 U.S.P.Q.2d (BNA) 1293 (Fed. Cir. 2007).

^{680.} *Id.* at 1349, 82 U.S.P.Q.2d (BNA) at 1294.

^{681.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1294. 682. *Id.* at 1350, 82 U.S.P.Q.2d (BNA) at 1295 (alterations in original).

^{683.} Id. at 1349, 82 U.S.P.Q.2d (BNA) at 1294.

^{684.} *Id.* at 1353, 82 U.S.P.Q.2d (BNA) at 1295 (quoting 35 U.S.C. § 255 (2000)).

clearly evident to one of skill in the art." Citing Superior Fireplace Co. v. Majestic Products Co., the Federal Circuit stated that there are three categories into which an error might fall. The first category involves mistakes that are obvious, thus leaving no doubt as to what the mistake is. In contrast, [the] second category includes those typographical mistakes not apparent to the reader at all; for example, a mistake resulting in another word that is spelled correctly and that reads logically in the context of the sentence. The third category includes those "where it is apparent that a mistake has been made, but it is unclear what the mistake is."

Since it is not evident to the reader of the public record how to appropriately correct mistakes of the second and third categories, those categories of error cannot be repaired by a certificate of correction if the effect would be to broaden the claim. The Federal Circuit concluded that "since the error corrected . . . was not clearly evident to one of skill in the art and the result of its correction was to broaden the claims, ACS should be granted summary judgment that the certificate of correction is not valid." Thus, the patent should continue to read as it did before the issuance of the certificate. 693

3. Interference

In *Henkel Corp. v. Procter & Gamble Co.*, ⁶⁹⁴ the Federal Circuit held that "as a matter of law, we do not require that a junior party in an interference demonstrate that it recognized the exact language of the ultimate count—only the subject matter of the invention." In this case, the invention involved dishwashing detergent tablets, which were divided into a "compressed" region and a "solidified solution or melt" region, wherein the compressed region dissolves "at a faster rate" than the solidified region. ⁶⁹⁶ The Board found that Henkel, the

^{685.} Id. at 1353, 82 U.S.P.Q.2d (BNA) at 1297.

^{686. 270} F.3d 1358, 60 U.S.P.Q.2d (BNA) 1668 (Fed. Cir. 2001).

^{687.} Cent. Admixture Pharmacy Servs., 482 F.3d at 1354, 82 U.S.P.Q.2d (BNA) at 1298.

^{688.} Id., 82 U.S.P.Q.2d (BNA) at 1298.

^{689.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1298 (quoting *Superior Fireplace*, 270 F.3d at 1370, 60 U.S.P.Q.2d (BNA) at 1677).

^{690.} Id., 82 Ù.S.P.Q.2d (BNA) at 1298 (quoting Superior Fireplace, 270 F.3d at 1370, 60 U.S.P.Q.2d (BNA) at 1677).

^{691.} Id., 82 U.S.P.Q.2d (BNA) at 1298.

^{692.} Id. at 1355, 82 U.S.P.Q.2d (BNA) at 1298.

^{693.} Id., 82 U.S.P.Q.2d (BNA) at 1298.

^{694. 485} F.3d 1370, 82 U.S.P.Q.2d (BNA) 1784 (Fed. Cir. 2007).

^{695.} *Id.* at 1375, 82 U.S.P.Q.2d (BNA) at 1788 (citing Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1336, 58 U.S.P.Q.2d (BNA) 1030, 1047 (Fed. Cir. 2001)).

^{696.} Id. at 1371, 82 U.S.P.Q.2d (BNA) at 1785.

designated junior party, had failed to prove that it had conceived of the invention and reduced it to practice before Procter & Gamble's constructive reduction to practice (filing) date, as Henkel's inventors had not "contemporaneously appreciated an embodiment that met all the limitations of the interference count."697

The Federal Circuit vacated and remanded that decision, finding that the Board had legally erred by requiring Henkel to show that its inventors and technicians had tested or calculated specific dissolution rates. 698 This "explicit calculation or measurement of quantitative dissolution rates is unnecessary," the court explained, as the interference count merely required "a showing of an appreciation by the inventors... that the dissolution of rate of the compressed region is greater than the dissolution rate of the other region" but not an "appreciation of specific dissolution rates." The court stated that this was not a case where there was "a significant danger that the inventors unwittingly and accidentally created something new; rather, they set out to design detergent tablets with a particular structure and did so, and the only question is whether they appreciated that the tablets met one limitation of the interference count."⁷⁰⁰ Once the count was properly construed, the court found ample evidence in the record of Henkel's appreciation of the different dissolution rates and objective corroboration of the inventors' testimony.⁷⁰¹

In In re Garner, 702 the applicant Garner appealed the decision of the PTO's Board of Patent Appeals and Interferences, awarding judgment against Garner for failure to make a prima facie showing of priority in an interference.⁷⁰³ Specifically, Garner appealed the Board's ruling on sufficiency and the Board's definition of "new evidence."⁷⁰⁴

Garner attempted to establish priority by showing that he actually reduced to practice an invention within the proposed count before the senior party patent's effective filing date. To this end, Garner submitted a declaration he executed on November 28, 2001 in the parent application."⁷⁰⁶ "The declaration had originally been submitted under 37 C.F.R. § 1.131 in an attempt to overcome a prior art re-

^{697.} Id. at 1373-74, 82 U.S.P.Q.2d (BNA) at 1786-87.

^{698.} *Id.* at 1374, 82 U.S.P.Q.2d (BNA) at 1787. 699. *Id.* at 1375, 82 U.S.P.Q.2d (BNA) at 1787.

^{700.} Id., 82 U.S.P.Q.2d (BNA) at 1788.

^{701.} *Id.* at 1375–76, 82 U.S.P.Q.2d (BNA) at 1788. 702. 508 F.3d 1376, 85 U.S.P.Q.2d (BNA) 1310 (Fed. Cir. 2007).

^{703.} *Id.* at 1377, 85 U.S.P.Q.2d (BNA) at 1311.

^{704.} *Id.*, 85 U.S.P.Q.2d (BNA) at 1311

^{705.} *Id.* at 1377–78, 85 U.S.P.Q.2d (BNA) at 1311.

^{706.} *Id.* at 1378, 85 U.S.P.Q.2d (BNA) at 1311.

jection in the parent application." After receiving a letter sent by the examiner that his 2001 declaration was "insufficient" to provoke an interference under 37 C.F.R. § 41.202(d) (Rule 202(d)), Garner retitled his 2001 Rule 131 declaration to be a "Rule 202(d) declaration" without making any substantive changes, re-executed, and filed it. 708 "The examiner forwarded Garner's request to provoke an interference to the Board."709

The Board found Garner's filing insufficient to establish a prima facie showing of priority. In accordance with Rule 202(d), the Board declared an interference and issued an Order to Show Cause why judgment should not be entered against him.711 In responding to the Order, Garner relied on three items that he did not submit in his original Rule 202(d) filing to show priority: "(i) a 37 C.F.R. § 1.131 declaration filed on September 2, 2003 in an attempt to overcome a prior art rejection ('2003 Garner declaration'); (ii) the specification of his provisional application; and (iii) the specification of his utility application."712

The Board found that these three items were "new evidence" that was not permitted under Rule 202(d) without a showing of good cause and that Garner had not attempted to show good cause for his belated reliance.⁷¹³ Therefore, the Board issued judgment against Garner, who then appealed the Board's ruling on sufficiency and the Board's definition of "new evidence."714

The Federal Circuit concluded that "the Board's interpretation of 'new evidence' is inconsistent with the regulation, as the Board interpreted Rule 202 in a way that requires it to consider the specification under [202](a), but not under [202](d), unless the applicant resubmits the specification."715 "Since the specifications were already before the Board in the interference proceeding pursuant to Rule 202(a), they cannot be new evidence under Rule 202(d)." Therefore, the Federal Circuit concluded the Board erred when it found that the specifications constitute "new evidence" under Rule 202(d).717 However, the Federal Circuit found that even with the pat-

^{707.} Id., 85 U.S.P.Q.2d (BNA) at 1311.

^{708.} *Id.*, 85 U.S.P.Q.2d (BNA) at 1311.

^{709.} *Id.*, 85 U.S.P.Q.2d (BNA) at 1311. 710. *Id.*, 85 U.S.P.Q.2d (BNA) at 1311. 711. *Id.*, 85 U.S.P.Q.2d (BNA) at 1312.

^{712.} *Id.*, 85 U.S.P.Q.2d (BNA) at 1312. 713. *Id.*, 85 U.S.P.Q.2d (BNA) at 1312.

^{714.} *Id.*, 85 U.S.P.Q.2d (BNA) at 1312. 715. *Id.* at 1380, 85 U.S.P.Q.2d (BNA) at 1313.

^{716.} *Id.*, 85 U.S.P.Q.2d (BNA) at 1313.

^{717.} Id., 85 U.S.P.Q.2d (BNA) at 1313.

ent specifications in evidence, Garner failed to establish a prima facie showing of priority. In order to establish an actual reduction to practice, the inventor must prove that: (1) he constructed an embodiment or performed a process that met all the limitations of the interference count; and (2) he determined that the invention would work for its intended purpose.

While "the law does not impose an impossible standard of 'independence' on corroborative evidence by requiring that every point of a reduction to practice be corroborated by evidence having a source totally independent of the inventor[,]" corroboration of the existence of the device is not sufficient in this case to establish corroboration of reduction to practice.⁷²⁰

The court added that "[i]t is also necessary to corroborate that the device worked for its intended purpose."⁷²¹

In an interference proceeding, a party may assert that the patentee did not invent the patented invention by showing derivation. The person challenging the senior party's priority date bears the burden of proof on derivation and must make two showings. First, he must "establish prior conception of the claimed subject matter." Second, he must prove "communication of that conception to the patentee that is 'sufficient to enable [him] to construct and successfully operate the invention."

This was the issue that arose in *Brand v. Miller*.⁷²⁶ The Federal Circuit reversed a decision of the Board of Patent Appeals and Interferences in an interference proceeding related to an invention concerning methods of cutting veneer from logs of wood.⁷²⁷ Robert Brand, the senior party in the interference and the inventor of the application at issue, was the chief engineer for Capital Machine Co. ("Capi-

^{718.} Id., 85 U.S.P.Q.2d (BNA) at 1313.

^{719.} *Id.*, 85 U.S.P.Q.2d (BNA) at 1313 (internal quotation marks omitted) (quoting Taskett v. Dentlinger, 344 F.3d 1337, 1340, 68 U.S.P.Q.2d (BNA) 1472, 1474 (Fed. Cir. 2003)).

^{720.} *Id.* at 1381, 85 U.S.P.Q.2d (BNA) at 1314 (alterations in original) (quoting Cooper v. Goldfarb, 154 F.3d 1321, 1330, 47 U.S.P.Q.2d (BNA) 1896, 1904 (Fed. Cir. 1998)).

^{721.} *Id.*, 85 U.S.P.Q.2d (BNA) at 1314 (citing Hahn v. Wong, 892 F.2d 1028, 1032, 13 U.S.P.Q.2d (BNA) 1313, 1317 (Fed. Cir. 1989).

^{722.} Price v. Symsek, 988 F.2d 1187, 1190, 26 U.S.P.Q.2d (BNA) 1031, 1033 (Fed. Cir. 1993).

^{723.} Id., 26 U.S.P.Q.2d (BNA) at 1031.

^{724.} *Id.*, 26 U.S.P.Q.2d (BNA) at 1031.

^{725.} Int'l Rectifier Corp. v. IXYS Corp., 361 F.3d 1363, 1376, 70 U.S.P.Q.2d (BNA) 1209, 1219 (Fed. Cir. 2004) (quoting Gambro Lundia AB v. Baxter Healthcare Corp., 110 F.3d 1573, 1577, 42 U.S.P.Q.2d (BNA) 1378, 1382 (Fed. Cir. 1997)).

^{726. 487} F.3d 862, 82 U.S.P.Q.2d (BNA) 1705 (Fed. Cir. 2007).

^{727.} *Id.* at 871, 82 U.S.P.Q.2d (BNA) at 1711.

tal"), which makes machines for cutting veneer. Thomas Miller, the junior party in the interference and inventor of the patent at issue, was the production manager of Miller Veneers, a customer of Capital. 729 The two companies had a close relationship during the relevant period, often sharing information related to veneer cutting technology. 730 Brand filed for its patent first, but Miller argued that he was entitled to priority because Brand derived the invention from Miller. 731 The Board, without citing evidence from the record, ruled that Miller had established derivation based on certain communications from Miller to Brand's then company, Capital. Brand and Capital appealed the Board's ruling. 733

This case turned on the communication of the conception between Miller and Brand, and, more specifically, on whether Miller's communications to Capital were sufficiently enabling.734 The Federal Circuit, citing § 706 of the Administrative Procedures Act, noted that findings of fact by the Board must in all cases be supported by substantial evidence in the record.735 The Federal Circuit held that "in the context of a contested case, it is impermissible for the Board to base its factual findings on its expertise, rather than on evidence in the record."⁷³⁶ Turning to the facts of the case, the Federal Circuit found that Miller's communications were sufficiently enabling, and the Board improperly substituted its own opinion for evidence of the knowledge of one or ordinary skill in the art. The court thus reversed the Board's award to Miller. 738

4. Disciplinary action

Bender v. Dudas⁷³⁹ involved a disciplinary action to exclude an attorney from practicing before the PTO, a case the Federal Circuit described as one that "reads like a novel but represents the true story of hopes dashed, fees wasted, and dreams lost by hundreds of individual inventors caught up in the world of self-interested promoters who promise the world and deliver very little."⁷⁴⁰ In a larger sense, this

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728. Id. at 865, 82 U.S.P.Q.2d (BNA) at 1706.
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^{729.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1706.

^{730.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1706. 731. *Id.* at 866, 82 U.S.P.Q.2d (BNA) at 1710. 732. *Id.* at 867, 82 U.S.P.Q.2d (BNA) at 1710.

^{733.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1710. 734. *Id.* at 870, 82 U.S.P.Q.2d (BNA) at 1711. 735. *Id.* at 869, 82 U.S.P.Q.2d (BNA) at 1711.

^{736.} Id., 82 U.S.P.Q.2d (BNA) at 1710.

^{737.} *Id.* at 870, 82 U.S.P.Q.2d (BNA) at 1711. 738. *Id.* at 871, 82 U.S.P.Q.2d (BNA) at 1711. 739. 490 F.3d 1361, 83 U.S.P.Q.2d (BNA) 1065 (Fed. Cir. 2007).

^{740.} *Id.* at 1362, 83 U.S.P.Q.2d (BNA) at 1067.

case expressed the Federal Circuit's concern for "[i]ndividual inventors . . . [who] are often unfamiliar with even the most basic principles of patent law, do not know where to turn for help, and are vulnerable to those who seek to take advantage of their experience." The real target of the court's ire were

so-called "invention promoters" who exploit unsophisticated inventors, heap every invention with praise regardless of the merits or the real prospects of legal protection, and entice inventors into engagement agreements filled with hollow guarantees of patent protection and promises of royalty-bearing licenses that seldom yield anything of any significant value.⁷⁴²

The prosecuting attorney in this case had worked under contract with American Inventors Corporation ("AIC"), an invention promoter that solicited inventors for their ideas, offered to pay all legal fees to procure a patent, and promised to promote the invention to manufacturers and other potential parties in exchange for a flat fee or fee plus royalty arrangement. The Federal Circuit found that substantial evidence supported the PTO's finding that the attorney had neglected a legal matter entrusted to him by failing to advise his clients on how best to protect their inventions. 44 Even though the attorney knew that many of his clients wanted a utility patent or did not understand the difference between design and utility patents, Bender continued to prosecute their applications as design patents.⁷⁴⁵ His form letter to his clients describing those differences was "an entirely hollow and formalistic gesture[,]" according to the court, "because it did not provide any of the . . . applicants with advice that directly related to the particular inventions at issue, the type of patent best suited to protect these particular inventions and the inventor's interests therein, or the consequences of pursuing a design patent instead of a utility patent."⁷⁴⁶

The Federal Circuit found that the PTO had carefully weighed the public interest, the seriousness of Bender's violations, the need for deterrence, the integrity of the legal profession, and other extenuating circumstances in deciding to exclude Bender from practicing before the PTO.⁷⁴⁷ In particular, Bender "refused to recognize the impropriety of his conduct or to express any remorse for his actions[,]"

^{741.} Id. at 1362-63, 83 U.S.P.Q.2d (BNA) at 1067.

^{742.} Id. at 1363, 83 U.S.P.Q.2d (BNA) at 1067.

^{743.} *Id.* at 1363–64, 83 U.S.P.Q.2d (BNA) at 1067–68.

^{744.} Id. at 1366, 83 U.S.P.Q.2d (BNA) at 1070.

^{745.} *Id.* at 1364, 83 U.S.P.Q.2d (BNA) at 1068.

^{746.} *Id.* at 1366, 83 U.S.P.Q.2d (BNA) at 1070.

^{747.} Id. at 1370, 83 U.S.P.Q.2d (BNA) at 1072.

which "created a likelihood that he would continue to violate the same disciplinary rules again."⁷⁴⁸ Even the best of intentions, the court added, "cannot absolve Bender's complicity with AIC in a scheme fraught with deception and adversely affecting a large number of unsuspecting inventors."749

Attorney-Client Privilege and Work Product Protection

The attorney-client privilege belongs to the client, who alone may waive it. The widely applied standard for determining the scope of a waiver . . . is that the waiver applies to all other communications relating to the same subject matter."⁷⁵¹ This broad scope is grounded in principles of fairness and serves to prevent a party from simultaneously using the privilege as both a sword and a shield; that is, it prevents the inequitable result of a party disclosing favorable communications while asserting the privilege as to less favorable ones. 752 Ultimately, however, "[t]here is no bright line test for determining what constitutes the subject matter of a waiver, rather courts weigh the circumstances of the disclosure, the nature of the legal advice sought and the prejudice to the parties of permitting or prohibiting further disclosures."753

The work product doctrine is "designed to balance the needs of the adversary system: promotion of an attorney's preparation in representing a client versus society's general interest in revealing all true and material facts to the resolution of a dispute."754 Unlike the attorney-client privilege, which provides absolute protection from disclosure, work product protection is qualified and may be overcome by need and undue hardship.⁷⁵⁵ However, the level of need and hardship required for discovery depends on whether the work product is

^{748.} Id., 83 U.S.P.Q.2d (BNA) at 1072.

^{749.} *Id.*, 83 U.S.P.Q.2d (BNA) at 1072.

^{750.} See Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp., 383 F.3d 1337, 1345, 72 U.S.P.Q.2d (BNA) 1560, 1565–66 (Fed. Cir. 2004) (noting that, to protect the interests of the client, most courts have declined to impose adverse inferences when a party invokes the attorney-client privilege and holding to apply that rule to the patent realm as well); Am. Standard, Inc. v. Pfizer, Inc., 828 F.2d 734, 745, 3 U.S.P.Q.2d (BNA) 1817, 1824 (Fed. Cir. 1987) (stating that the privilege belongs to the client, not the attorney).

^{751.} Fort James Corp. v. Solo Cup Co., 412 F.3d 1340, 1349, 75 U.S.P.Q.2d (BNA) 1257, 1264 (Fed. Cir. 2005).

^{257, 1204 (}red. Gif. 2003).
752. *Id.*, 75 U.S.P.Q.2d (BNA) at 1264.
753. *Id.* at 1349–50, 75 U.S.P.Q.2d (BNA) at 1264.
754. *In re* Martin Marietta Corp., 856 F.2d 619, 624 (4th Cir. 1988).

^{755.} See FED. R. CIV. PRO. 26(b)(3) ("Ordinarily, a party may not discover documents and tangible things that are prepared in anticipation of litigation or for trial by or for another party or its representative (including the other party's attorney, consultant, surety, indemnitor, insurer, or agent)[,]" but subject to Rule 26(b)(4) those materials may be discoverable in certain specified circumstances).

factual or the result of mental processes such as plans, strategies, tactics, and impressions, whether memorialized in writing or not. 756 Whereas factual work product can be discovered solely upon a showing of substantial need and undue hardship, mental process work product is afforded even greater, nearly absolute, protection.⁷⁵⁷

In Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp., 758 the Federal Circuit addressed an outgrowth of its willfulness doctrine. Over the years, the court had held that an accused infringer's failure to produce advice from counsel "would warrant the conclusion that it either obtained no advice of counsel or did so and was advised that its [activities] ... would be an infringement of valid U.S. patents."⁷⁵⁹ Recognizing that this inference can distort the attorney-client relationship, the Federal Circuit held that invoking the attorney-client privilege or work product protection does not give rise to an adverse inference. The court further held that an accused infringer's failure to obtain legal advice does not give rise to an adverse inference with respect to willfulness.761

More recently, in *In re EchoStar Communications Corp.*, ⁷⁶² the Federal Circuit addressed the scope of waiver resulting from the advice of counsel defense.⁷⁶³ First, the court concluded that relying on inhouse counsel's advice to refute a charge of willfulness triggers waiver of the attorney-client privilege. ⁷⁶⁴ Second, the court held that asserting the advice of counsel defense waives work product protection and the attorney-client privilege for all communications on the same subject matter, as well as any documents memorializing attorney-client communications. 765 However, the court held that waiver did not extend to work product that was not communicated to an accused infringer.766

The Federal Circuit, meeting en banc, returned to the issues of willfulness and its functional relationship to attorney-client privilege

757. See, e.g., Upjohn Co. v. United States, 449 U.S. 383, 400 (1981) (discussing courts' use of Rule 26 to safeguard against the disclosure of lawyers' mental impressions and legal theories).

^{756.} *Id*.

^{758. 383} F.3d 1337, 72 U.S.P.Q.2d (BNA) 1560 (Fed. Cir. 2004).

^{759.} *Id.* at 1343, 72 U.S.P.Q.2d (BNA) at 1564 (quoting Kloster Speedsteel AB v. Crucible Inc., 793 F.2d 1565, 1580, 23 U.S.P.Q. (BNA) 81, 91 (Fed. Cir. 1986)). 760. *Id.* at 1344–45, 72 U.S.P.Q.2d (BNA) at 1565. 761. *Id.* at 1345–46, 72 U.S.P.Q.2d (BNA) at 1566.

^{762. 448} F.3d 1294, 78 U.S.P.Q.2d (BNA) 1676 (Fed. Cir. 2006).

^{763.} *Id.*, 78 U.S.P.Q.2d (BNA) at 1676. 764. *Id.* at 1299, 78 U.S.P.Q.2d (BNA) at 1679. 765. *Id.* at 1299, 1302–03, 78 U.S.P.Q.2d (BNA) at 1679, 1681–82.

^{766.} Id. at 1303–04, 78 U.S.P.Q.2d (BNA) at 1682.

and the work-product doctrine in In re Seagate Technology, LLC. 767 With respect to attorney-client privilege, the court concluded "that asserting the advice of counsel defense and disclosing opinions of opinion counsel do not constitute waiver of the attorney-client privilege for communications with trial counsel."⁷⁶⁸ The court explained that the rule is not absolute, however, and trial courts have discretion in extending waiver to trial counsel, such as when the party or counsel engages in chicanery.⁷⁶⁹

With respect to the work product doctrine, the Federal Circuit similarly held that relying on opinion counsel's work product does not always waive trial counsel's work product immunity. The court stated that it was possible, however, that situations may arise in which waiver may be extended to trial counsel, again such as when the party or counsel engages in chicanery.⁷⁷¹ The court also noted that its ruling did not affect the general principles of work product protection. 772 As such, a party may still obtain discovery of work product absent waiver as long as it shows sufficient need and hardship, although a higher burden must still be met to obtain that pertaining to mental processes.⁷⁷³

The court also continued to hold that work product protection remains available for "nontangible" work product.⁷⁷⁴ Otherwise, attorneys' files would be protected from discovery, but attorneys themselves would have no work product objection to depositions. 775

K. Constitutional Issues

Sovereign immunity and the Eleventh Amendment

The Federal Circuit found that a state university had waived its sovereign immunity as a matter of contract in Baum Research and Development Co. v. University of Massachusetts at Lowell. 776 The University had entered into a license with the patent's inventor, which stated "all parties agree to proper venue and hereby submit to the jurisdiction in the appropriate State or Federal Courts of Record sitting in the State of Michigan[,]" the laws of which would further govern the con-

^{767. 497} F.3d 1360, 83 U.S.P.Q.2d (BNA) 1865 (Fed. Cir. 2007).

^{768.} *Id.* at 1374, 83 U.S.P.Q.2d (BNA) at 1873. 769. *Id.* at 1374–75, 83 U.S.P.Q.2d (BNA) at 1873.

^{770.} Id. at 1376, 83 U.S.P.Q.2d (BNA) at 1874.

^{771.} *Id.*, 83 U.S.P.Q.2d (BNA) at 1874. 772. *Id.*, 83 U.S.P.Q.2d (BNA) at 1874.

^{773.} *Id.*, 83 U.S.P.Q.2d (BNA) at 1874. 774. *Id.*, 83 U.S.P.Q.2d (BNA) at 1874. 775. *Id.*, 83 U.S.P.Q.2d (BNA) at 1874.

^{776. 503} F.3d 1367, 84 Ù.S.P.Q.2d (BNA) 1762 (Fed. Cir. 2007).

struction and application of the license in question. The Federal Circuit found this language "unequivocally expressed" the University's waiver of sovereign immunity,778 pursuant to the Supreme Court's holding in College Savings Bank v. Florida Prepaid Postsecondary Education Expense Board. The court further found that the plaintiff did not need to prove that the Massachusetts legislature had delegated the waiver of immunity to the University because there was no dispute that the University had the authority to enter into contracts of this nature and that the contracts frequently included the provision at issue.⁷⁸⁰

In Vas-Cath, Inc. v. Curators of University of Missouri, 781 the Federal Circuit found that a state university may also waive its sovereign immunity for purposes of judicial review by bringing an interference proceeding.⁷⁸² In this case, the University of Missouri had requested and prevailed in an interference proceeding against Vas-Cath.⁷⁸³ When Vas-Cath appealed the PTO's decision, the district court dismissed the appeal on Eleventh Amendment grounds.⁷⁸⁴

The Federal Circuit reversed the decision, finding that the Eleventh Amendment did not shield the University from Vas-Cath's appeal.⁷⁸⁵ Ordinarily, "a state does not waive its sovereign immunity simply by engaging in activities normally conducted by private individuals or corporations[,]" such as participating in a routine ex parte patent examination. ⁷⁸⁶ In this case, however, the University itself had requested that the PTO conduct a litigation-type activity, participated in the interference proceeding, and ultimately obtained a favorable ruling in a matter for which the statute authorizes judicial review.⁷⁸⁷ "It has long been recognized that a state's voluntary entry into federal court serves to waive state immunity from federal adjudication of that claim."⁷⁸⁸ Thus, the University had waived its constitutional immunity not only in that proceeding but also in the appeal taken by the losing

^{777.} *Id.* at 1368–69, 84 U.S.P.Q.2d (BNA) at 1764. 778. *Id.* at 1370, 84 U.S.P.Q.2d (BNA) at 1764.

^{779. 527} U.S. 666, 676 (1999).

^{780.} Baum, 503 F.3d at 1370, 84 U.S.P.Q.2d (BNA) at 1764.

^{781. 473} F.3d 1376, 81 U.S.P.Q.2d (BNÅ) 1524 (Fed. Cir. 2007).

^{782.} *Id.* at 1378, 81 U.S.P.Q.2d (BNA) at 1525.

^{783.} *Id.*, 81 U.S.P.Q.2d (BNA) at 1525.

^{784.} *Id.*, 81 U.S.P.Q.2d (BNA) at 1525. 785. *Id.*, 81 U.S.P.Q.2d (BNA) at 1525.

^{786.} Id. at 1383, 81 U.S.P.Q.2d (BNA) at 1528.

^{787.} *Id.*, 81 U.S.P.Q.2d (BNA) at 1528. 788. *Id.*, 81 U.S.P.Q.2d (BNA) at 1528; *see* Clark v. Barnard, 108 U.S. 436, 447 (1883) (noting that a state's immunity is a privilege and can be waived at its pleas-

party.⁷⁸⁹ Principles of fairness and consistency also prohibit the University from selectively asserting immunity, after having won the first round, in order to avoid an appeal by the loser.⁷⁹⁰

Vas-Cath was distinguished in Biomedical Patent Management Corp. v. California, 791 in which the Federal Circuit determined that a state may be entitled to assert its Eleventh Amendment sovereign immunity even after having waived such immunity in an earlier lawsuit on the same issues.⁷⁹² In pertinent part, the California Department of Health Services ("DHS") intervened in a lawsuit brought by its subcontractor for declaratory judgment that two patents owned by Biomedical Patent Management Corporation ("BPMC") were invalid and not infringed by DHS laboratory screening methods.⁷⁹³ BPMC filed compulsory counterclaims for infringement, but DHS successfully moved to dismiss the action for improper venue.⁷⁹⁴ Shortly thereafter, BPMC filed a new infringement action against DHS, which asserted a defense of sovereign immunity.⁷⁹⁵ The second action was also dismissed without prejudice after the Supreme Court granted certiorari of a case that was expected to impact, and ultimately did impact, the sovereign immunity of states in patent infringement actions. 796 In particular, the Supreme Court concluded in Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank⁷⁹⁷ that states retain their sovereign immunity in patent infringement suits and that Congress's attempt to abrogate state sovereign immunity in such cases was inva- $\mathbf{lid.}^{798}$

In February 2006, BPMC filed the present lawsuit against DHS, which again asserted a defense of sovereign immunity. The district court granted DHS's motion to dismiss the action, and BPMC appealed. 800 The Federal Circuit affirmed the district court's dismissal. 801

There was no dispute that DHS, as an arm of the State of California, is entitled to Eleventh Amendment immunity, except in cases where Congress has validly authorized a lawsuit in exercise of its power to enforce the Fourteenth Amendment or where the state has

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789. Id., 81 U.S.P.Q.2d (BNA) at 1528.
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^{790.} *Id.* at 1384, 81 U.S.P.Q.2d (BNA) at 1529.
791. 505 F.3d 1328, 85 U.S.P.Q.2d 1074 (BNA) (Fed. Cir. 2007).
792. *Id.* at 1330, 85 U.S.P.Q.2d (BNA) at 1075.

^{793.} *Id.* at 1331, 85 U.S.P.Q.2d (BNA) at 1076.

^{794.} *Id.*, 85 U.S.P.Q.2d (BNA) at 1076.

^{795.} Id. at 1332, 85 U.S.P.Q.2d at 1076.

^{796.} *Id.*, 85 U.S.P.Q.2d (BNA) at 1076.

^{797. 527} U.S. 627, 630 (1999).

^{798.} Id.

^{799.} Biomedical Patent Mgmt., 505 F.3d at 1332, 85 U.S.P.Q.2d (BNA) at 1076.

^{800.} *Id.*, 85 U.S.P.Q.2d (BNA) at 1076.

^{801.} Id., 85 U.S.P.Q.2d (BNA) at 1076.

waived its sovereign immunity by consenting to the lawsuit.⁸⁰² It was further agreed that DHS had waived its sovereign immunity in the first declaratory judgment action by moving to intervene and asserting claims against BPMC, thereby voluntarily invoking the district court's jurisdiction.803

The Federal Circuit, however, rejected BPMC's argument that DHS's waiver in the first lawsuit extended to the present lawsuit, even though both suits involved the same parties and subject matter.⁸⁰⁴ A waiver of sovereign immunity in an earlier action that was dismissed does not "carry over" to a new lawsuit, even if the lawsuits involve the same patents. 805 In so holding, the court distinguished Vas-Cath and other cases cited by BPMC in which the state's waiver of sovereign immunity was applied to "one continuous action" or proceeding. In Vas-Cath, for example, the "continuing proceeding" was an interference action followed by judicial review.

According to the Federal Circuit, the problems of "unfairness" or "inconsistency" that had prevented states from invoking sovereign immunity in Vas-Cath and other cases did not preclude DHS from asserting immunity in this case. 808 Private parties would not be forced to litigate in improper venues to avoid the risk of dismissal and sovereign immunity, as BPMC had argued, because "it is unlikely that venue considerations alone would govern a State's decision to assert sovereign immunity from a given lawsuit."809 Similarly, there was little risk that states would gain an unfair advantage by acquiring a private parties' Federal Rule of Civil Procedure 26 disclosures because "it defies common sense that a State keen on retaining its sovereign immunity would, as BPMC posits, risk subjecting itself to liability merely to obtain initial disclosures, hoping that the defendant will object to the chosen venue, which is, of course, a waivable defense."810 The Federal Circuit concluded, "[f]inally, BPMC ignores the fact that these concerns are not even present in this case, both because DHS did not choose the forum of the 1997 lawsuit—it intervened in ongo-

^{802.} Id. at 1332-33, 85 U.S.P.Q.2d (BNA) at 1077.

^{803.} *Id.* at 1333, 85 U.S.P.Q.2d (BNA) at 1077.

^{804.} Id. at 1336, 85 U.S.P.Q.2d (BNA) at 1079.

^{805.} *Id.* at 1334, 85 U.S.P.Q.2d (BNA) at 1078 (citing S. Pasadena v. Mineta, 284 F.3d 1154, 1157–58 (9th Cir. 2002)); Tegic Commc'n Corp. v. Bd. of Regents, 458 F.3d 1335, 1342–43, 80 U.S.P.Q.2d (BNA) 1201, 1205 (Fed. Cir. 2006).

^{806.} Biomedical Patent Mgmt., 505 F.3d at 1337, 85 U.S.P.Q.2d (BNA) at 1080.

^{807.} *Id.*, 85 U.S.P.Q.2d (BNA) at 1080. 808. *Id.* at 1340, 85 U.S.P.Q.2d (BNA) at 1082.

^{809.} Id., 85 U.S.P.Q.2d (BNA) at 1082.

^{810.} Id., 85 U.S.P.Q.2d (BNA) at 1082.

ing litigation—and because the current action was initiated in that same venue."811

The Federal Circuit was careful to note, however, that "we do not mean to draw a bright-line rule whereby a State's waiver of sovereign immunity can never extend to a re-filed or separate lawsuit."812 Rather, the court found that the case law cited by BPMC "does not support its contention that waiver of immunity in one suit should extend to a separate action simply because the action involves the same parties and same subject matter."813 The Federal Circuit thus extracted from the case law "two relevant principles": (1) "a State's waiver of immunity generally does *not* extend to a separate or re-file suit"; and (2) "even a waiver by litigation conduct must nonetheless be 'clear.' These principles, of course, are related, as a waiver that does not 'clearly' extend to a separate lawsuit generally would not preclude a State from asserting immunity in that separate action."814

The Federal Circuit also rejected BPMC's argument that DHS should be judicially estopped from asserting sovereign immunity because its intervention in the first case had rested on its own assertions that it was subject to the district court's jurisdiction.⁸¹⁵ Judicial estoppel should not apply, the court stated, because DHS's positions in the two cases were not clearly inconsistent. 816 Or, as the court explained, "[p]erhaps it is more precise to say that, although DHS's positions were inconsistent, the inconsistency is excused by an intervening change in the law" wrought by Florida Prepaid.817 Even though Florida Prepaid did not change the well-established principle that intervention in a lawsuit constitutes waiver of sovereign immunity, it did assure DHS that it could successfully assert a defense of sovereign immunity.818 Since DHS had had no such expectation of success prior to Florida Prepaid, it had had nothing to lose, and potentially much to gain, by intervening in the original declaratory judgment action.⁸¹⁹ "Accordingly, we reject BPMC's argument that Florida Prepaid did not effect a change in the law relevant to this case," the court concluded.820

^{811.} Id., 85 U.S.P.Q.2d (BNA) at 1082.

^{812.} *Id.* at 1339, 85 U.S.P.Q.2d (BNA) at 1082. 813. *Id.*, 85 U.S.P.Q.2d (BNA) at 1082.

^{814.} *Id.* at 1339–40, 85 U.S.P.Q.2d (BNA) at 1082.

^{815.} *Id.* at 1342, 85 U.S.P.Q.2d (BNA) at 1083.

^{816.} Id., 85 U.S.P.Q.2d (BNA) at 1083.

^{817.} Id., 85 U.S.P.Q.2d (BNA) at 1083. 818. Id., 85 U.S.P.Q.2d (BNA) at 1083–84. 819. Id., 85 U.S.P.Q.2d (BNA) at 1084.

^{820.} Id., 85 U.S.P.Q.2d (BNA) at 1084.

As for BPMC's argument that the State of California had generally waived sovereign immunity for all California State defendants by participating in the patent system and patent suits, the Federal Circuit found this argument "merits little discussion" and "must be rejected." "The Supreme Court in [College Savings] Bank expressly overruled prior case law supporting the notion BPMC urges—i.e., that a state can constructively waive its Eleventh Amendment immunity by its participation in a regulatory scheme." "822

Finally, the Federal Circuit rejected BPMC's argument that the Supreme Court had implicitly overruled *Florida Prepaid*⁸²³ in its more recent decision in *Central Virginia Community College v. Katz.*⁸²⁴ "The holding in *Katz* was so closely tied to the history of the Bankruptcy Clause and the unique aspects of bankruptcy jurisdiction that it cannot be read to extend to actions for patent infringement" and thus "cannot be read to overrule *Florida Prepaid*, either expressly or implicitly." For all these reasons, the Federal Circuit affirmed the district court's dismissal of BPMC's complaint because DHS had a viable defense of sovereign immunity. ⁸²⁶

2. Contracts with the government

In Sevenson Environmental Services, Inc. v. Shaw Environmental, Inc., ⁸²⁷ the Federal Circuit found that a government contractor was entitled to immunity from a patent infringement suit. ⁸²⁸ Defendant Shaw Environmental, Inc. ("Shaw"), a hazardous waste remediation firm, contracted with the U.S. Army Corps of Engineers in 2002 to provide certain clean-up and remediation services. ⁸²⁹ Sevenson Environmental Services, Inc. ("Sevenson") sued Shaw for allegedly infringing certain U.S. patents on methods for treating hazardous waste with phosphoric acid. ⁸³⁰ The district court entered summary judgment that Sevenson's suit against Shaw was barred by government contractor immunity under 28 U.S.C. § 1498. ⁸³¹ The Federal Circuit affirmed. ⁸³²

^{821.} Id. at 1343, 85 U.S.P.Q.2d (BNA) at 1084.

^{822.} Id., 85 U.S.P.Q.2d (BNA) at 1084.

^{823.} Id., 85 U.S.P.Q.2d (BNA) at 1084.

^{824. 546} U.S. 356 (2006).

^{825.} Biomedical Patent Mgt. Co., 505 F.3d at 1343, 85 U.S.P.Q.2d (BNA) at 1084.

^{826.} Id., 85 U.S.P.Q.2d (BNA) at 1084.

^{827. 477} F.3d 1361, 81 U.S.P.Q.2d (BNA) 1906 (Fed. Cir. 2007).

^{828.} Id. at 1363, 81 U.S.P.Q.2d (BNA) at 1907.

^{829.} Id. at 1362, 81 U.S.P.Q.2d (BNA) at 1907.

^{830.} Id., 81 U.S.P.Q.2d (BNA) at 1908.

^{831.} Id. at 1363, 81 U.S.P.Q.2d (BNA) at 1907.

^{832.} Id., 81 U.S.P.Q.2d (BNA) at 1907.

Shaw's relationship with the government was defined by two separate contracts-the "Total Environmental Restoration Contract" ("TERC"), and the "Pre-placed Remedial Action Contract" ("PRAC"), which replaced the TERC due to funding issues. 833 Both the TERC and PRAC required Shaw to provide hazardous waste remediation services at a number of government-owned waste sites. 834 Both contracts contained the same authorization and consent clause:

in performing this contract or any subcontract at any tier, of any invention described in and covered by a United States patent . . . used in machinery, tools, or methods whose use necessarily results from compliance by the Contractor or subcontractor with (i) specifications or written provisions forming a part of this contract or (ii) specific written instructions given by the Contracting Officer directing the manner of performance.835

As a result of the government's authorization and consent to Shaw's alleged use of the patented remediation methods, Shaw's alleged infringement "shall be construed as use or manufacture for the United States[,]" for which the only recourse would be an action against the United States in the U.S. Court of Federal Claims. 836 Accordingly, the Federal Circuit found that Shaw was entitled to immunity from suit under § 1498(a) as a government contractor.837

3. Supremacy Clause

In Biotechnology Industry Organization v. District of Columbia, 838 two industry organizations challenged the constitutionality of a statute by the District of Columbia to regulate the prices of prescription drugs.⁸³⁹ The Federal Circuit concluded that the D.C. statute was preempted by the Copyright and Patent Clause of the Constitution.⁸⁴⁰ Even though the District is technically not a state, Federal supremacy principles still applied. 841 Congress, the court explained, has determined the extent of rewards to be conferred upon inventors, including setting patent terms and allowing drug manufacturers to obtain extensions of patent terms under certain circumstances.⁸⁴² The District of Columbia was thus improperly trying to rebalance "the statu-

^{833.} Id., 81 U.S.P.Q.2d (BNA) at 1908.

^{834.} *Id.*, 81 U.S.P.Q.2d (BNA) at 1908. 835. *Id.*, 81 U.S.P.Q.2d (BNA) at 1908.

^{836.} Id. at 1365, 81 U.S.P.Q.2d (BNA) at 1909 (citing language from 28 U.S.C. § 1498(a) (2000)).

^{837.} Id., 81 U.S.P.Q.2d (BNA) at 1909.

^{838. 496} F.3d 1362, 83 U.S.P.Q.2d (BNA) 1639 (Fed. Cir. 2007).

^{839.} Id. at 1366, 83 U.S.P.Q.2d (BNA) at 1642.

^{840.} *Id.* at 1374, 83 U.S.P.Q.2d (BNA) at 1648.

^{841.} Id. at 1371–72, 83 U.S.P.Q.2d (BNA) at 1646.

^{842.} Id. at 1373, 83 U.S.P.Q.2d (BNA) at 1647.

tory framework of rewards and incentives insofar as it relates to inventive new drugs[,]" the court concluded.843

L. Statutory Interpretation

In Merck & Co. v. Hi-Tech Pharmacal Co., 844 a generic drug manufacturer was accused of infringing a patent that was subject to both a terminal disclaimer and a patent term extension under 35 U.S.C. § 156. 845 During prosecution of the U.S. Patent No. 4,797,413 ("the '413 patent"), assignee Merck filed a terminal disclaimer under 35 U.S.C. § 253 to overcome an obvious-type double patenting rejection over the claims of U.S. Patent No. 4,677,115 ("the '115 patent"), also assigned to Merck. 846 The patent terms of both the '413 and '115 patents, which coincided as a result of the terminal disclaimer, were extended by over five months as a result of the 1994 Uruguay Round Agreements Act ("URAA").847 The URAA changed the terms of patents then in force to the greater of seventeen years from the date of issue or twenty years from the earliest effective filing date. 848 In response to a request by Merck pursuant to 35 U.S.C. § 156, the PTO extended the term of the '413 patent approximately three and a half years based on the period of FDA review of the patented drug. 849

Defendant High-Tech moved to dismiss under Rule 12(b)(6), on the basis that Merck had disclaimed any extension of the patent term beyond the term of the '115 patent when it filed the terminal disclaimer. 850 Merck responded that 35 U.S.C. § 156 is unambiguous in that it states that the patent term "shall be extended" upon the satisfaction of the enumerated conditions and does not prohibit the extension of patent terms subject to terminal disclaimers.⁸⁵¹

The Federal Circuit agreed with Merck that the language of 35 U.S.C. § 156 is unambiguous and not in conflict with the provisions of 35 U.S.C. § 253.852 The Federal Circuit agreed with Merck that both the language and legislative history of the Hatch-Waxman Act

^{843.} *Id.* at 1374, 83 U.S.P.Q.2d (BNA) at 1648. 844. 482 F.3d 1317, 82 U.S.P.Q.2d (BNA) 1203 (Fed. Cir. 2007).

^{845.} *Id.* at 1318–19, 82 U.S.P.Q.2d (BNA) at 1204–05.

^{846.} Id. at 1319, 82 U.S.P.Q.2d (BNA) at 1204.

^{847.} Id., 82 U.S.P.Q.2d (BNA) at 1204.

^{848.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1204.

^{849.} Id., 82 U.S.P.Q.2d (BNA) at 1205. 35 U.S.C. § 156 (2000) is a portion of the Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"). 850. Merck, 482 F.3d at 1320, 82 U.S.P.Q.2d (BNA) at 1205.

^{851.} Id., 82 U.S.P.Q.2d (BNA) at 1206.

^{852.} Id. at 1323, 82 U.S.P.Q.2d (BNA) at 1206-07.

are "unambiguous" in allowing the extension and do not conflict with laws regarding disclaimers. 853

The computation of a Hatch-Waxman patent term extension is from the expiration date resulting from the terminal disclaimer and not from the date the patent would have expired in the absence of the terminal disclaimer. Any waiver of the term is thus not ignored or nullified because the terminal disclaimer provides the date from which the patent term extension begins.⁸⁵⁴

In Boston Scientific Scimed, Inc. v. Medtronic Vascular, Inc., 855 the Federal Circuit concluded that 35 U.S.C. § 119(a) does not permit an applicant for a U.S. patent to benefit from the priority of a foreign application previously filed by an entity that was not acting on behalf of the U.S. applicant at the time of the filing.⁸⁵⁶

Andrew Cragg and Michael Dake (collectively, "Cragg") filed their subject U.S. patent application on June 5, 1995, and assigned their rights to Boston Scientific, which later merged with Scimed.⁸⁵⁷ Thomas Fogarty, Timothy Ryan, and Kirsten Freislinger (collectively, "Fogarty") filed their U.S. patent application on the same date and assigned their rights to the company that later became Medtronic.858 The PTO's Board of Patent Appeals and Interferences initially designated Cragg as the senior party in the interference, based on a February 9, 1994, filing date of two related European patent applications, which had been filed by MinTec SARL ("MinTec"), a French company. 859 Fogarty successfully attacked this designation on the basis that neither Cragg nor Dake had assigned his rights to MinTec until after it had filed the European applications. 860 The Board reversed itself, denied Scimed (Cragg) the benefit of the European filing date, and designated Fogarty the senior party based on the June 8, 1994, filing date of a related U.S. patent application. 861 Scimed sued in the district court, which affirmed the Board's ruling, and then appealed to the Federal Circuit. 862

The Federal Circuit affirmed the rulings of the district court and the Board, for the following reasons:

^{853.} Id. at 1322, 82 U.S.P.Q.2d (BNA) at 1207.

^{854.} *Id.* at 1322–23, 82 U.S.P.Q.2d (BNA) at 1207. 855. 497 F.3d 1293, 83 U.S.P.Q.2d (BNA) 1669 (Fed. Cir. 2007).

^{856.} *Id.* at 1296–97, 83 U.S.P.Q.2d (BNA) at 1671.

^{857.} *Id.* at 1295, 83 U.S.P.Q.2d (BNA) at 1670. 858. *Id.* at 1296, 83 U.S.P.Q.2d (BNA) at 1670.

^{859.} Id., 83 U.S.P.Q.2d (BNA) at 1670.

^{860.} Id., 83 U.S.P.Q.2d (BNA) at 1670.

^{861.} Id., 83 U.S.P.Q.2d (BNA) at 1670.

^{862.} Id., 83 U.S.P.Q.2d (BNA) at 1670.

[W] hile the foreign application must obviously be for the same invention and may be filed by someone other than the inventor, section 119(a) also requires that a nexus exist between the inventor and the foreign applicant at the time the foreign application was filed. Indeed, as a matter of pure logic, an entity could not have filed a foreign application "on behalf of" an inventor without the inventor's knowledge or consent; that the foreign application may have been filed in accordance with the laws of the country in which it was filed has no bearing here. Therefore . . . we now explicitly hold that that a foreign application may only form the basis for priority under section 119(a) if that application was filed by either the U.S. applicant himself, or by someone acting on his behalf at the time the foreign application was filed.863

In the instant case, Scimed could not claim priority to the European applications because at the time they were filed, MinTec had no legal relationship to Cragg and was not acting on their behalf.⁸⁶⁴ The Federal Circuit also found that the district court had not erred in precluding Scimed from presenting new evidence because, although a party may ordinarily present new evidence in an appeal to a district court from a Board decision, in this case the submission was improper because Scimed had intended to use it to support new legal theories that it had not previously raised before the Board.⁸⁶⁵

In Somerset Pharmaceuticals, Inc. v. Dudas, 866 the Federal Circuit denied as moot Somerset's appeal to compel the PTO to issue his request for an interim extension of its reissue patent. 867 Specifically, Somerset applied for patent term extension under 35 U.S.C. § 156(d)(1) on April 27, 2006, followed on February 21, 2007, by a request for interim extension under 35 U.S.C. § 156(e)(2).868 In May 2007, Somerset filed an action to compel the Director of the PTO to act on its interim request and moved for a preliminary injunction.⁸⁶⁹ The district court denied that motion on June 29, 2007, and Somerset appealed.⁸⁷⁰ Not long afterwards, on July 12, 2007, the PTO denied both Somerset's request for an interim extension and its application for an extension on the merits.⁸⁷¹ Accordingly, Somerset withdrew that portion of its appeal that sought to compel the Direc-

^{863.} Id. at 1297-98, 83 U.S.P.Q.2d (BNA) at 1671-72.

^{864.} Id. at 1296, 83 U.S.P.Q.2d (BNA) at 1670.

^{865.} *Id.* at 1298, 83 U.S.P.Q.2d (BNA) at 1672. 866. 500 F.3d 1344, 84 U.S.P.Q.2d (BNA) 2023 (Fed. Cir. 2007).

^{867.} Id. at 1345, 84 U.S.P.Q.2d (BNA) at 2024.

^{868.} *Id.*, 84 U.S.P.Q.2d (BNA) at 2023–24. 869. *Id.*, 84 U.S.P.Q.2d (BNA) at 2024.

^{870.} Id., 84 U.S.P.Q.2d (BNA) at 2024.

^{871.} Id., 84 U.S.P.Q.2d (BNA) at 2024.

tor to act on its request for interim relief but continued its appeal regarding the denial of injunctive relief to compel the Director to grant that request.⁸⁷²

The Federal Circuit noted that the Director may grant an interim patent extension only if the patent would expire before a certificate of extension could be granted.⁸⁷³ Since the Director had already denied Somerset's application for an interim extension, the "Director has no statutory authority to issue the interim extension Somerset seeks[,]" and Somerset could not exhibit the reasonable likelihood of success needed for a preliminary injunction.⁸⁷⁴

III. PATENTABILITY AND VALIDITY

All patents are presumed valid, and each claim is "presumed valid independently of the validity of other claims." This presumption arises because it is assumed that the PTO examiner located the most relevant prior art and determined that all the requirements for patentability, including non-obviousness, were met before allowing the patent to issue. A court, however, is not bound by an examiner's findings. The presumption of validity may be overcome by clear and convincing evidence of invalidity. The presumption of validity may be overcome by clear and convincing evidence of invalidity.

