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2004 Patent Law Decisions of the Federal Circuit

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2004 Patent Law Decisions of the Federal Circuit

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AREA SUMMARIES

2004 PATENT LAW DECISIONS OF THE FEDERAL CIRCUIT

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INTRODUCTION

Although much ink has been spilled regarding the Federal Circuit's failure to achieve the very purpose for which it was created¹—to bring uniformity to patent law—the decisions in 2004 may have been the most frustrating year yet for practitioners, district court judges, and even the Federal Circuit judges themselves.² Indeed, the Federal Circuit

1. See, e.g., Mathew F. Weil & William C. Rooklidge, *Stare Un-Decisis: The Sometimes Rough Treatment of Precedent in Federal Circuit Decision-Making*, 80 J. PAT. & TRADEMARK OFF. SOC'Y 791, 791 (1998) (stating that the Federal Circuit was created in order to foster a uniform application of the patent law to allow research based on "well-established rules").

2. The only group that may be pleased by the Federal Circuit's consistent inconsistency is academia, which, as canvassed by Judge Rader, has generated a remarkable body of work critiquing the Federal Circuit's opinions. *Univ. of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303, 1314-25, 71 U.S.P.Q.2d (BNA) 1545, 1554-66 (Fed. Cir. 2004) (Rader,

characterized its own precedent as “inconsistent” and “confusing.”³ Seeming to realize that the resolution of claim construction disputes is highly panel dependent, the Federal Circuit announced that it would experiment with disclosing the panel composition the Thursday before the week of oral argument.⁴ The court also decided to review en banc the panel decision in *Phillips v. AWH Corp.*⁵ and requested briefing on seven different questions concerning claim construction. However, given that many of these questions were not even implicated in *Phillips*, together with the court’s penchant for balkanized opinions in en banc hearings, *Phillips* does not portend well for the much sought after uniformity in claim construction jurisprudence.

I. PROCEDURAL ASPECTS

A. Appellate Jurisdiction

In *Competitive Technologies, Inc. v. Fujitsu Ltd.*,⁶ defendant included several counterclaims in its answer to the plaintiff’s action for patent infringement, including state-law claims for breach of confidentiality, misappropriation of trade secrets, fraud, and negligent misrepresentation, as well as unfair competition and “abuse of process.”⁷ Plaintiff contended that these counterclaims should have been dismissed because, among other things, they violated its Eleventh Amendment sovereign immunity.⁸ Crediting plaintiff’s position, the district court determined that plaintiff was an “arm of the state” entitled to sovereign immunity under the Eleventh Amendment, but held that plaintiff had waived immunity to defendant’s counterclaims because such counterclaims were compelled by the underlying patent infringement action.⁹ The district court reasoned that defendant’s counterclaims were based on the same underlying factual allegations as its affirmative defenses, including unclean hands which “encompasses all of the conduct alleged in support of” the counterclaims at

J., dissenting from denial of en banc hearing); see also Paula K. Davis, *Questioning the Requirement for Written Description: Enzo Biochem v. Gen-Probe and Overly Broad Patent Cases*, 37 IND. L. REV. 467, 500 (2004) (arguing that lenient enforcement of the written description requirement slows the pace of scientific research); Harold C. Wegner, *The Disclosure Requirements of the 1952 Patent Act: Looking Back and a New Statute for the Next Fifty Years*, 37 AKRON L. REV. 243, 244 (2004) (criticizing changes to Section 112 as “an arcane deviation from the rest of the world”).

3. *Univ. of Rochester*, 375 F.3d at 1305, 1307, 71 U.S.P.Q.2d (BNA) at 1546, 1548.

4. In 2005, the Federal Circuit ended this experiment.

5. 376 F.3d 1382, 71 U.S.P.Q.2d (BNA) 1765 (Fed. Cir. 2004).

6. 374 F.3d 1098, 71 U.S.P.Q.2d (BNA) 1359 (Fed. Cir. 2004).

7. *Id.* at 1099, 71 U.S.P.Q.2d (BNA) at 1360-61.

8. *Id.* at 1100, 71 U.S.P.Q.2d (BNA) at 1361.

9. *Id.*, 71 U.S.P.Q.2d (BNA) at 1361.

issue.¹⁰ The court noted, however, that if it later determined that the affirmative defenses were not supported by the evidence or were otherwise insufficient as a matter of law, it would “revisit the question of [plaintiff’s] waiver of Eleventh Amendment immunity.”¹¹ Plaintiff appealed the district court’s decision on the waiver issue to the Federal Circuit.

As a threshold matter, the Federal Circuit held that it lacked jurisdiction over the appeal because (1) the judgment below lacked finality,¹² and (2) the district court did not issue the certificate required by Federal Rule of Civil Procedure 54(b) or 28 U.S.C. § 1292(b).¹³ The Federal Circuit was not persuaded by the plaintiff’s argument that the judgment was an appealable collateral order that fell within an exception to the final judgment rule under *Cohen v. Beneficial Industrial Loan Corp.*¹⁴ It explained that in deciding *Cohen*, the Supreme Court created an exception to the final judgment rule, “permitting immediate appeals from orders that ‘fall in that small class which finally determine claims of right separate from, and collateral to rights asserted in the action, too important to be denied review and too independent of the cause itself to require that appellate consideration be deferred until the whole case is adjudicated.’”¹⁵ Looking to later cases clarifying *Cohen*, however, the Federal Circuit held that the appealed judgment did not fall within the excepted class of orders.¹⁶

Specifically, the Federal Circuit explained that the appealed judgment did not “conclusively determine the disputed question” as required by *Cohen*.¹⁷ Because the district court stated that “it may be necessary to revisit the question of [plaintiff’s] waiver of Eleventh Amendment

10. *Id.*, 71 U.S.P.Q.2d (BNA) at 1361.

11. *Id.* at 1100-01, 71 U.S.P.Q.2d (BNA) at 1361-62 (quoting *Competitive Techs. v. Fujitsu Ltd.*, 286 F. Supp. 2d 1118, 1140 n.15 (N.D. Cal. 2003)).

12. Federal law provides that the federal Circuit Courts of Appeals, excepting the United States Court of Appeals for the Federal Circuit, shall have appellate jurisdiction from “all final decisions of the district courts of the United States . . .” 28 U.S.C. § 1291 (2000).

13. *Competitive Techs.*, 374 F.3d at 1101, 71 U.S.P.Q.2d (BNA) at 1362; *see also* 28 U.S.C. § 1292(b) (2000) (permitting the appeal of an interlocutory decision if such order “involves a controlling question of law as to which there is substantial ground for difference of opinion”); FED. R. CIV. P. 54(b) (allowing courts to enter final judgment as to fewer than all claims or parties “upon an express determination that there is no just reason for delay and upon express direction for the entry of judgment.”).

14. 337 U.S. 541 (1949).

15. *Competitive Techs.*, 374 F.3d at 1102, 71 U.S.P.Q.2d (BNA) at 1362.

16. *Id.* at 1103, 71 U.S.P.Q.2d (BNA) at 1363-64 (citing *Swint v. Chambers County Comm’n*, 514 U.S. 35, 42 (1995) (declining review of summary judgment where district court planned to review its ruling)).

17. Later cases clarifying *Cohen* relied upon by the court explained that “[t]o come within the ‘small class’ of decisions excepted from the final judgment rule by *Cohen*, the order must conclusively determine the disputed question, resolve an important issue completely separate from the merits of the action, and be effectively unreviewable on appeal from a final judgment.” *Coopers & Lybrand v. Livesay*, 437 U.S. 463, 468 (1978), *quoted in Competitive Techs.*, 374 F.3d at 1102, 71 U.S.P.Q.2d (BNA) at 1363.

immunity” if it were to determine that the affirmative defenses lacked sufficient evidentiary support,¹⁸ the Federal Circuit determined that the appealed judgment resembled those judgments in which appeals had been previously prohibited because they were “tentative, informal or incomplete,”¹⁹ “subject to revision in the District Court,”²⁰ or “subject to future reconsideration by the issuing court.”²¹ Furthermore, the Federal Circuit found that an appeal of the issue of waiver at the present stage would have been “particularly inappropriate” because the district court had not yet decided the propriety of the affirmative defenses, an issue that was “intimately bound up with the merits.”²² The Federal Circuit therefore concluded that the appealed judgment was distinguishable from *Cohen* which required collateral orders to be “not of such an interlocutory nature as to affect, or to be affected by, decision of the merits of th[e] case.”²³

In *TypeRight Keyboard Corp. v. Microsoft Corp.*,²⁴ plaintiff appealed a judgment that its patents were invalid and defendant cross-appealed the dismissal without prejudice of its claims of noninfringement.²⁵ The Federal Circuit held that it lacked appellate jurisdiction over defendant’s cross-appeal because the district court held that all asserted claims were invalid. In so doing, the Federal Circuit first explained that “[a] party that is not affected by a judgment lacks standing to appeal.”²⁶ The Federal Circuit then reasoned that “it is only necessary and appropriate to file a cross-appeal when a party seeks to enlarge its own rights under the judgment or to lessen the rights of its adversary under the judgment.”²⁷ Considering these rules, it held that “[w]here . . . [a] district court has entered a judgment of invalidity as to all of the asserted claims, there is no basis for a cross-appeal as to . . . claims of noninfringement,”²⁸ even where the

18. *Competitive Techs.*, 374 F.3d at 1100-01, 71 U.S.P.Q.2d (BNA) at 1361-62.

19. *Id.* at 1103, 71 U.S.P.Q.2d (BNA) at 1364 (quoting *Swint*, 514 U.S. at 42).

20. *Id.* at 1104, 71 U.S.P.Q.2d (BNA) at 1364 (quoting *Coopers & Lybrand*, 437 U.S. at 469).

21. *Id.*, 71 U.S.P.Q.2d (BNA) at 1364 (quoting *In re “Agent Orange” Prod. Liab. Litig.*, 745 F.2d 161, 163-64 (2d Cir. 1984)).

22. *Id.*, 71 U.S.P.Q.2d (BNA) at 1364.

23. *Id.*, 71 U.S.P.Q.2d (BNA) at 1364 (quoting *Cohen v. Beneficial Indus. Loan Corp.*, 337 U.S. 541, 546 (1949)).

24. 374 F.3d 1151, 71 U.S.P.Q.2d (BNA) 1501 (Fed. Cir. 2004).

25. A single judge initially denied TypeRight’s motion to dismiss by order, but the Federal Circuit later considered the issue of its jurisdiction over Microsoft’s cross-appeals in its final decision, holding that an order by a single judge does not bind the court. *Id.* at 1157 n.5, 71 U.S.P.Q.2d (BNA) at 1505 n.5.

26. *Id.* at 1156, 71 U.S.P.Q.2d (BNA) at 1504. The court explicitly found that the same rule necessarily applies to cross-appeals. *Id.*, 71 U.S.P.Q.2d (BNA) at 1504.

27. *Id.*, 71 U.S.P.Q.2d (BNA) at 1504 (quoting *Bailey v. Dart Container Corp.*, 292 F.3d 1360, 1362, 63 U.S.P.Q.2d (BNA) 1319, 1320 (Fed. Cir. 2002)).

28. *Id.* at 1157, 71 U.S.P.Q.2d (BNA) at 1504.

accused infringer has filed a counterclaim for a declaratory judgment of noninfringement.²⁹

Significantly, for litigants looking to appeal validity issues following a finding of noninfringement, the Federal Circuit went on to explain that the converse was not true: “a judgment of noninfringement does not necessarily moot validity issues on appeal.”³⁰ The Federal Circuit noted that “‘a determination of infringement applies only to a specific accused product or process,’ whereas ‘invalidity operates as a complete defense to infringement for any product, forever.’”³¹ Distinguishing defendant’s situation from circumstances in which an appellee urges invalidity as a new ground to support a judgment of noninfringement, necessitating a cross-appeal,³² the court found that defendant’s rights under the invalidity judgment were actually broader than what they would have been under a judgment of noninfringement. Therefore, the court found that defendant had not been adversely affected by the district court’s judgment.³³

In a similar case, *Novartis Pharmaceuticals Corp. v. Abbott Laboratories*,³⁴ the Federal Circuit refused to permit defendant to appeal a grant of a motion for judgment as a matter of law (“JMOL”) of noninfringement. Defendant “conditional[ly] cross-appealed” that, in the event the court reversed the JMOL, defendant was entitled to a new trial because the portion of the jury’s verdict which was not disturbed by the JMOL could not be reconciled with the infringement verdict that was disturbed.³⁵ The Federal Circuit held that the appeal was improper, explaining that “[a] party who prevails on noninfringement has no right to file a ‘conditional’ cross-appeal to introduce new argument or challenge a claim construction, but may simply assert alternative grounds in the record for affirming the judgment.”³⁶

In *Chamberlain Group, Inc. v. Skylink Tech., Inc.*,³⁷ the Federal Circuit

29. *Id.*, 71 U.S.P.Q.2d (BNA) at 1504 (citing *Weatherchem Corp. v. J.L. Clark, Inc.*, 163 F.3d 1326, 1335, 49 U.S.P.Q.2d (BNA) 1001, 1008 (Fed. Cir. 1998)).

30. *Id.*, 71 U.S.P.Q.2d (BNA) at 1504 (quoting *Cardinal Chem. Co. v. Morton Int’l, Inc.*, 508 U.S. 83, 98 (1993)).

31. *Id.*, 71 U.S.P.Q.2d (BNA) at 1504 (quoting *Weatherchem*, 163 F.3d at 1335-36, 49 U.S.P.Q.2d (BNA) at 1009).

32. *Id.* at 1157 n.4, 71 U.S.P.Q.2d (BNA) at 1504 n.4.

33. Because there was no jurisdiction, the court dismissed the cross-appeal and stated that it would treat Microsoft’s arguments in support of its cross-appeal “as an alternate ground for affirming the district court’s judgment” of invalidity. *Id.* at 1157, 71 U.S.P.Q.2d (BNA) at 1504-05. Considering Microsoft’s noninfringement arguments as an alternative ground for sustaining the lower court’s judgment, however, the court declined to reach the infringement question because the issue of noninfringement was not considered by the district court. *Id.* at 1160, 71 U.S.P.Q.2d (BNA) at 1507.

34. 375 F.3d 1328, 71 U.S.P.Q.2d (BNA) 1650 (Fed. Cir. 2004).

35. *Id.* at 1339, 71 U.S.P.Q.2d (BNA) at 1659.

36. *Id.*, 71 U.S.P.Q.2d (BNA) at 1659 (quoting *Phillips v. AWH Corp.*, 363 F.3d 1207, 1216, 70 U.S.P.Q.2d (BNA) 1417, 1423 (Fed. Cir. 2004)).

37. 381 F.3d 1178, 72 U.S.P.Q.2d (BNA) 1225 (Fed. Cir. 2004).

addressed the issue of whether it was vested with appellate jurisdiction when “all of the patent claims in [an] amended complaint were dismissed prior to [a] non-patent ruling on appeal.”³⁸ Noting that this question turned on whether the dismissal of the patent claims was with or without prejudice, the court explained that “[d]ismissals without prejudice are de facto amendments to the complaint,” and

[f]or purposes of determining Federal Circuit jurisdiction, we do not differentiate between actual and constructive amendments: both divest of us of jurisdiction if they eliminate all issues of patent law Dismissals with prejudice are adjudications on the merits and not constructive amendments to the complaint In all such cases, we retain jurisdiction to hear all appeals on all issues.³⁹

The Federal Circuit then reasoned that:

Taken together, whenever the complaint included a patent claim and the trial court’s rulings altered the legal status of the parties with respect to that patent claim, we retain appellate jurisdiction over all pendent claims in the complaint. In other words, if all patent claims raised in the amended complaint were dismissed *without prejudice*, the dismissal would divest us of jurisdiction; dismissals *with prejudice* would not Dismissals divest this court of jurisdiction only if “[t]he parties were left in the same legal position with respect to [all] patent claims as if they had never been filed. [T]he dismissal of a claim with prejudice operate[s] as an adjudication of that claim on the merits,” and preserves our jurisdiction.⁴⁰

The Federal Circuit thus concluded that despite the district court’s semantic characterization of a dismissal of a patent claim “as ‘without prejudice’ subject to a condition subsequent that can no longer occur,”⁴¹ and dismissal of other patent claims as “‘without prejudice’ except in a single forum,”⁴² the court possessed appellate jurisdiction given that the effect of the district court’s dismissals did not constitute “‘dismissal without prejudice’ because they alter the legal status of the parties vis-à-vis all of [plaintiff’s] asserted patent claims. [The parties] were not ‘left in the same legal position with respect to the patent claims as if they had never been filed.’”⁴³

38. *Id.* at 1189, 72 U.S.P.Q.2d (BNA) at 1232.

39. *Id.* at 1189-90, 72 U.S.P.Q.2d (BNA) at 1232.

40. *Id.* at 1190, 72 U.S.P.Q.2d (BNA) at 1233 (alterations in original) (citations omitted).

41. *Id.*, 72 U.S.P.Q.2d (BNA) at 1233.

42. *Id.*, 72 U.S.P.Q.2d (BNA) at 1233.

43. *Id.*, 72 U.S.P.Q.2d (BNA) at 1233 (quoting *Nilssen v. Motorola, Inc.*, 203 F.3d 782, 785, 53 U.S.P.Q.2d (BNA) 1765, 1767 (Fed. Cir. 2000)).

B. Declaratory Judgment Jurisdiction and Subject Matter Jurisdiction

*Gen-Probe Inc. v. Vysis, Inc.*⁴⁴ presented an appeal from a declaratory judgment action in which the jury returned verdicts of noninfringement and invalidity.⁴⁵ Rather than addressing the merits of the appeal, the Federal Circuit held that neither it nor the district court possessed jurisdiction to hear the case.⁴⁶ The trial record demonstrated that prior to commencement of the litigation, the defendant granted plaintiff a non-exclusive license to its patents in return for an upfront payment and an ongoing royalty.⁴⁷ On December 21, 1999, plaintiff sent defendant a letter indicating that it was exercising its license option relating to third-party uses of the licensed patents and stating its “intent to maintain the status quo [of the license agreement] by continuing to pay royalties throughout the litigation.”⁴⁸ The next day, plaintiff filed its declaratory judgment action, alleging that its products did not infringe on any of the licensed patents and that such patents were invalid.⁴⁹

Despite a full trial in the district court, the Federal Circuit began by observing that “[a]ny party or this court sua sponte may raise the question of subject matter jurisdiction.”⁵⁰ Addressing its own jurisdiction in declaratory judgment actions the Federal Circuit noted that “the long established rule of law is that a declaratory judgment plaintiff must establish an actual controversy on the ‘totality of the circumstances.’”⁵¹ Turning to the facts before it, the Federal Circuit determined that its decision in *C.R. Bard, Inc. v. Schwartz*⁵² was analogous.⁵³ Recognizing that while the *C.R. Bard* decision provided that “a patent license need not be terminated before a patent licensee may bring a declaratory judgment action,”⁵⁴ the court explained that *C.R. Bard* also involved “two critical circumstances” that vested the court with jurisdiction.⁵⁵ First, the licensee “had ceased payment of royalties under the agreement to licensor and patentee.”⁵⁶ The Federal Circuit further noted that the licensee’s cessation

44. 359 F.3d 1376, 70 U.S.P.Q.2d (BNA) 1087 (Fed. Cir. 2004).

45. *Id.* at 1377, 70 U.S.P.Q.2d (BNA) at 1087.

46. *Id.*, 70 U.S.P.Q.2d (BNA) at 1087.

47. *Id.* at 1378, 70 U.S.P.Q.2d (BNA) at 1088.

48. *Id.*, 70 U.S.P.Q.2d (BNA) at 1089.

49. *Id.*, 70 U.S.P.Q.2d (BNA) at 1088.

50. *Id.* at 1379, 70 U.S.P.Q.2d (BNA) at 1089.

51. *Id.*, 70 U.S.P.Q.2d (BNA) at 1089 (quoting *Spectronics Corp. v. H.B. Fuller Co.*, 940 F.2d 631, 634, 19 U.S.P.Q.2d (BNA) 1545, 1547 (Fed. Cir. 1991)).

52. 716 F.2d 874, 219 U.S.P.Q. (BNA) 197 (Fed. Cir. 1983).

53. *Gen-Probe*, 359 F.3d at 1380, 70 U.S.P.Q.2d (BNA) at 1090.

54. *Id.*, 70 U.S.P.Q.2d (BNA) at 1090 (quoting *C.R. Bard*, 716 F.2d at 875, 219 U.S.P.Q. (BNA) at 198).

55. *Id.*, 70 U.S.P.Q.2d (BNA) at 1090.

56. *Id.*, 70 U.S.P.Q.2d (BNA) at 1090 (quoting *C.R. Bard*, 716 F.2d at 880-81, 219 U.S.P.Q. (BNA) at 203).

of royalty payment constituted “a material breach of the agreement that . . . enabled [the licensor] to terminate the agreement.”⁵⁷ The Federal Circuit explained that the material breach granted the licensor “the power to file an infringement lawsuit against Bard at any time.”⁵⁸ Contrasting *C.R. Bard* to the circumstances on appeal, the Federal Circuit explained that plaintiff:

[D]id not cease paying royalties and materially breach its license agreement with [defendant]; [defendant] did not file a breach of contract action. In fact, [plaintiff] was a licensee in good standing that continued paying royalties throughout the declaratory judgment lawsuit. In fact, [plaintiff] expressly acknowledged its desire to maintain the status quo and remain a faithful licensee.⁵⁹

The Federal Circuit also placed significant weight on plaintiff’s decision to “exercise[] options to extend the duration of the license for its alliances with [third parties] contemporaneously with its filing of the declaratory judgment lawsuit. Far from breaching its license agreement, [plaintiff] affirmatively confirmed its desire to remain in good standing.”⁶⁰ Accordingly, the Federal Circuit held that no controversy existed sufficient to confer jurisdiction.⁶¹

Addressing the district court’s reliance on oral notifications and letters between plaintiff and defendant regarding possible infringement, the court explained that such communications occurred before the parties entered into the license agreement,⁶² and concluded that the license “insulated [plaintiff] from an infringement suit instituted by [defendant]” and “unless materially breached, obliterated any reasonable apprehension of a lawsuit based on prior circumstances cited by the district court.”⁶³

The Federal Circuit also discussed the district court’s reliance on *Lear v. Adkins*,⁶⁴ in which the Supreme Court held that a licensee can challenge the validity of a patent.⁶⁵ The Federal Circuit distinguished *Lear* by reasoning that it “does not grant every licensee in every circumstance the right to challenge the validity of the licensed patent.”⁶⁶ Then citing its holding in

57. *Id.*, 70 U.S.P.Q.2d (BNA) at 1090 (quoting *C.R. Bard*, 716 F.2d at 880-81, 219 U.S.P.Q. (BNA) at 203).

58. *Id.*, 70 U.S.P.Q.2d (BNA) at 1090.

59. *Id.*, 70 U.S.P.Q.2d (BNA) at 1090.

60. *Id.*, 70 U.S.P.Q.2d (BNA) at 1090.

61. *Id.* at 1382, 70 U.S.P.Q.2d (BNA) at 1092.

62. *Id.* at 1381, 70 U.S.P.Q.2d (BNA) at 1090.

63. *Id.*, 70 U.S.P.Q.2d (BNA) at 1091.

64. 395 U.S. 653 (1969).

65. *Id.* at 656, 671 (rejecting precedent of estopping licensees from attacking the validity of licensors’ patents in light of the “strong federal policy favoring free competition in ideas which do not merit patent protection.”).

66. *Gen-Probe*, 359 F.3d at 1381, 70 U.S.P.Q.2d (BNA) at 1091.

Studiengesellschaft Kohle M.B.H. v. Shell Oil Co.,⁶⁷ which provided that “a licensee . . . cannot invoke the protection of the *Lear* doctrine until it (i) actually ceases payment of royalties, and (ii) provides notice to the licensor that the reason for ceasing payment of royalties is because it has deemed the relevant claims to be invalid,”⁶⁸ the court held that, at minimum, a licensee must stop paying royalties before bringing suit to challenge the licensed patent.⁶⁹

In *Sierra Applied Sciences, Inc. v. Advanced Energy Industries, Inc.*,⁷⁰ the Federal Circuit again addressed whether plaintiff had properly established a “case or controversy” for seeking a declaratory relief of invalidity and noninfringement.⁷¹ The Federal Circuit began by articulating its two-pronged inquiry for determining whether a case or controversy exists in the context of “patent-based declaratory judgment suits,”⁷² stating that:

There must both be (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity.⁷³

The Federal Circuit explained that the first prong “looks to the patent holder’s conduct,”⁷⁴ while the second prong “looks to the potential infringer’s conduct.”⁷⁵ The Federal Circuit further noted that the potential infringer bears the burden of establishing that “jurisdiction over its declaratory judgment action existed at, and has continued since, the time the complaint was filed.”⁷⁶

Given that plaintiff sought declaratory judgment of noninfringement for three separate product categories,⁷⁷ the Federal Circuit explained that when a potential infringer seeks to “ground jurisdiction on activities involving distinct, technologically different products, the court must carefully calibrate its analysis to each of the products. To do otherwise would risk issuing an advisory opinion on one product—or on a method using that

67. 112 F.3d 1561, 42 U.S.P.Q.2d (BNA) 1674 (Fed. Cir. 1997).

68. *Id.* at 1568, 42 U.S.P.Q.2d (BNA) at 1681.

69. *Gen-Probe*, 359 F.3d at 1381, 70 U.S.P.Q.2d (BNA) at 1091.

70. 363 F.3d 1361, 70 U.S.P.Q.2d (BNA) 1577 (Fed. Cir. 2004).

71. *Id.* at 1363, 70 U.S.P.Q.2d (BNA) at 1578.

72. *Id.* at 1373, 70 U.S.P.Q.2d (BNA) at 1585.

73. *Id.*, 70 U.S.P.Q.2d (BNA) at 1585-86 (quoting *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978, 28 U.S.P.Q.2d (BNA) 1124, 1126 (Fed. Cir. 1993)).

74. *Id.*, 70 U.S.P.Q.2d (BNA) at 1586.

75. *Id.*, 70 U.S.P.Q.2d (BNA) at 1586.

76. *Id.*, 70 U.S.P.Q.2d (BNA) at 1586 (quoting *Int’l Med. Prosthetics Research Assocs., Inc. v. Gore Enter. Holdings, Inc.*, 787 F.2d 572, 575, 229 U.S.P.Q. (BNA) 278, 281 (Fed. Cir. 1986)).

77. *Id.*, 70 U.S.P.Q.2d (BNA) at 1586.

product—based on an actual controversy involving another product.”⁷⁸

Turning to the first prong, the Federal Circuit noted that the question of whether a patentee’s conduct “created a reasonable apprehension on the part of the declaratory plaintiff ‘is an objective one.’”⁷⁹ The Federal Circuit held that patentee’s letter stating that it “intended to aggressively protect its [patent] rights” and that “other patents [that] are pending and are expected to issue which will further cover our client’s technology,” was sufficient to establish a reasonable apprehension.⁸⁰ While noting that such apprehension waned over a period of time in which the parties did not correspond regarding the disputed products and patents, the Federal Circuit determined that the reasonable apprehension re-emerged in view of a subsequent letter from the patentee stating that if plaintiff “continue[s] to make, use, or sell infringing products . . . [it] seems likely to be considered intentional patent infringement.”⁸¹

Concerning the second prong’s requirement of “present activity,” the Federal Circuit explained that “later events may not create jurisdiction where none existed at the time of filing.”⁸² The Federal Circuit then held that although plaintiff’s damages exposure was minimal with respect to the first product category, the court possessed jurisdiction because the “Patent Act does not set a damages threshold for bringing suit, and thus a patent case or controversy can exist even where the conduct at issue would result in only de minimis damages.”⁸³ With respect to the second product category that plaintiff never made and no longer intended to manufacture, the Federal Circuit determined that it lacked jurisdiction because “[o]nce a development effort has been wholly abandoned, it can no longer be the basis for an ‘intent to engage’ case or controversy.”⁸⁴

Looking to the third product category, the court began by clarifying the legal standard for determining whether a declaratory plaintiff has taken “concrete steps” with intent to infringe.⁸⁵ The Federal Circuit explained that “Article III requires a dispute ‘of sufficient *immediacy and reality* to warrant the issuance of a declaratory judgment.’”⁸⁶ As to immediacy, the Federal Circuit stressed “the importance of the period of time between the

78. *Id.* at 1374, 70 U.S.P.Q.2d (BNA) at 1586.

