
AREA SUMMARIES

2009 PATENT LAW
DECISIONS OF THE FEDERAL CIRCUIT*

DONALD R. DUNNER**

BRYAN C. DINER***

ESTHER H. LIM****

TROY E. GRABOW*****

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** Partner, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP; J.D., *Georgetown University Law Center*, 1958; B.S., Chemical Engineering, *Purdue University*, 1953. Mr. Dunner served as a law clerk to the Honorable Noble J. Johnson, Chief Judge of the U.S. Court of Customs and Patent Appeals.

*** Partner, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP; J.D., *Seton Hall University School of Law*, 1987; B.S., Chemical Engineering, *New Jersey Institute of Technology*, 1984.

**** Partner, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP; J.D., *University of Maryland School of Law*, 1995; B.A., Computer Science and Mathematics, *Towson University*, 1992. Ms. Lim is the editor-in-chief of Finnegan's *Last Month at the Federal Circuit Newsletter*. She also served as a law clerk to the Honorable Randall R. Rader of the U.S. Court of Appeals for the Federal Circuit.

***** Partner, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP; J.D., *George Washington University School of Law*, 2000; B.S., Mechanical Engineering,

TINA E. HULSE*****

JOYCE CRAIG*****

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Union College, 1993. Mr. Grabow served as a law clerk to the Honorable Timothy B. Dyk of the U.S. Court of Appeals for the Federal Circuit.

***** Associate, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP; J.D., *University of California, Berkeley School of Law*, 2004; M.D., *Tufts University School of Medicine*, 2001; B.A., Molecular Biology, *Pomona College*, 1997. Dr. Hulse is an assistant editor of Finnegan's *Last Month at the Federal Circuit Newsletter*.

***** Associate, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP; J.D., *George Washington University School of Law*, 2004; M.S., Technology Management, *University of Maryland University College*, 2000; B.S., Computer Science, *Florida State University*, 1985. Ms. Craig is an associate editor of the firm's *Last Month at the Federal Circuit Newsletter*. She also served as a law clerk to the Honorable Joseph J. Farnan, Jr. of the U.S. District Court for the District of Delaware.

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INTRODUCTION

The year 2009 saw many changes in U.S. patent law across all three branches of the government. In the executive branch, following the historic election of President Obama, the new administration ushered in changes in personnel and policy at the United States Patent and Trademark Office (USPTO). Changes in personnel included many new appointments, the most notable being the appointment of David Kappos as Director of the USPTO.¹ With changes in personnel came a number of changes in policy. Under the new director's leadership, the USPTO removed from its regulations highly controversial rules regarding claims and continuation practice.²

Change also swept across the judicial branch at the U.S. Supreme Court and at the U.S. Court of Appeals for the Federal Circuit. On August 8, 2009, Sonia Sotomayor was sworn in as an Associate Justice of the Supreme Court,³ becoming the first Hispanic American and the third female to serve on the nation's highest court.⁴ Although the Court issued no patent decisions in 2009, it heard oral arguments in *Bilski v. Kappos*⁵ in November, setting the stage for a highly anticipated decision in 2010 that will address the most basic question of patent law: patentable subject matter.⁶

1. See Press Release, U.S. Dep't of Commerce, Locke Statement on Confirmation of David Kappos as Patent and Trade Director (Aug. 7, 2009), available at http://www.commerce.gov/NewsRoom/PressReleases_FactSheets/PROD01_008268 [hereinafter Locke Statement] (announcing Kappos's confirmation and summarizing his credentials).

2. See Press Release 09-21, U.S. Patent & Trademark Office, USPTO Rescinds Controversial Patent Regulations Package Proposed by Previous Administration (Oct. 8, 2009), available at http://www.uspto.gov/news/09_21.jsp [hereinafter Press Release 09-21] (indicating that the USPTO removed the regulations because they were "highly unpopular from the outset and were not well received by the applicant community").

3. U.S. Supreme Court, The Justices of the Supreme Court, <http://www.supremecourt.gov/about/biographies.aspx> (last visited Apr. 7, 2010).

4. Lisa Desjardins, Kristi Keck & Bill Mears, *Senate Confirms Sonia Sotomayor for Supreme Court*, CNN, Aug. 6, 2009, <http://www.cnn.com/2009/POLITICS/08/06/sonia.sotomayor/index.html>.

5. No. 08-964 (U.S. argued Nov. 9, 2009).

6. Compare Brief for Petitioners at 20, *Bilski v. Kappos*, No. 08-964 (U.S. July 30, 2009) [hereinafter Pet'rs' Brief] (arguing that the Court should not restrict patentable subject matter beyond the limits expressed by Congress), with Brief for Respondent at 26, *Bilski v. Kappos*, No. 08-964 (U.S. Sept. 25, 2009) [hereinafter Resp't's Brief] (arguing that a patentable "process" is limited to technological and industrial methods and excludes methods directed to such human activities).

At the Federal Circuit, Judge Alvin A. Schall took senior status on October 5, 2009,⁷ and Chief Judge Paul R. Michel announced that he will retire from the bench as of May 31, 2010.⁸ Chief Judge Michel is applauded for his leadership and contribution to the Federal Circuit, over two decades of distinguished service to the judiciary, and over four decades of dedication to public service.⁹ Judge Randall R. Rader will succeed him as the next Chief Judge.

In 2009, the Federal Circuit decided two cases en banc, making important changes in the law relating to 35 U.S.C. § 271(f)¹⁰ and product-by-process claims.¹¹ The Federal Circuit also agreed to hear another case en banc which concerns the written description requirement.¹²

Change also percolated in the legislative branch as Congress, for the third consecutive congressional session, tried to effect the most dramatic change in U.S. patent law since 1952.¹³ In March, 2009, members of Congress introduced a set of patent reform bills in both houses of Congress,¹⁴ contributing to an atmosphere of change on the Hill.

7. U.S. Court of Appeals for the Federal Circuit, Judicial Biographies, <http://www.cafc.uscourts.gov/judgbios.html> (last visited Apr. 7, 2010) [hereinafter Biographies].

8. See Chief Judge Paul R. Michel, U.S. Court of Appeals for the Federal Circuit, Remarks at the 25th Annual Federal Circuit Bar Association Dinner 3 (Nov. 20, 2009), http://www.cafc.uscourts.gov/pdf/CJ_Michel_11-20-09.pdf [hereinafter Remarks].

9. See Biographies, *supra* note 7 (noting the judge's reputation as one of the most influential people in the field of intellectual property).

10. See *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 576 F.3d 1348, 1365, 91 U.S.P.Q.2d (BNA) 1898, 1911–12 (Fed. Cir. 2009) (en banc) (holding that § 271(f) does not apply to method patents), *cert. denied*, 130 S. Ct. 1088 (2010).

11. See *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1293, 90 U.S.P.Q.2d (BNA) 1769, 1777–78 (Fed. Cir. 2009) (en banc) (holding that process terms in product-by-process claims may set limitations in determining whether there is patent infringement), *cert. denied sub nom. Astellas Pharma, Inc. v. Lupin Ltd.*, 130 S. Ct. 1052 (2010).

12. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 332 F. App'x 636, 637 (Fed. Cir. 2009) (granting the plaintiffs' motion for a rehearing en banc). Just before this Area Summary went to print, the Federal Circuit, sitting en banc, confirmed the separate requirements of written description and enablement, and thereby reversed in part and affirmed in part its previous panel decision. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, No. 2008-1248, 2010 WL 1007369 (Fed. Cir. Mar. 22, 2010) (en banc).

13. See Press Release, Senators Hatch, Leahy Introduce Patent Reform Act of 2009 (Mar. 3, 2009), available at http://hatch.senate.gov/public/index.cfm?FuseAction=PressReleases.Detail&PressRelease_id=ce28c6f0-1b78-be3e-e028-418ea18126e5.

14. Patent Reform Act of 2009, H.R. 1260, 111th Cong. (2009) (introduced simultaneously in the Senate as S. 515 and S. 610).

I. SIGNIFICANT CHANGES BY BRANCH

A. *The Executive Branch: New Personnel, Old Rules*

In 2009, the USPTO underwent important changes in both personnel and policy. On June 18, 2009, David J. Kappos, then Vice President and Assistant General Counsel for Intellectual Property Law at IBM, was nominated for Under Secretary of Commerce for Intellectual Property and Director of the USPTO.¹⁵ He was confirmed on August 7, 2009.¹⁶

After the appointment of a new Director in June, the rest of the senior management team transitioned. On October 2, Commerce Secretary Gary Locke appointed Sharon Barner as the Deputy Director of the USPTO.¹⁷ On the same day, John Doll retired from the post of Commissioner for Patents after thirty-five years at the agency.¹⁸ Longtime USPTO executive Robert Stoll took Doll's position.¹⁹ Finally, Margaret Focarino became the Deputy Commissioner for Patents.²⁰

Catching more headlines than the personnel changes was the roller-coaster development surrounding the new USPTO rules. In August, 2007, the USPTO published in the *Federal Register* changes to the rules of patent practice pertaining to requests for continued examination, continuing applications, and examination of claims.²¹ Specifically, the rules set a limit of two continuing applications and

15. Press Release, The White House, Office of the Press Sec'y, President Obama Announces More Key Administration Posts (Jun. 18, 2009), *available at* http://www.whitehouse.gov/the_press_office/president-obama-announces-more-key-administration-posts-6-18-09/. During Kappos's sixteen years managing IBM's intellectual property portfolio, the company had consistently been the leading recipient of U.S. patents.

16. Locke Statement, *supra* note 1. During his confirmation hearing, Kappos pledged to "completely remake the count system" in order to improve efficiency and morale at the USPTO. *Webcast: Nominations: Hearing on Nominations Before the S. Comm. on the Judiciary*, 111th Cong. (July 29, 2009), <http://judiciary.senate.gov/hearings/hearing.cfm?id=4006> (statement of David J. Kappos, Nominee for Under Secretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office).

17. See Press Release, U.S. Patent & Trademark Office, Commerce Secretary Gary Locke Appoints Sharon Barner Deputy Director of the U.S. Patent and Trademark Office (Oct. 2, 2009), *available at* http://www.uspto.gov/news/pr/2009/irl_2009oct02.jsp.

18. Press Release 09-14, U.S. Patent & Trademark Office, USPTO Announces Senior Management Changes (Sept. 3, 2009), *available at* <http://www.uspto.gov/web/offices/com/speeches/09-14.htm>.

19. *Id.*

20. *Id.*

21. 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).

one request for continued examination as a matter of right.²² In addition, the rules impose a limit of five independent claims and twenty-five total claims without any additional effort on the part of the applicant.²³

The new rules, while intended to deal with the heavy backlog of patent applications at the USPTO, sent shockwaves through the patent community.²⁴ In particular, the biotechnology and pharmaceutical industries expressed strong concern over the proposed rules' detrimental effect on innovation and industry when, in an unusual turn of events, the published rules became the subject of litigation. Triantafyllos Tafas, an inventor, sued the USPTO in the U.S. District Court for the Eastern District of Virginia, asserting that the agency overstepped its rulemaking authority.²⁵ In October 2007, GlaxoSmithKline (GSK) also filed a complaint against the USPTO, challenging the rules.²⁶ The district court consolidated the two cases and enjoined the USPTO from implementing the rules.²⁷ The USPTO appealed to the Federal Circuit.²⁸

After hearing oral arguments in December, 2008, the Federal Circuit issued a split-panel decision on March 20, 2009, holding that the rules restricting the number of continuing applications conflicted with 35 U.S.C. § 120 and were thus invalid.²⁹ On July 6, 2009, the Federal Circuit vacated the split-panel decision and heard the case en banc.³⁰ The court later granted the parties' Joint Consent Motion, staying the en banc proceedings until sixty days after the confirmation of the new director of the USPTO.³¹ On August 21,

22. *Id.* at 46,839–41.

23. *Id.* at 46,836.

24. See Press Release 09-21, *supra* note 2 (noting that the regulations were extremely unpopular and were not well received).

25. See *Tafas v. Dudas*, 541 F. Supp. 2d 805, 808, 86 U.S.P.Q.2d (BNA) 1623, 1625 (E.D. Va. 2008) (holding that the USPTO exceeded its statutory jurisdiction), *aff'd in part and vacated in part*, 559 F.3d 1345, 90 U.S.P.Q.2d (BNA) 1129 (Fed. Cir. 2009).

26. See Complaint at 2, *SmithKline Beecham Corp. v. Dudas*, 511 F. Supp. 2d 652, 86 U.S.P.Q.2d (BNA) 1548 (E.D. Va. 2007) (No. 1:07cv1008) (arguing that the final rules were "vague, arbitrary and capricious," and that they prevented the plaintiff from fully prosecuting and obtaining patents on its inventions).

27. See *infra* Part IV.A (providing a detailed litigation history).

28. Notice of Appeal, *Tafas v. Dudas*, 511 F. Supp. 2d 652, 86 U.S.P.Q.2d (BNA) 1548 (E.D. Va. 2007) (No. 1:07cv1008).

29. *Tafas v. Doll*, 559 F.3d 1345, 1364, 90 U.S.P.Q.2d (BNA) 1129, 1143 (Fed. Cir. 2009), *vacated*, 328 F. App'x 658, 91 U.S.P.Q.2d (BNA) 1153 (Fed. Cir. 2009) (per curiam).

30. *Tafas*, 328 F. App'x 658, 91 U.S.P.Q.2d (BNA) 1153.

31. *Tafas v. Doll*, 331 F. App'x 748, 748 (Fed. Cir. 2009) (order granting joint consent motion for a stay of en banc proceedings).

2009, the court lifted the stay, ordering the parties to file their briefs.³²

On October 8, 2009, the case reached a dramatic end, however, when the USPTO announced that the new director, David Kappos, signed a final rule rescinding the controversial regulations.³³ The USPTO, joined by GSK, filed a motion to dismiss the appeal and vacate the district court's decision.³⁴ Tafas filed a response, joining in the joint motion for dismissal of the appeal, but opposing the joint motion for vacatur.³⁵ The Federal Circuit ruled in Tafas's favor, granting the joint motion to dismiss while denying the motion to vacate.³⁶

The USPTO, in addition to rescinding the final rule, unveiled a series of proposals to bring significant change to the examiner "count system."³⁷ The proposals constitute the most significant changes to the count system proposed in more than thirty years.³⁸ According to the USPTO, the proposed changes are designed to:

- Set the foundation for long-term pendency improvements.
- Increase customer satisfaction by incentivizing quality work at the beginning of the examination process.
- Encourage examiners to identify allowable subject matter earlier in the examination process.
- Rebalance incentives both internally and externally to decrease rework.
- Increase examiner morale and reduce attrition.³⁹

32. *Tafas v. Kappos*, 332 F. App'x 635, 636 (Fed. Cir. 2009) (order requiring the parties to file their briefs within sixty days).

33. Press Release 09-21, *supra* note 2.

34. *Tafas v. Kappos*, 586 F.3d 1369, 92 U.S.P.Q.2d (BNA) 1693 (Fed. Cir. 2009).

35. *Id.* at 1371, 92 U.S.P.Q.2d (BNA) at 1694.

36. *See id.*, 92 U.S.P.Q.2d (BNA) at 1694 (stating that vacatur is inappropriate when mootness occurs as a result of actions taken by the losing party).

37. Press Release 09-19, U.S. Patent & Trademark Office, USPTO Joint Labor-Management Task Force Proposes Significant Changes to Examiner Count System (Sept. 30, 2009), *available at* <http://www.uspto.gov/web/offices/com/speeches/09-19.htm> [hereinafter Press Release 09-19]. The count system refers to the methodology for determining the time a patent examiner has to complete a patent examination and the amount of credit given for each stage of examination. *Id.* For the full proposal, *see* U.S. PATENT AND TRADEMARK OFFICE, JOINT LABOR AND MANAGEMENT COUNT SYSTEM TASK FORCE PROPOSAL (Sept. 30, 2009), http://www.uspto.gov/web/offices/ac/ahrpa/opa/documents/briefing_for_corps-final_draft-093009-external-jrb.pdf.

38. Press Release 09-19, *supra* note 37.

39. *Id.*

B. *The Judicial Branch: The Supreme Court and the Federal Circuit*

1. *Bilski at the Supreme Court*

For the first time in nearly three decades, the Supreme Court will address the question of whether a process is patentable subject matter.⁴⁰ Despite the Government's opposition to Bernard L. Bilski's petition for a writ of certiorari, the Supreme Court granted certiorari in *Bilski* on June 1, 2009, and certified two questions presented:

Whether the Federal Circuit erred by holding that a "process" must be tied to a particular machine or apparatus, or transform a particular article into a different state or thing ("machine-or-transformation" test), to be eligible for patenting under 35 U.S.C. § 101, despite this Court's precedent declining to limit the broad statutory grant of patent eligibility for "any" new and useful process beyond excluding patents for "laws of nature, physical phenomena, and abstract ideas."

Whether the Federal Circuit's "machine-or-transformation" test for patent eligibility, which effectively forecloses meaningful patent protection to many business methods, contradicts the clear Congressional intent that patents protect "method[s] of doing or conducting business."⁴¹

Addressing the first issue, Bilski's brief examined *Diamond v. Diehr*⁴² and *Diamond v. Chakrabarty*,⁴³ cases in which the Supreme Court interpreted § 101 to be extremely broad, only prohibiting the patenting of laws of nature, physical phenomena, and abstract ideas.⁴⁴ According to Bilski, the Court has twice rejected the "machine-or-transformation" test.⁴⁵

40. The Supreme Court most recently addressed patentable subject matter in *Diamond v. Diehr*, 450 U.S. 175, 209 U.S.P.Q. (BNA) 1 (1981). In the category of "manufacture" or "composition of matter," the Court later decided that "newly developed plant breeds fall within the terms of § 101." *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 145, 60 U.S.P.Q.2d (BNA) 1865, 1874 (2001).

41. Petition for Writ of Certiorari, *Bilski v. Kappos*, 129 S. Ct. 2735 (2009) (No. 08-964) (quoting 35 U.S.C. § 273 (2006)).

42. 450 U.S. 175, 209 U.S.P.Q. (BNA) 1 (1981).

43. 447 U.S. 303, 206 U.S.P.Q. (BNA) 193 (1980).

44. See Pet'rs' Brief, *supra* note 6, at 18–19 (arguing that principles of statutory construction mandate a broad reading of the term "process").

45. *Id.* at 20–21; see *Parker v. Flook*, 437 U.S. 584, 589 n.9, 198 U.S.P.Q. (BNA) 193, 197 n.9 (1978) (assuming that process is patent eligible even where the process is not "tied to a particular apparatus or operated to change materials"); *Gottschalk v. Benson*, 409 U.S. 63, 71, 175 U.S.P.Q. (BNA) 673, 676 (1972) (refusing to hold that a process patent must be "tied to a particular machine or apparatus or must operate to change articles or materials to a 'different state or thing'").

Nonetheless, the Federal Circuit majority in *In re Bilski*⁴⁶ relied on a quoted passage from the Supreme Court's opinion in *Gottschalk v. Benson*: "[T]ransformation and reduction of an article 'to a different state or thing' is the clue to the patentability of a process claim that does not include particular machines."⁴⁷ But, Bilski argued, the Court in *Benson* expressly did not hold that a process must be tied to a machine or transformation to be eligible for patenting.⁴⁸ He urged that the Federal Circuit erred in *In re Bilski* by subjecting process claims to additional conditions for patent eligibility.⁴⁹

In response, the Government stressed that § 101, though broad, imposes meaningful limits on the scope of patent protection.⁵⁰ As a result, the Government argued, patent law protects technological and industrial processes but not methods of organizing human activity.⁵¹ Also citing *Benson*, *Flook*,⁵² and *Diehr*, the Government argued that the Supreme Court has consistently used the "machine-or-transformation" test to identify patent-eligible processes.⁵³ It acknowledged that the Court did not decide the precise outer boundaries of the universe of patent-eligible processes.⁵⁴ The Government stated, however, that the "machine-or-transformation" test remains "the generally applicable standard."⁵⁵

On November 9, 2009, the long-awaited oral arguments at the Supreme Court took place. During the one-hour of arguments, certain Justices questioned Bilski's lawyer about hypothetical patents, such as patenting methods for tax avoidance, estate planning, resisting a corporate takeover, selecting a jury, winning friends, influencing people, and speed dating.⁵⁶ The Justices also had questions for the Government. For example, Justice Sotomayor

46. 545 F.3d 943, 88 U.S.P.Q.2d (BNA) 1385 (Fed. Cir. 2008) (en banc), cert. granted sub nom. *Bilski v. Doll*, 129 S. Ct. 2735 (2009), and argued sub nom. *Bilski v. Kappos*, No. 08-964 (U.S. Nov. 9, 2009).

47. *Id.* at 955–56, 88 U.S.P.Q.2d (BNA) at 1391 (quoting *Benson*, 409 U.S. at 70, 175 U.S.P.Q. (BNA) at 676).

48. See *Benson*, 409 U.S. at 71, 175 U.S.P.Q. (BNA) at 676 ("We do not hold that no process patent could ever qualify if it did not meet the requirements of our prior precedents.").

49. See Pet'rs' Brief, *supra* note 6, at 14 (stating that the Court erred in demanding a special test for "process" inventions).

50. Resp't's Brief, *supra* note 6, at 11.

51. *Id.* at 15–19.

52. 437 U.S. 584, 198 U.S.P.Q. (BNA) 193 (1978).

53. Resp't's Brief, *supra* note 50, at 29–33.

54. *Id.* at 32.

55. *Id.*

56. Transcript of Oral Argument at 4–7, *Bilski v. Kappos*, No. 08-964 (U.S. Nov. 9, 2009), available at http://www.supremecourtus.gov/oral_arguments/argument_transcripts/08-964.pdf.

asked, “[H]elp us with a test that doesn’t go to the extreme the Federal Circuit did.”⁵⁷

The patent bar eagerly awaits the Supreme Court’s decision in *Bilski*, which is expected to be issued in spring 2010. In the meantime, the Federal Circuit continued to apply the “machine-or-transformation” test in 2009, rejecting claims in two out of three such cases.⁵⁸ In the third case, the Federal Circuit applied the “machine-or-transformation” test and found that claimed methods of treatment were patent-eligible.⁵⁹

2. *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*

Title 35, § 271(f) of the United States Code creates a cause of action for patent infringement when “components” of a patented invention are “supplied” by or from a U.S. entity for assembly abroad. In *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*,⁶⁰ the Federal Circuit decided that § 271(f) does not apply to method patents.⁶¹ The Federal Circuit granted St. Jude’s petition for rehearing en banc to answer a single question: “Does 35 U.S.C. § 271(f) apply to method claims, as well as product claims?”⁶² In its opinion, the court stated that steps are the “components” of a method or process claim that “meet [the] definitional requirement of Section 271(f), but the steps are not the physical components used in [the] performance of the method.”⁶³ The court then held that § 271(f) could not apply because a method claim has only intangible steps, and because the term “supplied,” as used in the statute, implies the physical transfer of a tangible object.⁶⁴ In so doing, the Federal Circuit overruled its earlier decision in *Union Carbide Chemicals & Plastics Technology Corp.*

57. *Id.* at 37.

58. See *In re Comiskey*, 554 F.3d 967, 981, 89 U.S.P.Q.2d (BNA) 1655, 1665 (Fed. Cir. 2009) (rejecting the applicant’s claim which described a method of requiring and conducting arbitration); *In re Ferguson*, 558 F.3d 1359, 1366, 90 U.S.P.Q.2d (BNA) 1035, 1040 (Fed. Cir. 2009) (rejecting the applicant’s claim on the grounds that the applicant’s paradigm claim constituted no more than an abstract idea).

59. See *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336, 1349, 92 U.S.P.Q.2d (BNA) 1075, 1084 (Fed. Cir. 2009) (holding that the applicant’s invention of “a series of transformative steps that optimizes efficacy and reduces toxicity of a method of treatment for particular diseases using particular drugs” was a patentable subject-matter).

60. 576 F.3d 1348, 91 U.S.P.Q.2d (BNA) 1898 (Fed. Cir. 2009) (en banc), *cert. denied*, 130 S. Ct. 1088 (2010).

61. *Id.* at 1365, 91 U.S.P.Q.2d (BNA) at 1911–12.

62. *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 315 F. App’x 273, 274 (Fed. Cir. 2009) (order granting the defendants’ petition for rehearing en banc).

63. *Cardiac Pacemakers*, 576 F.3d at 1363, 91 U.S.P.Q.2d (BNA) at 1910.

64. *Id.* at 1364, 91 U.S.P.Q.2d (BNA) at 1910.

v. Shell Oil Co.,⁶⁵ which held that § 271(f) applied to the exportation of catalysts and the use of the patented method abroad.⁶⁶

Noting that Congress enacted § 271(f) to close the loophole that allowed infringers to ship unassembled patented products abroad for later assembly,⁶⁷ and observing that the legislative history of § 271(f) was “almost completely devoid of any reference to the protection of method patents,”⁶⁸ the Federal Circuit explained that its holding is “fully consistent with the legislative history of Section 271(f).”⁶⁹ The court followed the Supreme Court’s reasoning in *Microsoft Corp. v. AT&T Corp.*,⁷⁰ and resorted to the presumption against extraterritoriality before concluding that § 271(f) cannot apply to method claims.⁷¹

Judge Newman dissented, explaining that the court’s interpretation of § 271(f) as excluding all process inventions conflicts with the text of the statute.⁷² She viewed the statutory term “patented invention” in § 271(f) as “without discrimination or exception.”⁷³ Because the original language of § 271(f) expressly listed “a patented machine, manufacture, or composition of matter,”⁷⁴ while the final version was changed to “patented invention,” she believed that Congress intended to apply § 271(f) to process claims.⁷⁵

65. 425 F.3d 1366, 76 U.S.P.Q.2d (BNA) 1705 (Fed. Cir. 2005), *overruled by Cardiac Pacemakers*, 576 F.3d 1348, 91 U.S.P.Q.2d (BNA) 1898.

66. *Id.* at 1380, 76 U.S.P.Q.2d (BNA) at 1714.

67. *Cardiac Pacemakers*, 576 F.3d at 1364, 91 U.S.P.Q.2d (BNA) at 1911; *see DeepSouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 173 U.S.P.Q. (BNA) 769 (1972) (holding that making component parts of a patented invention and sending the parts abroad for assembly did not constitute patent infringement).

68. *Cardiac Pacemakers*, 576 F.3d at 1364, 91 U.S.P.Q.2d (BNA) at 1911.

69. *Id.*, 91 U.S.P.Q.2d (BNA) at 1911.

70. 550 U.S. 437, 82 U.S.P.Q.2d (BNA) 1400 (2007). In *Microsoft*, the Supreme Court held that a “master disk” is not a “component” for purposes of § 271(f) when it is copied abroad and then installed to form a system that would allegedly infringe AT&T’s patent. *Id.* at 446–47, 82 U.S.P.Q.2d (BNA) at 1406. In other words, under § 271(f), software abstracted from a tangible copy is not itself a combinable component of a tangible manufacture. *Id.* at 449–50, 82 U.S.P.Q.2d (BNA) at 1407–08. In reaching that conclusion, the Court stated: “Any doubt that Microsoft’s conduct [i.e., copying the master disk abroad] falls outside § 271(f)’s compass would be resolved by the presumption against extraterritoriality.” *Id.* at 454, 82 U.S.P.Q.2d (BNA) at 1410. However, the Court in *Microsoft* did not overrule *Union Carbide. Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 303 F. App’x 884, 893 (Fed. Cir. 2008).

71. *Cardiac Pacemakers*, 576 F.3d at 1365, 91 U.S.P.Q.2d (BNA) at 1911.

72. *Id.* at 1366, 91 U.S.P.Q.2d (BNA) at 1912 (Newman, J., dissenting).

73. *Id.*, 91 U.S.P.Q.2d (BNA) at 1912–13.

74. *Id.* at 1369–70, 91 U.S.P.Q.2d (BNA) at 1915 (quoting S. 2504, 93d Cong. § 2 (1974)).

75. *Id.* at 1370, 91 U.S.P.Q.2d (BNA) at 1916.

3. Abbott Laboratories v. Sandoz, Inc.

In a portion of the opinion that the court issued en banc sua sponte in *Abbott Laboratories v. Sandoz, Inc.*,⁷⁶ the Federal Circuit clarified the scope of product-by-process claims by applying the rule that it adopted in *Atlantic Thermoplastics Co. v. Faytex Corp.*,⁷⁷ and by overruling the holding in *Scripps Clinic & Research Foundation v. Genentech, Inc.*⁷⁸ to the extent that the case was inconsistent. That is, the Federal Circuit held that process terms in a product-by-process claim serve as limitations on the claim.⁷⁹ The court cited Supreme Court precedent as well as case law from its sister circuits.⁸⁰ According to the court, the Supreme Court “consistently noted that process terms that define the product in a product-by-process claim serve as enforceable limitations.”⁸¹

The court made it clear that it did not question whether product-by-process claims are permissible claims.⁸² Rather, the court limited the issue only to whether such claims are infringed by products made by processes other than the one claimed, and it held that they are not.⁸³

4. Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.

On August 21, 2009, the Federal Circuit vacated an earlier panel decision and granted a petition for rehearing en banc in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*⁸⁴ In its earlier panel decision, the court had reversed the district court and granted Eli Lilly and Company’s motion for judgment as a matter of law, holding that Ariad Pharmaceuticals, Inc.’s patent failed to meet the written

76. 566 F.3d 1282, 90 U.S.P.Q.2d (BNA) 1769 (Fed. Cir. 2009) (en banc), cert. denied sub nom. *Astellas Pharma, Inc. v. Lupin Ltd.*, 130 S. Ct. 1052 (2010).

77. See 970 F.2d 834, 846–47, 23 U.S.P.Q.2d (BNA) 1481, 1491 (Fed. Cir. 1992) (ruling that “process terms in product-by-process claims serve as limitations in determining infringement”).

78. See 927 F.2d 1565, 18 U.S.P.Q.2d (BNA) 1001 (Fed. Cir. 1991) (“[T]he correct reading of product-by-process claims is that they are not limited to product prepared by the process set forth in the claims.”), overruled by *Abbott Labs.*, 566 F.3d 1282, 90 U.S.P.Q.2d (BNA) 1769.

79. *Abbott Labs.*, 566 F.3d at 1293, 90 U.S.P.Q.2d (BNA) at 1778.

80. See *id.* at 1291–92, 90 U.S.P.Q.2d (BNA) at 1776 (citing seven Supreme Court cases and cases from the First and Third Circuits that support the proposition that process terms are enforceable limitations on patent infringement claims).

81. *Id.* at 1291, 90 U.S.P.Q.2d (BNA) at 1776.

82. *Id.* at 1293, 90 U.S.P.Q.2d (BNA) at 1778.

83. *Id.*, 90 U.S.P.Q.2d (BNA) at 1778.

84. 332 F. App’x 636, 637 (Fed. Cir. 2009). Just before this Area Summary went to print, the Federal Circuit, sitting en banc, confirmed the separate requirements of written description and enablement, and thereby reversed in part and affirmed in part its previous panel decision. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, No. 2008-1248, 2010 WL 1007369 (Fed. Cir. Mar. 22, 2010) (en banc).

description requirement under 35 U.S.C. § 112.⁸⁵ The court ordered the parties to address the following issues:

- (a) Whether 35 U.S.C. § 112, paragraph 1, contains a written description requirement separate from an enablement requirement.
- (b) If a separate written description requirement is set forth in the statute, what is the scope and purpose of the requirement?⁸⁶

Over twenty amicus briefs were filed by bar associations and companies.⁸⁷ On December 7, 2009, oral arguments took place, and the decision is anticipated in 2010.⁸⁸

C. *The Legislative Branch: 2009 Patent Reform Act*

Congress continued its efforts to bring about dramatic change in U.S. patent law. After the first two unsuccessful attempts at passing the Patent Reform Act,⁸⁹ members of Congress again introduced the bill in both houses in 2009 (the “2009 Act”).⁹⁰

The 2009 Act closely resembles the previously proposed legislation. The most significant provisions of the bill, as introduced, relate to the

85. See *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 560 F.3d 1366, 1376, 90 U.S.P.Q.2d 1549, 1556 (Fed. Cir. 2008) (overruling the jury’s determination that there was an adequate written description), *vacated*, 332 F. App’x 636 (Fed. Cir. 2009).

86. *Ariad*, 332 F. App’x at 637.

87. See Donald Zuhn, *Amicus Briefs in Ariad v. Lilly: Regents of Univ. of Cal. et al.*, PATENT DOCS (Dec. 6, 2009, 11:59 PM), <http://www.patentdocs.org/2009/12/amicus-briefs-in-ariad-v-lilly-regents-of-university-of-california-et-al.html> (listing all twenty-five amici and noting that nineteen briefs were filed in support of Lilly, six were filed in support of neither party, and none were filed in support of Ariad).

88. AM. INTELLECTUAL PROP. LAW ASSOC., EN BANC CAFC HEARS ARGUMENT IN WRITTEN DESCRIPTION CASE 1 (Dec. 9, 2009), http://www.aipla.org/Content/ContentGroups/About_AIPLA1/AIPLA_Reports/20098/091209AIPLAReports.pdf.

89. The Patent Reform Act of 2007 passed in the House but never made it to the Senate floor. See Govtrack.us, H.R. 1908: Patent Reform Act of 2007, <http://www.govtrack.us/congress/bill.xpd?bill=h110-1908> (last visited Apr. 7, 2010); Govtrack.us, S. 1145: Patent Reform Act of 2007, <http://www.govtrack.us/congress/bill.xpd?bill=s110-1145> (last visited Apr. 7, 2010). The bill that was introduced in 2005 never made it through congressional committees. See Govtrack.us, S. 3818: Patent Reform Act of 2006, <http://www.govtrack.us/congress/bill.xpd?bill=s109-3818> (last visited Apr. 7, 2010); Govtrack.us, H.R. 2795: Patent Act of 2005, <http://www.govtrack.us/congress/bill.xpd?bill=h109-2795> (last visited Apr. 7, 2010).

90. On March 3, 2009, Senator Patrick Leahy introduced the Senate bill, S. 515, 111th Cong. (2009), *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:s515rs.txt.pdf, and Representative John Conyers introduced the House bill, H.R. 1260, 111th Cong. (2009). Senator Jon Kyl introduced another patent reform bill, S. 610, 111 Cong. (2009), on March 17, 2009.

issues of first to file,⁹¹ damages,⁹² reexamination proceedings,⁹³ cancellation proceedings,⁹⁴ preissuance submissions,⁹⁵ and venue.⁹⁶

Despite its many similarities to previous Patent Reform Acts, the 2009 Act removed some controversial sections from the previous legislation. For example, applicants would no longer be required to conduct searches before filing an application. Additionally, the provision requiring patent applicants to act in “good faith” in order to enforce patents has been dropped from the current bill. Moreover, the bill does not include a provision granting the USPTO procedural or substantive rulemaking authority.

On March 10, 2009, the Senate Judiciary Committee heard testimony from witnesses in a hearing titled, “Patent Reform in the 111th Congress: Legislation and Recent Court Decisions.”⁹⁷ On April 2, 2009, the Committee voted 15-4 to bring the amended Senate Bill

91. S. 515, § 2. The 2009 Act continues to propose the switch from the present “first-to-invent” system to a “first-to-file” system. The provision would eliminate the one-year grace period for most cases. *Id.* The USPTO would no longer permit patent applicants, by the submission of sworn affidavits and documentary evidence, to “swear behind” newer references. Additionally, interferences would be abolished.

92. *Id.* § 4(a). Under the proposed bill, reasonable royalties would be based upon the “invention’s specific contribution over the prior art.” *Id.* The “entire market value” rule would be limited, but the law concerning lost profits would be unchanged. *Id.*

93. *Id.* § 5. Under the proposed bill, reexaminations may be requested based on published prior art, evidence of prior public use or sale in the United States, or patentee statements. *Id.* § 5(a)–(b). Estoppel would bar (1) asserting invalidity of any claim determined to be valid in *inter partes* reexamination on any ground raised in the reexamination, and (2) instituting an *inter partes* reexamination proceeding after a district court judgment on patent validity. *Id.* § 5(h).

94. *Id.* § 5(h). Under the proposed bill, within twelve months of the issuance of a patent, a third party may file a cancellation petition based on any ground of invalidity other than failure to disclose the best mode. *Id.* There would be no presumption of validity; instead, the challenging party would bear the burden of proof by a preponderance of the evidence. *Id.* Limited discovery may be permitted on order of the Director of the USPTO. *Id.*

95. *Id.* § 7. Under the proposed bill, third parties may submit information relevant to the examination of an application. *Id.*

96. *Id.* § 8(a). Under the proposed bill, venue in patent infringement litigation would be proper only if it is (1) the place of defendant’s principal place of business or incorporation; “(2) where the defendant has committed substantial acts of infringement and has a regular and established physical facility that the defendant controls and that constitutes a substantial portion of the operations of the defendant;” or (3) the residence of the primary or the sole plaintiff, if it is an institution of higher education, a nonprofit patent and licensing organization, or an individual inventor. *Id.* The court should transfer venue to avoid evidentiary burdens when transfer can be accomplished without causing undue hardship to the plaintiff. *Id.*

97. *Hearing on Patent Reform Before the S. Comm. on the Judiciary*, 111th Cong. (2009), available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_senate_hearings&docid=f:54059.pdf. One of the witnesses was David J. Kappos. Testifying on behalf of IBM, his former employer, Kappos offered his support for Senate Bill 515. See *id.* at 7–8 (statement of David J. Kappos, Vice President and Assistant General Counsel, Intellectual Property Law and Strategy, IBM Corp.).

515 before the full Senate. The amended bill includes several changes to the legislation. For example, the reasonable royalty proposal has been replaced by the “gatekeeper” provision, giving judges more authority to determine how to assess damages.⁹⁸ Prior use and sale provisions have also been removed from the post-grant review procedure.⁹⁹ Further, the proposal for limiting venue has been replaced by a provision that allows for the transfer of patent cases on a showing that the transferee district is clearly more convenient.¹⁰⁰

The Senate Committee on the Judiciary submitted a report on the amended bill on May 12, 2009, but there has been no progress since then.¹⁰¹ In the House, the Judiciary Committee held a hearing on the bill on April 30, 2009,¹⁰² but it has not yet marked up its bill or taken further action.

Various organizations have been active in participating in the patent reform discussion. One such organization is the Coalition for Patent Fairness (CPF). Members of CPF include the Business Software Alliance, Apple, Symantec, and Google.¹⁰³ According to CPF’s website, the organization supports patent reform on issues such as damages calculation, assessment of willful infringement, post-grant review, and forum shopping.¹⁰⁴ Another active organization is the Coalition for 21st Century Patent Reform (the “Coalition”). The Coalition is composed of approximately fifty companies, including 3M, Caterpillar, Eli Lilly, Motorola, Procter & Gamble, Pfizer, and Texas Instruments.¹⁰⁵ According to the Coalition, “[t]he damages provision should stay out of the bill . . . because the issue is being addressed by the courts.”¹⁰⁶ Indeed, the Federal Circuit, in a recent decision overturning a jury award of over \$357 million against

98. See S. 515, § 4.

99. *Id.* § 5.

100. *Id.* § 8.

101. S. Rep. No. 111–18 (2009), available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_reports&docid=f:sr018.pdf.

102. *The Patent Reform Act of 2009: Hearing on H.R. 1260 Before the H. Comm. on the Judiciary*, 111th Cong. (2009), available at http://judiciary.house.gov/hearings/hear_090430.html.

103. Patentfairness.org, Overview, <http://www.patentfairness.org/learn/about/> (last visited Apr. 7, 2010).

104. Patentfairness.org, What Needs To Change, <http://www.patentfairness.org/learn/what/> (last visited Apr. 7, 2010).

105. Patentsmatter.com, Who We Are: The Coalition for 21st Century Patent Reform, http://www.patentsmatter.com/about/who_we_are.php (last visited Apr. 7, 2010); Patentsmatter.com, Coalition Members, <http://www.patentsmatter.com/about/coalition.php> (last visited Apr. 7, 2010).

106. Stephanie Condon, *Patent Bill to be Reintroduced in Congress This Week*, CNET, Mar. 2, 2009, http://news.cnet.com/8301-13578_3-10155805-38.html.

Microsoft, set out to clarify the law on patent damages, including the application of the entire-market-value rule.¹⁰⁷ It is unclear whether the court's explanation will affect the outcome of the debate over the damages provision in the patent reform bill.

Meanwhile, on September 14, 2009, in his first major speech, USPTO Director Kappos declared: "The time is now to get patent reform done."¹⁰⁸ On October 5, 2009, Commerce Secretary Locke wrote a five-page letter to Senate Judiciary Committee Chairman Leahy, stating that the Obama administration is committed to working with Congress on patent reform.¹⁰⁹ Secretary Locke also stated, "We believe S. 515 incorporates the essential elements of patent reform; and, therefore, the Department of Commerce supports the bill with additional recommendations."¹¹⁰

Specifically, the Department of Commerce endorses granting the USPTO authority to adjust patent and trademark fees as well as substantive rulemaking authority to provide "flexibility in the administration of patent rules and procedures."¹¹¹ The Department also supports the shift from the first-to-invent system to a first-to-file system.¹¹² Regarding the procedures for post-grant review and *inter partes* reexamination, the Department advocates a phased-in procedure.¹¹³ On the damages issue, the Department generally supports "reasonable royalty damages through a 'gatekeeper' approach reflected in recent court decisions as well as the purpose of the willful infringement and enhanced damages standard."¹¹⁴

The following sections will summarize significant developments in patent law at the Federal Circuit in 2009. The sections are organized by issue and discuss key cases.

107. *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 92 U.S.P.Q.2d (BNA) 1555 (Fed. Cir. 2009), *petition for cert. filed*, 78 U.S.L.W. 3532 (U.S. Feb. 19, 2010) (No. 09-1006). Chief Judge Michel, the author of the *Lucent Technologies* opinion, has discussed concerns regarding excess damages, stating that fears of patent owners being compensated based on the entire value of a product rather than on a part covered by their patent are a myth not reflected in actual cases. See Chief Judge Paul R. Michel, U.S. Court of Appeals for the Fed. Circuit, Keynote Address at the Federal Trade Commission Hearings: The Evolving IP Marketplace (Dec. 5, 2008), *available at* <http://www.ftc.gov/bc/workshops/ipmarketplace/dec5/081205transcript.pdf>.

108. David Kappos, Dir. U.S. Patent & Trademark Office, Remarks to Intellectual Property Owners Annual Conference (Sept. 14, 2009), *available at* http://www.uspto.gov/main/homepagenews/2009sep14_kappos_ipo_speech.htm.

109. Letter from Gary Locke, U.S. Sec'y of Commerce, to Sens. Patrick J. Leahy and Jefferson B. Sessions, III (Oct. 5, 2009), *available at* <http://www.ogc.doc.gov/ogc/legreg/letters/111/S515Oct0509.pdf>.

110. *Id.*

111. *Id.* at 3.

112. *Id.*

113. *Id.*

114. *Id.* at 4.

II. DISTRICT COURT PRACTICE

A. *Transfer*

Where one venue would be more convenient or efficient than the one in which a patent action is filed, a defendant may move to transfer the action to the more convenient venue pursuant to 28 U.S.C. § 1404(a). Section 1404(a) provides that, “[f]or the convenience of parties and witnesses, in the interest of justice, a district court may transfer any civil action to any other district or division where it might have been brought.”¹¹⁵ The Federal Circuit applies regional circuit law to determine the propriety of a transfer of a patent infringement action under § 1404(a) because it considers such a determination procedural in nature.¹¹⁶

In 2008, in *In re TS Tech USA Corp.*,¹¹⁷ the Federal Circuit held that the U.S. District Court for the Eastern District of Texas clearly abused its discretion in denying the defendants’ motion to transfer the case to the U.S. District Court for the Southern District of Ohio, and granted the defendants’ petition for a writ of mandamus.¹¹⁸ In the wake of this ruling, the Federal Circuit considered four additional petitions for writs of mandamus in 2009, each filed by parties seeking to transfer cases out of the Eastern District of Texas.

In *In re Volkswagen of America, Inc.*,¹¹⁹ the Federal Circuit refused to grant the requested transfer because two other cases pending in the Eastern District of Texas involved the same patents.¹²⁰ The court applied Fifth Circuit law in considering “the ‘public’ and ‘private’ factors for determining *forum non conveniens* when assessing whether a defendant has met its burden of demonstrating the need to transfer.”¹²¹ The court found that “the existence of multiple lawsuits involving the same issues is a paramount consideration when determining whether a transfer is in the interest of justice.”¹²² Because the court found significant overlap in the issues that were

115. 28 U.S.C. § 1404(a) (2006).

116. See *In re TS Tech USA Corp.*, 551 F.3d 1315, 1319, 89 U.S.P.Q.2d (BNA) 1567, 1568 (Fed. Cir. 2008) (citing *Storage Tech. Corp. v. Cisco Sys. Inc.*, 329 F.3d 823, 836, 66 U.S.P.Q.2d (BNA) 1545, 1554 (Fed. Cir. 2003)) (applying Fifth Circuit law to a mandamus petition reviewing the denial of a motion to transfer under § 1404(a)).

117. 551 F.3d 1315, 89 U.S.P.Q.2d (BNA) 1567 (Fed. Cir. 2008).

118. *Id.* at 1322–23, 89 U.S.P.Q.2d (BNA) at 1571.

119. 566 F.3d 1349, 91 U.S.P.Q.2d (BNA) 1036 (Fed. Cir. 2009).

120. *Id.* at 1351, 91 U.S.P.Q.2d (BNA) at 1037–38.

121. *Id.*, 91 U.S.P.Q.2d (BNA) at 1037 (citing *In re TS Tech*, 551 F.3d at 1319, 89 U.S.P.Q.2d (BNA) at 1568–69; *In re Volkswagen of Am., Inc.*, 545 F.3d 304, 89 U.S.P.Q.2d (BNA) 1501 (5th Cir. 2008) (en banc), *cert. denied sub nom.* Singleton v. Volkswagen of Am., Inc., 129 S. Ct. 1336 (2009)).

122. *Id.*, 91 U.S.P.Q.2d (BNA) at 1037.

presented in the three lawsuits pending in Texas, it concluded that familiarity with the patents could preserve time and resources and, therefore, denied Volkswagen's petition.¹²³

In *In re Genentech, Inc.*,¹²⁴ however, the Federal Circuit granted the accused infringers' petition for a writ of mandamus ordering transfer from Texas to the U.S. District Court for the Northern District of California.¹²⁵ The Federal Circuit concluded that, because a substantial number of material witnesses resided in California and no witnesses resided in Texas, the district court clearly erred in not concluding that the "convenience for witnesses" factor weighed substantially in favor of transfer.¹²⁶ The Federal Circuit found further that convenience of the parties, availability of compulsory process, and access to evidence weighed in favor of transfer.¹²⁷

The Federal Circuit also rejected the two practical problems that the district court identified as weighing significantly against transfer. First, the Federal Circuit held that the district court clearly erred in relying on Genentech's earlier decision to file suit in the Eastern District of Texas; the court explained that Supreme Court precedent made it clear that each transfer requires "individualized, case-by-case consideration of convenience and fairness."¹²⁸ Second, the Federal Circuit concluded that the district court clearly erred when it relied on the possibility that the Northern District of California lacked personal jurisdiction over Sanofi-Aventis Deutschland GmbH.¹²⁹ Section 1404(a), the Federal Circuit explained, does not require that the transferee court have jurisdiction over the plaintiff; it only requires that the alternative venue have jurisdiction over the defendants.¹³⁰ Because Genentech and Biogen Idec Inc. met "their burden of establishing that the district court clearly abused its discretion in denying transfer . . . and because [the Federal Circuit] determine[d] that mandamus relief [was] appropriate," the Federal Circuit granted the petition for a writ of mandamus.¹³¹

In *In re Hoffmann-La Roche Inc.*,¹³² the Federal Circuit granted a petition for a writ of mandamus, finding that the Eastern District of

123. *Id.*, 91 U.S.P.Q.2d (BNA) at 1038.

124. 566 F.3d 1338, 91 U.S.P.Q.2d (BNA) 1027 (Fed. Cir. 2009).

125. *Id.* at 1348, 91 U.S.P.Q.2d (BNA) at 1035.

126. *Id.* at 1343, 91 U.S.P.Q.2d (BNA) at 1031.

127. *Id.* at 1345-46, 91 U.S.P.Q.2d (BNA) at 1033.

128. *Id.* at 1346, 91 U.S.P.Q.2d (BNA) at 1034 (quoting *Van Dusen v. Barrack*, 376 U.S. 612, 622 (1964)).

129. *Id.*, 91 U.S.P.Q.2d (BNA) at 1034.

130. *Id.*, 91 U.S.P.Q.2d (BNA) at 1034.

131. *Id.* at 1348, 91 U.S.P.Q.2d (BNA) at 1035.

132. 587 F.3d 1333, 92 U.S.P.Q.2d (BNA) 1861 (Fed. Cir. 2009).

Texas abused its discretion in denying a motion to transfer venue to the U.S. District Court for the Eastern District of North Carolina pursuant to § 1404(a).¹³³ The Federal Circuit found, as it did in *TS Tech*, *Volkswagen*, and *Genentech*, “a stark contrast in relevance, convenience and fairness between the two venues.”¹³⁴ The court also found “no connection between [the] case and the Eastern District of Texas except that in anticipation of . . . litigation, [plaintiff’s] counsel in California converted into electronic format 75,000 pages of documents demonstrating conception and reduction to practice and transferred them to the offices of its litigation counsel in Texas.”¹³⁵ The court reiterated that § 1404(a) “should be construed to prevent parties who are opposed to a change of venue from defeating a transfer which, but for their own deliberate acts or omissions, would be proper, convenient and just.”¹³⁶ The Federal Circuit also found that the district court gave too much weight to its ability to compel a witness’s attendance at trial.¹³⁷ The Federal Circuit pointed out that the district court in that case could have compelled only one potential nonparty witness to testify at trial, and that it could have done so only by inconveniencing that witness and by having the witness travel more than 100 miles to attend.¹³⁸ In contrast, the court found that the Eastern District of North Carolina could “compel at least four potential nonparty witnesses for both trial and deposition and could do so without similar inconvenience to those witnesses.”¹³⁹ The Federal Circuit stated further that “[t]he district court also disregarded *Volkswagen* and *Genentech* in holding that the Eastern District of North Carolina had no more of a local interest in deciding [the] matter than the Eastern District of Texas.”¹⁴⁰ The court noted that, “[w]hile the sale of an accused product offered nationwide does not give rise to a substantial interest in any single venue, if there are significant connections between a particular venue and the events that gave rise to a suit, this factor should be weighed in that venue’s favor.”¹⁴¹ Finding that the Eastern District of North Carolina’s

133. *Id.* at 1334–35, 92 U.S.P.Q.2d (BNA) at 1861–62.

134. *Id.* at 1336, 92 U.S.P.Q.2d (BNA) at 1863.

135. *Id.* 1336–37, 92 U.S.P.Q.2d (BNA) at 1863.

136. *Id.* at 1337, 92 U.S.P.Q.2d (BNA) at 1863 (citing *Van Dusen v. Barrack*, 376 U.S. 612, 625 (1964)).

137. *Id.* at 1338, 92 U.S.P.Q.2d (BNA) at 1864.

138. *Id.*, 92 U.S.P.Q.2d (BNA) at 1864.

139. *Id.*, 92 U.S.P.Q.2d (BNA) at 1864.

140. *Id.*, 92 U.S.P.Q.2d (BNA) at 1864.

141. *Id.*, 92 U.S.P.Q.2d (BNA) at 1864 (citing *In re TS Tech USA Corp.*, 551 F.3d 1315, 1321, 89 U.S.P.Q.2d (BNA) 1567, 1570 (Fed. Cir. 2008); *In re Volkswagen of Am., Inc.*, 545 F.3d 304, 89 U.S.P.Q.2d (BNA) 1501 (5th Cir. 2008) (en banc), *cert. denied sub nom. Singleton v. Volkswagen of Am., Inc.*, 129 S. Ct. 1336 (2009)).

interest was “self-evident,” the court granted the petition and ordered a transfer.¹⁴²

The court applied similar reasoning in *In re Nintendo Co.*¹⁴³ when it granted Nintendo Co. and Nintendo of America, Inc.’s petition for a writ of mandamus.¹⁴⁴ Nintendo sought transfer from the Eastern District of Texas to the U.S. District Court for the Western District of Washington pursuant to § 1404(a).¹⁴⁵ The court explained that it “has held and holds again in this instance that in a case featuring most witnesses and evidence closer to the transferee venue with few or no convenience factors favoring the venue chosen by the plaintiff, the trial court should grant a motion to transfer.”¹⁴⁶ In sum, the Federal Circuit concluded that the district court:

(1) applied too strict of a standard to allow transfer; (2) gave too much weight to the plaintiff’s choice of venue; (3) misapplied the forum non conveniens factors; (4) incorrectly assessed the [Fifth Circuit’s] 100-mile tenet; (5) improperly substituted its own central proximity for a measure of convenience of the parties, witnesses, and documents; and (6) glossed over a record without a single relevant factor favoring the plaintiff’s chosen venue.¹⁴⁷

In *In re Nintendo*, all of the key witnesses resided in Washington, Japan, Ohio, and New York, and no witnesses lived in Texas. The court applied the Fifth Circuit’s “100-mile” guideline, which states, “[W]hen the distance between an existing venue for trial of a matter and a proposed venue under § 1404(a) is more than 100 miles, the factor of inconvenience to witnesses increases in direct relationship to the additional distance to be traveled.”¹⁴⁸ The court found that the average travel required for each of the U.S.-based witnesses to Texas would have been approximately 700 miles more than travel to Washington.¹⁴⁹ The court concluded that the cost of attendance for willing witnesses clearly favored transfer.¹⁵⁰ The Federal Circuit also rejected the district court’s hypothesis that the Eastern District of Texas could serve as a “centralized location” when sources of proof were situated in distant locations like Japan,

142. *Id.*, 92 U.S.P.Q.2d (BNA) at 1864.

143. 589 F.3d 1194, 93 U.S.P.Q.2d (BNA) 1152 (Fed. Cir. 2009).

144. *Id.* at 1201, 93 U.S.P.Q.2d (BNA) at 1156.

145. *Id.* at 1197, 93 U.S.P.Q.2d (BNA) at 1153.

146. *Id.* at 1198, 93 U.S.P.Q.2d (BNA) at 1154.

147. *Id.* at 1200, 93 U.S.P.Q.2d (BNA) at 1155.

148. *Id.* at 1199, 93 U.S.P.Q.2d (BNA) at 1154 (quoting *In re Volkswagen of Am., Inc.*, 545 F.3d 304, 89 U.S.P.Q.2d (BNA) 1501 (5th Cir. 2008) (en banc), cert. denied *sub nom.* Singleton v. Volkswagen of Am., Inc., 129 S. Ct. 1336 (2009)).

149. *Id.*, 93 U.S.P.Q.2d (BNA) at 1155.

150. *Id.*, 93 U.S.P.Q.2d (BNA) at 1155.

Washington, California, and New York.¹⁵¹ Accordingly, the court granted Nintendo's petition and ordered transfer of the case to the Western District of Washington.¹⁵²

B. *Jurisdiction and Standing*

1. *Jurisdiction and standing in declaratory judgment actions*

The Declaratory Judgment Act provides that, in all cases of actual controversy where there is federal jurisdiction, district courts may preside over actions for the declaration of rights and other legal interests between parties.¹⁵³ In 2009, the Federal Circuit considered several cases that touched on jurisdictional and standing questions in declaratory judgment actions.

In *Autogenomics, Inc. v. Oxford Gene Technology Ltd.*,¹⁵⁴ the Federal Circuit affirmed a district court's decision that it lacked declaratory judgment jurisdiction over a British biotechnology company, Oxford Gene Technology Ltd.¹⁵⁵ In analyzing whether Oxford was subject to general personal jurisdiction, the court concluded that Oxford's contacts with the forum state did not qualify as "continuous and systematic general business contacts."¹⁵⁶ Specifically, the court was not persuaded that Oxford's attendance at several conferences in California and the existence of license agreements with a California corporation were evidence of continuous and systematic contacts.¹⁵⁷ The court also concluded that Oxford did not have minimum contacts with California sufficient to establish specific personal jurisdiction.¹⁵⁸ In so holding, the court followed the rule set forth in *Avocent Huntsville Corp. v. Aten International Co.*¹⁵⁹ that courts, when determining whether specific personal jurisdiction exists in a declaratory judgment action against a patentee, should consider only enforcement or defense efforts that relate to the patent and not the commercialization efforts of the patentee.¹⁶⁰ Although the court acknowledged its concern that "foreign patentees like Oxford may

151. *Id.* at 1199–200, 93 U.S.P.Q.2d (BNA) at 1155.

152. *Id.* at 1201, 93 U.S.P.Q.2d (BNA) at 1156.

153. 28 U.S.C. §§ 2201–02 (2006).

154. 566 F.3d 1012, 91 U.S.P.Q.2d (BNA) 1006 (Fed. Cir. 2009).

155. *Id.* at 1023–24, 91 U.S.P.Q.2d (BNA) at 1018.

156. *Id.* at 1017, 91 U.S.P.Q.2d (BNA) at 1009–10 (quoting *Helicopteros Nacionales de Columbia, S.A. v. Hall*, 466 U.S. 408, 416 (1984)).

157. *Id.* at 1018, 91 U.S.P.Q.2d (BNA) at 1010.

158. *Id.* at 1021, 91 U.S.P.Q.2d (BNA) at 1013.

159. 552 F.3d 1324, 89 U.S.P.Q.2d (BNA) 1481 (Fed. Cir. 2008), *cert. denied*, 129 S. Ct. 2796 (2009).

160. *Autogenomics*, 566 F.3d at 1020, 91 U.S.P.Q.2d (BNA) at 1012 (citing *Avocent*, 552 F.3d at 1336, 89 U.S.P.Q.2d (BNA) at 1487–88).

engage in significant commercialization and licensing efforts in a state while benefiting from the shelter of the *Avocent* rule,” the court noted that it is “nonetheless bound by *Avocent*.”¹⁶¹

In a dissenting opinion, Judge Newman argued that Oxford satisfied the minimum contacts requirement because many of Oxford’s contacts directly relate to the patent at issue in the lawsuit.¹⁶² Judge Newman pointed to Oxford’s ownership of several U.S. patents, its exercise of patent rights through licensees in California, its entrance into a manufacturing venture with a California company, its exhibition of its technology at trade shows in California, its employees’ travel to California to negotiate with potential licensees, and its sale of products to at least one customer in California.¹⁶³ Moreover, Judge Newman reasoned that even if the showing of minimum contacts was weak, considerations of fairness and reasonableness tilted the balance toward establishing jurisdiction.¹⁶⁴ She found that the majority’s holding was inconsistent with the court’s recent decision in *Synthes (U.S.A.) v. G.M. dos Reis Jr. Ind. Com. de Equip. Medico*,¹⁶⁵ which concerned a patent infringement suit filed against a Brazilian entity whose products were offered for sale at trade shows in the United States.¹⁶⁶ Judge Newman disagreed with the majority’s conclusion that *Synthes* was not relevant because the foreign party was the accused infringer and not the patentee in the declaratory judgment action.¹⁶⁷ She also disagreed that the panel was bound by the *Avocent* rule.¹⁶⁸

In *Revolution Eyewear, Inc. v. Aspex Eyewear, Inc. (Revolution Eyewear I)*,¹⁶⁹ the Federal Circuit considered the effect of a “covenant not to sue” on a court’s jurisdiction under the Declaratory Judgment Act.¹⁷⁰ The covenant was limited to the asserted patent and to activities prior to dismissal of the action.¹⁷¹ The accused infringer, Aspex Eyewear, Inc., objected to the district court’s dismissal of its counterclaims, arguing that an “actual controversy continued to exist because

161. *Id.* at 1021, 91 U.S.P.Q.2d (BNA) at 1012.

162. *Id.* at 1024–25, 91 U.S.P.Q.2d (BNA) at 1015 (Newman, J., dissenting).

163. *Id.* at 1024, 91 U.S.P.Q.2d (BNA) at 1015.

164. *Id.* at 1025, 91 U.S.P.Q.2d (BNA) at 1016 (quoting *Int’l Shoe Co. v. Washington*, 326 U.S. 310, 319 (1945)).

165. 563 F.3d 1285, 90 U.S.P.Q.2d (BNA) 1609 (Fed. Cir. 2009).

166. *Autogenomics*, 566 F.3d at 1026, 91 U.S.P.Q.2d (BNA) at 1016 (Newman, J., dissenting).

167. *Id.* at 1027, 91 U.S.P.Q.2d (BNA) at 1016–17.

168. *Id.*, 91 U.S.P.Q.2d (BNA) at 1017.

169. 556 F.3d 1294, 89 U.S.P.Q.2d (BNA) 1885 (Fed. Cir. 2009).

170. *Id.* at 1295, 89 U.S.P.Q.2d (BNA) at 1886.

171. *Id.* at 1296, 89 U.S.P.Q.2d (BNA) at 1887.

Revolution Eyewear's covenant applied only to past infringement."¹⁷² The Federal Circuit concluded that Revolution Eyewear retained the right to sue for future infringement and, therefore, "the district court erred in holding that Revolution's covenant not to sue for past infringement [divested] the court of jurisdiction [over] Aspex's counterclaims."¹⁷³ In so holding, the court stated that a declaratory action is available when the facts as alleged "show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."¹⁷⁴

In *Hewlett-Packard Co. v. Acceleron LLC*,¹⁷⁵ the Federal Circuit reversed dismissal for lack of declaratory judgment jurisdiction because "under the totality of the circumstances . . . it was not unreasonable for HP to interpret Acceleron's letters as implicitly asserting its rights under [a patent]."¹⁷⁶ The court explained that, "[i]n its first letter to HP, Acceleron identified itself as the owner of [U.S. Patent No. 6,948,021 ('the '021 patent')], which it described as 'relating to Blade Servers.'"¹⁷⁷ In this letter, Acceleron requested that HP "not file suit," and imposed a two-week deadline to respond.¹⁷⁸ In its second letter to HP, Acceleron again imposed a two-week deadline to respond "and insisted that if HP did not respond . . . by the deadline, it would understand that HP did not 'have anything to say about the *merits of this patent*, or its *relevance to [HP's] Blade Server products*.'"¹⁷⁹ The court reiterated that the test for declaratory judgment jurisdiction is "objective" and that "conduct that can be reasonably inferred as demonstrating intent to enforce a patent can create declaratory judgment jurisdiction."¹⁸⁰ Because an objective look at the facts "show[ed] that Acceleron took the affirmative step of twice contacting HP directly, making an implied assertion of its rights under the '021 patent against HP's Blade Server products, and [that] HP disagreed," the court found "a 'definite and concrete' dispute

172. *Id.*, 89 U.S.P.Q.2d (BNA) at 1887.

173. *Id.* at 1300, 89 U.S.P.Q.2d (BNA) at 1891.

174. *Id.* at 1297, 89 U.S.P.Q.2d (BNA) at 1888 (quoting *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127, 81 U.S.P.Q.2d (BNA) 1225, 1229 (2007)).

175. 587 F.3d 1358, 92 U.S.P.Q.2d (BNA) 1948 (Fed. Cir. 2009).

176. *Id.* at 1363, 92 U.S.P.Q.2d (BNA) at 1951.

177. *Id.* at 1362, 92 U.S.P.Q.2d (BNA) at 1951 (citation omitted).