However, the ease with which the clear and convincing standard is met is influenced by whether the examiner considered the same evidence or arguments presented in court. In particular, it may be easier to meet the clear and convincing standard if a challenging party can locate evidence more relevant than that before the examiner. For example,

^{872.} Id. at 1346, 84 U.S.P.Q.2d (BNA) at 2024.

^{873.} *Id.*, 84 U.S.P.Q.2d (BNA) at 2024 (discussing 35 U.S.C. § 156(e) (2) (2000)).

^{874.} *Id.*, 84 U.S.P.Q.2d (BNA) at 2024.

^{875. 35} U.S.C. § 282 (2000); see Union Oil Co. v. Atl. Richfield Co., 208 F.3d 989, 995, 54 U.S.P.Q.2d (BNA) 1227, 1231 (Fed. Cir. 2000) ("To prevail on anticipation at trial, the refiners had to prove their case by clear and convincing evidence. The law imposes this high burden because Unocal's patent, like any issued patent, enjoys a presumption of validity.") (citation omitted).

presumption of validity.") (citation omitted).

876. Smiths Indus. Med. Sys., Inc. v. Vital Signs, Inc., 183 F.3d 1347, 1356, 51 U.S.P.Q.2d (BNA) 1415, 1421 (Fed. Cir. 1999).

^{877.} Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1329, 56 U.S.P.Q.2d (BNA) 1481, 1448 (Fed. Cir. 2000).

^{`878.´} Ultra-Tex Surfaces, Inc. v. Hill Bros. Chem. Co., 204 F.3d 1360, 1367, 53 U.S.P.Q.2d (BNA) 1892, 1898 (Fed. Cir. 2000).

^{879.} Cf. Purdue Pharma, 230 F.3d at 1329, 56 U.S.P.Q.2d at 1448 (noting that "the correct legal principles [are] that the amended claims define the invention, that the support for the invention must be found in the specification as filed, and that the amended claims could not be used to provide that support"); Ultra-Tex Surfaces, 204 F.3d at 1367, 53 U.S.P.Q.2d at 1898 (explaining that "when a party alleges that a claim is invalid based on the very same references that were before the examiner when the claim was allowed, that party assumes . . . the added burden of overcoming

[w]hen no prior art other than that which was considered by the PTO examiner is relied on by the attacker, [the attacker] has the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job, which includes one or more examiners who are assumed to have some expertise in interpreting the references 880

A. Patentable Subject Matter

One of the fundamental requirements for patentability of an invention is that the invention comprises patentable subject matter. The statutory provision governing patentable subject matter is 35 U.S.C. § 101, which provides that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title."

Thus, the validity of a patent may be attacked if the claimed subject matter is not patentable under the patent law. However, a defense based upon non-patentable subject matter is seldom employed and rarely successful. In the words of the U.S. Supreme Court, Congress chose very expansive language in drafting § 101 such that "anything under the sun that is made by man" is patentable subject matter. Nonetheless, § 101 does have some limits. For example, laws of nature, physical phenomena, abstract ideas, and mathematical algorithms are not patentable. The Federal Circuit decided two important cases in 2007 which further defined the boundaries on patentable subject matter.

In *In re Comiskey*,⁸⁸⁴ the Federal Circuit revisited the patentability of business methods. Comiskey had applied for a patent directed to methods and systems for mandatory arbitration of legal documents, such as wills or contracts.⁸⁸⁵ The claims fell into two general catego-

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the deference that is due to a qualified government agency presumed to have properly done its job").

^{880.} *Ultra-Tex Surfaces*, 204 F.3d at 1367, 53 U.S.P.Q.2d (BNA) at 1898 (citing Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1359, 220 U.S.P.Q. (BNA) 763, 770 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 821 (1984)).

^{881. 35} U.S.C. § 101 (2000).

^{882.} Diamond v. Chakrabarty, 447 U.S. 303, 309, 206 U.S.P.Q. (BNA) 193, 197 (1980) (citation omitted). In *Chakrabarty*, the Supreme Court held that an oil-consuming bacteria, classified as a life form, was patentable. *Id.* at 318, 206 U.S.P.Q (BNA) at 201.

^{883.} Id., 206 U.S.P.Q. (BNA) at 197.

^{884. 499} F.3d 1365, 84 U.S.P.Q.2d (BNA) 1670 (Fed. Cir. 2007).

^{885.} Id. at 1368, 84 U.S.P.Q.2d (BNA) at 1671.

ries: (1) those that did not require the use of a computer or mechanical device (e.g., independent claims 1 and 32), and (2) those that did require such a device (e.g., claims 17 and 46). The PTO rejected the claims as obvious, and Comiskey appealed.⁸⁸⁷

After oral argument, the Federal Circuit requested additional briefing on the patentability of the subject matter in Comiskey's application under 35 U.S.C. § 101.888 Comiskey protested, stating that the Federal Circuit lacked the power to consider § 101 because it was not a ground for rejection relied upon by the PTO.889 The PTO, on the other hand, urged the court to consider § 101 to provide "needed guidance" in this area. 890

The Federal Circuit sided with the PTO and held that it could consider "a new legal ground for affirmance" that had not been considered by the PTO.⁸⁹¹ Under Supreme Court precedent, "a reviewing court can (and should) affirm an agency decision on a legal ground not relied on by the agency if there is no issue of fact, policy, or agency expertise."892 Since the patentability of subject matter under § 101 is a question of law, the Federal Circuit was not required to make factual or policy determinations that had not been made by the PTO. 893 Moreover, the court should consider a new legal ground for affirmance "where, as here, '[i]t would be wasteful to send' the case back to the agency for a determination as to patentable subject matter."894

After establishing its authority to consider § 101, the Federal Circuit affirmed the rejection of the claims that did not require the use of a computer or machine. 895 Business methods, the court explained, are "subject to the same legal requirements for patentability as applied to any other process or method."896 In particular, "abstract ideas" and "fundamental truths" are not patentable if they have no claimed practical application, whereas a claim reciting an algorithm or abstract concept is patentable "only if, as employed in the process,

^{886.} *Id.* at 1369–70, 84 U.S.P.Q.2d (BNA) at 1672. 887. *Id.* at 1370–71, 84 U.S.P.Q.2d (BNA) at 1672–73.

^{888.} *Id.* at 1371, 84 U.S.P.Q.2d (BNA) at 1673.

^{889.} Id., 84 U.S.P.Q.2d (BNA) at 1673.

^{890.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1673. 891. *Id.* at 1373, 84 U.S.P.Q.2d (BNA) at 1675.

^{892.} Id. at 1372, 84 U.S.P.Q.2d (BNA) at 1674 (quoting SEC v. Chenery Corp., 318 U.S. 80, 88 (1943))

^{893.} Id., 84 U.S.P.Q.2d (BNA) at 1675.

^{894.} Id., 84 U.S.P.Q.2d (BNA) at 1675 (alteration in original) (quoting Chenery Corp., 318 U.S. at 88).

 $^{895. \;\; \}textit{Id.}$ at 1380–81, 84 U.S.P.Q.2d (BNA) at 1680–81.

^{896.} Id. at 1374, 84 U.S.P.Q.2d (BNA) at 1676 (quoting State St. Bank & Trust Co. v. Signature Fin. Group, Inc., 149 F.3d 1368, 1375, 47 U.S.P.Q.2d (BNA) 1596, 1602 (Fed. Cir. 1998)).

it is embodied in, operates on, transforms, or otherwise involves another class of statutory subject matter, i.e., a machine, manufacture, or composition of matter."897 The court continued:

Thus, a claim that involves both a mental process and one of the other categories of statutory subject matter (i.e., a machine, manufacture, or composition) may be patentable under § 101. For example, we have found processes involving mathematical algorithms used in computer technology patentable because they claimed practical applications and were tied to specific machines.

However, mental processes—or processes of human thinking standing alone are not patentable even if they have practical application.

Following the lead of the Supreme Court, this court and our predecessor court have refused to find processes patentable when they merely claimed a mental process standing alone and untied to another category of statutory subject matter even when a practical application was claimed.898

The Federal Circuit concluded that Comiskey's first set of claims was not patentable because they constituted "particular business systems... that depend entirely on the use of mental processes."899 The court explained:

[T]he patent statute does not allow patents on particular systems that depend for their operation on human intelligence alone, a field of endeavor that both the framers and Congress intended to be beyond the reach of patentable subject matter. Thus, it is established that the application of human intelligence to the solution of practical problems is not in and of itself patentable. 900

Comiskey's second set of claims, in contrast, combined an "unpatentable mental process . . . with a machine [a computer]" and thus claimed patentable subject matter under § 101.901 Nonetheless, "[t]he routine addition of modern electronics to an otherwise unpatentable invention typically creates a prima facie case of obviousness."902 The Federal Circuit declined to decide the question of obvi-

^{897.} Id. at 1376, 84 U.S.P.Q.2d (BNA) at 1678.

^{898.} Id. at 1377–78, 84 U.S.P.Q.2d (BNA) at 1678.

^{899.} *Id.* at 1378, 84 U.S.P.Q.2d (BNA) at 1679. 900. *Id.* at 1378–79, 84 U.S.P.Q.2d (BNA) at 1679.

^{901.} Id. at 1379–80, 84 U.S.P.Q.2d (BNA) at 1680.

^{902.} Id. at 1380, 84 U.S.P.Q.2d (BNA) at 1680.

ousness but remanded those claims to the PTO to determine "whether the addition of general purpose computers or modern communication devices to Comiskey's otherwise unpatentable mental process would have been non-obvious to a person of ordinary skill in the art."903

In In re Nuijten, 904 the issue before the court was whether an electromagnetic signal is patentable subject matter. 905 Nuijten filed a patent application directed to improved methods for encoding watermarks in audio or video signals in order to lower distortion levels. 906 In the context of signal processing, a "watermark" is data embedded into audio, video, or image signals, or data files to identify a source or copyright status of the signals or data files.⁹⁰⁷ The claims sought to patent any "signal" that has been encoded in a particular manner. 908

The PTO rejected a claim directed to a storage medium and claims directed to signals under § 101 on the basis that they were directed to non-statutory subject matter. 909 On appeal, the Board of Patent Appeals and Interferences upheld the rejection of the signal claims because they did not fall within any of the four categories of patentable subject matter in § 101, i.e., process, machine, manufacture, or composition of matter.910

Thus, "[t]he essence of the dispute between the parties [was] whether a transitory signal is covered by any statutory category[,]" the Federal Circuit explained. 911 The only § 101 category worth serious consideration was that of a manufacture. "Manufacture," however, refers to articles resulting from the process of manufacturing and thus must be "tangible articles or commodities." The court reasoned that electromagnetic signals do not qualify as "tangible articles or commodities" because they are only "fleeting" energies "devoid of any semblance of permanence during transmission."914 Accordingly, the Federal Circuit found that electromagnetic signals are not patentable subject matter under § 101.

^{903.} Id. at 1380–81, 84 U.S.P.Q.2d (BNA) at 1681.

^{904. 500} F.3d 1346, 84 U.S.P.Q.2d (BNA) 1495 (Fed. Cir. 2007). 905. *Id.* at 1348, 84 U.S.P.Q.2d (BNA) at 1496.

^{906.} Id., 84 U.S.P.Q.2d (BNA) at 1496.

^{907.} *Id.* at 1348–49, 84 U.S.P.Q.2d (BNA) at 1497.

^{908.} *Id.* at 1351, 84 U.S.P.Q.2d (BNA) at 1498.

^{909.} Id., 84 U.S.P.Q.2d (BNA) at 1498.

^{910.} Id. at 1352, 84 U.S.P.Q.2d (BNA) at 1498–99.

^{911.} Id. at 1354, 84 U.S.P.Q.2d (BNA) at 1500.

^{912.} Id. at 1356-57, 84 U.S.P.Q.2d (BNA) at 1502.

^{913.} *Id.* at 1356, 84 U.S.P.Q.2d (BNA) at 1502.

^{914.} Id., 84 U.S.P.Q.2d (BNA) at 1502.

Judge Linn dissented in part, arguing that the definition of "manufacture" should not be limited to "non-transitory, tangible things." 915 Instead, Judge Linn advocated a more expansive view of the term "manufacture" given the "wide scope" of § 101, as noted by the Supreme Court in *Chakrabarty*. Judge Linn concluded that the signal claims should have been eligible for patenting under § 101.917

B. Anticipation

Under the doctrine of anticipation, a patent claim is invalid if the claimed invention lacks novelty. Anticipation, a question of fact, compares the "prior art" to a claim of the patent. [A] claim is anticipated if each and every limitation is found either expressly or inherently in a single prior art reference." This test is often referred to as the "four corners" doctrine. 921 Anticipation also requires that the prior art be enabling to one of ordinary skill in the art. 922 Anticipation thus prevents a patentee from obtaining claims that do not contribute to the store of knowledge of those in the field. 923 Additionally, anticipation "encourages prompt filing of patent applications after inventions have been completed and publicly used, and sets an outer limit to the term of exclusivity."924

The Federal Circuit confronted the question of inherent anticipation in In re Omeprazole Patent Litigation, a multiphase litigation involving three patents related to Omeprazole, which is sold under the brand name Prilosec. 926 Omeprazole functions by inhibiting the production of gastric acid when administered within an enteric coating and an additional separating layer. 927 AstraZeneca's U.S. Patent No.

917. *Id.* at 1369, 84 U.S.P.Q.2d (BNA) at 1511.

^{915.} Id. at 1358, 84 U.S.P.Q.2d (BNA) at 1503.

^{916.} Id., 84 U.S.P.Q.2d (BNA) at 1503.

^{918.} Karsten Mfg. Co. v. Cleveland Golf, 242 F.3d 1376, 1383, 58 U.S.P.Q.2d 1286, 1291 (Fed. Cir. 2001).

^{919.} Telemac Cellular Corp. v. Topp Telecomm., Inc., 247 F.3d 1316, 1327–28, 58 U.S.P.Q.2d 1545, 1552 (Fed. Cir. 2001); Celeritas Tech., Ltd. v. Rockwell Int'l Corp., 150 F.3d 1354, 1361, 47 U.S.P.Q.2d (BNA) 1516, 1522 (Fed. Cir. 1998). 920. Celeritas Tech., 150 F.3d at 1361, 47 U.S.P.Q.2d (BNA) at 1522.

^{921.} Advanced Display Sys., Inc. v. Kent State Univ., 212 F.3d 1272, 1282, 54 U.S.P.Q. (BNA) 1673, 1679 (Fed. Cir. 2000), cert. denied, 532 U.S. 904 (2001).

^{922.} See generally Bristol Meyers-Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 58 U.S.P.Q. (BNA) 1508 (Fed. Cir. 2001) (discussing enablement of an anticipatory reference).

^{923.} Woodland Trust v. Flowertree Nursery, Inc., 148 F.3d 1368, 1370, 47 U.S.P.Q.2d (BNA) 1363, 1365 (Fed. Cir. 1998).

^{924.} Allied Colloids, Inc. v. Am. Cyanamid Co., 64 F.3d 1570, 1574, 35 U.S.P.Q.2d (BNA) 1840, 1842 (Fed. Cir. 1995).

^{925. 483} F.3d 1364, 82 U.S.P.Q.2d (BNA) 1643 (Fed. Cir. 2007).

^{926.} Id. at 1367, 82 U.S.P.Q.2d (BNA) at 1645.

^{927.} Id., 82 U.S.P.Q.2d (BNA) at 1645–46.

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6,013,281 ("the '281 patent") was directed to a process for forming the coated pill, specifically, the formation in situ of a water-soluble separating layer between the acid-sensitive omeprazole core and the enteric coating due to a reaction between the alkaline reacting compound ("ARC") in the core and the enteric coating. 928 Claim 1, for example, required forming in situ a separating layer as a water soluble salt product between a core and a polymer coating layer. 929 In a twoone decision, the Federal Circuit found that the '281 patent was invalid as inherently anticipated. 930

According to the Federal Circuit, "the '281 process produces an omeprazole formulation with three distinct layers, but starts with only two of the three layers."931 Claim 1 recited a minimum ARC concentration in the core required to form the separating layer, and dependent claims recited specific ARC compounds. 932 The Federal Circuit found it noteworthy that the '281 patent specification contained process parameters, such as temperature, that were not recited in the claims. 935

A prior Korean patent application to Chong Dam Corporation ("CKD") recited all of the claim limitations of the asserted '281 patent, with the exception of the in situ formation of the separating layer. 934 The trial court found that the *in situ* separation necessarily formed when practicing the prior art. 935 AstraZeneca's own testing in connection with a lawsuit in Korea with CKD supported the conclusion that the CKD formulation created an *in situ* separating layer. ⁹³⁶

The Federal Circuit affirmed, finding no clear error in the factual findings of the district court.937 Notwithstanding the absence of a disclosure of the process used by CKD to make its formulation, the majority of the panel found that the presence of a separating layer in the CKD formulation was inherent from the combination of the ingredients specified in CKD's Korean patent application. 938

Judge Newman dissented, however, finding no basis in the CKD reference from which to conclude that the missing descriptive matter was necessarily present.⁹³⁹ Judge Newman insisted that the "inherent

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928. Id., 82 U.S.P.Q.2d (BNA) at 1646.
929. Id., 82 U.S.P.Q.2d (BNA) at 1647.
930. Id. at 1376, 82 U.S.P.Q.2d (BNA) at 1652.
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^{931.} Id. at 1367, 82 U.S.P.Q.2d (BNA) at 1646.

^{932.} *Id.* at 1367–68, 82 U.S.P.Q.2d (BNA) at 1646. 933. *Id.* at 1368, 82 U.S.P.Q.2d (BNA) at 1646.

^{934.} *Id.* at 1371, 82 U.S.P.Q.2d (BNA) at 1649.

^{935.} *Id.* at 1373, 82 U.S.P.Q.2d (BNA) at 1650.

^{936.} *Id.* at 1372, 82 U.S.P.Q.2d (BNA) at 1650. 937. *Id.* at 1373, 82 U.S.P.Q.2d (BNA) at 1650.

^{938.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1650.

^{939.} *Id.* at 1377, 82 U.S.P.Q.2d (BNA) at 1653 (Newman, J., dissenting).

information" must "be known to be present in the subject matter of the reference, when viewed by persons experienced in the field of the invention."940 The mere possibility that the CKD reference could be used by one of skill in the art to arrive at the claimed process was not enough, she wrote.⁹⁴¹ Judge Newman also emphasized that the CKD reference did not enable one of ordinary skill in the art to practice the claimed invention and thus could not anticipate the claims at issue. 942

In *In re Buszard*, ⁹⁴³ the Federal Circuit reversed the Board of Patent Appeals's § 102(b) rejection of claims, focusing particularly on the PTO's practice of giving claims their broadest reasonable interpretation.944

The claims at issue were directed to a flame retardant composition that produces a "flexible polyurethane foam reaction mixture," which the Board broadly interpreted to mean "any reaction mixture which produces, at least ultimately, a flexible polyurethane foam."945 The PTO maintained that when the Buszard claims were given their broadest interpretation, they were anticipated by a patent to Eling. 946 Buszard, on the other hand, argued that Eling shows only a rigid polyurethane foam that loses its rigidity when crushed.⁹⁴⁷

At oral argument before the Federal Circuit, the PTO solicitor contended, apparently for the first time, that when a rigid foam is crushed, the chemical bonds are broken, producing a flexible foam reaction mixture.948 The court found this contention was not sufficiently credible to warrant further consideration because the theory was proposed without support or citation, and Buszard had no chance to refute it. 949 The Federal Circuit concluded that Eling described only a rigid foam product that produces a rigid product. 950 As Judge Newman noted, "[n]o matter how broadly 'flexible foam' . . . is construed, it is not a rigid foam [I]t is not a reasonable claim interpretation to equate 'flexible' with 'rigid,' or to equate a crushed rigid polyurethane foam with a flexible polyurethane foam."951

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940. Id. at 1378, 82 U.S.P.Q.2d (BNA) at 1654.
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^{941.} Id., 82 U.S.P.Q.2d (BNA) at 1654.

⁹⁴⁹ Id. at 1380, 82 U.S.P.Q.2d (BNA) at 1656.

^{943. 504} F.3d 1364, 84 U.S.P.Q.2d (BNA) 1749 (Fed. Cir. 2007). 944. *Id.* at 1366–67, 84 U.S.P.Q.2d (BNA) at 1750–51.

^{945.} Id. at 1367, 84 U.S.P.Q.2d (BNA) at 1751.

^{946.} Id. at 1366, 84 U.S.P.Q.2d (BNA) at 1750.

^{947.} Id., 84 U.S.P.Q.2d (BNA) at 1750.

^{948.} *Id.* at 1367, 84 U.S.P.Q.2d (BNA) at 1751.

^{949.} Id., 84 U.S.P.Q.2d (BNA) at 1751.

^{950.} Id., 84 U.S.P.Q.2d (BNA) at 1751.

^{951.} Id., 84 U.S.P.Q.2d (BNA) at 1751.

In dissent, Judge Prost argued that the majority did not "apply the rule that the Board is entitled to give claim language its broadest reasonable interpretation."952 He also asserted that Buszard did not adequately define the term "flexible polyurethane foam reaction mixture" in the specification as to prevent anticipation by Eling. 953

In Zenon Environmental, Inc. v. United States Filter Corp., 954 the Federal Circuit reversed a finding of no anticipation on the basis that the grandchild patent ("the '319 patent") was not entitled to the priority date of the grandparent application ("the '373 patent"), due to a lack of continuity of disclosure between the grandparent and parent patent ("the '250 patent"). 955 Although anticipation is a question of fact, continuity of disclosure is a question of law subject to de novo review. 956

The '250 patent incorporated a description of a "vertical skein" from its grandparent '373 patent using the following language: "Further details relating to the construction and deployment of a most preferred skein are found in the parent U.S. Pat. No. 5,639,373, and in Ser. No. 08/690,045, the relevant disclosures of each of which are included by reference thereto as if fully set forth herein."957 The Federal Circuit found that the "plain language indicates that the subject matter that is being incorporated by reference pertains to the details relating to the construction and deployment of a vertical skein."958 The vertical skein, according to the '373 patent, "consisted of fibers, a pair of headers, and a permeate collection means, . . . [but] by definition, a skein does not include a gas distribution system." Accordingly, the court concluded that the '250 patent did not incorporate the gas distribution system of the grandparent '373 patent. 960 As a result, the chain of continuity was broken between the '373 patent and the grandchild '319 patent, which claimed a filtering apparatus comprising inter alia a gas distribution system. 961 The panel majority concluded that the grandparent '373 patent anticipated the '319 patent.⁹⁶²

Id. at 1368, 84 U.S.P.Q.2d (BNA) at 1751 (Prost, J., dissenting). 952.

^{953.} *Id.* at 1369–70, 84 U.S.P.Q.2d (BNA) at 1752–53

^{954. 506} F.3d 1370, 85 U.S.P.Q.2d 1118 (Fed. Cir. 2007).

^{955.} *Id.* at 1377–78, 85 U.S.P.Q.2d (BNA) at 1123.

^{956.} *Id.* at 1379, 85 U.S.P.Q.2d (BNA) at 1124.

^{957.} Id. at 1376, 85 U.S.P.Q.2d (BNA) at 1122.

^{958.} *Id.* at 1379, 85 U.S.P.Q.2d (BNA) at 1124.

^{959.} *Id.* at 1380, 85 U.S.P.Q.2d (BNA) at 1125. 960. *Id.*, 85 U.S.P.Q.2d (BNA) at 1125.

^{961.} *Id.* at 1380–81, 85 U.S.P.Q.2d (BNA) at 1124–25.

^{962.} Id. at 1382, 85 U.S.P.Q.2d (BNA) at 1126.

Judge Newman dissented from the majority opinion, arguing that "[t]he question of what material would be understood as incorporated is a question of fact," but the findings by the patent examiner and district court had not been shown to have been clearly erroneous. 963 Judge Newman further wrote that the panel's decision "casts doubt on the reliable use of this expedient [of using incorporation by reference]" and "raise[s] new risks of patent drafting" without adding anything to public knowledge, the patent's disclosure requirements, or compliance with § 120.964 The majority found the dissent "alarming[]," for "[t]he draftsman here made clear what was being incorporated by reference and, by difference, what was not. No doubt or risk arises from carefully drafted language that is interpreted to mean what it says."965

On-sale and public use bar

Under 35 U.S.C. § 102(b), once an invention is offered for sale or used in public, the inventor has one year in which to file a patent application. 966 If the invention was in public use or on sale more than one year prior to the filing date of the patent application, § 102(b) bars the ability to patent the invention. 967 An on-sale bar under § 102(b) requires that two conditions be satisfied: (1) the claimed invention must have been the subject of a commercial sale or offer for sale more than one year before the application was filed, and (2) the invention must have been ready for patenting. ⁹⁶⁸ An invention can be found to be "ready for patenting" in at least the following ways: (1) by proof that it was reduced to practice, or (2) by proof that 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. 969

In the following Federal Circuit decisions, invalidation frequently turned on the meaning of "public use" and "on sale." The Federal Circuit has described "public use" as including "any use of [the

968. Sparton Corp. v. United States, 399 F.3d 1321, 1323, 73 U.S.P.Q.2d (BNA) 1919, 1921 (Fed. Cir. 2005).

^{963.} Id. at 1384, 85 U.S.P.Q.2d (BNA) at 1128 (Newman, J., dissenting).

^{964.} *Id.* at 1385, 85 U.S.P.Q.2d (BNA) at 1129. 965. *Id.* at 1382 n.3, 85 U.S.P.Q.2d (BNA) at 1126 n.3.

^{966. 35} U.S.C. § 102(b) (2000).

^{967.} *Id*.

^{969.} Id., 73 U.S.P.Q.2d at 1921.

claimed] invention by a person other than the inventor who is under no limitation, restriction or obligation of secrecy to the inventor."970

In Cargill, Inc. v. Canbra Foods, Ltd., 971 Cargill accused Canbra of infringing four of its patents related to non-hydrogenated canola oil. 972 The district court found that two of the patents were invalid under the on-sale bar of 35 U.S.C. § 102(b) because Cargill had sold 400 pounds of the claimed composition prior to the critical date.⁹⁷³ The Federal Circuit, in a unanimous decision, affirmed the judgment of the district court that the two patents were invalid under § 102(b)'s on-sale bar rule. 974

In so holding, the Federal Circuit rejected Cargill's argument that the oil, which was the subject of the sale was not ready for patenting, and thus did not trigger the on-sale bar rule, because "an invention is only reduced to practice when it is shown to work for its intended purpose."975 The Federal Circuit responded that Cargill was aware of the utility of the claimed invention before its offer to sell the oil and that awareness of a general utility is sufficient for reduction to practice. 976 It is not necessary "to be aware of the specific characteristics that made the oil useful."

The court also found "powerful evidence" of a sales transaction" in a letter, including an amount to be delivered, a unit price and contract language allocating risks and responsibility between Cargill and the buyer. The Federal Circuit further rejected Cargill's argument that the sale was for "experimental purposes" by explaining that "even if [Cargill's predecessor in interest] offered to sell the oil to [Proctor & Gamble] for the purpose of continued testing, it does not prevent a finding that the oil had already been reduced to practice."979

In Honeywell International, Inc. v. Universal Avionics Systems Corp., 980 the Federal Circuit upheld the denial of defendant's remaining counterclaims of invalidity under 35 U.S.C. § 102(b). 981 Honeywell sued

^{970.} In re Smith, 714 F.2d 1127, 1134, 218 U.S.P.Q. (BNA) 976, 983 (Fed. Cir. 1983) (citing Egbert v. Lippmann, 104 U.S. 333, 336 (1881)).

^{971. 476} F.3d 1359, 81 U.S.P.Q.2d (BNA) 1705 (Fed. Cir. 2007). 972. *Id.* at 1361, 81 U.S.P.Q.2d (BNA) at 1706–07.

^{973.} Id. at 1363, 81 U.S.P.Q.2d (BNA) at 1707.

^{974.} *Id.* at 1372, 81 U.S.P.Q.2d (BNA) at 1714. 975. *Id.* at 1370, 81 U.S.P.Q.2d (BNA) at 1713.

^{976.} See id. at 1371 (citing Abbott Labs. v. Geneva Pharm., Inc., 182 F.3d 1315, 1318, 51 U.S.P.Q.2d 1307, 1309 (Fed. Cir. 1999), in which the court held that "[t]he fact that the claimed material was sold under circumstances in which no question existed that it was useful means that it was reduced to practice").

^{977.} Id., 81 U.S.P.Q.2d (BNA) at 1714.

^{978.} *Id.* at 1369, 81 U.S.P.Q.2d (BNA) at 1712. 979. *Id.* at 1371, 81 U.S.P.Q.2d (BNA) at 1714.

^{980. 488} F.3d 982, 82 U.S.P.Q.2d (BNA) 1886 (Fed. Cir. 2007).

^{981.} Id. at 987, 82 U.S.P.Q.2d (BNA) at 1890.

Universal Avionics Systems ("UAS") for infringing its patents on advanced terrain warning systems, which help prevent pilots from flying into mountains or hillsides.⁹⁸² Instead of relying on radio signals, as in the prior art, the patented invention used a virtual "look ahead" terrain warning system, which compared the aircraft's position to onboard digitized maps of the earth's terrain and man-made obstacles. 983 Two of the five asserted patents were at issue in this appeal the '080 patent, which covered certain input and output signals in the look-ahead system, and the '009 patent, which covered systems for displaying the contours of the terrain. 984

In this case, UAS argued that Honeywell's claims were invalid under § 102(b) because Honeywell had negotiated with Gulfstream and Canadair prior to the critical date to develop its invention for use in their luxury airplanes. 985 The Federal Circuit rejected this argument because Honeywell had to test the system's in-cockpit results to "determine that the invention worked for its intended purpose" and to demonstrate "the workability or utility of the claimed invention." 986 Accordingly, Honeywell's negotiations did not trigger the on-sale bar because the invention was not "ready for patenting" at that time. 987

The Federal Circuit also rejected UAS's argument that Honeywell's flight demonstrations had a commercial purpose or constituted an invalidating "public use" under § 102(b). In particular, a reporter was on board one of those flights and later published an article indicating the system was still under development.989 The court concluded that this was not a "public use" because it did not disclose "a completed invention in public, without confidentiality restrictions, and without permitted experimentation."990

In contrast, in Motionless Keyboard Co. v. Microsoft Corp., 991 the Federal Circuit, in a unanimous decision, reversed the district court's summary judgment of invalidity based on public use. 992 The two patents in question were directed to an ergonomic keyboard that required only slight finger gestures to actuate the keys.⁹⁹³ In pertinent

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982. Id. at 987–88, 82 U.S.P.Q.2d (BNA) at 1890–91.
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^{983.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1890–91.

^{984.} Id. at 989, 82 U.S.P.Q.2d (BNA) at 1891–92.

^{985.} *Id.* at 996, 82 U.S.P.Q.2d (BNA) at 1897. 986. *Id.* at 997, 82 U.S.P.Q.2d (BNA) at 1898.

^{987.} Id., 82 U.S.P.Q.2d (BNA) at 1898.

^{988.} Id. at 998, 82 U.S.P.Q.2d (BNA) at 1899.

^{989.} Id., 82 U.S.P.Q.2d (BNA) at 1899.

^{990.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1898. 991. 486 F.3d 1376, 82 U.S.P.Q.2d (BNA) 1801 (Fed. Cir. 2007).

^{992.} Id. at 1378, 82 U.S.P.Q.2d (BNA) at 1802.

^{993.} Id., 82 U.S.P.Q.2d (BNA) at 1802.

part, the inventor developed the Cherry Model 5 and other prototypes of his invention, which he demonstrated to numerous potential investors, a friend, a business partner, and a typing tester.994 None of those disclosures, save the one to the typing tester, involved connecting the Cherry Model 5 to a computer or using it to transmit data. 995 Instead, the disclosures were limited to a visual view of the new keyboard design without disclosing its ability to translate finger movements into the keys to transmit data.⁹⁹⁶

The Federal Circuit concluded that since the claims were directed to a device for transmitting data, the disclosures to the investors, friend, and business partner were inadequate to constitute an invalidating "public use" under § 102(b). 997 As for the disclosure to the typing tester, who had used the prototype to transmit data to a computer, her use had occurred less than a year before the filing date of the application for the '477 patent, and she had signed a nondisclosure agreement ("NDA") when she took the test. 998 For these reasons, her use did not qualify as a "public use" under § 102(b). 999

In Adenta GmbH v. OrthoArm Inc., 1000 the Federal Circuit, in another unanimous decision, held that the claims for an orthodontic bracket were invalid due to its public use or sale at a trade show more than one year prior to filing the application. The action was brought by patent licensee Adenta, which sought a declaratory judgment that the patent was invalid and unenforceable. OrthoArm argued that Adenta had failed to meet its burden of proof at trial because Adenta's witnesses all had an interest in declaring the patent invalid, and their testimony was not corroborated by the documentary evidence. 1003 The Federal Circuit disagreed, finding that corroboration was not at issue because this was not a case in which the witnesses were claiming to be the inventors. 1004 Rather, the question was the sufficiency of the evidence. The court found there was sufficient evidence to support the jury's verdict of invalidity because the different witnesses all corroborated each other, and their testimony was further supported by the documents in evidence, which included a

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994. Id. at 1385, 82 U.S.P.Q.2d (BNA) at 1807.
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^{995.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1807. 996. *Id.*, 82 U.S.P.Q.2d (BNA) at 1807.

^{997.} Id., 82 U.S.P.O.2d (BNA) at 1807. 998. Id., 82 U.S.P.O.2d (BNA) at 1807. 999. Id., 82 U.S.P.O.2d (BNA) at 1807.

^{1000. 501} F.3d 1364, 84 U.S.P.Q.2d (BNA) 1428 (Fed. Cir. 2007). 1001. *Id.* at 1366–67, 84 U.S.P.Q.2d (BNA) at 1429–30.

^{1002.} *Id.* at 1367, 84 U.S.P.Q.2d (BNA) at 1430.

^{1003.} Id. at 1367-68, 84 U.S.P.Q.2d (BNA) at 1431.

^{1004.} *Id.* at 1371–72, 84 U.S.P.Q.2d (BNA) at 1433–34.

^{1005.} Id., 84 U.S.P.Q.2d (BNA) at 1434.

letter from Adenta's German patent attorney informing its American patent attorney that the bracket had been on display and instructing him to file a patent application within a year. The Federal Circuit affirmed the district court's denial of OrthoArm's motion for judgment as a matter of law to overturn the jury's verdict of invalidity. 1007

C. Obviousness

One cannot discuss the Federal Circuit's 2007 decisions on obviousness without first mentioning the Supreme Court's landmark decision in KSR International Co. v. Teleflex, Inc. 1008 As explained in Part D.3, KSR reversed the Federal Circuit's mandatory application of the TSM test and seemingly broadened the grounds for finding obvious-Although not as radically transformative as many had predicted, KSR still represents a fundamental change in the concept of obviousness, a change reflected in the Federal Circuit's subsequent obviousness decisions. This section begins with a basic primer on obviousness, including a brief discussion of the Supreme Court's holding in KSR, followed by a discussion of the Federal Circuit's applications of KSR and its 2007 decisions either decided before KSR or involving aspects of obviousness uninfluenced by the Supreme Court's pronouncement in KSR.

A patent claim is invalid for obviousness if the differences between the claimed subject matter and the prior art are such that the claimed subject matter as a whole would have been obvious at the time of the invention to a person of ordinary skill in the relevant art. Obviousness is a question of law that is based on underlying factual considerations:

- 1. the scope and content of the prior art;
- 2. the differences between the prior art and the claims at issue;
- 3. the level of ordinary skill in the pertinent art; and
- 4. objective evidence of non-obviousness (i.e., secondary considerations).1010

It is against this factual background that the ultimate determination of obviousness is made. The inquiry into obviousness is an "expansive and flexible approach" rather than a "formalistic concep-

^{1006.} Id. at 1372-73, 84 U.S.P.Q.2d (BNA) at 1434.

^{1007.} Id. at 1373, 84 U.S.P.Q.2d (BNA) at 1435.

^{1008. 127} S. Ct. 1727, 82 U.S.P.Q.2d (BNA) 1385 (2007).

^{1009. 35} U.S.C. § 103(a) (2000). 1010. Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17, 148 U.S.P.Q. (BNA) 459, 467 (1966); Brown & Williamson Tobacco Corp. v. Phillip Morris Inc., 229 F.3d 1120, 1124, 56 U.S.P.Q.2d (BNA) 1456, 1459 (Fed. Cir. 2000).

tion."1011 A combination of familiar elements according to their established functions is probably obvious if the combination does no more than yield predictable results. 1012 If the combination is more than a predictable use of prior art, then the court must determine whether there was an "apparent reason to combine the known elements," by looking, e.g., at "interrelated teachings of multiple patents,; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art."1013 The court need not seek out precise teachings, but can consider the common sense "inferences and creative steps that a person of ordinary skill in the art would employ."1014

The fourth factual inquiry, referred to as objective evidence of nonobviousness or secondary considerations, must be resolved before coming to an obviousness conclusion. These considerations are important because they may provide circumstantial evidence of nonobviousness. 1016 Secondary considerations may include:

- 1. the commercial success of the claimed invention;
- 2. long-standing problems in the art solved by the invention;
- 3. widespread recognition and copying of the invention in the industry;
- 4. disbelief by experts that the invention would work;
- 5. failure of others;
- 6. unexpected results; and
- 7. praise and industry acceptance of the invention. 1017

^{1011.} KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1739, 1741, 82 U.S.P.Q.2d (BNA) 1385, 1395-96 (2007).

^{1012.} Id. at 1739, 82 U.S.P.Q.2d (BNA) at 1395.

^{1013.} *Id.* at 1740–41, 82 U.S.P.Q.2d (BNA) at 1396.

^{1014.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1396. 1015. Tex. Instruments Inc. v. U.S. Int'l Trade Comm'n, 988 F.2d 1165, 1178, 26 U.S.P.Q.2d (BNA) 1018, 1028 (Fed. Cir. 1993); Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc., 976 F.2d 1559, 1573, 24 U.S.P.Q.2d (BNA) 1321, 1333 (Fed. Cir. 1992); Vandenberg v. Dairy Equip. Co., 740 F.2d 1560, 1566–67, 224 U.S.P.Q. (BNA) 195, 198–99 (Fed. Cir. 1984); Standard Mfg. Co., Inc. v. United States, 25 Cl. Ct. 1, 52 n.40 (1991).

^{1016.} Graham v. John Deere Co., 383 U.S. 1, 17-18, 148 U.S.P.Q. (BNA) 459, 467 (1966).

^{1017.} See Tex. Instruments, 988 F.2d at 1178, 26 U.S.P.Q.2d (BNA) at 1028 (stating that obviousness is based on several factual determinations, including a consideration of "other objective evidence"); Minn. Mining & Mfg. Co., 976 F.2d at 1573, 24 U.S.P.Q.2d (BNA) at 1333 (examining commercial success, failure of others, longfelt need, and unexpected results when inquiring into secondary considerations); *Vandenberg*, 740 F.2d at 1566-67, 224 U.S.P.Q. (BNA) at 199 (noting that the appellants' device obtained widespread recognition and that evidence existed showing the device was copied in the industry); see also Graham, 383 U.S. at 17, 148 U.S.P.Q. (BNA) at 467 ("Such secondary considerations as commercial success, long felt but

In KSR International Co. v. Teleflex, Inc., 1018 a unanimous Supreme Court reasserted the primacy of Graham v. John Deere¹⁰¹⁹ in making an obviousness determination and warned that a rigid application of the teaching/suggestion/motivation test in an obviousness inquiry is inconsistent with the *Graham* framework. 1020 In effect, the Court reprimanded the Federal Circuit for its strict adherence to the TSM approach over the years. The Supreme Court did not reject the TSM test outright, however, but stripped it of its prominence as the determinative factor in an obviousness inquiry. 1021 The Court noted, "[t]here is no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis. But when a court transforms the general principle into a rigid rule that limits the obviousness inquiry, as the court of appeals did here, it errs."1022

The Supreme Court also weighed in on the combination of familiar elements in an invention, noting that "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. "1023" "If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability." The Federal Circuit also erred when it concluded that "a patent claim cannot be proved obvious merely by showing that the combination of elements was 'obvious to try.'",1025 According to the Supreme Court, in some circumstances "the fact that a combination was obvious to try might show that it was obvious under § 103."1026

unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented."); Brown & Williamson Tobacco Corp. v. Philip Morris Inc., 229 F.3d 1120, 1129, 56 U.S.P.Q.2d (BNA) 1456, 1463 (Fed. Cir. 2000) (listing secondary considerations that other courts have considered, including commercial success, long-felt but unfulfilled needs, failure of others, skepticism about the invention, copying, praise and acceptance, and unexpected results); *Standard Mfg.*, 25 Cl. Ct. at 51, 52 (tracing the evolution of secondary considerations and suggesting that they now "comprise a fourth factual inquiry . . . which now must be resolved before coming to a conclusion concerning obviousness"); 2 DONALD S. CHISUM, CHISUM ON PATENTS § 5.05 (1996) (discussing three views on the role of secondary considerations).

1018. KSR, 127 S. Ct. 1727, 82 U.S.P.Q.2d (BNA) 1385.

1019. Graham, 383 U.S. 1, 148 U.S.P.Q. (BNA) 459.

1020. KSR, 127 S. Ct. at 1741, 82 U.S.P.Q.2d (BNA) at 1396–97.

1021. *Id.*, 82 U.S.P.Q.2d (BNA) at 1396–97.

1022. *Id.*, 82 U.S.P.Q.2d (BNA) at 1396–97. 1023. *See id.* at 1739–40, 82 U.S.P.Q.2d (BNA) at 1395–96 (discussing the application of this doctrine in United States v. Adams, 383 U.S. 39, 148 U.S.P.Ö. (BNA) 479 (1966), the companion case to Graham, in Sakraida v. Ag Pro, Inc., 425 U.S. 273, 189 U.S.P.Q. (BNA) 449 (1976); and in *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 163 U.S.P.Q. (BNA) 673 (1969)). 1024. *Id.* at 1740, 82 U.S.P.Q.2d (BNA) at 1396.

1025. Id. at 1742, 82 U.S.P.Q.2d (BNA) at 1397.

1026. Id., 82 U.S.P.Q.2d (BNA) at 1397.

Leapfrog Enterprises, Inc. v. Fisher-Price, Inc. 1027 was one of the Federal Circuit's first obviousness cases after the Supreme Court's KSR ruling. Leapfrog, a manufacturer of children's educational products, sued Fisher-Price for infringing a patent on an interactive learning toy that makes a sound or says a phoneme when a child properly enters the letters. 1028 The Federal Circuit affirmed the district court's finding that the claims were obvious. 1029 The prior art in question included: (1) an electro-mechanical learning toy ("Bevan") in which a motor and internal record would say a phoneme when a particular letter was pressed; (2) an electronic reading toy ("SSR") by Texas Instruments; and (3) knowledge in the art about electronic "readers." The Federal Circuit concluded it would have been obvious to use SSR as a "roadmap" to update the Bevan device with modern electronic components, and then add a "reader" of the type well-known in the art. 1031 In the words of KSR, the patent was thus an obvious "combination of familiar elements . . . [and] known methods" that "yield[ed] predictable results." The court, in fact, found the prima facie showing of obviousness to be so strong that it overcame the secondary considerations of commercial success, praise, and long-felt-need. 1033

Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd. 1034 was the Federal Circuit's first obviousness case in the chemical arts after KSR. 1035 Takeda owned a patent directed to compounds that can be used as antidiabetic agents. Seeking approval to market its generic version of the same compounds, Alphapharm filed a Paragraph IV certification with its Abbreviated New Drug Application ("ANDA"), asserting that the patent at issue was invalid as obvious. 1037 Takeda filed suit against Alphapharm and three other generic drug manufacturers, alleging infringement of certain claims in Takeda's patent. 1038

The critical portion of the claimed compounds was an ethyl substituted pyridyl ring, which had four possible positions on which an al-

^{1027. 485} F.3d 1157, 82 U.S.P.Q.2d (BNA) 1687 (Fed. Cir. 2007).

Id. at 1158, 82 U.S.P.Q.2d (BNA) at 1688-89. 1028.

^{1029.} Id. at 1163, 82 U.S.P.Q.2d (BNA) at 1692.

^{1030.} Id. at 1158–59, 82 U.S.P.Q.2d (BNA) at 1689.

^{1031.} *Id.* at 1162, 82 U.S.P.Q.2d (BNA) at 1691–92. 1032. KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1739, 82 U.S.P.Q.2d (BNA) 1385, 1395 (2007).

<sup>1385, 1395 (2007).
1033.</sup> Leapfrog, 485 F.3d at 1162, 82 U.S.P.Q.2d (BNA) at 1692.
1034. 492 F.3d 1350, 83 U.S.P.Q.2d (BNA) 1169 (Fed. Cir. 2007).
1035. See id. at 1355-56, 83 U.S.P.Q.2d (BNA) at 173–74 (noting that obviousness had only recently been addressed by the Supreme Court and the opinion given by the district court was rendered before the Supreme Court's decision in KSR).

^{1036.} *Id.* at 1352, 83 U.S.P.Q.2d (BNA) at 1172–73. 1037. *Id.* at 1354, 83 U.S.P.Q.2d (BNA) at 1172.

^{1038.} Id., 83 U.S.P.Q.2d (BNA) at 1172.

kyl group could be located. The claimed compounds had an ethyl group attached to the 5-position. Alpharm cited prior art that included a similar compound ("compound b"), which had a methyl group attached to the 6-position. Relying on KSR, Alphapharm argue[d] that the claimed compounds would have been obvious because the prior art compound fell within 'the objective reach of the claim,' and the evidence demonstrated that using the techniques of homologation and ring-walking would have been 'obvious to try." The district court found "there was no motivation in the prior art to select compound b as the lead compound for antidiabetic research." In fact, "the prior art [actually] taught away from" compound b. The Federal Circuit affirmed, noting that Alphapharm "failed to show that there existed a reason, based on what was known at the time of the invention, to perform the chemical modifications necessary to achieve the claimed compounds."

The Federal Circuit stated that the test for prima facie obviousness in an invention concerning chemical compounds "is consistent with the legal principles enunciated in *KSR*[,]" and thus, "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." The Federal Circuit also found that, in contrast with *KSR*, "the prior art disclosed a broad selection of compounds any one of which could have been selected as a lead compound for further investigation[,]" as opposed to identifying predictable solutions. ¹⁰⁴⁶

In Aventis Pharma Deutschland GmbH v. Lupin, Ltd., 1047 the Federal Circuit reversed a pre-KSR district court decision in which patent claims to a certain pharmaceutical compound were found to be non-obvious over the prior art. 1048 The patent at issue was directed to a compound for blood pressure medication that was "substantially free of other isomers." 1049 The patent owner had argued that there was no explicit teaching to purify a stereoisomer from the mixture in which

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1039. Id. at 1353, 83 U.S.P.Q.2d (BNA) at 1172.
1040. Id. at 1354, 83 U.S.P.Q.2d (BNA) at 1172.
1041. Id., 83 U.S.P.Q.2d (BNA) at 1172.
1042. Id. at 1359, 83 U.S.P.Q.2d (BNA) at 1176.
1043. Id. at 1354, 83 U.S.P.Q.2d (BNA) at 1172–73.
1044. Id. at 1363, 83 U.S.P.Q.2d (BNA) at 1179.
1045. Id. at 1356–57, 83 U.S.P.Q.2d (BNA) at 1174.
1046. Id. at 1359, 83 U.S.P.Q.2d (BNA) at 1176.
1047. 499 F.3d 1293, 84 U.S.P.Q.2d (BNA) 1197 (Fed. Cir. 2007).
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^{1048.} *Id.* at 1299, 84 U.S.P.Q.2d (BNA) at 1202. 1049. *Id.* at 1296, 84 U.S.P.Q.2d (BNA) at 1200.

it was the active ingredient, and that the purified isomer exhibited the unexpected result of increased potency. 1050

The Federal Circuit, in a unanimous decision, reversed the district court, holding that the claimed composition was obvious because the inventors had merely isolated and purified the active ingredient in a mixture that existed in the prior art. 1051 The district court had erred in relying on a lack of clear and convincing evidence of any motivation in the art to separate active stereoisomer. The Federal Circuit stated that "[r]equiring an explicit teaching to purify the . . . [active] stereoisomer from a mixture in which it is the active ingredient is precisely the sort of rigid application of the TSM test that was criticized in KSR."1053

[I]f it is known that some desirable property of a mixture derives in whole or in part from a particular one of its components, or if the prior art would provide a person of ordinary skill in the art with reason to believe that this is so, the purified compound is prima facie obvious over the mixture even without an explicit teaching that the ingredient should be concentrated or purified. 1054

In In re Translogic Technology, Inc., 1055 the Federal Circuit affirmed the PTO's finding on reexamination that the claims of Translogic's '666 patent were invalid as obvious. 1056 Accused infringer Hitachi had petitioned the PTO to reexamine Translogic's '666 patent during the course of an infringement suit. 1057 While the appeal from the PTO was pending, the jury in Translogic's district court case found the patent valid and infringed, and awarded Translogic \$86.5 million in damages. 1058 The district court also entered a permanent injunction, which it stayed pending appeal. 1059 The Federal Circuit consolidated Translogic's appeals from the PTO and the district court, although the present decision addressed only the appeal from the reexamination. 1060

In affirming the PTO's obviousness determination, the Federal Circuit rejected Translogic's argument that the PTO had erred in construing the term "coupled to receive" to include terminals that

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1050. Id. at 1302, 84 U.S.P.Q.2d (BNA) at 1205.
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^{1051.} *Id.* at 1303, 84 U.S.P.Q.2d (BNA) at 1205. 1052. *Id.*, 84 U.S.P.Q.2d (BNA) at 1205.

^{1053.} Id. at 1301, 84 U.S.P.Q.2d (BNA) at 1204.

^{1054.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1204 (citing *In re* May, 574 F.2d 1082, 1090–94, 197 U.S.P.Q. (BNA) 601, 607–610 (C.C.P.A. 1978)).

^{1055. 504} F.3d 1249, 84 U.S.P.Q.2d (BNA) 1929 (Fed. Cir. 2007).

^{1056.} *Id.* at 1262, 84 U.S.P.Q.2d (BNA) at 1939.

^{1057.} *Id.* at 1251, 84 U.S.P.Q.2d (BNA) at 1930. 1058. *Id.*, 84 U.S.P.Q.2d (BNA) at 1930. 1059. *Id.*, 84 U.S.P.Q.2d (BNA) at 1930.