79. *Id.*, 70 U.S.P.Q.2d (BNA) at 1586 (quoting *Shell Oil Co. v. Amoco Corp.*, 970 F.2d 885, 888, 23 U.S.P.Q.2d (BNA) 1627, 1629 (Fed. Cir. 1992)).

80. *Id.*, 70 U.S.P.Q.2d (BNA) at 1587.

81. *Id.* at 1374-75, 70 U.S.P.Q.2d (BNA) at 1587.

82. *Id.* at 1376, 70 U.S.P.Q.2d (BNA) at 1588 (quoting *GAF Bldg. Materials Corp. v. Elk Corp.*, 90 F.3d 479, 483, 39 U.S.P.Q.2d (BNA) 1463, 1466 (Fed. Cir. 1996)).

83. *Id.* at 1377, 70 U.S.P.Q.2d (BNA) at 1588.

84. *Id.*, 70 U.S.P.Q.2d (BNA) at 1589.

85. *Id.* at 1378, 70 U.S.P.Q.2d (BNA) at 1589.

86. *Id.*, 70 U.S.P.Q.2d (BNA) at 1590 (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)).

date on which the complaint was filed and the date on which potentially infringing activities will begin. The greater the length of this interim period, the more likely the case lacks the requisite immediacy.”⁸⁷ As to reality, the Federal Circuit explained that:

The greater the variability of subject of a declaratory judgment suit, particularly as to its potentially infringing features, the greater the chance that the court’s judgment will be purely advisory, detached from the eventual, actual content of that subject—in short detached from eventual reality.⁸⁸

Accordingly, the Federal Circuit held that it lacked jurisdiction over the third product category because on the date the complaint was filed “it was impossible to determine—on that date—whether any eventual design of the [product] would infringe [defendant’s] patents.”⁸⁹

In *Capo, Inc. v. Dioptics Medical Products*,⁹⁰ plaintiff appealed an order dismissing its declaratory judgment action against defendant.⁹¹ Plaintiff was defendant’s long-time customer in the “wear-over” sunglass market. The parties’ dispute commenced when the defendant’s president informed plaintiff that he had seen plaintiff’s intent-to-use trademark application for wear-over sunglasses and that although defendant preferred to avoid legal disputes with good customers, it had a large patent portfolio covering wear-over sunglasses that it vigorously enforced against infringers.⁹² Plaintiff responded by stating that it had already obtained a detailed opinion of counsel indicating that its products did not infringe defendant’s patents.⁹³ Later the following month, defendant placed several calls to plaintiff stating that defendant had thirteen patents and would soon have forty patents covering all of the basic wear-over sunglass frame shapes, and that plaintiff was “charging down a path [towards infringement] that [was] going to end up into a multi-million dollar lawsuit.”⁹⁴

Plaintiff responded by filing the declaratory judgment action.⁹⁵ Rather than counterclaim infringement, however, defendant moved to dismiss the action on the basis that plaintiff could not have threatened suit for infringement because it had never seen plaintiff’s products, nor had it analyzed the products for possible infringement.⁹⁶ The district court agreed with the plaintiff, holding that an actual controversy existed but declining

87. *Id.* at 1378-79, 70 U.S.P.Q.2d (BNA) at 1590.

88. *Id.* at 1379, 70 U.S.P.Q.2d (BNA) at 1590.

89. *Id.* at 1380, 70 U.S.P.Q.2d (BNA) at 1591.

90. 387 F.3d 1352, 73 U.S.P.Q.2d (BNA) 1051 (Fed. Cir. 2004).

91. *Id.* at 1353, 73 U.S.P.Q.2d (BNA) at 1052.

92. *Id.*, 73 U.S.P.Q.2d (BNA) at 1052.

93. *Id.*, 73 U.S.P.Q.2d (BNA) at 1052.

94. *Id.*, 73 U.S.P.Q.2d (BNA) at 1052.

95. *Id.* at 1354, 73 U.S.P.Q.2d (BNA) at 1052.

96. *Id.*, 73 U.S.P.Q.2d (BNA) at 1052.

to exercise jurisdiction “in its considerable discretion under the Declaratory Judgment Act” because defendant had neither filed the compulsory counterclaim of infringement nor seen plaintiff’s product.⁹⁷

Reversing on appeal, the Federal Circuit explained that although a district court has “appropriate discretion” to decline a declaratory judgment action, this discretion is to be exercised “in accordance with the purposes of the Declaratory Judgment Act and the principles of sound judicial administration.”⁹⁸ In the absence of “well-founded” reasons for declining to entertain a declaratory action, the Federal Circuit stated that an accused infringer’s declaratory action should be permitted “when there has been a direct charge of infringement by the patentee, and an actual controversy exists due to ongoing activity that has been accused of infringement.”⁹⁹ In plaintiff’s case, the Federal Circuit found no good reason for dismissal, as defendant’s threats created an apprehension of suit, and the apprehension was reasonable because defendant was aware that plaintiff had entered into the marketplace of wear-over sunglasses.¹⁰⁰ The Federal Circuit also observed that the fact that defendant had not seen plaintiff’s products was irrelevant to whether defendant’s threats instilled a reasonable apprehension of suit.¹⁰¹ The Federal Circuit thus explained that it would impose no duty on the accused to ascertain whether the patentee had conducted a reasonable investigation prior to making its threats. Finally, the Federal Circuit dismissed the district court’s finding that the case was not ripe because defendant had other patent applications pending that it felt more closely covered the accused products, opining that “the possibility of future patents is irrelevant to present rights and liability.”¹⁰²

In *Laboratory Corp. of America Holdings v. Chiron Corp.*,¹⁰³ the Federal Circuit addressed the question of whether its own law or a regional circuit’s law applied when determining whether an injunction precluding a party from pursuing parallel actions in different district courts is appealable under 28 U.S.C. § 1292(a)(1).¹⁰⁴ While observing that the language of

97. *Id.*, 73 U.S.P.Q.2d (BNA) at 1053.

98. *Id.* at 1355, 73 U.S.P.Q.2d (BNA) at 1053.

99. *Id.*, 73 U.S.P.Q.2d (BNA) at 1054.

100. *Id.* at 1356, 73 U.S.P.Q.2d (BNA) at 1054.

101. The court noted that this fact may be relevant to whether the accuser acted “responsibly,” however. *Id.*, 73 U.S.P.Q.2d (BNA) at 1054.

102. *Id.* at 1357, 73 U.S.P.Q.2d (BNA) at 1055. Dioptics argued that Capo filed its declaratory judgment action solely as a pretext for obtaining access to Dioptics’s pending patent applications. The court agreed with Capo that it was Dioptics who injected its applications into controversy, but opined that it would be a valid exercise of judicial discretion to limit discovery of these pending applications in order to prevent prejudice to Dioptics. *Id.* at 1357, 73 U.S.P.Q.2d (BNA) at 1055.

103. 384 F.3d 1326, 72 U.S.P.Q.2d (BNA) 1745 (Fed. Cir. 2004).

104. *Id.* at 1327-28, 72 U.S.P.Q.2d (BNA) at 1747. Section 1292(a)(1) provides that the Circuit Courts of Appeals have jurisdiction from: “Interlocutory orders of the district courts of the United States . . . or of the judges thereof, granting, continuing, modifying, refusing

§ 1292(a)(1) “appears to be both unambiguous and compelling,”¹⁰⁵ the Federal Circuit noted that “there is a circuit split concerning whether injunctions enjoining co-pending actions in other courts are appealable under [that section].”¹⁰⁶ The circuit split was particularly important in the pending case because Federal Circuit law provided that such injunctions were appealable under § 1292(a)(1) whereas the Third Circuit had held the opposite.¹⁰⁷

The Federal Circuit explained that it applies its own law rather than a regional circuit’s law governing a procedural issue that does not itself involve substantive patent law when the issue: (1) “pertains to patent law,” (2) “bears an essential relationship to matters committed to our exclusive control by statute,” or (3) “clearly implicates the jurisprudential responsibilities of this court in a field within its exclusive jurisdiction.”¹⁰⁸ The court then analogized the pending case to its earlier decision in *Genentech, Inc. v. Eli Lilly & Co.*,¹⁰⁹ in which a party filed a declaratory judgment in the Southern District of Indiana and the patentee filed an action the next day in the Northern District of California.¹¹⁰ In *Genentech*, the court explained:

The question of whether a properly brought declaratory action to determine patent rights should yield to a later-filed suit for patent infringement raises the issue of national uniformity in patent cases, and invokes the special obligation of the Federal Circuit to avoid creating opportunities for dispositive differences among the regional circuits. Thus, although the Federal Circuit applies the procedural law of the regional circuit in matters that are not unique to patent law, . . . and although matters of procedure do not always carry substantive weight, the regional circuit practice need not control when the question is important to national uniformity in patent practice.¹¹¹

or dissolving injunctions, or refusing to dissolve or modify injunctions, except where a direct review may be had in the Supreme Court[.]” 28 U.S.C. § 1292(a)(1) (2000).

105. 384 F.3d at 1328, 72 U.S.P.Q.2d (BNA) at 1747.

106. *Id.*, 72 U.S.P.Q.2d (BNA) at 1747. Compare *FDIC v. Geldermann, Inc.*, 975 F.2d 695, 697 (10th Cir. 1992) (finding such injunctions appealable under 28 U.S.C. § 1292(a)(1)), *Phillips v. Charles Schreiner Bank*, 894 F.2d 127, 130 (5th Cir. 1990) (noting that § 1292(a)(1) authorizes an interlocutory appeal), and *Klein v. Adams & Peck*, 436 F.2d 337, 339 (2d Cir. 1971) (permitting an appeal where an order denies the application for the posting of security), with *Hershey Foods Corp. v. Hershey Creamery Co.*, 945 F.2d 1272, 1278-79 (3d Cir. 1991) (finding same injunctions to affect only venue, not substantive law at issue, and thus to be not appealable under 28 U.S.C. § 1292(a)(1)).

107. *Lab. Corp.*, 384 F.3d at 1328, 72 U.S.P.Q.2d (BNA) at 1747 (noting that case arose from a decision of the Delaware district court, which resides in the Third Circuit).

108. *Id.* at 1330, 72 U.S.P.Q.2d (BNA) at 1748 (quoting *Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356, 1359, 50 U.S.P.Q.2d (BNA) 1672, 1675 (Fed. Cir. 1999)).

109. 998 F.2d 931, 27 U.S.P.Q.2d (BNA) 1241 (Fed. Cir. 1993).

110. *Lab. Corp.*, 384 F.3d at 1330, 72 U.S.P.Q.2d (BNA) at 1749 (citing *Genentech*, 998 F.2d at 935, 27 U.S.P.Q.2d (BNA) at 1242).

111. *Genentech*, 998 F.3d at 937, 27 U.S.P.Q.2d (BNA) at 1244 (citation omitted).

Relying on the holding and rationale in *Genentech*, the Federal Circuit held that “injunctions arbitrating between co-pending patent declaratory judgment and infringement cases in different district courts are reviewed under the law of the Federal Circuit.”¹¹²

In reaching this holding the Federal Circuit addressed its decision in *Katz v. Lear Siegler, Inc.*,¹¹³ in which the court stated that it would “[apply] the law of the First Circuit”¹¹⁴ to review an order issued by the District of Massachusetts enjoining a patentee from prosecuting other pending actions in the Western District of New York.¹¹⁵ The Federal Circuit explained that the statement in *Katz* regarding application of First Circuit law “was not accompanied by an analysis or discussion of the policy issues relevant to the choice of law where there are material differences in Federal Circuit and regional circuit precedent.”¹¹⁶ The Federal Circuit thus determined that “the reference to First Circuit law in *Katz* . . . should not be read to foreclose consideration of the important policy factors dictating the choice of law in cases in which the regional circuit applies a different standard than the Federal Circuit.”¹¹⁷

In *Metabolite Laboratories, Inc. v. Laboratory Corp. of America Holdings*,¹¹⁸ the Federal Circuit held that the district court had no jurisdiction to consider defendant’s claims that one of plaintiff’s patent claims was invalid where the parties did not dispute that defendant continued to pay royalties on a license in effect on tests defendant performed that it alleged were covered by that claim. The Federal Circuit likened the situation to the scenario in which a patentee seeks a declaratory judgment against a future infringer and determined that there was no real case or controversy regarding the defendant test alleged to infringe that claim. The Federal Circuit explained that the license is essentially a licensor’s covenant not to sue the licensee.¹¹⁹

In turn, this court has held that a covenant not to sue deprives a court of declaratory judgment jurisdiction. Accordingly, a licensor who has implicitly covenanted not to sue a licensee by virtue of the license agreement itself cannot seek a declaratory judgment of infringement. Moreover, in light of [defendant’s] continuing royalty payments on the panel test, LabCorp cannot itself challenge the validity of a claim for

112. *Lab. Corp.*, 384 F.3d at 1331, 72 U.S.P.Q.2d (BNA) at 1749.

113. 909 F.2d 1459, 15 U.S.P.Q.2d (BNA) 1554 (Fed. Cir. 1990).

114. *Lab. Corp.*, 384 F.3d at 1329, 72 U.S.P.Q.2d (BNA) at 1748 (quoting *Katz*, 909 F.2d at 1462, 15 U.S.P.Q.2d (BNA) at 1557).

115. *Id.*, 72 U.S.P.Q.2d (BNA) at 1748 (citing *Katz*, 909 F.2d at 1462-64, 15 U.S.P.Q.2d (BNA) at 1557-58).

116. *Id.*, 72 U.S.P.Q.2d (BNA) at 1748.

117. *Id.*, 72 U.S.P.Q.2d (BNA) at 1748.

118. 370 F.3d 1354, 71 U.S.P.Q.2d (BNA) 1081 (Fed. Cir. 2004).

119. *Id.* at 1369, 71 U.S.P.Q.2d (BNA) at 1092.

which it continues to pay royalties.¹²⁰

C. Standing

In *Fieldturf, Inc. v. Southwest Recreational Industries, Inc.*,¹²¹ the Federal Circuit addressed the issue of whether an exclusive licensee has standing to sue for infringement. Plaintiff filed suit for infringement of a patent related to artificial athletic field surfaces and the district court dismissed the case with prejudice for lack of standing.¹²² The record revealed that plaintiff acquired its rights to the asserted patent through a variety of transactions, including two license agreements to which its predecessor-in-interest was a party. The first agreement gave the predecessor-in-interest the exclusive right to manufacture and market commercial embodiments of the patent, but reserved to the licensors the right of first refusal to enforce the patent, as well as a “limited right” to develop, display commercially, and market to potential costumers.¹²³ In the second transaction, the same parties essentially agreed that the predecessor-in-interest would continue to be the exclusive licensee, and that the second agreement would “cancel and replace” the first.¹²⁴

Plaintiff argued that it had standing to sue as an exclusive licensee of the patent on the licenses to which its predecessor was a party. The Federal Circuit, however, determined that two factors deprived plaintiff of standing. First, the Federal Circuit noted that the second agreement entered into by the predecessor-in-interest was “no more than a bare license,” despite the fact that it named the predecessor-in-interest as the exclusive licensee because it was silent with regard to who had “the right to enforce the patent.”¹²⁵ Second, the Federal Circuit observed that the predecessor-in-interest failed to acquire “all substantial rights” to the patent required for standing because the second agreement was silent with respect to the licensor’s retention of a limited right to develop and market the potential invention.¹²⁶ Thus, the Federal Circuit held that plaintiff’s claim for patent infringement must be dismissed and remanded for a determination of

120. *Id.*, 71 U.S.P.Q.2d (BNA) at 1092 (citations omitted).

121. 357 F.3d 1266, 69 U.S.P.Q.2d (BNA) 1795 (Fed. Cir. 2004).

122. *Id.* at 1267, 69 U.S.P.Q.2d (BNA) at 1796. The Federal Circuit reviewed the issue of Fieldturf’s standing to sue for infringement on appeal de novo, despite the fact that Southwest had already raised the issue in a preliminary motion to dismiss that was subsequently denied, citing the rule that “[a] motion to dismiss denied by the order of a single judge . . . does not become the law of the case.” *Id.* at 1268, 69 U.S.P.Q.2d (BNA) at 1797; *see also supra* text accompanying notes 34-36 (discussing similar holding in *Novartis Pharms. Corp. v. Abbott Labs.*, 375 F.3d 1328, 71 U.S.P.Q.2d (BNA) 1650 (Fed. Cir. 2004)).

123. *Fieldturf*, 357 F.3d at 1267, 69 U.S.P.Q.2d (BNA) at 1796.

124. *Id.* at 1267-68, 69 U.S.P.Q.2d (BNA) at 1796.

125. *Id.* at 1269, 69 U.S.P.Q.2d (BNA) at 1797.

126. *Id.* at 1269, 69 U.S.P.Q.2d (BNA) at 1798.

whether plaintiff's claim should be dismissed with prejudice. In particular, the Federal Circuit opined that joinder of certain parties, such as the predecessor-in-interest's licensor, might be required to complete plaintiff's standing. It further noted that plaintiff failed to produce any documentation evidencing the transfer of interests in the patent from the patent's original owner to the predecessor-in-interest's licensor. Even though plaintiff had argued that the licensor was a "successor in form" and was controlled by the same partner as the original patent owner, the Federal Circuit concluded that the argument was unhelpful in identifying the actual successor.¹²⁷

D. Collateral Estoppel

In *Novartis Pharmaceuticals Corp. v. Abbott Laboratories*,¹²⁸ plaintiff sued defendant for infringement of two of its patents (the "'625 patent" and the "'840 patent"), both directed to compositions of cyclosporine, a compound used to prevent organ rejection in transplant patients.¹²⁹ Two claims were at issue, one from each patent. The '625 patent required a "lipophilic phase component," the '840 patent required a "lipophilic component," and both patents required a "surfactant."¹³⁰ The parties agreed that "lipophilic component" and "lipophilic phase component," as used in the two patents, bore the same meaning.¹³¹

The jury returned a verdict that defendant did not infringe the '625 patent, but did infringe the '840 patent.¹³² Following the verdict, the district court granted defendant's JMOL with respect to the '840 patent, finding that defendant's accused composition did not have a "lipophilic component" as required by the asserted claim of that patent, either literally or under the doctrine of equivalents.

Defendant asserted that plaintiff was barred from challenging the court's JMOL of noninfringement of the '840 patent because it had failed to explicitly challenge the verdict on the '625 patent, and therefore any legal determinations or factual findings necessary to that verdict were given preclusive effect.¹³³ Plaintiff, in turn, argued that it had preserved its right to appeal the jury verdict on the '625 patent, and that collateral estoppel therefore did not bar its challenge to the JMOL on the '840 patent.¹³⁴ Referencing its discussion on the construction of the term "surfactant," plaintiff first asserted that the term was relevant only to the '625 patent.

127. *Id.* at 1270, 69 U.S.P.Q.2d (BNA) at 1798.

128. 375 F.3d 1328, 71 U.S.P.Q.2d (BNA) 1650 (Fed. Cir. 2004).

129. *Id.* at 1330, 71 U.S.P.Q.2d (BNA) at 1652.

130. *Id.* at 1330-31, 71 U.S.P.Q.2d (BNA) at 1652.

131. *Id.* at 1331, 71 U.S.P.Q.2d (BNA) at 1653.

132. *Id.*, 71 U.S.P.Q.2d (BNA) at 1653.

133. *Id.* at 1332, 71 U.S.P.Q.2d (BNA) at 1654.

134. *Id.* at 1332-33, 71 U.S.P.Q.2d (BNA) at 1654.

Plaintiff then asked the Federal Circuit to remand for further proceedings if it reversed the district court's claim construction but did not reinstate the jury infringement verdict on the '840 patent. Finally, defendant admitted that plaintiff's Notice of Appeal might have been broad enough to cover the '625 patent verdict. The Federal Circuit found none of these actions sufficient to preserve plaintiff's right to appeal the '625 patent jury verdict and instead held that plaintiff waived that right because, "from the beginning," it had maintained that it was appealing the entry of the JMOL of noninfringement.¹³⁵

Regardless of the fact that plaintiff had waived its right to appeal the '625 jury verdict, the Federal Circuit found that plaintiff was not collaterally estopped to challenge the '840 patent verdict.¹³⁶ Defendant had argued that, because the parties agreed that the terms "lipophilic component" and "surfactant" were common to the '625 and '840 patents, plaintiff's failure to challenge the construction of these terms in the '625 patent estopped it from challenging their construction in the '840 patent. Applying Third Circuit law, the Federal Circuit disagreed because the jury had not been requested to specify on its verdict form, the limitations in the claim of the '625 patent that it found Abbott's product did not contain, and because no record evidence explained the jury's rationale for its verdict.¹³⁷ Thus, the court explained, it could not conclude that the court's construction of "lipophilic phase component" proved necessary to the jury's noninfringement decision on the '625 patent, and Novartis was not collaterally estopped from challenging the claim construction and the JMOL with respect to the '840 patent.¹³⁸

*Monsanto Co. v. Bayer Bioscience N.V.*¹³⁹ involved an appeal from a grant of summary judgment "giving collateral estoppel effect to a decision in an earlier case between the predecessors of the parties in this case."¹⁴⁰

135. *Id.* at 1333, 71 U.S.P.Q.2d (BNA) at 1654-55. The court contrasted Novartis' case from that of *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 65 U.S.P.Q.2d (BNA) 1865 (Fed. Cir. 2003), in which the court "consented to construe terms that *did not* form a part of the appealed summary judgment because they 'may be relevant to the remand determination of infringement' and because they were found to be construed erroneously." *Novartis*, 375 F.3d at 1333, 71 U.S.P.Q.2d (BNA) at 1655 (quoting *Altiris*, 318 F.3d at 1366, 65 U.S.P.Q.2d (BNA) at 1866).

136. *Novartis*, 375 F.3d at 1334, 71 U.S.P.Q.2d (BNA) at 1655.

137. *Id.*, 71 U.S.P.Q.2d (BNA) at 1655. The Federal Circuit applied the law of the regional circuit—here, the Third Circuit—to the issue of collateral estoppel. *Id.* at 1333, 71 U.S.P.Q.2d (BNA) at 1654. Under the Third Circuit law, the party seeking collateral estoppel bears the burden of showing: "(1) the previous determination was necessary to the decision; (2) the identical issue was previously litigated; (3) the issue was actually decided in a decision that was final, valid, and on the merits; and (4) the party being precluded from relitigating the issue was adequately represented in the previous action." *Id.*, 71 U.S.P.Q.2d (BNA) at 1654 (quoting *Hawksbill Sea Turtle v. FEMA*, 126 F.3d 461, 475 (3d Cir. 1997)).

138. *Id.* at 1334, 71 U.S.P.Q.2d (BNA) at 1655.

139. 363 F.3d 1235, 70 U.S.P.Q.2d (BNA) 1257 (Fed. Cir. 2004).

140. *Id.* at 1242, 70 U.S.P.Q.2d (BNA) at 1262 (citation omitted).

Specifically, the district court ruled that the Federal Circuit's prior decision in *Plant Genetic Systems, N.V. v. DeKalb Genetics Corp.*,¹⁴¹ in which the court held that claims in a related patent were invalid for lack of enablement, compelled a holding that the asserted claims in the first disputed patent were not enabled and that the asserted claims in a second disputed patent were not infringed.¹⁴²

With respect to enablement, the Federal Circuit noted that to determine whether the claimed "transformation of monocots through the use of *Agrobacterium*" is enabled it is necessary to consult the specification of the disputed patents,¹⁴³ "which differ significantly from the specification of the patent at issue in the *Plant Genetic Systems* case."¹⁴⁴ The Federal Circuit thus vacated the grant of summary judgment based collateral estoppel, explaining that although the parties in *Plant Genetic Sys.* fully litigated

the issue of whether one of ordinary skill in the art in 1986 would be able to transform a monocot using *Agrobacterium* . . . collateral estoppel may bear on the enablement issue, but only if the district court concludes that the specifications of the [disputed] patents themselves do not teach the transformation of monocots.¹⁴⁵

With regard to infringement, the Federal Circuit also reversed the grant of summary judgment because the district court improperly "[applied] the claim construction in the *Plant Genetic Systems* case without examining the intrinsic evidence specific to the [disputed] patent."¹⁴⁶ The court explained that:

It is not enough for the court simply to rely on the conclusion of the court in *Plant Genetic Systems* that the prosecution history of the patent in that case and the corresponding extrinsic evidence support a narrow construction . . . because similar terms can have different meanings in different patents depending on the specifics of each patent.¹⁴⁷

The Federal Circuit thus held that defendant "should not now be precluded from arguing that the same claim term appearing in the claims of the [disputed] patent has a different meaning."¹⁴⁸

141. 315 F.3d 1335, 65 U.S.P.Q.2d (BNA) 1452 (Fed. Cir. 2003).

142. *Monsanto*, 363 F.3d at 1242, 70 U.S.P.Q.2d (BNA) at 1262-63.

143. *Id.* at 1243, 70 U.S.P.Q.2d (BNA) at 1263.

144. *Id.*, 70 U.S.P.Q.2d (BNA) at 1263.

145. *Id.* at 1243-44, 70 U.S.P.Q.2d (BNA) at 1264.

146. *Id.* at 1245, 70 U.S.P.Q.2d (BNA) at 1265.

147. *Id.* at 1244, 70 U.S.P.Q.2d (BNA) at 1264.

148. *Id.*, 70 U.S.P.Q.2d (BNA) at 1264.

*E. Trial Procedures**1. Jury instructions*

In *Sulzer Textil A.G. v. Picanol N.V.*,¹⁴⁹ plaintiff sued its competitor for infringement of two patents related to a method of weaving fabrics and operating a weaving machine. At trial, the jury returned a verdict of noninfringement and the district court denied plaintiff's motion for a new trial. On appeal, plaintiff argued that the district court erroneously instructed the jury that plaintiff carried the burden of establishing that defendants "manufactured" its weaving machines using a process that included all steps of the asserted claims, where the asserted claims only covered a method of operating weaving machines rather than the manufacture of such machines. Plaintiff contended that the error was prejudicial given the jury confusion that arose from the instruction coupled with plaintiff's failure to present any evidence showing defendant's manufacture of the accused machine.¹⁵⁰ The Federal Circuit rejected plaintiff's argument, holding that to the extent that any error existed, it was harmless. The Federal Circuit explained that the remainder of the jury instruction, besides the one statement questioned by plaintiff, properly addressed the method of operation of defendant's machine.¹⁵¹ The Federal Circuit further noted that the fact that the parties had put forth evidence relating solely to defendant's operation of the machine supported its decision.