178. *Id.*, 92 U.S.P.Q.2d (BNA) at 1951.

179. *Id.* at 1362-63, 92 U.S.P.Q.2d (BNA) at 1951 (citation omitted).

180. *Id.* at 1363, 92 U.S.P.Q.2d (BNA) at 1951 (emphasis omitted).

between HP and Acceleron.”¹⁸¹ Accordingly, the Federal Circuit reversed the district court’s dismissal and remanded.¹⁸²

2. *Jurisdiction over foreign defendants in patent-related actions*

The Federal Circuit found the exercise of personal jurisdiction pursuant to Federal Rule of Civil Procedure 4(k)(2) proper in two cases involving foreign defendants in 2009. Rule 4(k)(2) permits a court to exercise jurisdiction over a foreign defendant if (1) the claim against the defendant arises under federal law; (2) the defendant is not subject to the personal jurisdiction of any state court of general jurisdiction; and (3) the exercise of personal jurisdiction comports with due process.¹⁸³

In *Synthes (U.S.A.) v. G.M. dos Reis Jr. Ind. Com. de Equip. Medico*, which Judge Newman discussed in her dissent in *Autogenomics*,¹⁸⁴ the Federal Circuit reversed the decision of the district court to dismiss an infringement suit for lack of personal jurisdiction over the defendants.¹⁸⁵ The Federal Circuit held that, under Rule 4(k)(2), the defendant’s contacts within the United States as a whole were sufficient to give rise to federal district court personal jurisdiction.¹⁸⁶ The court found that the claim arose out of federal law, as it was a claim for patent infringement.¹⁸⁷ Further, the court noted that neither party disputed G.M. dos Reis’s contention that it is not subject to personal jurisdiction in any forum in the United States.¹⁸⁸ Under these circumstances, the court applied a due process analysis under Rule 4(k)(2) and considered G.M. dos Reis’s contacts with the nation as a whole.¹⁸⁹

The Federal Circuit agreed that the district court did not have general personal jurisdiction over G.M. dos Reis based on its minimal contacts, which included attendance at trade shows, purchases of parts and a machine, the sale of a product to one customer, and a pair of consultations about product development.¹⁹⁰ The court held that these contacts within the United States were not “continuous and

181. *Id.* at 1364, 92 U.S.P.Q.2d (BNA) at 1952.

182. *Id.*, 92 U.S.P.Q.2d (BNA) at 1952.

183. FED. R. CIV. P. 4(k)(2).

184. 566 F.3d 1012, 1026, 91 U.S.P.Q.2d (BNA) 1006, 1016 (Fed. Cir. 2009) (Newman, J., dissenting).

185. *Synthes (U.S.A.) v. G.M. dos Reis Jr. Ind. Com. de Equip. Medico*, 563 F.3d 1285, 90 U.S.P.Q.2d (BNA) 1609 (Fed. Cir. 2009).

186. *See id.* at 1296–300, 90 U.S.P.Q.2d (BNA) at 1616–19 (applying the Rule 4(k)(2) requirements).

187. *Id.* at 1296, 90 U.S.P.Q.2d (BNA) at 1616 (citing 28 U.S.C. § 1338 (2006)).

188. *Id.*, 90 U.S.P.Q.2d (BNA) at 1616.

189. *Id.*, 90 U.S.P.Q.2d (BNA) at 1616.

190. *Id.* at 1297, 90 U.S.P.Q.2d (BNA) at 1617.

systematic general business contacts.”¹⁹¹ The Federal Circuit, nonetheless, disagreed that the district court lacked specific personal jurisdiction over G.M. dos Reis.¹⁹² The court determined that by bringing its product into the United States and by displaying it at a trade show, G.M. dos Reis purposefully directed its activities toward the United States, even though it informed the trade show participants that its products were not for sale.¹⁹³ The court determined further that the claim for patent infringement arose out of G.M. dos Reis’s activities within the forum and that jurisdiction over G.M. dos Reis was reasonable and fair.¹⁹⁴ Accordingly, the Federal Circuit reversed the judgment of the district court dismissing Synthes’s complaint for lack of personal jurisdiction and remanded for further proceedings.¹⁹⁵

The court applied similar reasoning when it considered whether the act of filing an application for a U.S. patent at the USPTO is sufficient to subject a foreign attorney to personal jurisdiction in a malpractice claim based on that filing. In *Touchcom, Inc. v. Bereskin & Parr*,¹⁹⁶ a panel majority concluded that filing the application was sufficient to confer jurisdiction under Rule 4(k)(2) for several reasons. First, the court found that the Canadian attorney and law firm “purposefully directed their activities at parties in the United States and thus had ‘minimum contacts’ sufficient to satisfy due process.”¹⁹⁷ The court found further that the attorney and law firm entered into a contract to obtain a U.S. patent, thereby availing themselves of the laws of the United States.¹⁹⁸ The court also determined that Touchcom’s malpractice claims arose out of the attorney filing an allegedly deficient U.S. patent application with a U.S. agency and that the exercise of jurisdiction over the Canadian attorney and law firm was reasonable and fair.¹⁹⁹ Judge Prost dissented, stating that this case presented “one of the ‘rare situations’ in which minimum contacts are present but exercising personal jurisdiction would nevertheless violate due process.”²⁰⁰ Specifically, Judge Prost noted that “the plaintiff’s interest and the state’s interest

191. *Id.*, 90 U.S.P.Q.2d (BNA) at 1617 (citing *Helicopteros Nacionales de Colombia v. Hall*, 466 U.S. 408, 415–16 (1984)).

192. *Id.*, 90 U.S.P.Q.2d (BNA) at 1617.

193. *Id.* at 1297–98, 90 U.S.P.Q.2d (BNA) at 1617–19.

194. *Id.* at 1299, 90 U.S.P.Q.2d (BNA) at 1618.

195. *Id.* at 1300, 90 U.S.P.Q.2d (BNA) at 1619.

196. 574 F.3d 1403, 91 U.S.P.Q.2d (BNA) 1609 (Fed. Cir. 2009).

197. *Id.* at 1416, 91 U.S.P.Q.2d (BNA) at 1617.

198. *Id.*, 91 U.S.P.Q.2d (BNA) at 1617.

199. *Id.* at 1417–18, 91 U.S.P.Q.2d (BNA) at 1618–19.

200. *Id.* at 1419, 91 U.S.P.Q.2d (BNA) at 1619 (Prost, J., dissenting).

in adjudicating the dispute in the forum are so attenuated that they are clearly outweighed by the burden of subjecting the defendant to litigation within the forum.”²⁰¹

3. *Standing questions involving universities*

The Federal Circuit considered standing in the context of university research in two cases in 2009 and found that the plaintiffs lacked standing in both cases.

Defective title in the patents-in-suit deprived a plaintiff of standing in *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc.*²⁰² In that case, the Federal Circuit acknowledged that “questions of standing can be raised at any time and are not foreclosed by, or subject to, statutes of limitation,” and it considered whether certain patent assignment clauses created an automatic assignment or a mere obligation to assign.²⁰³ The inventor-plaintiff in that case signed multiple contracts concerning rights to his invention; for example, in a 1995 agreement with the Board of Trustees of Leland Stanford Junior University, the inventor agreed “to assign or confirm in writing to Stanford and/or Sponsors” the rights to inventions he may conceive or actually reduce to practice.²⁰⁴ The Federal Circuit concluded that this language showed only an agreement to assign the inventor’s invention rights at some future time and, thus, the university had not obtained title to the inventions, either at the time of signing the agreement or at the time of invention.²⁰⁵ A second agreement signed six years earlier, on the other hand, recited, “I will assign and *do hereby assign* to CETUS, my right, title, and interest in each of the ideas, inventions and improvements.”²⁰⁶ The court concluded that such language served to immediately transfer to CETUS equitable title in the inventions and that legal title vested in CETUS in 1992 when the patent application for the inventions was filed at the USPTO.²⁰⁷ Accordingly, the court determined that the inventor had no rights to transfer to the university in 1995.

201. *Id.*, 91 U.S.P.Q.2d (BNA) at 1619 (quoting *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1568, 30 U.S.P.Q.2d (BNA) 1001, 1009 (Fed. Cir. 1994)).

202. 583 F.3d 832, 848, 92 U.S.P.Q.2d (BNA) 1442, 1453 (Fed. Cir. 2009).

203. *Id.* at 841, 92 U.S.P.Q.2d (BNA) at 1448 (citing *Pandrol USA, LP v. Airboss Ry. Prods.*, 320 F.3d 1354, 1357, 65 U.S.P.Q.2d (BNA) 1985, 1994 (Fed. Cir. 2003)).

204. *Id.*, 92 U.S.P.Q.2d (BNA) at 1448.

205. *Id.* at 841–42, 92 U.S.P.Q.2d (BNA) at 1448.

206. *Id.* at 842, 92 U.S.P.Q.2d (BNA) at 1449 (emphasis added) (citation omitted).

207. *Id.*, 92 U.S.P.Q.2d (BNA) at 1449.

Stanford attempted to take complete rights to the inventions under 35 U.S.C. § 200 and 35 U.S.C. § 202, which allow “the Government to take title to ‘subject inventions’ under certain circumstances, . . . or the ‘contractor’ universities or inventors to retain ownership if the Government does not.”²⁰⁸ Citing its prior rulings, however, the Federal Circuit concluded that Stanford’s election of title under the Patent Act did not have “the power to void any prior, otherwise valid assignments of patent rights.”²⁰⁹ Because Stanford’s claim of title under the Patent Act occurred six years after the inventor’s valid transfer of rights to CETUS, the court concluded that election under the Patent Act did not give Stanford superior title to the patents.²¹⁰ For these reasons, the court concluded that Stanford lacked standing to sue for infringement of the patents, and the district court lacked jurisdiction over Stanford’s infringement claims.

In *AsymmetRx, Inc. v. Biocare Medical, LLC*,²¹¹ the Federal Circuit raised sua sponte the issue of AsymmetRx, Inc.’s lack of standing to sue for infringement without joining the President and Fellows of Harvard College.²¹² Harvard, the owner of rights in patents related to detecting malignant carcinoma, granted to Biocare Medical, LLC the right to make, use, and sell relevant antibodies.²¹³ The Biocare license stated that it did “not include a license under any U.S. or foreign patents.”²¹⁴

“A few years later, Harvard entered into an agreement with AsymmetRx . . . [giving AsymmetRx] ‘an exclusive commercial license’” to the patents-in-suit, but reserving certain rights for Harvard.²¹⁵ AsymmetRx subsequently sued Biocare for patent infringement. The Federal Circuit concluded that because Harvard retained substantial interests under the patents-in-suit, including the right to sue for infringement, AsymmetRx was a mere licensee, and Harvard had to join in any infringement suit.²¹⁶ The Federal Circuit further concluded that joining Harvard pursuant to Federal Rule of Civil Procedure 19 would not only resolve the standing issue, but

208. *Id.* at 844, 92 U.S.P.Q.2d (BNA) at 1450 (citing 35 U.S.C. § 202(a), (b), (d) (2006)).

209. *Id.* at 844–45, 92 U.S.P.Q.2d (BNA) at 1450–51.

210. *See id.*, 92 U.S.P.Q.2d (BNA) at 1450–51.

211. 582 F.3d 1314, 92 U.S.P.Q.2d (BNA) 1113 (Fed. Cir. 2009).

212. *Id.* at 1318, 92 U.S.P.Q.2d (BNA) at 1115–16.

213. *Id.* at 1316, 92 U.S.P.Q.2d (BNA) at 1114.

214. *Id.*, 92 U.S.P.Q.2d (BNA) at 1114 (quoting the parties’ license agreement).

215. *Id.*, 92 U.S.P.Q.2d (BNA) at 1114.

216. *Id.* at 1321, 92 U.S.P.Q.2d (BNA) at 1118.

would also facilitate resolution of the relationships between the three parties.²¹⁷

4. *Other jurisdiction and standing issues in patent infringement suits*

The question of jurisdiction also arose in the context of Federal Rule of Civil Procedure 60(b), which sets forth the grounds on which a court may relieve a party from an otherwise final judgment or order, including “voidness of the judgment.”²¹⁸ A judgment may be declared void if the court that rendered it lacked jurisdiction, or if the court’s action amounts to a violation of due process.²¹⁹

In *Garber v. Chicago Mercantile Exchange*,²²⁰ the Federal Circuit reversed the district court’s decision to deny a Rule 60(b)(4) motion, holding that a stipulation for dismissal without prejudice filed pursuant to Federal Rule of Civil Procedure 41(a)(1) divested the district court of subject matter jurisdiction.²²¹ The parties had filed a stipulated motion to dismiss the suit without prejudice.²²² In granting the motion, the district court gave the plaintiff one month “to move to reinstate this case.”²²³ After the deadline passed, the district court entered a second order dismissing the case *with* prejudice.²²⁴ The plaintiff sought to vacate as void the district court’s first dismissal order on the ground that the district court lacked subject matter jurisdiction over the case.²²⁵ The plaintiff argued, and the Federal Circuit agreed on appeal, that the joint stipulation of the parties was filed under Rule 41(a)(1), which served to dismiss the case without action from the district court.²²⁶ Because the dismissal orders entered by the district court were void ab initio, the Federal Circuit reversed the district court’s denial of the plaintiff’s motion for relief and vacated the orders.²²⁷

The Federal Circuit also considered the appropriateness of a dismissal with prejudice in the context of standing. In *University of Pittsburgh v. Varian Medical Systems, Inc.*,²²⁸ the Federal Circuit held that the district court erred when it dismissed with prejudice a suit

217. *Id.* at 1321–22, 92 U.S.P.Q.2d (BNA) at 1119.

218. FED. R. CIV. P. 60(b).

219. *See, e.g.*, *United States v. Boch Oldsmobile, Inc.*, 909 F.2d 657, 661 (1st Cir. 1990) (citing *V.T.A., Inc. v. Airco, Inc.*, 597 F.2d 220, 224 (10th Cir. 1979)).

220. 570 F.3d 1361, 91 U.S.P.Q.2d (BNA) 1377 (Fed. Cir. 2009).

221. *Id.* at 1364–65; 91 U.S.P.Q.2d (BNA) at 1380.

222. *Id.* at 1362, 91 U.S.P.Q.2d (BNA) at 1378.

223. *Id.* at 1363, 91 U.S.P.Q.2d (BNA) at 1378 (citation omitted).

224. *Id.*, 91 U.S.P.Q.2d (BNA) at 1378–79.

225. *Id.*, 91 U.S.P.Q.2d (BNA) at 1379.

226. *Id.* at 1364–65, 91 U.S.P.Q.2d (BNA) at 1380.

227. *Id.* at 1366, 91 U.S.P.Q.2d (BNA) at 1381.

228. 569 F.3d 1328, 91 U.S.P.Q.2d (BNA) 1251 (Fed. Cir. 2009).

brought by the University of Pittsburgh against Varian Medical Systems, Inc. Varian had moved for summary judgment, alleging that Carnegie Mellon University was a co-owner of the patents and, thus, the University of Pittsburgh alone lacked standing to sue for infringement.²²⁹ The University of Pittsburgh then moved to join Carnegie Mellon pursuant to Federal Rule of Civil Procedure 19, but the district court denied the motion without explanation.²³⁰ The district court dismissed the case with prejudice on the grounds that (1) the University of Pittsburgh should have joined Carnegie Mellon when it first brought suit, and (2) “Pitt’s attempt to join Carnegie Mellon was ‘untimely and unfair to Varian.’”²³¹

On appeal, the Federal Circuit applied an abuse of discretion standard and rejected both of the district court’s reasons for dismissing the case with prejudice.²³² The court held that, although all patent owners must be joined to maintain an infringement action, a dismissal for failure to join a necessary party or, more generally, for lack of standing, is not an adjudication on the merits and thus should not have preclusive effect.²³³ Specifically, the Federal Circuit held that, although the district court had the discretion to dismiss the case for lack of standing, or under Rule 12(b)(7) for failure to join a patent co-owner under Rule 19, it lacked the discretion to do so with prejudice.²³⁴

To determine whether dismissal with prejudice was an appropriate sanction, the court applied Third Circuit law, which provides that dismissal with prejudice is rarely a proper sanction.²³⁵ The Third Circuit instructs courts to analyze four nonexclusive factors to determine whether dismissal with prejudice is appropriate.²³⁶ Because the Federal Circuit found that the district court failed to discuss or provide support for any of the relevant factors, and because dismissal

229. *Id.* at 1330, 91 U.S.P.Q.2d (BNA) at 1253.

230. *Id.*, 91 U.S.P.Q.2d (BNA) at 1253.

231. *Id.* at 1331, 91 U.S.P.Q.2d (BNA) at 1253–54 (citation omitted).

232. *See id.*, 91 U.S.P.Q.2d (BNA) at 1253–54 (citing *H.R. Techs., Inc. v. Astechologies, Inc.*, 275 F.3d 1378, 1384, 61 U.S.P.Q.2d (BNA) 1271, 1275 (Fed. Cir. 2002) (noting that the Federal Circuit applies regional circuit law in reviewing cases dismissed with prejudice)).

233. *Id.* at 1332, 91 U.S.P.Q.2d (BNA) at 1254.

234. *Id.* at 1333, 91 U.S.P.Q.2d (BNA) at 1255.

235. *Id.* at 1334, 91 U.S.P.Q.2d (BNA) at 1256 (quoting *Donnelly v. Johns-Manville Sales Corp.*, 677 F.2d 339, 342 (3d Cir. 1982)).

236. *Id.*, 91 U.S.P.Q.2d (BNA) at 1256 (explaining that the four factors include “(1) the degree of the plaintiff’s personal responsibility for the delay; (2) prejudice to the defendant occasioned by the delay; (3) any history that the plaintiff proceeded in a dilatory manner; and (4) the effectiveness of sanctions other than dismissal” (quoting *Madesky v. Campbell*, 705 F.2d 703, 704 (3d Cir. 1983))).

with prejudice is a harsh sanction disfavored under Third Circuit law and not justified on the record, the Federal Circuit concluded that the district court improperly dismissed the case with prejudice.²³⁷ Accordingly, the court vacated the dismissal and remanded “with instructions to designate the dismissal as without prejudice to Pitt’s ability to establish standing through the joinder of Carnegie Mellon or the assignment of whatever rights Carnegie Mellon may have in the patents in suit.”²³⁸

The issue of standing also arose in the context of inventorship. In *Larson v. Correct Craft, Inc.*,²³⁹ the Federal Circuit concluded that it lacked jurisdiction to reach the merits of the appeal because Larson lacked standing in the district court to correct patents where a claim to correct inventorship under 35 U.S.C. § 256 was the only basis for removal from state court.²⁴⁰

Larson sued Correct Craft, Inc. in Florida state court, asserting state-law and declaratory judgment claims concerning the parties’ rights to the patents.²⁴¹ Correct Craft removed the case to federal court, citing Larson’s addition of the declaratory judgment claims, which sought removal of two individuals as coinventors of the patents.²⁴² The district court granted summary judgment in favor of the defendants.²⁴³ On appeal, the Federal Circuit considered two issues related to the basis of federal jurisdiction.²⁴⁴ First, the Federal Circuit examined “whether Correct Craft (in removing the case) and the district court (in exercising jurisdiction) correctly treated [Larson’s] declaratory-judgment claims as implicating [35 U.S.C.] § 256,” even though the claims did not actually invoke § 256.²⁴⁵ The court concluded that Larson sought a judicial determination that he, rather than the named coinventors, is the true and sole inventor of the patented invention.²⁴⁶ Because this “is the same relief that the patent statute provides in § 256,” the court accepted that Larson pled an action for correction of inventorship pursuant to federal law.²⁴⁷

237. *Id.* at 1335, 91 U.S.P.Q.2d (BNA) at 1256.

238. *Id.*, 91 U.S.P.Q.2d (BNA) at 1256.

239. 569 F.3d 1319, 91 U.S.P.Q.2d (BNA) 1342 (Fed. Cir. 2009).

240. *Id.* at 1327, 91 U.S.P.Q.2d (BNA) at 1346.

241. *Id.* at 1322, 91 U.S.P.Q.2d (BNA) at 1343.

242. *Id.*, 91 U.S.P.Q.2d (BNA) at 1343.

243. *Id.* at 1323, 91 U.S.P.Q.2d (BNA) at 1343.

244. *Id.*, 91 U.S.P.Q.2d (BNA) at 1344.

245. *Id.* at 1324, 91 U.S.P.Q.2d (BNA) at 1344.

246. *Id.* at 1325, 91 U.S.P.Q.2d (BNA) at 1345.

247. *Id.*, 91 U.S.P.Q.2d (BNA) at 1345.

The Federal Circuit also examined whether Larson, having not yet prevailed on his separate claim for equitable relief setting aside the patent assignments, nevertheless had standing to pursue a claim for correction of inventorship in federal court.²⁴⁸ The court noted that a plaintiff in an action under § 256 need not have an ownership interest at stake in the suit to have standing and that a “concrete financial interest” in the patents was enough to satisfy the requirements for constitutional standing—namely, injury, causation, and redressability.²⁴⁹ The court found that Larson had no concrete financial interest in the patents, however, because he had affirmatively transferred title to Correct Craft and thus stood “to reap no benefit from a preexisting licensing or royalties arrangement.”²⁵⁰ The court found that “[h]is only path to financial reward under § 256 [depended on] him first succeeding on his state-law claims and obtaining rescission of the patent assignments.”²⁵¹ Accordingly, the Federal Circuit held that Larson had no constitutional standing to sue for correction of inventorship in federal court, vacated the judgment of the district court, and remanded with instructions to return the case to state court.²⁵² The Federal Circuit left open the question of “whether a purely reputational interest is sufficient to confer standing for a § 256 claim.”²⁵³

Finally, the issue of standing arose in two cases in the context of patent ownership. In *Tyco Healthcare Group LP v. Ethicon Endo-Surgery, Inc.*,²⁵⁴ the Federal Circuit affirmed dismissal without prejudice where Tyco Healthcare Group LP failed to prove ownership of the asserted patents and thus lacked standing to sue.²⁵⁵ The court explained that, “as of March 1999, all necessary rights to enforce the [three patents-in-suit] resided in [U.S. Surgical Corporation (USSC)].”²⁵⁶ On April 1, 1999, USSC entered into a Contribution Agreement that transferred patents to Kendall LLP, except “any and all patents and patent applications relating to any pending litigation involving USSC.”²⁵⁷ Kendall eventually changed its name to Tyco Healthcare.²⁵⁸

248. *Id.*, 91 U.S.P.Q.2d (BNA) at 1345.

249. *Id.* at 1326, 91 U.S.P.Q.2d (BNA) at 1345–46 (citing *Chou v. Univ. of Chi.*, 254 F.3d 1347, 1359, 59 U.S.P.Q.2d (BNA) 1257, 1262 (Fed. Cir. 2001)).

250. *Id.*, 91 U.S.P.Q.2d (BNA) at 1346.

251. *Id.* at 1326–27, 91 U.S.P.Q.2d (BNA) at 1346.

252. *Id.* at 1328, 91 U.S.P.Q.2d (BNA) at 1347.

253. *Id.*, 91 U.S.P.Q.2d (BNA) at 1347.

254. 587 F.3d 1375, 92 U.S.P.Q.2d (BNA) 1940 (Fed. Cir. 2009).

255. *Id.* at 1377, 92 U.S.P.Q.2d (BNA) at 1941.

256. *Id.*, 92 U.S.P.Q.2d (BNA) at 1941.

257. *Id.*, 92 U.S.P.Q.2d (BNA) at 1941–42.

258. *Id.*, 92 U.S.P.Q.2d (BNA) at 1942.

The ownership of the patents-in-suit thus rested on the correct interpretation of the contractual phrase “related to pending litigation” under Third Circuit law.²⁵⁹ The court construed the phrase to mean that the patents “could not have been asserted in or affected by any litigation pending as of April 1, 1999.”²⁶⁰ Because “Tyco Healthcare bore the burden of proving that the patents-in-suit [were] not ‘related to’ any litigation pending at the time the Contribution Agreement was executed,” but failed to do so, the court affirmed the dismissal.²⁶¹ Turning to the nature of the dismissal, the Federal Circuit concluded that the district court did not abuse its discretion in dismissing without prejudice because Tyco Healthcare may become able to cure the ownership deficiency.²⁶² Moreover, because “the ownership issue was not identified to the court as an issue to be litigated during trial,” but was first raised during cross-examination of a witness at trial, the court found no undue prejudice to Ethicon Endo-Surgery, Inc.²⁶³ In a dissenting opinion, Judge Newman stated that “Tyco established, and Ethicon did not dispute, that the [patents-in-suit] were not related to any litigation pending on April 1, 1999” and, thus, the “patents were transferred by USSC to Tyco in accordance with the transfer in the Contribution Agreement.”²⁶⁴

In *Sky Technologies LLC v. SAP AG*,²⁶⁵ the Federal Circuit considered whether the district court correctly determined that patent ownership was properly transferred by operation of state foreclosure law.²⁶⁶ The patent owner, Ozro Inc., granted a security interest in the patents-in-suit to a lender.²⁶⁷ The court explained that if Ozro defaulted, the lender “had ‘the right to exercise all the remedies of a secured party upon such default under the Massachusetts [Uniform Commercial Code].’”²⁶⁸ Ozro subsequently defaulted on its loan obligations and the lender issued a foreclosure notice which “identified the patents-in-suit as those to be sold at public auction.”²⁶⁹ In the meantime, the inventor negotiated a transfer of the ownership of the patents-in-suit to his new company, Sky Technologies LLC.²⁷⁰

259. *Id.* at 1378, 92 U.S.P.Q.2d (BNA) at 1942.

260. *Id.* at 1379, 92 U.S.P.Q.2d (BNA) at 1943.

261. *Id.* at 1380, 92 U.S.P.Q.2d (BNA) at 1944.

262. *Id.*, 92 U.S.P.Q.2d (BNA) at 1944.

263. *Id.*, 92 U.S.P.Q.2d (BNA) at 1944.

264. *Id.* at 1385, 92 U.S.P.Q.2d (BNA) at 1948 (Newman, J., dissenting).

265. 576 F.3d 1374, 91 U.S.P.Q.2d (BNA) 1854 (Fed. Cir. 2009), *petition for cert. filed*, 78 U.S.L.W. 3419 (U.S. Dec. 24, 2009) (No. 09-819).

266. *Id.* at 1379, 91 U.S.P.Q.2d (BNA) at 1856–57.

267. *Id.* at 1376–77, 91 U.S.P.Q.2d (BNA) at 1855.

268. *Id.* at 1377, 91 U.S.P.Q.2d (BNA) at 1855 (internal citation omitted).

269. *Id.*, 91 U.S.P.Q.2d (BNA) at 1855.

270. *Id.*, 91 U.S.P.Q.2d (BNA) at 1855.

The lender purchased all of Ozro's assets at an auction and assigned all of its rights in the patents-in-suit to Sky.²⁷¹ After Sky sued SAP, SAP moved to dismiss Sky's complaint for lack of standing.²⁷² The Federal Circuit agreed with the district court, however, that because the lender properly complied with the Massachusetts UCC foreclosure requirements, title was transferred on the date of foreclosure and then transferred to Sky.²⁷³ Because the court found that the chain of title had not broken from Ozro to Sky, the court concluded that Sky had standing to sue for patent infringement.²⁷⁴

C. Standards of Pleading

1. Inequitable conduct

Federal Rule of Civil Procedure 9(b) requires that, "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." The Federal Circuit in 2009 reinforced the principle that inequitable conduct, while a broader concept than fraud, must be pled with particularity under Rule 9(b).

In *Exergen Corp. v. Wal-Mart Stores, Inc.*,²⁷⁵ the Federal Circuit affirmed the district court's denial of the defendant's motion for leave to amend its answer to allege inequitable conduct.²⁷⁶ In so doing, the court held that "in pleading inequitable conduct in patent cases, Rule 9(b) requires identification of the specific who, what, when, where, and how of the material misrepresentation or omission committed before the [US]PTO."²⁷⁷ Further, the court held that while

knowledge and "intent" may be averred generally, a pleading of inequitable conduct under Rule 9(b) must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the [US]PTO.²⁷⁸

The Federal Circuit agreed with the district court that the allegations of defendant S.A.A.T. Systems Application of Advanced

271. *Id.* at 1378, 91 U.S.P.Q.2d (BNA) at 1856.

272. *Id.*, 91 U.S.P.Q.2d (BNA) at 1856.

273. *See id.* at 1380–81, 91 U.S.P.Q.2d (BNA) at 1858.

274. *See id.* at 1382, 91 U.S.P.Q.2d (BNA) at 1859.

275. 575 F.3d 1312, 91 U.S.P.Q.2d (BNA) 1656 (Fed. Cir. 2009).

276. *Id.* at 1316, 91 U.S.P.Q.2d (BNA) at 1659.

277. *Id.* at 1327, 91 U.S.P.Q.2d (BNA) at 1667.

278. *Id.* at 1328–29, 91 U.S.P.Q.2d (BNA) at 1668.

Technology, Ltd. (SAAT) were “deficient with respect to both the particularity of the facts alleged and the reasonableness of the inference of scienter.”²⁷⁹ The court noted three factual deficiencies. First, SAAT’s pleading referred generally to “Exergen, its agents and/or attorneys,” and failed “to identify the ‘who’ of the material omissions and misrepresentation.”²⁸⁰ That is, the pleadings “fail[ed] to name the specific individual associated with the filing or prosecution of the application . . . who both knew of the material information and deliberately withheld or misrepresented it.”²⁸¹ Second, SAAT’s pleading failed to identify “the ‘what’ and ‘where’ of the material omissions,” namely, “which claims, and which limitations in those claims, the withheld references [were] relevant to, and where in those references the material information [was] found.”²⁸² Third, SAAT’s pleading did not explain “‘why’ the withheld information [was] material and not cumulative, and ‘how’ an examiner would have used this information in assessing the patentability of the claims.”²⁸³

Further, the Federal Circuit found that the facts alleged in SAAT’s pleading—that Exergen became aware of the withheld references during the prosecution of its prior applications—did not give rise to a reasonable inference of scienter because SAAT provided no factual basis to infer that any specific individual who owed a duty of disclosure knew of the allegedly material information.²⁸⁴ As for deceptive intent, while “[p]leading on ‘information and belief’ is permitted under Rule 9(b) when essential information lies uniquely within another party’s control,” the court held that the pleading must set “forth the specific facts upon which the belief is reasonably based.”²⁸⁵ The court found that SAAT’s pleading “provid[ed] neither the ‘information’ on which it reli[ed] nor any plausible reasons for its ‘belief.’”²⁸⁶ The court explained that “[t]he mere fact that an applicant disclosed a reference during prosecution of one application, but did not disclose it during prosecution of a related application, [was] insufficient to meet the threshold level of deceptive intent required to support an allegation of inequitable

279. *Id.* at 1329, 91 U.S.P.Q.2d (BNA) at 1668–69.

280. *Id.*, 91 U.S.P.Q.2d (BNA) at 1669.

281. *Id.*, 91 U.S.P.Q.2d (BNA) at 1669.

282. *Id.*, 91 U.S.P.Q.2d (BNA) at 1669 (citing *Regents of Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1570, 43 U.S.P.Q.2d (BNA) 1398, 1407 (Fed. Cir. 1997)).

283. *Id.* at 1329–30, 91 U.S.P.Q.2d (BNA) at 1669.

284. *Id.* at 1330, 91 U.S.P.Q.2d (BNA) at 1669.

285. *Id.*, 91 U.S.P.Q.2d (BNA) at 1670.

286. *Id.* at 1331, 91 U.S.P.Q.2d (BNA) at 1670.

conduct.”²⁸⁷ Accordingly, the Federal Circuit held that the district court “did not abuse its discretion in denying SAAT’s motion for leave to add these allegations to [its] original answer.”²⁸⁸

D. *Res Judicata*

The doctrine of res judicata, known as “claim preclusion” in modern parlance, “precludes the relitigation of a claim, or cause of action, or any possible defense to the cause of action which is ended by a judgment of the court.”²⁸⁹ In a patent case, the doctrine of claim preclusion requires an accused infringer to demonstrate that the accused product or process in the second suit is “essentially the same” as the accused product or process in the first suit.²⁹⁰

The Federal Circuit in 2009 considered a question of first impression—“whether [an] accused infringer may assert claim preclusion when [the product in a second suit] remain[s] unchanged” with respect to the sole claim limitations at issue in the first suit, even if there are changes with respect to other claim limitations.²⁹¹ The court had previously emphasized that the focus for claim preclusion should be on “material differences” between the two accused devices,²⁹² “but [had] not addressed directly whether the focus of the ‘material differences’ test is on the claim limitations at issue in each particular case.”²⁹³ In *Nystrom v. Trex Co.*,²⁹⁴ the court found that the same claim limitations were at issue in the first and second suits, that the constructions for those terms in the second suit were the same as the constructions in the first suit, and that the bases of noninfringement in the first suit were those constructions.²⁹⁵ Thus, even though defendants, for purposes of summary judgment, had conceded material differences between the products in the first and second suits as to other limitations, the court focused on the claim limitations at issue in the first suit.²⁹⁶ Concluding that the devices in the two cases were “insubstantially different” with respect to the pertinent claim elements involved in the first suit, the Federal

287. *Id.*, 91 U.S.P.Q.2d (BNA) at 1670.

288. *Id.*, 91 U.S.P.Q.2d (BNA) at 1670.

289. *Foster v. Hallco Mfg. Co.*, 947 F.2d 469, 476, 20 U.S.P.Q.2d (BNA) 1241, 1246 (Fed. Cir. 1991) (citing RESTATEMENT (SECOND) OF JUDGMENTS §§ 18, 19 (1982)).

290. *Id.* at 479–80, 20 U.S.P.Q.2d (BNA) at 1249.

291. *Nystrom v. Trex Co.*, 580 F.3d 1281, 1285, 92 U.S.P.Q.2d (BNA) 1060, 1062 (Fed. Cir. 2009).

292. *See Foster*, 947 F.2d at 480, 20 U.S.P.Q.2d (BNA) at 1249.

293. *Nystrom*, 580 F.3d at 1285, U.S.P.Q.2d (BNA) at 1062–63.

294. 580 F.3d 1281, 92 U.S.P.Q.2d (BNA) 1060 (Fed. Cir. 2009).

295. *Id.* at 1285, 92 U.S.P.Q.2d (BNA) at 1063.

296. *Id.* at 1285–86, 92 U.S.P.Q.2d (BNA) at 1063.

Circuit affirmed the district court's holding that the plaintiff was precluded on res judicata grounds from litigating an infringement claim.²⁹⁷

E. Awards of Attorneys' Fees and Costs

Attorneys' fees are warranted for litigation misconduct or "if both (1) the litigation is brought in subjective bad faith, and (2) the litigation is objectively baseless."²⁹⁸ The Federal Circuit upheld several awards of attorneys' fees in 2009 in circumstances involving litigation misconduct or willfulness.

In *ICU Medical, Inc. v. Alaris Medical Systems, Inc.*,²⁹⁹ the Federal Circuit held that the district court did not commit clear error in awarding attorneys' fees. Applying its own precedent, the Federal Circuit affirmed the district court's award of attorneys' fees under 35 U.S.C. § 285 for a portion of the litigation.³⁰⁰ The Federal Circuit found that "[t]he district court applied the appropriate legal standard and articulated several bases in support of the award, none of which ICU [showed] to be clearly erroneous."³⁰¹ The court explained, for example, that "the district court found that ICU made 'multiple, repeated misrepresentations . . . regarding its own patents in an effort to conceal . . . errors.'"³⁰² Further, the Federal Circuit held that the district court appropriately exercised its discretion in holding that ICU's misconduct warranted Rule 11 sanctions, and that some of the misconduct warranted an award of attorneys' fees.³⁰³

In *Revolution Eyewear, Inc. v. Aspex Eyewear, Inc. (Revolution Eyewear II)*,³⁰⁴ facts considered in an equitable intervening rights analysis—facts that would normally be considered under a willful infringement analysis—did not amount to "clear and convincing" evidence of willfulness to support finding the case "exceptional."³⁰⁵ After a jury trial, "the district court concluded that Revolution Eyewear was entitled to absolute intervening rights and reduced the damages

297. *See id.* at 1286, 92 U.S.P.Q.2d (BNA) at 1063.

298. *Brooks Furniture Mfg., Inc. v. Dutailier Int'l, Inc.*, 393 F.3d 1378, 1381, 73 U.S.P.Q.2d (BNA) 1475, 1460 (Fed. Cir. 2005) (citing *Profl Real Estate Investors v. Columbia Pictures Indus.*, 508 U.S. 49, 60–61 (1993)).

299. 558 F.3d 1368, 90 U.S.P.Q.2d (BNA) 1072 (Fed. Cir. 2009).

300. *Id.* at 1380, 90 U.S.P.Q.2d (BNA) at 1079.

301. *Id.*, 90 U.S.P.Q.2d (BNA) at 1079.

302. *Id.*, 90 U.S.P.Q.2d (BNA) at 1079 (citation omitted).

303. *Id.* at 1381, 90 U.S.P.Q.2d (BNA) at 1080.

304. 563 F.3d 1358, 90 U.S.P.Q.2d (BNA) 1733 (Fed. Cir. 2009).

305. *Id.* at 1372–74, 90 U.S.P.Q.2d (BNA) at 1743–44 (citing *Diego, Inc. v. Audible, Inc.*, 505 F.3d 1362, 1366–67, 85 U.S.P.Q.2d (BNA) 1246, 1248 (Fed. Cir. 2007)).

award.”³⁰⁶ The district court, however, rejected Revolution Eyewear’s equitable intervening rights defense, finding that the company acted with unclean hands after it learned of the district court’s summary judgment orders.³⁰⁷ The district court also denied the motion for attorneys’ fees filed by the counterclaimants, Contour Optik, Inc., Manhattan Design Studio, Inc., and Asahi Optical Co. (collectively “Contour”), based on Revolution Eyewear’s alleged willful infringement of the patent.³⁰⁸

On appeal, Contour argued that there was “no distinction between ‘intervening rights’ willfulness and ‘exceptional case’ willfulness and, therefore, the district court committed reversible error in denying [its motion for] attorney fees based on willful infringement.”³⁰⁹ The Federal Circuit noted that the issue of equitable intervening rights was entirely equitable in nature and, as such, issues of fact underlying the equitable intervening rights were matters for court, not jury disposition.³¹⁰ In contrast, the Federal Circuit noted that the issue of willful infringement remained with the fact-finder.³¹¹ The court explained that “Contour [had] failed to plead willful infringement, and the fact finder did not examine the issue.”³¹² This did not prevent the district court “from taking into account, *as dictated by the equities*, facts that would normally be considered under willful infringement analysis.”³¹³ But the court held that “such a limited finding [of willfulness] on an equitable issue [would not be] a sufficient clear and convincing finding of willfulness to support finding the case exceptional.”³¹⁴ Finding no clear error in the district court’s conclusion that the case was not exceptional, the Federal Circuit affirmed the district court’s denial of Contour’s motion for attorneys’ fees based on willful infringement.³¹⁵

In *Wedgetail, Ltd. v. Huddleston Deluxe, Inc.*,³¹⁶ the Federal Circuit found that a lack of detailed analysis by the district court did not warrant reversal and that the district court’s decision not to award attorneys’ fees was, at most, harmless error.³¹⁷ The Federal Circuit

306. *Id.* at 1365, 90 U.S.P.Q.2d (BNA) at 1737.

307. *Id.*, 90 U.S.P.Q.2d (BNA) at 1737.

308. *Id.*, 90 U.S.P.Q.2d (BNA) at 1737.

309. *Id.* at 1373, 90 U.S.P.Q.2d (BNA) at 1743.

310. *Id.*, 90 U.S.P.Q.2d (BNA) at 1743.

311. *Id.*, 90 U.S.P.Q.2d (BNA) at 1743.

312. *Id.*, 90 U.S.P.Q.2d (BNA) at 1744.

313. *Id.*, 90 U.S.P.Q.2d (BNA) at 1744.

314. *Id.*, 90 U.S.P.Q.2d (BNA) at 1744 (internal quotation marks omitted).

315. *Id.* at 1374, 90 U.S.P.Q.2d (BNA) at 1744.

316. 576 F.3d 1302, 91 U.S.P.Q.2d (BNA) 1782 (Fed. Cir. 2009).

317. *Id.* at 1307, 91 U.S.P.Q.2d (BNA) at 1786.

reminded that, “because of the high level of deference owed to district courts on this issue and the limited circumstances that could qualify as exceptional, this court has not imposed a blanket requirement that a district court provide its reasoning in attorney fee cases.”³¹⁸ The Federal Circuit concluded that because Huddleston Deluxe, Inc. could point to nothing in the record to support a finding of exceptionality or otherwise suggest a need for the district court to provide its reasoning, no useful purpose would be served by a remand.³¹⁹

The Federal Circuit also considered the issue of costs in the context of joint discovery. In *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories Inc.*,³²⁰ the Federal Circuit remanded an award of costs attributed to joint discovery for apportionment to prevent double recovery. As the prevailing party, Daiichi Pharmaceutical Co. submitted a bill of costs to the district court pursuant to Federal Rule of Civil Procedure 54(d) and 28 U.S.C. § 1920 seeking approximately \$2.2 million from Mylan Laboratories, Inc.³²¹ Mylan objected to Daiichi’s bill of costs on several grounds, for example, by pointing out the fact that certain discovery had been conducted jointly in this action and in a separate action against Teva Pharmaceuticals, Inc. in a different court.³²² Mylan asserted that “costs of the [joint] discovery should be apportioned between the two actions.”³²³ On appeal, the Federal Circuit reviewed the award of costs for abuse of discretion using Fourth Circuit law, under which Rule 54(d) “creates the presumption that costs are to be awarded to the prevailing party.”³²⁴ The Federal Circuit found that the Teva action had settled and that the district court, in its order dismissing it, stated that the parties would bear their own costs and attorneys’ fees.³²⁵ The Federal Circuit relied on general principles of law from other circuits, noting that in a case of joint discovery conducted in multiple actions pending in different district courts, there is a risk of impermissible double recovery.³²⁶

318. *Id.* at 1305, 91 U.S.P.Q.2d (BNA) at 1784.

319. *Id.* at 1307, 91 U.S.P.Q.2d (BNA) at 1785–86.

320. 569 F.3d 1353, 91 U.S.P.Q.2d (BNA) 1274 (Fed. Cir. 2009).

321. *Id.* at 1355, 91 U.S.P.Q.2d (BNA) at 1275.

322. *Id.*, 91 U.S.P.Q.2d (BNA) at 1275.

323. *Id.*, 91 U.S.P.Q.2d (BNA) at 1275.

324. *Id.* at 1356, 91 U.S.P.Q.2d (BNA) at 1276 (citing *Cherry v. Champion Int’l Corp.*, 186 F.3d 442, 446 (4th Cir. 1999)).

325. *Id.*, 91 U.S.P.Q.2d (BNA) at 1276.

326. *Id.* at 1357, 91 U.S.P.Q.2d (BNA) at 1277 (citing *Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 763–64 (8th Cir. 2006); *EnergyNorth Natural Gas, Inc. v. Century Indem. Co.*, 452 F.3d 44, 58 (1st Cir. 2006); *In re Derailment Cases*, 417 F.3d 840, 844 (8th Cir. 2005); *Anderson v. Griffin*, 397 F.3d 515, 522–23 (7th Cir. 2005);

The Federal Circuit concluded that Daiichi had, in effect, already recovered some costs through its settlement with Teva by agreeing not to seek actual payment of costs as consideration for Teva foregoing its appeal.³²⁷ The court further concluded that Daiichi could not recover more than its total entitlement by obtaining the same costs from Mylan.³²⁸ Accordingly, the court vacated the judgment of the district court with respect to the award of costs attributed to the joint discovery and remanded to the district court to apportion the disputed costs.³²⁹

F. Discovery Practices and Sanctions

Under the Hatch-Waxman Act,³³⁰ final Food and Drug Administration (FDA) approval of an Abbreviated New Drug Application (ANDA) is automatically stayed for thirty months when a patent owner files suit for patent infringement within forty-five days of receiving a Paragraph IV notice letter.³³¹ The purpose of the stay is to allow the parties to litigate the patent infringement claims while the ANDA filer pursues FDA approval of its generic drug. Pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), a district court may shorten or lengthen the thirty-month stay if “either party to the action failed to reasonably cooperate in expediting the action.”³³²

In *Eli Lilly & Co. v. Teva Pharmaceuticals USA, Inc.*,³³³ the Federal Circuit affirmed a holding that the statutory thirty-month stay may be extended based on a party’s uncooperative discovery practices, postponing the FDA’s final approval of Teva’s ANDA.³³⁴ In May 2006, Teva filed an ANDA and Lilly subsequently sued Teva for patent infringement.³³⁵ The FDA then stayed approval of Teva’s ANDA for thirty months.³³⁶ Thereafter, the district court set a trial date after the end of the thirty-month period.³³⁷ Less than two months before the

Concord Boat Corp. v. Brunswick Corp., 309 F.3d 494, 496–97 (8th Cir. 2002); Nelson-Salabes, Inc. v. Morningside Dev., LLC, 284 F.3d 505, 517 n.13 (4th Cir. 2002); *In re Paoli R.R. Yard PCB Litig.*, 221 F.3d 449, 469 (3d Cir. 2000); Chisholm v. UHP Projects, Inc., 205 F.3d 231, 237 (4th Cir. 2000); Camarillo v. Pabey, No. 2:05-CV-455 PS, 2007 WL 3102144 (N.D. Ind. Oct. 22, 2007).

327. *Id.* at 1358, 91 U.S.P.Q.2d (BNA) at 1277.

328. *Id.*, 91 U.S.P.Q.2d (BNA) at 1277.

329. *Id.*, 91 U.S.P.Q.2d (BNA) at 1278.

330. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355 (2006)).

331. 21 U.S.C. § 355(j)(5)(B)(iii) (2006).

332. *Id.*

333. 557 F.3d 1346, 89 U.S.P.Q.2d (BNA) 1921 (Fed. Cir. 2009).

334. *Id.* at 1347–48, 89 U.S.P.Q.2d (BNA) at 1922.

335. *Id.* at 1348–49, 89 U.S.P.Q.2d (BNA) at 1923.

336. *Id.* at 1349, 89 U.S.P.Q.2d (BNA) at 1923.

337. *Id.*, 89 U.S.P.Q.2d (BNA) at 1923.

discovery deadline, Teva amended its ANDA and produced one batch sample before and two batch samples and related documentation after the discovery deadline.³³⁸ Lilly moved the district court to extend the statutory thirty-month stay due to Teva's alleged discovery violations, and the district court granted the motion.³³⁹ Teva then filed a motion for an expedited appeal with the Federal Circuit.³⁴⁰

On appeal, a panel majority determined that the record contained sufficient evidence to support the order and that the district court did not abuse its discretion in extending the thirty-month stay.³⁴¹ In a dissenting opinion, Judge Prost argued that the majority misapplied the standard of review and granted too much deference to the district court in extending the stay.³⁴²

Discovery misconduct was also at issue in *ClearValue, Inc. v. Pearl River Polymers, Inc.*,³⁴³ where withholding relevant test results of an accused product was considered sanctionable misconduct.³⁴⁴ The Federal Circuit affirmed the district court's award of attorneys' fees under Federal Rules of Civil Procedure 26 and 37 as to the appellants, but reversed the sanction as to their attorney.³⁴⁵ ClearValue, Inc. and the inventor of the patent-in-suit filed an infringement suit in which the district court determined that ClearValue withheld, for over a year and a half, test results relevant to a critical issue in the case.³⁴⁶ The district court imposed the "severest sanctions" by striking the pleadings of ClearValue and the inventor, by entering judgment for the appellees, and by imposing monetary sanctions against ClearValue, the inventor, and their attorney, jointly and severally, in the amount of \$2,717,098.34.³⁴⁷

On appeal, the Federal Circuit first considered the district court's imposition of sanctions under Rules 26 and 37, and affirmed its finding of sanctionable conduct.³⁴⁸ The Federal Circuit also considered the district court's award of attorneys' fees under Rule 37 and found no abuse of discretion in the award as to ClearValue and

338. *Id.*, 89 U.S.P.Q.2d (BNA) at 1923.

339. *Id.*, 89 U.S.P.Q.2d (BNA) at 1923.

340. *Id.*, 89 U.S.P.Q.2d (BNA) at 1923.

341. *Id.* at 1350, 89 U.S.P.Q.2d (BNA) at 1924.

342. *See id.* at 1352-53, 89 U.S.P.Q.2d (BNA) at 1925-27 (Prost, J., dissenting) (arguing that interpretation of an ANDA stay is a "question of law reviewed without deference" (citing *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1375, 61 U.S.P.Q.2d (BNA) 1414, 1419 (Fed. Cir. 2002))).

343. 560 F.3d 1291, 90 U.S.P.Q.2d (BNA) 1358 (Fed. Cir. 2009).

344. *Id.* at 1303, 90 U.S.P.Q.2d (BNA) at 1366.

345. *Id.* at 1310, 90 U.S.P.Q.2d (BNA) at 1371.

346. *Id.* at 1296, 1298, 90 U.S.P.Q.2d (BNA) at 1361, 1363.

347. *Id.* at 1301, 90 U.S.P.Q.2d (BNA) at 1364-65.

348. *Id.* at 1304, 90 U.S.P.Q.2d (BNA) at 1366-67.

the inventor because the “[a]ppellees submitted affidavits as to the reasonableness of the attorney’s fees they incurred.”³⁴⁹ The Federal Circuit concluded, however, that the district court abused its discretion by imposing joint and several liability on the attorney under Rule 37.³⁵⁰ Specifically, the Federal Circuit found that the district court erred by failing to consider that the attorney did not have the ability to pay when it fashioned the sanction against him as required by the Fifth Circuit.³⁵¹ The Federal Circuit also found that the appellants’ misconduct was a discovery violation properly addressed under Rule 37 and that the district court abused its discretion by resorting to its inherent powers to impose sanctions on the appellants.³⁵²

In a separate opinion, Judge Newman dissented with respect to the panel’s exoneration of the attorney from the monetary consequences of his admittedly improper actions.³⁵³ Agreeing that “ability to pay is a factor that a court can consider,” Judge Newman found no evidence that the attorney could not pay any share of the reduced award.³⁵⁴ Accordingly, Judge Newman recommended that the matter be remanded to the district court so that the court could consider the attorney’s asserted inability to pay.³⁵⁵

In *ICU Medical*, the Federal Circuit held that the district court did not commit clear error when it granted Rule 11 sanctions.³⁵⁶ The Federal Circuit noted that “the Supreme Court has advised all appellate courts to ‘apply an abuse-of-discretion standard in reviewing all aspects of a district court’s Rule 11 determination.’”³⁵⁷ Under this standard, “[a] district court would necessarily abuse its discretion if it based its ruling on an erroneous view of the law or on a clearly erroneous assessment of the evidence.”³⁵⁸ The Federal Circuit applied Ninth Circuit law in determining whether a sanctions award under Rule 11 was appropriate, explaining that “a district court must conduct a two-prong inquiry to determine (1) whether the complaint [or relevant document] is legally or factually ‘baseless’ from an

349. *Id.* at 1305, 90 U.S.P.Q.2d (BNA) at 1367–68.

350. *Id.*, 90 U.S.P.Q.2d (BNA) at 1368.

351. *Id.* at 1305–06, 90 U.S.P.Q.2d (BNA) at 1368 (quoting *United States v. Garrett*, 238 F.3d 293, 298 (5th Cir. 2000)).

352. *Id.* at 1309, 90 U.S.P.Q.2d (BNA) at 1371.

353. *Id.* at 1311, 90 U.S.P.Q.2d (BNA) at 1372.

354. *Id.*, 90 U.S.P.Q.2d (BNA) at 1372.

355. *Id.*, 90 U.S.P.Q.2d (BNA) at 1372.

356. *ICU Med., Inc. v. Alaris Med. Sys., Inc.*, 558 F.3d 1368, 1381, 90 U.S.P.Q.2d (BNA) 1072, 1080 (Fed. Cir. 2009).

357. *Id.*, 90 U.S.P.Q.2d (BNA) at 1080 (citing *Cooter & Gell v. Hartmarx Corp.*, 496 U.S. 384, 405 (1990)).

358. *Id.*, 90 U.S.P.Q.2d (BNA) at 1080 (citing *Cooter & Gell*, 496 U.S. at 405).

objective perspective, and (2) if the attorney has conducted ‘a reasonable and competent inquiry’ before signing and filing it.”³⁵⁹ Applying these laws, the Federal Circuit found that the district court properly determined that ICU’s frivolous construction and assertion of certain claims in its amended complaint justified sanctions under Rule 11.³⁶⁰ The Federal Circuit also noted the district court’s decision not to award monetary sanctions for the violations of Rule 11, because the amount of the award of Rule 11 sanctions was “subsumed” by the amount of attorneys’ fees awarded under § 285, which “ha[d] sufficiently admonished ICU and its counsel for any improper conduct under Rule 11.”³⁶¹

G. Appointment of Expert Witnesses

Federal Rule of Evidence 706 allows courts to appoint expert witnesses in the interest of the people or to clarify existing testimony.³⁶² In *Monolithic Power Systems, Inc. v. O2 Micro International Ltd.*,³⁶³ the Federal Circuit found that a district court did not abuse its discretion on expert witness appointment when that court was confronted by an unusually complex and conflicting set of consolidated cases.³⁶⁴ Before trial commenced, the district court considered appointing an independent expert under Federal Rule of Evidence 706.³⁶⁵ The parties ultimately agreed upon an expert who testified at trial.³⁶⁶ The jury found the patent invalid under Monolithic Power Systems, Inc.’s “obviousness and on-sale bar theories.”³⁶⁷ The expert’s testimony was largely consistent with Monolithic’s theory of the case.³⁶⁸

On appeal, O2 Micro International Ltd. argued that the district court’s appointment of the expert unduly burdened its Seventh Amendment right to a jury trial and violated Ninth Circuit precedent establishing that there is no “complexity exception” to the Seventh Amendment right.³⁶⁹ Upon review of the record, the Federal Circuit found “no denial or encumbrance of O2 Micro’s jury demand or

359. *Id.*, 90 U.S.P.Q.2d (BNA) at 1080 (quoting *Christian v. Mattel, Inc.*, 286 F.3d 1118, 1127 (9th Cir. 2002)).

360. *Id.*, 90 U.S.P.Q.2d (BNA) at 1080.

361. *Id.*, 90 U.S.P.Q.2d (BNA) at 1080 (citation omitted).

362. FED. R. EVID. 706.

363. 558 F.3d 1341, 90 U.S.P.Q.2d (BNA) 1001 (Fed. Cir. 2009).

364. *Id.* at 1348, 90 U.S.P.Q.2d (BNA) at 1006.

365. *Id.* at 1345, 90 U.S.P.Q.2d (BNA) at 1004.

366. *Id.* at 1345–46, 90 U.S.P.Q.2d (BNA) at 1004.

367. *Id.* at 1346, 90 U.S.P.Q.2d (BNA) at 1004.

368. *Id.* at 1345–46, 90 U.S.P.Q.2d (BNA) at 1004.

369. *Id.* at 1347, 90 U.S.P.Q.2d (BNA) at 1005.

Seventh Amendment rights.”³⁷⁰ The court explained that the district court properly permitted the parties to show cause why an expert witness should not be appointed pursuant to Rule 706.³⁷¹ Moreover, the Federal Circuit noted that the Supreme Court has consistently acknowledged the constitutionality of court-appointed experts.³⁷² Accordingly, although it recognized “that Rule 706 should be invoked only in rare and compelling circumstances,” the Federal Circuit found no abuse of discretion in appointing an independent expert in this case “where the district court was confronted by what it viewed as an unusually complex case and what appeared to be starkly conflicting expert testimony.”³⁷³

III. FEDERAL CIRCUIT PRACTICE

A. *Writ of Mandamus*

A writ of mandamus is drastic relief available only in extraordinary circumstances to correct a clear abuse of discretion.³⁷⁴ A party seeking the relief bears the burden of proving that the grounds for the issuance of a writ are “clear and indisputable.”³⁷⁵ Courts have used the writ of mandamus to correct a patently erroneous denial of transfer of venue under 28 U.S.C. § 1404(a).³⁷⁶ A court may transfer venue of a case “[f]or the convenience of parties and witnesses, in the interest of justice.”³⁷⁷ In 2008, for example, the Fifth Circuit, sitting en banc, issued a writ of mandamus to transfer from the Marshall Division of the Eastern District of Texas to the Dallas Division of the Northern District of Texas a products liability suit arising out of a fatal automobile accident in Dallas.³⁷⁸ Following that decision, the

370. *Id.*, 90 U.S.P.Q.2d (BNA) at 1005.

371. *Id.*, 90 U.S.P.Q.2d (BNA) at 1005.

372. *Id.* at 1348, 90 U.S.P.Q.2d (BNA) at 1006.

373. *Id.*, 90 U.S.P.Q.2d (BNA) at 1006.

374. *See, e.g., In re Calmar, Inc.*, 854 F.2d 461, 464, 7 U.S.P.Q.2d (BNA) 1713, 1715 (Fed. Cir. 1988) (granting mandamus where the district court abused its discretion in sanctioning counsel when counsel’s statements of law were correct).

375. *Allied Chem. Corp. v. Daiflon, Inc.*, 449 U.S. 33, 35 (1980) (citing *Bankers Life & Cas. Co. v. Holland*, 346 U.S. 379, 384 (1953)).

376. *See, e.g., In re TS Tech USA Corp.*, 551 F.3d 1315, 1317–18, 89 U.S.P.Q.2d (BNA) 1567, 1567–68 (Fed. Cir. 2008) (holding that it was clear error for the district court to not consider the cost of witness travel and the importance of having local interests decided locally).

377. 28 U.S.C. § 1404(a) (2006).

378. *In re Volkswagen of Am., Inc.*, 545 F.3d 304, 89 U.S.P.Q.2d (BNA) 1501 (5th Cir. 2008) (en banc), *cert. denied sub nom. Singleton v. Volkswagen of Am., Inc.*, 129 S. Ct. 1336 (2009).

Federal Circuit in 2008 granted extraordinary relief to transfer a case out of the Eastern District of Texas.³⁷⁹

In 2009, the Federal Circuit addressed petitions for writs of mandamus to transfer cases out of the Eastern District of Texas in four cases.³⁸⁰ On a single day in May, the Federal Circuit issued rulings in two cases—one granting and the other denying the writ. In the first case, *In re Genentech, Inc.*, the Federal Circuit granted the accused infringer's petition for a writ of mandamus to direct the Eastern District of Texas to transfer the case to the Northern District of California.³⁸¹ The petition arose out of a patent infringement suit brought by Sanofi against California-based Genentech and Biogen.³⁸² The two biotechnology companies filed a related declaratory judgment action in the Northern District of California and then filed a motion to transfer the suit to California under 28 U.S.C. § 1404(a).³⁸³ Upon denial of the motion to transfer, Genentech and Biogen sought a writ of mandamus.³⁸⁴

The Federal Circuit determined that the convenience for the witnesses weighed substantially in favor of a transfer because a substantial number of material witnesses resided in California, and no witnesses resided in Texas.³⁸⁵ The court rejected a rigid application of the "100-mile" rule, because it would give undue weight to the inconvenience to European witnesses at the expense of creating unnecessary inconvenience for witnesses in the United States.³⁸⁶ Similarly, the court concluded that the convenience for the parties supported transfer because both Genentech and Biogen are California companies and European-based Sanofi would have to travel a great distance regardless of the venue.³⁸⁷ The court also rejected the district court's rationale that the physical location of documents had diminished relevance in light of electronic storage and transmission technology.³⁸⁸

379. See *TS Tech*, 551 F.3d at 1317–18, 89 U.S.P.Q.2d (BNA) at 1567–68 (issuing a writ of mandamus to transfer a patent case from the Eastern District of Texas to the Southern District of Ohio when none of the key witnesses resided in Texas and the pertinent evidence was located mainly in Ohio).

380. See *supra* Part II.A.

381. 566 F.3d 1338, 1340, 1348, 91 U.S.P.Q.2d (BNA) 1027, 1029, 1035 (Fed. Cir. 2009).

382. *Id.*, 91 U.S.P.Q.2d (BNA) at 1029.

383. *Id.* at 1341, 91 U.S.P.Q.2d (BNA) at 1029.

384. *Id.*, 91 U.S.P.Q.2d (BNA) at 1030.

385. *Id.* at 1345, 91 U.S.P.Q.2d (BNA) at 1032–33.

386. *Id.* at 1344, 91 U.S.P.Q.2d (BNA) at 1032.

387. *Id.* at 1345, 91 U.S.P.Q.2d (BNA) at 1033.

388. *Id.* at 1345–46, 91 U.S.P.Q.2d (BNA) at 1033.

In the second case, *In re Volkswagen of America, Inc.*, the Federal Circuit denied a petition for a writ of mandamus to transfer a case from the Eastern District of Texas to Michigan.³⁸⁹ MHL, Tek, LLC, a small Texas company operating out of Michigan, initiated two lawsuits in the Eastern District of Texas asserting patent infringement against thirty foreign and U.S. automobile companies, including Volkswagen.³⁹⁰ Volkswagen filed a declaratory judgment action against MHL on the same patents in the Eastern District of Michigan, which transferred the case to Texas “to avoid wasting judicial resources and risking inconsistent rulings on the same patents.”³⁹¹ The Federal Circuit upheld the denial of the transfer to Michigan under these circumstances based on the rationale that judicial economy is served by having the same court try the same patents.³⁹²

Later, in December 2009, the Federal Circuit granted petitions for writs of mandamus in two additional cases. In *In re Hoffmann-La Roche Inc.*,³⁹³ Novartis Vaccines and Diagnostics, Inc., a company headquartered in California, brought a patent infringement action in the Eastern District of Texas against the makers of a commercial HIV inhibitor drug.³⁹⁴ The Federal Circuit issued a writ of mandamus directing the Eastern District of Texas to transfer the case to the Eastern District of North Carolina.³⁹⁵ In granting the writ of mandamus, the court noted “a stark contrast in relevance, convenience, and fairness between the two venues.”³⁹⁶ The court relied on a number of factors that favored transfer to the Eastern District of North Carolina, including the fact that the accused drug was developed and tested there, that the documents and sources of proof were located there, that there existed strong local interest in the case, that four party witnesses resided within 100 miles of the court, and that the transferee court had a less congested docket.³⁹⁷

Furthermore, the court found that there was “no connection between [the] case and the Eastern District of Texas except [the] anticipation of this litigation.”³⁹⁸ The court viewed the plaintiff’s electronic transfer of 75,000 pages of documents to its Texas local counsel as “a fiction which appears to be have been [sic] created to

389. 566 F.3d 1349, 1350, 1352, 91 U.S.P.Q.2d (BNA) 1036, 1308 (Fed. Cir. 2009).

390. *Id.*, 91 U.S.P.Q.2d (BNA) at 1036–37.

391. *Id.* at 1351, 91 U.S.P.Q.2d (BNA) at 1037.

392. *Id.*, 91 U.S.P.Q.2d (BNA) at 1038.

393. 587 F.3d 1333, 92 U.S.P.Q.2d (BNA) 1861 (Fed. Cir. 2009).

394. *Id.* at 1334–35, 92 U.S.P.Q.2d (BNA) at 1861–62.

395. *Id.* at 1335, 92 U.S.P.Q.2d (BNA) at 1861.

