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2003 Patent Law Decisions of the Federal Circuit

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2003 Patent Law Decisions of the Federal Circuit

Keywords

Patent law, Federal Circuit decisions, patentability, patent procedural issues, claim construction, patent infringement, patent remedies

AREA SUMMARIES

2003 PATENT LAW DECISIONS OF THE FEDERAL CIRCUIT

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INTRODUCTION

To put the patent decisions from the year 2003 in some perspective, the prior year, 2002, will be remembered by the patent world for the impact of two Supreme Court decisions and four Federal Circuit patent decisions.

The Supreme Court, in *Holmes Group, Inc. v. Vornado Air Circulation Systems, Inc.*,¹ limited the jurisdiction of the Federal Circuit to those cases where the initial well-pleaded complaint raised an issue under the patent laws, thereby changing the calculus employed by defendants when contemplating counterclaims. In *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*² (“*Festo VIII*”), the Supreme Court criticized the Federal Circuit, while significantly narrowing the doctrine of equivalents (“DOE”).

Also in 2002, the Federal Circuit, in *CCS Fitness, Inc. v. Brunswick Corp.*³ and *Texas Digital Systems, Inc. v. Telegenix, Inc.*,⁴ ushered in the era of the “strong presumption” that claim terms must be construed as broadly as their plain and ordinary meaning permits and brought dictionaries to the forefront of the claim construction fray in what has become the ongoing battles of competing dictionary definitions. Further eroding the doctrine of equivalents, and heralding its treatment of DOE cases for 2003, a divided Federal Circuit held in

1. See 535 U.S. 826, 830, 62 U.S.P.Q.2d (BNA) 1801, 1803 (2002) (explaining that, under the well-pleaded-complaint rule, a plaintiff must plead a patent issue on the face of an initial complaint, not a counterclaim).

2. See 535 U.S. 722, 737, 740-41, 62 U.S.P.Q.2d (BNA) 1705, 1712-15 (2002) (rejecting the court of appeals rule that prosecution history per se bars future claims under the doctrine of equivalents and holding that prosecution history creates a presumption that an amendment surrenders any equivalents but stating that a patentee could rebut this presumption by showing that, at the time of the amendment, it was unreasonable to craft a claim to describe the equivalent literally).

3. See 288 F.3d 1359, 1366, 62 U.S.P.Q.2d (BNA) 1659, 1662 (Fed. Cir. 2002) (discussing the presumption that claim terms have ordinary meanings, which may be defined in dictionaries, and applying a presumption to interpret the claim term “member”).

4. See 308 F.3d 1193, 1202-03, 64 U.S.P.Q.2d (BNA) 1812, 1817-18 (Fed. Cir. 2002) (stating that dictionaries and encyclopedias are objective sources to establish claim terms).

*Johnson & Johnston Associates, Inc. v. R.E. Service Inc.*⁵ that unclaimed, disclosed subject matter cannot be captured as an equivalent, but rather is dedicated to the public.⁶ Finally, in what may be the final death blow to so-called submarine patents, the Federal Circuit, in *Symbol Technologies, Inc. v. Lemelson Medical*,⁷ reinvented the equitable doctrine of prosecution laches, a defense that will likely be subject to some elaboration by the Federal Circuit in 2004 as a result of the recent decision rendered by the district court on remand in the *Symbol Technologies* case.⁸

In 2003, no new Supreme Court jurisprudence arose, but the Federal Circuit was very active in the patent area. Its *en banc* decision in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*⁹ (“*Festo IX*”) changed the landscape insofar as litigating doctrine of equivalents issues, and it may start a new type of district court proceeding focused on whether, as a matter of law, a patentee is entitled to assert doctrine of equivalents; a so-called “*Festo* hearing.” In *Moba, B.V. v. Diamond Automation, Inc.*,¹⁰ a panel of the Federal Circuit heralded possible *en banc* review of the law of written description.¹¹ However, the two areas where the Federal Circuit was most active in 2003 was in claim construction and the doctrine of equivalents. The claim construction case law often arrived at breathtakingly broad constructions, thereby capturing more accused infringers under literal infringement. Ruling on cases from the district courts, as well as those remanded from the Supreme Court, the Federal Circuit narrowed the application of the doctrine of equivalents with its decision in *Festo IX*.

5. See 285 F.3d 1046, 62 U.S.P.Q.2d (BNA) 1225 (Fed. Cir. 2002).

6. See *id.* at 1054, 62 U.S.P.Q.2d (BNA) at 1230 (stating that allowing a patentee to use the doctrine of equivalents to recapture unclaimed, disclosed subject matter would conflict with the notion that the claim made in the patent determines the scope of protection).

7. See 277 F.3d 1361, 1364-66, 61 U.S.P.Q.2d (BNA) 1515, 1516 (Fed. Cir. 2002) (holding that even where a patentee acts in good faith, patent claims issued after unreasonable prosecution delays may be subject to prosecution laches).

8. See 301 F. Supp. 2d 1147, 1157, 69 U.S.P.Q.2d (BNA) 1738, 1745 (D. Nev. 2004) (finding the asserted claims unenforceable because “ample evidence of intervening rights” existed that fully demonstrate the injury that can result from “an unreasonable delay in prosecuting patent claims”).

9. See 344 F.3d 1359, 1363, 68 U.S.P.Q.2d (BNA) 1321, 1322 (Fed. Cir. 2003) (remanding the case to the district court to decide whether *Festo* could show that equivalents were unforeseeable at the time the claim was amended, and therefore rebut the presumption that *Festo* surrendered the equivalent subject matter).

10. 325 F.3d 1306, 1327, 66 U.S.P.Q.2d (BNA) 1429, 1443 (Fed. Cir. 2003).

11. See *id.*, 66 U.S.P.Q.2d (BNA) at 1429, 1443 (Radar, C.J., concurring) (urging the court to review and correct erroneous constructions of the Patent Act and, specifically, stating that the court erred in interpreting the Patent Act to require disclosure of DNA structures in biotechnology patent cases).

In 2004, we look for the court to continue to be active in the area of claim construction and doctrine of equivalents. We also expect that cases involving the written description requirement of § 112 will refine the law in that area.¹² Finally, in the face of what many in the patent community regard as a wholesale attack by plaintiffs on the defendant's attorney-client privilege, the *en banc* court contemplates the case of *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*,¹³ and may once again consider the twenty-one year-old duty to obtain advice of counsel in the face of an infringement allegation as imposed in *Underwater Devices, Inc. v. Morrison-Knudsen Co.*,¹⁴ as well as the adverse inference rule of *Kloster Speedsteel AB v. Crucible, Inc.*¹⁵

The following summary looks at some of the more notable cases decided by the Court of Appeals for the Federal Circuit in 2003.

I. PROCEDURAL ISSUES

This has been an interesting procedural year. In the course of 2003, the Federal Circuit addressed procedural issues including Federal Circuit jurisdiction, standing, personal jurisdiction, waivers, collateral estoppel, judicial estoppel, final judgments, judgment as a matter of law ("JMOLs"), claim preclusion, and Rule 11 sanctions.

A. Federal Circuit Jurisdiction

Applying the standard announced by the Supreme Court in *Holmes Group, Inc. v. Vornado Air Circulation Systems, Inc.*,¹⁶ the Federal Circuit found that it had appellate jurisdiction over a case because the plaintiff-appellant's complaint sought declaratory relief of patent non-infringement.¹⁷

In *Golan v. Pingel Enterprise, Inc.*,¹⁸ the plaintiff and the defendant were competitors in after-market motorcycle fuel valves for Harley-

12. See Patent Act, 35 U.S.C. § 112 (2000) ("The specification shall contain a written description of the invention and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same . . .").

13. 344 F.3d 1336, 1336-37, 68 U.S.P.Q.2d (BNA) 1383, 1384 (Fed. Cir. 2003).

14. See 717 F.2d 1380, 1389-90, 219 U.S.P.Q. (BNA) 569, 576 (Fed. Cir. 1983) (imposing a duty to seek legal advice if an activity might infringe on an existing patent).

15. See 793 F.2d 1565, 1580, 231 U.S.P.Q. (BNA) 160, 160 (Fed. Cir. 1986) (presuming that an alleged infringer's silence as to whether he sought legal advice indicated that he had either ignored counsel's advice that a particular act would infringe or acted without seeking legal advice).

16. 535 U.S. 826, 62 U.S.P.Q.2d (BNA) 1801 (2002).

17. See *Golan v. Pingel Enter., Inc.*, 310 F.3d 1360, 1366, 64 U.S.P.Q.2d (BNA) 1911, 1915 (Fed. Cir. 2003).

18. *Id.*, 64 U.S.P.Q.2d (BNA) at 1911.

Davidson motorcycles.¹⁹ The defendant, Pingel, an assignee of patents for the fuel valves, sent a cease-and-desist letter to Golan.²⁰ The defendant also sent letters to Golan's customers stating that Golan's fuel valves infringed Pingel's patents and trademarks.²¹ Golan sued, asserting U.S. federal and state antitrust claims,²² federal and state unfair competition claims,²³ state business tort claims,²⁴ and sought declaratory relief of patent non-infringement.²⁵ Subsequently, Pingel successfully moved for summary judgment on the antitrust, unfair competition, and state tort claims.²⁶ Golan appealed to the Federal Circuit.²⁷

Construing *Vornado* broadly, the Federal Circuit held that declaratory relief claims arise under federal law if the cause of action that the declaratory relief claims seeks to aver would arise under federal law.²⁸ The court held that a claim for declaratory relief of patent non-infringement seeks to aver a claim of patent infringement and, therefore, arises under the patent laws.²⁹

B. Supplemental Jurisdiction Based on State Law Claims

In *Silent Drive Inc. v. Strong Industries, Inc.*,³⁰ a factually complex case involving a complaint for declaratory judgment, the Federal Circuit reversed the district court's dismissal for lack of personal jurisdiction.³¹

The parties were competing manufacturers of trailing axles.³² Strong, a Texas company, obtained an injunction in an earlier state court case in Texas for misappropriation of trade secrets, which specifically enjoined Silent Drive.³³ Silent Drive, an Iowa company, was not a party to that earlier Texas case.³⁴ It was, however, involved in the joint development of the product involved in that case.³⁵ Strong also obtained a patent that it claimed was infringed by the

19. *Id.* at 1363, 64 U.S.P.Q.2d (BNA) at 1912.

20. *Id.* at 1363-64, 64 U.S.P.Q.2d (BNA) at 1913.

21. *Id.* at 1364, 64 U.S.P.Q.2d (BNA) at 1913.

22. *Id.* at 1365, 64 U.S.P.Q.2d (BNA) at 1913.

23. *Id.*, 64 U.S.P.Q.2d (BNA) at 1913.

24. *Id.*, 64 U.S.P.Q.2d (BNA) at 1913.

25. *Id.*, 64 U.S.P.Q.2d (BNA) at 1913.

26. *Id.* at 1365-66, 64 U.S.P.Q.2d (BNA) at 1914.

27. *Id.* at 1366, 64 U.S.P.Q.2d (BNA) at 1914.

28. *Id.* at 1367, 64 U.S.P.Q.2d (BNA) at 1915.

29. *Id.*, 64 U.S.P.Q.2d (BNA) at 1915.

30. 326 F.3d 1194, 66 U.S.P.Q.2d (BNA) 1602 (Fed. Cir. 2003).

31. *Id.* at 1197, 66 U.S.P.Q.2d (BNA) at 1603.

32. *Id.*, 66 U.S.P.Q.2d (BNA) at 1603.

33. *Id.* at 1197-98, 66 U.S.P.Q.2d (BNA) at 1603-04.

34. *Id.* at 1198, 66 U.S.P.Q.2d (BNA) at 1604.

35. *Id.*, 66 U.S.P.Q.2d (BNA) at 1604.

product that Silent Drive jointly developed with the party to the earlier Texas state court case.³⁶

Strong wrote letters to Silent Drive and to its customers outside of Iowa, notifying them about, and attaching copies of, the state court injunction and the patent.³⁷ Strong also issued a press release, which a potential customer of Silent Drive in Iowa received, describing the injunction and the patent.³⁸ In the press release, Strong indicated it would not be possible for anyone to make a certain kind of axle without infringing its patent.³⁹

Based on these letters, Silent Drive filed a declaratory judgment action in a federal court in Iowa seeking, among other things: (1) a declaration that the Texas state court injunction could not be enforced against Silent Drive; (2) a declaration of patent invalidity and non-infringement of the Strong patent; and (3) a finding of tortious interference with contractual relationships.⁴⁰ The district court dismissed the action for lack of personal jurisdiction despite finding that Strong intentionally sent the letters, which directly related to the patent claim, to the forum state.⁴¹

The Federal Circuit applied the law of the regional circuit to the personal jurisdiction issue.⁴² Although the court agreed that the letters sent by Strong did not confer personal jurisdiction by themselves over Strong on the patent count, and found that federal subject matter jurisdiction did not exist over the tortious interference count, the court never reached the question of personal jurisdiction on that count. Instead, the court found that Silent Drive properly asserted both subject matter and personal jurisdiction over the claim regarding the Texas state court injunction.⁴³ The Federal Circuit hinted that the issue of whether the Texas injunction could be enforced against Silent Drive required a federal due process analysis.⁴⁴ As part of that analysis, the court noted that the letters sent by Strong constituted an attempt to enforce the injunction against Silent Drive in Iowa, which subjected Strong to personal jurisdiction in Iowa.⁴⁵ Thus, the court concluded that the exercise of

36. *Id.*, 66 U.S.P.Q.2d (BNA) at 1604.

37. *Id.* at 1198-99, 66 U.S.P.Q.2d (BNA) at 1604-05.

38. *Id.* at 1199, 66 U.S.P.Q.2d (BNA) at 1605.

39. *Id.*, 66 U.S.P.Q.2d (BNA) at 1605.

40. *Id.* at 1199-200, 66 U.S.P.Q.2d (BNA) at 1605.

41. *Id.* at 1200, 66 U.S.P.Q.2d (BNA) at 1605.

42. *Id.* at 1200-01, 66 U.S.P.Q.2d (BNA) at 1606.

43. *Id.* at 1202-03, 66 U.S.P.Q.2d (BNA) at 1607-08.

44. *Id.* at 1203-04, 66 U.S.P.Q.2d (BNA) at 1608.

45. *Id.* at 1204-05, 66 U.S.P.Q.2d (BNA) at 1608-09.

supplemental jurisdiction over the other federal counts was proper and reversed the dismissal of the complaint.⁴⁶

C. Personal Jurisdiction—Minimum Contacts for Declaratory Judgment

In *Electronics for Imaging, Inc. v. Coyle*,⁴⁷ the Federal Circuit reversed a district court dismissal of an action filed in California. It held that the district court incorrectly found that it did not have personal jurisdiction over patent owner Kolbet Labs, a Nevada corporation, and its alleged alter ego, Jan Coyle, in a declaratory judgment suit filed by Electronics for Imaging (“EFI”), a Delaware corporation doing business principally in California.⁴⁸

EFI sued Kolbet Labs and Coyle for declaratory and injunctive relief of non-infringement, as well as for state law claims for non-breach of contract and non-misappropriation of trade secrets.⁴⁹ The Northern District of California granted the defendants’ motion to dismiss for lack of personal jurisdiction.⁵⁰

The court applied Federal Circuit law for purposes of claims arising out of the patent law, such as a claim for declaratory judgment of patent invalidity, and applied regional law, in this case Ninth Circuit law, for claims arising under state law.⁵¹ On the patent invalidity claim, the court analyzed whether Coyle had “purposefully directed” contacts at California and noted that defendants made telephone calls to EFI regarding the technology covered by the defendants’ patent application; sent two representatives to visit EFI’s facility to demonstrate defendants’ technology; and hired an attorney in California who periodically reported on the status of the defendants’ pending patent application.⁵² The court found those contacts were not “random, fortuitous or attenuated,” but rather “the totality of these contacts sufficiently” made out EFI’s *prima facie* case that Coyle “by ‘engaging in significant activities’ in California . . . purposefully directed [its] activities to California.”⁵³

This case appears to be a rare instance in which a court has considered the act of retaining counsel in a jurisdiction as a factor in establishing the “minimum contacts” necessary for the exercise of specific jurisdiction.

46. *Id.* at 1206, 66 U.S.P.Q.2d (BNA) at 1610.

47. 340 F.3d 1344, 67 U.S.P.Q.2d (BNA) 1940 (Fed. Cir. 2003).

48. *Id.* at 1346-47, 67 U.S.P.Q.2d (BNA) at 1941.

49. *Id.* at 1348, 1352, 67 U.S.P.Q.2d (BNA) at 1942, 1945.

50. *Id.*, 67 U.S.P.Q.2d (BNA) at 1942.

51. *Id.*, 67 U.S.P.Q.2d (BNA) at 1942.

52. *Id.* at 1350-51, 67 U.S.P.Q.2d (BNA) at 1944.

53. *Id.* at 1351, 67 U.S.P.Q.2d (BNA) at 1944.

D. Waiver of Defenses

In *Pandrol U.S.A., LP v. Airboss Railway Products, Inc.*,⁵⁴ (“*Pandrol I*”) a case involving invalidity defenses and counterclaims, the Federal Circuit ruled that the defendant’s failure to raise invalidity counterclaims against a summary judgment motion on infringement did not operate as a waiver of those validity defenses or counterclaims.⁵⁵

For purposes of the first appeal to the Federal Circuit in this matter,⁵⁶ the parties stipulated that defendants’ counterclaims were dismissed without prejudice and with permission to assert those claims if the case were remanded back to the district court after the appeal of the infringement ruling.⁵⁷

Based on the claim construction in *Pandrol U.S.A. LP v. Airboss Railway Products, Inc.*⁵⁸ (“*Pandrol I*”), the parties filed cross motions for summary judgment on the infringement issues.⁵⁹ Defendants did not, however, raise their affirmative validity defenses or counterclaims.⁶⁰ The district court granted plaintiff’s motion and found that the defendants had waived their validity defenses by failing to raise them in defense of plaintiff’s summary judgment motion on infringement.⁶¹ The Federal Circuit reversed and remanded again.⁶² The court noted that both Supreme Court and Federal Circuit precedent make clear that infringement and validity are separate issues⁶³—and that of the two—“validity has the greater public importance.”⁶⁴ Failure to raise the affirmative defense or

54. 320 F.3d 1354, 65 U.S.P.Q.2d (BNA) 1985 (Fed. Cir. 2003) [hereinafter “*Pandrol I*”].

55. *Id.* at 1357, 65 U.S.P.Q.2d (BNA) 1985, 1986-87.

56. *Pandrol USA, LP v. Airboss Ry. Prods., Inc.*, 10 Fed. Appx. 837, 841-42 (Fed. Cir. 2001) [hereinafter “*Pandrol I*”] (vacating the district court’s grant of summary judgment of non-infringement of U.S. Patent No. 5,110,046).

57. *Pandrol II*, 320 F.3d at 1359, 65 U.S.P.Q.2d (BNA) at 1988.

58. *Pandrol I*, 10 Fed. Appx. at 841-42.

59. *Pandrol II*, 320 F.3d at 1360, 65 U.S.P.Q.2d (BNA) at 1989.

60. *Id.*, 65 U.S.P.Q.2d (BNA) at 1989.

61. *Id.* at 1360-61, 65 U.S.P.Q.2d (BNA) at 1989.

62. *Id.* at 1369, 65 U.S.P.Q.2d (BNA) at 1995.

63. See *Cardinal Chem. Co. v. Morton Int’l, Inc.*, 508 U.S. 83, 102-03, 26 U.S.P.Q.2d (BNA) 1721, 1730 (1993) (holding that a finding of noninfringement has no bearing on the soundness of a counterclaim for patent invalidity); *Carman Indus., Inc. v. Wahl*, 724 F.2d 932, 936 n.2, 220 U.S.P.Q. (BNA) 481, 484 n.2 (Fed. Cir. 1983) (finding that the district court erred because it combined the validity analysis with the infringement issue); *Medtronic, Inc. v. Cardiac Pacemakers, Inc.*, 721 F.2d 1563, 1583, 220 U.S.P.Q. (BNA) 97, 111 (Fed. Cir. 1983) (noting that resolving the infringement issues, as well as the validity issue is the “better practice”).

64. *Pandrol II*, 320 F.3d at 1365, 65 U.S.P.Q.2d (BNA) at 1992 (quoting *Cardinal Chem. Co.*, 508 U.S. at 100, 26 U.S.P.Q.2d (BNA) at 1729).

counterclaim of invalidity in the context of a summary judgment motion on infringement is not a waiver of those issues.⁶⁵

E. Offensive Collateral Estoppel

In vacating a final judgment of patent infringement supported by offensive collateral estoppel, the Federal Circuit remanded *Dana v. E.S. Originals, Inc.*⁶⁶ for a finding of whether a plaintiff “could easily have joined” an earlier action and “therefore should be denied the benefits of a favorable outcome in that case because he chose not to expose himself to the risk of an unfavorable one.”⁶⁷

Dana, the prior owner of a patent for flashing disco shoes, sought damages for alleged pre-assignment infringement.⁶⁸ The district court in Florida granted partial summary judgment in his favor, finding that the defendants were collaterally estopped from contesting the issues of infringement and validity due to earlier orders issued by a sister court in California.⁶⁹ The California court granted partial summary judgment in favor of Dana’s assignee, holding that the patent was enforceable, the claims were not invalid, and that the defendants infringed under the doctrine of equivalents.⁷⁰ Shortly thereafter, the California parties entered into a settlement agreement memorialized by a consent decree.⁷¹

Applying the law of the Eleventh Circuit to this “procedural issue,” the Federal Circuit held that the plaintiff, as the party seeking collateral estoppel, successfully satisfied the legal requirements of collateral estoppel.⁷² Specifically, the court held that the issues of infringement and patent validity were identical to issues critical and necessary to the California orders, and the defendants had a full and fair opportunity to litigate these issues in the prior proceeding.⁷³ Using the Eleventh Circuit’s flexible approach that accords collateral estoppel effect to “orders that do not constitute final, appealable judgments if they are ‘sufficiently firm to be accorded conclusive effect,’”⁷⁴ the Federal Circuit noted that the California parties were aware of the potential preclusive effect of the rulings in which the

65. *Id.*, 65 U.S.P.Q.2d (BNA) at 1993.

66. 342 F.3d 1320, 68 U.S.P.Q.2d (BNA) 1138 (Fed. Cir. 2003).

67. *Id.* at 1327, 68 U.S.P.Q.2d (BNA) at 1143.

68. *Id.* at 1321-22, 68 U.S.P.Q.2d (BNA) at 1139.

69. *Id.* at 1322, 68 U.S.P.Q.2d (BNA) at 1139.

70. *Id.*, 68 U.S.P.Q.2d (BNA) at 1139.

71. *Id.*, 68 U.S.P.Q.2d (BNA) at 1139.

72. *Id.* at 1325, 68 U.S.P.Q.2d (BNA) at 1142.

73. *Id.* at 1324-25, 68 U.S.P.Q.2d (BNA) at 1141-42.

74. *Id.* at 1325, 68 U.S.P.Q.2d (BNA) at 1141 (quoting *Christo v. Padgett*, 223 F.3d 1324, 1339 n.47 (11th Cir. 2000)).

California court conducted hearings on both infringement and validity⁷⁵ and set forth its findings of fact and conclusions of law in fully reasoned opinions that made clear that the orders fully and finally resolved the matters addressed.⁷⁶

Nonetheless, the Federal Circuit invoked “equitable factors weighing against the offensive use of collateral estoppel” in determining that the Florida judgment of infringement was an abuse of discretion,⁷⁷ even though the Federal Circuit agreed that neither party established that the defendants’ exposure to damages would redundantly include its exposure in the California action.⁷⁸ Therefore, the California orders were not inconsistent with any previous judgments and the defendants would gain no previously unavailable procedural advantages in the second action.⁷⁹

The court emphasized the free rider problem implicated by the opportunistic nature of offensive collateral estoppel by stating:

Because potential plaintiffs are not bound by any decision favorable to the defendant in earlier lawsuits, but can seek to take advantage of any decision favorable to another plaintiff, the availability of offensive collateral estoppel creates a ‘no-lose’ incentive for plaintiffs to hold back and await developments in other plaintiffs’ cases.⁸⁰

As it was uncontroverted that Dana was aware of the California litigation, the Federal Circuit remanded for a finding of whether he “could easily have joined” that action, thereby precluding reliance on offensive collateral estoppel.⁸¹

F. Collateral Estoppel on Claim Construction

In *RF Delaware, Inc. v. Pacific Keystone Technologies, Inc.*,⁸² the Federal Circuit found no collateral estoppel resulted from a partial summary judgment in a prior litigation and reversed and remanded yet another case for what it considered to be an unduly restrictive claim construction.⁸³

The district court’s construction employed elements identical to those used in a claim construction ruling on partial summary judgment in a previous litigation in which the plaintiff, RF Delaware

75. *Id.* at 1323, 68 U.S.P.Q.2d (BNA) at 1140.

76. *Id.* at 1324, 68 U.S.P.Q.2d (BNA) at 1141.

77. *Id.* at 1325, 68 U.S.P.Q.2d (BNA) at 1142.

78. *Id.* at 1327, 68 U.S.P.Q.2d (BNA) at 1143.

79. *Id.*, 68 U.S.P.Q.2d (BNA) at 1143.

80. *Id.* at 1326, 68 U.S.P.Q.2d (BNA) at 1142.

81. *Id.* at 1327, 68 U.S.P.Q.2d (BNA) at 1143.

82. 326 F.3d 1255, 66 U.S.P.Q.2d (BNA) 1593 (Fed. Cir. 2003).

83. *Id.* at 1262, 66 U.S.P.Q.2d (BNA) at 1597.

(“RFD”), asserted the same patents against a different defendant.⁸⁴ Pacific Keystone argued that, irrespective of the reliability of the claim interpretation analysis by the district court, the prior district court’s claim construction should be given collateral estoppel effect.⁸⁵

Because the earlier action ended in an extra-judicial settlement without complete adjudication even as to liability, the Federal Circuit, applying regional law to this purely procedural issue, held that there was no collateral estoppel.⁸⁶ Citing the Eleventh Circuit, the court held that “collateral estoppel does not apply in the present case because no judgment, much less final judgment, was ever entered in the Virginia district court case.”⁸⁷

Moreover, the Federal Circuit held that the district court did not abuse its discretion by refusing to judicially estop RFD and found the Virginia district court’s claim interpretation binding on it because of its admission in a preliminary injunction proceeding.⁸⁸ Among other things, the court observed, RFD did not succeed in urging its position, as its motion for a preliminary injunction was denied, and the doctrine of judicial estoppel prevents only those who *successfully* urge a position from thereafter changing it.⁸⁹

G. Judicial Estoppel on Claim Construction

In a second appeal of *Middleton, Inc. v. Minnesota Mining & Manufacturing, Co.*,⁹⁰ the Federal Circuit reversed a summary judgment ruling, rejecting the very claim construction it appeared to embrace during the prior appeal.⁹¹ In a further exercise of careful parsing—drawing distinctions certain to impress even seasoned patent attorneys—the Federal Circuit also held that argument by the inventor in connection with a narrowing amendment to a parent application did not necessarily estop the patent holder from seeking a broader construction of that same term in a continuation patent.⁹²

In *Middleton*, the patent at issue claimed a material improved the finishing for the top surface of floors.⁹³ The key limitation of the

84. *Id.* at 1259, 66 U.S.P.Q.2d (BNA) at 1595.

85. *Id.* at 1260-61, 66 U.S.P.Q.2d (BNA) at 1596.

86. *Id.* at 1261, 66 U.S.P.Q.2d (BNA) at 1596.

87. *Id.*, 66 U.S.P.Q.2d (BNA) at 1596.

88. *Id.* at 1262, 66 U.S.P.Q.2d (BNA) at 1597.

89. *Id.*, 66 U.S.P.Q.2d (BNA) at 1597.

90. 311 F.3d 1384, 65 U.S.P.Q.2d (BNA) 1138 (Fed. Cir. 2002).

91. *Id.* at 1390, 65 U.S.P.Q.2d (BNA) at 1142; *see id.* at 1386, 65 U.S.P.Q.2d (BNA) 1139 (noting that the district court had adopted the Federal Circuit’s definition of the word “uniform” from the prior appeal).

92. *Id.* at 1388-89, 65 U.S.P.Q.2d (BNA) at 1138, 1141.

93. *Id.* at 1385, 65 U.S.P.Q.2d (BNA) at 1139.

claims required that the finish be “uniform.”⁹⁴ The district court construed “uniform” to require “a uniform thickness, and exclude[ed] material in which there are any variations in thickness.”⁹⁵

In a previous appeal, the Federal Circuit noted,

We understand the district court’s interpretation [of the term ‘uniform flexible film’] to mean that the film must have the same thickness throughout, except that normal manufacturing tolerances are allowed. Thus, while the film cannot have a thickness of 1 mil at one location and 25 mils at another, it may have variations in thickness due solely to the practical realities of the film manufacturing process. We note that at oral argument, the parties did not appear to dispute this reading of the district court’s claim construction.⁹⁶

However, in the present appeal, the Federal Circuit upbraided the district court for mistaking this passage as endorsement of the claim construction.⁹⁷ Considering the matter, *de novo*, the court construed “uniform” to apply to materials that are “uniform” in any number of ways, not just thickness.⁹⁸

The court also considered the prosecution history of the patent in suit to determine whether the patentee “clearly and unambiguously ‘disclaimed or disavowed’” an interpretation of the term “uniform” that could embrace the accused product.⁹⁹ During prosecution of the parent patent, the inventor had distinguished over a prior art reference by arguing that the relevant “uniformity” was a uniformity of *thickness*.¹⁰⁰ The court held that this argument, in connection with a bowling alley floor, did not constrain the patent holder from seeking a broader construction in relation to other sorts of floors.¹⁰¹

H. Retroactive Corporate Standing Cannot Save Original Case Filing

In *Paradise Creations, Inc. v. UV Sales, Inc.*,¹⁰² the Federal Circuit refused to recognize standing to bring a lawsuit based solely on a state corporate revival statute that purported to confer standing

94. *Id.* at 1387, 65 U.S.P.Q.2d (BNA) at 1140.

95. *Id.* at 1386, 65 U.S.P.Q.2d (BNA) at 1139.

96. *Id.*, 65 U.S.P.Q.2d (BNA) at 1139 (quoting *Middleton Inc. v. Minnesota Mining & Mfg. Co.*, No. 99-1201, 1999 WL 1072246 at *4 (Fed. Cir. Nov. 16, 1999)).

97. *Id.*, 65 U.S.P.Q.2d (BNA) at 1139-40.

98. *Id.* at 1386, 1389, 65 U.S.P.Q.2d (BNA) at 1140, 1142.

99. *Id.* at 1388, 65 U.S.P.Q.2d (BNA) at 1141.

100. *Id.* at 1388-89, 65 U.S.P.Q.2d (BNA) at 1141.

101. *Id.* at 1389, 65 U.S.P.Q.2d (BNA) at 1141-42.

102. 315 F.3d 1304, 65 U.S.P.Q.2d (BNA) 1293 (Fed. Cir. 2003).

retroactively where it did not exist at the time that the complaint for patent infringement was filed.¹⁰³

Paradise Creations was incorporated under Florida law in 1985.¹⁰⁴ In 1996, Paradise Creations was administratively dissolved.¹⁰⁵ It remained administratively dissolved until 2001.¹⁰⁶ While Paradise was in dissolution, they purportedly obtained “the exclusive, unlimited, irrevocable, worldwide right and license” to the patent in issue and filed a complaint for patent infringement against UV Sales.¹⁰⁷

UV filed a summary judgment motion, arguing that Paradise lacked the capacity to sue under Florida law and did not have standing to invoke the court’s jurisdiction.¹⁰⁸ After obtaining reinstatement as a corporation, Paradise filed its opposition, arguing that under Florida law, when a corporation that was administratively dissolved is reinstated, the reinstatement is retroactive to the date of dissolution and the corporation operates as though the dissolution had not occurred.¹⁰⁹

The district court rejected Paradise’s argument, finding that standing must exist at the time the action is brought and that Florida law cannot retroactively create jurisdiction that did not exist when the action was filed.¹¹⁰

The Federal Circuit affirmed, and applied the rule in *Enzo APA & Son, Inc. v. Geapag A.G.*¹¹¹ that a contract could not retroactively confer standing on an exclusive licensee who did not have all substantial rights to the patent at the time that it brought suit.¹¹² In applying *Enzo*, the Federal Circuit saw “no meaningful distinction between a contract provision that purports to vest title retroactively in the plaintiff and a state law that is alleged to vest enforceable title retroactively.”¹¹³

The Federal Circuit distinguished the facts in *Paradise* from its holding in *Mentor H/S, Inc. v. Medical Device Alliance, Inc.*,¹¹⁴ where it had held that a defect standing was curable where an exclusive licensee with less than all substantial rights in the patent filed a

103. *Id.* at 1310, 65 U.S.P.Q.2d (BNA) at 1297.

104. *Id.* at 1306, 65 U.S.P.Q.2d (BNA) at 1293.

105. *Id.*, 65 U.S.P.Q.2d (BNA) at 1293.

106. *Id.*, 65 U.S.P.Q.2d (BNA) at 1293.

107. *Id.*, 65 U.S.P.Q.2d (BNA) at 1293-94 (internal quotation and citation omitted).

108. *Id.*, 65 U.S.P.Q.2d (BNA) at 1294.

109. *Id.* at 1307, 65 U.S.P.Q.2d (BNA) at 1294.

110. *Id.*, 65 U.S.P.Q.2d (BNA) at 1294.

111. 134 F.3d 1090, 45 U.S.P.Q.2d (BNA) 1368 (Fed. Cir. 1998).

112. *Id.* at 1093-94, 45 U.S.P.Q.2d (BNA) at 1370-71.

113. *Paradise Creations*, 315 F.3d at 1310, 65 U.S.P.Q.2d (BNA) at 1296.

114. 240 F.3d 1016, 57 U.S.P.Q.2d (BNA) 1819 (Fed. Cir. 2001).

motion to join the patentee as a plaintiff, reasoning that as an exclusive licensee, Mentor, had a cognizable injury at the time of the inception of the suit.¹¹⁵ In contrast, Paradise did not have enforceable rights in the patent when the suit was filed, thus it lacked the cognizable injury necessary for Article III standing.¹¹⁶

I. *Claim Preclusion/Res Judicata*

In *Media Technologies Licensing, LLC v. Upper Deck Co.*,¹¹⁷ the Federal Circuit overturned a summary judgment that the suit by Media Technologies Licensing (“Media”) for patent infringement was barred by claim preclusion.¹¹⁸

A previous action on the same patent brought by Telepresence, an entity with common ownership to Media, had been dismissed with prejudice for lack of standing on a finding that Telepresence did not have sufficient ownership of the patent at the time the suit was filed.¹¹⁹ After that loss, the owner of Telepresence created the new entity, Media, and took steps to get all relevant patent rights into Media’s hands.¹²⁰ He then caused Media to sue the same defendant.¹²¹ Based on purported privity between Media and Telepresence, the district court held the claim was barred by the previous dismissal with prejudice.¹²²

Applying regional law, the Federal Circuit reversed, holding that the earlier dismissal was not an “adjudication on the merits,” a necessary condition to the application of claim preclusion.¹²³

The Federal Circuit expressly rejected the get-you-coming-and-going reasoning of the district court.¹²⁴ It pointed out that given the fact that the first action was dismissed due to a “deficient assignment between the inventor and Telepresence” it would hardly be just to dismiss the second action because of “a virtual representation relationship between Telepresence and Media.”¹²⁵ According to the Federal Circuit, a suit by Media is not the equivalent of Telepresence

115. *Id.* at 1018-19, 57 U.S.P.Q.2d (BNA) at 1821.

116. *Paradise Creations*, 315 F.3d at 1310, 65 U.S.P.Q.2d (BNA) at 1296-97.

117. 334 F.3d 1366, 67 U.S.P.Q.2d (BNA) 1374 (Fed. Cir. 2003).

118. *Id.* at 1368, 67 U.S.P.Q.2d (BNA) at 1375.

119. *Id.*, 67 U.S.P.Q.2d (BNA) at 1375.

120. *Id.* at 1368-69, 67 U.S.P.Q.2d (BNA) at 1375-76.

121. *Id.* at 1369, 67 U.S.P.Q.2d (BNA) at 1375.

122. *Id.*, 67 U.S.P.Q.2d (BNA) at 1376.

123. *Id.* at 1369-70, 67 U.S.P.Q.2d (BNA) at 1376-77.

124. *Id.* at 1370, 67 U.S.P.Q.2d (BNA) at 1377.

125. *Id.*, 67 U.S.P.Q.2d (BNA) at 1377.

taking “a second bite of the apple”; rather, it is a suit by “the entity with all the interest in the [patent in suit] that was lacking before.”¹²⁶

J. Final Judgments—Decision on Motion in Limine not Reviewable

Indicating that it is not interested in reviewing non-final judgments, the Federal Circuit, in *Ultra-Precision Manufacturing Ltd. v. Ford Motor Co.*,¹²⁷ dismissed an appeal of an *in limine* evidentiary ruling certified by the district court pursuant to Rule 54(b), and held that absent a final judgment on at least one claim, such a ruling could be appealed only pursuant to 28 U.S.C. § 1292(b).¹²⁸

The case arose out of a dispute between Ford and Ultra-Precision Manufacturing, from whom Ford sought technical assistance in the late 1980s in connection with problems associated with Ford’s air conditioning technology.¹²⁹ Ultra-Precision alleged that its technicians were co-inventors of a patent for its air conditioning compressor, which was subsequently obtained by Ford.¹³⁰

Ultra-Precision sued for, among other things, correction of inventorship and unjust enrichment.¹³¹ Ford sought summary judgment on these claims, as well as filed two motions *in limine* to exclude evidence of damages for any uses of technology disclosed in Ultra-Precision’s patents that were not claimed and evidence of damages for any use of the patent in issue because under 35 U.S.C. § 262, as a co-inventor, Ford could not be liable for damages.¹³² The district court granted both *in limine* motions, denied summary judgment, and granted Ultra-Precision’s request that the rulings be certified under Rule 54(b) for immediate appeal.¹³³

The Federal Circuit focused on the distinction between appeals allowed under Rule 54(b) and 28 U.S.C. § 1292(b), explaining that Rule 54(b) permits a court to enter a final judgment as to fewer than all pending claims only upon the express determination that there is not a just reason to delay the appeal of the claim.¹³⁴ On the other hand, under § 1292(b) an appeal may be permitted when a district judge issues an order that is not otherwise appealable because it is not finally adjudicated, but believes that the order involves a

126. *Id.*, 67 U.S.P.Q.2d (BNA) at 1377.

127. 338 F.3d 1353, 67 U.S.P.Q.2d (BNA) 1790 (Fed. Cir. 2003).

128. *Id.* at 1359-60, 67 U.S.P.Q.2d (BNA) at 1794.

129. *Id.* at 1354, 67 U.S.P.Q.2d (BNA) at 1790.

130. *Id.* at 1355, 67 U.S.P.Q.2d (BNA) at 1791.

131. *Id.*, 67 U.S.P.Q.2d (BNA) at 1791.

132. *Id.*, 67 U.S.P.Q.2d (BNA) at 1791.

133. *Id.* at 1355-56, 67 U.S.P.Q.2d (BNA) at 1791.

134. *Id.* at 1357, 67 U.S.P.Q.2d (BNA) at 1792.

controlling question of law where there is substantial grounds for differing opinions and an immediate appeal from the order may advance the litigation's conclusion.¹³⁵ The court may so state in writing and the appellate court has discretion to entertain an interlocutory appeal from such an order.¹³⁶

Because the district court's ruling related only to the exclusion of damages evidence, there was no final disposition of a claim.¹³⁷ Thus, the court found that certification of the appeal under Rule 54(b) was improper and dismissed the appeal for lack of jurisdiction.¹³⁸

Similarly, in *Nystrom v. TREX Co.*,¹³⁹ the Federal Circuit confirmed its long-standing position that claim construction rulings are not appealable as a matter of right.¹⁴⁰

In *Nystrom*, after the district court entered its ruling on claim construction and granted summary judgment of non-infringement, it entered an express final judgment of invalidity as to certain of the asserted patent claims.¹⁴¹ However, the district court stayed certain other counterclaims of invalidity and unenforceability.¹⁴² On appeal, the Federal Circuit held that the pendency of these remaining patent claims precluded the district court from effectively certifying an appeal pursuant to Rule 54(b).¹⁴³

In dismissing the appeal, the Federal Circuit reiterated that the purpose of the "final judgment rule"¹⁴⁴ is to prevent piecemeal litigation.¹⁴⁵ The Federal Circuit restated the four possible avenues of appeal as a matter of right: (1) a trial on the remaining counterclaims or otherwise a final disposition on the merits of those counterclaims; (2) a dismissal of the remaining counterclaims without prejudice (with or without finding that they were mooted by the summary judgment of non-infringement); (3) "an express determination that there is no just reason for delay' and then [an express direction of] entry of final judgment on fewer than all of the claims under Federal Rule of Civil Procedure 54(b)"; or (4) a certification of interlocutory judgments and orders of the district court pursuant to § 1292(b) or

135. *Id.*, 67 U.S.P.Q.2d (BNA) at 1792-93.

136. *Id.*, 67 U.S.P.Q.2d (BNA) at 1793.

137. *Id.* at 1358, 67 U.S.P.Q.2d (BNA) at 1793.

138. *Id.* at 1359-60, 67 U.S.P.Q.2d (BNA) at 1794.

139. 339 F.3d 1347, 67 U.S.P.Q.2d (BNA) 1858 (Fed. Cir. 2003).

140. *Id.* at 1350, 67 U.S.P.Q.2d (BNA) at 1860.

141. *Id.* at 1349, 67 U.S.P.Q.2d (BNA) at 1859.

142. *Id.*, 67 U.S.P.Q.2d (BNA) at 1859.

143. *Id.* at 1350, 67 U.S.P.Q.2d (BNA) at 1860.

144. 28 U.S.C. § 1295 (2000).

145. *Nystrom*, 339 F.3d at 1350, 67 U.S.P.Q.2d (BNA) at 1860.

(c)(1).¹⁴⁶ Noting that a stay order is generally not a final order, the Federal Circuit dismissed the present appeal because the district court did not choose one of the above approaches.¹⁴⁷

In dismissing the appeal, the Federal Circuit observed that claim construction rulings are often “determinative of either infringement or invalidity, but seldom both.”¹⁴⁸ However, such an appeal of one of these issues before determination of the other might serve judicial economy.¹⁴⁹ As the court noted, lower courts are obliged to follow the “final judgment rule” until the rule is changed.¹⁵⁰

K. Motion for JMOL Must Be Specific to Preserve Issue for Appeal

In *Duro-Last, Inc. v. Custom Seal, Inc.*,¹⁵¹ the Federal Circuit applied its own “nascent” law, and took a more exacting view than the regional circuits might have done, ruling that a motion for judgment as a matter of law (“JMOL” or formerly called “directed verdict”) at the close of evidence on the issue of inequitable conduct was not sufficient to preserve the right to seek review of the jury’s verdict that the art purportedly withheld from the United States Patent and Trademark Office (“PTO”) rendered the patented invention obvious.¹⁵²

Duro-Last sued Custom Seal for infringement of its patent of roofing products used to cover roof protrusions such as vent pipes and air conditioning units.¹⁵³ At the close of evidence, Duro-Last moved for JMOL under Rule 50 on Custom Seal’s defense of inequitable conduct.¹⁵⁴ When the jury later returned a verdict of invalidity under § 103,¹⁵⁵ apparently on the basis that the art purportedly withheld from the PTO rendered the patent invalid for obviousness, Duro-Last sought JMOL that the patent was not obvious.¹⁵⁶

146. *Id.* at 1350-51, 67 U.S.P.Q.2d (BNA) at 1860-61.

147. *Id.* at 1351, 67 U.S.P.Q.2d (BNA) at 1861.

148. *Id.* at 1350, 67 U.S.P.Q.2d (BNA) at 1860.

149. *See id.*, 67 U.S.P.Q.2d (BNA) at 1860 (stating “because claim construction is subject to de novo review as a matter of law, immediate appeal of an interlocutory claim construction ruling without resolution of all of the factual issues of infringement of validity dependent thereon is often desired by one or both of the parties for strategic or other reasons”).

150. *Id.*, 67 U.S.P.Q.2d (BNA) at 1860.

151. 321 F.3d 1098, 66 U.S.P.Q.2d (BNA) 1025 (Fed. Cir. 2003).

152. *Id.* at 1106, 66 U.S.P.Q.2d (BNA) at 1029.

153. *Id.* at 1102-03, 66 U.S.P.Q.2d (BNA) at 1026.

154. *Id.* at 1104, 66 U.S.P.Q.2d (BNA) at 1027-28.

155. Conditions for patentability; non-obvious subject matter, 33 U.S.C. § 103.

156. *Duro-Last, Inc.*, 321 F.3d at 1104-05, 66 U.S.P.Q.2d (BNA) at 1028.