Plaintiff also asserted prejudicial error in the district court's failure to include any instruction with regard to its earlier claim construction of disputed terms.¹⁵² While the district court construed the claim terms prior to the close of evidence, it had not provided its final constructions in the jury instructions. Plaintiff argued that the district court's omission left the jury to construe the claim terms any way it wanted. The Federal Circuit agreed on this point, explaining that because the meaning of claim terms are legal issues central to most patent cases, a district court is obligated to instruct the jury adequately to ensure that it "fully understands the court's claim construction rulings and what the patentee covered by the claims."¹⁵³ The Federal Circuit further stated that a district court must ensure that the jury understands it is not free to diverge from the predetermined constructions.

Nevertheless, the Federal Circuit held that plaintiff failed to establish

149. 358 F.3d 1356, 69 U.S.P.Q.2d (BNA) 1961 (Fed. Cir. 2004).

150. *Id.* at 1364, 69 U.S.P.Q.2d (BNA) at 1966-67.

151. *Id.* at 1365, 69 U.S.P.Q.2d (BNA) at 1967.

152. *Id.*, 69 U.S.P.Q.2d (BNA) at 1967-68.

153. *Id.* at 1366, 69 U.S.P.Q.2d (BNA) at 1968.

that it had been prejudiced by the district court's error. Plaintiff attempted to show prejudice by pointing to the testimony of its own expert witness, who arguably had suggested a construction of a claim term that was contrary to the construction finalized by the district court.¹⁵⁴ Plaintiff also relied on its own presentation of a demonstrative exhibit indicating a contradictory construction shown to the jury during the cross-examination of defendant's witness. The Federal Circuit determined that plaintiff's evidence of prejudice largely originated from its own witnesses' testimony or from its own actions. Accordingly, based on its determinations that any alleged confusion by jury was "invited" by plaintiff and that the other testimony at trial adequately reflected the district court's constructions, the court held that the district court's failure to restrict the jury to the claim constructions in its instruction did not prejudice plaintiff.¹⁵⁵

In *Chiron Corp. v. Genentech, Inc.*,¹⁵⁶ plaintiff argued that it was entitled to a new trial based on erroneous jury instructions issued by the district court.¹⁵⁷ The Federal Circuit explained that it "reviews jury instructions in their entirety and 'only orders a new trial when errors in the instructions as a whole clearly misled the jury.'"¹⁵⁸ The Federal Circuit also explained that a party seeking a new trial "must show both fatal flaws in the jury instruction and a request for alternative instructions which could have corrected the flaws."¹⁵⁹ The court then rejected plaintiff's argument that the district court erred by providing an instruction on the burden of proof necessary to invalidate a patent but failing to instruct the jury regarding a patent's presumption of validity.¹⁶⁰ The Federal Circuit explained that the "presumption of validity and heightened burden of proving invalidity 'are static and in reality different expressions of the same thing—a single hurdle to be cleared.'"¹⁶¹ The Federal Circuit therefore concluded that the instructions were proper because the jury applied the "correct 'clear and convincing evidence' standard."¹⁶²

Plaintiff also sought a new trial arguing that the district court erroneously

154. *Id.* at 1367, 69 U.S.P.Q.2d (BNA) at 1969.

155. *Id.*, 69 U.S.P.Q.2d (BNA) at 1969.

156. 363 F.3d 1247, 70 U.S.P.Q.2d (BNA) 1321 (Fed. Cir. 2004).

157. *Id.* at 1258, 70 U.S.P.Q.2d (BNA) at 1329.

158. *Id.*, 70 U.S.P.Q.2d (BNA) at 1329 (quoting *Delta-X Corp. v. Baker Hughes Prod. Tools, Inc.*, 984 F.2d 410, 415, 25 U.S.P.Q.2d (BNA) 1447, 1451 (Fed. Cir. 1993)).

159. *Id.*, 70 U.S.P.Q.2d (BNA) at 1329 (quoting *Delta-X*, 984 F.2d at 415, 25 U.S.P.Q.2d (BNA) at 1451).

160. *Id.*, 70 U.S.P.Q.2d (BNA) at 1329.

161. *Id.*, 70 U.S.P.Q.2d (BNA) at 1329 (quoting *Am. Hoist & Derrick Co. v. Sowa & Sons*, 725 F.2d 1350, 1360, 220 U.S.P.Q. (BNA) 763, 770 (Fed. Cir. 1984)). The court also explained that "the presumption is one of law, not fact, and does not constitute 'evidence' to be weighed against the challenger's evidence." *Id.* at 1258-59, 70 U.S.P.Q.2d (BNA) at 1329 (quoting *Avia Group Int'l, Inc. v. L.A. Gear Cal., Inc.*, 853 F.2d 1557, 1562, 7 U.S.P.Q.2d (BNA) 1548, 1552 (Fed. Cir. 1988)).

162. *Id.* at 1259, 70 U.S.P.Q.2d (BNA) at 1329.

instructed the jury regarding the standard for complying with the written description requirement.¹⁶³ The Federal Circuit, however, found no error with the instructions, explaining that courts “need not use identical language to this court’s opinions in its instructions.”¹⁶⁴

In *Norian Corp. v. Stryker Corp.*,¹⁶⁵ plaintiff sought a new trial on the issue of obviousness, arguing that “its case was prejudiced because the jury was allowed to hear evidence of [plaintiff’s] admitted misstatements to the examiner concerning the teachings of [a prior art] reference.”¹⁶⁶ At trial, plaintiff’s counsel admitted that, in preparation for trial, he had discovered that he made a “factual misstatement as to the [prior art reference’s] teaching” during prosecution of the asserted patent.¹⁶⁷ While the district court granted summary judgment that plaintiff did not commit inequitable conduct despite the admitted misstatement, the court allowed the jury to consider evidence of the misstatement in determining validity, particularly in “consider[ing] the proceedings before the examiner and the extent to which and the manner in which the prior art was considered by or before the examiner.”¹⁶⁸

Citing to the Federal Circuit’s decision in *Magnivision, Inc. v. Bonneau Co.*,¹⁶⁹ plaintiff argued that without sufficient evidence to establish the factual predicates of inequitable conduct, evidence concerning an examiner’s state of mind should not be admitted at trial as unduly prejudicial.¹⁷⁰ The court accepted plaintiff’s argument, explaining that “the presumption of validity is not subject to being diluted by ‘procedural lapses’ during prosecution.”¹⁷¹ The Federal Circuit further reasoned that:

[T]he presence and “strength” of the presumption of validity does not warrant inquiry into the examiner’s understanding or competence or gullibility Introspection and speculation into the examiner’s understanding of the prior art or the completeness or correctness of the examination process is not part of the objective review of patentability.¹⁷²

Accordingly, the Federal Circuit concluded that the district court “erred in instructing the jury that the presumption of validity varied with the jury’s

163. *Id.*, 70 U.S.P.Q.2d (BNA) at 1329.

164. *Id.*, 70 U.S.P.Q.2d (BNA) at 1330.

165. 363 F.3d 1321, 70 U.S.P.Q.2d (BNA) 1508 (Fed. Cir. 2004).

166. *Id.* at 1328, 70 U.S.P.Q.2d (BNA) at 1513.

167. *Id.*, 70 U.S.P.Q.2d (BNA) at 1514 (quoting *Norian Corp. v. Stryker Corp.*, 252 F. Supp. 2d 945, 961 (N.D. Cal. 2002)).

168. *Id.* (quoting *Norian*, 252 F. Supp. 2d at 960).

169. 115 F.3d 956, 960, 42 U.S.P.Q.2d (BNA) 1925, 1929 (Fed. Cir. 1997) (holding that “[p]rocedural lapses during examination, should they occur, do not provide grounds for invalidity.”).

170. *Norian*, 363 F.3d at 1329, 70 U.S.P.Q.2d (BNA) at 1514.

171. *Id.*, 70 U.S.P.Q.2d (BNA) at 1514.

172. *Id.*, 70 U.S.P.Q.2d (BNA) at 1514 (citations omitted).

view of whether the examiner believed the applicant's misstatements or otherwise did not 'properly focus on the prior art.'"¹⁷³ However, in light of plaintiff's failure to object to this instruction at trial, the court denied the motion for a new trial because it was "not persuaded that the error was prejudicial or the trial unfair."¹⁷⁴

2. *Jury composition*

In *Caterpillar, Inc. v. Sturman Industries, Inc.*,¹⁷⁵ the Federal Circuit reversed the district court's decision to empanel a juror whose spouse was an employee of the plaintiff.¹⁷⁶ During the jury selection stage of trial, defendant moved to dismiss for cause any current or former employees of plaintiff and their spouses.¹⁷⁷ The district court refused to grant defendant's blanket objection, but instructed defendant that it would consider individual motions for cause.¹⁷⁸ When defendant addressed each juror specifically, it "argued beyond the parameters of the initial blanket objection," focusing on potential jurors' additional connections to plaintiff.¹⁷⁹ While defendant was making these challenges, however, plaintiff repeatedly objected that defendant was merely rearguing its previous blanket objection.¹⁸⁰

During this process, the district court focused on whether each potential juror or his spouse held a management or union-contract position with plaintiff.¹⁸¹ It ultimately dismissed one juror whose husband was in management with plaintiff, but refused to dismiss jurors who were connected to plaintiff's union-contract employees.¹⁸² Defendant neither specifically objected to nor used a peremptory challenge against Juror No. 3, whose husband was an employee of plaintiff.¹⁸³ Juror No. 3 ultimately sat on the jury.¹⁸⁴ After receiving an unfavorable verdict at trial, defendant appealed the district court's decision to empanel Juror No. 3.¹⁸⁵

The Federal Circuit began its analysis of defendant's appeal by settling on a de novo standard of review. It reasoned that whether Juror No. 3 had a financial interest in the case or implicit bias¹⁸⁶ presented a question of

173. *Id.*, 70 U.S.P.Q.2d (BNA) at 1514.

174. *Id.* at 1330, 70 U.S.P.Q.2d (BNA) at 1515.

175. 387 F.3d 1358, 73 U.S.P.Q.2d (BNA) 1609 (Fed. Cir. 2004).

176. *Id.* at 1372-73, 73 U.S.P.Q.2d (BNA) at 1620.

177. *Id.* at 1364, 73 U.S.P.Q.2d (BNA) at 1613.

178. *Id.*, 73 U.S.P.Q.2d (BNA) at 1613.

179. *Id.* at 1369, 73 U.S.P.Q.2d (BNA) at 1617.

180. *Id.*, 73 U.S.P.Q.2d (BNA) at 1617.

181. *Id.*, 73 U.S.P.Q.2d (BNA) at 1617.

182. *Id.*, 73 U.S.P.Q.2d (BNA) at 1617.

183. *Id.* at 1364-65, 73 U.S.P.Q.2d (BNA) at 1613.

184. *Id.* at 1365, 73 U.S.P.Q.2d (BNA) at 1613.

185. *Id.* at 1366, 73 U.S.P.Q.2d (BNA) at 1615.

186. *Id.* at 1368, 73 U.S.P.Q.2d (BNA) at 1616.

law.¹⁸⁷

The Federal Circuit next considered whether defendant waived its objection to Juror No. 3.¹⁸⁸ Holding that it did not, the court reasoned that defendant had included Juror No. 3 in its original objection to all current and former plaintiff employees and their close family members.¹⁸⁹ The parties specifically argued about this particular ground for dismissal, and the judge ultimately ruled that no juror would be dismissed on this basis alone.¹⁹⁰ The Federal Circuit therefore held that it was “clear that [defendant] voiced its objection to these potential jurors for reasons of implied bias, and the court distinctly ruled on the objection.”¹⁹¹

The Federal Circuit rejected plaintiff’s argument that defendant was required to individually challenge Juror No. 3 in order to preserve an objection to her empanelment.¹⁹² The Federal Circuit first noted that plaintiff’s argument ran contrary to its repeated objections at trial that defendant was simply rearguing its blanket objection.¹⁹³ Further, although the district court judge advised defendant to object to specific jurors individually, the context of the instruction showed that the judge intended that defendant would elicit *supplemental* reasons for the jurors’ dismissal.¹⁹⁴ The Federal Circuit opined that “[t]his is best demonstrated by the fact that . . . [defendant] brought up additional facts about the individual jurors beyond the reasons given in the original blanket objection,” and was further demonstrated by the district court’s focus on whether the employees held management versus union-contract positions with plaintiff.¹⁹⁵

The Federal Circuit also found that defendant had specifically stated that it would not challenge Juror No. 3 despite having “additional” reasons for challenging her empanelment.¹⁹⁶ The defendant’s statement, the court found, again demonstrated that when the district court suggested that defendant make individual challenges, the request sought to elicit supplemental challenges in addition to defendant’s blanket objection to any juror’s employment with or spousal relationship with an employee of

187. *Id.*, 73 U.S.P.Q.2d (BNA) at 1616. The court contrasted the issue of implied bias with that of *actual* bias, an inquiry the court characterized as factual. *Id.* at 1367, 73 U.S.P.Q.2d (BNA) at 1615.

188. *Id.* at 1368, 73 U.S.P.Q.2d (BNA) at 1616.

189. *Id.*, 73 U.S.P.Q.2d (BNA) at 1616. The court found that Sturman had included Juror No. 3 in a list of eleven individuals who fell into the category to which its objection was directed. *Id.*, 73 U.S.P.Q.2d (BNA) at 1616.

190. *Id.* at 1369, 73 U.S.P.Q.2d (BNA) at 1617.

191. *Id.*, 73 U.S.P.Q.2d (BNA) at 1617.

192. *Id.* at 1369-70, 73 U.S.P.Q.2d (BNA) at 1617.

193. *Id.* at 1370, 73 U.S.P.Q.2d (BNA) at 1617.

194. *Id.*, 73 U.S.P.Q.2d (BNA) at 1617.

195. *Id.*, 73 U.S.P.Q.2d (BNA) at 1617-18.

196. *Id.*, 73 U.S.P.Q.2d (BNA) at 1618.

plaintiff.¹⁹⁷

The Federal Circuit finally considered whether Juror No. 3 was impliedly biased as a matter of law because of her spousal relationship with a plaintiff employee. Applying the law of the Seventh Circuit, it found that jurors are excluded for implied bias “in extraordinary circumstances,” but that even under this standard jurors had been excluded as a matter of law if the juror had “even a tiny financial interest in the case.”¹⁹⁸ Thus, the Federal Circuit found that because Juror No. 3’s husband worked for plaintiff, she had a financial interest that warranted her dismissal as a matter of law. The Federal Circuit deemed it legally irrelevant whether the juror’s financial interest arose due to the employee’s position in management or as a union-contract employee of plaintiff, and therefore disagreed with the district court’s basis for distinguishing between these roles. Because Juror No. 3 should have been excluded as a matter of law, yet actually sat on the jury, the Federal Circuit vacated the jury’s verdicts in favor of plaintiff and ordered a new trial.¹⁹⁹

3. *Motions for a judgment as a matter of law*

In *Gaus v. Conair Corp.*,²⁰⁰ plaintiff asserted that defendant waived its right to challenge the jury verdict of infringement under the doctrine of equivalents because “simply listing the grounds on which [defendant] based its Rule 50(a) motion was insufficient to put [plaintiff] on notice as what [defendant] alleged to be deficient in [plaintiff’s] evidence.”²⁰¹ Though noting that defendant’s “references to the ‘all elements’ rule and ‘specification estoppel’ constituted a terse—even cryptic—statement of the

197. *Id.*, 73 U.S.P.Q.2d (BNA) at 1618. The court distinguished the facts at hand from those in *Zamora v. Guam*, 394 F.2d 815 (9th Cir. 1968), in which the Ninth Circuit held that the defense had waived its right to object to a juror where the defense had made a general objection to the seating of jurors, who had been seated in a jury against the same defendant in another case, yet failed to question individual jurors as to any bias after the court “announced that defense counsel could explore the matter of prejudice with any juror.” *Caterpillar*, 387 F.3d at 1370, 73 U.S.P.Q.2d (BNA) at 1618 (citing *Zamora*, 394 F.2d at 816). In *Zamora*, the *Caterpillar* court explained, the issue was actual bias, a factual question that requires inquiry as to individual jurors. 387 F.3d at 1370-71, 73 U.S.P.Q.2d (BNA) at 1618. Implied bias, on the other hand, is a question of law which requires no such factual inquiry. *Id.* at 1371, 73 U.S.P.Q.2d (BNA) at 1618. In Sturman’s case, the record was complete because all relevant facts had been gathered through the voir dire process, including the employment and spousal ties of potential jurors to Caterpillar. *Id.*, 73 U.S.P.Q.2d (BNA) at 1618. Furthermore, Sturman had “expeditiously inform[ed]” the court about potential mistakes that might lead to reversal on appeal. *Id.*, 73 U.S.P.Q.2d (BNA) at 1618. The court found that these facts satisfied the two prongs of the rationale supporting the waiver doctrine, encouraging parties to develop a full record of the case and putting the court on notice of potential errors. *Id.*, 73 U.S.P.Q.2d (BNA) at 1618.

198. *Caterpillar*, 387 F.3d at 1371-72, 73 U.S.P.Q.2d (BNA) at 1618-19 (citing *United States v. Polichemi*, 219 F.3d 698, 704 (7th Cir. 2000)).

199. *Id.* at 1373, 73 U.S.P.Q.2d (BNA) at 1620.

200. 363 F.3d 1284, 70 U.S.P.Q.2d (BNA) 1380 (Fed. Cir. 2004).

201. *Id.* at 1287, 70 U.S.P.Q.2d (BNA) at 1382.

grounds” for a Rule 50(a) motion,²⁰² the Federal Circuit noted that the district court “was in the best position to judge the sufficiency of the Rule 50(a) motion in the context of the trial,” and affirmed the district court’s holding that no waiver occurred.²⁰³

In *Summit Technology, Inc. v. Nidek Co.*,²⁰⁴ the Federal Circuit set forth its standard for reviewing a motion for a JMOL, stating that “courts reviewing a jury verdict on a motion for judgment as a matter of law are required to review all of the evidence presented at trial.”²⁰⁵ The Federal Circuit further explained that such a review “requires an examination not merely of isolated snippets of testimony or abbreviated excerpts from documentary evidence divorced from the context in which they appear, but of all relevant evidence on which the jury verdict may have been based.”²⁰⁶

F. United States Patent and Trademark Office Procedures

*In re Watts*²⁰⁷ presented the issues of (1) waiver of arguments before the Board of Patent Appeals and Interferences (“Board”), and (2) the circumstances under which any Board error might preclude the need for remand.²⁰⁸ Regarding the first issue, the question before the Federal Circuit was whether appellant could challenge the Board’s decision on grounds not previously raised before the Board.²⁰⁹ Specifically, appellant sought to overturn the Board’s rejection under 35 U.S.C. § 103²¹⁰ by contending that the Board and the examiner mischaracterized a prior art reference.²¹¹ The Federal Circuit rejected this argument, reasoning that “[b]ecause the appellant failed to argue his current interpretation of the prior art below, we do not have the benefit of the Board’s informed judgment on the issue for our review.”²¹² The Federal Circuit then explained that given appellant’s failure to proffer a viable excuse for not raising the argument below, it declined to “hold that appellant has waived his argument.”²¹³

The Federal Circuit then addressed the question of whether the Board’s rejection of a subset of claims without specific analysis of those claims

202. *Id.*, 70 U.S.P.Q.2d (BNA) at 1382.

203. *Id.*, 70 U.S.P.Q.2d (BNA) at 1382. The district court reasoned that the Rule 50(a) motion was sufficient given that “liability under the doctrine of equivalents has been the central issue in this case since [it] determined . . . that [plaintiff’s] patent was not literally infringed.” *Id.*, 70 U.S.P.Q.2d (BNA) at 1382.

204. 363 F.3d 1219, 70 U.S.P.Q.2d (BNA) 1276 (Fed. Cir. 2004).

205. *Id.* at 1223, 70 U.S.P.Q.2d (BNA) at 1280.

206. *Id.*, 70 U.S.P.Q.2d (BNA) at 1280.

207. 354 F.3d 1362, 69 U.S.P.Q.2d (BNA) 1453 (Fed. Cir. 2004).

208. *Id.* at 1366, 1369, 69 U.S.P.Q.2d (BNA) at 1457, 1458.

209. *Id.*, 69 U.S.P.Q.2d (BNA) at 1457.

210. *Id.* at 1363, 69 U.S.P.Q.2d (BNA) at 1454.

211. *Id.* at 1366-67, 69 U.S.P.Q.2d (BNA) at 1458.

212. *Id.* at 1368, 69 U.S.P.Q.2d (BNA) at 1458.

213. *Id.*, 69 U.S.P.Q.2d (BNA) at 1458.

constituted reversible error.²¹⁴ Noting that it had “previously made clear that the harmless error rule applies to appeals from the Board just as it does in cases originating from district courts,”²¹⁵ the Federal Circuit explained that “to prevail appellant must not only show the existence of error, but also show that the error was in fact harmful because it affected the decision below.”²¹⁶ After reviewing the record, the Federal Circuit concluded that the Board’s error was harmless because appellant never explained why the subset of claims would be patentable if the other claims were properly rejected.²¹⁷

In the case of *In re Sullivan*,²¹⁸ the Federal Circuit resolved several procedural issues relating to interferences. Appellant owned a patent involved in an interference that had been provoked by a patent applicant who had copied appellant’s patent claims into its own application.²¹⁹ Some of the copied claims had been patented for over one year. Shortly after the first interference was provoked by the applicant, the Board redeclared the interference to add another patent owned by appellant and simultaneously amended one of the copied claims in the application.²²⁰ At this stage, Sullivan filed several preliminary motions, but the Board terminated the interference in favor of the other party without addressing these motions because appellant conceded that he did not have priority.²²¹

On appeal, the court reviewed the Board’s actions under the arbitrary and capricious standard set forth in the Administrative Procedure Act.²²² The appellant first argued that because the Board had no jurisdiction over an interference in which some of the claims involved were copied more than one year after their issuance,²²³ the Federal Circuit had no jurisdiction to review the Board’s final decision to terminate the interference.²²⁴ The Federal Circuit quickly dismissed this argument, and explained that even if the Board’s assertion of jurisdiction were improper the jurisdictional question was properly within the Federal Circuit’s appellate jurisdiction.²²⁵

The Federal Circuit also found appellant’s underlying argument

214. *Id.* at 1369, 69 U.S.P.Q.2d (BNA) at 1458.

215. *Id.*, 69 U.S.P.Q.2d (BNA) at 1458-59.

216. *Id.*, 69 U.S.P.Q.2d (BNA) at 1459.

217. *Id.* at 1370, 69 U.S.P.Q.2d (BNA) at 1459.

218. 362 F.3d 1324, 70 U.S.P.Q.2d (BNA) 1145 (Fed. Cir. 2004).

219. *Id.* at 1325, 70 U.S.P.Q.2d (BNA) at 1147.

220. *Id.*, 70 U.S.P.Q.2d (BNA) at 1147.

221. *Id.*, 70 U.S.P.Q.2d (BNA) at 1147.

222. *Id.* at 1326, 70 U.S.P.Q.2d (BNA) at 1147; *see also* 5 U.S.C. § 706(2)(A) (2000) (“The reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.”).

223. *Id.*, 70 U.S.P.Q.2d (BNA) at 1148.

224. *Id.*, 70 U.S.P.Q.2d (BNA) at 1148.

225. *Id.*, 70 U.S.P.Q.2d (BNA) at 1148.

regarding the Board's jurisdiction to be erroneous.²²⁶ The lawfulness of the Board's declaration of the original interference, it stated, was not at issue. Instead, the issue was whether the redeclaration of the interference was somehow unlawful.²²⁷ Appellant attacked the lawfulness of the redeclaration on the grounds that he had not been given adequate notice and an opportunity to be heard.²²⁸ The Federal Circuit rejected this interpretation of the facts, concluding that the Board had given notice to appellant of the redeclaration and that appellant had entered an opposition to the amendment that accompanied the redeclaration.²²⁹

After rejecting the challenges to the Board's redeclaration of the interference, the Federal Circuit addressed appellant's arguments that the Board inappropriately terminated the interference before addressing his preliminary motions. Appellant had argued that the parties' claims corresponding to the interference were unpatentable as obvious in view of certain prior art references.²³⁰ The Federal Circuit noted that the statute governing interferences provides that the Board "shall determine questions of priority of inventions and *may* determine questions of patentability."²³¹ The Federal Circuit interpreted this statute to vest the Board with discretion to address questions of patentability after it had determined priority. The Federal Circuit then held that the Board's decision not to exercise this discretion after appellant conceded priority was not arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.²³²

For its final line of attack against the Board's decision, appellant took issue with a standing order issued by the Board. The order regulated procedural issues such as the form of papers to be filed, the procedure for conferences, and the cross-examination of witnesses. Appellant contended that the Board had no authority to enter a standing order governing the procedure to be followed during the interference by virtue of 37 C.F.R. § 1.610, which provides that "times for taking action by a party in the interference will be set on a case-by-case basis by the administrative patent judge assigned to the interference."²³³ The Federal Circuit however, gave "controlling weight" to the United States Patent and Trademark Office's ("PTO") interpretation of § 1.610 to allow such standing orders because the Federal Circuit could not find that such interpretation was "plainly

226. *Id.*, 70 U.S.P.Q.2d (BNA) at 1148.

227. *Id.* at 1327, 70 U.S.P.Q.2d (BNA) at 1148.

228. *Id.*, 70 U.S.P.Q.2d (BNA) at 1148.

229. *Id.*, 70 U.S.P.Q.2d (BNA) at 1148.

230. *Id.*, 70 U.S.P.Q.2d (BNA) at 1148.

231. *Id.*, 70 U.S.P.Q.2d (BNA) at 1148 (emphasis added) (quoting 35 U.S.C. § 135(a) (2000)).

232. *Id.* at 1327-28, 70 U.S.P.Q.2d (BNA) at 1148-49.

233. *Id.* at 1328, 70 U.S.P.Q.2d (BNA) at 1149 (quoting 37 C.F.R. § 1.610(c) (2002)).

erroneous or inconsistent with the regulation.”²³⁴ The Federal Circuit reasoned that the administrative patent judge should not have to “reinvent the wheel” in such procedural matters for each interference proceeding, and the standing order specifically provided for its own modification by the judge when appropriate.²³⁵ The Federal Circuit thus affirmed the award of priority in favor of the patent applicant.

G. Statutory Interpretation

*Kinik Co. v. International Trade Commission*²³⁶ presented the issue of whether the defenses in 35 U.S.C. 271(g)(1)–(2)²³⁷ are applicable to infringement actions before the International Trade Commission (“ITC”).²³⁸ The appellant challenged the ITC’s holding that it could not invoke such defenses, arguing that pursuant to 19 U.S.C. § 1337(a),²³⁹ the ITC is obligated to consider “[a]ll legal and equitable defenses that may be presented in all cases.”²⁴⁰

The Federal Circuit began its analysis by reviewing the legislative history concerning § 271(g), which stated that the section was designed to provide patentees with the “new right to sue for damages and seek an injunction in federal district court when someone, without authorization, uses[,] sells[,] . . . or imports into the United States, a product made by [the patentee’s] patented process.”²⁴¹ The Federal Circuit thus explained that the purpose of § 271(g) is to “authorize the district courts to adjudicate and impose liability for infringement based on the overseas practice of processes patented in the United States, upon importation of the products of

234. *Id.*, 70 U.S.P.Q.2d (BNA) at 1149.

235. *Id.*, 70 U.S.P.Q.2d (BNA) at 1149.

236. 362 F.3d 1359, 70 U.S.P.Q.2d (BNA) 1300 (Fed. Cir. 2004).

237. Section 271(g) provides:

Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after—

(1) it is materially changed by subsequent processes; or

(2) it becomes a trivial and nonessential component of another product.

35 U.S.C. § 271(g) (2000).

238. *Kinik*, 362 F.3d at 1362, 70 U.S.P.Q.2d (BNA) at 1303.