396. *Id.* at 1336, 92 U.S.P.Q.2d (BNA) at 1863.

397. *Id.*, 92 U.S.P.Q.2d (BNA) at 1863.

398. *Id.* at 1336–37, 92 U.S.P.Q.2d (BNA) at 1863.

manipulate the propriety of venue.”³⁹⁹ The court similarly found unpersuasive the district court’s reliance on its ability to compel a witness to attend trial because the witness resided more than 100 miles away from the court, and the Eastern District of Texas lacked “absolute subpoena power.”⁴⁰⁰

Similarly, in *In re Nintendo Co.*, the Federal Circuit held that the Eastern District of Texas clearly abused its discretion when it denied the accused infringer’s motion to transfer venue to the Western District of Washington.⁴⁰¹ Motiva LLC sued Nintendo Co., Ltd. and Nintendo of America Inc. in the Eastern District of Texas, asserting that the Nintendo Wii infringed Motiva’s patent relating to a human movement measurement system.⁴⁰² Citing *Volkswagen, TS Tech, Genentech*, and *In re Hoffman-La Roche*, the Federal Circuit stated that “[t]his court has held and holds again in this instance that in a case featuring most witnesses and evidence closer to the transferee venue with few or no convenience factors favoring the venue chosen by the plaintiff, the trial court should grant a motion to transfer.”⁴⁰³

According to the court, “[n]o parties, witnesses, or evidence ha[d] any material connection to the venue chosen by the plaintiff.”⁴⁰⁴ For example, all identified key witnesses resided in Washington, Japan, Ohio, and New York, and no witnesses lived in Texas.⁴⁰⁵ In concluding that Nintendo had met the difficult burden of showing “a clear and indisputable right to a writ,”⁴⁰⁶ the Federal Circuit detailed the district court’s clear abuse of discretion as follows:

The district court: (1) applied too strict of a standard to allow transfer; (2) gave too much weight to the plaintiff’s choice of venue; (3) misapplied the *forum non conveniens* factors; (4) incorrectly assessed the 100-mile tenet; (5) improperly substituted its own central proximity for a measure of convenience of the parties, witnesses, and documents; and (6) glossed over a record without a single relevant factor favoring the plaintiff’s chosen venue.⁴⁰⁷

399. *Id.* at 1337, 92 U.S.P.Q.2d (BNA) at 1863.

400. *Id.* at 1337–38, 92 U.S.P.Q.2d (BNA) at 1864.

401. 589 F.3d 1194, 1196, 93 U.S.P.Q.2d (BNA) 1152, 1153 (Fed. Cir. 2009).

402. *Id.*, 93 U.S.P.Q.2d (BNA) at 1153.

403. *Id.* at 1198, 93 U.S.P.Q.2d (BNA) at 1154.

404. *Id.*, 93 U.S.P.Q.2d (BNA) at 1154.

405. *Id.* at 1199, 93 U.S.P.Q.2d (BNA) at 1154.

406. *Id.* at 1200, 93 U.S.P.Q.2d (BNA) at 1155.

407. *Id.*, 93 U.S.P.Q.2d (BNA) at 1155.

B. Recall of Mandate

When an appellate court “modifies or reverses a judgment with a direction that a money judgment be entered in the district court, the mandate must contain instructions about the allowance of interest.”⁴⁰⁸ Although the power to recall a mandate is exercised only in extraordinary circumstances,⁴⁰⁹ recall is appropriate when a mandate lacks instructions on interest, as Rule 37(b) requires.⁴¹⁰

In *Mars, Inc. v. Coin Acceptors, Inc.*,⁴¹¹ the Federal Circuit recalled its original mandate because it did not instruct the district court to award postjudgment interest to which Mars, Inc. was entitled under Rule 37(b).⁴¹² In its original mandate, the Federal Circuit determined that Mars lacked standing to recover damages from 1996 to 2003 and therefore reduced the amount of the district court’s damages.⁴¹³ The court affirmed-in-part and reversed-in-part the district court’s judgment and remanded for “recalculation of damages for the period prior to 1996 and for further proceedings.”⁴¹⁴ The mandate was defective in that it did not contain any directive governing an award of interest, so the court recalled the mandate to determine whether Mars was entitled to the award.⁴¹⁵ The court applied Third Circuit law under which plaintiffs are generally entitled to postjudgment interest when a decision is closer to an affirmance than a reversal.⁴¹⁶ The parties did not dispute that the Federal Circuit’s decision was closer to an affirmance; thus, the Federal Circuit recalled the original mandate and issued a new one, awarding postjudgment interest at the statutory rate as of the date of the district court judgment.⁴¹⁷

C. Administrative Procedure Act

Although the Administrative Procedure Act (APA) generally dictates the limited standards and grounds for review of agency action, the Federal Circuit has found that decisions can be reached on grounds beyond those considered by the USPTO.

408. FED. R. APP. P. 37(b).

409. *Calderon v. Thompson*, 523 U.S. 538, 550 (1998).

410. FED. R. APP. P. 37 advisory committee’s note (1967).

411. 557 F.3d 1377, 90 U.S.P.Q.2d (BNA) 1061 (Fed. Cir. 2009).

412. *Id.* at 1379, 90 U.S.P.Q.2d (BNA) at 1063.

413. *Id.*, 90 U.S.P.Q.2d (BNA) at 1063.

414. *Id.* at 1378, 90 U.S.P.Q.2d (BNA) at 1062 (quoting *Mars, Inc. v. Coin Acceptors, Inc.*, 527 F.3d 1359, 1374, 87 U.S.P.Q.2d (BNA) 1076, 1087 (Fed. Cir. 2008), *cert. denied*, 129 S. Ct. 653 (2008)).

415. *Id.* at 1379, 90 U.S.P.Q.2d (BNA) at 1063.

416. *Id.*, 90 U.S.P.Q.2d (BNA) at 1063 (citing *Loughman v. Consol. Penn. Coal Co.*, 6 F.3d 88, 97 (3d Cir. 1993)).

417. *Id.* at 1379–81, 90 U.S.P.Q.2d (BNA) at 1063–64.

In *In re Comiskey*,⁴¹⁸ the Federal Circuit affirmed the examiner's rejections based on grounds not even addressed by the USPTO.⁴¹⁹ In so doing, the court rejected Comiskey's argument that its review should be limited to the record before the USPTO under the APA.⁴²⁰ The Federal Circuit held that "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."⁴²¹ The Federal Circuit relied on the Supreme Court's decision in *SEC v. Chenery Corp.*,⁴²² stating that a lower court's decision "must be affirmed if the result is correct although the lower court relied upon a wrong ground or gave a wrong reason."⁴²³ The Federal Circuit emphasized the *Chenery* Court's reasoning that "[i]t would be wasteful to send a case back to a lower court to reinstate a decision which it had already made but which the appellate court concluded should properly be based on another ground within the power of the appellate court to formulate."⁴²⁴ Thus, although the USPTO Board of Patent Appeals and Interferences ("Board") had affirmed the examiner's rejections based on prior art under 35 U.S.C. § 103, the Federal Circuit did not consider that reasoning and instead affirmed the rejections of Comiskey's method claims on the ground that they did not recite patentable subject matter under 35 U.S.C. § 101.⁴²⁵ As to the machine claims, the court remanded the case to the USPTO to consider the § 101 question in the first instance.⁴²⁶

D. Frivolous Appeal

An appellate court may award damages or impose sanctions for a frivolous appeal.⁴²⁷ An appeal is "frivolous as filed" when an appellant grounds his appeal on arguments or issues 'that are beyond the reasonable contemplation of fair-minded people, and no basis for

418. 554 F.3d 967, 89 U.S.P.Q.2d (BNA) 1655 (Fed. Cir. 2009).

419. *Id.* at 973, 89 U.S.P.Q.2d (BNA) at 1659.

420. *Id.* at 973-74, 89 U.S.P.Q.2d (BNA) at 1659-60.

421. *Id.* at 974, 89 U.S.P.Q.2d (BNA) at 1659 (citing *SEC v. Chenery Corp.*, 318 U.S. 80, 88 (1943)).

422. 318 U.S. 80 (1943).

423. *Comiskey*, 554 F.3d at 974, 89 U.S.P.Q.2d (BNA) at 1659 (emphasis omitted) (quoting *Chenery*, 318 U.S. at 80).

424. *Id.*, 89 U.S.P.Q.2d (BNA) at 1659 (emphasis omitted) (quoting *Chenery*, 318 U.S. at 88).

425. *Id.* at 981, 89 U.S.P.Q.2d (BNA) at 1665.

426. *Id.*, 89 U.S.P.Q.2d (BNA) at 1665.

427. FED. R. APP. P. 38.

reversal in law or fact can be or is even arguably shown.”⁴²⁸ An appeal is “‘frivolous as argued’ when an appellant has not dealt fairly with the court, [or] has significantly misrepresented the law or facts.”⁴²⁹

In *E-Pass Technologies, Inc. v. 3Com Corp.*,⁴³⁰ the Federal Circuit granted PalmSource, Inc.’s motion for sanctions against E-Pass Technologies, Inc. for filing a frivolous appeal.⁴³¹ The court concluded that the appeal was frivolous at least because E-Pass failed to explain how the trial court erred or to present cogent or clear arguments for reversal.⁴³² The court also found that E-Pass made significant misrepresentations of the record and the law.⁴³³ The Federal Circuit imposed a sanction against E-Pass “equal to the amount of fees PalmSource incurred in defending th[e] appeal, including the filing of the motion for sanctions.”⁴³⁴ Although he did not take issue with most of the majority’s criticisms of E-Pass, Judge Bryson dissented because he identified one issue that was reasonable for E-Pass to pursue on appeal against PalmSource—whether the district court abused its discretion for awarding fees “for periods prior to the alleged misconduct.”⁴³⁵

IV. AGENCY PRACTICE

A. *United States Patent and Trademark Office*

At the USPTO, the biggest news of 2009 was the Federal Circuit’s decision to uphold three of the four Final Rules in the controversial August 2007 rules package and the USPTO’s subsequent withdrawal of the rules package. In one of the most anticipated decisions of the year, a panel of the Federal Circuit in March 2009 upheld three out of the four Final Rules in the USPTO’s new continuation rule

428. *Abbs v. Principi*, 237 F.3d 1342, 1345 (Fed. Cir. 2001) (quoting *State Indus., Inc. v. Mor-Flo Indus., Inc.*, 948 F.2d 1573, 1578, 20 U.S.P.Q.2d (BNA) 1738, 1742 (Fed. Cir. 1991)).

429. *Id.* (citation omitted).

430. 559 F.3d 1374, 90 U.S.P.Q.2d (BNA) 1168 (Fed. Cir. 2009).

431. *Id.* at 1376, 90 U.S.P.Q.2d (BNA) at 1169.

432. *Id.* at 1380, 90 U.S.P.Q.2d (BNA) at 1172 (“The tactics employed by E-Pass in this appeal, including both the misrepresentations made and the failure to cogently identify any reversible error of the district court, far outweigh any non-frivolous argument that may be lurking in its briefs.”).

433. *Id.* at 1377, 90 U.S.P.Q.2d (BNA) at 1170.

434. *Id.* at 1380, 90 U.S.P.Q.2d (BNA) at 1172.

435. *Id.* at 1381, 90 U.S.P.Q.2d (BNA) at 1173 (Bryson, J., dissenting).

package.⁴³⁶ The panel considered new Final Rules that set threshold limits of two continuing applications and one request for continuation.⁴³⁷ The rules also permit applicants to present five independent claims and twenty-five total claims and require applicants who wish to exceed those limits to file an examination support document.⁴³⁸

Shortly after the Final Rules were published in the *Federal Register*, Triantafyllos Tafas, Smithkline Beecham Corporation and Glaxo Group Ltd. (collectively “Tafas”) filed suit against the USPTO.⁴³⁹ Tafas moved for summary judgment, claiming that the Final Rules were invalid and seeking a permanent injunction.⁴⁴⁰ In April 2008, the Eastern District of Virginia granted summary judgment on the grounds that four of the Final Rules were invalid because they were “substantive rules that change[d] existing law and alter[ed] the rights of [the] [appellees] under the Patent Act,”⁴⁴¹ and therefore exceeded the USPTO’s rulemaking authority. The USPTO appealed.

On appeal, the Federal Circuit in March 2009 first addressed whether the USPTO’s rulemaking authority is subject to a procedural/substantive distinction. The court found that section 2(b)(2) of the Patent Act does not vest the USPTO with any general substantive rulemaking power.⁴⁴² The court then considered what level of deference it should give to the USPTO’s interpretation of statutes pertaining to procedural rules within the agency’s delegated authority and concluded that *Chevron* deference was appropriate.⁴⁴³ The Federal Circuit then turned to whether the final rules were substantive or procedural in nature and held that the four rules under consideration were procedural in nature rather than substantive.⁴⁴⁴

Having found that the final rules are procedural, the Federal Circuit then decided whether each of the rules is consistent with the Patent Act. The Federal Circuit agreed with the district court that the continuation application rule (Rule 78) was invalid because it added

436. *Tafas v. Doll*, 559 F.3d 1345, 90 U.S.P.Q.2d (BNA) 1129 (Fed. Cir. 2009), *reh’g en banc granted*, 328 F. App’x 658, 91 U.S.P.Q.2d (BNA) 1153 (Fed. Cir. 2009), *stay granted and appeal held in abeyance*, 331 F. App’x 748 (Fed. Cir. 2009).

437. *Id.* at 1350, 90 U.S.P.Q.2d (BNA) at 1132.

438. *Id.*, 90 U.S.P.Q.2d (BNA) at 1132.

439. *Id.*, 90 U.S.P.Q.2d (BNA) at 1132.

440. *Id.*, 90 U.S.P.Q.2d (BNA) at 1132.

441. *Id.* at 1350–51, 90 U.S.P.Q.2d (BNA) at 1132 (quoting *Tafas v. Dudas*, 541 F. Supp. 2d 805, 814 (E.D. Va. 2008)).

442. *Id.* at 1352, 90 U.S.P.Q.2d (BNA) at 1134.

443. *Id.* at 1353, 90 U.S.P.Q.2d (BNA) at 1134.

444. *Id.* at 1356, 90 U.S.P.Q.2d (BNA) at 1136.

an additional requirement that applicants could only claim the benefit of an earlier filing date if the application contained no amendments, arguments, or evidence that could have been submitted earlier.⁴⁴⁵ The court stated that such a requirement conflicted with the statutory language of 35 U.S.C. § 120, which provides that qualifying applicants “shall have” the benefit of the earlier priority date.⁴⁴⁶ Turning to the Request for Continued Examination (RCE) rule (Rule 114), the Federal Circuit overturned the district court’s ruling that it was invalid, holding that the Patent Act did not unambiguously require the USPTO to grant unlimited RCEs.⁴⁴⁷ Thus, the court held that the RCE rule did not conflict with the Patent Act.⁴⁴⁸ Lastly, the Federal Circuit held that the pre-examination search and examination support document rules (Rules 75 and 265) were valid and did not conflict with the Patent Act or existing precedent because they do not set an absolute limit on the number of claims and they do not alter the USPTO’s ultimate burden to prove claims unpatentable.⁴⁴⁹ The Federal Circuit reversed the district court determination that Rules 75 and 265 violated the Patent Act.

In summary, the Federal Circuit concluded that Rules 75, 78, 114, and 265 were all procedural rules within the scope of the USPTO’s rulemaking authority. The court found, however, that Rule 78 conflicts with 35 U.S.C. § 120 and is therefore invalid.⁴⁵⁰ The court ultimately remanded for proceedings consistent with the opinion.⁴⁵¹

On July 6, 2009, the Federal Circuit granted the USPTO’s petition for rehearing en banc and vacated the *Tafas* panel ruling.⁴⁵² In a motion filed on July 24, 2009, the private plaintiffs and the government jointly asked the Federal Circuit to stay its en banc review, including the briefing and oral argument schedules, until sixty days after the U.S. Senate confirmed David Kappos as the new director of the USPTO.⁴⁵³

In October 2009, approximately two months after the confirmation of Director Kappos, the USPTO announced that it was rescinding the disputed rules package—a move that was universally applauded by

445. *Id.* at 1360, 90 U.S.P.Q.2d (BNA) at 1139–40.

446. *Id.*, 90 U.S.P.Q.2d (BNA) at 1140 (citation omitted).

447. *Id.* at 1363, 90 U.S.P.Q.2d (BNA) at 1141–42.

448. *Id.*, 90 U.S.P.Q.2d (BNA) at 1143.

449. *Id.* at 1363–64, 90 U.S.P.Q.2d (BNA) at 1142–43.

450. *Id.* at 1364, 90 U.S.P.Q.2d (BNA) at 1143.

451. *Id.*, 90 U.S.P.Q.2d (BNA) at 1143.

452. *Tafas v. Doll*, 328 F. App’x 658, 91 U.S.P.Q.2d (BNA) 1153 (Fed. Cir. 2009), stay granted and appeal held in abeyance, 331 F. App’x 748 (Fed. Cir. 2009).

453. *Tafas v. Doll*, 331 F. App’x 748 (Fed. Cir. 2009).

the patent community.⁴⁵⁴ In the notice, the USPTO noted that the rule package included “provisions that were objectionable to a large segment of the patent user community,” and that “the [USPTO] is now considering other initiatives that would garner more of a consensus with the patent user community to address the challenges it currently faces.”⁴⁵⁵ Thus, the USPTO announced that it is no longer interested in pursuing the rules changes that were the subject of the *Tafas* litigation.

In the case *In re McNeil-PPC, Inc.*,⁴⁵⁶ the Federal Circuit examined the issue of whether the date that triggers the start of the two months to appeal is the date stamped on the decision or the mailing date.⁴⁵⁷ In that case, the timeliness of McNeil-PPC, Inc.’s appeal from a Board of Patent Appeals and Interferences (“Board”) decision was at issue.⁴⁵⁸ On August 1, 2008, McNeil filed a notice of appeal from a Board decision rejecting McNeil’s claims as obvious.⁴⁵⁹ The Board’s order included a typed date of decision of May 30, 2008, while the order’s mailing sheet was dated June 2, 2008.⁴⁶⁰ Under 35 U.S.C. § 142, a party enjoys sixty days to file a written notice of appeal, meaning that the timeliness of McNeil’s filing depended on whether May 30 or June 2 was considered “the date of the decision.”⁴⁶¹

The Federal Circuit ultimately found that the appeal was timely, holding that the date of decision was the mailing date.⁴⁶² The court noted that there was little guidance from the USPTO regulations or procedures as to what is meant by “date of decision.”⁴⁶³ The court commented that “there is little that indicates whether we should or must attribute any meaning” to that May 30 date.⁴⁶⁴ On appeal, the director did not provide any explanation of the Board’s internal procedure for issuing opinions or whether the mailing date reflects the decision’s public release. Nor did the director provide any explanation of why the “Transaction History” conflicted with the mailing sheet. With little guidance from the USPTO, the Federal Circuit looked to the declaration of a retired member of the Board,

454. 74 Fed. Reg. 52,686 (Oct. 14, 2009).

455. *Id.* at 52,687.

456. 574 F.3d 1393, 91 U.S.P.Q.2d (BNA) 1576 (Fed. Cir. 2009).

457. *Id.* at 1397–98, 91 U.S.P.Q.2d (BNA) at 1579.

458. *Id.* at 1397, 91 U.S.P.Q.2d (BNA) at 1578.

459. *Id.*, 91 U.S.P.Q.2d (BNA) at 1578.

460. *Id.* at 1396–97, 91 U.S.P.Q.2d (BNA) at 1578.

461. *Id.* at 1397, 91 U.S.P.Q.2d (BNA) at 1578–79.

462. *Id.* at 1398, 91 U.S.P.Q.2d (BNA) at 1579–80.

463. *Id.*, 91 U.S.P.Q.2d (BNA) at 1579.

464. *Id.*, 91 U.S.P.Q.2d (BNA) at 1579.

submitted by McNeil.⁴⁶⁵ The declaration explained that, “[h]istorically, the date the PTO mailed a document was the date that triggered any response period.”⁴⁶⁶ The declaration also explained that it was unclear why the opinion states May 30 but was not mailed until June 2 and suggested that perhaps the mailroom was slow or one of the Board members decided to revise or reconsider the opinion between May 30 and June 2.⁴⁶⁷ The Federal Circuit found that the declarant’s explanation was the “most plausible explanation for the conflicting evidence of when the Board took action,” and that the date of decision was therefore the June 2, 2008 mailing date.⁴⁶⁸ Thus, the court held that McNeil’s appeal was timely.⁴⁶⁹

In a dissenting opinion, Judge Dyk opined that the majority’s use of the mailing date was “contrary to the plain language of the regulation and precedent interpreting the nearly identical language of the predecessor rule.”⁴⁷⁰ Judge Dyk asserted that the date listed on an opinion’s front page conclusively shows when Board members author, sign, and decide the opinion.⁴⁷¹ Additionally, Judge Dyk argued that both Congress and the USPTO clearly rejected the mailing date when they chose the relevant date as the “date of decision.”⁴⁷² Judge Dyk noted that the USPTO, for example, specifically prescribes the “mailing date” as the time from which an appeal is due in the situation of petitions, but did not do so for Board decisions.⁴⁷³ Judge Dyk also cited previous decisions that had addressed the precise issue presented in *McNeil* and “uniformly rejected the majority’s approach.”⁴⁷⁴ Contrary to the majority’s holding, Judge Dyk believed the date of decision should be May 30, 2008.⁴⁷⁵

In *Touchcom, Inc. v. Bereskin & Parr*, the Federal Circuit reviewed whether the filing of a U.S. patent application subjects a foreign attorney to personal jurisdiction in federal district court in Virginia for malpractice claims. The Federal Circuit, in limiting its analysis to

465. *Id.*, 91 U.S.P.Q.2d (BNA) at 1579.

466. *Id.*, 91 U.S.P.Q.2d (BNA) at 1579.

467. *Id.*, 91 U.S.P.Q.2d (BNA) at 1579.

468. *Id.*, 91 U.S.P.Q.2d (BNA) at 1579.

469. *Id.*, 91 U.S.P.Q.2d (BNA) at 1580.

470. *Id.* at 1402, 91 U.S.P.Q.2d (BNA) at 1582 (Dyk, J., dissenting).

471. *Id.*, 91 U.S.P.Q.2d (BNA) at 1582.

472. *Id.*, 91 U.S.P.Q.2d (BNA) at 1582.

473. *Id.*, 91 U.S.P.Q.2d (BNA) at 1582.

474. *Id.* at 1402–03, 91 U.S.P.Q.2d (BNA) at 1582–83 (citing *Barbacid v. Brown*, 223 F. App’x 972, 973 (Fed. Cir. 2007); *In re Reese*, 359 F.2d 462, 463, 149 U.S.P.Q. (BNA) 362, 363 (C.C.P.A. 1966) (per curiam); *Burton v. Bentley*, 14 App. D.C. 471 (1899)).

475. *Id.* at 1403, 91 U.S.P.Q.2d (BNA) at 1583.

specific jurisdiction, found that merely filing a U.S. patent application and making related filings and communications with the USPTO in Virginia is insufficient to meet constitutional “minimum contacts” under Rule 4(k)(1)(A).⁴⁷⁶ The Federal Circuit also addressed personal jurisdiction under Rule 4(k)(2), finding that the patentee had made a prima facie case that the appellees were not subject to personal jurisdiction in any state’s courts of general jurisdiction.⁴⁷⁷ The Federal Circuit noted that this issue could be revisited on remand, and then turned to due process considerations, finding that the exercise of jurisdiction in this case met due process requirements.⁴⁷⁸

B. *International Trade Commission*

Under section 337 of the Tariff Act of 1930, the International Trade Commission (ITC) has the authority and obligation to investigate and prohibit importation based on unfair competition derived from patent, trademark, and copyright infringement.⁴⁷⁹ The ITC has increasingly gained popularity in recent years. Substantive decisions of the ITC are discussed elsewhere in this Area Summary; this Section focuses on changes in practice and procedure at the ITC.

In *Amgen, Inc. v. International Trade Commission*,⁴⁸⁰ the Federal Circuit granted a petition for rehearing to revise a portion of its 2008 decision.⁴⁸¹ The court’s 2009 decision modified the second part of the earlier decision but left the first part unchanged. In the first part, the court affirmed the ITC’s ruling that the safe harbor statute, 35 U.S.C. § 271(g), applies to process patents in actions under section 337 “when the imported product is used for the exempt purposes of 35 U.S.C. § 271(e)(1).”⁴⁸² In the revised second part, the court declined to answer whether the ITC had jurisdiction to address “imminent importations” in the absence of a contract for sale.⁴⁸³ The ITC argued that it has jurisdiction under 19 U.S.C. § 1337 “only when there is an importation, sale for importation, or sale within the United States after importation.”⁴⁸⁴ Amgen argued that

476. 574 F.3d 1403, 1412, 91 U.S.P.Q.2d (BNA) 1609, 1614 (Fed. Cir. 2009) (citing *Hanson v. Denckla*, 357 U.S. 235, 253 (1958)).

477. *Id.* at 1415, 91 U.S.P.Q.2d (BNA) at 1617.

478. *Id.* at 1416, 1418, 91 U.S.P.Q.2d (BNA) at 1617, 1619; *see supra* Part II.B.2.

479. 19 U.S.C. § 1337 (2006).

480. 565 F.3d 846, 90 U.S.P.Q.2d (BNA) 1843 (Fed. Cir. 2009).

481. *Id.* at 848 n.1, 90 U.S.P.Q.2d (BNA) at 1844.

482. *Id.* at 852, 90 U.S.P.Q.2d (BNA) at 1847.

483. *Id.* at 853, 90 U.S.P.Q.2d (BNA) at 1849.

484. *Id.*, 90 U.S.P.Q.2d (BNA) at 1849.

“an imminent importation will violate Section 337.”⁴⁸⁵ The court did not address the issue because it found jurisdiction based upon Amgen’s assertion of actual importation rather than upon the imminent importation theory.⁴⁸⁶

V. CLAIM CONSTRUCTION

The Federal Circuit has explained that “[i]t is a ‘bedrock principle’ of patent law that ‘the claims of a patent define the invention.’”⁴⁸⁷ The court will generally give the words of a patent claim their ordinary and customary meaning, as understood from the perspective of a person of ordinary skill in the art at the time of the invention.⁴⁸⁸ To understand those words, the court looks to “those sources available to the public that show what a person of skill in the art would have understood [the] claim . . . to mean.”⁴⁸⁹ Those public sources include the language of the claims, the specification, the prosecution history, and any relevant extrinsic evidence.⁴⁹⁰

Over the past year, the Federal Circuit has issued a number of decisions regarding claim construction, relying on each of these different public sources. In addition, the court issued several key decisions that clarified claim construction in special circumstances, including product-by-process claims⁴⁹¹ and copied claims in patent interferences.⁴⁹²

A. Claim Language

The claim itself can provide substantial guidance as to the meaning of the particular terms of the claim.⁴⁹³ In particular, the context in which a term is used in the asserted claim can be instructive.⁴⁹⁴ In *Ball Aerosol & Specialty Container, Inc. v. Ltd. Brands, Inc.*,⁴⁹⁵ the patent at

485. *Id.*, 90 U.S.P.Q.2d (BNA) at 1849.

486. *Id.* at 853–54, 90 U.S.P.Q.2d (BNA) at 1849.

487. *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)).

488. *Id.* at 1313–14, 75 U.S.P.Q.2d (BNA) at 1326–27.

489. *Id.* at 1314, 75 U.S.P.Q.2d (BNA) at 1327 (quoting *Innova/Pure Water, Inc.*, 381 F.3d at 1116, 72 U.S.P.Q.2d (BNA) at 1005).

490. *Id.*, 75 U.S.P.Q.2d (BNA) at 1327.

491. *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1291–95, 90 U.S.P.Q.2d (BNA) 1769, 1776–79 (Fed. Cir. 2009) (en banc), *cert. denied sub nom. Astellas Pharma, Inc. v. Lupin Ltd.*, 130 S. Ct. 1052 (2010).

492. *Agilent Techs., Inc. v. Affymetrix, Inc.*, 567 F.3d 1366, 1374–75, 91 U.S.P.Q.2d (BNA) 1161, 1166–67 (Fed. Cir. 2009).

493. *Phillips*, 415 F.3d at 1314, 75 U.S.P.Q.2d (BNA) at 1327.

494. *Id.* at 1315, 75 U.S.P.Q.2d (BNA) at 1327–28.

495. 555 F.3d 984, 89 U.S.P.Q.2d (BNA) 1870 (Fed. Cir. 2009).

issue involved “a candle tin with a removable cover that also acts as a base for the candle holder.”⁴⁹⁶ The patent also claimed protrusions, or feet, on the bottom of the candle holder that rest on top of the cover when used as a base.⁴⁹⁷ The Federal Circuit affirmed the district court’s construction of “to seat” to mean “either rest on or fit into the cover.”⁴⁹⁸ That is, the Federal Circuit held that the term did not require an engagement between the candle holder and the cover, as the defendants argued.⁴⁹⁹

In construing the claim term, the Federal Circuit first looked at the claim language. The claims recited “protrusions formed on the closed end of the holder and extending therefrom, the protrusions resting upon the closed end of the cover to seat the holder on the cover.”⁵⁰⁰ Thus, the court reasoned that, contrary to the defendants’ argument, the language of the claims made it clear that the feet were what would engage the cover, not the candle holder.⁵⁰¹

The language of other claims of the patent can also provide guidance as to the meaning of a claim term.⁵⁰² For example, the doctrine of claim differentiation teaches that “a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.”⁵⁰³ Accordingly, the court in *Ball Aerosol* noted that dependent “claim 2 specifically require[d] some engagement between the feet and a recess in the cover.”⁵⁰⁴ Thus, the court held that the term “to seat” as used in independent claim 1 did not require an engagement between the feet and the cover.⁵⁰⁵

Similarly, the Federal Circuit in *Blackboard, Inc. v. Desire2Learn, Inc.*⁵⁰⁶ applied the doctrine of claim differentiation to determine whether the asserted claims required a “single login” feature, which allowed a person to access multiple courses and multiple roles in an Internet-based educational support system.⁵⁰⁷ The court held that “[p]erhaps the strongest evidence” that the asserted claim did not require the “single login” feature was the fact that the dependent

496. *Id.* at 986, 89 U.S.P.Q.2d (BNA) at 1872.

497. *Id.*, 89 U.S.P.Q.2d (BNA) at 1872.

498. *Id.* at 988, 89 U.S.P.Q.2d (BNA) at 1873.

499. *Id.* at 989, 89 U.S.P.Q.2d (BNA) at 1874.

500. *Id.*, 89 U.S.P.Q.2d (BNA) at 1873.

501. *Id.* at 989–90, 89 U.S.P.Q.2d (BNA) at 1874.

502. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314, 75 U.S.P.Q.2d (BNA) 1321, 1327 (Fed. Cir. 2005) (en banc).

503. *Id.* at 1314–15, 75 U.S.P.Q.2d (BNA) at 1327.

504. 555 F.3d at 990, 89 U.S.P.Q.2d (BNA) at 1874.

505. *Id.*, 89 U.S.P.Q.2d (BNA) at 1874.

506. 574 F.3d 1371, 91 U.S.P.Q.2d (BNA) 1481 (Fed. Cir. 2009).

507. *Id.* at 1376, 91 U.S.P.Q.2d (BNA) at 1485.

claims (from a different independent claim with identical language as the asserted claim) included the limitation.⁵⁰⁸ Thus, the court held that the asserted claim did not require the feature, because if the court required otherwise, the dependent claims would be redundant.⁵⁰⁹

Claim differentiation, however, is not a “rigid rule.”⁵¹⁰ In *ICU Medical, Inc. v. Alaris Medical Systems, Inc.*,⁵¹¹ the parties disputed whether the claimed spike element had to be pointed and whether it had to be shaped so that it could pierce a fluid seal.⁵¹² The patentee relied on claim differentiation to support a broad construction that did not require that the spike be pointed so that it could pierce a seal.⁵¹³ Dependent claim 13 stated, in part, “wherein said end of said spike is pointed so that it can pierce said seal.”⁵¹⁴ The patentee argued that construing “spike” to require a pointed tip for piercing a seal would render “claim 13 superfluous.”⁵¹⁵ But as the Federal Circuit explained, the district court rejected this argument, noting that the dependent claim was added late in prosecution after the introduction of the allegedly infringing products.⁵¹⁶ The Federal Circuit affirmed the district court’s decision.

Similarly, in *Edwards Lifesciences LLC v. Cook Inc.*,⁵¹⁷ the Federal Circuit held that the claims directed to intraluminal grafts for treating blood vessel diseases required that the devices include wires.⁵¹⁸ Even though the patent included dependent claims that recited “a wire structure,” the Federal Circuit refused to apply the doctrine of claim differentiation because the specification made it clear that the claimed devices required wires.⁵¹⁹ The court stated that “claim differentiation is a rule of thumb that does not trump the clear import of the specification.”⁵²⁰

508. *Id.*, 91 U.S.P.Q.2d (BNA) at 1485.

509. *Id.*, 91 U.S.P.Q.2d (BNA) at 1485.

510. *Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1538, 19 U.S.P.Q.2d (BNA) 1367, 1371 (Fed. Cir. 1991).

511. 558 F.3d 1368, 90 U.S.P.Q.2d (BNA) 1072 (Fed. Cir. 2009).

512. *Id.* at 1373, 90 U.S.P.Q.2d (BNA) at 1074.

513. *Id.* at 1374, 90 U.S.P.Q.2d (BNA) at 1076.

514. *Id.* at 1376, 90 U.S.P.Q.2d (BNA) at 1076.

515. *Id.*, 90 U.S.P.Q.2d (BNA) at 1076.

516. *Id.*, 90 U.S.P.Q.2d (BNA) at 1076.

517. 582 F.3d 1322, 92 U.S.P.Q.2d (BNA) 1599 (Fed. Cir. 2009).

518. *Id.* at 1331–32, 92 U.S.P.Q.2d (BNA) at 1605–06.

519. *Id.* at 1332, 92 U.S.P.Q.2d (BNA) at 1606.

520. *Id.*, 92 U.S.P.Q.2d (BNA) at 1606.

B. Specification

The claims of a patent do not stand alone—they are part of a “fully integrated written instrument,” mainly the specification.⁵²¹ The Federal Circuit has made it clear that the specification “is always highly relevant to the claim construction analysis” and “is the single best guide to the meaning of a disputed term.”⁵²² The court has recognized the difficulty involved in using the specification to interpret the claims while refraining from importing limitations from the specification into the claims.⁵²³ But the court maintains that “the line between construing terms and importing limitations can be discerned with reasonable certainty and predictability if the court’s focus remains on understanding how a person of ordinary skill in the art would understand the claim terms.”⁵²⁴ Accordingly, the Federal Circuit has often found that the specification could not limit a broad construction. But, where appropriate, the Federal Circuit did not hesitate to find the specification limiting to justify a narrow claim construction.⁵²⁵

1. Cases where specification was found not limiting

Where the specification describes multiple embodiments, the Federal Circuit often interprets the claim terms broadly. In *Ball Aerosol*, for example, the figures of the specification illustrated feet both resting on the candle holder cover and locking into recesses in the cover.⁵²⁶ As such, the court concluded that the correct construction of the term “to seat” did not require an engagement between the feet and the cover.⁵²⁷

But even where the examples and embodiments of the specification were in line with the narrower construction, the Federal Circuit has not necessarily limited the scope of the claims. In *Linear Technology Corp. v. International Trade Commission*,⁵²⁸ the patent at issue related to switching-type voltage regulators. The ITC construed the claim terms “first state of circuit operation” and “second state of

521. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315, 75 U.S.P.Q.2d (BNA) 1321, 1327 (Fed. Cir. 2005) (en banc) (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978, 34 U.S.P.Q.2d (BNA) 1321, 1328 (Fed. Cir. 1995) (en banc)).

522. *Id.*, 75 U.S.P.Q.2d (BNA) at 1327 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582, 39 U.S.P.Q.2d (BNA) 1573, 1577 (Fed. Cir. 1996)) (internal quotation marks omitted).

523. *Id.* at 1323, 75 U.S.P.Q.2d (BNA) at 1334.

524. *Id.*, 75 U.S.P.Q.2d (BNA) at 1334.

525. *Id.* at 1324, 75 U.S.P.Q.2d (BNA) at 1334–35.

526. 555 F.3d 984, 990, 89 U.S.P.Q.2d (BNA) 1870, 1874 (Fed. Cir. 2009).

527. *Id.*, 89 U.S.P.Q.2d (BNA) at 1874.

528. 566 F.3d 1049, 91 U.S.P.Q.2d (BNA) 1065 (Fed. Cir. 2009).

circuit operation” to mean “that the first state of operation *can be* linked to high load currents, and the second state *can be* linked to low load currents, although the states of operation *do not necessarily* have to be linked to a high or low load current.”⁵²⁹ The alleged infringer argued that the first state of circuit operation occurred at high load currents, whereas the second state occurred only at low load currents.⁵³⁰ The Federal Circuit rejected this narrow construction. Although the patent at issue provided examples and embodiments where the “first state of circuit operation” may occur at high load currents and the “second state of circuit operation” may occur at low load currents, the court found that there was no “‘clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction,’ which is necessary to further narrow the claim language.”⁵³¹ The Federal Circuit noted that it has repeatedly held that even where only one embodiment is described, the “claims generally should not be narrowed to cover only the disclosed embodiments.”⁵³²

Likewise, in *Martek Biosciences Corp. v. Nutrinova, Inc.*,⁵³³ the Federal Circuit held that the district court erred in limiting the term “animal” to exclude humans.⁵³⁴ The court held that because the patentee explicitly defined “animal” in the specification to include humans, that definition controlled.⁵³⁵ Moreover, the court refused to limit the construction of the term based on the specification’s disclosure of only nonhuman animals in its preferred embodiments. The court noted that the embodiments were simply preferred embodiments and did not amount to a disavowal of claim scope.⁵³⁶ The court held that “the patentee has used no words or expressions that manifestly exclude coverage of humans, and thus, it would be improper to override the patentee’s express definition of ‘animal’ to limit the scope of the claims.”⁵³⁷

The Federal Circuit also looks at the description of the invention in the specification to determine whether there is a clear intent to limit

529. *Id.* at 1057, 91 U.S.P.Q.2d (BNA) at 1073 (internal quotation marks omitted).

530. *Id.*, 91 U.S.P.Q.2d (BNA) at 1073.

531. *Id.* at 1057–58, 91 U.S.P.Q.2d (BNA) at 1073 (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906, 69 U.S.P.Q.2d (BNA) 1801, 1807 (Fed. Cir. 2004)) (internal quotation marks omitted).

532. *Id.* at 1058, 91 U.S.P.Q.2d (BNA) at 1071.

533. 579 F.3d 1363, 92 U.S.P.Q.2d (BNA) 1148 (Fed. Cir. 2009).

534. *Id.* at 1379–80, 92 U.S.P.Q.2d (BNA) at 1159.

535. *Id.* at 1380, 92 U.S.P.Q.2d (BNA) at 1159 (“When a patentee explicitly defines a claim term in the patent specification, the patentee’s definition controls.”).

536. *Id.* at 1380–81, 92 U.S.P.Q.2d (BNA) at 1160.

537. *Id.* at 1381, 92 U.S.P.Q.2d (BNA) at 1160.

the claim scope. In *i4i Ltd. v. Microsoft Corp.*,⁵³⁸ the Federal Circuit rejected Microsoft's arguments when the corporation sought to limit the meaning of the term "distinct."⁵³⁹ The court held that the term did not require storage of the data in separate "files," as the specification consistently used broader, generic language that did not suggest a particular format.⁵⁴⁰ Moreover, the court held that the term did not require independent manipulation of the data.⁵⁴¹ Although the specification referred to working "solely" on one type of data, the court found that the specification's permissive language, "could be," "can be," and "ability to," did not clearly disclaim systems lacking these benefits.⁵⁴²

2. Cases where specification was found limiting

Despite the general rule that the claims should not be limited to the disclosed embodiments, the Federal Circuit has found the specification limiting in several cases.

In *ICU Medical*, the patented technology involved medical valves used in transmitting fluids to or from a patient, such as when using an IV.⁵⁴³ The medical valve receives fluid from a medical device, such as a syringe, without the use of an external needle.⁵⁴⁴ The asserted claims could be categorized into three groups: spike claims, spikeless claims, and tube claims.⁵⁴⁵ The parties disputed whether the spike must be shaped such that it could pierce the seal for fluid to be transmitted through the valve.⁵⁴⁶ The district court rejected the patentee's broad proposed construction of "an upward projection" and construed "spike" to mean "an elongated structure having a pointed tip for piercing the seal, which tip may be sharp or slightly rounded."⁵⁴⁷ The Federal Circuit affirmed, noting, as the district court did, that the specification "repeatedly and uniformly describe[d] the spike as a pointed instrument for the purpose of piercing a seal inside the valve."⁵⁴⁸

538. 589 F.3d 1246, 93 U.S.P.Q.2d (BNA) 1161 (Fed. Cir. 2009), *superseded on reh'g* by No. 2009-1504, 2010 WL 801705, 93 U.S.P.Q.2d (BNA) 1943 (Fed. Cir. 2010).

539. *Id.* at 1257, 93 U.S.P.Q.2d (BNA) at 1168.

540. *Id.* at 1258, 93 U.S.P.Q.2d (BNA) at 1168.

541. *Id.* at 1258, 93 U.S.P.Q.2d (BNA) at 1168.

542. *Id.* at 1260, 93 U.S.P.Q.2d (BNA) at 1169.

543. *ICU Med., Inc. v. Alaris Med. Sys., Inc.*, 558 F.3d 1368, 1372, 90 U.S.P.Q.2d (BNA) 1072, 1074 (Fed. Cir. 2009).

544. *Id.*, 90 U.S.P.Q.2d (BNA) at 1074.

545. *Id.* at 1372-73, 90 U.S.P.Q.2d (BNA) at 1074.

546. *Id.* at 1373, 90 U.S.P.Q.2d (BNA) at 1074.

547. *Id.* at 1374, 90 U.S.P.Q.2d (BNA) at 1075 (internal quotation marks omitted).

548. *Id.* at 1374-75, 90 U.S.P.Q.2d (BNA) at 1075 (internal quotation marks omitted).

Recognizing that the court should not import limitations from the specification into the claims, the Federal Circuit, citing *Phillips v. AWH Corp.*,⁵⁴⁹ noted that the court should focus on how a person of skill in the art would understand the claims “after reading the entire patent.”⁵⁵⁰ Because the patent specification never suggested that the spike could be anything other than pointed, as seen by each of the figures, the Federal Circuit held that the district court properly construed the term “spike” narrowly.⁵⁵¹

Similarly, in *Kinetic Concepts, Inc. v. Blue Sky Medical Group, Inc.*,⁵⁵² the Federal Circuit rejected the defendants’ proposed construction of “wound” as overly broad. The patents at issue related to treating a wound with negative pressure.⁵⁵³ The specification described numerous examples of types of wounds that could be treated, including open wounds, infected wounds, burn wounds, skin-graft and skin-flap wounds, decubitus ulcer wounds, and incisional wounds.⁵⁵⁴ While the defendants argued that the specification’s broad language supported a broad definition of “wound” consistent with the definition found in a medical dictionary, the majority agreed with the plaintiffs that all of the examples described in the specification involved skin wounds.⁵⁵⁵ The majority held that to construe the term “wound” to include anything other than skin wounds would “expand the scope of the claims far beyond anything described in the specification.”⁵⁵⁶

Likewise, in *Felix v. American Honda Motor Co.*,⁵⁵⁷ the Federal Circuit limited the construction of “mounted” to mean “securely affixed or fastened to,” based, in part, on the fact that the specification repeatedly used “mounted” to describe structures that must be securely affixed or fastened together.⁵⁵⁸ Although the plaintiff argued that the specification did not provide a specific method of mounting one item on or to another, the court noted that each of the examples described in the specification required securely affixing or fastening the structures together or else they would fall apart due to gravity.⁵⁵⁹

549. 415 F.3d 1303, 75 U.S.P.Q.2d (BNA) 1321 (Fed. Cir. 2005) (en banc).

550. *ICU Med.*, 558 F.3d at 1375, 90 U.S.P.Q.2d (BNA) at 1076 (quoting *Phillips*, 415 F.3d at 1321, 75 U.S.P.Q.2d (BNA) at 1332) (internal quotation marks omitted).

551. *Id.*, 90 U.S.P.Q.2d (BNA) at 1076.

552. 554 F.3d 1010, 89 U.S.P.Q.2d (BNA) 1801 (Fed. Cir. 2009), *cert. denied sub nom.* Medela AG v. Kinetic Concepts, Inc., 130 S. Ct. 624 (2009).

553. *Id.* at 1014, 89 U.S.P.Q.2d (BNA) at 1803.

554. *Id.* at 1018, 89 U.S.P.Q.2d (BNA) at 1806.

555. *Id.* at 1018–19, 89 U.S.P.Q.2d (BNA) at 1806.

556. *Id.* at 1019, 89 U.S.P.Q.2d (BNA) at 1806.

557. 562 F.3d 1167, 90 U.S.P.Q.2d (BNA) 1524 (Fed. Cir. 2009).

558. *Id.* at 1178–79, 90 U.S.P.Q.2d (BNA) at 1531.

559. *Id.* at 1178, 90 U.S.P.Q.2d (BNA) at 1530.

Accordingly, the Federal Circuit affirmed the district court's narrower construction.

In *Abbott Laboratories v. Sandoz, Inc.*,⁵⁶⁰ the district court construed the term "crystalline" to mean "Crystal A as outlined in the specification."⁵⁶¹ The patent at issue related to crystalline cefdinir (using its chemical name) and claimed priority to a Japanese patent application that described and claimed two crystalline forms of cefdinir, Crystal A and Crystal B.⁵⁶² But the specification of the patent at issue differed from the Japanese patent application in that it omitted the disclosure regarding Crystal B and drafted broader claims during prosecution.⁵⁶³

Claim 1 of the patent recited crystalline cefdinir as defined by seven powder x-ray diffraction (PXRD) angle peak limitations.⁵⁶⁴ PXRD is a method for identifying and distinguishing different crystalline compounds. The method beams X-rays at a powdered chemical and measures the diffraction angles of the X-rays as they reflect upon contact with the chemical.⁵⁶⁵ In contrast, claims 2–5 recited crystalline cefdinir without PXRD peak limitation, but with descriptions of processes used to obtain crystalline cefdinir.⁵⁶⁶ The court noted that "[t]he parties agreed that 'crystalline' ordinarily means exhibiting 'uniformly arranged molecule[s] or atoms.'"⁵⁶⁷ Relying on the intrinsic evidence, however, the district court construed the term using the more specific meaning disclosed in the specification.⁵⁶⁸

Specifically, the specification referred repeatedly to "Crystal A of the compound (I)," defined as "any crystal of the compound (I) which shows substantially the same diffraction pattern [as in the table in col.1/claim 1]."⁵⁶⁹ Although the Federal Circuit recognized that construing "crystalline" in claim 1 to mean "Crystal A" where "Crystal A" incorporated the seven PXRD peak limitations "arguably render[ed] the remainder of that claim redundant," the specification did not suggest that the disclosed processes could produce

560. 566 F.3d 1282, 90 U.S.P.Q.2d (BNA) 1769 (Fed. Cir. 2009) (en banc), cert. denied sub nom. *Astellas Pharma, Inc. v. Lupin Ltd.*, 130 S. Ct. 1052 (2010).

561. *Id.* at 1286, 90 U.S.P.Q.2d (BNA) at 1773 (internal quotation marks omitted).

562. *Id.* at 1287, 90 U.S.P.Q.2d (BNA) at 1772.

563. *Id.*, 90 U.S.P.Q.2d (BNA) at 1773.

564. *Id.* at 1286, 90 U.S.P.Q.2d (BNA) at 1772.

565. *Id.* at 1286–87, 90 U.S.P.Q.2d (BNA) at 1772.

566. *Id.* at 1286, 90 U.S.P.Q.2d (BNA) at 1772.

567. *Id.* at 1289, 90 U.S.P.Q.2d (BNA) at 1774.

568. *Id.*, 90 U.S.P.Q.2d (BNA) at 1774 (internal quotation marks omitted).

569. *Id.*, 90 U.S.P.Q.2d (BNA) 1774.

non-Crystal A compounds.⁵⁷⁰ This was particularly significant where the Crystal B formulation—as seen in the Japanese priority application—was known in the art.⁵⁷¹ The Federal Circuit therefore concluded that the patentee chose to claim only the Crystal A form in the patent-in-suit and that the district court correctly construed the term “crystalline.”⁵⁷²

As for claims 2–5, which did not recite PXRD peak limitations, the court held that “crystalline,” as used in these claims, was properly construed to be limited to “Crystal A.” The process steps recited in claims 2–5 corresponded to the processes for making Crystal A described in the specification.⁵⁷³ The Federal Circuit acknowledged that the mere fact that the specification disclosed only Crystal A did not justify limiting the meaning of “crystalline” to “Crystal A.”⁵⁷⁴ But the court found that the rest of the intrinsic evidence, mainly the prosecution history, supported this construction.⁵⁷⁵

In *Gemtron Corp. v. Saint-Gobain Corp.*,⁵⁷⁶ the patent was directed to a refrigerator shelf made of a one-piece open frame and a glass panel.⁵⁷⁷ The claimed shelf secured the glass panel in the frame using “relatively resilient” fingers so that the glass panel could be “snap secured” into place.⁵⁷⁸ Accordingly, the claims recited that the frame must include a “relatively resilient end edge portion which temporarily deflects and subsequently rebounds to snap-secure one of [the] glass piece front and rear edges.”⁵⁷⁹

The issue for claim construction was when the frame must be flexible to satisfy the “relatively resilient” limitation.⁵⁸⁰ The Federal Circuit found that the claim language and the specification consistently focused on the characteristics of the frame during assembly.⁵⁸¹ The specification lacked any discussion of the value of the “relatively resilient” frame for anything other than assembly.⁵⁸² Thus, the Federal Circuit affirmed the district court’s construction of

570. *Id.*, 90 U.S.P.Q.2d (BNA) at 1774.

571. *Id.*, 90 U.S.P.Q.2d (BNA) at 1775.

572. *Id.*, 90 U.S.P.Q.2d (BNA) at 1775.

573. *Id.* at 1290, 90 U.S.P.Q.2d (BNA) at 1775.

574. *Id.*, 90 U.S.P.Q.2d (BNA) at 1775.

575. *Id.*, 90 U.S.P.Q.2d (BNA) at 1775.

576. 572 F.3d 1371, 91 U.S.P.Q.2d (BNA) 1409 (Fed. Cir. 2009), *cert. denied*, 78 U.S.L.W. 3396 (U.S. Mar. 8, 2010) (No. 09-778).

577. *Id.* at 1378, 91 U.S.P.Q.2d (BNA) at 1413–14.

578. *Id.*, 91 U.S.P.Q.2d (BNA) at 1413–14 (internal quotation marks omitted).

579. *Id.* at 1377, 91 U.S.P.Q.2d (BNA) at 1413 (emphasis and internal quotation marks omitted).

580. *Id.*, 91 U.S.P.Q.2d (BNA) at 1413.

581. *Id.* at 1377–78, 91 U.S.P.Q.2d (BNA) at 1414.

582. *Id.* at 1378–79, 91 U.S.P.Q.2d (BNA) at 1414.

the limitation to mean “the end edge portion must be sufficiently resilient [such] that it can temporarily deflect and subsequently rebound when glass is being inserted into the frame.”⁵⁸³

In *Edwards Lifesciences*, the Federal Circuit construed the term “graft” to mean intraluminal in patents related to intraluminal grafts for treating blood vessel disease.⁵⁸⁴ The court noted that the specification used the terms “graft” and “intraluminal graft” interchangeably, and that the only devices described in the specification were intraluminal grafts.⁵⁸⁵ Moreover, the specification frequently described an “intraluminal graft” as “the present invention” or “this invention,” indicating an intent to limit the invention to intraluminal devices.⁵⁸⁶ Accordingly, the Federal Circuit affirmed the district court’s construction limiting “graft” to mean an “intraluminal graft.”⁵⁸⁷

C. Prosecution History

In addition to consulting the specification, courts consider the prosecution history, which is also intrinsic evidence. Because it represents the patentee’s attempts to explain and obtain the patent, the “prosecution history provides evidence of how the [US]PTO and the inventor understood the patent.”⁵⁸⁸ But the Federal Circuit also recognizes that the “prosecution history represents an ongoing negotiation between the [US]PTO and the applicant, rather than the final product of that negotiation.”⁵⁸⁹ Accordingly, for claim construction purposes, the prosecution history is not as useful as the specification.⁵⁹⁰ Nevertheless, the prosecution history may reveal whether the inventor limited the invention to obtain the patent, making the claim scope narrower than it would otherwise be.⁵⁹¹ The Federal Circuit has repeatedly held, however, that a prosecution history disclaimer requires “a clear and unmistakable surrender of subject matter.”⁵⁹² But the court has cautioned that even when an

583. *Id.* at 1379, 91 U.S.P.Q.2d (BNA) at 1414.

584. *Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1329, 92 U.S.P.Q.2d (BNA) 1599, 1604 (Fed. Cir. 2009).

585. *Id.*, 92 U.S.P.Q.2d (BNA) at 1604.

586. *Id.* at 1330, 92 U.S.P.Q.2d (BNA) at 1605.

587. *Id.* at 1331, 92 U.S.P.Q.2d (BNA) at 1605.

588. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317, 75 U.S.P.Q.2d (BNA) 1321, 1329 (Fed. Cir. 2005) (en banc).

589. *Id.*, 75 U.S.P.Q.2d (BNA) at 1329.

590. *Id.*, 75 U.S.P.Q.2d (BNA) at 1329.

591. *Id.*, 75 U.S.P.Q.2d (BNA) at 1329.

592. *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1251, 54 U.S.P.Q.2d 1711, 1717 (Fed. Cir. 2000) (internal quotation marks omitted).

isolated statement appears to surrender subject matter, the prosecution history as a whole may show that the patentee did not.⁵⁹³

In *Abbott Laboratories*, the Federal Circuit affirmed the district court's narrow construction of "crystalline" to mean "Crystal A."⁵⁹⁴ To support this narrow construction, the court looked to the prosecution history, including the Japanese patent application to which the patent at issue claimed priority.⁵⁹⁵ The court noted that the district court did not rely on statements made during prosecution of the Japanese patent application to support the construction because such statements have "a narrow application to U.S. claim construction."⁵⁹⁶ Instead, the district court relied on the contents of the foreign priority application.⁵⁹⁷ Because the Japanese application established that the patentee knew and could describe both Crystal A and Crystal B, the patentee could have included disclosure of Crystal B to support a broader construction.⁵⁹⁸ Instead, the Federal Circuit found it highly significant that the patentee chose to disclose and claim only Crystal A.⁵⁹⁹

Moreover, the court found that the prosecution history of the patent-in-suit showed a "clear and intentional disavowal of claim scope beyond Crystal A."⁶⁰⁰ One inventor submitted a declaration stating that he prepared a sample of Crystal A and that Crystal A was more stable than the prior art samples.⁶⁰¹ Furthermore, in its response to an office action, the applicant specifically limited the invention to Crystal A by arguing that "the *method of preparation* of the crystalline form of the presently claimed compounds is not considered the heart of the present invention," and that "[t]he crystalline form of the compound represents the inventive concept hereof, and it is clear that [the prior art] does not anticipate or suggest said crystalline form."⁶⁰² Thus, the Federal Circuit concluded that the exclusive focus on Crystal A in the specification along with

593. *Elbex Video, Ltd. v. Sensormatic Elecs. Corp.*, 508 F.3d 1366, 1372–73, 85 U.S.P.Q.2d 1137, 1141–42 (Fed. Cir. 2007).

594. *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1289–91, 90 U.S.P.Q.2d (BNA) 1769, 1774–76 (Fed. Cir. 2009) (en banc), *cert. denied sub nom. Astellas Pharma, Inc. v. Lupin Ltd.*, 130 S. Ct. 1052 (2010).

595. *Id.* at 1290, 90 U.S.P.Q.2d (BNA) at 1775.

596. *Id.*, 90 U.S.P.Q.2d (BNA) at 1775.

597. *Id.*, 90 U.S.P.Q.2d (BNA) at 1775.

598. *Id.*, 90 U.S.P.Q.2d (BNA) at 1775.

599. *Id.* at 1297, 90 U.S.P.Q.2d (BNA) at 1781.

600. *Id.* at 1290, 90 U.S.P.Q.2d (BNA) at 1775.

601. *Id.*, 90 U.S.P.Q.2d (BNA) at 1775.

602. *Id.*, 90 U.S.P.Q.2d (BNA) at 1775 (internal citation omitted).

the prosecution history warrants a narrow construction of “crystalline.”⁶⁰³

Similarly, the Federal Circuit in *Paragon Solutions, LLC v. Timex Corp.*⁶⁰⁴ found that the applicant had clearly limited the scope of the claimed invention. The patent-in-suit disclosed an exercise monitoring system that included a “data acquisition unit,” which itself included both an “electronic positioning device” and a “physiological monitor.”⁶⁰⁵ The district court construed “data acquisition unit” to mean “one structure that includes the electronic positioning device and the physiological monitor.”⁶⁰⁶ On appeal, the parties disputed whether the data acquisition unit had to be a single structure or whether it could consist of multiple, physically separate structures.⁶⁰⁷ Both the claim language and the specification supported a construction that included multiple structures.⁶⁰⁸ While the district court found that the applicants had disavowed the concept of an assemblage of interrelated parts, the Federal Circuit disagreed with the district court’s interpretation of the prosecution history.⁶⁰⁹ After its own review of the prosecution history, the court found that the applicants, in response to a rejection over prior art that disclosed a single structure, had “clearly and unmistakably disavowed a single structure” that included an electronic positioning device, a physiological monitor, and a display unit.⁶¹⁰ Accordingly, the court concluded that the claimed “data acquisition unit” was not limited to a single structure, “but may comprise multiple physically separate structures.”⁶¹¹

In *Edwards Lifesciences*, the Federal Circuit applied a prosecution history disclaimer where the inventors canceled claims that required “malleable wires” and replaced them with claims requiring only “wires.”⁶¹² Although the claims were arguably broadened, the court found that the inventors “conducted the prosecution as if the wires were required to be malleable.”⁶¹³ Thus, the court held that the change in claim language did not “affect the breadth of the claims

603. *Id.* at 1291, 90 U.S.P.Q.2d (BNA) at 1775–76.

604. 566 F.3d 1075, 91 U.S.P.Q.2d (BNA) 1082 (Fed. Cir. 2009).

605. *Id.* at 1078, 91 U.S.P.Q.2d (BNA) at 1083.

606. *Id.* at 1083, 91 U.S.P.Q.2d (BNA) at 1087.

607. *Id.*, 91 U.S.P.Q.2d (BNA) at 1087.

608. *Id.* at 1084–85, 91 U.S.P.Q.2d (BNA) at 1087–88.

609. *Id.* at 1085, 91 U.S.P.Q.2d (BNA) at 1088.

610. *Id.* at 1085–86, 91 U.S.P.Q.2d (BNA) at 1089.

611. *Id.* at 1086, 91 U.S.P.Q.2d (BNA) at 1089.

612. *Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1332–33, 92 U.S.P.Q.2d (BNA) 1599, 1606–07 (Fed. Cir. 2009).

613. *Id.* at 1333, 92 U.S.P.Q.2d (BNA) at 1607.

because the inventors' statements indicated that the claims remained narrow."⁶¹⁴

In *Ecolab, Inc. v. FMC Corp.*,⁶¹⁵ the Federal Circuit held that there was no prosecution history disclaimer where the applicants' statements were not sufficiently clear and unmistakable to limit the claim scope. The patents-in-suit recited the use of an antimicrobial compound called peracetic acid (PAA) as a sanitizer in beef and poultry processing.⁶¹⁶ The parties disputed whether the patentee disclaimed the use of compositions containing multiple antimicrobial agents during prosecution of the patent-in-suit.⁶¹⁷ To overcome a prior art rejection, the applicants argued, among other things, that its invention used sanitizing solutions containing PAA as the only antimicrobial agent, whereas the prior art did not teach the use of PAA alone as a sanitizer.⁶¹⁸ In response, the examiner noted that the claims recited the use of a composition "which consists essentially of" PAA and were therefore not limited to compositions containing PAA as the sole antimicrobial agent.⁶¹⁹ Afterwards, the applicants never made the allegedly disclaiming argument again and instead offered different reasons to overcome the prior art rejection.⁶²⁰ The examiner ultimately allowed the claims with the "consists essentially of" language.⁶²¹ The Federal Circuit held that while a reasonable reader of the prosecution history could interpret the applicants' initial statements as "hyperbolic or erroneous," the prosecution history as a whole did not show that the statements were "clear and unmistakable enough" to disclaim that subject matter.⁶²²

In *Martek Biosciences Corp. v. Nutrinova, Inc.*, the Federal Circuit held that there was no prosecution history disclaimer.⁶²³ The defendants argued that the district court misconstrued the term "non-chloride sodium salt" to include sodium hydroxide, contending that the patentee disclaimed sodium hydroxide during prosecution.⁶²⁴ The court held that while the statements in the two pages of prosecution history cited by the defendants arguably supported its

614. *Id.*, 92 U.S.P.Q.2d (BNA) at 1607.

615. 569 F.3d 1335, 91 U.S.P.Q.2d (BNA) 1225 (Fed. Cir. 2009), *amended in part on reh'g*, Nos. 2008-1228 & 2008-1252, 2009 WL 5865679 (Fed. Cir. Sept. 30, 2009).

616. *Id.* at 1340, 91 U.S.P.Q.2d (BNA) at 1227.

617. *Id.* at 1342, 91 U.S.P.Q.2d (BNA) at 1228.

618. *Id.* at 1343, 91 U.S.P.Q.2d (BNA) at 1229.

619. *Id.*, 91 U.S.P.Q.2d (BNA) at 1229.

620. *Id.*, 91 U.S.P.Q.2d (BNA) at 1229.

621. *Id.*, 91 U.S.P.Q.2d (BNA) at 1229.

622. *Id.*, 91 U.S.P.Q.2d (BNA) at 1229.

623. 579 F.3d 1363, 1377, 92 U.S.P.Q.2d (BNA) 1148, 1158 (Fed. Cir. 2009).

624. *Id.* at 1376-77, 92 U.S.P.Q.2d (BNA) at 1157.

construction, the statements were undercut by other statements in the prosecution history that explicitly stated that sodium hydroxide is a non-chloride sodium salt, thus distinguishing the prior art on “alternative grounds unrelated to the way [sodium hydroxide] was used in the prior art.”⁶²⁵ Taking the prosecution history as a whole, the Federal Circuit held that the patentee “committed no clear and unmistakable disavowal of claim scope.”⁶²⁶

Similarly, in *i4i Ltd. v. Microsoft Corp.*, the Federal Circuit found that arguments in the prosecution history did not limit the scope of the term “distinct.”⁶²⁷ The court noted that, “[i]n evaluating whether a patentee has disavowed claim scope, context matters.”⁶²⁸ Accordingly, the court found that the statements that Microsoft “pluck[ed] from the prosecution history” did not clearly and unmistakably disavow claim scope.⁶²⁹

D. Extrinsic Evidence

The Federal Circuit has acknowledged that district courts may rely on extrinsic evidence in claim construction.⁶³⁰ Extrinsic evidence “consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.”⁶³¹ But the court has cautioned that while extrinsic evidence may be useful in shedding light on the relevant art, it is “less significant” than intrinsic evidence in determining the meaning of claim language.⁶³²

The Federal Circuit has noted that dictionaries, particularly technical dictionaries, are especially useful in helping the court better understand the underlying technology and the way “in which one of skill in the art might use the claim terms.”⁶³³ Accordingly, in *Boston Scientific Scimed, Inc. v. Cordis Corp.*,⁶³⁴ the Federal Circuit

625. *Id.* at 1377, 92 U.S.P.Q.2d (BNA) at 1158.