To win review of the factual basis of the jury's verdict by the district court, Duro-Last argued that its JMOL motion on inequitable conduct had implicitly put in issue the question of obviousness.¹⁵⁷ According to Duro-Last, the question of whether the reference it was accused of concealing was material necessarily raised the underlying question of obviousness.¹⁵⁸

While acknowledging that Duro-Last's analysis might have prevailed under the law of some of the regional circuits, the Federal Circuit held that the sufficiency of a JMOL motion at the close of evidence to preserve the right to seek post-verdict JMOL on obviousness was a matter of Federal Circuit law; and, under that body of law, Duro-Last's post-evidence motion was insufficient.¹⁵⁹ The court specifically held that "the various unenforceability and invalidity defenses that may be raised by a defendant—inequitable conduct, the several forms of anticipation and loss of right under § 102, and obviousness under § 103—require different elements of proof."¹⁶⁰ Each must be raised specifically in a post-evidence JMOL if it is to be preserved.¹⁶¹

*L. Decision on JMOL Cannot Involve Post-Jury Instruction Claim
Construction/Doctrine of Equivalent Proofs*

In *Hewlett-Packard Co. v. Mustek Systems, Inc.*,¹⁶² the Federal Circuit held that it was improper for the district court to modify its claim construction after the instruction of the jury as to the meaning of claim terms.¹⁶³ The Federal Circuit refused to remand for a new trial on the doctrine of equivalents issues because the patentee had made no record to establish equivalency.¹⁶⁴ On a validity related issue, the court also held that an in-court demonstration of a prior art device was sufficient corroboration of oral evidence to support a finding of invalidity.¹⁶⁵

The two patents in suit involved optical scanner technology, in which images and text from a document are converted into electronic data.¹⁶⁶ The jury was instructed that a claimed "scan speed

157. *Id.* at 1107, 66 U.S.P.Q.2d (BNA) at 1029.

158. *Id.*, 66 U.S.P.Q.2d (BNA) at 1029.

159. *Id.* at 1106-07, 66 U.S.P.Q.2d (BNA) at 1029-30.

160. *Id.* at 1107-08, 66 U.S.P.Q.2d (BNA) at 1030.

161. *Id.* at 1108, 66 U.S.P.Q.2d (BNA) at 1030.

162. *Hewlett-Packard Co. v. Mustek Sys. Inc.*, 340 F.3d 1314, 67 U.S.P.Q.2d (BNA) 1825 (Fed. Cir. 2003).

163. *Id.* at 1321, 67 U.S.P.Q.2d (BNA) at 1829-30.

164. *Id.* at 1322-23, 67 U.S.P.Q.2d (BNA) at 1830-31.

165. *Id.* at 1325-26, 67 U.S.P.Q.2d (BNA) at 1832-33.

166. *Id.* at 1317, 67 U.S.P.Q.2d (BNA) at 1826.

indicating means” required a user selectable scan speed device.¹⁶⁷ Neither party objected to the instruction.¹⁶⁸ At trial, the jury found that Mustek literally infringed.¹⁶⁹ The jury did not address infringement under the doctrine of equivalents.¹⁷⁰

In a JMOL motion, Mustek challenged the finding of infringement urging that the claims require the user to select a specific scanning speed and the accused scanners, while permitting the user to select scan resolution, do not permit the user to select scanning speed.¹⁷¹ In denying Mustek’s motion, the district court elaborated on the claim construction provided to the jury and found, based on a more general definition, that the element was present, at least under the doctrine of equivalents.¹⁷² Mustek appealed.¹⁷³

Hewlett-Packard (“H-P”) argued that under the claim construction used by the district court in its decision on Mustek’s JMOL motion, infringement was present.¹⁷⁴ The Federal Circuit held that H-P could not challenge in post-trial motions the claim construction with which the jury was instructed: “[w]hen issues of claim construction have not been properly raised in connection with the jury instructions, it is improper for the district court to adopt a new or more detailed claim construction in connection with the JMOL motion.”¹⁷⁵ The court further found that using the claim construction with which the jury was instructed, the jury’s verdict of literal infringement was not supported by substantial evidence.¹⁷⁶ Citing *Lockheed Martin Corp. v. Space System/Loral, Inc.*,¹⁷⁷ the court noted that “[l]iteral infringement of a § 112, ¶ 6 claim requires that the relevant structure in the accused device perform the identical function recited in the claim and be identical or equivalent to the corresponding structure in the specification.”¹⁷⁸ The court held that “it was improper for the district court to expand [H-P’s] opposition to Mustek’s motion for JMOL of

167. *Id.* at 1319, 67 U.S.P.Q.2d (BNA) at 1828.

168. *Id.* at 1320, 67 U.S.P.Q.2d (BNA) at 1828.

169. *Id.* at 1318, 67 U.S.P.Q.2d (BNA) at 1827.

170. *Id.*, 67 U.S.P.Q.2d (BNA) at 1827.

171. *Id.* at 1320, 67 U.S.P.Q.2d (BNA) at 1830.

172. *Id.*, 67 U.S.P.Q.2d (BNA) at 1829 (defining the issue as whether evidence showed that the selection of scan speed and the selection of resolution were identical).

173. *Id.* at 1318, 67 U.S.P.Q.2d (BNA) at 1827.

174. *Id.* at 1321, 67 U.S.P.Q.2d (BNA) at 1829-30.

175. *Id.* at 1320, 67 U.S.P.Q.2d (BNA) at 1829.

176. *Id.* at 1321, 67 U.S.P.Q.2d (BNA) at 1829.

177. 324 F.3d 1308, 66 U.S.P.Q.2d 1671 (Fed. Cir. 2003).

178. *Hewlett-Packard Co.*, 340 F.3d at 1321, 67 U.S.P.Q.2d (BNA) at 1830 (quoting *Lockheed Martin Corp.*, 324 F.3d at 1320, 66 U.S.P.Q.2d (BNA) at 1679).

noninfringement to grant JMOL of infringement under the doctrine of equivalents in favor of [H-P].”¹⁷⁹

The Federal Circuit also found that a new trial was not appropriate because H-P “did not make a sufficient record with respect to the equivalents claim,” which would require “particularized testimony and linking argument . . . on a limitation-by-limitation basis.”¹⁸⁰

As to validity, the jury found that Mustek proved by clear and convincing evidence that certain patent claims were invalid based in part on testimony of prior public use, corroborated with a re-enactment of such use through an in-court demonstration using a prior art device.¹⁸¹ H-P argued that the evidence did not support the finding of obviousness, challenging the use of “uncorroborated” testimony regarding the use of the Mustek scanner.¹⁸² The Federal Circuit concluded that the testimonial evidence was sufficiently corroborated by the operation of the device itself, which was “made contemporaneously with the alleged prior invention.”¹⁸³

II. PATENTABILITY ISSUES

A. *Anticipation by Inherency Does Not Require Recognition of Results*

In *Schering Corp. v. Geneva Pharmaceuticals, Inc.*,¹⁸⁴ a case of first impression,¹⁸⁵ the Federal Circuit affirmed a lower court’s finding of anticipation of a drug metabolite where the prior art patent disclosed only the drug.¹⁸⁶ Finding that an enabling disclosure for use of the drug anticipated its metabolic product produced in the human body,¹⁸⁷ the *Schering* decision invalidated a patent for the first time where inherency supplied the entire anticipatory subject matter.¹⁸⁸

Claritin® is a non-drowsy antihistamine formulation marketed by Schering Corp. (“Schering”).¹⁸⁹ Its active component, loratadine, was covered to Schering by U.S. Pat. No. 4,282,233 (“the ‘233 patent”) which is now expired.¹⁹⁰ Ingestion of loratadine results in the

179. *Id.* at 1322, 67 U.S.P.Q.2d (BNA) at 1830.

180. *Id.* at 1322-23, 67 U.S.P.Q.2d (BNA) at 1830-31.

181. *Id.* at 1325-26, 67 U.S.P.Q.2d (BNA) at 1833.

182. *Id.* at 1326, 67 U.S.P.Q.2d (BNA) at 1833.

183. *Id.*, 67 U.S.P.Q.2d (BNA) at 1833.

184. 339 F.3d 1373, 67 U.S.P.Q.2d (BNA) 1664 (Fed. Cir. 2003).

185. *Id.* at 1378, 67 U.S.P.Q.2d (BNA) at 1668.

186. *Id.* at 1374, 67 U.S.P.Q.2d (BNA) at 1665.

187. *Id.* at 1381-82, 67 U.S.P.Q.2d (BNA) at 1670-71.

188. *Id.* at 1378-79, 67 U.S.P.Q.2d (BNA) at 1668-69.

189. *Id.* at 1375, 67 U.S.P.Q.2d (BNA) at 1665.

190. *Id.* at 1374-75, 67 U.S.P.Q.2d (BNA) at 1665.

breakdown product descarboethoxyloratadine (“DCL”).¹⁹¹ Schering’s subsequent patent, U.S. Pat. No. 4,659,716 (“the ‘716 patent”), covers the loratadine metabolite DCL.¹⁹² The ‘233 patent is prior art to the ‘716 patent, but does not expressly disclose DCL or refer to metabolites of loratadine.¹⁹³

Schering sued generic drug makers of loratadine for infringing the ‘716 patent.¹⁹⁴ The district court construed the claims to cover all forms of DCL, including forms “metabolized within the human body” and granted summary judgment of invalidity because DCL was formed as a metabolite through the process disclosed in Schering’s ‘233 patent.¹⁹⁵

The Federal Circuit strongly rejected the patentee’s contention that *recognition* of an inherent disclosure before the critical date of the ‘716 patent was a requirement for anticipation.¹⁹⁶ Precedent required only the missing feature to be necessarily present in the single prior art reference for anticipation.¹⁹⁷ *Later* recognition that loratadine was metabolized into DCL did not preclude the inherent characteristics in Schering’s ‘233 patent that DCL would be formed following ingestion of loratadine.¹⁹⁸

The issue before the court was whether anticipation could be found where *all* of the claimed subject matter was present only by inherency in the prior art.¹⁹⁹ Mindful that its prior cases involved inherent disclosure of only some of the claimed features, the court concluded that the extent of the inherent disclosure does not limit its anticipatory effect.²⁰⁰ Inherency places subject matter in the public domain to the same extent as does an express disclosure and applies equally to entire inventions as well as to single limitations.²⁰¹ Affirming summary judgment of invalidity, the court held that the ‘233 patent was anticipatory prior art because it discloses how to make DCL by disclosing administration of loratadine to patients, and

191. *Id.* at 1375, 67 U.S.P.Q.2d (BNA) at 1665.

192. *Id.* at 1374-75, 67 U.S.P.Q.2d (BNA) at 1665-66.

193. *Id.* at 1376, 67 U.S.P.Q.2d (BNA) at 1666.

194. *Id.*, 67 U.S.P.Q.2d (BNA) at 1666.

195. *Id.*, 67 U.S.P.Q.2d (BNA) at 1666-67 (quoting *Schering Corp. v. Geneva Pharm., Inc.*, 275 F. Supp. 2d 534, 539, 64 U.S.P.Q.2d (BNA) 1032, 1039 (D. N.J. 2002)).

196. *Id.* at 1377, 67 U.S.P.Q.2d (BNA) at 1667.

197. *Id.*, 67 U.S.P.Q.2d (BNA) at 1667 (citing *In re Cruciferous Sprouts Litig.*, 301 F.3d 1343, 1351, 64 U.S.P.Q.2d 1202, 1205 (Fed. Cir. 2002)).

198. *Id.* at 1381, 67 U.S.P.Q.2d (BNA) at 1670.

199. *Id.* at 1379, 67 U.S.P.Q.2d (BNA) at 1669.

200. *Id.*, 67 U.S.P.Q.2d (BNA) at 1669.

201. *Id.*, 67 U.S.P.Q.2d (BNA) at 1669.

substantial evidence showed DCL was necessarily formed upon digestion.²⁰²

The court stressed that while the claims in issue were anticipated for encompassing all forms of DCL, the holding did not preclude patentability of drug metabolites in general.²⁰³

B. Anticipation—The Relationship Between Enablement and Inherency

In a case involving a patent for transgenic rodents, the Federal Circuit reversed and remanded the grant of summary judgment of anticipation by inherency where the patent was found to be anticipated by a reference that prophetically contemplated the claimed rodents.²⁰⁴ The Federal Circuit held that invalidity based on anticipation requires that the reference must enable the subject matter of the claims at issue without undue experimentation.²⁰⁵

The district court granted the Mayo Foundation's motion for summary judgment of patent invalidity on the grounds that Elan's two patents in suit, both entitled "Transgenic Animals Harboring APP Allele Having Swedish Mutation" (collectively "the Elan patents"), were invalid as anticipated by a prior art patent to Mullan entitled "Nucleic Acids for Diagnosing and Modeling Alzheimer's Disease" ("the Mullan reference") under the principles of inherency.²⁰⁶

Alzheimer's disease is associated with abnormally high amounts of beta-amyloid peptide in the brain.²⁰⁷ This peptide is formed by cleavage of amyloid precursor protein ("APP") by two enzymes resulting in ATF-beta-APP and beta-amyloid peptide.²⁰⁸ It is unknown why certain individuals are prone to increased beta-amyloid peptide deposition.²⁰⁹ However, Mullan showed that individuals expressing a mutant form of APP, the "Swedish mutation," have a substantially increased likelihood of developing the disease.²¹⁰

The Mullan reference not only discloses the Swedish mutation, but it also contemplates creating a transgenic mouse for expressing an

202. *Id.* at 1381-82, 67 U.S.P.Q.2d (BNA) at 1671.

203. *Id.* at 1381, 67 U.S.P.Q.2d (BNA) at 1670.

204. *Elan Pharm., Inc. v. Mayo Found.*, 346 F.3d 1051, 1057, 68 U.S.P.Q.2d (BNA) 1373, 1377-78 (Fed. Cir. 2003).

205. *Id.* at 1054, 68 U.S.P.Q.2d (BNA) at 1376.

206. *Id.* at 1052, 68 U.S.P.Q.2d (BNA) at 1374 (citing *Elan Pharm. Inc. v. Mayo Found.*, 175 F. Supp. 2d 1209, 1214-15 (N.D. Cal. 2000)).

207. *Id.*, 68 U.S.P.Q.2d (BNA) at 1374.

208. *Id.* at 1053, 68 U.S.P.Q.2d (BNA) at 1374-75.

209. *Id.*, 68 U.S.P.Q.2d (BNA) at 1375 (noting, however, that "[h]umans who do not develop Alzheimer's disease are believed to break down the APP in a manner that does not form significant amounts of betaAP in the brain.>").

210. *Id.*, 68 U.S.P.Q.2d (BNA) at 1375.

APP containing it.²¹¹ To this end, Mullan provided a survey of a range of protocols for the genetic manipulation of rodents.²¹² However, no guidance was given as to which method would best succeed.²¹³ The inventors of the Elan patents ultimately used one of the cited protocols to create a rodent as contemplated by the Mullan reference.²¹⁴

The claims at issue related to transgenic rodents comprising a transgene encoding an APP having the Swedish mutation.²¹⁵ In order to distinguish the claimed subject matter from the Mullan prior art, the inventors amended the claims during prosecution to include the recitation that the mutant APP is processed to ATF-beta-APP in a sufficient amount to be detectable in the rodent's brain.²¹⁶

In support of its summary judgment motion, Mayo argued, and the district court agreed, that the claims were invalid because the Mullan reference inherently taught the claimed subject matter.²¹⁷ On appeal, the Federal Circuit noted that, in the course of the summary judgment proceeding, the factual basis of Elan's argument related to whether Mullan's disclosure was enabling.²¹⁸ Thus, the Federal Circuit held that enablement, not inherency, was at issue.²¹⁹ Citing *In re Donohue*,²²⁰ the Federal Circuit held that to be anticipating, the disclosure of a reference must be adequate to enable the possession of the claimed subject matter.²²¹ It is insufficient for the reference to simply name or describe the claimed subject matter, if, based on the reference disclosure, it cannot be produced without undue experimentation.²²²

The Federal Circuit remanded the case to the district court for a factual determination of anticipation based on enablement, taking into account whether the uncertainty and difficulty of producing a transgenic animal constitutes undue experimentation when presented in the context of a compilation of known methods of gene

211. *Id.* at 1055-56, 68 U.S.P.Q.2d (BNA) at 1377.

212. *Id.*, 68 U.S.P.Q.2d (BNA) at 1377.

213. *Id.* at 1056, 68 U.S.P.Q.2d (BNA) at 1377.

214. *Id.* at 1053, 68 U.S.P.Q.2d (BNA) at 1375 (noting that the Elan patents were "directed to transgenic rodents whose genetic makeup has been modified to include the Swedish mutation.").

215. *Id.*, 68 U.S.P.Q.2d (BNA) at 1375.

216. *Id.* at 1054, 68 U.S.P.Q.2d (BNA) at 1375.

217. *Id.* at 1056-57, 68 U.S.P.Q.2d (BNA) at 1377 (*Elan Pharm. Inc. v. Mayo Found.*, 175 F. Supp. 2d 1209, 1214-15 (N.D. Cal. 2000)).

218. *Id.* at 1054, 68 U.S.P.Q.2d (BNA) at 1375-76.

219. *Id.*, 68 U.S.P.Q.2d (BNA) at 1375.

220. *In re Donohue*, 766 F.2d 531, 226 U.S.P.Q.2d (BNA) 619 (Fed. Cir. 1985).

221. *Elan Pharm., Inc.*, 346 F.3d at 1055, 68 U.S.P.Q.2d (BNA) at 1376.

222. *Id.*, 68 U.S.P.Q.2d (BNA) at 1376.

transfer.²²³ For guidance in making such a determination, the court cited *Enzo Biochem, Inc. v. Calgene, Inc.*²²⁴ for the proposition that enablement is determined by whether undue experimentation would have been required to make and use the claimed invention at the time of filing the claimed subject matter.²²⁵ Accordingly, the issue on remand was whether the Mullan reference would have enabled a person of ordinary skill, at the time of filing the applications for the Elan patents, to practice the Elan patent claims without undue experimentation.²²⁶

This case is indicative of the tug-of-war in biotechnology between providing protection for disclosed prophetic ideas and rewarding those who later actually reduce those ideas to practice.²²⁷ Because of the incremental and sometimes unpredictable nature of the technology, subject matter that might appear to be obvious on its face may have proven difficult to implement based on prior art disclosures alone and is, therefore, rendered patentable as the prior art did not enable what is later claimed.²²⁸ Thus, it seems inevitable that the protracted “battle of the experts,” to determine what constitutes undue experimentation at a given point in time, will continue.²²⁹

C. Section 102(b) on Sale Bar

In *Minton v. National Ass’n of Securities Dealers, Inc.*,²³⁰ the Federal Circuit upheld a summary judgment that Minton’s patent for a computerized securities trading method was invalid because the invention was “on sale” more than a year before patent filing.²³¹ Before the critical date of his patent application, Minton leased a computer program that performed the patented process.²³² Minton argued, based on the *In re Kollar*²³³ decision, that the lease was not a “sale” for patent law purposes.²³⁴ The court distinguished *In re Kollar*,

223. *Id.* at 1057, 68 U.S.P.Q.2d (BNA) at 1378.

224. 188 F.3d 1362, 52 U.S.P.Q.2d (BNA) 1129 (Fed. Cir. 1999).

225. *Elan Pharm., Inc.*, 346 F.3d at 1056-57, 68 U.S.P.Q.2d (BNA) at 1377.

226. *Id.* at 1057, 68 U.S.P.Q.2d (BNA) at 1377-78.

227. See KENNETH J. BURCHFIEL, BIOTECHNOLOGY AND THE FEDERAL CIRCUIT 171 (1995) (stating that regarding biological inventions, it is widely recognized that enabling anyone to make living organisms through written descriptions is difficult).

228. See *id.* at 172 (adding that with genetic engineering techniques allowing skilled artisans to create and reproduce new life forms, courts have been forced to alter their principle that such enablement was often not possible).

229. See *id.* at 181-82 (discussing several irreconcilable decisions in cases where courts have had to determine undue experimentation standards).

230. 336 F.3d 1373, 67 U.S.P.Q.2d (BNA) 1614 (Fed. Cir. 2003).

231. *Id.* at 1374, 67 U.S.P.Q.2d (BNA) at 1615.

232. *Id.* at 1375, 67 U.S.P.Q.2d (BNA) at 1616.

233. 286 F.3d 1326, 62 U.S.P.Q.2d (BNA) 1425 (Fed. Cir. 2002).

234. *Minton*, 336 F.3d at 1376, 62 U.S.P.Q.2d (BNA) at 1617.

where the patent owner transferred technical information and, under a know-how agreement, licensed a process that required more development before commercialization.²³⁵ The court also distinguished the license of a potential patent right, which is not a sale under § 102(b), from a license or a lease of a product or device, which may be a sale under § 102(b).²³⁶

Judge Gajarsa's concurrence questioned the meaning of *In re Kollar* and said that if a process is ready for patenting under *Pfaff v. Wells Electronics, Inc.*,²³⁷ the transfer of the right to perform the process is a sale.²³⁸

In another 102(b) case, the Federal Circuit ruled in *Lacks Industries, Inc. v. McKechnie Vehicle Components USA, Inc.*²³⁹ that a determination of whether a patent barring offer for sale has been made must be based on contract law principles, but also must be predicated on standard practices within the applicable industry.²⁴⁰

In that case, Lacks Industries accused McKechnie of infringement of claims directed to automobile wheel chrome-plated cladding.²⁴¹ The district court adopted a special master's finding that the claims were invalid due to an offer for sale, which triggered an on sale bar.²⁴² The district court also granted summary judgment of invalidity of other claims based on the publication of a foreign counterpart of a related U.S. patent having common inventorship with the patent in suit.²⁴³ The Federal Circuit affirmed the grant of summary judgment based on § 102(b) but remanded the on sale issue for determination of industry practices.²⁴⁴

More than one year before its patent filing date, Lacks Industries engaged in sales promotion activities, none of which evidenced an offer to sell a particular article for a particular price.²⁴⁵ The special master, quoting *RCA Corp. v. Data General Corp.*,²⁴⁶ decided this activity constituted an offer for sale.²⁴⁷ The Federal Circuit noted that the incorrect legal standard was used because *RCA Corp.* was decided

235. *Id.* at 1377-78, 62 U.S.P.Q.2d (BNA) at 1618.

236. *Id.* at 1378, 62 U.S.P.Q.2d (BNA) at 1618.

237. 525 U.S. 55, 48 U.S.P.Q.2d (BNA) 1641 (1998).

238. *Minton*, 336 F.3d at 1382, 62 U.S.P.Q.2d (BNA) at 1621 (Gajarsa, J., concurring).

239. 322 F.3d 1335, 66 U.S.P.Q.2d (BNA) 1083 (Fed. Cir. 2003).

240. *Id.* at 1348, 66 U.S.P.Q.2d (BNA) at 1093.

241. *Id.* at 1339, 66 U.S.P.Q.2d (BNA) at 1085.

242. *Id.* at 1341, 66 U.S.P.Q.2d (BNA) at 1087.

243. *Id.* at 1340, 66 U.S.P.Q.2d (BNA) at 1086.

244. *Id.* at 1351, 66 U.S.P.Q.2d (BNA) at 1095.

245. *Id.* at 1348, 66 U.S.P.Q.2d (BNA) at 1092.

246. 887 F.2d 1056, 12 U.S.P.Q.2d (BNA) 1449 (Fed. Cir. 1989).

247. *Lacks Indus., Inc.*, 322 F.3d at 1341, 66 U.S.P.Q.2d (BNA) at 1087.

before the “totality of the circumstances test” was replaced in 1998 by the two-prong test of *Pfaff v. Wells Electronics, Inc.*²⁴⁸ that looked to a “commercial offer for sale” coupled with an invention ready for patenting.²⁴⁹ While *Pfaff* did not provide guidance on the meaning of a “commercial offer for sale,” the court noted that the legal standard was clarified by the Federal Circuit in *Group One, Ltd. v. Hallmark Cards, Inc.*,²⁵⁰ to require a communication, “which the other party could make into a binding contract by simple acceptance (assuming consideration).”²⁵¹ In *Group One, Ltd.*, the Federal Circuit also held that Federal Circuit law, and not state contract law, would control such a determination and that the Uniform Commercial Code (“UCC”) would be used for guidance.²⁵² In *Lacks Industries, Inc.*, the court remanded the on-sale issue for reconsideration based on the standard articulated in *Group One, Ltd.*, whether there had been a “formal offer under contract law principles.”²⁵³ The panel majority further suggested that evidence of the practice in the pertinent industry be considered to determine whether the commercial activity in question was an offer.²⁵⁴

Judge Newman’s partial dissent noted that the opinion in *Group One, Ltd.* recognized the need for nationwide uniformity when analyzing on sale bar activities.²⁵⁵ Judge Newman criticized the majority opinion as working against uniformity by allowing the analysis to depend on the practices of a particular industry.²⁵⁶ Thus, in Judge Newman’s view, the majority opinion reverted in the direction of the imprecise “totality of the circumstances” standard rejected in *Pfaff*.²⁵⁷

D. Section 102(e) Prior Art Cannot Be Work of Named Inventor(s)

In *Riverwood International Corp. v. R.A. Jones & Co.*,²⁵⁸ the Federal Circuit held that listing an earlier-issued patent in an Information

248. 525 U.S. 55, 48 U.S.P.Q.2d (BNA) 1641 (1998).

249. *Lacks Indus., Inc.*, 322 F.3d at 1347, 66 U.S.P.Q.2d (BNA) at 1092.

250. 254 F.3d 1041, 59 U.S.P.Q.2d (BNA) 1121 (Fed. Cir. 2001).

251. *Lacks Indus., Inc.*, 322 F.3d at 1347, 66 U.S.P.Q.2d (BNA) at 1092 (quoting *Group One, Ltd.*, 254 F.3d at 1048, 59 U.S.P.Q.2d (BNA) at 1126).

252. *Group One, Ltd.*, 254 F.3d at 1047, 59 U.S.P.Q.2d (BNA) at 1126.

253. *Lacks Indus., Inc.*, 322 F.3d at 1348, 66 U.S.P.Q.2d (BNA) at 1092-93.

254. *Id.*, 66 U.S.P.Q.2d (BNA) at 1093.

255. *Id.* at 1352, 66 U.S.P.Q.2d (BNA) at 1095 (Newman, J., concurring in part and dissenting in part).

256. *Id.*, 66 U.S.P.Q.2d (BNA) at 1095 (Newman, J., concurring in part and dissenting in part).

257. *Id.*, 66 U.S.P.Q.2d (BNA) at 1095 (Newman, J., concurring in part and dissenting in part).

258. 324 F.3d 1346, 66 U.S.P.Q.2d (BNA) 1331 (Fed. Cir. 2003).

Disclosure Statement (“IDS”) does not automatically result in finding that such earlier-issued patent is § 102(e) prior art to the later application.²⁵⁹ Where there is at least one inventor common to both the earlier-issued patent and the later application, one can avoid a determination of “prior art by admission” by showing that the inventor submitting the later application also invented the relevant portion of the subject matter disclosed in the earlier-issued patent.²⁶⁰

In this case, Riverwood sued Jones for infringing the ‘806 patent and two later patents, all directed to methods and machines for use in the packaging industry.²⁶¹ All three patents shared one common inventor, but did not have completely overlapping inventive entities.²⁶² During prosecution of the application for the two later patents, the inventors identified the ‘806 patent as prior art in an IDS.²⁶³ The district court deemed this an “admission” and so instructed the jury, which found the two later patents invalid as obvious in light of the ‘806 patent.²⁶⁴

On appeal, the Federal Circuit held that although a reference may constitute prior art based on admissions in an IDS, such is not the case when the reference is the inventor’s own work.²⁶⁵ If the relevant portion of the ‘806 patent was invented by the same inventive entity responsible for the allegedly obvious matter in the later patents, inclusion of the ‘806 patent in the IDS would not be an admission of prior art status.²⁶⁶ The Federal Circuit remanded the case for a determination of whether both the portion of the ‘806 patent relied on as prior art and the subject matter of the claims at issue were the work of a common inventive entity.²⁶⁷

E. Section 103 Obviousness

1. Prima facie obvious—claimed range is within prior art

In *In re Peterson*,²⁶⁸ the Federal Circuit held that a prior reference that discloses a broad range, which encompasses the narrower claimed range, is sufficient to establish prima facie obviousness.²⁶⁹

259. *Id.* at 1355-56, 66 U.S.P.Q.2d (BNA) at 1338.

260. *Id.*, 66 U.S.P.Q.2d (BNA) at 1338.

261. *Id.* at 1349, 66 U.S.P.Q.2d (BNA) at 1333.

262. *Id.*, 66 U.S.P.Q.2d (BNA) at 1333.

263. *Id.* at 1350-51, 66 U.S.P.Q.2d (BNA) at 1334.

264. *Id.* at 1351, 66 U.S.P.Q.2d (BNA) at 1335.

265. *Id.* at 1354-55, 66 U.S.P.Q.2d (BNA) at 1337-38.

266. *Id.* at 1355, 66 U.S.P.Q.2d (BNA) at 1338.

267. *Id.* at 1359, 66 U.S.P.Q.2d (BNA) at 1340-41.

268. 315 F.3d 1325, 65 U.S.P.Q.2d (BNA) 1379 (Fed. Cir. 2003).

269. *Id.* at 1332, 65 U.S.P.Q.2d (BNA) at 1384.

Peterson's application included the claims directed to a nickel-base alloy.²⁷⁰ The claims required about one to three percent rhenium, about fourteen percent chromium, and other specified ranges of specific elements.²⁷¹ The Board affirmed the examiner's rejection of the claims as obvious in view of a prior art reference that disclosed a similar alloy but taught broader ranges.²⁷² The prior art disclosed a preferred alloy containing no rhenium, as opposed to a range of small amounts of rhenium in the Peterson alloy.²⁷³

On appeal, Peterson argued that the prior art taught broad ranges and that the Board failed to appreciate the criticality of, and the unexpected results achieved by, the combination of the claimed range of rhenium with the claimed amount of chromium.²⁷⁴

In affirming the Board's decision, the Federal Circuit made a direct comparison of each component of Peterson's claim and the prior art disclosure, showing that each claimed range lay within a corresponding range disclosed in the prior art.²⁷⁵ The court cited a consistent line of decisions holding that cases involving overlapping ranges, even a slight overlap establishes a *prima facie* case of obviousness.²⁷⁶ The court reasoned that "[s]electing a narrow range from *within* a somewhat broader range disclosed in a prior art reference is no less obvious than identifying a range that simply *overlaps* a disclosed range."²⁷⁷ When prior art completely encompasses the claimed ranges, as was the case here, the conclusion is even stronger that there is a *prima facie* case of obviousness.²⁷⁸

The court also addressed the issue of motivation to select the claimed ranges by noting that "[t]he normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."²⁷⁹

2. *Prima facie obvious and the substantial evidence standard*

In the context of an interference between a patent and an allowed patent application, both directed toward the production of human fibrinogen protein in non-human milk, the Federal Circuit in

270. *Id.* at 1327, 65 U.S.P.Q.2d (BNA) at 1380.

271. *Id.*, 65 U.S.P.Q.2d (BNA) at 1380.

272. *Id.*, 65 U.S.P.Q.2d (BNA) at 1380-81.

273. *Id.*, 65 U.S.P.Q.2d (BNA) at 1380-81.

274. *Id.* at 1328, 65 U.S.P.Q.2d (BNA) at 1381.

275. *Id.* at 1329, 65 U.S.P.Q.2d (BNA) at 1382.

276. *Id.*, 65 U.S.P.Q.2d (BNA) at 1382.

277. *Id.* at 1329-30, 65 U.S.P.Q.2d (BNA) at 1382.

278. *Id.* at 1330, 65 U.S.P.Q.2d (BNA) at 1382-83.

279. *Id.*, 65 U.S.P.Q.2d (BNA) at 1382.

*Velander v. Garner*²⁸⁰ affirmed the decision of the Board that the claims were obvious, as being supported by “substantial evidence.”²⁸¹ Even though a determination of obviousness is a question of law to be decided *de novo*, the Federal Circuit deferred to the underlying factual determinations made by the Board regarding reasonable expectation of success in support of its obviousness determination.²⁸²

Fibrinogen is synthesized by the liver and utilized in the blood to form a clot.²⁸³ The production and isolation of recombinant fibrinogen provides a potentially unlimited source where a deficiency exists.²⁸⁴ The count in interference related to mammals capable of producing “recoverable amounts” of biocompetent human fibrinogen protein in the milk of transgenic non-human mammals carrying heterologous DNA segments encoding each of fibrinogen’s A α , B β and G γ chains and methods of making biocompetent fibrinogen therefrom.²⁸⁵

Garner moved for a finding that Velander’s claims were obvious over a reference disclosing the commercial desirability of producing human serum proteins in non-human milk (published as the “Hennighausen Review”) in view of a reference disclosing methods for the production of heterologous protein in the milk of transgenic mammals (published as the “Meade patent”).²⁸⁶ Velander admitted that the combination of prior art references contained all the limitations in its claims and one of skill in the art would be motivated to combine them.²⁸⁷ Thus, the only issue for the Board to decide was whether one of ordinary skill in the art would glean from the prior art a reasonable expectation of success to make and use the claimed mammal.²⁸⁸

The Board heard from a number of Velander’s expert witnesses who generally opined that a skilled artisan would not have been reasonably expected to succeed.²⁸⁹ However, the Board discounted those expert opinions because they were not corroborated by any published references.²⁹⁰ The Board also discounted other opinions

280. *Velander v. Garner*, 348 F.3d 1359, 68 U.S.P.Q.2d (BNA) 1769 (Fed. Cir. 2003).

281. *Id.* at 1361, 68 U.S.P.Q.2d (BNA) at 1770.

282. *Id.* at 1374, 68 U.S.P.Q.2d (BNA) at 1780.

283. *Id.* at 1361, 68 U.S.P.Q.2d (BNA) at 1770.

284. *Id.*, 68 U.S.P.Q.2d (BNA) at 1770.

285. *Id.* at 1362, 68 U.S.P.Q.2d (BNA) at 1770-71.

286. *Id.* at 1364, 68 U.S.P.Q.2d (BNA) at 1772.

287. *Id.*, 68 U.S.P.Q.2d (BNA) at 1773.

288. *Id.* at 1365, 68 U.S.P.Q.2d (BNA) at 1773.

289. *Id.* at 1366, 68 U.S.P.Q.2d (BNA) at 1774.

290. *Id.* at 1366-68, 68 U.S.P.Q.2d (BNA) at 1774-75.

specifically relating to issues of heterologous protein and hormone purification from, and expression in, milk, as not sufficiently calling into question whether the claimed “recoverable amounts” of fibrinogen could be expressed.²⁹¹ The Board noted that “absolute predictability is not a requirement for obviousness.”²⁹²

On appeal the Federal Circuit dismissed Velander’s argument that the Board had erred by placing the burden on Velander to prove an expectation of failure beyond Garner’s alleged expectation of success.²⁹³ The court determined that the Board was aware of the proper legal standard, but was simply not swayed by Velander’s arguments.²⁹⁴ The court noted that the arguments were either uncorroborated opinions or failed to consider problems relevant to the invention as claimed.²⁹⁵ Rather, the court found that in discounting Velander’s experts, the Board acted as a proper trier of fact, determining the weight and credibility to be given to uncorroborated, conclusory statements.²⁹⁶ The court indicated that under the “substantial evidence” standard, it would not reverse the Board in situations where the evidence supports several reasonable, but contradictory, conclusions.²⁹⁷

In support of its conclusion, the court considered Garner’s citation of several new references not relied on by the Board that went to the issue of whether several proteins with similar structural characteristics had successfully been produced in transgenic milk systems.²⁹⁸ The court relied, at least in part, on these new references in refusing to second guess the Board’s assessment of the evidence.²⁹⁹

In his dissenting opinion, Judge Gajarsa argued that the court’s review of substantial evidence should be limited to the record relied on by the Board.³⁰⁰ Judge Gajarsa asserted that the Board had not taken into account the new references relied on by Garner in the appeal and that without these references, the Board’s opinion was not supported by substantial evidence; the Board’s opinion made unwarranted assumptions with regard to differences between the prior art and the claims at issue as seen by a person of skill in the

291. *Id.*, 68 U.S.P.Q.2d (BNA) at 1774-75.

292. *Id.* at 1368, 68 U.S.P.Q.2d (BNA) at 1776.

293. *Id.* at 1370, 68 U.S.P.Q.2d (BNA) at 1777.

294. *Id.* at 1370-71, 68 U.S.P.Q.2d (BNA) at 1777-78.

295. *Id.* at 1370, 68 U.S.P.Q.2d (BNA) at 1777.

296. *Id.* at 1371, 68 U.S.P.Q.2d (BNA) at 1778.

297. *Id.* at 1374, 68 U.S.P.Q.2d (BNA) at 1780.

298. *Id.* at 1378-79, 68 U.S.P.Q.2d (BNA) at 1783-84.

299. *Id.*, 68 U.S.P.Q.2d (BNA) at 1784.

300. *Id.* at 1380, 68 U.S.P.Q.2d (BNA) at 1785 (Gajarsa, J., dissenting).

art.³⁰¹ By considering such evidence, Judge Gajarsa asserted that the Federal Circuit was simply substituting the grounds for administrative action as those the court would consider to have a more adequate and proper basis.³⁰²

3. *Suggestion or motivation to combine—substantial evidence standard*

The Federal Circuit affirmed the decision by the Board rejecting the appellants' application for "Mutated Recombinant Collagens" as obvious in *In re Berg*.³⁰³ The court applied the substantial evidence standard with some care and gave a high degree of deference in this complicated art to the "persons of scientific competence" at the PTO.³⁰⁴

Collagen is a natural protein found in humans that can be produced as a recombinant protein.³⁰⁵ In order to synthesize collagen, one typically starts with the precursor known as procollagen.³⁰⁶ Procollagen consists of collagen with additional peptide extensions at either end of the collagen chain, the N-terminus or the C-terminus.³⁰⁷ The extensions are then removed by enzymes that cleave, or cut off, the extensions at specific sites to produce collagen that can successfully be used in humans.³⁰⁸ Berg claimed a procollagen chain, which included a non-natural cut-off site between the collagen chain and the natural C-terminal extension, allowing the extension to be removed by using a specific enzyme that reacts with the non-natural site, leaving just the collagen.³⁰⁹

The issue was how broadly the teachings of a prior art suggestion to combine would be read.³¹⁰ The examiner and the Board viewed the prior art reference broadly, as disclosing that two proteins can be fused together for a variety of reasons, and once those proteins are expressed they can be chemically or enzymatically separated at

301. *Id.*, 68 U.S.P.Q.2d (BNA) at 1785 (Gajarsa, J., dissenting).

302. *See id.*, 68 U.S.P.Q.2d (BNA) at 1785 (Gajarsa, J., dissenting) (quoting *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947)) ("If those grounds [relied on by the agency in reviewing an administrative decision] are inadequate or improper, the court is powerless to affirm the administrative action by substituting what it considers to be a more adequate or proper basis").

303. 320 F.3d 1310, 65 U.S.P.Q.2d (BNA) 2003 (Fed. Cir. 2003).

304. *Id.* at 1315, 65 U.S.P.Q.2d (BNA) at 2007.

305. *Id.* at 1312, 65 U.S.P.Q.2d (BNA) at 2004.

306. *Id.*, 65 U.S.P.Q.2d (BNA) at 2004.

307. *Id.*, 65 U.S.P.Q.2d (BNA) at 2004.

308. *Id.* at 1312, 65 U.S.P.Q.2d (BNA) at 2004.

309. *Id.*, 65 U.S.P.Q.2d (BNA) at 2004.

310. *Id.* at 1314, 65 U.S.P.Q.2d (BNA) at 2006.

specific sites on the protein chain.³¹¹ Berg predictably urged a narrower reading.³¹²

The Federal Circuit gave considerable deference to the examiner and the Board, parroting the Board that it would have been

obvious to a person of ordinary skill in the art to create a recombinant DNA system for the production of procollagen in which the recombinant procollagen chain consisted of a natural collagen polypeptide and a first natural propeptide, with a first non-natural site-specific proteolytic agent recognition site located between them.³¹³

4. *Motivation may be found in general knowledge of one of ordinary skill in the art*

In an appeal from a PTO obviousness rejection, the Federal Circuit, in *In re Huston*,³¹⁴ affirmed the Board's rejection finding that a claimed invention of displaying position specific advertising to a golfer on a golf course to be obvious, based in part on the known benefit of global positioning satellite ("GPS") technology.³¹⁵

Huston filed a continuation-in-part application claiming the use of a GPS to display advertising messages to a golfer on a golf course.³¹⁶ The Board affirmed an obviousness rejection based on a GPS reference combined with a prior art, location-specific, golf course information reference.³¹⁷ The Board found that it would have been obvious to use GPS or "differential GPS" for the purpose of sending location-specific advertising to a golfer on the golf course despite the applicant's challenge that there was no motivation to combine the prior art references.³¹⁸

The Federal Circuit agreed with the Board that motivation to combine was found, in part, in the knowledge generally available to one of ordinary skill in the art, i.e., the known improvement in location accuracy of GPS over fixed position radio locating.³¹⁹ Additional motivation was found in the prior art's teaching of the benefit, such as greater accuracy, of "differential GPS" over GPS.³²⁰

311. *Id.* at 1314-15, 65 U.S.P.Q.2d (BNA) at 2006-07.

312. *Id.* at 1314, 65 U.S.P.Q.2d (BNA) at 2006.

313. *Id.* at 1313, 65 U.S.P.Q.2d (BNA) at 2005.

314. 308 F.3d 1267, 64 U.S.P.Q.2d (BNA) 1801 (Fed. Cir. 2002).

315. *Id.* at 1279, 64 U.S.P.Q.2d (BNA) at 1809.

316. *Id.* at 1270, 64 U.S.P.Q.2d (BNA) at 1802.

317. *Id.* at 1274, 64 U.S.P.Q.2d (BNA) at 1805.

318. *Id.* at 1273-74, 64 U.S.P.Q.2d (BNA) at 1804-05.

319. *Id.* at 1281, 64 U.S.P.Q.2d (BNA) at 1810.

320. *Id.* at 1282, 64 U.S.P.Q.2d (BNA) at 1811.

5. *Process not obvious from product*

In *TorPharm, Inc. v. Ranbaxy Pharmaceutical, Inc.*,³²¹ the Federal Circuit reversed and remanded the district court's summary judgment of obviousness, holding that a process claim is not rendered obvious by the lack of novelty of its products, even where the patentee argued during prosecution that the product's novelty justified the non-obviousness of the process.³²²

The patent in suit was directed to a process for producing "improved" Form 1 Ranitidine, which is used to treat ulcers.³²³ The improved Form 1 Ranitidine is denser than prior preparations with desirable filtration and drying characteristics.³²⁴ The patent claims required that the process involve a three- or four-carbon alcohol solvent and that it yield Form 1 Ranitidine in an improved form with specific density characteristics.³²⁵

During prosecution, the patentee added the density characteristics to overcome obviousness rejections over the patents disclosing Form 1 Ranitidine preparations.³²⁶ The patentee also argued that the improved Form 1 was novel.³²⁷ TorPharm owned a separate product patent for the improved product.³²⁸ Following the prosecution of the process patent, TorPharm's product patent was found invalid for prior sale by a company unrelated to TorPharm.³²⁹ There was no evidence that the process of the patent was used to produce the invalidating material.³³⁰

When TorPharm sued Ranbaxy for infringement, Ranbaxy filed a motion for summary judgment arguing that TorPharm should be precluded from claiming non-obviousness because it acquiesced to the examiner's obviousness rejection during prosecution by changing the claims to specify improved Form 1 that TorPharm claimed was novel.³³¹ The district court granted Ranbaxy's motion, stating that the claims of the patent would not have been granted but for the novelty of the product.³³²

321. 336 F.3d 1322, 67 U.S.P.Q.2d (BNA) 1511 (Fed. Cir. 2003).

322. *Id.* at 1324, 67 U.S.P.Q.2d (BNA) at 1512.

323. *Id.*, 67 U.S.P.Q.2d (BNA) at 1512.

324. *Id.*, 67 U.S.P.Q.2d (BNA) at 1512.

325. *Id.*, 67 U.S.P.Q.2d (BNA) at 1512.

326. *Id.* at 1325, 67 U.S.P.Q.2d (BNA) at 1512-13.

327. *Id.*, 67 U.S.P.Q.2d (BNA) at 1513.

328. *Id.*, 67 U.S.P.Q.2d (BNA) at 1513.

329. *Id.*, 67 U.S.P.Q.2d (BNA) at 1513.

330. *Id.*, 67 U.S.P.Q.2d (BNA) at 1513.

331. *Id.*, 67 U.S.P.Q.2d (BNA) at 1513.

332. *Id.* at 1326, 67 U.S.P.Q.2d (BNA) at 1513-14.

In reversing, the Federal Circuit held that while a process for a novel product is itself novel, the contrapositive is not necessarily true, because even if a product is not novel that does not mean that the process that produced it is not novel.³³³

As for the assertion that the process patent would not have been issued but for the novelty of the product, the court refused to speculate as to what an examiner would have done in light of the new information.³³⁴

As to acquiescence, the court noted that whether a patentee chose to dispute the examiner's view of matters is relevant to claim interpretation, not future litigation.³³⁵ While a patentee's acquiescence to an examiner's narrow view of a claim's meaning narrows that meaning, a patentee's decision to forgo a particular validity argument during prosecution does not preclude use of that argument in later litigation.³³⁶

6. *Secondary consideration of success discounted in the face of "massive marketing"*

In *McNeil-PPC, Inc. v. L. Perrigo Co.*³³⁷ the Federal Circuit discounted alleged secondary considerations of non-obviousness³³⁸ and affirmed a district court's holding that subsequent patent claims aimed at extending the period of exclusivity for a best selling, brand name drug are obvious over prior art, but reversed the lower court's finding that the accused infringer was entitled to an award of attorney's fees.³³⁹

Faced with the expiration of its patent covering the best-selling antidiarrheal drug Imodium® A-D, McNeil filed two sets of patent applications aimed at extending its market leader position.³⁴⁰ The first set of patents, the "Garwin patents," were subsequently issued with composition and method claims directed to an allegedly synergistic combination of the original Imodium® A-D's active ingredient, antidiarrheal loperamide, with a second active ingredient, simethicone.³⁴¹ A second set of patents, "the Stevens patents," were issued covering methods and tablets having a polymeric barrier between the two active ingredients, based on the discovery that a

333. *Id.* at 1327, 67 U.S.P.Q.2d (BNA) at 1514.

334. *Id.* at 1329-30, 67 U.S.P.Q.2d (BNA) at 1516.

335. *Id.* at 1330, 67 U.S.P.Q.2d (BNA) at 1517.