239. 19 U.S.C. § 1337(c) (2000) (detailing the adjudicative procedure of the ITC for cases involving importation of products that infringe protected U.S. intellectual property).

240. *Kinik*, 362 F.3d at 1362, 70 U.S.P.Q.2d (BNA) at 1302 (quoting 19 U.S.C. § 1337(c)).

241. *Id.*, 70 U.S.P.Q.2d (BNA) at 1302 (quoting S. REP. NO. 100-83, at 27 (1987)).

those processes.”²⁴² Noting that any ambiguity in § 1337, in light of § 271(g), would require deference to the ITC’s interpretation, the Federal Circuit affirmed the ITC’s holding because “no material changes were made in the text of § 1337(a)(1)(B)(ii) . . . despite the concurrent enactment of § 271(g).”²⁴³ The Federal Circuit supported its holding by referring to *Amgen, Inc. v. United States International Trade Commission*,²⁴⁴ in which the court observed that § 271(g) “expressly limited the new defenses to infringement ‘for purpose of this title.’”²⁴⁵

*Monsanto Co. v. McFarling*²⁴⁶ involved the question of whether by passage of the Plant Variety Protection Act,²⁴⁷ Congress intended to “preempt and invalidate all prohibitions on seed saving contained in utility-patent licenses.”²⁴⁸ Answering the question in the negative, the Federal Circuit relied on the Supreme Court’s holding in *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred International, Inc.*²⁴⁹ that plants were subject-matter eligible for utility protection under 35 U.S.C. § 101²⁵⁰ and that hybrid seeds are also eligible for protection under the Plant Variety Protection Act.²⁵¹

H. Miscellaneous Procedural Issues

The Federal Circuit in *Liquid Dynamics Corp. v. Vaughan Co.*²⁵² addressed the issue of whether a court may moot a defendant’s counterclaims of invalidity and unenforceability in the event it grants summary judgment of noninfringement in favor of the defendant. Despite the fact that a defendant who wins on the infringement issue may still have an interest in invalidating the patent to prevent the patentee from later asserting infringement of the same patent against new products or methods, and contrary to its rationale in *TypeRight Keyboard Corp. v. Microsoft Corp.*,²⁵³ the Federal Circuit stated that a district court has discretion either to hear such counterclaims or to dismiss them without prejudice, subject

242. *Id.*, 70 U.S.P.Q.2d (BNA) at 1302.

243. *Id.* at 1363, 70 U.S.P.Q.2d (BNA) at 1303.

244. 902 F.2d 1532, 14 U.S.P.Q.2d (BNA) 1734 (Fed. Cir. 1990).

245. 362 F.3d at 1363, 70 U.S.P.Q.2d (BNA) at 1303 (citing *Amgen*, 902 F.2d at 1540 n.13, 14 U.S.P.Q.2d (BNA) at 1741 n.13).

246. 363 F.3d 1336, 70 U.S.P.Q.2d (BNA) 1481 (Fed. Cir. 2004).

247. 7 U.S.C. §§ 2321-2583 (2000). *See also* 7 U.S.C. § 2543 (providing breeders of seed-derived plant varieties patent-like rights protecting the distribution and reproduction of their breeds).

248. *Monsanto*, 363 F.3d at 1344, 70 U.S.P.Q.2d (BNA) at 1487.

249. 534 U.S. 124 (2001).

250. 35 U.S.C. § 101 (2000) (“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor . . .”).

251. *Monsanto*, 363 F.3d at 1344, 70 U.S.P.Q.2d (BNA) at 1487.

252. 355 F.3d 1361, 69 U.S.P.Q.2d (BNA) 1595 (Fed. Cir. 2004).

253. 374 F.3d 1151, 71 U.S.P.Q.2d (BNA) 1501 (Fed. Cir. 2004).

only to abuse of discretion review.²⁵⁴ The Federal Circuit reached this conclusion despite its recognition that the Supreme Court's decision in *Cardinal Chemical Co. v. Morton International*²⁵⁵ rejected a strict per se policy of mooted claims of invalidity following rulings of noninfringement.

In *In re Violation of Rule 28(c)*,²⁵⁶ the Federal Circuit cautioned that serious violations of the Federal Rules of Appellate Procedure, even if inadvertent, may result in sanctions.²⁵⁷ At issue was a violation of Rule 28(c),²⁵⁸ which limits the contents of a cross-appellant's reply brief to the issues raised by the cross-appeal.²⁵⁹ The underlying suit involved a claim of patent infringement in which the district court found infringement and granted damages in favor of the plaintiff.²⁶⁰ The defendant appealed from the infringement judgment and the district court's calculation of damages.²⁶¹ The plaintiff cross-appealed, seeking to modify the judgment on damages.²⁶² Twenty of the twenty-three pages of the cross-appellant's reply brief, however, addressed issues pertinent only to the main appeal and not to the cross-appeal.²⁶³ Finding no ambiguity in the language of Rule 28(c), the Federal Circuit explained that the rule prohibits the cross-appeal reply brief from addressing the issues raised in the main appeal.²⁶⁴ Because the failure to comply with the rule in this case was inadvertent, however, the Federal Circuit did not exercise its authority under Rule 46(c) to impose sanctions.²⁶⁵ Nevertheless, the Federal Circuit warned that "in future cases, serious violations of applicable rules, whether or not 'inadvertent,' will potentially subject counsel to sanctions."²⁶⁶

II. PATENTABILITY AND VALIDITY

A. 35 U.S.C. § 101

In *SmithKline Beecham Corp. v. Apotex Corp.*,²⁶⁷ Judge Gajarsa wrote a concurring opinion explaining that he would hold a claim directed solely to "crystalline paroxetine hydrochloride hemihydrate" to be invalid under

254. *Liquid Dynamics*, 355 F.3d at 1370, 69 U.S.P.Q.2d (BNA) at 1602.

255. 508 U.S. 83 (1993).

256. 388 F.3d 1383, 73 U.S.P.Q.2d (BNA) 1151 (Fed. Cir. 2004).

257. *Id.* at 1385, 73 U.S.P.Q.2d (BNA) at 1152.

258. FED. R. APP. P. 28(c).

259. *Id.*

260. *In re Violation of Rule 28(c)*, 388 F.3d at 1384, 73 U.S.P.Q.2d (BNA) at 1151.

261. *Id.*, 73 U.S.P.Q.2d (BNA) at 1151.

262. *Id.*, 73 U.S.P.Q.2d (BNA) at 1151.

263. *Id.* at 1385, 73 U.S.P.Q.2d (BNA) at 1152.

264. *Id.*, 73 U.S.P.Q.2d (BNA) at 1152.

265. *Id.*, 73 U.S.P.Q.2d (BNA) at 1152.

266. *Id.*, 73 U.S.P.Q.2d (BNA) at 1152.

267. 365 F.3d 1306, 70 U.S.P.Q.2d (BNA) 1737 (Fed. Cir. 2004).

§ 101.²⁶⁸ The concurrence noted that the “question of patentability under Section 101 does not arise often, and a court’s decision to raise it sua sponte is even less common.”²⁶⁹ However, citing to the Supreme Court’s decisions in *Slawson v. Grand Street Railroad*²⁷⁰ and *Richards v. Chase Elevator Co.*,²⁷¹ the concurrence explained that “the question of whether the invention which is the subject-matter in controversy is patentable or not is always open to consideration of the court, whether the point is raised by the answer or not.”²⁷² The concurrence also acknowledged that while § 101 should be “given wide scope,” the statute “nevertheless excludes laws of nature, natural phenomena, and abstract ideas.”²⁷³ The concurrence then set forth that “the critical distinction guiding all Section 101 inquires into the patentability of subject matter is that human-made, or synthetic, products or processes are patentable, while products and processes of nature are not.”²⁷⁴

The concurrence explained that the asserted claim covered “a natural physical process whereby paroxetine anhydrate . . . could, under normal climatic conditions with no human intervention, bond with water molecules and convert itself into paroxetine hemihydrate.”²⁷⁵ Observing that the disputed claim covering paroxetine hemihydrate “forces the courts to consider the patentability of products and/or process launched in a laboratory and released into nature,” the concurrence concluded that:

[A] natural reproduction process, whether sexual, asexual, part of a chain reaction, or a process of decay, is ineligible for patent protection under Section 101 An item reproduced by such a natural process, whether an inorganic structure or a life form, must ipso facto be ineligible for patent protection under Section 101.²⁷⁶

Addressing the concurrence’s discussion of § 101, the majority opinion

268. *Id.* at 1321, 70 U.S.P.Q.2d (BNA) at 1748 (Gajarsa, J., concurring). Section 101 provides that “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” 35 U.S.C. § 101 (2000).

269. *SmithKline Beecham*, 365 F.3d at 1321, 70 U.S.P.Q.2d (BNA) at 1748 (Gajarsa, J., concurring).

270. 107 U.S. 649 (1883) (upholding decision that found a patent invalid despite the fact that neither party put the validity in dispute).

271. 158 U.S. 299 (1895) (dismissing a patent for lack of novelty).

272. *SmithKline Beecham*, 365 F.3d at 1321, 70 U.S.P.Q.2d (BNA) at 1748 (Gajarsa, J., concurring) (quoting *Slawson*, 107 U.S. at 652). The court also canvassed various decisions from circuit courts in which issues relating to patentable subject matter under § 101 were raised sua sponte. *Id.* at 1321-23, 70 U.S.P.Q.2d (BNA) at 1748-50 (Gajarsa, J., concurring).

273. *Id.* at 1329, 70 U.S.P.Q.2d (BNA) at 1755 (Gajarsa, J., concurring).

274. *Id.* at 1330, 70 U.S.P.Q.2d (BNA) at 1755 (Gajarsa, J., concurring).

275. *Id.*, 70 U.S.P.Q.2d (BNA) at 1755 (Gajarsa, J., concurring).

276. *Id.* at 1331-32, 70 U.S.P.Q.2d (BNA) at 1756 (Gajarsa, J., concurring) (citations omitted).

explained that “the claimed invention is without question a ‘composition of matter’ or an article of ‘manufacture’ within the terms of § 101. Accordingly, the claimed invention represents subject matter eligible for patent protection.”²⁷⁷

B. 35 U.S.C. § 102

1. Printed publication

In *Norian Corp. v. Stryker Corp.*,²⁷⁸ the Federal Circuit addressed whether an “Abstract” presented at a dental research conference constituted prior art that was “described in a printed publication” more than one year before publication pursuant to § 102(b).²⁷⁹ Affirming the district court’s holding that the abstract did not qualify as a printed publication for purposes of anticipation, the Federal Circuit explained that “the lack of substantial evidence of actual availability of the Abstract adequately supports the court’s conclusion that dissemination of the Abstract was not established.”²⁸⁰ In particular, the Federal Circuit credited testimony from a co-author of the Abstract that he did not recall whether he attended the conference and did not recall whether the Abstract was actually distributed to conference participants.²⁸¹

*In re Klopfenstein*²⁸² presented the issue of whether a slide presentation that was pasted onto poster boards and “displayed continuously for two and a half days”²⁸³ at an industry conference and displayed again for less than a day at another industry conference constituted a “printed publication” for purposes of § 102(b).²⁸⁴ The appellant argued that the presentation was not a “printed publication” because it had not been “disseminated by the distribution of reproduction or copies and/or indexed in a library or database.”²⁸⁵ The Federal Circuit rejected this argument, explaining that its precedent does not limit a “printed publication” only to material that is indexed or distributed.²⁸⁶ Rather, the Federal Circuit opined that:

[T]hroughout our case law, public accessibility has been the criterion by

277. *Id.* at 1316, 70 U.S.P.Q.2d (BNA) at 1744 (Gajarsa, J., concurring).

278. 363 F.3d 1321, 70 U.S.P.Q.2d (BNA) 1508 (Fed. Cir. 2004).

279. *Id.* at 1330, 70 U.S.P.Q.2d (BNA) at 1515; *see also* 35 U.S.C. § 102(b) (2000) (prohibiting issuance of patent if an invention was published more than a year before patent application).

280. *Norian*, 363 F.3d at 1330, 70 U.S.P.Q.2d (BNA) at 1515. The court’s reference to “the lack of substantial evidence” is at odds with its statement that “[w]hether a document is a prior publication is a question of law.” *Id.*, 70 U.S.P.Q.2d (BNA) at 1515.

281. *Id.*, 70 U.S.P.Q.2d (BNA) at 1515.

282. 380 F.3d 1345, 72 U.S.P.Q.2d (BNA) 1117 (Fed. Cir. 2004).

283. *Id.* at 1347, 72 U.S.P.Q.2d (BNA) at 1118.

284. *Id.* at 1348, 72 U.S.P.Q.2d (BNA) at 1118.

285. *Id.*, 72 U.S.P.Q.2d (BNA) at 1118.

286. *Id.*, 72 U.S.P.Q.2d (BNA) at 1118.

which a prior art reference will be judged for purposes of § 102(b). Oftentimes courts have found it helpful to rely on distribution and indexing as proxies for public accessibility. But when they have done so, it has not been to the exclusion of all other measures of public accessibility. In other words, distribution and indexing are not the only factors to be considered in a § 102(b) “printed publication inquiry.”²⁸⁷

Providing an example, the Federal Circuit reasoned that

a public billboard targeted to those of ordinary skill in the art that describes all of the limitations of an invention and that is on display for the public for months may be neither “distributed” nor “indexed”—but it most surely is “sufficiently accessible to the public interested in the art” and therefore . . . a “printed publication.”²⁸⁸

The Federal Circuit also explained that determining whether a reference constitutes a “printed publication” requires “a case-by-case inquiry into the facts and circumstances surrounding the reference’s disclosure to members of the public.”²⁸⁹

Having concluded that the presentation at issue was available to the public only during certain periods of time at industry conferences, the Federal Circuit identified several factors for determining whether a temporarily displayed reference is sufficiently accessible to the public to qualify as a “printed publication”:

The factors relevant to the facts of this case are: the length of time the display was exhibited, the expertise of the target audience, the existence (or lack thereof) of reasonable expectations that the material displayed would not be copied, and the simplicity or ease with which the material displayed could have been copied.²⁹⁰

The Federal Circuit instructed that “[o]nly after considering and balancing these factors can we determine whether or not the [presentation] was sufficiently accessible to be a ‘printed publication.’”²⁹¹

In analyzing these factors, the Federal Circuit first explained that “duration of the display is important in determining the opportunity of the public in capturing, processing, and retaining the information conveyed by the reference,” and that the more “transient the display, the less likely it is to be considered a ‘printed publication.’”²⁹² The Federal Circuit noted that the presentation was displayed for a total of approximately three days.²⁹³ The Federal Circuit also determined that the intended target audience of the

287. *Id.* at 1350, 72 U.S.P.Q.2d (BNA) at 1120.

288. *Id.* at 1348, 72 U.S.P.Q.2d (BNA) at 1119.

289. *Id.* at 1350, 72 U.S.P.Q.2d (BNA) at 1120.

290. *Id.*, 72 U.S.P.Q.2d (BNA) at 1120.

291. *Id.*, 72 U.S.P.Q.2d (BNA) at 1120.

292. *Id.*, 72 U.S.P.Q.2d (BNA) at 1120.

293. *Id.* at 1351, 72 U.S.P.Q.2d (BNA) at 1121.

presentation was those of ordinary skill in the art.²⁹⁴ The Federal Circuit further reasoned that no expectation existed that the presentation would not be copied given the absence of any measures taken to protect the displayed information.²⁹⁵ Finally, the Federal Circuit concluded that the presentation was displayed in a simple manner and “copying of the information it contained would have been a relatively simple undertaking.”²⁹⁶ Accordingly, the Federal Circuit held that the cumulative weight of these factors established that the presentation “was sufficiently publicly accessible to count as a ‘printed publication.’”²⁹⁷

2. *Anticipation*

a. *Inherency*

In *Toro Co. v. Deere & Co.*,²⁹⁸ the asserted patents were directed to a machine for lifting and fracturing soil to decrease subsurface soil density, thereby increasing turf growth. In support of its motion for summary judgment of invalidity, defendant argued that one of the asserted claims was anticipated by a reference that expressly disclosed two of the three claim limitations, and inherently disclosed the third. The district court rejected defendant’s argument concerning inherency, stating that “no reasonable factfinder could find that one of skill in the art would discern from the [prior art] patent the unique combination of all of the necessary parameters to produce the aeration method claimed in the [asserted] patent The [prior art] patent does not thus anticipate the [asserted] patent.”²⁹⁹

On appeal, the Federal Circuit identified numerous errors in the district court’s analysis. First, the Federal Circuit explained that the district court erroneously failed to construe the claim limitation at issue, and that such failure rendered it impossible to decide whether the prior art inherently disclosed the limitation. The Federal Circuit further noted that the district court had suggested contradictory constructions by stating in one part of its opinion that the terms and phrases should be given their ordinary meaning, and, in another part of its opinion, incorporating specific operational features described in the specification of the asserted patent, including those described in the preferred embodiments but not recited in the asserted

294. *Id.*, 72 U.S.P.Q.2d (BNA) at 1121.

295. *Id.*, 72 U.S.P.Q.2d (BNA) at 1121.

296. *Id.* at 1352, 72 U.S.P.Q.2d (BNA) at 1121.

297. *Id.*, 72 U.S.P.Q.2d (BNA) at 1121.

298. 355 F.3d 1313, 69 U.S.P.Q.2d (BNA) 1584 (Fed. Cir. 2004).

299. *Id.* at 1319, 69 U.S.P.Q.2d (BNA) at 1589 (quoting *Toro Co. v. John Deere & Co.*, 143 F. Supp. 2d 1122, 1130 (D. Minn. 2001)).

claim.³⁰⁰

The Federal Circuit also found error in the district court's failure to address "a critical question" for inherent anticipation: whether, as a matter of fact, practicing the prior art invention necessarily featured or resulted in the allegedly inherent limitation of the asserted patent.³⁰¹ Stating that proof of inherent anticipation required that the "missing descriptive matter is necessarily present in the thing described in the reference, *and that it would be so recognized by one of ordinary skill in the art,*" the court opined that the district court erroneously suggested that the inventor or other artisans must have recognized that practicing the invention would result in the allegedly inherent characteristic.³⁰² The Federal Circuit pointed to its decision in *Schering Corp. v. Geneva Pharmaceuticals, Inc.*,³⁰³ which held that a characteristic that is a necessary feature or result of a prior art embodiment, sufficiently described and enabled, suffices for an inherent disclosure even if such feature or result was unknown at the time of the prior invention.

Along similar lines, the Federal Circuit found flaws in the district court's statement that "no reasonable factfinder could find that one of skill in the art would discern from the [prior art reference] the unique combination of all of the necessary parameters to produce the aeration method claimed in the '168 patent.'"³⁰⁴ The Federal Circuit explained that this statement was made without a "proper construction" of the relevant limitation and "a corresponding factual analysis of [the prior art reference's] embodiments."³⁰⁵ Further, the Federal Circuit noted that a proper construction of the disputed term could demonstrate that the claim was not restricted to the precise numerical ranges included in the specification, thereby rendering irrelevant the absence of numerical ranges in the prior art reference.

In *Glaxo Group Ltd. v. Apotex, Inc.*,³⁰⁶ defendant appealed the district court's finding that two of plaintiff's patents directed to the antibiotic known by the trade name of Ceftin® were not anticipated or made obvious by a third patent owned by Glaxo.³⁰⁷ Defendant had presented expert testimony that performance of the experiments recited in the examples of

300. The Federal Circuit, however, stopped short of construing the claims because the appellate record did not contain sufficient evidence to guide it, and instead remanded the issue back to the district court. *Id.* at 1321, 69 U.S.P.Q.2d (BNA) at 1591.

301. *Id.* at 1320, 69 U.S.P.Q.2d (BNA) at 1589-90.

302. *Id.*, 69 U.S.P.Q.2d (BNA) at 1590 (quoting *Toro*, 143 F. Supp. 2d at 1129-30).

303. 339 F.3d 1373, 1377-78, 67 U.S.P.Q.2d (BNA) 1664, 1667-68 (Fed. Cir. 2003).

304. *Toro*, 355 F.3d at 1319, 1321, 69 U.S.P.Q.2d (BNA) at 1589-90 (quoting *Toro*, 143 F. Supp. 2d at 1130).

305. *Id.* at 1321, 69 U.S.P.Q.2d (BNA) at 1590.

306. 376 F.3d 1339, 71 U.S.P.Q.2d (BNA) 1801 (Fed. Cir. 2004).

307. *Id.* at 1343, 1348, 71 U.S.P.Q.2d (BNA) at 1803, 1807.

the allegedly anticipating reference resulted in the features claimed by the asserted patents, necessitating a finding that those features were inherent in the reference.³⁰⁸ The district court discredited this testimony because the expert had admitted to deviating from the examples in performing his experiments.³⁰⁹ Furthermore, the expert admitted that he had read the patents asserted by plaintiff prior to performing the experiments.³¹⁰ The district court opined that these facts rendered the expert's experiments "highly suspect" and that therefore the experiments did not constitute clear and convincing evidence of the patents' invalidity. The Federal Circuit found no error in the district court's conclusions.³¹¹

b. Anticipation by a printed publication under 35 U.S.C. § 102(b)

In the case of *In re Ngai*,³¹² an inventor appealed the Board of Patent Appeals and Interference's decision that its patent claims were anticipated or rendered obvious by the prior art. The patent at issue was generally directed to methods for "amplifying" and "normalizing" ribonucleic acids ("RNA") in order to prepare sufficient quantities of RNA for experimentation. Although most claims covered methods, the only claim at issue on appeal was drawn to a "kit" for normalizing and amplifying RNA populations comprising several components including "instructions describing the method of claim 1."³¹³ The Board held that kits existed in the prior art, which contained all of the claimed components including instructions, and thus the claim was anticipated. Relying on the court's *In re Gulack*³¹⁴ decision for the proposition that "[d]ifferences between an invention and the prior art cited against it cannot be ignored merely because those differences reside in the content of the printed matter,"³¹⁵ appellant contended that its claims could be distinguished from the prior art because no prior art kit had instructions bearing the same *content*.

The Federal Circuit determined that the circumstances on appeal were not analogous to *Gulack*. The invention in *Gulack* was a circular band bearing printed numbers that could be used for math education and recreation. Although bands with numbers printed on them were widely

308. *Id.* at 1345, 71 U.S.P.Q.2d (BNA) at 1804.

309. *Id.* at 1348, 71 U.S.P.Q.2d (BNA) at 1807.

310. *Id.* at 1345, 1348, 71 U.S.P.Q.2d (BNA) at 1804, 1807.

311. *Id.* at 1345, 1348-49, 71 U.S.P.Q.2d (BNA) at 1804, 1807. It further found that secondary factors of non-obviousness including commercial success, long felt but unresolved need, and unexpected results favored the non-obvious determination reached by the court below, especially considering the admission of Apotex's expert that the patent Apotex relied upon did not suggest the benefits of the additional features of the inventions covered by the asserted patents. *Id.* at 1349, 71 U.S.P.Q.2d (BNA) at 1807.

312. 367 F.3d 1336, 70 U.S.P.Q.2d (BNA) 1862 (Fed. Cir. 2004).

313. *Id.* at 1337, 70 U.S.P.Q.2d (BNA) at 1863.

314. 703 F.2d 1381, 217 U.S.P.Q. (BNA) 401 (Fed. Cir. 1983).

315. *Id.* at 1385, 217 U.S.P.Q. (BNA) at 403.

known in the prior art, the numbers in Gulack's invention had a functional relationship to the band: the band supported the digits, and the digits exploited the endless nature of the band. In contrast, *Ngai*'s printed matter in no way "depend[ed] on the kit, and the kit [did] not depend on the printed matter."³¹⁶ The Federal Circuit thus held that even *Gulack* pointed out that printed matter would not distinguish the invention from prior art where the printed matter is not functionally related to the substrate. The Federal Circuit also observed that accepting appellant's position would require the PTO to grant patents on a product to anyone who would attach a new instruction sheet to it.

*Kioto Manufacturing Co. v. Turn-Key-Tech, LLC*³¹⁷ involved an appeal from a district court's grant of a JMOL holding claims directed to methods for injection molding of plastic products invalid as anticipated.³¹⁸ On appeal, the patentee argued that the district court erred because the plaintiff "merely submitted th[e] [prior art] reference into evidence and made no specific mention of it at trial."³¹⁹ The Federal Circuit began its analysis by stating that a party advancing an anticipation shoulders "an especially heavy burden."³²⁰ In reviewing the trial record, the Federal Circuit observed that although plaintiff entered the prior art reference into evidence, it "otherwise failed to provide any testimony or other evidence that would demonstrate to the jury how that reference met the limitations of the claims . . . or how the reference enabled one of ordinary skill in the art to practice the claimed invention."³²¹ The Federal Circuit also observed that plaintiff's invalidity expert never specifically mentioned the prior art reference during his testimony and "offered a conclusion of invalidity relating to a quintet of prior art patents which included [the prior art reference]."³²²

In reversing the district court's grant of judgment as a matter of law, the Federal Circuit explained:

Typically, testimony concerning anticipation must be testimony from one skilled in the art and must identify each claim element, state the witnesses' interpretation of the claim element, and explain in detail how each claim element is disclosed in the prior art reference. The testimony is insufficient if it is merely conclusory.³²³

316. *In re Ngai*, 367 F.3d at 1339, 70 U.S.P.Q.2d (BNA) at 1864.

317. 381 F.3d 1142, 72 U.S.P.Q.2d (BNA) 1190 (Fed. Cir. 2004).

318. *Id.* at 1144-45, 72 U.S.P.Q.2d (BNA) at 1191-92.

319. *Id.* at 1151, 72 U.S.P.Q.2d (BNA) at 1196.

320. *Id.*, 72 U.S.P.Q.2d (BNA) at 1197 (quoting *N.V. Akzo v. E.I. DuPont de Nemours*, 810 F.2d 1148, 1150-51, 1 U.S.P.Q.2d (BNA) 1704, 1707 (Fed. Cir. 1987)).

321. *Id.*, 72 U.S.P.Q.2d (BNA) at 1197.

322. *Id.* at 1151-52, 72 U.S.P.Q.2d (BNA) at 1197.

323. *Id.* at 1152, 72 U.S.P.Q.2d (BNA) at 1197 (quoting *Schumer v. Lab. Computer Sys., Inc.*, 308 F.3d 1304, 1315-16, 64 U.S.P.Q.2d (BNA) 1832, 1841 (Fed. Cir. 2002)).

The Federal Circuit thus concluded that the “general and conclusory testimony” provided by plaintiff’s invalidity expert “does not suffice as substantial evidence of invalidity This is so even when the [prior art] reference has been submitted into evidence before the jury.”³²⁴

*In re Elsner*³²⁵ presented an appeal from the PTO’s finding that claims directed to geranium and rose plants were anticipated under § 102(b).³²⁶ In particular, the PTO determined the appellants’ published Plant Breeder’s Rights patent applications disclosed the claimed inventions while the foreign sales of the claimed plants placed the possession of the inventions in those skilled in the art.³²⁷ The Federal Circuit explained that the precise issue on appeal was “whether evidence of foreign sale of a claimed reproducible plant variety may enable an otherwise non-enabled printed publication disclosing that plant, thereby creating a § 102(b) bar.”³²⁸ The Federal Circuit began by noting that while “foreign sales of an invention in combination with a publication will not constitute a bar because such a result would circumvent the established rules that neither non-enabling publications nor foreign sales can bar one’s right to a patent,”³²⁹ the case before it was distinct because “it deals with plant patents, which may be granted to ‘[w]hoever invents or discovers and asexually reproduces any distinct and new variety of plant.’”³³⁰ The Federal Circuit thus reasoned that “only when possession derived in this manner enables a person of skill in the art to practice asexual reproduction of the plant in a manner consistent with the statute can a non-enabling publication and a foreign sale act as a § 102(b) bar.”³³¹

The Federal Circuit rejected appellant’s argument that its holding would create a printed publication bar when a non-enabling publication could be coupled with a foreign sale, explaining that:

When a publication identifies the plant that is involved or discovered and a foreign sale occurs that puts one of ordinary skill in the art in possession of the plant itself, which, based on the level of ordinary skill in the art, permits asexual reproduction without undue experimentation, that combination of facts and events so directly conveys the essential knowledge of the invention that the sale combines with the publication to erect a statutory bar.³³²

The Federal Circuit also affirmed the PTO’s use of the published patent

324. *Id.* at 1152, 72 U.S.P.Q.2d (BNA) at 1197.