^{1060.} Id., 84 U.S.P.Q.2d (BNA) at 1930.

were merely capable of receiving signals.¹⁰⁶¹ The Federal Circuit found the PTO's construction to be correct because the claims and specification did not specify any particular structural connection, and the input variables (signals) were not part of the claimed invention.¹⁰⁶²

The Federal Circuit also affirmed the PTO's finding that the Gorai reference was relevant prior art to the technical field of the '666 patent. Translogic, in contrast, was "making the same error corrected by the Supreme Court in *KSR*," namely, that variants of the circuit disclosed in the prior art reference were not relevant prior art because they did not address the same problem as the '666 patent. However, this argument overlooks the fundamental proposition that the series circuits in Gorai are prior art within the public domain and the common knowledge of a person of ordinary skill in the art. The Federal Circuit further rejected Translogic's argument that, from the viewpoint of a skilled artisan, the Gorai reference disclosed only an algorithm to perform certain logic functions but not an actual multiplexer.

Finally, the Federal Circuit affirmed the PTO's finding that the '666 patent claims were obvious over a combination of the Gorai and Weste references. Translogic's arguments to the contrary were based on the absence of a teaching, suggestion, or motivation to combine the references—a test that is no longer mandatory after the Supreme Court's *KSR* decision. Instead, the court found that the PTO had properly taken into account "the inferences and creative steps that a person of ordinary skill in the art would employ," pursuant to *KSR*.

In *In re Icon Health and Fitness, Inc.*, ¹⁰⁷⁰ the Federal Circuit affirmed the Board of Patent Appeals decision holding the patentee's claims to a treadmill with a folding base unpatentable as obvious. ¹⁰⁷¹ Icon was the patent holder of the '624 patent, which requires that the folding base have a gas spring "to assist in stably retaining" the treadmill base in

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1061. Id. at 1258, 84 U.S.P.Q.2d (BNA) at 1935.
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^{1062.} Id., 84 U.S.P.Q.2d (BNA) at 1935-36.

^{1063.} Id. at 1261, 84 U.S.P.Q.2d (BNA) at 1938.

^{1064.} Id., 84 U.S.P.Q.2d (BNA) at 1938.

^{1065.} Id., 84 U.S.P.Q.2d (BNA) at 1938.

^{1066.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1938.

^{1067.} Id. at 1262, 84 U.S.P.Q.2d (BNA) at 1938–39.

^{1068.} *Id.* at 1261–62, 84 U.S.P.Q.2d (BNA) at 1938–39.

^{1069.} *Id.* at 1262, 84 U.S.P.Q.2d (BNA) at 1939 (quoting KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1741, 82 U.S.P.Q.2d (BNA) 1385, 1396 (2007)).

^{1070. 496} F.3d 1374, 83 U.S.P.Q.2d (BNA) 1746 (Fed. Cir. 2007).

^{1071.} Id. at 1382, 83 U.S.P.Q.2d (BNA) at 1752.

the upright position. On reexamination, the examiner rejected Icon's claims as obvious . . . based on the combination of an advertisement [for a folding treadmill] by Damark International, Inc. ('Damark') and U.S. Patent No. 4,370,766 to Teague, Jr. ("Teague")," which teaches the use of gas springs in a bed that folds up into a cabinet. 1073 The Board affirmed the examiner's determination of obviousness over the combination of Damark and Teague, noting the breadth of Icon's claim limitation with respect to the gas spring and the pertinence of Teague. 1074

On appeal, Icon focused on two major arguments. First, Icon argued that Teague, describing a folding bed, falls outside of the "treadmill art" and addresses a different problem than the '624 patent, thus removing it from the relevant prior art. 1075 Second, Icon argued that Teague, which references use of a dual-action spring, teaches away from Icon's invention. The Federal Circuit rejected both arguments, noting that Teague indeed addresses the same problem as Icon's. 1077 Citing In re Clay, 1078 the Federal Circuit noted that "[a] reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem." Further, the Federal Circuit, citing KSR, noted that "familiar items may have obvious uses beyond their primary purposes." The Federal Circuit stated that there was "[n]othing about Icon's folding mechanism [that] requires any particular focus on treadmills; it generally addresses [the] problems of supporting the weight of such a mechanism and providing a stable resting position." Moreover, the Federal Circuit found that a variety of sources may have led one skilled in the art to combine the teachings of Damark and Teague to produce a device meeting all of the limitations of the '624 patent claims. 1082

1072. Id. at 1377, 83 U.S.P.Q.2d (BNA) at 1748.

^{1073.} *Id.*, 83 U.S.P.Q.2d (BNA) at 1748.

^{1074.} *Id.* at 1378, 83 U.S.P.Q.2d (BNA) at 1749. 1075. *Id.* at 1379, 83 U.S.P.Q.2d (BNA) at 1750.

^{1076.} *Id.* at 1381, 83 U.S.P.Q.2d (BNA) at 1751.

^{1070.} Id. at 1301, 63 U.S.P.Q.2d (BNA) at 1751.
1077. Id. at 1379–80, 83 U.S.P.Q.2d (BNA) at 1751.
1078. 966 F.2d 656, 659, 23 U.S.P.Q.2d (BNA) 1058, 1061 (Fed. Cir. 1992).
1079. Icon Health & Fitness, 496 F.3d at 1379–80, 83 U.S.P.Q.2d (BNA) at 1750 (quoting Clay, 966 F.2d at 659, 23 U.S.P.Q.2d (BNA) at 1061).

⁽Habing Gas), 500 F.2u at 059, 25 U.S.P.Q.2d (BNA) at 1061). 1080. *Id.* at 1380, 83 U.S.P.Q.2d (BNA) at 1750 (quoting KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1742, 82 U.S.P.Q.2d (BNA) 1385, 1397 (Fed. Cir. 2007)). 1081. *Id.*, 83 U.S.P.Q.2d (BNA) at 1750.

^{1082.} Id., 83 U.S.P.Q.2d (BNA) at 1750.

Regarding Icon's second argument that Teague teaches away from Icon's invention, the Federal Circuit noted that Teague disclosed two types of gas spring mechanisms, neither of which was undesirable for Icon's purpose. 1083 The Federal Circuit further noted that Icon's broad claims encompassing anything that assists in stably retaining the tread base undermined their argument. 1084 Accordingly, the Federal Circuit affirmed the Board's decision that the claims were obvi-OUS. 1085

The Federal Circuit also affirmed the PTO's finding of obviousness in In re Trans Texas Holdings Corp. 1086 Trans Texas held two related patents on methods for insulating deposit and loan accounts from inflation and providing stability to financial institutions by matching inflation-adjusted payments to depositors with increased inflationadjusted interest payments from borrowers. 1087 At Trans Texas's request, the PTO reexamined each of the patents in question, but rejected Trans Texas's argument that the Office was bound by a district court's claim construction in an earlier infringement proceeding on the same patents. 1088 The PTO eventually rejected all the claims as obvious, and Trans Texas appealed. 1089 The Federal Circuit found the claims were obvious either because the limitation in question was disclosed in the prior art or because a combination of the prior art with a "well-known practice" in the field yielded predictable results. 1090 Accordingly, the Federal Circuit affirmed the PTO's rejection of all of the reexamined claims as obvious. 1091

In In re Sullivan, 1092 the patent applicants appealed a decision of the Board of Patent Appeals and Interferences affirming the Examiner's rejection of the invention as obvious. 1093 The applicants claimed an antivenom for treating rattlesnake bites, wherein the composition was characterized by the use of a fragment of an antibody, rather than an intact antibody, even though such fragments are not generally used for antivenoms. 1094 The Board found that the applicants' composition

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1083. Id. at 1381-82, 83 U.S.P.Q.2d (BNA) at 1752.
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^{1084.} Id., 83 U.S.P.Q.2d (BNA) at 1751.

^{1085.} Id. at 1382, 83 U.S.P.Q.2d (BNA) at 1752.

^{1086. 498} F.3d 1290, 1292, 83 U.S.P.Q.2d (BNA) 1835, 1836 (Fed. Cir. 2007).

^{1080. 436} F.3d 1236, 1236, 33 C.3.1. 22d (B14), 1666, 1686 (188). 108. 1d., 83 U.S.P.Q.2d (BNA) at 1836. 1088. 1d. at 1294, 83 U.S.P.Q.2d (BNA) at 1838. 1089. 1d. at 1295, 83 U.S.P.Q.2d (BNA) at 1838. 1090. 1d. at 1299–1301, 83 U.S.P.Q.2d (BNA) at 1841–43 (citing KSR Int'l Co. v. 1707 (188) (1892–1304) (1 Teleflex Inc., 127 S. Ct. 1727, 1739, 82 U.S.P.Q.2d (BNA) 1385, 1394 (2007)).

^{1091.} *Id.* at 1301, 83 U.S.P.Q.2d (BNA) at 1843. 1092. 498 F.3d 1345, 84 U.S.P.Q.2d (BNA) 1034 (Fed. Cir. 2007).

^{1093.} Id. at 1347, 84 U.S.P.Q.2d (BNA) at 1035.

^{1094.} Id. at 1348, 84 U.S.P.Q.2d (BNA) at 1036.

was obvious in view of a combination of one of the inventor's own references that taught the use of an intact antibody in a rattlesnake antivenom and another reference that taught the use of an antibody fragment to detect rattlesnake venom. The Board found that the applicant's intended use of the composition to neutralize, rather than detect, rattlesnake venom did not render the composition nonobvious.1096

The Federal Circuit held that the Board erroneously failed to consider the applicants' rebuttal evidence, which included declarations from the inventors and their experts. 1097 The Board was mistaken in finding that the declarations related only to the use of the claimed composition. 1098 Rather, the declarations also showed "an unexpected result from the use of the claimed composition," namely, the "unexpected property of neutralizing the lethality of rattlesnake venom while reducing the occurrence of adverse immune reactions in humans."1099 In addition, the declarations explained that the prior art taught away from the composition and that there was a long-felt need for this new antivenom. 1100

Conversely, the Federal Circuit reversed the district court's judgment of non-obviousness in Daiichi Sankyo Co. v. Apotex, Inc. 1101 The patent in question was directed to a method for treating bacterial ear infections using antibiotic ofloxacin, which is a gyrase inhibitor. 1102 Daiichi sued Apotex for infringement after Apotex filed an Abbreviated New Drug Application ("ANDA") for generic ear drops. 1103 At trial, Apotex argued that the patent was invalid as obvious in view of the Ganz reference, which taught the use of ear drops containing a certain gyrase inhibitor to treat middle ear infections. In pertinent part, Ganz stated that "gyrase inhibitors 'should be used only in difficult cases and exclusively by the *otologist*." The district court, however, concluded that the person of ordinary skill in the art would have been "a pediatrician or general practitioner." Accordingly, the district court rejected Apotex's argument that it would have been ob-

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1095. Id. at 1348-49, 84 U.S.P.Q.2d (BNA) at 1036-37.
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^{1096.} *Id.* at 1349, 84 U.S.P.Q.2d (BNA) at 1036–37. 1097. *Id.* at 1352–53, 84 U.S.P.Q.2d (BNA) at 1039–40.

^{1098.} *Id.* at 1353, 84 U.S.P.Q.2d (BNA) at 1040.

^{1099.} *Id.* at 1352, 84 U.S.P.Q.2d (BNA) at 1039–40. 1100. *Id.* at 1353, 84 U.S.P.Q.2d (BNA) at 1040.

^{1101. 501} F.3d 1254, 84 U.S.P.Q.2d (BNA) 1285 (Fed. Cir. 2007).

^{1102.} Id. at 1258, 84 U.S.P.Q.2d (BNA) at 1288.

^{1103.} *Id.* at 1256, 84 U.S.P.Q.2d (BNA) at 1286. 1104. *Id.* at 1258, 84 U.S.P.Q.2d (BNA) at 1287–88.

^{1105.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1288 (emphasis added).

^{1106.} Id. at 1256, 84 U.S.P.Q.2d (BNA) at 1286 (emphasis added).

vious to use of loxacin, a gyrase inhibitor, to topically treat bacterial ear infections. 1107

The Federal Circuit, in a rather unusual step, found that the district court had clearly erred in determining that a person skilled in the art would have been a general practitioner and not a specialist. The court noted that the inventors of the patent were specialists in drug treatments for ear infections, and not pediatricians or general practitioners, who generally would have lacked the training or knowledge to have developed the claimed compound. The Federal Circuit concluded that the patent would have been obvious to persons having that higher skill level, as Apotex had argued.

In Dippin' Dots, Inc. v. Mosey, 1111 a case decided prior to KSR, the Federal Circuit examined the experimental use exception in the context of obviousness. 1112 When Dippin' Dots sued Mosey for infringing its patented process for making a novelty ice cream product, the jury found that the claims were invalid in view of sales made more than a year before the application date. 1113 Dippin' Dots argued on appeal that those sales were experimental and did not trigger the on-sale bar.1114 The Federal Circuit disagreed, noting that the inventor himself had testified that the sales were made to determine the marketability of the product, not to improve its technical aspects.¹¹¹⁵ A person skilled in the art would have been motivated to combine the process used to make those products with other relevant prior art, the court found. 1116 In particular, a skilled artisan would have sought the appropriate temperature ranges to prepare and serve the product and thus would have found it obvious to use the higher temperatures set forth in the claims. 1117 The Federal Circuit thus affirmed the district court's determination that the claims were obvious, even under the higher pre-KSR standard. 1118

In *PharmaStem Therapeutics*, *Inc.* v. Viacell, *Inc.*, ¹¹¹⁹ PharmaStem sued six defendants for infringement of two patents on compositions and

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1107. Id. at 1258, 84 U.S.P.Q.2d (BNA) at 1288.
1108. Id. at 1257, 84 U.S.P.Q.2d (BNA) at 1287.
1109. Id., 84 U.S.P.Q.2d (BNA) at 1287.
1110. Id. at 1258–59, 84 U.S.P.Q.2d (BNA) at 1288.
1111. 476 F.3d 1337, 81 U.S.P.Q.2d (BNA) 1633 (Fed. Cir. 2007).
1112. Id. at 1343–44, 81 U.S.P.Q.2d (BNA) at 1638.
1113. Id. at 1344, 81 U.S.P.Q.2d (BNA) at 1639.
1114. Id. at 1344, 81 U.S.P.Q.2d (BNA) at 1638.
1115. Id., 81 U.S.P.Q.2d (BNA) at 1638.
1116. Id., 81 U.S.P.Q.2d (BNA) at 1638.
1117. Id. at 1345, 81 U.S.P.Q.2d (BNA) at 1639.
1118. Id., 81 U.S.P.Q.2d (BNA) at 1639.
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1119. 491 F.3d 1342, 83 U.S.P.Q.2d (BNA) 1289 (Fed. Cir. 2007).

methods for using cryopreserved umbilical cord stem cells for rebuilding a person's compromised blood and immune systems. 120 The jury returned verdicts for PharmaStem that the patents were infringed and valid, and the court denied defendants' motion for IMOL that the claims were invalid. 1121 The Federal Circuit reversed the JMOL and held the patents were invalid as obvious. 1122

The obviousness issue largely turned on whether the prior art gave a reasonable expectation of success in using cord blood in transplants for hematopoietic reconstitution. The Federal Circuit found that the inventors had demonstrated only the presence of stem cells in cord blood, which was also inferred by prior art.1124 Judge Bryson. writing for the majority, explained:

While the inventors may have proved conclusively what was strongly suspected before—that umbilical cord blood is capable of hematopoietic reconstitution—and while their work may have significantly advanced the state of the science of hematopoietic transplantations by eliminating any doubt as to the presence of stem cells in cord blood, the mouse experiments and the conclusions drawn from them were not inventive in nature. Instead, the inventors merely used routine research methods to prove what was already believed to be the case. Scientific confirmation of what was already believed to be true may be a valuable contribution, but it does not give rise to a patentable invention. 1125

Judge Newman strongly dissented, noting that after a three-week trial the jury sustained the validity of the patents, the district court upheld their validity, and their validity was confirmed in several reexaminations by the PTO. 1126 Judge Newman wrote, "[t]he undisputed evidence at trial was that these long-sought life-saving inventions were achieved amid general scientific skepticism, despite the extensive research that was being conducted by many scientists in this field," and that her colleagues on the panel "reconstruct[ed] these inventions by selection and inference, with perfect hindsight of the discoveries."1127

^{1120.} Id. at 1346-47, 83 U.S.P.Q.2d (BNA) at 1291.

^{1121.} Id., 83 U.S.P.Q.2d (BNA) at 1291.

^{1122.} Id. at 1347, 83 U.S.P.Q.2d (BNA) at 1291.

^{1123.} *Id.* at 1360, 83 U.S.P.Q.2d (BNA) at 1301. 1124. *Id.* at 1363, 83 U.S.P.Q.2d (BNA) at 1304.

^{1125.} *Id.* at 1363–64, 83 U.S.P.Q.2d (BNA) at 1304 (citing KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1732, 82 U.S.P.Q.2d (BNA) 1385, 1389–90 (Fed. Cir. 2007); Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348, 1367-69, 82 U.S.P.Q.2d (BNA) 1321, 1334–37 (Fed. Cir. 2007))

^{1126.} Id. at 1367, 83 U.S.P.Q.2d (BNA) at 1307.

^{1127.} Id., 83 U.S.P.Q.2d (BNA) at 1307.

Judge Newman also emphasized that based on the strong secondary considerations, the patent claims were not obvious. 1128

In Pfizer, Inc. v. Apotex, Inc., 1129 one of the last appellate opinions on obviousness prior to KSR, the Federal Circuit reversed a district court ruling that Pfizer's claims were not obvious. 1130 Pfizer's claims were directed to the use of a besylate salt form of one of the drug's key ingredients, amlodipine. 1131 The PTO's allowance of the claims, as well as the district court's ruling of validity, turned largely on a declaration from one of the inventors that the amlodipine besylate salt was a unique compound with highly desirable yet unpredictable properties. 1132 The declaration also attested to the difficulty in selecting that besylate salt from a number of other options. 1133

The Federal Circuit found clear motivation to combine references, speaking, of course, from a pre-KSR vantage point. 1134 The Federal Circuit also found that a skilled artisan would have had a reasonable expectation of success in making amlodipine besylate because the prior art "contained a strong suggestion that any and all pharmaceutically-acceptable anions would form non-toxic acid addition salts and would work for their intended purpose." Evidence of secondary considerations was not sufficient to overcome the strong showing of obviousness, in the court's view. 1136 The Federal Circuit concluded that "[a]t most, then, Pfizer engaged in routine, verification testing to optimize selection of one of several known and clearly suggested pharmaceutically-acceptable salts to ease its commercial manufacturing and marketing of the tablet form of the therapeutic amlodipine."1137

Pfizer unsuccessfully petitioned the Federal Circuit for a panel rehearing or rehearing en banc. 1138 Judges Newman, Bryson, and Rader dissented from the denial of rehearing en banc because they believed the panel had improperly relied on an "obvious to try" standard and substituted its own fact-finding for that of the district court, where

^{1128.} Id. at 1375-78, 83 U.S.P.Q.2d (BNA) at 1313-16.

^{1129. 480} F.3d 1348, 82 U.S.P.Q.2d (BNA) 1321 (Fed. Cir. 2007), reh'g and reh'g en banc denied, 488 F.3d 1377, 82 U.S.P.Q.2d (BNA) 1852 (Fed. Cir. 2007). 1130. Id. at 1352–53, 82 U.S.P.Q.2d (BNA) at 1324.

^{1131.} Id. at 1352, 82 U.S.P.Q.2d (BNA) at 1323.

^{1132.} *Id.* at 1355, 82 U.S.P.Q.2d (BNA) at 1326.

^{1133.} Id., 82 U.S.P.Q.2d (BNA) at 1326.

^{1134.} *Id.* at 1361–62, 82 U.S.P.Q.2d (BNA) at 1331.

^{1135.} Id. at 1364-65, 82 U.S.P.Q.2d (BNA) at 1333.

^{1136.} *Id.* at 1372, 82 U.S.P.Q.2d (BNA) at 1338. 1137. *Id.* at 1371, 82 U.S.P.Q.2d (BNA) at 1338.

^{1138.} Pfizer, Inc. v. Apotex, Inc., 488 F.3d 1377, 1378, 82 U.S.P.Q.2d (BNA) 1852, 1853 (Fed. Cir. 2007).

there was no showing of clear error. The judges also expressed concern that the panel's decision would adversely impact the pharmaceutical and chemical industries because it failed to appreciate the importance of the unexpected benefits of compounds and the difficulty in identifying and pursuing them. 1140

D. 35 U.S.C. § 112, ¶¶ 1 & 2

1. Enablement

A patent must contain "the manner and process of making and using [the invention] in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." This is known as the enablement requirement. 1142

The essence of this requirement is that patent protection is granted in return for an enabling disclosure of the invention, "not for vague intimations of general ideas that may or may not be workable.",1143 Enablement is a question of law, although it may contain subsidiary questions of law and fact. 1144 Whether a disclosure is enabling is determined as of the filing date of the application. 1145

Enablement requires that the specification teach those of ordinary skill in the art to make and use the full scope of the claimed invention without "undue experimentation." Undue experimentation is determined according to a "standard of reasonableness, having due regard for the nature of the invention and the state of the art." In other words, "a patent specification complies with the statute even if a 'reasonable' amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must

^{1139.} See id. at 1384, 82 U.S.P.Q.2d (BNA) at 1857 (noting that the "obvious to try" standard has a very limited application here, as in all cases that involve the pharmaceutical invention field).

^{1140.} Id. at 1380, 82 Ú.S.P.Q.2d (BNA) at 1854.

^{1141. 35} U.S.C. § 112, para. 1 (2000). 1142. *E.g.*, Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1371, 52 U.S.P.Q.2d (BNA) 1129, 1135 (Fed. Cir. 1999).

^{1143.} Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366, 42 U.S.P.Q.2d (BNA) 1001, 1005 (Fed. Cir. 1997) (citing Brenner v. Manson, 383 U.S. 519, 536, 148 U.S.P.Q. (BNA) 689, 696 (1966)).

^{1144.} Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342, 1354, 47 U.S.P.Q.2d (BNA) 1705, 1713 (Fed. Cir. 1998).

^{1145.} Enzo, 188 F.3d at 1371, 52 U.S.P.Q.2d (BNA) at 1135; In re Brana, 51 F.3d 1560, 1567 n.19, 34 U.S.P.Q.2d (BNA) 1436, 1441 n.19 (Fed. Cir. 1995).

^{1146.} Genentech, 108 F.3d at 1365, 42 U.S.P.Q.2d (BNA) at 1004; In re Wands, 858 F.2d 731, 737, 8 U.S.P.Q.2d (BNA) 1400, 1404 (Fed. Cir. 1988).
1147. Wands, 858 F.2d at 737, 8 U.S.P.Q.2d (BNA) at 1404 (citing Ansul Co. v. Uni-

royal, Inc., 448 F.2d 872, 878–79, 169 U.S.P.Q. (BNA) 759, 762–63 (2d Cir. 1971)).

not be 'undue." A specification need not disclose what is well known in the art but must supply the novel aspects of the inventions. 1149

In Ormco Corp. v. Align Technology, Inc., 1150 the Federal Circuit found enablement was lacking based on the testimony of the inventors. 1151 One of the inventors of Ormco's patents on computer-aided design and manufacture of custom orthodontic appliances testified that Ormco had never attempted to create a computerized system that automatically determined tooth positions without human decision making.¹¹⁵² While the goal was to have the software generate final tooth positions without use of a manual override, in fact "the manual override had been used on all of the approximately forty cases treated using the product" because "variations in human anatomy had prevented the attainment of that goal."1153 The Federal Circuit stated that "[i]f an inventor attempts but fails to enable his invention in a commercial product that purports to be an embodiment of the patented invention, that is strong evidence that the patent specification lacks enablement."¹¹⁵⁴ In this case, "[s]ubstantial doubt concerning the enablement of the invention was cast by the inventors."1155

In Liebel-Flarsheim v. Medrad, Inc., 1156 the Federal Circuit, in affirming summary judgment of non-enablement, emphasized that the full scope of the patent claims must be enabled. 1157 During prosecution, patentee Liebel had removed all references to a pressure jacket in claims directed to a "method of loading a tubular replacement syringe in a high-pressure power injector for injecting fluid into an animal."1158 Medrad argued, and the district court agreed, that Liebel had deleted such references in order to encompass Medrad's jacketless injector system. 1159 The district court concluded that the claims,

1148. Enzo, 188 F.3d at 1371, 52 U.S.P.Q.2d (BNA) at 1135 (citing Wands, 858 F.2d at 736-37, 8 U.S.P.Q.2d (BNA) at 1404).

^{1149.} See Genentech, 108 F.3d at 1366, 42 U.S.P.Q.2d (BNA) at 1005 (stating that the specification should facilitate the public in understanding and carrying out the invention).

^{1150. 498} F.3d 1307, 84 U.S.P.Q.2d (BNA) 1146 (Fed. Cir. 2007).

^{1151.} Id. at 1318, 84 U.S.P.Q.2d (BNA) at 1154.

^{1152.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1154–55. 1153. *Id.*, 84 U.S.P.Q.2d (BNA) at 1155. 1154. *Id.* at 1319, 84 U.S.P.Q.2d (BNA) at 1155.

^{1155.} Id., 84 U.S.P.Q.2d (BNA) at 1155.

^{1156. 481} F.3d 1371, 82 U.S.P.Q.2d (BNA) 1113 (Fed. Cir. 2007). 1157. *Id.* at 1379, 82 U.S.P.Q.2d (BNA) at 1118.

^{1158.} Id. at 1373, 82 U.S.P.Q.2d (BNA) at 1115.

^{1159.} Id., 82 U.S.P.Q.2d (BNA) at 1115.

while infringed, were invalid for lack of enablement and insufficient written description. 1160

On appeal, Liebel argued that since the claims do not require the absence of a pressure jacket, the district court had erroneously focused its enablement analysis on an embodiment without a pressure jacket and did not consider an injector with a pressure jacket. The Federal Circuit disagreed, finding that the district court had correctly considered whether the full scope of the construed claims had been enabled.¹¹⁶² Since the specification teaches away from an embodiment without a pressure jacket, the Federal Circuit found, "where the specification teaches against a purported aspect of an invention, such a teaching 'is itself evidence that at least a significant amount of experimentation would have been necessary to practice the claimed invention." The court also noted that "[t]he irony of this situation is that Liebel successfully pressed to have its claims include a jacketless system, but, having won that battle, it then had to show that such a claim was fully enabled, a challenge it could not meet."1164

Liebel-Flarsheim figured prominently in the Federal Circuit's affirmance of the district court's summary judgment of non-enablement in Automotive Technologies International, Inc. v. BMW of North America, Inc. 1165 Automotive Technologies International ("ATI") was the assignee of a patent, which was directed to side impact sensors. Although the patent's claims covered both mechanical and electronic sensors, the patent included a detailed description of mechanical sensors but very little on electronic sensors. The Federal Circuit, citing Liebel-Flarsheim, pointed out that there "must be 'reasonable enablement of the scope of the range." In particular, there must be sufficient enablement of electronic sensors because they are "distinctly different" from the enabled mechanical sensors. 1169 Although ATI maintained that a person of ordinary skill in the art would have been able to construct an electronic side impact sensor based on the disclosure provided, ATI and the patent's inventor admitted that they

^{1160.} Id. at 1378, 82 U.S.P.Q.2d (BNA) at 1118.

^{1161.} Id., 82 U.S.P.Q.2d (BNA) at 1118.

^{1162.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1118. 1163. *Id.* at 1379, 82 U.S.P.Q.2d (BNA) at 1119 (citing AK Steel Corp. v. Sollac & Ugine, 344 F.3d 1234, 1244, 68 U.S.P.Q.2d (BNA) 1280, 1287 (Fed. Cir. 2003)).

^{1164.} *Id.* at 1380, 82 U.S.P.Q.2d (BNA) at 1120. 1165. 501 F.3d 1274, 84 U.S.P.Q.2d (BNA) 1108 (Fed. Cir. 2007).

^{1166.} *Id.* at 1277, 84 U.S.P.Q.2d (BNA) at 1111. 1167. *Id.* at 1285, 84 U.S.P.Q.2d (BNA) at 1116.

^{1168.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1116 (internal quotation omitted) (quoting Libel-Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371, 1380, 82 U.S.P.Q.2d (BNA) 1113, 1120 (Fed. Cir. 2007)).

^{1169.} Id., 84 U.S.P.Q.2d (BNA) at 1116.

had not known of any electronic side impact sensors at the time of filing.1170 Moreover, an expert from Delphi (Counterclaimant Defendant-Appellee) testified that a great deal of experimentation would have been required to make an electronic sensor using only the disclosure in the patent. 1171 Based on this evidence, the Federal Circuit concluded that the enablement requirement was not satisfied by the patent's limited disclosure of electronic sensors. 1172

In Monsanto Co. v. Syngenta Seeds, Inc., 1173 the district court held that certain claims of Monsanto's patent were invalid under § 112 because the specification did not "enable the full scope of the broad functional language in claim 1 without undue experimentation." The language in question was the term "in plant cells." According to the Federal Circuit, "[t]he district court correctly construed claim 1... to require the claimed gene to function in any plant cell, including both dicots and monocots."1176 The court stated that "those skilled in the art could not transform a monocot plant cell as of the filing date of the patent application." Further, "[t]he claim requires transformation of the plant cell." The court went on to state that "[w]ithout the ability to transform a monocot cell, one skilled in the art could not determine whether the plant gene could carry out the claimed functions and thus fall within the scope of the claim."1179 Monsanto argued that "the disputed claim language merely describes the operation of the discrete gene components in a plant cell, but does not operate as a limitation." Stated differently, the court noted, "Monsanto argue[d] that the term 'plant cell' should not convert chimeric gene claims into claims directed to plants or plant cells transformed with the claimed gene, particularly where the patent already contains separate claims directed to such plants and plant cells."1181 The Federal Circuit agreed with the district court, holding that "Monsanto's patent recites broad functional language in its

^{1170.} *Id.* at 1284, 84 U.S.P.Q.2d (BNA) at 1115.

^{1171.} Id., 84 U.S.P.Q.2d (BNA) at 1115.

Id. at 1285, 84 U.S.P.Q.2d (BNA) at 1115-16. 1172.

^{1173. 503} F.3d 1352, 84 U.S.P.Q.2d (BNA) 1705 (Fed. Cir. 2007).

^{1174.} Id. at 1360, 84 U.S.P.Q.2d (BNA) at 1711.

^{1175.} *Id.* at 1360–61, 84 U.S.P.Q.2d (BNA) at 1711.

^{1176.} *Id.* at 1361, 84 U.S.P.Q.2d (BNA) at 1711.

^{1177.} Id., 84 U.S.P.Q.2d (BNA) at 1711.

^{1178.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1711. 1179. *Id.*, 84 U.S.P.Q.2d (BNA) at 1711.

^{1180.} Id., 84 U.S.P.Q.2d (BNA) at 1711.

^{1181.} Id., 84 U.S.P.Q.2d (BNA) at 1711.

claims," and "the evidence here does not demonstrate that as of the filing date of the ... patent ... the invention was enabled."1182

2. Best mode

In addition to requiring that the specification disclose the invention in sufficient detail as to enable one skilled in the art to make and use the claimed invention, § 112 further requires that the specification "set forth the best mode contemplated by the inventor of carrying out his invention." 1183 Or, as elaborated by the Federal Circuit, the inventor must disclose the "best mode contemplated by him, as of the time he executes the application, of carrying out his invention." This "best mode" requirement prevents inventors from obtaining patent protection while concealing from the public the preferred embodiments of their inventions. 1185 "The best mode requirement creates a statutory bargained-for-exchange by which a patentee obtains the right to exclude others from practicing the claimed invention for a certain time period, and the public receives knowledge of the preferred embodiments for practicing the claimed invention."1186

The best mode analysis, a question of fact, has two components. 1187 "First, a fact-finder must determine whether at the time an applicant filed an application for a patent, he or she had a best mode of practicing the invention; this is a subjective determination." Second, the fact-finder must determine "whether the specification adequately disclosed what the inventor contemplated as the best mode so that

^{1182.} Id. at 1361-62, 84 U.S.P.Q.2d (BNA) at 1711.

^{1183.}

³⁵ U.S.C. § 112, para. 1 (2000). Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1532, 3 U.S.P.Q.2d 1184. (BNA) 1737, 1742 (Fed. Cir. 1987) (quoting *In re* Gay, 309 F.2d 769, 772, 135 U.S.P.Q. (BNA) 311, 315 (C.C.P.A. 1962)); *see also* Glaxo Inc. v. Novopharm Ltd., 52 F.3d 1043, 1050, 34 U.S.P.Q.2d (BNA) 1565, 1569 (Fed. Cir. 1995) (noting that an inquiry into the best mode requirement should focus on the inventor's state of

^{1185.} Glaxo, 52 F.3d at 1050, 34 U.S.P.Q.2d (BNA) at 1569.

^{1186.} Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 963, 58 U.S.P.Q.2d (BNA) 1869, 1874 (Fed. Cir. 2001) (citing Spectra-Physics, 827 F.2d at 1532, 3 U.S.P.Q.2d (BNA) at 1742).

^{1187.} N. Telecom Ltd. v. Samsung Elecs. Co., 215 F.3d 1281, 1286, 55 U.S.P.Q.2d (BNA) 1065, 1068 (Fed. Cir. 2000).

^{1188.} Fonar Corp. v. Gen. Elec. Co., 107 F.3d 1543, 1548, 41 U.S.P.Q.2d (BNA) 1801, 1804 (Fed. Cir. 1997); see also In re Hayes Microcomputer Prod., Inc. Patent Litig., 982 F.2d 1527, 1536, 25 U.S.P.Q.2d (BNA) 1241, 1248 (Fed. Cir. 1992) (stating that this inquiry focuses on whether the inventor, at the time of filing his patent application, knew of a mode of practicing that he felt was better than any other).

those having ordinary skill in the art could practice it." The second prong is an objective determination. 1190

In Allvoice Computing PLC v. Nuance Communications, Inc., 1191 the Federal Circuit further explained that "[o]nly the claimed invention is subject to the best mode requirement." The claims at issue, which "cover[ed] an interface between a speech recognition engine and various end-user application programs on a personal computer[,]" recited an "output means for outputting the recognised words into at least any one of the plurality of different computerrelated applications to allow processing of the recognised words as input text."1193

The Federal Circuit reversed both determinations, largely on the basis of the district court's erroneous construction of the term "output means" to "require[] a system outputting, alternately, to a plurality of different word processing or other application programs." The "alternately" requirement, the court found, was not suggested or required by the claims. 1195 As a result, the alleged undisclosed best mode fell outside the scope of the claims and thus was "not a best mode of practicing the claimed invention." The Federal Circuit concluded that the patent did not violate the best mode requirement, regardless of the lack of disclosure of the subject matter in question. 1197

3. Written description

A third requirement of 35 U.S.C. § 112, ¶ 1 is that "[t]he specification shall contain a written description of the invention." The Federal Circuit has held that this language gives rise to a requirement separate and distinct from the enablement and best mode require-

^{1189.} Young Dental Mfg. Co. v. Q3 Special Prods., Inc., 112 F.3d 1137, 1144, 42 U.S.P.Q.2d (BNA) 1589, 1594 (Fed. Cir. 1997) (citing U.S. Gypsum Co. v. Nat'l Gypsum Co., 74 F.3d 1209, 1212, 37 U.S.P.Q.2d 1388, 1390 (Fed. Cir. 1996)).

^{1190.} E.g., Fonar Corp., 107 F.3d at 1548, 41 U.S.P.Q.2d (BNA) at 1804. 1191. 504 F.3d 1236, 84 U.S.P.Q.2d (BNA) 1886 (Fed. Cir. 2007). 1192. Id. at 1246, 84 U.S.P.Q.2d (BNA) at 1894 (citing Randomex, Inc. v. Scopus Corp., 849 F.2d 585, 588, 7 U.S.P.Q.2d (BNA) 1050, 1053 (Fed. Cir. 1988) ("It is concealment of the best mode of practicing the *claimed invention* that section 112 ¶ 1 is designed to prohibit."); DeGeorge v. Bernier, 768 F.2d 1318, 1325, 226 U.S.P.Q. (BNA) 758, 763 (Fed. Cir. 1985) (reversing a Patent Appeals Board determination on the basis that it extended the best mode beyond the proper scope of the claim)).

^{1193.} *Id.* at 1238, 84 U.S.P.Q.2d (BNA) at 1888. 1194. *Id.* at 1241, 84 U.S.P.Q.2d (BNA) at 1890 (emphasis added) (quoting Allvoice Computing PLC v. Scansoft, Inc., No. H-02-4471 (S.D. Tex. Oct. 13, 2005)).

^{1195.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1890. 1196. *Id.* at 1246, 84 U.S.P.Q.2d (BNA) at 1893.

^{1197.} Id. at 1248, 84 U.S.P.Q.2d (BNA) at 1895.

^{1198. 35} U.S.C. § 112, para. 1 (2000).

ments. 1199 In other words, a specification may enable the practice of an invention and disclose its best mode but still not adequately describe the invention. 1200 The Federal Circuit has stated as follows:

Satisfaction of the description requirement insures that subject matter presented in the form of a claim subsequent to the filing date of the application was sufficiently disclosed at the time of filing so that the prima facie date of invention can fairly be held to be the filing date of the application. 1201

The written description requirement, an issue of fact, is satisfied if persons skilled in the art would recognize from the patent specification that the inventor invented what is claimed. Stated another way, the disclosure in the patent must reasonably convey to one of ordinary skill in the art that the inventor "possessed" the claimed subject matter at the time of the invention and described it "with all its claimed limitations."1203

Since satisfaction of the first paragraph of § 112 must be judged as of the filing date of the patent, 1204 the focus of the inquiry is on the patent's "original" disclosure, i.e., the disclosure contained in the originally filed patent application, including the originally filed claims. 1205 Therefore, when original claims are at issue, disclosure as of the filing date is ensured, and the written description requirement is likely satisfied. 1206

In Hyatt v. Dudas, 1207 the Federal Circuit examined the written description requirement in the context of an action under 35 U.S.C. § 145. 1208 Hyatt was prosecuting five applications that all shared the same specification when, at one point, it withdrew all of the claims and proposed over 1,100 new claims. The Examiner, relying on

^{1199.} In re Alton, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d (BNA) 1578, 1581 (Fed. Cir. 1996).

^{1200.} Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1561, 19 U.S.P.Q.2d (BNA) 1111, 1115 (Fed. Cir. 1991).

^{1201.} In re Smith, 481 F.2d 910, 914, 178 U.S.P.Q. (BNA) 620, 623 (C.C.P.A. 1973). 1202. Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 1479, 45 U.S.P.Q.2d (BNA) 1498, 1503 (Fed. Cir. 1998).

Id., 45 U.S.P.Q.2d (BNA) at 1503 (quoting Lockwood v. Am. Airlines, Inc., 107 F.3d 1565, 1572, 41 U.S.P.Q.2d (BNA) 1961, 1966 (Fed. Cir. 1997)); see also Tronzo v. Biomet, Inc., 156 F.3d 1154, 1158, 47 U.S.P.Q.2d (BNA) 1829, 1833 (Fed. Cir. 1998) (explaining that a disclosure that "merely renders the later-claimed invention obvious is not sufficient to meet the written description requirement").

^{1204.} U.S. Steel Corp. v. Phillips Petroleum Co., 865 F.2d 1247, 1251, 9 U.S.P.Q.2d (BNA) 1461, 1464 (Fed. Cir. 1989)

^{1205.} Hyatt v. Boone, 146 F.3d 1348, 1352, 47 U.S.P.Q.2d (BNA) 1128, 1130 (Fed. Cir. 1998); *Gentry*, 134 F.3d at 1479, 45 U.S.P.Q.2d (BNA) at 1503; *In re* Benno, 768 F.2d 1340, 1346, 226 U.S.P.Q. (BNA) 683, 686–87 (Fed. Cir. 1985).

^{1206.} *In re* Smith, 481 F.2d 910, 914, 178 U.S.P.Q. (BNA) 620, 624 (C.C.P.A. 1973). 1207. 492 F.3d 1365, 83 U.S.P.Q.2d (BNA) 1373 (Fed. Cir. 2007). 1208. *Id.* at 1367–68, 83 U.S.P.Q.2d (BNA) at 1374.

^{1209.} Id. at 1367, 83 U.S.P.Q.2d (BNA) at 1374.

the Manual of Patent Examining Procedure § 2163.04(I)(B), analyzed representative claims and rejected them for failing the written description test. 1210 Rather than responding to the merits of the rejection, Hyatt argued that the PTO's prima facie test was improper and section 2163.04(I)(B) of the MPEP was not good law. 1211 After failing to persuade the Examiner and the Board of Patent Appeals and Interferences, Hyatt appealed successfully to the U.S. District Court for the District of Columbia, which found that the examiner had improperly used "vague and unspecific language" in the rejection.¹²¹² The PTO appealed to the Federal Circuit.¹²¹³

The Federal Circuit reversed the district court's judgment that the PTO had failed to establish a prima facie case of inadequate written description when it rejected the patent claims. 1214 When the specification lacks any written description to support a claim, "the only thing the PTO can reasonably be expected to do is to point out its nonexistence" and "specify which claim limitation is lacking adequate support in the written description."1215

In this case, the examiner had notified Hyatt that support for his amended claims was missing, which shifted the burden to Hyatt to show where support for those new claim limitations could be found in order to overcome the rejection. Because Hyatt refused to do so at the appropriate time, the claims were properly rejected. 1217

In Frazer v. Schlegel, 1218 the Federal Circuit held that in an interference proceeding, an appellant is entitled to the benefit of a foreign priority document that is "disclosed in the [same] manner provided by the first paragraph of section 112," for the disclosure of a species of the count. 1219 On that basis, the court reversed the Board of Patent Appeals and Interferences' determination of priority in a patent interference case. 1220

In this case, Frazer and Schlegel both claimed inventions related to human papillomavirus ("HPV") vaccines comprising HPV-like parti-

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1210. Id., 83 U.S.P.Q.2d (BNA) at 1374.
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^{1211.} *Id.*, 83 U.S.P.Q.2d (BNA) at 1374. 1212. *Id.* at 1368, 83 U.S.P.Q.2d (BNA) at 1374.

^{1213.} Id. at 1367, 83 U.S.P.Q.2d (BNA) at 1374.

^{1214.} Id., 83 U.S.P.Q.2d (BNA) at 1374.

^{1215.} *Id.* at 1370, 83 U.S.P.Q.2d (BNA) at 1376 (citing MPEP sec. 2163.04(I)). 1216. *Id.* at 1371, 83 U.S.P.Q.2d (BNA) at 1377.

^{1217.} Id., 83 U.S.P.Q.2d (BNA) at 1377.

^{1218. 498} F.3d 1283, 83 U.S.P.Q.2d (BNA) 1850 (Fed. Cir. 2007).

^{1219.} Id. at 1287, 83 U.S.P.Q.2d (BNA) at 1853 (quoting 35 U.S.C. § 119(e)(1)

^{1220.} Id. at 1289, 83 U.S.P.Q.2d (BNA) at 1851.

cles. 1221 Schlegel, having the earlier U.S. filing date, was declared the senior party. 1222 Frazer's U.S. application, however, claimed priority to an Australian patent application, which he had filed prior to Schlegel's U.S. filing date. 1223 Frazer's Australian application disclosed a vector "designed to coexpress the L1 and L2 late genes of human papillomavirus" yielded HPV-like particles, which "could provide a safe source of material for the development of a vaccine."1224 The interference count recited an HPV-like particle made by "constructing a recombinant DNA molecule that contains a sequence encoding a papillomavirus L1 protein; transfecting a host cell with the recombinant DNA molecule; [and] expressing papillomavirus viruslike particles from the transfected host cell." In view of Schlegel's priority, however, the Board determined that Frazer was not entitled to the benefit of the Australian application because at the time he filed it, "Frazer believed that both the L1 and L2 genes had to be expressed together from the same plasmid," while Frazer's "later work shows that only L1 protein was necessary." 1226 As a result, the Board found that Frazer's Australian application "did not provide a described and enabled anticipation under 35 U.S.C. § 102(g) of the subject matter of the count."1227

The Federal Circuit reversed the Board's decision with regard to Schlegel's priority. 1228

Although the Board analyzed the Australian application in terms of "conception," when reliance is on a patent document already filed, the question is whether the document discloses the invention of the count by meeting the written description and enablement requirements of 35 U.S.C. § 112[, paragraph 1], for a filed application serves as a constructive reduction to practice of its content.¹²²⁶

Thus, "[i]n accordance with United States law, when the priority claim is based on subject matter disclosed in a foreign patent application whose filing date is properly claimed" under 35 U.S.C. § 119(a) and which complies with § 112(a), "the foreign application has the same effect as if filed in the United States."1230

^{1221.} Id. at 1284, 83 U.S.P.Q.2d (BNA) at 1851.

^{1222.} *Id.* at 1286, 83 U.S.P.Q.2d (BNA) at 1853. 1223. *Id.* at 1283–84, 83 U.S.P.Q.2d (BNA) at 1851.

^{1224.} Id. at 1284, 83 U.S.P.Q.2d (BNA) at 1851 (quoting Jian Zhou et al., Expression of Vaccinia Recombinant HPV 16 L1 and L2 ORF Proteins in Epithelial Cells is Sufficient for Assembly of HPV Virion-Like Particles, 185 VIROLOGY 251, 251 (1991)).

^{1225.} *Id.* at 1286, 83 U.S.P.Q.2d (BNA) at 1853. 1226. *Id.* at 1287, 83 U.S.P.Q.2d (BNA) at 1854.

^{1227.} *Id.*, 83 U.S.P.Q.2d (BNA) at 1854. 1228. *Id.* at 1289, 83 U.S.P.Q.2d (BNA) at 1855. 1229. *Id.* at 1287, 83 U.S.P.Q.2d (BNA) at 1854.

^{1230.} Id., 83 U.S.P.Q.2d (BNA) at 1853.

The court then found that Frazer's "Australian application contained complete details of the method that is the subject of the interference count, and depicts the papillomavirus-like particle of the count with full disclosure of how to produce it." Notwithstanding Frazer's disclosure of the expression of both the L1 and L2 genes in the Australian application, "his later discovery that either the L1 protein or both the L1 and L2 proteins led to capsid formation does not negate or contradict his disclosure and constructive reduction to practice of the method of the count that produced the papillomavirus-like particle of the count." Accordingly, "the description [in Frazer's Australian application] of the procedures used, and the successful production of the virus-like particles there achieved and reported, disclose and enable a species within the count."

4. Claim definiteness

The second paragraph of 35 U.S.C. § 112 requires that a patent specification "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." This is referred to as the "definiteness requirement," which is a question of law. "[P]aragraph two of section 112 'is essentially a requirement for precision and definiteness of claim language." In other words, "'the requirement is that language of the claims must make it clear what subject matter they encompass."

The definiteness requirement serves two primary purposes. First, it ensures that those skilled in the art can understand and apply the teachings of the invention. Second, it encourages enterprise and experimentation by requiring certainty as to the scope of the inven-

^{1231.} Id. at 1288, 83 U.S.P.Q.2d (BNA) at 1854.

^{1232.} Id., 83 U.S.P.Q.2d (BNA) at 1854.

^{1233.} Id. at 1289, 83 U.S.P.Q.2d (BNA) at 1855.

^{1234. 35} U.S.C. § 112 (2000).

^{1235.} Gen. Elec. Co. v. Wabash Appliance Corp., 304 U.S. 364, 369, 37 U.S.P.Q. (BNA) 466, 471 (1938); Stiftung v. Renishaw PLC, 945 F.2d 1173, 1181, 20 U.S.P.Q.2d (BNA) 1094, 1095 (Fed. Cir. 1991).

^{1236.} PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1562, 37 U.S.P.Q.2d (BNA) 1618, 1621 (Fed. Cir. 1996) (quoting *In re* Borkowski, 422 F.2d 904, 909, 164 U.S.P.Q. (BNA) 642, 646 (C.C.P.A. 1970)).

^{1237.} *Id.*, 37 U.S.P.Q.2d (BNA) at 1621 (quoting *In re* Hammack, 427 F.2d 1378, 1382, 166 U.S.P.Q. (BNA) 204, 208 (C.C.P.A. 1970)).

^{1238.} Ga.-Pac. Corp. v. U.S. Plywood Corp., 258 F.2d 124, 136, 118 U.S.P.Q. (BNA) 122, 136 (2d Cir. 1958).

tion. 1239 The Supreme Court identified the policy served by the definiteness requirement in *United Carbon Co. v. Binney & Smith Co.*: 1240

The statutory requirement of particularity and distinctness in claims is met only when they clearly distinguish what is claimed from what went before in the art and clearly circumscribe what is foreclosed from future enterprise. A zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims would discourage invention only a little less than unequivocal foreclosure of the field. Moreover, the claims must be reasonably [clear-cut] to enable courts to determine whether novelty and invention are genuine. 1241

Claim definiteness depends on whether the inventor's claim language conveys to those skilled in the art the scope of coverage. 1242 The specification informs the meaning of the claims. Thus, claims can be held indefinitely if there is a conflict between the claimed subject matter and the specification that would render the scope uncertain. 1243 Additionally, "the amount of detail required to [meet the definiteness standard]... depends on the particular invention and the prior art," for the language of the claim need only be as precise as the subject matter permits. 1245

The definiteness of the claims is judged as of the date the application was filed. 1246 It is permissible, however, to use patents and publications appearing after the filing date to construe the claim language. 1247 Moreover, it is possible for the claims to fail to adequately define the scope of the subject matter of the invention even if the

^{1239.} Id., 118 U.S.P.Q. (BNA) at 136.

^{1240. 317} U.S. 228, 55 U.S.P.Q. (BNA) 381 (1942).

^{1241.} *Id.* at 236, 55 U.S.P.Q. (BNA) at 385–86. 1242. Credle v. Bond, 25 F.3d 1566, 1576, 30 U.S.P.Q.2d (BNA) 1911, 1919 (Fed. Cir. 1994).

^{1243.} See In re Cohn, 438 F.2d 989, 993, 169 U.S.P.Q. (BNA) 95, 98 (C.C.P.A. 1971) (rejecting claims as indefinite upon a finding of an inconsistency between the claims).

^{1244.} Polymer Indus. Prods. Co. v. Bridgestone/Firestone, Inc., 10 F. App'x 812, 817 (Fed. Cir. 2001) (quoting Shatterproof Glass Corp. v. Libbey-Owens Ford Co., 758 F.2d 613, 624, 225 U.S.P.Q. (BNA) 634, 641 (Fed. Cir. 1985)).

^{1245.} N. Am. Vaccine, Inc. v. Am. Cyanamid Co., 7 F.3d 1571, 1579–80, 28 U.S.P.Q.2d (BNA) 1333, 1339 (Fed. Cir. 1993).