336. *Id.*, 67 U.S.P.Q.2d (BNA) at 1517.

337. 337 F.3d 1362, 67 U.S.P.Q.2d (BNA) 1649 (Fed. Cir. 2003).

338. *Id.* at 1370, 67 U.S.P.Q.2d (BNA) at 1654.

339. *Id.* at 1373, 67 U.S.P.Q.2d (BNA) at 1656.

340. *Id.*, 67 U.S.P.Q.2d (BNA) at 1650.

341. *Id.*, 67 U.S.P.Q.2d (BNA) at 1650.

decrease in biavailability results if simethicone directly contacts loperamide.³⁴²

McNeil sued the generic drug maker, Perrigo, for infringement of the Garwin and Stevens patents.³⁴³ The district court held that the patents in suit were invalid as obvious³⁴⁴ and awarded Perrigo attorney's fees, finding exceptional conduct based on "McNeil's repeated erroneous representations, failure to disclose relevant prior art, and overall persistence in prosecuting exceedingly obvious 'inventions.'"³⁴⁵

The Federal Circuit agreed that patent claims directed to combinations of loperamide and simethicone were rendered obvious by the prior art, which disclosed the use of various antidiarrheal compounds and simethicone.³⁴⁶ The court discounted the alleged secondary indicia of non-obviousness, indicating that massive marketing and advertising obscured evidence of commercial success, while finding evidence of unexpected results statistically insignificant and inconsistent.³⁴⁷

The patents directed to a polymeric barrier to separate the two active ingredients were also held invalid as obvious.³⁴⁸ Here, the Federal Circuit pointed to the Garwin patents, which disclosed the separation of loperamide and simethicone into different layers of a tablet, viewed in light of a prior patent disclosing separation of simethicone from other ingredients in combination products through use of a polymeric barrier.³⁴⁹ The Federal Circuit discounted McNeil's contention that the prior art patents did not identify the problem of loperamide's short shelf life in combination tablets with simethicone, and found sufficient motivation to combine in the teaching of an impermeable barrier to prevent simethicone migration to an adjacent pharmaceutical-containing layer.³⁵⁰

However, the Federal Circuit reversed the award of attorney fees, noting that short of inequitable conduct or litigation misconduct, McNeil was entitled to file patent applications on what it considered

342. *Id.* at 1365, 67 U.S.P.Q.2d (BNA) at 1650.

343. *Id.*, 67 U.S.P.Q.2d (BNA) at 1651.

344. *Id.* at 1365-67, 67 U.S.P.Q.2d (BNA) at 1652.

345. *Id.* at 1367, 67 U.S.P.Q.2d (BNA) at 1652 (quoting *McNeil-PPC, Inc. v. L. Perrigo Co.*, 207 F. Supp. 2d 356, 374, 63 U.S.P.Q.2d (BNA) 1493 (Fed. Cir. 2002)).

346. *Id.* at 1369-70, 67 U.S.P.Q.2d (BNA) at 1654.

347. *Id.* at 1370, 67 U.S.P.Q.2d (BNA) at 1654.

348. *Id.* at 1370-71, 67 U.S.P.Q.2d (BNA) at 1654-55.

349. *Id.*, 67 U.S.P.Q.2d (BNA) at 1654-55.

350. *Id.* at 1370-71, 67 U.S.P.Q.2d (BNA) at 1654-55.

patentable inventions, regardless of the motive to extend protection on an expiring patent.³⁵¹

F. *Section 112 Written Description*

1. *Possible en banc review of Lilly rule*

Heralding a possible *en banc* consideration of the written description rule from the 1997 *Regents of the University of California v. Eli Lilly & Co.*³⁵² (“*Eli Lilly*” or “*Lilly*”), and further eroding that rule, the Federal Circuit in *Moba B.V. v. Diamond Automation, Inc.* affirmed denial of a motion for judgment as a matter of law (“JMOL”) of a jury verdict of validity in a case where claims to an egg sorting machine were construed to cover a conveyor design that was not illustrated or described in the written description of the patent in suit.³⁵³

The patent in suit is directed to an egg sorter.³⁵⁴ Food Processing System, Inc. (“FPS”) contended that if the conveyor element of the patent claims was construed to encompass lifting eggs from a moving conveyor, the claims would be invalid as no such conveyor mechanism is disclosed in the patent.³⁵⁵ Two prior Federal Circuit decisions were distinguished in this case: *Gentry Gallery, Inc. v. Berklene Corp.*³⁵⁶ and *Eli Lilly*.³⁵⁷

As explained by the court, in *Eli Lilly* “this court invoked the written description requirement in a case without priority issues” to require “a precise definition of a DNA sequence in the patent specification.”³⁵⁸ This has become known as the *Lilly* rule.

Here, in a *per curiam* panel decision, the Federal Circuit found that there was “substantial evidence” to support a jury verdict that the patent in suit was “not invalid for lack of an adequate written description,” dismissing FPS’ contention that the patent in suit did not adequately disclose a mechanism for lifting eggs from a moving conveyor as an attempt to “merely revive[] its non-infringement argument in the cloak of a validity challenge.”³⁵⁹ Without directly distinguishing the 1997 *Lilly* decision, the court, citing to its 2002

351. *Id.* at 1373, 67 U.S.P.Q.2d (BNA) at 1656.

352. 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997).

353. *Moba B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1317, 66 U.S.P.Q.2d (BNA) 1429, 1436 (Fed. Cir. 2003).

354. *Id.* at 1309, 66 U.S.P.Q.2d (BNA) at 1431.

355. *Id.* at 1319, 66 U.S.P.Q.2d (BNA) at 1437.

356. 134 F.3d 1473, 45 U.S.P.Q.2d (BNA) 1498 (Fed. Cir. 1988).

357. *Eli Lilly*, 119 F.3d 1559, 43 U.S.P.Q.2d (BNA) 1398.

358. *Moba B.V.*, 325 F.3d at 1320, 66 U.S.P.Q.2d (BNA) at 1438.

359. *Id.* at 1321, 66 U.S.P.Q.2d (BNA) at 1439.

decision in *Enzo Biochem, Inc. v. Gen-Probe, Inc.*,³⁶⁰ simply noted that “[i]n more recent cases . . . this court has distinguished *Lilly*.”³⁶¹

In a concurring opinion, Judge Radar took on the *Lilly* rule directly, characterizing it as a precedent-defying, statute-distorting mistake³⁶² and arguing that it turned a “routine claim construction argument [into] a validity challenge under [a] non-statutory doctrine.”³⁶³ Judge Radar urged “*en banc* correction” of the *Lilly* rule.³⁶⁴ Judge Bryson, who was a member of the panel that decided the *Lilly* case, also wrote a concurring opinion.³⁶⁵ Judge Bryson traced the *Lilly* rule back to the Court of Customs and Patent Appeals (“CCPA”) decision in *In re Ruschig*,³⁶⁶ in which CCPA found the written description and enablement requirements to be separate requirements of § 112, ¶ 1.³⁶⁷ In Judge Bryson’s opinion, if *Ruschig* is correct, “it is difficult to find a principled basis for restricting that requirement to cases involving priority disputes” as urged by Judge Radar.³⁶⁸ Thus, in Judge Bryson’s view, *en banc* review may be appropriate for the “entire line of cases stemming from *Ruschig*.”³⁶⁹

2. *Written description process does not satisfy written description for product of process*

In the context of a priority dispute or interference, the Federal Circuit in *Chen v. Bouchard*³⁷⁰ held that even though a product is inherently produced by a disclosed process, the written description requirement for claims directed to the product is not satisfied when one of skill in the art, reading the application, would not have been aware that the product is produced.³⁷¹

Chen’s 1992 patent application disclosed a process to produce taxol derivatives and precursors of taxol.³⁷² The disclosed method did not explicitly state that cyclopropataxols were produced as required by the interference count.³⁷³ Chen argued that cyclopropataxols were

360. 323 F.3d 956, 63 U.S.P.Q.2d (BNA) 1609 (Fed. Cir. 2002).

361. *Moba B.V.*, 325 F.3d at 1320, 66 U.S.P.Q.2d (BNA) at 1438.

362. *Id.* at 1326-27, 66 U.S.P.Q.2d (BNA) at 1443 (Radar, J., concurring).

363. *Id.* at 1323, 66 U.S.P.Q.2d (BNA) at 1440 (Radar, J., concurring).

364. *Id.* at 1327, 66 U.S.P.Q.2d (BNA) at 1443 (Radar, J., concurring).

365. *Id.*, 66 U.S.P.Q.2d (BNA) at 1443.

366. 379 F.2d 990, 154 U.S.P.Q. (BNA) 118 (C.C.P.A. 1967).

367. *Moba B.V.*, 325 F.3d at 1327, 66 U.S.P.Q.2d (BNA) at 1444 (Bryson, J., concurring).

368. *Id.*, 66 U.S.P.Q.2d (BNA) at 1444 (Bryson, J., concurring).

369. *Id.* at 1328, 66 U.S.P.Q.2d (BNA) at 1444 (Bryson, J., concurring).

370. 347 F.3d 1299, 68 U.S.P.Q.2d (BNA) 1705 (Fed. Cir. 2003).

371. *Id.* at 1307, 68 U.S.P.Q.2d (BNA) at 1710-11.

372. *Id.* at 1301, 68 U.S.P.Q.2d (BNA) at 1706.

373. *Id.* at 1307, 68 U.S.P.Q.2d (BNA) at 1710.

inherently described since the process described in examples will “invariably” result in those compounds.³⁷⁴

The Federal Circuit concluded that Chen was not entitled to the benefit of his earlier applications.³⁷⁵ The Federal Circuit noted that there was no explicit description of the claimed product in the 1992 patent application and, as the patent did accurately describe another product, fluorotaxol derivatives, made by the process, there was no error in the disclosure.³⁷⁶ The court noted that the 1992 patent application did not describe any physical characteristics of the claimed product and that there was no evidence that a person of ordinary skill in the art would have recognized that the product of the count would have been produced from the disclosed process.³⁷⁷

G. Section 112 Enactment—Enablement in Biotechnology

In two biotech cases decided early in 2003, the Federal Circuit discussed the written description and enablement requirements of § 112. The court upheld a district court’s finding that a written description of a particular embodiment was sufficient to support broad patent claims to a pharmaceutical composition.³⁷⁸

In the first case, *Amgen Inc. v. Hoechst Marion Roussel, Inc.*,³⁷⁹ the Federal Circuit relied upon the plain meaning of the claim terms at issue to determine the scope of the claim.³⁸⁰ The court found that the claim limitation “erythropoietin glycoprotein” should not be construed as also requiring “exogenous DNA sequences” based upon the plain language of the claims and the presence of that very limitation in other claims of the patent.³⁸¹ The court so held despite statements in the specification that the invention is “uniquely characterized by being the product of . . . exogenous DNA sequences . . .”³⁸² and despite statements by the examiner that a related patent “teaches and enables only cells transformed with exogenous DNA.”³⁸³ The Federal Circuit distinguished the examiner’s statement because it was based upon then-pending claims,

374. *Id.* at 1305, 68 U.S.P.Q.2d (BNA) at 1709.

375. *Id.* at 1312, 68 U.S.P.Q.2d (BNA) at 1714.

376. *Id.* at 1305, 68 U.S.P.Q.2d (BNA) at 1709.

377. *Id.* at 1307, 68 U.S.P.Q.2d (BNA) at 1710.

378. *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1334, 65 U.S.P.Q.2d 1385, 1399-1400 (Fed. Cir. 2003). *See also* *Plant Genetic Sys., N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335, 65 U.S.P.Q.2d (BNA) 1452 (Fed. Cir. 2003).

379. 314 F.3d 1313, 65 U.S.P.Q.2d (BNA) 1385 (Fed. Cir. 2003).

380. *Id.* at 1326, 65 U.S.P.Q.2d (BNA) at 1393.

381. *Id.* at 1325, 65 U.S.P.Q.2d (BNA) at 1393.

382. *Id.*, 65 U.S.P.Q.2d (BNA) at 1393.

383. *Id.* at 1325-26, 65 U.S.P.Q.2d (BNA) at 1393-94.

which also required high production levels of the erythropoietin (“EPO”).³⁸⁴

The Amgen patent related to the production of erythropoietin, an endogenous hormone that regulates red blood cell formation.³⁸⁵ In part, Hoechst argued the patent specification failed to satisfy the written description requirement in the support of a claim to a “pharmaceutical composition . . . of erythropoietin . . . purified from mammalian cells grown in culture”³⁸⁶ because the patent failed to sufficiently describe “all vertebrate and mammalian cells as engineered in the claimed invention.”³⁸⁷ The Federal Circuit upheld the district court’s finding of validity stating “the descriptions adequately described to those of ordinary skill in the art in 1984 the use of the broad class of available mammalian and vertebrate cells to produce the claimed high levels of human EPO in culture.”³⁸⁸

The Federal Circuit distinguished its *Regents of the University of California v. Eli Lilly and Co.*³⁸⁹ and *Enzo Biochem, Inc. v. Gen-Probe Inc.*³⁹⁰ discussions regarding the written description of claims encompassing genetic material.³⁹¹ In *Eli Lilly*, claims to a human cDNA sequence of an insulin gene were held invalid where only the insulin gene of a rat complementary deoxyribonucleic acid (“cDNA”) sequence was disclosed.³⁹² In *Enzo Biochem*, the court clarified that the written description requirement may be satisfied where one of skill in the art would have knowledge that a functional description of genetic material is correlated to a particular, known structure.³⁹³ In *Amgen*, the court found that “the claim terms at issue here are not directed to new or unknown biologic materials that ordinarily skilled artisans would easily miscomprehend.”³⁹⁴ Rather, the claims simply recite “types of cells that can be used to produce recombinant human EPO.”³⁹⁵ Therefore, according to the majority of the panel, while Hoechst might have been justified in challenging the “adequacy of disclosure of the vertebrate or mammalian host cell,” the court found

384. *Id.* at 1326-27, 65 U.S.P.Q.2d (BNA) at 1394.

385. *Id.* at 1335, 65 U.S.P.Q.2d (BNA) at 1398.

386. *Id.* at 1347, 65 U.S.P.Q.2d (BNA) at 1410.

387. *Id.* at 1332, 65 U.S.P.Q.2d (BNA) at 1398.

388. *Id.* at 1331, 65 U.S.P.Q.2d (BNA) at 1397.

389. 119 F.3d 1559, 43 U.S.P.Q.2d (BNA) 1398 (Fed. Cir. 1997).

390. 323 F.3d 956, 63 U.S.P.Q.2d (BNA) 1609 (Fed. Cir. 2002).

391. *Amgen*, 314 F.3d at 1332, 65 U.S.P.Q.2d (BNA) at 1398.

392. *Eli Lilly*, 119 F.3d at 1566-67, 43 U.S.P.Q.2d (BNA) at 1406.

393. *Enzo Biochem*, 323 F.3d at 964, 63 U.S.P.Q.2d (BNA) at 1613.

394. *Amgen*, 314 F.3d at 1332, 65 U.S.P.Q.2d (BNA) at 1398.

395. *Id.*, 65 U.S.P.Q.2d (BNA) at 1398.

it was not warranted in challenging the adequacy of the disclosure of the “human DNA itself.”³⁹⁶

Hoechst also challenged the district court’s finding that a skilled artisan could have used various cultured vertebrate and mammalian cells to produce EPO.³⁹⁷ Here, the district court credited Amgen’s witnesses stating “any challenge which one of ordinary skill in 1984 may have encountered in attempting to make and use the claimed invention using other cultured mammalian cells could be resolved by experimentation falling short of undue.”³⁹⁸

There was a vigorous dissent on this point.³⁹⁹ Judge Clevenger, citing precedent, including *Eli Lilly*, called into question the written description, stating that “disclosure of a species may not suffice to describe a genus”⁴⁰⁰ and citing *In re Mayhew*⁴⁰¹ to assert that “claims failing to recite a necessary element of the invention fail for lack of an enabling disclosure.”⁴⁰² Judge Clevenger called into question the enablement by stating that “[a]t the very least, the absence of structural limitations in the patent [claims] raises questions of its enablement”⁴⁰³

In the second case, *Plant Genetic Systems, NV v. DeKalb Genetics Corp.*,⁴⁰⁴ much to the patentee’s chagrin, the Federal Circuit did not apply such deference to the predictability of cell transformations in the plant kingdom.⁴⁰⁵ In this case, the Federal Circuit affirmed the district court’s holding that the asserted patent claims were invalid for lack of enablement.⁴⁰⁶

Plant Genetic Systems, now known as Aventis, had claims that were drawn to genetically engineered, herbicide-resistant plant cells, which Aventis contended applied broadly to dicot and monocot plants.⁴⁰⁷ The Federal Circuit concluded that the full scope of the invention, as claimed by Aventis, was not enabled.⁴⁰⁸ While the specification disclosed transformation of dicots, the court affirmed the district

396. *Id.*, 65 U.S.P.Q.2d (BNA) at 1398.

397. *Id.* at 1334, 65 U.S.P.Q.2d (BNA) at 1400.

398. *Id.* at 1337, 65 U.S.P.Q.2d (BNA) at 1402.

399. *Id.* at 1358, 65 U.S.P.Q.2d (BNA) at 1419 (Clevenger, J., dissenting).

400. *Amgen*, 314 F.3d at 1361, 65 U.S.P.Q.2d (BNA) at 1421 (Clevenger, J., dissenting) (citing *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d (BNA) 1398, 1405-06 (Fed. Cir. 1997)).

401. 527 F.2d 1229, 1233, 188 U.S.P.Q. (BNA) 356 (C.C.P.A. 1976).

402. *Amgen*, 314 F.3d at 1360, 65 U.S.P.Q.2d (BNA) at 1420 (citing *In re Mayhew*, 527 F.2d 1229, 1233, 188 U.S.P.Q. (BNA) 356, 358 (C.C.P.A. 1976)).

403. *Id.*, 65 U.S.P.Q.2d (BNA) at 1421.

404. 315 F.3d 1335, 65 U.S.P.Q.2d (BNA) 1452 (Fed. Cir. 2003).

405. *Id.* at 1345-46, 65 U.S.P.Q.2d (BNA) at 1460-61.

406. *Id.*, 65 U.S.P.Q.2d (BNA) at 1461.

407. *Id.* at 1337-38, 65 U.S.P.Q.2d (BNA) at 1454.

408. *Id.* at 1344, 65 U.S.P.Q.2d (BNA) at 1459.

court decision which had stated that DeKalb proved by clear and convincing evidence that “practicing stable gene transformation for monocots cells [at the time of patent filing] in 1987 required undue experimentation.”⁴⁰⁹ Based on *In re Hogan*⁴¹⁰ the court held that if “an inventor [claims] what was specifically desired but difficult to obtain at the time the application was filed,” the claims were enabled only “[if] the patent discloses how to make and use it.”⁴¹¹ While transformed monocots were desired, as of the filing date “stably transformed monocot cells were difficult to produce and the [patent] gave no instruction how.”⁴¹² Further, the court found that the district court properly used a post-filing date report, indicating the first transformation of corn cells, to support its holding.⁴¹³

The court also rejected Aventis’ argument that the district court erred in not making a finding regarding the pioneering nature of the invention.⁴¹⁴ The court explained that “pioneer inventions” are not deserving of a lower standard of enablement and that any statement in *Hogan* to the contrary was *dicta*.⁴¹⁵

H. Section 112 Indefiniteness

1. What does “a” mean?

Unwilling to permit the word “a” to be construed to mean “and,” the Federal Circuit held that unless a certification of correction has been issued by the PTO under §§ 254 or 255, a district court may only correct an error in a patent if the correction is not subject to reasonable debate and if the prosecution history does not suggest a different interpretation.⁴¹⁶

Novo Industries sued Micro Molds for infringement of its patent on a carrier assembly for window blinds that permits realignment of misaligned slats.⁴¹⁷ The claim at issue reads, in part, “stop means formed on *a rotatable with* said support finger and extending outwardly there from into engaging relation with one or two spaced

409. *Id.* at 1338, 65 U.S.P.Q.2d (BNA) at 1554 (citing *Plant Genetic Systems N.V. v. DeKalb Genetics Corp.*, 175 F. Supp. 2d 246, 265 (D. Conn. 2001)).

410. *See* 559 F.2d 595, 605, 194 U.S.P.Q. (BNA) 527, 537 (C.C.P.A. 1977) (finding that enablement is determined as of the effective filing date of the patent).

411. *Plant Genetic Sys.*, 315 F.3d at 1340, 65 U.S.P.Q.2d (BNA) at 1456.

412. *Id.*, 65 U.S.P.Q.2d (BNA) at 1456.

413. *Id.* at 1343-44, 65 U.S.P.Q.2d (BNA) at 1459.

414. *Id.* at 1341, 65 U.S.P.Q.2d (BNA) at 1456-57.

415. *Id.*, 65 U.S.P.Q.2d (BNA) at 1457.

416. *Novo Indus. Inc. v. Micro Molds Corp.*, 350 F.3d 1348, 1353, 69 U.S.P.Q.2d (BNA) 1128, 1131 (Fed. Cir. 2003).

417. *Id.* at 1350-52, 69 U.S.P.Q.2d (BNA) at 1129-31.

apart stop members formed on said frame.”⁴¹⁸ The words “a rotatable with” did not appear in the original application.⁴¹⁹ Novo argued that the claim contained an obvious typographical error that could be corrected.⁴²⁰

Micro Molds argued that the “addition of the words ‘rotatable with’ indicated that the applicant had abandoned coverage of a stop means on the support finger itself and, therefore, the claim could not be construed to include a stop means on the support finger.”⁴²¹ Rather, according to Micro Molds, the stop means had to be located on a separate “rotatable.”⁴²² “Because the ‘rotatable’ is not identified, Micro Molds argued, the claim is invalid for indefiniteness.”⁴²³

The district court instructed the jury that “[t]he claim language includes an obvious typographical error, ‘a’ should be read as—and—.”⁴²⁴ With that construction the district court did not reach the indefiniteness issue, and the jury found that Micro Molds had literally infringed the patent.⁴²⁵

The Federal Circuit observed that Novo never sought nor obtained a certificate of correction from the PTO pursuant to 35 U.S.C. § 255 and formulated the issue as whether a district court can correct an error in a patent by interpretation, where no certificate of correction has been sought nor obtained.⁴²⁶

Noting that nothing in the enactment of §§ 254 and 255 suggests that Congress intended to deny limited correction authority to the district courts, the court reasoned that “for causes of action that arise before the correction becomes effective, the patent must be considered without the benefit of correction.”⁴²⁷

The court stressed that the district courts do not have the authority to correct “any and all errors that the PTO is authorized to correct under §§ 254 and 255.”⁴²⁸ If the district courts were allowed to correct those errors that are correctable under §§ 254 and 255, “[t]he

418. *Id.* at 1352, 69 U.S.P.Q.2d (BNA) at 1130 (emphasis added) (reciting section “g” of the list).

419. *Id.*, 69 U.S.P.Q.2d (BNA) at 1130-31.

420. *Id.*, 69 U.S.P.Q.2d (BNA) at 1131.

421. *Id.*, 69 U.S.P.Q.2d (BNA) at 1131.

422. *Id.*, 69 U.S.P.Q.2d (BNA) at 1131.

423. *Id.*, 69 U.S.P.Q.2d (BNA) at 1131.

424. *Id.* at 1353, 69 U.S.P.Q.2d (BNA) at 1131.

425. *See id.*, 69 U.S.P.Q.2d (BNA) at 1131 (finding by the jury that the defendant was guilty of “willful infringement”).

426. *Id.* at 1355-56, 69 U.S.P.Q.2d (BNA) at 1133-34.

427. *Id.* at 1356, 69 U.S.P.Q.2d (BNA) at 1133 (citing *Southwest Software, Inc. v. Harlequin Inc.*, 226 F.3d 1280, 1297, 56 U.S.P.Q.2d (BNA) 1161, 1171 (Fed. Cir. 2000)).

428. *Id.*, 69 U.S.P.Q.2d (BNA) at 1134.

district court always would apply its own corrections retroactively in the action before it, unlike the certificates of correction issued by the PTO, which apply retroactively only in actions brought after the certificate of correction is issued.”⁴²⁹ The court concluded that the district court can only correct two types of errors, “(1) [where] the correction is not subject to reasonable debate based on consideration of the claim language and the specification, and (2) the prosecution history does not suggest a different interpretation of the claims.”⁴³⁰

Applying that rule to the present case, the court noted that not only did Novo itself suggest two different corrections: (1) deletion of “a rotatable with” and (2) deletion of “with said;” but the district court, by changing “a” to “and,” raised a third possibility.⁴³¹ Recognizing this, the Federal Circuit noted that “since we cannot know what correction is necessarily appropriate or how the claim should be interpreted, we must hold [the] claim . . . of . . . [the] patent invalid for indefiniteness in its present form.”⁴³²

2. “Vivid color”

In a case involving metallic, vivid color sunglass lenses, the Federal Circuit in *Oakley, Inc. v. Sunglass Hut International*,⁴³³ analyzed each of the factors involved in the grant of a preliminary injunction: irreparable harm, balance of hardship, public interest, and likelihood of success on the merits.⁴³⁴

Predictably, the major issue on appeal was likelihood of success on the merits. Here the Federal Circuit considered and rejected each of defendant Sunglass Hut’s invalidity defenses, finally agreeing with the district court that none raised a substantial question of invalidity.⁴³⁵

Two interesting aspects of this case are that the preliminary injunction was sustained even though the Federal Circuit arrived at a slightly different claim construction than the district court and that the issue of claim indefiniteness under § 112, ¶ 2 focused on the claim term “vivid colored appearance,” which the Federal Circuit opined must be construed as it would be by one of skill in the art and in light of the specification.⁴³⁶ In doing so, the Federal Circuit used the

429. *Id.* at 1357, 69 U.S.P.Q.2d (BNA) at 1134 (citing *Southwest Software*, 226 F.3d at 1297, 56 U.S.P.Q.2d (BNA) at 1171).

430. *Id.* at 1357, 69 U.S.P.Q.2d (BNA) at 1134 (referring to these as “Essex type errors” from *I.T.S. v. Essex Rubber Co.*, 272 U.S. 429 (1926)).

431. *Id.*, 69 U.S.P.Q.2d (BNA) at 1134.

432. *Id.* at 1358, 69 U.S.P.Q.2d (BNA) at 1135.

433. 316 F.3d 1331, 65 U.S.P.Q.2d (BNA) 1321 (Fed. Cir. 2003).

434. *Id.* at 1338-39, 65 U.S.P.Q.2d (BNA) at 1324-25.

435. *Id.* at 1340-42, 65 U.S.P.Q.2d (BNA) at 1326-27.

436. *Id.* at 1340-41, 65 U.S.P.Q.2d (BNA) at 1326.

associated concept of “differential effect” and the numerical examples and ranges from the specification to decide when a differential effect qualifies as “vivid.”⁴³⁷

3. *Claim term which signifies a condition dependant, variable value is definite*

In a heavily fact dependent case, the Federal Circuit, in *BJ Services Co. v. Halliburton Energy Services, Inc.*,⁴³⁸ turned back a determined written description and claim indefiniteness assault by Halliburton.⁴³⁹

In the underlying action, BJ Services sued Halliburton for infringing claims of a patent directed to a method of fracturing subterranean formations to stimulate oil and gas wells.⁴⁴⁰ Halliburton argued that the patent was invalid for, *inter alia*, lack of adequate written description and lack of enablement.⁴⁴¹ At trial, the jury rejected these arguments, found Halliburton to have infringed, and awarded damages of \$98.1 million.⁴⁴²

On appeal, Halliburton argued that the patent specification was not enabling as it failed to quantify or state how to obtain a particular value recited in the claims, the so-called C* value,⁴⁴³ defined in the patent as the “concentration necessary to cause polymer chain overlap.”⁴⁴⁴ At trial, “Halliburton merely showed that the value of C* could vary depending upon the chosen conditions; it did not call its expert to testify about the measurement conditions one of skill in the art would employ.”⁴⁴⁵ According to the Federal Circuit, this showing was insufficient to undercut the jury’s finding of enablement.⁴⁴⁶ As to Halliburton’s contention that the claim limitation “about 0.06” was not sufficiently definite, the court held that substantial evidence supported the jury’s conclusion that one of ordinary skill in the art would understand what is claimed when the claim is read in argument that the term “about” is intended to encompass the range of experimental error that occurs in any measurement and that one of skill in the art would readily understand the range that “about 0.06” was intended to include.

437. *Id.* at 1341-42, 65 U.S.P.Q.2d (BNA) at 1326-27.

438. 338 F.3d 1368, 67 U.S.P.Q.2d (BNA) 1692 (Fed. Cir. 2003).

439. *Id.* at 1370-71, 67 U.S.P.Q.2d (BNA) at 1693-94.

440. *Id.* at 1370, 67 U.S.P.Q.2d (BNA) at 1693.

441. *Id.* at 1371, 67 U.S.P.Q.2d (BNA) at 1694.

442. *Id.*, 67 U.S.P.Q.2d (BNA) at 1694.

443. *Id.*, 67 U.S.P.Q.2d (BNA) at 1694.

444. *Id.* at 1370-71, 67 U.S.P.Q.2d (BNA) at 1693-94.

445. *Id.* at 1372, 67 U.S.P.Q.2d (BNA) at 1695.

446. *Id.* at 1373-74, 67 U.S.P.Q.2d (BNA) at 1696.

Halliburton also argued that the patent in suit was invalid for failing to name the proper inventors, specifically the person who allegedly invented the CMG polymer used in practicing the claimed invention. The court held that Halliburton had failed to prove by clear and convincing evidence that the omitted “inventor” had conceived any of the claimed invention, which involved a method of fracturing a subterranean formation (and not the polymer itself). The patentee presented evidence at trial that the omitted “inventor” had no knowledge of the method, how the polymer would be used, or the C* value.

4. *How much disclosure of “corresponding structure” is needed to avoid rendering a means-plus-function claim element indefinite?*

In *Intel Corp. v. VIA Technologies, Inc.*,⁴⁴⁷ a case exploring how much corresponding structure must be disclosed to prevent a means-plus-function claim element from being subject to § 112, ¶ 2 invalidity,⁴⁴⁸ the Federal Circuit predictably set an objective standard based on the knowledge of one of skill in the art.⁴⁴⁹

The Federal Circuit agreed with the district court that the claims at issue were not invalid for indefiniteness for failure to disclose adequate structure corresponding to the function recited in a means-plus-function claim element.⁴⁵⁰ The Federal Circuit posed the test as whether VIA had proven, “by clear and convincing evidence, that the specification lacks adequate disclosure of structure, to be understood by one of skill in the art as able to perform the recited functions.”⁴⁵¹ Answering in the negative, the Federal Circuit held that the patent “is not indefinite merely because no specific circuitry is disclosed” to show how the core logic is modified to perform the recited Fast Write function.⁴⁵² The court reasoned that “[h]ow to modify the core logic to perform Fast Write on the circuitry level may . . . be properly left to the knowledge of those skilled in the art, and need not be specified in the patent.”⁴⁵³

The Federal Circuit noted that the specification of the patent included three diagrams, “35 signal charts and a detailed written description explaining the invention . . . [and a] generic description of the core logic, as adapted to practice Fast Write pursuant to the

447. 319 F.3d 1357, 65 U.S.P.Q.2d (BNA) 1934 (Fed. Cir. 2003).

448. *Id.* at 1359, 67 U.S.P.Q.2d (BNA) at 1935.

449. *Id.* at 1365-66, 65 U.S.P.Q.2d (BNA) at 1940.

450. *Id.*, 65 U.S.P.Q.2d (BNA) at 1940.

451. *Id.* at 1366, 65 U.S.P.Q.2d (BNA) at 1940.

452. *Id.*, 65 U.S.P.Q.2d (BNA) at 1941.

453. *Id.* at 1366-67, 65 U.S.P.Q.2d (BNA) at 1941.

specification.”⁴⁵⁴ Thus, the court found sufficient corresponding structure notwithstanding the absence of circuitry.⁴⁵⁵

Finally, the Federal Circuit rejected VIA’s argument that absent a disclosure of structure regarding circuitry, the scope of what constitutes corresponding disclosed structure plus equivalents is indefinite, making it impossible for competitors to design around the patent.⁴⁵⁶ The Federal Circuit held that even if there are multiple ways to implement the claimed function in circuitry, the claim was not invalid simply because the universe of such implementations is undefined.⁴⁵⁷ Rather, the court noted that the “novelty of the invention . . . lies in the signal protocol for implementing Fast Write . . . not in unclaimed circuitry for carrying out the specified protocol.”⁴⁵⁸ “Thus, one may design around the invention by using another signal protocol.”⁴⁵⁹

I. Reexamination—Substantially New Questions of Patentability

In a case of historical more than prospective interest, the Federal Circuit in *In re Bass* considered the application of an amended reexamination statute to a prior reexamination proceeding and affirmed a rejection by the Board.⁴⁶⁰ The court clarified that only prior art from a prior completed reexamination proceeding completed before the November 2, 2002 amendment to the reexamination statute⁴⁶¹ is prohibited from being relied upon to establish a “substantial new question of patentability” in the subsequent reexamination proceeding.⁴⁶²

The decision in *Bass* comes on the heels of amendments to the reexamination statute,⁴⁶³ which effectively overruled *In re Portola Packaging*⁴⁶⁴ for any reexamination declared after November 2, 2002, by codifying that “a substantial new question of patentability is not precluded by the fact that a patent or printed publication was

454. *Id.* at 1366, 65 U.S.P.Q.2d (BNA) at 1941.

455. *Id.*, 65 U.S.P.Q.2d (BNA) at 1941.

456. *Id.* at 1367, 65 U.S.P.Q.2d (BNA) at 1941.

457. *Id.*, 65 U.S.P.Q.2d (BNA) at 1941.

458. *Id.*, 65 U.S.P.Q.2d (BNA) at 1941.

459. *Id.*, 65 U.S.P.Q.2d (BNA) at 1941.

460. *In re Bass*, 314 F.3d 575, 65 U.S.P.Q.2d (BNA) 1156 (Fed. Cir. 2003).

461. 35 U.S.C. § 302.

462. *In re Bass*, 314 F.3d at 577, 65 U.S.P.Q.2d (BNA) at 1157 (citing *In re Borkowski*, 505 F.2d 713, 718, 184 U.S.P.Q. (BNA) 29, 32-33 (C.C.P.A. 1974) for the proposition that reexamination must be completed).

463. 35 U.S.C. § 303(a) (2000).

464. 110 F.3d 786, 791, 42 U.S.P.Q.2d 1295, 1300 (BNA) (Fed. Cir. 1997) (interpreting the pre-amendment § 303 to prohibit raising a substantial new question of patentability).

previously cited by or to the Office or considered by the Office.”⁴⁶⁵ Thus, the holding in *Bass* only applies to reexaminations that were declared prior to November 2, 2002.⁴⁶⁶

J. Interference

1. Interference-in-fact—the two-way test

In *Eli Lilly & Co. v. Board of Regents of the University of Washington*,⁴⁶⁷ the Federal Circuit confirmed that it is within the discretion of the PTO to apply a two-way unpatentability test as a threshold for declaring an interference.⁴⁶⁸

Eli Lilly successfully requested the PTO to declare an interference for its reissue application of a patent assigned to the University of Washington.⁴⁶⁹ The reissue application recited a species claim to a cDNA sequence that codes for human protein C.⁴⁷⁰ Lilly proposed a genus claim construction and a species claim construction for claim 1 of the University of Washington patent.⁴⁷¹ As Judge Lourie pointed out in dissent, neither claim construction met the two-way test for declaring an interference⁴⁷² even though the genus construction met the one-way test.⁴⁷³

The Board granted the University of Washington’s motion to dismiss due to no interference-in-fact.⁴⁷⁴ Relying on prior Board precedent *Winter v. Fujita*⁴⁷⁵ and the 37 C.F.R. § 1.601(n) requirements of a two-way unpatentability test, the Board held that regardless of whether the patent was construed to have a genus claim or a species claim, the Lilly reissue application did not define the same patentable invention as required by regulation to declare an

465. 35 U.S.C. § 303(a) (2003).

466. *In re Bass*, 314 F.3d at 577, 65 U.S.P.Q.2d (BNA) at 1157.

467. 334 F.3d 1264, 67 U.S.P.Q.2d (BNA) 1161 (Fed. Cir. 2003).

468. *Id.* at 1272, 67 U.S.P.Q.2d (BNA) at 1167.

469. *Id.* at 1265, 67 U.S.P.Q.2d (BNA) at 1162.

470. *Id.*, 67 U.S.P.Q.2d (BNA) at 1162.

471. *See id.* at 1266, 67 U.S.P.Q.2d (BNA) at 1162 (discussing Eli Lilly’s motion to redefine the subject matter of Claim 1 after the University of Washington successfully won on a motion of no interference-of-fact regarding Claim 3).

472. *See id.* at 1271-72, 67 U.S.P.Q.2d (BNA) at 1166-67 (noting that neither the species or genus claim established an interference-in-fact in relation to the University of Washington because Lilly’s claims did not “teach or suggest the cDNA sequences claimed in the corresponding claims”).

473. *See id.* at 1272-74, 67 U.S.P.Q.2d (BNA) at 1167-68 (Lourie, J., dissenting) (arguing that under the one-way test of 37 C.F.R. § 1.601(n) there would be an interference-in-fact).

474. *Id.* at 1272, 67 U.S.P.Q.2d (BNA) at 1167.

475. No. 104-523, 1999 WL 1327616, 53 U.S.P.Q.2d (BNA) 1234 (Bd. Pat. App. & Interferences 1999).

interference.⁴⁷⁶ In the 1999 *Winter* decision, the Board defined the two-way unpatentability test as satisfied when claim A is anticipated or rendered obvious by claim B if claim B were prior art to claim A *and* claim B is anticipated or rendered obvious by claim A if claim A were prior art to claim B.⁴⁷⁷ Lilly appealed.⁴⁷⁸

The Federal Circuit affirmed the dismissal, finding that the PTO has discretion to choose between the two-way unpatentability test and the one-way unpatentability test.⁴⁷⁹ The court noted that the one-way unpatentability test is over-inclusive since, if the genus were ultimately determined to have priority over the species, separate patents could properly issue to each and the interference would have been in vain.⁴⁸⁰ The court also noted that the two-way test is under-inclusive since it would prevent the canceling of genus claims that did not have priority to the species.⁴⁸¹ However, the court determined that neither test was inconsistent with § 1.601(n), and the PTO could reasonably choose one over the other.⁴⁸²

Judge Lourie dissented on the grounds that the two-way test is not consistent with the plain language of § 1.60(n).⁴⁸³ Judge Lourie noted that the Board's decision in *Winter*, which established the two-way unpatentability test, is not binding on the court and is also "unsupported by any reasoning."⁴⁸⁴ Judge Lourie reasoned that the mere fact that an interference may be conducted in vain and potentially increase the burden on the PTO in doing so should not permit the PTO to shy away from its duty of determining priority to ensure that only one patent issues to the first inventor.⁴⁸⁵ Judge Lourie also noted that the two-way test will simply shift the burden from the personnel at the PTO with expertise in interference practice to the already overburdened district courts that do not have expertise.⁴⁸⁶

In *Medichem, S.A. v. Rolabo, S.L.*, another case involving the two-way test for an interference-in-fact, the Federal Circuit held that the standard for an interference between two patents, even in a district

476. *Eli Lilly*, 334 F.3d at 1272-73, 67 U.S.P.Q.2d (BNA) at 1167 (Lourie, J., dissenting).

477. *Winter*, No. 104-283, 1999 WL 1327616, at *11, 53 U.S.P.Q.2d (BNA) at 1243.

478. *Eli Lilly*, 334 F.3d at 1266, 67 U.S.P.Q.2d (BNA) at 1162.

479. *Id.* at 1272, 67 U.S.P.Q.2d (BNA) at 1167.

480. *Id.* at 1268, 67 U.S.P.Q.2d (BNA) at 1164.

481. *Id.* at 1270, 67 U.S.P.Q.2d (BNA) at 1165.

482. *Id.*, 67 U.S.P.Q.2d (BNA) at 1165.

483. *Id.* at 1273, 67 U.S.P.Q.2d (BNA) at 1167 (Lourie, J., dissenting).

484. *Id.*, 67 U.S.P.Q.2d (BNA) at 1167 (Lourie, J., dissenting).

485. *Id.* at 1273-74, 67 U.S.P.Q.2d (BNA) at 1168 (Lourie, J., dissenting).

486. *Id.* at 1274, 67 U.S.P.Q.2d (BNA) at 1168 (Lourie, J., dissenting).

court § 291 proceeding, should mirror PTO regulations.⁴⁸⁷ The court vacated the district court's priority determination for failure to meet the jurisdictional limitation of interference-in-fact using the proper analysis.⁴⁸⁸

The parties involved, Medichem and Rolabo, manufacture loratadine, the active antihistamine ingredient in Claritin®.⁴⁸⁹ Medichem appealed from a decision brought under 35 U.S.C. § 291 of no interference-in-fact between the claimed inventions of Medichem's and Rolabo's respective patents.⁴⁹⁰ Each patent claims a process for the preparation of loratadine.⁴⁹¹ The claims in the Medichem patent claimed the process in the presence of a tertiary amine.⁴⁹² The claims in the Rolabo patent were silent as to this element but were otherwise substantially the same.⁴⁹³ The lower court awarded priority to Medichem but found the absence of a tertiary amine in the Rolabo patent claims to be not obvious over the Medichem patent.⁴⁹⁴ Medichem appealed.⁴⁹⁵

The Federal Circuit held that the first step in any district court interference proceeding between two patents is the evaluation of whether an interference-in-fact exists.⁴⁹⁶ Establishing the existence of interference-in-fact between two patents is a jurisdictional limitation under § 291.⁴⁹⁷ Citing *Eli Lilly*⁴⁹⁸ and *Albert v. Kevelex Corp.*⁴⁹⁹ the court reiterated that analyzing the existence of an interference-in-fact under the two-way test is a prerequisite for jurisdiction to make a priority determination.⁵⁰⁰ While the PTO regulations do not bind a district court, the court noted that a district court must nevertheless define the subject matter of an interference between two patents in the same manner as would the PTO, which is to apply the two-way test.⁵⁰¹ By PTO regulation, the underlying analysis for the interference-in-fact inquiry is whether invention A is anticipated

487. *Medichem, S.A. v. Rolabo, S.L.*, 353 F.3d 928, 932, 69 U.S.P.Q.2d (BNA) 1283, 1286 (Fed. Cir. 2003).

488. *Id.* at 936, 69 U.S.P.Q.2d (BNA) at 1289.

489. *Id.* at 930, 69 U.S.P.Q.2d (BNA) at 1284.

490. *Id.* at 930-31, 69 U.S.P.Q.2d (BNA) at 1285.

491. *Id.* at 930, 69 U.S.P.Q.2d (BNA) at 1284.

492. *Id.*, 69 U.S.P.Q.2d (BNA) at 1284.

493. *Id.*, 69 U.S.P.Q.2d (BNA) at 1284-85.

494. *Id.* at 930-31, 69 U.S.P.Q.2d (BNA) at 1285.

495. *Id.* at 931, 69 U.S.P.Q.2d (BNA) at 1285.

496. *Id.* at 934, 69 U.S.P.Q.2d (BNA) at 1287.

497. *Id.*, 69 U.S.P.Q.2d (BNA) at 1287.

498. 334 F.3d 1264, 1265, 67 U.S.P.Q.2d (BNA) 1161, 1162 (Fed. Cir. 2003).

499. 729 F.2d 757, 760, 221 U.S.P.Q. (BNA) 202, 205 (Fed. Cir. 1984).

500. *Medichem*, 353 F.3d at 934, 935, 69 U.S.P.Q.2d (BNA) at 1287-88, 1288-89.

501. *Id.* at 934, 69 U.S.P.Q.2d (BNA) at 1287.

under § 102 or meets obviousness under § 103 by invention B, assuming invention B meets the first step of prior art.⁵⁰²

The court held that, properly construed, the claims of the Rolabo patent could include additional steps such as tertiary amines, because the claims use the transitional term “comprising.”⁵⁰³ Based on this claim construction, the Federal Circuit reversed the district court, holding that the species claims of the Medichem patent fell within the scope of, and, therefore, anticipated the genus claims of the Rolabo patent under § 102.⁵⁰⁴ However, because the lower court made no findings regarding the second leg of the test of whether invention B is anticipated by or obvious in view of invention A, the court remanded for further determination on whether the genus claims of the ‘827 patent anticipated or rendered obvious the species claims of the ‘100 patent.⁵⁰⁵

2. *Priority proofs*

In *In re Jolley*,⁵⁰⁶ the Federal Circuit declined to adopt a rule that a research proposal is not evidence of conception or that “evidence of diligence that *must* be excluded if there is any possibility that it could be construed in support of an invention beyond the reach of the [interference] count.”⁵⁰⁷

Senior party Jolley appealed from a decision of the Board awarding priority to junior party McGraw in a five-way interference.⁵⁰⁸ The interference count was directed to a liquid composition comprising a hydrofluorocarbon refrigerant (“HFC”) and a soluble organic lubricant comprising an effective amount of an ester.⁵⁰⁹ The Board determined that McGraw had an earlier conception date than Jolley based on an e-mail from McGraw’s co-inventor, Ward.⁵¹⁰ Even though Jolley was found to have reduced his invention to practice earlier than McGraw, the Board determined that McGraw was entitled to the priority award based on his prior conception coupled with diligence.⁵¹¹

502. *Id.* at 932, 69 U.S.P.Q.2d (BNA) at 1286 (citing *Eli Lilly*, 334 F.3d at 1267-69, 67 U.S.P.Q.2d (BNA) at 1163-65).

503. *Id.* at 933, 69 U.S.P.Q.2d (BNA) at 1287.

504. *Id.* at 934-35, 69 U.S.P.Q.2d (BNA) at 1288.

505. *Id.* at 935, 69 U.S.P.Q.2d (BNA) at 1288.