325. 381 F.3d 1125, 72 U.S.P.Q.2d (BNA) 1038 (Fed. Cir. 2004).

326. *Id.* at 1126, 72 U.S.P.Q.2d (BNA) at 1039.

327. *Id.* at 1126-27, 72 U.S.P.Q.2d (BNA) at 1039-40.

328. *Id.* at 1128, 72 U.S.P.Q.2d (BNA) at 1041.

329. *Id.*, 72 U.S.P.Q.2d (BNA) at 1041.

330. *Id.*, 72 U.S.P.Q.2d (BNA) at 1041 (quoting 35 U.S.C. § 161 (2000)).

331. *Id.* at 1128-29, 72 U.S.P.Q.2d (BNA) at 1041.

332. *Id.* at 1129, 72 U.S.P.Q.2d (BNA) at 1041.

applications together with the sales of the claimed plants “to show that the public was in possession of the claimed plants and thus that the [patent] applications were enabled anticipatory references”³³³ because its precedent “supports the use of secondary references to show that a primary § 102(b) reference was in fact enabled.”³³⁴

In *Nystrom v. Trex Co.*,³³⁵ the Federal Circuit applied its precedent in *Hockerson-Halberstadt, Inc. v. Avia Group International, Inc.*³³⁶ and *In re Wright*³³⁷ to determine whether a patent figure anticipated a claim limitation directed to a radius of curvature to width ratio of a surface of a board used for constructing outdoor decks. The patentee argued that the district court incorrectly based its anticipation decision on data generated by an employee of defendant, who made a software model of the boards depicted in the perspective drawings of the allegedly anticipatory patent figure, and then performed computation to determine that the figure displayed the recited ratio. The district court concluded that the precedents of *Hockerson-Halberstadt* and *Wright* were not applicable as it found that “the correct inquiry [was] whether a person of ordinary skill in the art would use measurements from the [cited] reference to ascertain the degree of curvature.”³³⁸

The Federal Circuit disagreed, holding that the district court erroneously applied precedents that indicated the court’s “disfavor in reading precise proportions into patent drawings which do not expressly provide such proportions.”³³⁹ Because the district court improperly relied on defendant’s data, which assumed the patent figure was drawn to scale, in its holding that certain claims of plaintiff’s patent were anticipated, the Federal Circuit reversed the court’s grant of summary judgment of invalidity.³⁴⁰

c. On-sale bar and public use

In *Elan Corp. v. Andrx Pharmaceuticals, Inc.*,³⁴¹ the Federal Circuit reversed a finding that plaintiff’s patent covering a sustained release formulation of the anti-inflammatory composition, naproxen sodium, was

333. *Id.*, 72 U.S.P.Q.2d (BNA) at 1042.

334. *Id.*, 72 U.S.P.Q.2d (BNA) at 1042.

335. 374 F.3d 1105, 71 U.S.P.Q.2d (BNA) 1241 (Fed. Cir. 2004).

336. 222 F.3d 951, 55 U.S.P.Q.2d (BNA) 1487 (Fed. Cir. 2000) (affirming the district court’s judgment of noninfringement in a patent infringement case concerning an article of outer footwear).

337. 569 F.2d 1124, 193 U.S.P.Q. (BNA) 332 (C.C.P.A. 1977) (holding that appellant’s invention concerning a whiskey barrel croze would have been obvious, at the time it was made, to a person of ordinary skill).

338. 374 F.3d at 1116, 71 U.S.P.Q.2d (BNA) at 1250.

339. *Id.* at 1117, 71 U.S.P.Q.2d (BNA) at 1250.

340. *Id.* at 1117-18, 71 U.S.P.Q.2d (BNA) at 1251.

341. 366 F.3d 1336, 70 U.S.P.Q.2d (BNA) 1722 (Fed. Cir. 2004).

invalid under the on-sale bar.³⁴² Defendant asserted that the patent was barred by plaintiff's offer to supply the composition to several pharmaceutical companies in the United States in excess of one year before the patent's application filing date.³⁴³ The district court agreed, finding that a letter drafted by a plaintiff's executive to a potential licensee, dated approximately four years before plaintiff filed its patent application, constituted an offer for sale for purposes of the statutory bar.³⁴⁴ The letter "confirmed" plaintiff's plans to be in a position to file an Investigational New Drug ("IND") by the following year, and to file a New Drug Application ("NDA") after two years of collecting necessary data and developing a sustained-release naproxen sodium compound. The letter also expressed plaintiff's interest in seeking a partner in such licensing and development and specified the licensing and clinical fees that would be associated with partnership.³⁴⁵ The letter further "confirmed" that plaintiff would be responsible for supplying bulk tablets to the potential customer under a price structure that would allow the potential licensee an "initial gross margin based on current naproxen prices of not less than 70% after taking into account [its] processing charge . . . , A.I. cost, packaging and royalty."³⁴⁶

Reversing the judgment on appeal, the Federal Circuit determined that its previous decisions, such as *In re Kollar*,³⁴⁷ made clear that "an offer to license a patent claiming an invention after future research and development had occurred, without more, is not an offer to sell the invention."³⁴⁸ The Federal Circuit further explained that "a sale of rights in a patent, as distinct from a sale of the invention itself, is not within the scope of the statute, and thus does not implicate the on-sale bar."³⁴⁹ Thus, contrary to the district court's opinion, the Federal Circuit found that plaintiff's letter to the potential licensee was merely an offer to enter into a license under a patent for future sale of the invention "when and if it has been developed."³⁵⁰ The Federal Circuit explained that the letter lacked provisions for quantities, time of delivery, place of delivery, and detailed product specifications. The Federal Circuit also noted that the price terms provided for in the letter were labeled "licensing fees," and therefore merely represented the amount that plaintiff requested to form and continue

342. *Id.* at 1337, 70 U.S.P.Q.2d (BNA) at 1723.

343. *Id.* at 1339, 70 U.S.P.Q.2d (BNA) at 1724.

344. *Id.* at 1337-39, 70 U.S.P.Q.2d (BNA) at 1723-25.

345. *Id.* at 1337-38, 70 U.S.P.Q.2d (BNA) at 1723-24.

346. *Id.* at 1338, 70 U.S.P.Q.2d (BNA) at 1723.

347. 286 F.3d 1326, 62 U.S.P.Q.2d (BNA) 1425 (Fed. Cir. 2002).

348. *Elan*, 366 F.3d at 1341, 70 U.S.P.Q.2d (BNA) at 1725-26.

349. *Id.*, 70 U.S.P.Q.2d (BNA) at 1725 (quoting *Group One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041, 1049, 59 U.S.P.Q.2d (BNA) 1121, 1127 (Fed. Cir. 2001)).

350. *Id.* at 1341, 70 U.S.P.Q.2d (BNA) at 1726.

a partnership with the potential licensee. The fees were not, the Federal Circuit explained, price terms for the sale of tablets. The court also found important the absence of any terms linking prices to quantities of tablets. Finally, the Federal Circuit held that plaintiff's "confirmation" that it would supply bulk tablets according to a specified price structure was not a "price term" because the actual prices would not be determinable until the sustained release formulation was approved as safe and effective, and the charges for processing, packaging, and etcetera would not be determinable until later.³⁵¹

*Bernhardt, L.L.C. v. Collezione Europa USA, Inc.*³⁵² addressed the validity of six design patents owned by plaintiff, a furniture sales company that provided customers and industry representatives a preview of its new furniture designs one month before a biannual, industry-wide "Market" event.³⁵³ Plaintiff's preview event was called "Pre-Market." Plaintiff's standard procedures at Pre-Market required attendants to be named on a special list of invitees and to present identification twice at the exhibition before being escorted by a sales representative around the showroom. No pictures were allowed, and no one could take anything from the showroom when they left the exhibition. In September 1999, plaintiff hosted a preview event at which it showcased a line of furniture that it later adopted as its "Coronado Collection."³⁵⁴ The designs of this particular furniture collection were the subject of the six asserted patents.

The district court held that four of the asserted patents were invalid under § 102(b) as a result of plaintiff's exhibition of its designs at the September 1999 Pre-Market.³⁵⁵ On appeal, plaintiff argued that (1) the Pre-Market event was not "public" for purposes of § 102(b), and that (2) defendant failed to adduce sufficient evidence that the designs exhibited at the September 1999 Pre-Market were actually covered by the asserted patents. The court first focused on whether defendant had sufficiently proven that the exhibited designs fell within the scope of the patents at issue. The evidence proffered by defendant showed that four stock keeping units ("SKUs"), used by plaintiff to track its designs, had been included in a "Pre-Market Wish List," a document listing the SKUs of the furniture that would be exhibited at Pre-Market events. Defendant argued that these SKUs corresponded to furniture designs covered by the asserted patents. Defendant also presented a document from plaintiff summarizing comments gathered from the invitees to the September 1999 Pre-Market

351. *Id.* at 1342, 70 U.S.P.Q.2d (BNA) at 1726-27.

352. 386 F.3d 1371, 72 U.S.P.Q.2d (BNA) 1901 (Fed. Cir. 2004).

353. *Id.* at 1373-74, 72 U.S.P.Q.2d (BNA) at 1903-04.

354. *Id.* at 1373-75, 72 U.S.P.Q.2d (BNA) at 1903-04.

355. *Id.* at 1375, 72 U.S.P.Q.2d (BNA) at 1904.

event that named three such SKUs. The district court concluded from this evidence that it was highly likely that “the furniture designs for the four SKUs corresponding to the patents were shown at the 1999 Pre-Market.”³⁵⁶

The Federal Circuit found the district court’s analysis of this question to be lacking. Although the district court had found that the furniture pieces corresponding to the “SKUs” were “similar to” the furniture design shown in each patent, the court did not apply the “ordinary observer test” or the “points of novelty test” to determine whether the designs actually displayed were “substantially similar in appearance in the eyes of an ordinary observer . . . or appropriated the points of novelty of the patented designs.”³⁵⁷

Next, the Federal Circuit considered whether the Pre-Market exhibition was “public” within the meaning of § 102(b). The district court had held that the Pre-Market exhibition was public because it found that plaintiff had produced insufficient evidence that the Pre-Market invitees were under any duty or ethical obligation of confidentiality when they viewed the items displayed. The Federal Circuit found that this conclusion was “misdirected.”³⁵⁸ Contrary to the implications of the district court’s opinion, it held that the presence or absence of confidentiality agreements was not dispositive of whether use is public under § 102(b), and that the appropriate inquiry mandates review of the totality of the circumstances surrounding the allegedly barred use.³⁵⁹ Specifically, it found the district court had failed to analyze how plaintiff’s Pre-Market exhibition comported with the policies underlying the public use bar. This failure was enough for the Federal Circuit to find the court’s analysis incomplete and to justify vacating the court’s holding.

In *SmithKline Beecham Corp. v. Apotex Corp.*,³⁶⁰ the court explained that the public use defense under § 102(b)³⁶¹ incorporates the same “ready for patenting” analysis as the on-sale bar.³⁶² The court explained that while the commercial sale prong of the on-sale bar does not apply, public use “includes any use of the *claimed invention* by a person other than the inventor who is under no limitation, restriction, or obligation of secrecy to the inventor.”³⁶³ The Federal Circuit thus made clear that the public use

356. *Id.* at 1376, 72 U.S.P.Q.2d (BNA) at 1905 (quoting *Bernhardt L.L.C. v. Collezione Eurpoa USA, Inc.*, 280 F. Supp. 2d 485, 495 (M.D.N.C. 2003)).

357. *Id.* at 1378, 72 U.S.P.Q.2d (BNA) at 1907.

358. *Id.* at 1381, 72 U.S.P.Q.2d (BNA) at 1908.

359. *Id.* at 1379, 1381, 72 U.S.P.Q.2d (BNA) at 1907, 1909.

360. 365 F.3d 1306, 70 U.S.P.Q.2d (BNA) 1737 (Fed. Cir. 2004).

361. Section 102(b) provides in relevant part that a claim is invalid if “the invention was . . . in public use or on sale in this country more than one year prior to the date of the application for the patent in the United States.” 35 U.S.C. § 102(b) (2000).

362. *SmithKline*, 365 F.3d at 1316-17, 70 U.S.P.Q.2d (BNA) at 1745.

363. *Id.* at 1317, 70 U.S.P.Q.2d (BNA) at 1745 (quoting *Netscape Communications*

defense “erects a bar where, before the critical date, the invention was ready for patenting and was used by a person other than the inventor who is under no confidentiality obligation.”³⁶⁴

Turning to the undisputed facts in the record, the Federal Circuit held the claim invalid observing that “the record shows that [the claimed compound] PHC hemihydrate was in public use before the critical date.”³⁶⁵ In particular, the Federal Circuit noted that the plaintiff “placed PHC hemihydrate in public clinical trials in the United States Moreover, [plaintiff] administered PHC hemihydrate to patients without any apparent confidentiality restrictions on the patients or the administering physicians.”³⁶⁶

The Federal Circuit also addressed plaintiff’s argument that the clinical trials constituted experimental use exempt from the reach of the public use bar, explaining that: “Testing or experimentation performed with respect to non-claimed features of the device does not show that the invention was the subject of experimentation. In other words, an experimental use only negates a statutory bar when the inventor was testing claimed features of the invention.”³⁶⁷ Then, noting its adoption of plaintiff’s own construction of PHC hemihydrate as not limited by any considerations of “efficacy, commercial use, or pharmaceutical viability,”³⁶⁸ the Federal Circuit held that “clinical trials designed to establish the efficacy and safety of the compound as an antidepressant for FDA approval are not experimental uses of that claimed invention.”³⁶⁹ The Federal Circuit further elaborated that “[i]n other words, the claim covers the compound regardless of its use as an antidepressant. The antidepressant properties of the compound are simply not claimed features.”³⁷⁰ The Federal Circuit also explained that potential confusion may exist between experimental use and the “separate requirement of patent law to test an invention for utility, i.e., to show that it works for its intended propose.”³⁷¹ While noting a “potential overlap for utility and experimental testing,”³⁷² the Federal Circuit held that “utility testing (reduction to practice) and experimental use testing are not synonymous,”³⁷³ and “after the invention is reduced to practice, further testing will not qualify as experimental use for purposes of negating a bar

Corp. v. Konrad, 295 F.3d 1315, 1321, 63 U.S.P.Q.2d (BNA) 1580, 1583 (Fed. Cir. 2002)).

364. *Id.*, 70 U.S.P.Q.2d (BNA) at 1745.

365. *Id.*, 70 U.S.P.Q.2d (BNA) at 1745.

366. *Id.*, 70 U.S.P.Q.2d (BNA) at 1745.

367. *Id.*, 70 U.S.P.Q.2d (BNA) at 1745 (internal quotations and citations omitted).

368. *Id.* at 1318, 70 U.S.P.Q.2d (BNA) at 1746.

369. *Id.*, 70 U.S.P.Q.2d (BNA) at 1746.

370. *Id.*, 70 U.S.P.Q.2d (BNA) at 1746.

371. *Id.*, 70 U.S.P.Q.2d (BNA) at 1746.

372. *Id.*, 70 U.S.P.Q.2d (BNA) at 1746.

373. *Id.*, 70 U.S.P.Q.2d (BNA) at 1746.

under § 102(b).³⁷⁴

The Federal Circuit also stated that it was aware of its decisions in *EZ Dock, Inc. v. Schafer Systems, Inc.*,³⁷⁵ *Seal-Flex, Inc. v. Athletic Track & Court Construction*,³⁷⁶ and *Manville Sales Corp. v. Paramount Systems, Inc.*,³⁷⁷ in which the experimental use was found despite “testing that did not focus on an expressly claimed feature.”³⁷⁸ The court, however, explained that “[e]ach of those cases permitted testing to negate the bar when the experimentation improves or verifies a feature inherent in the express claims of the invention.”³⁷⁹

With respect to *Manville*, the Federal Circuit noted that the decision explicitly provided that the inventor’s testing was necessary because “durability in an outdoor environment is inherent to the purpose of the invention,” a covered light pole used for highway repairs.³⁸⁰ Discussing *Seal-Flex*, the Federal Circuit explained that the case involved claims directed to “an all-weather track” and “experimentation again focused on features inherent to the claimed invention.”³⁸¹ With regard to *EZ Dock*, the Federal Circuit explained that although that case involved claims covering a “floating dock” without an express limitation on performance in “choppy water,” the claim language “carried the implication that the invention must perform in rough water. Thus, again the experimentation verified or improved a feature inherent to the claimed invention.”³⁸² Having

374. *Id.*, 70 U.S.P.Q.2d (BNA) at 1746. The court also explained that experimental testing and utility testing stemmed from “different origins and purposes, the narrower experimental use negation does not extend beyond perfecting claimed features.” *Id.* at 1319, 70 U.S.P.Q.2d (BNA) at 1746.

375. 276 F.3d 1347, 61 U.S.P.Q.2d (BNA) 1289 (Fed. Cir. 2002) (remanding a patent infringement case regarding a polyethylene floating dock to determine factual issues as to whether sale of the dock before the critical date was experimental).

376. 98 F.3d 1318, 40 U.S.P.Q.2d (BNA) 1450 (Fed. Cir. 1996) (reversing the district court’s summary judgment of a patent infringement case concerning all-weather athletic track because factual questions existed on the issue of patentability of invention under on-sale bar).

377. 917 F.2d 544, 16 U.S.P.Q.2d (BNA) 1587 (Fed. Cir. 1990) (finding that the use of iris guide arms for self-centering luminaire assembly for lighting poles on one pole at one site was experimental for purposes of on-sale and public use bars).

378. *SmithKline*, 365 F.3d at 1318, 70 U.S.P.Q.2d (BNA) at 1746.

379. *Id.* at 1319, 70 U.S.P.Q.2d (BNA) at 1746.

380. *Id.*, 70 U.S.P.Q.2d (BNA) at 1747 (quoting *Manville*, 917 F.2d at 551, 16 U.S.P.Q.2d (BNA) at 1592).

381. *Id.*, 70 U.S.P.Q.2d (BNA) at 1747. The court noted that *Seal-Flex* was decided under the “totality of the circumstances” standard rendered inapplicable by a subsequent Supreme Court opinion. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55 (1998) (rejecting totality of circumstances test as “undermin[ing] the interest in certainty” and adopting a two-prong test for the on-sale bar). The court further explained that the *Seal-Flex* decision did not affirmatively hold that experimental use was applicable, but rather vacated the district court’s grant of summary judgment on invalidity and remanded the case. *SmithKline*, 365 F.3d at 1319, 70 U.S.P.Q.2d (BNA) at 1747.

382. *SmithKline*, 365 F.3d at 1319, 70 U.S.P.Q.2d (BNA) at 1747. The court again explained that in *EZ Dock* there was no definitive holding that the experimental use exception was applicable, but instead a vacate of summary judgment of invalidity and a

canvassed its decisions in these cases, the Federal Circuit concluded that its jurisprudence “has remained faithful to the strict requirements of the experimental use negation by limiting it to testing to perfect claimed features, or, in a few instances, testing to perfect features inherent to the claimed invention.”³⁸³ The Federal Circuit then instructed that: “[A] patentee should understand that testing the properties, uses, and commercial significance of a compound claimed solely in structural terms may start the clock under § 102(b) for filing a claim that is not limited by any property, commercially significant amount, or other use of the compound.”³⁸⁴

*Poly-America, L.P. v. GSE Lining Technology, Inc.*³⁸⁵ involved the question of whether a pre-patenting sale of a device that was capable of performing the patented process rendered the disputed patent claims invalid under the on-sale bar of § 102(b).³⁸⁶ In affirming the jury’s verdict that the claims were not invalid, the Federal Circuit explained that substantial evidence established that the sold device was not designed to perform the patented process and was not used to perform the patented process until after the asserted claims had issued.³⁸⁷

C. 35 U.S.C. § 103—Obviousness

In *Ruiz v. A.B. Chance Co.*,³⁸⁸ the Federal Circuit affirmed the district court’s holding that a patent directed to a screw anchor system that was used to support and stabilize slouching buildings was invalid as obvious in light of the prior art. The asserted claims recited an elongated shaft with a screw tip and a transversely extending load-bearing metal bracket. Of the two prior art patents relied upon by the district court, one disclosed the screw anchor component and the other disclosed the metal bracket

remand to the district court. *Id.*, 70 U.S.P.Q.2d (BNA) at 1747.

383. *Id.* at 1319-20, 70 U.S.P.Q.2d (BNA) at 1747. While concurring with the majority’s holding that the asserted claim was invalid, Judge Gajarsa wrote a concurring opinion explaining that he would affirm the district court’s decision that plaintiff is entitled to summary judgment that the claim is not invalid under public use because “the control [plaintiff] actually exercised over the trials was sufficient to demonstrate that the trials were in the nature of experimentation rather than mere commercial use.” *Id.* at 1324, 70 U.S.P.Q.2d (BNA) at 1750-51 (quoting *SmithKline Beechum v. Apotex Corp.*, 286 F. Supp. 2d 925, 934 (N.D. Ill. 2001)). The concurrence also noted that the majority opinion failed to explain why out of the cases discussed, only the plaintiff in the case at bar “had reduced its claimed invention to practice sufficiently to preclude the experimental use doctrine.” *Id.* at 1325, 70 U.S.P.Q.2d (BNA) at 1751.

384. *Id.* at 1320, 70 U.S.P.Q.2d (BNA) at 1747-48.

385. 383 F.3d 1303, 72 U.S.P.Q.2d (BNA) 1685 (Fed. Cir. 2004).

386. *Id.* at 1308-09, 72 U.S.P.Q.2d (BNA) at 1688-89. Section 102(b) provides, in pertinent part, that “[a] person shall be entitled to a patent unless . . . (b) the invention was . . . on sale in this country, more than one year prior to the date of the application for patent in the United States.” 35 U.S.C. § 102(b) (2000).

387. *Poly-America*, 383 F.3d at 1309, 72 U.S.P.Q.2d (BNA) at 1688-89.

388. 357 F.3d 1270, 69 U.S.P.Q.2d (BNA) 1686 (Fed. Cir. 2004).

component. Both references disclosed systems for supporting building foundations.

The Federal Circuit had previously remanded the case because the district court had not made specific findings on the motivation to combine the prior art references, the level of ordinary skill in the art, and whether and to what extent secondary considerations were probative in its obviousness analysis.³⁸⁹ Upon remand, the district court again came to its original conclusion: the asserted claims were obvious in light of the cited references, stating that motivation to combine the references was found in the problem of underpinning foundations to which the asserted patent and the prior art references were addressed.³⁹⁰ The district court also explained that the patentee's evidence of commercial success and doubt of expert witnesses were weak.

On appeal, the Federal Circuit affirmed and rejected the patentee's argument that the district court exercised hindsight in its obviousness analysis, explaining that motivation to combine prior art references can be found in the nature of the problem to be solved, particularly with "simpler mechanical technologies." The Federal Circuit noted that it was therefore proper for the district court to find a motivation to combine "because the two references address precisely the same problem," underpinning structural foundations.³⁹¹ The Federal Circuit also rejected the patentee's contention that the district court employed hindsight in identifying the required motivation to combine. The Federal Circuit pointed to the district court's careful consideration and ultimate dismissal of a witness's testimony that actually supported a finding of a motivation to combine, and declared that this careful consideration "show[ed] further that it performed a detailed and reasoned analysis of the evidence, rather than a conclusion-oriented discussion that typically accompanies a hindsight analysis."³⁹²

In *National Steel Car, Ltd. v. Canadian Pacific Railway*,³⁹³ the Federal Circuit reversed the district court's conclusion that plaintiff's patents were not invalid as obvious over two prior art references. The primary issues were: (1) whether either reference disclosed the "drop-deck" or "intermediate depressed floor section" limitation of the asserted claims, in which the floor of the rail car between the end truck assemblies was lower than the portion of the floor over the end truck assemblies, and (2) whether there existed a motivation to combine the references.³⁹⁴ The Federal Circuit found that one reference disclosed a rail car with a floor while the

389. *Id.* at 1274, 69 U.S.P.Q.2d (BNA) at 1689.

390. *Id.*, 69 U.S.P.Q.2d (BNA) at 1689.

391. *Id.* at 1276, 69 U.S.P.Q.2d (BNA) at 1690.

392. *Id.* at 1277, 69 U.S.P.Q.2d (BNA) at 1691.

393. 357 F.3d 1319, 69 U.S.P.Q.2d (BNA) 1641 (Fed. Cir. 2004).

394. *Id.* at 1322-25, 69 U.S.P.Q.2d (BNA) at 1643-45.

other reference disclosed a railcar in which the bottom's center portion was lower than the portion over the ends. The fact that the second reference's bottom was not load-bearing, as the district court construed the term "floor" to require, was not problematic the Federal Circuit reasoned, because it found a load-bearing floor could be found in the first reference.

Plaintiff argued that even if these two references disclosed all of the limitations of its asserted claims, defendant did not demonstrate a sufficient motivation to combine them in order to raise a substantial question of invalidity for obviousness. The Federal Circuit, however, rejected that argument, explaining that defendant produced two pieces of documentary evidence supporting its position that one of ordinary skill in the art would have been motivated to combine the references.³⁹⁵

The Federal Circuit thoroughly criticized the district court's reasoning underlying its conclusion that plaintiff's patent was obvious. First, addressing the district court's conclusion that neither reference had been disclosed to a sufficient number of people in order to qualify as "prior art," the court emphasized that "[p]ublic distribution is irrelevant" as it has "long been the law that the motivation to combine need not be found in prior art references, but equally can be found in the knowledge generally available to one of ordinary skill in the art."³⁹⁶ The Federal Circuit explained that the question was not whether others learned of the drawing evidencing the motivation to combine, as it would be if the issue was whether the drawing constituted prior art; rather the inquiry was whether the drawing demonstrated that persons of ordinary skill in the art would have considered it obvious to combine the elements found in the prior art references.³⁹⁷

Second, the Federal Circuit found clear error in the district court's dismissal of one of the references as prior art on the basis that it was created by a person without knowledge of engineering or rail car design. The court explained that the fact that the creator of a work allegedly showing the motivation to combine had less skill than one of ordinary skill in the art is actually *probative* of what one of ordinary skill in the art would have found obvious.³⁹⁸

Third, the Federal Circuit rejected the district court's conclusion that because the references addressed goals different from those served by the asserted patent, they "taught away" from the claimed invention. The Federal Circuit reasoned that "[a] finding that two inventions were designed to resolve different problems . . . is insufficient to demonstrate

395. *Id.* at 1337-38, 69 U.S.P.Q.2d (BNA) at 1655.

396. *Id.* at 1337, 69 U.S.P.Q.2d (BNA) at 1655 (internal quotations omitted).

397. *Id.* at 1338, 69 U.S.P.Q.2d (BNA) at 1655.