^{1246.} See U.S. Steel Corp. v. Phillips Petroleum Co., 865 F.2d 1247, 1251, 9 U.S.P.Q.2d (BNA) 1461, 1464 (Fed. Cir. 1989) (explaining that specification language is to be construed for what it meant to one with "ordinary skill in the art" at the time of filing); In re Glass, 492 F.2d 1228, 1232, 181 U.S.P.Q. (BNA) 31, 34 (C.C.P.A. 1974) (noting that a specification should be interpreted as of the date of

^{1247.} U.S. Steel Corp., 865 F.2d at 1251, 9 U.S.P.Q.2d (BNA) at 1464.

disclosures in the specification are adequate to satisfy the enablement and written description requirements. 12-

In Young v. Lumenis, Inc., 1249 the Federal Circuit explained that claims are indefinite only when they are "not amenable to construction or are insolubly ambiguous." The claims in that case were directed to a surgical method for removing a claw from a domesticated cat, such claims including the step of "forming [an] incision in the epidermis near the edge of the ungual crest." The district court found the term "near" to be indefinite because it "fails to distinguish the invention over the prior art and does not permit one of ordinary skill to know what activity constitutes infringement." The Federal Circuit reversed. Noting that the definiteness of claim terms depends on whether those terms can be given any reasonable meaning, the Federal Circuit found that the patent's drawings and references to measurements were sufficient to permit persons skilled in the art to understand what was claimed and to resolve the meaning of the term "near." 1253

The Federal Circuit also reversed the district court's indefiniteness determination in Allvoice Computing PLC v. Nuance Communications, Inc. 1254 due to a flawed claim construction. 1255 The district court had held that the claims on "an interface between a speech recognition engine and various end-user application programs on a personal computer" were invalid because the means-plus-function elements in three claims were indefinite. 1256 In particular, the district court construed the claimed "output means for outputting the recognised words into at least any one of the plurality of different computer related applications to allow processing of the recognised words as input text" to require "a system outputting, alternately, to a plurality of different word processing or other application programs." The Federal Circuit found that the district court had improperly "added the requirement that the system be able to output 'alternately' to different

^{1248.} In re Borkowski, 422 F.2d 904, 909, 16 U.S.P.Q. (BNA) 642, 645 (C.C.P.A. 1970).

^{1249. 492} F.3d 1336, 83 U.S.P.Q.2d (BNA) 1191 (Fed. Cir. 2007).

^{1250.} *Id.* at 1346, 83 U.S.P.Q.2d (BNA) at 1197 (quoting Datamize, LLC v. Plumtree Software, Inc., 417 F.3d 1342, 1347, 75 U.S.P.Q.2d (BNA) 1801, 1804 (Fed. Cir.

^{1251.} *Id.* at 1340, 83 U.S.P.Q.2d (BNA) at 1193. 1252. *Id.* at 1343, 83 U.S.P.Q.2d (BNA) at 1194.

^{1253.} Id. at 1346-47, 83 U.S.P.Q.2d (BNA) at 1197.

^{1254. 504} F.3d 1236, 84 U.S.P.Q.2d (BNA) 1886 (Fed. Cir. 2007).

^{1255.} Id. at 1248, 84 U.S.P.Q.2d (BNA) at 1895.

^{1256.} Id. at 1238, 84 U.S.P.Q.2d (BNA) at 1888.

^{1257.} Id. at 1238, 1241, 84 U.S.P.Q.2d (BNA) at 1888, 1890 (emphasis added).

programs," even though "the claim does not suggest the requirement that the means do so *alternately*." Once this extraneous limitation was disregarded, "an artisan of ordinary skill would understand the bounds of the claim when read in light of the specification." The Federal Circuit concluded that the claim at issue satisfied the definiteness requirement. 1260

In Biomedino, LLC v. Waters Technologies Corp., 1261 the Federal Circuit unanimously confirmed the district court's determination that certain claims of U.S. Patent No. 6,602,002 ("the '002 patent") were invalid for indefiniteness, "[b]ecause the claim limitation 'control means' had no corresponding structure described in the specification as required by 35 U.S.C. § 112(6)." The district court construed the term "control means" to raise the presumption that § 112(6) applied.¹²⁶³ The court found that the word "control" did not identify structure, and thus the presumption that the claim limitation was a means-plus-function claim was unrebutted. 1264 In reviewing the specifications to determine what structure constitutes the means for performing the specified function, the district court identified a box labeled control in Figure 6 and a statement that "the invention 'may be controlled automatically by known differential pressure, valving and control equipment."1265

The appellant, Biomedino, argued that one of ordinary skill in the art would identify structure from the written description provided by the specification. 1266 Appellee argued that no specific structure was disclosed in the specifications to correspond to the claimed function of automatically operating the invention, and the proper inquiry was whether one of ordinary skill in the art would understand the specification itself to disclose the structure. 1267 Citing Medical Instrumentation & Diagnostics Corp. v. Elekta AB, 1268 the Federal Circuit stated that the proper inquiry is "whether one of [ordinary] skill in the art would understand the specification itself to disclose a structure, not simply

^{1258.} Id. at 1241, 84 U.S.P.Q.2d (BNA) at 1890 (emphasis added).

^{1259.} *Id.* at 1242, 84 U.S.P.Q.2d (BNA) at 1891; *see also* KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1742, 82 U.S.P.Q.2d (BNA) 1385, 1397 (2007) ("A person of ordinary skill is also a person of ordinary creativity, not an automaton."). 1260. *Allvoice*, 504 F.3d at 1240, 84 U.S.P.Q.2d (BNA) at 1890.

^{1261. 490} F.3d 946, 83 U.S.P.Q.2d (BNA) 1118 (Fed. Cir. 2007).

^{1262.} *Id.* at 948, 83 U.S.P.Q.2d (BNA) at 1119. 1263. *Id.* at 949, 83 U.S.P.Q.2d (BNA) at 1120.

^{1264.} Id., 83 U.S.P.Q.2d (BNA) at 1120.

^{1265.} Id., 83 U.S.P.Q.2d (BNA) at 1120. 1266. Id. at 950, 83 U.S.P.Q.2d (BNA) at 1120. 1267. Id. at 951, 83 U.S.P.Q.2d (BNA) at 1121. 1268. 344 F.3d 1205, 68 U.S.P.Q.2d (BNA) 1263 (Fed. Cir. 2003).

whether that person would be capable of implementing a structure."1269

The Federal Circuit held that "a bare statement that known techniques or methods can be used does not disclose structure."1270 On that basis, the Federal Circuit affirmed "the judgment of the district court holding claims 13-17 and 40 of the '502 patent as invalid for indefiniteness."1271

E. Double Patenting

Obviousness-type double patenting is a judicially created doctrine designed to prevent a patentee from claiming essentially the same invention in two patents to effectively extend the lifetime of patent protection. 1272 The analysis has two steps—the claims of the two patents are first construed, and then they are compared to determine if they are patentably distinct. 1273 If they are not, the later claims are inva-

In In re Metoprolol Succinate Patent Litigation, 1275 the Federal Circuit affirmed the district court's summary judgment that the patent at issue was invalid for obviousness-type double patenting. Plaintiffs (collectively, "Astra") sued for infringement of its patent on pharmaceutical compositions containing metoprolol succinate, a pharmaceutical used to treat angina, hypertension, and congestive heart failure. 1277 (Astra's second patent was not at issue in this portion of the appeal. 1278) Construction of the '154 patent's single claim was not disputed, so the district court proceeded to compare the '154 patent to claim 8 of Astra's earlier '318 patent (U.S. Patent No. 4,780,318), which claimed an oral composition having a core of metoprolol succinate surrounded by two controlled-release layers. 1279 The district court concluded that the '154 patent claimed a patentably indistinct

^{1269.} Biomedino, 490 F.3d at 953, 83 U.S.P.Q.2d (BNA) at 1123 (citing Med. Instrumentation, 344 F.3d at 1212, 68 U.S.P.Q.2d (BNA) at 1269).

^{1270.} Id., 83 U.S.P.Q.2d (BNA) at 1123.

^{1271.} *Id.*, 83 U.S.P.Q.2d (BNA) at 1123.

^{1272.} In ne Metoprolol Succinate Patent Litig., 494 F.3d 1011, 1016, 83 U.S.P.Q.2d (BNA) 1545, 1548 (Fed. Cir. 2007).

^{1273.} *Id.*, 83 U.S.P.Q.2d (BNA) at 1548. 1274. *Id.*, 83 U.S.P.Q.2d (BNA) at 1548.

^{1275.} Metoprolol, 494 F.3d 1011, 83 U.S.P.Q.2d (BNA) 1545.

^{1276.} Id. at 1016, 83 U.S.P.Q.2d (BNA) at 1548.

^{1277.} Id. at 1013, 83 U.S.P.Q.2d (BNA) at 1545.

^{1278.} Id. at 1014, 83 U.S.P.Q.2d (BNA) at 1546-47. The district court also found both patents unenforceable due to inequitable conduct. Id. at 1015, 83 U.S.P.Q.2d (BNA) at 1547. Astra appealed that decision as well, which is discussed infra Part \widetilde{V} . 1279. Id. at 1016, 83 U.S.P.Q.2d (BNA) at 1548.

genus of the species claimed by the earlier-issued '318 patent and entered summary judgment of invalidity. 1280 Astra appealed.

The majority of the Federal Circuit panel, over Judge Schall's dissent, affirmed the district court's summary judgment of obviousnesstype double patenting. 1281 The court rejected as irrelevant Astra's "semantic distinction" that the '154 and '318 patents were not in a genus/species relationship but an element/combination relationship. 1282 The Federal Circuit then affirmed that it would have been obvious to omit the outer layers in claim 8 of the '318 patent and produce the metoprolol succinate compound claimed in the '154 patent because "the omission of the known elements from the composition . . . is 'the product not of innovation but of ordinary skill and common sense." Allowing the inventors to patent the drug itself after having patented a combination of the drug with a carrier would unlawfully extend the first patent and deprive the public of the use of the drug beyond the allowed term of the earlier patent. Accordingly, the Federal Circuit affirmed the district court's holding that the '154 patent was invalid for obviousness-type double patenting.¹²⁸⁵

In so holding, the Federal Circuit agreed with Astra that a patent cited in support of a double-patenting rejection cannot be used as "prior art" for a § 102 or § 103 rejection, but stated the "critical" focus of a double-patenting analysis is on "what is claimed, as opposed to what is disclosed to one skilled in the art." Moreover, the scope of double-patenting is not limited to \S 101's statutory prohibition against claims to the same invention. That prohibition, the court explained, could be easily circumvented by drafting claims that varied only slightly from the earlier patent. 1288

Judge Schall dissented, finding that the '154 patent was "patentably distinct" because it "lack[ed] any semblance to the second two elements [(the inner and outer layers)] in the three-element composition of claim 8" of the '318 patent. 1289 Also, since metoprolol succinate was only one of the eleven possible compounds recited in claim

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1280. Id. at 1013, 83 U.S.P.Q.2d (BNA) at 1546.
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^{1281.} *Id.*, 83 U.S.P.Q.2d (BNA) at 1546.

^{1282.} *Id.* at 1016-17, 83 U.S.P.Q.2d (BNA) at 1548–49. 1283. *Id.* at 1017 n.2, 83 U.S.P.Q.2d (BNA) at 1549 n.2 (quoting KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1742, 82 U.S.P.Q.2d (BNA) 1385, 1397 (2007)).

^{1284.} Id. at 1017–18, 83 U.S.P.Q.2d (BNA) at 1549.

^{1285.} *Id.* at 1020, 83 U.S.P.Q.2d (BNA) at 1551.

^{1286.} *Id.* at 1018, 83 U.S.P.Q.2d (BNA) at 1548 (citing Gen. Foods Corp. v. Studiengesellschaft Kohle mbH, 972 F.2d 1272, 1281-82, 23 U.S.P.Q.2d (BNA) 1839, 1846–47 (Fed. Cir. 1992)).

^{1287.} Id., 83 U.S.P.Q.2d (BNA) at 1550.

^{1288.} Id. at 1018-19, 83 U.S.P.Q.2d (BNA) at 1550.

^{1289.} *Id.* at 1023, 83 U.S.P.Q.2d (BNA) at 1553 (Shall, J., dissenting).

8, Judge Schall did not believe that claim 8 was equivalent to the claim for metoprolol succinate in the '154 patent or rendered that claim obvious. 1290 The law of double patenting, he wrote, does not invalidate a claim "simply because a later claimed element is set forth in an earlier claim to a combination."1291

IV. INFRINGEMENT

"[W]hoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." Determining patent infringement "entails two steps: (1) the claims must be construed; and (2) the properly construed claims must be compared to the allegedly infringing device."1293

A. Claim Construction

"It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude." Because the claims are the language the patentee chose to define the invention, claim construction must begin and remain centered on the language of the claims themselves. The evidentiary review is hierarchical, focusing first on the claims, then on the patent specification, next on the file history, and finally on the "extrinsic" evidence if appropriate. 1296 In determining the proper meaning of claim terms, the patent specification "is always highly relevant to the

^{1290.} Id. at 1021, 83 U.S.P.Q.2d (BNA) at 1552.

^{1291.} Id. at 1023, 83 U.S.P.Q.2d (BNA) at 1553.

⁵² F.3d 967, 976, 34 U.S.P.Q. (BNA) 1321, 1326 (Fed. Cir. 1995), aff'd, 517 U.S. 370, 38 U.S.P.Q.2d (BNA) 1461 (1996))

^{1294.} Phillips v. AWH Corp., 415 F.3d 1303, 1312, 75 U.S.P.Q.2d (BNA) 1321, 1325 (Fed. Cir. 2005) (en banc) (quoting Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1115, 72 U.S.P.Q.2d (BNA) 1001, 1004 (Fed. Cir. 2004)); see also Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582, 39 U.S.P.Q.2d (BNA) 1573, 1576 (Fed. Cir. 1996) (noting that the words of the claim itself are used to define the scope of the patent, and that the patentee "may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning").

^{1295.} Innova/Pure Water, 381 F.3d at 1116, 72 U.S.P.Q.2d (BNA) at 1004; see also Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc., 334 F.3d 1294, 1298, 67 U.S.P.Q.2d (BNA) 1132, 1136 (Fed. Cir. 2003) (beginning its analysis of claim construction with the claim language).

^{1296.} E.g., Vitronics, 90 F.3d at 1582–83, 39 U.S.P.Q.2d (BNA) at 1576–77.

claim construction analysis." It is typically dispositive; "it is the single best guide to the meaning of a disputed term." The importance of the specification in claim construction "derives from its statutory role. The close kinship between the written description and the claims is enforced by the statutory requirement that the specification describe the claimed invention in 'full, clear, concise, and exact terms." It is therefore "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." 1300

While the Federal Circuit has acknowledged the maxim that claims should be construed to preserve their validity, the court has not applied that principle broadly and has not endorsed a regime in which a validity analysis is conducted as a regular component of claim construction. 1301 Instead, the Federal Circuit has limited the maxim to cases in which "the court concludes, after applying all the available tools of claim construction, that the claim is still ambiguous."1302

In Saunders Group, Inc. v. Comfortrac, Inc., 1803 the Federal Circuit rejected an interpretation of the claims that would preserve their validity. 1304 In pertinent part, the appeal focused on Saunders' '690 patent (U.S. Patent Number 6,899,690), which was a continuation of the '174 patent (U.S. Patent Number 6,506,174). 1305 The '174 patent claimed a lumbar traction system having a pneumatic cylinder with at least one pressure activated seal; claims 1 and 16 of the '690 patent had no such limitation. 1306

The district court found that "[a]t the very least, the specification and prosecution history... make claims 1 and 16 of the '690 patent ambiguous as to whether the pneumatic cylinder must utilize at least

^{1297.} Phillips, 415 F.3d at 1315, 75 U.S.P.Q.2d (BNA) at 1327.

^{1298.} Id., 75 U.S.P.Q.2d (BNA) at 1327.

^{1299.} Id. at 1316, 75 U.S.P.Q.2d (BNA) at 1328 (quoting 35 U.S.C. § 112, para. 1 (2000)).

^{1300.} Id. at 1317, 75 U.S.P.Q.2d (BNA) at 1329.

^{1301.} *Id.* at 1327, 75 U.S.P.Q.2d (BNA) at 1336 (citing Nazomi Commc'ns, Inc. v. Arm Holdings, PLC, 403 F.3d 1364, 1368–69, 74 U.S.P.Q.2d (BNA) 1458, 1461–62 (Fed. Cir. 2005))

^{1302.} *Id.*, 75 U.S.P.Q.2d (BNA) at 1337 (quoting Liebel-Flarsheim v. Medrad, Inc., 358 F.3d 898, 911, 69 U.S.P.Q.2d (BNA) 1801, 1811 (Fed. Cir. 2004)); *see also* Generation II Orthotics Inc. v. Med. Tech. Inc., 263 F.3d 1356, 1365, 59 U.S.P.Q.2d (BNA) 1919, 1927 (Fed. Cir. 2001) (citing Rhine v. Casio, Inc., 183 F.3d 1342, 1345, 51 U.S.P.Q.2d (BNA) 1377, 1379 (Fed. Cir. 1999)) ("[C]laims can only be construed to preserve their validity where the proposed claim construction is 'practicable,' is based on sound claim construction principles, and does not revise or ignore the explicit language of the claims.").

1303. 492 F.3d 1326, 83 U.S.P.Q.2d (BNA) 1225 (Fed. Cir. 2007).

1304. Id. at 1329, 83 U.S.P.Q.2d (BNA) at 1226.

^{1305.} Id., 83 U.S.P.Q.2d (BNA) at 1226.

^{1306.} Id. at 1329–30, 83 U.S.P.Q.2d (BNA) at 1226–27.

one pressure activated seal." The only pneumatic cylinder described in the specification had at least one pressure-activated seal, according to the court, while "the inventors made clear that they did not believe an ordinary O-ring seal would work in a device of the sort they claimed." Accordingly, the district court construed the claims narrowly to preserve their validity because a broader construction would have rendered the claims invalid for lack of enablement. 1309 The Federal Circuit reversed and found that it was error for the district court to consider the possible invalidity of the broader claims as a basis for construing them narrowly. 1310 In particular, the Federal Circuit stated, "[t]hat is not to say that we reject the district court's validity analysis; we hold only that the court's validity analysis cannot be used as basis for adopting a narrow construction of the claims."1311 Instead, any invalidity defenses "the defendants [may] have preserved and wish[ed] to press [could] be addressed on remand." 1312

When construing a patent's claims, a court must begin by "look[ing] to the words of the claims themselves... to define the scope of the patented invention." "In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words."1314

In Acumed LLC v. Stryker Corp., 1315 Acumed sued Stryker for infringement of a patent on "an orthopedic nail for treatment of fractures in the humerus." Stryker argued on appeal that the district court had erred in construing the term "curved shank" to mean a shank having "a bend or deviation from a straight line without sharp corners or sharp angles." Stryker argued that the term "curved"

^{1307.} Id. at 1335, 83 U.S.P.Q.2d (BNA) at 1231.

^{1308.} Id., 83 U.S.P.Q.2d (BNA) at 1231.

^{1309.} *Id.*, 83 U.S.P.Q.2d (BNA) at 1231 (citing Phillips v. AWH Corp., 415 F.3d 1303, 1326, 75 U.S.P.Q.2d (BNA) 1321, 1336 (Fed. Cir. 2005)).

^{1310.} Id., 83 U.S.P.Q.2d (BNA) at 1231.

^{1311.} *Id.*, 83 U.S.P.Q.2d (BNA) at 1231. 1312. *Id.*, 83 U.S.P.Q.2d (BNA) at 1231 (citing Liebel-Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371, 82 U.S.P.Q.2d (BNA) 1113 (Fed. Cir. 2007)).

^{1313.} Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582, 39 U.S.P.Q.2d (BNA) 1573, 1576 (Fed. Cir. 1996).

^{1314.} Phillips v. AWH Corp., 415 F.3d 1303, 1314, 75 U.S.P.Q.2d (BNA) 1321, 1327 (Fed. Cir. 2005) (citing Brown v. 3M, 265 F.3d 1349, 1352, 60 U.S.P.Q.2d (BNA) 1375, 1377 (Fed. Cir. 2001)). 1315. 483 F.3d 800, 82 U.S.P.Q.2d (BNA) 1481 (Fed. Cir. 2007).

^{1316.} Id. at 802–03, 82 U.S.P.Q.2d (BNA) at 1482.

^{1317.} Id. at 804, 82 U.S.P.Q.2d (BNA) at 1483-84.

should not be afforded its ordinary meaning. 1318 Instead, Stryker asserted that the patent specification implicitly assigned the term a more narrow meaning as "a nonangular continuous bend," which covered only embodiments having a curvature that allowed them to be inserted into a broached hole without bends or small radius curves. 1319 The majority disagreed, stating that Stryker's "assertion is flawed: it is an attempt to import a feature from a preferred embodiment into the claims."1320

The Federal Circuit similarly rejected Stryker's argument that the term "transverse holes" should be limited to holes that are perpendicular to the nail shaft, and exclude holes that are tilted so that one end of the hole is vertically offset from the other end. According to the majority, once again Stryker was improperly trying to read into the claims a limitation from the preferred embodiments, all of which featured the transverse holes as going perpendicularly through the shaft. 322 Quoting Phillips v. AWH Corp., the Federal Circuit stated "'[a]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments. The majority concluded that the district court had properly defined "transverse holes" to mean "holes across the butt portion of the nail." 1324

Judge Moore disagreed with the majority's construction of the term "transverse holes." Judge Moore believed the district court had improperly begun its construction with the dictionary and construed the claim term in accord with the broader of "two definitions for the term 'transverse': '(1) acting, lying, or being across: set crosswise; (2) made at right angles to the anterior-posterior axis of the body." According to Judge Moore, "the patentee used the two words to clearly specify which of the definitions of transverse applied to his invention; the purpose of using the word 'perpendicular' was to further describe what the inventor meant by the term 'transverse,' not to distinguish it as the majority suggests."1327

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1318. Id. at 805, 82 U.S.P.Q.2d (BNA) at 1484.
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^{1319.} Id. at 804, 82 U.S.P.Q.2d (BNA) at 1484.

^{1320.} *Id.* at 805, 82 U.S.P.O.2d (BNA) at 1485. 1321. *Id.* at 803, 82 U.S.P.O.2d (BNA) at 1483. 1322. *Id.* at 807, 82 U.S.P.O.2d (BNA) at 1486.

^{1323.} Id., 82 U.S.P.Q.2d (BNA) at 1486 (quoting Phillips v. AWH Corp., 415 F.3d

^{1303, 1323, 82} U.S.P.Q.2d (BNA) 1321, 1334 (Fed. Cir. 2005)).

^{1324.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1486. 1325. *Id.* at 812–18, 82 U.S.P.Q.2d (BNA) at 1490-95 (Moore, J., dissenting).

^{1326.} Id. at 813, 82 U.S.P.Q.2d (BNA) at 1490.

^{1327.} Id., 82 U.S.P.Q.2d (BNA) at 1491.

In Foremost in Packaging Systems, Inc. v. Cold Chain Technologies, Inc., 1328 the Federal Circuit relied on the claims themselves to affirm the district court's claim construction and non-infringement finding. 1329 Specifically, in a patent directed to insulated containers, the claims required that an "insulated block," which extended from the container cover, "slidably engage the coolant cavity, thereby the coolant and the insulated block together substantially filling the coolant cavity."1330 The district court construed this term to require that the container cover extend into the coolant cavities on the sides of the device and concluded that the accused products did not infringe because their insulated blocks merely covered the coolant cavities but did not extend into them. 1331

On appeal, the Federal Circuit rejected appellant Foremost's argument that the term "slidably engage" did not require that the insulated block extend into the coolant cavities. 1332 The court explained, if the insulated block did not extend into the cavity then the block and coolant "together" did not fill the cavity or "minimiz[e] air spaces within the cavities," as required by the claims. 1333 The court indicated that since "[o]ur interpretation of these claims rests upon their language," it did not need to analyze the specification or file history to any degree in its opinion. The Federal Circuit thus affirmed the district court's claim construction and summary judgment of non-infringement. 1335

Similarly, in In re Gabapentin Patent Litigation, 1336 the Federal Circuit was not persuaded by the Appellees' extensive reliance on the prosecution history to support their construction, particularly since the claim language and specification provided a clear definition of the disputed claim term. 1837 According to the court, "the plain language of the claim supports the construction that the anion specifically is derived from a mineral acid." Accordingly, the court found the "assertion that the claimed anion refer[ed] to total chloride ions or anions from any source that is 'capable of' forming a mineral acid

^{1328. 485} F.3d 1153, 82 U.S.P.Q.2d (BNA) 1606 (Fed. Cir. 2007).

^{1329.} *Id.* at 1154, 82 U.S.P.Q.2d (BNA) at 1607.

^{1330.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1607. 1331. *Id.*, 82 U.S.P.Q.2d (BNA) at 1607.

^{1332.} *Id.* at 1155–56, 82 Ù.S.P.Q.2d (BNA) at 1607–08. 1333. *Id.* at 1156, 82 U.S.P.Q.2d (BNA) at 1608.

^{1334.} Id., 82 U.S.P.Q.2d (BNA) at 1608.

^{1335.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1608. 1336. 503 F.3d 1254, 84 U.S.P.Q.2d (BNA) 1651 (Fed. Cir. 2007).

^{1337.} Id. at 1264, 84 U.S.P.Q.2d (BNA) at 1658.

^{1338.} Id. at 1263, 84 U.S.P.Q.2d (BNA) at 1658.

[wa]s unsupported by the claim language." 1339 Moreover, if the patentees had "intended the anion to refer to any anion, regardless of its source, the patentees could have simply claimed 'anions' and omitted the phrase 'of a mineral acid.'" The Federal Circuit further explained that "the construction adopted by the district court g[ave] full meaning to every word of the entire claim term." Thus, in light of the Federal Circuit's "review of the prosecution history, [it found] district for reversing the court's construction, which . . . comport[ed] with the claim language and specification." 1342

In explaining the importance of referring to the specification in determining and understanding the meaning and scope of a patent claim, the Federal Circuit has stated that "the specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'",1343

In SafeTCare Manufacturing, Inc. v. Tele-Made, Inc., 1344 the Federal Circuit found the specification dispositive in determining the inventor's intention. 1345 In particular, the Federal Circuit considered whether a claimed motor that "exert[ed] a pushing force on said . . . deck section" of a hospital bed included a motor that exerted a pulling force against a lift dog, or bracket, which caused the deck section to rotate upward. 1346 The Federal Circuit rejected this broad construction of the claim because the patentee had repeatedly emphasized in the specification that its invention applied pushing forces, not pulling forces, to the lift dogs and distinguished prior art beds that exerted pulling forces on the structural members of the bed frame. Based on the patentee's clear disavowal of the use of pulling forces, the appeals court affirmed the district court's summary judgment of non-infringement, both literally and under the doctrine of equivalents. 1348

The court again focused on the importance of the specification in In re Buszard. 1349 In this case, applicants attempting to patent "a flame

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1339. Id., 84 U.S.P.Q.2d (BNA) at 1657.
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^{1340.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1657.

^{1341.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1658. 1342. *Id.* at 1264, 84 U.S.P.Q.2d (BNA) at 1658.

^{1343.} Phillips v. AWH Corp., 415 F.3d 1303, 1315, 75 U.S.P.Q.2d (BNA) 1321, 1327 (Fed. Cir. 2005) (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582, 39 U.S.P.Q.2d (BNA) 1573, 1577 (Fed. Cir. 1996)).

1344. 497 F.3d 1262, 83 U.S.P.Q.2d (BNA) 1618 (Fed. Cir. 2007).

^{1345.} Id. at 1269, 83 U.S.P.Q.2d (BNA) at 1623.

^{1346.} *Id.*, 83 U.S.P.Q.2d (BNA) at 1622 (emphasis added). 1347. *Id.*, 83 U.S.P.Q.2d (BNA) at 1623. 1348. *Id.* at 1270–71, 83 U.S.P.Q.2d (BNA) at 1624.

^{1349. 504} F.3d 1364, 84 U.S.P.Q.2d (BNA) 1749 (Fed. Cir. 2007).

retardant composition that produces a flexible polyurethane foam" sought "review of the decision of the Board of Patent Appeals and Interferences holding all of the claims in the[ir] patent application unpatentable on the ground of anticipation." Particularly, "[t]he Board held Buszard's claims to be anticipated because the appellants claimed reaction mixture includes any reaction mixture which produces, at least ultimately, a flexible polyurethane foam." Buszard argued "that his claims explicitly state[d] the requirement of a flexible polyurethane foam reaction mixture, and that this claim element is not shown in the [cited] reference, thereby negating anticipation."1352 The Board interpreted the claim term "'flexible polyurethane foam reaction mixture' to mean 'any reaction mixture which produces, at least ultimately, a flexible polyurethane foam." 1353 Buszard argued that those "persons experienced in the field of polyurethane foams know that a flexible polyurethane foam reaction mixture is different from a rigid polyurethane foam reaction mixture, and that this process limitation cannot be found in [the reference], no matter how broadly that reference is read."1354

The Federal Circuit determined that Buszard's specification and claims specifically require a flexible polyurethane foam reaction mixture. 1355 The court explained that "[n]o matter how broadly 'flexible foam reaction mixture' is construed, it is not a rigid foam reaction mixture." Here, the reference "describes only a rigid foam reaction mixture that produces a rigid product." In dissent, Judge Prost took a more stringent approach, stating "[i]t is the applicant['s] burden to precisely define the invention, not the PTO's." According to Judge Prost, "courts examine the claims, the specification, the prosecution history, and possibly extrinsic evidence—all in an effort to determine what the applicant regards as his invention." There is no need to "engage in a guessing game during patent prosecution. If a claim term is ambiguous or confusing, the applicant can (and

(Fed. Cir. 2005)).

^{1350.} Id. at 1365, 84 U.S.P.Q.2d (BNA) at 1749 (internal footnote omitted).

^{1351.} *Id.* at 1366, 84 U.S.P.Q.2d (BNA) at 1750 (internal quotations omitted).

^{1352.} Id., 84 U.S.P.Q.2d (BNA) at 1750 (internal quotations omitted).

^{1353.} Id. at 1367, 84 U.S.P.Q.2d (BNA) at 1751.

^{1354.} Id., 84 U.S.P.Q.2d (BNA) at 1751.

^{1354.} *Id.*, 64 U.S.P.Q.2d (BNA) at 1751. 1355. *Id.*, 84 U.S.P.Q.2d (BNA) at 1751. 1357. *Id.*, 84 U.S.P.Q.2d (BNA) at 1751. 1357. *Id.*, 84 U.S.P.Q.2d (BNA) at 1751.

^{1358.} *Id.* at 1369, 84 U.S.P.Q.2d (BNA) at 1753 (Prost, J., dissenting) (quoting *In re* Morris, 127 F.3d 1048, 1056, 44 U.S.P.Q.2d (BNA) 1023, 1029 (Fed. Cir. 1997)). 1359. *Id.* at 1368, 84 U.S.P.Q.2d (BNA) at 1752 (internal quotations omitted) (citing Phillips v. AWH Corp., 415 F.3d 1303, 1312, 75 U.S.P.Q.2d (BNA) 1321, 1325

should) clarify it." ludge Prost continued, explaining that "if an applicant wants a claim term to have a specific meaning, the applicant can either amend the claim to expressly convey the applicant's intended meaning or provide an express definition for the claim term in the specification." ¹³⁶¹

In E-Pass Technologies, Inc. v. 3Com Corp., 1362 the Federal Circuit ultimately agreed with the district court that the specification made clear the construction of the term at issue. 1363 The Federal Circuit affirmed an order granting summary judgment that none of the multiple defendants (including Palm, Handspring, and Visa) infringed, either literally or by equivalents, E-Pass's patents on a method and device for simplifying the use of credit cards. 1364

This was the second appeal in this litigation. ¹³⁶⁵ In the earlier case, which involved two of the defendants, the Federal Circuit had held that the district court erred in its claim construction by limiting the term "card" to the "dimensions of a standard credit card." On remand, the district court again granted summary judgment of noninfringement as to all defendants, based on two independent grounds: 1367

First, it held that even under a broader construction of "card," none of the accused devices could infringe the "electronic multifunction card" limitation. Second, it held that E-Pass had failed to adduce sufficient evidence to support a finding that any of the defendants or their customers had practiced all of the steps of the claimed method. 1368

E-Pass again appealed to the Federal Circuit. 1369 On the second appeal, the Federal Circuit agreed with the district court, explaining as follows: "By vacating, we signaled that, although the district court's prior decision rested upon erroneous grounds, a proper claim construction might support a judgment (summary or otherwise) in favor of either party.... The Federal Circuit agreed with the district court that "the specification . . . ma[de] it clear that a 'card,' as used

^{1360.} Id., 84 U.S.P.Q.2d (BNA) at 1752.

^{1361.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1752 (citing *In re* Morris, 127 F.3d at 1054, 44 U.S.P.Q.2d (BNA) at 1027-28; *In re* Yamamoto, 740 F.2d 1569, 1571–72, 222 U.S.P.Q. (BNA) 934, 936–37 (Fed. Cir. 1984)).

^{1362. 473} F.3d 1213, 81 U.S.P.Q.2d (BNA) 1385 (Fed. Cir. 2007).

^{1363.} Id. at 1215, 81 U.S.P.Q.2d (BNA) at 1386.

^{1364.} *Id.*, 81 U.S.P.Q.2d (BNA) at 1386.

^{1364.} Id., 81 U.S.P.Q.2d (BNA) at 1386–87.
1365. Id. at 1216, 81 U.S.P.Q.2d (BNA) at 1386–87.
1366. Id., 81 U.S.P.Q.2d (BNA) at 1387 (internal quotation marks omitted).
1367. Id. at 1216–17, 81 U.S.P.Q.2d (BNA) at 1387.
1368. Id., 81 U.S.P.Q.2d (BNA) at 1387 (internal citations omitted).
1369. Id., 81 U.S.P.Q.2d (BNA) at 1387.

^{1370.} Id. at 1218, 81 U.S.P.Q.2d (BNA) at 1388.

in the patent's claims, is something a user will 'carry about.'" The accused devices, however, had buttons, joysticks and keyboards, which projected above the surface. 1372 "Although not a precise restriction on size or portability, the attributes of being able to be 'carried about' and of not having protruding buttons, keyboards, antennae, indented display screens, or hinged covers are characteristics that a complete claim construction of 'card' can be expected to embrace."1373 Accordingly, the Federal Circuit affirmed the district court's ruling of no literal infringement. 1374

The Federal Circuit also stated that it need not decide whether the district court's judgment as to the doctrine of equivalents could be sustained on other grounds. To survive the defendants' motions for summary judgment, E-Pass had to "make a showing sufficient to establish the existence of [each] element essential to [its] case." 1376 Because most of the steps of the "method claim refer[red] to the completed results of the prior step, E-Pass [had to] show that all of those steps were performed in order." E-Pass failed to meet its burden because its evidence showed, at best, that the defendants taught their customers to perform each step of the claimed method in isolation.¹³⁷⁸ "Nowhere do the manual excerpts teach all of the steps of the claimed method together, much less in the required order."1379

Verizon Services Corp. v. Vonage Holdings Corp. 1380 also turned on issues of claim construction. 1381 Vonage appealed from a jury verdict that found that Vonage had infringed three of Verizon's patents. 1382 The majority agreed with Verizon with respect to two patents and found that Vonage was improperly attempting to read limitations from the

^{1371.} Id. at 1219, 81 U.S.P.Q.2d (BNA) at 1389.

^{1372.} *Id.* at 1220, 81 U.S.P.Q.2d (BNA) at 1390. 1373. *Id.* at 1219, 81 U.S.P.Q.2d (BNA) at 1389.

^{1374.} Id. at 1220, 81 U.S.P.Q.2d (BNA) at 1390. 1375. Id. at 1220–21, 81 U.S.P.Q.2d (BNA) at 1390–91. 1376. Id. at 1222, 81 U.S.P.Q.2d (BNA) at 1391 (quoting Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986)). 1377. *See id.*, 81 U.S.P.Q.2d (BNA) at 1391 (citing Mantech Envtl. Corp. v. Hudson

Envtl. Servs., Inc., 152 F.3d 1368, 1376, 47 U.S.P.Q.2d (BNA) 1732, 1739 (Fed. Cir. 1998)) (holding that "the sequential nature of the claim steps is apparent from the plain meaning of the claim language and nothing in the written description suggests otherwise").

^{1378.} Id. at 1222-23, 81 U.S.P.Q.2d (BNA) at 1392.

^{1379.} *Id.*, 81 U.S.P.Q.2d (BNA) at 1391. 1380. 503 F.3d 1295, 84 U.S.P.Q.2d (BNA) 1609 (Fed. Cir. 2007).

^{1381.} *Id.* at 1301, 84 U.S.P.Q.2d (BNA) at 1614.

^{1382.} Id. at 1298, 84 U.S.P.Q.2d (BNA) at 1611.

specification into the claims of two patents, when there was no valid basis to depart from the ordinary meanings of those terms. 1383

With respect to a third patent, the majority agreed with Vonage that the district court had construed the term "localized wireless gateway system" too broadly by not limiting it to systems that operated within a "range of a few feet." The majority found that the patentees had limited their invention to short-range systems by unambiguously disavowing longer-range systems during prosecution of a related patent to overcome the prior art. 1385 Interestingly, this disclaimer was effective against the third patent even though it had been made after that patent had already issued. 1386 Relying on Microsoft Corp. v. Multi-Tech Systems, 1387 the court reiterated "that a statement made by the patentee during prosecution history of a patent in the same family as the patent-in-suit can operate as a disclaimer." The majority also found that the district court had erred in not limiting the claimed "localized wireless gateway system" to systems that compress, decompress, and packetize voice signals because the "Disclosure of the Invention" portion of the specification described the "present invention" as including that limitation. "When a patent thus describes the features of the 'present invention' as a whole, this description limits the scope of the invention," the majority held. 1390

In other cases, the Federal Circuit also examined the doctrine of claim differentiation, which presumes that there is a difference in claim meaning and scope when different words or phrases are used in separate claims.¹³⁹¹ To the extent that the absence of such difference in meaning and scope would make a claim superfluous, the doctrine of claim differentiation states the presumption that the difference between claims is significant. 1392

^{1383.} Id., 84 U.S.P.Q.2d (BNA) at 1611.

^{1384.} *Id.* at 1306, 84 U.S.P.Q.2d (BNA) at 1617.

^{1385.} Id., 84 U.S.P.Q.2d (BNA) at 1617-18.
1386. Id., 84 U.S.P.Q.2d (BNA) at 1617.
1387. 357 F.3d 1340, 69 U.S.P.Q.2d (BNA) 1815 (Fed. Cir. 2004).
1388. Verizon, 503 F.3d at 1306, 84 U.S.P.Q.2d (BNA) at 1617 (citing Microsoft Corp., 357 F.3d at 1356-57, 69 U.S.P.Q.2d (BNA) at 1828) ("To operate as a disclaimer, the statement in the prosecution history must be clear and unambiguous, and constitute

a clear disavowal of scope.").

1389. *Id.* at 1308, 84 U.S.P.Q.2d (BNA) at 1618.

1390. *Id.*, 84 U.S.P.Q.2d (BNA) at 1618 (citing Honeywell Int'l, Inc. v. ITT Indus., Inc., 452 F.3d 1312, 1318–19, 79 U.S.P.Q.2d (BNA) 1294, 1300-01 (Fed. Cir. 2006); U.S.P.Q.2d (BNA) 1059, 1064 (Fed. Cir. 2001)). 1391. *E.g.*, D.M.I., Inc. v. Deere & Co., 755 F.2d 1570, 1574, 225 U.S.P.Q. (BNA) 236, 239 (Fed. Cir. 1985). SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1343, 58

^{1392.} Id., 225 U.S.P.Q. (BNA) at 239.

In Intamin, Ltd. v. Magnetar Technologies Corp., 1393 the Federal Circuit vacated and remanded the district court's summary judgment that Magnetar did not infringe a patent directed to a magnetic braking system for amusement park rides. ¹³⁹⁴ Specifically, Intamin sued Magnetar for infringement of a patent that required, inter alia, "an intermediary disposed between adjacent pairs of [a] plurality of magnet elements."1395 Magnetar moved for summary judgment of noninfringement on the basis that its brakes did not include the claimed "intermediary" or "conductive rail." The district court granted Magnetar's motion, based on its construction of the term "intermediary" to require a non-magnetic structure. 1397 The district court did not rule, however, on whether there was infringement under the doctrine of equivalents. The Federal Circuit, citing *Phillips*, reversed the district court claim construction of the term "intermediary." ¹⁴⁰⁰ The Federal Circuit found that "the term 'intermediary' can embrace magnetic substances, albeit only if the additional term requirement of 'alternating polarity' allows for it." The court also concluded that, pursuant to the doctrine of claim differentiation, claim 1 impliedly embraced non-magnetic intermediaries because dependent claim 2 required the intermediary to be magnetic. ¹⁴⁰² Accordingly, the Federal Circuit directed the district court to determine on remand "whether the patent limit[ed] the term 'adjacent magnets of alternating polarity' to magnet's of opposite polarity" and thus whether Magnetar's brakes infringed literally or under the doctrine of equivalents.1403

In contrast to the doctrine of claim differentiation, which assumes that different words in different claims describe a separate invention, the Federal Circuit will apply a "presumption that the same terms appearing in different portions of the claims should be given the same meaning unless it is clear from the specification and prosecution history that the terms have different meanings at different portions of

1393. 483 F.3d 1328, 82 U.S.P.Q.2d (BNA) 1545 (Fed. Cir. 2007).

^{1394.} *Id.* at 1339, 82 U.S.P.Q.2d (BNA) at 1552. 1395. *Id.* at 1332, 82 U.S.P.Q.2d (BNA) at 1547.

^{1396.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1547. 1397. *Id.*, 82 U.S.P.Q.2d (BNA) at 1547–48.

^{1398.} *Id.* at 1337, 82 U.S.P.Q.2d (BNA) at 1551.

^{1399.} Phillips v. AWH Corp., 415 F.3d 1303, 75 U.S.P.Q.2d (BNA) 1321 (Fed. Cir. 2005).

^{1400.} Intamin, 483 F.3d at 1335, 82 U.S.P.Q.2d (BNA) at 1549.

^{1401.} Id., 82 U.S.P.Q.2d (BNA) at 1550.

^{1402.} *Id.* at 1334-35, 82 U.S.P.Q.2d (BNA) at 1549.

^{1403.} Id. at 1335, 82 U.S.P.Q.2d (BNA) at 1550.

the claims." ¹⁴⁰⁴ In *PODS, Inc. v. Porta Stor, Inc.*, ¹⁴⁰⁵ "Porta Stor argue[d] that the district court erred in not construing the phrases 'carrier frame' and 'around' in claim 29 to have the same meaning as they undisputedly have in claim 1, namely a four-sided rectangular shaped frame that completely surrounds the container on all four sides." 1406 The Federal Circuit determined that because the parties agreed that the structure described as a "carrier frame" in claim 1 is "a four-sided or rectangular-shaped carrier frame" that surrounds the container on all sides, 1407 and PODS failed to provide evidence in the specification or the prosecution history that the term "carrier frame" in claim 29 had a meaning different from the uncontested meaning in claim 1; the term "carrier frame" in claim 29, as in claim 1, required "a foursided or rectangular shape." 1408 Moreover, PODS had noted in its brief that a claim that "recites a four-sided 'carrier frame' . . . placing that four-sided carrier frame 'around the container' would result in 'all four sides' of the carrier frame being 'around' the container." ¹⁴⁰⁹ Based on that representation, the court construed the term "around" to require the frame to be on all sides of the container. 1410 The court found that under that claim construction, there was no infringement.1411

In determining the breadth of a claim's scope, the term "comprising" raises a presumption that the list of elements is nonexclusive. 1412 However, the Federal Circuit has stated "'[c]omprising' is not a weasel word with which to abrogate claim limitations." In two cases, the Federal Circuit reviewed the breadth of the term "comprising" and in a third clarified the scope of the term "comprised of."

In *Dippin' Dots, Inc. v. Mosey*, ¹⁴¹⁴ the Federal Circuit limited the scope of the term "comprising." The claims at issue were directed

^{1404.} Fin Control Sys. Pty, Ltd. v. OAM, Inc., 265 F.3d 1311, 1318, 60 U.S.P.Q.2d (BNA) 1203, 1208 (Fed. Cir. 2001) (citing Phonometrics, Inc. v. N. Telecom, Inc., 133 F.3d 1459, 1465, 45 U.S.P.Q.2d (BNA) 1421, 1426 (Fed. Cir. 1998)); see also Phillips, 415 F.3d at 1314, 75 U.S.P.Q.2d (BNA) at 1327 (explaining that the usage of a term in one claim can elucidate the meaning of the same term in other sections).

^{1405. 484} F.3d 1359, 82 U.S.P.Q.2d (BNA) 1553 (Fed. Cir. 2007).

^{1406.} Id. at 1366, 82 U.S.P.Q.2d (BNA) at 1558.

^{1407.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1558. 1408. *Id.* at 1367, 82 U.S.P.Q.2d (BNA) at 1558.

^{1409.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1558. 1410. *Id.*, 82 U.S.P.Q.2d (BNA) at 1558.

^{1411.} Id., 82 U.S.P.Q.2d (BNA) at 1558.

^{1412.} Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 U.S.P.Q.2d (BNA) 1608, 1613 (Fed. Cir. 1997).

^{1413.} Spectrum Int'l, Inc. v. Sterilite Corp., 164 F.3d 1372, 1380, 49 U.S.P.Q.2d (BNA) 1065, 1070 (Fed. Cir. 1998).

^{1414.} Dippin' Dots, Inc. v. Mosey, 476 F.3d 1337, 81 U.S.P.Q.2d (BNA) 1633 (Fed. Cir. 2007).

to "[a] method of preparing and storing a free-flowing, frozen alimentary dairy product, comprising the steps of . . . freezing said dripping alimentary composition into beads." The Federal Circuit found that the district court had properly interpreted the term "beads" to mean "small frozen droplets... which have a smooth, spherical (round or ball shaped) appearance" and rejected Dippin' Dots' argument that it could also include "irregular or odd shaped particles such as 'popcorn.'" Having failed on this issue, Dippin' Dots tried to reach the same result by arguing that the claim should be broadly construed to cover processes that produce some irregularly shaped particles because "comprising the steps of" in the preamble is a non-exclusive term. The Federal Circuit was not persuaded, stating that although "comprising" does indicate that an infringing process could practice other steps in addition to those recited in the claim, nonetheless those enumerated steps must all be practiced as recited in order for an accused process to infringe. 1419 "The presumption raised by the term 'comprising' does not reach into each of the six steps to render every word and phrase therein open-ended—especially where, as here, the patentee has narrowly defined the claim term it now seeks to have broadened."1420 The Federal Circuit concluded that the district court had properly excluded from the claim processes that produce some irregularly shaped particles. 1421

In Bass Pro Trademarks, L.L.C. v. Cabela's, Inc., 1422 Bass Pro tried to use the term "comprising" to overcome limitations imputed on the claim by the prosecution. In particular, Bass Pro stressed that the use of "comprising" in claim 1 allowed the claim's "combination vest and pivotable seat member," which phrase was added in response to a rejection, to encompass "Cabela's device that contain[ed] only a dorsal member and shoulder supports, and that it [wa]s incorrect to read the claim as also requiring a vest, a term that appears in what Bass Pro designate[d] as a preamble." 1424 Cabela's argued that "vest" is a substantive claim limitation, not merely a word of "preamble." ¹⁴²⁵

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1415. Id. at 1343, 81 U.S.P.Q.2d (BNA) at 1637 (citing Spectrum Int'l, 164 F.3d at
1380, 49 U.S.P.Q.2d (BNA) at 1070).
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^{1416.} Id. at 1340, 81 U.S.P.Q.2d (BNA) at 1635.

^{1417.} Id. at 1342–43, 81 U.S.P.Q.2d (BNA) at 1637.

^{1418.} Id. at 1343, 81 U.S.P.Q.2d (BNA) at 1637.

^{1419.} Id., 81 U.S.P.Q.2d (BNA) at 1637.

^{1420.} Id., 81 U.S.P.Q.2d (BNA) at 1637.

^{1421.} Id., 81 U.S.P.Q.2d (BNA) at 1637.

^{1422. 485} F.3d 1364, 82 U.S.P.Q.2d (BNA) 1364 (Fed. Cir. 2007). 1423. *Id.* at 1366–67, 82 U.S.P.Q.2d (BNA) at 1366.

^{1424.} *Id.* at 1368–69, 82 U.S.P.O.2d (BNA) at 1367–68.

^{1425.} Id. at 1369, 82 U.S.P.Q.2d (BNA) at 1367.

bela's also argued that the district court erred in ruling that the claim did not require a full vest because the specification and claim described the invention as a "combination of a vest and a folding seat, and that the prosecution history reinforces that the invention is more than a 'dorsal' panel of fabric on the wearer's back with shoulder support means. 1,1426 The Federal Circuit agreed, and further found that the applicants had amended the claims during prosecution to include a vest, and had "relied on the vest to distinguish the combination from the [prior art]."1427 Therefore, Bass Pro's argument that the vest "adds nothing" to the claim was contrary to the claims, specification, and prosecution history. 1428 Because the vest was a material part of the claim, the Federal Circuit found the garment produced by Cabela's did not infringe the claim and vacated the district court's ruling.1429

In CIAS, Inc. v. Alliance Gaming Corp., 1430 "[t] he district court found that the meaning of 'comprised of' ha[d] not been clearly resolved in patent-specific precedent, and therefore the court held that the 'ordinary and customary meaning' should be used." In so ruling, the court found that "comprised of does not have the same open-ended meaning as 'comprising,' which also appears in [the claim at issue]."1432 Additionally, the court stated that

"comprised of" should be construed as a closed-end term that excludes the presence of all elements beyond those presented in the "comprised of" clause. Thus the court defined "comprised of" as "a limiting description of composition," reasoning that "[t]his construction preserves the distinction between 'comprised of' and 'comprising,' the latter of which in fact is a patent term of art when used in a transitional phrase "1433

The Federal Circuit reversed this ruling, stating that "[a]lthough 'comprised of' is not used as regularly as 'comprising,' and 'comprised of is sometimes used other than as a 'transition phrase,' nonetheless it partakes of long-standing recognition as an open-ended term."1434 According to the court, "[t]he usual and generally consistent meaning of 'comprised of,' when it is used as a transition phrase, is, like 'comprising,' that the ensuing elements or steps are not limit-

^{1426.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1367. 1427. *Id.*, 82 U.S.P.Q.2d (BNA) at 1367. 1428. *Id.*, 82 U.S.P.Q.2d (BNA) at 1367. 1429. *Id.*, 82 U.S.P.Q.2d (BNA) at 1367. 1430. 504 F.3d 1356, 84 U.S.P.Q.2d (BNA) 1737 (Fed. Cir. 2007).

^{1431.} Id. at 1359, 84 U.S.P.Q.2d (BNA) at 1740.