506. 308 F.3d 1317, 64 U.S.P.Q.2d (BNA) 1901 (Fed. Cir. 2002).

507. *Id.* at 1328, 64 U.S.P.Q.2d (BNA) at 1910.

508. *Id.* at 1319, 64 U.S.P.Q.2d (BNA) at 1902-03.

509. *Id.* at 1320, 64 U.S.P.Q.2d (BNA) at 1904.

510. *Id.* at 1321, 64 U.S.P.Q.2d (BNA) at 1904.

511. *Id.* at 1326-29, 64 U.S.P.Q.2d (BNA) at 1908-10.

In the e-mail, Ward suggested the possibility of using blends of polyglycol with esters as lubricants for HFC, a suggestion consistent with research for air compressor lubricants, which were polyglycol/ester blends.⁵¹² Jolley argued that McGraw's initial conception was not directed to a two component system of HFC and ester, in the interference count, but to a three component system of HFC, polyglycol, and ester.⁵¹³

The court held that although the evidence of conception indicated overlapping inventions, an invention within the count and an invention outside the count, it is open to other ingredients, such as a polyglycol, because the count uses the term "comprising."⁵¹⁴ The court noted that:

The question of whether an alleged conception discloses the subject matter of the interference count with sufficient particularity is a fact-intensive inquiry, based on whether the evidence of conception fairly suggests to one of ordinary skill in the subject matter of the count, without the need for extensive experimentation to ascertain whether the matter encompassed by the disclosure suggests the desirable features of compositions belonging to the count.⁵¹⁵

The court dismissed Jolley's argument discounting the e-mail as a "research proposal," stating that "the conception inquiry is fact-intensive and no per se rule excludes 'research proposals' as evidence of conception."⁵¹⁶ According to the court, "[t]he determinative inquiry is not whether McGraw's disclosure was phrased certainly or tentatively, but whether the idea expressed therein was sufficiently developed to support conception of the subject matter of the interference count."⁵¹⁷ While the e-mail largely referred to ester in general terms, it also referenced the polyglycol/ester blends found in certain air compressor lubricant patents.⁵¹⁸ The court found this reference to be of sufficient specificity to support the Board's finding of a conception.⁵¹⁹

The evidence also showed that "McGraw reduced to practice a two-component (ester/refrigerant) system meeting all limitations of the count . . . and reduced to practice three-component (polyol/ester/

512. *Id.* at 1326, 64 U.S.P.Q.2d (BNA) at 1908.

513. *Id.* at 1327, 64 U.S.P.Q.2d (BNA) at 1908-09.

514. *Id.*, 64 U.S.P.Q.2d (BNA) at 1909.

515. *Id.* at 1323, 64 U.S.P.Q.2d (BNA) at 1906.

516. *Id.*, 64 U.S.P.Q.2d (BNA) at 1906.

517. *Id.* at 1324, 64 U.S.P.Q.2d (BNA) at 1906.

518. *Id.* at 1321, 1324, 64 U.S.P.Q.2d (BNA) at 1904, 1906.

519. *Id.* at 1324, 1326, 64 U.S.P.Q.2d (BNA) at 1906, 1908.

refrigerant) systems.”⁵²⁰ Jolley argued that the Board cannot make a determination of diligence based on evidence that includes an invention inside the count, such as the two component system, and an invention outside the count such as the three component system.⁵²¹

The court declined to adopt a rule that evidence of diligence must be excluded if there is any possibility that it could be construed in support of an invention beyond the reach of the count: “[W]here two different, inconsistent conclusions may reasonably be drawn from the evidence in record, an agency’s decision to favor one conclusion over the other is the epitome of a decision that must be sustained upon review for substantial evidence.”⁵²²

3. *Actual reduction to practice*

In affirming the priority award of the Board, the Federal Circuit in *Taskett v. Dentlinger*⁵²³ held that an inventor is not required to test an invention under conditions of actual use to establish that an invention will work for its intended purpose.⁵²⁴

In the interference proceeding before the Board, Taskett was named senior party based on filing the application six days prior to the filing date of Dentlinger’s application, the junior party.⁵²⁵ The count in the interference covered a process for the automated purchasing of prepaid telephone services.⁵²⁶ While Taskett relied on its filing date, Dentlinger presented evidence of an earlier conception and actual reduction to practice, the latter in the form of a test using a dummy checking account and an internal switch.⁵²⁷ In the test, an ATM device received a request to purchase a specified amount of telephone service, “withdrew” money from the dummy account through the internal switch, and printed a receipt.⁵²⁸ Based on that evidence, the Board found that Dentlinger established conception and actual reduction to practice prior to Taskett’s filing date and awarded Dentlinger priority of invention.⁵²⁹

Taskett appealed, arguing that Dentlinger did not prove a successful actual reduction to practice prior to Taskett’s priority

520. *Id.* at 1326, 64 U.S.P.Q.2d (BNA) at 1908.

521. *Id.* at 1328, 64 U.S.P.Q.2d (BNA) at 1910.

522. *Id.* at 1329, 64 U.S.P.Q.2d (BNA) at 1910.

523. 344 F.3d 1337, 68 U.S.P.Q.2d (BNA) 1472 (Fed. Cir. 2003).

524. *Id.* at 1342, 68 U.S.P.Q.2d (BNA) at 1476.

525. *Id.* at 1338, 68 U.S.P.Q.2d (BNA) at 1473.

526. *Id.*, 68 U.S.P.Q.2d (BNA) at 1473.

527. *Id.* at 1338-40, 68 U.S.P.Q.2d (BNA) at 1473-75.

528. *Id.* at 1341, 68 U.S.P.Q.2d (BNA) at 1475.

529. *Id.* at 1338-39, 69 U.S.P.Q.2d (BNA) at 1473-74.

date.⁵³⁰ Taskett argued that since only a dummy account and an internal switch were used in the test, no financial transaction occurred and, therefore, the test did not establish that the invention would work for its intended purposes.⁵³¹

The Federal Circuit rejected Taskett's argument, holding that Dentlinger was not required to test the invention under conditions of actual use to determine that the invention would work for its intended purpose: "to hold otherwise would be to require an inventor to have created a viable commercial embodiment before the Board or a court could find reduction to practice. This the law does not require."⁵³²

K. Inventorship—Misjoinder and Nonjoinder

In *Board of Education ex rel. Board of Trustees of Florida State University v. American Bioscience, Inc.*,⁵³³ the Federal Circuit emphasized that "the burden of showing misjoinder or nonjoinder of inventors is a heavy one and must be proved by clear and convincing evidence."⁵³⁴

The Board of Education (collectively "FSU"), sued American Bioscience, Inc. ("ABI") and Tao to add three FSU inventors and remove three named ABI inventors.⁵³⁵ The claims of the patent covered three compounds that were analogs of taxotere (docetaxel), a compound that differs from taxol, a natural compound that is an effective chemotherapeutic agent.⁵³⁶ ABI filed an application for the subject patent with broad claims, but limited the claims for issue and determined the named inventorship was proper.⁵³⁷

The district court found that ABI inventors contributed to the claimed invention and that the presumption that the named inventors are the true and only inventors was overcome by "clear and convincing evidence," which demonstrated that the inventors contributed to the patented compound.⁵³⁸

In conducting *de novo* review of the inventorship determination, the Federal Circuit found that there was no evidence on record that the idea of making taxol analogs came from anyone other than the named ABI inventors who contributed to the conception of the

530. *Id.* at 1339, 68 U.S.P.Q.2d (BNA) at 1474.

531. *Id.* at 1340, 68 U.S.P.Q.2d (BNA) at 1374-75.

532. *Id.* at 1342, 68 U.S.P.Q.2d (BNA) at 1476.

533. 333 F.3d 1330, 67 U.S.P.Q.2d (BNA) 1252 (Fed. Cir. 2003).

534. *Id.* at 1337, 67 U.S.P.Q.2d (BNA) at 1257.

535. *Id.* at 1332, 67 U.S.P.Q.2d (BNA) at 1253.

536. *Id.*, 67 U.S.P.Q.2d (BNA) at 1253.

537. *Id.* at 1335-36, 67 U.S.P.Q.2d (BNA) at 1255-56.

538. *Id.* at 1337, 67 U.S.P.Q.2d (BNA) as 1257.

invention.⁵³⁹ In relying on *Amgen Inc. v. Chugai Pharmaceutical Co.*,⁵⁴⁰ the court stated that “invention requires conception, and ‘conception does not occur unless one has a mental picture of the structure of the chemical . . . or whatever characteristics sufficiently distinguish it.’”⁵⁴¹

According to the Federal Circuit, FSU’s arguments fell short of meeting the “clear and convincing” evidence standard because there was no evidence of conception by anyone at FSU of the three compounds covered by the limited claims of the patent.⁵⁴² The Federal Circuit discounted allegations that Tao learned of FSU’s “secret” methods to make the claimed compound in the patent, noting that only the ABI inventors were in possession of both the structure and the operative method of making the claimed compounds.⁵⁴³

L. Ownership: State Law Issues

Applying state law to a breach of contract issue involving a university patent policy concerning ownership of patents, the Federal Circuit, in *Regents of the University of New Mexico v. Knight*,⁵⁴⁴ found that university faculty members were contractually bound by the patent policy and that their patent applications, including a series of CIP applications, were owned by the university.⁵⁴⁵ In doing so, the Federal Circuit dismissed as irrelevant the requirement for new assignments insofar as CIP applications are concerned⁵⁴⁶ and held that under principles of inherency, the “in part” subject matter (a chemical structure) would not have been “new matter” vis-à-vis the original application, which described the chemical and physical characteristics of the compounds.⁵⁴⁷ In any event, the Federal Circuit reasoned that the CIP applications “only clarified and corrected the erroneous characterization of the already disclosed inventions,”⁵⁴⁸ and the chemical structure was not separable from the properties of the compound; rather, it was just another way of describing the same invention.⁵⁴⁹

539. *Id.* at 1339, 67 U.S.P.Q.2d (BNA) at 1259.

540. 927 F.2d 1200, 18 U.S.P.Q.2d (BNA) 1016 (Fed. Cir. 1991).

541. *Bd. of Educ.*, 333 F.3d at 1340, 67 U.S.P.Q.2d (BNA) at 1259 (quoting *Amgen*, 927 F.2d at 1206, 18 U.S.P.Q.2d (BNA) at 1021).

542. *Id.* at 1341, 67 U.S.P.Q.2d (BNA) at 1260.

543. *Id.* at 1341-42, 67 U.S.P.Q.2d (BNA) at 1260-61.

544. 321 F.3d 1111, 66 U.S.P.Q.2d (BNA) 1001 (Fed. Cir. 2003).

545. *Id.* at 1119-20, 66 U.S.P.Q.2d (BNA) 1006-07.

546. *Id.* at 1121, 66 U.S.P.Q.2d (BNA) at 1008.

547. *Id.* at 1121-22, 66 U.S.P.Q.2d (BNA) at 1008-09.

548. *Id.* at 1122, 66 U.S.P.Q.2d (BNA) at 1009.

549. *Id.*, 66 U.S.P.Q.2d (BNA) at 1009.

III. CLAIM CONSTRUCTION

A. *The Plain and Ordinary Meaning of the Claim Terms*

In 2003, the Federal Circuit's perception of the plain meaning of the claims reigned. Many of the court's decisions devoted substantial effort to developing the claim construction rules set forth the previous year in *CCS Fitness, Inc. v. Brunswick Corp.*⁵⁵⁰ and in *Texas Digital Systems, Inc. v. Telegenix, Inc.*⁵⁵¹ Given this trend, it was not surprising that the Federal Circuit issued numerous decisions overturning district courts that relied upon either the specification or the prosecution history to construe the scope of the claim terms at issue.

For example, in *Sunrace Roots Enterprise Co. v. SRAM Corp.*⁵⁵² the Federal Circuit reversed and remanded a declaratory judgment of non-infringement of a patent relating to bicycle gear-shifting devices, holding the district court erred in its construction of the claim term "shift actuator."⁵⁵³

In *Sunrace*, the patent at issue contained "both method and apparatus claims related to gear-shifting on multi-speed bicycles through the use of a shift actuator" designed to control the derailleur.⁵⁵⁴ Multi-speed bicycles utilize indexed shifting by employing a cam mechanism, in which "a cylindrical cam member fits over the bicycle's handlebar and a cam operating face interacts with a cam pin as the shift actuator is rotated."⁵⁵⁵ The method claims of the patent included the limitation "shift actuator" without reference to a cam.⁵⁵⁶

The district court concluded that "the plain and ordinary meaning of the term 'shift actuator' is 'a mechanism that controls the changing of gears.'"⁵⁵⁷ However, the district court ruled that in light of the specification and prosecution history, "the term 'shift actuator' as used in the '291 patent is limited to 'a mechanism for controlling the changing of gears that contains a cam configured with a series of lobes and valleys that rotate so as to engage a cam follower.'"⁵⁵⁸ The

550. 288 F.3d 1359, 62 U.S.P.Q.2d (BNA) 1658 (Fed. Cir. 2002).

551. 308 F.3d 1193, 64 U.S.P.Q.2d (BNA) 1812 (Fed. Cir. 2002).

552. 336 F.3d 1298, 67 U.S.P.Q.2d (BNA) 1438 (Fed. Cir. 2003).

553. *Id.* at 1299, 67 U.S.P.Q.2d (BNA) at 1439.

554. *Id.*, 67 U.S.P.Q.2d (BNA) at 1439.

555. *Id.*, 67 U.S.P.Q.2d (BNA) at 1439.

556. *Id.*, 67 U.S.P.Q.2d (BNA) at 1439.

557. *Id.* at 1302-02, 67 U.S.P.Q.2d (BNA) at 1441.

558. *Id.* at 1302, 67 U.S.P.Q.2d (BNA) at 1441.

parties stipulated that, under the district court's interpretation, the accused devices did not infringe.⁵⁵⁹ SRAM appealed.⁵⁶⁰

The Federal Circuit first noted that claim terms "must be given their ordinary and accustomed meaning unless the patent expresses an intention to impart novel meaning to the claim terms."⁵⁶¹ The court found that since the cam structure was recited in other claims, the doctrine of claim differentiation supported the use of the plain and ordinary meaning of the term "shift actuator."⁵⁶² The court further found that nothing in the patent's specification or the prosecution history indicated the invention was directed exclusively to cams, or that systems not employing cams were outside the scope of the invention.⁵⁶³ Moreover, the court stated that consideration of extrinsic evidence was inappropriate because the intrinsic evidence resolved any ambiguity regarding the disputed claim term.⁵⁶⁴ Accordingly, the court held that because the intrinsic evidence did not clearly narrow the disputed claim term, the ordinary meaning of the claim term "shift actuator" applied.⁵⁶⁵

In *Springs Window Fashions v. Novo Industries*,⁵⁶⁶ notwithstanding its decisions in *Rambus v. Infineon Technologies AG*⁵⁶⁷ and *Storage Technology Corp. v. Cisco Systems, Inc.*,⁵⁶⁸ the Federal Circuit reaffirmed the time-honored rule that saddles inventors with the errors of the lawyers who prosecute their patents. It reaffirmed that arguments in the prosecution history distinguishing the claimed invention over prior art result in the surrender of patent scope, even when the argument turns out to have been a misstatement.⁵⁶⁹ The court observed, "[i]f the applicant mistakenly disclaimed coverage of the claimed invention, then the applicant should have amended the file to reflect the error, as the applicant is the party in the best position to do so."⁵⁷⁰ Here, the Federal Circuit, agreeing with the district court, held that the statements distinguishing the prior art reference cited by the examiner were "detailed, consistent, and repeated."⁵⁷¹ According to

559. *Id.*, 67 U.S.P.Q.2d (BNA) at 1441.

560. *Id.*, 67 U.S.P.Q.2d (BNA) at 1441.

561. *Id.*, 67 U.S.P.Q.2d (BNA) at 1441.

562. *Id.* at 1302-03, 67 U.S.P.Q.2d (BNA) at 1441-42.

563. *Id.* at 1306-07, 67 U.S.P.Q.2d (BNA) at 1444-45.

564. *Id.* at 1307, 67 U.S.P.Q.2d (BNA) at 1445.

565. *Id.* at 1307-08, 67 U.S.P.Q.2d (BNA) at 1445.

566. 323 F.3d 989, 65 U.S.P.Q.2d (BNA) 1826 (Fed. Cir. 2003).

567. 318 F.3d 1081, 65 U.S.P.Q.2d (BNA) 1705 (Fed. Cir. 2003).

568. 329 F.3d 823, 66 U.S.P.Q.2d (BNA) 1545 (Fed. Cir. 2003).

569. *Springs Window*, 323 F.3d at 995, 65 U.S.P.Q.2d (BNA) at 1830.

570. *Id.*, 65 U.S.P.Q.2d (BNA) at 1830.

571. *Id.* at 996, 65 U.S.P.Q.2d (BNA) at 1830.

the court, “[a] reasonable competitor would have believed that the applicant’s disclaiming statements were not a mere mistake.”⁵⁷²

In *ResQNet.com, Inc. v. Lansa, Inc.*,⁵⁷³ the Federal Circuit reiterated that a claim term should be construed according to its plain language and ordinary meaning and should be limited in scope only if the applicant clearly and unmistakably disavowed that ordinary meaning.⁵⁷⁴ Applying that principle, the Federal Circuit found that the claim terms “each field,” “each of plurality of fields,” “particular fields,” and “a plurality of specific [fields],” all have different meanings.⁵⁷⁵

The claim language at issue arose from three patents asserted by ResQNet.⁵⁷⁶ The three patents were directed to software for analyzing field attributes downloaded from a mainframe computer to a PC for permitting multiple PC users to access one mainframe and display a unique graphical user interface (“GUI”) for each user.⁵⁷⁷

The district court had analyzed claim language requiring that “said ID [to be] generated as a function of the number, location, and length of *each field*”⁵⁷⁸ and had concluded that claim term “every field” means “all fields.”⁵⁷⁹ Noting that the claim element in question was presented in means-plus-function format, the Federal Circuit first identified the claimed function and the corresponding structure, “an algorithm which recognizes the screen layout and fields therein.”⁵⁸⁰ Then, considering the claim language as a whole, the Federal Circuit agreed with the district court “that the claimed algorithm evaluates attributes of each (and every) field in the information to be displayed.”⁵⁸¹ The court then noted that “the specification sets forth only one embodiment of the algorithm”⁵⁸² and that the description of that algorithm “suggests that characteristics of all, not just some, fields are inputs into the algorithm” and that “[n]owhere does the specification suggest otherwise.”⁵⁸³

However, the Federal Circuit reversed the district court’s construction of the term “each of a plurality of fields” set forth in the

572. *Id.*, 65 U.S.P.Q.2d (BNA) at 1830.

573. 346 F.3d 1374, 68 U.S.P.Q.2d (BNA) 1619 (Fed. Cir. 2003).

574. *Id.* at 1378, 68 U.S.P.Q.2d (BNA) at 1622.

575. *Id.* at 1382-83, 68 U.S.P.Q.2d (BNA) at 1625-26.

576. *Id.* at 1375, 68 U.S.P.Q.2d (BNA) at 1620.

577. *Id.* at 1375-76, 68 U.S.P.Q.2d (BNA) at 1620.

578. *Id.* at 1377, 68 U.S.P.Q.2d (BNA) at 1621.

579. *Id.* at 1378, 68 U.S.P.Q.2d (BNA) at 1621.

580. *Id.* at 1379, 68 U.S.P.Q.2d (BNA) at 1622 (citation omitted).

581. *Id.*, 68 U.S.P.Q.2d (BNA) at 1622.

582. *Id.*, 68 U.S.P.Q.2d (BNA) at 1623.

583. *Id.*, 68 U.S.P.Q.2d (BNA) at 1623.

second, related patent.⁵⁸⁴ The Federal Circuit found that in the context of the second patent, the claim language at issue required use only “of at least two fields”⁵⁸⁵—not every field.⁵⁸⁶ In this regard, the court noted that the slightly different algorithm disclosed in the second patent could select for analysis “potentially a subset of all fields.”⁵⁸⁷ The Federal Circuit also reversed the district court’s construal of “a plurality of specific [fields].”⁵⁸⁸ Finding no clear and unambiguous surrender of subject matter, the court invoked the plain meaning rule and construed the term “a plurality of specific screen identifying information” to require only “at least two pieces of . . . information.”⁵⁸⁹

In *Tehrani v. Hamilton Medical, Inc.*,⁵⁹⁰ the Federal Circuit analyzed competing dictionary definitions to find that the district court erred in its claim construction.

The patent at issue related to an apparatus and method that automatically controls a respirator used for mechanical ventilation of a patient who needs assistance in breathing.⁵⁹¹ The claimed apparatus controls both breath frequency, which is the number of breaths delivered to the patient per minute, and the tidal volume or ventilation, which is the volume of gas delivered with each breath, by calculating the proper breath frequency and tidal volume.⁵⁹² The calculations are based on data representing at least five factors: air viscosity in the lungs, lung elastance, barometric pressure, oxygen level of the patient and carbon dioxide level of the patient.⁵⁹³

The accused ventilator included an adaptive support ventilation (“ASV”) mode in which the device evaluated the patient’s breathing effort.⁵⁹⁴ If the device detected no breathing effort, it provided full mechanical ventilation for the patient, but if it detected some patient effort, the device supplemented the patient’s effort to achieve the target ventilation.⁵⁹⁵ The device calculated the target breathing pattern using an algorithm for calculating the tidal volume and frequency of breaths needed to provide proper gas exchange.⁵⁹⁶ The

584. *Id.* at 1382-83, 68 U.S.P.Q.2d (BNA) at 1625-26.

585. *Id.*, 68 U.S.P.Q.2d (BNA) at 1625-26.

586. *Id.*, 68 U.S.P.Q.2d (BNA) at 1626.

587. *Id.* at 1382, 68 U.S.P.Q.2d (BNA) at 1625.

588. *Id.* at 1383, 68 U.S.P.Q.2d (BNA) at 1626.

589. *Id.*, 68 U.S.P.Q.2d (BNA) at 1626.

590. 331 F.3d 1355, 67 U.S.P.Q.2d (BNA) 1015 (Fed. Cir. 2003).

591. *Id.* at 1356, 67 U.S.P.Q.2d (BNA) at 1016.

592. *Id.*, 67 U.S.P.Q.2d (BNA) at 1016.

593. *Id.* at 1356-57, 67 U.S.P.Q.2d (BNA) at 1016.

594. *Id.* at 1358, 67 U.S.P.Q.2d (BNA) at 1017.

595. *Id.*, 67 U.S.P.Q.2d (BNA) at 1017.

596. *Id.*, 67 U.S.P.Q.2d (BNA) at 1017.

accused ventilator contains no sensor to measure the oxygen or carbon dioxide levels in the patient's blood or expired gas.⁵⁹⁷ Rather, the operator of the device must measure the patient's levels of oxygen and carbon dioxide manually and then make corresponding settings on the ventilator.⁵⁹⁸

The district court concluded that two of the operator settings corresponded to the claimed means for processing data representing measured levels of carbon dioxide and oxygen concentration respectively.⁵⁹⁹ As explained by the district court, "[a]lthough the [setting] may not represent the actual carbon dioxide level, carbon dioxide must be measured by some means for proper operation of the [ventilator] and the dial is adjusted accordingly."⁶⁰⁰ Similarly, the district court relied on an operator-controlled oxygen setting to satisfy the limitation regarding the processing of data representing the oxygen level of the patient.⁶⁰¹

Hamilton Medical appealed, arguing that the claims required the algorithm to use each of the five specified data values to calculate tidal volume and breath frequency.⁶⁰² The Federal Circuit agreed that "the claims must be construed to require that the device first process the five data values and then use those data values to calculate tidal volume and breath frequency."⁶⁰³

With regard to claim terms such as "representing" and "indicative," in connection with the input data, both sides relied on dictionary definitions.⁶⁰⁴ Looking to the ordinary meaning of the term "representing," the court noted that when a term has multiple dictionary definitions, the intrinsic record is used "to identify which of the different possible dictionary meanings of the claim terms in issue is the most consistent with the use of the words by the inventor."⁶⁰⁵ Here, the court found that the ordinary meaning of "representing" includes "symbolizing" or "to stand for," but not in the case of two items that are related only in some attenuated way.⁶⁰⁶ The court asserted that "the first item must be directly related to and stand for, or be a reasonable proxy for, the latter item."⁶⁰⁷ The court

597. *Id.*, 67 U.S.P.Q.2d (BNA) at 1017.

598. *Id.*, 67 U.S.P.Q.2d (BNA) at 1017.

599. *Id.* at 1359, 67 U.S.P.Q.2d (BNA) at 1018.

600. *Id.*, 67 U.S.P.Q.2d (BNA) at 1018.

601. *Id.*, 67 U.S.P.Q.2d (BNA) at 1018.

602. *Id.* at 1360, 67 U.S.P.Q.2d (BNA) at 1018-19.

603. *Id.*, 67 U.S.P.Q.2d (BNA) at 1019.

604. *Id.*, 67 U.S.P.Q.2d (BNA) at 1019.

605. *Id.* at 1361, 67 U.S.P.Q.2d (BNA) at 1019.

606. *Id.*, 67 U.S.P.Q.2d (BNA) at 1019.

607. *Id.*, 67 U.S.P.Q.2d (BNA) at 1019.

rejected Tehrani's argument that the claim term "indicative of" is broader than "representing," noting that the patent used the terms interchangeably, and, therefore, construed them to have the same meaning.⁶⁰⁸

In *AK Steel Corp. v. Sollac*,⁶⁰⁹ the Federal Circuit agreed with the district court's findings that the term "consisting essentially of aluminum," when referring to the coating metal, meant that "the silicon should not exceed 0.5%."⁶¹⁰ The specification clarified that any amount of silicon greater than about 0.5% would "materially affect the basic and novel properties of the invention."⁶¹¹ Because Sollac's coating metal contained both aluminum and 8.0 to 8.5% silicon,⁶¹² the Federal Circuit noted that the district court found different constructions for similar claims from different patents that were supported by the same specification, a situation it regarded as "unusual."⁶¹³ However, according to the court, those constructions were a "necessary consequence" of clear statements in the specification, the prosecution history and the canon of claim differentiation.⁶¹⁴ Accordingly, even if two sets of similar claims from two separate-but-related patents share the same specification, the claims may be properly construed differently.⁶¹⁵

In *Jansen v. Rexall Sundown, Inc.*,⁶¹⁶ the Federal Circuit upheld the construction of a claim to a method of treating a specific disease by administering an over-the-counter formulation to a "human in need thereof" to require that those consuming the claimed formulation do so specifically intending to treat the claimed disease.⁶¹⁷

The asserted claims related to a method of treating macrocytic megaloblastic anemia, also known as pernicious anemia.⁶¹⁸ Pernicious anemia is a condition caused by either vitamin B12 or folic acid deficiency.⁶¹⁹ Jansen tried but failed to obtain claims to a method of treating *any* anemia with a formulation of both compounds.⁶²⁰ After twenty stubborn years of prosecution spanning seven generations of continuation applications, Jansen finally obtained U.S. Pat. No.

608. *Id.*, 67 U.S.P.Q.2d (BNA) at 1019-20.

609. 344 F.3d 1234, 68 U.S.P.Q.2d (BNA) 1280 (Fed. Cir. 2003).

610. *Id.* at 1239, 68 U.S.P.Q.2d (BNA) at 1283.

611. *Id.*, 68 U.S.P.Q.2d (BNA) at 1283.

612. *Id.* at 1238, 68 U.S.P.Q.2d (BNA) at 1282.

613. *Id.* at 1243, 68 U.S.P.Q.2d (BNA) at 1286.

614. *Id.*, 68 U.S.P.Q.2d (BNA) at 1286.

615. *Id.*, 68 U.S.P.Q.2d (BNA) at 1286.

616. 342 F.3d 1329, 68 U.S.P.Q.2d (BNA) 1154 (Fed. Cir. 2003).

617. *Id.* at 1333-34, 68 U.S.P.Q.2d (BNA) at 1158.

618. *Id.* at 1330, 68 U.S.P.Q.2d (BNA) at 1155.

619. *Id.*, 68 U.S.P.Q.2d (BNA) at 1155.

620. *Id.* at 1331, 68 U.S.P.Q.2d (BNA) at 1155-56.

4,945,083 (“the ‘083 patent”) by a showing of commercial success for vitamin B12 and folic acid formulations in treating and preventing pernicious anemia.⁶²¹ However, in order to obtain allowance, Jansen was forced to restrict his claims to a “method of treating or preventing *macrocytic megaloblastic anemia*”⁶²² limited “to a human in *need thereof*.”⁶²³

Rexall marketed a non-prescription supplement having vitamin B12 and folic acid in proportions claimed by the ‘083 patent.⁶²⁴ However, Rexall expressly marketed the product only for the maintenance of blood homocysteine levels.⁶²⁵ Consequently, Jansen sued Rexall for “the inducement of and the contributory infringement of the ‘083 patent.”⁶²⁶

The district court had not adopted Jansen’s position that *all* people are “humans in need” of treatment or prevention of macrocytic megaloblastic anemia.⁶²⁷ It had construed the claim phrase, “treating or preventing macrocytic megaloblastic anemia” to require that the human taking the claimed composition do so with the specific intent of treating macrocytic megaloblastic anemia.⁶²⁸ The court had noted that there was no evidence on record that Rexall’s customer had the required state of mind and, as such, granted its motion for summary judgment of non-infringement.⁶²⁹

The Federal Circuit affirmed, finding that the district court did not add any limitation not compelled by the language of the claims themselves.⁶³⁰ First, the court held that particular emphasis should be placed on the limitations “treating or preventing macrocytic megaloblastic anemia” and “a human in need thereof” because their addition to the claims made the claims allowable.⁶³¹ Second, because these limitations were simultaneously added, the court noted that the limitations should be read together and, therefore, the term “thereof” refers only to the treatment of macrocytic megaloblastic anemia.⁶³² Third, the court construed the term “need” to require a need that is “recognized and appreciated” because “otherwise the

621. *Id.*, 68 U.S.P.Q.2d (BNA) at 1156.

622. *Id.*, 68 U.S.P.Q.2d (BNA) at 1156.

623. *Id.*, 68 U.S.P.Q.2d (BNA) at 1156 (emphasis added).

624. *Id.*, 68 U.S.P.Q.2d (BNA) at 1156.

625. *Id.*, 68 U.S.P.Q.2d (BNA) at 1156.

626. *Id.*, 68 U.S.P.Q.2d (BNA) at 1156.

627. *Id.*, 68 U.S.P.Q.2d (BNA) at 1156.

628. *Id.*, 68 U.S.P.Q.2d (BNA) at 1156.

629. *Id.*, 68 U.S.P.Q.2d (BNA) at 1156.

630. *Id.* at 1333, 68 U.S.P.Q.2d (BNA) at 1158.

631. *Id.*, 68 U.S.P.Q.2d (BNA) at 1158.

632. *Id.* at 1334, 68 U.S.P.Q.2d (BNA) at 1158.

added phrases do not carry the meaning that the circumstances of their addition suggest they carry.”⁶³³ Any other interpretation would result in the claims covering almost any physical condition and would, therefore, amount to a recapture of subject matter disclaimed during prosecution.⁶³⁴

Jansen argued that even under Rexall’s claim construction, Rexall’s labeling and formulation provide circumstantial evidence of direct infringement by Rexall’s customers and that this evidence provided sufficient support to defeat a motion for summary judgment.⁶³⁵ The court disagreed, indicating that the theoretical possibility that customers were using Rexall’s formulation for treating macrocytic megaloblastic anemia is insufficient to create a *genuine* issue of fact.⁶³⁶

The Federal Circuit also refused to insert timing or sequence requirements to the claims at issue in a number of appeals this past year. For example, in *Bio-Technology General Corp. v. Duramed Pharmaceuticals, Inc.*,⁶³⁷ the Federal Circuit held that infringement may exist if evidence establishes that a “menstrual shift” occurs after a woman begins taking the accused contraceptive product, such that the use of the accused product after an initial period of time results in a dosing that follows the patented method and product.⁶³⁸

Duramed involved an oral contraceptive regimen marketed under the brand name Mircette.⁶³⁹ Mircette is sold in a 28-pill blister pack.⁶⁴⁰ A woman using Mircette is instructed to sequentially take the 28 pills.⁶⁴¹ The first twenty-one pills comprise a combination of progestin and estrogen, followed by two placebos with the final five pills containing estrogen alone.⁶⁴²

The district court granted Duramed’s motion for summary judgment of noninfringement because a single package of the Duramed product reversed the delivery sequence prescribed by claim 1, estrogen before progestin.⁶⁴³ The district court reasoned that a woman would have to take at least two packages of the accused contraceptive in order to complete the claimed regimen and that because “the elements of the accused product are placed in a

633. *Id.*, 68 U.S.P.Q.2d (BNA) at 1158.

634. *Id.*, 68 U.S.P.Q.2d (BNA) at 1158.

635. *Id.*, 68 U.S.P.Q.2d (BNA) at 1158-59.

636. *Id.* at 1334-35, 68 U.S.P.Q.2d (BNA) at 1159.

637. 325 F.3d 1356, 66 U.S.P.Q.2d (BNA) 1360 (Fed. Cir. 2003).

638. *Id.* at 1361, 66 U.S.P.Q.2d (BNA) at 1364.

639. *Id.* at 1358, 66 U.S.P.Q.2d (BNA) at 1362.

640. *Id.*, 66 U.S.P.Q.2d (BNA) at 1362.

641. *Id.*, 66 U.S.P.Q.2d (BNA) at 1362.

642. *Id.*, 66 U.S.P.Q.2d (BNA) at 1362.

643. *Id.* at 1358-59, 66 U.S.P.Q.2d (BNA) at 1362-63.

reversed order to achieve a different result than that obtained in the patented system,” there was no infringement under the doctrine of equivalents.⁶⁴⁴

The Federal Circuit reversed, finding that the district court construed the claims too narrowly by limiting them to a particular arrangement of estrogen and progestin pills in a single one-month package.⁶⁴⁵ Instead, the Federal Circuit found that a proper claim construction would include estrogen pills taken at the beginning of a woman’s menstrual cycle, followed by progestin pills for the remainder of the menstrual cycle.⁶⁴⁶

In *3M Innovative Properties Co. v. Avery Dennison Corp.*,⁶⁴⁷ the Federal Circuit again relied upon the plain meaning of the claims to hold that the asserted claim requiring “at least one surface that has a multiple embossed pattern having a first embossed pattern and a second embossed pattern”⁶⁴⁸ did not impose a limitation upon the sequence of embossing.⁶⁴⁹ In coming to its conclusion, the court found probative the absence of any sequential language in the claim at issue in contrast to the presence of similar language in an unasserted product-by-process claim.⁶⁵⁰ The court found less relevant the statements in the prosecution history that 3M’s claimed invention pertained to embossed patterns where the first embossed pattern “survives” the embossing of the second pattern.⁶⁵¹ The court found that 3M’s statement did not constitute a “clear and unambiguous” surrender of subject matter and thus did not limit the claim.⁶⁵²

B. Proper and Improper Use of the Specification During Construction

This year, the specification’s main role in claim construction was to assist in determining which dictionary definitions were clearly inapplicable. For example, in *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*⁶⁵³ the Federal Circuit reversed a district court’s grant of summary judgment based on its finding that the coverage a patent directed to robotic surgical systems having a telecommunications link

644. *Id.* at 1359-60, 66 U.S.P.Q.2d (BNA) at 1363.

645. *Id.* at 1363-64, 66 U.S.P.Q.2d (BNA) at 1366.

646. *Id.*, 66 U.S.P.Q.2d (BNA) at 1366.

647. 350 F.3d 1365, 69 U.S.P.Q.2d (BNA) 1050 (Fed. Cir. 2003).

648. *Id.* at 1368, 69 U.S.P.Q.2d (BNA) at 1052.

649. *Id.* at 1371, 69 U.S.P.Q.2d (BNA) at 1055.

650. *Id.* at 1373, 69 U.S.P.Q.2d (BNA) at 1056.

651. *Id.*, 69 U.S.P.Q.2d (BNA) at 1056.

652. *Id.*, 69 U.S.P.Q.2d (BNA) at 1056.

653. 334 F.3d 1294, 67 U.S.P.Q.2d (BNA) 1132 (Fed. Cir. 2003).

permitting a surgeon to operate from a “remote location” extended to locations in the operating room.⁶⁵⁴

The district court held that “remote location” meant “a location outside the operating room where the patient undergoing surgery is located”⁶⁵⁵ and granted summary judgment in favor of Intuitive.⁶⁵⁶ Brookhill appealed, arguing that “the plain meaning of the claim term, the patent’s written description, the prosecution history and extrinsic evidence all support a broader reading that does not restrict the surgeon to a location outside the operating room.”⁶⁵⁷ Specifically, Brookhill argued that the ordinary and customary meaning of “remote location” means any location beyond arm’s length.⁶⁵⁸

While noting the parties’ battle of dictionaries offered in support of the competing ordinary and customary meaning of the disputed claim term, the Federal Circuit stated that “consulting dictionary definitions is simply a first step in the claim construction analysis and is another reason why resort must always be made up to the surrounding text of the claims in question, the other claims, the written description and the prosecution history.”⁶⁵⁹ The court instructed that dictionary definitions “must always be compared against the use of the terms in context, and the intrinsic record must always be consulted to identify which of the different possible dictionary meanings is most consistent with the use of the words by the inventor.”⁶⁶⁰

The court found “no specific parameters as to the distance between the surgeon and patient, but [found that the written description] teaches generally that a surgeon using the disclosed assembly may operate without directly touching the patient . . . regardless of the extent of the physical separation between [them].”⁶⁶¹ Although the Federal Circuit conceded that the patent “contemplates that a principal use of the invention is to allow a surgeon to operate at some distance, possibly across the world, from the operating room in which the patient is located,”⁶⁶² it found that such an capability is only posited as an advantage and does not constitute “a limitation on the scope of the invention.”⁶⁶³ Accordingly, the court, relying on

654. *Id.* at 1304, 67 U.S.P.Q.2d (BNA) at 1140.

655. *Id.* at 1297, 67 U.S.P.Q.2d (BNA) at 1135.

656. *Id.*, 67 U.S.P.Q.2d (BNA) at 1135.

657. *Id.* at 1298, 67 U.S.P.Q.2d (BNA) at 1135.

658. *Id.* at 1299, 67 U.S.P.Q.2d (BNA) at 1136.

659. *Id.* at 1300, 67 U.S.P.Q.2d (BNA) at 1137.

660. *Id.*, 67 U.S.P.Q.2d (BNA) at 1137.

661. *Id.*, 67 U.S.P.Q.2d (BNA) at 1137.

662. *Id.* at 1301, 67 U.S.P.Q.2d (BNA) at 1138.

663. *Id.*, 67 U.S.P.Q.2d (BNA) at 1138.

dictionary definitions, construed the term “remote location” to “encompass not just locations that are ‘far apart’ or ‘distant,’ but also those locations that are merely ‘separated by intervals greater than usual; even if inside the operating room.’”⁶⁶⁴

Finally, the Federal Circuit also faulted the district court for consulting a number of references dated after the filing date:

They are not contemporaneous with the patent, do not reflect the meanings that would have been attributed to the words in dispute by persons of ordinary skill in the art as of the grant of the ‘003 patent, and for those reasons are not considered in our de novo claim construction analysis.⁶⁶⁵

In *Resonate Inc. v. Alteon Websystems, Inc.*,⁶⁶⁶ the Federal Circuit rejected the district court’s “level of detail” analysis⁶⁶⁷ and concluded that when a patent sets out novel solutions to two different problems in the prior art, it is not necessary for each claim to address both solutions.⁶⁶⁸

The patent-in-suit related to a website system used for handling client requests when accessing a website that uses a server farm.⁶⁶⁹ The specification described two problems with a prior art process for distributing client requests among multiple servers in the farm so that no single server was overloaded.⁶⁷⁰ In the prior art, a router was placed between the client and the servers to route all requests to a server.⁶⁷¹ The first problem identified with such a system was that each server had to maintain a complete copy of the website.⁶⁷² The second identified problem was that all data transfers had to go through the router, which could cause bottlenecks.⁶⁷³ The claimed invention pertained to a system that provided a solution to both of those problems, in part by permitting data transmitted from the server to the client to bypass the router and, in part, by distributing the website content among the servers.⁶⁷⁴

At issue was the proper construction of the phrase “transmitting the requested resource to the client.”⁶⁷⁵ The dispute centered on whether, as the district court had held, the phrase required the

664. *Id.* at 1302, 67 U.S.P.Q.2d (BNA) at 1138.

665. *Id.* at 1299, 67 U.S.P.Q.2d (BNA) at 1137.

666. 338 F.3d 1360, 67 U.S.P.Q.2d (BNA) 1771 (Fed. Cir. 2003).

667. *Id.* at 1365, 67 U.S.P.Q.2d (BNA) at 1775.

668. *Id.* at 1367, 67 U.S.P.Q.2d (BNA) at 1776-77.

669. *Id.* at 1361-62, 67 U.S.P.Q.2d (BNA) at 1772-73.

670. *Id.* at 1362-63, 67 U.S.P.Q.2d (BNA) at 1773.

671. *Id.* at 1362, 67 U.S.P.Q.2d (BNA) at 1773.

672. *Id.*, 67 U.S.P.Q.2d (BNA) at 1773.

673. *Id.* at 1363, 67 U.S.P.Q.2d (BNA) at 1773.

674. *Id.*, 67 U.S.P.Q.2d (BNA) at 1773.

675. *Id.* at 1364, 67 U.S.P.Q.2d (BNA) at 1774.

router to be bypassed.⁶⁷⁶ The district court based its analysis on the high level of detail of the other elements in the claim, including details of the relationship between the client, load balancer and server, concluding that if the requested data were to pass through the load balancer on its way to the client, the claim would have detailed that step as well.⁶⁷⁷ The court thus concluded that while the claim language at issue did not recite a router, the court could infer the patentee's intent to include the bypass of the router feature.⁶⁷⁸

The Federal Circuit began its claim construction inquiry with the ordinary meaning attributed to the words of the claim.⁶⁷⁹ The court then reviewed the specification to determine if the patentee's use of the term "transmitting" was consistent with the ordinary meaning.⁶⁸⁰ Finally, the court turned to the prosecution history to determine its relevance to claim construction.⁶⁸¹ The Federal Circuit concluded there was nothing in the claim language itself, "transmitting the requested resource to the client," that limited the path of transmission to bypass the router.⁶⁸²

The Federal Circuit criticized the district court's level of detail analysis, stating that "[c]ourts may not rewrite claim language based on what has been omitted from a claim."⁶⁸³ Although the preferred embodiment included the bypass feature, the court noted that limitations may not be read into a claim from a preferred embodiment "when the claim language is broader than that embodiment"⁶⁸⁴ and concluded the bypass feature was not included in the claim element at issue.⁶⁸⁵

Alteon argued that the claim required the bypass feature because the bypass was one of the main inventive features.⁶⁸⁶ The court disagreed, noting that where an invention includes two (or presumably more) inventive features, each feature need not be addressed in every claim.⁶⁸⁷ The court found the claim at issue was directed to the prior art problem of storing a copy of the website on each server, not to resolving the bottleneck problem.⁶⁸⁸

676. *Id.*, 67 U.S.P.Q.2d (BNA) at 1774.

677. *Id.* at 1365, 67 U.S.P.Q.2d (BNA) at 1775.

678. *Id.* at 1364, 67 U.S.P.Q.2d (BNA) at 1774.

679. *Id.*, 67 U.S.P.Q.2d (BNA) at 1774-75.

680. *Id.*, 67 U.S.P.Q.2d (BNA) at 1774.

681. *Id.* at 1364-65, 67 U.S.P.Q.2d (BNA) at 1775.

682. *Id.* at 1365, 67 U.S.P.Q.2d (BNA) at 1775.

683. *Id.*, 67 U.S.P.Q.2d (BNA) at 1775.

684. *Id.* at 1364-65, 67 U.S.P.Q.2d (BNA) at 1775.

685. *Id.* at 1368, 67 U.S.P.Q.2d (BNA) at 1777-78.

686. *Id.* at 1366, 67 U.S.P.Q.2d (BNA) at 1776.

687. *Id.* at 1367, 67 U.S.P.Q.2d (BNA) at 1776.

688. *Id.*, 67 U.S.P.Q.2d (BNA) at 1776-77.

In *RF Delaware, Inc. v. Pacific Keystone Technologies, Inc.*,⁶⁸⁹ the Federal Circuit reversed the claim construction of the district court,⁶⁹⁰ which the lower court had adopted in part from a claim construction ruling on partial summary judgment in previous litigation in which the plaintiff, RF Delaware (RFD), had asserted the same patents against a different defendant.⁶⁹¹ Pacific Keystone argued that regardless of the soundness of the district court's claim interpretation analysis, the prior district court's claim construction should be given collateral estoppel effect.⁶⁹² Because earlier action ended in an extra-judicial settlement, however, without complete adjudication even as to liability, the Federal Circuit (applying regional law to this purely procedural issue) rejected collateral estoppel as a defense.⁶⁹³ Citing Eleventh Circuit cases, the court held that "[c]ollateral estoppel does not apply in the present case because no judgment, much less final judgment, was ever entered in the Virginia district court case."⁶⁹⁴

Moreover, the Federal Circuit concluded that the district court "did not abuse its discretion in declining to hold RFD judicially estopped by its admission in a preliminary injunction proceeding that, in the context of that proceeding, the claim interpretation of the Virginia district court was binding."⁶⁹⁵ Among other things, the court observed, RFD did not succeed in urging its position (its motion for a preliminary injunction was denied), and the doctrine of judicial estoppel prevents only those who *successfully* urge a position from thereafter changing it.⁶⁹⁶

On appeal, the Federal Circuit found that the district court had improperly imported limitations from the specification and from narrower or dependent claims into the patents' broad, independent claims.⁶⁹⁷ Specifically, the Federal Circuit held that the district court erred in construing the claim terms "filter bed" and "first particle filter media" (as used in the asserted claims of the patents in suit, relating to the use and washing of an upflow filter in combination with upflow and downflow water filtration systems) unduly narrowly in limiting the claim to a system using multiple filter layers.⁶⁹⁸

689. 326 F.3d 1255, 66 U.S.P.Q.2d (BNA) 1593 (Fed. Cir. 2003).