398. *Id.* at 1338, 69 U.S.P.Q.2d (BNA) at 1655-56.

that one invention teaches away from another.”³⁹⁹

Finally, addressing secondary considerations, the Federal Circuit concluded that the district court’s finding that a long-felt but unsatisfied need for the invention existed was “flatly contradictory” with its additional finding that customers were satisfied with railcars that already existed on the market. The Federal Circuit further noted that the other secondary considerations considered by the district court were insufficient by themselves to uphold its conclusion with regard to obviousness.⁴⁰⁰ Accordingly, the Federal Circuit reversed the grant of a preliminary injunction.

In *Knoll Pharmaceutical Co. v. Teva Pharmaceuticals USA, Inc.*,⁴⁰¹ the Federal Circuit reversed a grant of summary judgment that plaintiff’s drug patent was invalid as obvious. The patent was directed to a composition of ibuprofen and hydrocodone and methods of administering such composition to treat pain. The district court found the prior art suggesting combination of hydrocodone and ibuprofen to be invalidating.⁴⁰² On appeal, the Federal Circuit explained that the district court erred by failing to look to the specification’s acknowledgment that the analgesic effect resulting from the combination was greater than that provided by using either ibuprofen or hydrocodone alone. Furthermore, the Federal Circuit found the district court improperly excluded the patentee’s evidence of studies conducted after the patent was granted that demonstrated the synergistic interaction of hydrocodone and ibuprofen. The Federal Circuit held that such “[e]vidence developed after the patent grant is not excluded from consideration” because it provides an “understanding of the full range of an invention is not always achieved at the time of filing the patent application.”⁴⁰³

The Federal Circuit also found error in the district court’s treatment of certain evidence of the failure of others to develop similar combination drugs, including evidence that others had abandoned their FDA registration applications for related compounds. The district court did not ignore this evidence altogether, but dismissed it on the basis that several similar combinations had made it to market. The Federal Circuit deemed these materials to be objective evidence of others’ failure to make the invention, and held that the district court improperly weighed conflicting evidence instead of viewing the evidence in the light most favorable to the opponent of summary judgment.⁴⁰⁴ As the Federal Circuit saw it, “[a]t a minimum

399. *Id.* at 1339, 69 U.S.P.Q.2d (BNA) at 1656.

400. *Id.* at 1340, 69 U.S.P.Q.2d (BNA) at 1657.

401. 367 F.3d 1381, 70 U.S.P.Q.2d (BNA) 1957 (Fed. Cir. 2004).

402. *Id.* at 1384, 70 U.S.P.Q.2d (BNA) at 1959.

403. *Id.* at 1385, 70 U.S.P.Q.2d (BNA) at 1960.

404. *Id.*, 70 U.S.P.Q.2d (BNA) at 1960.

the conflicting evidence reinforced the patentee's argument that the activity observed for the patented combination [was] not routinely present for all [related] combinations."⁴⁰⁵

In *TypeRight Keyboard Corp. v. Microsoft Corp.*,⁴⁰⁶ plaintiff sued defendant for infringement of its various patents directed to certain V-shaped ergonomic keyboards.⁴⁰⁷ The district court granted a motion for summary judgment of invalidity, finding that all of the asserted claims were obvious in light of prior art.⁴⁰⁸ Defendant relied primarily on one reference created by a German company called Marquardt ("the document") which included several pictures of V-shaped keyboards similar to the claimed invention. The document, however, was undated, and therefore the main issue was whether it in fact constituted prior art. The district court heard several of defendant's witnesses testify to the effect that the document had been published at a trade show in Germany in 1986, prior to the critical date, and therefore determined that it was prior art.

On appeal, the Federal Circuit held that genuine issues existed as to the credibility of defendant's witnesses and therefore summary judgment had been improperly granted. First, the Federal Circuit concluded that defendant's testimony that the document was publicly available in 1986 was tentative—one witness had said he thought the document had been handed out at the 1986 trade show, and the other testified only that he remembered seeing documents "similar" to the document at the trade show.⁴⁰⁹ Furthermore, the Federal Circuit observed that these same witnesses testified that the document had been found in a file dated 1990 and that the document had served as the basis for patent applications filed in 1991, and would have barred those patent applications had it been published in 1986. Finally, the Federal Circuit noted that although the witnesses had testified that it was possible to verify the exact date of the document, no evidence suggested that such a step had been taken.⁴¹⁰

Under these circumstances, the Federal Circuit determined that summary judgment of invalidity was improperly granted.⁴¹¹ The Federal Circuit explained that although a naked statement that witnesses should not be believed would not prohibit summary judgment, "where the opposing party offers specific facts that call into question the credibility of the movants

405. *Id.*, 70 U.S.P.Q.2d (BNA) at 1960.

406. 374 F.3d 1151, 71 U.S.P.Q.2d (BNA) 1501 (Fed. Cir. 2004).

407. *Id.* at 1154, 71 U.S.P.Q.2d (BNA) at 1502.

408. *Id.* at 1155, 71 U.S.P.Q.2d (BNA) at 1503.

409. *Id.* at 1158, 71 U.S.P.Q.2d (BNA) at 1505.

410. *Id.* at 1158, 71 U.S.P.Q.2d (BNA) at 1505.

411. The court did not discuss the fact that had the document been published as late as 1990, it still could have been considered prior art.

[sic] witnesses” summary judgment is not appropriate.⁴¹²

In *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*,⁴¹³ the Federal Circuit held that a prior art reference’s recognition of a problem to be solved did not render obvious subsequent claims for solving that problem.⁴¹⁴ *Cardiac Pacemakers* involved an appeal from a district court’s grant of a JMOL, holding claims directed to cardiac defibrillators that are permanently installed under a patient’s skin invalid for obviousness.⁴¹⁵ In granting the JMOL, the district court reasoned that all the elements of the disputed claims were well known in the prior art and found a “compelling motivation” to combine the various elements in light of a prior art reference that identified the same problem and solved the disputed claims.⁴¹⁶ Reversing the grant of the JMOL, the Federal Circuit explained that the district court “applied an incorrect standard to the ultimate question” of obviousness:⁴¹⁷

Recognition of the problem of treating complex heart arrhythmias does not render obvious the eventual solution. Recognition of a need does not render obvious the achievement that meets that need. There is an important distinction between the general motivation to cure an uncured disease . . . and the motivation to create a particular cure.⁴¹⁸

Though opining that “[t]here can of course arise situations wherein identification of the problem is itself the invention,” the Federal Circuit explained that “in the case at bar the problem was well-recognized . . . [and] the solution of this problem, according to trial proceedings, had not previously been achieved.”⁴¹⁹ The Federal Circuit therefore determined that “[r]ecognition of an unsolved problem does not render the solution obvious.”⁴²⁰

*In re Fulton*⁴²¹ involved an appeal from the Board’s obviousness rejection of claims directed to an improved shoe sole.⁴²² The Federal Circuit first noted that “[w]hen a rejection depends on combination of prior art references, there must be some teaching, suggestion, or motivation to combine the references.”⁴²³ The Federal Circuit also explained that the source of the motivation to combine may be “the nature of the problem, the

412. *TypeRight Keyboard*, 374 F.3d at 1158, 71 U.S.P.Q.2d (BNA) at 1505-06.

413. 381 F.3d 1371, 72 U.S.P.Q.2d (BNA) 1333 (Fed. Cir. 2004).

414. *Id.* at 1377, 72 U.S.P.Q.2d (BNA) at 1337.

415. *Id.* at 1374, 72 U.S.P.Q.2d (BNA) at 1335.

416. *Id.* at 1376-77, 72 U.S.P.Q.2d (BNA) at 1337.

417. *Id.* at 1377, 72 U.S.P.Q.2d (BNA) at 1337.

418. *Id.*, 72 U.S.P.Q.2d (BNA) at 1337.

419. *Id.*, 72 U.S.P.Q.2d (BNA) at 1337.

420. *Id.*, 72 U.S.P.Q.2d (BNA) at 1337.

421. 391 F.3d 1195, 73 U.S.P.Q.2d (BNA) 1141 (Fed. Cir. 2004).

422. *Id.* at 1196-97, 73 U.S.P.Q.2d (BNA) at 1142-43.

423. *Id.* at 1200, 73 U.S.P.Q.2d (BNA) at 1145 (quoting *In re Rouffet*, 149 F.3d 1350, 1355, 47 U.S.P.Q.2d (BNA) 1453, 1456 (Fed. Cir. 1998)).

teachings of the pertinent references, or the ordinary knowledge of those skilled in the art.”⁴²⁴

Appellant argued that the Board’s finding of a motivation to combine lacked substantial evidence because it failed to show that the characteristics in the prior art reference “are preferred over other alternatives disclosed in the prior art.”⁴²⁵ The court rejected this argument and explained:

[O]ur case law does not require that a particular combination must be the preferred, or the most desirable, combination described in the prior art in order to provide motivation for the current invention. “The question is whether there is something in the prior art as a whole to suggest the *desirability*, and thus the obviousness, of making the combination,” not whether there is something in the prior art as a whole to suggest that the combination is the *most desirable* combination available.⁴²⁶

Accordingly, the Federal Circuit held that “a finding that the prior art as a whole suggests the desirability of a particular combination need not be supported by a finding that the prior art suggests that the combination claimed by the patent applicant is the preferred, or most desirable, combination.”⁴²⁷

Relying on its precedent that a reference “teach[es] away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference,”⁴²⁸ appellant also argued that the Board erred in finding that none of the prior art references taught away from the combination of prior art references relied upon for the rejection.⁴²⁹ The Federal Circuit also rejected this argument, reasoning that “[t]he prior art’s mere disclosure of more than one alternative does not constitute a teaching away from any of [the] alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed in the [appellant’s] application.”⁴³⁰

Appellant further argued that the Board erred by failing to establish that the prior art contained a teaching identifying the importance of a feature covered by the claimed invention.⁴³¹ The Federal Circuit also declined to accept this argument, noting that it “relies on the mistaken premise that the prior art must teach that a particular combination is preferred, or ‘optimal,’

424. *Id.*, 73 U.S.P.Q.2d (BNA) at 1145 (citations omitted) (quoting *In re Rouffet*, 149 F.3d at 1355, 47 U.S.P.Q.2d (BNA) at 1456).

425. *Id.*, 73 U.S.P.Q.2d (BNA) at 1145.

426. *Id.*, 73 U.S.P.Q.2d (BNA) at 1145 (quoting *In re Beattie*, 974 F.2d 1309, 1311, 24 U.S.P.Q.2d (BNA) 1040, 1042 (Fed. Cir. 1992)).

427. *Id.*, 73 U.S.P.Q.2d (BNA) at 1145.

428. *Id.* at 1201, 73 U.S.P.Q.2d (BNA) at 1145 (quoting *In re Gurley*, 27 F.3d 551, 553, 31 U.S.P.Q.2d (BNA) 1130, 1131 (Fed. Cir. 1994)).

429. *Id.*, 73 U.S.P.Q.2d (BNA) at 1145-46.

430. *Id.*, 73 U.S.P.Q.2d (BNA) at 1146.

431. *Id.*, 73 U.S.P.Q.2d (BNA) at 1146.

for the combination to be obvious.”⁴³² Citing *In re Gurley*,⁴³³ the court stated that “as long as some motivation or suggestion to combine the references is provided by the prior art taken as a whole, the law does not require that the reference be combined for the reasons contemplated by the inventor.”⁴³⁴

*In re Bigio*⁴³⁵ presented the question of whether prior art references relating to toothbrushes constituted analogous art for purposes of determining whether claims directed to a hair brush would have been obvious.⁴³⁶ The Federal Circuit observed that:

[t]wo separate tests define the scope of analogous prior art: (1) whether the art is from the same field of endeavor, regardless of the problem addressed and, (2) if the reference is not within the field of the inventor’s endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.⁴³⁷

Challenging the Board’s application of the field of endeavor test, appellant argued that such an approach is “unworkable because the lack of clear guidelines leaves the application of this test to an examiner’s subjective judgment.”⁴³⁸ The Federal Circuit rejected this argument, explaining that “the field of endeavor test is neither wholly subjective nor unworkable. The test for analogous art requires the PTO to determine the appropriate field of endeavor by reference to explanations of the invention’s subject matter in the patent application, including the embodiments, function, and structure of the claimed invention.”⁴³⁹ The Federal Circuit further observed that:

Although the majority of the case law precedent for analogous arts hinges on the second test, this court detects no ambiguity in the “field of endeavor” test. While the scope of any field of endeavor will vary with the factual description of each invention, that variability does not equate with ambiguity and absence of a neutral standard.⁴⁴⁰

Turning to the record, the Federal Circuit affirmed the Board’s determination that the toothbrush references were analogous art to claims directed to a hair brush “because the structural similarities between toothbrushes and small brushes for hair would have led one of ordinary skill in the art working in the specific field of hairbrushes to consider all

432. *Id.* at 1201-02, 73 U.S.P.Q.2d (BNA) at 1146.

433. 27 F.3d 551, 31 U.S.P.Q.2d (BNA) 1130.

434. *Fulton*, 391 F.3d at 1202, 73 U.S.P.Q.2d (BNA) at 1146 (citations omitted) (quoting *In re Beattie*, 974 F.2d 1309, 1312, 24 U.S.P.Q.2d (BNA) 1040, 1042 (Fed. Cir. 1992)).

435. 381 F.3d 1320, 72 U.S.P.Q.2d (BNA) 1209 (Fed. Cir. 2004).

436. *Id.* at 1325, 72 U.S.P.Q.2d (BNA) at 1211.

437. *Id.*, 72 U.S.P.Q.2d (BNA) at 1212.

438. *Id.*, 72 U.S.P.Q.2d (BNA) at 1212.

439. *Id.*, 72 U.S.P.Q.2d (BNA) at 1212.

440. *Id.* at 1326, 72 U.S.P.Q.2d (BNA) at 1212.

similar brushes including toothbrushes.”⁴⁴¹ The Federal Circuit also affirmed the Board’s finding that one skilled in the art would have considered toothbrushes and hairbrushes “to be within the same endeavor.”⁴⁴² Accordingly, the Federal Circuit affirmed the Board’s rejection of the claims “[b]ecause there is no dispute that the combination of the three toothbrush references renders [appellant’s] invention obvious.”⁴⁴³

In dissent, Judge Newman explained that the “toothbrush art is not analogous to the hair brush art. [Appellant’s] patent application is directed to a hair brush, and his claims are limited to a hair brush” and “[a] brush for hair has no more relation to a brush for teeth than does hair resemble teeth.”⁴⁴⁴ Judge Newman further reasoned that:

The mode and mechanics of brushing teeth cannot reasonably be viewed as analogous to the mode and mechanics of brushing hair. To state the obvious: teeth require a brush that penetrates around the edges of relatively large and hard substrates, a brush that administers a soapy abrasive, a brush that works in the up-and-down and circular motion needed to scrub teeth; a brush for hair must serve entirely different shapes and textures and purposes.⁴⁴⁵

*Iron Grip Barbell Co. v. USA Sports, Inc.*⁴⁴⁶ involved an appeal from a grant of summary judgment holding invalid as obvious a claim directed to a weight plate “formed with solely a triad of spaced apart elongated handle openings.”⁴⁴⁷ In comparing the claims to the prior art, the Federal Circuit emphasized its precedent warning against use of hindsight to evaluate the prior art and explained that the “district court’s use of an ‘overall picture’ and ‘common sense’ test of obviousness falls squarely into the hindsight trap.”⁴⁴⁸ Then noting that the requirement for a motivation to combine prior art “prevents the use of ‘the inventor’s disclosure as a blueprint for piecing together the prior art to defeat patentability—the essence of hindsight,’”⁴⁴⁹ the Federal Circuit reasoned that the appeal presented circumstances in which the disputed claim limitation fell within a range disclosed in the prior art references.⁴⁵⁰ The Federal Circuit observed that:

Where the “prior art . . . discloses a range encompassing a somewhat

441. *Id.*, 72 U.S.P.Q.2d (BNA) at 1212.

442. *Id.* at 1327, 72 U.S.P.Q.2d (BNA) at 1213.

443. *Id.*, 72 U.S.P.Q.2d (BNA) at 1213.

444. *Id.*, 72 U.S.P.Q.2d (BNA) at 1213 (Newman, J., dissenting).

445. *Id.*, 72 U.S.P.Q.2d (BNA) at 1213 (Newman, J., dissenting).

446. 392 F.3d 1317, 73 U.S.P.Q.2d (BNA) 1225 (Fed. Cir. 2004).

447. *Id.* at 1319, 73 U.S.P.Q.2d (BNA) at 1225 (quoting U.S. Patent No. 6,436,015 (issued Aug. 20, 2002)).

448. *Id.* at 1320, 73 U.S.P.Q.2d (BNA) at 1227.

449. *Id.*, 73 U.S.P.Q.2d (BNA) at 1227.

450. *Id.*, 73 U.S.P.Q.2d (BNA) at 1227.

narrower claimed range,” the narrower range may be obvious . . . “[W]hen the difference between the claimed invention and the prior art is the range or value of a particular variable,” then a patent should not issue if “the difference in range or value is minor.”⁴⁵¹

The Federal Circuit thus reasoned that “simply because an invention falls within a range disclosed by the prior art does not necessarily make it per se obvious. Both the genus and species may be patentable.”⁴⁵² The Federal Circuit further explained that “where there is a range disclosed in the prior art, and the claimed invention falls within that range, there is a presumption of obviousness,”⁴⁵³ but observed that the presumption could be rebutted if: (1) the prior art teaches away from the claimed invention, or (2) the claimed invention results in unexpected results not disclosed in the prior art.⁴⁵⁴

Reviewing the record evidence, the Federal Circuit reasoned that:

The prior art suggested that a large number of elongated grips in exercise weights was beneficial, thus plainly suggesting that one skilled in the art look to the range appearing in the prior art. The prior art disclosed weight plates with one, two, or four elongated handles. [Plaintiff] is claiming a weight plate with three elongated handles, within the range of the prior art.⁴⁵⁵

The Federal Circuit then noted that, other than a conclusory statement, plaintiff offered no evidence that the prior art taught away from the invention.⁴⁵⁶ The Federal Circuit further observed that plaintiff failed to adduce any evidence showing the three-grip barbell produced unexpected results, particularly because “[t]here is no indication of any new and unexpected results from the use of a three-grip plate in the . . . patent or the prosecution history.”⁴⁵⁷ Accordingly, the Federal Circuit held that the claim was invalid as obvious “absent substantial evidence of pertinent secondary factors supporting patentability.”⁴⁵⁸

Finally, addressing the record evidence on secondary considerations, the Federal Circuit determined that plaintiff failed to establish commercial success of the claimed invention.⁴⁵⁹ In particular, the Federal Circuit observed that “[t]he only evidence of marketplace success that [plaintiff] proffers is that six retail competitors offered three-grip plates, and three of

451. *Id.* at 1321, 73 U.S.P.Q.2d (BNA) at 1227-28 (quoting *Haynes Int'l v. Jessop Steel Co.*, 8 F.3d 1573, 1577 n.3, 28 U.S.P.Q.2d (BNA) 1652, 1655 (Fed. Cir. 1993)).

452. *Id.*, 73 U.S.P.Q.2d (BNA) at 1228.

453. *Id.* at 1322, 73 U.S.P.Q.2d (BNA) at 1228.

454. *Id.*, 73 U.S.P.Q.2d (BNA) at 1228.

455. *Id.*, 73 U.S.P.Q.2d (BNA) at 1228.

456. *Id.*, 73 U.S.P.Q.2d (BNA) at 1228.

457. *Id.* at 1323, 73 U.S.P.Q.2d (BNA) at 1228.

458. *Id.*, 73 U.S.P.Q.2d (BNA) at 1229.

459. *Id.* at 1324, 73 U.S.P.Q.2d (BNA) at 1229.

those competitors have entered into license agreements with respect to the . . . patent.”⁴⁶⁰ The Federal Circuit explained that such evidence was insufficient to raise a genuine issue of material fact because plaintiff “did not explain the terms of the licenses nor the circumstances under which they were granted Our cases specifically require affirmative evidence of nexus where the evidence of commercial success presented is a license, because it is often ‘cheaper to take licenses than to defend infringement suits.’”⁴⁶¹

Then addressing plaintiff’s evidence of copying, the Federal Circuit explained that “[n]ot every competing product that arguably falls within the scope of a patent is evidence of copying. Otherwise every infringement suit would automatically confirm the nonobviousness of the patent.”⁴⁶² The Federal Circuit thus concluded that evidence that competitors abandoned one-arm plates in favor of three-arm plates was insufficient to establish copying.⁴⁶³

D. 35 U.S.C. § 112

1. Written description

Although in 2004 the Federal Circuit as a whole continued to debate at a conceptual level what role, if any, the written description requirement should play in patent jurisprudence, the court’s individual decisions reaffirmed that the written description requirement provides a viable challenge to the validity or the patentability of claims.

*University of Rochester v. G.D. Searle & Co.*⁴⁶⁴ involved an appeal from a grant of summary judgment holding claims covering methods of selectively inhibiting COX-2 enzymes invalid for failure to comply with the written description requirement of § 112, ¶ 1.⁴⁶⁵ On appeal, plaintiff first argued that the district court erred in holding the claims invalid because “no written description requirement exists independent of enablement.”⁴⁶⁶ The Federal Circuit rejected this argument, providing an

460. *Id.*, 73 U.S.P.Q.2d (BNA) at 1230.

461. *Id.*, 73 U.S.P.Q.2d (BNA) at 1230 (quoting *EWP Corp. v. Reliance Universal, Inc.*, 755 F.2d 898, 908, 225 U.S.P.Q. (BNA) 20, 26 (Fed. Cir. 1985)).

462. *Id.* at 1325, 73 U.S.P.Q.2d (BNA) at 1230.

463. *Id.*, 73 U.S.P.Q.2d (BNA) at 1230.

464. 358 F.3d 916, 69 U.S.P.Q.2d (BNA) 1886 (Fed. Cir. 2004).

465. *Id.* at 917-19, 69 U.S.P.Q.2d (BNA) at 1888-89. Section 112 states that the patent 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, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112 (2000).

466. *Univ. of Rochester*, 358 F.3d at 920, 69 U.S.P.Q.2d (BNA) at 1890.

extensive analysis establishing that written description and enablement are two separate and independent requirements that must both be satisfied by the patentee.⁴⁶⁷ The Federal Circuit began by noting that § 112, ¶ 1, provides three separate criteria for patentability “referred to as the ‘written description requirement,’ the ‘enablement requirement,’ and the best mode requirement.”⁴⁶⁸ The Federal Circuit explained that:

Although there is often significant overlap between the three requirements, they are nonetheless independent of each other Thus, an invention may be described without an enabling disclosure of how to make and use it. A description of a chemical compound without a description of how to make and use it, unless within the skill of one of ordinary skill in the art, is an example. Moreover, an invention may be enabled even though it has not been described Such can occur when enablement of a closely related invention A that is both described and enabled would similarly enable an invention B *if* B were described. A specification can likewise describe an invention without enabling the practice of the full breadth of its claims. Finally, still further disclosure might be necessary to satisfy the best mode requirement if otherwise only an inferior mode would be disclosed.⁴⁶⁹

The Federal Circuit also reasoned that the written description requirement “serves a teaching function, as a ‘quid pro quo’ in which the public is given ‘meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.’”⁴⁷⁰ Then providing a historical analysis of the case law addressing § 112, ¶ 1, the Federal Circuit made clear that its “precedent clearly recognizes a separate written description requirement.”⁴⁷¹

Plaintiff next argued that the Federal Circuit’s decisions in *Regents of University of California v. Eli Lilly & Co.*,⁴⁷² *Fiers v. Reval*,⁴⁷³ and *Enzo*

467. *Id.* at 921-23, 69 U.S.P.Q.2d (BNA) at 1890-92.

468. *Id.* at 921, 69 U.S.P.Q.2d (BNA) at 1890.

469. *Id.* at 921-22, 69 U.S.P.Q.2d (BNA) at 1891 (citations omitted).

470. *Id.* at 922, 69 U.S.P.Q.2d (BNA) at 1891 (quoting *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 970, 63 U.S.P.Q.2d 1609, 1617 (Fed. Cir. 2002)). Rejecting plaintiff’s argument that the public notice function of the written description requirement “became redundant with the advent of claims in 1870,” the court stated that “[s]tatutory language does not become redundant unless repealed by Congress in which case it no longer exists.” *Id.*, 69 U.S.P.Q.2d (BNA) at 1891.

471. *Id.*, 69 U.S.P.Q.2d (BNA) at 1891. The court examined the following cases: *Enzo*, 323 F.3d at 956, 63 U.S.P.Q.2d (BNA) at 1609; *Regents of Univ. of California v. Eli Lilly & Co.*, 119 F.3d 1559, 43 U.S.P.Q.2d (BNA) 1398 (Fed. Cir. 1997); *Fiers v. Reval*, 984 F.2d 1164, 25 U.S.P.Q.2d (BNA) 1601 (Fed. Cir. 1993); *In re Smith*, 481 F.2d 910, 178 U.S.P.Q. (BNA) 620 (C.C.P.A. 1973); *In re Ruschig*, 379 F.2d 990, 154 U.S.P.Q. (BNA) 118 (C.C.P.A. 1967); *Jepson v. Coleman*, 314 F.2d 553, 136 U.S.P.Q. (BNA) 647 (C.C.P.A. 1963); *In re Sus*, 306 F.2d 494, 134 U.S.P.Q. (BNA) 301 (C.C.P.A. 1962); and *In re Moore*, 155 F.2d 379, 69 U.S.P.Q. (BNA) 524 (C.C.P.A. 1946). *Univ. of Rochester*, 358 F.3d at 922, 69 U.S.P.Q.2d (BNA) at 1891.

472. 119 F.3d 1559, 43 U.S.P.Q.2d (BNA) 1398.

473. 984 F.2d 1164, 25 U.S.P.Q.2d (BNA) 1601.

*Biochem, Inc. v. Gen-Probe, Inc.*⁴⁷⁴ were not applicable on the grounds that those cases “all related to genetic material whereas this case does not.”⁴⁷⁵ The Federal Circuit found plaintiff’s distinction to be “irrelevant” because the written description statute “applies to all types of inventions” and there was “no reason for the rule to be any different when non-genetic materials are at issue.”⁴⁷⁶ The Federal Circuit also rejected the plaintiff’s contention that “those cases were limited to composition of matter claims, whereas the [asserted] patent is directed to a method.”⁴⁷⁷ The Federal Circuit opined that:

Regardless whether a compound is claimed per se or a method is claimed that entails the use of the compound, the inventor cannot lay claim to that subject matter unless he can provide a description of the compound sufficient to distinguish infringing compounds from non-infringing compounds, or infringing methods from non-infringing methods.⁴⁷⁸

The Federal Circuit clarified its reasoning by explaining that it was not suggesting that “the written description requirement can be satisfied only by providing a description of an actual reduction to practice.”⁴⁷⁹ Rather, the Federal Circuit instructed that “[c]onstrucive reduction to practice is an established method of disclosure, but the application must nonetheless ‘describe the claimed subject matter in terms that establish that [the applicant] was in possession of the . . . claimed invention.’”⁴⁸⁰

The plaintiff also challenged the district court’s grant of summary judgment, contending that a “‘patent-in-suit cannot be per se invalid’ because written description is a question of fact.”⁴⁸¹ The Federal Circuit found this argument unavailing, reasoning that “although compliance with the written description requirement is a question of fact . . . [plaintiff’s] argument that a patent may not be held invalid on its face is contrary to our case law After all, it is in the patent specification where the written description must be met.”⁴⁸² In a related argument, plaintiff argued that “because [defendant] adduced no evidence, other than the patent in suit, to support its written description defense, [plaintiff] was entitled to summary judgment on that issue.”⁴⁸³ The Federal Circuit likewise rejected this argument explaining “[a]lthough section 282 of the Patent Act places the

474. 323 F.3d 956, 970, 63 U.S.P.Q.2d 1609, 1617.