^{1432.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1740. 1433. *Id.* at 1359–60, 84 U.S.P.Q.2d (BNA) at 1740 (alteration in original).

^{1434.} *Id.* at 1360, 84 U.S.P.Q.2d (BNA) at 1740.

ing. The conventional usage of 'comprising' generally also applies to 'comprised of.'"1435

The Federal Circuit turned to the precision of claimed logarithmic ranges in U.S. Philips Corp. v. Iwasaki Electric Co. 1436 Philips argued on appeal that the district court had erred in construing the term "between 10^6 and 10^4 µmol/mm³" to mean "between 1 x 10^6 and 1 x 10^4 umol/mm³" because the term expresses a range of orders of magnitude, not a range of more-precise numbers. 1437

According to U.S. Philips, one of ordinary skill in the art of lamp chemistry would understand '10⁴' to mean something different and less precise than '1 x 10⁴'; i.e., the absence of the coefficient ('1') means that the term encompasses all values that are closer on a logarithmic scale to 10^4 than to 10^5 or 10^3 . 1438

The Federal Circuit disagreed and affirmed the district court's construction. 1439 Even though the "upper and lower bounds of the claimed range [were] expressed as powers of ten," the Federal Circuit found "no reason for treating them as anything other than the ordinary numbers they [were]."1440 As the district court had noted, the phrase "'a quantity between — and —'... 'implies a specific range It does not imply a range between two values which are themselves ranges." Nonetheless, the court emphasized that the endpoints of the claimed ranges "should not be read . . . with greater precision than the claim language warrants."1442 The court explained that, "in some specific contexts, [the number] '1' represents a less precise quantity than '1.0,' and '1' may encompass values such as 1.1 that '1.0' may not." As "'10⁶' and '10⁴' are simply the numbers 0.000001 and 0.0001 expressed as powers of ten, the claim language provide[d] no basis for inferring any level of precision beyond the single digit '1.'" The use of power-of-ten quantities in the specification confirmed that the claims were not intended to express precise quantities. 1445 Thus, appellee's assertion that "10" should be inter-

^{1435.} Id., 84 U.S.P.Q.2d (BNA) at 1740.

^{1436. 505} F.3d 1371, 85 U.S.P.Q.2d (BNA) 1097 (Fed. Cir. 2007).

^{1437.} Id. at 1376, 85 U.S.P.Q.2d (BNA) at 1100.

^{1438.} Id., 85 U.S.P.Q.2d (BNA) at 1100.

^{1438.} *Id.*, 65 U.S.P.Q.2d (BNA) at 1101. 1440. *Id.*, 85 U.S.P.Q.2d (BNA) at 1101. 1441. *Id.*, 85 U.S.P.Q.2d (BNA) at 1101. 1441. *Id.*, 85 U.S.P.Q.2d (BNA) at 1101.

^{1442.} Id., 85 U.S.P.Q.2d (BNA) at 1102.

^{1443.} *Id.*, 85 U.S.P.Q.2d (BNA) at 1102 (citing Viskase Corp. v. Am. Nat'l Can Co., 261 F.3d 1316, 1320–21, 59 U.S.P.Q.2d (BNA) 1823, 1825 (Fed. Cir. 2001)).

^{1444.} Id. at 1377, 85 U.S.P.Q.2d (BNA) at 1102.

^{1445.} *Id.*, 85 U.S.P.Q.2d (BNA) at 1101.

preted to mean "1.0 x 10" was technically incorrect. Rather, the claim simply referred to "1 x 10"," which is less precise than "1.0 x 10 x ...,1447

Ortho-McNeil Pharmaceutical, Inc. v. Caraco Pharmaceutical Laboratories, Ltd. 1448 focused on the proper construction of the term "about 1:5" in Ortho's claim "to a pharmaceutical composition comprising certain weight ratios of two known drugs, tramadol and acetaminophen." 1449 The patent taught that the pharmacological effects of these components are synergistic when they are used in certain ratios. 1450 While Ortho found that the preferred ratios of tramadol to acetaminophen are from about 1:19 to about 1:50, it also disclosed and claimed compositions wherein the ratio is from about 1:1 to 1:5. 1451 In claim 6 in particular, Ortho recited a pharmaceutical composition with a ratio of tramodol to acetaminophen of about 1:5.1452 Ortho sued Caraco for infringement of claim 6 after Caraco filed an ANDA for regulatory approval to market a pharmaceutical composition containing these ingredients in a ratio of no less than 1:7.5. 1453

On Caraco's motion for summary judgment of non-infringement, the district court interpreted "about 1:5" to mean "approximately 1:5, encompassing a range of ratios no greater than 1:3.6 to 1:7.1," based on both intrinsic and extrinsic evidence, including opinions from Ortho's experts. 1454 The district court held that Caraco's product, which had an average weight ratio of 1:8.67, did not infringe the claim at issue literally or by equivalents. 1455

The Federal Circuit affirmed the district court's grant of summary judgment of non-infringement, agreeing with the district court that the term "about 1:5" should be construed to mean "approximately 1:5, encompassing a range of ratios no greater than about 1:3.6 to 1:7.1." The Federal Circuit focused on the fact that in some of the claims, Ortho recited a single weight ratio, while in other claims it recited ranges of weight ratios. 1457 Accordingly, the Federal Circuit noted, "one of ordinary skill in the art would understand the inven-

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1446. Id. at 1377-78, 85 U.S.P.Q.2d (BNA) at 1101-02.
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^{1447.} *Id.* at 1378, 85 U.S.P.Q.2d (BNA) at 1102. 1448. 476 F.3d 1321, 81 U.S.P.Q.2d (BNA) 1427 (Fed. Cir. 2007). 1449. *Id.* at 1322–23, 81 U.S.P.Q.2d (BNA) at 1428 ("Both of these drugs are pain relievers, i.e., analgesics.").
1450. *Id.* at 1323, 81 U.S.P.Q.2d (BNA) at 1428.
1451. *Id.*, 81 U.S.P.Q.2d (BNA) at 1428.
1452. *Id.*, 81 U.S.P.Q.2d (BNA) at 1428.
1453. *Id.*, 81 U.S.P.Q.2d (BNA) at 1428.

^{1454.} *Id.* at 1324, 81 U.S.P.Q.2d (BNA) at 1429. 1455. *Id.* at 1325, 81 U.S.P.Q.2d (BNA) at 1430. 1456. *Id.* at 1328, 81 U.S.P.Q.2d (BNA) at 1432 (internal quotations omitted).

^{1457.} Id. at 1327–28, 81 U.S.P.Q.2d (BNA) at 1432.

tors intended a range when they claimed one and something more precise when they did not." Moreover, the court noted that the patentees, despite disclosing data points for ratios of 1:1, 1:3, 1:5, 1:5.7, and 1:15, chose to specifically claim ratios of 1:1 and 1:5 instead of ratios in the "range of 'about 1:1 to about 1:5' or even a ratio range of 'about 1:3 to about 1:5." The Federal Circuit concluded that the "dichotomy between the specific ratio of 1:5 and the broader ratio ranges of the other claims points to a narrow scope for the 'about 1:5' limitation." In view of this construction, the Federal Circuit agreed with the district court that there was no literal infringement. 1461 The court also agreed that there was no infringement under the doctrine of equivalents, for to expand the weight ratio of "about 1.5" to encompass a composition having an average weight ratio of 1:8.76 "would eviscerate the limitation." 1465

The Federal Circuit has further held that in addition to consulting the specification, "a court should also consider the patent's prosecution history, if it is in evidence."¹⁴⁶³ The prosecution history, which is "designated as part of the 'intrinsic evidence,' consists of the complete record of the proceedings before the PTO and includes the prior art cited during the examination of the patent." ¹⁴⁶⁴ "[1]ike the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent." ¹⁴⁶⁵

In Gillespie v. Dywidag Systems International, USA, 1466 the Federal Circuit found that prosecution arguments limited the claim scope. 1467 In particular, the Federal Circuit held that a patentee was bound by limiting remarks made during prosecution, even if the distinction drawn between the invention and the prior art was not material to the grant

^{1458.} *Id.* at 1327, 81 U.S.P.Q.2d (BNA) at 1432. 1459. *Id.* at 1327–28, 81 U.S.P.Q.2d (BNA) at 1432.

^{1460.} *Id.* at 1328, 81 U.S.P.Q.2d (BNA) at 1432.

^{1461.} Id., 81 U.S.P.Q.2d (BNA) at 1432.

^{1462.} *Id.* at 1329–30, 81 U.S.P.Q.2d (BNA) at 1432. 1463. Phillips v. AWH Corp., 415 F.3d 1303, 1317, 75 U.S.P.Q.2d (BNA) 1321, 1329 (Fed. Cir. 2005) (quoting Markman v. Westview Instruments, Inc., 52 F.3d 967, 980, 34 U.S.P.Q.2d (BNA) 1321, 1330 (Fed. Cir. 1995)); see also Graham v. John Deere Co., 383 U.S. 1, 33, 148 U.S.P.Q. (BNA) 459, 473 (1966) ("[A]n invention is construed not only in the light of the claims, but also with reference to the file wrapper or prosecution history in the Patent Office.").

^{1464.} *Phillips*, 415 F.3d at 1317, 75 U.S.P.Q.2d (BNA) at 1329. 1465. *Id.*, 75 U.S.P.Q.2d (BNA) at 1329 (citing Lemelson v. Gen. Mills, Inc., 968 F.2d 1202, 1206, 23 U.S.P.Q.2d (BNA) 1284, 1287 (Fed. Cir. 1992)) (determining the meaning of a claim by closely examining claim language and prosecution history) (internal citation omitted).

^{1466. 501} F.3d 1285, 84 U.S.P.Q.2d (BNA) 1051 (Fed. Cir. 2007).

^{1467.} Id. at 1290, 84 U.S.P.Q.2d (BNA) at 1055.

of the patent. 1468 The patents at issue were directed to a mine roof bolt having a drive collar with a hexagonal outer shape to engage the driving mechanism of a mine roof bolting machine. 1469 The examiner had rejected the original claims as obvious over a bolt-like rock anchor that had a recessed head for accepting a rotational tool. 1470 The patentee distinguished his invention by arguing that the outer surface of the prior art bolt was cylindrical and thus incapable of being driven by a mine roof bolting machine. 1471 Nonetheless, Gillespie argued on appeal that its claims did not exclude the prior art structure "because the [examiner's] Reasons for Allowance did not depend on how the drive collar is rotated."¹⁴⁷²

The Federal Circuit rejected this argument. 1473 During prosecution, Gillespie had clearly argued that the cylindrical outside surface of the prior art "bolt head rendered it incapable of being driven by a mine roof bolting machine." The fact that the examiner had not mentioned this distinction in the Reasons for Allowance was not material. 1475 A patentee is bound by what he declares during prosecution, and thus Gillespie had disclaimed coverage of roof bolts having a cylindrical outer surface that could not be grasped by a drive tool. 1476 Based on this construction, the Federal Circuit reversed the district court's summary judgment of literal infringement. 1477

In contrast, in Elbex Video, Ltd. v. Sensormatic Electronics Corp., 1478 the Federal Circuit majority found that the district court had erred in determining that the inventor's remarks during prosecution limited the claimed "receiving means for receiving said video signals and said 1st code signals" to "a structure through which a video monitor receives the 1st code signal from a camera." According to the majority, the statement in question was not a clear disavowal of other structures because the applicants also referred to the receipt of the first code signals by other receiving devices, statements that were "fully supported" by the specification. 1480 In contrast, the court found the statement relied upon by the district court to be "unsupported by

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1468. Id. at 1291, 84 U.S.P.Q.2d (BNA) at 1055.
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^{1469.} *Id.* at 1287, 84 U.S.P.Q.2d (BNA) at 1053–55. 1470. *Id.* at 1290, 84 U.S.P.Q.2d (BNA) at 1054. 1471. *Id.*, 84 U.S.P.Q.2d (BNA) at 1055.

^{1472.} Id., 84 U.S.P.Q.2d (BNA) at 1054.

^{1473.} *Id.* at 1291, 84 U.S.P.Q.2d (BNA) at 1054.

^{1474.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1055.

^{1475.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1055. 1476. *Id.*, 84 U.S.P.Q.2d (BNA) at 1055.

^{1477.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1055. 1478. 508 F.3d 1366, 85 U.S.P.Q.2d (BNA) 1137 (Fed. Cir. 2007). 1479. *Id.* at 1369, 85 U.S.P.Q.2d (BNA) at 1138.

^{1480.} *Id.* at 1372, 85 U.S.P.Q.2d (BNA) at 1142.

even a shred of evidence from the specification[,]" which "never suggests that the monitor of the receiving means receives the first code signals." The court further noted that the accused infringer's own expert had attested that if the statement in question were taken literally, the claimed system would be "inoperable." The Federal Circuit concluded that the district court had based its summary judgment of non-infringement on this unduly narrow construction of "receiving means." Nonetheless, the court found independent bases to affirm that two of the three accused systems did not infringe the claims. District Judge Cote, sitting by designation, dissented, finding "clear and unambiguous evidence" in the intrinsic record that Elbex had made a strategic choice and unmistakably surrendered receiving devices other than a "monitor." In her view, Elbex was improperly attempting to recapture that which it had chosen to abandon during prosecution.

In Andersen Corp. v. Fiber Composites, LLC, 1487 Anderson had four patents on composite materials made from polymers and wood fibers (the "Group I" patents) and two patents on extruded members made from polymers and wood fibers (the "Group II" patents). On summary judgment, the district court found that Fiber Composites's products did not infringe the Group I products because the "composite compositions' claimed in the Group I patents [were] limited to materials . . . extruded to make pellets or the linear extrudate from which pellets can be cut." However, the district court found that some Fiber Composite products infringed the Group II patents because the composite structural members of Group II were not limited to items made of the Group I composite compositions. 1490

The Federal Circuit agreed with the district court's construction of the Group I claims, noting that "[t]he portions of the specification that describe how the physical properties of the claimed composite composition are obtained make clear that the formation of linear extrudates or pellets is not merely a preferred embodiment, but is a critical element in the process that produces those properties." ¹⁴⁹¹

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1481. Id., 85 U.S.P.Q.2d (BNA) at 1141. 1482. Id. at 1373, 85 U.S.P.Q.2d (BNA) a
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^{1482.} *Id.* at 1373, 85 U.S.P.Q.2d (BNA) at 1142. 1483. *Id.* at 1375, 85 U.S.P.Q.2d (BNA) at 1144.

^{1484.} *Id.* at 1373–75, 85 U.S.P.Q.2d (BNA) at 1142–44.

^{1485.} *Id.* at 1376, 85 U.S.P.Q.2d (BNA) at 1144 (Cote, J., dissenting).

^{1486.} Id. at 1375, 85 U.S.P.Q.2d (BNA) at 1144.

^{1487. 474} F.3d 1361, 81 U.S.P.Q.2d (BNA) 1545 (Fed. Cir. 2007).

^{1488.} *Id.* at 1364, 81 U.S.P.Q.2d (BNA) at 1547–48.

^{1489.} Id., 81 U.S.P.Q.2d (BNA) at 1548.

^{1490.} *Id.*, 81 U.S.P.Q.2d (BNA) at 1548.

^{1491.} Id. at 1367, 81 U.S.P.Q.2d (BNA) at 1550.

The Federal Circuit thus affirmed that Fiber Composite's products did not infringe the Group I patents because Fiber Composite did not use pellets or a linear extrudate introducing its products. 1492

However, the Federal Circuit reversed with respect to the Group II claims, finding that the claims were limited to structural members made from pellets claimed in the Group I patents because Andersen had distinguished the structural members from the prior art by relying heavily on the role of pelletization in fabricating the structural members. 1493 In addition, the Federal Circuit found that the specifications of both groups of patents use language of "requirement" rather than preference insofar as they stated that the composition of the structural members required a pelletizing step and attributed the desirable properties of the structural members to the nature of the pellets. 1494 As a result, the court reversed the district court's determination of infringement with respect to the Group II claims. 1495

B. Infringement

1. Literal infringement

The determination of whether a claim of a patent is infringed reguires a two-step analysis: first, the claims are construed to determine their scope and meaning; second, the claims are compared to the accused device or process. Each element is considered to be material and essential to the claim; thus, a finding of infringement requires that each or every element or its equivalent be present in the accused device. 1497 Dependent claims can be found infringed, literally or under the doctrine of equivalents, only if the claims from which they depend are infringed. 1498 "It is axiomatic that dependent claims cannot be found infringed unless the claims from which they depend have been found to have been infringed."1499

^{1492.} Id. at 1376, 81 U.S.P.Q.2d (BNA) at 1558.

^{1493.} *Id.* at 1372–74, 81 U.S.P.Q.2d (BNA) at 1557–58. 1494. *Id.* at 1373–74, 81 U.S.P.Q.2d (BNA) at 1557.

^{1495.} Id. at 1374, 81 U.S.P.Q.2d (BNA) at 1557.

^{1496.} E.g., Lockwood v. Am. Airlines, Inc., 107 F.3d 1565, 1573, 41 U.S.P.Q.2d (BNA) 1961, 1966 (Fed. Cir. 1997); Markman v. Westview Instruments, Inc., 52 F.3d 967, 976, 34 U.S.P.Q.2d (BNA) 1321, 1326 (Fed. Cir. 1995).

^{1497.} See, e.g., Laitram Corp. v. Rexnord, Inc., 939 F.2d 1533, 1535, 19 U.S.P.Q.2d (BNA) 1367, 1369–70 (Fed. Cir. 1991) (articulating how to establish infringement). 1498. See, e.g., Wahpeton Canvas Co. v. Frontier, Inc., 870 F.2d 1546, 1553, 10 U.S.P.Q.2d (BNA) 1201, 1207-08 (Fed. Cir. 1989) (reviewing the state of the law for dependent claim infringement)

^{1499.} Wahpeton Canvas, 870 F.2d at 1553 n.9, 10 U.S.P.Q.2d (BNA) at 1208 n.9.

In Z4 Technologies, Inc. v. Microsoft Corp., 500 the Federal Circuit rejected Microsoft's arguments that the district court had erred in denying JMOL of non-infringement. 1501 The patent was directed to preventing software piracy by requiring users to submit registration information in order to control the number of authorized copies that could be made. 1502 The parties disputed the level of user interaction in the registration process required to infringe the claims. ¹⁵⁰³ Both the district court and Federal Circuit found that even though the specification and claims "clearly contemplate[] a user choice as to whether registration will be automatic or manual," the claims themselves were silent as to the initiation of a registration process. ¹⁵⁰⁴ The court found that "the claims require at least a minimal level of user interaction to select ['automatic'] registration mode." 1505 though the specification teaches that automatic registration is performed "without user intervention," nothing in the claims or specification precludes user interaction in the selection or initialization of the automatic registration. 1506 Thus, the Federal Circuit found that "the district court correctly rejected Microsoft's attempt to exclude any user interaction from the claims" and affirmed its construction of this term. 1507

The Federal Circuit elaborated that "even under Microsoft's proposed construction, its sole non-infringement argument [was] artificial at best." 1508 More precisely, Microsoft argued that "although the accused products allow users to choose between [activation by] Internet (i.e., automatic or electronic) or phone (i.e., manual)," selection of the Internet option means "nothing happens after that manual choice until the user additionally manually presses the 'next' button."1509 Therefore, even under Microsoft's construction, a reasonable juror could conclude that "manually press[ing] the 'next' button' is merely part of the selection process." Therefore, the Federal Circuit affirmed the judgment of infringement with respect to those limitations. 1511

1500. 507 F.3d 1340, 85 U.S.P.Q.2d (BNA) 1340 (Fed. Cir. 2007).

^{1501.} *Id.* at 1351, 85 U.S.P.Q.2d (BNA) at 1348. 1502. *Id.* at 1347, 85 U.S.P.Q.2d (BNA) at 1342.

^{1503.} *Id.* at 1350–51, 85 U.S.P.Q.2d (BNA) at 1347.

^{1504.} *Id.* at 1351, 85 U.S.P.Q.2d (BNA) at 1348 (alteration in original).

^{1505.} Id., 85 U.S.P.Q.2d (BNA) at 1348.

^{1506.} Id., 85 U.S.P.Q.2d (BNA) at 1348.

^{1507.} Id., 85 U.S.P.Q.2d (BNA) at 1348 (emphasis removed).

^{1508.} *Id.*, 85 U.S.P.Q.2d (BNA) at 1348. 1509. *Id.*, 85 U.S.P.Q.2d (BNA) at 1348.

^{1510.} *Id.*, 85 U.S.P.Q.2d (BNA) at 1348.

^{1511.} Id., 85 U.S.P.Q.2d (BNA) at 1348.

In Monsanto Co. v. Syngenta Seeds, Inc., 1512 Monsanto appealed the district court's summary judgment ruling of non-infringement arguing that Syngenta infringed the asserted patents under 35 U.S.C. § 271(a) or, in the alternative, under § 271(g). The lower court determined that "because Syngenta did not infringe the methods of the independent claims, it could not infringe the methods of the asserted dependent claims." 1514 Monsanto contended that, even if the asserted claims of the patents were dependent, Syngenta should still be liable for infringing them because it had performed each limitation of the independent claims. 1515 Alternatively, Monsanto also contended that, even if the asserted claims of the patents were dependent claims, "Syngenta should still be liable for infringing them, because Syngenta infringes any 'four-step' claimed process by completing the last step of 'obtaining progeny' during the patent term."¹⁵¹⁶

The Federal Circuit was not persuaded. Relying on Wahpeton Canvas Co. v. Frontier, Inc., 1517 the court stated Monsanto's argument "cannot prevail." The Federal Circuit quoted Wahpeton as follows: "One may infringe an independent claim and not infringe a claim dependent on that claim. The reverse is not true. One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim." ¹⁵¹⁹

BMC Resources, Inc. v. Paymentech, L.P. 1520 addressed "the proper standard for [determining] joint infringement by multiple parties of

^{1512. 503} F.3d 1352, 84 U.S.P.Q.2d (BNA) 1705 (Fed. Cir. 2007). 1513. Id . at 1354, 84 U.S.P.Q.2d (BNA) at 1706. For the text of § 271(a), see infra text accompanying note 1527. Section 271(g) states:

Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after-

⁽¹⁾ it is materially changed by subsequent processes; or

⁽²⁾ it becomes a trivial and nonessential component of another product.

³⁵ U.S.C. § 274(g) (2000).

^{1514.} Monsanto, 503 F.3d at 1359, 84 U.S.P.Q.2d (BNA) at 1709. 1515. Id., 84 U.S.P.Q.2d (BNA) at 1709. 1516. Id., 84 U.S.P.Q.2d (BNA) at 1709. 1517. 870 F.2d 1546, 10 U.S.P.Q.2d (BNA) 1201 (Fed. Cir. 1989).

^{1518.} *Monsanto*, 503 F.3d at 1359, 84 U.S.P.Q.2d (BNA) at 1709–10. 1519. *Id.*, 84 U.S.P.Q.2d (BNA) at 1710 (quoting *Wahpeton Canvas*, 870 F.2d at 1552 n.9, 10 U.S.P.Q.2d (BNA) at 1211 n.9).

^{1520. 498} F.3d 1373, 84 U.S.P.Q.2d (BNA) 1545 (Fed. Cir. 2007).

a single claim." BMC Resources ("BMC") appealed the district court's summary judgment that Paymentech did not infringe two BMC patents because it did not perform all of the steps of the asserted method claims. 1522 Interestingly, the parties did not dispute that Paymentech did not perform every step of the claimed method, and that certain third-party financial institutions performed the other steps. 1523 Paymentech could not be held liable for indirect infringement, the court explained, because there was no showing that "some party amongst the accused actors has committed the entire act of direct infringement." Paymentech and the third parties *collectively* practiced all of the claimed steps, but none of them practiced all the steps individually. 1525

The Federal Circuit also examined whether Paymentech may be liable for direct infringement under 35 U.S.C. § 271(a). 1526 Section 271(a) states: "Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." The court determined Paymentech could not be held liable as a direct infringer because it did not perform all the claimed steps. 1528 Consequently, Paymentech could be held liable for infringement only if it were vicariously liable for the acts of the third parties if Paymentech "controlled the conduct of the acting party." 1529 The Federal Circuit explained that "[i]n the context of patent infringement, a defendant cannot thus avoid liability for direct infringement by having someone else carry out one or more of the claimed steps on its behalf." 1530

The Federal Circuit, however, found no evidence of a contractual or other relationship between Paymentech and the third-party finan-

^{1521.} Id. at 1378, 84 U.S.P.Q.2d (BNA) at 1548.

^{1522.} Id. at 1375–78, 84 U.S.P.Q.2d (BNA) at 1546–48. 1523. Id. at 1379–80, 84 U.S.P.Q.2d (BNA) at 1548. 1524. Id. at 1379–80, 84 U.S.P.Q.2d (BNA) at 1548 (citing Dynacore Holdings Corp. v. U.S. Philips Corp., 363 F.3d 1263, 1272, 70 U.S.P.Q.2d (BNA) 1369, 1376 (Fed. Cir. 2004)).

^{1525.} *Id.* at 1375–78, 1381, 84 U.S.P.Q.2d (BNA) at 1545–47, 1550–51.

^{1526.} Id. at 1378, 84 U.S.P.Q.2d (BNA) at 1548.

^{1527. 35} U.S.C. § 271(a) (2000). 1528. *BMC Resources*, 498 F.3d at 1379, 84 U.S.P.Q.2d (BNA) at 1549 (citing Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc., 424 F.3d 1293, 1311, 76 U.S.P.Q.2d (BNA) 1662, 1676 (Fed. Cir. 2005); Fromson v. Advance Offset Plate, Inc., 720 F.2d 1565, 1568, 219 U.S.P.Q. (BNA) 1137, 1139 (Fed. Cir. 1983)).

^{1529.} Id., 84 U.S.P.Q.2d (BNA) at 1548.

^{1530.} Id., 84 U.S.P.Q.2d (BNA) at 1548.

cial institutions. 1531 "Without this direction or control of both the debit networks and the financial institutions, Paymentech did not perform or cause to be performed each and every element of the claims." 1532 None of the financial institutions, debit networks, payment services provider, or Paymentech, bore responsibility for any the actions of the other parties. ¹⁵³³ "Because the record contain[ed] no basis to hold Paymentech vicariously responsible for the actions of the unrelated parties who carried out the other steps, [the Federal Circuit] affirm[ed] the finding of non-infringement." 1534

2. Induced infringement

In order to prevail on an inducement claim, the patentee must establish "first that there has been direct infringement, and second that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement." Specific intent requires a "showing that the alleged infringer's actions induced infringing acts and that he knew or should have known his actions would induce actual infringements."1536

In ACCO Brands, Inc. v. ABA Locks Manufacturer Co., 1537 Belkin Components ("Belkin") appealed from the judgment of the district court following a jury verdict that Belkin willfully induced infringement. 1538 Belkin also appealed from the court's denial of JMOL that the patent was invalid and unenforceable, its grant of enhanced damages and attorney fees, and its claim construction order. 1539 The Federal Circuit determined that the verdict of direct infringement was not supported by "substantial evidence." The court reversed the district court's judgment of infringement and inducement and vacated the court's judgment with respect to willfulness, enhanced damages, and attorney fees. 1541

The parties did not dispute that the accused device could "be operated in either of two modes—the infringing Dornfeld method or

^{1531.} Id. at 1381-82, 84 U.S.P.Q.2d (BNA) at 1550.

^{1532.} *Id.* at 1382, 84 U.S.P.Q.2d (BNA) at 1550. 1533. *Id.* at 1381–82, 84 U.S.P.Q.2d (BNA) at 1550.

^{1534.} *Id.* at 1375, 84 U.S.P.Q.2d (BNA) at 1545.

^{1535.} Minn. Mining & Mfg. Co. v. Chemque, Inc., 303 F.3d 1294, 1304–05, 64 U.S.P.Q.2d (BNA) 1270, 1276–77 (Fed. Cir. 2002) (internal citation omitted).

^{1536.} DSU Med. Corp. v. JMS Co., 471 F.3d 1293, 1304, 81 U.S.P.Q.2d (BNA) 1238, 1246 (Fed. Cir. 2006) (en banc in relevant part) (internal quotations omitted) (quoting Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 554, 16 U.S.P.Q.2d (BNA) 1587, 1594 (Fed. Cir. 1990)).

⁽BNA) 1367, 1354 (Fed. GII. 1990)). 1537. 501 F.3d 1307, 84 U.S.P.Q.2d (BNA) 1267 (Fed. Cir. 2007). 1538. *Id.* at 1309, 84 U.S.P.Q.2d (BNA) at 1268. 1539. *Id.*, 84 U.S.P.Q.2d (BNA) at 1268. 1540. *Id.*, 84 U.S.P.Q.2d (BNA) at 1268.

^{1541.} Id., 84 U.S.P.Q.2d (BNA) at 1268.

the non-infringing press-to-lock method." The Federal Circuit stated that in order to prove direct infringement, ACCO "must either point to specific instances of direct infringement or show that the accused device necessarily infringes the patent in suit." ACCO contended that the jury was entitled to accept its expert's testimony that all users of the key lock would use it in an infringing manner at least some of the time. 1544 The Federal Circuit was not persuaded, explaining that "[b]ecause the accused device can be used at any given time in a noninfringing manner," it did not necessarily infringe the patent. 1545

Moreover, the Federal Circuit was not convinced by ACCO's reliance on Hilgraeve Corp. v. Symantec Corp., 1546 which held "that an accused device may be found to infringe a product claim 'if it is reasonably capable of satisfying the claim limitations, even though it may also be capable of non-infringing modes of operation." According to the court, that broad legal statement did not alter ACCO's need to prove specific instances of direct infringement or that the accused device necessarily infringes the patent in suit. 1548 "Hypothetical instances of direct infringement are insufficient to establish vicarious liability or indirect infringement." 1549 Quoting Dynacore Holdings Corp. v. U.S. Phillips Corp., 1550 the court stated "[t]he mere sale of a product capable of substantial non-infringing uses does not constitute indirect infringement of a patent."1551

In Wechsler v. Macke International Trade, Inc., 1552 the Federal Circuit examined when the sole shareholder of an inducing corporation can be held personally liable for infringement. 1553 The defendant in this case was the founder, president, sole stockholder, and sole employee of Macke International Trade, Inc. ("Macke"), which developed,

^{1542.} Id. at 1313, 84 U.S.P.Q.2d (BNA) at 1270.

^{1543.} Id., 84 U.S.P.Q.2d (BNA) at 1270 (citing Dynacore Holdings Corp. v. U.S. Phillips Corp., 363 F.3d 1263, 1275-76, 70 U.S.P.Q.2d (BNA) 1369, 1378 (Fed. Cir. 2004)).

^{1544.} Id. at 1312, 84 U.S.P.Q.2d (BNA) at 1270.

^{1545.} *Id.* at 1313, 84 U.S.P.Q.2d (BNA) at 1270. 1546. 265 F.3d 1336, 60 U.S.P.Q.2d (BNA) 1291 (Fed. Cir. 2001).

^{1547.} Id. at 1343, 60 U.S.P.Q.2d (BNA) at 1296, quoted in ACCO Brands, 501 F.3d at 1313, 84 U.S.P.Q.2d (BNA) at 1271.

^{1548.} ACCO Brands, 501 F.3d at 1313, 84 U.S.P.Q.2d (BNA) at 1271.

^{1549.} Id., 84 U.S.P.Q.2d (BNA) at 1271.

^{1550. 363} F.3d 1263, 70 U.S.P.Q.2d (BNA) 1369 (Fed. Cir. 2004).

^{1551.} ACCO Brands, 501 F.3d at 1313–14, 84 U.S.P.Q.2d (BNA) at 1271 (quoting Dynacore, 363 F.3d at 1275, 70 U.S.P.Q.2d (BNA) at 1378) (alteration in original).

^{1552. 486} F.3d 1286, 82 U.S.P.Q.2d (BNA) 1742 (Fed. Cir. 2007).

^{1553.} Id. at 1289, 82 U.S.P.Q.2d (BNA) at 1743.

manufactured, and marketed pet products. 1554 While prosecuting a patent application for a portable water dispensing device for pets (called "Handi-Drink"), the owner learned of another patent (the "'592 patent") on a similar device. 1555 After negotiations for a license proved unsuccessful, the patentee, Wechsler, sued Macke and its owner for infringement. Defendants subsequently redesigned the Handi-Drink device but kept the original Handi-Drink on the market for another year. 1557

The jury found that the defendants had willfully infringed the '592 patent but the owner was not personally liable for inducement. 1558 The district court found these verdicts "inconsistent and unreasonable" because the company could not act independently of its owner. 1559 In an attempt to reconcile these two verdicts, the district court essentially discarded the verdict finding the owner not personally liable. The owner appealed and the Federal Circuit reversed. 1561

The Federal Circuit explained that "[u]nless the corporate structure is a sham, ... personal liability for inducement must be supported by evidence of personal culpability." This requires a showing that the officer possessed "a specific intent to 'aid and abet' the infringement." Willful infringement, however, considers "whether the infringer had a good faith belief that the patent was invalid and/or not infringed." The two standards are different, the court stated. 1565 For example, if a corporate officer negligently believed a patent was invalid or not infringed, the corporation may be liable for willful infringement but not the officer. The Federal Circuit con-

^{1554.} Id., 82 U.S.P.Q.2d (BNA) at 1743.

^{1555.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1743–44. 1556. *Id.* at 1289–90, 82 U.S.P.Q.2d (BNA) at 1744. 1557. *Id.* at 1290, 82 U.S.P.Q.2d (BNA) at 1744.

^{1558.} Id., 82 U.S.P.Q.2d (BNA) at 1744.

^{1559.} Id. at 1292, 82 U.S.P.Q.2d (BNA) at 1746.

^{1560.} *Id.* at 1291, 82 U.S.P.Q.2d (BNA) at 1745. 1561. *Id.* at 1289, 82 U.S.P.Q.2d (BNA) at 1743.

^{1562.} Id. at 1292, 82 U.S.P.Q.2d (BNA) at 1745 (citing Hoover Group, Inc. v. Custom Metalcraft, Inc., 84 F.3d 1408, 1412, 38 U.S.P.Q.2d (BNA) 1860, 1862 (Fed. Cir. 1996)).

^{1563.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1745 (citing Water Techs. Corp. v. Calco, Ltd., 850 F.2d 660, 668, 7 U.S.P.Q.2d (BNA) 1097, 1103 (Fed. Cir. 1988)).

^{1564.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1745 (citing SRI Int'l, Inc. v. Advanced Tech. Labs., Inc., 127 F.3d 1462, 1464, 44 U.S.P.Q.2d (BNA) 1422, 1423–24 (Fed. Cir. 1997)).

^{1565.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1745. 1566. *Id.*, 82 U.S.P.Q.2d (BNA) at 1745 (citing Biotec Biologische Naturverpackungen GmbH & Co. KG v. Biocorp, Inc., 249 F.3d 1341, 1356, 58 U.S.P.Q.2d (BNA) 1737, 1747 (Fed. Cir. 2001)).

cluded that the district court had erred in finding the two verdicts inconsistent and reinstated the jury's original verdicts. 1567

3. Contributory infringement

Section 271(c) of the Patent Act provides, in pertinent part, that a contributory infringer is one who "offers to sell or sells within the United States . . . a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process." Although that language describes various ways of creating liability for contributory infringement, all of those descriptions refer to the sale of a product, not the sale or provision of a service. Under the plain language of the statute, a service provider that assists another in committing patent infringement may be subject to liability under § 271(b), for active inducement of infringement, but not under § 271(c), for contributory infringement.

The legislative background of § 271(c) makes it clear that this interpretation is correct. Prior to the 1952 Patent Act, there was no statute that defined contributory infringement. Instead, courts had divided infringement into two categories: "'direct infringement,' which was the unauthorized making, using or selling of the patented invention and 'contributory infringement,' which was any other activity where, although not technically making, using or selling, the defendant displayed sufficient culpability to be held liable as an infringer." The 1952 Act did not make a substantive change in the law of contributory infringement, but it divided the judicially created category of contributory infringement into two statutory subsections: § 271(b) (inducement of infringement) and § 271(c) (contributory infringement). Section 271(c) in particular codified the most common type of pre-1952 contributory infringement cases, namely, those in which a seller would sell a component that was not covered by the

^{1567.} Id., 82 U.S.P.Q.2d (BNA) at 1745.

^{1568. 35} U.S.C. § 271(c) (2000).

^{1569.} In two recent decisions, the Federal Circuit restated that claims not tied to a tangible medium are not patentable under 35 U.S.C. *See generally In re* Comiskey, 499 F.3d 1365, 84 U.S.P.Q.2d (BNA) 1670 (Fed. Cir. 2007) (human-implemented arbitration process for legal documents); *In re* Nuijten, 500 F.3d 1346, 84 U.S.P.Q.2d (BNA) 1495 (Fed. Cir. 2007) (electrical and electromagnetic signals containing digital watermarks).

^{1570.} Compare § 271(b) ("Whoever actively induces infringement of a patent shall be liable as an infringer.") (emphasis added), with § 271(c) ("Whoever offers to sell or sells . . . shall be liable as a contributory infringer.").

^{1571.} Hewlett-Packard Co. v. Bausch & Lomb, Inc., 909 F.2d 1464, 1469, 15 U.S.P.Q.2d (BNA) 1525, 1528 (Fed. Cir. 1990).

claims of a patent but which did not have any other use except the claimed product or process. 1572

In PharmaStem Therapeutics, Inc. v. ViaCell, Inc., 1573 Pharmastem argued that defendants had contributorily infringed the patented method because they did not themselves practice all of the claimed steps. 1574 The jury returned verdicts in favor of the patentee. 1575 The district court, however, entered IMOL reversing the jury's verdict with respect to contributory infringement because the defendants could not be found liable under § 271(c) merely for providing a service to their customers. 1576

The Federal Circuit affirmed the district court's JMOL and rejected PharmaStem's argument that the defendants could still be held liable under § 271(c) for selling a service. 1577 Not only are sales of services excluded under § 271(c), but the Federal Circuit concluded that there was no evidence that any of the defendants actually sold any products or services. 1578 To the contrary, the evidence showed that the defendants provided a service to donor families, for which the families paid a fee, but "there was no sale of any sort by the defendants to transplanters or any fee paid by the transplanters to the defendants."1579 "The defendants simply transferred the cord blood units to designated transplanters upon direction from the families."1580 Thus, the Federal Circuit determined, "such a transaction did not constitute a 'sale' to a transplanter under any definition of the term 'sale.'" Accordingly, the Federal Circuit upheld that portion of the district court's IMOL finding no contributory infringement of the patent.1582

4. Infringement under the doctrine of equivalents

The doctrine of equivalents was judicially created to "prevent[] the pirating of the patentee's invention in the absence of literal infringement when liability is nevertheless warranted." If a device

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1572. Id. at 1469, 15 U.S.P.Q.2d (BNA) at 1529.
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^{1573. 491} F.3d 1342, 83 U.S.P.Q.2d (BNA) 1289 (Fed. Cir. 2007).

^{1574.} *Id.* at 1346, 83 U.S.P.Q.2d (BNA) at 1291.

^{1575.} *Id.* at 1347, 83 U.S.P.Q.2d (BNA) at 1291. 1576. *Id.*, 83 U.S.P.Q.2d (BNA) at 1291.

^{1577.} *Id.* at 1347, 1355, 83 U.S.P.Q.2d (BNA) at 1291, 1297. 1578. *Id.* at 1355, 83 U.S.P.Q.2d (BNA) at 1297. 1579. *Id.* at 1359, 83 U.S.P.Q.2d (BNA) at 1301.

^{1580.} *Id.*, 83 U.S.P.Q.2d (BNA) at 1301. 1581. *Id.*, 83 U.S.P.Q.2d (BNA) at 1301.

^{1582.} *Id.*, 83 U.S.P.Q.2d (BNA) at 1301. 1583. Miles Labs., Inc. v. Shandon, Inc., 997 F.2d 870, 876, 27 U.S.P.Q.2d (BNA) 1123, 1127 (Fed. Cir. 1993) (citing Hormone Research Found., Inc. v. Genentech, Inc., 904 F.2d 1558, 1564, 15 U.S.P.Q.2d (BNA) 1039, 1044 (Fed. Cir. 1990)).

does not literally infringe a patent, it may still be found to infringe under the doctrine of equivalents. 1584 Under this doctrine, a product that is not literally covered by the express terms of a patent claim may nevertheless infringe if there is "equivalence" (i.e., an insubstantial change) between the accused product and each and every element of the claimed invention. 1585

Equivalency is determined by whether each limitation of a claim is present literally or by equivalence in the accused product, and not by looking at the invention as a whole. 1586 The context of the patent, the prior art, and the particular circumstance of the case must all be considered in determining equivalence. 1587 If the accused device escapes literal infringement solely because of some inconsequential or insubstantial change from the patented device, the doctrine of equivalents may be applied to find the accused device infringing. To be a "substantial equivalent," the element substituted in the accused device for the element set forth in the claim must not be such as would substantially change the way in which the function of the claimed invention is performed. 1589

An objective standard is used to assess the substantiality of the differences between the claimed and accused products or processes. 1590 For example, the tripartite "function-way-result" test may be applied, which considers whether the accused product or process "performs substantially the same function in substantially the same way to obtain [substantially] the same result." The "essential inquiry" of equivalence may also be determined by considering whether there are "insubstantial differences" between the claimed element and the ele-

^{1584.} Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 21, 41 U.S.P.Q.2d (BNA) 1865, 1869 (1997).

^{1585.} See Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 609, 85 U.S.P.Q. (BNA) 328, 331 (1950) ("An important factor is whether persons reasonably skilled in the art would have known of the interchangeability of an ingredient not

contained in the patent with one that was.").
1586. See Warner-Jenkinson, 520 U.S. at 29, 41 U.S.P.Q.2d (BNA) at 1871 ("Where a claim to an invention is expressed as a combination of elements, as here, 'equivalents' in the sobriquet 'Doctrine of Equivalents' refers to the equivalency of an element or part of the invention with one that is substituted in the accused product or process.*) (citation omitted).

^{1587.} *Graver Tank*, 339 U.S. at 609, 85 U.S.P.Q. (BNA) at 330.

^{1588.} *Id.* at 608, 85 U.S.P.Q. (BNA) at 330. 1589. *See id.*, 85 U.S.P.Q. (BNA) at 330 (recognizing that "if two devices do the same work in substantially the same way, and accomplish substantially the same result, they are the same").

^{1590.} Id., 85 U.S.P.Q. (BNA) at 330.

^{1591.} Id., 85 U.S.P.Q. (BNA) at 330 (quoting Sanitary Refrigerator Co. v. Winters, 280 U.S. 30, 3 U.S.P.Q. (BNA) 40 (1929)).

ment of the accused product. [A] nalysis of the role played by each element in the context of the specific patent claim . . . inform[s] the inquiry as to whether a substitute element matches the function, way, and result of the claimed element, or whether the substitute element plays a role substantially different from the claimed element." Important factors include whether a person skilled in the art would recognize the interchangeability of two elements. Evidence of independent experimentation by the alleged infringer may be probative of such knowledge. 1595

The doctrine of equivalents does not permit claim limitations to be ignored. 1596 "It is . . . well settled that each element of a claim is material and essential, and that in order for a court to find infringement, the plaintiff must show the presence of every element or its substantial equivalent in the accused device." For example, there can be no infringement if the theory of equivalence would vitiate a claim term. This doctrine is known as the "all-elements rule." The issue of equivalents must therefore be tested on an element-by-element basis for each and every element of the claim. 1600 Thus, infringement by equivalents may only be found if each limitation in the claim is found somewhere in the accused device, either literally or by equivalents. 1601 Although the doctrine of equivalents must be applied to every limitation in the claim, a one-to-one correspondence of claim limitations and components is not required. So, for example, infringement may be found if two components of an accused device perform the function of a single claim limitation, or if separate claim limitations are combined into a single component of an accused device. 1603

^{1592.} Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 19, 41 U.S.P.Q.2d (BNA) 1865, 1867 (1997).

^{1593.} *Id.* at 40, 41 U.S.P.Q.2d (BNA) at 1875. 1594. *Id.*, 41 U.S.P.Q.2d (BNA) at 1875.

^{1595.} Id., 41 U.S.P.Q.2d (BNA) at 1875.

^{1596.} Pennwalt Corp. v. Durand-Wayland, Inc., 833 F.2d 931, 935, 4 U.S.P.Q.2d (BNA) 1737, 1740 (Fed. Cir. 1987).

^{1597.} Id., 4 U.S.P.Q.2d (BNA) at 1740 (alteration in original) (quoting Lemelson v. United States, 752 F.2d 1538, 1551, 224 U.S.P.Q. (BNA) 526, 533 (Fed. Cir. 1985)).

^{1598.} See Wilson Sporting Goods Co. v. David Geoffrey & Assocs., 904 F.2d 677, 683, 14 U.S.P.Q.2d (BNA) 1942, 1948 (Fed. Cir. 1990) (examining alleged infringement of a golf ball).

^{1599.} *Pennwalt*, 833 F.2d at 949, 4 U.S.P.Q.2d (BNA) at 1751–52. 1600. *Id.*, 4 U.S.P.Q.2d (BNA) at 1751.

^{1601.} Athletic Alternatives v. Prince Mfg., Inc., 73 F.3d 1573, 1581–82, 37 U.S.P.Q.2d (BNA) 1365, 1373 (Fed. Cir. 1996); *Pennwalt*, 833 F.2d at 934–35, 4 U.S.P.Q.2d (BNA) at 1739–40.

^{1602.} Pennwalt, 833 F.2d at 946, 4 U.S.P.Q.2d (BNA) at 1749.

^{1603.} Dolly, Inc. v. Spalding & Evenflo Cos., 16 F.3d 394, 398, 29 U.S.P.Q.2d (BNA) 1767, 1770 (Fed. Cir. 1994).

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. 1604 came before the Federal Circuit again in 2007. This time, the Federal Circuit examined the question of whether an equivalent was foreseeable within the meaning of Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. 1605 and thus subject to surrender under the doctrine of prosecution history estoppel. 1606 The court concluded that "foreseeability does not require the applicant to be aware that a particular equivalent would satisfy the insubstantial differences test or the function/way/result test with respect to the claim as amended." According to the Federal Circuit, Festo proffered no persuasive explanation as to why the function-way-result test applied to the claims, as amended, should be used to determine foreseeability. 1608 The insubstantial differences test or function-way-result test is devised "to determine whether the alternative is sufficiently close to the claimed feature that the patentee should be able to capture the equivalent and bar its use by a competitor." It "is not designed to determine whether prosecution history estoppel applies as a result of a limiting amendment." ¹⁶¹⁰

The court warned that accepting Festo's understanding of foreseeability would likely dispose of prosecution history estoppel as a constraint on the doctrine of equivalents in most cases. 1611 The Federal Circuit determined that the issue is "not whether after the narrowing amendment the alternative was a known equivalent, but rather whether it was a known equivalent before the narrowing amendment."1612 If the equivalent was known at the time of the amendment in the pertinent prior art, "the applicant should not be able to recapture it simply by establishing that a property of the equivalent irrelevant to the broader claim before amendment—was relevant but unknown with respect to the objectives of the narrower amended claim." Stated differently, "an equivalent that is foreseeable as an alternative to the broader claimed feature does not become unforeseeable simply because the claimed feature is narrowed." The court stated the following as an example:

^{1607.} *Id.*, 83 U.S.P.Q.2d (BNA) at 1386. 1608. *Id.* at 1380, 83 U.S.P.Q.2d (BNA) at 1393.

^{1609.} Id., 83 U.S.P.Q.2d (BNA) at 1393.

^{1610.} Id., 83 U.S.P.Q.2d (BNA) at 1393.

^{1611.} *Id.*, 83 U.S.P.Q.2d (BNA) at 1393. 1612. *Id.* at 1381, 83 U.S.P.Q.2d (BNA) at 1394 (emphasis removed).

^{1613.} Id., 83 U.S.P.Q.2d (BNA) at 1394.

^{1614.} Id., 83 U.S.P.Q.2d (BNA) at 1394.

[I]f a claim before amendment broadly claimed a metal filament for a light bulb but was later amended to avoid prior art and to specify metal A because of its longevity, the equivalent metal B, known in the prior art to function as a bulb filament, is not unforeseeable even though its longevity was unknown at the time of $amendment. ^{^{1615}} \\$

Judge Newman dissented because "[f] oreseeability is determined as of the time of the application," not at the time of the amendment. 1616 Judge Newman stated that the majority had departed from precedent:

[T]his court has confounded the issue by creating a new and incorrect criterion for the measurement of "foreseeability," the court now holding that an existing structure need not be recognized, or even recognizable, as an equivalent at the time of the patent application or amendment, in order to be "foreseeable" if it is later used as an equivalent. 1617

Judge Newman went on to express that "[t]he unforeseen does not become foreseeable after someone later discovers it. If the prior art does not support a finding of equivalency, the applicant cannot be charged with foreseeability of the equivalent." 1618

A patentee's evidentiary burden under the doctrine of equivalents must be addressed on a limitation-by-limitation basis. 1619 A fundamental principal in establishing infringement under the doctrine of equivalents requires that a patentee must "provide particularized testimony and linking argument as to the 'insubstantiality of the differences' between the claimed invention and the accused device or process." 1620 Or, with respect to the function-way-result test, the patentee must meet the same burden when such evidence is presented to support a finding of infringement under the doctrine of equiva-Since evidence must be presented on a limitation-bylimitation basis, "[g]eneralized testimony as to the overall similarity between the claims and the accused infringer's product or process will not suffice."1622

In Aquatex Industries, Inc. v. Techniche Solutions, 1623 the Federal Circuit affirmed the district court's summary judgment of no infringe-

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1615. Id., 83 U.S.P.Q.2d (BNA) at 1394.
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^{1616.} *Id.* at 1383, 83 U.S.P.Q.2d (BNA) at 1396 (Newman, J., dissenting). 1617. *Id.*, 83 U.S.P.Q.2d (BNA) at 1395. 1618. *Id.* at 1385, 83 U.S.P.Q.2d (BNA) at 1397.

^{1619.} Tex. Instruments, Inc. v. Cypress Semiconductor Corp., 90 F.3d 1558, 1567, 39 U.S.Q.P.Q.2d (BNA) 1492, 1499 (Fed. Cir. 1996).

^{1620.} *Id.*, 39 U.S.Q.P.Q.2d (BNA) at 1499. 1621. *Id.*, 39 U.S.Q.P.Q.2d (BNA) at 1499. 1622. *Id.*, 39 U.S.Q.P.Q.2d (BNA) at 1499.