690. *Id.* at 1268, 66 U.S.P.Q.2d (BNA) at 1602.

691. *Id.*, 66 U.S.P.Q.2d (BNA) at 1602.

692. *Id.* at 1260, 66 U.S.P.Q.2d (BNA) at 1596.

693. *Id.* at 1261, 66 U.S.P.Q.2d (BNA) at 1596.

694. *Id.*, 66 U.S.P.Q.2d (BNA) at 1596.

695. *Id.* at 1262, 66 U.S.P.Q.2d (BNA) at 1597.

696. *Id.*, 66 U.S.P.Q.2d (BNA) at 1597.

697. *Id.*, 66 U.S.P.Q.2d (BNA) at 1597.

698. *Id.*, 66 U.S.P.Q.2d (BNA) at 1597.

In *Prima Tek II, L.L.C. v. Polypap*,⁶⁹⁹ the Federal Circuit vacated the district court's grant of a summary judgment of non-infringement, finding that the district court construed the patent claims in question too narrowly.⁷⁰⁰

The patent-in-suit described a "Decorative Assembly for a Floral Grouping."⁷⁰¹ The district court construed the claim term "floral holding material" to be limited to "a three-dimensional solid, semi-solid, or granular material capable of giving support to individual flowers when their stems are inserted into the material."⁷⁰² The district court also required that the floral stems be "inserted into the floral holding material."⁷⁰³ Based on its construction, the district court found that the product at issue did not infringe the Prima Tek patent, either literally or under the doctrine of equivalents, because "the flowers and stem ends are not actually inserted into and through the actual plastic material of the cone."⁷⁰⁴

The Federal Circuit reversed, reasoning that the district court impermissibly read limitations into the claims from the specification.⁷⁰⁵

[N]either the phrase "inserted into" nor "inserted through" appears in any of the asserted claims. Instead, all of the claims at issue require that the "floral holding material" be constructed of "material capable of receiving a portion of the floral grouping and supporting the floral grouping without any pot means" The claim language does not require that the stem end of the flower be inserted into and through the floral holding material.⁷⁰⁶

The court rejected Polypap's attempt to limit the claim terms by reference to the written description and prosecution history that indicated that the "floral holding material" was either floral foam or soil.⁷⁰⁷ The Federal Court dismissed this argument as unpersuasive because the written description failed to "describe 'with reasonable clarity, deliberateness, and precision' the definition of 'floral holding material' proposed by Polypap."⁷⁰⁸ The Federal Circuit pointed out that the written description only stated that the floral holding

699. 318 F.3d 1143, 65 U.S.P.Q.2d (BNA) 1818 (Fed. Cir. 2003).

700. *Id.* at 1154, 65 U.S.P.Q.2d (BNA) at 1825-26.

701. *Id.* at 1145, 65 U.S.P.Q.2d (BNA) at 1819.

702. *Id.* at 1147, 65 U.S.P.Q.2d (BNA) at 1820.

703. *Id.*, 65 U.S.P.Q.2d (BNA) at 1820.

704. *Id.*, 65 U.S.P.Q.2d (BNA) at 1820.

705. *Id.* at 1149, 65 U.S.P.Q.2d (BNA) at 1822.

706. *Id.*, 65 U.S.P.Q.2d (BNA) at 1822.

707. *Id.*, 65 U.S.P.Q.2d (BNA) at 1822.

708. *Id.* at 1150, 65 U.S.P.Q.2d (BNA) at 1823 (citation omitted).

material “‘may be’ (not *must* be)” foam or soil.⁷⁰⁹ “[I]ndeed the many uses of the term throughout the ‘856 patent are consistent with a broader definition, one encompassing material of any shape or type.”⁷¹⁰

Citing the general rule “that claims of a patent are not limited to the preferred embodiment, unless by their own language,”⁷¹¹ the Federal Circuit noted that the written description used the term “floral holding material” at various points to refer to material of any shape or type, and that no “special and particular definition” had been created.⁷¹² Thus, the court found no reason to depart from the general rule.⁷¹³ The court also concluded “that the prosecution history does not attribute a special meaning to the phrase ‘floral holding material,’ as there were no express representations made in obtaining the patent regarding the scope and meaning of the claim terms.”⁷¹⁴

In *Combined Systems, Inc. v. Defense Technology Corp. of America*,⁷¹⁵ the Federal Circuit affirmed the district court’s ruling of summary judgment of non-infringement, construing a claim directed to a method of making a low lethality projectile based on the syntax used in the claim, as informed by the context of the specification.⁷¹⁶

Combined Systems, Inc. (CSI) sued Defense Technology Corporation of America (DTCA) for infringement of its patent directed to a method of shaping projectiles so that they are less likely to kill persons upon impact.⁷¹⁷ Claim 1 recited in part the steps of “forming folds in [the rear of a] tubular sock-like projectile body” after filling the projectile body with some amount of lead shot and “inserting said formed folds” into the open end of a projectile compartment (*i.e.*, an empty shotgun shell).⁷¹⁸

The district court construed the “forming folds” limitation to require “the deliberate and systematic creation of folds.”⁷¹⁹ The court looked to the ordinary meaning of the term “inserting said formed folds” to conclude that the folds “are formed prior to—not during—

709. *Id.*, 65 U.S.P.Q.2d (BNA) at 1823.

710. *Id.*, 65 U.S.P.Q.2d (BNA) at 1823.

711. *Id.* at 1151, 65 U.S.P.Q.2d (BNA) at 1823.

712. *Id.*, 65 U.S.P.Q.2d (BNA) at 1823.

713. *Id.*, 65 U.S.P.Q.2d (BNA) at 1823.

714. *Id.*, 65 U.S.P.Q.2d (BNA) at 1823.

715. 350 F.3d 1207, 68 U.S.P.Q.2d (BNA) 1933 (Fed. Cir. 2003).

716. *Id.* at 1215-16, 68 U.S.P.Q.2d (BNA) at 1939.

717. *Id.* at 1208, U.S.P.Q.2d (BNA) at 1934.

718. *Id.*, 68 U.S.P.Q.2d (BNA) at 1934.

719. *Id.* at 1209, 68 U.S.P.Q.2d (BNA) at 1934 (quotations omitted).

insertion in the empty shotgun shell.”⁷²⁰ Because DTCA’s manufacturing process did not create folds prior to the insertion of the projectile into the shell, but rather only during insertion, the district court granted DTCA a motion for summary judgment of non-infringement.⁷²¹ The district court also found that DTCA’s folds were not formed in a “systematic or deliberate matter,”⁷²² but were merely a consequence of inserting the projectile into the shell.⁷²³

In affirming the district court’s decision, the Federal Circuit held as a matter of grammar that the recitation of “‘inserting said formed folds . . . into said projectile compartment’ forecloses a construction permitting the ‘folds’ to be formed after or during insertion.”⁷²⁴ The Federal Circuit dismissed CSI’s argument that the “forming folds” limitation should be construed to include “gathers in the material that incidentally occur” when the sock-like body is closed using a tie or a pull-string.⁷²⁵ The court held that the affirmative recitation of “forming folds” as a step in the claimed process was consistent with the lower court’s determination that when the claim limitation was read in the context of the entire specification, the claim required the “deliberate” forming of folds.⁷²⁶

In response to CSI’s contention that the district court erred in its use of a dictionary definition of “fold” in its claim construction analysis, the Federal Circuit stated that if the lower court “relied exclusively on a dictionary definition or allowed it to overcome clear language in the patent itself, its methodology (although not necessarily its conclusion) would have been wrong.”⁷²⁷ The court further noted that the specification should not be consulted “solely for the limited purpose of determining whether it contradicts the dictionary meaning of a claim term.”⁷²⁸ Rather, “the written description must be examined in every case, because it is relevant not only to aid in the claim construction analysis, but also to determine if the presumption of ordinary and customary meaning is rebutted.”⁷²⁹

The Federal Circuit still defers to the specification, however, when it provides a specific definition of the claim term in question.⁷³⁰ In

720. *Id.*, 68 U.S.P.Q.2d (BNA) at 1935 (quotations omitted).

721. *Id.*, 68 U.S.P.Q.2d (BNA) at 1935.

722. *Id.*, 68 U.S.P.Q.2d (BNA) at 1935 (quotations omitted).

723. *Id.*, 68 U.S.P.Q.2d (BNA) at 1935.

724. *Id.* at 1211-12, 68 U.S.P.Q.2d (BNA) at 1937 (citation omitted).

725. *Id.* at 1214, 68 U.S.P.Q.2d (BNA) at 1938.

726. *Id.*, 68 U.S.P.Q.2d (BNA) at 1938.

727. *Id.* at 1215, 68 U.S.P.Q.2d (BNA) at 1939.

728. *Id.* at 1215-16, 68 U.S.P.Q.2d (BNA) at 1939.

729. *Id.* at 1216, 68 U.S.P.Q.2d (BNA) at 1939.

730. *See, e.g.,* Abbott Labs. v. Novopharm Ltd., 323 F.3d 1324, 1330, 66 U.S.P.Q.2d

Abbott Laboratories v. Novopharm Limited,⁷³¹ the Federal Circuit affirmed a grant of summary judgment, finding that a generic fenofibrate composition did not infringe Abbott Laboratories' patent for a therapeutic fenofibrate composition sold under the brand name Tricor and used to treat high cholesterol.⁷³² Novopharm filed an Abbreviated New Drug Application (ANDA), seeking U.S. Food and Drug Administration (FDA) approval to market a generic micronized formulation of fenofibrate before the expiration of Abbott's patent.⁷³³ Novopharm argued to the FDA that its proposed formulation would not infringe the Abbott patent.⁷³⁴ Abbott sued for infringement, seeking to stay FDA approval.⁷³⁵ In granting summary judgment of non-infringement to Novopharm, the district court construed the claim term "co-micronization" to require micronization of fenofibrate and a solid surfactant "in the absence of other excipients."⁷³⁶ Novopharm argued that its process did not include micronization of fenofibrate and a solid surfactant.⁷³⁷ Abbott appealed.⁷³⁸

The Federal Circuit, while observing that the ordinary meaning of the term "co-micronization" did not necessarily exclude the presence of ingredients not specifically recited in the claim, nevertheless found that by explicitly defining the term "co-micronization" as "micronization of an intimate mixture of fenofibrate and a solid surfactant," the inventor had "chosen to be his own lexicographer."⁷³⁹ Accordingly, the court found that claims at issue require co-micronization of a mixture consisting essentially of only fenofibrate and a solid surfactant.⁷⁴⁰ "Had that term not been explicitly defined in the . . . patent specification, we might well agree with the appellants that that term . . . would not necessarily exclude the presence of ingredients not specifically recited in the claim."⁷⁴¹ Since it is undisputed that fenofibrate and a solid surfactant are not mixed in Novopharm's process without the presence of other significant

(BNA) 1200, 1205 (Fed. Cir. 2003).

731. *Id.* at 1324, 66 U.S.P.Q.2d (BNA) at 1200.

732. *Id.* at 1325-26, 66 U.S.P.Q.2d (BNA) at 1201.

733. *Id.* at 1326, 66 U.S.P.Q.2d (BNA) at 1201.

734. *Id.*, 66 U.S.P.Q.2d (BNA) at 1201.

735. *Id.*, 66 U.S.P.Q.2d (BNA) at 1201-02.

736. *Id.* at 1328, 66 U.S.P.Q.2d (BNA) at 1202. Micronization is the process of reducing something to particles of only a few microns in diameter. DORLAND'S MEDICAL DICTIONARY 1112 (29th ed. 2000). An excipient is an inert substance used as a vehicle for a drug. *Id.* at 631.

737. *Abbott*, 323 F.3d at 1328, 66 U.S.P.Q.2d (BNA) at 1203.

738. *Id.* at 1329, 66 U.S.P.Q.2d (BNA) at 1204.

739. *Id.* at 1330, 66 U.S.P.Q.2d (BNA) at 1205.

740. *Id.*, 66 U.S.P.Q.2d (BNA) at 1205.

741. *Id.*, 66 U.S.P.Q.2d (BNA) at 1205.

ingredients, the Federal Circuit held that “there is no genuine issue of material fact as to literal infringement in this case.”⁷⁴²

The Federal Circuit also affirmed the finding of no infringement under the doctrine of equivalents, noting particularly that the process described in Novopharm’s ANDA did not include any step in which fenofibrate and a solid surfactant were present in a mixture, irrespective of the presence or absence of other excipients.⁷⁴³ The Federal Circuit concluded that holding otherwise would vitiate the claim limitation altogether, in contravention of the all-elements rule, which requires all claim elements to be either literally or equivalently present in the infringing product or process before infringement will be found.⁷⁴⁴

C. *The Prosecution History—Need for “Clear and Unmistakable” Surrender*

This past year, the Federal Circuit limited the scope of the claims based upon the prosecution history only in the rarest of circumstances. In *Omega Engineering, Inc. v. Raytek Corp.*,⁷⁴⁵ the Federal Circuit held that the doctrine of prosecution disclaimer may only be used to narrow the ordinary meaning of a patent claim based on statements during prosecution if the allegedly disavowing statements or actions are “clear and unmistakable.”⁷⁴⁶

Omega Engineering involved three patents that disclosed a laser sighting system used to target infrared thermometer scans.⁷⁴⁷ The district court’s claim construction analysis focused on language in the patents describing the use of lasers to *outline* a target energy zone.⁷⁴⁸ The district court read the means-plus-function claim language directed to this feature to exclude targeting that involved a laser beam that struck *inside* the target energy zone.⁷⁴⁹ The district court’s claim construction rested heavily on the application of the doctrine of prosecution disclaimer.⁷⁵⁰ The lower court found that the plaintiff had made numerous statements during the prosecution of the patents in suit that narrowed the scope of the disputed claims.⁷⁵¹ Based on its narrowed claim construction, the district court granted

742. *Id.*, 66 U.S.P.Q.2d (BNA) at 1205.

743. *Id.* at 1331, 66 U.S.P.Q.2d (BNA) at 1205-06.

744. *Id.*, 66 U.S.P.Q.2d (BNA) at 1206.

745. 334 F.3d 1314, 67 U.S.P.Q.2d (BNA) 1321 (Fed. Cir. 2003).

746. *Id.* at 1325-26, 67 U.S.P.Q.2d (BNA) at 1329.

747. *Id.* at 1317-18, 67 U.S.P.Q.2d (BNA) at 1322-23.

748. *Id.* at 1318-19, 67 U.S.P.Q.2d (BNA) at 1323-24.

749. *Id.* at 1322, 67 U.S.P.Q.2d (BNA) at 1326.

750. *Id.* at 1321-23, 1327, 67 U.S.P.Q.2d (BNA) at 1326-27, 1330.

751. *Id.* at 1319-20, 67 U.S.P.Q.2d (BNA) at 1324.

summary judgment of non-infringement and, in the alternative, granted summary judgment invalidating two of the disputed claims.⁷⁵²

The Federal Circuit reversed and remanded.⁷⁵³ In a panel decision authored by Judge Clevinger, the court acknowledged the general rule that “where the patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender.”⁷⁵⁴ However, the court held that the doctrine of prosecution disclaimer does not apply “where the alleged disavowal of claim scope is ambiguous.”⁷⁵⁵

Rather, the court explained that the doctrine of prosecution disclaimer requires that the defendant demonstrate a “clear and unmistakable disclaimer,” reasoning that such a disclaimer is necessary to maintain the balance between the need for adequate public notice and the right to seek broad patent coverage.⁷⁵⁶ The court noted in a footnote that “this is the same standard applicable, in the context of the doctrine of equivalents, to the doctrine of argument-based estoppel. . . .”⁷⁵⁷

The Federal Circuit then found that the district court had mistakenly used a number of ambiguous statements in the prosecution history to narrow the scope of the patents in suit.⁷⁵⁸ The court also held that after the erroneous claims construction had been corrected, triable issues of material fact remained, and thus reversed and remanded for further proceedings.⁷⁵⁹ *Cordis Corp. v. Medtronic Ave, Inc.*,⁷⁶⁰ presents another example of the Federal Circuit’s reluctance to limit the scope of the claims based on the prosecution history.⁷⁶¹

In *Rambus Inc. v. Infineon Technologies AG*,⁷⁶² the Federal Circuit ruled, over vigorous dissent, that the plain meaning of a claim trumps even directly inaccurate remarks in a patent’s prosecution history

752. *Id.* at 1320, 67 U.S.P.Q.2d (BNA) at 1324.

753. *Id.* at 1336, 67 U.S.P.Q.2d (BNA) 1321, 1337.

754. *Id.* at 1324, 67 U.S.P.Q.2d (BNA) at 1328.

755. *Id.*, 67 U.S.P.Q.2d (BNA) at 1327.

756. *Id.* at 1325-26, 67 U.S.P.Q.2d (BNA) at 1328-29.

757. *Id.* at 1326 n.1, 67 U.S.P.Q.2d (BNA) at 1329 n.1.

758. *Id.* at 1330, 67 U.S.P.Q.2d (BNA) at 1332.

759. *Id.* at 1328-29, 67 U.S.P.Q.2d (BNA) at 1331.

760. 339 F.3d 1352, 67 U.S.P.Q.2d (BNA) 1876 (Fed. Cir. 2003).

761. *Id.* at 1363, 67 U.S.P.Q.2d (BNA) at 1884 (holding that to invoke argument-based estoppel, as the infringer in this case attempted to do, a patent’s prosecution history must evince a clear and unmistakable surrender of the subject matter at issue, which the court could not find in this case).

762. 318 F.3d 1081, 65 U.S.P.Q.2d (BNA) 1705 (Fed. Cir. 2003).

statement⁷⁶³ and that withholding information concerning one's own patent portfolio from others in a standard-setting body is not necessarily actionable fraud.⁷⁶⁴

When adding certain claims during the prosecution of the patent in suit, the patent attorney representing Rambus characterized the claims as all containing particular limitations.⁷⁶⁵ In fact, the wording of the claims themselves made clear that only one of the several newly offered claims contained each of the recited limitations.⁷⁶⁶ In construing the claims, however, the district court accepted Infineon's invitation to read the missing limitations into the claims based on the patent attorney's representations to the PTO.⁷⁶⁷ Based on the claim construction, the district court entered a judgment of non-infringement.⁷⁶⁸

The Federal Circuit held that the district court erred in adopting a claim construction inconsistent with the plain meaning of the claim language, the attorney argument during prosecution notwithstanding: "The claim language itself controls the bounds of the claim, not a facially inaccurate remark during prosecution."⁷⁶⁹ In a heavily criticized observation,⁷⁷⁰ the majority noted its belief that "a reasonable competitor would not rely on an untrue statement in the prosecution history over the express terms of the claims."⁷⁷¹

Similarly, in *Storage Technology Corp. v. Cisco Systems, Inc.*,⁷⁷² the Federal Circuit reversed a district court's narrow claim construction, noting that an applicant's inaccurate statement about its pending claims does not override the claim language as issued.⁷⁷³

The Storage Technology patent related to the efficient enforcement of network policies in a high-speed packet data network.⁷⁷⁴ As the court summarized:

763. *Id.* at 1090, 65 U.S.P.Q.2d (BNA) at 1711.

764. *Id.* at 1084, 65 U.S.P.Q.2d (BNA) at 1706.

765. *Id.* at 1089-90, 65 U.S.P.Q.2d (BNA) at 1710-11.

766. *Id.* at 1088, 65 U.S.P.Q.2d (BNA) at 1709.

767. *Id.*, 65 U.S.P.Q.2d (BNA) at 1709 (considering Infineon's alternate meaning of the term "integrated circuit device" based upon representations made during patent prosecution and upon the principle that "inventors may act as their own lexicographers" and supply alternate meanings to terms).

768. *Id.*, 65 U.S.P.Q.2d (BNA) at 1709.

769. *Id.* at 1090, 65 U.S.P.Q.2d (BNA) at 1711.

770. *See id.* at 1115, 65 U.S.P.Q.2d (BNA) at 1730 (Prost, J., dissenting in part) (accusing the majority of ignoring the broad disclosure duty set out in a standard-setting body's policy manual upon which a competitor-member of the body might reasonably rely).

771. *Id.* at 1090, 65 U.S.P.Q.2d (BNA) at 1711.

772. 329 F.3d 823, 66 U.S.P.Q.2d (BNA) 1545 (Fed. Cir. 2003).

773. *Id.* at 832, 66 U.S.P.Q.2d (BNA) at 1551.

774. *Id.* at 826, 66 U.S.P.Q.2d (BNA) at 1546-47.

In the system described in the patent, network policy information that is used frequently by the processor is stored in cache memory for easy and fast accessibility. A processor in a network device implementing the invention examines the header of an arriving packet to determine whether, based on selection criteria, it is related to other packets that have been received.⁷⁷⁵

The district court construed the claim limitation “network policy” to mean “a filtering or auditing rule, which determines if and why a PDU (Protocol Data Unit) should be forwarded.”⁷⁷⁶ The district court also construed the step of “caching policy identification information” to mean “storing information that identifies and is used to retrieve a separately cached instance of network policy.”⁷⁷⁷ Thus, as construed by the district court, the claims required two caches: “one for storing information identifying a policy, and a second for storing a copy of the policy itself.”⁷⁷⁸ On the basis of that claim construction, the district court found no literal infringement.⁷⁷⁹

StorageTek appealed, challenging the district court’s construction of the “caching policy identification information” and “protocol data unit (PDU) network policy” claim limitations.⁷⁸⁰ The Federal Circuit first noted that the claim at issue was “a method claim with two steps—determining an instance of network policy to be applied to related PDUs based on the contents of one PDU, and caching policy identification information identifying that instance of network policy.”⁷⁸¹ In other words, the court found that the plain language of the claim did not “include any step relating to caching the instance of network policy or any limitation indicating that the instance of the network policy is stored in or retrieved from a cache.”⁷⁸²

As viewed by the Federal Circuit, the district court erred by considering the phrase “policy caching method,” or “policy cache,” found in the preamble of the independent claims, to be a claims limitation.⁷⁸³ The court determined that the written description and claims simply use the terms “policy caching method” and “policy cache” to “refer to the invention as a whole, not to the specific step of

775. *Id.* at 826-27, 66 U.S.P.Q.2d (BNA) at 1547.

776. *Id.* at 828, 66 U.S.P.Q.2d (BNA) at 1548.

777. *Id.* at 828, 66 U.S.P.Q.2d (BNA) at 1548.

778. *Id.* at 828, 66 U.S.P.Q.2d (BNA) at 1548.

779. *Id.* at 829, 66 U.S.P.Q.2d (BNA) at 1548-49.

780. *Id.* at 830, 66 U.S.P.Q.2d (BNA) at 1549.

781. *Id.*, 66 U.S.P.Q.2d (BNA) at 1550.

782. *Id.*, 66 U.S.P.Q.2d (BNA) at 1550.

783. *Id.* at 831, 66 U.S.P.Q.2d (BNA) at 1550.

storing an instance of network policy or the cache that stores the instance of network policy.”⁷⁸⁴

The Federal Circuit also admonished the district court for relying on the written description, prosecution history and a declaration by Cisco’s expert witness in limiting the claims to a cache for the instance of network policy.⁷⁸⁵ “In so doing, the district court disregarded the well-established rule that while proper claim construction requires an examination of the written description and relevant prosecution history to determine the meaning of claim limitations, additional limitations may not be read into the claims.”⁷⁸⁶

Finally, the court noted that during prosecution “the patent applicants stated that the invention as recited in [the claims], the instance of network policy and the policy identification information are both cached.”⁷⁸⁷ The court conceded that “on its face this statement appears to limit claim scope.”⁷⁸⁸ However, citing to its recent *Rambus* decision, the Federal Circuit held that such a statement was not alone limiting.⁷⁸⁹ Rather, the court found the statement from the prosecution history “erroneously suggests that the independent claims include a cache for the instance of network policy. The applicants’ inaccurate statement cannot override the claim language itself, which controls the bounds of the claim.”⁷⁹⁰

In *Abbott Laboratories v. Baxter Pharmaceuticals, Inc.*,⁷⁹¹ the Federal Circuit reversed a finding of non-infringement based on its conclusion that the district court had improperly construed the terms “amount effective” and “amount sufficient.”⁷⁹²

Abbott had accused Baxter of infringement of its patent directed to an anesthetic composition containing a sevoflurane and a Lewis acid inhibitor such as water in an amount effective to prevent degradation by a Lewis acid of the sevoflurane compound.⁷⁹³

During prosecution of the patent, Abbott filed an Information Disclosure Statement (IDS) containing a reference indicating that at least one year before the filing date of the patent, “Abbott sold sevoflurane in glass bottles with a water content up to 131 ppm.”⁷⁹⁴

784. *Id.*, 66 U.S.P.Q.2d (BNA) at 1550.

785. *Id.*, 66 U.S.P.Q.2d (BNA) at 1550.

786. *Id.*, 66 U.S.P.Q.2d (BNA) at 1550.

787. *Id.* at 832, 66 U.S.P.Q.2d (BNA) at 1551.

788. *Id.*, 66 U.S.P.Q.2d (BNA) at 1551.

789. *Id.*, 66 U.S.P.Q.2d (BNA) at 1551.

790. *Id.*, 66 U.S.P.Q.2d (BNA) at 1551.

791. 334 F.3d 1274, 67 U.S.P.Q.2d (BNA) 1191 (Fed. Cir. 2003).

792. *Id.* at 1276-77, 67 U.S.P.Q.2d (BNA) at 1192-93.

793. *Id.* at 1276, 67 U.S.P.Q.2d (BNA) at 1192-93.

794. *Id.* at 1277, 67 U.S.P.Q.2d (BNA) at 1193.

Based on that IDS “admission,” Baxter asserted that its generic sevoflurane, with a water content of no more than 130 ppm, fell within the prior art and, therefore, did not infringe the patent.⁷⁹⁵ The district court agreed and construed the claim terms “amount effective” and “amount sufficient” to mean amounts above 131 ppm of water.⁷⁹⁶ Based on this claim construction, the district court granted summary judgment of non-infringement, finding that the prior sale of sevoflurane by Abbott surrendered the subject matter of the sale.⁷⁹⁷

The Federal Circuit disagreed, stating that the fundamental issue was the construction of the term “effective amount,” a term that the court stated has a customary usage.⁷⁹⁸ In light of the term’s customary usage, the court construed “effective amount” to mean “the amount of Lewis acid inhibitor that will prevent the degradation of sevoflurane by a Lewis acid.”⁷⁹⁹ The Federal Circuit reasoned that the specification taught that “an effective amount of any given Lewis acid inhibitor will vary depending upon the conditions to which sevoflurane is subjected.”⁸⁰⁰

As noted by the court, the term “effective amount” was broadly described in the “Summary of the Invention” as an “effective stabilizing amount of Lewis Acid inhibitor” that “prevents the degradation of the fluoroether compound by a Lewis acid.”⁸⁰¹ Therefore, the Federal Circuit stated that the specification supported the concept that “the amount of Lewis acid inhibitor depends on many environmental considerations.”⁸⁰²

Finally, the Federal Circuit found that the district court incorrectly viewed the IDS as a limitation on the term “effective amount.”⁸⁰³ According to the Federal Circuit, “simply disclosing a previous sale of sevoflurane” in an IDS, “without saying or doing anything more, did not disavow or relinquish all water concentrations below 131 ppm”⁸⁰⁴ because the patent disclosed that “the effective amount of Lewis acid inhibitor depends on the specific storage conditions of the sevoflurane.”⁸⁰⁵ The court also stated that the “mere submission of an

795. *Id.*, 67 U.S.P.Q.2d (BNA) at 1193.

796. *Id.*, 67 U.S.P.Q.2d (BNA) at 1193.

797. *Id.*, 67 U.S.P.Q.2d (BNA) at 1193-94.

798. *Id.*, 67 U.S.P.Q.2d (BNA) at 1194.

799. *Id.*, 67 U.S.P.Q.2d (BNA) at 1194.

800. *Id.* at 1278, 67 U.S.P.Q.2d (BNA) at 1194.

801. *Id.*, 67 U.S.P.Q.2d (BNA) at 1194.

802. *Id.*, 67 U.S.P.Q.2d (BNA) at 1194.

803. *Id.* at 1279, 67 U.S.P.Q.2d (BNA) at 1195.

804. *Id.*, 67 U.S.P.Q.2d (BNA) at 1195.

805. *Id.*, 67 U.S.P.Q.2d (BNA) at 1195.

IDS to the [Patent Office] does not constitute the patent applicant's admission that any reference in the IDS is material prior art."⁸⁰⁶

In *Invitrogen Corp. v. BioCrest Manufacturing, L.P.*,⁸⁰⁷ the Federal Circuit reversed summary judgment of noninfringement after finding error in the district court's construction.⁸⁰⁸ The asserted patent was directed to a process for producing transformable *E. coli* cells of improved competence.⁸⁰⁹ The claimed process required performance of three steps in a specific order, including the step of rendering said *E. coli* cells competent after growing the cells in a medium at temperature in the range of 18 to 32°C.⁸¹⁰ BioCrest made and sold competent *E. coli* cell lines using a process that includes "incubating" the cells at 37°C and then growing the cells in a fermenter at 26°C.⁸¹¹

During prosecution, the PTO examiner stated that the claimed range of 18 to 32°C was essential to the invention.⁸¹² The applicants then amended the claims to add the language "*improved competence*"⁸¹³ to the preamble and to replace the originally recited open range of "*less than 37°C*" with "*18 to 32°C*" and argued that the amendment distinguished the claimed invention from prior art that showed growth at 37°C.⁸¹⁴

The district court construed the claim to require that cell "growth must be performed at a temperature within 18 to 32°C"⁸¹⁵ and rejected Invitrogen's argument that the open-ended transition term "comprising" in the preamble permitted coverage over a process with an additional step of growing cells at 37°C before the step of growing cells in the recited range.⁸¹⁶

The Federal Circuit reversed, finding that the claim did not preclude additional steps, such as the defendant's incubation step, before or after the recited steps. Specifically, the court found that the transitional term "comprising" opened the claim to additional, unrecited steps and did not preclude growth by incubation at 37°C in advance of the first step.⁸¹⁷

806. *Id.*, 67 U.S.P.Q.2d (BNA) at 1195.

807. 327 F.3d 1364, 66 U.S.P.Q.2d (BNA) 1631 (Fed. Cir. 2003).

808. *Id.* at 1366, 66 U.S.P.Q.2d (BNA) at 1632.

809. *Id.*, 66 U.S.P.Q.2d (BNA) at 1632.

810. *Id.*, 66 U.S.P.Q.2d (BNA) at 1632.

811. *Id.*, 66 U.S.P.Q.2d (BNA) at 1632.

812. *Id.* at 1368, 66 U.S.P.Q.2d (BNA) at 1633.

813. *Id.* at 1370, 66 U.S.P.Q.2d (BNA) at 1635.

814. *Id.* at 1368, 66 U.S.P.Q.2d (BNA) at 1633.

815. *Id.* at 1367-68, 66 U.S.P.Q.2d (BNA) at 1633 (citation omitted).

816. *Id.* at 1368, 66 U.S.P.Q.2d (BNA) at 1633.

817. *Id.*, 66 U.S.P.Q.2d (BNA) at 1633-34.

Also, the Federal Circuit noted that the district court's claim construction would exclude an embodiment set forth in an example, a construction that is "rarely, if ever correct and [that] would require highly persuasive evidentiary support" not found here.⁸¹⁸

Finally, the Federal Circuit found that the district court claim construction improperly ignored the "improved competence" language in the preamble: "[C]lear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention."⁸¹⁹ Here, the court found that the term "improved competence" should have been construed "to require at least a ten-fold competence increase" over the prior art method.⁸²⁰

In a pair of related cases, *Inverness Medical Switzerland GmbH v. Warner Lambert Co.*⁸²¹ and *Inverness Medical Switzerland GmbH v. Princeton Biomeditech Corp.*,⁸²² the Federal Circuit again emphasized that it will not limit claim terms by the specification⁸²³ and that prosecution history must be unambiguous to be limiting.⁸²⁴

The appeals arose from two cases Inverness filed against Warner Lambert and Princeton for infringement of three patents directed toward a pregnancy-testing device using a strip of porous material that facilitated a chemical reaction between a reagent, proteins found in urine, and a colored label.⁸²⁵ After the district court granted each of the defendants summary judgment of non-infringement, Inverness appealed.⁸²⁶ In separate opinions, the Federal Circuit vacated the judgments.⁸²⁷

In *Princeton*, the district court based its summary judgment of non-infringement on its construction of the claim limitation "wherein

818. *Id.* at 1369, 66 U.S.P.Q.2d (BNA) at 1634 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583, 39 U.S.P.Q.2d (BNA) 1573, 1578 (Fed. Cir. 1996)) (quotations omitted).

819. *Id.* at 1370, 66 U.S.P.Q.2d (BNA) at 1635 (quoting *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808-09, 62 U.S.P.Q.2d (BNA) 1781, 1785 (Fed. Cir. 2002) (citation omitted)).

820. *Id.*, 66 U.S.P.Q.2d (BNA) at 1635.

821. 309 F.3d 1373, 64 U.S.P.Q.2d (BNA) 1933 (Fed. Cir. 2002).

822. 309 F.3d 1365, 64 U.S.P.Q.2d (BNA) 1926 (Fed. Cir. 2002).

823. *Warner Lambert Co.*, 309 F.3d at 1379, 64 U.S.P.Q.2d (BNA) at 1937; *Princeton Biomeditech Corp.*, 309 F.3d at 1371, 64 U.S.P.Q.2d (BNA) at 1931.

824. *Warner Lambert Co.*, 309 F.3d at 1382, 64 U.S.P.Q.2d (BNA) at 1939; *Princeton Biomeditech Corp.*, 309 F.3d at 1373, 64 U.S.P.Q.2d (BNA) at 1932.

825. *Warner Lambert Co.*, 309 F.3d at 1376-77, 64 U.S.P.Q.2d (BNA) at 1935; *Princeton Biomeditech Corp.*, 309 F.3d at 1367-68, 64 U.S.P.Q.2d (BNA) at 1928-29.

826. *Warner Lambert Co.*, 309 F.3d at 1377, 64 U.S.P.Q.2d (BNA) at 1935; *Princeton Biomeditech Corp.*, 309 F.3d at 1368, 64 U.S.P.Q.2d (BNA) at 1929.

827. *Warner Lambert Co.*, 309 F.3d at 1382, 64 U.S.P.Q.2d (BNA) at 1939; *Princeton Biomeditech Corp.*, 309 F.3d at 1373, 64 U.S.P.Q.2d (BNA) at 1932.

mobility of said labeled reagent within said test strip is facilitated by . . . a material comprising a sugar.”⁸²⁸ The court found that the limitation required a sugar that improved mobility of the reagent at the point of its release from the test strip (*i.e.*, when the reagent comes into contact with urine), which did not occur in the Princeton product.⁸²⁹ Inverness argued on appeal that the facilitation of mobility could occur either at the time of release or during subsequent transit of the reagent.⁸³⁰

Based on the dictionary definition and the discussion in the patents, the Federal Circuit found that “mobility” of the reagent referred to both the point-of-release from the test strip as well as post-release, and the use of the term “mobility” in other claims contradicted Princeton’s construction.⁸³¹

In the *Warner Lambert* appeal, the same argument was presented regarding the term “mobility.”⁸³² Warner Lambert also argued that the claim limitations “said labeled reagent is dry *on* said test strip” and “drying said labeled reagent *onto* a portion of said test strip” required surface disposition of the reagent, which was not present in its product.⁸³³ Inverness argued that the phrases “on” and “onto” should be more broadly construed to include disposition of the labeled reagent within the test strip.⁸³⁴

The Federal Circuit noted the dictionary definitions of “on” and “onto” were identical and, unless limited by the specification or prosecution history, could refer to either a surface location or a presence within the test strip: “a word that has an ordinary meaning encompassing two relevant alternatives may be construed to encompass both alternatives.”⁸³⁵ The court then looked to the specification, which only discussed a *surface* application of the reagent, but found this to only be a preferred embodiment that did not preclude the claims from encompassing a test strip containing the reagent within its inner layers.⁸³⁶ Next, the court addressed the prosecution history of the patents.⁸³⁷ Warner Lambert argued that Inverness had amended its claims using the “on/onto” language in

828. *Princeton Biomeditech Corp.*, 309 F.3d at 1368, 64 U.S.P.Q.2d (BNA) at 1929.

829. *Id.* at 1368-69, 64 U.S.P.Q.2d (BNA) at 1929.

830. *Id.* at 1369, 64 U.S.P.Q.2d (BNA) at 1930.

831. *Id.* at 1369-73, 64 U.S.P.Q.2d (BNA) at 1930-32.

832. *Warner Lambert Co.*, 309 F.3d at 1377, 64 U.S.P.Q.2d (BNA) at 1939.

833. *Id.* at 1376, 64 U.S.P.Q.2d (BNA) at 1935.

834. *Id.* at 1377-78, 64 U.S.P.Q.2d (BNA) at 1935-36.

835. *Id.* at 1379, 64 U.S.P.Q.2d (BNA) at 1937 (citing *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1343, 60 U.S.P.Q.2d (BNA) 1851, 1855 (Fed. Cir. 2001)).

836. *Id.*, 64 U.S.P.Q.2d (BNA) at 1937.

837. *Id.* at 1379-80, 64 U.S.P.Q.2d (BNA) at 1937.

response to the examiner's finding that that scope of enablement was limited to surface application of the labeled reagent.⁸³⁸ Inverness argued that the examiner also had invited it to show that the prior art recognized alternative means, other than surface application, of providing mobilization.⁸³⁹ The Federal Circuit acknowledged that "failure to object to an examiner's interpretation of a claim ordinarily disclaims a broader interpretation" but found that was not the case here.⁸⁴⁰ Rather, the Federal Circuit found that it was not clear from the prosecution history whether the patentee had foreclosed the broader dictionary definition (which encompassed both surface application and internal positioning of sugar) in response to the examiner's rejection.⁸⁴¹ Thus, the court stated that it would be "inappropriate to limit broad definition of a claim term based on prosecution history that is itself ambiguous."⁸⁴²

The Federal Circuit's reluctance to rely upon the prosecution history worked both ways, however there was still the occasional exception to the rule. In *Biogen, Inc. v. Berlex Laboratories, Inc.*,⁸⁴³ a case involving an attempt to rely on the prosecution history to enlarge (rather than revisit) the claims,⁸⁴⁴ the Federal Circuit substantially upheld a district court's decision that Berlex's patent claims did not cover Biogen's method of making the multiple sclerosis drug AVONEX.⁸⁴⁵ The court noted that "[r]epresentations during prosecution cannot enlarge the content of the specification. . . ."⁸⁴⁶

Biogen and Berlex Laboratories make competing formulations of a genetically engineered protein (human β -interferon) for the treatment of multiple sclerosis.⁸⁴⁷ Berlex's BETASERON is produced in bacteria, while Biogen's AVONEX is produced in cultured mammalian cells.⁸⁴⁸ As a result, BETASERON and AVONEX differ in their sugar attachments and in a minor amino acid sequence

838. *Id.* at 1380, 64 U.S.P.Q.2d (BNA) at 1937.

839. *Id.*, 64 U.S.P.Q.2d (BNA) at 1937.

840. *Id.*, 64 U.S.P.Q.2d (BNA) at 1937 (citing *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 979, 52 U.S.P.Q.2d (BNA) 1109, 1113-14 (Fed. Cir. 1999), *cert. denied*, 529 U.S. 1066, 120 S. Ct. 1672, 146 L.Ed.2d 482 (2000)).

841. *Id.* at 1381-82, 64 U.S.P.Q.2d (BNA) at 1938-39.

842. *Id.* at 1382, 64 U.S.P.Q.2d (BNA) at 1939.

843. 318 F.3d 1132, 65 U.S.P.Q.2d (BNA) 1809 (Fed. Cir. 2003).

844. *Id.* at 1137, 65 U.S.P.Q.2d (BNA) at 1813.

845. *Id.* at 1140, 65 U.S.P.Q.2d (BNA) at 1815.

846. *Id.*, 65 U.S.P.Q.2d (BNA) at 1815 (citing *Texas Instruments, Inc. v. Int'l Trade Comm'n*, 846 F.2d 1369, 1371-72, 6 U.S.P.Q.2d (BNA) 1886, 1889 (Fed. Cir. 1988) and *Slimfold Mfg. Co. v. Kinkead Indus., Inc.*, 810 F.2d 1113, 1116-17, 1 U.S.P.Q.2d (BNA) 1563, 1566 (Fed. Cir. 1987)).

847. *Id.* at 1132, 65 U.S.P.Q.2d (BNA) at 1809.

848. *Id.* at 1136, 65 U.S.P.Q.2d (BNA) at 1812.

variation.⁸⁴⁹ Berlex sued Biogen for infringement of two patents directed to methods for making human β -interferon in mammalian cells, but the district court found non-infringement by Biogen.⁸⁵⁰ After the trial, Berlex and Biogen settled, with the amount of a final payment by Biogen dependent upon the outcome of an appeal to the Federal Circuit.⁸⁵¹

According to the Federal Circuit, the principal issue was whether the claims of the patent directed to the production of β -interferon in mammalian cells were correctly construed.⁸⁵² The district court limited the claim scope to the use of a single DNA vector to introduce both the interferon gene and a selectable marker gene into the cells (so-called "linked co-transformation," as disclosed in the specification).⁸⁵³ The scope of the claims did not cover the use of separate DNA vectors for the separate genes (so-called "unlinked co-transformation" used by the Biogen method to make AVONEX).⁸⁵⁴ The Federal Circuit agreed that the claims did not cover unlinked co-transformation, despite arguments made by Berlex during the patent prosecution history that the allowed claims "do not depend on any particular nucleic acid construct configuration."⁸⁵⁵

In *Glaxo Wellcome, Inc. v. Andrx Pharmaceuticals, Inc.*⁸⁵⁶ the Federal Circuit vacated a district court's summary judgment that Andrx Pharmaceuticals' proposed generic drug did not infringe Glaxo Wellcome's patent covering its antidepressant Wellbutrin SR and remanded for further proceedings on the issue of infringement.⁸⁵⁷

Glaxo's patent covered sustained release formulations containing the active ingredient bupropion hydrochloride.⁸⁵⁸ The claims at issue

849. See Christopher Webster et al., *Biologics: Can There be Abbreviated Applications, Generics, or Follow-on Products? Controversial Topics*, BIOPHARM INT'L, July 1, 2003, at 28, 32 (discussing the product differences between BETASERON and AVONEX).

850. *Biogen, Inc.*, 318 F.3d at 1133-34, 65 U.S.P.Q.2d (BNA) at 1810.

851. See Carey Krause, *Biogen, Berlex Settle Dispute on Patent Infringement Issue*, CHEM. MKT. RPTR., Jan. 28, 2002, at 7 (noting Biogen's payment to Berlex of \$20 million to license the Berlex patents at issue and explaining the parties' agreement to specific settlement terms depending on the Federal Circuit court's decision: if the court affirmed the district court's decision, Biogen would pay nothing more; if the court reversed the lower court's grant of summary judgment, Biogen would pay \$55 million; if the court reversed the district court ruling entirely, Biogen would pay \$230 million); see also Randall Osborne, *Biogen To Pay Schering \$ 55m Bringing MS Dispute To End*, BIOWORLD TODAY, Feb. 4, 2003, § 23 (noting Biogen's \$55 million settlement payment to Berlex pursuant to the Federal Circuit's opinion).

852. *Biogen, Inc.*, 318 F.3d at 1133, 65 U.S.P.Q.2d (BNA) at 1810.

853. *Id.* at 1135, 65 U.S.P.Q.2d (BNA) at 1811.

854. *Id.* at 1139, 65 U.S.P.Q.2d (BNA) at 1814.

855. *Id.* at 1138, 65 U.S.P.Q.2d (BNA) at 1813.

856. 344 F.3d 1226, 68 U.S.P.Q.2d (BNA) at 1302 (Fed. Cir. 2003).

857. *Id.* at 1227, 1234, 68 U.S.P.Q.2d (BNA) at 1303, 1308.

858. *Id.* at 1227, 68 U.S.P.Q.2d (BNA) at 1303.

recited the active ingredient, which is the controlled release agent hydroxypropyl methylcellulose (“HPMC”), the particular release rates, and plasma levels.⁸⁵⁹ Glaxo sold the corresponding tablets as the antidepressant Wellbutrin SR and the anti-smoking medicine Zyban.⁸⁶⁰ Andrx filed two abbreviated new drug applications (“ANDA”) seeking approval of generic counterparts of these medications, claiming identity of the drugs’ active ingredients and properties.⁸⁶¹

During prosecution of the patent in suit, Glaxo had limited the claims to the release agent HPMC and introduced an amendment reciting the release rate of the active ingredient.⁸⁶² In granting summary judgment of non-infringement to Andrx, the district court found that, based on the recitation of a particular release rate, the claims could no longer encompass all grades of HPMC and construed the amended claims as limited to the particular grade of HPMC recited in the example.⁸⁶³ Andrx argued that its HPMC was of lower molecular weight and viscosity than the grade recited in the example of Glaxo’s patent in suit, and Andrx’s HPMC did not affect the release rate.⁸⁶⁴ Glaxo countered that this argument was inconsistent with the representation made by Andrx to the FDA that Andrx’s tablets are bioequivalent to the Glaxo tablets.⁸⁶⁵

Relying on the claims, specification, prosecution history, and expert testimony, the Federal Circuit decided that the lower court erred in construing the claims as limited to a particular grade or molecular weight of HPMC.⁸⁶⁶ According to the Federal Circuit, the correctly construed claims only require that HPMC be present in the recited amount and that the product have the release rate and other properties recited in the claims.⁸⁶⁷ Pointing to the fact that the properties and use of HPMC to control release rates are well known, the Federal Circuit noted that “[w]hen a claim term has an accepted scientific meaning, that meaning is generally not subject to restriction to the specific examples in the specification.”⁸⁶⁸

859. *Id.* at 1228-29, 68 U.S.P.Q.2d (BNA) at 1304.