475. *Univ. of Rochester*, 358 F.3d at 925, 69 U.S.P.Q.2d (BNA) at 1893.

476. *Id.*, 69 U.S.P.Q.2d (BNA) at 1893.

477. *Id.* at 926, 69 U.S.P.Q.2d (BNA) at 1894.

478. *Id.*, 69 U.S.P.Q.2d (BNA) at 1894 (emphasis omitted).

479. *Id.*, 69 U.S.P.Q.2d (BNA) at 1894.

480. *Id.*, 69 U.S.P.Q.2d (BNA) at 1894 (quoting *Hyatt v. Boone*, 146 F.3d 1348, 1353, 47 U.S.P.Q.2d (BNA) 1128, 1131 (Fed. Cir. 1998)).

481. *Id.*, 69 U.S.P.Q.2d (BNA) at 1894 (emphasis omitted).

482. *Id.* at 927, 69 U.S.P.Q.2d (BNA) at 1895 (citations omitted).

483. *Id.* at 930, 69 U.S.P.Q.2d (BNA) at 1897.

burden of proof on the party seeking to invalidate a patent, it does not foreclose the possibility of that party demonstrating that the patent in suit proves its own invalidity.”⁴⁸⁴

Following issuance of the panel opinion in *University of Rochester v. G.D. Searle & Co.*,⁴⁸⁵ the plaintiff filed a petition for rehearing to the panel and then a petition for rehearing en banc.⁴⁸⁶ The petition for rehearing en banc was denied by one vote, with five judges writing separate opinions to express their views on the state of law of the written description requirement.⁴⁸⁷ Judge Newman dissented from the denial of rehearing en banc, citing the need for the court to resolve “the burgeoning conflict in the pronouncements of this court concerning the written description and the enablement requirements of the Patent Act. This question has been promoted from simple semantics into a fundamental conflict concerning patent scope and the support needed to claim biological products.”⁴⁸⁸ Interestingly, while dissenting from the denial of the en banc hearing, Judge Newman explained that she “fully share[s] Judge Lourie’s understanding of the law. The continuing attack on well-established and heretofore unchallenged decisions . . . is not only unwarranted, but is disruptive of the stability with which this court is charged.”⁴⁸⁹ Rather, Judge Newman observed that:

[T]he issue of whether patent law contains a separate written description requirement has percolated through various panels of this court, on a variety of facts. The differences of opinion among the judges of the Federal Circuit are, in microcosm, the “percolation” that scholars feared would be lost by a national court at the circuit level. Percolation is the great justifier of conflict among the regional circuits.⁴⁹⁰

Judge Newman then addressed the concerns advanced by the biotechnology industry concerning the written description requirement:

The new biology has indeed raised new and important questions, with implications for policy as well as law. However, the answer is not the simplistic one espoused by some commentators; it is simply incorrect to say that there is not now and never has been a “written description” requirement in the patent law. It has always been necessary to disclose

484. *Id.*, U.S.P.Q.2d (BNA) at 1897. Addressing the plaintiff’s argument that the district court’s decision “vitiates universities’ ability to bring pioneering innovations to the public” as intended by the Bayh-Dole Act, the court found the argument to be “unsound” because “no connection exists between the Bayh-Dole Act and the legal standards that courts employ to assess patentability.” *Id.* at 929, 69 U.S.P.Q.2d (BNA) at 1896.

485. 375 F.3d 1303, 71 U.S.P.Q.2d (BNA) 1545 (Fed. Cir. 2004).

486. *Id.* at 1304, 71 U.S.P.Q.2d (BNA) at 1545.

487. *Id.*, 71 U.S.P.Q.2d (BNA) at 1545.

488. *Id.*, 71 U.S.P.Q.2d (BNA) at 1546 (Newman, J., dissenting).

489. *Id.*, 71 U.S.P.Q.2d (BNA) at 1546 (citations omitted) (Newman, J., dissenting).

490. *Id.* at 1305, 71 U.S.P.Q.2d (BNA) at 1546 (Newman, J., dissenting).

and describe what is patented. It has never been the law that one can claim what is not made known and set forth in the patent.⁴⁹¹

Judge Newman further explained that “[i]f the nature of the subject matter is not amenable to precise description, some alternative mode of disclosure is required, such as deposit in a public depository However, the public purpose of patents is seriously disserved by eliminating the description requirement entirely.”⁴⁹²

Judge Lourie, the author of the original *Rochester* opinion, concurred in the court’s decision not to rehear the case en banc,⁴⁹³ explaining that:

Contrary to the assertions of the appellant, certain amici, and some of the dissenters, there is and always has been a separate written description requirement in the patent law. The requirement to describe one’s invention is basic to the patent law, and every patent draftsman knows that he or she must describe a client’s invention independently of the need to enable one skilled in the relevant art to make and use the invention. The specification then must also describe how to make and use the invention (i.e., enable it), but that is a different task.⁴⁹⁴

Judge Lourie further reasoned that the written description requirement cannot be swept away by claiming that it relates only to priority issues or that the prohibition on introduction of new matter takes care of the need for a written description. The statute does not contain a limitation that it pertains only to priority issues. Moreover, the prohibition on introduction of new matter . . . is not a substitute for the written description requirement.⁴⁹⁵

Addressing arguments that the court’s recent application of the written description requirement was not consonant with the historical use of § 112, ¶ 1, Judge Lourie opined that:

The fact, if it is a fact, that written description has only been relied upon in recent years as a ground of invalidity does not remove that requirement from the statute. Legal holdings arise when they do because litigants raise them and courts have to decide them. Contrary to what has been asserted, the interpretation of the statute as containing a separate written description requirement did not originate with [*Eli*] *Lilly* It has always been there.⁴⁹⁶

Judge Rader, joined by Judges Gajarsa and Linn, dissented from the court’s decision not to hear the case en banc, noting that “[b]y a narrow margin . . . this court avoids the opportunity to clarify and correct its confusing jurisprudence on the new written description invalidity

491. *Id.* at 1304, 71 U.S.P.Q.2d (BNA) at 1546 (Newman, J., dissenting).

492. *Id.*, 71 U.S.P.Q.2d (BNA) at 1546 (Newman, J., dissenting).

493. *Id.* at 1305, 71 U.S.P.Q.2d (BNA) at 1547 (Newman, J., dissenting).

494. *Id.*, 71 U.S.P.Q.2d (BNA) at 1547 (Newman, J., dissenting).

495. *Id.*, 71 U.S.P.Q.2d (BNA) at 1547 (Newman, J., dissenting).

496. *Id.* at 1306, 71 U.S.P.Q.2d (BNA) at 1547 (Newman, J., dissenting).

doctrine.”⁴⁹⁷ Judge Rader’s motivation for an en banc hearing was his disagreement with the court’s decision in *Eli Lilly* and its progeny:

[T]his court for the first time applied the written description language of 35 U.S.C. § 112 . . . as a general disclosure requirement in place of enablement, rather than in its traditional role as a doctrine to prevent applicants from adding new inventions to an older disclosure In simple terms, contrary to logic and the statute itself, *Eli Lilly* requires one part of the specification (the written description) to provide “adequate support” for another part of the specification (the claims). Neither *Eli Lilly* nor this case has explained either the legal basis for this new validity requirement or the standard for “adequate support.” Because this new judge-made doctrine has created enormous confusion which this court declines to resolve, I respectfully dissent.⁴⁹⁸

Judge Rader noted that the *Eli Lilly* opinion engendered the court’s opinion in *Enzo*, which “[f]ollowing issuance, withdrawal, and reissuance . . . [caused the] court [to] engage in lengthy debate over the new disclosure validity doctrine” and “[t]hat debate continued in [the] court’s subsequent cases.”⁴⁹⁹ Judge Rader observed that “a brief survey of the literature on this topic, an astounding amount in a few short years, shows thirty-one articles criticizing the *Eli Lilly* doctrine, seven articles defending the doctrine, and sixteen neutrally commenting on the state of this evolving case law.”⁵⁰⁰

Addressing the hypothetical provided in the *Rochester* opinion for explaining the necessity of a written description requirement separate from an enablement requirement, Judge Rader opined:

The hypothetical actually facilitates a policy analysis that explains the reasons that the new 1997 requirement is both superfluous and dangerous. In the first place, the hypothetical rarely, if ever, happens. No actual case presents the hypothetical. In both *Eli Lilly* and *Rochester*, for instance, the invention A (rat insulin in *Eli Lilly*; an assay for Cox 1 and 2 in *Rochester*) was enabled and described, but the invention B (human insulin in *Eli Lilly*; a Cox 2 inhibitor in *Rochester*) was not enabled.

In understandable terms, the hypothetical says that an inventor invents the radio, but his invention solves a problem that enables those of ordinary skill in the art to know how to make and use both a radio and a TV. His patent disclosure only describes a radio but he claims broadly an “electrical receiver.” Thus, his claims seem to encompass the TV which his specification does not describe but would enable if it were described.

497. *Id.* at 1307, 71 U.S.P.Q.2d (BNA) at 1548 (Rader, J., dissenting).

498. *Id.* at 1307-08, 71 U.S.P.Q.2d (BNA) at 1548-49 (citations omitted) (Rader, J., dissenting).

499. *Id.* at 1308, 71 U.S.P.Q.2d (BNA) at 1549 (Rader, J., dissenting).

500. *Id.* at 1309, 71 U.S.P.Q.2d (BNA) at 1549 (Rader, J., dissenting).

In that context, the reason the hypothetical does not occur becomes obvious. If everyone of *ordinary* skill in the art knows from the disclosure how to make and use the TV, the exceptionally talented inventor will also. To avoid any risk of losing the TV invention, the inventor will fully disclose it and claim it, probably in a separate application. For this very practical reason, no case has ever presented the hypothetical. Inventors know when they have made an invention and realize that they must properly disclose it or risk losing it entirely.⁵⁰¹

Joined by Judge Rader and Judge Gajarsa, Judge Linn also dissented from the court's denial of en banc consideration, explaining that the *Rochester* panel opinion "perpetuates the confusion our precedent in [*Eli Lilly* and *Enzo*] has engendered in establishing 'written description' as a separate requirement of 35 U.S.C. § 112, paragraph 1, on which a patent may be held invalid."⁵⁰² Judge Linn reasoned that:

The question presented by 35 U.S.C. § 112, paragraph 1, is not, "Does the written description disclose what the invention is?" The question is, "Does the written description describe the invention recited in the claims—themselves part of the specification—in terms that are sufficient to enable one of skill in the art to make and use the claimed invention and practice the best mode contemplated by the inventor?" That is the mandate of the statute and is all our precedent demanded prior to [*Eli Lilly*].

Reading into paragraph 1 of section 112 an independent written description requirement, divorced from enablement, sets up an inevitable clash between the claims and the written description as the focus of the scope of coverage. This is ill-advised. Surely there is no principle more firmly established in patent law than the primacy of the claims in establishing the bounds of the right to exclude.⁵⁰³

Accordingly, Judge Linn concluded that "[c]onstruing section 112 to contain a separate written description requirement beyond enablement and best mode creates confusion as to where the public and the courts should look to determine the scope of the patentee's right to exclude."⁵⁰⁴

Finally, Judge Dyk wrote separately explaining that while he concurred in the court's decision not to hear the case en banc "[f]or the reasons set forth in the panel opinion and in Judge Lourie's opinion concurring in the denial of en banc review," his vote to deny en banc review "should not be taken as an endorsement of our existing written description jurisprudence. In my view we have yet to articulate satisfactory standards that can be

501. *Id.* at 1312, 71 U.S.P.Q.2d (BNA) at 1552 (Rader, J., dissenting).

502. *Id.* at 1325, 71 U.S.P.Q.2d (BNA) at 1566 (Linn, J., dissenting).

503. *Id.*, 71 U.S.P.Q.2d (BNA) at 1566-67 (Linn, J., dissenting).

504. *Id.* at 1326, 71 U.S.P.Q.2d (BNA) at 1567 (Linn, J., dissenting).

applied to all technologies.”⁵⁰⁵

*Chiron Corp. v. Genentech, Inc.*⁵⁰⁶ involved an appeal from a denial of plaintiff’s motion for a JMOL that claims directed to monoclonal antibodies were invalid under 35 U.S.C. § 102 because those claims could not claim priority back to earlier applications.⁵⁰⁷ The Federal Circuit began its analysis by noting that § 120 provides that an

“[A]pplication for [a] patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States . . . shall have the same effect, as to such invention, as though filed on the date of the prior application.”⁵⁰⁸

The Federal Circuit then explained that a claim “may only claim priority to an earlier application if the earlier application fulfills the requirements of § 112, first paragraph.”⁵⁰⁹

Turning to the trial record, the Federal Circuit noted that “genetically engineered antibodies, specifically chimeric antibodies, first appeared as a successful technology in the literature of this art field in May 1984, four months after the filing date of the first application” to which plaintiff claimed priority.⁵¹⁰ The Federal Circuit thus observed that the “jury may have found that the [first application] does not provide any support for the new matter . . . [b]ecause chimeric antibody technology did not even exist at the time of the 1984 filing.”⁵¹¹ The Federal Circuit thus concluded that “the record conclusively supports that the [plaintiff’s] scientists did not possess and disclose this technology in the February 1984 filing.”⁵¹²

In *Koito Manufacturing Co. v. Turn-Key-Tech, LLC*,⁵¹³ plaintiff advanced two separate theories in arguing that the disputed claims failed to satisfy the written description requirement.⁵¹⁴ First, plaintiff argued that the patentee amended the patent specification through a certificate of

505. *Id.* at 1327, 71 U.S.P.Q.2d (BNA) at 1568 (Dyk, J., dissenting) (emphasis omitted).

506. 363 F.3d 1247, 70 U.S.P.Q.2d (BNA) 1321 (Fed. Cir. 2004).

507. *See Chiron*, 363 F.3d at 1249-50, 70 U.S.P.Q.2d (BNA) at 1322-23. The parties stipulated before trial that the claims would be invalid under § 102 based on intervening prior art if the claims were entitled to a priority filing date of earlier applications. *Id.* at 1252, 70 U.S.P.Q.2d (BNA) at 1324.

508. *See id.* at 1253, 70 U.S.P.Q.2d (BNA) at 1325 (quoting 35 U.S.C. § 120).

509. *Id.*, 70 U.S.P.Q.2d (BNA) at 1325. The first paragraph of § 112 provides that:

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, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112 (2000).

510. *Chiron*, 363 F.3d at 1254, 70 U.S.P.Q.2d (BNA) at 1326.

511. *Id.* at 1255, 70 U.S.P.Q.2d (BNA) at 1326.

512. *Id.*, 70 U.S.P.Q.2d (BNA) at 1326.

513. 381 F.3d 1142, 72 U.S.P.Q.2d (BNA) 1190 (Fed. Cir. 2004).

514. *See id.* at 1153-54, 72 U.S.P.Q.2d (BNA) at 1198-99.

correction in a manner that was not supported by the original disclosure.⁵¹⁵ The Federal Circuit noted that “a change to correct an error is not considered new matter if ‘one skilled in the art would appreciate not only the existence of an error in the specification but what the error is.’”⁵¹⁶ The Federal Circuit then rejected the written description challenge, concluding that “[b]ecause the amended material is inherently contained in the original application, it cannot constitute new matter.”⁵¹⁷

Second, plaintiff argued that claims requiring a “significantly thicker and wider” flow channel were not supported because such structure was not depicted by certain figures in the patent specification.⁵¹⁸ The Federal Circuit rejected this argument and upheld the jury’s verdict that the claims were adequately supported by the specification, explaining that “the written description requirement can be satisfied by ‘words, structures, *figures*, *diagrams*, formulas, etc.’”⁵¹⁹ The Federal Circuit then concluded that figure 1 of the patent “clearly shows that [the] flow channel . . . is ‘significantly thicker and wider.’”⁵²⁰

*In re Wallach*⁵²¹ involved an appeal from the Board’s rejection of pending claims for failure to satisfy the written description requirement.⁵²² The appellants had two pending applications before the PTO—one application contained claims directed to proteins capable of inhibiting the cytotoxic effect of tumor neurosis factor, and a second application with claims directed to deoxyribonucleic acid (“DNA”) molecules capable of encoding such proteins.⁵²³ The claims at issue on appeal were the latter.⁵²⁴ Challenging the Board’s finding, the appellants argued that the specification itself “establishes that the present inventors were in fact in possession of the entire claimed genus of DNA sequences at the time the application was filed.”⁵²⁵ In response, the PTO argued that the specification “includes neither any actual DNA sequence within the scope of the claims nor the complete amino acid sequence of the [claimed] protein, but only the sequence of . . . [certain] amino acids that make up the protein.”⁵²⁶

515. *Id.* at 1153, 72 U.S.P.Q.2d (BNA) at 1198.

516. *Id.* at 1154, 72 U.S.P.Q.2d (BNA) at 1199 (quoting *In re Oda*, 443 F.2d 1200, 1206, 170 U.S.P.Q. (BNA) 268, 272 (C.C.P.A. 1971)).

517. *Id.*, 72 U.S.P.Q.2d (BNA) at 1199.

518. *Id.*, 72 U.S.P.Q.2d (BNA) at 1199.

519. *Id.*, 72 U.S.P.Q.2d (BNA) at 1199 (quoting *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d (BNA) 1961, 1966 (Fed. Cir. 1997)).

520. *Id.* at 1155, 72 U.S.P.Q.2d (BNA) at 1199.

521. 378 F.3d 1330, 71 U.S.P.Q.2d (BNA) 1939 (Fed. Cir. 2004).

522. *Id.* at 1331, 71 U.S.P.Q.2d (BNA) at 1940-41.

523. *Id.* at 1331-32, 71 U.S.P.Q.2d (BNA) at 1940-41.

524. *Id.* at 1332, 71 U.S.P.Q.2d (BNA) at 1941.

525. *Id.* at 1333, 71 U.S.P.Q.2d (BNA) at 1941.

526. *Id.*, 71 U.S.P.Q.2d (BNA) at 1942.

While noting that it saw “no reason to require a patent applicant to list every possible permutation of the nucleic acid sequences that can encode a particular protein for which the amino acid sequence is disclosed,”⁵²⁷ the Federal Circuit explained that the appellants “did not claim the nucleic acid molecules that encode the simple protein sequence that they disclosed. Rather, they claimed the nucleic acids encoding a protein for which they provided only a partial sequence.”⁵²⁸ The Federal Circuit also rejected appellant’s argument that because it demonstrated possession of the claimed protein, it was also “necessarily in possession of its inherent amino acid sequence, as well as all of the DNA sequences encoding that amino acid sequence.”⁵²⁹ The Federal Circuit reasoned that

[w]hether Appellants were in possession of the protein says nothing about whether they were in possession of the protein’s amino acid sequence. Although Appellants correctly point out that a protein’s amino acid sequence is an inherent property of the protein, the fact that the Appellants may have isolated and thus physically possessed [the claimed protein] does not amount to knowledge of that protein’s sequence or possession of any of its other descriptive properties.⁵³⁰

The Federal Circuit further explained that while it has “recognized that the written description requirement can in some cases be satisfied by functional description . . . such functional description can be sufficient only if there is also a structure-function relationship known to those of ordinary skill in the art.”⁵³¹ The Federal Circuit thus concluded that without a sequence “or with only a partial sequence, those structures cannot be determined and the written description requirement is consequently not met.”⁵³²

In a series of cases in 2004, the court addressed the issue of whether disclosure of a species could support claims broadly directed to a genus. *In re Curtis*⁵³³ was an appeal of the Board’s re-examination decision holding that the patentee could not overcome a prior art rejection by claiming the benefit of an earlier application.⁵³⁴ The rejected claims were directed to dental floss covering a genus of friction-enhancing coating, while the earlier application disclosed only micro-crystalline wax (“MCW”)

527. *Id.* at 1334, 71 U.S.P.Q.2d (BNA) at 1942.

528. *Id.*, 71 U.S.P.Q.2d (BNA) at 1942.

529. *Id.*, 71 U.S.P.Q.2d (BNA) at 1943.

530. *Id.* at 1334-35, 71 U.S.P.Q.2d (BNA) at 1943.

531. *Id.* at 1335, 71 U.S.P.Q.2d (BNA) at 1943 (citations omitted).

532. *Id.*, 71 U.S.P.Q.2d (BNA) at 1943.

533. 354 F.3d 1347, 69 U.S.P.Q.2d (BNA) 1274 (Fed. Cir. 2004).

534. *Id.* at 1348, 69 U.S.P.Q.2d (BNA) at 1275 (explaining that patentee’s earlier application “failed to adequately describe the subject matter encompassed by the rejected claims under 35 U.S.C. § 112, ¶ 1.”).

coating.⁵³⁵ Because the parties agreed that the patentee could overcome the anticipation and obviousness rejections only by obtaining the benefit of the earlier application's filing date, the sole issue was whether substantial evidence supported the Board's finding that the earlier application did not provide "a written description of [appellant's] later-claimed genus of friction enhancing coatings."⁵³⁶

Concluding that substantial evidence supported the Board's findings, the Federal Circuit explained that the earlier application was replete with passages describing MCW as the only suitable coating.⁵³⁷ The Federal Circuit observed that the single test example in the earlier application involved MCW coating and the application did not name "a suitable friction enhancing coating for . . . dental floss other than MCW."⁵³⁸ The Federal Circuit further underscored its conclusion by noting that during prosecution of the earlier application, the patentee submitted declarations "demonstrating that MCW coating was in fact the only friction enhancing coating conveyed by [appellant] at the time the [earlier] application was filed and that dental flosses . . . would not be expected to be commercially acceptable when coated with other materials."⁵³⁹

As a collateral attack on the Board's decision, the patentee argued that under the reasoning of *In re Smythe*,⁵⁴⁰ the earlier application provided adequate support for the later genus claims because it "convey[ed] how and why individual species of the genus are operable in the invention."⁵⁴¹ In *Smythe*, the Federal Circuit's predecessor allowed later genus claims because an earlier application "clearly convey[ed] to one skilled in the art that in this invention the characteristics of a fluid are what make segmentizing medium work"⁵⁴² The Court of Customs and Patents Appeals ("C.C.P.A."), however, qualified its holding by explaining that "where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus or combination claimed at a later date in the prosecution of a patent application."⁵⁴³

The Federal Circuit rejected appellant's analogy to *Smythe*, explaining

535. *Id.* at 1349, 69 U.S.P.Q.2d (BNA) at 1275-76.

536. *Id.* at 1352, 69 U.S.P.Q.2d (BNA) at 1278.

537. *Id.*, 69 U.S.P.Q.2d (BNA) at 1278.

538. *Id.* at 1352-53, 69 U.S.P.Q.2d (BNA) at 1278-79.

539. *Id.*, 69 U.S.P.Q.2d (BNA) at 1278-79.

540. 480 F.2d 1376, 178 U.S.P.Q. (BNA) 279 (C.C.P.A. 1973).

541. *Curtis*, 354 F.3d at 1354, 69 U.S.P.Q.2d (BNA) at 1279-80.

542. *Id.* at 1355, 69 U.S.P.Q.2d (BNA) at 1280 (quoting *In re Smythe*, 480 F.2d at 1382, 178 U.S.P.Q. (BNA) at 284).

543. *Id.*, 69 U.S.P.Q.2d (BNA) at 1280 (quoting *In re Smythe*, 480 F.2d at 1382, 178 U.S.P.Q. (BNA) at 284-85).

that the substantial evidence supported the Board's finding of unpredictability in the art of dental floss.⁵⁴⁴ The Federal Circuit explained that

[u]nlike the circumstances *In re Smythe* presented, the instant facts present a case in which there is 'unpredictability in performance of certain species or subcombinations other than those specifically enumerated As such, mere recitation of properties common to all species of friction enhancing coatings in the [earlier] [a]pplication did not put persons of ordinary skill in the art in possession of the full range of later-claimed friction enhancing coatings.⁵⁴⁵

The Federal Circuit further noted that, though in certain cases a disclosure of a species may support later claims of a genus,

. . . we have never held that in all such cases, including those in which persons of ordinary skill in the art could not predict the operability of undisclosed species, the decision in *In re Smythe* compels a finding that the claim to the genus is adequately described under § 112, ¶ 1.⁵⁴⁶

*Noelle v. Lederman*⁵⁴⁷ was an appeal from an interference proceeding involving inter alia an issue of whether a junior party's earlier application could provide support for later claims directed to monoclonal antibodies.⁵⁴⁸ At the PTO, the Board predicated its analysis by analogizing the antibody claims to DNA claims, and denied the junior party the benefit of an earlier filing date because the earlier application "failed to describe any structural features of the human or genus antibodies or antigens."⁵⁴⁹

Accepting the Board's analogy to precedent analyzing the written description requirement in the context of DNA claims, the Federal Circuit began by noting that "[a]n earlier application that describes later-claimed genetic material only by a statement of function or result may be insufficient to meet the written description requirement."⁵⁵⁰ Rather, the Federal Circuit explained that "a description of DNA 'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention."⁵⁵¹

The Federal Circuit then affirmed the Board's finding, explaining that the earlier application did not provide sufficient support for claims "to the human CD40CR antibody" in the earlier application because the junior party "failed to disclose the structural elements of human CD40CR

544. *Id.*, 69 U.S.P.Q.2d (BNA) at 1280.

545. *Id.*, 69 U.S.P.Q.2d (BNA) at 1280 (citations omitted).

546. *Id.* at 1356, 69 U.S.P.Q.2d (BNA) at 1281.

547. 355 F.3d 1343, 69 U.S.P.Q.2d (BNA) 1508 (Fed. Cir. 2004).

548. *Id.* at 1346, 69 U.S.P.Q.2d (BNA) at 1511.

549. *Id.*, 69 U.S.P.Q.2d (BNA) at 1511.

550. *Id.* at 1348, 69 U.S.P.Q.2d (BNA) at 1513.

551. *Id.*, 69 U.S.P.Q.2d (BNA) at 1513.

antibody or antigen in his earlier . . . application.”⁵⁵² The Federal Circuit also noted that the junior party “only described [a] mouse antigen when he claimed mouse, human, and genus forms of CD40CR antibodies by citing to the ATCC number of the hybridoma secreting the mouse DC40CR antibody.”⁵⁵³ The court further stated that the junior party could not claim a genus form of the CD40CR antibody by simply describing mouse CD40CR antigen, explaining that “a patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated.”⁵⁵⁴

Bilstad v. Wakalopulos,⁵⁵⁵ involved an appeal from the Board of Patent Appeals and Interference’s judgment that appellant’s patent application lacked a sufficient written description under § 112. Appellant provoked an interference by copying claims of appellee’s patent into the patent application. The technology to which the application and patent were directed was an apparatus for sterilizing three-dimensional objects using ionizing radiation without hurting the objects.⁵⁵⁶ The relevant portions of the interference count read as follows: “A sterilization apparatus comprising, an electron beam tube . . . and a moveable member *manipulating objects in a plurality of directions* within the reactive volume wherein the manipulated objects are sterilized.”⁵⁵⁷

Having construed “plurality” to connote an “indefinite numerical range,” ranging from two to infinity, the Board concluded that appellant’s application disclosing manipulation in only a small number of directions did not support the interference count.⁵⁵⁸ On appeal, appellant argued that the Board erred in requiring that the application describe every embodiment within the range of two to infinity attributed to the term “plurality” by the Board. The Federal Circuit approached this question by reviewing the “spectrum of cases” discussing whether disclosure of a species supports a claim covering a genus, including *In re Smythe*,⁵⁵⁹ *In re Rasmussen*,⁵⁶⁰ *Ralston Purina Co. v. Far-Mar-Co, Inc.*,⁵⁶¹ *Ethicon Endo-Surgery, Inc. v. United States Surgical Corp.*,⁵⁶² *In re Curtis*,⁵⁶³ and *Tronzo*

552. *Id.* at 1349, 69 U.S.P.Q.2d (BNA) at 1514.