^{1623. 479} F.3d 1320, 81 U.S.P.Q.2d (BNA) 1865 (Fed. Cir. 2007).

ment by equivalents due to the patentee's failure to present evidence sufficient to create a genuine issue of material fact. 1624 In particular, the court found that AquaTex, in response to Techniche's summary judgment motion: (1) "provided no particularized testimony from an expert or person skilled in the art that specifically addressed equivalents 'on a limitation-by-limitation basis;" (2) did not explain the "insubstantiality of the differences between the patented method and the accused product;" and (3) did not address the function-way-result test. 1625 The only evidence presented by AquaTex on the issue of equivalents was the deposition testimony of Techniche's Chief Executive Officer, which was found to be inadequate on these points. 1626

Similarly, in Motionless Keyboard Co. v. Microsoft Corp., 1627 the Federal Circuit found that "the accused . . . Sidewinder joysticks" did "not literally infringe" the Motionless patent because they "lack[ed] a concavity in the housing and a keyboard within the cavity." Neither was there sufficient evidence of infringement under the doctrine of equivalents, as Motionless had presented only conclusory statements about equivalents, and not particularized evidence that connected the accused products to the patent on a limitation-by-limitation basis. 1629 The Federal Circuit found Motionless's conclusory statements were inadequate to defeat a motion for summary judgment of noninfringement, which demands that the patentee present "particularized evidence and linking argument as to the 'insubstantiality of the differences' between the claimed invention and the accused device, or with respect to the 'function/way/result' test." 1630

In contrast, the Federal Circuit found that expert testimony offered by Paice in Paice LLC v. Toyota Motor Corp. 1631 plainly satisfied the requirement that "a patentee . . . provide particularized testimony and linking argument... with respect to the function, way, result test when such evidence is presented to support a finding of infringement under the doctrine of equivalents." In this case, the expert gave sub-

^{1624.} Id. at 1323, 81 U.S.P.Q.2d (BNA) at 1866.

^{1625.} Id. at 1329, 81 U.S.P.Q.2d (BNA) at 1871.

^{1626.} Id., 81 U.S.P.Q.2d (BNA) at 1871.

^{1627. 486} F.3d 1376, 82 U.S.P.Q.2d (BNA) 1801 (Fed. Cir. 2007).

^{1628.} Id. at 1381, 82 U.S.P.Q.2d (BNA) at 1804.

^{1629.} See id. at 1382-83, 82 U.S.P.Q.2d (BNA) at 1805 (explaining that absent particularized evidence, a court cannot find infringement under the doctrine of equivalents).

^{1630.} *Id.* at 1882, 82 U.S.P.Q.2d (BNA) at 1805 (citation omitted).

^{1631. 504} F.3d 1293, 85 U.S.P.Q.2d (BNA) 1001 (Fed. Cir. 2007). 1632. *Id.* at 1304–05, 85 U.S.P.Q.2d (BNA) at 1009 (quoting Tex. Instruments Inc. v. Cypress Semiconductor Corp., 90 F.3d 1558, 1567, 39 U.S.P.Q.2d (BNA) 1492, 1499 (Fed. Cir. 1996)).

stantial testimony, which covered over seventy pages of transcript pertaining to the technology of the patents and the inner workings of the vehicles' transaxle units at issue before he began to discuss the topic of infringement. 1633

"Prosecution history estoppel continues to be available as a defense to infringement."1634 Under this theory, statements, claim amendments, and arguments made during prosecution of a patent application can create an estoppel that prevents the patentee from recapturing subject matter through equivalents that was surrendered during prosecution. 1635 In addition, concessions or positions taken to demonstrate patentability in view of the prior art may also create an estoppel. 1636 Thus, estoppel can arise from arguments made by an applicant to distinguish a prior art reference regardless of whether they are associated with claim amendments. 1637 In addition, "the limits imposed by prosecution history estoppel on the permissible range of equivalents can be broader than those imposed by the prior art."1638 Moreover, "[c]lear assertions made during prosecution in support of patentability, whether or not actually required to secure allowance of the claim, may also create an estoppel."¹⁶³

The Supreme Court has affirmed that "a narrowing amendment made to satisfy any requirement of the Patent Act may give rise to an estoppel."1640 The statutory requirements for patentability include novelty (§ 102), nonobviousness (§ 103), patentable subject matter (§§ 101, 102, 103, 112), utility (§ 101), written description (§ 112(1)),

^{1633.} Id. at 1305, 85 U.S.P.Q.2d (BNA) at 1009-10.

^{1634.} Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 40, 41 U.S.P.Q.2d (BNA) 1865, 1876 (1997).

^{1635.} See Loctite Corp. v. Ultraseal, Ltd., 781 F.2d 861, 870, 228 U.S.P.Q. (BNA) 90, 96 (Fed. Cir. 1985) (explaining that prosecution history estoppel is judicially created to provide liability when there is no actual infringement); see also Warner-Jenkinson, 520 U.S. at 30, 41 U.S.P.Q.2d (BNA) at 1871 (noting that any surrender of material precludes the patentee from using the doctrine of equivalents to recapture the subject matter); Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1580, 34 U.S.P.Q.2d (BNA) 1673, 1680 (Fed. Cir. 1995) (stating that the court must look into the reason for a surrender of materials when applying prosecution history estoppel). 1636. Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1220, 36 U.S.P.Q.2d (BNA) 1225, 1231 (Fed. Cir. 1995).

^{1637.} See Ekchian v. Home Depot, Inc., 104 F.3d 1299, 1304, 41 U.S.P.Q.2d (BNA) 1364, 1368–69 (Fed. Cir. 1997) (determining that prosecution history estoppel was present from an argument that distinguished prior art presented in an information disclosure statement); Hoganas AB v. Dresser Indus., Inc., 9 F.3d 948, 952-53, 28 U.S.P.Q.2d (BNA) 1936, 1939-40 (Fed. Cir. 1993) (finding prosecution history estoppel from an argument without an accompanying amendment made to distinguish prior art).

^{1638.} Southwall, 54 F.3d at 1581, 34 U.S.P.Q.2d (BNA) at 1681. 1639. Id. at 1583, 34 U.S.P.Q.2d (BNA) at 1682.

^{1640.} Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. (Festo VIII), 535 U.S. 722, 736, 62 U.S.P.Q.2d (BNA) 1705, 1711–12 (2002).

enablement (§ 112(1)), best mode disclosure (§ 112(1)) and definiteness (§ 112(2)). 1641 If the patentee is unable to explain the reason for amendment, the court should presume that the "patentee surrendered all subject matter between the broader and the narrower language" and find an estoppel. 1642

Nonetheless, prosecution estoppel is not necessarily a complete bar, for its effect requires a close examination of the subject matter surrendered. 1643 An amendment is considered to disclaim "the territory between the original claim and the amended claim." The Supreme Court has further clarified that because "language remains an imperfect fit for invention . . . [t] here is no reason why a narrowing amendment should be deemed to relinquish equivalents unforeseeable at the time of the amendment and beyond a fair interpretation of what was surrendered."1645 The Supreme Court has indicated that there are some cases where a particular equivalent has not been surrendered by the amendment, such as when the equivalent is "unforeseeable at the time of the application," or when the rationale underlying the amendment bears "no more than a tangential relation to the equivalent in question," or if there is another "reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question." 1646

In Hutchins v. Zoll Medical Corp., 1647 the Federal Circuit found that the patentee was estopped from reading the term "general purpose computer" to cover a RISC microprocessor because he had disclaimed that subject matter scope during prosecution in order to distinguish his invention from the prior art, which disclosed similar devices with dedicated microprocessor units. 1648 In particular, the patentee, representing himself pro se, had charged Zoll Medical Corporation with infringing his '685 patent (United States Patent No. 5,913,685) on "CPR Computer Aiding." All of the '685 claims required a "general purpose computer system," which the parties agreed should be defined as "a computer capable of running multiple unrelated programs, which are selected by the user and loaded

^{1641.} Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 566-67, 56 U.S.P.Q.2d (BNA) 1865, 1870-71 (Fed. Čir. 2000), rev'd on other grounds, 535 U.S. 722, 62 U.S.P.Q.2d (BNA) 1705 (2002).

^{1642.} Festo VIII, 535 U.S. at 740, 62 U.S.P.Q.2d (BNA) at 1713.

^{1643.} *Id.* at 741, 62 U.S.P.Q.2d (BNA) at 1714.

^{1644.} Id. at 740, 62 U.S.P.Q.2d (BNA) at 1713.

^{1645.} Id. at 738, 62 U.S.P.Q.2d (BNA) at 1712.

^{1646.} *Id.* at 740–41, 62 U.S.P.Q.2d (BNA) at 1714. 1647. 492 F.3d 1377, 83 U.S.P.Q.2d (BNA) 1264 (Fed. Cir. 2007).

^{1648.} *Id.* at 1381–82, 83 U.S.P.Q.2d (BNA) at 1266–67.

^{1649.} Id. at 1380, 83 U.S.P.Q.2d (BNA) at 1266.

into the device." ¹⁶⁵⁰ Zoll's accused device contained a dedicated Hitachi SuperH RISC (Reduced Instruction Set Computer) microprocessor. 1651 The Federal Circuit agreed with the district court in finding the term "general purpose computer" was added to Hutchins' claims during prosecution in order to differentiate the invention from prior art that displayed similar devices with dedicated microprocessor units. 1652 According to the court, "[t] his produced an estoppel against reading the term 'general purpose computer' to include a dedicated microprocessor such as a RISC, for the claims had been amended in response to the PTO rejection, thereby estopping recovery of the same subject matter that the claims had been amended to exclude." The court also noted that the term "general purpose computer" was incorporated into every dependent claim because it was recited in each independent claim. 1654

In Ormco Corp. v. Align Technology, Inc., 1655 the Federal Circuit found that although statements in the specification did not conclusively limit the claims for forming "ideal dental archforms" to automatic methods for determining final tooth positions, certain statements made by the inventors during prosecution made that limitation clear. 1656 Statements made during prosecution of a "parent" application can be binding on the "child" application. In addition, the Federal Circuit held that before a disclaimer can narrow claim scope, there must be some relationship between the disclaimer and the affected claim. 1658 Thus, the Federal Circuit proceeded to affirm the summary judgment of non-infringement. 1659

District Judge Kathleen O'Malley, sitting by designation, chastised the majority because "[p]rosecution disclaimer requires a patentee to clearly and unmistakably disavow certain interpretations, and I find no such disavowal here."1660 She continued:

Importantly, while the quotations lifted from the . . . patent history do appear to support the majority's conclusion that the process contemplated in that potential invention was a highly automated

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1650. Id. at 1381, 83 U.S.P.Q.2d (BNA) at 1267.
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^{1651.} *Id.*, 83 U.S.P.Q.2d (BNA) at 1267.

^{1652.} *Id.*, 83 U.S.P.Q.2d (BNA) at 1267. 1653. *Id.* at 1381–1382, 83 U.S.P.Q.2d (BNA) at 1267.

^{1654.} Id. at 1382, 83 U.S.P.Q.2d (BNA) at 1267.

^{1655. 498} F.3d 1307, 84 U.S.P.Q.2d (BNA) 1146 (Fed. Cir. 2007). 1656. *Id.* at 1314–15, 84 U.S.P.Q.2d (BNA) at 1151–52.

^{1657.} Id. at 1315, 84 U.S.P.Q.2d (BNA) at 1151.
1658. Id. at 1313, 84 U.S.P.Q.2d (BNA) at 1150.
1659. Id. at 1317, 84 U.S.P.Q.2d (BNA) at 1154.
1660. Id. at 1325, 84 U.S.P.Q.2d (BNA) at 1159 (O' Malley, J., concurring in part and dissenting in part) (citing SanDisk Corp. v. Memorex Prods., Inc., 415 F.3d 1278, 1287, 75 U.S.P.Q.2d (BNA) 1475, 1482 (Fed. Cir. 2005)).

one, that language was proffered to the examiner in connection with claims in that patent which do not share claim language with the majority of the claims at issue in this suit. 1661

Judge O'Malley thus dissented, finding that the patent claims did require a fully automated process. 1662

In Schwarz Pharma, Inc. v. Paddock Laboratories, Inc., 1663 the district court determined that an estoppel was created when the applicants amended their claims by replacing a "metal containing solubilizer" and "an alkali or alkaline earth-metal salt" in the original claims with "an alkali or alkaline earth metal carbonate" in order to overcome an obviousness rejection. 1664 Schwarz argued on appeal that a person skilled in the art would construe "metal containing stabilizer" and "alkali or alkaline earth metal salt" in the original claims to include only alkali or alkaline earth metal cations and carbonate, borate, or silicate anions, and not MgO. 1665 Since MgO had never fallen within the scope of the claims, there had been no disclaimer of compositions and processes involving MgO, according to Schwarz. 1666 The Federal Circuit disagreed.

The Federal Circuit determined that the alleged equivalent was "clearly... within the territory between the language of the original and the amended claims," which gave rise to the presumption of surrender. 1667 Schwarz, however, had failed to rebut the presumption that MgO was surrendered during prosecution as a foreseeable equivalent of an alkali or alkaline earth metal carbonate because it was known in the art to use the alleged equivalent as a stabilizer. 1668 The Federal Circuit explained that "an alternative is foreseeable if it is known in the field of the invention as reflected in the claim scope before amendment' and that it would be inappropriate to apply an insubstantial differences or function/way/result test in order to determine foreseeability." Since prosecution history estoppel barred Schwarz from claiming the MgO as an equivalent, the Federal Circuit

^{1661.} Id., 84 U.S.P.Q.2d (BNA) at 1159-60.

^{1662.} Id., 84 U.S.P.Q.2d (BNA) at 1159–60.

^{1663. 504} F.3d 1371, 84 Ù.S.P.Q.2d (BNA) 1900 (Fed. Cir. 2007).

^{1664.} Id. at 1373, 84 U.S.P.Q.2d (BNA) at 1902.

^{1665.} *Id.* at 1375, 84 U.S.P.Q.2d (BNA) at 1904. 1666. *Id.*, 84 U.S.P.Q.2d (BNA) at 1904. 1667. *Id.* at 1376–77, 84 U.S.P.Q.2d (BNA) at 1905.

^{1668.} *Id.* at 1377, 84 U.S.P.Q.2d (BNA) at 1905. 1669. *Id.* at 1377, 84 U.S.P.Q.2d (BNA) at 1905 (quoting Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 493 F.3d 1368, 1379, 83 U.S.P.Q.2d (BNA) 1385, 1392 (Fed. Cir. 2007)).

affirmed the district court's summary judgment of infringement. 1670

Cross Medical Products, Inc. v. Medtronic Sofamor Danek, Inc. 1671 similarly involved *Festo*'s presumption that a patentee is estopped from recapturing subject matter surrendered during prosecution to obtain a patent. 1672 Accused infringer Medtronic had replaced the threading below the diameter of a rod with an undercut that did not engage any surface on the corresponding set screw. 1673 The district court rejected Medtronic's argument that that limitation had been the subject of a narrowing amendment by Cross Medical during prosecution of its patent, and found instead that Cross Medical had successfully rebutted the Festo presumption by showing that the amendment bore no more than a tangential relationship to the equivalent structure. 1674 The Federal Circuit disagreed, finding that Cross Medical did not satisfy its burden of overcoming the Festo presumption by showing either that the amendment was only tangentially related to the limitation or that it was unforeseeable. 1675 In particular, a patentee can rebut the presumption of prosecution history estoppel only

by showing that the alleged equivalent was unforeseeable at the time the amendment was made, that the alleged equivalent was tangential to the purpose of the amendment, or that there was some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question.1676

Judge Rader, in a concurrence, explained that the tangential relation criterion for overcoming the *Festo* presumption is very narrow:

In my view, the tangential rebuttal principle exacerbates the policy deficiencies of the doctrine of equivalents. Upon invoking tangentiality, the patentee has already admitted that the equivalent falls within the scope of surrendered subject matter. Further, if the case permitted, any patentee would invoke the primary "foreseeability" rebuttal factor. Thus, an invocation of "tangentiality" often admits that the equivalent was both within the scope of the surrender and foreseeable at the time of prosecution. In other words, the patent drafter could have claimed the surrendered and foreseeable technology, but declined to do so.1677

^{1670.} Id. at 1378, 84 U.S.P.Q.2d (BNA) at 1906.

^{1671. 480} F.3d 1335, 82 U.S.P.Q.2d (BNA) 1065 (Fed. Cir. 2007) (per curiam).

Id. at 1341, 82 U.S.P.Q.2d (BNA) at 1070. 1672.

^{1673.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1069. 1674. *Id.* at 1341–42, 82 U.S.P.Q.2d (BNA) at 1070.

^{1675.} *Id.* at 1344, 82 U.S.P.Q.2d (BNA) at 1072.

^{1676.} *Id.* at 1341, 82 U.S.P.Q.2d (BNA) at 1070 (quoting Chimie v. PPG Indus. Inc., 402 F.3d 1371, 1382, 74 U.S.P.Q.2d (BNA) 1321, 1329 (Fed. Cir. 2005)).

^{1677.} Id. at 1347, 82 U.S.P.Q.2d (BNA) at 1074 (Rader, J., concurring).

Judge Rader further asserted that "[t]his 'tangential' rebuttal principle becomes even more difficult in practice. What neutral standard makes some surrendered and unclaimed technologies infringing equivalents while others enjoy no protection? This tangential concept has no analogue in patent law. How tangential does it have to be?"¹⁶⁷⁸

Prosecution history estoppel can also arise in the context of continuation applications, as shown in Hakim v. Cannon Avent Group, Hakim had re-filed his patent application with broader claims in order to avoid any unnecessary restrictions that may have crept in during prosecution of the original application. 1680 The Federal Circuit "recognized that an applicant can broaden as well as restrict his claims during the procedures of patent examination, and that continuing applications may present broader claims than were allowed in the parent." The court noted, however, that an applicant cannot ordinarily recapture claim scope that he has surrendered or disclaimed.¹⁶⁸² Although an applicant may attempt to rescind a disclaimer made during prosecution in order to recapture disclaimed subject matter, "the prosecution history must be sufficiently clear to inform the examiner that the previous disclaimer, and the prior art that it was made to avoid, may need to be re-visited." In this case, Hakim's attempted rescission was not sufficiently clear as to preclude the examiner from allowing the continuation claims without further prosecution based on limiting arguments made during prosecution of the parent application. Accordingly, the Federal Circuit affirmed the district court's summary judgment of non-infringement. 1685

It is well-established that "when a specification excludes certain prior art alternatives from the literal scope of the claims and criticizes those prior art alternatives, the patentee cannot then use the doctrine of equivalents to capture those alternatives." The Federal Circuit has also established that the doctrine of equivalents is unavailable to recapture subject matter that was "specifically identified,"

^{1678.} Id. at 1348, 82 U.S.P.Q.2d (BNA) at 1075.

^{1679. 479} F.3d. 1313, 81 U.S.P.Q.2d (BNA) 1900 (Fed. Cir. 2007).

^{1680.} Id. at 1317, 81 U.S.P.Q.2d (BNA) at 1903.

^{1681.} *Id.*, 81 U.S.P.Q.2d (BNA) at 1903 (citing Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found., 422 F.3d 1378, 1385, 76 U.S.P.Q.2d (BNA) 1354, 1360 (Fed. Cir. 2005)).

^{1682.} *Id.*, 81 U.S.P.Q.2d (BNA) at 1904.

^{1683.} Id. at 1318, 81 U.S.P.Q.2d (BNA) at 1904.

^{1684.} *Id.* at 1317, 81 U.S.P.Q.2d (BNA) at 1904.

^{1685.} Id. at 1318, 81 U.S.P.Q.2d (BNA) at 1904.

^{1686.} L.B. Plastics, Inc. v. Amerimax Home Prods., Inc., 499 F.3d 1303, 1309, 84 U.S.P.Q.2d (BNA) 1341, 1345 (Fed. Cir. 2007).

criticized, and disclaimed;" thus, a "patentee cannot . . . invoke the doctrine of equivalents 'to embrace a structure that was specifically excluded from the claims."1687

In L.B. Plastics, Inc. v. Amerimax Home Products, Inc., 1688 the Federal Circuit found that the patentee could not invoke the doctrine of equivalents to capture certain alternatives to the claimed attachment means, when the specification specifically criticized those alternatives in the prior art. 1689 In particular, the specification stated:

Unlike some prior art gutter guards which have a relatively finemesh metal layer overlying a perforated polymer guard panel, the gutter guard of the present invention includes a coated mesh layer and perforated guard panel formed of like polymer materials, such as PVC. This novel construction facilitates an effective and secure attachment of the composite by ultrasonic or heat welding along the entire length of the gutter guard. The attachment means used in other prior art gutter guards incorporating multiple layers is generally less effective, and more costly, time consuming, and labor intensive.1690

L.B. Plastics contended "that the prior art referenced in the specification did not specifically disclose a continuous attachment using adhesives." The Federal Circuit disagreed, finding that adhesives were among the prior art attachment means criticized in the specification as "generally less effective, and more costly, time consuming, and labor intensive." Furthermore, the patentee had limited its claims to continuous welded attachments. As a result, the court found that persons skilled in the art who read the specification would "conclude that the inventor thought that adhesive attachments generally were undesirable." 1694 Under these circumstances L.B. Plastics could not use the doctrine of equivalents to include adhesive attachments in the scope of the claims. 1695

^{1687.} SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1345, 58 U.S.P.Q.2d (BNA) 1059, 1066 (Fed. Cir. 2001) (quoting Dolly, Inc. v. Spalding & Evenflo Cos., 16 F.3d 394, 400, 29 U.S.P.Q.2d (BNA) 1767, 1771 (Fed. Cir. 1994)).

^{1688.} L.B. Plastics, 499 F.3d 1303, 84 U.S.P.Q.2d (BNA) 1341.

^{1689.} *Id.* at 1309, 84 U.S.P.Q.2d (BNA) at 1345 (citing Schwing GmbH v. Putzmeister Aktiengesellschaft, 305 F.3d 1318, 1329, 64 U.S.P.Q.2d (BNA) 1641, 1649 (Fed. Cir. 2002); SciMed Life Sys., 242 F.3d at 1345, 58 U.S.P.Q.2d (BNA) at 1066; Dawn Equip. Co. v. Ky. Farms, Inc., 140 F.3d 1009, 1015, 46 U.S.P.Q.2d (BNA) 1109, 1113 (Fed. Cir. 1998)).

^{1690.} Id. at 1309 n.3, 84 U.S.P.Q.2d (BNA) at 1345 n.3.

^{1691.} Id. at 1310, 84 U.S.P.Q.2d (BNA) at 1345.

^{1692.} *Id.* at 1309, 84 U.S.P.Q.2d (BNA) at 1345. 1693. *Id.* at 1310, 84 U.S.P.Q.2d (BNA) at 1345.

^{1694.} Id., 84 U.S.P.Q.2d (BNA) at 1345.

^{1695.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1345.

Furthermore, the Federal Circuit has held that:

A holding that the doctrine of equivalents cannot be applied to an accused device because it "vitiates" a claim limitation is nothing more than a conclusion that the evidence is such that no reasonable jury could conclude that an element of an accused device is equivalent to an element called for in the claim, or that the theory of equivalence to support the conclusion of infringement otherwise lacks legal sufficiency. 1696

The Federal Circuit rejected the accused infringer's theory of claim vitiation in Abbott Laboratories v. Andrx Pharmaceuticals, Inc. 1697 The patent claims in question recited a "pharmaceutically acceptable polymer," but the accused products used a glyceryl monostearate ("GMS") material. Andrx asserted that GMS, a hydrophobic, water insoluble non-polymer was the opposite of the hydrophilic, water soluble polymer required by the claims. 1699 Andrx thus argued that equivalency would vitiate the claim limitation in its entirety, regardless of any insubstantial differences between the claimed and accused devices.1700

The Federal Circuit disagreed. The Federal Circuit found that the district court had erred in limiting the claimed "pharmaceutically acceptable polymer" to hydrophilic, water-soluble substances. Nonetheless, the court concluded that despite the district court's erroneous claim construction and equivalence analysis, its finding of equivalence would apply even under a claim construction that was not erroneously narrowed.¹⁷⁰² The Federal Circuit thus affirmed the district court's grant of a preliminary injunction against the accused infringer, albeit on different grounds. 1703

In contrast to the above case, the Federal Circuit accepted the accused infringer's theory of claim vitiation in Ortho-McNeil Pharmaceutical, Inc. v. Caraco Pharmaceutical, Ltd. 1704 The case turned primarily on the proper construction of the term "about 1:5" in Ortho's claim to "a pharmaceutical composition comprising certain weight ratios of the two known [analgesics], tramadol and acetaminophen." The

^{1696.} DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., 469 F.3d 1005, 1018-19, 80 U.S.P.Q.2d (BNA) 1865, 1874 (Fed. Cir. 2006).

^{19,} ou U.S.P.Q.2d (BNA) 1805, 1674 (red. Cir. 2000). 1697. 473 F.3d 1196, 81 U.S.P.Q.2d (BNA) 1289 (Fed. Cir. 2007). 1698. Id. at 1207–08, 81 U.S.P.Q.2d (BNA) at 1297. 1699. Id. at 1211, 81 U.S.P.Q.2d (BNA) at 1300–01. 1700. Id. at 1211–12, 81 U.S.P.Q.2d (BNA) at 1300–01. 1701. Id. at 1212–13, 81 U.S.P.Q.2d (BNA) at 1301.

^{1702.} *Id.* at 1213, 81 U.S.P.Q.2d (BNA) at 1301–02. 1703. *Id.*, 81 U.S.P.Q.2d (BNA) at 1302.

^{1704. 476} F.3d 1321, 81 U.S.P.Q.2d (BNA) 1427 (Fed. Cir. 2007).

^{1705.} *Id.* at 1323–24, 81 U.S.P.Q.2d (BNA) at 1428–29.

Federal Circuit affirmed the district court's interpretation of the term "about 1:5' to mean approximately 1:5, encompassing a range of ratios no greater than 1:3.6 to 1:7.1"1706 In accordance with this construction, the Federal Circuit agreed that there was no infringement under the doctrine of equivalents, for to expand the weight ratio of "about 1.5" to encompass a composition having an average weight ratio of 1:8.76 "would eviscerate the limitation." ¹⁷⁰

Claim precision and vitiation were also issues in U.S. Philips Corp. v. Iwasaki Electric Co. 1708 In particular, the district court held that the numerical ranges in the claim were expressed with "the type of precision that is closely analogous to the metes and bounds of a deed of real property." Accordingly, the district court concluded that a determination of infringement would vitiate the claim limitation and foreclose an application of the doctrine of equivalents as a matter of law. 1710

The Federal Circuit disagreed, "conclud[ing] that resort to the doctrine of equivalents [was] not foreclosed with respect to the claimed concentration range." In this respect, the court found this case indistinguishable from Warner-Jenkinson Co. v. Hilton Davis Chemical Co. 1712 or Abbott Laboratories v. Dey, L.P., 1713 wherein the Federal Circuit permitted consideration of proposed equivalents to a claimed numerical range because "the fact that a claim recites numeric ranges does not, by itself, preclude . . . [reliance] on the doctrine of equivalents."1714 The court continued:

Here, as in Abbott Labs and Warner-Jenkinson, a numeric range is claimed. The language "between x and y" of the present case has the same meaning as the phrase "x-y" of Abbott Labs. Likewise, the phrase is also essentially the same as that used in Warner-Jenkinson, with the exception of the absence of the qualifier "approximately." However, terms like "approximately" serve only to expand the scope of literal infringement, not to enable application of the doctrine of equivalents. Notably, the Supreme Court in Warner-

^{1706.} Id. at 1328, 81 U.S.P.Q.2d (BNA) at 1432.

^{1707.} *Id.* at 1329, 81 U.S.P.Q.2d (BNA) at 1433. 1708. 505 F.3d 1371, 85 U.S.P.Q.2d (BNA) 1097 (Fed. Cir. 2007).

^{1709.} *Id.* at 1378, 85 U.S.P.Q.2d (BNA) at 1102. 1710. *Id.*, 85 U.S.P.Q.2d (BNA) at 1102.

^{1711.} *Id.*, 85 U.S.P.Q.2d (BNA) at 1102. 1712. 520 U.S. 17, 32–33, 41 U.S.P.Q.2d (BNA) 1865, 1872 (1997) (allowing the court to consider the doctrine of equivalents with respect to a claim to a pH range from approximately 6.0 to 9.0).

^{1713. 287} F.3d 1097, 1107–08, 62 U.S.P.Q.2d (BNA) 1545, 1552 (Fed. Cir. 2002) (allowing consideration of a claim with a range of phospholipids content of 68.6% to 90.7%).

^{1714.} U.S. Phillips, 505 F.3d at 1378, 85 U.S.P.Q.2d (BNA) at 1102 (alteration in original) (quoting Abbott Labs., 287 F.3d at 1107-08, 62 Ù.S.P.Q.2d (BNA) at 1552).

Jenkinson did not even mention the qualifier in allowing consideration of the doctrine of equivalents.¹⁷¹

The Federal Circuit further rejected Iwasaki's argument that the doctrine of equivalents was unavailable to the patentee because Philips had included the upper concentration limit to avoid a prior art patent.¹⁷¹⁶ The court found instead that Philips had not "surrendered" anything with respect to the claims at issue because there had been no narrowing amendment to the claim at issue and thus no prosecution history estoppel.¹⁷¹⁷ The only relevant inquiry, according to the court, was "whether 'a hypothetical claim that literally recites the range of equivalents asserted to infringe . . . could have been allowed by the PTO over the prior art." The Federal Circuit concluded that such a claim could have issued because the allegedly equivalent halogen concentrations were below the ranges disclosed in the prior art; none of the prior art lamps in question met all of the limitations of the claims; and Iwasaki had not established that the prior art reference, alone or in combination with others, would have obviated the claimed lamps.¹⁷¹⁹ The court thus vacated the district court's summary judgment of non-infringement under the doctrine of equivalents. 1720

5. Section 271(e)(1)—Research exemption to infringement

In Integra Lifesciences I, Ltd. v. Merck KGaA, 1721 the Federal Circuit explored the scope of the safe harbor created by 35 U.S.C. § 271(e)(1), which exempts from infringement all uses of patented compounds "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." The Federal Circuit had originally found that the statute's safe harbor did not apply to the accused infringer's research activities, 1723 but that decision was vacated and remanded by the Supreme Court. 1724 In particu-

^{1715.} Id. at 1379, 85 U.S.P.Q.2d (BNA) at 1103.

^{1716.} *Id.* at 1379–80, 85 U.S.P.Q.2d (BNA) at 1103–04.

^{1717.} *Id.* at 1380, 85 U.S.P.Q.2d (BNA) at 1104. 1718. *Id.*, 85 U.S.P.Q.2d (BNA) at 1104 (alteration in original) (quoting *Abbott* Labs., 287 F.3d at 1105, 62 U.S.P.Q.2d (BNA) at 1551).

^{1719.} Id., 85 U.S.P.Q.2d (BNA) at 1104.

^{1720.} *Id.*, 85 U.S.P.Q.2d (BNA) at 1104.

^{1721. 496} F.3d 1334, 83 Ù.S.P.Q.2d (BNA) 1673 (Fed. Cir. 2007).

^{1722.} *Id.* at 1337, 83 U.S.P.Q.2d (BNA) at 1676 (quoting 35 U.S.C. 274(e)(1) (2000)).

^{1723.} Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 201, 74 U.S.P.Q.2d (BNA) 1801, 1805 (2005).

^{1724.} Id. at 208, 74 U.S.P.Q.2d (BNA) at 1808.

lar, the Supreme Court held that § 271(e)(1) "exempted from infringement all uses of patented compounds 'reasonably related' to the process of developing information for submission" to the FDA. 1725 "Reasonably related" may include "research . . . conducted after the biological mechanism and physiological effect of a candidate drug have been recognized, such that if the research is successful it would appropriately be included in a submission to the FDA." The FDA Exemption may also apply to experimentation on drug candidates or the use of patented compounds even if they are not ultimately submitted to the FDA, for "§ 271(e)(1)'s safe harbor leaves adequate space for experimentation and failure on the road to regulatory approval." The FDA Exemption does not apply, however, "to basic scientific research unrelated to the development of a particular drug."1728

On remand, the Federal Circuit found that all of the challenged experiments were performed after the discovery that a cyclic RGD peptide inhibited angiogenesis, and that "[a]ll of the experiments charged with infringement were conducted for the purposes of determining the optimum candidate angiogenesis inhibitor and proceeding with commercial development of the selected candidate in compliance with regulatory procedures, initially using three structurally related RGD peptides." The court added "[t]hat the experiments contributed to scientific knowledge does not deprive them of the safe-harbor benefit of § 271(e)(1) when the requirements therefor are met."1730

The court further rejected Integra's argument that Scripps's experiments were "not within the FDA Exemption because the other peptides were not the subject of an IND application." The FDA Exemption, the Supreme Court has held, applies to research on a "compound for which there was a reasonable basis for believing that it may have the desired biological property, research that 'if successful would be appropriate for FDA submission." The court also rejected Integra's argument that Scripps's experiments should be classified as "discovery" or "routine," and thus outside the FDA

^{1725.} Id. at 206, 74 U.S.P.Q.2d (BNA) at 1807.

^{1726.} Merck KGaA, 496 F.3d at 1339, 83 U.S.P.Q.2d (BNA) at 1677.

^{1727.} *Id.* at 1340, 83 U.S.P.Q.2d (BNA) at 1677 (alteration in original) (quoting *Merck KGaA*, 545 U.S. at 207, 74 U.S.P.Q.2d (BNA) at 1807).

^{1728.} Id. at 1339, 83 U.S.P.Q.2d (BNA) at 1677.

^{1729.} Id. at 1340, 83 U.S.P.Q.2d (BNA) at 1678.

^{1730.} *Id.* at 1347, 83 U.S.P.Q.2d (BNA) at 1683. 1731. *Id.* at 1340, 83 U.S.P.Q.2d (BNA) at 1678.

^{1732.} Id., 83 U.S.P.Q.2d (BNA) at 1678 (quoting Merck KGaA, 545 U.S. at 207, 74 U.S.P.Q.2d (BNA) at 1807).

Exemption. The safe harbor of § 271(e)(1) "does not depend on a distinction between 'discovery' and 'routine,' but on whether the threshold biological property and physiological effect had already been recognized as to the candidate drug."1734 The court recognized that experiments are conducted in order to gain information, no matter the phase of the research. 1735

The Federal Circuit did not address "research tools" because "the parties emphatically confirmed that research tools were not at issue."¹⁷³⁶ Although he found the majority's interpretation of § 271(e)(1) "overly expansive," Judge Rader stated in his dissent-inpart and concurrence-in-part that he would have addressed research tool patents.¹⁷³⁷ In his view,

the exemption covers activities that develop information that will ultimately be submitted to the FDA, not patented processes and tools beyond the scope of the "patented compounds" that the Supreme Court placed within the statutory exemption. In this case, two of the patents are research tools that deserve protection. This court should remand with instructions that the district court examine and protect these research tool patents. 1738

6. Design patents

There are two distinct requirements for establishing design patent infringement. The first, called the ordinary observer test, requires that "in the eye of an ordinary observer, giving such attention as a purchaser usually gives, two designs are substantially the same, if the resemblance is such as to deceive such an observer, inducing him to purchase one supposing it to be the other." The second, called the point of novelty test, requires that "no matter how similar two items look, 'the accused device must appropriate the novelty in the patented device which distinguishes it from the prior art." Both the

^{1733.} Id. at 1347, 83 U.S.P.Q.2d (BNA) at 1683.

^{1734.} *Id.*, 83 U.S.P.Q.2d (BÑA) at 1683. 1735. *Id.*, 83 U.S.P.Q.2d 1683 (citing *Merck KGaA*, 545 U.S. at 202, 74 U.S.P.Q.2d (BNA) at 1805).

^{1736.} Id. at 1348, 83 U.S.P.Q.2d (BNA) at 1683.

^{1737.} Id. at 1348-49, 83 U.S.P.Q.2d (BNA) at 1684-85 (Rader, J., concurring in part and dissenting in part).

^{1738.} *Id.* at 1348, 83 U.S.P.Q.2d (BNA) at 1684.

^{1739.} See Bernhardt, L.L.C. v. Collezione Europa USA, Inc., 386 F.3d 1371, 1383, 72 U.S.P.Q.2d (BNA) 1901, 1910 (Fed. Cir. 2004) (stating that a claim alleging design patent infringement is only successful if both the ordinary observer and point of novelty tests are satisfied).

^{1740.} Gorham Co. v. White, 81 U.S. (14 Wall.) 511, 528 (1871). 1741. Litton Sys., Inc. v. Whirlpool Corp., 728 F.2d 1423, 1444, 221 U.S.P.Q. (BNA) 97, 109 (Fed. Cir. 1984) (quoting Sears, Roebuck & Co. v. Talge, 140 F.2d 395, 396, 60 U.S.P.Q. (BNA) 434, 434 (8th Cir. 1944)).

ordinary observer and point of novelty tests are factual inquiries that are undertaken by the fact finder during the infringement stage of proceedings, after the claim has been construed by the court."1742

Because the point of novelty determination is part of the infringement analysis, the initial burden is on the patentee to "present, in some form, its contentions as to points of novelty." The point of novelty can be either a single novel design element or a combination of elements that are individually known in the prior art. 1744 The patentee is not free to set forth any combination of elements as the point of novelty; rather, the point of novelty must include features of the claimed design that distinguish it from the prior art. 1745

In Egyptian Goddess, Inc. v. Swisa, Inc., 1746 Egyptian Goddess asserted its design patent on an "ornamental nail buffer." The district court granted Swisa's motion for summary judgment of non-infringement on the ground that the Swisa nail buffers did not contain the point of novelty of the patented design, i.e., the "fourth side without a pad" required by the claims. 1748 Egyptian Goddess appealed the judgment but not the underlying claim construction. 1749

The Federal Circuit affirmed the district court's decision to limit the claimed design to a "hollow tubular frame of generally square cross section . . . with rectangular abrasive pads . . . affixed to three sides of the frame . . . with the fourth side of the frame bare." Because the parties agreed that the "Swisa buffers do not contain a fourth side without a raised pad," the Federal Circuit found that the summary judgment of non-infringement had been properly granted.¹⁷⁵¹ The court concluded that "no reasonable juror could conclude that [the patentee's] asserted point of novelty constituted a non-trivial advance over the prior art" because the difference be-

^{1742.} Bernhardt, 386 F.3d at 1383, 72 U.S.P.Q.2d (BNA) at 1910.

^{1743.} *Id.* at 1384, 72 U.S.P.Q.2d (BNA) at 1911.

^{1744.} See Lawman Armor Corp. v. Winner Int'l, LLC, 449 F.3d 1190, 1192, 79 U.S.P.Q.2d (BNA) 1382, 1382 (Fed. Cir. 2006) (supplemental opinion on petition for rehearing) (clarifying the definition of a point of novelty to include a combination of design elements in appropriate situations).

1745. See Goodyear Tire & Rubber Co., 162 F.3d

^{1113, 1118, 48} U.S.P.Q.2d (BNA) 1767, 1770 (Fed. Cir. 1998) ("The accused design must also contain substantially the same points of novelty that distinguished the patented design from the prior art."); *Litton*, 728 F.2d at 1444, 221 U.S.P.Q. (BNA) at 110 (declaring that infringement occurs when the point of novelty is not distinguishable from the prior art).
1746. 498 F.3d 1354, 84 U.S.P.Q.2d (BNA) 1046 (Fed. Cir. 2007).

^{1747.} *Id.* at 1355, 84 U.S.P.Q.2d (BNA) at 1047. 1748. *Id.* at 1356, 84 U.S.P.Q.2d (BNA) at 1048.

^{1749.} Id., 84 U.S.P.Q.2d (BNA) at 1048.

^{1750.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1047. 1751. *Id.* at 1358–59, 84 U.S.P.Q.2d (BNA) at 1049.

^{1752.} Id. at 1358, 84 U.S.P.Q.2d (BNA) at 1049.

tween the Swisa buffer and the claimed design was not minor in view of the prior art. 1753

Judge Dyk dissented. In his view, the "non-trivial advance" standard created a new rule that "eviscerates the statutory presumption of validity" because it "conflat[es] the criteria for infringement and obviousness," and thus improperly requires the patentee to affirmatively prove non-obviousness. Iudge Dyk also believed that the "nontrivial advance" test was too narrow to be applied to all designs, improperly extended a "obviousness-like test" to each point of novelty, and was "devoid of support in the case law" and "contrary" to several precedential cases. 1755

On November 27, 2007, the Federal Circuit vacated the majority opinion and granted Egyptian Goddess's petition to rehear the case en banc. 1756

In Arminak & Associates, Inc. v. Saint-Gobain Calmar, Inc., 1757 Calmar argued that the district court had construed the claims of its design patent too narrowly by adding excessive detail on the ornamental features rather than simply describing what is shown in their drawings. 1758 The Federal Circuit disagreed, finding that the court's "meticulous and accurate description . . . did not constitute error." The Federal Circuit explained, "[o]ur case law does not prohibit detailed claim construction of design patent drawings. It merely disapproves claim construction that goes beyond the novel, nonfunctional ornamental features visually represented by the claimed drawings, or that fails to encompass the claimed ornamental features of the design as a whole."1760

The Federal Circuit also affirmed the district court's finding that an "ordinary observer" was a "contract or industrial buyer for companies that purchase the stand-alone trigger sprayer devices, not the retail purchasers of the finished product," as Calmar had argued. 1761 This marked the first time that the court had "squarely addressed" this "unanswered question remaining after Gorham." 1762 Ordinary ob-

^{1753.} Id., 84 U.S.P.Q.2d (BNA) at 1049.

^{1754.} *Id.* at 1359, 84 U.S.P.Q.2d (BNA) at 1050 (Dyk, J., dissenting). 1755. *Id.* at 1359–60, 84 U.S.P.Q.2d (BNA) at 1050–51.

^{1756.} Egyptian Goddess, Inc. v. Swisa, Inc., No. 2006-1562, 2007 WL 4179111 (Fed. Cir. Nov. 26, 2007).

^{1757. 501} F.3d 1314, 84 U.S.P.Q.2d (BNA) 1258 (Fed. Cir. 2007).

^{1758.} Id. at 1319, 84 U.S.P.Q.2d (BNA) at 1261.

^{1759.} *Id.* at 1321, 84 U.S.P.Q.2d (BNA) at 1262.

^{1760.} Id., 84 U.S.P.Q.2d (BNA) at 1262 (citation omitted).

^{1761.} Id. at 1324, 84 U.S.P.Q.2d (BNA) at 1264.

^{1762.} Id. at 1322, 84 U.S.P.O.2d (BNA) at 1263 (discussing Gorham Co. v. White, 81 U.S. (14 Wall.) 511, 528 (1871)).

servers, the court noted, are typically "those who buy and use . . . the actual product that is presented for purchase," even if it is but a component of an assembled product. ¹⁷⁶³ In this case, the record showed that Calmar had never sold any of its patented shrouds directly to retail customers but to contract buyers or industrial purchasers who assembled the final product. ¹⁷⁶⁴ The court then stated the following:

To hold that such a purchaser is the appropriate hypothetical ordinary observer fits squarely with our precedent that the ordinary observer is a person who is either a purchaser of, or sufficiently interested in, the item that displays the patented designs and who has the capability of making a reasonably discerning decision when observing the accused item's design whether the accused item is substantially the same as the item claimed in the design patent. ¹⁷⁶⁵

Since the evidence showed that a contract or industrial purchaser would not be deceived into thinking that Arminak's accused shroud was one of the patented designs, there was no infringement.¹⁷⁶⁶

The Federal Circuit also determined no infringement under the "point of novelty" test because the Arminak products did not appropriate the "prominent horizontal line" or "bulge outwardly in a bulbous fashion" features of the Calmar patents. ¹⁷⁶⁷ In so holding, the court found that the district court had not improperly merged the point of novelty test and the ordinary observer test, and had properly compared the accused design to "the design feature, as it appears in the Figures of the patent as issued," and not to the patentee's own description of its patents. ¹⁷⁶⁸

V. INEQUITABLE CONDUCT

The Federal Circuit recently stated in *Cargill, Inc. v. Canbra Foods, Ltd.*¹⁷⁶⁹ that "[t]o hold a patent unenforceable due to inequitable conduct, there must be clear and convincing evidence that the applicant (1) made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information, and (2) intended to deceive the U.S. Patent and Trademark Office ("PTO")."

The court further added that the materiality element of inequitable conduct may be satisfied by "the standard for materiality set forth

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1763. Id., 84 U.S.P.Q.2d (BNA) at 1263 (quoting Gorham, 81 U.S. at 527). 1764. Id. at 1321, 84 U.S.P.Q.2d (BNA) at 1262. 1765. Id. at 1323, 84 U.S.P.Q.2d (BNA) at 1264. 1766. Id. at 1324, 84 U.S.P.Q.2d (BNA) at 1264. 1767. Id. at 1325, 84 U.S.P.Q.2d (BNA) at 1265. 1768. Id. at 1327, 84 U.S.P.Q.2d (BNA) at 1267.
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^{1769. 476} F.3d 1359, 81 U.S.P.Q.2d (BNA) 1705 (Fed. Cir. 2007).

^{1770.} Id. at 1363, 81 U.S.P.Q.2d (BNA) at 1708.

in the current version of PTO Rule 56 . . . [or] the earlier 'reasonable examiner' standard." The intent element of inequitable conduct requires that 'the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive." Intent to deceive in certain instances is "inferred from the facts and circumstances surrounding the conduct at issue."1773

The court continued, stating that "[i]f a district court finds that the requirements of materiality and intent have been established by clear and convincing evidence, it must then 'balance the equities to determine whether the patentee has committed inequitable conduct that warrants holding the patent unenforceable." Accordingly, "[u]nder the balancing test, '[t]he more material the omission or the misrepresentation, the lower the level of intent required to establish inequitable conduct, and vice versa." 1775

The Federal Circuit reviews "the district court's findings on the threshold issues of materiality and intent for clear error." By contrast, "the ultimate decision regarding inequitable conduct [is re-

1771. Id. at 1364, 81 U.S.P.Q.2d (BNA) at 1708. The pertinent part of the current version of Rule 56 states as follows:

[I]nformation 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 an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

37 C.F.R. § 1.56(b) (2006). The earlier reasonable examiner standard states that "information is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent." *Cargill*, 476 F.3d at 1364, 81 U.S.P.Q.2d (BNA) at 1708 (quoting 37 C.F.R. § 1.56(a) (1991)).

1772. *Cargill*, 476 F.3d at 1364, 81 U.S.P.Q.2d (BNA) at 1708 (quoting Impax Labs., Inc. v. Aventis Pharm., Inc., 468 F.3d 1366, 1374-75, 81 U.S.P.Q.2d (BNA) 1001, 1007 (Fed. Cir. 2006)).

1773. Id., 81 U.S.P.Q.2d (BNA) at 1708.

1774. *Id.*, 81 U.S.P.Q.2d (BNA) at 1708 (citations omitted).

1775. Id., 81 U.S.P.Q.2d (BNA) at 1708 (quoting Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1256, 43 U.S.P.Q.2d (BNA) 1666, 1668 (Fed.

1776. Id., 81 U.S.P.Q.2d (BNA) at 1708.

viewed] for abuse of discretion."1777 The court will find abuse of discretion "when (1) the court's decision is clearly unreasonable, arbitrary, or fanciful, (2) the court's decision is based on an erroneous construction of the law, (3) the court's factual findings are clearly erroneous, or (4) the record contains no evidence upon which the court rationally could have based its decision."1778

In Dippin' Dots, Inc. v. Mosey, 1779 the Federal Circuit affirmed the district court's judgment of inequitable conduct. The court relied on the "reasonable examiner" standard in determining that the applicant's failure to disclose sales more than a year prior to the filing of the patent application was material, because the reasonable examiner would have considered the sales important in determining whether to allow the application.¹⁷⁸¹ Combining the omission of disclosure of sales prior to the critical date with the applicant's touting of postcritical sales as evidence of commercial success to overcome an obviousness rejection provided justification for an inference of deceptive intent required for a finding of inequitable conduct. 1782

In Cargill Inc. v. Canbra Foods Ltd., 1783 discussed above, the Federal Circuit affirmed the district court's judgment that two related patents were unenforceable due to inequitable conduct.¹⁷⁸⁴ The district court found that two documents, which contained the applicant's internal testing data but were not disclosed to the examiner during prosecution, "unquestionably would have been viewed as worthy of serious consideration by the PTO."1785 The Federal Circuit determined that the district court's finding effectively applied the "reasonable examiner" standard for materiality because the undisclosed documents contained data on a "crucial issue during prosecution" and were contrary to assertions made by applicants to the Patent Office about a claimed feature (i.e., the oxidative stability) of the claimed invention. 1786 The Federal Circuit found that "[a] reasonable examiner would certainly want to consider test data that is directly related to an important issue of patentability, along with the applicant's interpretation of that data," and thus held that the district court's determina-

^{1777.} Id. at 1365, 81 U.S.P.Q.2d (BNA) at 1709.

^{1778.} *Id.*, 81 U.S.P.Q.2d (BNA) at 1709 (quoting Impax Labs., Inc. v. Aventis Pharm., Inc., 468 F.3d 1366, 1375, 81 U.S.P.Q.2d (BNA) 1001, 1007 (Fed. Cir.

^{1779. 476} F.3d 1337, 81 U.S.P.Q.2d (BNA) 1633 (Fed. Cir. 2007). 1780. *Id.* at 1346, 81 U.S.P.Q.2d (BNA) at 1642.

^{1781.} Id. at 1345, 81 U.S.P.Q.2d (BNA) at 1639.

^{1782.} *Id.* at 1346, 81 U.S.P.Q.2d (BNA) at 1639-40.

^{1783.} Cargill, 476 F.3d 1359, 81 U.S.P.Q.2d (BNA) 1705.

^{1784.} Id. at 1362, 81 U.S.P.Q.2d (BNA) at 1706.

^{1785.} Id. at 1365, 81 U.S.P.Q.2d (BNA) at 1709.

^{1786.} Id., 81 U.S.P.Q.2d (BNA) at 1709.

tion regarding the materiality of the undisclosed documents was not clearly erroneous. 1787

The Federal Circuit also affirmed the district court's finding of an intent to deceive, based on three circumstantial factors: (1) the applicant's repeated omission of the data, (2) the applicant's "specific motive to conceal the two specific documents," and (3) "the high degree of materiality of the undisclosed test data." The Federal Circuit found that each of the examiner's five rejections involved the issue of the oxidative stability of the applicant's claimed composition, and thus "[t]he repeated nature of that rejection demonstrates that the applicant should have been aware of the materiality of the omitted test data." 1789 Relying on Critikon, Inc. v. Beacton Dickinson Vascular Access Inc., 1790 the Federal Circuit held that "[s]uch a high degree of materiality, coupled with evidence that applicant should have known of that materiality, creates a strong inference of an intent to deceive."1791

With respect to the ultimate issue of inequitable conduct, the Federal Circuit affirmed the district court's judgment of unenforceability, finding it within the district court's discretion to weigh its findings of materiality and intent against the reasons offered for withholding the highly material test data to determine that the rationale for withholding the test data did not overcome the weight of the evidence proving inequitable conduct. 1792

The Federal Circuit also affirmed the district court's judgment of inequitable conduct in eSpeed, Inc. v. Brokertec USA, LLC. First, the Federal Circuit found that the district court had not clearly erred in concluding that the false statements in the declarations the applicants had submitted to the PTO were material. 1794 Second, the Federal Circuit, relying on Rohm & Hass v. Crystal Chemical Co., 1795 affirmed the district court's finding of an intent to deceive, stating "[t]he district court was free to draw an inference that these declarations were 'the chosen instrument of an intentional scheme to de-

^{1787.} Id. at 1366, 81 U.S.P.Q.2d (BNA) at 1710.