860. *Id.* at 1227, 68 U.S.P.Q.2d (BNA) at 1303.

861. *Id.*, 68 U.S.P.Q.2d (BNA) at 1303.

862. *Id.* at 1229-30, 68 U.S.P.Q.2d (BNA) at 1305.

863. *Id.* at 1230, 68 U.S.P.Q.2d (BNA) at 1305.

864. *Id.*, 68 U.S.P.Q.2d (BNA) at 1305-06.

865. *Id.*, 68 U.S.P.Q.2d (BNA) at 1306.

866. *Id.*, 68 U.S.P.Q.2d (BNA) at 1305.

867. *Id.* at 1233, 68 U.S.P.Q.2d (BNA) at 1307-08.

868. *Id.*, 68 U.S.P.Q.2d (BNA) at 1308.

*D. Use of Extrinsic Evidence**1. Dictionaries and learned treatises are welcome*

Consistent with its ruling in *Texas Digital*, dictionaries and learned treatises are now well-received claim construction tools—a “special” type of extrinsic evidence. In *Abbott Laboratories v. Syntron Bioresearch, Inc.*,⁸⁶⁹ the Federal Circuit reversed a finding of non-infringement based on erroneous district court jury instructions relating to the construction of the claim term “non-diffusively bound.”⁸⁷⁰

Abbott sued Syntron for infringement of two patents⁸⁷¹ relating to the detection and analysis of small amounts of chemical substances in biological fluids.⁸⁷² The asserted claims required the bonding of a “non-diffusively bound” reactant in a particular medium (*e.g.*, a ligand or an analyte).⁸⁷³

The district court construed “non-diffusively bound” to mean “a reactant immobilized in the reaction zone so as to provide a detectable signal indicating the presence or absence of analyte in the solution, and the reactant is not capable of detaching from the medium, spreading out, and moving along the test strip”⁸⁷⁴ The district court further found that “a reactant is non-diffusively bound only if it is found in such a manner that a sufficient and reproducible amount of reactant remains bound in the reactive zone or zones to conduct both quantitative and qualitative assays.”⁸⁷⁵

On appeal, Abbott argued that the jury’s finding of non-infringement, based on the failure to satisfy the claim term “non-diffusively bound,” was not sustainable because the construction of the claim term should not have required quantitative analysis of the analyte.⁸⁷⁶ Abbott, instead, urged a claim construction that required “. . . only that the reactant be immobilized sufficiently to permit detection of the analyte. . . .”⁸⁷⁷

The Federal Circuit, citing *Texas Digital*, stated that the first step in the analysis was to determine the ordinary meaning of the claim terms and looked to the dictionary for evidence of a claim term’s ordinary meaning.⁸⁷⁸ Looking to WEBSTER’S THIRD INTERNATIONAL

869. 334 F.3d 1343, 67 U.S.P.Q.2d (BNA) 1337 (Fed. Cir. 2003).

870. *Id.* at 1351, 67 U.S.P.Q.2d (BNA) at 1342-43.

871. *Id.* at 1347-48, 67 U.S.P.Q.2d (BNA) at 1340.

872. *Id.* at 1346, 67 U.S.P.Q.2d (BNA) at 1339.

873. *Id.* at 1348, 67 U.S.P.Q.2d (BNA) at 1340.

874. *Id.* at 1350, 67 U.S.P.Q.2d (BNA) at 1341 (citation omitted).

875. *Id.*, 67 U.S.P.Q.2d (BNA) at 1341 (citation omitted).

876. *Id.*, 67 U.S.P.Q.2d (BNA) at 1341.

877. *Id.*, 67 U.S.P.Q.2d (BNA) at 1341 (citation omitted).

878. *Id.*, 67 U.S.P.Q.2d (BNA) at 1341-42.

DICTIONARY, the Federal Circuit determined that the district court unduly narrowed the plain meaning of the term “non-diffusively bound” in requiring “quantitative analysis” of the analyte, rather than mere detection.⁸⁷⁹

The Federal Circuit also evaluated the disputed claim term in the context of the claims as a whole and found that the language of the disputed claim term reinforced the plain meaning, *i.e.*, that “quantitative analysis should not be read as a requirement of the term ‘non-diffusively bound.’”⁸⁸⁰ Specifically, the court noted that each of the asserted claims only required “detecting the presence of analyte,” suggesting that this language was broad enough to encompass either qualitative or quantitative analysis, without specifically requiring quantitative analysis.⁸⁸¹

In *Boehringer Ingelheim Vet-Medica, Inc. v. Schering-Plough Corp.*,⁸⁸² the Federal Circuit upheld a jury verdict that Schering-Plough infringed a patent for a method of isolating and growing the virus that causes the “Mystery Swine Disease” (Porcine Reproductive Respiratory Syndrome or PRRS), under the doctrine of equivalents.⁸⁸³

PRRS was a major killer of piglets in the 1980s.⁸⁸⁴ Using a method of growing the virus in pig tissue culture, inoculating cultured monkey cells with the virus, and incubating the monkey cells until scientists observed a cytopathic effect (CPE), scientists at Boehringer discovered that a previously unknown virus caused PRRS.⁸⁸⁵ The asserted patent claimed this method.⁸⁸⁶

Both Boehringer and Schering developed and produced vaccines against PRRS by weakening the PRRS virus in monkey cell cultures.⁸⁸⁷ Because Schering’s vaccine production process measured the incubation by elapsed time, rather than by an achieved observational result as claimed, the district court precluded literal infringement and the jury returned a verdict of infringement under the doctrine of equivalents.⁸⁸⁸ The issue on appeal was whether the district court erred in its claim construction.⁸⁸⁹

879. *Id.* at 1350-51, 67 U.S.P.Q.2d (BNA) at 1342.

880. *Id.* at 1351, 67 U.S.P.Q.2d (BNA) at 1342.

881. *Id.*, 67 U.S.P.Q.2d (BNA) at 1342.

882. 320 F.3d 1339, 65 U.S.P.Q.2d (BNA) 1961 (Fed. Cir. 2003).

883. *Id.* at 1342-44, 65 U.S.P.Q.2d (BNA) at 1963-64.

884. *Id.* at 1343, 65 U.S.P.Q.2d (BNA) at 1963.

885. *Id.*, 65 U.S.P.Q.2d (BNA) at 1963-64.

886. *Id.*, 65 U.S.P.Q.2d (BNA) at 1963.

887. *Id.* at 1343-44, 65 U.S.P.Q.2d (BNA) at 1963-64.

888. *Id.* at 1344, 65 U.S.P.Q.2d (BNA) at 1964.

889. *Id.*, 65 U.S.P.Q.2d (BNA) at 1964.

The claimed method was one “of growing and *isolating*” the subject virus.⁸⁹⁰ The Federal Circuit construed the term “isolating,” as found in the claim preamble, to be limiting, indeed “the *raison d’être* of the claimed method itself.”⁸⁹¹ The district court, citing a “common definition” found in the RANDOM HOUSE COLLEGE DICTIONARY, concluded that the PRRS virus was “isolated” in each serial passage when the virus separated from the infected cells.⁸⁹² Schering, citing THE DICTIONARY OF MICROBIOLOGY AND MOLECULAR BIOLOGY, a technical dictionary, argued on appeal for a more microbiological definition of “isolation,” defining the term as the “process of obtaining a pure culture from a naturally occurring population.”⁸⁹³ The Federal Circuit, citing negatively to the technical dictionary, upheld the district court’s construction, noting that the customary meaning of “isolating” in the field of the invention encompasses more than the microbiological definitions of initial isolation of a virus from an infected tissue sample.⁸⁹⁴

The issue regarding the claim term “ATCC-VR2332” was one of scope.⁸⁹⁵ Schering argued for a definition encompassing only disease-causing viruses, while Boehringer argued for a broader definition that would include any attenuated strain, disease-causing or not.⁸⁹⁶ Based on the reference to the American Type Culture Collection (ATCC) in the claim term and the patentee’s failure to use a broader claim term, *e.g.*, “PRRS virus,” the Federal Circuit agreed with the district court that the term referred to the specific “strain of PRRS virus . . . deposited with the ATCC.”⁸⁹⁷

Finally, the court considered the meaning of the claimed step of “incubating . . . until CPE is observed” to determine whether the claim was limited to only a minimum incubation period or to an end period beyond which incubation was not permitted.⁸⁹⁸ Analogizing the claimed step to an instruction to cook a turkey until the skin is browned, the district court construed the claim as requiring a clear stopping point.⁸⁹⁹ The Federal Circuit did not see the initial observation of CPE as limiting the end of the incubation period, reasoning that because the utility of the claimed process “is not

890. *Id.* at 1344-45, 65 U.S.P.Q.2d (BNA) at 1964.

891. *Id.* at 1345, 65 U.S.P.Q.2d (BNA) at 1964-65.

892. *Id.* at 1346, 65 U.S.P.Q.2d (BNA) at 1965.

893. *Id.*, 65 U.S.P.Q.2d (BNA) at 1966.

894. *Id.* at 1346-47, 65 U.S.P.Q.2d (BNA) at 1966.

895. *Id.* at 1347-48, 65 U.S.P.Q.2d (BNA) at 1966-67.

896. *Id.* at 1347, 65 U.S.P.Q.2d (BNA) at 1966-67.

897. *Id.* at 1348, 65 U.S.P.Q.2d (BNA) at 1967.

898. *Id.* at 1349, 65 U.S.P.Q.2d (BNA) at 1967.

899. *Id.*, 65 U.S.P.Q.2d (BNA) at 1968.

premised on a particular stopping point, there is no barrier to additional incubation periods.⁹⁰⁰ Nevertheless, the court held that the error was harmless.⁹⁰¹

In *Intellectual Property Development, Inc. v. UA-Columbia Cablevision of Westchester, Inc.*,⁹⁰² the Federal Circuit upheld a construction of the claim term “high frequency” where the district court used dictionary definitions to supply the ordinary and customary meaning of the term.⁹⁰³

The patent claim at issue recited a broadcasting system that transports signals between a central office and its various subscribers via a “high frequency” carrier signal.⁹⁰⁴ The parties disputed the range of frequencies that would qualify as a “high frequency.”⁹⁰⁵ When the district court initially construed “high frequency,” it held that the term would encompass frequencies within a 54-216 MHz range.⁹⁰⁶ Upon reconsideration, however, the court relied on a dictionary definition and further limited the range of “high frequency” to the more narrow range of 3-30 MHz.⁹⁰⁷ Because Cablevision’s system operated in the 30-300 MHz range, the district court also granted Cablevision’s motion for non-infringement.⁹⁰⁸ IPD appealed, arguing that the district court erred in referring to extrinsic evidence, such as dictionaries, when “the intrinsic evidence, including the claim language, the specification, and the prosecution history, establishes that ‘high frequency’ encompasses any frequency at which a conventional TV receiver can receive and display a signal.”⁹⁰⁹

Affirming the lower court’s claim construction and its determination of non-infringement, the Federal Circuit rejected the patentee’s argument that the lower court “‘put the cart before the horse’ by looking at dictionary definitions first instead of the specification to determine the meaning of the term ‘high frequency.’”⁹¹⁰ Rather, the court reasoned that “[c]onsulting the written description and prosecution history as a threshold step in the claim construction process, before any effort is made to discern the

900. *Id.* at 1350, 65 U.S.P.Q.2d (BNA) at 1968.

901. *Id.*, 65 U.S.P.Q.2d (BNA) at 1968.

902. 336 F.3d 1308, 67 U.S.P.Q.2d (BNA) 1385 (Fed. Cir. 2003).

903. *Id.* at 1313-14, 67 U.S.P.Q.2d (BNA) at 1389.

904. *Id.* at 1311-12, 67 U.S.P.Q.2d (BNA) at 1387.

905. *Id.* at 1312, 67 U.S.P.Q.2d (BNA) at 1387-88.

906. *Id.*, 67 U.S.P.Q.2d (BNA) at 1387.

907. *Id.* at 1312-13, 67 U.S.P.Q.2d (BNA) at 1388.

908. *Id.* at 1313, 67 U.S.P.Q.2d (BNA) at 1388.

909. *Id.* at 1313-14, 67 U.S.P.Q.2d (BNA) at 1388.

910. *Id.* at 1315, 67 U.S.P.Q.2d (BNA) at 1389.

ordinary and customary meanings attributed to the words themselves, invites a violation of our precedent counseling against importing limitations into the claims.⁹¹¹ In its analysis, the Federal Circuit created a rebuttable presumption that a definition, such as that found in a dictionary, is the ordinary and customary meaning of a claim term: “In the absence of an express intent to impart a novel meaning to claim terms, the words are presumed to take on the ordinary and customary meanings attributed to them by those of ordinary skill in the art.”⁹¹²

In rejecting IDP’s argument that dictionary definitions should not be used in place of the patent specifications to define claim terms, the Federal Circuit noted that “dictionaries, encyclopedias, and treatises, publicly available at the time the patent is issued, are objective resources that serve as reliable sources of information.”⁹¹³ Citing *Texas Digital*, the Federal Circuit also rejected IDP’s argument that the use of dictionaries is inappropriate because definitions of “high frequency” are not consistent from dictionary to dictionary: “[T]he intrinsic record must always be consulted to identify which of the different possible dictionary meanings of the claim terms in issue is most consistent with the use of the words by the inventor.”⁹¹⁴

In *Ferguson Beauregard/Logic Controls v. Mega Systems, LLC*,⁹¹⁵ the Federal Circuit overturned a decision of non-infringement by a district court and found that the district court’s reliance on the patent specification, rather than on dictionary definitions, yielded an erroneous claim construction because the lower court improperly read into the claim language limitations found in the specification but not included in the dictionary definition or required by the claim language.⁹¹⁶

The patents-in-suit claimed various aspects of control systems and related methods used in the production of petroleum products from a well.⁹¹⁷ At issue was the construction of claim language directed to a plunger operation used to extract and deliver liquid petroleum products from the well.⁹¹⁸ Particularly, the parties disputed the scope of “normal” and “predetermined” in the claim elements, “normal

911. *Id.*, 67 U.S.P.Q.2d (BNA) at 1389 (citation omitted).

912. *Id.* at 1314, 67 U.S.P.Q.2d (BNA) at 1389 (citation omitted).

913. *Id.* at 1315, 67 U.S.P.Q.2d (BNA) at 1389.

914. *Id.*, 67 U.S.P.Q.2d (BNA) at 1390.

915. 350 F.3d 1327, 69 U.S.P.Q.2d (BNA) 1001 (Fed. Cir. 2003).

916. *Id.* at 1338-41, 69 U.S.P.Q.2d (BNA) at 1008-11.

917. *Id.* at 1331, 69 U.S.P.Q.2d (BNA) at 1004.

918. *Id.*, 1333-35, 69 U.S.P.Q.2d (BNA) at 1004-06.

plunger performance” and “predetermined plunger performance.”⁹¹⁹ Based on an example described in the patent specification, the district court had limited both claim terms to a performance that occurred within an independent adjustable period of time of good window operation and, thus, implicitly interpreted both disputed claim terms identically.⁹²⁰

In its analysis, the Federal Circuit panel looked first to a dictionary to ascertain the scope of the disputed claim terms,⁹²¹ and then reviewed the patent specification to determine if the specification contradicted the dictionary definitions.⁹²² The Court reasoned:

In the absence of an express intent to impart a novel meaning to the claim terms, the words take on the full breadth of the ordinary and customary meanings attributed to them by those of ordinary skill in the art. The ordinary and customary meaning of a claim term may be determined by reviewing a variety of sources. Some of these sources include the claims themselves . . . dictionaries and treatises . . . and the written description, the drawings, and the prosecution history.⁹²³

Based on the appropriate dictionary definition and consistent with the specification, the Federal Circuit agreed with the district court that a “normal plunger performance” is a performance during a good window of operation.⁹²⁴ The Federal Circuit, however, found that the district court erred in further limiting the claim term by requiring that the window of operation fall within an independent adjustable period of time as described in the specification.⁹²⁵ The Federal Circuit reasoned that the district court erred because “it read into the claim a limitation of independent adjustability of the upper and lower values not specified or required by the claim language, as properly construed.”⁹²⁶

Similarly, the Federal Circuit disagreed with the district court’s implicit conclusion that “predetermined plunger performance” necessarily has the same construction as “normal plunger performance.”⁹²⁷ The Federal Circuit reasoned:

The coincidence of a particular predetermined window with a good window is irrelevant There is no requirement, either in

919. *Id.* at 1337, 69 U.S.P.Q.2d (BNA) at 1008.

920. *Id.*, 69 U.S.P.Q.2d (BNA) at 1008.

921. *Id.* at 1339, 69 U.S.P.Q.2d (BNA) at 1009.

922. *Id.* at 1339-40, 69 U.S.P.Q.2d (BNA) at 1009-10.

923. *Id.* at 1338, 69 U.S.P.Q.2d (BNA) at 1009 (citations omitted).

924. *Id.* at 1339, 69 U.S.P.Q.2d (BNA) at 1009.

925. *Id.* at 1340, 69 U.S.P.Q.2d (BNA) at 1010.

926. *Id.*, 69 U.S.P.Q.2d (BNA) at 1010.

927. *Id.*, 69 U.S.P.Q.2d (BNA) at 1010.

the claim itself or in the written description, that the values selected beforehand in the limitation “predetermined plunger performance” must represent the good window, as with “normal plunger performance.” There is also nothing in the claim language, written description, or prosecution history to require that the upper and lower values that define the window of “predetermined plunger performance” be set independently of each other. The values must just be determined beforehand.⁹²⁸

In *Waner v. Ford Motor Co.*,⁹²⁹ the Federal Circuit reversed the district court’s claim construction and found that Ford Motor Company did not infringe Waner’s patent for a fender liner used on dual rear wheel trucks.⁹³⁰ Specifically, the Federal Circuit disagreed with the district court’s construction of the claim term “flange.”⁹³¹ Relying on a dictionary definition as well as intrinsic evidence (*i.e.*, the “structure of the language of the claim”), the court decided that the claimed fender liner must have a “flange,” that is, a raised or projecting edge, and that the flange must exist prior to installation of the fender liner.⁹³² Because Ford’s fender liner was a single planar sheet before installation, the Federal Circuit ruled that no reasonable jury could have found infringement.⁹³³

2. *Prior art patents—it’s a mixed bag*

In *E-Pass Technologies, Inc. v. 3Com Corp.*,⁹³⁴ the Federal Circuit overturned a grant of summary judgment in favor of 3Com,⁹³⁵ holding that the district court had erroneously restricted a claim limitation to the industry standard meaning of a term rather than giving the term its plain, every day meaning.⁹³⁶

The case involves 3Com’s popular “Palm Pilot” personal digital assistant and accusations that it infringes patent claims drawn to the use of an “electronic multi-function card.”⁹³⁷ Based in part on a discussion in the specification, and also on the industry standard usage of the term “card” at the time the patent was issued, the district court interpreted the term “card” to mean a component having the dimensions of a standard credit card.⁹³⁸ Observing that the district

928. *Id.*, 69 U.S.P.Q.2d (BNA) at 1010.

929. 331 F.3d 851, 66 U.S.P.Q.2d (BNA) 1943 (Fed. Cir. 2003).

930. *Id.* at 852, 66 U.S.P.Q.2d (BNA) at 1944.

931. *Id.* at 854, 66 U.S.P.Q.2d (BNA) at 1945.

932. *Id.* at 854-55, 66 U.S.P.Q.2d (BNA) at 1946.

933. *Id.* at 855-56, 66 U.S.P.Q.2d (BNA) at 1947.

934. 343 F.3d 1364, 67 U.S.P.Q.2d (BNA) 1947 (Fed. Cir. 2003).

935. *Id.* at 1365-66, 67 U.S.P.Q.2d (BNA) at 1947.

936. *Id.* at 1368, 67 U.S.P.Q.2d (BNA) at 1950.

937. *Id.* at 1365-67, 67 U.S.P.Q.2d (BNA) at 1947-49.

938. *Id.* at 1366, 67 U.S.P.Q.2d (BNA) at 1948.

court gave too much weight to the specification's discussion of the "object of the invention" and too little weight to the strong presumption in favor of giving terms their "ordinary and customary meaning," the Federal Circuit found this to be an error of construction and held that the ordinary meaning of the term "card" should apply (that is, "a flat, rectangular piece of stiff material").⁹³⁹

According to the court, there was nothing in the claim language or the steps of the method that suggest a size limitation, and the court found nothing in the industry standards to suggest that they "apply outside the limited area of credit cards, i.e., to cards generally or to electronic multifunction cards, or that either was intended to define the term 'card' or 'electronic multifunction card.'"⁹⁴⁰ Absent a clear statement of intent by the inventor to narrow the meaning of the claim, the court determined, the claim should be given the broadest meaning consistent with customary usage.⁹⁴¹

In *Kumar v. Ovonic Battery Co., Inc.*,⁹⁴² the Federal Circuit reversed the district court's grant of summary judgment of non-infringement,⁹⁴³ and found that the prior art definition of the claim term "amorphous" preferable to the dictionary definition.⁹⁴⁴

The patent concerned a battery that employs a certain alloy to store hydrogen in a rechargeable battery, overcoming the "inevitable fracturing associated with repeated recharging."⁹⁴⁵ The claimed alloy had a molecular structure that is less ordered than prior art materials, and thus more immune than highly ordered structures to material fracture caused by repeated recharging.⁹⁴⁶ The parties disputed the construction of the claim term "amorphous" and whether it should be construed to mean "completely amorphous," i.e., no ordering of molecules, or, using a prior art definition, be construed to "cover all partially crystalline alloys with long range order less than 100 nm."⁹⁴⁷ The district court found that the specification and prosecution history supported the plain meaning of the term "amorphous," and that the patentees proposed a definition relying on a prior art reference that was "developed *after* his patent was filed, and therefore

939. *Id.* at 1368-71, 67 U.S.P.Q.2d (BNA) at 1950-51.

940. *Id.* at 1368, 67 U.S.P.Q.2d (BNA) at 1949-50.

941. *Id.* at 1370, 67 U.S.P.Q.2d (BNA) at 1951.

942. 351 F.3d 1364, 69 U.S.P.Q.2d (BNA) 1220 (Fed. Cir. 2003).

943. *Id.*, 69 U.S.P.Q.2d (BNA) at 1221.

944. *Id.* at 1368, 69 U.S.P.Q.2d (BNA) at 1223.

945. *Id.* at 1366, 69 U.S.P.Q.2d (BNA) at 1221.

946. *Id.*, 69 U.S.P.Q.2d (BNA) at 1221.

947. *Id.* at 1367, 69 U.S.P.Q.2d (BNA) at 1222 (brackets in original).

[could not] be taken to describe accurately what he sought to patent.”⁹⁴⁸

On appeal (where the patent owner appeared *pro se*),⁹⁴⁹ the Federal Circuit reversed.⁹⁵⁰ In its analysis, the panel (citing *Texas Digital*) looked to a dictionary to ascertain the plain meaning of the disputed claim term, but then considered the alternative definition found in a prior art reference cited and extensively discussed during prosecution.⁹⁵¹ The court reasoned that “although the dictionary can be an important tool in claim construction by providing a starting point for determining the ordinary meaning of a term to a person of skill in the art, ‘the intrinsic record’ can solve ambiguity in claim language or, where clear, trump an inconsistent dictionary definition.”⁹⁵² The court looked at the prior art cited in the patent as intrinsic evidence and further explained:

... when prior art that sheds light on the meaning of a term is cited by the patentee, it can have particular value as a guide to the proper construction of the term, because it may indicate not only the meaning of the term to persons skilled in the art, but also that the patentee intended to adopt that meaning.⁹⁵³

The Federal Circuit also considered the patentee’s own lexicography in defining the term “amorphous.”⁹⁵⁴ After noting that precedent gives significance to terms such as “completely” or “normally,” the court found that in this case the specification and prosecution history did not clearly and deliberately define the term “amorphous” as “completely amorphous,” and thus did not support a construction of the disputed term contrary to the meaning established in the prior art reference.⁹⁵⁵ The court noted that it would be inappropriate to limit a broad definition of a claim term based on prosecution history that is itself ambiguous.⁹⁵⁶

In a concurring opinion, Justice Bryson agreed with the panel, but did so only after considering “the totality of the evidence” and indicated that he would expand the scope of the remand to include whether a person skilled in the field of amorphous solids would find the phrase “random atomic orientation” indicative of a particular

948. *Id.*, 69 U.S.P.Q.2d (BNA) at 1222 (emphasis in original).

949. *Id.* at 1365, 69 U.S.P.Q.2d (BNA) at 1221.

950. *Id.* at 1373, 69 U.S.P.Q.2d (BNA) at 1227.

951. *Id.* at 1367-68, 69 U.S.P.Q.2d (BNA) at 1222-23.

952. *Id.*, 69 U.S.P.Q.2d (BNA) at 1222-23.

953. *Id.* at 1368, 69 U.S.P.Q.2d (BNA) at 1223 (citations omitted).

954. *Id.* at 1368-70, 69 U.S.P.Q.2d (BNA) at 1223-24.

955. *Id.* at 1369, 69 U.S.P.Q.2d (BNA) at 1224.

956. *Id.* at 1371-72, 69 U.S.P.Q.2d (BNA) at 1225-26.

class of structures, or whether the term is too indefinite to provide any significant guidance as to the bounds of the term “amorphous.”⁹⁵⁷

3. *Expert testimony—meaning of claim term to one of skill in the art*

In *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*,⁹⁵⁸ the Federal Circuit affirmed a lower court’s ruling of infringement, construing a claim directed to a treatment for bone reabsorption and urolithiasis to encompass the use of a pharmaceutical formulation of the active agent.⁹⁵⁹

The drug Fosamax was marketed by Merck and approved by the FDA for the treatment of osteoporosis and Paget’s disease.⁹⁶⁰ The active agent of the product is formulated as a salt having the common name alendronate salt.⁹⁶¹ The patent at issue contained a single claim directed to a method of treating bone reabsorption and urolithiasis through the administration of the non-salt form of the compound, alendronic acid.⁹⁶²

When the generic drug maker Teva Pharmaceuticals filed for regulatory approval to sell the alendronate salt form, Merck sued Teva for infringement, alleging that the delivery of the acid as recited in the claimed method includes the delivery of the salt form.⁹⁶³ Teva defended its actions on the basis that the alendronate salt is distinct from the claimed acid form.⁹⁶⁴ The district court found that the method administering alendronic acid was infringed by the administration of alendronate salt.⁹⁶⁵

In construing the claim, the Federal Circuit noted that while extrinsic evidence cannot change the meaning of a term as it is used in the specification, expert opinion can explain the meaning of claim language used in the patent as it would be understood by those skilled in the field of the invention.⁹⁶⁶ Here, the court framed the issue to be whether a person skilled in pharmacology would understand from the specification that the claimed method of treatment by administering alendronic acid encompassed administering alendronate salt.⁹⁶⁷

957. *Id.* at 1373-74, 69 U.S.P.Q.2d (BNA) at 1227.

958. 347 F.3d 1367, 68 U.S.P.Q.2d (BNA) 1857 (Fed. Cir. 2003).

959. *Id.* at 1371-72, 68 U.S.P.Q.2d (BNA) at 1860-61.

960. *Id.* at 1369, 68 U.S.P.Q.2d (BNA) at 1858.

961. *Id.*, 68 U.S.P.Q.2d (BNA) at 1858.

962. *Id.*, 68 U.S.P.Q.2d (BNA) at 1858.

963. *Id.* at 1369-70, 68 U.S.P.Q.2d (BNA) at 1858-59.

964. *Id.* at 1369, 68 U.S.P.Q.2d (BNA) at 1858.

965. *Id.* at 1372, 68 U.S.P.Q.2d (BNA) at 1861.

966. *Id.*, 68 U.S.P.Q.2d (BNA) at 1860.

967. *Id.* at 1371-72, 68 U.S.P.Q.2d (BNA) at 1860.

Affirming the district court's finding of infringement, the Federal Circuit found that the claimed acid form was exemplified in the specification in formulations that included the salt and usage of the active agent in the salt form for the treatment of bone disorders was presented in the specification.⁹⁶⁸ The court further found extensive evidence in the record that persons experienced in the field refer to the active ingredient in the form of the salt and that qualified witnesses in the field of pharmacology understood that the acid, which is administered in the form of the salt, is the active agent.⁹⁶⁹

E. Means Plus Function Claim Elements

The Federal Circuit actively addressed § 112, ¶ 6⁹⁷⁰ claim issues in 2003.

1. The word "means" raises rebuttable presumption that § 112, ¶ 6 has been invoked

In *Apex Inc. v. Raritan Computer, Inc.*,⁹⁷¹ the Federal Circuit, noted that use of "the word 'means' invokes a rebuttable presumption that § 112, ¶ 6 applies"⁹⁷² and that "a claim term that does not use 'means' will trigger the rebuttable presumption that § 112, ¶ 6 does not apply."⁹⁷³ This presumption places the burden of going forward with rebuttal evidence on the party seeking to overcome the presumption.⁹⁷⁴ To overcome the burden that a claim term that does not use the word "means" should nevertheless be construed under § 112, ¶ 6, a party must demonstrate "that the claim term fails to 'recite sufficiently definite structure' or else recites a 'function without reciting sufficient structure for performing that function.'"⁹⁷⁵

968. *Id.* at 1370, 68 U.S.P.Q.2d (BNA) at 1859.

969. *Id.* at 1370-71, 68 U.S.P.Q.2d (BNA) at 1859-60.

970. Title 35, Section 112 of the United States Code provides:

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

35 U.S.C. § 12 (2000).

971. 325 F.3d 1364, 66 U.S.P.Q.2d (BNA) 1444 (Fed. Cir. 2003).

972. *Id.* at 1371, 66 U.S.P.Q.2d (BNA) at 1450 (quoting *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1369, 62 U.S.P.Q.2d (BNA) 1658, 1664 (Fed. Cir. 2002)) (quotations omitted).

973. *Id.* at 1371-72, 66 U.S.P.Q.2d (BNA) at 1450 (quoting *CCS Fitness*, 288 F.3d at 1369, 62 U.S.P.Q.2d (BNA) at 1664) (quotations omitted).

974. *Id.* at 1372, 66 U.S.P.Q.2d (BNA) at 1450.

975. *Id.*, 66 U.S.P.Q.2d (BNA) at 1450 (quoting *CCS Fitness*, 288 F.3d at 1369, 62 U.S.P.Q.2d (BNA) at 1665).

The burden is met by a mere preponderance of the evidence standard.⁹⁷⁶

2. *Corresponding structure is limited by recited function*

In *Altiris, Inc. v. Symantic Corp.*,⁹⁷⁷ the court chastised as “careless” the way a district court applied the test of *Interactive Gift Express Inc. vs. Compuserve, Inc.*⁹⁷⁸ to require that method steps be performed in the order recited.⁹⁷⁹ According to the Federal Circuit, a court must preserve the recited order only when logic and grammar dictate it do so.⁹⁸⁰ Where, as in *Interactive Gift*, no such indications exist, a court may resort to the specification to determine if it “directly or implicitly requires such a narrow construction.”⁹⁸¹ If not, the original sequence is not required.⁹⁸²

In *Altiris*, the court also noted that when construing a means-plus-function claim element under § 112, ¶ 6, “Structure disclosed in the specification is ‘corresponding’ structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim.”⁹⁸³ Applying this rule, the court in *Altiris* reversed the district court’s holding that certain software commands used for booting a computer must be resident on a server, because the preferred disclosed embodiment provided possible alternate residences for the commands.⁹⁸⁴

A similar result occurred in *Northrop Grumman Corp. v. Intel Corp.*⁹⁸⁵ There, the Federal Court reversed the district court’s construction of two means-plus-function claim elements, finding that the construction improperly included not only the circuit as a corresponding structure, but also the signals that the circuit used to perform the claimed function.⁹⁸⁶

The claims at issue in *Northrop* concerned a bus interface unit used in a computer network.⁹⁸⁷ The bus interface reactions included a “means for monitoring a plurality of logical signals” and a “means for

976. *Id.* at 1372, 66 U.S.P.Q.2d (BNA) at 1450.

977. 318 F.3d 1363, 65 U.S.P.Q.2d (BNA) 1865 (Fed. Cir. 2003).

978. 256 F.3d 1323, 59 U.S.P.Q.2d 1401 (Fed. Cir. 2000).

979. 318 F.3d at 1369, 65 U.S.P.Q.2d (BNA) at 1869.

980. *Id.* at 1369-70, 65 U.S.P.Q.2d (BNA) at 1869.

981. *Id.*, 65 U.S.P.Q.2d (BNA) at 1869.

982. *Id.* at 1370, 65 U.S.P.Q.2d (BNA) at 1869.

983. *Id.* at 1375, 65 U.S.P.Q.2d (BNA) at 1874 (quoting *B. Braun Med. v. Abbott Labs.*, 124 F.3d 1419, 1424, 43 U.S.P.Q.2d (BNA) 1896, 1900 (Fed. Cir. 1997)) (internal quotations omitted).

984. *Id.* at 1376-77, 65 U.S.P.Q.2d (BNA) at 1874-75.

985. 325 F.3d 1346, 66 U.S.P.Q.2d (BNA) 1341 (Fed. Cir. 2003).

986. *Id.* at 1352, 66 U.S.P.Q.2d (BNA) at 1345.

987. *Id.* at 1347-48, 66 U.S.P.Q.2d (BNA) at 1342.

defining the functional state of the bus interface units.”⁹⁸⁸ In construing each of these elements as means-plus-function limitations, the district court dutifully identified the function performed by each claim element and then identified the corresponding disclosed structure that performed that recited function.⁹⁸⁹

In its analysis, the district court found that the “monitoring means” performed two functions: “monitoring a plurality of logical signals characterizing the operational status of the bus interface unit” and “generating a plurality of control signals regulating a data transfer process.”⁹⁹⁰ Focusing on a passage of the specification to discern the corresponding structure, the district court identified a sequence logic circuit that receives a set of signals to regulate the data transfer process between the bus and the memory port as the corresponding structure.⁹⁹¹ The district court included both a sequence logic circuit and a particular signal as the corresponding structure for the claimed defining means.⁹⁹²

The Federal Circuit reversed, finding that the district court improperly included signals in the corresponding structure for performing the “monitoring” and “defining” functions.⁹⁹³ The Federal Circuit reasoned, “the signals that are monitored by the ‘means for monitoring’ cannot be part of the structure that does the monitoring.”⁹⁹⁴ Accordingly, the Federal Circuit held that the sequence logic circuit was the only structure that fell within the scope for “means for monitoring” and “means for defining.”⁹⁹⁵

In *Medical Instrumentation and Diagnostics Corp. v. Elekta AB*,⁹⁹⁶ another software-related case, the Federal Circuit held that it was error to include software as an additional corresponding structure to a means-plus-function claim term where the specification failed to clearly link software as a structure to perform the identified function.⁹⁹⁷

The asserted patent claim described a system for planning surgical treatment using a presentation of images from multiple scanning sources and recites a “means for converting said plurality of images

988. *Id.* at 1349, 66 U.S.P.Q.2d (BNA) at 1343.

989. *Id.* at 1350-52, 66 U.S.P.Q.2d (BNA) at 1344-45.

990. *Id.* at 1350, 66 U.S.P.Q.2d (BNA) at 1344.

991. *Id.* at 1350-52, 66 U.S.P.Q.2d (BNA) at 1344-45.

992. *Id.* at 1352, 66 U.S.P.Q.2d (BNA) at 1345.

993. *Id.*, 66 U.S.P.Q.2d (BNA) at 1345.

994. *Id.*, 66 U.S.P.Q.2d (BNA) at 1345.

995. *Id.* at 1353-54, 66 U.S.P.Q.2d (BNA) at 1346-47.

996. 344 F.3d 1205, 68 U.S.P.Q.2d (BNA) 1263 (Fed. Cir. 2003).

997. *Id.* at 1211, 68 U.S.P.Q.2d (BNA) at 1268.

into a selected format” limitation.⁹⁹⁸ In construing that limitation, the district court applied the traditional two-step analysis.⁹⁹⁹ First, the court identified the particular function performed by the claimed means: “converting said plurality of images into a selected format.”¹⁰⁰⁰ Then the court examined the specification to identify the corresponding disclosed structures for performing that function.¹⁰⁰¹ The accused structure used a software based digital-to-digital conversion technique.¹⁰⁰² Recognizing that the only corresponding structures explicitly described in the specification were analog-to-digital conversion circuits, *i.e.*, a frame grabber video display board and a computer video processor, the district court nevertheless concluded that “because techniques for performing [digital-to-digital] conversions were known to those of skill in the art at the time the application was filed, a person of skill in the art would understand software to be the corresponding structure for a converting function.”¹⁰⁰³

The Federal Circuit reversed, noting that rather than inquiring whether a person of ordinary skill in the art would have been able to write a software program to perform the identified function, a court should ask whether a person of ordinary skill in the art would have understood the *specification* to encompass software for digital-to-digital conversion as structure corresponding to the claimed function.¹⁰⁰⁴ The court reasoned that “[i]f the specification is not clear as to the structure that the patentee intends to correspond to the claimed function, then the patentee has not paid that price but is rather attempting to claim in functional terms unbounded by any reference to structure in the specification.”¹⁰⁰⁵ Because neither the specification nor the prosecution history clearly linked software to the converting means, the Federal Circuit held that the district court erred in identifying software as a corresponding structure for the “means for converting” and granted a judgment of non-infringement as a matter of law.¹⁰⁰⁶

998. *Id.* at 1207-08, 68 U.S.P.Q.2d (BNA) at 1265-66.

999. *Id.* at 1209, 68 U.S.P.Q.2d (BNA) at 1266.

1000. *Id.*, 68 U.S.P.Q.2d (BNA) at 1266.

1001. *Id.*, 68 U.S.P.Q.2d (BNA) at 1266.

1002. *Id.*, 68 U.S.P.Q.2d (BNA) at 1266.

1003. *Id.* at 1211, 68 U.S.P.Q.2d (BNA) at 1268.

1004. *Id.* at 1212, 68 U.S.P.Q.2d (BNA) at 1269.

1005. *Id.* at 1211, 68 U.S.P.Q.2d (BNA) at 1268.

1006. *Id.* at 1222, 68 U.S.P.Q.2d (BNA) at 1277.

3. *Recited claim function is not limited by patent specification*

A similar analysis of a § 112, ¶ 6 issue doomed the grant of a summary judgment motion in *Omega Engineering, Inc. v. Raytek Corp.*,¹⁰⁰⁷ where the Federal Circuit cautioned that “[w]hen construing the functioned statement in a means-plus-function limitation, we must take great care not to impermissibly limit the function by adopting a function different from that explicitly recited in the claim.”¹⁰⁰⁸ In the context of an invention directed to a laser sighting system for use on infrared thermometers, the Federal Circuit found that the district court impermissibly limited the functional statement of a § 112, ¶ 6 claim element.¹⁰⁰⁹ The claim element in question recited a “means” that causes “at least one laser beam to strike the periphery of the energy zone... for visibly outlining the entire zone.”¹⁰¹⁰ Focusing on the word “periphery,” the district court construed the claim to require the laser only strike the periphery, not the interior of the energy zone.¹⁰¹¹ In reversing, the Federal Circuit panel noted that this “negative limitation finds no anchor in the explicit claim language.”¹⁰¹²

F. *Claim Preamble: Preamble Limiting When Method Steps Require Use of Structure Recited in Preamble*

In *Eaton Corp. v. Rockwell Int’l Corp.*,¹⁰¹³ the Federal Circuit addressed the significance of the preamble of a claim directed to a method for automatically shifting gears in a heavy-duty truck transmission.¹⁰¹⁴ The claim preamble recited, in part, a method for controlling “an automatic mechanical vehicle driveline system having a throttle controlled engine.”¹⁰¹⁵ The preamble went on to recite the driveline system in some detail, followed by two method steps.¹⁰¹⁶ Here, the Federal Circuit found the preamble to be limiting because the method steps required structure recited in the preamble.¹⁰¹⁷ Thus,

1007. 334 F.3d 1314, 67 U.S.P.Q.2d (BNA) 1321 (Fed. Cir. 2003).

1008. *Id.* at 1322, 67 U.S.P.Q.2d (BNA) at 1326 (quoting *Generation II Orthotics, Inc. v. Med. Tech., Inc.*, 263 F.3d 1356, 1364-65, 59 U.S.P.Q.2d (BNA) 1919, 1926 (Fed. Cir. 2001)).

1009. *Id.* at 1321-23, 67 U.S.P.Q.2d (BNA) at 1325-27.

1010. *Id.* at 1322, 67 U.S.P.Q.2d (BNA) at 1326.

1011. *Id.* at 1322-23, 67 U.S.P.Q.2d (BNA) at 1326-27.

1012. *Id.* at 1322, 67 U.S.P.Q.2d (BNA) at 1326.

1013. 323 F.3d 1332, 66 U.S.P.Q.2d (BNA) 1271 (Fed. Cir. 2003).

1014. *Id.* at 1335, 66 U.S.P.Q.2d (BNA) at 1273.

1015. *Id.*, 66 U.S.P.Q.2d (BNA) at 1273.

1016. *Id.* at 1335-36, 66 U.S.P.Q.2d (BNA) at 1273-74.

1017. *Id.* at 1342, 66 U.S.P.Q.2d (BNA) at 1278.

the court concluded that both the preamble and the recited steps defined the claimed invention.¹⁰¹⁸

IV. INFRINGEMENT

A. *Infringement: All Elements Rule and Claim Element Vitiating*

In *Lockheed Martin Corp. v. Space Systems/Loral Inc.*,¹⁰¹⁹ on remand for reconsideration in light of the Supreme Court's decision in *Festo VIII*,¹⁰²⁰ the Federal Circuit sidestepped the *Festo* issue and decided the case based on the "all elements" rule which holds that "there can be no infringement under the doctrine of equivalents if even one limitation of a claim or its equivalent is not present in the accused device."¹⁰²¹

The patented system compensated for angular drift of geosynchronous satellites by manipulation of speed and angular momentum of a momentum wheel, having an axis parallel to the yaw axis of the satellite (pointing toward the center of the earth), so as to tilt the satellite and keep it continuously pointed at a target on the earth's surface.¹⁰²² The claimed system included an element specified as a "means for rotating said wheel in accordance with a *predetermined* rate schedule, which *varies sinusoidally* over the orbit at the orbital frequency of the satellite."¹⁰²³ The Federal Circuit's decision on remand focused on two functional limitations on this "means" element: the predetermined rate schedule and the sinusoidal variation.¹⁰²⁴

The lower court interpreted the sinusoidal variation limitation to mean that the speed variation passed through zero and changed direction or sign.¹⁰²⁵ The parties apparently did not dispute this interpretation.¹⁰²⁶ While the wheel in the SSL satellite varied its speed, it did so with respect to a bias speed and, consequently, did not pass through zero, *i.e.*, did not change direction or sign.¹⁰²⁷

The Federal Circuit adopted the lower court interpretation of the "predetermined" limitation requiring that the sinusoidal control

1018. *Id.*, 66 U.S.P.Q.2d (BNA) at 1278.

1019. 324 F.3d 1308, 66 U.S.P.Q.2d (BNA) 1282 (Fed. Cir. 2003).

1020. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 62 U.S.P.Q.2d 1705 (2002).

1021. 324 F.3d at 1321, 66 U.S.P.Q.2d (BNA) at 1291.

1022. *Id.* at 1311-12, 66 U.S.P.Q.2d (BNA) at 1284-85.

1023. *Id.* at 1315, 66 U.S.P.Q.2d (BNA) at 1286 (emphasis added).

1024. *Id.* at 1318-21, 66 U.S.P.Q.2d (BNA) at 1289-92.

1025. *Id.* at 1316-17, 66 U.S.P.Q.2d (BNA) at 1288-89.

1026. *Id.* at 1317, 66 U.S.P.Q.2d (BNA) at 1289.

1027. *Id.* at 1321, 66 U.S.P.Q.2d (BNA) at 1292.

function “not include any unfixed real-time inputs, such as those from an earth sensor.”¹⁰²⁸ The rate schedule used in the SSL satellite control responded “to an actual real-time error sensed by the earth sensor.”¹⁰²⁹ Over arguments by Lockheed regarding the open-ended nature of the claim, the Federal Circuit concluded that the accused satellite control did not utilize a “predetermined” rate schedule.¹⁰³⁰

Finally, despite expert testimony as to the overall equivalence between the recited function as construed by the Federal Circuit and the function performed by SSL satellite, the court concluded that there was no element that performed the properly construed function, and, therefore, the claimed “means” element was entirely missing from the SSL satellite.¹⁰³¹ The Federal Circuit held that a finding of infringement by equivalents, in the absence of operations that literally satisfied the two functional requirements, would “entirely vitiate the limitations” of the “means-for rotating” claim element.¹⁰³²

B. Doctrine of Equivalents

1. Cases remanded after the Supreme Court decision (*Festo VIII*)

a. Canceling broader claims constitutes a narrowing amendment

In *Pioneer Magnetics, Inc. v. Micro Linear Corp.*,¹⁰³³ a post-*Festo VIII* case decided on remand from the Supreme Court, the Federal Circuit held that an inadvertent limitation of a claim by a patent lawyer is not a defense to prosecution history estoppel.¹⁰³⁴ If related to patentability, even a voluntarily added limitation may reduce or eliminate the available range of equivalents.¹⁰³⁵

In this case, the accused devices had only “non-switching [analog] multiplier” circuits which the plaintiff attempted to prove were equivalent to a claimed “switching” analog multiplier circuit.¹⁰³⁶

The “switching” limitation appeared in a dependent claim added after filing.¹⁰³⁷ The examiner had rejected the original claims as

1028. *Id.*, 66 U.S.P.Q.2d (BNA) at 1292.