626. *Id.*, 92 U.S.P.Q.2d (BNA) at 1158.

627. 589 F.3d 1246, 1258, 93 U.S.P.Q.2d (BNA) 1161, 1168 (Fed. Cir. 2009), *superceded on reh'g* by No. 2009-1504, 2010 WL 801705, 93 U.S.P.Q.2d (BNA) 1943 (Fed. Cir. 2010).

628. *Id.*, 93 U.S.P.Q.2d (BNA) at 1168.

629. *Id.*, 93 U.S.P.Q.2d (BNA) at 1168.

630. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1317, 75 U.S.P.Q.2d (BNA) 1321, 1329 (Fed. Cir. 2005) (en banc) (authorizing district courts to rely on extrinsic evidence, despite the importance of intrinsic evidence in claim construction).

631. *Id.* at 1317, 75 U.S.P.Q.2d (BNA) at 1329 (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980, 34 U.S.P.Q.2d (BNA) 1321, 1330 (Fed. Cir. 1995) (en banc)).

632. *Id.* at 1317, 75 U.S.P.Q.2d (BNA) at 1329.

633. *Id.* at 1318, 75 U.S.P.Q.2d (BNA) at 1330.

634. 554 F.3d 982, 89 U.S.P.Q.2d (BNA) 1704 (Fed. Cir. 2009), *cert. dismissed*, 130 S. Ct. 50 (2009).

affirmed the district court's construction of "non-thrombogenic" as claimed in the patent-in-suit, which related to a drug-eluting expandable stent with a coating that has a non-thrombogenic surface.⁶³⁵ The Federal Circuit found that the specification and the prosecution history supported the district court's construction.⁶³⁶ The accused infringer argued, however, that the district court erred because it relied on dictionary definitions of "thrombogenic" and "thrombolytic" that did not appear in the claim.⁶³⁷ The Federal Circuit rejected the accused infringer's argument, holding that the district court permissibly looked to these definitions to inform the meaning of "non-thrombogenic," particularly where the dictionary definitions did not contradict the intrinsic evidence.⁶³⁸

In *Felix*, the Federal Circuit noted that "it is improper to read [a claim] term to encompass a broader definition simply because it may be found in a dictionary, treatise, or other extrinsic source."⁶³⁹ The court in that case rejected the plaintiff's argument that the definition of "mount" includes "to put or have in position," which supported its broad proposed construction of "positioned."⁶⁴⁰ First, the court noted that the plaintiff misquoted the definition by omitting language from the definition.⁶⁴¹ The actual definition in the cited dictionary was "to put or have (*as artillery*) in position."⁶⁴² But the court also noted that the more general definition of "to attach to a support" was consistent with the patent's use of the term "mounted."⁶⁴³ Thus, the Federal Circuit concluded that the district court's definition of "mounted" as "securely affixed or fastened to" was correct.⁶⁴⁴

In *Ultimax Cement Manufacturing Corp. v. CTS Cement Manufacturing Corp.*,⁶⁴⁵ the district court construed the term "soluble CaSO₄ anhydride" to mean "a compound formed from an acid by removal of water," but the court relied heavily on a single dictionary definition to reach its construction.⁶⁴⁶ On appeal, the Federal Circuit held that the

635. *Id.* at 983–84, 86, 89 U.S.P.Q.2d (BNA) at 1706, 1708.

636. *Id.* at 987, 89 U.S.P.Q.2d (BNA) at 1709.

637. *Id.*, 89 U.S.P.Q.2d (BNA) at 1709.

638. *Id.*, 89 U.S.P.Q.2d (BNA) at 1709.

639. *Felix v. American Honda Motor Co.*, 562 F.3d 1167, 1178, 90 U.S.P.Q.2d (BNA) 1524, 1530 (Fed. Cir. 2009) (alteration in original) (quoting *Nystrom v. TREX Co.*, 424 F.3d 1136, 1145, 76 U.S.P.Q.2d (BNA) 1481, 1488 (Fed. Cir. 2005)).

640. *Id.* at 1178, 90 U.S.P.Q.2d (BNA) at 1530.

641. *Id.*, 90 U.S.P.Q.2d (BNA) at 1530.

642. *Id.* at 1178–79, 90 U.S.P.Q.2d (BNA) at 1530.

643. *Id.* at 1179, 90 U.S.P.Q.2d (BNA) at 1531.

644. *Id.*, 90 U.S.P.Q.2d (BNA) at 1531.

645. 587 F.3d 1339, 92 U.S.P.Q.2d (BNA) 1865 (Fed. Cir. 2009).

646. *Id.* at 1346, 92 U.S.P.Q.2d (BNA) at 1869.

district court erred in relying on the dictionary definition without properly considering the intrinsic evidence.⁶⁴⁷ As the Federal Circuit noted, “courts may ‘rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents.’”⁶⁴⁸ Moreover, the court stated that “[a] claim should not rise or fall based upon the preferences of a particular dictionary editor, or the court’s independent decision, uninformed by the specification, to rely on one dictionary rather than another.”⁶⁴⁹ Accordingly, when read in context in light of the claim language and the specification, the court construed the disputed term to mean “soluble anhydrous calcium sulfate.”⁶⁵⁰

The Federal Circuit has also acknowledged the value of expert testimony for a variety of different purposes. For example, experts may provide background on the relevant technology, “explain how an invention works,” ensure that the court’s understanding is “consistent with that of a person of skill in the art, or establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field.”⁶⁵¹ In *Ecolab, Inc. v. FMC Corp.*, the parties disputed the meaning of the term “sanitize.”⁶⁵² The patent specification stated that the term “sanitize” “denote[s] a bacterial population reduction to a level that is safe for human handling and consumption.”⁶⁵³ The accused infringer argued that its product could not infringe because it alone did not make raw poultry safe for human consumption, as cooking was also required.⁶⁵⁴ The Federal Circuit found that the definition of “sanitize” was ambiguous in that it did not indicate when consumption took place—immediately after the PAA was applied or at a later time after the meat was cooked.⁶⁵⁵ The Federal Circuit noted that the testimony of the accused infringer’s expert who admitted that in-plant inspectors examine poultry that has been treated with PAA to determine if it is “fit for

647. *Id.* at 1347–48, 92 U.S.P.Q.2d (BNA) at 1869–70.

648. *Id.* at 1347, 92 U.S.P.Q.2d (BNA) at 1869 (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1322–23, 75 U.S.P.Q.2d (BNA) 1321, 1334 (Fed. Cir. 2005) (en banc)).

649. *Id.*, 92 U.S.P.Q.2d (BNA) at 1869–70 (quoting *Phillips*, 415 F.3d at 1322, 75 U.S.P.Q.2d (BNA) at 1333).

650. *Id.* at 1348, 92 U.S.P.Q.2d (BNA) at 1870.

651. *Phillips*, 415 F.3d at 1318, 75 U.S.P.Q.2d (BNA) at 1330.

652. *Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335, 1344, 91 U.S.P.Q.2d (BNA) 1225, 1230 (Fed. Cir. 2009), *amended in part on reh’g*, Nos. 2008-1228 & 2008-1252, 2009 WL 5865679 (Fed. Cir. Sept. 30, 2009).

653. *Id.*, 91 U.S.P.Q.2d (BNA) at 1230 (alteration in original).

654. *Id.*, 91 U.S.P.Q.2d (BNA) at 1230.

655. *Id.* at 1345, 91 U.S.P.Q.2d (BNA) at 1230.

human consumption.”⁶⁵⁶ The court found that the inspectors must not require that the poultry be fit for human consumption in its uncooked state.⁶⁵⁷ Thus, the Federal Circuit held that “sanitize” must mean that “the treated meat has become safe for human handling and postcooking consumption.”⁶⁵⁸

Similarly, in *Callaway Golf Co. v. Acushnet Co.*,⁶⁵⁹ the claim construction issue related to whether the term “cover layer having a Shore D hardness” in the asserted patents directed to multilayer golf balls required the Shore D hardness measurement to be made on the golf ball or on a sample of the cover layer off the ball.⁶⁶⁰ After reviewing the specification and finding that it supported requiring on-the-ball measurements, the Federal Circuit noted that the defendant’s own vice president of development testified that technical people in the golf-ball industry typically measured hardness on the ball.⁶⁶¹ The court stated that “[s]uch evidence of accepted practice within the art, when not at variance with the intrinsic evidence, is relevant to the question of how a person of skill in the pertinent field would understand a term.”⁶⁶² Accordingly, the Federal Circuit affirmed the district court’s interpretation of the phrase “cover layer having a Shore D hardness” as one that refers to an “on-the-ball hardness measurement.”⁶⁶³

Another source of extrinsic evidence is the accused products themselves. A court may not rely on the accused product for claim construction just so that it can include or exclude the accused product.⁶⁶⁴ But a court may rely on the accused product to provide meaningful context for claim construction.⁶⁶⁵ As such, in *Every Penny Counts, Inc. v. American Express Co.*,⁶⁶⁶ the Federal Circuit rejected the patentee’s argument that the district court erred by “tailoring its claim construction to fit the dimensions of the accused product.”⁶⁶⁷

656. *Id.*, 91 U.S.P.Q.2d (BNA) at 1230.

657. *Id.*, 91 U.S.P.Q.2d (BNA) at 1230.

658. *Id.*, 91 U.S.P.Q.2d (BNA) at 1230.

659. 576 F.3d 1331, 91 U.S.P.Q.2d (BNA) 1705 (Fed. Cir. 2009), *cert. denied*, 78 U.S.L.W. 3374 (U.S. Feb. 22, 2010) (No. 09-702).

660. *Id.* at 1337, 91 U.S.P.Q.2d (BNA) at 1710.

661. *Id.* at 1338, 91 U.S.P.Q.2d (BNA) at 1710.

662. *Id.*, 91 U.S.P.Q.2d (BNA) at 1711.

663. *Id.*, 91 U.S.P.Q.2d (BNA) at 1711.

664. *See Wilson Sporting Goods Co. v. Hillerich & Bradsby Co.*, 442 F.3d 1322, 1331, 78 U.S.P.Q.2d (BNA) 1382, 1389 (Fed. Cir. 2006) (noting that courts may not construe claims to exclude or include specific features of the accused product or process).

665. *Id.* at 1326–27, 78 U.S.P.Q.2d (BNA) at 1386.

666. 563 F.3d 1378, 90 U.S.P.Q.2d (BNA) 1851 (Fed. Cir. 2009), *cert. denied*, 130 S. Ct. 565 (2009).

667. *Id.* at 1383, 90 U.S.P.Q.2d (BNA) at 1854.

To elicit the parties' views on the meaning of the term "excess cash," the district court asked the parties what "excess cash" meant in a series of hypothetical transactions, including ones that involved the accused products.⁶⁶⁸ The Federal Circuit held that this was acceptable and that the patentee's argument that this was improper was "way wide of the mark."⁶⁶⁹ The Federal Circuit therefore affirmed the district court's construction.⁶⁷⁰

E. Special Claim Construction Issues

In 2009, the Federal Circuit addressed very specific claim construction issues in two cases. First, in *Abbott Laboratories*, the Federal Circuit addressed prior inconsistent precedent and, in an en banc portion of the opinion, clarified the proper claim construction analysis for product-by-process claims.⁶⁷¹ Second, in *Agilent Technologies, Inc. v. Affymetrix, Inc.*,⁶⁷² the Federal Circuit clarified the proper claim construction analysis to determine whether claims that have been copied from another patent to provoke an interference have sufficient written description support.⁶⁷³ These two cases and the special claim construction issues addressed therein are discussed in detail below.

1. Product-by-process claims

In *Abbott Laboratories*, the patent at issue related to crystalline cefdinir, an antibiotic.⁶⁷⁴ Claim 1 recited crystalline cefdinir (using its chemical name) and defined its unique characteristics with seven powder X-ray diffraction (PXRD) angle peaks.⁶⁷⁵ Claims 2–5 recited crystalline cefdinir but did not claim any PXRD peak limitations; instead, they claimed descriptions of processes used to obtain crystalline cefdinir.⁶⁷⁶ As an initial matter, the Federal Circuit held that the district court correctly categorized claims 2–5 as product-by-process claims.⁶⁷⁷ On appeal, in a portion of the opinion that the court heard en banc sua sponte, the Federal Circuit clarified the

668. *Id.*, 90 U.S.P.Q.2d (BNA) at 1855.

669. *Id.*, 90 U.S.P.Q.2d (BNA) at 1855.

670. *Id.* at 1384, 90 U.S.P.Q.2d (BNA) at 1855.

671. *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1291–95, 90 U.S.P.Q.2d (BNA) 1769, 1776–79 (Fed. Cir. 2009) (en banc), *cert. denied sub nom. Astellas Pharma, Inc. v. Lupin Ltd.*, 130 S. Ct. 1052 (2010).

672. 567 F.3d 1366, 91 U.S.P.Q.2d (BNA) 1161 (Fed. Cir. 2009).

673. *Id.* at 1374–75, 91 U.S.P.Q.2d (BNA) at 1165–68.

674. *Abbott Labs.*, 566 F.3d at 1286, 90 U.S.P.Q.2d (BNA) at 1772.

675. *Id.*, 90 U.S.P.Q.2d (BNA) at 1772.

676. *Id.*, 90 U.S.P.Q.2d (BNA) at 1772.

677. *Id.* at 1291, 90 U.S.P.Q.2d (BNA) at 1776.

scope of product-by-process claims by adopting the rule in *Atlantic Thermoplastics Co. v. Faytex Corp.* and, to the extent the case was inconsistent, overruling the holding in *Scripps Clinic & Research Foundation v. Genentech*.⁶⁷⁸ That is, the Federal Circuit held that process terms in a product-by-process claim serve as limitations of the claim.⁶⁷⁹

To support its decision, the majority cited Supreme Court precedent and case law from its sister circuits.⁶⁸⁰ According to the majority, the Supreme Court has “consistently noted that process terms that define the product in a product-by-process claim serve as enforceable limitations.”⁶⁸¹ Moreover, the majority reasoned that the Federal Circuit’s binding predecessor courts, the U.S. Court of Customs and Patent Appeals and the U.S. Court of Claims, followed the same rule,⁶⁸² and it noted that its sister courts followed this general rule as well.⁶⁸³ The majority made clear that it did “not question at all” whether product-by-process claims are permissible claims.⁶⁸⁴ Rather, the majority stated that the issue here was only whether such claims are infringed by products made by processes other than the one claimed, and the court held that they are not.⁶⁸⁵

The primary concern raised by the two dissenting opinions was that for certain inventions, the precise structure of a new product may not be known from the information available when the patent application was filed.⁶⁸⁶ According to the dissents, the law allowed applicants to claim such products through a process whereby validity and infringement were determined as a product independent of any process term that was used to describe and define the product.⁶⁸⁷

The majority dismissed the dissents’ concerns, stating that if an applicant invents a product that has a structure that is not fully known or is too complex to analyze, the applicant may still use the process steps to define the product.⁶⁸⁸ But because the inventor chose to define its product in terms of its process, the majority reasoned

678. See *supra* notes 76–83 and accompanying text.

679. *Abbott Labs.*, 566 F.3d at 1291–93, 90 U.S.P.Q.2d (BNA) at 1776–78.

680. *Id.* at 1291–92, 90 U.S.P.Q.2d (BNA) at 1776–77.

681. *Id.* at 1291, 90 U.S.P.Q.2d (BNA) at 1776.

682. *Id.* at 1291–92, 90 U.S.P.Q.2d (BNA) at 1776.

683. *Id.* at 1292, 90 U.S.P.Q.2d (BNA) at 1776.

684. *Id.* at 1293, 90 U.S.P.Q.2d (BNA) at 1778.

685. *Id.*, 90 U.S.P.Q.2d (BNA) at 1778.

686. *Id.* at 1300, 1320, 90 U.S.P.Q.2d (BNA) at 1783, 1798–99 (Newman, J., dissenting).

687. *Id.* at 1319–20, 90 U.S.P.Q.2d (BNA) at 1798.

688. *Id.* at 1294, 90 U.S.P.Q.2d (BNA) at 1778 (majority opinion).

that that definition must govern the enforcement of the bounds of the patent right.⁶⁸⁹ Accordingly, the majority held that it “cannot simply ignore as verbiage the only definition supplied by the inventor.”⁶⁹⁰ Thus, the majority affirmed the district court’s construction of claims 2–5 as requiring the recited process steps for any infringement analysis.⁶⁹¹

2. *Copied claims in an interference for written description*

In *Agilent Technologies, Inc. v. Affymetrix, Inc.*, the plaintiff sought review in district court of an adverse decision of the USPTO Board of Patent Appeals and Interferences (“Board”) from an interference action under 35 U.S.C. § 146.⁶⁹² To provoke the interference, the defendant copied claims from the plaintiff’s patent into its patent application.⁶⁹³ During the interference, the plaintiff challenged the defendant’s copied claims, asserting that they lacked written description support in the defendant’s patent application specification.⁶⁹⁴ In determining the parties’ cross-motions for summary judgment on written description, the district court construed the claims. In doing so, the district court construed the copied claims in light of the host application specification, rather than the patent specification from which the claims were copied.⁶⁹⁵ On appeal, the Federal Circuit addressed the impropriety of the district court’s claim construction analysis.⁶⁹⁶

The court examined two of its prior decisions in its analysis.⁶⁹⁷ In *In re Spina*,⁶⁹⁸ the applicant copied a claim from a patent to provoke an interference.⁶⁹⁹ To determine whether the applicant’s specification contained an adequate written description of the copied claim, the Board viewed the claim in light of the patent specification.⁷⁰⁰ The Federal Circuit affirmed the Board’s approach, stating, “[w]hen interpretation is required of a claim that is copied for interference purposes, the copied claim is viewed in the context of the patent from which it is copied.”⁷⁰¹

689. *Id.*, 90 U.S.P.Q.2d (BNA) at 1778.

690. *Id.*, 90 U.S.P.Q.2d (BNA) at 1778.

691. *Id.*, 90 U.S.P.Q.2d (BNA) at 1779.

692. 567 F.3d 1366, 91 U.S.P.Q.2d (BNA) 1161 (Fed. Cir. 2009).

693. *Id.* at 1368–69, 91 U.S.P.Q.2d (BNA) at 1163.

694. *Id.* at 1373, 91 U.S.P.Q.2d (BNA) at 1165.

695. *Id.* at 1374, 91 U.S.P.Q.2d (BNA) at 1165.

696. *Id.* at 1375, 91 U.S.P.Q.2d (BNA) at 1167.

697. *Id.* at 1374, 91 U.S.P.Q.2d (BNA) at 1166.

698. 975 F.2d 854, 24 U.S.P.Q.2d (BNA) 1142 (Fed. Cir. 1992).

699. *Id.* at 855, 24 U.S.P.Q.2d (BNA) at 1143.

700. *Id.* at 857, 24 U.S.P.Q.2d (BNA) at 1144.

701. *Id.* at 856, 24 U.S.P.Q.2d (BNA) at 1144.

In *Rowe v. Dror*,⁷⁰² on the other hand, although the applicant copied claims from the patent, the Federal Circuit interpreted the copied claims in light of the applicant's specification for purposes of determining patentability over prior art.⁷⁰³ The *Rowe* court distinguished *Spina*, noting that in *Spina*, the court considered "whether an applicant was eligible to copy a patentee's claim and thereby challenge priority of invention, a question that turned on whether the copying party's specification adequately supported the subject matter claimed by the other party."⁷⁰⁴ In that context, the claims must be construed in light of the originating specification.⁷⁰⁵ In contrast, the court noted that the *Spina* rule does not apply in cases like *Rowe*, "where the issue is whether the claim is patentable to one or the other party in light of prior art."⁷⁰⁶ In such cases, the claims must be construed in light of the specification in which they appear.⁷⁰⁷

In *Agilent*, the Federal Circuit held that the case at hand called for application of the *Spina* rule because the question was whether the applicant's specification adequately supported the subject matter claimed by the patentee.⁷⁰⁸ Although 37 C.F.R. § 41.200(b) states that "[a] claim shall be given its broadest reasonable construction in light of the specification of the application or patent in which it appears," the Federal Circuit noted in *Agilent*, as it did in *Rowe*, that "administrative regulations cannot trump judicial directives."⁷⁰⁹ As such, the court held that "when a party challenges written description support for an interference count or the copied claim in an interference, the originating disclosure provides the meaning of the pertinent claim language."⁷¹⁰ However, "when a party challenges a claim's validity under 35 U.S.C. §§ 102 or 103, . . . [the] court and the Board must interpret the claim in light of the specification in which it appears."⁷¹¹

702. 112 F.3d 473, 42 U.S.P.Q.2d (BNA) 1550 (Fed. Cir. 1997).

703. *Id.* at 479, 42 U.S.P.Q.2d (BNA) at 1554.

704. *Id.*, 42 U.S.P.Q.2d (BNA) at 1554.

705. *Id.*, 42 U.S.P.Q.2d (BNA) at 1554.

706. *Id.*, 42 U.S.P.Q.2d (BNA) at 1554.

707. *Id.*, 42 U.S.P.Q.2d (BNA) at 1554.

708. 567 F.3d 1366, 1375, 91 U.S.P.Q.2d (BNA) 1161, 1166 (Fed. Cir. 2009).

709. *Id.*, 91 U.S.P.Q.2d (BNA) at 1166.

710. *Id.*, 91 U.S.P.Q.2d (BNA) at 1167.

711. *Id.*, 91 U.S.P.Q.2d (BNA) at 1167.

VI. PATENTABILITY AND VALIDITY

This Section covers all aspects of patentability (for pending applications) and validity (for litigated patents) treated by the Federal Circuit in 2009. It opens with cases directed to patentable subject matter under 35 U.S.C. § 101, an area garnering quite a bit of attention this year, and then moves into several of the formal requirements for patent specifications governed by 35 U.S.C. § 112. The Section then treats prior art-based issues of patentability/validity, and concludes with a discussion of the cases addressing double-patenting and inventorship issues.

A. Patentable Subject Matter

Patent eligibility starts with 35 U.S.C. § 101. Section 101 provides that an applicant may obtain a patent for discovering or inventing a “new and useful process, machine, manufacture, or composition of matter.”⁷¹² For many years, or at least before the advent of business method inventions, much of the developing jurisprudence relating to § 101 arose out of the chemical and biological technology areas. That jurisprudence focused on the usefulness requirement of § 101 when assessing the patent eligibility of, for example, new chemical compounds or biotechnology inventions for which no utility or an incredible utility was provided (e.g., curing cancer).⁷¹³

Like all things “living,” technology evolved and new technologies emerged. The information technology era was born. It dramatically affected the world in many ways, including how business is conducted. It was inevitable that information technology would make its mark on the patent law landscape. “Business method inventions” arose out of this era of change. These inventions, and others of similar ilk, have garnered attention in several areas of the patent law, including § 101, and have raised questions concerning their eligibility for patent protection.

The Federal Circuit has already weighed in on the question in *In re Bilski*,⁷¹⁴ but it will not have the final word. The Supreme Court granted certiorari on June 1, 2009.⁷¹⁵ The oral hearing took place on

712. 35 U.S.C. § 101 (2006).

713. See *Brenner v. Manson*, 383 U.S. 519, 534–35, 148 U.S.P.Q. (BNA) 689, 695 (1966) (requiring an invention to have “substantial utility” and “specific benefit . . . in currently available form”); *Cross v. Iizuka*, 753 F.2d 1040, 1050–51, 224 U.S.P.Q. (BNA) 739, 747–48 (Fed. Cir. 1985) (finding that practical utility may be established by *in vitro* testing of a compound).

714. 545 F.3d 943, 88 U.S.P.Q.2d (BNA) 1385 (Fed. Cir. 2008) (en banc), cert. granted *sub. nom.* *Bilski v. Doll*, 129 S. Ct. 2735 (2009).

715. *Bilski*, 129 S. Ct. 2735.

November 9, 2009, and the case is now under advisement. While patent practitioners worldwide anxiously await the Supreme Court's ruling, the Federal Circuit's decision remains the law for now and was applied in several cases in 2009.

1. *Patent eligibility of process and system claims*

In *In re Bilski*, the Federal Circuit, sitting en banc, overruled its earlier decisions in *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*⁷¹⁶ and *AT&T Corp. v. Excel Communications, Inc.*,⁷¹⁷ to the extent that they relied on a “useful, concrete, and tangible result” as the test for patent eligibility under § 101.⁷¹⁸ The court then redefined the patent eligibility standard for process claims, articulating the so-called “machine-or-transformation” test.⁷¹⁹ Arguably making it more difficult to patent business-method claims and system or paradigm claims, the “machine-or-transformation” test would find a process patent eligible only “if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.”⁷²⁰

In 2009, the Federal Circuit applied the *In re Bilski* test several times. In each case, the Federal Circuit applied the “machine-or-transformation” test as the sole test for determining patent eligibility for process inventions.

In the first case, *In re Comiskey*, the applicants claimed methods and systems for performing mandatory arbitration resolution regarding one or more legal documents.⁷²¹ In a revised opinion, the court held that the claims reciting methods for mandatory arbitration resolution, which Comiskey admitted did not recite any computer or other apparatus, were impermissible attempts “to patent the use of human intelligence in and of itself.”⁷²² Regarding Comiskey's system claims, the court's revised decision omitted the original holding that the system claims, which did recite computer components, recited patentable subject matter under § 101.⁷²³ Instead, the court remanded the case to the USPTO to consider in the first instance

716. 149 F.3d 1368, 47 U.S.P.Q.2d (BNA) 1596 (Fed. Cir. 1998).

717. 172 F.3d 1352, 50 U.S.P.Q.2d (BNA) 1447 (Fed. Cir. 1999).

718. *In re Bilski*, 545 F.3d at 959–60, 88 U.S.P.Q.2d (BNA) at 1395–96.

719. *Id.*, 88 U.S.P.Q.2d (BNA) at 1395–96.

720. *Id.* at 954, 88 U.S.P.Q.2d (BNA) at 1391.

721. 554 F.3d 967, 970, 89 U.S.P.Q.2d (BNA) 1655, 1656–57 (Fed. Cir. 2009).

722. *Id.* at 981, 89 U.S.P.Q.2d (BNA) at 1665.

723. *Id.*, 89 U.S.P.Q.2d (BNA) at 1665.

whether the recitation of computer components in those claims satisfied the *In re Bilski* test and complied with § 101.⁷²⁴

In the second case, *In re Ferguson*,⁷²⁵ the applicants' process claims (directed to a method of marketing a product) and paradigm claims (directed to a paradigm for marketing software) suffered a similar fate upon application of the "machine-or-transformation" test.⁷²⁶ In rejecting Ferguson's argument that the method claims are tied to the use of a shared marketing force, the court emphasized that a machine or apparatus is "a concrete thing, consisting of parts, or of certain devices and combination of devices,"⁷²⁷ and concluded that a shared marketing force is not a machine or an apparatus.⁷²⁸ The court stated: "At best it can be said that Applicants' methods are directed to organizing business or legal relationships in the structuring of a sales force (or marketing company)."⁷²⁹ Regarding its paradigm claims—which were clearly not a process, a manufacture, or a composition of matter—the court noted that the methods were also not a machine and not patent eligible.⁷³⁰ They "d[id] not recite 'a concrete thing, consisting of parts, or of certain devices and combination of devices,'" and therefore were no more than an abstract idea.⁷³¹

Finally, in a case dealing with diagnostic tools and pharmaceuticals, *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*,⁷³² the Federal Circuit applied the "machine-or-transformation" test from *In re Bilski* and found that claimed methods of treatment were patent eligible because the claims covered transformative methods of treatment, which were a particular application of natural processes, and not simply the correlation itself.⁷³³ The claims in *Prometheus* generally included two steps: "(a) 'administering' a drug that provides [6-thioguanine ("6-TG")] to a subject, and (b) 'determining' the levels of the drug's metabolites, 6-TG and/or [6-methylmercaptapurine ("6-MMP")], in the subject."⁷³⁴ The claims further recited comparing the metabolite levels to predetermined metabolite

724. *Id.* at 981–82, 89 U.S.P.Q.2d (BNA) at 1665.

725. 558 F.3d 1359, 90 U.S.P.Q.2d (BNA) 1035 (Fed. Cir. 2009).

726. *Id.* at 1363–66, 90 U.S.P.Q.2d (BNA) at 1037–42.

727. *Id.* at 1366, 90 U.S.P.Q.2d (BNA) at 1040 (quoting *In re Nuijten*, 500 F.3d 1346, 1355, 84 U.S.P.Q.2d (BNA) 1495, 1502 (Fed. Cir. 2007)).

728. *Id.* at 1363–64, 90 U.S.P.Q.2d (BNA) at 1038–39.

729. *Id.* at 1364, 90 U.S.P.Q.2d (BNA) at 1038.

730. *Id.* at 1365–66, 90 U.S.P.Q.2d (BNA) at 1039–40.

731. *Id.* at 1366, 90 U.S.P.Q.2d (BNA) at 1040 (quoting *In re Nuijten*, 500 F.3d at 1355, 84 U.S.P.Q.2d (BNA) at 1502).

732. 581 F.3d 1336, 92 U.S.P.Q.2d (BNA) 1075 (Fed. Cir. 2009).

733. *Id.* at 1349, 92 U.S.P.Q.2d (BNA) at 1084–85.

734. *Id.* at 1339, 92 U.S.P.Q.2d (BNA) at 1077.

levels, where “the measured metabolite levels ‘indicate a need’ to” vary the amount of drugs administered to maximize efficacy and minimize toxicity.⁷³⁵ The Federal Circuit concluded that the claimed methods of treatment were directed to “patentable subject matter because they ‘transform an article into a different state or thing,’ and this transformation is ‘central to the purpose of the claimed process.’”⁷³⁶ The court held that the transformation occurred in the human body where the administered drug underwent various chemical and physical changes, enabling its metabolite concentrations to be determined.⁷³⁷ Moreover, the court noted that methods of treatment “are always transformative when a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition.”⁷³⁸ Because the claimed methods met the transformation prong under *In re Bilski*, the court did not consider whether they also met the machine prong.⁷³⁹

The Federal Circuit also acknowledged that the claims contained some mental steps that were “not patent-eligible per se.”⁷⁴⁰ But it noted that a “mental step does not, by itself, negate the transformative nature of prior steps.”⁷⁴¹ The data generated in the administering and determining steps for use in the mental step were obtained by an overall process that fell “well within the realm of patentable subject matter.”⁷⁴² The court observed that “even though a fundamental principle itself is not patent-eligible, processes incorporating a fundamental principle may be patent-eligible.”⁷⁴³

B. Indefiniteness

The second paragraph of 35 U.S.C. § 112 requires that the claims of a patent particularly point out and distinctly claim the subject matter the inventor regards as his invention.⁷⁴⁴ The statutory mandate to distinctly claim the subject matter of the invention has developed into a definiteness or clarity requirement for the claimed

735. *Id.*, 92 U.S.P.Q.2d (BNA) at 1077.

736. *Id.* at 1345, 92 U.S.P.Q.2d (BNA) at 1082 (quoting *In re Bilski*, 545 F.3d 943, 962, 88 U.S.P.Q.2d (BNA) 1385, 1396 (Fed. Cir. 2008) (en banc), cert. granted sub. nom. *Bilski v. Doll*, 129 S. Ct. 2735 (2009)).

737. *Id.* at 1346, 92 U.S.P.Q.2d (BNA) at 1082.

738. *Id.*, 92 U.S.P.Q.2d (BNA) at 1082.

739. *Id.*, 92 U.S.P.Q.2d (BNA) at 1082.

740. *Id.* at 1348, 92 U.S.P.Q.2d (BNA) at 1084.

741. *Id.*, 92 U.S.P.Q.2d (BNA) at 1084.

742. *Id.*, 92 U.S.P.Q.2d (BNA) at 1084.

743. *Id.* at 1349, 92 U.S.P.Q.2d (BNA) at 1084 (quoting *In re Bilski*, 545 F.3d 943, 958, 88 U.S.P.Q.2d (BNA) 1385, 1394 (Fed. Cir. 2008) (en banc), cert. granted sub. nom. *Bilski v. Doll*, 129 S. Ct. 2735 (2009)).

744. 35 U.S.C. § 112 (2006).

invention. Definiteness is evaluated both at the time of filing and through the eyes of one skilled in the art who has both the specification and the knowledge in art at their disposal at the time of filing.⁷⁴⁵ Establishing indefiniteness requires an exacting standard, showing the claim to be either not amenable to construction or “insolubly ambiguous.”⁷⁴⁶ If the claims are discernible but the interpretation is one over which reasonable persons may differ, the claims are not insolubly ambiguous and not invalid for indefiniteness.⁷⁴⁷

In *In re Skvorecz*,⁷⁴⁸ the Federal Circuit reversed and remanded the Board’s decision rejecting a claim for indefiniteness under 35 U.S.C. § 112, ¶ 2. Skvorecz sought to reissue U.S. Patent No. 5,996,948 (“the ‘948 patent”), which was directed to a wire chafing stand used for supporting a chafer (i.e., a device for keeping food warm).⁷⁴⁹ The claim recited a wire chafing stand, “wherein said plurality of offsets are welded to said wire legs at the separation of the upright sections into segments.”⁷⁵⁰ The USPTO asserted two independent bases for its finding of indefiniteness: (1) the phrase “at the separation” lacked antecedent basis; and (2) the phrase “at the separation” rendered the term “segments” indefinite because “segments” was not defined in the specification.⁷⁵¹ The Federal Circuit noted that “[s]ome latitude in the manner of expression and the aptness of terms should be permitted even though the claim

745. See, e.g., *Energizer Holdings, Inc. v. Int’l Trade Comm’n*, 435 F.3d 1366, 1370, 77 U.S.P.Q.2d 1625, 1628 (Fed. Cir. 2006) (“Claim definiteness is analyzed ‘not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art.’” (quoting *In re Moore*, 439 F.2d 1232, 1236, 169 U.S.P.Q. (BNA) 236, 238 (C.C.P.A. 1971))).

746. See *Marley Mouldings Ltd. v. Mikron Indus., Inc.*, 417 F.3d 1356, 1361, 75 U.S.P.Q.2d 1954, 1957 (Fed. Cir. 2005) (“When a claim ‘is not insolubly ambiguous, it is not invalid for indefiniteness.’” (quoting *Bancorp Servs., L.L.C. v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1372, 69 U.S.P.Q.2d (BNA) 1996, 1999 (Fed. Cir. 2004))); *Honeywell Int’l, Inc. v. Int’l Trade Comm’n*, 341 F.3d 1332, 1338, 68 U.S.P.Q.2d 1023, 1028 (Fed. Cir. 2003) (stating that the definiteness requirement mandates only “that the claims be amenable to construction, however difficult that task may be” (quoting *Exxon Research & Eng’g Co. v. United States*, 265 F.3d 1371, 1375, 60 U.S.P.Q.2d (BNA) 1272, 1276 (Fed. Cir. 2001))).

747. See *Exxon Research & Eng’g Co.*, 265 F.3d at 1375, 60 U.S.P.Q.2d (BNA) at 1276 (“If the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, we have held the claim sufficiently clear to avoid invalidity on indefiniteness grounds.”).

748. 580 F.3d 1262, 92 U.S.P.Q.2d (BNA) 1020 (Fed. Cir. 2009).

749. *Id.* at 1263, 92 U.S.P.Q.2d (BNA) at 1021–22.

750. *Id.* at 1266, 92 U.S.P.Q.2d (BNA) at 1023.

751. *Id.* at 1268–69, 92 U.S.P.Q.2d (BNA) at 1025.

language is not as precise as the examiner might desire.”⁷⁵² It found that the phrase “at the separation” did “not require further antecedent basis” and was not indefinite because a person of ordinary skill in the art would understand the claim in view of the specification.⁷⁵³

In *Amgen Inc. v. F. Hoffmann-La Roche Ltd.*,⁷⁵⁴ the Federal Circuit affirmed the district court’s finding that the patents at issue were not invalid for indefiniteness, holding that the definitions of erythropoietin (EPO) and the source limitations in the claims were definite because the product-by-process nature of the claims allowed Amgen to define the claimed product by its source.⁷⁵⁵ Roche argued that, at the time of the invention, a person having ordinary skill in the art did not know the exact amino acid sequence of human EPO.⁷⁵⁶ Roche also argued that the source limitation of the claims at issue was indefinite because the claim on its face did not distinguish functional and structural differences from the prior art.⁷⁵⁷ Relying on expert testimony, however, the court rejected Roche’s argument, noting that an ordinarily skilled person may still know the scope of the invention even though he may not know the exact components of the invention.⁷⁵⁸ The court reasoned that where the differences between the claimed product and the prior art are not susceptible to definition, “the product-by-process format allows the patentee to obtain a patent on the product even though the patentee cannot adequately describe the features that distinguish it from prior art products.”⁷⁵⁹ Finding that the claims were not invalid for indefiniteness, the Federal Circuit stated that, “to call the process limitation indefinite in this situation would defeat one of the purposes of product-by-process claims, namely permitting product-by-process claims reciting new products lacking physical description.”⁷⁶⁰

In *Source Search Technologies LLC v. LendingTree, LLC*,⁷⁶¹ the Federal Circuit refused to “load the indefiniteness requirement with this unreasonable baggage” and underscored that the definiteness of

752. *Id.* at 1269, 92 U.S.P.Q.2d (BNA) at 1025 (quoting MANUAL OF PATENT EXAMINING PROCEDURE § 2173.02 (2008)).

753. *Id.*, 92 U.S.P.Q.2d (BNA) at 1025.

754. 580 F.3d 1340, 92 U.S.P.Q.2d (BNA) 1289 (Fed. Cir. 2009).

755. *Id.* at 1372–74, 92 U.S.P.Q.2d (BNA) at 1315–16.

756. *Id.* at 1371, 92 U.S.P.Q.2d (BNA) at 1313.

757. *Id.* at 1373, 92 U.S.P.Q.2d (BNA) at 1315.

758. *Id.* at 1372, 92 U.S.P.Q.2d (BNA) at 1314.

759. *Id.* at 1373, 92 U.S.P.Q.2d (BNA) at 1315.

760. *Id.* at 1374, 92 U.S.P.Q.2d (BNA) at 1315.

761. 588 F.3d 1063, 92 U.S.P.Q.2d (BNA) 1907 (Fed. Cir. 2009).

claims is viewed with the knowledge of one skilled in the art.⁷⁶² The patent-in-suit claimed a computerized “service for matching potential buyers with potential vendors [of goods and services] over a network.”⁷⁶³ During the litigation, the district court construed “goods and services” to be “*standardized* articles of trade and performances of work for another.”⁷⁶⁴ The accused infringer argued that the district court’s use of “standardized” introduced a subjective element rendering the claim indefinite because a skilled person would not be able to differentiate between “standard” and “non-standard” “goods or services.”⁷⁶⁵ In rejecting that argument, the Federal Circuit stated that indefiniteness is judged “according to an objective measure that recognizes [that] artisans of ordinary skill are not mindless ‘automatons,’” and that the subjective impression of any particular user of the claimed system is not relevant.⁷⁶⁶ From that vantage point, the court found that the skilled person “will understand the markets and the system enough to determine what is a ‘standard’ item” and ultimately rejected the indefiniteness challenge.⁷⁶⁷

The mere act of claiming an invention broadly will not render the claim indefinite.⁷⁶⁸ The *Ultimax* decision also explained that, under certain circumstances, a court can correct a patent when evaluating the definiteness of the claims.⁷⁶⁹ In that case, the patent-in-suit claimed a high strength cement that contained a particular crystalline compound, denoted as “crystal X” in the specification, and another chemical compound that seemingly required the presence of both a fluorine and a chlorine atom, a combination that could not actually exist in nature.⁷⁷⁰ The claim defined “crystal X” using a complex chemical formula that encompassed over 5000 possible combinations.⁷⁷¹ The district court held that the claimed invention was indefinite because the formula for “crystal X” was too broad.⁷⁷² It also held that the claim was indefinite for lacking a comma separating the fluorine and chlorine atoms in the definition of the other compound, “(f cl),” ostensibly requiring the presence of both

762. *Id.* at 1076, 92 U.S.P.Q.2d (BNA) at 1916.

763. *Id.* at 1066, 92 U.S.P.Q.2d (BNA) at 1909.

764. *Id.* at 1075, 92 U.S.P.Q.2d (BNA) at 1916 (emphasis added).

765. *Id.* at 1076, 92 U.S.P.Q.2d (BNA) at 1916.

766. *Id.* at 1077, 92 U.S.P.Q.2d (BNA) at 1917 (quoting *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421, 82 U.S.P.Q.2d 1385, 1397 (2007)).

767. *Id.*, 92 U.S.P.Q.2d (BNA) at 1917.

768. *Ultimax Cement Mfg. Corp. v. CTS Cement Mfg. Corp.*, 587 F.3d 1339, 1352 92 U.S.P.Q.2d (BNA) 1865, 1873 (Fed. Cir. 2009).

769. *Id.* at 1353, 92 U.S.P.Q.2d (BNA) at 1874.

770. *Id.* at 1344–45, 92 U.S.P.Q.2d (BNA) at 1867–68.

771. *Id.* at 1345, 92 U.S.P.Q.2d (BNA) at 1868.

772. *Id.* at 1350–51, 92 U.S.P.Q.2d (BNA) at 1872.

fluorine and chlorine in that compound.⁷⁷³ Although the lower court acknowledged that the skilled person would have recognized the error caused by the missing comma, it refused to correct the patent.⁷⁷⁴

The Federal Circuit reversed the district court on both holdings of indefiniteness.⁷⁷⁵ The court stated that “[m]erely claiming broadly does not render a claim insolubly ambiguous, nor does it prevent the public from understanding the scope of the patent.”⁷⁷⁶ The court held that the crystal structure formula, though complex and broad, was not ambiguous because the skilled person could determine whether its activities fell inside or outside of the formula’s defined boundaries.⁷⁷⁷ Regarding the missing comma between fluorine and chlorine, the Federal Circuit took a more expansive view of a court’s authority to correct a patent. It stated that while a court cannot correct material errors in claims, it can correct obvious typographical errors that the skilled person would not reasonably dispute after having considered the claim language, the specification, and the prosecution history.⁷⁷⁸ Because the district court acknowledged that a compound with both fluorine and chlorine corresponded to “no known mineral,” and the ordinary skilled person would have also known that the formula should contain a comma, the Federal Circuit found the formula not indefinite and directed the district court to enter judgment accordingly.⁷⁷⁹

C. *Written Description*

1. *Possession of the claimed invention*

35 U.S.C. § 112, ¶ 1 requires a patent specification to “contain a written description of the invention.”⁷⁸⁰ Federal Circuit decisions have historically held that this requirement is separate from the enablement requirement, which is also part of § 112, ¶ 1 and states that “[t]he specification shall contain . . . the manner and process of making and using [the claimed invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same.”⁷⁸¹ With broadly

773. *Id.* at 1351, 92 U.S.P.Q.2d (BNA) at 1872.

774. *Id.*, 92 U.S.P.Q.2d (BNA) at 1872.

775. *Id.* at 1353, 92 U.S.P.Q.2d (BNA) at 1874.

776. *Id.* at 1352, 92 U.S.P.Q.2d (BNA) at 1873.

777. *Id.*, 92 U.S.P.Q.2d (BNA) at 1873.

778. *Id.* at 1353, 92 U.S.P.Q.2d (BNA) at 1874.

779. *Id.*, 92 U.S.P.Q.2d (BNA) at 1874.

780. 35 U.S.C. § 112 (2006).

781. *Id.*; *see* Univ. of Rochester v. G.D. Searle & Co., 375 F.3d 1303, 1326, 71 U.S.P.Q.2d (BNA) 1545, 1567 (Fed. Cir. 2004) (Linn, J., dissenting) (describing

drafted claims, particularly those that cover chemical and biotechnology inventions, written description issues often arise regarding whether the specification establishes that the inventors were in possession of the invention as claimed.⁷⁸² Claiming an invention by what it does (i.e., functionally), rather than by what it is, has run afoul of the written description requirement.⁷⁸³

In *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*,⁷⁸⁴ the Federal Circuit reversed a jury finding that the Ariad patent-in-suit provided an adequate written description of the invention claimed.⁷⁸⁵ In reversing, the court found that the specification did not show that the inventors had possession of the broadly claimed invention—effectively a method of reducing a cellular activity known as NF-κB activity.⁷⁸⁶ Although the claims recited achieving the reduction by “reducing binding of NF-κB to NF-κB recognition sites on genes,” the court looked to the specification for molecules capable of reducing the claimed activity.⁷⁸⁷ The specification disclosed three classes of molecules.⁷⁸⁸ Yet, in the primitive and uncertain field to which the invention pertained, the Federal Circuit remained unconvinced that the disclosed molecules and a hypothesis that they

the primary role of the written description but critiquing a construction of § 112 that requires a separate written description beyond the enablement requirement); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1560–61, 19 U.S.P.Q.2d (BNA) 1111, 1114–15 (Fed. Cir. 1991) (exploring the historical origins of the dual written description and enablement requirements and canvassing policy rationales supporting the continuation of the dual requirements).

^{782.} See *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 924, 69 U.S.P.Q.2d 1886, 1892–96 (Fed. Cir. 2004) (holding that the applicant did not provide adequate description to show that inventors had possession or knowledge of the compound at issue); *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1562, 43 U.S.P.Q.2d (BNA) 1398, 1400, 1404 (Fed. Cir. 1997) (asserting that in order to meet the written description requirement, the specification must describe an invention in enough detail so that one skilled in the art could easily know that the inventor actually invented what is claimed); *Fiers v. Revel*, 984 F.2d 1164, 1169–71, 25 U.S.P.Q.2d (BNA) 1601, 1605 (Fed. Cir. 1993) (emphasizing that an applicant’s mere reference to a potential method for isolating DNA was not enough to show that he was in possession of the DNA and thus insufficient to satisfy the written description requirement).

^{783.} See *Regents of the Univ. of Cal.*, 119 F.3d at 1568, 43 U.S.P.Q.2d (BNA) at 1406 (“A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.” (citing *Fiers*, 984 F.2d at 1169–71, 25 U.S.P.Q.2d (BNA) at 1605–06)).

^{784.} 560 F.3d 1366, 90 U.S.P.Q.2d (BNA) 1549 (Fed. Cir. 2009). Just before this Area Summary went to print, the Federal Circuit, sitting en banc, confirmed the separate requirements of written description and enablement, and thereby reversed in part and affirmed in part its previous panel decision. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, No. 2008-1248, 2010 WL 1007369 (Fed. Cir. Mar. 22, 2010) (en banc).

^{785.} *Id.* at 1376, 90 U.S.P.Q.2d (BNA) at 1555.

^{786.} *Id.* at 1370–71, 90 U.S.P.Q.2d (BNA) at 1550–51.

^{787.} *Id.* at 1370, 90 U.S.P.Q.2d (BNA) at 1551.

^{788.} *Id.* at 1373, 90 U.S.P.Q.2d (BNA) at 1553.

could reduce NF-κB activity showed possession of the full scope of the invention covered by the generic claims.⁷⁸⁹ Accordingly, the Federal Circuit held that the claims were invalid under § 112, ¶ 1 for lacking written descriptive support.⁷⁹⁰

The court's rationale in *Ariad Pharmaceuticals* may seem more reflective of an enablement violation than a transgression of the written description requirement. Indeed, in his concurrence, Judge Linn seems to suggest as much: "Because the court relies upon [the written description] requirement to reverse the district court, it does not reach the important enablement issue raised by Lilly."⁷⁹¹ Judge Linn's concurrence goes further, however. It specifically raised the question of whether written description should be a separate requirement from enablement and lamented a lost opportunity for the court to resolve it: "I write separately to emphasize, as I have before, my belief that our engrafting of a separate written description requirement onto section 112, paragraph 1 is misguided."⁷⁹² Judge Linn went on to state: "This is an important issue that we have left unresolved. It is an issue that we would have been compelled to reach had the case been decided on enablement grounds."⁷⁹³

On August 21, 2009, the entire court answered Judge Linn, vacating the earlier opinion of April 3, 2009 and ordering an en banc hearing.⁷⁹⁴ The order requested the parties to address the following issues:

- (a) Whether 35 U.S.C. § 112, paragraph 1, contains a written description requirement separate from an enablement requirement.
- (b) If a separate written description requirement is set forth in the statute, what is the scope and purpose of the requirement?⁷⁹⁵

In another case turning on whether the specification conveyed that the patentee had possession of a claimed invention, the Federal Circuit found that claims broadened to omit an element lacked

789. *Id.* at 1376–77, 90 U.S.P.Q.2d (BNA) at 1555–56.

790. *Id.* at 1373, 90 U.S.P.Q.2d (BNA) at 1553.

791. *Id.* at 1381, 90 U.S.P.Q.2d (BNA) at 1559 (Linn, J., concurring).

792. *Id.* at 1380, 90 U.S.P.Q.2d (BNA) at 1559.

793. *Id.* at 1381, 90 U.S.P.Q.2d (BNA) at 1560.

794. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 332 F. App'x 636 (Fed. Cir. 2009). Just before this Area Summary went to print, the Federal Circuit, sitting en banc, confirmed the separate requirements of written description and enablement, and thereby reversed in part and affirmed in part its previous panel decision. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, No. 2008-1248, 2010 WL 1007369 (Fed. Cir. Mar. 22, 2010) (en banc).

795. *Ariad Pharms.*, 332 F. App'x at 637.

written description support and were therefore invalid under § 112, ¶ 1. In *ICU Medical, Inc. v. Alaris Medical Systems, Inc.*,⁷⁹⁶ a patent-in-suit was directed to a valve used with a syringe to transmit fluids to a medical patient (such as through an intravenous line).⁷⁹⁷ During prosecution of the patent, ICU modified the claims to make a spike used as a component of the valve optional.⁷⁹⁸ It did this after Alaris introduced its spikeless valve on the market.⁷⁹⁹ In other words, the spike-optional claims covered “valves that operate with a spike and those that operate without a spike.”⁸⁰⁰ This aspect of the case is discussed at Part V.B.2.

The Federal Circuit affirmed the district court’s summary judgment ruling that held that the ICU’s spike-optional claims were invalid for lack of written description support.⁸⁰¹ Alaris had argued that “the specification clearly limited ICU’s invention to valves with a spike and does not demonstrate that the inventor possessed a medical valve without a spike.”⁸⁰² The Federal Circuit agreed, noting that “the specification describes only medical valves with spikes” and rejecting ICU’s contentions that “the figures and descriptions that include spikes somehow demonstrate that the inventor possessed a medical valve that operated without a spike.”⁸⁰³ ICU also argued, as support for its spike-optional claims, that a person skilled in the art would have recognized that the specification’s disclosure of a pre-cut seal in the valve would eliminate the need for a spike.⁸⁰⁴ The Federal Circuit countered, however, stating that “[i]t is not enough that it would have been obvious to a person of ordinary skill that a [pre-cut] seal could be used without a spike,” for ICU did not “point to any disclosure in the patent specification that describes a spikeless valve with a [pre-cut] seal.”⁸⁰⁵

It is well established that the language of a claim need not have *ipsis verbis* support to satisfy the written description requirement.⁸⁰⁶ But the specification must still convey that the inventor possessed the

796. 558 F.3d 1368, 90 U.S.P.Q.2d (BNA) 1072 (Fed. Cir. 2009).

797. *Id.* at 1372, 90 U.S.P.Q.2d (BNA) at 1073–74.

798. *Id.*, 90 U.S.P.Q.2d (BNA) at 1074.

799. *Id.* at 1376, 90 U.S.P.Q.2d (BNA) at 1076.

800. *Id.* at 1378, 90 U.S.P.Q.2d (BNA) at 1078.

801. *Id.*, 90 U.S.P.Q.2d (BNA) at 1078.

802. *Id.* at 1377, 90 U.S.P.Q.2d (BNA) at 1077.

803. *Id.* at 1378, 90 U.S.P.Q.2d (BNA) at 1078.

804. *Id.*, 90 U.S.P.Q.2d (BNA) at 1078.

805. *Id.* at 1379, 90 U.S.P.Q.2d (BNA) at 1078.

806. See *Martin v. Johnson*, 454 F.2d 746, 751, 172 U.S.P.Q. (BNA) 391, 395 (C.C.P.A. 1972) (“[T]he description need not be in *ipsis verbis* [i.e., “in the same words”] to be sufficient.”).

invention recited in the claims.⁸⁰⁷ In *Martek Biosciences Corp. v. Nutrinova, Inc.*, the patentee, Martek Biosciences Corp., sought to rely on the filing date of its priority application to avoid intervening prior art.⁸⁰⁸ Martek's patent related to specified microorganisms useful for the commercial production of docosahexaenoic acid (DHA).⁸⁰⁹ The issue was whether the priority application provided written description support for two limitations: "mixed culture" and "food product."⁸¹⁰ In holding that Martek's priority application supported the claims of the patent, the Federal Circuit reiterated that "the earlier application need not describe the claimed subject matter in precisely the same terms as found in the claims at issue."⁸¹¹ *The Federal Circuit determined that the test is "whether the disclosure of the application relied upon 'reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.'"*⁸¹²

Regarding the "mixed culture" limitation, the Federal Circuit found that Martek's expert explained how a person of ordinary skill in the art would recognize that at least one passage in the priority application disclosed the process of extracting lipids from a mixed culture of fermenting microorganisms.⁸¹³ Noting that a patent claim does not necessarily lack written description support because it is broader than the specific examples disclosed, the court rejected the defendants' argument that the expert's interpretation of the parent application was not reasonably reliable because the application did not contain any working examples that consolidated cells from different strains.⁸¹⁴ Further, the court disagreed with the defendants' argument that the parent application taught away from growing the two strains together.⁸¹⁵ The court found no evidence to suggest that the two strains could not be grown together.⁸¹⁶ Therefore, the court

807. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d (BNA) 1111, 1116 (Fed. Cir. 1991) (noting that the test for sufficiency of support in a parent application is whether the disclosure of the application that was relied upon reasonably conveys that the inventor had possession at the time of the later claimed subject matter).

808. 579 F.3d 1363, 1369–70, 92 U.S.P.Q.2d (BNA) 1148, 1152 (Fed. Cir. 2009).

809. *Id.* at 1367, 92 U.S.P.Q.2d (BNA) at 1150.

810. *Id.* at 1370, 92 U.S.P.Q.2d (BNA) at 1152.

811. *Id.* at 1369, 92 U.S.P.Q.2d (BNA) at 1152 (quoting *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1331, 88 U.S.P.Q.2d (BNA) 1865, 1877 (Fed. Cir. 2008)).

812. *Id.*, 92 U.S.P.Q.2d (BNA) at 1152 (quoting *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575, 227 U.S.P.Q. (BNA) 177, 179 (Fed. Cir. 1985)).

813. *Id.* at 1370–71, 92 U.S.P.Q.2d (BNA) at 1152–54.

814. *Id.*, 92 U.S.P.Q.2d (BNA) at 1152–54.

815. *Id.* at 1371, 92 U.S.P.Q.2d (BNA) at 1154.

816. *Id.*, 92 U.S.P.Q.2d (BNA) at 1154.

found substantial evidence to support the jury's finding that the parent application adequately described the "mixed culture" limitation of the claims.⁸¹⁷

Regarding the "food product" limitation, the court found that the priority application disclosed "vegetable or other edible oil" and "food additives."⁸¹⁸ In addition, Martek's expert explained that vegetable and edible oils are understood to be "food materials."⁸¹⁹ Accordingly, the court held that substantial evidence supported the jury's finding that the patent claims were entitled to the date of the priority application.⁸²⁰

2. *Failure of the claims to satisfy identified problems in the art*

In *Revolution Eyewear, Inc. v. Aspex Eyewear, Inc. (Revolution Eyewear II)*,⁸²¹ the claim under attack for violation of the written description requirement dealt with one of the two problems that the invention disclosed in the specification.⁸²² Revolution Eyewear, however, argued that the problems alleged to be addressed by the invention were tied to each other and were directly related.⁸²³ In affirming the district court's finding of a sufficient written description in support of the claim, the Federal Circuit stated that "when the specification sets out two different problems present in the prior art, it is unnecessary for each and every claim in the patent to address both problems."⁸²⁴ The court then dismissed Revolution Eyewear's attempt at "tying" the two problems together, noting that Revolution Eyewear's argument "is based on the false premise that if the problems addressed by the invention are related, then a claim addressing only one of the problems is invalid for lack of sufficient written description."⁸²⁵ The court further noted that "[i]nventors can frame their claims to address one problem or several, and the written description requirement will be satisfied as to each claim as long as the description conveys that the inventor was in possession of the invention recited in that claim."⁸²⁶

817. *Id.* at 1372, 92 U.S.P.Q.2d (BNA) at 1154.

818. *Id.*, 92 U.S.P.Q.2d (BNA) at 1154.

819. *Id.*, 92 U.S.P.Q.2d (BNA) at 1154.

820. *Id.* at 1374, 92 U.S.P.Q.2d (BNA) at 1154.

821. 563 F.3d 1358, 90 U.S.P.Q.2d (BNA) 1733 (Fed. Cir. 2009).

822. *Id.* at 1362–63, 90 U.S.P.Q.2d (BNA) at 1735–36.

823. *Id.* at 1367, 90 U.S.P.Q.2d (BNA) at 1739.

824. *Id.*, 90 U.S.P.Q.2d (BNA) at 1739 (citations omitted).

825. *Id.*, 90 U.S.P.Q.2d (BNA) at 1739.

826. *Id.*, 90 U.S.P.Q.2d (BNA) at 1739.

3. *Written description in an interference*

As a general matter, courts construe claims in light of the specification of the patent in which they exist. In the special circumstances of an interference, however, that might not be the case. In *Agilent*, the Federal Circuit addressed an interesting question of which specification should be used to construe claims when those claims are copied from another party's specification and when written description support for the copied claims is challenged.⁸²⁷ Affymetrix copied claims from Agilent's patent to provoke an interference against that patent.⁸²⁸ During the subsequently declared interference, Agilent challenged Affymetrix's written description support for the claims it copied.⁸²⁹ As previously discussed, the Federal Circuit held that the sufficiency of Affymetrix's specification to support its claim would be assessed after construing that claim in light of the specification of the Agilent patent—the specification from which the claim was copied and originated.⁸³⁰ The claim construction holding placed Affymetrix in a particularly vulnerable position, and it ultimately failed in its attempt to prove that its specification provided written description support for a claim originating from Agilent's patent.⁸³¹

In *In re Skvorecz*, discussed above, the Federal Circuit also reversed a finding by the Board that a reissue patent application for a wire chafing stand did not meet the written description requirement.⁸³² Despite the USPTO's contention that the claim element "plurality of offsets located . . . in said first rim" was not described in the specification, the court noted that "[a]n applicant's disclosure obligation varies according to the art to which the invention pertains."⁸³³ The court found that certain figures, although they did not show the full structure of the chafing stand, showed sufficient detail in conjunction with other figures of the specification to provide support for the offsets in the rim.⁸³⁴

D. *Enablement*

The enablement requirement embraced by 35 U.S.C. § 112 has two components: "how to make" and "how to use" the invention claimed.

827. 567 F.3d 1366, 1374, 91 U.S.P.Q.2d (BNA) 1161, 1165–66 (Fed. Cir. 2009).

828. *Id.*, 91 U.S.P.Q.2d (BNA) at 1166.

829. *Id.* at 1373–74, 91 U.S.P.Q.2d (BNA) at 1165.

830. *Id.* at 1375, 91 U.S.P.Q.2d (BNA) at 1167.

831. *Id.* at 1383, 91 U.S.P.Q.2d (BNA) at 1173.

832. 580 F.3d 1262, 1270, 92 U.S.P.Q.2d (BNA) 1020, 1026 (Fed. Cir. 2009).

833. *Id.* at 1269–70, 92 U.S.P.Q.2d (BNA) at 1026.

834. *Id.*, 92 U.S.P.Q.2d (BNA) at 1026.

The “how to use” aspect of enablement is closely tied to the utility requirement of 35 U.S.C. § 101. A specification failing to provide basic utility in compliance with § 101 will not satisfy the use aspect of the enablement requirement. In *In re ‘318 Patent Infringement Litigation*,⁸³⁵ the Federal Circuit affirmed the district court’s decision to invalidate a patent for lack of enablement by essentially finding that the specification did not provide a utility for the invention.⁸³⁶

The patent at issue, U.S. Patent No. 4,663,318 (“the ‘318 patent”), is directed to a method for treating Alzheimer’s disease, which was comprised of administering an effective amount of galantamine to the patient.⁸³⁷ The specification was fairly short, being just over one page in length and providing “short summaries of six scientific papers in which galantamine had been administered to humans or animals.”⁸³⁸ The Federal Circuit stated that the specification did not provide analysis or insights connecting the results of any of these six studies to galantamine’s potential to treat Alzheimer’s disease in humans.⁸³⁹ Nor did the specification provide any *in vitro* test results or animal test results involving the use of galantamine to treat Alzheimer’s-like conditions.⁸⁴⁰ According to the court, there was no “evidence that a person skilled in the art would infer galantamine’s utility from the specification, even if inferences could substitute for an explicit description of utility.”⁸⁴¹

The Federal Circuit recognized the close link between the requirement of utility and enablement, stating that “[i]f a patent claim fails to meet the utility requirement because it is not useful or operative, then it also fails to meet the how-to-use aspect of the enablement requirement.”⁸⁴² It found that “at the end of the day, the specification, even read in the light of the knowledge of those skilled in the art, does no more than state a hypothesis and propose testing to determine the accuracy of that hypothesis.”⁸⁴³ As a result, the Federal Circuit held that the ‘318 patent did not satisfy the enablement requirement because it did not establish utility.⁸⁴⁴

835. 583 F.3d 1317, 92 U.S.P.Q.2d (BNA) 1385 (Fed. Cir. 2009).

836. *Id.* at 1327, 92 U.S.P.Q.2d (BNA) at 1392.

837. *Id.* at 1320, 92 U.S.P.Q.2d (BNA) at 1386.

838. *Id.* at 1321, 92 U.S.P.Q.2d (BNA) at 1386.

839. *Id.*, 92 U.S.P.Q.2d (BNA) at 1387.

840. *Id.* at 1325, 92 U.S.P.Q.2d (BNA) at 1390.

841. *Id.* at 1326, 92 U.S.P.Q.2d (BNA) at 1391.

842. *Id.* at 1324, 92 U.S.P.Q.2d (BNA) at 1389 (emphasis and citation omitted).

843. *Id.* at 1327, 92 U.S.P.Q.2d (BNA) at 1391.

844. *Id.*, 92 U.S.P.Q.2d (BNA) at 1392.