^{1788.} *Id.* at 1366–68, 81 U.S.P.Q.2d (BNA) at 1710–11.

^{1789.} *Id.* at 1366, 81 U.S.P.Q.2d (BNA) at 1710. 1790. 120 F.3d 1253, 43 U.S.P.Q.2d (BNA) 1666 (Fed. Cir. 1997).

^{1791.} Cargill, 476 F.3d at 1367, 81 U.S.P.Q.2d (BNA) at 1711.

^{1792.} *Id.* at 1368, 81 U.S.P.Q.2d (BNA) at 1711. 1793. 480 F.3d 1129, 1139, 82 U.S.P.Q.2d (BNA) 1183, 1190 (Fed. Cir. 2007).

^{1794.} Id. at 1137, 82 U.S.P.Q.2d (BNA) at 1189.

^{1795. 722} F.2d 1556, 220 U.S.P.Q. (BNA) 289 (Fed. Cir. 1983).

ceive the PTO,' because '[t]he affirmative act of submitting an affidavit must be construed as intended to be relied upon."1796

In In re Omeprazole Patent Litigation, 1797 the Federal Circuit affirmed the district court's conclusion that Andrx's counterclaims were moot, that there was no inequitable conduct, fraud, or unclean hands in Astra's prosecution of one patent, and that Astra's two related patents were not unenforceable through "infectious unenforceability." In particular, when the district court found that the asserted claims of the last patent at issue were invalid as anticipated, the court properly declined to consider defendant Andrx's related inequitable conduct and fraud defenses.¹⁷⁹⁹ "The district court did consider Andrx's 'unclean hands' argument, but found no evidence to support a finding of 'unclean hands.'"1800

In McKesson Information Solutions, Inc. v. Bridge Medical, Inc., 1801 the Federal Circuit affirmed the district court's judgment that the '716 patent at issue (U.S. Patent No. 4,857,716) was unenforceable due to McKesson's failure to disclose three items of information during prosecution. 1802 The facts in McKesson are complex and only briefly described here.

First, the Federal Circuit found no clear error in the district court's finding of inequitable conduct due to the non-disclosure of the socalled Baker patent (U.S. Patent No. 4,456,793), a prior art reference upon which a patent examiner had relied in rejecting claims of a copending patent application being prosecuted by the same prosecuting attorney. 1803 The Federal Circuit agreed that the Baker patent was material to the prosecution of the '716 patent because the '716 patent contained the same limitations that had been rejected in the copending application over Baker. 1804 In so holding, the Federal Circuit rejected McKesson's argument that Baker was not material because similar subject matter had been disclosed in other references cited in the '716 patent's application. The court found instead that "the importance of Baker" was not limited to one particular limitation but "could be material quite apart from the disclosure of anything analo-

^{1796.} eSpeed, 480 F.3d at 1138, 82 U.S.P.Q.2d (BNA) at 1190 (citations omitted).

^{1797. 483} F.3d 1364, 82 U.S.P.Q.2d (BNA) 1643 (Fed. Cir. 2007).

^{1798.} *Id.* at 1376, 82 U.S.P.Q.2d (BNA) at 1653. 1799. *Id.*, 82 U.S.P.Q.2d (BNA) at 1652–53.

^{1800.} *Id.* at 1374, 82 U.S.P.Q.2d (BNA) at 1651. 1801. 487 F.3d 897, 82 U.S.P.Q.2d (BNA) 1865 (Fed. Cir. 2007).

^{1802.} *Id.* at 926, 82 U.S.P.Q.2d (BNA) at 1886.

^{1803.} *Id.* at 919, 82 U.S.P.Q.2d (BNA) at 1880. 1804. *Id.* at 909, 82 U.S.P.Q.2d (BNA) at 1873.

^{1805.} Id. at 916, 82 U.S.P.Q.2d (BNA) at 1878.

gous to [that] unique identifier limitation." In addition, "the existence of differences between Baker and the '716 claims does not, standing alone, render Baker immaterial." The court concluded that, "[a]s the district court held, the overwhelming circumstantial evidence, coupled with the lack of any credible explanation for nondisclosure of Baker, supports the finding of deceptive intent." ¹⁸⁰⁸

The Federal Circuit also affirmed that inequitable conduct arose from the prosecuting attorney's failure to disclose the first examiner's rejections of the co-pending application, which contained similar subject matter and limitations as the '716 patent at issue. 1809 The district court had not erred, the Federal Circuit found, by considering whether the claims between the two applications were "in some respects identical," as opposed to "substantially similar,' and substantial similarity 'in content and scope.'" According to the court, "materiality may be proven in numerous ways," and "to the extent there is a difference among 'in some respects identical,' 'substantially similar,' and substantial similarity 'in content and scope,' that difference is inconsequential so long as the evidence clearly and convincingly proves materiality in one of the accepted ways." 1811 On that basis, the Federal Circuit found no clear error in the district court's finding that the first examiner's rejections in the first application were material to the second application. 1812

The Federal Circuit also rejected as "untenable" McKesson's argument that the prosecuting attorney had acted in good faith by twice disclosing the co-pending application during prosecution of the '716 patent.¹⁸¹³ According to the Federal Circuit, the MPEP in the mid-1980s broadly defined the duty of disclosure to include material information obtained from co-pending applications, which left "no doubt that material rejections in co-pending applications fall squarely within the duty of candor." The Federal Circuit concluded that the district court had not clearly erred in finding that the prosecuting attorney intended to deceive the PTO by not disclosing the first exam-

^{1806.} Id. at 914, 82 U.S.P.Q.2d (BNA) at 1876.

^{1800.} Id. at 914, 82 U.S.P.Q.2d (BNA) at 1878. 1807. Id. at 915, 82 U.S.P.Q.2d (BNA) at 1878. 1808. Id. at 919, 82 U.S.P.Q.2d (BNA) at 1880. 1809. Id. at 901, 908, 911, 82 U.S.P.Q.2d (BNA) at 1867, 1872, 1875.

^{1810.} Id. at 920, 82 U.S.P.Q.2d (BNA) at 1881.

^{1811.} *Id.* at 919–20, 82 U.S.P.Q.2d (BNA) at 1881. 1812. *Id.* at 926, 82 U.S.P.Q.2d (BNA) at 1886.

^{1813.} *Id.* at 922, 924–25, 82 U.S.P.Q.2d (BNA) at 1883, 1885.

^{1814.} *Id.* at 923, 925, 82 U.S.P.Q.2d (BNA) at 1884–85.

iner's rejections of the co-pending application during prosecution of the '716 patent.1815

The Federal Circuit also found inequitable conduct based on the prosecuting attorney's failure to disclose a notice of allowance of a third co-pending application, which ultimately issued as the '372 patent (U.S. Patent No. 4,835,372). In so holding, the court rejected McKesson's argument that inequitable conduct required a "substantial likelihood" that the examiner would have issued a doublepatenting rejection in view of the allowance of the '372 patent.¹⁸¹⁷ Rather, materiality could be found where the allowance of the '372 patent "plainly [gave] rise to a conceivable double patenting rejection." "Material information," the court explained, "is not limited to information that would invalidate the claims under examination" but includes information a reasonable examiner would have considered important, whether or not the information would have conclusively decided the issue of patentability.¹⁸¹⁹ The fact that the same examiner had examined both of the applications in question, and that the prosecuting attorney had informed the examiner of the two applications, did not alter this result, where the prosecuting attorney testified that the identity of the examiner had not been a factor in his decisions and materiality rested on other grounds. 1820 Consequently, the Federal Circuit concluded that there was no clear error in the district court's findings on materiality or deceptive intent, and hence affirmed the district court's judgment that the '716 patent was unenforceable due to inequitable conduct before the PTO. 1821

Judge Newman dissented from this result, finding that the facts did not rise to the level of clear and convincing evidence of deceptive intent, as opposed to a mere mistake, particularly where the applicant had informed the examiner of the co-pending applications and the same examiner had been involved in the prosecution of two of the applications. 1822 "This court," she warned, "returns to the 'plague' of encouraging unwarranted charges of inequitable conduct, spawning the opportunistic litigation that here succeeded despite consistently contrary precedent." ¹⁸²³

^{1815.} *Id.* at 924–25, 82 U.S.P.Q.2d (BNA) at 1885. 1816. *Id.* at 925–26, 82 U.S.P.Q.2d (BNA) at 1885–86.

^{1817.} *Id.* at 925, 82 U.S.P.Q.2d (BNA) at 1885.

^{1818.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1885. 1819. *Id.*, 82 U.S.P.Q.2d (BNA) at 1885.

^{1820.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1885. 1821. *Id.* at 926, 82 U.S.P.Q.2d (BNA) at 1886. 1822. *Id.* at 926–27, 82 U.S.P.Q.2d (BNA) at 1886 (Newman, J., dissenting).

^{1823.} Id., 82 U.S.P.Q.2d (BNA) at 1886.

In In re Metoprolol Succinate Patent Litigation, 1824 the Federal Circuit vacated the district court's finding of inequitable conduct because it had erroneously equated an incentive to deceive with an intent to deceive on summary judgment. 1825 In particular, the district court had found "that Astra's motivation to not reveal the [inventorship] dispute was great based on the risk of losing its [claims] ... as anticipated by the prior art," and thus concluded on summary judgment that "[t]he intent to deceive [was] clearly present." The Federal Circuit, however, found a genuine issue of material fact as to whether Astra had intended to deceive the PTO because Astra's in-house patent counsel testified in his deposition that he "did not know of and was not concerned about the incentives identified by the district court in its but for analysis."1827

In Nilssen v. Osram Sylvania, Inc., 1828 the Federal Circuit affirmed the district court's judgment that fifteen patents prosecuted pro se by the inventor were unenforceable due to inequitable conduct. 1829 In particular, the court agreed that the applicant had: (1) submitted affidavits in support of patentability without informing the examiner of the affiant's relationship to the inventor, (2) misrepresented small entity status to justify small entity payments, (3) misclaimed priority dates, (4) failed to disclose relevant litigation, and (5) failed to disclose material prior art. 1830 Regarding the applicant's misrepresentation of priority dates, the court relied on Digital Control, Inc. v. Charles Machine Works 1831 for the proposition that "a misrepresentation that would not have immediately affected the patentability is still material."1832 The Federal Circuit then held 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."1833

In Apotex Corp. v. Merck & Co., 1834 the Federal Circuit affirmed summary judgment that Merck had not committed fraud on the court or made false statements or misrepresentations in an earlier district

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1824. 494 F.3d 1011, 83 U.S.P.Q.2d (BNA) 1545 (Fed. Cir. 2007).
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^{1825.} *Id.* at 1013, 83 U.S.P.Q.2d (BNA) at 1556. 1826. *Id.* at 1020, 83 U.S.P.Q.2d (BNA) at 1551.

^{1827.} Id. at 1020, 63 U.S.F.Q.2d (BNA) at 1331.
1827. Id. at 1021, 83 U.S.P.Q.2d (BNA) at 1551.
1828. 504 F.3d 1223, 84 U.S.P.Q.2d (BNA) 1811 (Fed. Cir. 2007).
1829. Id. at 1229, 1235–36, 84 U.S.P.Q.2d (BNA) at 1815, 1820.
1830. Id. at 1229–36, 84 U.S.P.Q.2d (BNA) at 1815–20.
1831. 437 F.3d 1309, 1318, 77 U.S.P.Q.2d (BNA) 1823, 1830 (Fed. Cir. 2006).

^{1832.} Nilssen, 504 F.3d at 1233, 84 U.S.P.Q.2d (BNA) at 1818 (citing Digital Control, 437 F.3d at 1318, 77 U.S.P.Q.2d (BNA) at 1830).

^{1833.} Id., 84 U.S.P.Q.2d (BNA) at 1818.

^{1834. 507} F.3d 1357, 85 Ù.S.P.Q.2d (BNA) 1302 (Fed. Cir. 2007).

court case such as to warrant reopening that litigation. 1835 The allegations stemmed from the district court's ruling that the Apotex patents at issue were invalid under 35 U.S.C. § 102(g) because Merck had invented and been using the claimed process before Apotex had made the claimed invention. The Federal Circuit affirmed this ruling. 1837 Apotex subsequently alleged that Merck had obtained these invalidity rulings by fraud, e.g., by leaving out the type of mixing equipment, duration of mixing, and other key details of its process of making the drug at issue during a videotaped deposition in a Canadian litigation and making other misrepresentations and misstatements of material fact. 1838 The district court rejected Apotex's arguments as attorney argument, unsupported by factual testimony or evidence. 1839

The Federal Circuit unanimously affirmed. 1840 "We agree that Merck's processing details, which are not asserted to be invented by Apotex, did not warrant detailed disclosure, and that the presentation of the Merck process did not establish fraud on the court," the court explained. 1841 The Federal Circuit further noted, "Fraud upon the court requires that there was a material subversion of the legal process . . . [and] it requires rigorous proof, as do other challenges to final judgment, lest the finality established by Rule 60(b) be overwhelmed by continuing attacks on the judgment."1842 In addition, the court found that Merck's omission of certain process details was immaterial, in that those details were not a part of Apotex's patented process. 1843

VI. REMEDIES

A. Permanent Injunction

Historically, permanent injunctions have been a standard part of patent cases that result in final judgments of infringement and no in-

^{1835.} Id. at 1361-62, 85 U.S.P.Q.2d (BNA) at 1305-06.

^{1836.} *Id.* at 1359, 85 U.S.P.Q.2d (BNA) at 1303. 1837. Apotex USA, Inc. v. Merck & Co., 254 F.3d 1031, 59 U.S.P.Q.2d (BNA) 1139 (Fed. Cir. 2001).

^{1838.} Apotex Corp., 507 F.3d at 1362, 85 U.S.P.Q.2d (BNA) at 1305.

^{1839.} Id. at 1360, 85 U.S.P.Q.2d (BNA) at 1304.
1840. Id. at 1362, 85 U.S.P.Q.2d (BNA) at 1306.
1841. Id., 85 U.S.P.Q.2d (BNA) at 1305–06.
1842. Id. at 1360–61, 85 U.S.P.Q.2d (BNA) at 1304–05 (citing Broyhill Furniture Indus. v. Craftmaster Furniture Corp., 12 F.3d 1080, 1085, 29 U.S.P.Q.2d (BNA) 1283, 1287 (Fed. Cir. 1993)).

^{1843.} Id. at 1362, 85 U.S.P.Q.2d (BNA) at 1305.

validity. 1844 The Federal Circuit applied a "general rule that courts will issue permanent injunctions against patent infringement absent exceptional circumstances." In 2006, the U.S. Supreme Court reversed this "general rule." In particular, in eBay Inc. v. MercExchange, L.L.C., 1847 the Court stated that the principles of equity "apply with equal force to disputes arising under the Patent Act." The Court recognized, "a major departure from the long tradition of equity practice should not be lightly implied. Nothing in the Patent Act indicates that Congress intended such a departure. To the contrary, the Patent Act expressly provides that injunctions 'may' issue 'in accordance with the principles of equity." 1849

The Court stated as follows:

[A] plaintiff seeking a permanent injunction must satisfy a fourfactor test before a court may grant such relief. A plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.¹⁸

In Forest Laboratories, Inc. v. Ivax Pharmaceuticals, Inc., 1851 the Federal Circuit affirmed the district court's entry of a permanent injunction against co-defendants Ivax and Cipla but narrowed it to cover only the pharmaceutical product (escitalopram oxalate, or "EO") that was the subject of the Ivax abbreviated new drug application ("ANDA"), which had given rise to the infringement suit. 1852 The original language of the injunction "extending to 'any products that infringe the '712 patent" was overly broad because a court could enjoin infringement of the patent by an adjudicated product, or colorable variations thereof. 1853 Thus, the injunction could not extend to any

^{1844.} See, e.g., Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1247, 9 U.S.P.Q.2d (BNA) 1913, 1929 (Fed. Cir. 1989) (confirming the existence of a long standing general rule in favor of issuing an injunction upon a finding of infringement).

^{1845.} MercExchange, L.L.C. v. eBay, Inc., 401 F.3d 1323, 1339, 74 U.S.P.Q.2d (BNA) 1225, 1238 (Fed. Cir. 2005), *rev'd*, 126 S. Ct. 1837, 78 U.S.P.Q.2d (BNA) 1577 (2006).

^{1846.} eBay Inc. v. MercExchange, L.L.C., 126 S. Ct. 1837, 78 U.S.P.Q.2d (BNA) 1577 (2006).

^{1847.} Id. at 1837, 78 U.S.P.Q.2d (BNA) 1577.

^{1848.} Id. at 1839, 78 U.S.P.Q.2d (BNA) at 1579.

^{1849.} *Id.*, 78 U.S.P.Q.2d (BNA) at 1579 (citations omitted).

^{1850.} *Id.*, 78 U.S.P.Q.2d (BNA) at 1579. 1851. 501 F.3d 1263, 84 U.S.P.Q.2d (BNA) 1099 (Fed. Cir. 2007). 1852. *Id.* at 1271–72, 84 U.S.P.Q.2d (BNA) at 1106.

^{1853.} Id. at 1271, 84 U.S.P.Q.2d (BNA) at 1106.

drug that was not the subject of the ANDA, even if that drug were within the scope of the '712 patent.1854

At the same time, the Federal Circuit affirmed the inclusion of codefendant Cipla in the injunction. 1855 Cipla had been providing information and material that Ivax was using to obtain FDA approval, and was actively inducing Ivax's direct infringement by planning "to manufacture and sell infringing EO products to Ivax for resale in the United States." Even though there was no infringement as long as Ivax was pursuing FDA approval, Ivax would be liable for, and hence could be enjoined from, commercial exploitation of EO once it was approved by the FDA. 1857 Thus, Cipla could also be enjoined because "[t]hey are partners." Judge Schall dissented from this portion of the opinion because Cipla did not file the ANDA and only provided information protected by 35 U.S.C. § 271(e)(1); thus, its actions did not trigger a cause of action under § 271(e)(2). 1859

The permanent injunction in Cross Medical Products, Inc. v. Medtronic Sofamor Danek, Inc. 1860 raised unique jurisdictional issues for the court to consider. Medtronic argued that the Federal Circuit did not have jurisdiction to consider arguments related to a permanent injunction that Cross Medical did not present on cross-appeal. 1861 Cross Medical responded that the court may consider arguments as an "alternative" basis for supporting the court's permanent injunction. 1862 The Federal Circuit found, "[o]n the jurisdictional inquiry, this court need not consider whether the district court could have issued the second permanent injunction on some other grounds. Rather, this court reviews the district court's judgment with an eye to whether an alternative basis might support that decision." ¹⁸⁶³ In light of the court's finding that there were genuine issues of material fact regarding infringement, the court declined to consider the merits of the arguments and vacated and remanded the district court's summary judgment for further proceedings. 1864

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1854. Id., 84 U.S.P.Q.2d (BNA) at 1106.
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^{1855.} *Id.* at 1272, 84 U.S.P.Q.2d (BNA) at 1106.

^{1856.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1106. 1857. *Id.*, 84 U.S.P.Q.2d (BNA) at 1106.

^{1858.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1105–06.

^{1859.} *Id.* at 1274, 84 U.S.P.Q.2d (BNA) at 1108 (Schall, J., dissenting). 1860. 480 F.3d 1335, 82 U.S.P.Q.2d (BNA) 1065 (Fed. Cir. 2007) (per curiam).

^{1861.} *Id.* at 1345, 82 U.S.P.Q.2d (BNA) at 1072.

^{1862.} Id., 82 U.S.P.Q.2d (BNA) at 1072.

^{1863.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1073 (citing Laitram Corp. v. NEC Corp., 115 F.3d 947, 954, 42 U.S.P.Q.2d (BNA) 1897, 1903 (Fed. Cir. 1997)).

^{1864.} *Id.* at 1345–46, 82 U.S.P.Q.2d (BNA) at 1073.

In Acumed LLC v. Stryker Corp., 1865 the Federal Circuit vacated a permanent injunction because the district court had relied on an outdated rule "that an injunction will issue, once infringement and validity have been adjudged . . . unless there are some exceptional circumstances that justify denying injunctive relief." That rule has since been replaced by the traditional four-factor test for injunctions in eBay Inc. v. MercExchange, L.L.C. The Federal Circuit declined to determine whether the "facts found by the district court [could] serve as independent support for the injunction," even under the new rule, because the court "would effectively be exercising [its] own discretion as if [it] were the first-line court of equity. That role belongs exclusively to the district court."1868

In Abbott Laboratories v. TorPharm, Inc., 1869 the Federal Circuit affirmed that a district court has jurisdiction to entertain a contempt proceeding to enforce a permanent injunction, even though it reversed the district court on the merits. 1870 The district court had enjoined co-defendant Apotex from "commercially manufacturing, using, selling, offering to sell, or importing into the United States" a generic anti-seizure medication after finding that Apotex's filing of an ANDA infringed two of Abbott's patents. 1871 While Apotex attempted to design around the Abbott patents, it arranged for Nu-Pharm to file a new ANDA and assume the "litigation risks" in exchange for Apotex's payment of the costs. 1872 The district court found no colorable difference between the Apotex and Nu-Pharm drug products and held Apotex in contempt for violating the injunction. 1873 The Federal Circuit held that even though the Hatch-Waxman Act does not specifically grant a district court jurisdiction to pursue a contempt proceeding, filing an ANDA is an act of infringement and is therefore subject to the same discretionary authority of the district court to entertain contempt proceedings as in any other case of patent infringement.¹⁸⁷⁴ The Federal Circuit concluded that the district court did not abuse its discretion in holding contempt proceedings

1865. 483 F.3d 800, 82 U.S.P.Q.2d (BNA) 1481 (Fed. Cir. 2007).

^{1866.} *Id.* at 811, 82 U.S.P.Q.2d (BNA) at 1489. 1867. 126 S. Ct. 1837, 1839, 78 U.S.P.Q.2d (BNA) 1577, 1579 (2006). 1868. *Acumed*, 483 F.3d at 811, 82 U.S.P.Q.2d (BNA) at 1489. 1869. 503 F.3d 1372, 84 U.S.P.Q.2d (BNA) 1829 (Fed. Cir. 2007).

^{1870.} *Id.* at 1375–76, 84 U.S.P.Q.2d (BNA) at 1831.

^{1871.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1831. 1872. *Id.* at 1377, 84 U.S.P.Q.2d (BNA) at 1832.

^{1873.} Id. at 1377–78, 84 U.S.P.Q.2d (BNA) at 1833.

^{1874.} *Id.* at 1378–79, 84 U.S.P.Q.2d (BNA) at 1833–34.

and expanding its injunction to prohibit the FDA from approving not only the original Apotex ANDA but the Nu-Pharm ANDA as well. 1875

Nonetheless, the Federal Circuit reversed the district court's finding of contempt. 1876 Apotex's efforts to design around the drug occurred entirely outside the United States, and thus did not violate the injunction's prohibition on making, using, selling, offering to sell, or importing the generic drug into the United States before the Abbott patents expired. 1877 The injunction also contained no "explicit notice" to Apotex that filing a new ANDA, whether by itself or through a "straw party," was forbidden. 1878

Judge Dyk dissented from this portion of the opinion, finding that the majority's conclusion raised a "fair ground of doubt as to the wrongfulness" of Apotex's conduct, which should have rendered the summary contempt proceedings inappropriate in the first place.¹⁸⁷⁹ He argued that the finding of infringement should have been vacated and remanded for further consideration. 1880

B. Preliminary Injunction

Unlike a permanent injunction, a preliminary injunction is entered before trial to protect the rights of parties while an infringement trial is pending. 1881 Preliminary injunctions are rarely granted and require a consideration of four factors, none of which is dispositive: (1) probability of success on the merits, (2) harm to the moving party if the injunction is not granted, (3) the balance of hardships, and (4) the impact of the injunction on the public interest. 1882

In Monsanto Co. v. McFarling, 1883 the district court enjoined a farmer from infringing a Monsanto patent by saving and replanting genetically modified soybean seeds in subsequent years, in violation of his license agreement with Monsanto. 1884 The injunction, however, allowed the farmer to "plant Roundup Ready soybeans acquired from any lawful dealer, but to do so [the farmer] must sign any applicable

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1875. Id. at 1381, 84 U.S.P.Q.2d (BNA) at 1835.
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^{1876.} *Id.* at 1383, 84 U.S.P.Q.2d (BNA) at 1837. 1877. *Id.* at 1382, 84 U.S.P.Q.2d (BNA) at 1836.

^{1878.} *Id.* at 1383, 84 U.S.P.Q.2d (BNA) at 1837. 1879. *Id.*, 84 U.S.P.Q.2d (BNA) at 1837 (Dyk, J., dissenting). 1880. *Id.* at 1385, 84 U.S.P.Q.2d (BNA) at 1838.

^{1881.} See, e.g., Cordis Corp. v. Medtronic, Inc., 835 F.2d 859, 863, 5 U.S.P.Q.2d (BNA) 1118, 1121 (Fed. Cir. 1987) ("The purpose of an interlocutory injunction is to preserve the status quo and to protect the respective rights of the parties pending a determination on the merits.")

^{1882.} Nutrition 21 v. United States, 930 F.2d 867, 869, 18 U.S.P.Q.2d (BNA) 1347, 1348-49 (Fed. Cir. 1991).

^{1883. 488} F.3d 973, 82 U.S.P.Q.2d (BNA) 1942 (Fed. Cir. 2007).

^{1884.} Id. at 976, 82 U.S.P.Q.2d (BNA) at 1943-44.

technology agreement required by Monsanto." Monsanto objected to the clause allowing the farmer to buy the seeds from a lawful dealer, but the Federal Circuit found it was up to Monsanto to ensure that its dealers did not sell the seeds against its wishes. 1886

GP Industries, Inc. v. Eran Industries, Inc. 1887 involved a rare form of an injunction against communications. 1888 After Eran Industries fired several employees, they formed a competing company, GP Industries, Inc. 1889 Eran sent letters to its distributors and contractors warning them not to buy a GP product that Eran alleged infringed its patent. 1890 On GP's complaint, the district court granted a preliminary injunction enjoining Eran from sending such letters due to its tortious interference with GP's business relationships. ¹⁸⁹¹ In addition, the district court found "that Eran's accusations were made in disregard of the truth or falsity of the purported infringement" because Eran had not examined any product actually sold or distributed by GP or made any effort to determine whether the GP prototype it had examined was on the market. 1892 The court also reasoned that Eran had an adequate remedy if GP were found to have infringed the patent.¹⁸⁹³

The Federal Circuit reversed the grant of a preliminary injunction as an abuse of discretion. ¹⁸⁹⁴ Injunctions against communicating with others about one's patent rights are rare, the court explained, because they are much more serious than injunctions against infringement. 1895 "One has a right to inform others of his or her patent rights. Thus, an injunction against communication is strong medicine that must be used with care and only in exceptional circumstances."1896

The Federal Circuit also found that Eran's conduct did not reach the "objectively baseless" threshold for bad faith required by Globetrot-

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1885. Id. at 981, 82 U.S.P.Q.2d (BNA) at 1948.
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^{1886.} Id. at 981-82, 82 U.S.P.Q.2d (BNA) at 1948.

^{1887. 500} F.3d 1369, 84 U.S.P.Q.2d (BNA) 1604 (Fed. Cir. 2007).

^{1888.} *Id.* at 1372, 84 U.S.P.Q.2d (BNA) at 1605. 1889. *Id.* at 1371, 84 U.S.P.Q.2d (BNA) at 1605.

^{1890.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1605. 1891. *Id.*, 84 U.S.P.Q.2d (BNA) at 1605.

^{1892.} *Id.* at 1372, 84 U.S.P.Q.2d (BNA) at 1606. 1893. *Id.*, 84 U.S.P.Q.2d (BNA) at 1606 (stating that, if successful, Eran "can recoup any royalties under its patent and can recover damages for other breaches if proven").

^{1894.} *Id.* at 1374, 84 U.S.P.Q.2d (BNA) at 1607.

^{1895.} *Id.* at 1373–74, 84 U.S.P.Q.2d (BNA) at 1607.

^{1896.} Id. at 1374, 84 U.S.P.Q.2d (BNA) at 1607 (citation omitted).

ter Software, Inc. v. Elan Computer Group, Inc. 1897 "Objectively baseless," the Supreme Court explained in Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc., 1898 requires a showing "that no reasonable litigant could realistically expect success on the merits." In GP Industries, the Federal Circuit found that the district court had "not considere[d] the objectively baseless standard in its discussion of bad faith" and had even made statements that demonstrated that Eran's allegations were not objectively baseless, which rendered its findings of subjective bad faith immaterial. Finding that Eran's assertions were not objectively baseless, the court reversed the entry of preliminary injunction. 1901

C. Damages

1. Lost profits

In Wechsler v. Macke International Trade, Inc., 1902 the Federal Circuit reversed the lower court's denial of JMOL, because "the jury's award of lost profit damages was not supported by substantial evidence." 1903 The court noted that the plaintiff did not produce a product and did not have the capacity to do so until after the infringement ended. 1904 In particular, "Wechsler's expert's opinion that Wechsler had the capability to manufacture and market his device during the period of infringement was based solely on the fact that Wechsler manufactured and marketed his product after the period of infringement." ¹⁹⁰⁵ The court also found no evidence that Macke's infringing sales preempted subsequent sales by Wechsler or resulted in a lower price for Wechsler's sales because "Wechsler and his expert presented little more than conclusory evidence on these theories."1906

In Mitutoyo Corp. v. Central Purchasing, LLC, 1907 the Federal Circuit affirmed the district court's finding that Mitutoyo was not entitled to lost profits due to the lack of evidence of any market overlap between

^{1897.} Id. at 1375, 84 U.S.P.Q.2d (BNA) at 1608 (citing Globtrotter Software, Inc. v. Elan Computer Group, Inc., 362 F.3d 1367, 1375, 70 U.S.P.Q.2d (BNA) 1161, 1168 (Fed. Cir. 2004)).

^{1898. 508} U.S. 49, 26 U.S.P.Q.2d (BNA) 1641 (1992).

^{1899.} Id. at 60, 26 U.S.P.Q.2d (BNA) at 1646.

^{1900.} GP Indus., 500 F.3d at 1375, 84 U.S.P.Q.2d (BNA) at 1607-08.

^{1901.} Id. at 1375–76, 84 U.S.P.Q.2d (BNA) at 1608.

^{1902. 486} F.3d 1286, 82 U.S.P.Q.2d (BNA) 1742 (Fed. Cir. 2007). 1903. *Id.* at 1297, 82 U.S.P.Q.2d (BNA) at 1749.

^{1904.} *Id.* at 1293, 82 U.S.P.Q.2d (BNA) at 1747. 1905. *Id.* at 1294, 82 U.S.P.Q.2d (BNA) at 1747. 1906. *Id.*, 82 U.S.P.Q.2d (BNA) at 1747.

^{1907. 499} F.3d 1284, 84 Ù.S.P.Q.2d (BNA) 1001 (Fed. Cir. 2007).

its products and Central's infringing products. 1908 Mitutoyo's products were much more complex and expensive than those sold by Central, so there was little overlap in price or prospective customers. 1909 Central also showed that demand for its products was sensitive to price, "meaning that Mitutoyo's products are sold almost entirely outside the price range in which Central customers are likely to buy." 1910

2. Reasonable royalty

The Federal Circuit affirmed the court's award of a 140% royalty in Monsanto Co. v. McFarling. 1911 The case involved a farmer who had saved and replanted patented genetically modified soybean seeds in violation of a license agreement with Monsanto. 1912 The district court awarded a reasonable royalty of \$40 per fifty-pound bag even though the customary royalty was only \$6.50 per bag, in addition to \$22 for the seeds themselves. 1913 The Federal Circuit affirmed the royalty award of 140% of the normal sales price of the seeds, explaining that the license agreement conferred non-monetary advantages on Monsanto, such as decreasing the risk of underreporting and the consequent harm to Monsanto's reputation among farmers, "ensur[ing] Monsanto's knowledge of the quality of seeds planted each year, and provid[ing] a bargaining chip for signing up new seed companies."1914 The court also considered that farmers using Monsanto's genetically modified seeds saved approximately \$31-61 per acre compared to using conventional soybean seeds. 1915

The Federal Circuit also found no clear error in the 29.2% royalty rate awarded in Mitutoyo Corp. v. Central Purchasing, LLC, in light of the contentious history between Central and Mitutoyo and other evidence of record. 1916 However, the Federal Circuit reversed the district court's inclusion of sales to consumers by another company in the royalty base, finding that there was no corporate relationship between Central and that third-party, "and there are no courses of dealing or other evidence to suggest that Central would have agreed to pay roy-

^{1908.} Id. at 1291, 84 U.S.P.Q.2d (BNA) at 1006.

^{1909.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1006.

^{1910.} *Id.*, 84 U.S.P.Q.2d (BNA) at 1006. 1911. 488 F.3d 973, 981, 82 U.S.P.Q.2d (BNA) 1942, 1947 (Fed. Cir. 2007).

^{1912.} Id. at 976, 82 U.S.P.Q.2d (BNA) at 1943-44.

^{1913.} *Id.* at 976–77, 82 U.S.P.Q.2d (BNA) at 1944. 1914. *Id.* at 980, 82 U.S.P.Q.2d (BNA) at 1947.

^{1915.} *Id.* at 981, 82 U.S.P.O.2d (BNA) at 1947.

 $^{1916. \}quad 499 \; F.3d \; 1284, 1292, 84 \; U.S.P.Q.2d \; (BNA) \; 1001, \; 1006 \; (Fed. \; Cir. \; 2007).$

alties based on both its sales" and the consumer sales of the other company. 1917

The Federal Circuit vacated the royalty award in Paice LLC v. Toyota Motor Corp. 1918 due to a lack of evidence. 1919 The district court had imposed sua sponte an "ongoing royalty" of twenty-five dollars per automobile after a jury found that Toyota had infringed one of Paice's patents on drive trains for hybrid automobiles under the doctrine of equivalents. 1920 The Federal Circuit vacated the district court's "ongoing royalty" because the order provided "no reasoning to support the selection of . . . the royalty rate." In so holding, the court also noted that "the fact that monetary relief is at issue in this case does not, standing alone, warrant a jury trial" under the Seventh Amendment because not all monetary relief is properly characterized as "damages." 1922

In a concurring opinion, Judge Rader contended that the case should have been remanded for a determination of the reasonable royalty rate because "the parties had no meaningful chance to present evidence to the district court on an appropriate royalty rate to compensate Paice for Toyota's future acts of infringement." Judge Rader added, "in the case of the patentee, who has proven infringement of its property right, an opportunity to negotiate its own ongoing royalty is a minimal protection for its rights extending for the remainder of the patent term." 1924

3. Enhanced damages

The Federal Circuit has held that an award of enhanced damages requires a showing of willful infringement. The court fashioned a

^{1917.} Id., 84 U.S.P.Q.2d (BNA) at 1007.

^{1918. 504} F.3d 1293, 85 U.S.P.Q.2d (BNA) 1001 (Fed. Cir. 2007). 1919. *Id.* at 1315–16, 85 U.S.P.Q.2d (BNA) at 1017–18.

^{1920.} Id. at 1296, 85 U.S.P.Q.2d (BNA) at 1003.

^{1921.} Id. at 1315, 85 U.S.P.Q.2d (BNA) at 1017.

^{1922.} Id. at 1316, 85 U.S.P.Q.2d (BNA) at 1017 (citing Root v. Ry. Co., 105 U.S. 189, 207 (1881)).

^{1923.} Id., 85 Ú.S.P.Q.2d (BNA) at 1018 (Rader, J., concurring).

^{1924.} Id. at 1317, 85 U.S.P.Q.2d (BNA) at 1018.

^{1925.} See, e.g., Beatrice Foods Co. v. New England Printing & Lithographing Co., 923 F.2d 1576, 1578, 17 U.S.P.Q.2d (BNA) 1553, 1555 (Fed. Cir. 1991) (citing Reactive Metals & Alloys Corp. v. ESM, Inc., 769 F.2d 1578, 1582, 226 U.S.P.Q. 821, 824 (Fed. Cir.1985)) ("[I]f a district court enhances damages, it must explain and articulate through findings the basis upon which it concludes that there has been willful infringement or bad faith."); see also Jurgens v. CBK, Ltd., 80 F.3d 1566, 1570, 38 U.S.P.Q.2d 1397, 1400 (Fed. Cir. 1996) (holding that bad faith infringement, which is a type of willful infringement, is required for enhanced damages).

standard for evaluating willful infringement in *Underwater Devices Inc.* v. Morrison-Knudsen Co.: 1926

Where . . . a potential infringer has actual notice of another's patent rights, he has an affirmative duty to exercise due care to determine whether or not he is infringing. Such an affirmative duty includes, inter alia, the duty to seek and obtain competent legal advice from counsel before the initiation of any possible infringing activity. 1927

The term "willful" is not unique to patent law and has a wellestablished meaning in the civil context. The Supreme Court addressed the meaning of willfulness as a statutory condition of civil liability for punitive damages. 1928 The case involved the Fair Credit Reporting Act ("FCRA"), which imposes civil liability for failure to comply with its requirements. Whereas an affected consumer can recover only actual damages for negligent violations of the FCRA, 1930 he can also recover punitive damages for willful violations. ¹⁹³¹ The Court concluded that the "standard civil usage" of "willful" includes reckless behavior. 1932 "In contrast, the duty of care announced in Underwater Devices sets a lower threshold for willful infringement that is more akin to negligence."1933

A unanimous en banc panel substantially rewrote the law of willfulness and enhanced damages in In re Seagate Technology, LLC. 1934 The portion of the court's decision that is likely to have the greatest long-term impact is its determination to replace the "affirmative duty of care" standard set forth in *Underwater Devices* with a requirement that the patentee prove that the accused infringer was "objectively reckless" in infringing the patent at issue. 1935 In other words, "a patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of valid patent" in order to establish willful infringement. This requires a two-step analysis: (1) there must be

^{1926. 717} F.2d 1380, 219 U.S.P.Q. (BNA) 569 (Fed. Cir. 1983), overruled by In re Seagate Tech., LLC, 497 F.3d 1360, 83 U.S.P.Q.2d (BNA) 1865 (Fed. Cir. 2007).

^{1927.} *Id.* at 1389–90, 219 U.S.P.Q. (BNA) at 576 (citations omitted).

^{1928.} Safeco Ins. Co. of Am. v. Burr, 127 S. Ct. 2201 (2007).

^{1929.} *Id.* at 2205.

^{1930. 15} U.S.C. § 1681o(a) (2006). 1931. 15 U.S.C. § 1681n(a) (2006). 1932. Safeto, 127 S. Ct. at 2203. 1933. In re Seagate Tech., LLC, 497 F.3d 1360, 1371, 83 U.S.P.Q.2d (BNA) 1865, 1870 (Fed. Cir. 2007) (discussing Underwater Devices Inc. v. Morrison-Knudsen Co., 717 F.2d 1380, 219 U.S.P.Q. (BNA) 569 (Fed. Cir. 1983)). 1934. 497 F.3d 1360, 83 U.S.P.Q.2d (BNA) 1865.

^{1935.} Id. at 1371, 83 U.S.P.Q.2d (BNA) at 1870.

^{1936.} Id., 83 U.S.P.Q.2d (BNA) at 1870.

clear and convincing evidence that the infringer acted despite an objectively high likelihood that the actions infringed a valid patent, and (2) if the patentee meets the first requirement, it must then show that that risk was known or should have been known by the infringer. 1937 The infringer's subjective state of mind is irrelevant to the first prong. 1938 As the court explained:

We fully recognize that "the term [reckless] is not self-defining." However, "[t]he civil law generally calls a person reckless who acts... in the face of an unjustifiably high risk of harm that is either known or so obvious that it should be known." Accordingly, to establish willful infringement, a patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent. The state of mind of the accused infringer is not relevant to this objective inquiry. If this threshold objective standard is satisfied, the patentee must also demonstrate that this objectivelydefined 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. We leave it to future cases to further develop the application of this standard. 1939

As a result of abandoning the "duty of care" standard, the court also emphasized that "there is no affirmative obligation to obtain opinion of counsel." The court, as explained in an earlier section, also emphasized that "asserting the advice of counsel defense and disclosing opinions of opinion counsel do not constitute waiver of the attorney-client privilege for communications with trial counsel,"1941 and "relying on opinion counsel's work product does not waive work product immunity with respect to trial counsel."1942

4. Attorney's fees and costs

In Propat International Corp. v. RPost, Inc., 1943 the district court refused to award the defendant its attorneys' fees and costs even though it had dismissed the suit because Propat did not own the subject patent and thus lacked standing to sue. 1944 The Federal Circuit affirmed the lower court's refusal to award fees and costs because Propat's interpretation of the ownership issue "was not so reckless as

^{1937.} *Id.*, 83 U.S.P.Q.2d (BNA) at 1870. 1938. *Id.*, 83 U.S.P.Q.2d (BNA) at 1870.

^{1939.} *Id.*, 83 U.S.P.Q.2d (BNA) at 1870–71 (citations omitted).

^{1940.} *Id.*, 83 U.S.P.Q.2d (BNA) at 1870.

^{1941.} *Id.* at 1374, 83 U.S.P.Q.2d (BNA) at 1873. 1942. *Id.* at 1376, 83 U.S.P.Q.2d (BNA) at 1874.

^{1943. 473} F.3d 1187, 81 U.S.P.Q.2d (BNA) 1350 (Fed. Cir. 2007).

^{1944.} *Id.* at 1188–89, 81 U.S.P.Q.2d (BNA) at 1351.

to warrant sanctioning" and "the conduct of both parties' counsel 'fell far short of a model prosecution and defense of a patent action." Thus, the court affirmed the district court's decision "to leave the parties where it f[ound] them." 1946

In RFR Industries, Inc. v. Century Steps, Inc., 1947 the Federal Circuit found the award of attorney's fees to be improper because the action was dismissed upon RFR's filing of a notice of dismissal. 1948 Voluntary dismissal did not bestow "prevailing party" status on Century, which is a prerequisite for the award of attorney's fees under 35 U.S.C. § 285. 1949

Digeo, Inc. v. Audible, Inc. 1950 involved an allegedly "exceptional" case under 35 U.S.C. § 285. 1951 Digeo acquired the patent at issue at a bankruptcy sale from IPDN Corporations, the successor in interest to Microtome. 1952 About a year after filing suit against Audible for infringement, however, Digeo discovered that the signatures allegedly assigning the patent to Microtome had been forged. 1953 The district court dismissed Digeo's case for lack of title, but denied Audible's motion for attorneys' fees under § 285. 1954

The Federal Circuit affirmed the denial of attorneys' fees. 1955 The court explained, "If there is clear and convincing evidence that a plaintiff has brought a baseless or frivolous suit against an accused infringer, that is a sufficient basis to require a district court to deem the case exceptional under § 285."1956 The court, however, rejected Audible's argument that the district court had improperly shifted "the burden of proof to Audible to show that Digeo had not performed an appropriate pre-suit" inquiry into its claim. 1957 Audible, the court noted, had not filed a motion under Rule 11, which authorizes "sanctions for failure to conduct a reasonable inquiry into the legal and factual bases of claims." Rather, Audible brought its motion under § 285, which "grant[s] district courts discretionary authority to award reasonable attorneys' fees to the prevailing party in exceptional cas-

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1945. Id. at 1195, 81 U.S.P.Q.2d (BNA) at 1356.
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^{1946.} Id., 81 U.S.P.Q.2d (BNA) at 1356.

^{1947. 477} F.3d 1348, 81 U.S.P.Q.2d (BNA) 1915 (Fed. Cir. 2007).

^{1948.} *Id.* at 1352, 81 U.S.P.Q.2d (BNA) at 1918. 1949. *Id.* at 1353, 81 U.S.P.Q.2d (BNA) at 1918–19.

^{1950. 505} F.3d 1362, 85 U.S.P.Q.2d (BNA) 1246 (Fed. Cir. 2007). 1951. *Id.* at 1366–67, 85 U.S.P.Q.2d (BNA) at 1248.

^{1952.} Id. at 1365, 85 U.S.P.Q.2d (BNA) at 1247.

^{1953.} Id. at 1366, 85 U.S.P.Q.2d (BNA) at 1247. 1954. *Id.* at 1367, 85 U.S.P.Q.2d (BNA) at 1247–48.

^{1955.} Id. at 1366-67, 85 U.S.P.Q.2d (BNA) at 1248-49.

^{1956.} Id. at 1367, 85 U.S.P.Q.2d (BNA) at 1248.

^{1957.} *Id.* at 1367–69, 85 U.S.P.Q.2d (BNA) at 1249–50.

^{1958.} *Id.* at 1368, 85 U.S.P.Q.2d (BNA) at 1249.

es."1959 Whereas Rule 11 shifts the burden to the nonmovant (plaintiff) to prove that it had made a reasonable pre-suit inquiry into its claim, under § 285 the burden remains on the movant to show by clear and convincing evidence that the case is exceptional. 1960 though a Rule 11 violation can serve as the basis for finding a case exceptional, Audible's failure to file such a motion rendered that point moot. 1961

The Federal Circuit also rejected Audible's argument that buying something "as-is" raised the standard for a pre-suit investigation because of a greater likelihood that the patent is faulty. 1962 The court found that not only did Audible's argument lack legal support, but "negligent conduct does not suffice to establish that a case is exceptional." 1963 Rather, a party moving under § 285 "must prove actual wrongful intent or gross negligence" in order to show that a case is exceptional, explained the court. Since there was no evidence suggesting that Digeo had been negligent in not learning of the defect in the patent title, the Federal Circuit found that the district court had properly determined that this was not an exceptional case. 1965

5. Pre-filing investigation under Rule 11

In Intamin, Ltd. v. Magnetar Technologies, Corp., 1966 the Federal Circuit held that there was no blanket rule that a plaintiff in a patent infringement suit must obtain and thoroughly analyze a sample of the alleged infringer's product in order to satisfy its Rule 11 obligation. 1967 In so holding, the Federal Circuit distinguished Judin v. United States, 1968 in which the patentee could have very easily obtained a sample of the accused product for a nominal price and deconstructed that sample to avoid violating Rule 11. 1969 The Federal Circuit held that *Judin* did not create a blanket rule for all cases, however. ¹⁹⁷⁰ The court explained that in this case, unlike Judin, "the technology presented the patentee with unreasonable obstacles to any effort to ob-

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1959. Id., 85 U.S.P.Q.2d (BNA) at 1249.
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^{1960.} *Id.*, 85 U.S.P.Q.2d (BNA) at 1249.

^{1961.} *Id.*, 85 U.S.P.Q.2d (BNA) at 1249. 1962. *Id.* at 1369, 85 U.S.P.Q.2d (BNA) at 1250.

^{1963.} *Id.*, 85 U.S.P.Q.2d (BNA) at 1250. 1964. *Id.*, 85 U.S.P.Q.2d (BNA) at 1250 (citing Mach. Corp. of Am. v. Gullfiber AB, 774 F.2d 467, 473, 227 U.S.P.Q. (BNA) 368, 373 (Fed. Cir. 1985)).

^{1965.} *Id.*, 85 U.S.P.Q.2d (BNA) at 1250.

^{1966. 483} F.3d 1328, 82 U.S.P.Q.2d (BNA) 1545 (Fed. Cir. 2007).

^{1967.} Id. at 1338, 82 U.S.P.Q.2d (BNA) at 1552.

^{1968. 110} F.3d 780, 42 U.S.P.Q.2d (BNA) 1300 (Fed. Cir. 1997).

^{1969.} Intamin, 483 F.3d at 1338, 82 U.S.P.Q.2d (BNA) at 1552.

^{1970.} Id., 82 U.S.P.Q.2d (BNA) at 1552.

tain a sample of Magnetar's amusement ride brake system, let alone the difficulty of opening the casing." Thus, the Federal Circuit rejected the defendant's argument that the suit was frivolous and sanctions appropriate merely because Intamin had not obtained the allegedly infringing product and cut it open for analysis. 1972

VII. INTERNATIONAL TRADE COMMISSION

A. Standing

Standing to appeal from an ITC determination was the central issue in Fuji Photo Film Co. v. International Trade Commission, 1973 which also marked the fifth time that the Federal Circuit had heard an appeal from the ITC's investigation into lens-fitted film packages, 1974 from related district court and U.S. Customs proceedings. 1975

This particular appeal stemmed from an ITC enforcement proceeding, in which the Commission imposed a civil penalty of \$13.7 million on respondent Jazz Camera for importing over twenty-five million disposable cameras that had been impermissibly reconstructed. 1976 The Commission also imposed civil penalties on two of Jazz's officers, one of whom appealed while the other settled with the ITC. 1977 Fuji, the patent holder and complainant, appealed the Commission's determination that the remaining 1.7 million disposable cameras imported by Jazz had been permissibly repaired. 1978

The Federal Circuit dismissed Fuji's appeal for lack of standing. 1979 A private plaintiff, unlike the federal government, may not sue to assess civil penalties for past violations, unless the private plaintiff is threatened with injury as a consequence of ongoing unlawful conduct. 1980 In this case, there was no threat of ongoing harm to Fuji because Jazz had gone bankrupt and been liquidated under Chapter 11, while its sanctioned officer was proscribed only from activities con-

^{1971.} Id., 82 U.S.P.Q.2d (BNA) at 1552.

^{1972.} Id., 82 U.S.P.Q.2d (BNA) at 1552.

^{1973. 474} F.3d 1281, 82 U.S.P.Q.2d (BNA) 1495 (Fed. Cir. 2007).

^{1974.} For the International Trade Commission's notice of determination on remand, see Certain Lens-Fitted Film Packages, Inv. No. 337-TA-406 (Int'l Trade Comm'n Sept. 12, 2007), http://www.usitc.gov/secretary/fed_reg_notices/337/337-TA-406.Notice.1189628776.pdf (reducing the civil penalty on remand).

1975. Fuji, 474 F.3d at 1285, 82 U.S.P.Q.2d (BNA) at 1497.

1976. Id. at 1288–89, 82 U.S.P.Q.2d (BNA) at 1499.

^{1977.} Id. at 1289, 82 U.S.P.Q.2d (BNA) at 1499-1500.

^{1978.} *Id.*, 82 U.S.P.Q.2d (BNA) at 1500. 1979. *Id.*, 82 U.S.P.Q.2d (BNA) at 1500.