1029. *Id.*, 66 U.S.P.Q.2d (BNA) at 1292.

1030. *Id.*, 66 U.S.P.Q.2d (BNA) at 1292.

1031. *Id.*, 66 U.S.P.Q.2d (BNA) at 1292.

1032. *Id.*, 66 U.S.P.Q.2d (BNA) at 1291.

1033. 330 F.3d 1352, 66 U.S.P.Q.2d (BNA) 1859 (Fed. Cir. 2003).

1034. *Id.* at 1356, 66 U.S.P.Q.2d (BNA) at 1861.

1035. *Id.* at 1357, 66 U.S.P.Q.2d (BNA) at 1862.

1036. *Id.* at 1355-56, 66 U.S.P.Q.2d (BNA) at 1861.

1037. *Id.* at 1355, 66 U.S.P.Q.2d (BNA) at 1860-61 (discussing the addition of the “switching” limitation to claim 1, which incorporated by reference the original claims

anticipated even though the patent number that the examiner used as a reference did not disclose a “switching” multiplier.¹⁰³⁸

When amending the claims, the Pioneer Magnetics’ lawyer imported the “switching” limitation from the dependent claim into new independent claim 1.¹⁰³⁹ Contrary to the remarks accompanying the amendment, new claim 1 included all the limitations of the original claims, plus the “switching” limitation.¹⁰⁴⁰ The dependent claim still included, *inter alia*, the “switching” limitation.¹⁰⁴¹

The district court ruled that because the switching limitation was added to overcome a cited reference, Pioneer Magnetics was not entitled to a range of equivalence on this element.¹⁰⁴²

The Federal Circuit, citing *Festo VI*,¹⁰⁴³ originally affirmed the district court’s claim construction and grant of summary judgment.¹⁰⁴⁴ Upon Pioneer Magnetics’ petition to the Supreme Court for a *writ of certiorari*, the Court vacated the Federal Circuit’s decision and remanded the case, along with a number of others, for further consideration in light of *Festo VIII*.¹⁰⁴⁵

Pioneer Magnetics fared no better under *Festo VIII*. The Federal Circuit noted that because the amendment in question narrowed the claim, Pioneer Magnetics had the burden of showing that the amendment was not related to patentability.¹⁰⁴⁶

Relying on a *mea culpa* declaration from its patent lawyer, Pioneer Magnetics argued that it added the “switching” limitation through “inadvertence.”¹⁰⁴⁷ Emphasizing the importance of the prosecution history, the Federal Circuit rejected this evidence because it was not part of the public record of the patent.¹⁰⁴⁸ Pioneer Magnetics also pointed to a discrepancy between the amendment and the accompanying remarks to suggest that it only amended claim 1 to

not containing this limitation).

1038. *Id.*, 66 U.S.P.Q.2d (BNA) at 1860. Pioneer Magnetics did not object to the examiner’s rejection but instead proceeded to amend the original claims. *Id.*, 66 U.S.P.Q.2d (BNA) at 1860.

1039. *Id.*, 66 U.S.P.Q.2d (BNA) at 1860-61.

1040. *Id.*, 66 U.S.P.Q.2d (BNA) at 1860-61 (noting that Pioneer Magnetics never explained why the new amended claim added the “switching” limitation).

1041. *Id.*, 66 U.S.P.Q.2d (BNA) at 1860-61.

1042. *Id.*, 66 U.S.P.Q.2d (BNA) at 1861.

1043. *Festo Corp. v. Shoketsu Kinzoko Kogyo Kabushiki Co.*, 234 F.3d 558, 56 U.S.P.Q.2d (BNA) 1865 (Fed. Cir. 2000).

1044. *Pioneer Magnetics, Inc. v. Micro Linear Corp.*, 238 F.3d 1341, 1346-47, 57 U.S.P.Q.2d (BNA) 1553, 1557 (Fed. Cir. 2001).

1045. 535 U.S. 722, 62 U.S.P.Q.2d (BNA) 1705 (2002).

1046. *Pioneer Magnetics*, 330 F.3d at 1356, 66 U.S.P.Q.2d (BNA) at 1861.

1047. *Id.*, 66 U.S.P.Q.2d (BNA) at 1861.

1048. *Id.*, 66 U.S.P.Q.2d (BNA) at 1861-62.

incorporate certain limitations from the original claims.¹⁰⁴⁹ Pioneer Magnetics argued that the remarks were evidence that the amendment was inadvertent.¹⁰⁵⁰ The court disagreed, pointing out that it was equally likely that the mistake was in the remarks and the amendment was intended.¹⁰⁵¹

The Federal Circuit then considered whether Pioneer Magnetics could prove that the particular equivalent at issue, a “non-switching” multiplier, was unforeseeable at the time of the prosecution of the patent.¹⁰⁵² Since the prior art in the case showed a “non-switching” multiplier, the Federal Circuit concluded that Pioneer Magnetics could not meet its burden that such a structure was not foreseeable.¹⁰⁵³

In *Genzyme Corporation v. Transkaryotic Therapies, Inc.*,¹⁰⁵⁴ the Federal Circuit affirmed a district court’s summary judgment that Transkaryotic Therapies, Inc. (TKT) did not infringe a patent on methods of producing a therapeutic human enzyme,¹⁰⁵⁵ despite an “after final” amendment on which Genzyme relied to broaden the claims.¹⁰⁵⁶

The patent-in-suit claimed “a method of producing human α -galactosidase A (α -Gal A) and cells engineered to express and secrete active human α -Gal A,” which is useful for treating patients suffering from Fabry disease.¹⁰⁵⁷ The claimed method encompassed “culturing a mammalian cell containing a chromosomally integrated nucleotide sequence encoding human α -galactosidase A.”¹⁰⁵⁸ TKT’s allegedly infringing product utilized a technique known as gene activation and involved insertion of a regulatory DNA sequence into a human host cell to activate expression of the endogenous human α -Gal A protein from the endogenous human cellular gene.¹⁰⁵⁹ Neither of the parties disputed that TKT’s technique did not introduce an exogenous α -Gal A gene into human host cells.¹⁰⁶⁰

TKT argued that the term “chromosomally integrated” required the action of inserting a human α -Gal A gene into the host

1049. *Id.*, 66 U.S.P.Q.2d (BNA) at 1861.

1050. *Id.*, 66 U.S.P.Q.2d (BNA) at 1861.

1051. *Id.*, 66 U.S.P.Q.2d (BNA) at 1862.

1052. *Id.* at 1357, 66 U.S.P.Q.2d (BNA) at 1862.

1053. *Id.*, 66 U.S.P.Q.2d (BNA) at 1862.

1054. 346 F.3d 1094, 68 U.S.P.Q.2d (BNA) 1596 (Fed. Cir. 2003).

1055. *Id.* at 1096, 68 U.S.P.Q.2d (BNA) at 1597.

1056. *Id.* at 1102, 68 U.S.P.Q.2d (BNA) at 1602.

1057. *Id.* at 1096, 68 U.S.P.Q.2d (BNA) at 1597-98.

1058. *Id.*, 68 U.S.P.Q.2d (BNA) at 1598.

1059. *Id.*, 68 U.S.P.Q.2d (BNA) at 1598.

1060. *Id.*, 68 U.S.P.Q.2d (BNA) at 1598.

chromosome.¹⁰⁶¹ Genzyme countered that the claims encompassed TKT's gene activation techniques involving activation of an endogenous α -Gal A gene because the origin of nucleotide sequences inserted into a target cell's chromosome was not specified.¹⁰⁶² According to Genzyme, the claims required only that a chromosome in the cell contain a nucleotide sequence that encoded human α -Gal A enzyme.¹⁰⁶³ After the district court rejected Genzyme's position on the meaning of the term "chromosomally integrated," Genzyme conceded it could not prevail on infringement.¹⁰⁶⁴

The Federal Circuit, noting that the specification did not expressly define "chromosomally integrated," initially looked to the ordinary and accustomed meaning of the term and found that the claim language suggested the incorporation of exogenous genetic code into the chromosomal material of the host cell.¹⁰⁶⁵

The remaining issue was whether the exogenous sequences had to come from outside the host cell or could derive from within the host cell but outside the critical chromosome.¹⁰⁶⁶

The court rejected Genzyme's argument that a supplemental, after final amendment broadened the claims to eliminate the requirement for inserting an exogenous gene into a host cell.¹⁰⁶⁷ The court noted that the prosecution history here was silent about the broadening amendment in contravention of applicable PTO rules requiring that after-final claim amendments altering the substantive scope of claims be accompanied by an explanation about the necessity of the amendment.¹⁰⁶⁸ The court refused to accept Genzyme's position that the examiner vastly broadened the claims upon entering the supplemental after final amendment to embrace the over-expression of human α -Gal A sequences endogenous to a host cell.¹⁰⁶⁹ The court found that the combined weight of an applicant's submission of exogenous vector sequences (in compliance with the deposit requirement), the specification, the arguments made to distinguish prior art, the examiner's responses, and a third-party declaration touting the inventiveness of the recombinant expression scheme

1061. *Id.* at 1097, 68 U.S.P.Q.2d (BNA) at 1598.

1062. *Id.* at 1098, 68 U.S.P.Q.2d (BNA) at 1599.

1063. *Id.*, 68 U.S.P.Q.2d (BNA) at 1599.

1064. *Id.* at 1097, 68 U.S.P.Q.2d (BNA) at 1598.

1065. *Id.* at 1098, 68 U.S.P.Q.2d (BNA) at 1599.

1066. *Id.* at 1098-99, 68 U.S.P.Q.2d (BNA) at 1599-1600.

1067. *Id.* at 1103, 68 U.S.P.Q.2d (BNA) at 1603.

1068. *Id.*, 68 U.S.P.Q.2d (BNA) at 1603.

1069. *Id.*, 68 U.S.P.Q.2d (BNA) at 1603.

outweighed an eleventh-hour amendment unaccompanied by an explanation.¹⁰⁷⁰

b. If it is in the prior art—it is foreseeable

In another post-*Festo VIII* decision, *Talbert Fuel Systems Patents Co. v. Unocal Corp.*,¹⁰⁷¹ the Federal Circuit affirmed a district court decision and held that a plaintiff patentee was precluded from proving infringement under the doctrine of equivalents due to prosecution history estoppel.¹⁰⁷²

Talbert sued Unocal for the infringement of a patent directed to certain reformulated gasolines that reduce emissions while maintaining their performance boundaries.¹⁰⁷³ The infringement issue focused on a limitation found in all of the claims requiring the gasoline boiling point to be within of a range of 121°F to 345°F.¹⁰⁷⁴ In the original suit between Talbert and Unocal,¹⁰⁷⁵ the court relied on the absolute bar established by *Festo VI*¹⁰⁷⁶ to deny Talbert access to the doctrine of equivalents.¹⁰⁷⁷ The Supreme Court's vacatur of that decision¹⁰⁷⁸ led to the remand of this case on the issue of prosecution history estoppel.¹⁰⁷⁹

As initially filed, claim 1 recited no temperature range and was rejected based on references that showed gasolines of various hydrocarbon contents and boiling ranges with an upper boiling range of 390°F to 420°F.¹⁰⁸⁰ Unocal's accused fuels had a boiling point range of 373.8°F to 472.9°F.¹⁰⁸¹ Finding that the "temperature limit was placed in the claims at the examiner's insistence, to distinguish over prior art that . . . showed hydrocarbon fuels with an endpoint 'within the range of 390°F and about 420°F,'"¹⁰⁸² the court

1070. *Id.*, 68 U.S.P.Q.2d (BNA) at 1603.

1071. *Talbert Fuel Sys. Patents Co. v. Unocal Corp.*, 347 F.3d 1355, 68 U.S.P.Q.2d (BNA) 1691 (Fed. Cir. 2003).

1072. *Id.* at 1360, 68 U.S.P.Q.2d (BNA) at 1695.

1073. *Id.* at 1356-57, 68 U.S.P.Q.2d (BNA) at 1692. Talbert's claim, as initially filed, stated that the reformulated gasoline would "substantially eliminate evaporative loss and . . . raise the burn rate of the remaining hydrocarbons." *Id.* at 1358, 68 U.S.P.Q.2d (BNA) at 1693.

1074. *Id.* at 1357, 68 U.S.P.Q.2d (BNA) at 1692.

1075. *Talbert Fuel Sys. Patents Co. v. Unocal Corp.*, 275 F.3d 1371, 61 U.S.P.Q.2d (BNA) 1363 (Fed. Cir. 2002).

1076. *Festo Corp. v. Shoketsu Kinzoko Kogyo Kabushiki Co.*, 234 F.3d 558, 56 U.S.P.Q.2d (BNA) 1865 (Fed. Cir. 2000).

1077. *Talbert Fuel Sys.*, 275 F.3d at 1377, 61 U.S.P.Q.2d (BNA) at 1367.

1078. *Talbert Fuel Sys. Patents Co. v. Unocal Corp.*, 537 U.S. 802 (2002).

1079. *Talbert Fuel Sys. Patents Co. v. Unocal Corp.*, 347 F.3d 1355, 68 U.S.P.Q.2d (BNA) 1691 (Fed. Cir. 2003).

1080. *Id.* at 1358, 68 U.S.P.Q.2d (BNA) at 1693.

1081. *Id.* at 1357, 68 U.S.P.Q.2d (BNA) at 1692.

1082. *Id.*, 68 U.S.P.Q.2d (BNA) at 1693.

found there was no “reasonable explanation” of how the “designated endpoint of 345°F is correctly construed to include fuels with endpoints of 373°F and higher”¹⁰⁸³ and held that there was no literal infringement.¹⁰⁸⁴

Talbert requested a remand to the district court for retrial on the issue of infringement under the doctrine of equivalents in view of *Festo VIII* and argued that the 345°F limit does not describe the actual composition that is distilled, at least for carbonated fuels, and would be so recognized by one of skill in the art.¹⁰⁸⁵ Talbert further argued that the evidence would show it did not disclaim coverage of gasolines having an endpoint higher than 345°F, except for gasified fuels.¹⁰⁸⁶ The court had little trouble finding that Talbert’s amendment was a “presumptive surrender of gasolines boiling in the range” between Talbert’s endpoint and the endpoint taught in the prior art that had been cited and applied by the examiner.¹⁰⁸⁷ The court also noted that the record demonstrated that Talbert could not meet the “rebuttal criteria” as articulated by the Supreme Court to avoid the *Festo* presumption.¹⁰⁸⁸

The court noted that the Unocal fuels were foreseeable at the time of the application since the accused gasolines’ boiling point (373.8°F) fell between the highest range of the ‘356 patent (345°F) and the prior art (endpoint 390°F).¹⁰⁸⁹ Moreover, the court noted that by amending the claim during prosecution, Talbert specifically disclaimed fuels at higher boiling points to get its patent approved, and it could not be credibly argued now that it was unforeseeable that fuels with higher boiling ranges than 345°F would be equivalent to the fuels as limited by the amendment.¹⁰⁹⁰

The court further noted that the amendment was not tangential to the alleged equivalent (the Unocal fuel) because the boiling point range of the patented fuels was at issue during prosecution (*i.e.*, it was the direct, not tangential reason for narrowing).¹⁰⁹¹ Finally, the court found Talbert proffered no “other reason” for avoiding estoppel.¹⁰⁹²

1083. *Id.*, 68 U.S.P.Q.2d (BNA) at 1693.

1084. *Id.* at 1357-58, 68 U.S.P.Q.2d (BNA) at 1693.

1085. *Id.* at 1358-59, 68 U.S.P.Q.2d (BNA) at 1694.

1086. *Id.* at 1359, 68 U.S.P.Q.2d (BNA) at 1694.

1087. *Id.*, 68 U.S.P.Q.2d (BNA) at 1694.

1088. *Id.*, 68 U.S.P.Q.2d (BNA) at 1694.

1089. *Id.*, 68 U.S.P.Q.2d (BNA) at 1694-95.

1090. *Id.* at 1359-60, 68 U.S.P.Q.2d (BNA) at 1694-95.

1091. *Id.* at 1360, 68 U.S.P.Q.2d (BNA) at 1695.

1092. *Id.*, 68 U.S.P.Q.2d (BNA) at 1695.

2. Festo IX

In the ninth judicial decision in a lawsuit that was originally filed about fifteen years ago, the Federal Circuit, sitting *en banc* after sifting through no less than fifteen *amicus* briefs, laid down a new set of rules for determining the scope of a prosecution history estoppel.¹⁰⁹³ As recently affirmed by the Supreme Court (in *Festo VIII*), whenever an applicant for a patent narrows the scope of his or her claims by amendment and the patent owner later tries to rely on the doctrine of equivalents to establish infringement, in order to avoid prosecution history estoppel, the patent owner must demonstrate that the amendment was not made for a reason “relating to patentability.”¹⁰⁹⁴

If the applicant cannot demonstrate that he or she amended the claims for reasons unrelated to patentability, the application of prosecution history estoppel will prevent the scope of a patent claim from being expanded under the doctrine of equivalents to embrace a product or process that is only insubstantially different from the element that was amended.¹⁰⁹⁵ Once a court determines that estoppel does apply, the insubstantially different element in the accused product or process will only be embraced as an equivalent if the patent owner can prove that “one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent.”¹⁰⁹⁶

In *Festo VIII*, the Supreme Court said the patent owner can meet this test if “the rationale underlying the amendment [bears] no more than a tangential relationship to the equivalent in question,”¹⁰⁹⁷ or “there [is] some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question.”¹⁰⁹⁸

The Federal Circuit in *Festo IX* reaffirmed these principals and went on to set forth guidelines as to when each of these tests could be met.¹⁰⁹⁹ Before addressing the guidelines, the Federal Circuit

1093. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 68 U.S.P.Q.2d (BNA) 1321 (Fed. Cir. 2003) [hereinafter *Festo IX*].

1094. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 740-41, 62 U.S.P.Q.2d (BNA) 1705, 1713-14 (2002).

1095. *Id.*, 62 U.S.P.Q.2d (BNA) at 1713-14.

1096. *Id.* at 741, 62 U.S.P.Q.2d (BNA) at 1714.

1097. *Id.* at 740, 62 U.S.P.Q.2d (BNA) at 1714.

1098. *Id.* at 740-41, 62 U.S.P.Q.2d (BNA) at 1714.

1099. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1368-70, 68 U.S.P.Q.2d (BNA) 1321, 1327-28 (Fed. Cir. 2003) (stating: (1) that the “unforeseeable at the time of the amendment” test is an objective inquiry into the knowledge of those of ordinary skill in art at the time of the amendment; (2) that amendments made to avoid prior art that contains the equivalent in question are not

addressed an overarching issue, holding that it is up to the court, not the jury, to decide whether the evidence is sufficient to overcome estoppel: “Questions relating to the application and scope of prosecution history estoppel . . . fall within the exclusive province of the court.”¹¹⁰⁰

Then, directing its attention to the first test—when the equivalent would have been unforeseeable at the time of the amendment—the Federal Circuit said the demarcation of such evidence “is best left to development on a case-by-case basis.”¹¹⁰¹ Nevertheless, the court provided “general guidance,” noting that unforeseeability must be determined from the perspective of a hypothetical person of ordinary skill in the art.¹¹⁰² The court said that an allegedly equivalent element that was not known at the time of the amendment “would not have been foreseeable.”¹¹⁰³ An allegedly equivalent element that was known at the time of the amendment “would more likely have been foreseeable.”¹¹⁰⁴ If the element was also known in the field of the invention at the time of the amendment, the court said that the equivalent “certainly should have been foreseeable.”¹¹⁰⁵

The Federal Circuit pointed out that the second test—the “tangential relation” test—examines “whether the reason for the narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent.”¹¹⁰⁶ While the court did not define the scope of this test any more precisely, it did state that an amendment made to avoid prior art that contains the equivalent is not tangential.¹¹⁰⁷ The court said that the tangential relation test must be determined solely based on the prosecution history record.¹¹⁰⁸ Still, the court left the door open to testimony from those skilled in the art “when necessary” to explain the meaning of the record.¹¹⁰⁹

tangential under the “rationale underlying the narrowing amendment” test; and (3) that the “some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question” test must be applied narrowly, only being satisfied when there is some reason, such as the shortcomings of language, why the patentee was prevented from adequately describing the alleged equivalent).

1100. *Id.* at 1368, 68 U.S.P.Q.2d (BNA) at 1327.

1101. *Id.*, 68 U.S.P.Q.2d (BNA) at 1327.

1102. *Id.* at 1368-69, 68 U.S.P.Q.2d (BNA) at 1327.

1103. *Id.* at 1369, 68 U.S.P.Q.2d (BNA) at 1327.

1104. *Id.*, 68 U.S.P.Q.2d (BNA) at 1327.

1105. *Id.*, 68 U.S.P.Q.2d (BNA) at 1328.

1106. *Id.*, 68 U.S.P.Q.2d (BNA) at 1328.

1107. *Id.*, 68 U.S.P.Q.2d (BNA) at 1328.

1108. *Id.* at 1370, 68 U.S.P.Q.2d (BNA) at 1328.

1109. *Id.*, 68 U.S.P.Q.2d (BNA) at 1328.

The Federal Circuit observed that the third test—the “some other reason” inquiry—“while vague, must be a narrow one.”¹¹¹⁰ The court said the test may be satisfied by proof that there was “some reason, such as the shortcomings of language, why the patentee was prevented from describing the alleged equivalent when it narrowed the claim.”¹¹¹¹ Proof that the equivalent was an “inferior and unacceptable design,” however, is insufficient to meet this requirement.¹¹¹² The court also said that the proof should be limited to the prosecution history record “[w]hen at all possible,”¹¹¹³ but did not explain when extrinsic proof would be permitted.

3. *Doctrine of equivalent cases after Festo IX: Canceling broad claims and leaving narrow ones remains a Festo-type narrowing amendment*

In the first post *Festo IX* case decided by the Federal Circuit (on remand from the Supreme Court after *Festo XIII*), *Deering Precision Instruments, L.L.C. v. Vector Distribution Systems, Inc.*,¹¹¹⁴ the Federal Circuit ruled that canceling broader claims and retaining narrower ones re-written in independent form is effectively a *Festo*-type narrowing amendment and presumptively results in no range of equivalents for the narrowed limitation.¹¹¹⁵

Deering’s patent was directed to a compact pocket scale.¹¹¹⁶ An important aspect of the invention was a sliding counterweight that could move closer to the plane of the scale’s fulcrums, thereby minimizing the overall weight of the scale.¹¹¹⁷ In the application originally filed with the PTO, independent claim 1 was the broadest, with no limitation drawn to the exact location of the counterweight.¹¹¹⁸ Claim 3 of the application, dependent on claim 1, included an additional limitation concerning the location of the sliding weight (a limitation that the parties referred to as the “Zero Position Limitation”).¹¹¹⁹ In response to a PTO rejection of claim 1,

1110. *Id.*, 68 U.S.P.Q.2d (BNA) at 1328.

1111. *Id.*, 68 U.S.P.Q.2d (BNA) at 1328.

1112. *Id.* at 1373, 68 U.S.P.Q.2d (BNA) at 1331.

1113. *Id.* at 1370, 68 U.S.P.Q.2d (BNA) at 1328.

1114. 347 F.3d 1314, 68 U.S.P.Q.2d (BNA) 1716 (Fed. Cir. 2003).

1115. *Id.* at 1325-26, 68 U.S.P.Q.2d (BNA) at 1723-24.

1116. *Id.* at 1317, 68 U.S.P.Q.2d (BNA) at 1717.

1117. *Id.* at 1318, 68 U.S.P.Q.2d (BNA) at 1718.

1118. *Id.*, 68 U.S.P.Q.2d (BNA) at 1719. The court stated the claim as defining a light-weight portable scale having a base, a beam with a substance holder at one end and a scale extending in an opposite direction, a sliding weight movably carried by the beam for movement along the scale, a pair of metallic fulcrum posts projecting upwardly from the base, and a pair of metallic bearing inserts in the beam for cooperation with the fulcrum posts.

Id.

1119. *Id.*, 68 U.S.P.Q.2d (BNA) at 1719.

the applicants canceled claim 1 and submitted a new claim 11 which was the original claim 3 rewritten in independent form.¹¹²⁰

Vector conceded that the accused product literally met every limitation of the asserted claims other than the zero position limitation.¹¹²¹ Vector argued that the zero position limitation was absent literally because the key claim term (substantially) required the weight to actually penetrate the plane of the fulcrums.¹¹²² Moreover, based on the prosecution history, Vector argued that the zero position limitation was entitled to no range of equivalents under *Festo VI*.¹¹²³

The district court adopted Vector's construction and its view of the prosecution history, entering a summary judgment of non-infringement.¹¹²⁴

The Federal Circuit agreed with the district court's claim construction and analysis that *Festo* applied to the case.¹¹²⁵ However, in light of the ruling in *Festo XIII* that the presumption is not absolute, the Federal Circuit remanded for the district court to consider whether Deering could rebut the *Festo* presumption that it gave up the right to claim as an equivalent everything between the narrower claims granted and the broader ones canceled.¹¹²⁶

V. DEFENSES

A. *Experimental Use*

1. *Experimental use is a narrow infringement defense*

In a case brought by a former research professor against Duke University for infringing two patents relating to free electron laser technology, the Federal Circuit held that "experimental use" lives on as a narrow defense to a claim infringement.¹¹²⁷

The Federal Circuit held that, despite the Supreme Court ruling in *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*¹¹²⁸ that intent plays no role in the application of the doctrine of equivalents,¹¹²⁹ the defense

1120. *Id.* at 1319, 68 U.S.P.Q.2d (BNA) at 1719.

1121. *Id.* at 1321, 68 U.S.P.Q.2d (BNA) at 1720.

1122. *Id.*, 68 U.S.P.Q.2d (BNA) at 1720.

1123. *Id.*, 68 U.S.P.Q.2d (BNA) at 1720.

1124. *Id.*, 68 U.S.P.Q.2d (BNA) at 1720.

1125. *Id.* at 1324, 68 U.S.P.Q.2d (BNA) at 1723.

1126. *Id.* at 1327, 68 U.S.P.Q.2d (BNA) at 1725.

1127. *Madey v. Duke Univ.*, 307 F.3d 1351, 64 U.S.P.Q.2d (BNA) 1737 (Fed. Cir. 2002).

1128. 520 U.S. 17, 41 U.S.P.Q.2d (BNA) 1865 (1997).

1129. *Id.* at 36, 41 U.S.P.Q.2d (BNA) at 1874.

of “experimental use” is not an “inescapable” intent inquiry¹¹³⁰ and the defense persists, “albeit in the very narrow form articulated by this court in *Embrex . . .*”¹¹³¹ The Federal Circuit further explained that experimental use is not necessarily an affirmative defense and need not be raised as such, *i.e.*, in the answer to the complaint, in order to be preserved.¹¹³² Finally, the court noted that the accused infringer must establish the defense, if available.¹¹³³

In this case, the Federal Circuit reversed the district court’s grant of summary judgment that Duke University’s use of the patented technology was experimental, holding:

[R]egardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer’s legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or nonprofit status of the user is not determinative.¹¹³⁴

In a widely discussed landmark case of first impression, *Integra Lifesciences, Ltd. v. Merck KgaA*,¹¹³⁵ the Federal Circuit affirmed a lower court’s finding of infringement for drug development activity directed to identifying improved compounds for clinical trials, finding that Merck’s biomedical experimentation does not qualify for the U.S. Food and Drug Administration (FDA) exemption.¹¹³⁶ The *Integra* decision significantly clarifies the scope of the FDA exemption.

Integra sued Merck for infringement of five patents related to RGD-containing peptides which can be used in medical devices and therapeutic treatments.¹¹³⁷ *Integra* asserted that the acts of identifying the best of several candidates for clinical development constituted infringing commercial activities.¹¹³⁸ As part of its defense, Merck argued that its drug development activities fell within the FDA exemption of the Hatch-Waxman Act¹¹³⁹ which provides a safe harbor for patents infringement for activity “solely for uses reasonably

1130. *Madey*, 307 F.3d at 1360-61, 64 U.S.P.Q.2d (BNA) at 1745.

1131. *Id.* at 1361, 64 U.S.P.Q.2d (BNA) at 1745. See *Embrex, Inc. v. Serv. Engineering Corp.*, 216 F.3d 1343, 1349, 55 U.S.P.Q.2d (BNA) 1161, 1163 (Fed. Cir. 2000).

1132. *Madey*, 307 F.3d at 1361, 64 U.S.P.Q.2d (BNA) at 1745.

1133. *Id.*, 64 U.S.P.Q.2d (BNA) at 1746.

1134. *Id.* at 1362, 64 U.S.P.Q.2d (BNA) at 1746.

1135. 331 F.3d 860, 66 U.S.P.Q.2d (BNA) 1865 (Fed. Cir. 2003).

1136. *Id.* at 862, 66 U.S.P.Q.2d (BNA) at 1866.

1137. *Id.* at 862-63, 66 U.S.P.Q.2d (BNA) at 1866-67.

1138. *Id.* at 863, 66 U.S.P.Q.2d (BNA) at 1867.

1139. 35 U.S.C. § 271(e)(1) (2000).

related to the development and submission of information” to the FDA.¹¹⁴⁰

The issue decided by the Federal Circuit was whether pre-clinical research identifying the best drug candidate to subject to the FDA approval process was exempt from infringement under the provisions of 35 U.S.C. § 271(e).¹¹⁴¹ Interpreting the statutory language, the court found that the exemption is limited to the uses “reasonably related to the development and submission of information” for FDA safety and effectiveness approval processes.¹¹⁴² The Federal Circuit indicated that activities that do not directly produce information for [the] FDA strain the boundaries of this relationship and noted that the exemption should be confined to activity that “‘would contribute (relatively directly)’ to information the FDA considers in approving a drug.”¹¹⁴³ The court held that Merck’s research activities fell outside of this relationship because identification of an improved drug candidate constitutes only general biomedical research.¹¹⁴⁴ Affirming the district court’s finding that Merck infringed the Integra patents, the court stated that the FDA has no interest in the hunt for drugs, and Merck’s research activities failed to result in clinical testing that provided information to the FDA.¹¹⁴⁵

2. *Importation of the product of a patent process—§ 271(g)*

In a case of first impression, the Federal Circuit in *Bayer AG v. Housey Pharmaceuticals, Inc.*,¹¹⁴⁶ affirmed a lower court’s order dismissing a counterclaim alleging infringement under 35 U.S.C. § 271(g) of four U.S. patents relating to processes of screening for substances that inhibit or activate a protein because the accused drug products “were not ‘manufactured’ by a process claimed in the asserted patents.”¹¹⁴⁷

In 1988 Congress passed the Process Patents Amendments Act,¹¹⁴⁸ enacting § 271(g) which made it an act of infringement to perform a process in another country that would infringe a process claim of a U.S. patent and then import the product into the United States.¹¹⁴⁹

1140. *Id.*

1141. *Integra*, 331 F.3d at 865-66, 66 U.S.P.Q.2d (BNA) at 1868.

1142. *Id.* at 866, 66 U.S.P.Q.2d (BNA) at 1869 (quoting 35 U.S.C. § 271(e)(1)).

1143. *Id.* at 867, 66 U.S.P.Q.2d (BNA) at 1870 (quoting *Intermedics v. Ventritex*, 775 F. Supp. 1269, 1280 (N.D. Cal. 1991)).

1144. *Id.* at 866, 66 U.S.P.Q.2d (BNA) at 1869.

1145. *Id.*, 66 U.S.P.Q.2d (BNA) at 1869.

1146. 340 F.3d 1367, 68 U.S.P.Q.2d (BNA) 1001 (Fed. Cir. 2003).

1147. *Id.* at 1368, 68 U.S.P.Q.2d (BNA) at 1002.

1148. 35 U.S.C. § 271 (1988).

1149. *Id.* § 271(g) (2000).

At issue before the Federal Circuit in this case was the meaning of the phrase “a product which is made by a process” as found in § 271(g).¹¹⁵⁰ Housey argued that the information generated by the patented method fit within the statutory meaning of § 271(g), which should be interpreted broadly to cover any patented method, whether or not the method produces a physical product.¹¹⁵¹ Bayer argued that § 271(g) applies only to manufacturing processes that result in a physical product.¹¹⁵² Since Bayer had imported only information, there could be no infringement of the Housey patent claims.¹¹⁵³

After analyzing the words of the statute as well as the extensive legislative history of the Process Patents Amendments Act, the Federal Circuit concluded that § 271(g) applied only to importation of physical objects derived from manufacturing processes.¹¹⁵⁴ The court also found that processes of identification and data generation are not steps in the manufacture of a product because they are not directly used in the synthesis of the product.¹¹⁵⁵ Consequently, the Federal Circuit held that Bayer’s importation of information derived from its screening activities was not an infringement of the Housey patents.¹¹⁵⁶

B. Implied License: Sale of Product by Patentee That Can Only Be Used in a Patented Combination is Subject to an Implied License To Do So

In *Anton/Bauer, Inc. v. PAG, Ltd.*,¹¹⁵⁷ the Federal Circuit vacated a preliminary injunction and found that purchasers of a patentee’s “female plate” battery pack had an implied license to mate the battery pack with a “male” charging plate and thus obviated any direct infringement of the claimed combination of a male and female plate.¹¹⁵⁸

The issue presented to the Federal Circuit stemmed from Anton/Bauer’s manufactured batteries which, in order to be properly used with a video camera or battery charger, required a specific connective device.¹¹⁵⁹ The patent-in-suit, a connective device allowing

1150. *Bayer*, 340 F.3d at 1371, 68 U.S.P.Q.2d (BNA) at 1004.

1151. *Id.*, 68 U.S.P.Q.2d (BNA) at 1004.

1152. *Id.*, 68 U.S.P.Q.2d (BNA) at 1004.

1153. *Id.*, 68 U.S.P.Q.2d (BNA) at 1004.

1154. *Id.* at 1377, 68 U.S.P.Q.2d (BNA) at 1008.

1155. *Id.*, 68 U.S.P.Q.2d (BNA) at 1009.

1156. *Id.* at 1378, 68 U.S.P.Q.2d (BNA) at 1009.

1157. 329 F.3d 1343, 66 U.S.P.Q.2d (BNA) 1675 (Fed. Cir. 2003).

1158. *Id.* at 1353, 66 U.S.P.Q.2d (BNA) at 1681-82.

1159. *Id.* at 1346, 66 U.S.P.Q.2d (BNA) at 1676.

“a battery pack to be ‘quickly and efficiently replaced upon discharge of the batteries[,]’” claimed:

a combination of a female plate and a male plate, where the female plate contain[ed] a plurality of . . . slots and the male plate contain[ed] a plurality of projections that correspond[ed] to the female . . . slots. The claimed combination . . . formed when a female . . . and a male plate [were] fitted together to form a mechanical and an electrical connection.¹¹⁶⁰

In the instant case, Anton/Bauer sold its female plates directly to the camera industry and also indirectly to end-users.¹¹⁶¹ In addition, Anton/Bauer separately sold battery packs that contained male plates.¹¹⁶² PAG, Ltd. (PAG), the alleged infringer, sold a battery pack with male plates compatible with Anton/Bauer’s female plates.¹¹⁶³ In the subsequent infringement suit, Anton/Bauer claimed that PAG’s battery pack “induced infringement of [its] patent and/or contributed to the infringement of [its] patent by Anton/Bauer’s customers.”¹¹⁶⁴

The district court issued a preliminary injunction against PAG, holding Anton/Bauer’s claims likely to prevail and, in turn, rejected the argument “that Anton/Bauer had exhausted its patents rights” and “had granted its customers an implied license to practice the claimed invention.”¹¹⁶⁵

On appeal, PAG argued that the Federal Circuit should properly apply the implied license test of *Met-Coil Systems Corp. v. Korners Unlimited, Inc.*¹¹⁶⁶ because the district court failed to do so “by requiring that the accused battery pack be a replacement for an element of the claimed combination and by requiring a showing of affirmative acts on the part of Anton/Bauer that would lead a customer to believe that an implied license had[,] in fact, been granted.”¹¹⁶⁷ The Federal Circuit agreed, noting that “[t]he sale of the unpatented female plate by Anton/Bauer [constituted] a complete transfer of the [plate] ownership,” extinguishing

1160. *Id.*, 66 U.S.P.Q.2d (BNA) at 1676.

1161. *Id.* at 1347, 66 U.S.P.Q.2d (BNA) at 1676-77.

1162. *Id.*, 66 U.S.P.Q.2d (BNA) at 1677.

1163. *Id.*, 66 U.S.P.Q.2d (BNA) at 1677.

1164. *Id.*, 66 U.S.P.Q.2d (BNA) at 1677.

1165. *Id.*, 66 U.S.P.Q.2d (BNA) at 1677.

1166. 803 F.2d 684, 687, 231 U.S.P.Q. (BNA) 474, 476 (Fed. Cir. 1986). In *Met-Coil*, the Federal Circuit held that “[a] patent owner’s unrestricted sales of a machine useful only in performing the claimed process and producing the claimed product ‘plainly indicate that the grant of a license should be inferred.’” *Id.*, 231 U.S.P.Q. (BNA) 474, 476.

1167. *Anton/Bauer*, 329 F.3d at 1350, 66 U.S.P.Q.2d (BNA) at 1679.

“Anton/Bauer’s right to control the use of the plate[.]”¹¹⁶⁸ The court held that “the plate [could] only be used in the patented combination and [that] the combination must [have been] complete[d] by the purchaser.”¹¹⁶⁹

Because Anton/Bauer did not expressly restrict customer use of the female plates, the court held that “Anton/Bauer grant[ed] an implied license to its customers to employ the combination claimed in the . . . patent. Accordingly, there [was] no direct infringement to support a claim of either inducement of infringement or contributory infringement.”¹¹⁷⁰

VI. HATCH-WAXMAN ACT CASES § 271(E)(2)

A. *Off Label Use Not Actionable Under § 271(e); But May or May Not Constitute Actionable Inducement*

In *Warner-Lambert Co. v. Apotex Corp.*,¹¹⁷¹ the Federal Circuit upheld the grant of summary judgment of non-infringement of a patent claiming a method of using the drug gabapentin to treat “neurodegenerative diseases” where the defendant applied to use the drug for the treatment of epilepsy.¹¹⁷²

Warner-Lambert (now Pfizer) sued Apotex under 35 U.S.C. § 271(e)(2)(a), alleging that Apotex’s filing of an abbreviated new drug application (ANDA) to market a generic gabapentin for the treatment of epilepsy infringed Warner-Lambert’s patent.¹¹⁷³ It was undisputed that the FDA has approved the use of gabapentin only for treatment of epilepsy and that its use in the treatment of neurodegenerative disease would constitute an additional use.¹¹⁷⁴

Although Apotex never sought or received approval for the use of gabapentin to treat neurodegenerative diseases, Warner-Lambert argued that Apotex’s filing of the ANDA constituted infringement of Warner-Lambert’s patent because patients had used Warner-Lambert’s product for treating neurodegenerative diseases and would likely use Apotex’s gabapentin for this purpose as well.¹¹⁷⁵

The Federal Circuit rejected Warner-Lambert’s contention that § 271(e) prohibits submission of an ANDA seeking approval to make,

1168. *Id.* at 1351, 66 U.S.P.Q.2d (BNA) at 1680.

1169. *Id.*, 66 U.S.P.Q.2d (BNA) at 1680.

1170. *Id.*, 66 U.S.P.Q.2d (BNA) at 1680.

1171. 316 F.3d 1348, 65 U.S.P.Q.2d (BNA) 1481 (Fed. Cir. 2003).

1172. *Id.* at 1351, 65 U.S.P.Q.2d (BNA) at 1482.

1173. *Id.* at 1353, 65 U.S.P.Q.2d (BNA) at 1483.

1174. *Id.* at 1352, 65 U.S.P.Q.2d (BNA) at 1482.

1175. *Id.* at 1353, 65 U.S.P.Q.2d (BNA) at 1483.

use, or sell a drug for an approved use if any other use of the drug is claimed in a non-expired patent.¹¹⁷⁶ To the contrary, the Federal Circuit held that “it is not an act of infringement to submit an ANDA for approval to market a drug for a use when neither the drug nor the use is covered by an existing patent, and the patent at issue is for a use not approved [by the FDA].”¹¹⁷⁷

In *Alergen, Inc. v. Alcon Labs., Inc.*,¹¹⁷⁸ the Federal Circuit, following the precedent set in *Warner-Lambert Co. v. Apotex Corp.*, once again held that 35 U.S.C. § 271(e)(2) does not permit innovator drug companies to enjoin ANDA filers from marketing a generic drug where the ANDA filer’s liability is based upon an allegation of inducement of infringement.¹¹⁷⁹ The Federal Circuit held that because defendants Alcon and Bausch & Lomb’s ANDA requested approval for a method of using an approved drug, but the requested method was not covered by the innovator’s patent, the defendants could not be liable for infringement under § 271(e)(2).¹¹⁸⁰ Judge Clevenger wrote for the panel.

In an unusual turn of events, separate, concurring opinions were filed by Judges Schall and Linn. In Judge Schall’s concurring opinion, in which Judge Clevenger joined, the *Warner-Lambert* opinion was well roasted, even though the panel felt constrained to follow it.¹¹⁸¹ In the opinion of this panel, the statutory language of the Hatch-Waxman Act does permit § 271(e)(2) suits for inducing infringement.¹¹⁸² It could seem that the rationale of *Warner-Lambert* is ripe for *en banc* review or possible legislative “correction.”

B. FDA Practices Pass Federal Circuit Muster

In a case that turned on statutory interpretation and that involved Apotex’s application to market a generic version of SmithKline Beecham Corporation’s (SmithKline) antidepressant Paxil, the Federal Circuit upheld various FDA practices relating to the implementation of the Hatch-Waxman Act.¹¹⁸³

Under the Hatch-Waxman Act, the FDA permits companies to file an ANDA where the drug is “a generic version of an approved

1176. *Id.* at 1355, 65 U.S.P.Q.2d (BNA) at 1484.

1177. *Id.* at 1354-55, 65 U.S.P.Q.2d (BNA) at 1484.

1178. 324 F.3d 1322, 66 U.S.P.Q.2d (BNA) 1225 (Fed. Cir. 2003).

1179. *Id.* at 1330, 66 U.S.P.Q.2d (BNA) at 1231.

1180. *Id.* at 1334, 66 U.S.P.Q.2d (BNA) at 1234.

1181. *Id.*, 66 U.S.P.Q.2d (BNA) at 1234.

1182. *Id.*, 66 U.S.P.Q.2d (BNA) at 1234.

1183. *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1352, 68 U.S.P.Q.2d (BNA) 1725, 1738 (Fed. Cir. 2003); *see* 21 U.S.C. § 355 (2000).

drug.”¹¹⁸⁴ New Drug Application (NDA) applicants must identify and the FDA must list patents that claim either NDA drugs or “a method of using such drug [through which] a claim of patent infringement could reasonably be asserted’ against a party who made, used or sold the drug.”¹¹⁸⁵ In turn, with regard to each patent listed by the FDA in the Orange Book, ANDA applicants are obligated to verify either “that no patent information has been filed with the FDA[,]” that the patent has or will expire on a particular date, or “that the patent is invalid or will not be infringed by the . . . generic drug.”¹¹⁸⁶

Apotex, Inc. filed an ANDA for a generic version of the drug Paxil.¹¹⁸⁷ At the time of filing, only one patent was listed relating to SmithKline’s NDA for Paxil.¹¹⁸⁸ Because Apotex’s proposed generic drug contained as an active ingredient an anhydrous form of Paxil’s active ingredient, Apotex filed a certification asserting that its generic would not infringe the listed patent.¹¹⁸⁹ SmithKline responded with an infringement action, causing the implementation of an automatic thirty month stay for ANDA regulatory approval.¹¹⁹⁰ SmithKline subsequently was issued five additional patents relating to the anhydrate form of Paxil’s active ingredient and submitted each for listing by the FDA.¹¹⁹¹ Apotex filed certifications for each of “the newly listed patents” and SmithKline, in turn, responded with separate infringement actions, each triggering a separate thirty month stay.¹¹⁹²

Apotex filed a complaint alleging, *inter alia*, that the five subsequently issued patents did “not claim Paxil or a method of using Paxil as approved in the original NDA” and did not satisfy the statutory requirements for listing in the Orange Book; that the FDA must determine whether patents qualify for listing; that “the FDA’s practice of requiring an ANDA applicant to certify patents [listed] after an ANDA ha[d] been submitted violate[d] the Hatch-Waxman Act;” and that “the FDA’s regulation permitting the listing of patents as part of NDA supplements violate[d] the Act[.]”¹¹⁹³

Construing the plain statutory language as well as interpreting congressional intent, the Federal Circuit concluded that nothing in

1184. *Apotex*, 347 F.3d at 1338, 68 U.S.P.Q.2d (BNA) at 1727.

1185. *Id.*, 68 U.S.P.Q.2d (BNA) at 1727 (quoting 21 U.S.C. § 355(b)(1)).

1186. *Id.*, 68 U.S.P.Q.2d (BNA) at 1727.

1187. *Id.* at 1339, 68 U.S.P.Q.2d (BNA) at 1728.

1188. *Id.*, 68 U.S.P.Q.2d (BNA) at 1728.

1189. *Id.*, 68 U.S.P.Q.2d (BNA) at 1728.

1190. *Id.*, 68 U.S.P.Q.2d (BNA) at 1728.

1191. *Id.* at 1340, 68 U.S.P.Q.2d (BNA) at 1728-29.

1192. *Id.*, 68 U.S.P.Q.2d (BNA) at 1729.