*E. Qualifying as Prior Art**1. Printed publication*

In general:

A document is publicly accessible if it has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it and recognize and comprehend therefrom the essentials of the claimed invention without need of further research or experimentation.⁸⁴⁵

Consistent with this statement, the Federal Circuit previously noted that “[w]here professional and behavioral norms entitle a party to a reasonable expectation” that information will not be copied or further distributed, a document disseminated in such a community may not render the document a printed publication even in the absence of a confidentiality agreement.⁸⁴⁶ On the facts in *Cordis Corp. v. Boston Scientific Corp.*,⁸⁴⁷ the Federal Circuit held exactly that.⁸⁴⁸

The inventor distributed two monographs, which would otherwise qualify as 35 U.S.C. § 102(b) art, to academic and research colleagues and two commercial entities.⁸⁴⁹ The Federal Circuit, however, recognized the importance of “‘preserv[ing] the incentive for inventors to participate in academic presentations or discussions’ by noting that professional norms may support expectations of confidentiality.”⁸⁵⁰ The court found that the record contained clear evidence that “such academic norms gave rise to an expectation that disclosures will remain confidential,” and ultimately concluded that the distribution to the two commercial entities did not render the monographs printed publications within the meaning of 35 U.S.C. § 102(b).⁸⁵¹ Whether or not they were legally obligated to do so, the entities had kept their copies confidential, and the district court noted that there was no evidence that the entities would have distributed, or in fact did distribute, the document outside of the

845. *Cordis Corp. v. Boston Scientific Corp.*, 561 F.3d 1319, 1333, 90 U.S.P.Q.2d (BNA) 1401, 1411 (Fed. Cir. 2009) (citation and internal quotation marks omitted), *cert. denied*, 130 S. Ct. 749 (2009).

846. *In re Klopfenstein*, 380 F.3d 1345, 1350–51, 72 U.S.P.Q.2d (BNA) 1117, 1120–21 (Fed. Cir. 2004).

847. 561 F.3d 1319, 90 U.S.P.Q.2d (BNA) 1401 (Fed. Cir. 2009), *cert. denied*, 130 S. Ct. 749 (2009).

848. *Id.* at 1332–35, 90 U.S.P.Q.2d (BNA) 1401, 1411–13.

849. *Id.* at 1333, 90 U.S.P.Q.2d (BNA) at 1411.

850. *Id.* at 1334, 90 U.S.P.Q.2d (BNA) at 1412 (alteration in original) (citation omitted).

851. *Id.* at 1334–35, 90 U.S.P.Q.2d (BNA) at 1412–13.

company.⁸⁵² Nor was there any showing that these or similar commercial entities had made similar documents in the past available to the public.⁸⁵³ The court concluded that “[t]he mere fact that there was no legal obligation of confidentiality—all that was shown here—is not in and of itself sufficient to show that [the patentee’s] expectation of confidentiality was not reasonable.”⁸⁵⁴

The Federal Circuit also evaluated the requirements for a “printed publication” in *In re Lister*.⁸⁵⁵ The “printed publication” at issue in that case was a manuscript by the inventor that described his invention of a new method of playing golf.⁸⁵⁶ The inventor had submitted the manuscript to the United States Copyright Office with the objective of obtaining intellectual property protection.⁸⁵⁷ After learning that he needed to obtain a patent rather than a copyright to protect his invention, he filed a patent application describing the same invention in the USPTO more than two years after he submitted the manuscript to the Copyright Office.⁸⁵⁸

In determining whether the manuscript qualified as a printed publication, the court noted that there were three relevant databases to consider: the Copyright Office’s automated catalog and third-party databases Westlaw and Dialog, which obtained their data from the Copyright Office.⁸⁵⁹ Whereas the Copyright Office’s catalog was searchable only by an author’s last name or the first word of the work’s title, Westlaw and Dialog allowed for keyword searches of the full titles but not the full texts of the works.⁸⁶⁰ The government conceded that the search format of the Copyright Office’s catalog would not have guided a researcher interested in the inventor’s golfing method to the manuscript.⁸⁶¹ However, the Federal Circuit concluded that a reasonably diligent researcher could have found the manuscript in the Westlaw and Dialog databases, making it publicly accessible as of the date the manuscript was included in either Westlaw or Dialog.⁸⁶²

Turning then to the question of whether the manuscript was publicly accessible in Westlaw or Dialog more than one year prior to

852. *Id.*, 90 U.S.P.Q.2d (BNA) at 1412–13.

853. *Id.* at 1335, 90 U.S.P.Q.2d (BNA) at 1413.

854. *Id.*, 90 U.S.P.Q.2d (BNA) at 1413.

855. 583 F.3d 1307, 92 U.S.P.Q.2d (BNA) 1225 (Fed. Cir. 2009).

856. *Id.* at 1309, 92 U.S.P.Q.2d (BNA) at 1225–26.

857. *Id.* at 1309–10, 92 U.S.P.Q.2d (BNA) at 1226.

858. *Id.*, 92 U.S.P.Q.2d (BNA) at 1226.

859. *Id.* at 1315, 92 U.S.P.Q.2d (BNA) at 1230.

860. *Id.*, 92 U.S.P.Q.2d (BNA) at 1230.

861. *Id.*, 92 U.S.P.Q.2d (BNA) at 1230.

862. *Id.* at 1315–16, 92 U.S.P.Q.2d (BNA) at 1230–31.

the critical date, the court noted that there was no other evidence regarding the timing or process used by Westlaw or Dialog to incorporate the Copyright Office's information.⁸⁶³ Absent such evidence, the court determined that it could not conclude that the manuscript was publicly accessible prior to the critical date.⁸⁶⁴ The court also rejected the government's argument that it made a prima facie showing that the manuscript was included in the commercial databases shortly after the Copyright Office granted the certificate of registration that justified shifting the burden to Dr. Lister to present evidence to the contrary.⁸⁶⁵ In sum, the court found that all the evidence showed was that, at some point in time, the commercial databases incorporated the Copyright Office's automated catalog information about the Lister manuscript into their own databases.⁸⁶⁶ The court concluded that, absent any evidence pertaining to the general practices of Westlaw and Dialog regarding the timing of updates from the Copyright Office, the government's presumption that the manuscript was added to Westlaw and Dialog prior to the critical date would be "pure speculation."⁸⁶⁷

In *Iovate Health Sciences, Inc. v. Bio-Engineered Supplements & Nutrition*,⁸⁶⁸ the Federal Circuit addressed the issue of whether an advertisement published in a magazine anticipated the claimed use of certain health supplements.⁸⁶⁹ The claims at issue were directed to "[a] method for enhancing muscle performance or recovery from fatigue" using specified nutritional supplements.⁸⁷⁰ The district court ruled that the claims were invalid under 35 U.S.C. § 102(b) as anticipated by advertisements published before the critical date in *Flex Magazine*.⁸⁷¹ The ads included a list of ingredients, which identified the claimed nutritional supplements, directions for administering the supplements orally to humans, as well as claims and testimonials from bodybuilders regarding the supplements' effectiveness in promoting muscle protein synthesis and growth, building thick, dense muscle mass, and accelerating muscle recovery.⁸⁷²

863. *Id.* at 1316, 92 U.S.P.Q.2d (BNA) at 1231.

864. *Id.* at 1316–17, 92 U.S.P.Q.2d (BNA) at 1231.

865. *Id.* at 1317, 92 U.S.P.Q.2d (BNA) at 1231–32.

866. *Id.*, 92 U.S.P.Q.2d (BNA) at 1231–32.

867. *Id.*, 92 U.S.P.Q.2d (BNA) at 1232.

868. 586 F.3d 1376, 92 U.S.P.Q.2d (BNA) 1672 (Fed. Cir. 2009).

869. *Id.* at 1380, 92 U.S.P.Q.2d (BNA) at 1674.

870. *Id.* at 1378, 92 U.S.P.Q.2d (BNA) at 1673.

871. *Id.* at 1379–80, 92 U.S.P.Q.2d (BNA) at 1673–74.

872. *Id.* at 1379, 92 U.S.P.Q.2d (BNA) at 1674.

On appeal, Iovate argued mainly that the ads did not disclose each and every limitation of the claims or enable one of skill in the art to practice the claimed invention before the critical date.⁸⁷³ Specifically, Iovate relied on the preamble of the claims (enhancing muscle performance or recovery from fatigue) to argue that the ad's disclosure of promoting muscle synthesis and growth was not synonymous with "enhancing muscle performance," and that the ad's general concepts of muscle recuperation and postworkout recovery did not address the claim term enhancing "recovery from fatigue."⁸⁷⁴ The court rejected Iovate's argument as bordering on "frivolous," particularly noting that the specification and Iovate's infringement allegations refer to muscle strength as a proxy for "enhancing muscle performance."⁸⁷⁵ The court also rejected Iovate's attempt to avoid anticipation by reading an effectiveness requirement into the preamble, stating that the claims do not require any further measurement or determination of any result achieved by administering the claimed composition.⁸⁷⁶ The court found, moreover, that the ad's disclosure of a certain composition taken for a certain purpose with specific instructions regarding the administration and dosage of the supplement was sufficient for the purpose of anticipation.⁸⁷⁷

Regarding the enablement issue, Iovate argued that the ad lacked any guidance on appropriate ingredient dosages.⁸⁷⁸ The court again disagreed, stating that "all one of ordinary skill in the art would need to do to practice an embodiment of the invention is to mix together the known ingredients listed in the ad and administer the composition as taught by the ad."⁸⁷⁹ Even if the claims required an effectiveness element, "one of skill in the art would have been able to determine such an amount based on" the knowledge at the time and the ad's disclosure of the amount or dosage of the claimed components.⁸⁸⁰ The court concluded that, "[b]ecause no reasonable fact-finder could conclude other than that the . . . ad discloses each limitation of the claimed method in an enabling manner," the ad

873. *Id.* at 1380–81, 1383, 92 U.S.P.Q.2d (BNA) at 1675–77.

874. *Id.* at 1380–81, 92 U.S.P.Q.2d (BNA) at 1675.

875. *Id.* at 1381, 92 U.S.P.Q.2d (BNA) at 1675.

876. *Id.* at 1382, 92 U.S.P.Q.2d (BNA) at 1676.

877. *Id.*, 92 U.S.P.Q.2d (BNA) at 1676.

878. *Id.*, 92 U.S.P.Q.2d (BNA) at 1676.

879. *Id.* at 1382–83, 92 U.S.P.Q.2d (BNA) at 1676.

880. *Id.* at 1383, 92 U.S.P.Q.2d (BNA) at 1676.

qualified as a printed publication that invalidated the asserted claims.⁸⁸¹

2. *On sale or public use*

a. *Experimental use*

The Federal Circuit has applied a “totality of the circumstances” test to determine whether precritical date activity is experimental or commercial.⁸⁸² It has catalogued a set of instructive, and in certain cases dispositive, factors to determine the issue:

(1) [T]he necessity for public testing, (2) the amount of control over the experiment retained by the inventor, (3) the nature of the invention, (4) the length of the test period, (5) whether payment was made, (6) whether there was a secrecy obligation, (7) whether records of the experiment were kept, (8) who conducted the experiment, . . . (9) the degree of commercial exploitation during testing[,] . . . (10) whether the invention reasonably requires evaluation under actual conditions of use, (11) whether testing was systematically performed, (12) whether the inventor continually monitored the invention during testing, and (13) the nature of contacts made with potential customers.⁸⁸³

Of course, the outcome of applying such a thirteen-factor test, which necessarily involves certain balancing among the factors, is unpredictable and depends highly on the specific factual pattern of the case. In each specific case, the court does not necessarily consider all thirteen factors.

In *Clock Spring, L.P. v. Wrapmaster, Inc.*,⁸⁸⁴ the Federal Circuit found several factors dispositive and affirmed a district court’s grant of summary judgment of invalidity due to a prior demonstration.⁸⁸⁵ The court noted that the demonstration lasted after the patent application was filed, and that no report of the demonstration in any way suggested that the demonstration of the claimed invention was designed to test durability for the purposes of the patent application to the USPTO.⁸⁸⁶ Moreover, the Federal Circuit observed that the

881. *Id.*, 92 U.S.P.Q.2d (BNA) at 1677.

882. *See, e.g.*, *TP Labs., Inc. v. Prof'l Positioners, Inc.*, 724 F.2d 965, 972, 220 U.S.P.Q. 577, 582 (Fed. Cir. 1984) (“[A] decision on whether there has been a ‘public use’ can only be made upon consideration of the entire surrounding circumstances.”).

883. *Allen Eng’g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1353, 63 U.S.P.Q.2d 1269, 1779 (Fed. Cir. 2002) (alterations in original) (citation omitted).

884. 560 F.3d 1317, 90 U.S.P.Q.2d (BNA) 1212 (Fed. Cir. 2009).

885. *Id.* at 1324–29, 90 U.S.P.Q.2d (BNA) at 1215–19.

886. *Id.* at 1328, 90 U.S.P.Q.2d (BNA) at 1218 (internal quotation marks omitted).

reports clearly stated that the demonstration was to seek “input from people in the industry on the performance of the bands and the practicality of their installation techniques.”⁸⁸⁷ Accordingly, the Federal Circuit upheld the district court’s judgment that the demonstration for “acceptance by regulators and the pipeline industry” constituted commercial use that invalidated the patent.⁸⁸⁸

F. Novelty

1. An anticipatory reference

It has long been recognized that to destroy the novelty of a claimed invention, a reference must not only disclose each and every limitation of the claim, it must enable the subject of the invention it discloses. In the chemical context, for example, “[t]he mere naming of a compound in a reference, without more, cannot constitute a description of the compound.”⁸⁸⁹ However, the question arose as to whether being enabled means enabled for both “how to make” and “how to use” a chemical. The Federal Circuit addressed this question in *In re Gleave*,⁸⁹⁰ and held that anticipation requires only that the prior art enable the making of the invention without undue experimentation.⁸⁹¹ There is no additional requirement of enabling the use of the claimed invention.⁸⁹²

Gleave claimed antisense oligonucleotides generally “of sufficient length to act as an antisense inhibitor” of both human insulin growth factor binding protein-2 (IGFBP-2) and human IGFBP-5 synthesis (i.e., bispecificity).⁸⁹³ The Federal Circuit effectively read the prior art, a PCT application to Wraight, to disclose all of the claimed elements.⁸⁹⁴ All that remained with respect to the issue of

887. *Id.*, 90 U.S.P.Q.2d (BNA) at 1218 (internal quotation marks omitted).

888. *Id.* at 1328–29, 90 U.S.P.Q.2d (BNA) at 1218–19.

889. *In re Wiggins*, 488 F.2d 538, 543, 179 U.S.P.Q. (BNA) 421, 425 (C.C.P.A. 1973).

890. 560 F.3d 1331, 90 U.S.P.Q.2d (BNA) 1235 (Fed. Cir. 2009).

891. *Id.* at 1335, 90 U.S.P.Q.2d (BNA) at 1238–39.

892. *Id.*, 90 U.S.P.Q.2d (BNA) at 1238.

893. *Id.* at 1333, 90 U.S.P.Q.2d (BNA) at 1237.

894. *Id.* at 1336, 90 U.S.P.Q.2d (BNA) at 1239 (emphasis added). Wraight disclosed a list of every fifteen-base-long *sense* oligonucleotide in the IGFBP-2 gene. *Id.* at 1333, 90 U.S.P.Q.2d (BNA) at 1237. Although that list included more than 1400 sequences, Wraight disclosed “the general concepts that *antisense* oligonucleotides are preferably between fifteen and twenty-five bases in length, and that some antisense oligonucleotides may be bispecific (i.e., capable of inhibiting ‘an IGFBP such as IGFBP-2 and/or IGFBP-3’).” *Id.*, 90 U.S.P.Q.2d (BNA) at 1237. Wraight disclosed “that ‘[a]ntisense oligonucleotides to IGFBP-2 may be selected from molecules capable of interacting with one or more’ of the sense oligonucleotides described in the long list.” *Id.* at 1333–34, 90 U.S.P.Q.2d (BNA) at 1237 (alteration in original).

anticipation was enablement of the claimed invention by Wraight. For “composition of matter” claims, such as Gleave’s antisense oligonucleotides, the Federal Circuit stated that “a reference satisfies the enablement requirement of [35 U.S.C.] § 102(b) by showing that one of skill in the art would know how to make the relevant sequences disclosed in Wraight.”⁸⁹⁵ The court continued, explaining that “[a] thorough reading of our case law . . . makes clear that a reference need disclose no independent use or utility to anticipate a claim under § 102.”⁸⁹⁶ Since Gleave admitted that one of ordinary skill in the art can “make any oligodeoxynucleotide sequence,” the court found that Wraight provided an “enabling disclosure sufficient to anticipate Gleave’s invention under § 102(b).”⁸⁹⁷

In addition, the Federal Circuit distinguished the facts before it from the broad statement in *In re Wiggins*⁸⁹⁸ that the “mere naming of a compound in a reference, without more, cannot constitute a description of the compound.”⁸⁹⁹ The court indicated that “[w]ithout more’ is the key phrase,” and read the “more” as the ability of one skilled in the art to make the claimed compound.⁹⁰⁰ According to the Federal Circuit, “a person of ordinary skill in the art equipped with an IGFBP sequence is admittedly capable of envisioning how to make any antisense sequence.”⁹⁰¹

A claim that includes the transition term “comprising” does not preclude anticipation by a reference that discloses the claimed elements as well as certain features not expressly present in the claim.⁹⁰² In *Exergen Corp. v. Wal-Mart Stores, Inc.*,⁹⁰³ the claim at issue was directed to “[a] method of detecting temperature of biological tissue comprising,” among other steps, “electronically detecting the peak radiation from the multiple areas to obtain a peak temperature signal.”⁹⁰⁴ At trial, Exergen’s expert admitted that a prior art reference disclosed all limitations of the claim at issue except the electronically detecting step.⁹⁰⁵ Exergen argued that the prior art

895. *Id.* at 1336, 90 U.S.P.Q.2d (BNA) at 1239.

896. *Id.* at 1335, 90 U.S.P.Q.2d (BNA) at 1238.

897. *Id.* at 1336, 90 U.S.P.Q.2d (BNA) at 1239.

898. *In re Wiggins*, 488 F.2d 538, 179 U.S.P.Q. (BNA) 421 (C.C.P.A. 1973).

899. *In re Gleave*, 560 F.3d at 1337–38, 90 U.S.P.Q.2d (BNA) at 1240–41 (quoting *In re Wiggins*, 488 F.2d at 543, 179 U.S.P.Q. (BNA) at 425).

900. *Id.* at 1337, 90 U.S.P.Q.2d (BNA) at 1240.

901. *Id.* at 1338, 90 U.S.P.Q.2d (BNA) at 1240.

902. *See Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1318–30, 91 U.S.P.Q.2d (BNA) 1656, 1660–69 (Fed. Cir. 2009) (explaining that the term “comprising” means “including but not limited to” in the context of patent law).

903. 575 F.3d 1312, 91 U.S.P.Q.2d (BNA) 1656 (Fed. Cir. 2009).

904. *Id.* at 1318, 91 U.S.P.Q.2d (BNA) at 1660.

905. *Id.*, 91 U.S.P.Q.2d (BNA) at 1660.

method heated the probe unit to 98°F and that it was the radiation given off by the heated probe in addition to radiation from the patient that was detected.⁹⁰⁶ The Federal Circuit rejected this argument, finding that the use of the term “comprising” in the claim at issue did not require detection of radiation solely from the biological tissue, and thus did not prevent the reference from anticipating the claim.⁹⁰⁷ Regarding the claimed requirement that radiation be detected from multiple areas, the Federal Circuit also rejected Exergen’s contention that the reference method detected radiation only from a single spot.⁹⁰⁸ The court noted that Exergen’s expert admitted that the reference inherently disclosed this limitation because the device necessarily detected radiation from the patient’s face, outer ear, and ear canal as the probe unit was moved into position in the ear canal.⁹⁰⁹ Accordingly, the court held that the claim at issue was anticipated.⁹¹⁰

Conversely, in reversing a determination of anticipation by the Board, the Federal Circuit pointed out that “comprising” does not render a claim to be anticipated by a device that contains less than what is claimed.⁹¹¹

2. *Product-by-process claims*

In *F. Hoffman-La Roche Ltd.*, discussed above, the Federal Circuit addressed the question of whether the product patent claims at issue were anticipated by the prior art teaching of an erythropoietin (EPO) purified from a different source.⁹¹² The Federal Circuit acknowledged that an old product is not patentable even if it is made by a new process, but pointed out that “a new product may be patented by reciting source or process limitations so long as the product is new and unobvious.”⁹¹³ The district court construed the claims at issue to include a source limitation wherein said EPO is “purified from mammalian cells grown in culture.”⁹¹⁴ The specification, prosecution history, and expert testimony indicated that EPO purified from mammalian cells had a higher

906. *Id.* at 1318–19, 91 U.S.P.Q.2d (BNA) at 1660–61.

907. *Id.* at 1319, 91 U.S.P.Q.2d (BNA) at 1661.

908. *Id.* at 1319–20, 91 U.S.P.Q.2d (BNA) at 1661.

909. *Id.*, 91 U.S.P.Q.2d (BNA) at 1661.

910. *Id.* at 1316, 91 U.S.P.Q.2d (BNA) at 1659.

911. *In re Skvorecz*, 580 F.3d 1262, 1268, 92 U.S.P.Q.2d (BNA) 1020, 1024 (Fed. Cir. 2009).

912. *Amgen Inc. v. F. Hoffmann-La Roche Ltd.*, 580 F.3d 1340, 1366–67, 92 U.S.P.Q.2d (BNA) 1289, 1309–10 (Fed. Cir. 2009).

913. *Id.*, 92 U.S.P.Q.2d (BNA) at 1310.

914. *Id.* at 1367, 92 U.S.P.Q.2d (BNA) at 1310 (internal quotation marks omitted).

molecular weight and different charge than urinary EPO due to differences in carbohydrate composition.⁹¹⁵ The court found that this distinction was sufficient to impart novelty on the claimed products.⁹¹⁶

3. *Subject matter incorporated by reference*

For the purpose of anticipation, “[m]aterial not explicitly contained in the single, prior art document may still be considered . . . if that material is incorporated by reference into the document.”⁹¹⁷ To incorporate matter by reference, “[a] host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents.”⁹¹⁸ In *Callaway Golf Co. v. Acushnet Co.*,⁹¹⁹ the Federal Circuit considered whether and what subject matter from an incorporated patent could be used in assessing novelty based on the main prior art patent.⁹²⁰ The court acknowledged that “language nearly identical to that used in [the main prior art patent] (‘[r]eference is made to’) can be sufficient to indicate to one of skill in the art that the referenced material is fully incorporated in the host document.”⁹²¹ After considering the passages of the prior art patent, the court found that the patent identified with specificity both what material was being incorporated by reference and where it could be found (in the referenced patent).⁹²² Accordingly, the Federal Circuit held that the prior art patent incorporated by reference the material described in the referenced patent and remanded the case for further proceedings to decide whether the prior art patent with the incorporated subject matter anticipated the claimed invention.⁹²³

G. *Obviousness*

In 2007, the Supreme Court, in *KSR International Co. v. Teleflex Inc.*,⁹²⁴ significantly tempered the impact on the so-called “teaching,

915. *Id.*, 92 U.S.P.Q.2d (BNA) at 1310.

916. *Id.*, 92 U.S.P.Q.2d (BNA) at 1310.

917. *Callaway Golf Co. v. Acushnet Co.*, 576 F.3d 1331, 1346, 91 U.S.P.Q.2d (BNA) 1705, 1716–17 (Fed. Cir. 2009) (alteration in original) (citation omitted), *cert. denied*, 78 U.S.L.W. 3374 (U.S. Feb. 22, 2010) (No. 09-702).

918. *Id.*, 91 U.S.P.Q.2d (BNA) at 1717.

919. 576 F.3d 1331, 91 U.S.P.Q.2d (BNA) 1705 (Fed. Cir. 2009), *cert. denied*, 78 U.S.L.W. 3374 (U.S. Feb. 22, 2010) (No. 09-702).

920. *Id.* at 1346–48, 91 U.S.P.Q.2d (BNA) at 1716–18.

921. *Id.* at 1346, 91 U.S.P.Q.2d (BNA) at 1717 (second alteration in original).

922. *Id.*, 91 U.S.P.Q.2d (BNA) at 1717.

923. *Id.* at 1348, 91 U.S.P.Q.2d (BNA) at 1718.

924. 550 U.S. 398, 82 U.S.P.Q.2d (BNA) 1385 (2007).

suggestion, motivation” test when assessing the obviousness of a claimed invention under 35 U.S.C. § 103.⁹²⁵ The Court implemented a more flexible approach centered around four factors articulated in the seminal case of *Graham v. John Deere Co.*⁹²⁶: (1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; (3) the level of ordinary skill in the art, and (4) objective evidence (sometimes referred to as secondary considerations) of nonobviousness.⁹²⁷ Though tempered, motivation to make a claimed invention is still a necessary component to the obviousness determination. A prima facie case of obviousness requires a showing of both “motivat[ion] to combine the teachings of the prior art . . . to achieve the claimed invention, and . . . a reasonable expectation of success in doing so.”⁹²⁸

This Section covers cases dealing with these two requirements, as well as those touching on questions of “obvious to try,” which constitute an important change in the obviousness calculus wrought by *KSR*. The Section concludes with a discussion of cases that involve objective evidence or indicia of nonobviousness.

1. *Lack of motivation*

In *Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc.*,⁹²⁹ the Federal Circuit affirmed the trial court’s decision that a new compound for treatment of osteoporosis was not obvious over a related positional isomer⁹³⁰ “because a person having ordinary skill in the art would not have had reason to make [the new compound] based on the prior art.”⁹³¹ The patent-in-suit, U.S. Patent No. 5,583,122 (“the ‘122 patent”), claimed risedronate, a 3-pyr EHDP, as the active ingredient of an osteoporosis drug marketed under the trademark ACTONEL.⁹³² Teva alleged that the ‘122 patent was invalid as obvious in light of another Procter & Gamble patent, U.S. Patent No. 4,761,406 (“the ‘406 patent”).⁹³³ The ‘406 patent identified the positional isomer, 2-pyr EHDP, in a list of eight

925. *Id.* at 399, 82 U.S.P.Q.2d (BNA) at 1391.

926. 383 U.S. 1, 17–18, 148 U.S.P.Q. (BNA) 459, 467 (1966).

927. 550 U.S. at 399, 82 U.S.P.Q.2d (BNA) at 1388.

928. *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 994, 90 U.S.P.Q.2d (BNA) 1947, 1949 (Fed. Cir. 2009) (citation omitted).

929. 566 F.3d 989, 90 U.S.P.Q.2d (BNA) 1947 (Fed. Cir. 2009).

930. Positional isomers are chemical compounds that contain the same atoms arranged in different ways.

931. *Procter & Gamble Co.*, 566 F.3d at 995, 90 U.S.P.Q.2d (BNA) at 1950.

932. *Id.* at 992, 90 U.S.P.Q.2d (BNA) at 1948.

933. *Id.* at 992–93, 90 U.S.P.Q.2d (BNA) at 1948.

compounds as preferred to treat osteoporosis.⁹³⁴ Thus, the issue was the obviousness of the claimed 3-pyr EHDP in view of the known isomer, 2-pyr EHDP. Essentially, the difference between the compounds resided in the relative position of a nitrogen atom.

The Federal Circuit recognized that “[s]tructural relationships often provide the requisite motivation to modify known compounds to obtain new compounds.”⁹³⁵ Although that might occur, it did not occur here where the structural similarity was contrasted with unpredictable properties for the class of compounds at issue (biphosphonates).⁹³⁶ The court found that “[b]ecause the nitrogen atom is in a different position in the two molecules, they differ in three dimensional shape, charge distribution and hydrogen bonding properties.”⁹³⁷ It also noted that biphosphonates are compounds of “extremely unpredictable nature.”⁹³⁸ That unpredictability was confirmed by the closely structurally related 4-pyr EHDP, which showed no activity in an assay used to screen a compound’s ability to treat osteoporosis.⁹³⁹ Quoting *Eisai Co. v. Dr. Reddy’s Laboratories, Ltd.*,⁹⁴⁰ the Federal Circuit stated that, “[t]o the extent an art is unpredictable, as the chemical arts often are, *KSR*’s focus on [] ‘identified, predictable solutions’ may present a difficult hurdle because potential solutions are less likely to be genuinely predictable.”⁹⁴¹ Agreeing with the district court that Teva failed to clear the unpredictability hurdle, the Federal Circuit affirmed the lower court’s ruling that Teva established an “insufficient motivation for a person of ordinary skill to synthesize and test [the claimed 3-pyr EHDP].”⁹⁴²

Not all patents are so well-served by an unpredictable field of art. Post-*KSR*, patents in more predictable fields seem to have fallen on difficult times. Indeed, in reversing a trial court’s denial of summary judgment of invalidity on a patent directed to a candle tin, the Federal Circuit in *Ball Aerosol & Specialty Container, Inc. v. Ltd. Brands, Inc.*,⁹⁴³ referred to the lower court’s characterization of the

934. *Id.* at 993, 90 U.S.P.Q.2d (BNA) at 1948–49.

935. *Id.* at 995, 90 U.S.P.Q.2d (BNA) at 1950 (quoting *In re Mayne*, 104 F.3d 1339, 1343, 41 U.S.P.Q.2d (BNA) 1451, 1454 (Fed. Cir. 1997)).

936. *Id.* at 995–96, 90 U.S.P.Q.2d (BNA) at 1950–51.

937. *Id.* at 995, 90 U.S.P.Q.2d (BNA) at 1950.

938. *Id.* at 993, 90 U.S.P.Q.2d (BNA) at 1949.

939. *Id.* at 996, 90 U.S.P.Q.2d (BNA) at 1951.

940. 533 F.3d 1353, 1359, 87 U.S.P.Q.2d (BNA) 1452, 1457 (Fed. Cir. 2008).

941. *Proctor & Gamble Co.*, 566 F.3d at 996, 90 U.S.P.Q.2d (BNA) at 1951 (alteration in original) (citation omitted).

942. *Id.*, 90 U.S.P.Q.2d (BNA) at 1951.

943. 555 F.3d 984, 89 U.S.P.Q.2d (BNA) 1870 (Fed. Cir. 2009).

patented technology as “simple and easily understandable.”⁹⁴⁴ The patent-in-suit claimed a candle tin with a removable cover and protrusions (or feet) on the bottom of the tin.⁹⁴⁵ The cover also acted as a base for the candle tin.⁹⁴⁶ The patent also claimed putting the candle tin (protrusion side) on top of the cover.⁹⁴⁷ That arrangement was said to minimize scorching that could otherwise occur if a lit candle tin was placed directly on a surface.⁹⁴⁸ Citing *KSR*, the Federal Circuit found that putting feet on the bottom of the candle tin and using the cover as a base was a predictable variation that was obvious to the skilled person, particularly since the prior art taught raising a candle holder off of a supporting surface to avoid scorching.⁹⁴⁹

In *Boston Scientific Scimed, Inc. v. Cordis Corp.*,⁹⁵⁰ the Federal Circuit reversed the district court’s denial of Cordis’s motion for judgment as a matter of law, finding the patented invention obvious in view of a prior art patent showing two adjacent figures that together disclosed all the elements of that claim.⁹⁵¹ The claim at issue was directed to a stent coated with an undercoat that incorporated a biologically active material and a topcoat comprising a non-thrombogenic material that provided “long term non-thrombogenicity . . . during and after release of the biologically active material.”⁹⁵² Specifically, Figure 3B of the prior art document “Wolff” showed “a polymer stent made of a drug-eluting polymer with a barrier topcoat.”⁹⁵³ Figure 4 of Wolff showed “a metallic stent with a drug-eluting polymer coating.”⁹⁵⁴ The court found that all of the limitations of the claim at issue were found in two separate embodiments pictured side-by-side in Wolff, not in one embodiment.⁹⁵⁵ Nevertheless, the court explained that “[c]ombining two embodiments disclosed adjacent to each other in a prior art patent does not require a leap of inventiveness.”⁹⁵⁶ The court concluded that a person of ordinary skill would have been motivated to coat the metal stent of Figure 4, including its layer of

944. *Id.* at 992, 89 U.S.P.Q.2d (BNA) at 1876 (internal quotation marks omitted).

945. *Id.* at 986, 89 U.S.P.Q.2d (BNA) at 1872.

946. *Id.*, 89 U.S.P.Q.2d (BNA) at 1872.

947. *Id.*, 89 U.S.P.Q.2d (BNA) at 1872.

948. *Id.*, 89 U.S.P.Q.2d (BNA) at 1872.

949. *Id.* at 992–93, 89 U.S.P.Q.2d (BNA) at 1876.

950. 554 F.3d 982, 89 U.S.P.Q.2d (BNA) 1704 (Fed. Cir. 2009), *cert. dismissed*, 130 S. Ct. 50 (2009).

951. *Id.* at 988–92, 89 U.S.P.Q.2d (BNA) at 1710–13.

952. *Id.* at 984, 89 U.S.P.Q.2d (BNA) at 1706.

953. *Id.* at 988, 89 U.S.P.Q.2d (BNA) at 1710.

954. *Id.*, 89 U.S.P.Q.2d (BNA) at 1710.

955. *Id.* at 991, 89 U.S.P.Q.2d (BNA) at 1712.

956. *Id.*, 89 U.S.P.Q.2d (BNA) at 1712.

drug-containing polymer, with a second layer of polymer, like the layer depicted in Figure 3B, to arrive at the patented invention.⁹⁵⁷

Even scintillating new chemical technology used to increase lubricity of sexual devices did not avoid the post-*KSR* obviousness rub. In *Ritchie v. Vast Resources, Inc.*,⁹⁵⁸ the patent at issue claimed a “sexual aid . . . fabricated of a generally lubricious glass-based material containing an appreciable amount of an oxide of boron to render it lubricious and resistant to heat, chemicals, electricity and bacterial absorptions.”⁹⁵⁹ Until the patentee began manufacturing the patented sexual devices, “glass sexual devices were made out of soda-lime glass, the most common form of glass.”⁹⁶⁰ In the court’s view, “[t]his class of inventions is well illustrated by efforts at routine experimentation with different standard grades of a material used in a product-standard in the sense that their properties, composition, and method of creation are well known, making successful results of the experimentation predictable.”⁹⁶¹ The court concluded that, because borosilicate glass (an oxide of boron) is a “standard product with well-known properties,” including those listed in the patent, “to experiment with substituting borosilicate glass for ordinary glass in a sexual device was not a venture into the unknown.”⁹⁶²

In *Fresenius USA, Inc. v. Baxter International, Inc.*,⁹⁶³ discussed previously, the Federal Circuit reversed the district court’s determination that Fresenius had failed to demonstrate the required motivation to combine prior art elements in support of the jury’s obviousness determination.⁹⁶⁴ Although the district court issued its opinion before *KSR* was decided, the Federal Circuit noted that it remains appropriate post-*KSR* “to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.”⁹⁶⁵

The patented inventions covered “a hemodialysis machine integrated with a touch screen user interface.”⁹⁶⁶ In support of its

957. *Id.*, 89 U.S.P.Q.2d (BNA) at 1712.

958. 563 F.3d 1334, 90 U.S.P.Q.2d (BNA) 1668 (Fed. Cir. 2009), *cert. denied*, 130 S. Ct. 269 (2009).

959. *Id.* at 1335–36, 90 U.S.P.Q.2d (BNA) at 1668 (alteration in original).

960. *Id.* at 1335, 90 U.S.P.Q.2d (BNA) at 1668.

961. *Id.* at 1337, 90 U.S.P.Q.2d (BNA) at 1669.

962. *Id.*, 90 U.S.P.Q.2d (BNA) at 1669.

963. 582 F.3d 1288, 92 U.S.P.Q.2d (BNA) 1163 (Fed. Cir. 2009), *petition for cert. filed*, 78 U.S.L.W. 3550 (U.S. Feb. 16, 2010) (No. 09-1096).

964. *Id.* at 1301–02, 92 U.S.P.Q.2d (BNA) at 1173–74.

965. *Id.* at 1300, 92 U.S.P.Q.2d (BNA) at 1173 (quoting *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418, 82 U.S.P.Q.2d (BNA) 1385, 1396 (2007)) (internal quotation marks omitted).

966. *Id.* at 1300, 92 U.S.P.Q.2d (BNA) at 1166.

obviousness argument, Fresenius presented a prior art publication that disclosed a touch screen interface on an anesthesia-delivery system.⁹⁶⁷ The publication mentioned that advancing areas of medicine, such as hemodialysis, could benefit from an improved user interface.⁹⁶⁸ Fresenius also presented evidence describing the ease and prevalence of “integrating a touch screen into some kind of a computer-controlled machine,” such as a hemodialysis machine.⁹⁶⁹

The Federal Circuit explained that, “[u]nder *KSR*, ‘if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.’”⁹⁷⁰ The court reasoned that the jury had “implicitly found that the prior art suggested combining a touch screen with . . . a hemodialysis machine.”⁹⁷¹ That finding was supported by substantial evidence because a reasonable jury could have concluded that the publication contained an explicit suggestion to combine the benefits of a touch screen interface with a hemodialysis machine.⁹⁷² Based on the testimony, the jury could also have reasonably concluded that an “ordinarily skilled artisan would have known how to make” that same combination.⁹⁷³

2. *Reasonable expectation of success*

One challenging a patent for obviousness must clearly and convincingly prove that a person of ordinary skill in the art would have had both “motivat[ion] to combine the teachings of the prior art . . . to achieve the claimed invention, and . . . a reasonable expectation of success in doing so.”⁹⁷⁴ The Federal Circuit in *Procter & Gamble* not only agreed with the district court’s finding of a lack of motivation, it also concluded that “there was an insufficient showing

967. *Id.* at 1301, 92 U.S.P.Q.2d (BNA) at 1173.

968. *Id.*, 92 U.S.P.Q.2d (BNA) at 1173–74.

969. *Id.* at 1301, 92 U.S.P.Q.2d (BNA) at 1174 (internal quotation marks omitted).

970. *Id.*, 92 U.S.P.Q.2d (BNA) at 1174 (quoting *KSR*, 550 U.S. at 417, 82 U.S.P.Q.2d (BNA) at 1389).

971. *Id.*, 92 U.S.P.Q.2d (BNA) at 1174.

972. *Id.*, 92 U.S.P.Q.2d (BNA) at 1174.

973. *Id.*, 92 U.S.P.Q.2d (BNA) at 1174.

974. *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 994, 90 U.S.P.Q.2d (BNA) 1947, 1949 (Fed. Cir. 2009) (quoting *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361, 82 U.S.P.Q.2d (BNA) 1321, 1330 (Fed. Cir. 2007)) (internal quotation marks omitted).

that a person of ordinary skill in the art would have had a ‘reasonable expectation of success’ in synthesizing and testing risedronate.”⁹⁷⁵

3. *Obvious to try*

“Obvious to try” does not equate with obviousness, even after *KSR*. The Federal Circuit in *In re Kubin*⁹⁷⁶ addressed two scenarios where “obvious to try” would not lead to a holding of obviousness.⁹⁷⁷ In the first class of scenarios, a challenger to an invention’s obviousness “merely throws metaphorical darts at a board filled with combinatorial prior art possibilities,” though the prior art provides no guidance or direction as to which of many possible choices is likely to be successful.⁹⁷⁸ That situation should be contrasted, however, with a situation referred to by the Supreme Court in *KSR* “where a skilled artisan merely pursues ‘known options’ from a ‘finite number of identified, predictable solutions.’”⁹⁷⁹ A second “obvious to try” scenario envisioned by the court that should not result in a holding of obviousness occurs where “what was ‘obvious to try’ was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.”⁹⁸⁰

In *In re Kubin*, the Federal Circuit did not find that the claimed invention fit into either of these two scenarios. *Kubin*’s invention was directed to a genus of isolated polynucleotides encoding a protein that binds CD48 and was at least eighty percent identical to the disclosed amino acid sequence for the CD48-binding region of Natural Killer Cell Activation Inducing Ligand (NAIL).⁹⁸¹ The court found that the prior art disclosed the protein of interest, “a motivation to isolate the gene coding for that protein, and illustrative instructions to use a monoclonal antibody specific to the protein for cloning th[e] gene.”⁹⁸² On that record, the Federal Circuit concluded that deriving the claimed invention in light of the

975. *Id.* at 996, 90 U.S.P.Q.2d (BNA) at 1951 (quoting *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1360, 83 U.S.P.Q.2d (BNA) 1289, 1301 (Fed. Cir. 2007)).

976. 561 F.3d 1351, 90 U.S.P.Q.2d (BNA) 1417 (Fed. Cir. 2009).

977. *Id.* at 1359, 90 U.S.P.Q.2d (BNA) at 1423 (citing *In re O’Farrell*, 853 F.2d 894, 903, 7 U.S.P.Q.2d (BNA) 1673, 1680–81 (Fed. Cir. 1988)).

978. *Id.* at 1359, 90 U.S.P.Q.2d (BNA) at 1423.

979. *Id.*, 90 U.S.P.Q.2d (BNA) at 1423 (quoting *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 421, 82 U.S.P.Q.2d (BNA) 1385, 1397 (2007)).

980. *Id.*, 90 U.S.P.Q.2d (BNA) at 1423 (quoting *In re O’Farrell*, 853 F.2d at 903, 7 U.S.P.Q.2d at 1681).

981. *Id.* at 1352–53, 90 U.S.P.Q.2d (BNA) at 1418.

982. *Id.* at 1356–61, 90 U.S.P.Q.2d (BNA) at 1421–24.

prior art would have been reasonably expected.⁹⁸³ In addition, the court declined to limit *KSR* to the “‘predictable arts’ (as opposed to the ‘unpredictable art’ of biotechnology)” and noted that the record showed that one of skill in that advanced art would have found the claimed results predictable.⁹⁸⁴ It further noted that it would not, “in the face of *KSR*, cling to formalistic rules for obviousness, customize its legal tests for specific scientific fields in ways that deem entire classes of prior art teachings irrelevant, or discount the significant abilities of artisans of ordinary skill in an advanced area of art.”⁹⁸⁵

In a case dealing with formulation chemistry and pharmaceuticals, the Federal Circuit found that the art presented a finite number of predictable solutions the skilled person would have tried in arriving at the claimed invention.⁹⁸⁶ In *Bayer Schering Pharma AG v. Barr Laboratories, Inc.*,⁹⁸⁷ the patent covered a micronized, uncoated formulation of a known compound, drospirenone.⁹⁸⁸ The formulation was sold by Bayer as an oral contraceptive.⁹⁸⁹ Drospirenone was poorly bioavailable.⁹⁹⁰ It was known that micronizing could improve the bioavailability of compounds that were poorly absorbed into the blood stream.⁹⁹¹ Drospirenone, however, was also an acid-sensitive compound known to be susceptible to degradation in the gastric acid juices of the stomach.⁹⁹² Enteric coatings, therefore, were typically used to avoid degradation of acid-sensitive compounds, allowing them to pass through the stomach and be absorbed through the intestines and into the blood stream.⁹⁹³

Bayer stated that the innovative aspect of the patented invention was that micronized drospirenone demonstrated the same bioavailability as enteric-coated drospirenone and could be administered as a normal, uncoated pill.⁹⁹⁴ That, according to Bayer,

983. *Id.* at 1360, 90 U.S.P.Q.2d (BNA) at 1424.

984. *Id.*, 90 U.S.P.Q.2d (BNA) at 1424.

985. *Id.*, 90 U.S.P.Q.2d (BNA) at 1424.

986. *Bayer Schering Pharma AG v. Barr Labs., Inc.*, 575 F.3d 1341, 1350, 91 U.S.P.Q.2d (BNA) 1569, 1574–75 (Fed. Cir. 2009), *petition for cert. filed*, 78 U.S.L.W. 3523 (U.S. Feb. 23, 2010) (No. 09-1022).

987. 575 F.3d 1341, 91 U.S.P.Q.2d (BNA) 1569 (Fed. Cir. 2009), *petition for cert. filed*, 78 U.S.L.W. 3523 (U.S. Feb. 23, 2010) (No. 09-1022).

988. *Id.* at 1345, 91 U.S.P.Q.2d (BNA) at 1571.

989. *Id.* at 1343, 91 U.S.P.Q.2d (BNA) at 1569.

990. *Id.*, 91 U.S.P.Q.2d (BNA) at 1570.

991. *Id.* at 1343–44, 91 U.S.P.Q.2d (BNA) at 1570.

992. *Id.* at 1343, 91 U.S.P.Q.2d (BNA) at 1570.

993. *Id.* at 1344, 91 U.S.P.Q.2d (BNA) at 1570.

994. *Id.* at 1345–48, 91 U.S.P.Q.2d (BNA) at 1571–73.

was unexpected and contrary to the teachings in the prior art.⁹⁹⁵ Defendant Barr countered that it would have been obvious to try an uncoated micronized pill because “enteric coating is so complicated, expensive, cumbersome to manufacture, and prone to variability that it only would be used as a last resort by formulation scientists working with an acid-sensitive drug.”⁹⁹⁶

The Federal Circuit found that while Bayer argued that the “prior art teaches away from using micronized drospirenone[,]” and Barr argued that the “prior art teaches away from using an enteric coating[,]” the parties actually presented the two options available to a pharmaceutical formulator to solve the problem of acid-sensitive but hydrophobic drospirenone.⁹⁹⁷ The panel majority explained that, “[a]t this point, a person having ordinary skill in the art . . . must choose between two known options: delivery of micronized drospirenone by a normal pill . . ., or delivery of drospirenone by an enteric-coated pill,” and concluded that “[b]ecause the selection of micronized drospirenone in a normal pill led to the result anticipated by the [prior art], the invention would have been obvious.”⁹⁹⁸

In a decision concerning a method of managing bulk email (“spam”), the Federal Circuit held that when a method claim is limited to repeating previously known steps, there is a “finite number of identified, predictable solutions” suggesting that the method would have been obvious to try.⁹⁹⁹ In *Perfect Web Technologies, Inc. v. InfoUSA, Inc.*,¹⁰⁰⁰ the sole independent claim of the patent at issue, as summarized by the court, was drawn to a method of managing bulk email distribution comprising the steps of: (1) targeting a group or recipients, (2) sending email to the recipients, (3) calculating the number of successfully delivered emails, and (4) repeating steps (1)–(3) until the number of successfully delivered emails exceeds a predetermined value.¹⁰⁰¹ Neither party disputed that the sole prior art reference disclosed the first three steps of the claim but failed to disclose the final step.¹⁰⁰² Additionally, both parties understood that

995. *Id.* at 1347–48, 91 U.S.P.Q.2d (BNA) at 1573.

996. *Id.* at 1348, 91 U.S.P.Q.2d (BNA) at 1573–74.

997. *Id.* at 1349, 91 U.S.P.Q.2d (BNA) at 1574.

998. *Id.* at 1350, 91 U.S.P.Q.2d (BNA) at 1575–76.

999. *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1331–32, 92 U.S.P.Q.2d (BNA) 1849, 1855 (Fed. Cir. 2009) (quoting *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 421, 82 U.S.P.Q.2d (BNA) 1385, 1397 (2007)) (internal quotation marks omitted).

1000. 587 F.3d 1324, 92 U.S.P.Q.2d (BNA) 1849 (Fed. Cir. 2009).

1001. *Id.* at 1326, 92 U.S.P.Q.2d (BNA) at 1851.

1002. *Id.* at 1327, 92 U.S.P.Q.2d (BNA) at 1852.

the level of skill in the art was relatively low.¹⁰⁰³ Against this factual background, the court held that merely repeating the known process to obtain better results was obvious to try.¹⁰⁰⁴ Citing *In re Kubin*, the court found no evidence that one of skill in the art would have needed to “vary all parameters or try each of numerous possible choices,” or “explore a new technology or general approach . . . where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.”¹⁰⁰⁵ Thus, the court concluded that the claim was obvious to try.¹⁰⁰⁶

4. *Teaching all claimed limitations*

Sometimes overlooked by parties seeking to establish obviousness is the requirement that the resultant modification of the prior art must embody all of the elements of the claimed invention. In *Süd-Chemie, Inc. v. Multisorb Technologies, Inc.*,¹⁰⁰⁷ the Federal Circuit vacated the district court’s grant of summary judgment that Süd-Chemie’s patent was invalid for obviousness because the prior art did not teach using materials with a specifically claimed property.¹⁰⁰⁸ The district court ruled that Süd-Chemie’s patent, directed to desiccant containers requiring a laminate formed from combining “compatible” films/materials, was obvious over a single prior art patent to Komatsu.¹⁰⁰⁹ The lower court construed “compatible” to mean films/materials capable of “mix[ing] on a molecular scale” with similar “softening points.”¹⁰¹⁰ Komatsu disclosed materials in the same class described in Süd-Chemie’s patent, but it failed to disclose combining materials with similar softening points. The Komatsu materials “are different in a way that the [Süd-Chemie] patent treats as important to the invention.”¹⁰¹¹ Having failed to recognize that Komatsu disclosed “the use of incompatible materials” where the Süd-Chemie patent required compatible materials, the district court incorrectly concluded that Komatsu “teaches the same container as that claimed in the [Süd-Chemie] patent.”¹⁰¹²

1003. *Id.*, 92 U.S.P.Q.2d (BNA) at 1852.

1004. *Id.* at 1331, 92 U.S.P.Q.2d (BNA) at 1855.

1005. *Id.*, 92 U.S.P.Q.2d (BNA) at 1855 (internal citation and quotation marks omitted).

1006. *Id.*, 92 U.S.P.Q.2d (BNA) at 1855.

1007. 554 F.3d 1001, 89 U.S.P.Q.2d (BNA) 1768 (Fed. Cir. 2009).

1008. *Id.* at 1004, 89 U.S.P.Q.2d (BNA) at 1770–71.

1009. *Id.* at 1003–04, 89 U.S.P.Q.2d (BNA) at 1069–70.

1010. *Id.* at 1006, 89 U.S.P.Q.2d (BNA) at 1772.

1011. *Id.* at 1008, 89 U.S.P.Q.2d (BNA) at 1773.

1012. *Id.*, 89 U.S.P.Q.2d (BNA) at 1774.

In *Source Search Technologies*, the Federal Circuit held that material factual disputes precluded summary judgment on obviousness with respect to a computerized service that matches potential buyers with potential vendors over a network.¹⁰¹³ The claimed method included sending over a data network a request for a quotation from a potential buyer, filtering the request to ascertain a set of potential sellers, obtaining quotes from potential sellers, and forwarding the quotes to the potential buyer.¹⁰¹⁴ The claimed method purported to return a manageable and sufficient number of search results, addressing the common problems encountered by Internet search engines, which usually return either “too little” or “too much” information.¹⁰¹⁵ The district court ruled by summary judgment that the claim was obvious over two sets of prior art references: the e-commerce prior art (early e-commerce systems employing the Internet for access and distribution of information), and the bricks and mortar prior art (pre-Internet referral services, such as home contractor networks or social services networks).¹⁰¹⁶ The Federal Circuit vacated and remanded.¹⁰¹⁷

The Federal Circuit’s decision focused on the claimed term “quotes” and on the step of “filtering.” The district court did not specifically construe the term “quotes,” but from the context, the Federal Circuit inferred that that term should be construed as “price and other terms of a particular transaction in sufficient detail to constitute an offer capable of acceptance.”¹⁰¹⁸ The court found that none of the prior-art-returned quotes were ready to be accepted in a contractual sense.¹⁰¹⁹ Specifically, the court rejected the accused infringer’s argument that the “patent disclose[d] nothing more than a computerized version of the bricks and mortar prior art.”¹⁰²⁰ The court noted that those bricks and mortar prior-art network services merely connected the client and potential service provider without providing any quotes before a potential client could meet with the provider.¹⁰²¹

The court further recognized that, even if the prior art included a quoting feature, a person of ordinary skill in the art would still have

1013. *Source Search Techs. LLC v. LendingTree, LLC*, 588 F.3d 1063, 1066, 92 U.S.P.Q.2d (BNA) 1907, 1908–09 (Fed. Cir. 2009).

1014. *Id.*, 92 U.S.P.Q.2d (BNA) at 1909.

1015. *Id.* at 1066–67, 92 U.S.P.Q.2d (BNA) at 1909.

1016. *Id.* at 1069, 92 U.S.P.Q.2d (BNA) at 1911.

1017. *Id.* at 1066, 92 U.S.P.Q.2d (BNA) at 1909.

1018. *Id.* at 1071, 92 U.S.P.Q.2d (BNA) at 1913 (internal quotation marks omitted).

1019. *Id.* at 1072, 92 U.S.P.Q.2d (BNA) at 1913.

1020. *Id.*, 92 U.S.P.Q.2d (BNA) at 1913.

1021. *Id.*, 92 U.S.P.Q.2d (BNA) at 1913.

to take the step of “equating the ‘filtering’ done by human judgment in the bricks and mortar systems with the search results of the e-commerce procurement services.”¹⁰²² At the time of the invention, “the dawn of the internet era,” an ordinarily skilled person “may not have even recognized the problem addressed by the filtering feature of the claimed invention;” and even if the problem was recognized, the solution may not have been straightforward.¹⁰²³ The court therefore concluded that “[g]enuine issues of material fact related to the understanding of a person of ordinary skill, the character and number of the differences between the claimed invention and the prior art, and even the scope of those prior art references prevent a grant of summary judgment.”¹⁰²⁴

5. *Lead compound analysis*

In chemical cases, particularly those involving new chemical compounds, the obviousness determination starts with a selection by one skilled in the art that the chemical compound is the “lead compound” for further structural modification.¹⁰²⁵ Importantly, it does not have to be the structurally closest compound to the invention. Rather, it is a selection driven by what the state of the art would have suggested should be the lead compound.¹⁰²⁶ The “lead compound” determination can be pivotal—much like claim construction can be outcome determinative of infringement. Patentees have subsequently used this determination effectively to overcome what would appear to be very close structural obviousness predicaments.¹⁰²⁷

In 2009, the lead compound inquiry came up in the *Procter & Gamble* case, and while the Federal Circuit did not reach a decision

1022. *Id.* at 1072–73, 92 U.S.P.Q.2d (BNA) at 1913–14.

1023. *Id.* at 1073, 92 U.S.P.Q.2d (BNA) at 1914.

1024. *Id.*, 92 U.S.P.Q.2d (BNA) at 1914.

1025. *Eisai Co. v. Dr. Reddy’s Labs., Ltd.*, 533 F.3d 1353, 1359, 87 U.S.P.Q.2d (BNA) 1452, 1457 (Fed. Cir. 2008); *see, e.g.*, *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1355–60, 83 U.S.P.Q.2d (BNA) 1169, 1173–77 (Fed. Cir. 2007) (rejecting a competitor’s claim of obviousness because a person of ordinary skill in the art would not have selected the closest prior art compound as the lead compound for antidiabetic treatment).

1026. *See, e.g.*, *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1379, 81 U.S.P.Q.2d (BNA) 1324, 1330 (Fed. Cir. 2006) (finding that the state of the art directed the skilled person away from unfluorinated compounds (the closest prior art) because the state of the art suggested a preference for halogen containing compounds).

1027. *See Takeda*, 492 F.3d at 1355, 83 U.S.P.Q.2d (BNA) at 1173 (finding the claimed compound unobvious over positional isomer); *Eli Lilly*, 471 F.3d at 1377–78, 81 U.S.P.Q.2d (BNA) at 1329–30 (finding the claimed compound unobvious over adjacent homolog).

on the lead compound, it still recognized its viability. The court noted, “An obviousness argument based on structural similarity between claimed and prior art compounds ‘clearly depends on a preliminary finding that one of ordinary skill in the art would have selected [the prior art compound] as a lead compound.’”¹⁰²⁸

6. *Sufficiency of the articulated reasons supporting obviousness*

After *KSR* eliminated the requirement that there be some suggestion in the art to modify prior art teachings, practitioners feared that examiners and challengers to validity would toss out any basis, no matter how frail, to support a claim of obviousness. In a terse, nonprecedential opinion, without much explanation, the Federal Circuit concluded that “substantial evidence supports the Board’s finding that each disputed limitation is present in at least one of the references and that the Board’s opinion contained ‘articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.’”¹⁰²⁹ However, in the *Procter & Gamble* case, the Federal Circuit provided some guidance with respect to what is necessary when addressing the obviousness of new chemical compounds:

A known compound may suggest its homolog, analog, or isomer because such compounds often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties [However,] *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.*¹⁰³⁰

Subsequently, in *Perfect Web*, the Federal Circuit emphasized the need for courts to set forth their analysis, particularly when common sense is relied on to support a determination of obviousness.¹⁰³¹ In affirming the district court’s application of common sense, the Federal Circuit held that an obviousness determination under *Graham* “may include recourse to logic, judgment, and common sense available to the person of ordinary skill that do not necessarily

1028. *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 994, 90 U.S.P.Q.2d (BNA) 1947, 1950 (Fed. Cir. 2009) (alteration in original) (quoting *Takeda*, 492 F.3d at 1357, 83 U.S.P.Q.2d (BNA) at 1175).

1029. *In re Baggett*, 326 F. App’x 569, 570 (Fed. Cir. 2009) (quoting *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 418, 82 U.S.P.Q.2d (BNA) 1385, 1396 (2007)).

1030. *Procter & Gamble*, 566 F.3d at 995–96, 90 U.S.P.Q.2d (BNA) at 1950–51 (alterations in original) (emphasis added) (quoting *Takeda*, 492 F.3d at 1356–57, 83 U.S.P.Q.2d (BNA) at 1174).

1031. 587 F.3d 1324, 1330, 92 U.S.P.Q.2d (BNA) 1849, 1854 (Fed. Cir. 2009).

require explication in any reference or expert opinion.”¹⁰³² While the factual basis for reliance on common sense does not need to be explicit in any reference, the Federal Circuit specifically reiterated that a court’s analysis with respect to obviousness should be made explicit.¹⁰³³ The district court found that the prior art in *Perfect Web* disclosed the first three steps but not the last, which required repeating the first three until a predetermined value was obtained.¹⁰³⁴ On these facts, the Federal Circuit affirmed the district court’s finding that a person of skill in the art would have applied common sense to repeat those first three steps until a successful result was achieved.¹⁰³⁵

7. *Secondary considerations*

The Supreme Court in *KSR* instructed that an obviousness determination turns on four factors articulated in the seminal case of *Graham*.¹⁰³⁶ The fourth of these factors refers to so-called secondary considerations or objective indicia of patentability and includes: (1) commercial success; (2) long-felt but unsolved need; (3) failure of others; and (4) unexpected results.¹⁰³⁷ Objective indicia of nonobviousness “is not just a cumulative or confirmatory part of the obviousness calculus but constitutes independent evidence of nonobviousness.”¹⁰³⁸ Indeed, the Federal Circuit has stated that it “may often be the most probative and cogent evidence of nonobviousness in the record.”¹⁰³⁹

The following Subsections address the 2009 Federal Circuit cases dealing with these secondary indicia of nonobviousness and the particular issues they raise.

1032. *Id.* at 1329, 92 U.S.P.Q.2d (BNA) at 1854.

1033. *Id.* at 1330, 92 U.S.P.Q.2d (BNA) at 1854 (citing *Ball Aerosol & Specialty Container, Inc. v. Ltd. Brands, Inc.*, 555 F.3d 984, 993, 89 U.S.P.Q.2d (BNA) 1870, 1877 (Fed. Cir. 2009)).

1034. *Id.* at 1326, 92 U.S.P.Q.2d (BNA) at 1851.

1035. *Id.* at 1330, 92 U.S.P.Q.2d (BNA) at 1854.

1036. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406–07, 82 U.S.P.Q.2d (BNA) 1385, 1391 (2007) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17–18, 148 U.S.P.Q. (BNA) 459, 467 (1966)).

1037. *Graham*, 383 U.S. at 17, 148 U.S.P.Q. (BNA) at 467.

1038. *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1365, 86 U.S.P.Q.2d (BNA) 1196, 1202 (Fed. Cir. 2008).

1039. *Catalina Lighting, Inc. v. Lamps Plus, Inc.*, 295 F.3d 1277, 1288, 63 U.S.P.Q.2d (BNA) 1545, 1552 (Fed. Cir. 2002) (quoting *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1579, 42 U.S.P.Q.2d (BNA) 1378, 1384 (Fed. Cir. 1997)).

a. Commercial success

An invention's success in the marketplace can constitute independent, objective evidence of its nonobviousness. The rationale underlying the probative value of commercial success as part of the obviousness inquiry is that "the law presumes an idea would successfully have been brought to market sooner, in response to market forces, had the idea been obvious to persons skilled in the art."¹⁰⁴⁰ Relying on commercial success requires showing a "nexus" between the claimed invention and the commercial success. If the commercial success is due to an unclaimed feature of the device, it is irrelevant to the obviousness determination.¹⁰⁴¹ Additionally, if it can be shown that an impediment exists to parties other than the patentee to bring a related product to market, commercial success may not materially impact the obviousness analysis. A patentee owning prior art patents that block others from practicing an embodiment related to the patent for which commercial success is alleged may see the probative value of the commercial success evidence become diluted.¹⁰⁴² For example, in *Proctor & Gamble*, as discussed previously, the claimed invention covered compounds known as 3-pyr EHDP.¹⁰⁴³ Proctor & Gamble's commercial 3-pyr EHDP had undisputed commercial success, having amassed \$2.7 billion in aggregate domestic sales.¹⁰⁴⁴ Yet the Federal Circuit supported the lower court's decision to give little weight to this evidence. It reasoned that because the prior art, the positional isomer 2-pyr EHDP, was found only in a patent owned by Proctor & Gamble, the public could not freely work with and develop that prior art product.¹⁰⁴⁵

b. Long-felt need

Long-felt and unmet need constitutes another type of secondary indicia of nonobviousness. Wielded properly, such need can demonstrate unpredictability in the art to counter a prima facie showing of a reasonable expectation of success. But like commercial success, the long-felt need must have a nexus to the claimed invention. In *Boston Scientific*, the patentee pointed to the apparent

1040. *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1376, 73 U.S.P.Q.2d (BNA) 1641, 1651 (Fed. Cir. 2005).

1041. *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311–12, 79 U.S.P.Q.2d (BNA) 1931, 1941 (Fed. Cir. 2006).

1042. *Merck & Co.*, 395 F.3d at 1377, 73 U.S.P.Q.2d (BNA) at 1651.

1043. 566 F.3d 989, 996, 90 U.S.P.Q.2d (BNA) 1947, 1951 (Fed. Cir. 2009).

1044. *Id.* at 998, 90 U.S.P.Q.2d (BNA) at 1952.

1045. *Id.* at 998 n.2, 90 U.S.P.Q.2d (BNA) at 1953 n.2.

failure of others to design a drug-eluting stent as claimed, i.e., one having a drug-containing undercoat and a drug-free topcoat.¹⁰⁴⁶ The court found that the argument and evidence offered in support of long-felt need was not persuasive, noting that “the failure [of others] was due to the difficulty in finding a suitable drug, rather than an inability to conceive of a drug-containing undercoat combined with a drug-free topcoat.”¹⁰⁴⁷

Long-felt need is assessed no later than the filing date of the patent application directed to the invention in question.¹⁰⁴⁸ In *Procter & Gamble*, the defendant, Teva, argued that “the long-felt need must be unmet at the time the invention becomes available on the market, when it can actually satisfy that need.”¹⁰⁴⁹ In that case, the difference in time between filing and marketing was significant. Whereas “in the mid-1980s [the time of filing], osteoporosis was recognized as a serious disease and existing treatments were inadequate,” by the time Procter & Gamble’s product, risedronate, entered the market, a competing drug, alendronate, was already available, allowing Teva to contend that “risedronate could not have satisfied any unmet need.”¹⁰⁵⁰ The Federal Circuit rejected Teva’s argument on the timing for assessing long-felt need and affirmed the district court’s decision to evaluate long-felt need at the time Procter & Gamble filed its patent application covering risedronate.¹⁰⁵¹

c. Unexpected results

Reliance on unexpected results most often appears in chemical and biotechnology cases. Once a patent challenger establishes a prima facie case of obviousness, the patentee may rebut it by proffering “unexpected results” and essentially by showing “that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected.”¹⁰⁵²

The Federal Circuit in *Procter & Gamble* held that, “even if Teva could establish a prima facie case of obviousness, P & G had introduced sufficient evidence of unexpected results to rebut such a

1046. *Boston Scientific Scimed, Inc. v. Cordis Corp.*, 554 F.3d 982, 989, 89 U.S.P.Q.2d (BNA) 1704, 1710 (Fed. Cir. 2009), cert. dismissed, 130 S. Ct. 50 (2009).