^{1980.} Id. at 1289-90, 82 U.S.P.Q.2d (BNA) at 1500 (citing Friends of the Earth, Inc. v. Laidlaw Envtl. Servs., Inc., 528 U.S. 167, 188 (2000)).

ducted "for, with, or otherwise on behalf of' Jazz." Moreover, even if Fuji had been harmed by Jazz's importation of 1.7 million allegedly reconstructed cameras, the Commission would not necessarily impose any additional penalties for those cameras, while any penalties it did impose would have been paid to the U.S. government, not Fuji. 1982

The cessation of Jazz's operations also meant there was no continuing need for Customs to determine which Jazz cameras would be excluded from entry. Thus, even if the Federal Circuit's interpretation of Jazz's cease and desist order might affect the interpretation of the general exclusion order, this was not a sufficient basis to establish standing. The appropriate route to clarify the exclusion order was through the ITC, where all parties could participate, and not by obtaining an advisory opinion from the Federal Circuit when there was no Article III case or controversy. 1985

B. Claim Construction

In OSRAM GmbH v. International Trade Commission, 1986 the Federal Circuit reversed the Commission's determination of no violation of § 337 due to an erroneous claim construction. The patent claims in question included certain luminous pigment powders, "which produce a spectral shift in the light emitted by . . . LEDs" and other electroluminescent devices such that the light appears white. The claims required that the pigments have a "mean grain diameter" of a certain size. The Commission interpreted this term to refer to the "volume-based average[, which] is calculated by multiplying the diameter of each grain by its volume, summing the products thereof, and dividing that sum by the sum of the volumes of the grains. "1990"

The panel majority disagreed, finding that the "mean grain diameter" should be calculated as a "number-based average," which is "the sum of the diameters of all the grains, divided by the number of grains." Although both methods were used in the art to calculate mean grain diameter, the majority found that "experts for both sides were in full and emphatic agreement that the ordinary meaning of

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1981. Id. at 1290, 82 U.S.P.Q.2d (BNA) at 1500.
1982. Id. at 1289, 82 U.S.P.Q.2d (BNA) at 1500.
1983. Id. at 1290, 82 U.S.P.Q.2d (BNA) at 1501.
1984. Id., 82 U.S.P.Q.2d (BNA) at 1501.
1985. Id. at 1290–91, 82 U.S.P.Q.2d (BNA) at 1501.
1986. 505 F.3d 1351, 85 U.S.P.Q.2d (BNA) 1161 (Fed. Cir. 2007).
1987. Id. at 1359, 85 U.S.P.Q.2d (BNA) at 1166.
1988. Id. at 1354, 85 U.S.P.Q.2d (BNA) at 1162.
1989. Id. at 1355, 85 U.S.P.Q.2d (BNA) at 1163.
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^{1990.} *Id.*, 85 U.S.P.Q.2d (BNA) at 1164.

^{1991.} *Id.* at 1355, 1357, 85 U.S.P.Q.2d (BNA) at 1164, 1165.

the average diameter of these particles is the number-based average," although respondent's expert later changed his position when he realized this question could decide the issue of liability. 1992 The court also found that the patent specifications were "in accordance with the number-based" mean, which better reflects the homogeneity of particle size. 1993 In contrast, the volume-based mean overemphasizes large particles, which are "not as effective at scattering light to produce a uniform color and intensity" and are thus detrimental to the invention. 1994 Furthermore, it was undisputed that "a volume-based measure would exclude the OSRAM products the patents were designed to

Judge Dyk dissented, finding no "full and emphatic agreement" among the experts on this construction nor any "conflicting testimony" on the part of respondent's expert. 1996 Judge Dyk also found the majority's assumption that the claim term sought to emphasize small particles over large particles to be "unsupported" and "entirely speculative."1997

The Federal Circuit also reversed the Commission's claim construction in Sinorgchem Co., Shandong v. International Trade Commission 1998 and adopted instead a more narrow construction of the term "controlled amount" of protic material. 1999 Although there was no dispute that "controlled amount" had no well-accepted meaning in the chemical arts, the inventors defined the term in the specification as follows: "A 'controlled amount' of protic material is an amount up to that which inhibits the reaction of aniline with nitrobenzene, e.g., up to about 4% of H₂O based on the volume of the reaction mixture when aniline is utilized as the solvent."2000

The panel majority interpreted this passage as imposing a numerical limit of up to about 4% H₂O on the "controlled amount"; thus, "each asserted claim can encompass processes that utilized at most 4% water when aniline is the solvent." Since it was undisputed that respondent Sinorgchem always uses more than 4% water when it reacts aniline with nitrobenzene, the majority reversed the Commis-

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1992. Id. at 1356, 85 U.S.P.Q.2d (BNA) at 1164.
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^{1993.} Id., 85 U.S.P.Q.2d (BNA) at 1164.

^{1994.} Id. at 1357, 85 U.S.P.Q.2d (BNA) at 1165.

^{1995.} *Id.* at 1358, 85 U.S.P.Q.2d (BNA) at 1166. 1996. *Id.* at 1360, 85 U.S.P.Q.2d (BNA) at 1167–68 (Dyke, J., dissenting).

^{1997.} Id. at 1362, 85 U.S.P.Q.2d (BNA) at 1169.

^{1998.} No. 2006-1633, 2007 WL 4465270 (Fed. Cir. Dec. 21, 2007).

^{1999.} *Id.* at *3-7.

^{2000.} Id. at *4 (emphasis added).

^{2001.} Id. at *8.

sion's determination of literal infringement and remanded the case for consideration of infringement under the doctrine of equivalents and invalidity under the new construction. 2002

In so holding, the Federal Circuit rejected the ITC's finding that the phrase "e.g., up to 4% H₂O . . . when aniline is utilized as the solvent" was only exemplary language and not part of the limiting definition of "controlled amount." The Commission had relied on a passage in the specification that "the amount of protic material tolerated will vary with type of base, amount of base, and base cation, used in the various solvent systems."2004 The panel majority, however, found "[t]his vague language cannot override the express definitional language," which they found unambiguously and completely defined the "controlled amount" as "up to about 4% H_aO based on the volume of the reaction mixture" when aniline is the solvent.²⁰⁰⁵ The panel also "attribute[d] no weight" to the expert testimony cited by the ITC because "the experts did not identify any evidence that those skilled in the art would recognize that 'controlled amount,' or any term used in the specification has an accepted meaning in the field of chemistry."2006 In addition, the panel rejected the ITC's argument that this construction was inconsistent with certain embodiments in the specification, explaining, "where . . . multiple embodiments are disclosed, we have previously interpreted claims to exclude embodiments where those embodiments are inconsistent with unambiguous language in the patent's specification or prosecution history."2007

Judge Newman sharply dissented:

[T]here was no disclaimer of the scope set forth in the patent specifications and claims; there is no prior art to limit the claims in the way selected by the panel majority; and there is no reason to insert an absolute numerical limit of "about 4%" protic material into the claims that do not contain a numerical limit, when the specifications of both patents demonstrate significantly higher percentages. There was no evidence contradicting the evidence of the experts concerning the range of protic material set forth in the specifications' text and illustrated in the specific examples. 2008

"The panel majority," she continued, "adds inconsistency and unpredictability [to claim construction] by arbitrarily limiting the scope

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2002. Id.
2003. Id. at *4-5.
2004. Id. (quoting U.S. Patent No. 5,117,063 (filed June 21, 1991)).
2005. Id. at *5.
2006. Id. at *5 n.3.
2007. Id. at *6.
2008. Id. at *8 (Newman, J., dissenting).
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of the claimed invention in a way that conflicts with the teachings of the specifications and the knowledge in the field of the inventions. "2009 In contrast, she found "no error of fact or law" in the Commission's claim construction or infringement finding, which were "not only supportable on the required standard of review, but they also are correct."2010

C. Imposing a Cease and Desist Order Against an Individual

In the same Fuji Photo Film Co. v. International Trade Commission²⁰¹¹ opinion discussed above in Part VII.A, the Federal Circuit affirmed the authority of the ITC to impose and enforce a cease and desist order against a corporate officer. The Federal Circuit found that the Commission "could properly enjoin Jazz's officers, employees, and agents from causing Jazz to engage in future violations" when it found Jazz was infringing Fuji's patents.²⁰¹³ In addition, the cease and desist order against Jazz was specifically directed against Jazz's "principals, stockholders, officers, directors, employees, agents, . . . and to each of them, insofar as they are engaging in conduct prohibited by" the cease and desist order. 2014 The Federal Circuit, however, declined to consider the corporate officer's argument that he had not been given adequate notice of the cease and desist order, finding that he had failed to properly raise it in his opening brief.²⁰¹⁵

D. Stay of District Court Proceedings

In In re Princo Corp., 2016 the Federal Circuit examined when an ITC decision "becomes final" for purposes of lifting a district court's stay of related proceedings, pursuant to 28 U.S.C. § 1659(a). In particular, § 1659 provides that a district court, on timely request by an ITC respondent, must stay a related proceeding with respect to any

2010. Id. at *8-9.

^{2009.} Id. at *13.

^{2011. 474} F.3d 1281, 82 U.S.P.Q.2d (BNA) 1495 (Fed. Cir. 2007); see supra Part VII.A (discussing standing to appeal). 2012. Fuji, 474 F.3d at 1291, 82 U.S.P.Q.2d (BNA) at 1501.

^{2013.} Id., 82 U.S.P.Q.2d (BNA) at 1501; see Wilson v. United States, 221 U.S. 361, 376 (1911) ("A command to the corporation is in effect a command to those who are officially responsible for the conduct of its affairs.").

^{2014.} Fuji, 474 F.3d at 1292, 82 U.S.P.Q.2d (BNA) at 1502.

^{2015.} Id. at 1293, 82 U.S.P.Q.2d (BNA) at 1502.

^{2016. 478} F.3d 1345, 81 U.Š.P.Q.2d (BNA) 1997 (Fed. Cir. 2007), reh'g denied, 486 F.3d 1365 (Fed. Cir. 2007).

^{2017.} Id. at 1348, 81 U.S.P.Q.2d (BNA) at 1998.

claim that involves the same issues as those before the ITC until the ITC's determination "becomes final." 2018

In this case, Philips sued Princo in district court for infringing six patents on technology for manufacturing compact disks. ²⁰¹⁹ Princo intervened in an ITC investigation on the same patents and moved the district court to stay its proceedings, pursuant to § 1659(a).²⁰²⁰ The district court granted the stay but refused to extend it after the Commission made a final determination. While the appeal was pending, the district court rejected Princo's patent misuse defense and entered summary judgment of infringement in favor of Philips.²⁰²² The Federal Circuit, in separate appeals, reversed the Commission's patent misuse determination, vacated the district court's judgment against Princo, and remanded both matters back to the presiding forums. 2023 The district court again denied Princo's motion for a stay, granted summary judgment to Philips, and rejected Princo's patent misuse defense. 2024

Princo filed a petition for a writ of mandamus to vacate the district court's order and stay the case until the Commission had concluded its remand proceedings. 2025 The Federal Circuit temporarily stayed the district court's proceedings pending its decision. ²⁰²⁶ On the merits, the Federal Circuit found that the phrase "becomes final" in § 1659 is similar to language in other statutes, which have been interpreted to refer to the time when the decision is no longer subject to appellate review. 2027 In contrast, other statutes that use "materially different" phrases, such "final decisions," have been construed as referring to finality by the presiding forum. 2028 The court also found that the purpose behind § 1659, to avoid concurrent infringement proceedings in two different forums, would be best served by extending the stay to include the appeal. Accordingly, the Federal Circuit granted Princo's petition and held that the district court proceedings must remain stayed until the Commission's determination was no longer subject to judicial review. 2030

^{2018.} Id. at 1348-49, 81 U.S.P.Q.2d (BNA) at 1999.

^{2019.} *Id.* at 1348, 81 U.S.P.Q.2d (BNA) at 1999.

^{2020.} *Id.*, 81 U.S.P.Q.2d (BNA) at 1999. 2021. *Id.* at 1349, 81 U.S.P.Q.2d (BNA) at 1999.

^{2022.} Id., 81 U.S.P.Q.2d (BNA) at 1999.

^{2023.} Id. at 1349–50, 81 U.S.P.Q.2d (BNA) at 2000.

^{2024.} Id. at 1350, 81 U.S.P.Q.2d (BNA) at 2000. 2025. Id. at 1350-51, 81 U.S.P.Q.2d (BNA) at 2000.

^{2026.} Id. at 1351, 81 U.S.P.Q.2d (BNA) at 2000.

^{2027.} *Id.* at 1354, 81 U.S.P.Q.2d (BNA) at 2003. 2028. *Id.* at 1355, 81 U.S.P.Q.2d (BNA) at 2003.

^{2029.} Id., 81 U.S.P.Q.2d (BNA) at 2004.

^{2030.} Id. at 1357, 81 U.S.P.Q.2d (BNA) at 2005.

The Federal Circuit added that the stay should be continued even though the only issue before the district court was damages, an issue over which the Commission has no jurisdiction.²⁰³¹ Section 1659, the court explained, does not limit the stay to individual issues pending in the Commission, but extends to any district court "proceedings" on a *claim* that *involves* the same issues in the proceeding before the Commission.²⁰³² Since the damages involved the same issues as the infringement issues in the Commission, the district court's proceeding remained stayed.²⁰³³

The Federal Circuit also rejected Philips's argument that Princo was not entitled to a stay because the appeals court had already rejected Princo's patent misuse defense. Princo had diligently pursued its motion to stay, and its entitlement to a stay was not dependent upon a showing that Princo was likely to prevail on the common issues.

Philips petitioned for a panel rehearing, arguing that the term "becomes final" in § 1659 should be construed in the same fashion as in 19 U.S.C. § 1337, which authorizes the ITC to conduct the type of intellectual property investigations at issue. The panel disagreed and found that the different purposes and legislative histories behind the two statutory provisions "make it appropriate to interpret the 'becomes final' language in § 1337 and § 1659 differently." The panel reiterated: "Becomes final' in that context [in § 1659] refers to finality *after* judicial review."

E. Temporary Stay of an Exclusion Order

In *Epistar Corp. v. ITC*, ²⁰³⁹ appellant/respondent Epistar Corporation moved the Federal Circuit to stay the ITC's limited exclusion order pending the appeal. ²⁰⁴⁰ Interestingly, the Federal Circuit did not require Epistar to first exhaust its administration remedies in the ITC before filing its stay motion in the Federal Circuit. ²⁰⁴¹ Instead, the

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2031. Id. at 1356, 81 U.S.P.Q.2d (BNA) at 2004.
2032. Id., 81 U.S.P.Q.2d (BNA) at 2004.
2033. Id., 81 U.S.P.Q.2d (BNA) at 2004.
2034. Id., 81 U.S.P.Q.2d (BNA) at 2004.
2035. Id., 81 U.S.P.Q.2d (BNA) at 2005.
2036. In re Princo Corp., 486 F.3d 1365 (Fed. Cir. 2007).
2037. Id. at 1368.
2038. Id.
2039. No. 07-1457 (Fed. Cir. Sept. 28, 2007).
2040. Motion of Appellant, Epistar Corp. v. Int'l Trade Comm'n, No. 07-1457 (Fed. Cir. July 13, 2007).
2041. This allowance was in stark contrast to general procedural rules. See FED. R.
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APP. P. 18(a) (stating that a motion must either show that the agency denied the mo-

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Federal Circuit permitted Epistar to pursue its stay motion in the court at the same time it was pursuing the same stay motion in the ITC.²⁰⁴² The Federal Circuit also temporarily granted Epistar's stay motion before the ITC or the complainant/intervenor even had a chance to respond.²⁰⁴³ Although the Federal Circuit ultimately denied Epistar's motion for a stay, the cost was a two-month delay in enforcing the exclusion order. 2044

tion or that moving before the agency would be impracticable); FED. CIR. R. 18(a)

⁽stating the same).

2042. Brief of Intervenor at 16-17, Epistar Corp. v. Int'l Trade Comm'n, No. 07-1457 (Fed. Cir. Dec. 26, 2007).

^{2043.} See Epistar v. Int'l Trade Comm'n, No. 07-1457 (Fed. Cir. July 16, 2007) (referencing, in docket entry number eleven, the Federal Circuit temporarily granting

Epistar Corp.'s motion to stay).
2044. *Id.* (referencing, in docket entry number fifty-seven, the Federal Circuit denying the Epistar Motion to stay).

APPENDIX—STATISTICAL FACTS

Table 1

Table 1 presents the total number of patent appeals adjudicated on the merits during the twelve-month period ending December 31, 2007.

The dispositions are broken down by precedential ("P") opinions and non-precedential ("N") opinions and orders as designated by the United States Court of Appeals for the Federal Circuit ("CAFC") on its daily log, which can be accessed at http://www.cafc.uscourts.gov/d ailylog.html.

Table 1 also includes the origin of the precedential and nonprecedential opinions and orders, the reversal percentage, and the time in months from docketing date to disposition date.

Table 1 - CAFC Patent Appeals Adjudicated on the Merits During the 12-Month Period Ending December 31, 2007

				Percent	Time
Origin of Appeal	A	Adjudicated on t	the Merits	Reversed(c)	(months)
	Р	N	P+N		
District Court	101	54	155	28%	14.0
USPTO	12	5	17	18%	12.7
ITC	3	0	3	67%	19.8
US Court of Claims	0	0	0	-	-
Total	116	59	175	29%	14.1
Notes:					

⁽a) P = Precedential opinion as identified by the Federal Circuit and listed in Table 8.

⁽b) N = Non precedential opinion as identified by the Federal Circuit and listed in Table 8.

⁽c) Percent reversed = [number of cases reversed (i.e., in-whole or in-part) / total number of cases adjudicated on the merits] x 100. See Table 2 for a summary the results of the cases listed in Table 8.

⁽d) Time - mean number of months from docketing date to disposition date, calculated from docketing date or date of reinstatement, whichever is later. Reporting the arithmetic mean and assuming 1 month equals 30 days

Table 2 summarizes the disposition of precedential opinions and non-precedential patent opinions and orders of the Federal Circuit from January 1, 2007 through December 31, 2007. A list of the patent opinions presented in this analysis is presented in *Table 8* of this Appendix.

Table 2 – Results of Opinions During the 12-Month Period Ending December 31, 2007(a)

Affirmed	92
Affirmed-in-part, dismissed-in-part	2
Affirmed-in-part, reversed-in-part	4
Affirmed-in-part, reversed-in-part and remanded	9
Affirmed-in-part, reversed-in-part and remanded-in-part	1
Affirmed-in-part, reversed-in-part, vacated and remanded	1
Affirmed in part, reversed in part and vacated in part	1
Affirmed-in-part, reversed-in-part, vacated-in-part and remanded	6
Affirmed-in-part, vacated-in-part and remanded	11
Affirmed-in-part, vacated-in-part, dismissed-in-part and remanded	1
Dismissed	2
Mandamus granted, reversed, and vacated	1
Petition granted and remanded	1
Reversed	13
Reversed and remanded	10
Reversed and vacated	1
Reversed, vacated and remanded	1
Reversed-in-part, vacated-in-part and remanded	1
Transferred	1
Vacated	1
Vacated and remanded	12
Vacated and remanded, cross appeal dismissed	1
Vacated, reversed and remanded	1
Vacated-in-part and reversed-in-part	1
Total	175

Notes:

(a) All opinions as identified by the Federal Circuit and listed in Table 8.

Table 3 shows the disposition of precedential opinions and non-precedential patent opinions and orders according to the unanimity of the panel. Decisions where all the judges on the panel join the opinion of the court were counted as unanimous decisions in Table 3. Decisions where at least one judge concurred in the judgment but not the opinion and no judge dissented were counted as decisions with concurrence in Table 3. Decisions in which a judge dissented from a panel opinion were counted as decisions with dissent in Table 3.

Table 3 - Number and Unanimity of Patent Opinions Merits During the 12-Month Period Ending December 31, 2007

Degree of Unanimity	Peceder	ntial (P)	Non Prece	edential (N)	Combine	d (P+N)					
Unanimous	81	70%	56	95%	137	78%					
With Concurrence (b)	9	8%	0	0%	9	5%					
With Dissent (c)	26	22%	3	5%	29	17%					
Total	116		59		175						
(a) P = Precedential opinion as	identified by t	he Federal C	ircuit and list	 ed in Table 8.							
(b) N = Non precedential opini	on as identified	by the Fede	ral Circuit and	d listed in Tab	le 8.						
(c) Unanimous = All judges joi	(c) Unanimous = All judges joined the panel opinion.										
(d) With Concurrance = At lea	(d) With Concurrance = At least one judge concurred or concurred-in-part and no judge dissented.										
(e) With Dissent = At least on	e judge dissent	ted in whole	or in part.								

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Table 4

Table 4 illustrates the disposition of precedential opinions and non-precedential patent opinions and orders based on the origin of the case.

Table 4 - Origin and Disposition of Cases During the 12-Month Period Ending December 31, 2007

Origin			Dispo	osition			Tota	ıl (a)
	Reve	rsed (b)	Vaca	ted (c)	Affin	med (d)	Total 177 16 12 111 8 7 7 7 6 6 6 6 5 5 5 4 4 4 4 3 3 3 3 2 2 2 2 2 2 2 1 1 1 1 1 1 1 1 1	
B.P.A.I	3	18%	3	18%	11	65%	17	10%
C. D. Cal.	5	31%	2	13%	9	56%	16	9%
D. Del.	1	8%	1	8%	10	83%	12	7%
D.N.Y.	3	27%	1	9%	7	64%	11	6%
V.D. III.	3	38%	2	25%	3	38%	8	5%
D. Mass	2	29%	0	0%	5	71%	7	4%
S.D. Tex.	2	29%	1	14%	4	57%	7	4%
V.D. Cal.	2	29%	2	29%	3	43%	7	4%
D. Minn.	3	50%	1	17%	2	33%	6	3%
D. N.J.	3	50%	1	17%	2	33%	6	3%
D. D.C.	1	17%	0	0%	5	83%	6	3%
N.D. Tex.	3	60%	0	0%	2	40%	5	3%
.D. Tex.	1	20%	1	20%	3	60%	5	3%
.D. Cal.	3	75%	1	25%	0	0%	4	2%
D. Va.	2	50%	1	25%	1	25%	4	296
V.D. Wis.	2	50%	1	25%	1	25%	4	2%
O. Or.	1	25%	2	50%	1	25%		296
J.S.I.T.C.	3	100%	0	0%	0	0%		2%
D. Col.	0	0%	0	0%	3	100%	3	2%
V.D. Wa.	0	0%	1	33%	2	67%		296
.D. Tenn.	1	50%	0	0%	1	50%		1%
.D. Ohio	1	50%	0	0%	1	50%		196
V.D. N.C.	1	50%	0	0%	1	50%		1%
V.D. Mo.	i	50%	1	50%	0	0%		196
D. Mich.	0	0%	0	0%	2	100%		1%
.D. Pa.	0	0%	0	0%	2	100%		196
D. Fla.	0	0%	0	0%	2	100%		196
V.D. Tex	0	0%	0	0%	2	100%		1%
D. Mo.	0	0%	1	50%	1	50%		1%
M.D. Tenn.	0	0%	1	50%	1	50%		1%
D. Md.	1	100%	0	0%	0	0%		196
D. Neb.	1	100%	0	0%	0	0%		1%
D. Utah	î	100%	0	0%	Ö	0%		196
4.D. Fl.	î	100%	0	0%	ő	0%		1%
N.D. Ala.	1	100%	0	0%	0	0%		196
V.D. Ohio	1	100%	0	0%	0	0%		1%
D. S.C.	0	0%	0	0%	1	100%		196
D. Cal.	0	0%	0	0%	1	100%		196
E.D. Kv.	0	0%	0	0%	1	100%		1%
E.D. Wi.	0	0%	0	0%	1	100%		196
4.D. N.C.	0	0%	0	0%	1	100%		196
J.D. Ga	0	0%	0	0%	1	100%		196
V.D. La.	0	0%	0	0%	1	100%		1%
V.D. Mich.	0	0%	0	0%	1	100%		196
V.D. N.Y.	0	0%	0	0%	1	100%		1%
V.D. Okla.	0	0%	1	100%	0	0%		1%
V.D. Tenn.	0	0%	1	100%	0	0%	1	196
W.D. Tellii.	0	076	1	100%	U	076	1	176
Tota	53	30%	26	15%	96	55%	175	
Tota	35	30%	20	13%	90	33%	1/3	

Notes
(a) Precedential and nonprecedential opinions as identified by the Federal Circuit and listed in Table 10.
(b) "Reversed" = all cases reversed in-whole or in-part whether or not remanded (e.g., reversed, reversed-in-part and affirmed-in-part

⁽c) "Vacated" = includes cases vacated-in-part and affirmed-in-part

⁽d) "Affirmed" = cases affirmed in-whole by the panel majority

Table 5 shows the origin and disposition of precedential opinions and non-precedential patent opinions and orders for cases on appeal from summary judgment.

Table 5 - Origins and Disposition of Cases on Appeal from Summary Judgment During the 12-Month Period Ending December 31, 2007

Origin			Disp	osition			Total (a)	
	Reve	rsed (b)	Vac	ated (c)	Affin	ned (d)		
C. D. Cal.	4	44%	1	11%	4	44%	9	
O. Minn.	2	40%	1	20%	2	40%	5	
S.D. Tex.	1	20%	0	0%	4	80%	5	
V.D. Cal.	2	50%	1	25%	1	25%	4	
S.D.N.Y.	1	25%	0	0%	3	75%	4	
D. Mass	2	67%	0	0%	1	33%	3	
D. N.J.	1	33%	1	33%	1	33%	3	
N.D. III.	1	33%	1	33%	1	33%	3	
D. Del.	0	0%	1	33%	2	67%	3	
E.D. Va.	2	100%	0	0%	0	0%	2	
D. Or.	1	50%	0	0%	1	50%	2	
S.D. Ohio	1	50%	0	0%	1	50%	2	
W.D. N.C.	1	50%	0	0%	1	50%	2	
W.D. Wis.	1	50%	1	50%	0	0%	2	
D. D.C.	0	0%	0	0%	2	100%	2	
E.D. Mich.	0	0%	0	0%	2	100%	2	
E.D. Tex.	0	0%	0	0%	2	100%	2	
N.D. Tex.	0	0%	0	0%	2	100%	2	
O. Md.	1	100%	0	0%	0	0%	1	
N.D. Ala.	1	100%	0	0%	0	0%	1	
D. Col.	0	0%	0	0%	1	100%	1	
E.D. Ky.	0	0%	0	0%	1	100%	1	
E.D. Pa.	0	0%	0	0%	1	100%	1	
M.D. Tenn.	0	0%	0	0%	1	100%	1	
N.D. Ga	0	0%	0	0%	1	100%	1	
W.D. La.	0	0%	0	0%	1	100%	1	
W.D. N.Y.	0	0%	0	0%	1	100%	1	
W.D. Tex.	0	0%	0	0%	1	100%	1	
E.D. Mo.	0	0%	1	100%	0	0%	1	
V.D. Tenn.	0	0%	1	100%	0	0%	1	
W.D. Wa.	0	0%	1	100%	0	0%	1	
T-4-1	22	219/	10	1.49/	20	5.49/	70	
Total	22	31%	10	14%	38	54%	70	

⁽a) Precedential and nonprecedential opinions as identified by the Federal Circuit and listed in Table 8.
(b) "Reversed" – all cases reversed in-whole or in-part whether or not remanded (e.g., reversed, reversed-in-part and affirmed-in-part

⁽c) "Vacated" = includes cases vacated-in-part and affirmed-in-part

⁽d) "Affirmed" = cases affirmed in-whole by the panel majority

Table 6 presents the frequency with which individual judges joined the opinion of the court for precedential opinions and nonprecedential patent opinions and orders. Each opinion was analyzed to identify the panel members and whether each member joined the opinion of the court. The number of panels in which each judge participated was then counted. The number of panels in which each judge participated is presented in the "Total" column. The number of occurrences in which each judge joined the opinion of the court is presented in the "Joined Opinion of Court" column. The frequency with which each judge joined the opinion of the court was calculated by dividing the reported number of occurrences in which that judge "Joined Opinion of the Court" by the reported number panels in which that judge participated, i.e., "Total Cases." For the purposes of this analysis, a plurality opinion that announced the judgment of the court was counted as the opinion of the court.

Table 6 - Profile of Opinions by Individual Judge During the 12-Month Period Ending December 31, 2007

Judge	Authored Ma	jority Opinion	Joined Opinion of	f Court (a),(b),(f),	With Cond	turrence (c)	With Di	ssent (d)	Total (e)
Michel	12	28%	42	98%	0	0%	1	2%	43
Freidman	2	17%	9	75%	2	17%	1	8%	12
Newman	15	38%	30	77%	2	5%	7	18%	39
Archer	4	40%	10	100%	0	0%	0	0%	10
Mayer	3	9%	30	88%	0	0%	4	12%	34
Plager	2	20%	7	70%	2	20%	1	10%	10
Lourie	18	49%	37	100%	0	0%	0	0%	37
Clevenger	3	33%	9	100%	0	0%	0	0%	9
Rader	12	26%	44	94%	2	4%	1	2%	47
Schall	3	9%	29	91%	1	3%	2	6%	32
Bryson	13	35%	36	97%	1	3%	0	0%	37
Gajarsa	14	38%	34	92%	2	5%	1	3%	37
Linn	12	40%	27	90%	2	7%	1	3%	30
Dyk	11	28%	32	80%	3	8%	5	13%	40
Prost	13	29%	43	96%	0	0%	2	4%	45
Moore	13	39%	31	94%	1	3%	1	3%	33
Other	10	27%	34	92%	1	3%	2	5%	37
Per Curiam	15		-		-		-		-
Total	175								

- (a) Precedential and nonprecedential patent opinions issued by Federal Court during 2007 as listed in Table 8 (b) A plutify opinion that announced the judgment of the Court is counted as the opinion of the Court. (c) Opinions concurring-in-part and concurring-in-the-judgment are counted as concurrences. (d) Opinions of concurring-in-part and dissenting-in-part are counted as dissents. (e) Number of panels that each judge participated in.

Table 7 presents a profile of voting alignments between the judges in the precedential patent opinions of the Federal Circuit from January 1, 2007 through December 31, 2007.

Each opinion was analyzed to identify the panel members and whether each member joined the opinion of the court, concurred with the opinion of the court, or dissented from the opinion of the court. The data were then analyzed to determine the number of common panels in which each pair of judges participated. For each pair of judges this number is reported in a cell labeled "CP." The data were further analyzed to determine the number of common opinions shared by each pair of judges in which that pair participated. For each pair of judges the number of occurrences in which each pair of judges shared a common opinion is reported in a cell labeled "CD." The frequency with which each pair of judges shared a common opinion was then calculated by dividing the of number of occurrences in which each pair of judges shared a common opinion by the number of common panels in which each judge participated (i.e., CD/CP).

A common opinion for the purposes of this analysis means that both judges joined the opinion of the court, concurred in the judgment of the court or dissented with the opinion of the court. A plurality opinion that announced the judgment of the court was counted as the opinion of the court. Opinions concurring-in-part and concurring-in-the-judgment were counted as concurrences. Opinions concurring-in-part and dissenting-in-part were counted as dissents.

Table 7 (cont'd)

Note:

(a) Precedential and non precedital opinions insidensis by the CAPO in 2007.

(a) CP = Number of common passes each part of judges participated in.

(b) CD = Number of common opinions, i.e., majory of opinions and occumences or disserts shared by each part of judges in all the common opinions, i.e., majory of opinions and occumences or disserts shared by each part of judges participated.

(c) % - CDOCP

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Table 7 - Number of Common Panels and Decalons Between Judges During the 12-Month Period Ending December 31, 20

Table 8 lists the patent appeals broken down by precedential ("P") opinions and nonprecedential ("N") opinions and orders as designated by the United States Court of Appeals for the Federal Circuit ("CAFC") on its daily log during the twelve-month period ending December 31, 2007.

Table 8 - List of Examined Precedential and Nonprecedential Opinions Issued During the 12-Month Period Ending December 31, 2007

No.	Date	Dkt#	Origin	Case Name	P/N
1	1/4/2007	06-1168	DCT	Desa IP, LLC v. EML Techs., LLC	N
2	1/4/2007	06-1222	DCT	Propat Int'l Corp. v. Rpost	P
3	1/5/2007	06-1101	DCT	Abbott Labs. v. Andrx Pharms.	P
4	1/8/2007	06-1096	DCT	Amini Innovation Corp. v. California	N
5	1/9/2007	06-1245	DCT	Aspex Eyewear v. Concepts in Optics	N
6	1/9/2007	06-1556	DCT	Grasty v. U.S. Patent & Trademark Off.	N
7	1/9/2007	06-1575	DCT	Roper v. Jo-Ann Stores	N
8	1/10/2007	07-1017	DCT	Parker v. Microsoft	N
9	1/10/2007	06-1272	DCT	Shanghai Meihao Elec. v. Leviton	N
10	1/11/2007	04-1618	ITC	Fuji Photo Film Co. v. International Trade Commission	P
11	1/12/2007	06-1356	DCT	E-Pass Techs. v. 3Com Corp. (also known as 3Com)	P
12	1/18/2007	06-1077	DCT	Transclean Corp. v. Jiffy Lube Int'l	P
13	1/19/2007	06-1102	DCT	Ortho-McNeil Pharm. v. Caraco Pharm. Labs., Ltd.	P
14	1/23/2007	06-1100	DCT	VAS-CATH v. Curators of the University of Missouri	P
15	1/24/2007	06-1062	DCT	MBO Labs. v. Dickinson & Co.	P
16	1/25/2007	06-1376	DCT	Adrain v. Superchips	N
17	1/25/2007	06-1188	DCT	Hydril Co.,. LP v. Grant Prideco LP	P
18	1/25/2007	06-1114	DCT	Logan, Jr. v Hormel Foods	N
19	1/26/2007	05-1434	DCT	Andersen Corp. v. Fiber Composites, LLC	P
20	1/29/2007	06-1218	DCT	Israel Bio-Engineering, Project v. Amgen	P
21	1/30/2007	06-1404	DCT	Time 'N Temperature v. Sensitech	N
22	2/1/2007	05-1238	DCT	Voda v. Cordis Corp.	P
	2/5/2007	06-1289	DCT	Medtronic Navigation v. Brainlab Medizinische Computersysteme	N
23				GMBH	
24	2/9/2007	05-1330	DCT	Dippin' Dots v. Mosey v. Esty, Ir.	P
25	2/14/2007	06-1265	DCT	Cargill v. Cambra Foods	P
26	2/14/2007	06-1231	DCT	Colassi v. Cybex Int'l	N
27	2/15/2007	06-1450	PTO	Mukherjee v. Chu	N
28	2/16/2007	05-1610	DCT	RFR Indus. v. Century Steps	P
29	2/20/2007	06-1147	DCT	MyMail, Ltd. v. America Online	P
30	2/21/2007	06-1391	DCT	Severson Env't Servs. v. Shaw Env't, Inc.	P
31	2/23/2007	05-1398	DCT	Hakim v. Cannon Avent Group, PLC	P
32	2/27/2007	06-1407	DCT	Aquatex Indus. v. Techniche Solutions [reposted with cover sheet]	P
	3/1/2007	06-1442	DCT	Franklin Elec. Co. v. Dover Corp. (doing business as OPW Fueling	N
33				Components)	
34	3/1/2007	MISC841	DCT	In re Princo Corp.	P
35	3/2/2007	06-1190	DCT	Sawgrass Techs. v. Texas Original Graphics	N
	3/2/2007	06-1420	DCT	Walter Kidde Portable Equipment v. Universal Security Instruments	P
36					
37	3/6/2007	06-1242	PTO	In re Serenkin	P
38	3/13/2007	06-1497	DCT	Polypro v. Addison	N
	3/19/2007	06-1514	DCT	Cellco P'ship. (doing business as. Verizon Wireless) v. Broadcam	N
39				Corp.	
40	3/20/2007	05-1415	DCT	Cross Medical Products v. Medtronic Sofamor Danek	P
41	3/20/2007	06-1385	DCT	eSpeed v. Brokertec USA, L.L.C.	P
42	3/21/2007	06-1261	DCT	Pfizer v. Apotex (formerly known as TorPharm)	P
43	3/22/2007	06-1156	DCT	Liebel-Flarsheim Co. v. Medrad	P
44	3/26/2007	05-1587	DCT	RFR Indus. v. Rex-Hide Indus. v. Century Step	N
45	3/26/2007	05-1300	DCT	Sandisk Corp. STMicroelectronics	P

Table 8 (cont'd)

Table 8 - List of Examined Precedential and Nonprecedential Opinions Issued During the 12-Month Period Ending December 31, 2007

No.	Date	Dkt#	Origin	Case Name	P/N
46	3/29/2007	06-1211	DCT	Citizen Elecs. Co. v. Osram GMBH	N
47	3/29/2007	06-1401	DCT	March & Co. v. HI-TECH Pharmacal Co.	P
48	3/30/2007	05-1601	DCT	AFG. Indus. v. Cardinal IG Co.	N
49	3/30/2007	06-1181	DCT	Teva Pharms. USA . Novartis Pharms. Corp.	P
	4/3/2007	06-1307	DCT	Cent. Admixture Pharmacy Sers. v. Advanced Cardiac Solutions	P
50					
51	4/4/2007	05-1358	DCT	Immersion Corp. v. Sony Computer Entm't Am.	N
52	4/5/2007	07-1029	DCT	Korsinsky v. Dudas	N
53	4/6/2007	06-1276	DCT	Bass Pro Trademarks v. Cabela's	P
54	4/12/2007	06-1260	DCT	Acumed LLC v. Stryker Corp.	P
55	4/18/2007	05-1546c	DCT	Intamin, LTD. v. Magnetar Techs., Corp. [corrected cover sheet on 04/26/07]	P
56	4/19/2007	05-1546e	DCT	Advanced Tech. Materials v. Praxair, Inc.	N
57	4/20/2007	04-1621	DCT	In re Omeprazole Patent Litigation	P
58	4/25/2007	07-1240no	DCT	Verizon Servs. Corp. v. Vonage Holdings Corp.	N
59	4/27/2007	06-1504	DCT	Pods v. Porta Stor	P
60	5/2/2007	06-1604	DCT	EPass Techs. v. Microsoft Corp.	N
61	5/2/2007	06-1582	DCT	Foremost in Packaging Sys. (Doing Business as Envirocooler) v. Cold Chain Techs.	p
62	5/3/2007	06-1203	DCT	Syngenta Seeds v. Monsanto Co.	N
63	5/9/2007	06-1402	DCT	Leapfrog Enterprises v. Fisher-Price	P
64	5/11/2007	06-1542	PTO	Henkel Corp. v. The Procter & Gamble Co.	P
65	5/14/2007	06-1419	PTO	Brand v. Miller	P
66	5/16/2007	06-1569	DCT	General Mills v. Kraft Foods Global	P
67	5/17/2007	06-1120	DCT	Hildebrand v. Steck Mfg. Co.	N
68	5/18/2007	06-1517	DCT	McKesson Info. Solutions, Inc. v. Bridge Medical, Inc.	P
69	5/18/2007	05-1242	DCT	Wechsler v. Macke Int'l Trade	P
70	5/21/2007	06-1523	DCT	Byrne v. The Black & Decker Corp.	N
71	5/23/2007	07-1064	DCT	Furnace Brook, LLC v. Overstock.com	N
72	5/24/2007	05-1570	DCT	Monsanto Co. v. McFarling	P
73	5/25/2007	05-1112	DCT	Honeywell Intl'I. Inc. v. Universal A	P
74	5/29/2007	06-1490	DCT	Haberman v. Gerber Products Co.	N
75	5/29/2007	05-1497	DCT	Motionless Keyboard Co. v. Microsoft Corp.	P
76	5/31/2007	06-1587	DCT	Automated Techs. v. Knapp Logistics & Automation	N
77	6/6/2007	06-1645	DCT	NMT Medical v. Cardia	N
78	6/13/2007	04-1440	DCT	Entegris, Inc. v. Pall Corp.	P
79	6/15/2007	07-1056	PTO	In re Margolin	N
80	6/18/2007	06-1350	DCT	Biomedino LLC v. Waters Techs. Corp.	P
81	6/21/2007	06-1243	DCT	Bender v. Dudas	P
82	6/25/2007	06-1320	DCT	Microstrategy Inc. v. Bus. Objects Am.	N
83	6/27/2007	06-1576	DCT	The Saunders Group, Inc. v. Comfortrac, Inc.	P
84	6/27/2007	06-1455	DCT	Young v. Lumenis, Inc.	P
85	6/28/2007	06-1171	DCT	Hyatt v. Dudas	p p
86	6/28/2007	06-1329 06-1584	DCT	Takeda Chemical Indus. v. Alphapharm P'ship, LTD. Frazier v. Lavne Christensen Co.	N
87	7/3/2007	06-1584	DCT	Frazier v. Layne Christensen Co. Honeywell Int'l Inc. v. Unviersal Avionics Systems Corp.	P
88 89	7/3/2007	06-1539	DCT	Hutchins v. Zoll Medical Corp.	P
	7/5/2007	05-1492	DCT	Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki	P
90 91	7/9/2007	05-1492	DCT	PharmaStem Therapeutics, Inc. v. ViaCell, Inc.	P
92	7/16/2007	06-1620	DCT	Automed Techs. v. Microfil, LLC	N
92	7/10/2007	30-1020	DCI	Patromena Peteris. V. Sellertijin, E.E.C.	14

Table 8 (cont'd)

Table 8 - List of Examined Precedential and Nonprecedential Opinions Issued During the 12-Month Period Ending December 31, 2007

No.	Date	Dkt#	Origin	Case Name	P/N
93	7/20/2007	06-1122	DCT	Benitec Australia, LTD. v. Nucleonics, Inc.	P
	7/23/2007	06-1254	DCT	In re Metoprolol Succinate Patent Litig., Astrzeneca AB v. KV Pharm.	P
94				Co.	
95	7/24/2007	07-1092	DCT	Cybersettle v. Nat'l Arbitration Forum	N
96	7/27/2007	06-1471	DCT	Boynton v. Headwaters (formerly known as Covol Techs.)	N
97	7/27/2007	02-1052c	SC US	Integra Lifesciences I, LTD. v. Merch KGaA [corrected]	P
98	8/1/2007	06-1593	DCT	Biotechnology Indus. Org. v. District of Columbia	P
99	8/1/2007	06-1573	PTO	In re Icon Health & Fitness, Inc.	P
100	8/3/2007	06-1535	DCT	Safetcare Mfg., Inc. v. Tele-Made, Inc.	P
101	8/3/2007	06-1363	DCT	Sony Elecs. v. Guardian Media Techs.	P
	8/8/2007	06-1434	DCT	Boston Scientific Scimed (formerly known as Scimed Life Sys.) v.	P
102				Medtronic Vascular (also known as Medtronic AVE)	
103	8/13/2007	06-1592	DCT	Nisus Corp. v. Perma-Chink Sys., Inc. v. Teschner	P
104	8/20/2007	M830	DCT	In re Seagate Tech., LLC.	P
105	8/20/2007	06-1154	PTO	Frazer v. Schlegel	
106	8/22/2007	06-1599	PTO	In re Trans Tex. Holdings Corp.	P
107	8/24/2007	06-1240	DCT	Ormco Corp. v. Align Tech., Inc.	P
108	8/24/2007	06-1249	DCT	Shum v. Intel Corp.	P
109	8/29/2007	06-1562	DCT	Egyptian Goddess, Inc. v. Swisa, Inc.	P
110	8/29/2007	06-1507	PTO	In re Sullivan	P
111	9/5/2007	07-1059	DCT	Forest Labs., Inc. v. Ivax Pharms., Inc.	P
112	9/5/2007	06-1312	DCT	Mitutoyo Corp. v. Cent. Purchasing, LLC	P
113	9/6/2007	06-1013	DCT	Automotive Techs. Int'l, Inc. v. BMW of N. Am., Inc.	P
114	9/6/2007	06-1603	DCT	Data Encrytption Corp. v. Microsoft Corp.	N
115	9/6/2007	06-1382	DCT	Gillespie v. DYWIDAG Sys. Int'l, USA	P
116	9/6/2007	06-1612	DCT	Toshiba Corp. v. Juniper Networks, Inc.	N
117	9/11/2007	06-1530	DCT	Aventis Pharma Deutschland GMBH v. Lupin, LTD.	P
	9/12/2007	06-1570	DCT	Acco Brands, Inc. (doing business as Kensington Tech. Group) v. ABA	P
118				Locks Manufacturer Co, LTD	
	9/12/2007	06-1561	DCT	Arminak and Associates, Inc. v. Saint-Gobain Calmar, Inc. (now	P
119				known as MeadWestvaco Calmar, Inc.)	
	9/12/2007	06-1564r	DCT	Daiichi Sankyo Co., LTD (formerly known as Daiichi Pharm. Co., Ltd)	P
120				v. Apotex, Inc. [reissued as a precedential opinion]	
720	9/12/2007	06-1465	DCT	L.B. Plastics, Inc. v. Amerimax Home Products, Inc. (doing business as	P
121				Gutter World)	
.21	9/14/2007	06-1548	DCT	McZeal, Jr. (doing business as Int'l Walkie Talkie) v. Sprint Nextel	P
122				Corp.	
123	9/19/2007	06-1571	DCT	Adenta GMBH v. Orthoarm, Inc.	P
124	9/19/2007	06-1512	DCT	Morrow v. Microsoft Corp.	P
125	9/20/2007	06-1503	DCT	BMC Resources, Inc. v. Paymentech, L.P.	P
126	9/20/2007	07-1087	DCT	GP Indus., Inc. v. Eran Indus., Inc.	P
.20	9/20/2007	06-1305	DCT	MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp.	N
127					
128	9/20/2007	06-1286	PTO	In re Comiskey	P
129	9/20/2007	06-1371	PTO	In re Nuijten	P
130	9/21/2007	06-1572	DCT	In re Gabapentin Patent Litig.	P
131	9/24/2007	07-1108	DCT	Maurice Mitchell Innovations, L.P. v. Intel Corp.	N
132	9/26/2007	07-1240	DCT	Verizon Servs. Corp. v. Vonage Holdings Corp.	P
133	9/27/2007	06-1342	DCT	CIAS, Inc. v. Alliance Gaming Corp.	P
134	9/27/2007	07-1132	DCT	EON-Net LP v. Flagstar Bancorp	N

Table 8 (cont'd)

Table 8 - List of Examined Precedential and Nonprecedential Opinions Issued During the 12-Month Period Ending December 31, 2007

No.	Date	Dkt#	Origin	Case Name	P/N
135	9/27/2007	06-1489	PTO	In re Buszard	P
136	9/28/2007	06-1012	DCT	IpVenture, Inc. v. ProStar Computer, Inc.	P
137	10/4/2007	06-1472	DCT	Monsanto Co. v. Syngenta Seeds	P
138	10/4/2007	07-1447r	DCT	Somerset Pharms. v. Dudas [resissued as precedential]	P
	10/10/2007	06-1330	DCT	Baum Research and Development Co., Inc. v. University of	P
139				Massachusetts at Lowell	
	10/10/2007	06-1550	DCT	Nilssen v. Osram Sylvania, Inc.	P
141	10/11/2007	07-1019	DCT	Abbott Labs. v. Torpharm, Inc.	P
142	10/12/2007	05-1387	DCT	Translogic Tech., Inc. v. Hitachi, LTD	N
	10/12/2007	06-1440	DCT	Allvoice Computing PLC v. Nuance Communications, Inc. (formerly	P
143				known as ScanSoft, Inc.)	
	10/12/2007	07-1074	DCT	Schwarz Pharma, Inc. v. Paddock Labs., Inc.	P
	10/12/2007	06-1192	PTO	In re Translogic Tech., Inc.	P
	10/15/2007	07-1035	DCT	Air Measurement Techs., Inc. v. Akin Gump Strauss Hauer & Feld,	P
	10/15/2007	07-1206	DCT	F&G Research, Inc. v. Paten Wireless Tech., Inc.	N
	10/15/2007	06-1432	DCT	Immunocapt, LLC v. Fulbright & Jaworski, LLP	P
	10/15/2007	07-1034	DCT	Int'l Gamco v. Multimedia Games	P
150	10/18/2007	06-1610	DCT	Paice, LLC v. Toyota Motor Corp.	P
151	10/23/2007	06-1515	DCT	Biomedical Patent Mgmt. Corp. v. State of California, Dept. of Health	P
152	10/24/2007	07-1026	DCT	Wisconsin Alumni Research Found. v. Xenon Pharms., Inc	N
153	10/25/2007	07-1120	PTO	Adang v. Umbeck	N
154	10/26/2007	07-1093	DCT	Pharm. Res., Inc. v. Roxane Labs., Inc.	N
155	10/26/2007	07-1162	DCT	Sys. Division, Inc. v. Tehnek Elecs., LTD.	N
156	10/31/2007	06-1282	USITC	Osram GMBH v. International Trade Commission	P
157	11/1/2007	07-1133	DCT	Digeo, Inc. v. Audible, Inc.	P
158	11/2/2007	07-1117	DCT	U.S. Philips Corp. v. Iwasaki Elec. Co. LTD.	P
159	11/6/2007	07-1396	DCT	Hutchins v. Zoll Medical Corp.	N
160	11/7/2007	06-1266	DCT	Zenon Env't, Inc. v. United States Filter Corp. (now known as Water	P
161	11/13/2007	06-1522	DCT	HIF Bio v. Yung Shin Pharms. Indus. Co., LTD	P
162	11/15/2007	07-1083	DCT	Connell v. KLN Steel Prods. Co.	N
163	11/16/2007	06-1405	DCT	Apotex Corp. v. Merck & Co.	P
164	11/16/2007	06-1615	DCT	Canon, Inc. v. GCC Int'l Ltd.	N
165	11/16/2007	06-1638	DCT	Z4 Techs., Inc. v. Microsoft Corp.	P
166	11/19/2007	07-1150	PTO	In re Chatani	N
167	11/29/2007	07-1196	PTO	In re Lew	N
168	11/28/2007	07-1097	DCT	Elbex Video, Ltd. v. Sensormatic Elecs.	P
169	11/28/2007	07-1186	DCT	Stumbo v. Eastman Outdoors, Inc.	N
170	12/5/2007	07-1403	DCT	Millman v. U.S. PTO	N
171	12/5/2007	07-1221	PTO	In re Garner	P
172	12/12/2007	1204, 1238	DCT	MPT Inc., v. Marathon Labels, Inc et al.	N
173	12/19/2007	07-1273	DCT	Wleklinski v. Targus, Inc.	N
174	12/21/2007	06-1633	ITC	Sinorgchem Co., Shandong v. ITC and Flexsys America LP	P
175	12/26/2007	1176	DCT	Hyperphase Technologies, LLC and Hyperphase, Inc. v. Google.	N
	Notes:				
	(a) Informatio	n collected fro	m http:/www	.cafc.uscourts.gov/dailylog.html.	
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