1193. *Id.*, 68 U.S.P.Q.2d (BNA) at 1729.

the Hatch-Waxman Act obligates the FDA to screen Orange Book submissions and to refuse patent listings that do not satisfy the statutory requirements for listing.¹¹⁹⁴ The Federal Circuit also concluded that the statutory language showed clear congressional intent “to require certification whenever an ANDA applicant seeks approval of a drug that is claimed by a [listed] patent[.]”¹¹⁹⁵ Furthermore, it upheld the FDA’s requirement of certification of “patent information . . . submitted after [an] ANDA is . . . filed.”¹¹⁹⁶ Additionally, it supported the FDA regulation that required supplemental NDA patents to “be listed in the Orange Book[.]” characterizing it as “consistent with the procedures for submitting patent information for both pending and approved NDAs[.]”¹¹⁹⁷

VII. INEQUITABLE CONDUCT

A. *The Sanction for Inequitable Conduct May Be Less Than Unenforceability*

In a case where the Federal Circuit affirmed the United States District Court for the Northern District of California’s holding of inequitable conduct on some, but not all, of the relied upon bases, it proceeded to remand the case for a determination of whether the incidents of inequitable conduct on which it affirmed justified the sanction of unenforceability.¹¹⁹⁸

The patent in question generally was directed to enzymes used in DNA replication termed “DNA polymerase” or, more specifically, to a *Thermus aquaticus* bacterium enzyme, or “Taq” polymerase.¹¹⁹⁹ Hoffman-La Roche, Inc. (“Roche”) alleged that Promega Corp. (“Promega”) breached its licensing agreement with Roche, and thereby became an infringer of the patent.¹²⁰⁰ Promega counterclaimed, alleging the patent “unenforceable due to inequitable conduct[.]”¹²⁰¹ The district court declared the patent unenforceable based on eight separate material representations and

1194. *Id.* at 1347-49, 68 U.S.P.Q.2d (BNA) at 1734-36.

1195. *Id.* at 1350, 68 U.S.P.Q.2d (BNA) at 1737.

1196. *Id.* at 1350-51, 68 U.S.P.Q.2d (BNA) at 1737.

1197. *Id.* at 1352, 68 U.S.P.Q.2d (BNA) at 1738.

1198. *Hoffman-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1372, 66 U.S.P.Q.2d (BNA) 1385, 1398 (Fed. Cir. 2003).

1199. *Id.* at 1358, 66 U.S.P.Q.2d (BNA) at 1387.

1200. *Id.* at 1359, 66 U.S.P.Q.2d (BNA) at 1388.

1201. *Id.*, 66 U.S.P.Q.2d (BNA) at 1388.

omissions, of which three were addressed in the summary judgment state and the remainder after a bench-trial.¹²⁰²

The panel majority reviewed the district court's finding of inequitable conduct using the clear error standard, stating that the "findings on materiality and intent . . . [would] not be overturned in the absence of a 'definite and firm conviction' that a mistake [had] been made."¹²⁰³ While parsing through the eight issues one-by-one and evaluating the sub-issues of materiality and intent for each, the Federal Circuit reversed some and affirmed others.¹²⁰⁴

In the end, the court noted that "[o]nce the requisite levels of materiality and intent are shown, the district court must determine whether the equities warrant a conclusion that the patentee has engaged in inequitable conduct."¹²⁰⁵ The Federal Circuit remanded the case to the district court to determine, in its discretion, whether the material misstatements or omissions were "sufficiently serious in light of the evidence of intent to deceive . . . to warrant the severe sanction of holding the patent unenforceable."¹²⁰⁶

Judge Newman vociferously dissented on the "clear error" standard of review, arguing that the majority cast aside the safeguard previously established by the court by requiring that material misrepresentation and intent to deceive be shown by clear and convincing evidence.¹²⁰⁷ She noted that this requirement was established in response to "the past 'plague' of charges of 'inequitable conduct'" and cautioned that the decision may bring a similar "[n]ew [p]lague."¹²⁰⁸ In Judge Newman's view, Promega's arguments illustrated "litigation tactic[s]" and she insisted that the "clear and convincing" standard of proof should be used both at trial and on review.¹²⁰⁹

B. Acts of Foreign Patent Agent Give Rise to Inequitable Conduct and Non-Enabling Prior Art May Still Be Material

Reinvigorating the inequitable conduct defense, the Federal Circuit affirmed the ruling of the district court, which held

1202. *Id.*, 66 U.S.P.Q.2d (BNA) at 1388.

1203. *Id.*, 66 U.S.P.Q.2d (BNA) at 1388 (quoting *Molins PLC v. Textron Inc.*, 48 F.3d 1172, 1178, 33 U.S.P.Q.2d (BNA) 1823, 1827 (Fed. Cir. 1995)).

1204. *Id.* at 1359-60, 66 U.S.P.Q.2d (BNA) at 1388.

1205. *Id.* at 1359, 66 U.S.P.Q.2d (BNA) at 1388.

1206. *Id.* at 1372, 66 U.S.P.Q.2d (BNA) at 1398.

1207. *Id.* at 1372-73, 66 U.S.P.Q.2d (BNA) at 1398 (Newman, J., dissenting).

1208. *Id.* at 1372, 1381, 66 U.S.P.Q.2d (BNA) at 1398, 1405.

1209. *Id.* at 1373-74, 1381, 66 U.S.P.Q.2d (BNA) at 1399, 1405.

unenforceable patents to a method of synthesizing taxol, a cancer drug, because they were obtained by inequitable conduct.¹²¹⁰

The patents in question stemmed from a scientific article written by the named inventors and published in the JOURNAL OF THE AMERICAN CHEMICAL SOCIETY (“JACS”).¹²¹¹ The inventors submitted the draft article to a French patent agent in the employ of Rhône-Poulenc Rorer (“RPR”).¹²¹² The article explained that the method the inventors devised used “protecting groups” to prevent particular hydroxyl groups from interfering with the formation of taxol.¹²¹³ Both the draft article and the inventor’s invention disclosure explained certain limitations, of which the inventors were aware, with regard to the protecting groups.¹²¹⁴ However, the draft application, prepared for filing in France by RPR’s agent, did not specify hydroxyl-protecting group limitations.¹²¹⁵ Rather, the French application stated that the TMS and MOM groups, which consisted of the very groups that the inventors explained should not act as protecting groups, were permissible hydroxyl-protecting groups.¹²¹⁶ A U.S. patent lawyer, who later received the French application, had it translated and filed as a U.S. application.¹²¹⁷

The JACS article was never disclosed to the PTO.¹²¹⁸ It was, however, uncovered as the result of a computer search performed by the PTO scientific library at the Examiner’s request.¹²¹⁹ Because of its non-prior art publication date, the Examiner apparently did not consider it.¹²²⁰

The district court found, by clear and convincing evidence, that the inventors failed to provide material information by not providing the JACS article to the PTO, and that the Examiner did not review the JACS article before issuing the patent.¹²²¹

In an opinion written by Judge Prost, which contained a fact-specific analysis, the Federal Circuit affirmed the district court.¹²²² Judge Prost noted that, despite the JACS article, the patents

1210. Bristol-Myers Squibb Co. v. Rhône-Poulenc Rorer, Inc., 326 F.3d 1226, 1229, 66 U.S.P.Q.2d (BNA) 1481, 1482 (Fed. Cir. 2003).

1211. *Id.* at 1230, 66 U.S.P.Q.2d (BNA) at 1483.

1212. *Id.*, 66 U.S.P.Q.2d (BNA) at 1483.

1213. *Id.* at 1229-30, 66 U.S.P.Q.2d (BNA) at 1482-83.

1214. *Id.* at 1230, 66 U.S.P.Q.2d (BNA) at 1483.

1215. *Id.* at 1231, 66 U.S.P.Q.2d (BNA) at 1483.

1216. *Id.*, 66 U.S.P.Q.2d (BNA) at 1483.

1217. *Id.*, 66 U.S.P.Q.2d (BNA) at 1484.

1218. *Id.*, 66 U.S.P.Q.2d (BNA) at 1484.

1219. *Id.*, 66 U.S.P.Q.2d (BNA) at 1484.

1220. *Id.* at 1231-33, 66 U.S.P.Q.2d (BNA) at 1484-85.

1221. *Id.* at 1233, 66 U.S.P.Q.2d (BNA) at 1485.

1222. *Id.* at 1242, 66 U.S.P.Q.2d (BNA) at 1492.

“specifically recommend[ed]” using groups that resulted in an unstable esterification process and additionally recommended one group that could not be removed after the esterification.¹²²³ Judge Prost agreed with the district court, finding:

a reasonable patent examiner reviewing the subject patent application would have expected the use of TMS and MOM groups to yield more than trace amounts of taxol, but that a review of the JACS article would have raised doubts that the use of TMS and MOM would produce taxol in more than trace amounts.¹²²⁴

Thus, Judge Prost found the JACS article to be material, notwithstanding the fact that the district court denied Bristol-Myers’ summary judgment motion for lack of enablement.¹²²⁵ He stated:

The district court’s holding on inequitable conduct is not contradictory to its holding on enablement. The issue of whether a reference would be considered important by a reasonable examiner in determining whether a patent application is allowable, including whether the invention is enabled, is a separate issue from whether the invention is actually enabled.¹²²⁶

The court, in affirming the holding of the district court on the issue of intent, stated:

In a case such as this, where [the RPR agent] was intimately familiar with the article because the inventors with whom he worked wrote it, [where] he approved the article for publication, and [where] the article was in his possession while he was drafting the French patent application, the determination that [the RPR agent] knew of the significance of the JACS article in combination with the finding that [the RPR agent] knew of the duty to disclose is sufficient to establish intent.¹²²⁷

C. Failure to Disclose Rejection by Another Examiner is Material

Although it reversed and remanded a district court summary judgment of inequitable conduct because of a factual dispute on the issue of intent, the Federal Circuit made clear that an applicant’s failure to disclose a rejection by a different examiner of a claim similar to that in issue meets the materiality prong of an inequitable conduct defense.¹²²⁸

1223. *Id.* at 1234, 66 U.S.P.Q.2d (BNA) at 1486.

1224. *Id.*, 66 U.S.P.Q.2d (BNA) at 1486.

1225. *Id.* at 1238, 66 U.S.P.Q.2d (BNA) at 1489.

1226. *Id.* at 1238-39, 66 U.S.P.Q.2d (BNA) at 1489.

1227. *Id.* at 1240, 66 U.S.P.Q.2d (BNA) at 1491.

1228. *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1368, 66 U.S.P.Q.2d (BNA) 1801, 1808 (Fed. Cir. 2003).

The patents-in-suit claimed priority “through a string of continuation applications.”¹²²⁹ The family of applications for the patents-in-suit and a related family of applications were assigned to two different examiners.¹²³⁰ The examiner of the related family of applications (Examiner A) was made aware of the applications for the patent-in-suit.¹²³¹ However, the examiner of the patent-in-suit (Examiner B) was not made aware of the existence of the family of related applications.¹²³² The claims in the related family of applications were substantially identical to the claims of the patents-in-suit and were rejected by Examiner A on the three separate occasions.¹²³³ Examiner B was neither advised of these rejections, nor was the prior art cited by Examiner A brought to Examiner B’s attention.¹²³⁴

The district court found that Dayco committed inequitable conduct when it “intentionally withheld material prior art and information concerning [the] co-pending [196] application from the patent examiner [assigned to the patents-in-suit]” and granted summary judgment.¹²³⁵ Dayco appealed.¹²³⁶

The Federal Circuit reversed and remanded but, in doing so, agreed with the district court that under the “reasonable examiner” standard of materiality, a co-pending application is “highly material” where “it could have conceivably served as the basis of a double patenting rejection.”¹²³⁷ The court rejected Dayco’s argument that its filing of a terminal disclaimer limiting the term of the related application (to the terminal date of another issued patent) obviated the materiality of the non-disclosure: “a copending application may be material even though it cannot result in a shorter patent term when it could affect the rights of the patentee to assign the issue patents.”¹²³⁸ Thus, the court reasoned that the disclosure of the copending application “could have led to double patenting rejections

1229. *Id.* at 1360, 66 U.S.P.Q.2d (BNA) at 1803.

1230. *Id.* at 1361, 66 U.S.P.Q.2d (BNA) at 1803.

1231. *Id.*, 66 U.S.P.Q.2d (BNA) at 1803.

1232. *Id.*, 66 U.S.P.Q.2d (BNA) at 1803.

1233. *Id.*, 66 U.S.P.Q.2d (BNA) at 1803.

1234. *Id.* at 1361-62, 66 U.S.P.Q.2d (BNA) at 1804.

1235. *Id.* at 1362, 66 U.S.P.Q.2d (BNA) at 1804.

1236. *Id.*, 66 U.S.P.Q.2d (BNA) at 1804.

1237. *Id.* at 1365, 66 U.S.P.Q.2d (BNA) at 1806 (quoting *Akron Polymer Container Corp. v. Exxel Container, Inc.*, 148 F.3d 1380, 1382, 47 U.S.P.Q.2d (BNA) 1533, 1534 (Fed. Cir. 1998)).

1238. *Id.*, 66 U.S.P.Q.2d (BNA) at 1806.

in the applications that issued as the patents-in-suit¹²³⁹ and that the pending, related application was therefore material.¹²⁴⁰

Regarding the applicant's failure to disclose the prior rejection, the court held that "a contrary decision of another examiner reviewing a substantially similar claim meets the *Akron Polymer*¹²⁴¹ 'reasonable examiner' threshold materiality test of 'any information that a reasonable examiner would substantially likely consider important in deciding whether to allow an application to issue as a patent.'¹²⁴² The court reasoned that "[a]lthough examiners are not bound to follow other examiners' interpretations, knowledge of a potentially different interpretation is clearly information that an examiner could consider important when examining an application."¹²⁴³ However, the court remanded the case for a determination of a finding regarding intent to deceive.¹²⁴⁴

D. Commercial Test Results Not Material to Patentability

In *CFMT, Inc. v. Yieldup Int'l Corp.*,¹²⁴⁵ the Federal Circuit vacated a district court's summary judgment of lack of enablement and reversed its finding of inequitable conduct, holding instead that an applicant does not necessarily have a duty to disclose disappointing test results.¹²⁴⁶

The two patents in suit were directed to systems for cleaning semiconductor wafers.¹²⁴⁷ While the applications were still pending, the inventors tested the patented machine at a Texas Instruments (TI) facility, where it failed to meet TI's cleanliness standards for removing particulates.¹²⁴⁸ In response, the inventors came up with improvements for which they sought and obtained another patent.¹²⁴⁹

The district court found the claims of the patents in suit were not enabled because the claimed invention failed to remove particulates.¹²⁵⁰ The court also held that the issuance of the improvement patent showed that undue experimentation was

1239. *Id.*, 66 U.S.P.Q.2d (BNA) at 1807.

1240. *Id.* at 1365-66, 66 U.S.P.Q.2d (BNA) at 1807.

1241. *Akron Polymer*, 148 F.3d at 1380, 47 U.S.P.Q.2d (BNA) at 1533.

1242. *Dayco*, 329 F.3d at 1368, 66 U.S.P.Q.2d (BNA) at 1808 (quoting *Akron Polymer*, 148 F.3d at 1382, 47 U.S.P.Q.2d (BNA) at 1534).

1243. *Id.*, 66 U.S.P.Q.2d (BNA) at 1808.

1244. *Id.*, 66 U.S.P.Q.2d (BNA) at 1808.

1245. 349 F.3d 1333, 68 U.S.P.Q.2d (BNA) 1940 (Fed. Cir. 2003).

1246. *Id.* at 1342-43, 68 U.S.P.Q.2d (BNA) at 1947.

1247. *Id.* at 1335, 68 U.S.P.Q.2d (BNA) at 1941.

1248. *Id.* at 1336, 68 U.S.P.Q.2d (BNA) at 1942.

1249. *Id.*, 68 U.S.P.Q.2d (BNA) at 1942.

1250. *Id.* at 1336-37, 68 U.S.P.Q.2d (BNA) at 1943.

required to practice the patents in suit.¹²⁵¹ The district court further found the inventors had committed inequitable conduct by failing to disclose the negative TI test results to the PTO.¹²⁵²

Construing the claims to require any level—not some specific level—of contaminant removal, the Federal Circuit found the claims were enabled by the specification because the inventors' prototype removed penciled grease marks.¹²⁵³ The Federal Circuit observed that the enablement requirement “does not require that a patent disclosure enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect.”¹²⁵⁴ Moreover, the Federal Circuit found that even if the prototype did not achieve “complete cleaning,” the claimed invention would not be inoperative on that ground alone.¹²⁵⁵ The Federal Circuit rejected the district court's holding that the improvement patent demonstrated that undue experimentation was required to enable the claims of the two patents in suit.¹²⁵⁶

As to unenforceability, the Federal Circuit held the negative TI test results were not material to the patentability of the claimed invention because the TI data “reflects a commercial, not a statutory, standard for enablement.”¹²⁵⁷

E. Payment of Maintenance Fees at Small Entity May Constitute Inequitable Conduct—But Not Patent Expiration

In a case involving multiple payments of maintenance fees at the small entity rate, even after the patent had been licensed to non-qualified licensees, the Federal Circuit applied its traditional “inequitable conduct” analysis in vacating and remanding a summary judgment ruling that a patent owner engaged in inequitable conduct by falsely claiming small entity status.¹²⁵⁸

When the patent in suit was assigned to Lex Computer, it qualified as a small entity.¹²⁵⁹ Lex later signed a non-exclusive license with Adobe Systems, a company having more than 500 employees.¹²⁶⁰ Lex subsequently submitted a petition to the PTO to accept late payment

1251. *Id.* at 1337, 68 U.S.P.Q.2d (BNA) at 1943.

1252. *Id.*, 68 U.S.P.Q.2d (BNA) at 1943.

1253. *Id.* at 1338-39, 68 U.S.P.Q.2d (BNA) at 1944.

1254. *Id.* at 1338, 68 U.S.P.Q.2d (BNA) at 1944.

1255. *Id.* at 1339, 68 U.S.P.Q.2d (BNA) at 1945.

1256. *Id.* at 1340, 68 U.S.P.Q.2d (BNA) at 1945.

1257. *Id.* at 1342, 68 U.S.P.Q.2d (BNA) at 1947.

1258. *Ulead Sys., Inc. v. Lex Computer & Mgmt. Corp.*, 351 F.3d 1139, 1150, 69 U.S.P.Q.2d (BNA) 1097, 1105 (Fed. Cir. 2003).

1259. *Id.* at 1142, 69 U.S.P.Q.2d (BNA) at 1099.

1260. *Id.*, 69 U.S.P.Q.2d (BNA) at 1099.

of the second maintenance fee at the reduced (small entity) amount and a verified statement, signed by its president, claiming small entity status.¹²⁶¹ The petition was granted and the patent was reinstated.¹²⁶² Lex paid the third maintenance fee (this time the petition was signed by its patent lawyer in a similar manner).¹²⁶³ During litigation, when the maintenance issue fee issue was raised, Lex Computer paid the fee difference, submitting its payments under 37 C.F.R. § 1.28(c).¹²⁶⁴

Ulead sought declaratory judgment that the subject patent is invalid, unenforceable, and not infringed and filed a motion for summary judgment urging that Lex's false claim of small entity status renders the patent unenforceable or invalid, and that Lex's failure to pay the correct maintenance fee and payment of the incorrect small entity fee without "good faith" caused the patent to expire.¹²⁶⁵

Lex's president testified that when he signed this declaration, he was unaware that a non-exclusive license could result in the forfeiture of small entity status.¹²⁶⁶ Lex's patent lawyer explained that when he paid the third maintenance fee, he was unaware that Lex had finalized license agreements with any companies having more than 500 employees.¹²⁶⁷

The Federal Circuit, applying its traditional inequitable conduct analysis from the *en banc*, *Kingsdown* decision,¹²⁶⁸ an analysis based on materiality and intent factors, concluded that Lex's misrepresentation to the PTO regarding its small entity status was material because it affected the "survival of the patent" but ruled that there are genuine issues of material fact regarding Lex's intent.¹²⁶⁹ The Federal Circuit stated that the facts might show gross negligence, but "gross negligence is not, in and of itself, sufficient to satisfy the intent element of inequitable conduct."¹²⁷⁰

The Federal Circuit noted that § 1.28(c) is the only provision "governing expiration for failure to pay the full maintenance fee because of an erroneous claim to small entity status," and that the regulation does not require or authorize an inquiry into "good faith" by the PTO or by the district court when determining whether a

1261. *Id.*, 69 U.S.P.Q.2d (BNA) at 1099.

1262. *Id.* at 1143, 69 U.S.P.Q.2d (BNA) at 1099.

1263. *Id.*, 69 U.S.P.Q.2d (BNA) at 1099-1100.

1264. *Id.*, 69 U.S.P.Q.2d (BNA) at 1099.

1265. *Id.*, 69 U.S.P.Q.2d (BNA) at 1099.

1266. *Id.* at 1147, 69 U.S.P.Q.2d (BNA) at 1102.

1267. *Id.* at 1147-48, 69 U.S.P.Q.2d (BNA) at 1103.

1268. *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 9 U.S.P.Q.2d (BNA) 1384 (Fed. Cir. 1988).

1269. *Ulead Sys.*, 351 F.3d at 1146, 69 U.S.P.Q.2d (BNA) at 1101-02.

1270. *Id.* at 1148, 69 U.S.P.Q.2d (BNA) at 1102.

patent has expired for failure to pay maintenance fees.¹²⁷¹ However, this does not mean inequitable conduct cannot be found in connection with such a payment.¹²⁷² The Federal Circuit reasoned that if a patent owner knew that it did not qualify as a small entity when it paid a maintenance fee at the reduced, small entity rate, but attempts to submit the correct payment using the vehicle of § 1.28(c) to pay the difference, “the patentee may be found to have engaged in inequitable conduct.”¹²⁷³

In a vigorous dissent, Judge Newman asserted that the majority had made it easier to revoke a granted property right.¹²⁷⁴ She argued that the majority’s rationale changes the standard applied to revoking a patent due to incorrectly paying maintenance fees from the higher fraud standard to the lower inequitable conduct standard.¹²⁷⁵

VIII. REMEDIES

A. Reasonable Royalties

1. Sale of non-infringing products may be relevant to reasonable royalty damages

In *Micro Chemical, Inc. v. Lextron, Inc.*,¹²⁷⁶ the Federal Circuit affirmed the trial court’s admission into evidence of expert testimony regarding sales of non-infringing products that were promoted by making the infringing product available free of charge as relevant to a reasonable royalty determination.¹²⁷⁷

In an effort to promote sales of their animal health products, Micro Chemical and Lextron provided their feedlot customers with computerized medical records systems for tracking health histories and medical treatments of livestock.¹²⁷⁸ Micro Chemical’s medical records system was the commercial embodiment of the invention described and claimed in the patent in issue.¹²⁷⁹

Lextron’s co-defendant, Turnkey Computer Systems, supplied accounting system software to feedlots, including an animal records

1271. *Id.* at 1149, 69 U.S.P.Q.2d (BNA) at 1104.

1272. *Id.* at 1150, 69 U.S.P.Q.2d (BNA) at 1105.

1273. *Id.*, 69 U.S.P.Q.2d (BNA) at 1105.

1274. *Id.* at 1155, 69 U.S.P.Q.2d (BNA) at 1108 (Newman, J., dissenting).

1275. *Id.* at 1150-51, 69 U.S.P.Q.2d (BNA) at 1105.

1276. 317 F.3d 1387, 65 U.S.P.Q.2d (BNA) 1532 (Fed. Cir. 2003).

1277. *Id.* at 1389, 65 U.S.P.Q.2d (BNA) at 1533.

1278. *Id.*, 65 U.S.P.Q.2d (BNA) at 1533.

1279. *Id.*, 65 U.S.P.Q.2d (BNA) at 1533.

module that tracks health and treatment histories of livestock.¹²⁸⁰ Turnkey allegedly underpriced its animal records module in order to support sales of its accounting system.¹²⁸¹

Prior to trial, the defendants unsuccessfully sought to exclude testimony that a reasonable royalty for Lextron's infringing computer systems should be based on revenues from sales of its animal health products.¹²⁸² The district court ruled that while Micro Chemical could not recover a royalty on the animal health products themselves, it could present testimony that sales of animal health products were relevant to a reasonable royalty determination based on Micro Chemical's allegation that the defendants used their infringing system as a loss leader to promote animal health product sales.¹²⁸³

The Federal Circuit rejected the defendants' argument that the trial court failed to exercise its gatekeeping function: "When, as here, the parties' experts rely on conflicting sets of facts, it is not the role of the trial court to evaluate the correctness of facts underlying one expert's testimony."¹²⁸⁴

2. *Post-judgment interest calculated from date of order under appeal*

A no doubt red-faced Federal Circuit corrected an obvious oversight in *Tronzo v. Biomet*,¹²⁸⁵ finding that post-judgment interest on a \$20 million punitive damages award should be calculated from the date of the district court's amended judgment after appeal and not from the date of its original judgment.¹²⁸⁶

The plaintiff sued Biomet for the patent infringement, fraud, and breach of confidential relationship.¹²⁸⁷ In 1996, a jury awarded Tronzo almost \$4 million in compensatory damages, which the district court enhanced by almost \$2 million based on the jury finding of willful infringement.¹²⁸⁸ The plaintiff was also awarded punitive damages of \$20 million.¹²⁸⁹ On appeal, the Federal Circuit ruled that the plaintiff's patent was invalid and remanded the case for a recomputation of compensatory damages based only on the tort claims.¹²⁹⁰ On remand, the district court reduced the compensatory

1280. *Id.*, 65 U.S.P.Q.2d (BNA) at 1533.

1281. *Id.*, 65 U.S.P.Q.2d (BNA) at 1533.

1282. *Id.* at 1390, 65 U.S.P.Q.2d (BNA) at 1534.

1283. *Id.*, 65 U.S.P.Q.2d (BNA) at 1534.

1284. *Id.* at 1392, 65 U.S.P.Q.2d (BNA) at 1535.

1285. 318 F.3d 1378, 65 U.S.P.Q.2d (BNA) 1861 (Fed. Cir. 2003).

1286. *Id.* at 1379, 65 U.S.P.Q.2d (BNA) at 1863.

1287. *Id.*, 65 U.S.P.Q.2d (BNA) at 1862.

1288. *Id.*, 65 U.S.P.Q.2d (BNA) at 1862.

1289. *Id.*, 65 U.S.P.Q.2d (BNA) at 1862.

1290. *Id.*, 65 U.S.P.Q.2d (BNA) at 1862.

damages as instructed.¹²⁹¹ Despite the fact that the award of punitive damages was never appealed, the district court also reduced the punitive damages award to \$52,000 on the grounds that the original award was excessive in light of the reduction in compensatory damages.¹²⁹² The Federal Circuit reversed the reduction in punitive damages, holding that the district court exceeded its mandate on the remand by disturbing the unappealed punitive damages award.¹²⁹³ The district court entered yet another amended final judgment and awarded the plaintiff post-judgment interest from August 6, 1996, the date of the original judgment on the punitive damages award.¹²⁹⁴

Biomet appealed, arguing that the calculation of interest on the punitive damages award should run from July 27, 2002, not from August 6, 1996.¹²⁹⁵ The Federal Circuit, recognizing that it erred in not instructing the district court on the interest calculation (as it was required to do by Federal Rule of Appellate Procedure 37(b)), called its prior decision an appellate lapse and gave the interest issue plenary review.¹²⁹⁶ Applying the law of the regional circuit, the court used a “meaningful ascertainment” test for determining when post-judgment interest should begin to run and held that because the plaintiff’s initial compensatory and punitive damages award was modified when the plaintiff’s patent was held invalid, and because the full punitive damages award was not reinstated until after the Federal Circuit’s mandate, post-judgment interest should run from the district court’s July 2001 judgment.¹²⁹⁷

B. Attorney Fees

In addition to the *McNeil-PPC* case discussed *supra*, the following cases are of interest:

1. Pre-litigation conduct not germane to attorney fees

In *Forest Laboratories, Inc. v. Abbott Laboratories*,¹²⁹⁸ the Federal Circuit, finding that conduct that gives rise to an equitable estoppel defense is not an appropriate basis for awarding attorney fees, reversed a district

1291. *Id.*, 65 U.S.P.Q.2d (BNA) at 1862.

1292. *Id.*, 65 U.S.P.Q.2d (BNA) at 1862.

1293. *Id.*, 65 U.S.P.Q.2d (BNA) at 1862.

1294. *Id.*, 65 U.S.P.Q.2d (BNA) at 1864.

1295. *Id.*, 65 U.S.P.Q.2d (BNA) at 1862.

1296. *Id.* at 1379-80, 65 U.S.P.Q.2d (BNA) at 1862-63.

1297. *Id.* at 1381-82, 65 U.S.P.Q.2d (BNA) at 1864.

1298. 339 F.3d 1324, 67 U.S.P.Q.2d (BNA) 1682 (Fed. Cir. 2003).

court in finding that a case was “exceptional” under 35 U.S.C. § 285.¹²⁹⁹

The *Abbott* case concerned two patents, licensed by Abbot, that were directed to a lung surfactant composition for treating respiratory distress syndrome in premature babies (the Tanabe patents).¹³⁰⁰ Pursuant to its license, Abbott developed a commercial product known as Survanta®.¹³⁰¹ ONY developed its own product, Calf Lung Surfactant Extract (CLSE), which was further developed and marketed by Forest Laboratories under the trade name Infasurf®.¹³⁰²

Throughout the 1980s, Abbott and ONY discussed the development of CLSE.¹³⁰³ Abbott informed ONY that it had opted not to develop CLSE.¹³⁰⁴ In 1984, after conducting a patentability search, Abbott told ONY that CLSE was likely not patentable in light of two “pertinent references,” but did not mention the Tanabe patents.¹³⁰⁵ Abbott and ONY discussed future collaboration and the possibility of joint development of CLSE.¹³⁰⁶ Abbott monitored the development of CLSE while internally expressing concern that ONY might receive FDA approval for its Infasurf® product before Abbott could receive approval for Survanta®.¹³⁰⁷

However, in 1991, Abbott received FDA approval and orphan drug status for Survanta®.¹³⁰⁸ Abbott subsequently informed ONY and Forest that it had reason to believe that Infasurf® would infringe the Tanabe patents if it were marketed.¹³⁰⁹ When ONY filed a new drug application in 1995 for approval to market Infasurf®, the FDA notified ONY that Infasurf® was the “same drug” as Survanta® under the Orphan Drug Act, and it therefore could not be approved for sale until Abbott’s seven-year market exclusivity period expired.¹³¹⁰

ONY and Forest sued Abbott seeking a declaratory judgment of non-infringement and invalidity of the Tanabe patents. Abbott counterclaimed for infringement.¹³¹¹ The district court granted ONY and Forest a judgment of non-infringement as a matter of law

1299. *Id.* at 1326, 67 U.S.P.Q.2d (BNA) at 1682.

1300. *Id.*, 67 U.S.P.Q.2d (BNA) at 1683.

1301. *Id.*, 67 U.S.P.Q.2d (BNA) at 1683.

1302. *Id.*, 67 U.S.P.Q.2d (BNA) at 1683.

1303. *Id.*, 67 U.S.P.Q.2d (BNA) at 1683.

1304. *Id.*, 67 U.S.P.Q.2d (BNA) at 1683.

1305. *Id.*, 67 U.S.P.Q.2d (BNA) at 1683.

1306. *Id.*, 67 U.S.P.Q.2d (BNA) at 1683-84.

1307. *Id.*, 67 U.S.P.Q.2d (BNA) at 1684.

1308. *Id.*, 67 U.S.P.Q.2d (BNA) at 1684.

1309. *Id.*, 67 U.S.P.Q.2d (BNA) at 1684.

1310. *Id.*, 67 U.S.P.Q.2d (BNA) at 1684.

1311. *Id.* at 1327, 67 U.S.P.Q.2d (BNA) at 1684.

(JMOL) finding that Abbott failed to present any evidence to show CLSE infringed the Tanabe patents and that Abbott was equitably estopped from asserting infringement of the Tanabe patents against ONY and Forest.¹³¹² The district court based its equitable estoppel ruling on its finding that Abbott misled ONY and Forest to believe that “it would not assert infringement by encouraging their development of Infasurf® and by neglecting its duty to inform them of any possible infringement,” upon which ONY and Forest reasonably relied.¹³¹³

The district court also granted ONY and Forest’s motion for attorney fees and expenses finding the case to be “exceptional” under § 285.¹³¹⁴ The district court found that Abbott, in bad faith, encouraged ONY to develop CLSE, disregarded its duty to advise ONY and Forest of possible infringement, and pursued its infringement counterclaim with a “reckless disregard for the facts in an attempt to prevent Infasurf® from reaching the market.”¹³¹⁵

The Federal Circuit reversed, finding that “exceptional” cases under § 285 are those cases involving “inequitable conduct before the [patent office]; litigation misconduct; vexatious, unjustified, and otherwise bad faith litigation; a frivolous suit or willful infringement.”¹³¹⁶ Since none of those circumstances was present, it was error for the district court, in its “expansive reading of § 285,” to find the case exceptional.¹³¹⁷ The Federal Circuit noted, “[W]e have not . . . upheld a finding of exceptionality based on a patentee’s bad-faith business conduct toward an accused infringer prior to litigation, and we decline to expand the scope of the statutory term ‘exceptional’ in that manner.”¹³¹⁸ While equitable estoppel may be imposed when a patentee induces another party to believe that it will not be sued for infringement, the consequence of that estoppel is the loss of the cause of action, not attorney fees, “under the rubric of exceptional case.”¹³¹⁹

2. *Vexatious suit merits attorney fee award*

In a sharply-worded *per curiam* opinion, the Federal Circuit upheld the district court in the latest of a long series of appeals involving

1312. *Id.*, 67 U.S.P.Q.2d (BNA) at 1684.

1313. *Id.*, 67 U.S.P.Q.2d (BNA) at 1684.

1314. *Id.*, 67 U.S.P.Q.2d (BNA) at 1684.

1315. *Id.*, 67 U.S.P.Q.2d (BNA) at 1684 (citation omitted).

1316. *Id.* at 1329, 67 U.S.P.Q.2d (BNA) at 1685 (citation omitted).

1317. *Id.*, 67 U.S.P.Q.2d (BNA) at 1685.

1318. *Id.*, 67 U.S.P.Q.2d (BNA) at 1686.

1319. *Id.*, 67 U.S.P.Q.2d (BNA) at 1686.

Phonometrics and its claims to telephone billing display technology and sanctioned the appellant.¹³²⁰ The opinion is principally noteworthy for the court's order that Phonometrics and its attorney, jointly and severally, be required to pay Westin \$3,000 as a sanction for making frivolously unmeritorious arguments before the appeals court.¹³²¹

Among other things, the court rejected attempts by Phonometrics to argue that an earlier, non-precedential decision was not binding on it (even though it was a party to that earlier case).¹³²² The court held that Phonometrics was not free to reargue positions it had lost on the earlier appeal.¹³²³

The court also rejected Phonometric's argument that the district judge should have recused himself because he:

- (1) ruled against it on every issue; (2) awarded attorney fees every time a defendant sued by Phonometrics has requested them; (3) insisted on adopting a consistent claim construction and (4) disagreed with Phonometrics' proffered construction of the phrase 'substantially instantaneous' after [the Federal Circuit's] decision in [the earlier], non-precedential case.¹³²⁴

C. Sanctions: Where District Court Misapprehended Substantive Law, Sanction Award Reversed

In *Waymark Corp., et al. v. Porta Systems Corp.*,¹³²⁵ a case decided more on substantive issues than damages issues, the Federal Circuit reversed a district court's award of attorneys' fees imposed on plaintiffs for pursuing claims that, according to the district court, presented "no basis for recovery."¹³²⁶ The Federal Circuit found the district court sanctioned the plaintiffs based on its own misunderstanding of the governing law.¹³²⁷

Waymark and the Caravello Family Limited Partnership sued Porta Systems Corp. for patent infringement as well as the infringement of the trademark "Battscan."¹³²⁸ The complaint alleged the partnership was the owner of the patent, and Waymark was the exclusive

1320. *Phonometrics, Inc., v. Westin Hotel Co.*, 319 F.3d 1328, 1329, 65 U.S.P.Q.2d (BNA) 1949, 1950 (Fed. Cir. 2003).

1321. *Id.* at 1334, 65 U.S.P.Q.2d (BNA) at 1954.

1322. *Id.* at 1332, 65 U.S.P.Q.2d (BNA) at 1952.

1323. *Id.*, 65 U.S.P.Q.2d (BNA) at 1952-53.

1324. *Id.* at 1333, 65 U.S.P.Q.2d (BNA) at 1953.

1325. 334 F.3d 1358, 67 U.S.P.Q.2d (BNA) 1303 (Fed. Cir. 2003).

1326. *Id.* at 1362, 67 U.S.P.Q.2d (BNA) at 1306.

1327. *Id.* at 1366, 67 U.S.P.Q.2d (BNA) at 1309.

1328. *Id.* at 1360, 67 U.S.P.Q.2d (BNA) at 1304-05.

licensee.¹³²⁹ The district court granted summary judgment of non-infringement for Porta Systems on the patent count and dismissed the trademark and trade dress count for lack of standing.¹³³⁰ While that decision was on appeal to the Federal Circuit, the district court granted a motion by Porta Systems for attorneys' fees.¹³³¹ The court based its sanction on its finding that there was not basis for the plaintiffs' trademark infringement claim due to the fact the plaintiffs' trademark had not been registered until more than a year after the suit was filed.¹³³² The district court further found that there was no written exclusive patent license agreement from the partnership to Waymark and, thus, Waymark did not have standing to file suit for patent infringement.¹³³³ Finally, the court found the plaintiffs "provided a misleading response" to Porta Systems' discovery request for a copy of the written patent assignment to Waymark and the district court's order to show cause as to the legal sufficiency of the oral license agreement.¹³³⁴ The district court found the case "exceptional" and held that "had Plaintiffs conducted a proper pre-filing investigation, Defendant would not have incurred the substantial attorney[s'] fees and costs it now claims."¹³³⁵ The district court also based its sanction on the 28 U.S.C. § 1927 prohibition against vexatious litigation.¹³³⁶

The Federal Circuit applied the law of the Eleventh Circuit to the sanction order.¹³³⁷ The Federal Circuit found that the district court erred in basing its sanction order on the fact the plaintiffs' trademark was not registered at the time the action was filed.¹³³⁸ The court explained that because the complaint sought relief under § 43(a) of the Lanham Act, which provides a remedy for infringement of both registered and unregistered trademarks, the district court's award of sanctions was based on a misunderstanding of the governing law.¹³³⁹

The Federal Circuit also found that the district court did not correctly state the Law relating to the plaintiffs' standing to bring their patent infringement claims, explaining that only assignments

1329. *Id.*, 67 U.S.P.Q.2d (BNA) at 1305.

1330. *Id.*, 67 U.S.P.Q.2d (BNA) at 1305.

1331. *Id.* at 1361, 67 U.S.P.Q.2d (BNA) at 1306.

1332. *Id.*, 67 U.S.P.Q.2d (BNA) at 1306.

1333. *Id.*, 67 U.S.P.Q.2d (BNA) at 1306.

1334. *Id.* at 1361-62, 67 U.S.P.Q.2d (BNA) at 1306.

1335. *Id.* at 1362, 67 U.S.P.Q.2d (BNA) at 1306 (alteration from original) (citation omitted).

1336. *Id.*, 67 U.S.P.Q.2d (BNA) at 1306.

1337. *Id.*, 67 U.S.P.Q.2d (BNA) at 1306.

1338. *Id.* at 1363, 67 U.S.P.Q.2d (BNA) at 1308.

1339. *Id.* at 1363-64, 67 U.S.P.Q.2d (BNA) at 1307-08.

need be in writing; licenses may be oral.¹³⁴⁰ While a holder of an oral license can sue for patent infringement “only in extremely limited circumstances,” the court noted that one of the plaintiffs here claimed a written assignment of the patent and clearly had standing to sue.¹³⁴¹

Finally, the court reversed the imposition of sanctions under 28 U.S.C. § 1927, explaining that § 1927 must be strictly construed, and sanctions under that statute are to only be assessed against counsel “who willfully abuse the judicial process by conduct tantamount to bad faith.”¹³⁴² The court held that Porta Systems was required to show more than lack of merit to the plaintiffs’ claims to serve as a basis for sanctions under § 1927.¹³⁴³

D. Punitive Damages: \$50 Million Punitive Damage Award Comports with Due Process

The Federal Circuit previously affirmed a verdict that DeKalb Genetics Corp. fraudulently induced Rhône-Poulenc Agro, S.A. (RPA) to enter into a 1994 license agreement relating to an optimized transit peptide (OTP) genetic material useful in growing herbicide-resistant corn plants, and approved a \$50 million punitive damage award.¹³⁴⁴ On remand from the Supreme Court to reconsider the reward in light of the Supreme Court’s latest pronouncements regarding due process constraints on punitive damages awards,¹³⁴⁵ the Federal Circuit found DeKalb’s conduct was sufficiently reprehensible to support the punitive damages award.¹³⁴⁶

The case arose from RPA’s claims that DeKalb fraudulently induced RPA to enter into the license agreement by failing to share certain successful field test results with RPA which were the result of collaborative efforts between the two companies.¹³⁴⁷ Instead of sharing those results, DeKalb allegedly used them to backcross the successful OTP-containing corn plants with commercial corn

1340. *Id.*, 67 U.S.P.Q.2d (BNA) at 1308.

1341. *Id.*, 67 U.S.P.Q.2d (BNA) at 1308.

1342. *Id.* at 1365, 67 U.S.P.Q.2d (BNA) at 1308-09 (quoting *Malautea v. Suzuki Motor Co., Ltd.*, 987 F.2d 1536, 1544 (11th Cir. 1993)).

1343. *Id.* at 1366, 67 U.S.P.Q.2d (BNA) at 1309.

1344. *Rhône-Poulenc Agro, S.A. v. DeKalb Genetics Corp.*, 272 F.3d 1335, 60 U.S.P.Q.2d (BNA) 1769 (Fed. Cir. 2001).

1345. *See State Farm v. Campbell*, 538 U.S. 408 (2003) (prohibiting grossly excessive punitive damage awards as violations of the Fourteenth Amendment because they further no legitimate state purpose and constitute an arbitrary deprivation of property).

1346. *Rhône-Poulenc Agro, S.A. v. DeKalb Genetics Corp.*, 345 F.3d 1366, 68 U.S.P.Q.2d (BNA) 1314 (Fed. Cir. 2003).

1347. *Id.* at 1368, 68 U.S.P.Q.2d (BNA) at 1315-16.

varieties, thus gaining an advantage on any potential competition.¹³⁴⁸ RPT alleged that by withholding its knowledge of the successful field test results, DeKalb was able to negotiate a more advantageous license agreement with RPA.¹³⁴⁹

At trial, the jury awarded RPA \$1 in nominal damages, \$15 million in unjust enrichment recovery, and \$50 million in punitive damages.¹³⁵⁰ In its 2001 opinion, the Federal Circuit affirmed, finding that the jury's award of punitive damages was not unconstitutionally excessive.¹³⁵¹ The court based its decision on the factors set forth by the Supreme Court in the 1996 *BMW vs. Gore*¹³⁵² decision, and found "DeKalb's conduct was sufficiently reprehensible to support the award of punitive damages."¹³⁵³

The Supreme Court vacated the Federal Circuit decision¹³⁵⁴ and remanded the case for reconsideration in light of its recent punitive damages opinion in *State Farm*.¹³⁵⁵ In its decision on remand, the Federal Circuit found that DeKalb's conduct fell within the specific *State Farm* factors that weighed in favor of sustaining a punitive damages award.¹³⁵⁶ The Federal Circuit noted that the *State Farm* court explicitly listed "intentional malice, trickery, or deceit" as factors to consider in determining whether a party's conduct was "reprehensible" for purposes of imposing punitive damages, and asserted: "The Supreme Court's addition of 'intentional malice, trickery, or deceit' as a specifically identified criterion for determining reprehensibility directly supports [our prior] holding."¹³⁵⁷

The Federal Circuit also rejected DeKalb's claim that under *State Farm*, the \$50 million in punitive damages unconstitutionally exceeded the \$15 million in compensatory damages awarded by the jury.¹³⁵⁸ As noted by the Federal Circuit, under *State Farm* "an award

1348. *Id.*, 68 U.S.P.Q.2d (BNA) at 1316.

1349. *Id.*, 68 U.S.P.Q.2d (BNA) at 1316.

1350. *Id.* at 1369, 68 U.S.P.Q.2d (BNA) at 1316.

1351. Rhône-Poulenc Agro, S.A. v. DeKalb Genetics Corp., 272 F.3d 1335, 1352, 60 U.S.P.Q.2d (BNA) 1769, 1780 (Fed. Cir. 2001).

1352. *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 574-75 (1996) (listing the three factors as: (1) the degree of responsibility of the defendant's misconduct; (2) the disparity between the harm suffered by the plaintiff and the punitive damages award; and (3) the difference between the punitive damages awarded by the jury and the civil penalties authorized or imposed in comparable cases).

1353. *Rhône-Poulenc Agro*, 272 F.3d at 1349, 60 U.S.P.Q.2d (BNA) at 1777.

1354. *DeKalb Genetics Corp. v. Bayer Crop Sci., S.A.*, 123 S. Ct. 1828 (2003).

1355. *State Farm v. Campbell*, 538 U.S. 408 (2003).

1356. *Rhône-Poulenc Agro, S.A. v. DeKalb Genetics Corp.*, 345 F.3d 1366, 1371, 68 U.S.P.Q.2d (BNA) 1314, 1318 (Fed. Cir. 2003).

1357. *Id.*, 68 U.S.P.Q.2d (BNA) at 1317-18.

1358. *Id.*, 68 U.S.P.Q.2d (BNA) at 1318.

of more than four times the amount of compensatory damages might be close to the line of constitutional impropriety,”¹³⁵⁹ but found that here “the proportion of punitive damages to compensatory damages does not even approach the possible threshold of constitutional impropriety.”¹³⁶⁰

1359. *Id.*, 68 U.S.P.Q.2d (BNA) at 1318 (citation omitted).

1360. *Id.* at 1372, 68 U.S.P.Q.2d (BNA) at 1318.