1047. *Id.* at 991, 89 U.S.P.Q.2d (BNA) at 1712.

1048. *Procter & Gamble Co.*, 566 F.3d at 998, 90 U.S.P.Q.2d (BNA) at 1953.

1049. *Id.*, 90 U.S.P.Q.2d (BNA) at 1953.

1050. *Id.*, 90 U.S.P.Q.2d (BNA) at 1952–53.

1051. *Id.*, 90 U.S.P.Q.2d (BNA) at 1953.

1052. *Id.* at 994, 90 U.S.P.Q.2d (BNA) at 1950 (quoting *In re Soni*, 54 F.3d 746, 750, 34 U.S.P.Q.2d (BNA) 1684, 1687 (Fed. Cir. 1995)).

showing.”¹⁰⁵³ The court noted that “P & G’s witnesses consistently testified that the properties of risedronate were not expected” and “could not have been predicted,” including unexpected potency, “unexpectedly improved properties,” and “properties that the prior art does not have.”¹⁰⁵⁴ Some of the evidence in the case that supported these positions included the “low dose at which risedronate was effective,” that “risedronate outperformed 2-pyr EHDP by a substantial margin,” that “2-pyr EHDP was lethal at a dose of 1.0 mg P/kg/day while risedronate was not,” and that at a concentration three-fold greater than the lead compound, 2-pyr EHDP, risedronate showed “no observable toxic effect.”¹⁰⁵⁵ The Federal Circuit affirmed the district court’s conclusion—which was based on weighing the evidence and evaluating the credibility of the witnesses—that the record contained sufficient evidence of unexpected results to rebut any finding of obviousness.¹⁰⁵⁶

H. Double-Patenting

There are two types of double-patenting. The first type is statutory double-patenting, sometimes referred to as “same invention” double-patenting. It prevents from issuing two patents that claim the exact same invention.¹⁰⁵⁷ If there is any variation in scope between the claims of the two patents, then obviousness-type double-patenting may apply.¹⁰⁵⁸ This second type of double-patenting was judicially created and is meant to prevent unjustified extensions of patent term among patents claiming patentably indistinct inventions.¹⁰⁵⁹ Normally, the test for obviousness-type double-patenting is applied in one direction (the so-called “one-way test”). Under the one-way test,

1053. *Id.* at 997, 90 U.S.P.Q.2d (BNA) at 1952.

1054. *Id.*, 90 U.S.P.Q.2d (BNA) at 1952 (quoting *In re Dillon*, 919 F.2d 688, 692–93, 16 U.S.P.Q.2d (BNA) 1897, 1901 (Fed. Cir. 1990)).

1055. *Id.* at 997–98, 90 U.S.P.Q.2d (BNA) at 1952.

1056. *Id.*, 90 U.S.P.Q.2d (BNA) at 1952.

1057. *See* *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 197–98 (1894) (discussing authorities that prevent patents from issuing for an invention covered by an earlier patent); *In re Vogel*, 422 F.2d 438, 441, 164 U.S.P.Q. (BNA) 619, 622 (C.C.P.A. 1970) (noting a statutory prohibition on the issuance of a second patent for an invention covered by an earlier patent); *In re Ockert*, 245 F.2d 467, 469, 114 U.S.P.Q. (BNA) 330, 332 (C.C.P.A. 1957) (observing that precedent requires the granting of one patent per invention).

1058. *See In re Goodman*, 11 F.3d 1046, 1052, 29 U.S.P.Q.2d (BNA) 2010, 2015 (Fed. Cir. 1993) (asserting that the doctrine of obviousness-type double-patenting prevents “application claims to subject matter different but not patentably distinct from the subject matter claimed in a prior patent”); *In re Longi*, 759 F.2d 887, 892, 225 U.S.P.Q. (BNA) 645, 648 (Fed. Cir. 1985) (same).

1059. *In re Berg*, 140 F.3d 1428, 1431, 46 U.S.P.Q.2d (BNA) 1226, 1229 (Fed. Cir. 1998).

the claims of an earlier-issued patent are applied as if they were prior art against the claims of the later-issued patent.¹⁰⁶⁰ If the earlier-issued claims would render the later claims unpatentable, either because they anticipate or render them obvious, the later claims are deemed invalid for obviousness-type double-patenting.¹⁰⁶¹

Sometimes, due to delays in the USPTO's examination of two applications, the earlier-filed application does not always issue first. In some cases, the order becomes reversed, where the second-filed application issues first. Indeed, hiccups or irregularities in the examination process can cause a patent that covers a subsequently conceived improvement invention to issue before the patent that covers the basic invention. In such instances, double-patenting may be assessed in two directions under the so-called "two-way test." The rationale behind the two-way test is that "an applicant . . . should not be penalized by the rate of progress of the applications through the [US]PTO, a matter over which the applicant does not have complete control."¹⁰⁶² In such a situation, the order of issuance is effectively ignored and patentability is assessed in the opposite direction. The relevant determination becomes whether the claims covering the improvement invention are patentably distinct from the claims of the basic invention.¹⁰⁶³

1. *The two-way test*

The Federal Circuit in *In re Fallaux*¹⁰⁶⁴ denied Dr. Fallaux the benefit of the two-way test, holding that "Dr. Fallaux was entirely responsible for the delay" that caused the later-filed reference patent to issue first.¹⁰⁶⁵ The court found that the specification of the first application in the patent family chain supported the later claims that were rejected for double-patenting.¹⁰⁶⁶ It noted that Dr. Fallaux elected to prosecute other applications and delay filing the appealed application until six years after the original filing date, during which time the reference patents were filed and issued.¹⁰⁶⁷ The Federal Circuit held that the USPTO was not responsible for the delay.¹⁰⁶⁸

1060. *Id.* at 1432, 46 U.S.P.Q.2d (BNA) at 1229.

1061. *Id.* at 1431-32, 46 U.S.P.Q.2d (BNA) at 1229.

1062. *In re Braat*, 937 F.2d 589, 593, 19 U.S.P.Q.2d (BNA) 1289, 1292 (Fed. Cir. 1991).

1063. *Id.* at 593-94, 19 U.S.P.Q.2d 1289 (BNA) at 1292-93.

1064. 564 F.3d 1313, 90 U.S.P.Q.2d (BNA) 1860 (Fed. Cir. 2009).

1065. *Id.* at 1316, 90 U.S.P.Q.2d (BNA) at 1862.

1066. *Id.* at 1317, 90 U.S.P.Q.2d (BNA) at 1863.

1067. *Id.*, 90 U.S.P.Q.2d (BNA) at 1862.

1068. *Id.*, 90 U.S.P.Q.2d (BNA) at 1862.

Dr. Fallaux argued that the delay should not be attributed to him because he prosecuted the patents “in the ordinary course of business” and did not “proactively manipulate[] prosecution for an improper purpose or to gain some advantage.”¹⁰⁶⁹ The Federal Circuit stated that “[t]he rule is not, as Dr. Fallaux seems to suggest, that an applicant is entitled to the two-way test absent proof of nefarious intent to manipulate prosecution.”¹⁰⁷⁰ Rather, the court indicated that the two-way test carves out a narrow exception when the USPTO is at fault for the delay that causes the improvement patent to issue before the basic patent.¹⁰⁷¹

Dr. Fallaux then argued that issuing his application would not result in an unjustified extension of the patent term because the application and the double-patenting reference, having claimed the benefit of the same filing date, would expire on the same day, twenty years from filing.¹⁰⁷² The Federal Circuit, however, rejected this argument, indicating that “[i]n some cases there may still be the possibility of an unjust time-wise extension of a patent arising from patent term adjustment under § 154 or patent term extension under § 156.”¹⁰⁷³ It also noted that double-patenting seeks to prevent multiple lawsuits from different patentees based on patents covering patentably indistinct subject matter.¹⁰⁷⁴ Apparently, Dr. Fallaux could not file a terminal disclaimer agreeing to keep the reference patents and the application under appeal commonly owned.¹⁰⁷⁵

2. *Timing to determine “patentable distinctness”*

When applying the test for double-patenting, questions have arisen concerning the cut-off date for prior art when assessing obviousness. Specifically, should the prior art cut-off be the filing date of the double-patenting reference, the filing date of the patent itself, or the actual filing date of the application under attack for double-patenting or no cut-off date? The Federal Circuit held in *Takeda Pharmaceutical Co. v. Doll*¹⁰⁷⁶ that an applicant can rely on developments in the art up to the filing date of the later-filed application to show patentable distinctiveness.¹⁰⁷⁷ In *Takeda*, the applicant appealed a double-

1069. *Id.*, 90 U.S.P.Q.2d (BNA) at 1862 (alteration in original).

1070. *Id.*, 90 U.S.P.Q.2d (BNA) at 1862–63.

1071. *Id.*, 90 U.S.P.Q.2d (BNA) at 1862–63.

1072. *Id.* at 1318, 90 U.S.P.Q.2d (BNA) at 1864.

1073. *Id.* at 1319, 90 U.S.P.Q.2d (BNA) at 1864.

1074. *Id.*, 90 U.S.P.Q.2d (BNA) at 1864.

1075. *Id.* at 1319 n.5, 90 U.S.P.Q.2d (BNA) at 1864 n.5.

1076. 561 F.3d 1372, 90 U.S.P.Q.2d (BNA) 1496 (Fed. Cir. 2009).

1077. *Id.* at 1378, 90 U.S.P.Q.2d (BNA) at 1500.

patenting rejection of a process patent over a product patent.¹⁰⁷⁸ Section 806.05(f) of the Manual of Patent Examining Procedure provides that process and product claims are patentably distinct if “the product as claimed can be made by another materially different process.”¹⁰⁷⁹ The applicant sought to present postinvention evidence of alternative processes of making the product to establish patentable distinctiveness and overcome the double-patenting rejection.¹⁰⁸⁰ The USPTO argued that the date of invention governs the relevance of products and processes in the double-patenting context and refused to consider Takeda’s postinvention evidence.¹⁰⁸¹ Takeda appealed the USPTO’s decision under 35 U.S.C. § 145 to the U.S. District Court for the District of Columbia. The district court agreed with Takeda, holding that “subsequent developments in the art [are relevant to] determining whether alternative processes exist” when weighing patentable distinctions for double-patenting.¹⁰⁸²

The Federal Circuit found neither party’s position persuasive.¹⁰⁸³ The court recognized that the second-filed application actually triggers the potential for an “unjustified extension of patent term,” and that when filing the second application, “the applicant essentially avers that the product and process are patentably distinct.”¹⁰⁸⁴ Thus, the court concluded that the relevant date for determining whether a product and process are patentably distinct should be the filing date of the second application.¹⁰⁸⁵ The court articulated that this rule gives the applicant the benefit of future developments in the art that the applicant can rely on to show that the product and process are patentably distinct.¹⁰⁸⁶ At the same time, this approach “prevents the inequitable situation that arises when an applicant attempts to rely on developments occurring decades after the filing date of the secondary application.”¹⁰⁸⁷ The court further reasoned that “[t]his approach should encourage the swift development of materially distinct, alternative processes.”¹⁰⁸⁸

1078. *Id.* at 1375–76, 90 U.S.P.Q.2d (BNA) at 1499.

1079. MANUAL OF PATENT EXAMINING PROCEDURE § 806.05(f) (2006).

1080. *Takeda*, 561 F.3d at 1378, 90 U.S.P.Q.2d (BNA) at 1500.

1081. *Id.* at 1375–76, 90 U.S.P.Q.2d (BNA) at 1499.

1082. *Id.* at 1374, 90 U.S.P.Q.2d (BNA) at 1498 (alteration in original) (citation omitted).

1083. *Id.* at 1377, 90 U.S.P.Q.2d (BNA) at 1500.

1084. *Id.*, 90 U.S.P.Q.2d (BNA) at 1500 (internal quotation marks omitted).

1085. *Id.*, 90 U.S.P.Q.2d (BNA) at 1500.

1086. *Id.*, 90 U.S.P.Q.2d (BNA) at 1500.

1087. *Id.*, 90 U.S.P.Q.2d (BNA) at 1500.

1088. *Id.*, 90 U.S.P.Q.2d (BNA) at 1500.

The Federal Circuit clarified the principle enunciated in *Takeda* regarding the use of postfiling date evidence for the purpose of showing patentable distinctiveness in *F. Hoffmann-La Roche*.¹⁰⁸⁹ In that case, the court declared that a challenger may not use evidence produced after the filing date of the first-filed patent to support a prima facie case of obviousness-type double-patenting, because that would conflict with the principle underlying 35 U.S.C. § 120 that the later-filed patent that claims priority to the first-filed patent enjoys the benefit of the earlier filing date.¹⁰⁹⁰ The court acknowledged that this “could ‘provide the patentee with the best of both worlds: the applicant can use the filing date as a shield, enjoying the earlier priority date in order to avoid prior art, *and* rely on later-developed alternative processes as a sword to defeat double patenting challenges.’”¹⁰⁹¹ However, the court noted that there are limits to *Takeda*’s application.¹⁰⁹² If the patentee relies on evidence developed after the first-filed patent to show the existence of alternative processes to make a product, the challenger would then be free to use postfiling evidence to rebut the patentee’s assertions.¹⁰⁹³

3. *Safe harbor*

Section 121 provides a safe harbor against double-patenting if (1) the challenged patent or application resulted from a restriction requirement, and (2) the claims of the challenged patent or application are consonant with the restriction requirement.¹⁰⁹⁴ The protected applications or patents referred to in § 121 include the original application containing the restriction requirement and any divisional applications.¹⁰⁹⁵

In *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, the Federal Circuit held that the safe harbor did not apply to applications that descended solely from continuation applications.¹⁰⁹⁶ In that case, the reference patent was an ancestor of the patents at issue.¹⁰⁹⁷ The patents at issue descended exclusively from applications designated as continuation

1089. *Amgen Inc. v. F. Hoffmann-La Roche Ltd.*, 580 F.3d 1340, 92 U.S.P.Q.2d (BNA) 1289 (Fed. Cir. 2009).

1090. *Id.* at 1357, 92 U.S.P.Q.2d (BNA) at 1302.

1091. *Id.*, 92 U.S.P.Q.2d (BNA) at 1302 (quoting *Takeda Pharm. Co. v. Doll*, 561 F.3d 1372, 1377, 90 U.S.P.Q.2d (BNA) 1496, 1500 (Fed. Cir. 2009)).

1092. *See id.* at 1358, 92 U.S.P.Q.2d (BNA) at 1303 (“*Takeda* is a two-way street within its own confines.”).

1093. *Id.*, 92 U.S.P.Q.2d (BNA) at 1302–03.

1094. 35 U.S.C. § 121 (2006).

1095. *Id.*

1096. *Amgen Inc. v. F. Hoffmann-La Roche Ltd.*, 580 F.3d 1340, 1352–53, 92 U.S.P.Q.2d (BNA) 1289, 1298–99 (Fed. Cir. 2009).

1097. *Id.* at 1346–48, 92 U.S.P.Q.2d (BNA) at 1293–95.

applications of the reference patent.¹⁰⁹⁸ Since there was a restriction requirement issued during the prosecution of the reference patent, the patentee argued generally that the Federal Circuit should look at the substance rather than the designation, and particularly that the continuation applications could have been filed as divisional applications.¹⁰⁹⁹ Unlike *Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*,¹¹⁰⁰ where the patent at issue was a continuation-in-part of the reference patent,¹¹⁰¹ the Federal Circuit recognized that Amgen's applications may have satisfied all of the substantive requirements of a divisional application.¹¹⁰² Interpreting the statute literally, however, the court refused to extend the benefits that are accorded to divisional applications further to continuation applications.¹¹⁰³

The Federal Circuit distinguished this case from situations such as those in *Applied Materials, Inc. v. Advanced Semiconductor Materials America, Inc.*¹¹⁰⁴ and *Symbol Technologies, Inc. v. Opticon, Inc.*,¹¹⁰⁵ where a divisional application was properly filed in response to a restriction requirement, and continuation applications were filed off the divisional applications.¹¹⁰⁶ The court upheld the principles in those cases, stating that "intervening continuation applications do not render a patent ineligible for § 121 protection so long as they descended from a divisional application filed as a result of a restriction requirement."¹¹⁰⁷

I. Inventorship

1. Contribution to the invention

In *Nartron Corp. v. Schukra U.S.A., Inc.*,¹¹⁰⁸ the Federal Circuit reversed the lower court's dismissal of a patent infringement complaint because of the plaintiff's failure to join as a party to the suit an alleged coinventor.¹¹⁰⁹ The Federal Circuit held that "the alleged coinventor[] provided only an insignificant

1098. *Id.*, 92 U.S.P.Q.2d (BNA) at 1293-95.

1099. *Id.* at 1351, 92 U.S.P.Q.2d (BNA) at 1297.

1100. 518 F.3d 1353, 86 U.S.P.Q.2d (BNA) 1001 (Fed. Cir. 2008).

1101. *Id.* at 1358-59, 86 U.S.P.Q.2d (BNA) at 1004-05.

1102. *F. Hoffman-La Roche*, 580 F.3d at 1353, 92 U.S.P.Q.2d (BNA) at 1299.

1103. *Id.*, 92 U.S.P.Q.2d (BNA) at 1299.

1104. 98 F.3d 1563, 40 U.S.P.Q.2d (BNA) 1481 (Fed. Cir. 1996).

1105. 935 F.2d 1569, 19 U.S.P.Q.2d (BNA) 1241 (Fed. Cir. 1991).

1106. *F. Hoffman-La Roche*, 580 F.3d at 1353-54, 92 U.S.P.Q.2d (BNA) at 1299.

1107. *Id.* at 1354, 92 U.S.P.Q.2d (BNA) at 1299.

1108. 558 F.3d 1352, 89 U.S.P.Q.2d (BNA) 2047 (Fed. Cir. 2009).

1109. *Id.* at 1358-59, 89 U.S.P.Q.2d (BNA) at 2051-52.

contribution” to the patented invention; therefore, that person was not an indispensable party and dismissal was therefore improper.¹¹¹⁰

Nartron Corp. sued Borg Indak, Inc. for contributory infringement of a patent relating to “a control system that would provide existing automobile seats with massage functionality.”¹¹¹¹ Years earlier, Schukra U.S.A. had engaged Nartron Corp. to design a control system that would provide existing automobile seats with massage functionality.¹¹¹² Nartron Corp. designed such a system and then applied for a patent, which matured into the patent-in-suit.¹¹¹³ Borg Indak, Inc. moved to dismiss the lawsuit on the ground that a Schukra employee named Benson was allegedly a coinventor of a dependent claim in the patent for having suggested the use of a component referred to as an “extender,” which the dependent claim specifically recited and which was the sole added limitation in that claim.¹¹¹⁴

The court found that the extender was known in the prior art.¹¹¹⁵ Emphasizing that inventorship looks to the claim as a whole, the court noted that “a dependent claim adding one claim limitation to a parent claim is still a claim to the invention of the parent claim, albeit with the added feature; it is not a claim to the added feature alone.”¹¹¹⁶ The invention was to a “control system,” not an “extender.”¹¹¹⁷ The Federal Circuit further found that:

[T]he contribution of the extender is *insignificant* when measured against the full dimension of the [claimed] invention . . . not just because it was in the prior art, but because it was part of existing automobile seats, and therefore including it as part of the claimed invention was merely the basic exercise of ordinary skill in the art.¹¹¹⁸

Applying this reasoning, the court concluded: “There is not, and could not be, any claim that the addition of the extender here was anything but obvious. Benson’s contribution therefore does not make him a coinventor of the subject matter of claim 11.”¹¹¹⁹

1110. *Id.* at 1353, 89 U.S.P.Q.2d (BNA) at 2048.

1111. *Id.* at 1354, 89 U.S.P.Q.2d (BNA) at 2048.

1112. *Id.*, 89 U.S.P.Q.2d (BNA) at 2048.

1113. *Id.*, 89 U.S.P.Q.2d (BNA) at 2048.

1114. *Id.* at 1358, 89 U.S.P.Q.2d (BNA) at 2051–52.

1115. *Id.* at 1357, 89 U.S.P.Q.2d (BNA) at 2051.

1116. *Id.* at 1358, 89 U.S.P.Q.2d (BNA) at 2051–52.

1117. *Id.*, 89 U.S.P.Q.2d (BNA) at 2051.

1118. *Id.* at 1357, 89 U.S.P.Q.2d (BNA) at 2050 (emphasis added).

1119. *Id.* at 1358, 89 U.S.P.Q.2d (BNA) at 2051.

2. “Scientific certainty” regarding conception

Proof that an invention will work to a scientific certainty is not required for a completed conception of a claimed invention. In *University of Pittsburgh v. Hedrick*,¹¹²⁰ an inventorship dispute arose between the University of Pittsburgh and the defendants, who argued that the Pittsburgh researchers’ work was inconclusive and highly speculative until the defendant researchers helped them confirm the claimed properties.¹¹²¹ The Federal Circuit rejected the defendants’ argument that the Pittsburgh researchers had to know with scientific certainty that the invention contained every limitation of the claim at the time of conception.¹¹²² The court noted that proof that an invention works with scientific certainty is required for reduction to practice.¹¹²³ In contrast, all that is required for conception is whether the idea expressed by the inventors was sufficiently developed to support conception of the subject matter.¹¹²⁴ Accordingly, the Federal Circuit found that the evidence showed that the Pittsburgh researchers conceived the invention before the defendants.¹¹²⁵

VII. INFRINGEMENT

There are several components to establishing infringement as well as several types of infringement. It all starts with construing the scope of the claims. Since at least the Supreme Court’s decision in *Markman v. Westview Instruments, Inc.*,¹¹²⁶ claim construction has taken on a much more pivotal role than it has ever before taken in determining infringement.¹¹²⁷ Indeed, its role has become so prominent that Judge Newman of the Federal Circuit referred to the claim construction process as its own “cottage industry.”¹¹²⁸

Once the claims have been construed, the alleged infringing product or process is then compared against the claims to first determine if literal infringement exists, i.e., whether all elements of the claim are found in the alleged infringing product or process. If not literally infringed, a claim can still be infringed under the doctrine of equivalents—a judicially created inquiry that considers

1120. 573 F.3d 1290, 91 U.S.P.Q.2d (BNA) 1423 (Fed. Cir. 2009).

1121. *Id.* at 1299, 91 U.S.P.Q.2d (BNA) at 1429.

1122. *Id.*, 91 U.S.P.Q.2d (BNA) at 1429.

1123. *Id.*, 91 U.S.P.Q.2d (BNA) at 1429.

1124. *Id.*, 91 U.S.P.Q.2d (BNA) at 1429.

1125. *Id.*, 91 U.S.P.Q.2d (BNA) at 1429–30.

1126. 517 U.S. 370, 38 U.S.P.Q.2d (BNA) 1461 (1996).

1127. *Id.* at 372, 38 U.S.P.Q.2d at 1463 (holding that claim construction is a matter of law reserved for the court and not for a jury).

1128. *Energizer Holdings, Inc. v. U.S. Int’l Trade Comm’n*, 275 F. App’x 969, 980 (Fed. Cir. 2008) (Newman, J., dissenting), *cert. denied*, 129 S. Ct. 1662 (2009).

whether any claim elements not specifically found in the alleged infringing product or process are nonetheless equivalently present.

Both literal and equivalent infringement constitute forms of “direct” infringement. The law permits a finding of infringement even as to those who do not directly infringe a patent claim—this is called “indirect” infringement. One may indirectly infringe by contributing to or inducing another to directly infringe a patent claim.¹¹²⁹ The following subsections will explore 2009 Federal Circuit decisions that dealt with these forms of infringement.

A. *Literal infringement*

1. *Product claims with process steps or functional language*

The Federal Circuit held in *Ball Aerosol & Specialty Container, Inc. v. Ltd. Brands, Inc.*¹¹³⁰ that where a claim specifically requires a particular configuration, an accused product reasonably capable of being configured in a manner that would meet the claimed requirement may not infringe.¹¹³¹ In that case, the patent at issue was directed to a candle tin with a removable cover that also acts as a base for the candle holder.¹¹³² The patent claims specifically stated that the cover would be placed as a base on which the candle tin and its feet would be placed.¹¹³³ The accused product was a candle tin with a removable cover and four protrusions on the closed end of the candle holder.¹¹³⁴ Though it may have been capable of being assembled or configured in a manner that would infringe, the patentee offered no evidence that the accused product was ever so configured.¹¹³⁵ Still, the patentee contended that it infringed because it was reasonably capable of being configured in an infringing manner.¹¹³⁶ In reversing the district court’s grant of summary judgment in favor of the patentee, the Federal Circuit held that it was improper to find infringement of the claims where the accused product was only “reasonably capable” of being configured in a way that would meet the claim limitations.¹¹³⁷ The case law supports a “reasonably capable” theory of infringement where the claims contain language drawn to a

1129. 35 U.S.C. § 271(b)–(c) (2006).

1130. 555 F.3d 984, 89 U.S.P.Q.2d (BNA) 1870 (Fed. Cir. 2009).

1131. *Id.* at 995, 89 U.S.P.Q.2d (BNA) at 1878.

1132. *Id.* at 986, 89 U.S.P.Q.2d (BNA) at 1872.

1133. *Id.*, 89 U.S.P.Q.2d (BNA) at 1872.

1134. *Id.* at 987, 89 U.S.P.Q.2d (BNA) at 1872–73.

1135. *Id.* at 994, 89 U.S.P.Q.2d (BNA) at 1877.

1136. *Id.*, 89 U.S.P.Q.2d (BNA) at 1877–78.

1137. *Id.*, 89 U.S.P.Q.2d (BNA) at 1878.

particular capability or functionality.¹¹³⁸ The claims of the patent-in-suit were not so drawn, requiring instead a particular configuration.¹¹³⁹ No proof of actual infringement of the accused device existed in the record, nor did the facts indicate that the device necessarily had to be placed in the infringing configuration.¹¹⁴⁰

In *Gemtron Corp. v. Saint-Gobain Corp.*,¹¹⁴¹ the Federal Circuit affirmed the district court's grant of partial summary judgment where the defendant infringed a patent directed to a refrigerator shelf.¹¹⁴² The principle claim element in dispute required "a relatively resilient end edge portion which temporarily deflects and subsequently rebounds to snap-secure one of said glass piece front and rear edges."¹¹⁴³ The defendant argued that it did not infringe because it assembled the shelf in Mexico, where the "temporary deflecting" and "subsequently rebounding" aspects of the end portion occurred.¹¹⁴⁴ The court first pointed out that the defendant, Saint-Gobain, never disputed that the end portions of its accused frames *could* deflect and subsequently rebound to accommodate insertion of the glass during manufacture.¹¹⁴⁵ In ultimately rejecting Saint-Gobain's argument that no infringing activities occurred in the United States, however, the court construed the deflecting and rebounding requirements as structural characteristics of the "relatively resilient end edge portion."¹¹⁴⁶ Finding that Saint-Gobain's imported shelf had these "structural" characteristics, it concluded that the shelf infringed under § 271(a) and dismissed the argument that the deflecting and rebounding steps of the claim occurred outside the United States.¹¹⁴⁷

2. *Proof of infringement*

In some instances, a patentee may prove infringement circumstantially rather than with a direct comparison with the alleged infringing product or process. In *Martek Biosciences Corp. v. Nutrinova, Inc.*,¹¹⁴⁸ the Federal Circuit held that the patentee did not need to conduct a comparative analysis to show infringement, that the

1138. *Id.* at 994–95, 89 U.S.P.Q.2d (BNA) at 1878.

1139. *Id.* at 994, 89 U.S.P.Q.2d (BNA) at 1878.

1140. *Id.* at 994–95, 89 U.S.P.Q.2d (BNA) at 1877–78.

1141. 572 F.3d 1371, 91 U.S.P.Q.2d (BNA) 1409 (Fed. Cir. 2009), *cert. denied*, 78 U.S.L.W. 3396 (U.S. Mar. 8, 2010) (No. 09-778).

1142. *Id.* at 1373, 91 U.S.P.Q.2d (BNA) at 1410.

1143. *Id.* at 1375–76, 91 U.S.P.Q.2d (BNA) at 1412 (emphasis omitted).

1144. *Id.* at 1380, 91 U.S.P.Q.2d (BNA) at 1415.

1145. *Id.* at 1381, 91 U.S.P.Q.2d (BNA) at 1416.

1146. *Id.*, 91 U.S.P.Q.2d (BNA) at 1416.

1147. *Id.*, 91 U.S.P.Q.2d (BNA) at 1416.

1148. 579 F.3d 1363, 92 U.S.P.Q.2d (BNA) 1148 (Fed. Cir. 2009).

patentee “may prove infringement by any method of analysis that is probative of the fact of infringement,” and that “circumstantial evidence may be sufficient.”¹¹⁴⁹ The claims at issue were directed to specific microorganisms useful in commercially making docosahexaenoic acid.¹¹⁵⁰ The trial court construed a key limitation in one of the patents-in-suit to require that the accused culture medium cause “less chemical wear” than a hypothetical culture medium containing sodium chloride as the primary source of sodium.¹¹⁵¹ The accused infringer argued that the patentee failed to prove infringement because it did not conduct comparative testing between the accused culture medium and the hypothetical medium.¹¹⁵²

Although the patentee relied on the testimony of two experts to prove infringement, it was not pure, unsubstantiated opinion testimony.¹¹⁵³ The first expert testified that the defendant used vessels made of a stainless steel that were “highly susceptible to corrosion,” that the literature clearly recognized “the corrosive effects of chlorides on stainless steels,” and that it is “scientific fact” that if one increases the chloride concentrations in the aqueous medium present in the infringing process, greater corrosion results.¹¹⁵⁴ The second expert testified that he calculated (from the defendant’s fermentation records) the concentration of chloride ions in the defendant’s culture medium, that he compared that concentration to the concentration of chloride ions in the hypothetical medium, and that he found that the defendant’s culture medium had only one third of the chloride ions present in the hypothetical medium.¹¹⁵⁵ Because the defendant’s culture medium had significantly less chloride ions, the second expert concluded that it would logically cause less corrosion than the hypothetical medium.¹¹⁵⁶ On the basis of the experts’ testimony, the court found that Martek had carried its burden of proving infringement without having conducted any actual comparative analyses.¹¹⁵⁷

Similarly, in *Vita-Mix Corp. v. Basic Holding, Inc.*,¹¹⁵⁸ the Federal Circuit held that infringement can be proven by circumstantial

1149. *Id.* at 1372, 92 U.S.P.Q.2d (BNA) at 1154.

1150. *Id.* at 1367, 92 U.S.P.Q.2d (BNA) at 1150.

1151. *Id.* at 1372, 92 U.S.P.Q.2d (BNA) at 1154.

1152. *Id.*, 92 U.S.P.Q.2d (BNA) at 1154.

1153. *Id.* at 1373–74, 92 U.S.P.Q.2d (BNA) at 1155.

1154. *Id.* at 1373, 92 U.S.P.Q.2d (BNA) at 1154–55.

1155. *Id.*, 92 U.S.P.Q.2d (BNA) at 1155.

1156. *Id.*, 92 U.S.P.Q.2d (BNA) at 1155.

1157. *Id.* at 1374, 92 U.S.P.Q.2d (BNA) at 1155.

1158. 581 F.3d 1317, 92 U.S.P.Q.2d (BNA) 1340 (Fed. Cir. 2009).

evidence. In that case, the patentee pled inducement and contributory charges of infringement, among other infringement claims.¹¹⁵⁹ The district court summarily determined that the defendant did not indirectly infringe (i.e., contribute to or induce infringement) because the patentee failed to provide actual evidence of direct infringement.¹¹⁶⁰ The patent at issue was “directed to a method of preventing the formation of an air pocket around the moving blades of a consumer food blender.”¹¹⁶¹ The method involved inserting a plunger into the body of the blender to block the air channel that creates air pockets when ingredients are mixed.¹¹⁶² The accused blenders had an opening that could receive a stir stick, whose configuration could, under certain circumstances, prevent the creation of air pockets.¹¹⁶³

The Federal Circuit concluded that the district court erred as a matter of law in disposing of the direct infringement claims by requiring actual evidence of infringement.¹¹⁶⁴ The Federal Circuit found that the district court improperly discounted the accusations of direct infringement by two witnesses because of a lack of testimony or footage showing actual infringement.¹¹⁶⁵ The testimony of one of the patentee’s expert witnesses established that these two witnesses would necessarily infringe under certain circumstances.¹¹⁶⁶ Because direct infringement can be proven by circumstantial evidence, and the district court improperly disposed of the direct infringement count without considering the circumstantial proof, the Federal Circuit reversed and remanded for further proceedings.¹¹⁶⁷

Restating the principle that “one cannot avoid infringement merely by adding elements,” the Federal Circuit in *Amgen Inc. v. F. Hoffmann-La Roche Ltd.*¹¹⁶⁸ rejected Roche’s position that it did not infringe because it formed its erythropoietin (“EPO”) through pegylation.¹¹⁶⁹ Amgen’s claims were directed to EPO, while Roche’s alleged infringing product was directed to pegylated EPO, which essentially added PEG to recombinant EPO.¹¹⁷⁰ The Federal Circuit affirmed the

1159. *Id.* at 1322, 92 U.S.P.Q.2d (BNA) at 1343–44.

1160. *Id.* at 1326, 92 U.S.P.Q.2d (BNA) at 1346.

1161. *Id.* at 1321, 92 U.S.P.Q.2d (BNA) at 1342.

1162. *Id.*, 92 U.S.P.Q.2d (BNA) at 1342–43.

1163. *Id.* at 1321–22, 92 U.S.P.Q.2d (BNA) at 1343.

1164. *Id.* at 1326, 92 U.S.P.Q.2d (BNA) at 1346.

1165. *Id.*, 92 U.S.P.Q.2d (BNA) at 1346.

1166. *Id.*, 92 U.S.P.Q.2d (BNA) at 1346.

1167. *Id.*, 92 U.S.P.Q.2d (BNA) at 1346–47.

1168. 580 F.3d 1340, 92 U.S.P.Q.2d (BNA) 1289 (Fed. Cir. 2009).

1169. *Id.* at 1378, 92 U.S.P.Q.2d (BNA) at 1319.

1170. *Id.* at 1347–48, 92 U.S.P.Q.2d (BNA) at 1294–95.

district court's finding of literal infringement, holding that the addition of PEG to recombinant EPO infringed claims reciting recombinant EPO because the PEG was simply an additional element, not a fundamental chemical transformation.¹¹⁷¹

In *Exergen Corp. v. Wal-Mart Stores, Inc.*,¹¹⁷² the Federal Circuit held that an oral thermometer did not infringe a claim directed to measuring internal temperature, construed as the temperature of the temporal artery beneath the skin of the forehead.¹¹⁷³ The claim at issue recited a radiation detector comprising, among other things, "a display for providing an indication of the internal temperature."¹¹⁷⁴ The dispositive evidence was the patentee's expert/coinventor's testimony that the number shown on the display of the claimed device must be the value of the internal temperature and could not be some other value requiring further computation before arriving at the internal temperature.¹¹⁷⁵ Because the accused device measured radiation from the user's forehead and then calculated an oral temperature, it did not determine the claimed "internal temperature" and could not infringe.¹¹⁷⁶

B. Doctrine of Equivalents

When a claim is not literally infringed, it may still be infringed under the doctrine of equivalents if an accused device or process insubstantially differs from the claimed invention.¹¹⁷⁷ The substantiality of the differences is determined on a claimed element-by-element basis.¹¹⁷⁸ To prove infringement by equivalents, the patentee must present "particularized testimony and linking argument as to the 'insubstantiality of the differences' between the [claimed invention and the alleged infringing device or process], or with respect to the function, way, result test."¹¹⁷⁹ The "function,

1171. *Id.* at 1376, 92 U.S.P.Q.2d (BNA) at 1317.

1172. 575 F.3d 1312, 91 U.S.P.Q.2d (BNA) 1656 (Fed. Cir. 2009).

1173. *Id.* at 1321, 91 U.S.P.Q.2d (BNA) at 1663.

1174. *Id.* at 1320, 91 U.S.P.Q.2d (BNA) at 1662.

1175. *Id.* at 1321, 91 U.S.P.Q.2d (BNA) at 1662–63.

1176. *Id.*, 91 U.S.P.Q.2d (BNA) at 1663.

1177. See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 733, 62 U.S.P.Q.2d (BNA) 1705, 1710–11 (2002) ("The doctrine of equivalents allows the patentee to claim those insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes.").

1178. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40, 41 U.S.P.Q.2d (BNA) 1865, 1876 (1997).

1179. *Amgen Inc. v. F. Hoffmann-La Roche*, 580 F.3d 1340, 1382, 92 U.S.P.Q.2d (BNA) 1289, 1322 (Fed. Cir. 2009) (quoting *Tex. Instruments Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1567, 39 U.S.P.Q.2d (BNA) 1492, 1497–98 (Fed. Cir. 1996)).

way, result test,” coined by the Supreme Court in *Graver Tank & Manufacturing Co. v. Linde Air Products Co.*,¹¹⁸⁰ assesses whether an accused device “performs substantially the same function in substantially the same way to obtain the same result” as the claim limitation.¹¹⁸¹

For example, in *F. Hoffmann-La Roche*, the Federal Circuit affirmed the district court’s judgment as a matter of law (JMOL) overturning a jury’s verdict of infringement under the doctrine of equivalents for a specific claim because Amgen failed to present sufficient evidence that any limitation of the claim was equivalently infringed.¹¹⁸² Amgen argued that it presented equivalents evidence relating to the claimed therapeutically effective amount of EPO.¹¹⁸³ But the Federal Circuit viewed the evidence as pertaining to Amgen’s literal infringement argument and not to the type of particularized testimony of equivalency sufficient to link the insubstantiality of the differences between the claimed composition and Roche’s accused drug.¹¹⁸⁴ Accordingly, the Federal Circuit affirmed the district court’s holding of no infringement for the specific claim.¹¹⁸⁵

1. *Prosecution history estoppel*

a. *Amendment-based estoppel*

Even if an accused device might factually constitute an equivalent to the claimed device, a court may still decide not to apply the doctrine of equivalents. Indeed, the doctrine of prosecution history estoppel tempers the expansive effect of the doctrine of equivalents. The Supreme Court held in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*¹¹⁸⁶ that arguments or amendments made for purposes of patentability could give rise to prosecution history estoppel.¹¹⁸⁷ Specifically, the Court held that “[a] patentee’s decision to narrow his claims through amendment may be presumed to be a general disclaimer of the territory between the original claim and the

1180. 339 U.S. 605, 85 U.S.P.Q. (BNA) 382 (1950).

1181. *Id.* at 608, 85 U.S.P.Q. (BNA) at 330 (quoting *Sanitary Refrigerator Co. v. Winters*, 280 U.S. 30, 42, 3 U.S.P.Q. (BNA) 40, 47–48 (1929)).

1182. *Amgen Inc. v. F. Hoffmann-La Roche Ltd.*, 580 F.3d 1340, 1383–86, 92 U.S.P.Q.2d (BNA) 1289, 1323–25 (Fed. Cir. 2009).

1183. *Id.* at 1384, 92 U.S.P.Q.2d (BNA) at 1323–24.

1184. *Id.* at 1385–86, 92 U.S.P.Q.2d (BNA) at 1324–25.

1185. *Id.* at 1386, 92 U.S.P.Q.2d (BNA) at 1325.

1186. 535 U.S. 722, 62 U.S.P.Q.2d (BNA) 1705 (2002).

1187. *Id.* at 733–34, 62 U.S.P.Q.2d (BNA) at 1710–11.

amended claim.”¹¹⁸⁸ A patentee, however, may rebut that presumption of estoppel by demonstrating that “[t]he equivalent may have been unforeseeable at the time of the application; the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question; or there may be some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question.”¹¹⁸⁹

In *Felix v. American Honda Motor Co.*,¹¹⁹⁰ the Federal Circuit rejected Felix’s argument that he rebutted the presumption of prosecution history estoppel by showing that the narrowing amendment made during the prosecution was tangential.¹¹⁹¹ The patent at issue related to a built-in storage compartment for beds of pickup trucks.¹¹⁹² The court first considered whether the amendment adding a gasket limitation to the claimed compartment gave rise to a presumption of surrender.¹¹⁹³ During prosecution, in response to an obviousness rejection, Felix canceled an independent claim without replacing it with any claim reciting the same subject matter and rewrote a dependent claim containing both a channel limitation and a gasket limitation into independent form.¹¹⁹⁴ The amendment did not overcome the examiner’s rejection, and the rewritten claim was again rejected.¹¹⁹⁵ In a second amendment, Felix canceled the rewritten claim containing the channel and gasket limitations without replacing it and rewrote another independent claim incorporating all of the canceled limitations plus an additional limitation.¹¹⁹⁶ The newly rewritten claim was allowed and was subsequently issued as the asserted claim.¹¹⁹⁷ Even though the first narrowing amendment did not succeed and a further amendment was required to place the claim in allowable form, the court held that the presumption of prosecution history estoppel still attached since it is the patentee’s response to a rejection that gives rise to prosecution history estoppel, not the examiner’s ultimate allowance of a claim.¹¹⁹⁸ In addition,

1188. *Id.* at 740, 62 U.S.P.Q.2d (BNA) at 1713 (citing *Exhibit Supply Co. v. Ace Patents Corp.*, 315 U.S. 126, 136–37, 52 U.S.P.Q. (BNA) 275, 279 (1942)).

1189. *Id.* at 740–41, 62 U.S.P.Q.2d (BNA) at 1714.

1190. 562 F.3d 1167, 90 U.S.P.Q.2d (BNA) 1524 (Fed. Cir. 2009).

1191. *Id.* at 1181–85, 90 U.S.P.Q.2d (BNA) at 1532–35.

1192. *Id.* at 1171–72, 90 U.S.P.Q.2d (BNA) at 1526.

1193. *Id.* at 1182, 90 U.S.P.Q.2d (BNA) at 1533.

1194. *Id.* at 1182–84, 90 U.S.P.Q.2d (BNA) at 1533–34.

1195. *Id.*, 90 U.S.P.Q.2d (BNA) at 1533–34.

1196. *Id.* at 1175, 1182, 90 U.S.P.Q.2d (BNA) at 1527–28, 1533.

1197. *Id.*, 90 U.S.P.Q.2d (BNA) at 1533.

1198. *Id.* at 1182–83, 90 U.S.P.Q.2d (BNA) at 1533 (citing *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 727, 62 U.S.P.Q.2d (BNA) 1705, 1708 (2002)).

the court found it immaterial that the cancellation and the amendment went to claims different from those that resulted in the asserted claim.¹¹⁹⁹

Turning to the presumption of surrender, the court held that equivalents were presumptively not available as to any of the limitations added in Felix's first amendment.¹²⁰⁰ Noting that it was immaterial that Felix chose to add both the channel and gasket limitations rather than just the channel limitation Felix argued was necessary, the court held that Felix was presumptively barred from relying on the doctrine of equivalents to prove that Honda's In-Bed Trunk met the gasket limitation.¹²⁰¹

Next, the court considered Felix's argument that he rebutted the presumption of prosecution history estoppel as to the gasket limitation because the narrowing amendment was tangential.¹²⁰² The court rejected Felix's argument that the first amendment was made because the applicant thought the prior art lacked a channel, not because of the presence or position of a gasket.¹²⁰³ The court then held that it was not objectively apparent from this argument that "the channel was the only reason for canceling [the original independent claim] and rewriting [the dependent claim] in independent form."¹²⁰⁴ The court explained that if Felix had intended only to add a channel and not a gasket, he could have simply amended the independent claim to add that limitation.¹²⁰⁵ The Federal Circuit affirmed the district court's judgment under the doctrine of equivalents.¹²⁰⁶

b. Argument-based estoppel

Often, the same rationale used to construe claims narrowly tends to similarly constrict the subsequent application of the doctrine of equivalents. In *Edwards Lifesciences LLC v. Cook Inc.*,¹²⁰⁷ the Federal Circuit affirmed the district court's narrow construction of the claim term "wires," which required that they be malleable, because the inventor disclaimed the use of resilient, or self-expanding, wires by disparaging prior art resilient wires in the "background art" section of the specification.¹²⁰⁸ When assessing whether the accused device's use

1199. *Id.* at 1182 & n.5, 90 U.S.P.Q.2d (BNA) at 1533, 1534 & n.5.

1200. *Id.* at 1183–84, 90 U.S.P.Q.2d (BNA) at 1534.

1201. *Id.* at 1184, 90 U.S.P.Q.2d (BNA) at 1534.

1202. *Id.* at 1184–85, 90 U.S.P.Q.2d (BNA) at 1535.

1203. *Id.* at 1184, 90 U.S.P.Q.2d (BNA) at 1535.

1204. *Id.*, 90 U.S.P.Q.2d (BNA) at 1535.

1205. *Id.*, 90 U.S.P.Q.2d (BNA) at 1535.

1206. *Id.* at 1185, 90 U.S.P.Q.2d (BNA) at 1535.

1207. 582 F.3d 1322, 92 U.S.P.Q.2d (BNA) 1599 (Fed. Cir. 2009).

1208. *Id.* at 1332, 92 U.S.P.Q.2d (BNA) at 1606–07.

of resilient wires infringed under the doctrine of equivalents, the Federal Circuit decided against the patentee, finding that “the inventors disclaimed resilient wires and cannot use the doctrine of equivalents to recapture the disclaimed scope.”¹²⁰⁹

c. Dedication of embodiments to the public

In *Abbott Laboratories v. Sandoz, Inc.*,¹²¹⁰ Lupin, a codefendant, contested infringement under the doctrine of equivalents of, among others, claim 1 of the patent, which recited a product unlimited by process limitations.¹²¹¹ The claim recited a crystalline form of the drug cefdinir and defined it by an X-ray diffraction pattern with specifically identified peaks.¹²¹² The Federal Circuit construed the claim to be directed to the “Crystal A” form of cefdinir.¹²¹³ The bulk of Lupin’s product contained a “Crystal B” form of cefdinir, with a question of whether it also contained some Crystal A.¹²¹⁴ But the issue of literal infringement was not before the court on appeal.¹²¹⁵ Abbott only appealed the issue of infringement under the doctrine of equivalents.¹²¹⁶

The Federal Circuit concluded that Lupin’s product did not infringe the claim under the doctrine of equivalents.¹²¹⁷ It stated that “the bounds of Crystal A equivalents cannot ignore the limits on Crystal A in the . . . patent, which . . . includes a conscious decision to distinguish Crystal B from the claimed invention.”¹²¹⁸ Moreover, Abbott chose not to claim Crystal B, though it clearly could have.¹²¹⁹ As the court pointed out, “the applicant removed Crystal B from the U.S. prosecution of the parent JP ‘199 application.”¹²²⁰ Expanding the claim under the doctrine of equivalents to cover Crystal B would effectively ignore the limitation directed to Crystal A, as construed by the court, and would impermissibly allow Abbott to recapture subject matter that it could have claimed and did not.¹²²¹ Citing to its previous decision in *Johnson & Johnston Associates Inc. v. R.E. Service*

1209. *Id.* at 1335–36, 92 U.S.P.Q.2d (BNA) at 1609.

1210. 566 F.3d 1282, 90 U.S.P.Q.2d (BNA) 1769 (Fed. Cir. 2009), *cert. denied sub nom.* Astellas Pharma, Inc. v. Lupin Ltd., 130 S. Ct. 1052 (2010).

1211. *Id.* at 1289, 90 U.S.P.Q.2d (BNA) at 1780.

1212. *Id.* at 1286, 90 U.S.P.Q.2d (BNA) at 1772.

1213. *Id.* at 1291, 90 U.S.P.Q.2d (BNA) at 1775–76.

1214. *Id.* at 1297, 90 U.S.P.Q.2d (BNA) at 1780–81.

1215. *Id.*, 90 U.S.P.Q.2d (BNA) at 1781.

1216. *Id.*, 90 U.S.P.Q.2d (BNA) at 1780–81.

1217. *Id.*, 90 U.S.P.Q.2d (BNA) at 1780–81.

1218. *Id.*, 90 U.S.P.Q.2d (BNA) at 1780.

1219. *Id.*, 90 U.S.P.Q.2d (BNA) at 1780.

1220. *Id.*, 90 U.S.P.Q.2d (BNA) at 1780.

1221. *Id.*, 90 U.S.P.Q.2d (BNA) at 1781.

Co.,¹²²² the Federal Circuit noted that, by removing Crystal B from the U.S. application, the applicants “dedicat[ed] that embodiment to the public and foreclos[ed] any recapture under the doctrine of equivalents.”¹²²³

The Federal Circuit also dismissed Abbott’s assertion that “Lupin effectively admitted infringement by equivalents when it claimed before the [FDA] that its cefdinir generic was a bioequivalent to Abbott’s Omnicef product.”¹²²⁴ The court noted that, “[w]hile bioequivalency may be relevant to the function prong of the function-way-result [doctrine of equivalents] test, bioequivalency and equivalent infringement are different inquiries,” and “bioequivalency of an accused product with a product produced from the patent at issue is not sufficient to establish infringement by equivalents.”¹²²⁵

2. “Ensnaring the prior art” as a defense

The Federal Circuit in *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*,¹²²⁶ explained that “[e]nsnarement bars a patentee from asserting a scope of equivalency that would encompass, or ‘ensnare,’ the prior art.”¹²²⁷ In that case, the court first rejected Medtronic’s argument that ensnarement, like infringement, must be tried to a jury when requested by the defendant.¹²²⁸ The court held that ensnarement, like prosecution history estoppel, is a legal limitation on the doctrine of equivalents, and that its application is to be decided by the court, not a jury.¹²²⁹ The court stated that this legal limitation would be imposed even if a jury has found equivalence to each claim element.¹²³⁰ The court also added that “[t]he ensnarement inquiry is separate and distinct from the jury’s element-by-element equivalence analysis, and it has no bearing on the validity of the actual claims.”¹²³¹ Thus, the court held that the ensnarement defense is “to be determined by the court, either on a pretrial motion for partial

1222. 285 F.3d 1046, 62 U.S.P.Q.2d (BNA) 1225 (Fed. Cir. 2002) (en banc) (per curiam).

1223. *Abbott Labs.*, 566 F.3d at 1297, 90 U.S.P.Q.2d (BNA) at 1781.

1224. *Id.* at 1298, 90 U.S.P.Q.2d (BNA) at 1781.

1225. *Id.*, 90 U.S.P.Q.2d (BNA) at 1781.

1226. 567 F.3d 1314, 90 U.S.P.Q.2d (BNA) 1865 (Fed. Cir. 2009).

1227. *Id.* at 1322, 90 U.S.P.Q.2d (BNA) at 1870 (citing *Wilson Sporting Goods Co. v. David Geoffrey & Assoc.*, 904 F.2d 677, 683, 14 U.S.P.Q.2d (BNA) 1942, 1947 (Fed. Cir. 1990), *overruled in part* by *Cardinal Chem. Co. v. Morton Int’l, Inc.*, 508 U.S. 83, 92 n.12, 26 U.S.P.Q.2d (BNA) 1721, 1726 n.12 (1993)).

1228. *Id.* at 1322–24, 90 U.S.P.Q.2d (BNA) at 1870–71.

1229. *Id.* at 1324, 90 U.S.P.Q.2d (BNA) at 1871.

1230. *Id.* at 1323, 90 U.S.P.Q.2d (BNA) at 1870.

1231. *Id.*, 90 U.S.P.Q.2d (BNA) at 1871.

summary judgment or on a motion for judgment as a matter of law at the close of the evidence and after [the] jury verdict.”¹²³²

As to factual issues related to ensnarement, the court drew an “analogy to prosecution history estoppel, particularly in the context of rebutting the presumption of surrender under the ‘foreseeability’ criterion.”¹²³³ The Federal Circuit pointed out that a district court may hear expert testimony and may consider other extrinsic evidence regarding the various factors for determining obviousness.¹²³⁴ The court explained that “[i]f a district court believes that an advisory verdict would be helpful, and that a ‘hypothetical claim’ construct would not unduly confuse the jury as to equivalence and validity, then one may be obtained under Federal Rule of Civil Procedure 39(c).”¹²³⁵

The Federal Circuit next analyzed whether the district court erred in denying Medtronic’s ensnarement defense.¹²³⁶ Ensnarement is sometimes referred to as the “hypothetical claim analysis,” which had its genesis in the 1990s in Judge Rich’s decision in *Wilson Sporting Goods Co. v. David Geoffrey & Associates*.¹²³⁷ The framework for determining ensnarement begins with a court’s construction of a hypothetical claim that literally covers the accused device.¹²³⁸ The court then assesses whether the hypothetical claim is novel and unobvious over the prior art.¹²³⁹ If it is not, the patentee has overreached, and the accused device does not infringe as a matter of law.¹²⁴⁰ In *DePuy Spine*, the Federal Circuit agreed with the district court that the prior art proffered by Medtronic would not have rendered the hypothetical obvious and affirmed the lower court’s denial of Medtronic’s ensnarement defense.¹²⁴¹

1232. *Id.* at 1324, 90 U.S.P.Q.2d (BNA) at 1871 (quoting *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 39 n.8, 41 U.S.P.Q.2d (BNA) 1865, 1875 n.8 (1997)).

1233. *Id.*, 90 U.S.P.Q.2d (BNA) at 1871.

1234. *Id.*, 90 U.S.P.Q.2d (BNA) at 1871.

1235. *Id.*, 90 U.S.P.Q.2d (BNA) at 1841.

1236. *Id.*, 90 U.S.P.Q.2d (BNA) at 1871.

1237. 904 F.2d 677, 685, 14 U.S.P.Q.2d (BNA) 1942, 1949 (Fed. Cir. 1990).

1238. *DePuy Spine, Inc.*, 567 F.3d at 1324–25, 90 U.S.P.Q.2d (BNA) at 1871–72.

1239. *Id.* at 1325, 90 U.S.P.Q.2d (BNA) at 1872.

1240. *Id.*, 90 U.S.P.Q.2d (BNA) at 1872 (quoting *Interactive Pictures Corp. v. Infinite Pictures, Inc.*, 274 F.3d 1371, 1380, 61 U.S.P.Q.2d (BNA) 1152, 1159 (Fed. Cir. 2001)).

1241. *Id.* at 1329, 90 U.S.P.Q.2d (BNA) at 1875.

C. *Indirect Infringement*

There are two types of “indirect” infringement: inducing infringement and contributory infringement.¹²⁴² Section 271(b) covers inducement and provides that “[w]hoever actively induces infringement of a patent shall be liable as an infringer.”¹²⁴³ Under recent decisions, this section has been interpreted as requiring proof that the alleged infringer knew or should have known that its actions would cause direct infringement.¹²⁴⁴ Section 271(c) defines “contributory infringement” as, for example, supplying a component for use in a patented product or process, knowing it to be specially made or adapted for use in infringement of the patent, and not a staple article or commodity suitable for a substantial noninfringing use.¹²⁴⁵ As a general rule, a finding of direct infringement is a prerequisite to a finding of indirect infringement.¹²⁴⁶

1. *Inducing infringement*

a. *Proving direct infringement*

Because the patentee in *Exergen Corp.* failed to prove direct infringement, the Federal Circuit found no induced infringement of the claims at issue.¹²⁴⁷ Those claims required a determination of the “temperature of the temporal artery through skin.”¹²⁴⁸ The accused device measured the surface temperature of the skin that covers the temporal artery and then converted the skin temperature to the oral temperature, which was different from measuring the temperature of the temporal artery.¹²⁴⁹ Since the accused device converted the skin temperature measurement to the oral temperature and not to the temporal artery temperature, a user of the accused device could not

1242. 35 U.S.C. § 271(b)–(c) (2006).

1243. *Id.* § 271(b).

1244. *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306, 81 U.S.P.Q.2d (BNA) 1238, 1247 (Fed. Cir. 2006).

1245. 35 U.S.C. § 271(c).

1246. *See, e.g.*, *Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1274, 70 U.S.P.Q.2d (BNA) 1369, 1376 (Fed. Cir. 2004); *Met-Coil Sys. Corp. v. Korner's Unlimited, Inc.*, 803 F.2d 684, 687, 231 U.S.P.Q.2d (BNA) 474, 477 (Fed. Cir. 1986); *see also Stukenborg v. Teledyne, Inc.*, 441 F.2d 1069, 1072, 169 U.S.P.Q. (BNA) 584, 586 (9th Cir. 1971) (“Absent direct infringement of the patent claims, there can be neither contributory infringement nor inducement of infringement.”).

1247. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1325, 91 U.S.P.Q.2d (BNA) 1656, 1665 (Fed. Cir. 2009).

1248. *Id.* at 1324, 91 U.S.P.Q.2d (BNA) at 1665.

1249. *Id.*, 91 U.S.P.Q.2d (BNA) at 1665.

directly infringe those claims, and the potential for induced infringement on the manufacturer's part was eliminated.¹²⁵⁰

In *Lucent Technologies, Inc. v. Gateway, Inc.*,¹²⁵¹ the Federal Circuit agreed that Lucent's actual evidence of direct infringement was limited, but found circumstantial evidence adequate to permit a jury to find that at least one person had performed the claimed method.¹²⁵² The Federal Circuit concluded that Lucent's circumstantial evidence of infringement was "something less than the weight of the evidence,"¹²⁵³ yet was just "more than a mere scintilla,"¹²⁵⁴ thus satisfying the requirements for a finding of direct infringement.

As the Federal Circuit explained, "[when there is] no evidence of any 'specific instance of direct infringement,' [a patentee is] required to show that 'the accused device necessarily infringes the patent in suit.'"¹²⁵⁵ One claim at issue in *Exergen* required the step of "laterally scanning a temperature detector across a forehead" to obtain the temperature of a patient.¹²⁵⁶ The parties agreed that "laterally" meant "horizontal relative to the human body."¹²⁵⁷ The alleged infringer's instructions for customers read: "Scan with the thermometer *around the temple area* (marked as [a] dotted area in the drawing)," or "Place the thermometer's soft touch tip just outside the eyebrow (in the temple region of the forehead) and slowly *slide upwards* to just below the hairline."¹²⁵⁸ The patentee argued that these instructions involved at least some horizontal component.¹²⁵⁹ But the court explained that even if that was true, the patentee's argument ignored the claim language requiring the lateral scan to occur "across the forehead."¹²⁶⁰ Since no reasonable jury would have found that a purchaser of the accused device would perform the steps as required by the claim at issue, the Federal Circuit held that the defendant's device did not

1250. *Id.* at 1325, 91 U.S.P.Q.2d (BNA) at 1665.

1251. 580 F.3d 1301, 92 U.S.P.Q.2d (BNA) 1555 (Fed. Cir. 2009).

1252. *Id.* at 1318, 92 U.S.P.Q.2d (BNA) at 1566.

1253. *Id.* at 1319, 92 U.S.P.Q.2d (BNA) at 1567 (quoting *Consolo v. Fed. Mar. Comm'n*, 383 U.S. 607, 620 (1966)).

1254. *Id.*, 92 U.S.P.Q.2d (BNA) at 1567 (quoting *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938)).

1255. *Exergen Corp.*, 575 F.3d at 1321–22, 92 U.S.P.Q.2d (BNA) at 1663 (quoting *ACCO Brands, Inc. v. ABA Locks Mfrs. Co.*, 501 F.3d 1307, 1313, 84 U.S.P.Q.2d (BNA) 1267, 1270–71 (Fed. Cir. 2007)).

1256. *Id.* at 1322, 92 U.S.P.Q.2d (BNA) at 1663.

1257. *Id.*, 92 U.S.P.Q.2d (BNA) at 1663.

1258. *Id.*, 92 U.S.P.Q.2d (BNA) at 1663–64.

1259. *Id.* at 1323, 92 U.S.P.Q.2d (BNA) at 1664.

1260. *Id.*, 92 U.S.P.Q.2d (BNA) at 1664.

necessarily directly infringe, and that induced infringement was thus negated.¹²⁶¹

b. Intent to induce infringement and “practicing prior art” to negate intent

The Federal Circuit previously held in *DSU Medical Corp. v. JMS Co.*¹²⁶² that proving induced infringement requires not only a showing of direct infringement but also that the defendant “possessed specific intent to encourage another’s infringement.”¹²⁶³ In *Vita-Mix*, the court affirmed a finding of no inducement because it found the record devoid of direct or circumstantial evidence of the accused manufacturer’s intent to encourage customers to infringe the patent at issue.¹²⁶⁴ The court found that the accused manufacturer’s product instructions did not evidence a specific intent to encourage infringement, since they either taught a stirring action—which the manufacturer could have reasonably believed was noninfringing—or evidenced an intent to discourage infringement.¹²⁶⁵ Looking to product design, the court held that although a vertical position of the stir stick—which corresponded to the claimed element at issue in the infringement inquiry—may lead to infringing use under certain conditions, there was no evidence that the accused manufacturer intended users to maintain the stir stick in the vertical position.¹²⁶⁶

By contrast, in *Lucent Technologies*, although the Federal Circuit agreed with the defendant, Microsoft, that the evidence of its intent to induce infringement was not strong, the court was not persuaded that the jury’s finding that Microsoft possessed the requisite intent to induce at least one user of its products to infringe the claimed methods was unreasonable.¹²⁶⁷ The Federal Circuit affirmed the district court’s denial of Microsoft’s motion for JMOL that Microsoft did not induce infringement.¹²⁶⁸

1261. *Id.* at 1324, 92 U.S.P.Q.2d (BNA) at 1664–65.

1262. 471 F.3d 1293, 81 U.S.P.Q.2d (BNA) 1238 (Fed. Cir. 2006).

1263. *Id.* at 1306, 81 U.S.P.Q.2d (BNA) at 1247 (quoting *MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp.*, 420 F.3d 1369, 1378, 76 U.S.P.Q.2d (BNA) 1276, 1283–84 (Fed. Cir. 2005)).

1264. *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1328–29, 92 U.S.P.Q.2d (BNA) 1340, 1348–49 (Fed. Cir. 2009).

1265. *Id.*, 92 U.S.P.Q.2d (BNA) at 1348–49.

1266. *Id.* at 1329, 92 U.S.P.Q.2d (BNA) at 1349.

1267. *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1323, 92 U.S.P.Q.2d (BNA) 1555, 1570 (Fed. Cir. 2009).

1268. *Id.*, 92 U.S.P.Q.2d (BNA) at 1570.

In *i4i Ltd. v. Microsoft Corp.*,¹²⁶⁹ the Federal Circuit affirmed a jury's findings of inducement to infringe in another decision against Microsoft.¹²⁷⁰ The patent at issue included claims drawn to a method of editing documents containing markup language, such as XML.¹²⁷¹ MICROSOFT WORD allegedly infringed the claims by including an XML editor in certain copies of the popular program.¹²⁷² In *i4i*, the court concluded that a jury could have found direct infringement based on the testimony of i4i's expert, who testified that certain copies of MICROSOFT WORD could perform all of the steps of i4i's method claim.¹²⁷³ Further, because following Microsoft's instructional materials would infringe i4i's patent, the instructions themselves were substantial evidence that Microsoft intended its product to be used in an infringing manner.¹²⁷⁴ In contrast to the instructions in *Vita-Mix*, the Court held that substantial evidence existed indicating that Microsoft knew its instructions would lead to an infringing use.¹²⁷⁵ For example, internal emails indicated both knowledge of the i4i technology and the belief that Microsoft's product would make i4i's program obsolete.¹²⁷⁶

Often, alleged infringers proffer noninfringement defenses based on validity. They will claim that they do not infringe because the claims are invalid, and one cannot infringe an invalid patent. This ensnarement defense to infringement (also referred to as "practicing the prior art") constitutes a backdoor way of arguing validity in the context of infringement, where the burden of proof is "preponderance of the evidence" as contrasted with the higher burden of "clear and convincing evidence." Courts tend to look unfavorably upon such attempts to end-run one's evidentiary burden of proof.¹²⁷⁷ Nonetheless, practicing the prior art may be relied on to manifest one's state of mind and establish a lack of intent to infringe in the context of indirect infringement.

1269. 589 F.3d 1246, 93 U.S.P.Q.2d (BNA) 1161 (Fed. Cir. 2009), *superseded on reh'g* by No. 2009-1504, 2010 WL 801705, 93 U.S.P.Q.2d (BNA) 1943 (Fed. Cir. 2010).

1270. *Id.* at 1254-55, 93 U.S.P.Q.2d (BNA) at 1165-66.

1271. *Id.* at 1255, 93 U.S.P.Q.2d (BNA) at 1166.

1272. *Id.* at 1264-65, 93 U.S.P.Q.2d (BNA) at 1173.

1273. *Id.* at 1266, 93 U.S.P.Q.2d (BNA) at 1174.

1274. *Id.* at 1267, 93 U.S.P.Q.2d (BNA) at 1175.

1275. *Id.*, 93 U.S.P.Q.2d (BNA) at 1175.

1276. *Id.*, 93 U.S.P.Q.2d (BNA) at 1175.

1277. *See, e.g.*, *Tate Access Floors, Inc. v. Interface Architectural Res., Inc.*, 279 F.3d 1357, 1367, 61 U.S.P.Q.2d (BNA) 1647, 1654 (Fed. Cir. 2002) ("[A]ccused infringers are not free to flout the requirement of proving invalidity by clear and convincing evidence by asserting a 'practicing prior art' defense to literal infringement under the less stringent preponderance of the evidence standard.").

In *Kinetic Concepts, Inc. v. Blue Sky Medical Group, Inc.*,¹²⁷⁸ the Federal Circuit, while acknowledging that “practicing the prior art” is not an effective defense for infringement, endorsed the use of the practice to negate the necessary intent for a charge of inducing infringement.¹²⁷⁹ The court explained that, even though “‘practicing the prior art’ is not a defense to patent infringement[,] . . . it does not follow that a defendant’s belief that it can freely practice inventions found in the public domain cannot support a jury’s finding that the intent required for induced infringement was lacking.”¹²⁸⁰

2. *Contributory infringement*

The *Lucent Technologies* court also addressed contributory infringement by Microsoft as part of the Federal Circuit’s indirect infringement analysis.¹²⁸¹ The issue under consideration in that case was whether the “material or apparatus” required by the patent is the entire software package or just the particular tool (e.g., the calendar date-picker) that performs the claimed method.¹²⁸² The court found that a date-picker tool was suitable only for an infringing use, while the software package as a whole was capable of substantial noninfringing use.¹²⁸³ The court concluded that “[i]nclusion of the date-picker feature within a larger program does not change the date-picker’s ability to infringe,” that a jury could reasonably conclude that Microsoft intended users to use the tool, and that the only intended use of the tool infringed the patent.¹²⁸⁴

In *Vita-Mix*, the Federal Circuit considered whether noninfringing use of a stirring stick in the accused blender was sufficiently substantial to avoid contributing infringement.¹²⁸⁵ In deciding this question, the court adopted, *arguendo*, the opinion of the patentee’s expert and assumed that a customer’s use of the accused device may directly infringe.¹²⁸⁶ Even then, the court found that no reasonable jury could find that using the stir stick, which was specifically

1278. 554 F.3d 1010, 89 U.S.P.Q.2d (BNA) 1801 (Fed. Cir. 2009), *cert. denied sub nom.* Medela AG v. Kinetic Concepts, Inc., 130 S. Ct. 624 (2009).

1279. *Id.* at 1024–25, 89 U.S.P.Q.2d (BNA) at 1810–11.

1280. *Id.* at 1025, 89 U.S.P.Q.2d (BNA) at 1811.

1281. *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1320, 92 U.S.P.Q.2d (BNA) 1555, 1568 (Fed. Cir. 2009).

1282. *Id.*, 92 U.S.P.Q.2d (BNA) at 1568.

1283. *Id.* at 1320–21, 92 U.S.P.Q.2d (BNA) at 1568–69.

1284. *Id.* at 1321, 92 U.S.P.Q.2d (BNA) at 1569.

1285. *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1327–28, 92 U.S.P.Q.2d (BNA) 1340, 1347–48 (Fed. Cir. 2009).

1286. *Id.* at 1327, 92 U.S.P.Q.2d (BNA) at 1347–48.

disavowed by the patentee through statements made in the specification, was an insubstantial use of the accused device.¹²⁸⁷ Accordingly, the court affirmed the district court's grant of summary judgment, concluding that there was no contributory infringement.¹²⁸⁸

Additionally, in *i4i*, the Federal Circuit found that while noninfringing uses existed, they were not substantial noninfringing uses.¹²⁸⁹ Quoting *Vita-Mix*, the court noted that “[w]hether a use is ‘substantial,’ rather than just ‘unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental’ cannot be evaluated in a vacuum.”¹²⁹⁰ With respect to the proffered noninfringing uses, the jury heard evidence that the uses were not practical and that they “deprived users of the very benefit XML was intended to provide.”¹²⁹¹ As there was also evidence that Microsoft knew its product would infringe, the court determined that a jury could have reasonably found contributory infringement.¹²⁹²

3. *Infringement under 35 U.S.C. § 271(f) and (g)*

a. *Applicability to process claims*

35 U.S.C. § 271(f)(1) deals with inducing infringement outside of the United States based on acts occurring in the United States. It provides that one who:

[S]upplies . . . 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 . . . shall be liable as an infringer.¹²⁹³

Section 271(f)(2) contains similar language directed to contributory infringement. The language of § 271 refers generally to the “patented invention,” without discriminating between, for example, product or process inventions.¹²⁹⁴

1287. *Id.* at 1328, 92 U.S.P.Q.2d (BNA) at 1348.

1288. *Id.*, 92 U.S.P.Q.2d (BNA) at 1348.

1289. *i4i Ltd. v. Microsoft Corp.*, 589 F.3d 1246, 1266, 93 U.S.P.Q.2d (BNA) 1161, 1174 (Fed. Cir. 2009), *superseded on reh'g* by No. 2009-1504, 2010 WL 801705, 93 U.S.P.Q.2d (BNA) 1943 (Fed. Cir. 2010).

1290. *Id.*, 93 U.S.P.Q.2d (BNA) at 1174 (quoting *Vita-Mix*, 581 F.3d at 1327, 92 U.S.P.Q.2d (BNA) at 1347).

1291. *Id.*, 93 U.S.P.Q.2d (BNA) at 1174.

1292. *Id.*, 93 U.S.P.Q.2d (BNA) at 1174.

1293. 35 U.S.C. § 271(f)(1) (2006).

1294. *See* 35 U.S.C. § 271(f)(2) (“Whoever without authority supplies . . . any component of a patented invention that is especially made or especially adapted for

In *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*,¹²⁹⁵ the patentee, Cardiac Pacemakers, asserted infringement under § 271(f), arguing that the statute applied to the sale of products that were used abroad to practice a patented method.¹²⁹⁶ To Cardiac Pacemakers, a component of a patented invention—in this case, a process or method invention—encompassed “the apparatus that performed the process,” not a step of that process.¹²⁹⁷ The district court ruled in Cardiac’s favor, holding that § 271(f) applied to method claims and that St. Jude’s shipment of the accused product abroad for use in the claimed method violated the statute.¹²⁹⁸ An initial panel of the Federal Circuit affirmed the district court in this regard.¹²⁹⁹ But after review en banc, the Federal Circuit reversed, vacating its initial panel decision and overruling *Union Carbide Chemicals & Plastics Technology Corp. v. Shell Oil Co.*,¹³⁰⁰ including any implications in other decisions that § 271(f) applies to method patents.¹³⁰¹

The Federal Circuit, sitting en banc, rejected the patentee’s arguments that a component of a patented invention within the meaning of § 271(f) could be an apparatus that performed the process.¹³⁰² It first construed “component” in § 271(f) based on the use of the term in other sections of the statute, noting that § 271(c) uses “component” when referring to product inventions (“a component of a patented machine, manufacture, combination, or composition”) and “material or apparatus” when referring to process inventions (“material or apparatus for use in practicing a patented process”).¹³⁰³ It stated that an apparatus used to practice a process invention is therefore not a “component” of that process.¹³⁰⁴ Indicating that the components of process inventions are their steps, the court then observed that § 271(f) further requires that the

use in the invention . . . where such component is uncombined in whole or in part . . . shall be liable as an infringer.”).

1295. 576 F.3d 1348, 91 U.S.P.Q.2d (BNA) 1898 (Fed. Cir. 2009) (en banc), cert. denied, 130 S. Ct. 1088 (2010).

1296. *Id.* at 1365, 91 U.S.P.Q.2d (BNA) at 1912.

1297. *Id.* at 1363, 91 U.S.P.Q.2d (BNA) at 1910.

1298. *Id.* at 1359, 91 U.S.P.Q.2d (BNA) at 1907 (citing *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 418 F. Supp. 2d 1021, 1042–44 (S.D. Ind. 2005), vacated, 315 F. App’x 273 (Fed. Cir. 2009)).

1299. *Id.*, 91 U.S.P.Q.2d (BNA) at 1907.

1300. 425 F.3d 1366, 76 U.S.P.Q.2d (BNA) 1705 (Fed. Cir. 2005), overruled by *Cardiac Pacemakers*, 576 F.3d 1348, 91 U.S.P.Q.2d (BNA) 1898.

1301. *Id.*, 91 U.S.P.Q.2d (BNA) at 1907.

1302. *Id.* at 1362, 91 U.S.P.Q.2d (BNA) at 1909.

1303. *Id.* at 1363, 91 U.S.P.Q.2d (BNA) at 1910 (quoting 35 U.S.C. § 271(c) (2006)).

1304. *Id.* at 1364, 91 U.S.P.Q.2d (BNA) at 1910.

components be “supplied.”¹³⁰⁵ It defined “supply” to mean to furnish provisions or equipment, and since it would be physically impossible to supply an intangible step, the court held that the “supply” requirement effectively “eliminates method patents from Section 271(f)’s reach.”¹³⁰⁶ The court also noted that its interpretation was fully consistent with the legislative history, which focused on the patented product rather than the protection of method patents.¹³⁰⁷

b. Infringement under § 271(g)

In *Hoffman-La Roche*, the court addressed infringement under 35 U.S.C. § 271(g), which prohibits the importation of a product made by a patented process into the United States that is materially changed by subsequent processes or that forms a trivial or nonessential component of another product.¹³⁰⁸ The court noted that, “[i]n the biotechnology context, a significant change in a protein’s structure and/or properties would constitute a material change.”¹³⁰⁹ For the product in *Hoffman-La Roche*, however, the court found that the structure and functional differences between the recombinant EPO made by the claimed processes and the PEG-EPO imported by Roche were not material because the infringing product merely contained an additional element of PEG, which did not impart a materially different function.¹³¹⁰

D. Willful Infringement

1. Evidence of copying

In *DePuy Spine*, the Federal Circuit upheld the district court’s grant of judgment as a matter of law because the patentee failed to provide a “legally sufficient evidentiary basis to find an objectively high likelihood . . . that the [accused device] infringed” the patent at issue.¹³¹¹ Moreover, because the patentee failed to meet that first threshold requirement, the court did not need to consider evidence

1305. *Id.*, 91 U.S.P.Q.2d (BNA) at 1910.

1306. *Id.*, 91 U.S.P.Q.2d (BNA) at 1910.

1307. *See id.*, 91 U.S.P.Q.2d (BNA) at 1910 (“Section 271(f) will ‘prevent copiers from avoiding U.S. patents by shipping overseas the components of a product patented in this country so that assembly of the components will be completed abroad.’” (quoting S. Rep. No. 98-663, at 6 (1984))).

1308. *Amgen Inc. v. F. Hoffmann-La Roche Ltd.*, 580 F.3d 1340, 1378–79, 92 U.S.P.Q.2d (BNA) 1289, 1318–19 (Fed. Cir. 2009).

1309. *Id.* at 1379, 92 U.S.P.Q.2d (BNA) at 1319.

1310. *Id.*, 92 U.S.P.Q.2d (BNA) at 1320.

1311. *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1336, 90 U.S.P.Q.2d (BNA) 1865, 1880 (Fed. Cir. 2009).

of copying by the infringer, as it would have been relevant only to what the infringer knew or should have known about the likelihood of its infringement.¹³¹²

The Federal Circuit's rationale followed the standard set forth in *In re Seagate Technology, LLC*¹³¹³ to determine the willfulness of a patent infringement. In that case, the court held that to establish willful infringement, "a patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent."¹³¹⁴ The court further held that "if this threshold objective standard is satisfied, the patentee must also demonstrate that this objectively-defined risk (determined by the record developed in the infringement proceeding) was either known or so obvious that it should have been known to the accused infringer."¹³¹⁵

As pointed out by the *DePuy Spine* court, the "first prong is objective" and does not look to the state of mind of the accused infringer.¹³¹⁶ Because *DePuy Spine* failed to satisfy *In re Seagate's* first prong, the court did not need to address *DePuy Spine's* arguments "concerning 'copying' and Medtronic's rebuttal evidence concerning 'designing around,' both of which [we]re relevant only to Medtronic's mental state regarding its direct infringement under *In re Seagate's* second prong."¹³¹⁷ Accordingly, the Federal Circuit affirmed the district court's grant of judgment as a matter of law.¹³¹⁸

VIII. INEQUITABLE CONDUCT AND OTHER DEFENSES

A. *Inequitable Conduct*

An applicant for a patent owes a "duty of candor" while dealing with the USPTO.¹³¹⁹ A breach of this duty constitutes "inequitable conduct," which can lead to invalidity or unenforceability of a

1312. *Id.*, 90 U.S.P.Q.2d (BNA) at 1880.

1313. 497 F.3d 1360, 83 U.S.P.Q.2d (BNA) 1865 (Fed. Cir. 2007) (en banc), *cert. denied*, 552 U.S. 1230 (2008).

1314. *Id.* at 1371, 83 U.S.P.Q.2d (BNA) at 1870.

1315. *Id.*, 83 U.S.P.Q.2d (BNA) at 1870.

1316. *DePuy Spine*, 567 F.3d at 1336, 90 U.S.P.Q.2d (BNA) at 1880 ("[E]vidence of copying in a case of direct infringement is relevant only to *Seagate's* second prong, as it may show what the accused infringer knew or should have known about the likelihood of its infringement.").

1317. *Id.* at 1337, 90 U.S.P.Q.2d (BNA) at 1881.

1318. *Id.*, 90 U.S.P.Q.2d (BNA) at 1881.

1319. *Hyatt v. Doll*, 576 F.3d 1246, 1274 & n.9, 91 U.S.P.Q.2d (BNA) 1865, 1886 & n.9 (Fed. Cir. 2009), *reh'g en banc granted*, No. 2007-1066, 2010 WL 597219, 93 U.S.P.Q.2d (BNA) 1871 (Fed. Cir. Feb. 17, 2010) (en banc) (per curiam).

patent.¹³²⁰ In order to prove inequitable conduct, defendants must present evidence of (1) an affirmative misrepresentation of material fact, failure to disclose material information, or submission of false material information, and (2) intent to deceive the USPTO.¹³²¹ Both materiality and intent to deceive require proof by clear and convincing evidence.¹³²² The materiality of information turns on whether “a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.”¹³²³ If a defendant succeeds in proving materiality and intent to deceive, the court must weigh these findings in light of all the circumstances and determine if there was inequitable conduct.¹³²⁴

Over two decades ago, the Federal Circuit commented that “the habit of charging inequitable conduct in almost every major patent case has become an absolute plague.”¹³²⁵ While some panels seemed to treat inequitable conduct as a “plague,” others were more than willing to find inequitable conduct. After an incredibly busy year in 2008 for the Federal Circuit in this area, the court continued to make new law in 2009. Various panels and judges seemed to push the court in different directions, marking an area ripe with disagreement.

In *Rothman v. Target Corp.*,¹³²⁶ the Federal Circuit held that the district court erred in upholding a jury verdict that a nursing garment patent was unenforceable due to inequitable conduct.¹³²⁷ First, the court held that one undisclosed prior-art nursing garment supporting the inequitable-conduct findings was cumulative of other cited references.¹³²⁸ Indeed, the court found that at least two cited

1320. *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1363, 81 U.S.P.Q.2d (BNA) 1705, 1708 (Fed. Cir. 2007).

1321. *Id.*, 81 U.S.P.Q.2d (BNA) at 1708.

1322. *Id.*, 81 U.S.P.Q.2d (BNA) at 1708.

1323. *Symantec Corp. v. Computer Assocs. Int'l, Inc.*, 522 F.3d 1279, 1297, 86 U.S.P.Q.2d (BNA) 1449, 1460 (Fed. Cir. 2008) (quoting *eSpeed, Inc. v. BrokerTec USA L.L.C.*, 480 F.3d 1129, 1136, 83 U.S.P.Q.2d (BNA) 1183, 1187 (Fed. Cir. 2007)).

1324. *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1366, 57 U.S.P.Q.2d (BNA) 1647, 1652 (Fed. Cir. 2001).

1325. *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422, 7 U.S.P.Q.2d (BNA) 1158, 1161 (Fed. Cir. 1988).

1326. 556 F.3d 1310, 89 U.S.P.Q.2d (BNA) 1897 (Fed. Cir. 2009), *cert. denied*, 130 S. Ct. 626 (2010).

1327. The Federal Circuit noted that inequitable conduct is an equitable defense to patent infringement most appropriately reserved for the court. *Id.* at 1322, 89 U.S.P.Q.2d (BNA) at 1905 (citing *Baxter Healthcare Corp. v. Spectramed, Inc.*, 49 F.3d 1575, 1584, 34 U.S.P.Q.2d (BNA) 1120, 1127 (Fed. Cir. 1995)). Nevertheless, district courts occasionally delegate aspects of the inequitable conduct inquiry to juries. *Id.*, 89 U.S.P.Q.2d (BNA) at 1905. In *Rothman*, the parties agreed to submit factual inquiries and the ultimate question of inequitable conduct to the jury. *Id.* at 1323, 89 U.S.P.Q.2d (BNA) at 1905. The Federal Circuit noted that this is not the preferred course. *Id.*, 89 U.S.P.Q.2d (BNA) at 1905.

1328. *Id.* at 1326, 89 U.S.P.Q.2d (BNA) at 1908 (citing 37 C.F.R. § 1.56(b) (2008)).

references were substantially more probative of patentability than the uncited garment.¹³²⁹ Thus, the court held that no reasonable jury could have relied on the uncited garment to support the inequitable conduct finding.¹³³⁰

Next, the Federal Circuit rejected the defendants' argument that the patentee's failure to disclose a second garment style was an alternative basis for the jury's inequitable conduct verdict.¹³³¹ The court held that there could be no deceptive intent largely due to the defendants' conduct in informing the patentee of this second garment style.¹³³² The court said that, "[r]eceipt of threatening letters containing vague descriptions of unsubstantiated prior art at the tail end of a souring business relationship does not create an automatic duty of disclosure."¹³³³ Here, the accused infringer apparently did not provide sufficient information detailing the alleged style, nor did it send a sample, photograph, drawing, or description.¹³³⁴ Thus, the Federal Circuit held that the patentee "cannot be charged with 'culpable intent in withholding information that [it] did not have.'"¹³³⁵ Of particular note to practitioners, the court focused on the defendants' actions in delaying notification of the prior art to the patentee.¹³³⁶ Moreover, the court found that the patentee had a good-faith basis for believing that the alternative style was not prior art, and thus concluded that the record contains no substantial evidence that the patentee intended to deceive the USPTO in withholding the alternative style.¹³³⁷

The Federal Circuit also rejected the defendants' third argument that the patentee's attorney had made misrepresentations of material fact.¹³³⁸ In response to an obviousness argument, the patentee's attorney had argued that nursing garments are not analogous art to women's garments in general.¹³³⁹ The court held that a "prosecuting attorney is free to present argument in favor of patentability without fear of committing inequitable conduct."¹³⁴⁰ The court noted that the examiner has the discretion to reject or accept an applicant's

1329. *Id.* at 1327, 89 U.S.P.Q.2d (BNA) at 1909.

1330. *Id.*, 89 U.S.P.Q.2d (BNA) at 1909.

1331. *Id.*, 89 U.S.P.Q.2d (BNA) at 1909.

1332. *Id.*, 89 U.S.P.Q.2d (BNA) at 1909.

1333. *Id.*, 89 U.S.P.Q.2d (BNA) at 1909.

1334. *Id.*, 89 U.S.P.Q.2d (BNA) at 1909.

1335. *Id.*, 89 U.S.P.Q.2d (BNA) at 1909 (alteration in original) (quoting *Herbert v. Lisle Corp.*, 99 F.3d 1109, 1116, 40 U.S.P.Q.2d (BNA) 1611, 1615 (Fed. Cir. 1996)).

1336. *Id.* at 1328, 89 U.S.P.Q.2d (BNA) at 1909-10.

1337. *Id.*, 89 U.S.P.Q.2d (BNA) at 1910.

1338. *Id.*, 89 U.S.P.Q.2d (BNA) at 1910.

1339. *Id.*, 89 U.S.P.Q.2d (BNA) at 1910.

1340. *Id.* at 1328-29, 89 U.S.P.Q.2d (BNA) at 1910.

arguments.¹³⁴¹ The court appeared to give considerable leeway in making arguments as long as there was no misstating of material facts.¹³⁴² In the end, the court held that the defendants had not presented substantial evidence of inequitable conduct and reversed the jury verdict of inequitable conduct.¹³⁴³ The court also held that because the district court based its award of costs on its finding of inequitable conduct, the award must be vacated.¹³⁴⁴

In *Larson Manufacturing Co. v. AluminArt Products Ltd.*,¹³⁴⁵ the Federal Circuit again vacated a district court finding of inequitable conduct.¹³⁴⁶ In that case, the district court found that the patentee failed to disclose three items of prior art and two office actions issued in the prosecution of a continuation application that grew out of the application that resulted in the patent-in-suit.¹³⁴⁷ The district court “rejected [the patentee’s] argument that the three items of prior art [and the office actions] were cumulative of prior art which already was before the Reexamination Panel.”¹³⁴⁸ The district court found an intent to deceive the Reexamination Panel, and after balancing materiality and intent, held that there was inequitable conduct.¹³⁴⁹

On appeal, the Federal Circuit first considered the three items of prior art, referred to as the “Genius Literature,” the “German Patent,” and the “Preferred Engineering Literature.”¹³⁵⁰ With respect to the Genius Literature and the German Patent, the court found that the references were cumulative because their material aspects were already disclosed in another patent before the Reexamination Panel.¹³⁵¹ The court determined that testimony as to characteristics of the prior art was irrelevant to the claim limitations at issue, and that the analysis must stay focused on the claim limitations at issue.¹³⁵² The court then considered the Preferred Engineering Literature, holding that the limitation found material by the district court was already disclosed in another reference that was before the Reexamination Panel.¹³⁵³ The court thus held that regardless of whether the

1341. *Id.* at 1329, 89 U.S.P.Q.2d (BNA) at 1910.

1342. *Id.*, 89 U.S.P.Q.2d (BNA) at 1910–11.

1343. *Id.* at 1329, 89 U.S.P.Q.2d (BNA) at 1910–11.

1344. *Id.*, 89 U.S.P.Q.2d (BNA) at 1911.

1345. 559 F.3d 1317, 90 U.S.P.Q.2d (BNA) 1257 (Fed. Cir. 2009).

1346. *Id.* at 1320, 90 U.S.P.Q.2d (BNA) at 1259.

1347. *Id.*, 90 U.S.P.Q.2d (BNA) at 1258.

1348. *Id.*, 90 U.S.P.Q.2d (BNA) at 1258.

1349. *Id.*, 90 U.S.P.Q.2d (BNA) at 1258–59.

1350. *Id.* at 1327, 90 U.S.P.Q.2d (BNA) at 1263.

1351. *Id.* at 1327–28, 90 U.S.P.Q.2d (BNA) at 1263.

1352. *Id.* at 1332–33, 90 U.S.P.Q.2d (BNA) at 1266.

1353. *Id.* at 1336, 90 U.S.P.Q.2d (BNA) at 1268.

Preferred Engineering Literature disclosed these references, it was cumulative of prior art already before the USPTO.¹³⁵⁴

The Federal Circuit then turned to the patentee's failure to disclose the two office actions from the continuation application.¹³⁵⁵ Although the art cited in the office actions had been cited in the reexamination proceedings, the court held that the examiner's adverse decisions about substantially similar claims, as in the reexamination proceedings, were material.¹³⁵⁶ The court cited *Dayco Products, Inc. v. Total Containment, Inc.*,¹³⁵⁷ in which the Federal Circuit had held that a patentee's failure to disclose contrary decisions of another examiner of a substantially similar claim was material.¹³⁵⁸ The Federal Circuit held that because the examiner in the two office actions gave a different explanation and interpretation of the prior art, this was information that an examiner would clearly consider important and, thus, material.¹³⁵⁹

The Federal Circuit then turned to the intent prong, and held that because the district court's finding of intent was based on the materiality of the three prior art references, the deceptive intent finding could not stand.¹³⁶⁰ The court thus remanded for a determination of whether the patentee withheld the only remaining material items—the two office actions—with a threshold level of deceptive intent, and if so, whether balancing the level of intent with the level of materiality warranted a finding of unenforceability.¹³⁶¹ The court then provided the trial court with the following guidance on remand: (1) it was not necessary for the district court to accept additional evidence; (2) materiality did not presume intent, and nondisclosure, by itself, could not satisfy the deceptive intent element; (3) the district court should take into account any evidence of good faith by the patentees—for example, that the patentees notified the reexamination panel of the simultaneous prosecution of the continuation application and several pleadings from this lawsuit, which militated against a finding of deceptive intent; and (4) if the district court found intent, it had to then balance the levels of

1354. *Id.* at 1337, 90 U.S.P.Q.2d (BNA) at 1269.

1355. *Id.*, 90 U.S.P.Q.2d (BNA) at 1269.

1356. *Id.* at 1338, 90 U.S.P.Q.2d (BNA) at 1270.

1357. 329 F.3d 1358, 66 U.S.P.Q.2d (BNA) 1801 (Fed. Cir. 2003).

1358. *Larson Mfg.*, 559 F.3d at 1338, 90 U.S.P.Q.2d (BNA) at 1270 (citing *Dayco Prods., Inc.*, 329 F.3d at 1368, 66 U.S.P.Q.2d (BNA) at 1808).

1359. *Id.* at 1339, 90 U.S.P.Q.2d (BNA) at 1271.

1360. *Id.*, 90 U.S.P.Q.2d (BNA) at 1271.

1361. *Id.* at 1340, 90 U.S.P.Q.2d (BNA) at 1271.

materiality and intent to determine if a finding of inequitable conduct was warranted.¹³⁶²

In a concurring opinion, Judge Linn called for en banc review of the inequitable conduct standard, citing “[t]he ease with which inequitable conduct can be pled, but not dismissed,” due to what he referred to as a lower standard that has significantly diverged from the Supreme Court’s standard.¹³⁶³ Specifically, Judge Linn opined that a lower standard than even “gross negligence” (which alone does not justify an inference of intent to deceive) has propagated through Federal Circuit case law.¹³⁶⁴ According to Judge Linn, this lower standard permits an inference of deceptive intent when “(1) highly material information is withheld; (2) the applicant knew of the information [and] . . . knew or should have known of the materiality of the information; and (3) the applicant has not provided a credible explanation for the withholding.”¹³⁶⁵ Judge Linn noted that this test is problematic because it conflates materiality with intent and incorrectly shifts the burden to the patentee to prove that it did not intend to deceive.¹³⁶⁶ Thus, Judge Linn opined that the time has come for the court to review the standard for inequitable conduct en banc.¹³⁶⁷

In *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*,¹³⁶⁸ the Federal Circuit affirmed the district court’s ruling that the patent-in-suit was not unenforceable for inequitable conduct.¹³⁶⁹ Of particular note to patent prosecutors, that case dealt in part with the issue of mistakes made in an application that were not corrected. In the patent figures, there were several mistakes that the district court found to be material but were not corrected prior to issuance of the patent.¹³⁷⁰ After one of the employees pointed out the error to one of the prosecuting attorneys, the mistake was corrected in one but not all of

1362. *Id.* at 1340–41, 90 U.S.P.Q.2d (BNA) at 1272.

1363. *Id.* at 1342–43, 90 U.S.P.Q.2d (BNA) at 1273–74 (Linn, J., concurring).

1364. *Id.* at 1343, 90 U.S.P.Q.2d (BNA) at 1274.

1365. *Id.*, 90 U.S.P.Q.2d (BNA) at 1274 (alterations in original) (quoting *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1313–14, 88 U.S.P.Q.2d (BNA) 1705, 1710 (Fed. Cir. 2008)) (internal quotation marks omitted).

1366. *Id.* at 1343–44, 90 U.S.P.Q.2d (BNA) at 1274–75.

1367. *Id.* at 1344, 90 U.S.P.Q.2d (BNA) at 1275.

1368. 560 F.3d 1366, 90 U.S.P.Q.2d (BNA) 1549 (Fed. Cir. 2009). Just before this Area Summary went to print, the Federal Circuit, sitting en banc, confirmed the separate requirements of written description and enablement, and thereby reversed in part and affirmed in part its previous panel decision. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, No. 2008-1248, 2010 WL 1007369 (Fed. Cir. Mar. 22, 2010) (en banc).

1369. *Id.* at 1380, 90 U.S.P.Q.2d (BNA) at 1559.

1370. *Id.* at 1377–78, 90 U.S.P.Q.2d (BNA) at 1557.

the applications which were then transferred to another firm.¹³⁷¹ The court held that the new attorney never knew of the errors, and that the attorney who knew of the errors, but did not correct them, was merely following the law firm's standard procedures not to make corrections until the USPTO indicated the claims were allowable.¹³⁷² The court thus held that more was needed to prove that deceptive intent was "the single most reasonable inference able to be drawn from the evidence."¹³⁷³ The court then held that the applicants' failure to submit certain references that were not prior art but would have been relevant to inherent anticipation did not prove intent to deceive, even though Ariad Pharmaceuticals again did not dispute that the references were material.¹³⁷⁴

Turning to intent, the Federal Circuit held that Eli Lilly & Co. could not prove deceptive intent by clear and convincing evidence "simply by relying on the materiality of the errors."¹³⁷⁵ The court noted that under existing law, "[o]nly after a district court makes independent findings of both materiality and intent may it weigh the two against each other in its ultimate determination of inequitable conduct."¹³⁷⁶ The court further elaborated that "[m]ateriality and intent are different requirements, and absent a finding of deceptive intent, no amount of materiality gives the district court discretion to find inequitable conduct."¹³⁷⁷ Thus, the court held that because Eli Lilly & Co. failed to establish the "threshold level of intent to deceive . . . by clear and convincing evidence," the district court correctly held that the patent was not unenforceable due to inequitable conduct.¹³⁷⁸

The Federal Circuit affirmed a summary judgment of no inequitable conduct in *AstraZeneca Pharmaceuticals LP v. Teva Pharmaceuticals USA*.¹³⁷⁹ At issue in that case was the extent to which a patent applicant, after fully disclosing relevant prior art and comparative data to a patent examiner's satisfaction, must also

1371. *Id.* at 1378, 90 U.S.P.Q.2d (BNA) at 1557.

1372. *Id.*, 90 U.S.P.Q.2d (BNA) at 1557.

1373. *Id.* at 1379, 90 U.S.P.Q.2d (BNA) at 1557–58 (quoting *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366, 88 U.S.P.Q.2d (BNA) 1001, 1007 (Fed. Cir. 2008), *cert. denied*, 129 S. Ct. 1595 (2009)) (internal quotation marks omitted).

1374. *Id.* at 1379, 90 U.S.P.Q.2d (BNA) at 1558.

1375. *Id.* at 1380, 90 U.S.P.Q.2d (BNA) at 1558.

1376. *Id.*, 90 U.S.P.Q.2d (BNA) at 1558.

1377. *Id.*, 90 U.S.P.Q.2d (BNA) at 1558 (citing *Star Scientific*, 537 F.3d at 1365, 88 U.S.P.Q.2d (BNA) at 1006).

1378. *Id.*, 90 U.S.P.Q.2d (BNA) at 1558–59 (quoting *Star Scientific*, 537 F.3d at 1365, 88 U.S.P.Q.2d (BNA) at 1006) (internal quotation marks omitted).

1379. 583 F.3d 766, 769, 92 U.S.P.Q.2d (BNA) 1481, 1482 (Fed. Cir. 2009).

“present any additional unpublished information in the applicant’s possession concerning other less structurally similar compounds, and must also synthesize additional compounds for comparative testing.”¹³⁸⁰ The appellants based their argument on the omission of test data for one compound and the submission of test data for another compound.¹³⁸¹ The Federal Circuit rejected this argument, concluding that the evidence did not support a misrepresentation or the omission of material information.¹³⁸² Also, no evidence existed that any information from the requested test data, if the tests were conducted, would have been material to patentability.¹³⁸³

The Federal Circuit also rejected the appellants’ assertion that showing a high degree of materiality required only a proportionally lesser showing of intent to deceive.¹³⁸⁴ The court reiterated that simple “[e]vidence of mistake or negligence, even gross negligence, is not sufficient to support inequitable conduct.”¹³⁸⁵ Only after a threshold showing of materiality and intent to deceive does the court weigh and balance the findings.¹³⁸⁶ Additionally, the Federal Circuit noted that inequitable conduct requires intent to deceive, not intent to withhold.¹³⁸⁷ As the court explained, “[i]ntent to deceive cannot be inferred simply from the decision to withhold [information] where the reasons given for withholding are plausible.”¹³⁸⁸ Accordingly, the court held that appellants failed to prove intent to deceive.¹³⁸⁹

Although the Federal Circuit did not change the substantive law of inequitable conduct in *Exergen Corp. v. Wal-Mart Stores, Inc.*, this case is likely to have the most significant effect of any 2009 Federal Circuit decision in deterring allegations of inequitable conduct. In *Exergen*, the Federal Circuit specifically took the opportunity to clarify the heightened pleading requirements of inequitable conduct under Federal Rule of Civil Procedure 9(b).¹³⁹⁰

1380. *Id.* at 770, 92 U.S.P.Q.2d (BNA) at 1483.

1381. *Id.* at 776, 92 U.S.P.Q.2d (BNA) at 1488.

1382. *Id.*, 92 U.S.P.Q.2d (BNA) at 1488.

1383. *Id.* at 774, 92 U.S.P.Q.2d (BNA) at 1487.

1384. *Id.* at 776, 92 U.S.P.Q.2d (BNA) at 1488.

1385. *Id.*, 92 U.S.P.Q.2d (BNA) at 1488 (citing *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876, 9 U.S.P.Q.2d (BNA) 1384, 1392 (Fed. Cir. 1988) (en banc)).

1386. *Id.*, 92 U.S.P.Q.2d (BNA) at 1488.

1387. *Id.* at 777, 92 U.S.P.Q.2d (BNA) at 1489.

1388. *Id.*, 92 U.S.P.Q.2d (BNA) at 1489 (quoting *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1367, 66 U.S.P.Q.2d (BNA) 1801, 1808 (Fed. Cir. 2003)) (internal quotation marks omitted).

1389. *Id.*, 92 U.S.P.Q.2d (BNA) at 1489.

1390. *See supra* Subsection II.C.1. (providing a full discussion of the *Exergen* case).

B. *Inventorship*

A patent is presumed to name the correct inventors, and a party claiming coinventorship must prove his claim by clear and convincing evidence.¹³⁹¹ An alleged coinventor must prove that he contributed to the conception of the claimed invention.¹³⁹² As a matter of law, an alleged coinventor's own statements are inadequate to prove conception and must be corroborated by independent evidence.¹³⁹³

In *Martek Biosciences Corp. v. Nutrinova, Inc.*, the defendants attempted to show that the patent was invalid by introducing the testimony of an alleged prior inventor under 35 U.S.C. § 102(g).¹³⁹⁴ The alleged inventor sought to corroborate testimony of prior reduction to practice by offering an abandoned patent application.¹³⁹⁵ The Federal Circuit affirmed the district court decision that the abandoned patent application was insufficient to corroborate the testimony.¹³⁹⁶ The abandoned patent application may provide the necessary contemporaneous documentary evidence to corroborate an inventor's testimony.¹³⁹⁷ This evidence, however, only goes to conception and remains insufficient to prove reduction to practice.¹³⁹⁸ The court distinguished cases involving abandoned patent applications with additional evidence, noting that no case existed where an application "alone was deemed sufficient to meet the corroboration requirement."¹³⁹⁹

C. *Laches*

The affirmative defense of laches is an equitable determination that is reviewed under the abuse of discretion standard.¹⁴⁰⁰ To prove laches, a defendant must show that (1) the plaintiff delayed for an unreasonable and inexcusable amount of time in filing suit, and

1391. *Hess v. Advanced Cardiovascular Sys., Inc.*, 106 F.3d 976, 980, 41 U.S.P.Q.2d (BNA) 1782, 1785-86 (Fed. Cir. 1997).

1392. *Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1460, 45 U.S.P.Q.2d (BNA) 1545, 1548 (Fed. Cir. 1998) (quoting *Burroughs Wellcome Co. v. Barr. Lab., Inc.*, 40 F.3d 1223, 1227-28, 32 U.S.P.Q.2d (BNA) 1915, 1919 (Fed. Cir. 1994)).

1393. *Id.* at 1461, 45 U.S.P.Q.2d (BNA) at 1548 (quoting *Price v. Symsek*, 988 F.2d 1187, 1194, 26 U.S.P.Q.2d (BNA) 1031, 1036 (Fed. Cir. 1993)).

1394. 579 F.3d 1363, 1374, 92 U.S.P.Q.2d (BNA) 1148, 1155 (Fed. Cir. 2009).

1395. *Id.* at 1375, 92 U.S.P.Q.2d (BNA) at 1156.

1396. *Id.*, 92 U.S.P.Q.2d (BNA) at 1156.

1397. *Id.*, 92 U.S.P.Q.2d (BNA) at 1156.

1398. *Id.*, 92 U.S.P.Q.2d (BNA) at 1156.

1399. *Id.* at 1376, 92 U.S.P.Q.2d (BNA) at 1157.

1400. *A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020, 1038-39, 22 U.S.P.Q.2d (BNA) 1321, 1333 (Fed. Cir. 1992).

(2) the defendant was prejudiced as a result of the delay.¹⁴⁰¹ The length of the plaintiff's delay is measured from the time the alleged infringing act became known or reasonably should have been known to the commencement of litigation.¹⁴⁰² A rebuttable presumption of laches arises when a patentee delays suit for more than six years after actual or constructive knowledge of the defendant's alleged infringing activity.¹⁴⁰³ Laches is not a complete defense and only bars relief with respect to damages accrued before suit.¹⁴⁰⁴ The Federal Circuit reviewed several summary judgment decisions on laches in 2009.

In *Vita-Mix Corp. v. Basic Holding, Inc.*,¹⁴⁰⁵ the Federal Circuit affirmed the district court's summary judgment that laches did not apply.¹⁴⁰⁶ Vita-Mix brought suit five years after learning of the accused infringement.¹⁴⁰⁷ Although insufficient to trigger the rebuttable presumption for laches, an unreasonable length of time enjoys "no fixed boundaries but rather depends on the circumstances."¹⁴⁰⁸ The court reviewed the defendant's alleged economic prejudice from the delay, because the corporation claimed that "it would have changed its product instructions to avoid infringement" during the period of delay.¹⁴⁰⁹ The court rejected this argument, noting that the product instruction changes only affect indirect infringement and not direct infringement.¹⁴¹⁰ Because the court ruled that the defendant did not indirectly infringe, there was no prejudice from the defendant's lost opportunity to change its product instructions.¹⁴¹¹ The court, therefore, affirmed the grant of summary judgment of no laches.¹⁴¹²

The Federal Circuit reversed a grant of summary judgment of laches in *Ultimax Cement Manufacturing Corp. v. CTS Cement Manufacturing Corp.*¹⁴¹³ The dispute focused on the start date for measuring the delay.¹⁴¹⁴ The district court found that the plaintiff was

1401. *Gasser Chair Co. v. Infanti Chair Mfg. Corp.*, 60 F.3d 770, 773, 34 U.S.P.Q.2d (BNA) 1822, 1824 (Fed. Cir. 1995).

1402. *Aukerman*, 960 F.2d at 1032, 22 U.S.P.Q.2d (BNA) at 1328.

1403. *Id.* at 1034, 22 U.S.P.Q.2d (BNA) at 1330.

1404. *Id.* at 1041, 22 U.S.P.Q.2d (BNA) at 1335.

1405. 581 F.3d 1317, 92 U.S.P.Q.2d (BNA) 1340 (Fed. Cir. 2009).

1406. *Id.* at 1321, 92 U.S.P.Q.2d (BNA) at 1342.

1407. *Id.* at 1333, 92 U.S.P.Q.2d (BNA) at 1352.

1408. *Id.*, 92 U.S.P.Q.2d (BNA) at 1352 (quoting *Aukerman*, 960 F.2d at 1032, 22 U.S.P.Q.2d (BNA) at 1328) (internal quotation marks omitted).

1409. *Id.*, 92 U.S.P.Q.2d (BNA) at 1352.

1410. *Id.*, 92 U.S.P.Q.2d (BNA) at 1352.

1411. *Id.*, 92 U.S.P.Q.2d (BNA) at 1352.

1412. *Id.*, 92 U.S.P.Q.2d (BNA) at 1352.

1413. 587 F.3d 1339, 92 U.S.P.Q.2d (BNA) 1865 (Fed. Cir. 2009).

1414. *Id.* at 1349–50, 92 U.S.P.Q.2d (BNA) at 1871–72.

on “inquiry notice” at the time that the patent was issued, resulting in a delay period of twelve years before filing suit.¹⁴¹⁵ The district court thus presumed prejudice to the defendant, and further “found prejudice in the loss of testimony of a [defendant] employee who had died in the interim and the loss of records.”¹⁴¹⁶ The defendant did not dispute that the plaintiff could not have tested its product for the presence of the claimed soluble anhydrite limitation.¹⁴¹⁷ In addition, the court found that the plaintiff could not have investigated the defendant’s method to determine infringement until discovery occurred in the suit.¹⁴¹⁸ The Federal Circuit reversed, noting that the only relevant time period was after the plaintiff knew or should have known of the allegedly infringing product.¹⁴¹⁹ The court determined that genuine issues of material fact on this issue precluded summary judgment.¹⁴²⁰ Due to the claim limitation that was undetectable in the finished product, the court found it reasonable that the plaintiff “might not have known or been able to find out whether [the defendant] infringed.”¹⁴²¹ These genuine issues of material facts precluded summary judgment, resulting in a remand for a trial on laches.¹⁴²²

IX. REMEDIES

A. *Permanent Injunctions*

The 2006 Supreme Court decision in *eBay, Inc. v. MercExchange, L.L.C.*¹⁴²³ forced the Federal Circuit to refocus upon district court rulings on permanent injunctions, and 2009 continued the trend. In *eBay*, the Supreme Court vacated a permanent injunction after the courts below incorrectly applied the traditional four-factor framework governing the award of injunctive relief.¹⁴²⁴ This traditional four-factor framework requires a plaintiff to 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

1415. *Id.* at 1348, 92 U.S.P.Q.2d (BNA) at 1871.

1416. *Id.* at 1349, 92 U.S.P.Q.2d (BNA) at 1871.

1417. *Id.* at 1350, 92 U.S.P.Q.2d (BNA) at 1872.

1418. *Id.*, 92 U.S.P.Q.2d (BNA) at 1872.

1419. *Id.*, 92 U.S.P.Q.2d (BNA) at 1872.

1420. *Id.* at 1349, 92 U.S.P.Q.2d (BNA) at 1871.

1421. *Id.* at 1350, 92 U.S.P.Q.2d (BNA) at 1872.

1422. *Id.*, 92 U.S.P.Q.2d (BNA) at 1872.

1423. 547 U.S. 388, 78 U.S.P.Q.2d (BNA) 1577 (2006).

1424. *Id.* at 394, 78 U.S.P.Q.2d (BNA) at 1580.

is warranted; and (4) that the public interest would not be disserved by a permanent injunction.¹⁴²⁵

Therefore, the Court held, the Court of Appeals erred when it categorically granted such relief after finding patent infringement and validity.¹⁴²⁶

In *Ecolab, Inc. v. FMC Corp.*,¹⁴²⁷ the Federal Circuit vacated the district court's denial of a motion for a permanent injunction and remanded "for the district court to perform the required analysis."¹⁴²⁸ The Federal Circuit found that the district court abused its discretion when it "failed to consider any of the *eBay* factors[,] . . . failed to make any factual findings regarding those factors[,] . . . [and] failed to apply any of the traditional equitable principles discussed in *eBay*."¹⁴²⁹ Declining to conduct the correct analysis in the first instance, the court vacated and remanded the case.¹⁴³⁰

The Federal Circuit also briefly addressed permanent injunctions in *Fresenius USA, Inc. v. Baxter International, Inc.*,¹⁴³¹ holding that the district court did not abuse its discretion in granting permanent injunctive relief, but vacating and remanding so that the district court could reconsider its decision in view of the Federal Circuit's reversal of a portion of the district court's grant of judgment as a matter of law.¹⁴³² The Federal Circuit rejected the argument that the district court had found the injunction "all but inevitable" following infringement, noting that the district court made this comment when it criticized the defendant for taking no action to implement any alternative to the infringing device.¹⁴³³ The Federal Circuit found that this statement did not amount to legal error, particularly because the district court properly applied the *eBay* factors and explained its analysis.¹⁴³⁴ The Federal Circuit also rejected the defendant's argument that the district court "ignored" evidence, explaining that the district court opinion need not discuss every single fact alleged by the defendant.¹⁴³⁵

1425. *Id.* at 391, 78 U.S.P.Q.2d (BNA) at 1578.

1426. *Id.* at 393-94, 78 U.S.P.Q.2d (BNA) at 1579-80.

1427. 569 F.3d 1335, 91 U.S.P.Q.2d (BNA) 1225 (Fed. Cir. 2009), *amended in part on reh'g*, Nos. 2008-1228 & 2008-1252, 2009 WL 5865679 (Fed. Cir. Sept. 30, 2009).

1428. *Id.* at 1351, 91 U.S.P.Q.2d (BNA) at 1235.

1429. *Id.* at 1352, 91 U.S.P.Q.2d (BNA) at 1235-36.

1430. *Id.*, 91 U.S.P.Q.2d (BNA) at 1236.

1431. 582 F.3d 1288, 92 U.S.P.Q.2d (BNA) 1163 (Fed. Cir. 2009), *petition for cert. filed*, 78 U.S.L.W. 3550 (U.S. Feb. 16, 2010) (No. 09-1096).

1432. *Id.* at 1303, 92 U.S.P.Q.2d (BNA) at 1175.

1433. *Id.* at 1302 n.4, 92 U.S.P.Q.2d (BNA) at 1175 n.4.

1434. *Id.*, 92 U.S.P.Q.2d (BNA) at 1175 n.4.

1435. *Id.* at 1303, 92 U.S.P.Q.2d (BNA) at 1175.

In *i4i Ltd. v. Microsoft Corp.*,¹⁴³⁶ the Federal Circuit affirmed a jury verdict of infringement, an assessment of damages of over \$240 million, and a permanent injunction against Microsoft, but modified the effective date of the injunction to January 11, 2010.¹⁴³⁷ With respect to the injunction, the district court granted a permanent injunction prohibiting Microsoft from selling, offering to sell, importing, or using trademarked MICROSOFT WORD versions that included the infringing technology—a custom XML editor.¹⁴³⁸ The district court limited the injunction to copies of MICROSOFT WORD purchased or licensed after its effective date.¹⁴³⁹ The effective date was originally set as sixty days from the injunction order¹⁴⁴⁰ but was stayed by the Federal Circuit in September, 2009, pending the outcome of the appeal.¹⁴⁴¹ On appeal, Microsoft challenged a number of district court findings, including the scope and effective date of the permanent injunction.¹⁴⁴²

The Federal Circuit reviewed the permanent injunction under an abuse of discretion standard, using the factors set forth in *eBay*.¹⁴⁴³ The court noted that the scope of the injunction was narrow because it only applied to users who purchase or license MICROSOFT WORD after the date on which the injunction takes effect.¹⁴⁴⁴ The court agreed that i4i suffered irreparable harm, noting that it was proper for the district court to consider evidence of past harm to i4i.¹⁴⁴⁵ The court noted that although injunctions are tools for prospective relief, “the first *eBay* factor looks, in part, at what has already occurred,” including past harm to the patentee’s market share, revenue, and brand recognition.¹⁴⁴⁶ The Federal Circuit found that the district court properly considered evidence that Microsoft’s infringement rendered i4i’s product obsolete for much of the market.¹⁴⁴⁷ With respect to the second factor—whether there were adequate remedies at law—the court found that the losses of market share, brand recognition, and customer goodwill are “particularly difficult to quantify,” especially when forcing a small company to

1436. 589 F.3d 1246, 93 U.S.P.Q.2d (BNA) 1161 (Fed. Cir. 2009), *superseded on reh'g* by No. 2009-1504, 2010 WL 801705, 93 U.S.P.Q.2d (BNA) 1943 (Fed. Cir. 2010).

1437. *Id.* at 1254–55, 1278, 93 U.S.P.Q.2d (BNA) at 1165–66, 1183.

1438. *Id.* at 1275, 93 U.S.P.Q.2d (BNA) at 1181.

1439. *Id.*, 93 U.S.P.Q.2d (BNA) at 1181.

1440. *Id.* at 1278, 93 U.S.P.Q.2d (BNA) at 1183.

1441. *Id.* at 1254, 93 U.S.P.Q.2d (BNA) at 1166.

1442. *Id.* at 1256, 1277, 93 U.S.P.Q.2d (BNA) at 1167, 1183.

1443. *Id.* at 1275, 93 U.S.P.Q.2d (BNA) at 1181.

1444. *Id.*, 93 U.S.P.Q.2d (BNA) at 1181.

1445. *Id.* at 1276, 93 U.S.P.Q.2d (BNA) at 1181–82.

1446. *Id.*, 93 U.S.P.Q.2d (BNA) at 1181.

1447. *Id.*, 93 U.S.P.Q.2d (BNA) at 1181.

change its business strategy.¹⁴⁴⁸ This led the court to agree that there were inadequate remedies at law to compensate i4i for the infringement.¹⁴⁴⁹ In finding that the balance of hardships also favored i4i, the court considered a variety of factors, including “the parties’ sizes, products, and revenue sources.”¹⁴⁵⁰ The court explained that the patented technology was central to i4i’s business, while the infringing XML editor related to only a small fraction of Microsoft’s business.¹⁴⁵¹ The Federal Circuit also noted that the district court properly ignored Microsoft’s expenses in creating the infringing product and the costs to Microsoft of redesigning the infringing products.¹⁴⁵² With respect to the public interest factor, the court found that the narrow scope of the injunction substantially mitigated any negative effects on the public, both practically and economically.¹⁴⁵³ Therefore, the Federal Circuit concluded, the district court did not abuse its discretion in granting the permanent injunction.¹⁴⁵⁴ However, the court noted that the record did not support an effective date only sixty days from the order¹⁴⁵⁵ and modified the injunction to take effect on January 11, 2010.¹⁴⁵⁶

B. Preliminary Injunctions

The Federal Circuit also had opportunities to clarify the requirements for preliminary injunctions in 2009. The decision to grant or deny a preliminary injunction lies within the sound discretion of the district court.¹⁴⁵⁷ Courts consider four factors when determining whether a preliminary injunction is appropriate: “(1) a reasonable likelihood of success on the merits; (2) irreparable harm if an injunction is not granted; (3) a balance of hardships tipping in its favor; and (4) the injunction’s favorable impact on the public interest.”¹⁴⁵⁸

In *Altana Pharma AG v. Teva Pharmaceuticals USA, Inc.*,¹⁴⁵⁹ the Federal Circuit affirmed the district court’s denial of a

1448. *Id.*, 93 U.S.P.Q.2d (BNA) at 1182.

1449. *Id.*, 93 U.S.P.Q.2d (BNA) at 1182.

1450. *Id.* at 1277, 93 U.S.P.Q.2d (BNA) at 1182.

1451. *Id.*, 93 U.S.P.Q.2d (BNA) at 1182.

1452. *Id.*, 93 U.S.P.Q.2d (BNA) at 1182.

1453. *Id.*, 93 U.S.P.Q.2d (BNA) at 1182.

1454. *Id.* at 1276–77, 93 U.S.P.Q.2d (BNA) at 1182.

1455. *Id.* at 1277–78, 93 U.S.P.Q.2d (BNA) at 1183.

1456. *Id.* at 1278, 93 U.S.P.Q.2d (BNA) at 1183.

1457. *Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1334, 79 U.S.P.Q.2d (BNA) 1321, 1323 (Fed. Cir. 2006).

1458. *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350, 57 U.S.P.Q.2d (BNA) 1747, 1751 (Fed. Cir. 2001).

1459. 566 F.3d 999, 91 U.S.P.Q.2d (BNA) 1018 (Fed. Cir. 2009).

preliminary injunction.¹⁴⁶⁰ The district court found that Altana had failed to establish a likelihood of success on the merits because it could not rebut a substantial question of invalidity.¹⁴⁶¹ Additionally, the district court found that the alleged harms were not irreparable and that a judgment at trial could be satisfied.¹⁴⁶²

On review, the Federal Circuit first addressed the correct burden of proof for establishing a likelihood of success on the merits.¹⁴⁶³ Ultimately, the court explained, the accused infringer bears the burden of showing a substantial question of invalidity in order to overcome a preliminary injunction at trial.¹⁴⁶⁴ At the preliminary injunction stage, however, an accused infringer need only show vulnerability, a lower burden than ultimately proving invalidity at trial.¹⁴⁶⁵ The Federal Circuit rejected Altana's argument that the district court incorrectly placed the burden on Altana to show that an obviousness defense lacked substantial merit, and that the district court should have placed the burden on the defendants to establish a substantial question of invalidity.¹⁴⁶⁶ The Federal Circuit clarified that after an accused infringer raises a substantial question concerning validity, the movant must then show that the defense lacks substantial merit.¹⁴⁶⁷ On the merits, the Federal Circuit found that the district court did not abuse its discretion when it determined that the defendants' obviousness defense had substantial merit.¹⁴⁶⁸

Additionally, the Federal Circuit agreed with the district court that Altana failed to demonstrate irreparable harm.¹⁴⁶⁹ The Federal Circuit rejected the notion that the district court categorically dismissed the alleged harms.¹⁴⁷⁰ The future harms associated with the expiration of a Hatch-Waxman stay was found by the district court to be "exaggerated," a ruling that the Federal Circuit found not clearly

1460. *Id.* at 1002, 91 U.S.P.Q.2d (BNA) at 1020.

1461. *Id.* at 1005, 91 U.S.P.Q.2d (BNA) at 1022.

1462. *Id.*, 91 U.S.P.Q.2d (BNA) at 1022.

1463. *Id.* at 1006, 91 U.S.P.Q.2d (BNA) at 1023.

1464. *Id.*, 91 U.S.P.Q.2d (BNA) at 1023 (quoting *Genentech, Inc. v. Novo Nordisk*, 108 F.3d 1361, 1364, 42 U.S.P.Q.2d (BNA) 1001, 1003 (Fed. Cir. 1997)).

1465. *Id.*, 91 U.S.P.Q.2d (BNA) at 1023 (quoting *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1359, 57 U.S.P.Q.2d (BNA) 1747, 1758 (Fed. Cir. 2001)).

1466. *Id.*, 91 U.S.P.Q.2d (BNA) at 1023.

1467. *Id.*, 91 U.S.P.Q.2d (BNA) at 1023 (citing *Entegris, Inc. v. Pall Corp.*, 490 F.3d 1340, 1351, 83 U.S.P.Q.2d (BNA) 1001, 1010 (Fed. Cir. 2007)).

1468. *Id.* at 1010, 91 U.S.P.Q.2d (BNA) at 1026.

1469. *Id.* at 1011, 91 U.S.P.Q.2d (BNA) at 1027.

1470. *Id.* at 1010-11, 91 U.S.P.Q.2d (BNA) at 1027.

erroneous.¹⁴⁷¹ Thus, the court affirmed the denial of a preliminary injunction.¹⁴⁷²

In *Titan Tire Corp. v. Case New Holland, Inc.*,¹⁴⁷³ the Federal Circuit again affirmed a denial of a preliminary injunction and addressed the requirements for such relief.¹⁴⁷⁴ The court emphasized and attempted to clarify the first factor, where the parties' arguments "reflect[ed] a possible misunderstanding of the applicable law."¹⁴⁷⁵ The court noted that the "precise meaning" of an alleged infringer raising a "substantial question" and a patentee's obligation to show that the defense lacks substantial merit "is less than entirely clear, and leaves room for different interpretations."¹⁴⁷⁶ The Federal Circuit clarified that the role of the district court is to "examin[e] the alleged infringer's evidence of invalidity" and to "consider[] rebuttal evidence" in order to determine "whether the patentee can show that the invalidity defense lacks substantial merit."¹⁴⁷⁷ Therefore, the court explained, the trial court should look to both sides of the evidence.¹⁴⁷⁸

After clarifying the trial court's role in assessing evidence, the Federal Circuit addressed the meaning of raising a "substantial question" of invalidity.¹⁴⁷⁹ A "substantial question" includes views that it either represents a procedural step or a substantive conclusion.¹⁴⁸⁰ The court stated, "Our precedents establish that the phrase refers to a conclusion reached by the trial court after considering the evidence on both sides of the validity issue."¹⁴⁸¹ Therefore, the trial court "must weigh the evidence both for and against validity that is available at this preliminary stage in the proceedings."¹⁴⁸² If a substantial question concerning validity exists, then a "patentee has not succeeded in showing it is likely to succeed at trial on the merits of the validity issue."¹⁴⁸³

1471. *Id.* at 1011, 91 U.S.P.Q.2d (BNA) at 1027.

1472. *Id.* at 1002, 91 U.S.P.Q.2d (BNA) at 1020.

1473. 566 F.3d 1372, 90 U.S.P.Q.2d (BNA) 1918 (Fed. Cir. 2009).

1474. *Id.* at 1374, 90 U.S.P.Q.2d (BNA) at 1920.

1475. *Id.* at 1376, 90 U.S.P.Q.2d (BNA) at 1921.

1476. *Id.* at 1377, 90 U.S.P.Q.2d (BNA) at 1922.

1477. *Id.* at 1378, 90 U.S.P.Q.2d (BNA) at 1922 (quoting *New England Braiding Co., Inc. v. A.W. Chesterton Co.*, 970 F.2d 878, 883, 23 U.S.P.Q.2d (BNA) 1622, 1626 (Fed. Cir. 1992)) (internal quotation marks omitted).

1478. *Id.*, 90 U.S.P.Q.2d (BNA) at 1923.

1479. *Id.*, 90 U.S.P.Q.2d (BNA) at 1923.

1480. *Id.*, 90 U.S.P.Q.2d (BNA) at 1923.

1481. *Id.* at 1378–79, 90 U.S.P.Q.2d (BNA) at 1923.

1482. *Id.* at 1379, 90 U.S.P.Q.2d (BNA) at 1923.

1483. *Id.*, 90 U.S.P.Q.2d (BNA) at 1923 (citing *New England Braiding Co., Inc. v. A.W. Chesterton Co.*, 970 F.2d 878, 883, 23 U.S.P.Q.2d (BNA) 1622, 1626 (Fed. Cir. 1992)).

In *Titan Tire*, the Federal Circuit further refined the trial court's responsibility for preliminary injunctions. First, the court explained that the evidentiary standard of "substantial evidence" is separate from the "substantial question" concept, noting that the "substantial question" threshold is not an evidentiary test.¹⁴⁸⁴ Nor is it necessary for an alleged infringer to prove invalidity by a "clear and convincing" standard.¹⁴⁸⁵

Thus, when analyzing the likelihood of success factor, the trial court, after considering all the evidence available at this early stage of the litigation, must determine whether it is more likely than not that the challenger will be able to prove at trial, by clear and convincing evidence, that the patent is invalid.¹⁴⁸⁶

As a result, the ultimate clear and convincing evidence standard is "a consideration for the judge to take into account."¹⁴⁸⁷ If that standard is met, a judge should then rule that a patentee failed to prove likelihood of success and should deny a preliminary injunction.¹⁴⁸⁸ If not, then the judge should look to the other three factors in determining whether to issue a preliminary injunction.¹⁴⁸⁹

C. Damages

The current version of 35 U.S.C. § 284 gives little guidance to courts as it provides only that damages be "adequate to compensate for the infringement but in no event less than a reasonable royalty."¹⁴⁹⁰ Consequently, the statute leaves great leeway for the Federal Circuit to mold this area of patent law. The year 2009 marked another year where the Federal Circuit influenced and changed the law with respect to damages, but many changes still lie on the horizon. The Patent Reform Act of 2009 has multiple bills in the Senate and a counterpart in the House of Representatives.¹⁴⁹¹ These bills include a substantial overhaul of § 284 and aim to give courts greater guidance and attempt to stress the real economic value of a patent.¹⁴⁹² Whether the changes represent a system overhaul or

1484. *Id.*, 90 U.S.P.Q.2d (BNA) at 1923–24.

1485. *Id.*, 90 U.S.P.Q.2d (BNA) at 1924.

1486. *Id.*, 90 U.S.P.Q.2d (BNA) at 1924.

1487. *Id.* at 1380, 90 U.S.P.Q.2d (BNA) at 1924.

1488. *Id.*, 90 U.S.P.Q.2d (BNA) at 1924.

1489. *Id.*, 90 U.S.P.Q.2d (BNA) at 1924.

1490. 35 U.S.C. § 284 (2006).

1491. *See, e.g.*, S. 515, 111th Cong. (2009); S. 610, 111th Cong. (2009); H.R. 1260, 111th Cong. (2009).

1492. Posting of Dennis Crouch to Patent Law Blog (Patently-O), <http://www.patentlyo.com/patent/2009/03/patent-reform-act-of-2009.html> (Mar. 3, 2009, 14:58 EST) (explaining the proposed amendments to 35 U.S.C. § 284).

the codification of present law remains questioned and debated. Federal Trade Commission (FTC) hearings on “The Evolving Intellectual Property Marketplace,” including discussion regarding patent damage awards, are further stoking the flames of debate.¹⁴⁹³

1. *Lost profits and reasonable royalty*

The Federal Circuit reviewed and clarified the law of lost profit damages in *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*¹⁴⁹⁴ In its decision, the court modified a damages award including unpatented “pull-through” product damages, “which neither compete nor function with the patented invention.”¹⁴⁹⁵ At trial, the jury awarded DePuy Spine lost profits of \$149 million for patented pedicle screws and \$77 million for unpatented “pull-through” products.¹⁴⁹⁶ The district court applied the four-factor test for lost profits from *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*,¹⁴⁹⁷ which required DuPuy Spine to show “(1) demand for the patented product, (2) absence of acceptable noninfringing substitutes, (3) manufacturing and marketing capability to exploit the demand, and (4) the amount of profit that would have been made.”¹⁴⁹⁸ The Federal Circuit rejected challenges under the first two factors for the patented product and affirmed the award of lost profit damages.¹⁴⁹⁹

Medtronic did not dispute that demand generally existed for the products and that the products were covered by DePuy Spine’s patent.¹⁵⁰⁰ The Federal Circuit clarified the application of several often cited cases such as *Grain Processing Corp. v. American Maize-Products Co.*¹⁵⁰¹ and held that the elimination or substitution of particular features corresponding to claim limitations goes to the availability of acceptable noninfringing substitutes under the second *Panduit* factor.¹⁵⁰² Medtronic had argued under the first factor that the “requisite demand . . . is demand for the specific feature (i.e., claim limitation) that distinguishes the patented product from a

1493. See generally FEDERAL TRADE COMMISSION, THE EVOLVING IP MARKETPLACE (2009),

<http://www.ftc.gov/bc/workshops/ipmarketplace/may4/090504transcript.pdf>.

1494. 567 F.3d 1314, 90 U.S.P.Q.2d (BNA) 1865 (Fed. Cir. 2009).

1495. *Id.* at 1320, 90 U.S.P.Q.2d (BNA) at 1868.

1496. *Id.* at 1329, 90 U.S.P.Q.2d (BNA) at 1875.

1497. 575 F.2d 1152, 197 U.S.P.Q. (BNA) 726 (6th Cir. 1978).

1498. *DePuy Spine*, 567 F.3d at 1329, 90 U.S.P.Q.2d (BNA) at 1875 (citing *Panduit*, 575 F.2d at 1156, 197 U.S.P.Q. (BNA) at 730).

1499. *Id.* at 1330–31, 90 U.S.P.Q.2d (BNA) at 1875, 1877.

1500. *Id.* at 1330, 90 U.S.P.Q.2d (BNA) at 1876.

1501. 979 F. Supp. 1233, 44 U.S.P.Q.2d (BNA) 1782 (N.D. Ind. 1997), *aff'd*, 185 F.3d 1341, 51 U.S.P.Q.2d (BNA) 1556 (Fed. Cir. 1999).

1502. *DePuy Spine*, 567 F.3d at 1331, 90 U.S.P.Q.2d (BNA) at 1876–77.

noninfringing substitute, not simply demand for the patented product.”¹⁵⁰³ The court rejected this argument as improperly combining the first and second factors.¹⁵⁰⁴ Instead, the court instructed that the first factor simply asks “whether demand existed for the patented product,” not various limitations from a patent claim.¹⁵⁰⁵ Therefore, focusing on particular features corresponding to individual claim limitations is unnecessary when applying the first factor.¹⁵⁰⁶

The court then turned to the second factor—noninfringing substitutes. Medtronic asserted that DePuy Spine did not establish the second *Panduit* factor because noninfringing products were available.¹⁵⁰⁷ Because Medtronic did not “have a noninfringing substitute ‘on the market’ during the relevant accounting period, it . . . bore the burden of overcoming the inference of unavailability.”¹⁵⁰⁸ The court affirmed the jury’s factual finding “that no acceptable noninfringing alternative was available,” because the alternative “would not have been available or acceptable to consumers before the end of the period.”¹⁵⁰⁹

The jury awarded DePuy Spine \$77 million in profits for “pull-through” products sold by virtue of the business relationship created when customers bought the patented product.¹⁵¹⁰ These products were not covered by the patent at issue, nor did they compete, rely functionally upon, or require use with the patented product.¹⁵¹¹ Relying on *Rite-Hite Corp. v. Kelley Co.*,¹⁵¹² the Federal Circuit found no legal basis to award lost profits on unpatented items that neither competed nor functioned with the patented product.¹⁵¹³ The court therefore reversed the award of lost-profit damages for the “pull-through” products.¹⁵¹⁴

1503. *Id.* at 1330, 90 U.S.P.Q.2d (BNA) at 1875.

1504. *Id.*, 90 U.S.P.Q.2d (BNA) at 1875.

1505. *Id.*, 90 U.S.P.Q.2d (BNA) at 1875 (citing *Panduit Corp. v. Stahl Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1156, 197 U.S.P.Q. (BNA) 726, 730 (6th Cir. 1978)) (internal quotation marks omitted).

1506. *Id.* at 1331, 90 U.S.P.Q.2d (BNA) at 1876.

1507. *Id.*, 90 U.S.P.Q.2d (BNA) at 1877.

1508. *Id.*, 90 U.S.P.Q.2d (BNA) at 1877 (citing *Grain Processing Corp., v. Am. Maize-Prod. Co.*, 185 F.3d 1341, 1353, 51 U.S.P.Q.2d (BNA) 1556, 1565 (Fed. Cir. 1999)).

1509. *Id.* at 1332, 90 U.S.P.Q.2d (BNA) at 1877–78.

1510. *Id.* at 1333, 90 U.S.P.Q.2d (BNA) at 1878.

1511. *Id.*, 90 U.S.P.Q.2d (BNA) at 1878.

1512. 56 F.3d 1538, 35 U.S.P.Q.2d (BNA) 1065 (Fed. Cir. 1995).

1513. *DePuy Spine*, 567 F.3d at 1334, 90 U.S.P.Q.2d (BNA) at 1878–79.

1514. *Id.*, 90 U.S.P.Q.2d (BNA) at 1879.

DePuy Spine also challenged the district court's denial of a motion for a new trial on the issues of reasonable royalty damages. The Federal Circuit found that the verdict of zero percent damages was an inconsistent verdict but held that DePuy Spine had not timely objected.¹⁵¹⁵

In *Revolution Eyewear, Inc. v. Aspex Eyewear, Inc. (Revolution Eyewear II)*,¹⁵¹⁶ the Federal Circuit affirmed several district court rulings on damages and jury calculations.¹⁵¹⁷ During trial, the parties advocated for damages of either \$11 million or \$312,000, and the jury returned a verdict of \$4.3 million.¹⁵¹⁸ On appeal, the Federal Circuit rejected arguments that the jury verdict was "mathematically impossible," that it exceeded the reasonable royalty rate, and that it was grossly excessive.¹⁵¹⁹ The court found that there was sufficient evidence to support the jury verdict which was "well within the range of damages advocated by the parties."¹⁵²⁰ The defendant contended that a "'fatal inconsistency' in the interrogatories of the Special Verdict necessitate[d] a new trial," arguing that the jury verdict of \$4.3 million was not based on its average price.¹⁵²¹ The court rejected this view, holding that the damages award based on a reasonable royalty is "only the floor, not the exact amount," a view supported by the statutory language of 35 U.S.C. § 284.¹⁵²²

In *Fresenius*, the district court ordered the defendants to pay an ongoing royalty for any infringing machine sold before January 1, 2009 (the date the injunction took effect), and a different royalty for all disposable products linked to infringing machines that were sold from 2002 until the patents expired.¹⁵²³ The Federal Circuit passed on determining whether the royalty award was proper and instead vacated and remanded the case in view of the court's reversal of portions of the district court's order granting judgment as a matter of law.¹⁵²⁴ The Federal Circuit ruled that the district court acted within its discretion to award a royalty on postverdict sales of disposable

1515. *Id.* at 1335, 90 U.S.P.Q.2d (BNA) at 1879.

1516. 563 F.3d 1358, 90 U.S.P.Q.2d (BNA) 1733 (Fed. Cir. 2009).

1517. *Id.* at 1374, 90 U.S.P.Q.2d (BNA) at 1744.

1518. *Id.* at 1371, 90 U.S.P.Q.2d (BNA) at 1742.

1519. *Id.* at 1371-72, 90 U.S.P.Q.2d (BNA) at 1742-43.

1520. *Id.* at 1372, 90 U.S.P.Q.2d (BNA) at 1742-43.

1521. *Id.* at 1371-72, 90 U.S.P.Q.2d (BNA) at 1742.

1522. *Id.* at 1372, 90 U.S.P.Q.2d (BNA) at 1743.

1523. *Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 582 F.3d 1288, 1303, 92 U.S.P.Q.2d (BNA) 1163, 1175 (Fed. Cir. 2009), *petition for cert. filed*, 78 U.S.L.W. 3550 (U.S. Feb. 16, 2010) (No. 09-1096).

1524. *Id.*, 92 U.S.P.Q.2d (BNA) at 1175.

products in order to fully compensate the patentee for preverdict infringing sales.¹⁵²⁵

In *Lucent Technologies, Inc. v. Gateway, Inc.*,¹⁵²⁶ the Federal Circuit vacated a \$358 million jury award to Lucent for patent infringement by Microsoft and remanded for a new trial on damages.¹⁵²⁷ At trial, a jury found that Microsoft programs (MICROSOFT MONEY, MICROSOFT OUTLOOK, and WINDOWS MOBILE) indirectly infringed Lucent's patent and awarded a lump-sum royalty payment of approximately \$358 million to Lucent.¹⁵²⁸ Microsoft appealed the district court's denial of judgment as a matter of law and its denial of a new damages trial.¹⁵²⁹

The Federal Circuit first noted that it reviews a district court's decision concerning methodology for calculating damages for abuse of discretion¹⁵³⁰ and a jury's determination of the amount of damages, an issue of fact, for substantial evidence.¹⁵³¹ The court began its reasonable-royalty analysis by noting that parties commonly use two approaches for calculating a reasonable royalty damages award.¹⁵³² The first approach focuses on the infringer's projections of profit for the infringing device.¹⁵³³ The other more common approach uses a hypothetical negotiation to calculate a "royalty upon which the parties would have agreed had they successfully negotiated an agreement just before infringement began."¹⁵³⁴ Both parties here adopted the hypothetical negotiation approach, which "necessarily involves an element of approximation and uncertainty."¹⁵³⁵ Relying on the damages award framework from *Georgia-Pacific Corp. v. United States Plywood Corp.*,¹⁵³⁶ the court reviewed whether substantial evidence supported the lump sum royalty payment of \$358 million.¹⁵³⁷

1525. *Id.*, 92 U.S.P.Q.2d (BNA) at 1175-76.

1526. 580 F.3d 1301, 92 U.S.P.Q.2d (BNA) 1555 (Fed. Cir. 2009).

1527. *Id.* at 1308, 92 U.S.P.Q.2d (BNA) at 1558.

1528. *Id.* at 1308-09, 92 U.S.P.Q.2d (BNA) at 1559.

1529. *Id.* at 1309, 92 U.S.P.Q.2d (BNA) at 1559.

1530. *Id.* at 1310, 92 U.S.P.Q.2d (BNA) at 1560 (citing *Unisplay, S.A. v. Am. Elec. Sign Co.*, 69 F.3d 512, 517 n.8, 36 U.S.P.Q.2d (BNA) 1540, 1544 n.8 (Fed. Cir. 1995)).

1531. *Id.*, 92 U.S.P.Q.2d (BNA) at 1560 (citing *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 926 F.2d 1161, 1164 n.2, 17 U.S.P.Q.2d (BNA) 1922, 1927 n.2 (Fed. Cir. 1989)).

1532. *Id.* at 1324, 92 U.S.P.Q.2d (BNA) at 1571.

1533. *Id.*, 92 U.S.P.Q.2d (BNA) at 1571.

1534. *Id.*, 92 U.S.P.Q.2d (BNA) at 1571.

1535. *Id.* at 1325, 92 U.S.P.Q.2d (BNA) at 1572 (quoting *Unisplay*, 69 F.3d at 517, 36 U.S.P.Q.2d (BNA) at 1544).

1536. 318 F. Supp. 1116, 166 U.S.P.Q. (BNA) 235 (S.D.N.Y. 1970).

1537. *Lucent Techs.*, 580 F.3d at 1325, 92 U.S.P.Q.2d (BNA) at 1572.

The Federal Circuit focused upon the second *Georgia-Pacific* factor, which evaluates the “rates paid by the licensee for the use of other patents comparable to the patent in suit.”¹⁵³⁸ This factor “examines whether the licenses relied on by the patentee in proving damages are sufficiently comparable to the hypothetical license at issue in suit,” and whether the parties “would have agreed to a lump-sum payment or instead to a running royalty based on ongoing sales or usage.”¹⁵³⁹ The Federal Circuit stressed the “[s]ignificant differences” between running-royalty licenses and lump-sum licenses.¹⁵⁴⁰ Running-royalty licenses tie the amount of money payable to how often the licensed invention is used or incorporated into products and shift risks to the licensor due to an unguaranteed payment.¹⁵⁴¹ In contrast, lump-sum royalties enable the raising of quick cash and cap liability for the licensee.¹⁵⁴² The lump-sum license avoids “ongoing administrative burdens of monitoring usage” and risks of underreporting.¹⁵⁴³ The Federal Circuit noted that the lump-sum license removes the ability to reevaluate a license and can lead to remorse for under- or overvaluing the technology.¹⁵⁴⁴

At trial, Lucent argued for damages based solely upon a running royalty license and contended that the evidence supported the jury award on appeal.¹⁵⁴⁵ The Federal Circuit found both the evidence and the approach problematic for several reasons.¹⁵⁴⁶ First, the evidence did not address expectations of consumer use.¹⁵⁴⁷ Second, the jury did not hear factual testimony explaining how running-royalty agreements are probative of lump-sum payments.¹⁵⁴⁸ Finally, the license agreements in evidence “were created from events far different” from the current events.¹⁵⁴⁹ The court found no evidence from which a reasonable jury could estimate that the patented

1538. *Id.*, 92 U.S.P.Q.2d (BNA) at 1572 (quoting *Georgia-Pacific*, 318 F. Supp. at 1120, 166 U.S.P.Q. (BNA) at 238).

1539. *Id.* at 1325–26, 92 U.S.P.Q.2d (BNA) at 1572.

1540. *Id.* at 1326, 92 U.S.P.Q.2d (BNA) at 1572.

1541. *Id.*, 92 U.S.P.Q.2d (BNA) at 1572.

1542. *Id.*, 92 U.S.P.Q.2d (BNA) at 1572 (citing RICHARD F. CAULEY, WINNING THE PATENT DAMAGES CASE: A LITIGATOR’S GUIDE TO ECONOMIC MODELS AND OTHER DAMAGE STRATEGIES 47 (2009)).

1543. *Id.*, 92 U.S.P.Q.2d (BNA) at 1572–73.

1544. *Id.*, 92 U.S.P.Q.2d (BNA) at 1573.

1545. *Id.* at 1326–27, 92 U.S.P.Q.2d (BNA) at 1573.

1546. *Id.* at 1327, 92 U.S.P.Q.2d (BNA) at 1573.

1547. *Id.*, 92 U.S.P.Q.2d (BNA) at 1573.

1548. *Id.*, 92 U.S.P.Q.2d (BNA) at 1573.

1549. *Id.*, 92 U.S.P.Q.2d (BNA) at 1573.

feature would have been frequently used or valued as to command a lump-sum payment of eight percent of the infringing product.¹⁵⁵⁰

Additionally, the Federal Circuit found the explanation of Lucent's damages expert insufficient in that it "urg[ed] jurors to rely on speculation" for calculating an acceptable lump sum.¹⁵⁵¹ The eight license agreements that Lucent argued supported the jury verdict were also found lacking.¹⁵⁵² The court concluded that the agreements either differed "radically" from the hypothetical agreement or the subject matter was unascertainable, leaving the court unable to understand how a jury could evaluate their probative value.¹⁵⁵³ The expert testimony on these agreements provided no assistance, as either the expert "supplied no explanation" or gave "superficial testimony."¹⁵⁵⁴ The court noted that "[t]he law does not require an expert to convey all his knowledge to the jury about each license agreement in evidence, but a lump-sum damages award cannot stand solely on evidence which amounts to little more than a recitation of royalty numbers."¹⁵⁵⁵ The court found that the "jury had almost no testimony with which to recalculate in a meaningful way the value of any of the running royalty agreements to arrive at the lump-sum damages award."¹⁵⁵⁶ As a result, the court found that the second *Georgia-Pacific* factor weighed strongly against the jury award.¹⁵⁵⁷

The Federal Circuit next turned to *Georgia-Pacific* factors ten and thirteen. Factor ten is "[t]he nature of the patented invention; the character of the commercial embodiment of it as owned and produced by the licensor; and the benefits to those who have used the invention."¹⁵⁵⁸ Factor thirteen is "[t]he portion of the realizable profit that should be credited to the invention as distinguished from non-patented elements, the manufacturing process, business risks, or significant features or improvements added by the infringer."¹⁵⁵⁹ The court stated that these factors "aim to elucidate how the parties would have valued the patented feature during the hypothetical

1550. *Id.*, 92 U.S.P.Q.2d (BNA) at 1573.

1551. *Id.*, 92 U.S.P.Q.2d (BNA) at 1573.

1552. *Id.*, 92 U.S.P.Q.2d (BNA) at 1574.

1553. *Id.* at 1327-28, 92 U.S.P.Q.2d (BNA) at 1574.

1554. *Id.* at 1328-29, 92 U.S.P.Q.2d (BNA) at 1574-75.

1555. *Id.* at 1329, 92 U.S.P.Q.2d (BNA) at 1575.

1556. *Id.* at 1330, 92 U.S.P.Q.2d (BNA) at 1575.

1557. *Id.* at 1332, 92 U.S.P.Q.2d (BNA) at 1577.

1558. *Id.*, 92 U.S.P.Q.2d (BNA) at 1577 (alteration in original) (quoting *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)).

1559. *Id.*, 92 U.S.P.Q.2d (BNA) at 1577 (alteration in original) (quoting *Georgia-Pacific*, 318 F. Supp. at 1120, 166 U.S.P.Q. (BNA) at 238)).

negotiation.”¹⁵⁶⁰ Finding the infringing feature to be “but a tiny feature” in an “enormously complex software program,” the court found it “inconceivable to conclude” that the small feature constituted a substantial amount of the infringing product’s value.¹⁵⁶¹ Therefore, factors ten and thirteen provided little support for the jury award.¹⁵⁶²

The Federal Circuit then turned to *Georgia-Pacific* factor eleven— “[t]he extent to which the infringer has made use of the invention; and any evidence probative of the value of that use.”¹⁵⁶³ Factor eleven looks to how parties would have valued the patented feature in negotiations and relies upon how much the patented invention has been used.¹⁵⁶⁴ The court noted that evidence of usage may “be helpful to the jury and the court in assessing whether a royalty is reasonable.”¹⁵⁶⁵ Such data provides information that parties use during negotiations, where parties “often have rough estimates as to the expected frequency of use.”¹⁵⁶⁶ However, the evidence here was “conspicuously devoid” of any such data, with the only evidence being that “at least one person performed the patented method one time in the United States sometime during the relevant period.”¹⁵⁶⁷ Therefore, “all the jury had was speculation,” and Lucent thus failed to meet its “burden to prove that the extent to which the infringing method has been used supports the lump-sum damages award.”¹⁵⁶⁸

The Federal Circuit also looked at other *Georgia-Pacific* factors, but concluded that none of them overcame the “substantial infirmities in the evidence” from the other factors discussed above.¹⁵⁶⁹ The court was “left with the unmistakable conclusion that the jury’s damages award is not supported by substantial evidence, but is based mainly on speculation or guesswork.”¹⁵⁷⁰ Although creating a licensing agreement is “at best, an inexact science,” the court stated that the damages evidence “was neither very powerful, nor presented very well

1560. *Id.*, 92 U.S.P.Q.2d (BNA) at 1577.

1561. *Id.*, 92 U.S.P.Q.2d (BNA) at 1577.

1562. *Id.* at 1333, 92 U.S.P.Q.2d (BNA) at 1578.

1563. *Id.*, 92 U.S.P.Q.2d (BNA) at 1578 (alteration in original) (quoting *Georgia-Pacific*, 318 F. Supp. at 1120, 166 U.S.P.Q. (BNA) at 238)).

1564. *Id.*, 92 U.S.P.Q.2d (BNA) at 1578.

1565. *Id.* at 1333–34, 92 U.S.P.Q.2d (BNA) at 1578.

1566. *Id.* at 1334, 92 U.S.P.Q.2d (BNA) at 1578.

1567. *Id.*, 92 U.S.P.Q.2d (BNA) at 1579.

1568. *Id.* at 1334–35, 92 U.S.P.Q.2d (BNA) at 1579.

1569. *Id.* at 1335, 92 U.S.P.Q.2d (BNA) at 1579.

1570. *Id.*, 92 U.S.P.Q.2d (BNA) at 1579.

by either party.”¹⁵⁷¹ Therefore, a new trial on damages was necessary.¹⁵⁷²

The Federal Circuit also addressed Microsoft’s argument that the jury erroneously applied the entire-market-value rule.¹⁵⁷³ The court began its analysis by noting that a “patentee must prove that the patent-related feature is the basis for customer demand.”¹⁵⁷⁴ The court noted that in the 1800s, “before a contemporary appreciation of the economics of infringement damages, the Supreme Court seemingly set forth rigid rules concerning the entire market value rule.”¹⁵⁷⁵ The court noted the challenge of translating the Supreme Court’s early concerns into “a precise, contemporary, economic paradigm.”¹⁵⁷⁶ When conducting this analysis, “the objective of the Court’s concern has been two-fold: determining the correct (or at least approximately correct) value of the patented invention, when it is but one part or feature among many, and ascertaining what the parties would have agreed to in the context of a patent license negotiation.”¹⁵⁷⁷ The Federal Circuit stressed that “[l]itigants must realize that the two objectives do not always meet at the same precise number.”¹⁵⁷⁸

The court noted that the first flaw in applying the entire-market-value rule in the present case was the lack of evidence demonstrating that the patented invention formed the basis of consumer demand.¹⁵⁷⁹ The court concluded that the patented invention was not the reason why consumers purchased MICROSOFT OUTLOOK.¹⁵⁸⁰ A second flaw existed with the approach of Lucent’s licensing expert.¹⁵⁸¹ Originally, the expert applied the rule to the sale of “infringing” computers at a one percent royalty rate.¹⁵⁸² However, the district court granted a motion *in limine* to exclude such testimony.¹⁵⁸³ At trial, the expert applied the rule to the infringing software but

1571. *Id.* at 1336, 92 U.S.P.Q.2d (BNA) at 1580.

1572. *Id.* at 1335, 92 U.S.P.Q.2d (BNA) at 1580.

1573. *Id.* at 1336, 92 U.S.P.Q.2d (BNA) at 1580.

1574. *Id.*, 92 U.S.P.Q.2d (BNA) at 1580 (internal quotation marks omitted) (quoting *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1549, 35 U.S.P.Q.2d (BNA) 1065, 1072 (Fed. Cir. 1995)) (citing several cases where the Supreme Court had concerns about basing damages on the value of the entire product).

1575. *Id.* at 1336–37, 92 U.S.P.Q.2d (BNA) at 1580.

1576. *Id.* at 1337, 92 U.S.P.Q.2d (BNA) at 1581.

1577. *Id.* at 1337, 92 U.S.P.Q.2d (BNA) at 1581.

1578. *Id.*, 92 U.S.P.Q.2d (BNA) at 1581.

1579. *Id.*, 92 U.S.P.Q.2d (BNA) at 1581.

1580. *Id.* at 1338, 92 U.S.P.Q.2d (BNA) at 1581.

1581. *Id.*, 92 U.S.P.Q.2d (BNA) at 1581.

1582. *Id.*, 92 U.S.P.Q.2d (BNA) at 1581.

1583. *Id.*, 92 U.S.P.Q.2d (BNA) at 1581.

increased the royalty rate to eight percent.¹⁵⁸⁴ The Federal Circuit found that the expert attempted to reach the same damages number he would have obtained if he were allowed to use the entire computer as a royalty base.¹⁵⁸⁵ The court determined that this approach was unacceptable as it ignored what the district court's evidentiary ruling tried to accomplish.¹⁵⁸⁶

The Federal Circuit went further with its discussion of the entire-market-value rule, instructing that "courts must nevertheless be cognizant of a fundamental relationship between the entire market value rule and the calculation of a running royalty damages award."¹⁵⁸⁷ The base for a running-royalty calculation "can always be the value of the entire commercial embodiment, as long as the magnitude of the rate is within an acceptable range."¹⁵⁸⁸ As a result, even patented inventions consisting only of a small component in a much larger commercial product may economically justify a reasonable royalty based on either sale price or number of units sold.¹⁵⁸⁹ The court even took on the suggestion of some commentators that "the entire market value rule should have little role in reasonable royalty law."¹⁵⁹⁰ The court found that these propositions "ignore the realities of patent licensing and the flexibility needed in transferring intellectual property rights."¹⁵⁹¹ The court further noted that "[t]he evidence of record in the present dispute illustrates the importance the entire market value may have in reasonable royalty cases."¹⁵⁹² The court opined that "[t]he license agreements admitted into evidence . . . highlight how sophisticated parties routinely enter into license agreements that base the value of the patented inventions as a percentage of the commercial products' sales price."¹⁵⁹³ Therefore, the court concluded, "[t]here is nothing inherently wrong with using the market value of the entire product, especially when there is no established market value for the infringing component or feature, so long as the multiplier accounts for the proportion of the base represented by the infringing component or feature."¹⁵⁹⁴ Lastly, the Federal Circuit held that although several amici challenged the

1584. *Id.*, 92 U.S.P.Q.2d (BNA) at 1581.

1585. *Id.*, 92 U.S.P.Q.2d (BNA) at 1582.

1586. *Id.*, 92 U.S.P.Q.2d (BNA) at 1582.

1587. *Id.*, 92 U.S.P.Q.2d (BNA) at 1582.

1588. *Id.* at 1338–39, 92 U.S.P.Q.2d (BNA) at 1582.

1589. *Id.* at 1339, 92 U.S.P.Q.2d (BNA) at 1582.

1590. *Id.*, 92 U.S.P.Q.2d (BNA) at 1582.

1591. *Id.*, 92 U.S.P.Q.2d (BNA) at 1582.

1592. *Id.*, 92 U.S.P.Q.2d (BNA) at 1582.

1593. *Id.*, 92 U.S.P.Q.2d (BNA) at 1582.

1594. *Id.*, 92 U.S.P.Q.2d (BNA) at 1582.

district court's jury instruction on the entire-market-value rule, the instructions were not challenged at trial.¹⁵⁹⁵

The Federal Circuit reviewed another damages award against Microsoft in *i4i Ltd. v. Microsoft Corp.*,¹⁵⁹⁶ a case in which Microsoft unsuccessfully challenged a \$200 million reasonable royalty damages award on several grounds.¹⁵⁹⁷

Microsoft first challenged evidentiary rulings admitting expert testimony and a survey relied on by the expert. Microsoft challenged the ninety-eight dollar royalty rate calculated by i4i's damages expert.¹⁵⁹⁸ The Federal Circuit noted that Microsoft's challenges to i4i's expert were directed at the expert's "conclusions, not his methodology."¹⁵⁹⁹ The Federal Circuit noted that Rule 702 of the Federal Rules of Civil Procedure and the Supreme Court ruling in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*¹⁶⁰⁰ are "safeguards against unreliable or irrelevant opinions, not guarantees of correctness."¹⁶⁰¹ The combination of expert testimony based upon the accepted use of hypothetical negotiations, *Georgia-Pacific* factors, and methodical explanations of royalty-rate calculations led the court to conclude that the district court did not abuse its discretion.¹⁶⁰² Additionally, the court found that the expert's opinion was sufficiently based on facts or data.¹⁶⁰³ Rule 702 requires that experts rely on facts sufficiently related to the disputed issue, and the mere existence of other facts does not fail this standard.¹⁶⁰⁴ Questions over the relevance or reliability of facts used to calculate a reasonable royalty are appropriately left to the jury.¹⁶⁰⁵

Microsoft also urged the Federal Circuit to hold that \$200 million is not a reasonable royalty, citing the recent decision in *Lucent Technologies*.¹⁶⁰⁶ The court rejected this argument because Microsoft failed to file a preverdict motion for judgment as a matter of law on damages.¹⁶⁰⁷ Therefore, on appeal, the court could not decide whether there was a sufficient evidentiary basis for the jury's damages

1595. *Id.*, 92 U.S.P.Q.2d (BNA) at 1582-83.

1596. 589 F.3d 1246, 93 U.S.P.Q.2d (BNA) 1161 (Fed. Cir. 2009), *superceded on reh'g* by No. 2009-1504, 2010 WL 801705, 93 U.S.P.Q.2d (BNA) 1943 (Fed. Cir. 2010).

1597. *Id.* at 1255, 93 U.S.P.Q.2d (BNA) at 1166.

1598. *Id.* at 1268, 93 U.S.P.Q.2d (BNA) at 1176.

1599. *Id.* at 1269, 93 U.S.P.Q.2d (BNA) at 1177.

1600. 509 U.S. 579, 27 U.S.P.Q.2d (BNA) 1200 (1993).

1601. *i4i*, 589 F.3d at 1269, 93 U.S.P.Q.2d (BNA) at 1177.

1602. *Id.* at 1269-70, 93 U.S.P.Q.2d (BNA) at 1177.

1603. *Id.* at 1270, 93 U.S.P.Q.2d (BNA) at 1177 (quoting FED. R. EVID. 702).

1604. *Id.* at 1271, 93 U.S.P.Q.2d (BNA) at 1178.

1605. *Id.*, 93 U.S.P.Q.2d (BNA) at 1178.

1606. *Id.* at 1272, 93 U.S.P.Q.2d (BNA) at 1179.

1607. *Id.*, 93 U.S.P.Q.2d (BNA) at 1179.

award.¹⁶⁰⁸ Instead, the court's appellate authority was limited to applying the stricter standard for denials of new trial motions.¹⁶⁰⁹ A "clear showing of excessiveness" based upon the evidence was necessary to set aside the damages award and remand for a new trial.¹⁶¹⁰ Microsoft failed to meet this higher standard because the testimony of i4i's damages and survey experts supported the jury's award.¹⁶¹¹

Finally, Microsoft challenged the district court's decision to enhance damages under 35 U.S.C. § 284.¹⁶¹² At trial, the jury found willful infringement and the district court awarded \$40 million in enhanced damages on i4i's post-trial motion.¹⁶¹³ The Federal Circuit held that the district court did not abuse its discretion since it made detailed factual findings, it properly declined to reapply the willfulness test from *In re Seagate Technology, LLC*,¹⁶¹⁴ and it correctly applied the *Read Corp. v. Portec, Inc.*¹⁶¹⁵ factors for enhanced damages.¹⁶¹⁶ The court also rejected Microsoft's argument that the district court enhanced damages solely because of the litigation misconduct of Microsoft's counsel, ruling that the district court properly considered the misconduct only after finding that the other *Read* factors favored enhanced damages.¹⁶¹⁷

In *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*,¹⁶¹⁸ the Federal Circuit reviewed district court damage rulings and, notably, interpreted 35 U.S.C. § 271(f) to not cover method claims.¹⁶¹⁹ The two issues on appeal were (1) a district court ruling that limited damages to only devices performing the claimed method steps, and (2) a rejected motion to limit damages to only U.S. sales under § 271(f).¹⁶²⁰ On the first issue, the Federal Circuit upheld the district court ruling that infringement damages could be received only on

1608. *Id.*, 93 U.S.P.Q.2d (BNA) at 1179.

1609. *Id.* at 1273, 93 U.S.P.Q.2d (BNA) at 1179 (citing *Duff v. Werner Enters.*, 489 F.3d 727, 730 (5th Cir. 2007)).

1610. *Id.*, 93 U.S.P.Q.2d (BNA) at 1179 (quoting *Duff*, 489 F.3d at 730).

1611. *Id.*, 93 U.S.P.Q.2d (BNA) at 1179.

1612. *Id.*, 93 U.S.P.Q.2d (BNA) at 1179.

1613. *Id.* at 1273, 93 U.S.P.Q.2d (BNA) at 1180.

1614. 497 F.3d 1360, 83 U.S.P.Q.2d (BNA) 1865 (Fed. Cir. 2007) (en banc), *cert. denied*, 552 U.S. 1230 (2008).

1615. 970 F.2d 816, 23 U.S.P.Q.2d (BNA) 1426 (Fed. Cir. 1992).

1616. *i4i*, 589 F.3d at 1274, 93 U.S.P.Q.2d (BNA) at 1180.

1617. *Id.* at 1274–75, 93 U.S.P.Q.2d (BNA) at 1180–81.

1618. 576 F.3d 1348, 91 U.S.P.Q.2d (BNA) 1898 (Fed. Cir. 2009), *cert. denied*, 130 S. Ct. 1088 (2010).

1619. *Id.* at 1359, 91 U.S.P.Q.2d (BNA) at 1907.

1620. *Id.* at 1354, 91 U.S.P.Q.2d (BNA) at 1903 (citing *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 418 F. Supp. 2d 1021, 1040–44 (S.D. Ind. 2005), *vacated*, 315 F. App'x 273 (Fed. Cir. 2009)).

devices actually performing the patented method.¹⁶²¹ With respect to the second issue, the district court ruled that “[35 U.S.C. § 271(f)] applied to method claims and . . . [the] shipment of [infringing devices] abroad could result in a violation of that section.”¹⁶²² The Federal Circuit reversed, holding that § 271(f) does not cover method claims and is not implicated in this case.¹⁶²³

2. Attorneys’ fees

Under 35 U.S.C. § 285, a court in “exceptional cases may award reasonable attorney fees to the prevailing party.”¹⁶²⁴ The Federal Circuit in 2009 reviewed instances where attorneys’ fees were awarded for litigation misconduct and a frivolous appeal.

In *ICU Medical, Inc. v. Alaris Medical Systems, Inc.*,¹⁶²⁵ the Federal Circuit affirmed an award of attorneys’ fees for litigation misconduct. Attorneys’ fees may be warranted for litigation misconduct or “if both (1) the litigation is brought in subjective bad faith, and (2) the litigation is objectively baseless.”¹⁶²⁶ The district court “determined that this case was exceptional because ICU’s [temporary restraining order/preliminary injunction] request and the amended complaint’s assertion of [certain] claims were objectively baseless and brought in bad faith.”¹⁶²⁷ On review, the Federal Circuit found that “the district court applied the appropriate legal standard and articulated several bases in support of the award.”¹⁶²⁸ The district court had several bases, including “multiple, repeated misrepresentations,” that were not shown to be clearly erroneous.¹⁶²⁹ Additionally, the Federal Circuit held that the district court appropriately exercised its discretion in finding that Rule 11 sanctions were warranted.¹⁶³⁰

In *E-Pass Technologies, Inc. v. 3Com Corp.*,¹⁶³¹ the Federal Circuit addressed the issue of frivolous appeals. The court explained that “[a]n appeal can be ‘frivolous as filed’ and/or ‘frivolous as

1621. *Id.* at 1359, 91 U.S.P.Q.2d (BNA) at 1907.

1622. *Id.*, 91 U.S.P.Q.2d (BNA) at 1907 (citing *Cardiac Pacemakers*, 418 F. Supp. 2d at 1042–44).

1623. *Id.*, 91 U.S.P.Q.2d (BNA) at 1907.

1624. 35 U.S.C. § 285 (2006).

1625. 558 F.3d 1368, 90 U.S.P.Q.2d (BNA) 1072 (Fed. Cir. 2009).

1626. *Id.* at 1379, 90 U.S.P.Q.2d (BNA) at 1079 (quoting *Brooks Furniture Mfg., Inc. v. Dutailier Int’l, Inc.*, 393 F.3d 1378, 1381, 73 U.S.P.Q.2d (BNA) 1457, 1460 (Fed. Cir. 2005)).

1627. *Id.*, 90 U.S.P.Q.2d (BNA) at 1079.

1628. *Id.* at 1380, 90 U.S.P.Q.2d (BNA) at 1079.

1629. *Id.*, 90 U.S.P.Q.2d (BNA) at 1079 (quoting *ICU Med., Inc. v. Alaris Med. Sys., Inc.*, No. SA CV 04-00689 MRP, 2007 WL 6137003, at *7 (C.D. Cal. Apr. 16, 2007)).

1630. *Id.* at 1380–81, 90 U.S.P.Q.2d (BNA) at 1080.

1631. 559 F.3d 1374, 90 U.S.P.Q.2d (BNA) 1168 (Fed. Cir. 2009).

argued.”¹⁶³² The court discussed that “[a]n appeal is frivolous as filed ‘when an appellant grounds his appeal on arguments or issues that are beyond the reasonable contemplation of fair-minded people, and no basis for reversal in law or fact can be or is even arguably shown.’”¹⁶³³ When frivolous as argued, the “appellant has not dealt fairly with the court, [or] has significantly misrepresented the law or facts.”¹⁶³⁴

The Federal Circuit found the E-Pass appeal frivolous for a “host of reasons,” but chose to focus upon only two.¹⁶³⁵ First, E-Pass failed to explain trial court errors and did not present cogent or clear arguments for reversal.¹⁶³⁶ Second, E-Pass made “significant misrepresentations of the record and the law to the court.”¹⁶³⁷ The court went through a lengthy discussion of the multiple misrepresentations, which included misstatements about the record below and misrepresentations of the legal standard.¹⁶³⁸ The court found E-Pass’s appeal frivolous and granted PalmSource’s motion for sanctions.¹⁶³⁹ The court did, however, alter the amount of fees to only those incurred in defending the appeal, including the filing of the motion for sanctions.¹⁶⁴⁰ Additionally, due to the frivolous nature of the advocacy, the court held E-Pass’s counsel jointly and severally liable for the sanctions.¹⁶⁴¹

Judge Bryson dissented, opining that although E-Pass’s briefs fell far short of the standards expected of counsel to the court, the shortfall was not so egregious as to call for the imposition of sanctions.¹⁶⁴²

3. *Marking*

35 U.S.C. § 287(a) requires “[p]atentees, and persons making, offering for sale, or selling within the United States any patented article” to give notice to the public of their patent.¹⁶⁴³ Accordingly,

1632. *Id.* at 1377, 90 U.S.P.Q.2d (BNA) at 1170.

1633. *Id.*, 90 U.S.P.Q.2d (BNA) at 1170 (internal quotation marks omitted) (quoting *Abbs v. Principi*, 237 F.3d 1342, 1345 (Fed. Cir. 2001)).

1634. *Id.*, 90 U.S.P.Q.2d (BNA) at 1170 (alteration in original) (quoting *Abbs*, 237 F.3d at 1345).

1635. *Id.*, 90 U.S.P.Q.2d (BNA) at 1170.

1636. *Id.*, 90 U.S.P.Q.2d (BNA) at 1170 (quoting *Abbs*, 237 F.3d at 1345).

1637. *Id.*, 90 U.S.P.Q.2d (BNA) at 1170 (citing *Abbs*, 237 F.3d at 1345).

1638. *Id.* at 1378–80, 90 U.S.P.Q.2d (BNA) at 1171–72.

1639. *Id.* at 1380, 90 U.S.P.Q.2d (BNA) at 1172.

1640. *Id.*, 90 U.S.P.Q.2d (BNA) at 1172.

1641. *Id.*, 90 U.S.P.Q.2d (BNA) at 1173.

1642. *Id.* at 1382, 90 U.S.P.Q.2d (BNA) at 1174 (Bryson, J., dissenting).

1643. 35 U.S.C. § 287(a) (2006).

a patentee failing to mark a patented article is not entitled to damages for infringement prior to actual notice.

In *Crown Packaging Technology Inc. v. Rexam Beverage Can Co.*,¹⁶⁴⁴ the Federal Circuit reversed a district court ruling that had incorrectly applied the marking law.¹⁶⁴⁵ The district court granted a motion for summary judgment dismissing a counterclaim on the basis of a failure to mark under § 287(a).¹⁶⁴⁶ The petition for appeal contended that the ruling would not implicate § 287(a) due to the assertion of only method, and not machine, claims.¹⁶⁴⁷ The Federal Circuit agreed because precedent made clear that the notice provisions of § 287(a) do not apply for process or method patents.¹⁶⁴⁸ The court noted that *Hanson v. Alpine Valley Ski Area, Inc.*¹⁶⁴⁹ mandates that § 287(a) does not apply when only a process or method claim is asserted.¹⁶⁵⁰ The court therefore reversed the district court because the patentee only asserted the method claims, to which the marking requirements of § 287(a) did not apply.¹⁶⁵¹

The Federal Circuit also reviewed false marking under 35 U.S.C. § 292. Section 292 imposes a fine of “not more than \$500” for marking an unpatented article “for the purpose of deceiving the public.”¹⁶⁵² By a preponderance of the evidence, a false marking claimant must prove that the defendant (1) marked an unpatented article as patented and (2) did so with the intent to deceive the public.¹⁶⁵³ An intent to deceive arises “when a party acts with sufficient knowledge that what it is saying is not so and consequently that the recipient of its saying will be misled into thinking that the statement is true.”¹⁶⁵⁴

In *Forest Group, Inc. v. Bon Tool Co.*,¹⁶⁵⁵ the Federal Circuit reviewed both a district court finding that Forest Group falsely marked its product, as well as a fine of \$500 imposed by the district court for a

1644. 559 F.3d 1308, 90 U.S.P.Q.2d (BNA) 1186 (Fed. Cir. 2009).

1645. *Id.* at 1310, 90 U.S.P.Q.2d (BNA) at 1187.

1646. *Id.*, 90 U.S.P.Q.2d (BNA) at 1188.

1647. *Id.* at 1316, 90 U.S.P.Q.2d (BNA) at 1191.

1648. *Id.*, 90 U.S.P.Q.2d (BNA) at 1192 (citing *Bandag, Inc. v. Gerrard Tire Co.*, 704 F.2d 1578, 1581, 217 U.S.P.Q. (BNA) 977, 979 (Fed. Cir. 1983)).

1649. 718 F.2d 1075, 219 U.S.P.Q. (BNA) 679 (Fed. Cir. 1983).

1650. *Crown Packaging*, 559 F.3d at 1316, 90 U.S.P.Q.2d (BNA) at 1192 (citing *Hanson*, 718 F.2d at 1082–83, 219 U.S.P.Q. (BNA) at 685).

1651. *Id.* at 1317, 90 U.S.P.Q.2d (BNA) at 1192.

1652. 35 U.S.C. § 292 (2006).

1653. *Clontech Labs. Inc. v. Invitrogen Corp.*, 406 F.3d 1347, 1352, 74 U.S.P.Q.2d (BNA) 1598, 1602 (Fed. Cir. 2005).

1654. *Id.*, 74 U.S.P.Q.2d (BNA) at 1602 (citing *Seven Cases of Eckman's Alterative v. United States*, 239 U.S. 510, 517–18, (1916)).

1655. 590 F.3d 1295, 93 U.S.P.Q.2d (BNA) 1097 (Fed. Cir. 2009).

single decision to falsely mark.¹⁶⁵⁶ Bon Tool filed numerous counterclaims at the district court, including a false-marking counterclaim pursuant to § 292.¹⁶⁵⁷ Bon Tool prevailed on the infringement charges, but appealed the false-marking decision on various grounds.¹⁶⁵⁸ First, Bon Tool asserted that the district court erred when it concluded that Forest Group did not have the requisite intent to falsely mark prior to November 15, 2007 (the date of a summary judgment of noninfringement in a related case).¹⁶⁵⁹ The Federal Circuit rejected Bon Tool's arguments that Forest Group had such intent earlier, pointing to the district court's finding that Forest Group genuinely believed its products were covered by the patent prior to this date, as well the fact that the patentees did not have strong academic backgrounds or "in-depth appreciation of patent law."¹⁶⁶⁰

The second question on appeal was whether the district court misinterpreted 35 U.S.C. § 292(a) by assessing only a \$500 penalty for a single decision to falsely mark.¹⁶⁶¹ The Federal Circuit found the "statute's plain language requires the penalty to be imposed on a per article basis."¹⁶⁶² In so finding, the court rejected the patentee's argument, based on the First Circuit's decision in *London v. Everett H. Dunbar Corp.*,¹⁶⁶³ that the statute imposes a single fine for continuous false marking.¹⁶⁶⁴ The Federal Circuit noted that the version of the false-marking statute at issue in *London* was significantly different than the current one and that the 1952 amendment to the statute was not taken into account in that case.¹⁶⁶⁵ The court also rejected the time-based approach adopted by a number of courts, where a penalty is imposed for each day, week, or month that products were falsely marked.¹⁶⁶⁶ The court opined that the time-based approach does not find support in the plain language of § 292(a), which "clearly requires a per article fine."¹⁶⁶⁷ The court also noted that policy considerations also support the per article interpretation of

1656. *Id.* at 1297, 93 U.S.P.Q.2d (BNA) at 1098.

1657. *Id.* at 1299, 93 U.S.P.Q.2d (BNA) at 1099.

1658. *Id.*, 93 U.S.P.Q.2d (BNA) at 1099.

1659. *Id.* at 1299–300, 93 U.S.P.Q.2d (BNA) at 1099.

1660. *Id.* at 1300, 93 U.S.P.Q.2d (BNA) at 1100 (quoting *Forest Group, Inc. v. Bon Tool Co.*, 2008 U.S. Dist. LEXIS 57134, at *15 n.5 (S.D. Tex. 2008)).

1661. *Id.* at 1300–01, 93 U.S.P.Q.2d (BNA) at 1100.

1662. *Id.*, 93 U.S.P.Q.2d (BNA) at 1100.

1663. 179 F. 506 (1st Cir. 1910).

1664. *Forest Group*, 590 F.3d at 1301, 93 U.S.P.Q.2d (BNA) at 1101.

1665. *Id.* at 1302, 93 U.S.P.Q.2d (BNA) at 1101.

1666. *Id.*, 93 U.S.P.Q.2d (BNA) at 1101–02.

1667. *Id.*, 93 U.S.P.Q.2d (BNA) at 1102.

§ 292(a).¹⁶⁶⁸ False marking deters innovation, stifles competition, and raises competitor costs; these considerations increase with each falsely marked article.¹⁶⁶⁹ The court noted that the patentee's proposed statutory construction "would render the statute completely ineffective."¹⁶⁷⁰ The court also rejected the patentee's argument that "interpreting the fine . . . to apply on a per article basis would encourage 'a new cottage industry' of false-marking litigation by plaintiffs who have not suffered any direct harm."¹⁶⁷¹ The court noted that "the false marking statute explicitly permits *qui tam* actions," thus further supporting the per article construction.¹⁶⁷²

The Federal Circuit also noted that district courts may exercise discretion with the fine amount.¹⁶⁷³ This discretion balances enforcing public policy and imposing proportionate penalties.¹⁶⁷⁴ Since the district court did not determine the number of articles falsely marked, the Federal Circuit vacated the \$500 fine and remanded for further determinations.¹⁶⁷⁵

X. ALTERNATE SOURCES OF LIABILITY OR RELINQUISHMENT OF RIGHTS

A. Patent Exhaustion

In *TransCore, LP v. Electronic Transaction Consultants Corp.*,¹⁶⁷⁶ the Federal Circuit held that "an unconditional covenant not to sue authorizes sales by the covenantee for purposes of patent exhaustion."¹⁶⁷⁷ In doing so, the Federal Circuit affirmed the district court's grant of summary judgment, whereby TransCore, LP's patent infringement claims against Electronic Transaction Consultants Corp. (ETC) were barred by patent exhaustion in view of a settlement agreement between TransCore and the supplier of the products that ETC installed, Mark IV.¹⁶⁷⁸

The district court had held that "Mark IV's sales of the toll collection systems installed by ETC were authorized by the TransCore-Mark IV settlement agreement, such that TransCore's

1668. *Id.*, 93 U.S.P.Q.2d (BNA) at 1102.

1669. *Id.* at 1302-03, 93 U.S.P.Q.2d (BNA) at 1102.

1670. *Id.* at 1303, 93 U.S.P.Q.2d (BNA) at 1102.

1671. *Id.*, 93 U.S.P.Q.2d (BNA) at 1102.

1672. *Id.* at 1303-04, 93 U.S.P.Q.2d (BNA) at 1102.

1673. *Id.* at 1304, 93 U.S.P.Q.2d (BNA) at 1103.

1674. *Id.*, 93 U.S.P.Q.2d (BNA) at 1103.

1675. *Id.*, 93 U.S.P.Q.2d (BNA) at 1103.

1676. 563 F.3d 1271, 90 U.S.P.Q.2d (BNA) 1372 (Fed. Cir. 2009).

1677. *Id.* at 1274, 90 U.S.P.Q.2d (BNA) at 1375.

1678. *Id.*, 90 U.S.P.Q.2d (BNA) at 1374-75.

patent rights were exhausted as to those systems.”¹⁶⁷⁹ The Federal Circuit agreed, relying on the Supreme Court’s recent “unequivocal[.]” reiteration in *Quanta Computer, Inc. v. LG Electronics, Inc.*¹⁶⁸⁰ that “[t]he longstanding doctrine of patent exhaustion provides that the initial authorized sale of a patented item terminates all patent rights to that item,”¹⁶⁸¹ and that “[e]xhaustion is triggered only by a sale authorized by the patent holder.”¹⁶⁸²

TransCore argued that the “sales under a covenant not to sue are not ‘authorized,’” citing previous case law differentiating the roles of licenses and covenants not to sue, but the Federal Circuit dismissed the argument because the case law was inapposite.¹⁶⁸³ Instead, the court observed that “a patentee, by license or otherwise, cannot convey an affirmative right to practice a patented invention,” but it can “convey a freedom from suit.”¹⁶⁸⁴ Equating a nonexclusive license to a covenant not to sue, viewing both as authorizations, the court framed “the pertinent question here [as] not whether but what the TransCore-Mark IV settlement agreement authorizes [and whether it] authorize[s] sales.”¹⁶⁸⁵ The Federal Circuit held that it did, noting that the “language of the TransCore-Mark IV settlement agreement is unambiguous: ‘[TransCore] agrees and covenants not to bring any demand, claim, lawsuit, or action against Mark IV for future infringement.’”¹⁶⁸⁶ The court concluded that “[t]his term, without apparent restriction or limitation, thus authorizes all acts that would otherwise be infringements: making, using, offering for sale, selling, or importing.”¹⁶⁸⁷ As a result, the Federal Circuit agreed with the district court’s finding that the sales were authorized and that TransCore’s patent rights were exhausted.¹⁶⁸⁸

1679. *Id.*, 90 U.S.P.Q.2d (BNA) at 1375.

1680. 128 S. Ct. 2109, 86 U.S.P.Q.2d (BNA) 1673 (2008).

1681. *TransCore*, 563 F.3d at 1274, 90 U.S.P.Q.2d (BNA) at 1375 (alteration in original) (quoting *Quanta*, 128 S. Ct. at 2115, 86 U.S.P.Q.2d (BNA) at 1677).

1682. *Id.*, 90 U.S.P.Q.2d (BNA) at 1375 (quoting *Quanta*, 128 S. Ct. at 2121, 86 U.S.P.Q.2d (BNA) at 1681) (alteration in original).

1683. *Id.* at 1274–75, 90 U.S.P.Q.2d (BNA) at 1375.

1684. *Id.* at 1275, 90 U.S.P.Q.2d (BNA) at 1375–76.

1685. *Id.* at 1276, 90 U.S.P.Q.2d (BNA) at 1376.

1686. *Id.*, 90 U.S.P.Q.2d (BNA) at 1376 (alterations in original).

1687. *Id.*, 90 U.S.P.Q.2d (BNA) at 1376.

1688. *Id.* at 1277, 90 U.S.P.Q.2d (BNA) at 1377.

B. Implied License

1. “Have made” rights

In *CoreBrace LLC v. Star Seismic LLC*,¹⁶⁸⁹ the Federal Circuit held that a licensee did not breach the license by contracting with a third party to have the licensed products made for its own use.¹⁶⁹⁰ The court found that “[t]he right to ‘make, use, and sell’ a product inherently includes the right to have it made by a third party, absent a clear indication of intent to the contrary.”¹⁶⁹¹ That was so despite an express prohibition of sublicensing and despite a clause in the agreement that all remaining rights not expressly granted (i.e., those other than rights to “make, use, and sell”) were reserved to the patentee.¹⁶⁹²

The Federal Circuit’s decision was grounded on Court of Claims precedent established in *Carey v. United States*.¹⁶⁹³ Nevertheless, the patentees attempted to distinguish *Carey*, arguing that inherent, have-made rights should be limited to exclusive licensees that also have the right to sublicense.¹⁶⁹⁴ For two reasons, however, the Federal Circuit dismissed that argument. First, the court found that the court in *Carey* did not base its conclusion on exclusivity or the right to sublicense, but on the right to “produce, use, and sell.”¹⁶⁹⁵ It noted that the *Carey* court specifically stated that

“[a] licensee having the right to produce, use and sell might be interested only in using the article or in selling it; in order to use it or sell it, the article must be produced; to have it produced, his license permits him to engage others” to produce it for him.¹⁶⁹⁶

Second, the court noted that the distinction between having an exclusive and nonexclusive license is of no importance here, because it has “no relevance to how a licensee obtains the product it is entitled to make, use, and sell.”¹⁶⁹⁷ Thus, the court held that the logic of the holding in *Carey* was not limited to exclusive licenses or licenses that include a right to sublicense.

1689. 566 F.3d 1069, 91 U.S.P.Q.2d (BNA) 1209 (Fed. Cir. 2009).

1690. *Id.* at 1072, 91 U.S.P.Q.2d (BNA) at 1211.

1691. *Id.* at 1072–73, 91 U.S.P.Q.2d (BNA) at 1211.

1692. *Id.* at 1070, 91 U.S.P.Q.2d (BNA) at 1210.

1693. 326 F.2d 975, 140 U.S.P.Q. (BNA) 345 (Ct. Cl. 1964).

1694. *CoreBrace*, 566 F.3d at 1073, 91 U.S.P.Q.2d (BNA) at 1212.

1695. *Id.*, 91 U.S.P.Q.2d (BNA) at 1212.

1696. *Id.*, 91 U.S.P.Q.2d (BNA) at 1212 (alteration in original) (quoting *Carey*, 326 F.2d at 979, 140 U.S.P.Q. (BNA) at 348).

1697. *Id.* at 1074, 91 U.S.P.Q.2d (BNA) at 1212.

C. False Advertisement

In *Baden Sports, Inc. v. Molten USA, Inc.*,¹⁶⁹⁸ the Federal Circuit, applying Ninth Circuit law, held that *Dastar Corp. v. Twentieth Century Fox Film Corp.*¹⁶⁹⁹ precluded Baden Sports's false advertising claim.¹⁷⁰⁰ Both Baden Sports and Molten sold high-end basketballs.¹⁷⁰¹ Baden Sports owned a patent directed to a ball with "raised seams" and a "layer of padding underneath the outer covering."¹⁷⁰² Baden Sports sued Molten for false advertising under section 43 of the Lanham Act¹⁷⁰³ based on Molten's use of the term "innovative" in its advertisements for basketballs utilizing Baden Sports's patented technology.¹⁷⁰⁴ Baden Sports claimed that using "innovative" in Molten's advertisement falsely implied that the dual-cushion technology was a Molten innovation.¹⁷⁰⁵

The Federal Circuit explained that the Supreme Court in *Dastar* held that "'origin of goods,' as that term is used in § 43(a), does not refer to 'the person or entity that originated the ideas or communications that 'goods' embody or contain.'"¹⁷⁰⁶ Instead, the Supreme Court read "'origin of goods' as referring 'to the producer of the tangible goods that are offered for sale, and not to the author of any idea, concept, or communication embodied in those goods.'"¹⁷⁰⁷ Because *Dastar* was "the 'origin,' or producer, of the products it sold, the Court held that *Dastar* was not liable for false advertising under the Lanham Act."¹⁷⁰⁸

The Federal Circuit then evaluated "whether Molten's advertising refer[red] to the 'producer of the tangible goods,' in which case a claim under § 43(a)(1)(A) would be proper, or whether it refer[red] to 'the author of' the idea or concept behind Molten's basketballs, in which case the claim would be foreclosed by *Dastar*."¹⁷⁰⁹ The court found that Baden Sports did not argue "that someone other than

1698. 556 F.3d 1300, 89 U.S.P.Q.2d (BNA) 1878 (Fed. Cir. 2009), *cert. denied*, 130 S. Ct. 111 (2009).

1699. 539 U.S. 23, 66 U.S.P.Q.2d (BNA) 1641 (2003).

1700. *Baden Sports*, 556 F.3d at 1305, 89 U.S.P.Q.2s (BNA) at 1880–81.

1701. *Id.* at 1302, 89 U.S.P.Q.2d (BNA) at 1880.

1702. *Id.*, 89 U.S.P.Q.2d (BNA) at 1880.

1703. 15 U.S.C. § 1125 (2006).

1704. *Baden Sports*, 556 F.3d at 1302–03, 89 U.S.P.Q.2d (BNA) at 1880.

1705. *Id.* at 1303, 89 U.S.P.Q.2d (BNA) at 1880.

1706. *Id.* at 1306, 89 U.S.P.Q.2d (BNA) at 1882 (quoting *Dastar Corp. v. Twentieth Century Fox Film Corp.*, 539 U.S. 23, 32, 66 U.S.P.Q.2d (BNA) 1641, 1645 (2003)).

1707. *Id.*, 89 U.S.P.Q.2d (BNA) at 1882 (quoting *Dastar*, 539 U.S. at 37, 66 U.S.P.Q.2d (BNA) at 1647).

1708. *Id.*, 89 U.S.P.Q.2d (BNA) at 1882 (citing *Dastar*, 539 U.S. at 38, 66 U.S.P.Q.2d (BNA) at 1647–48).

1709. *Id.*, 89 U.S.P.Q.2d (BNA) at 1882.

Molten produce[d] the infringing basketballs, and nothing in the record indicate[d] that Molten [was] not in fact the producer of the balls.”¹⁷¹⁰ Thus, the court concluded that “Baden’s claims [were] not actionable under § 43(a)(1)(A) because they d[id] not ‘cause confusion . . . as to the origin’ of the basketballs.”¹⁷¹¹

The Federal Circuit then explained that § 43(a)(1)(B) also did not apply to Baden Sports’s claims, as the Ninth Circuit does not interpret this section to apply to false designation of authorship. The court noted that, following the Ninth Circuit’s interpretation of § 43(a)(1)(B) in *Sybersound Records, Inc. v. UAV Corp.*,¹⁷¹² to read the section otherwise would create an overlap between the Lanham and Patent Acts.¹⁷¹³ Section 43(a)(1)(B) applies to the characteristics of the goods, the court explained, and authorship is not a nature, characteristic, or quality of the goods as those terms are used in § 43(a)(1)(B).¹⁷¹⁴ The court concluded that Baden Sports had alleged nothing more than false designation of authorship because no physical or functional attributes of the basketballs are implied by Molten’s advertisements.¹⁷¹⁵ In the court’s view, the term “[i]nnovative’ only indicate[d], at most, that its manufacturer created something new, or that the product [was] new, irrespective of who created it.”¹⁷¹⁶ Thus, the court concluded that Baden Sports could not “avoid the holding in *Dastar* by framing a claim based on false attribution of authorship as a misrepresentation of the nature, characteristics, and qualities of a good.”¹⁷¹⁷

D. Assignments

In *Euclid Chemical Co. v. Vector Corrosion Technologies, Inc.*,¹⁷¹⁸ the Federal Circuit ruled on a patent ownership dispute, applying state contract law to construe a patent assignment agreement and vacating a district court’s summary judgment regarding Vector Corrosion Technologies, Inc.’s ownership of the patent-in-suit.¹⁷¹⁹ The district court held that an assignment that specifically listed a named patent and “any and all divisional applications, continuations,

1710. *Id.*, 89 U.S.P.Q.2d (BNA) at 1882.

1711. *Id.*, 89 U.S.P.Q.2d (BNA) at 1882–83.

1712. 517 F.3d 1137, 1144, 86 U.S.P.Q.2d (BNA) 1065, 1070 (9th Cir. 2008).

1713. *Baden Sports*, 556 F.3d at 1307, 89 U.S.P.Q.2d (BNA) at 1883.

1714. *Id.*, 89 U.S.P.Q.2d (BNA) at 1883.

1715. *Id.*, 89 U.S.P.Q.2d (BNA) at 1883.

1716. *Id.*, 89 U.S.P.Q.2d (BNA) at 1883.

1717. *Id.*, 89 U.S.P.Q.2d (BNA) at 1883.

1718. 561 F.3d 1340, 90 U.S.P.Q.2d (BNA) 1220 (Fed. Cir. 2009).

1719. *Id.* at 1341, 1343, 90 U.S.P.Q.2d (BNA) at 1221, 1223.

and continuations in part [‘CIP’]” unambiguously conveyed a patent that issued from a CIP application of the named patent before the assignment was executed.¹⁷²⁰ The Federal Circuit disagreed, reversing and remanding the case for further consideration because the assignment was not unambiguous, being subject to “at least two reasonable interpretations,” and because the district court erred by not having considered “[e]xtrinsic evidence . . . to ascertain the parties’ intent.”¹⁷²¹

The assignment, dated December 20, 2001, named one patent, U.S. Patent No. 6,033,553 (“the ‘553 patent”), and assigned it and “any and all divisional applications, continuations, and continuations in part . . . and any and all Letters Patent which may issue or be reissued for said invention” to Vector.¹⁷²² The patent-in-suit, which was a CIP of the ‘553 patent, existed before the execution date of the assignment, having issued in April 2001.¹⁷²³ While the patent-in-suit was unambiguously a CIP of the assigned patent, the court did not consider its transfer unambiguous.¹⁷²⁴ The court noted that the assignment’s language suggested that it was not intended to effect an assignment of the patent-in-suit for it referred to “applications for patents” in the plural and “issued U.S. Patent” in the singular.¹⁷²⁵ The court reasoned that “[h]ad the assignee intended, through the assignment of ‘continuations in part’ to assign other *issued* U.S. patents, it would be expected that the Assignment would have said that the inventor was assigning ‘his issued U.S. patents’—plural—and even recited the patent number of the issued [patent-in-suit].”¹⁷²⁶ Because the assignment was susceptible to at least two reasonable interpretations, it was ambiguous, and the lower court erred in not considering extrinsic evidence to ascertain the parties’ intent.¹⁷²⁷ Accordingly, the Federal Circuit vacated and remanded the case for the district court to consider the extrinsic relevance regarding transfer of ownership of the patent-in-suit to Vector.¹⁷²⁸

1720. *Id.* at 1342, 90 U.S.P.Q.2d (BNA) at 1222.

1721. *Id.* at 1344, 90 U.S.P.Q.2d (BNA) at 1223.

1722. *Id.* at 1342, 90 U.S.P.Q.2d (BNA) at 1222.

1723. *Id.*, 90 U.S.P.Q.2d (BNA) at 1222.

1724. *Id.* at 1344, 90 U.S.P.Q.2d (BNA) at 1223.

1725. *Id.*, 90 U.S.P.Q.2d (BNA) at 1223.

1726. *Id.*, 90 U.S.P.Q.2d (BNA) at 1223.

1727. *Id.*, 90 U.S.P.Q.2d (BNA) at 1223.

1728. *Id.*, 90 U.S.P.Q.2d (BNA) at 1223–24.