553. *Id.*, 69 U.S.P.Q.2d (BNA) at 1514.

554. *Id.* at 1350, 69 U.S.P.Q.2d (BNA) at 1514.

555. 386 F.3d 1116, 72 U.S.P.Q.2d (BNA) 1785 (Fed. Cir. 2004).

556. *Id.* at 1118, 72 U.S.P.Q.2d (BNA) at 1786-87.

557. *Id.* at 1119, 72 U.S.P.Q.2d (BNA) at 1787.

558. *Id.*, 72 U.S.P.Q.2d (BNA) at 1787.

559. 480 F.2d 1376, 178 U.S.P.Q. (BNA) 279 (C.C.P.A. 1973).

560. 650 F.2d 1212, 211 U.S.P.Q. (BNA) 323 (C.C.P.A. 1981).

561. 772 F.2d 1570, 7 U.S.P.Q. (BNA) 177 (Fed. Cir. 1985) (finding that a parent written description supported several open-ended ranges).

562. 93 F.3d 1572, 40 U.S.P.Q.2d (BNA) 1019 (Fed. Cir. 1996).

563. 354 F.3d 1347, 69 U.S.P.Q.2d (BNA) 1274 (Fed. Cir. 2004); *see also supra* notes

*v. Biomet, Inc.*⁵⁶⁴ It noted that although the “general rule” was that “disclosure of a species provides sufficient written description support for a later filed claim directed to the genus,”⁵⁶⁵ exceptions to this rule exist where the art is unpredictable such that persons skilled in the art would not readily discern the other members of the genus that would perform similarly to the disclosed members,⁵⁶⁶ and like in *Tronzo*, where the specification specifically distinguished the disclosed invention from other members of the genus.⁵⁶⁷

The Federal Circuit disapproved of the Board’s analysis of this question. Though the Board found that appellant’s disclosure of manipulation of an object in only a small number of directions was insufficient to support the claim to manipulation of objects in a range from two to infinity, the Federal Circuit held that the Board failed to analyze “what one skilled in the art would have understood from the Bilstad disclosure or the degree of predictability of technical variations in this field of art.”⁵⁶⁸ The Federal Circuit thus remanded for reconsideration under the “proper test” for support of the interference count.

2. *Enablement*

In *Chiron Corp. v. Genentech, Inc.*,⁵⁶⁹ the Federal Circuit explained that in order to support a claim of priority, the earlier application must satisfy both the enablement requirement and written description requirement of § 112.⁵⁷⁰ The Federal Circuit then canvassed the applicable enablement law, explaining that to satisfy the enablement requirement requires that “one skilled in the art, after reading their disclosures, could practice the invention . . . without undue experimentation.”⁵⁷¹ The Federal Circuit explained that simply because some experimentation is necessary “does not preclude enablement; what is required is that the amount of experimentation ‘must not be unduly extensive.’”⁵⁷² The Federal Circuit

534-539 and accompanying text (reviewing implications of species disclosure in *In re Curtis*, 354 F.3d 1347, 69 U.S.P.Q.2d (BNA) 1274 (Fed. Cir. 2004)).

564. 156 F.3d 1154, 47 U.S.P.Q.2d (BNA) 1829 (Fed. Cir. 1998) (holding that there was insufficient evidence for a verdict that a parent disclosing only a trapezoidal shape supported claims to a hip prosthesis of a generic shape).

565. *Bilstad v. Wakalopoulos*, 386 F.3d 1116, 1125, 72 U.S.P.Q.2d (BNA) 1785, 1791 (Fed. Cir. 2004).

566. *See supra* notes 540-546 and accompanying text (discussing *In re Curtis*, 354 F.3d 1347, 69 U.S.P.Q.2d (BNA) 1274 (Fed. Cir. 2004), where the Federal Circuit stated that prior disclosure of species is unlikely to support a later claim of genus where one skilled in the art is unlikely to be able to predict operation of other species).

567. *See supra* note 564.

568. *Bilstad*, 386 F.3d at 1126, 72 U.S.P.Q.2d (BNA) at 1792.

569. 363 F.3d 1247, 70 U.S.P.Q.2d (BNA) 1321 (Fed. Cir. 2004).

570. *Id.* at 1253, 70 U.S.P.Q.2d (BNA) at 1325.

571. *Id.*, 70 U.S.P.Q.2d (BNA) at 1325.

572. *Id.*, 70 U.S.P.Q.2d (BNA) at 1325 (quoting *PPG Indus., Inc. v. Guardian Indus.*

further noted that while the full scope of the claim must be enabled,

[t]hat is not to say that the specification itself must necessarily describe how to make and use every possible variant of the claimed invention, for the artisan's knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond disclosed embodiments, depending upon the predictability of the art.⁵⁷³

The Federal Circuit also observed that enablement is determined as of the filing date of the application, and explained that nascent technology "must be enabled with a 'specific and useful teaching' . . . because a person of ordinary skill in the art has little or no knowledge independent from the patentee's instruction."⁵⁷⁴

Turning to the trial record, the Federal Circuit explained that "the jury was entitled to determine as a matter of fact that chimeric antibodies were not future technology, but were nascent technology requiring a 'specific and useful teaching.'"⁵⁷⁵ The Federal Circuit noted that "[e]vidence presented to the jury showed that creation of genetically engineered antibodies, such as chimeric antibodies, required significant experimentation in 1985 and 1986 because those antibodies were unpredictable at that early stage of development."⁵⁷⁶ In particular, the Federal Circuit noted that the record evidence demonstrated that only a few laboratories contained the necessary equipment to make chimeric antibodies, that the plaintiff's applications did not disclose how to make or use chimeric antibodies, and that the applications did not provide any working examples of chimeric antibodies within the scope of the disputed claims.⁵⁷⁷ The Federal Circuit further observed that while plaintiff's applications "certainly enable[d] murine antibodies, they [did] not enable chimeric antibodies."⁵⁷⁸ As a result, the applications failed to enable all

Corp., 75 F.3d 1558, 1564, 37 U.S.P.Q.2d (BNA) 1618, 1623 (Fed. Cir. 1996)). The court also identified the *Wands* factors that are used to gauge whether undue experimentation would be required to practice the claimed invention:

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

Id. at 1255-56, 70 U.S.P.Q.2d (BNA) at 1327 (quoting *In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d (BNA) 1400, 1404 (Fed. Cir. 1988)).

573. *Id.* at 1253, 70 U.S.P.Q.2d (BNA) at 1325 (quoting *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244, 68 U.S.P.Q.2d (BNA) 1280, 1287 (Fed. Cir. 2003)).

574. *Id.* at 1254, 70 U.S.P.Q.2d (BNA) at 1326 (quoting *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1368, 42 U.S.P.Q.2d (BNA) 1001, 1006 (Fed. Cir. 1997)).

575. *Id.* at 1255, 70 U.S.P.Q.2d (BNA) at 1327 (quoting *Genentech*, 108 F.3d at 1368, 42 U.S.P.Q.2d (BNA) at 1006).

576. *Id.* at 1256, 70 U.S.P.Q.2d (BNA) at 1327.

577. *Id.*, 70 U.S.P.Q.2d (BNA) at 1327.

578. *Id.*, 70 U.S.P.Q.2d (BNA) at 1327.

antibodies within the scope of the asserted claims, which covered both murine and chimeric antibodies.⁵⁷⁹

The Federal Circuit also rejected plaintiff's argument that the applications "need not specifically enable chimeric antibodies, because technicians of ordinary skill in this art could make and use them by that time without undue experimentation."⁵⁸⁰ The Federal Circuit explained that the record contained substantial evidence to support the jury's finding of non-enablement, including expert testimony that the ability to manufacture chimeric antibodies was not routine technology when plaintiff's applications were filed;⁵⁸¹ evidence that very few laboratories had the capacity and expertise necessary to make genetically engineered antibodies;⁵⁸² and an article published in 1989 that described techniques of chimeric antibodies as "obviously those of a very young and very ambitious field."⁵⁸³

In a concurring opinion, Judge Bryson explained that "enablement must be judged in light of the state of the art at the time of the application."⁵⁸⁴ In so doing, the concurrence cautioned against interpreting the Federal Circuit's predecessor's opinion *In re Hogan*⁵⁸⁵ as holding that "claims that are enabled by original application may be construed broadly enough to encompass technology that is not developed until later and was not enabled by the original application."⁵⁸⁶ The concurrence thus opined that the proper approach "is to address cases of new technology by construing claims, where possible, as they would have been understood by one of skill in the art at the time of the invention, and not construing them to reach the as-yet-undeveloped technology that the applicant did not enable."⁵⁸⁷

In *Koito Manufacturing Co. v. Turn-Key-Tech, LLC*,⁵⁸⁸ plaintiff argued that the patent specification failed to enable claims directed to injection-molded plastics because the patentee did not disclose a "proprietary formula for achieving the claimed predetermined flow direction."⁵⁸⁹ Rejecting this argument, the Federal Circuit explained that

579. *Id.*, 70 U.S.P.Q.2d (BNA) at 1327.

580. *Id.*, 70 U.S.P.Q.2d (BNA) at 1327.

581. *Id.*, 70 U.S.P.Q.2d (BNA) at 1328.

582. *Id.*, 70 U.S.P.Q.2d (BNA) at 1328.

583. *Id.*, 70 U.S.P.Q.2d (BNA) at 1328 (quoting Sherie L. Morrison, *Genetically Engineered (Chimeric) Antibodies*, HOSP. PRACTICE, Oct. 15, 1989, at 75). The court also explained that the Plaintiff's failure to produce a commercial embodiment "also bears on whether chimeric or humanized antibodies with the scope of the claims of the [asserted] patent were routine technology. Accordingly, that evidence is relevant to enablement." *Id.* at 1260-61, 70 U.S.P.Q.2d (BNA) at 1331.

584. *Id.* at 1262, 70 U.S.P.Q.2d (BNA) at 1332 (Bryson, J., concurring).

585. 559 F.2d 595, 194 U.S.P.Q. (BNA) 527 (C.C.P.A. 1977).

586. *Chiron*, 363 F.3d at 1262, 70 U.S.P.Q.2d (BNA) at 1333 (Bryson, J., concurring).

587. *Id.* at 1263, 70 U.S.P.Q.2d (BNA) at 1333 (Bryson, J., concurring).

588. 381 F.3d 1142, 72 U.S.P.Q.2d (BNA) 1190 (Fed. Cir. 2004).

589. *Id.* at 1155, 72 U.S.P.Q.2d (BNA) at 1199.

[w]hile this evidence may go to best mode, it does not demonstrate that any certain formula for achieving flow direction was required for one of ordinary skill in the art to practice the claimed invention or that undue experimentation would be required for one of ordinary skill in the art to predetermine flow direction through trial and error.⁵⁹⁰

The Federal Circuit also rejected plaintiff's argument that the enablement requirement was not met because the patentee omitted a disclosure of certain injection parameters and gate size. Observing that "[t]his Court has repeatedly explained that a patent applicant does not need to include in the specification that which is already known to and available to one of ordinary skill in the art,"⁵⁹¹ the Federal Circuit concluded that plaintiff did not provide clear and convincing evidence that knowledge of injection parameters and gate size were necessary to practice the claims without undue experimentation.⁵⁹²

3. *Best mode*

The Federal Circuit's disposition of best mode issues⁵⁹³ in 2004 was consistent with its earlier proclamation that "[i]n the history of this court and our predecessor courts, we have held claims invalid for failure to satisfy the best mode requirement on only seven occasions."⁵⁹⁴ The Federal Circuit's opinions, however, appeared to graft a subjective "intent to conceal" requirement as part of the second prong of the best mode inquiry—whether the patent application disclosed the inventor's best mode of practicing the claimed invention—that has long been classified as an objective test.⁵⁹⁵

590. *Id.*, 72 U.S.P.Q.2d (BNA) at 1199.

591. *Id.* at 1156, 72 U.S.P.Q.2d (BNA) at 1200.

592. *Id.*, 72 U.S.P.Q.2d (BNA) at 1200.

593. 35 U.S.C. § 112 (2000) provides:

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, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

594. *Bayer AG v. Schein Pharms., Inc.*, 301 F.3d 1306, 1316, 64 U.S.P.Q.2d (BNA) 1001, 1008 (Fed. Cir. 2002).

595. *See, e.g., Eli Lilly & Co. v. Barr Labs, Inc.*, 251 F.3d 955, 963, 58 U.S.P.Q.2d (BNA) 1869, 1874-75 (Fed. Cir. 2001); *N. Telecom Ltd. v. Samsung Elecs. Co.*, 215 F.3d 1281, 1286, 55 U.S.P.Q.2d (BNA) 1065, 1068 (Fed. Cir. 2000) (stating that the "[first] inquiry is wholly subjective . . . [t]he second inquiry . . . is objective and depends upon the scope of the claimed invention and the level of skill in the relevant art"); *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1064, 46 U.S.P.Q.2d (BNA) 1097, 1101 (Fed. Cir. 1998), *cert. denied*, 525 U.S. 876 (1998) ("[W]hether the best mode was disclosed in sufficient detail to allow a skilled artisan to practice it without undue experimentation . . . is an objective determination."); *Fonar Corp. v. Gen. Elec. Co.*, 107 F.3d 1543, 1548, 41 U.S.P.Q.2d 1801, 1804 (Fed. Cir. 1997), *cert. denied*, 522 U.S. 908 (1997) (stating that determining whether a patent satisfies the best mode requirement involves two factual inquiries. First, a fact-finder must determine whether at the time an

*High Concrete Structures, Inc. v. New Enterprises Stone & Lime, Inc.*⁵⁹⁶ involved an appeal from a grant of summary judgment holding the disputed claims invalid under the best mode requirement.⁵⁹⁷ The disputed claims were directed to use of pre-formed concrete frames that orientated heavy cargo at an angle such that the cargo would not extend too far beyond a transporting truck's flat bed.⁵⁹⁸ The district court held that the inventors violated the best mode requirement because the specification failed to disclose "that a crane was the preferred mode of carrying out the method of loading and tilting the [concrete] frame."⁵⁹⁹

In reversing the grant of summary judgment, the Federal Circuit first explained that "[i]nvalidation for failure to satisfy the best mode requires (1) the inventor knew of a better mode than was disclosed, and (2) the inventor concealed the better mode."⁶⁰⁰ With respect to the second prong, the Federal Circuit further elaborated that a best mode violation "requires that the inventor knew of and intentionally concealed a better mode than was disclosed."⁶⁰¹ Then, apparently accepting that use of a crane was the inventors' preferred mode of carrying out the invention, the Federal Circuit determined that the best mode requirement was not violated because that the record was devoid of evidence regarding the inventors' intent to conceal use of cranes:

[Defendant] conceded that use of a crane to assist with heavy loads is well known to person in the field of loading cargo. There was neither evidence nor inference of concealment of this information by the inventors. Deliberate concealment is not charged. The best mode requirement of § 112 is not violated by unintentional omission of information that would be readily known to persons in the field of the invention.⁶⁰²

The Federal Circuit also distinguished its decisions in *Northern Telecom, Inc. v. Datapoint Corp.*⁶⁰³ and *Dana Corp. v. IPC Ltd.*,⁶⁰⁴ explaining that in

applicant filed an application for a patent, he or she had a best mode of practicing the invention; this is a subjective determination. Second, if the inventor had a best mode of practicing the invention, the fact-finder must determine whether the best mode was disclosed in sufficient detail to allow one skilled in the art to practice it, which is an objective determination.

).

596. 377 F.3d 1379, 71 U.S.P.Q.2d (BNA) 1948 (Fed. Cir. 2004).

597. *Id.* at 1380, 71 U.S.P.Q.2d (BNA) at 1948-49.

598. *Id.* at 1380-82, 71 U.S.P.Q.2d (BNA) at 1948-50.

599. *Id.* at 1383, 71 U.S.P.Q.2d (BNA) at 1950.

600. *Id.* at 1382, 71 U.S.P.Q.2d (BNA) at 1950.

601. *Id.* at 1383, 71 U.S.P.Q.2d (BNA) at 1950.

602. *Id.*, 71 U.S.P.Q.2d (BNA) at 1950-51.

603. 908 F.2d 931, 940, 15 U.S.P.Q.2d (BNA) 1321, 1328 (Fed. Cir. 1990) (affirming the district court's determination that the inventors deliberately concealed the usage of tape and cassettes of their own design in a patent for an invention to capture data on standard audio magnetic tape cassettes).

604. 860 F.2d 415, 419-20, 8 U.S.P.Q.2d (BNA) 1692, 1696-97 (Fed. Cir. 1988) (finding

“the case before us it was undisputed that anyone with experience of heavy loads would know to use a crane to move the load.”⁶⁰⁵ The Federal Circuit thus held that “[k]nown ways of performing a known operation cannot be deemed intentionally concealed absent evidence of intent to deliberately withhold that information.”⁶⁰⁶

*Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*⁶⁰⁷ also involved a best mode challenge to the validity of claims directed at cardiac defibrillators that are permanently installed under a patient’s skin.⁶⁰⁸ The case came to the court on appeal from a grant of a JMOL that the claims were invalid after a jury verdict finding no best mode violation.⁶⁰⁹ The Federal Circuit framed the question as whether the best mode requirement creates a disclosure “obligation with respect to subject matter that is not part of the invention, but that is used in conjunction therewith—here the battery for use with the battery-powered [cardiac defibrillators].”⁶¹⁰ In particular, the issue was whether the inventors were required to disclose a battery specifically designed by a third-party for use with the claimed cardiac defibrillators.⁶¹¹

The Federal Circuit began its analysis by stating that “invalidity for omission of a better mode than was revealed requires knowledge of concealment of that better mode.”⁶¹² The Federal Circuit then explained that “[t]he obligation to disclose the best mode relates to the invention that is described and claimed. Subject matter that is not part of the invention that is claimed need not be included in the specification, and thus is not subject to the best mode requirement.”⁶¹³ Upon review of the record, the Federal Circuit determined that substantial evidence supported the jury’s verdict that the best mode had not been violated, including testimony that the “invention was not about batteries, that there was not intent to conceal

that the best mode requirement was violated because it was not disclosed that a technique of applying silicone to rubber surfaces was known to be essential for the successful operation of the claimed stem seals for valves).

605. *High Concrete Structures*, 377 F.3d at 1384, 71 U.S.P.Q.2d (BNA) at 1951.

606. *Id.*, 71 U.S.P.Q.2d (BNA) at 1951.

607. 381 F.3d 1371, 72 U.S.P.Q.2d (BNA) 1333 (Fed. Cir. 2004).

608. *Id.* at 1374, 72 U.S.P.Q.2d (BNA) at 1335.

609. *Id.* at 1374-75, 72 U.S.P.Q.2d (BNA) at 1335.

610. *Id.* at 1378-79, 72 U.S.P.Q.2d (BNA) at 1338.

611. *See id.* at 1379, 72 U.S.P.Q.2d (BNA) at 1338-39 (stating that the inventors asked the third party to develop a battery to use with the cardiac devices, but then decided not to include this battery in the patent specification since there were many different battery choices that could be made and the inventors actually chose a different battery for their commercial device).

612. *Id.* at 1378, 72 U.S.P.Q.2d (BNA) at 1338 (citing *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1575, 24 U.S.P.Q.2d 1401, 1415 (Fed. Cir. 1992); *In re Gay*, 309 F.3d 769, 772, 135 U.S.P.Q. 311, 315 (C.C.P.A. 1962)).

613. *Id.* at 1379, 72 U.S.P.Q.2d (BNA) at 1339 (citing *Engel Indus., Inc. v. Lockformer Co.*, 946 F.2d 1528, 1532, 20 U.S.P.Q.2d 1300, 1303 (Fed. Cir. 1991)).

the [third-party] or any battery, and that it was not concealed,”⁶¹⁴ and evidence that “persons knowledgeable in the field of the invention would know the sources of batteries for pacemakers and related devices.”⁶¹⁵ Accordingly, the Federal Circuit reversed the grant of a JMOL because “[t]here was no evidence of concealment, and the jury had evidence that the [third-party] battery was published in a publication for battery specialists.”⁶¹⁶

4. *Indefiniteness*

The volume of cases in which the indefiniteness defense was considered and rejected by the court in 2004 underscores two recently emerging themes in patent litigation: (1) defendants will frequently avail themselves of the indefiniteness argument under § 112, ¶ 2 and (2) the Federal Circuit will reject such a defense almost as frequently as it is raised.

*Bancorp Services, L.L.C. v. Hartford Life Insurances Co.*⁶¹⁷ involved the issue of whether the claim term “surrender value protected investment credits” was indefinite⁶¹⁸ under § 112, ¶ 2 of the Patent Act.⁶¹⁹ Seeking to invalidate the claims, defendant argued that the term was indefinite because (1) the patent did not expressly define the term, (2) the meaning of the term could not be determined from the patent, and (3) the term did not have an understood meaning by those skilled in the field of the invention.⁶²⁰ In response, plaintiff argued that “surrender value protected investment credits” meant the same thing as “stable value protected investment credits,” which is a term that appeared throughout the patent and had a well-established meaning in the field.⁶²¹

The Federal Circuit began by canvassing its indefiniteness jurisprudence, noting that the indefiniteness analysis is akin to “the court’s performance of its duty as the construer of patent claims [and] therefore, like claim construction, is a question of law.”⁶²² The Federal Circuit explained that indefiniteness is determined by “whether those skilled in the art would understand what is claimed when the claim is read in light of the specification.”⁶²³ The Federal Circuit stated that “a claim is not indefinite

614. *Id.*, 72 U.S.P.Q.2d (BNA) at 1338-39.

615. *Id.*, 72 U.S.P.Q.2d (BNA) at 1339.

616. *Id.*, 72 U.S.P.Q.2d (BNA) at 1339.

617. 359 F.3d 1367, 69 U.S.P.Q.2d (BNA) 1996 (Fed. Cir. 2004).

618. *Id.* at 1371, 69 U.S.P.Q.2d (BNA) at 1999.

619. 35 U.S.C. § 112 (2004) (providing that claims must “particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention.”).

620. *Bancorp Servs.*, 359 F.3d at 1371-72, 69 U.S.P.Q.2d (BNA) at 1999.

621. *Id.* at 1372, 69 U.S.P.Q.2d (BNA) at 1999.

622. *Id.* at 1371, 69 U.S.P.Q.2d (BNA) at 1999 (quoting *Atmel Corp. v. Info. Storage Devices, Inc.*, 198 F.3d 1374, 1378, 53 U.S.P.Q.2d 1225, 1227 (Fed. Cir. 1999)).

623. *Id.*, 69 U.S.P.Q.2d (BNA) at 1999 (citing *Personalized Media Communications, Inc. v. Int’l Trade Comm’n*, 161 F.3d 696, 705, 48 U.S.P.Q.2d (BNA) 1880, 1888 (Fed. Cir.

merely because it poses a difficult issue of claim construction; if the claim is subject to construction . . . it is not invalid for indefiniteness.”⁶²⁴ Rather, the Federal Circuit explained that “if the meaning of the claim is discernible, ‘even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, we have held the claim sufficiently clear to avoid invalidity on indefiniteness grounds.’”⁶²⁵ The Federal Circuit further explained that “[b]y finding claims indefinite only if reasonable efforts at claim construction prove futile, we accord respect to the statutory presumption of patent validity Thus ‘close questions of indefiniteness in litigation involving issued patents are properly resolved in favor of the patentee.’”⁶²⁶

While noting that the entire term “surrender value protected investment credits” is not defined in the patent, the Federal Circuit concluded that the claims were not indefinite because “the components of the term have well-recognized meanings, which allow the reader to infer the meaning of the entire phrase with reasonable confidence.”⁶²⁷ The Federal Circuit first noted that “the term ‘surrender value’ has a clear meaning to one of ordinary skill in the relevant art.”⁶²⁸ The Federal Circuit then stated that the patent specification and extrinsic evidence demonstrate that the term “protected investment” likewise has a clear meaning.⁶²⁹ The Federal Circuit also explained the specification provides a clear meaning for “credits.”⁶³⁰ Thus, viewing the various parts of the claim term together, the Federal Circuit concluded that the meaning of the term “surrender value protected investment credits” could be reasonably determined,⁶³¹ and explained that “[t]he failure to define [a claim] term is, of course, not fatal, for if the meaning of the term is fairly inferable from the patent, an express definition is not necessary.”⁶³²

In reaching its conclusion, the Federal Circuit credited plaintiff’s argument that the correspondence between “surrender value protected

1998); *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 U.S.P.Q.2d (BNA) 1081, 1088 (Fed. Cir. 1986)).

624. *Id.*, 69 U.S.P.Q.2d (BNA) at 1999 (citing *Honeywell Int’l, Inc. v. Int’l Trade Comm’n*, 341 F.3d 1332, 1338-39, 68 U.S.P.Q.2d (BNA) 1023, 1028 (Fed. Cir. 2003)).

625. *Id.*, 69 U.S.P.Q.2d (BNA) at 1999 (quoting *Exxon Research & Eng’g Co. v. United States*, 265 F.3d 1371, 1375, 60 U.S.P.Q.2d (BNA) 1272, 1276 (Fed. Cir. 2001)).

626. *Id.*, 69 U.S.P.Q.2d (BNA) at 1999 (quoting *Exxon Research & Eng’g*, 265 F.3d at 1380, 60 U.S.P.Q.2d (BNA) at 1276).

627. *Id.* at 1372, 69 U.S.P.Q.2d (BNA) at 1999.

628. *Id.*, 69 U.S.P.Q.2d (BNA) at 1999.

629. *Id.*, 69 U.S.P.Q.2d (BNA) at 2000.

630. *Id.*, 69 U.S.P.Q.2d (BNA) at 2000.

631. *See id.*, 69 U.S.P.Q.2d (BNA) at 2000 (concluding that “‘surrender value protected investment’ means the difference between the actual value of a protected investment and the targeted return value of that investment at the time the protected life insurance policy is surrendered.”).

632. *Id.* at 1373, 69 U.S.P.Q.2d (BNA) at 2000.

investment credits” used in the claims and the reference to “SVP writer” in specification “provides substantial support . . . that, as used in the patent, the terms ‘stable value protected investment,’ ‘surrender value protected investment,’ and ‘SVP’ are equivalent.”⁶³³ The Federal Circuit also explained that “evidence of defendants’ knowledge of the use of the term prior to patenting is relevant to show that the term was in use and had a discernible meaning to at least some persons practicing in the field.”⁶³⁴

In *SmithKline Beecham Corp. v. Apotex Corp.*,⁶³⁵ the district court construed a claim covering the chemical compound “[c]rystalline paroxetine hydrochloride hemihydrate”⁶³⁶ (“CPH hemihydrate”) as limited to commercially significant quantities of CPH hemihydrate, reasoning that if the claim covered trace amounts of the compound then “potential infringers would not be able to determine (and avoid) infringement if they [could not] detect the claimed compound.”⁶³⁷ In reversing the district court’s holding, the Federal Circuit explained that “[t]he test for indefiniteness does not depend on a potential infringer’s ability to ascertain the nature of its own accused product to determine infringement, but instead on whether the claim delineates to a skilled artisan the bounds of the invention.”⁶³⁸ The Federal Circuit further explained that the fact that defendant could not “accurately ascertain the nature of its own product”⁶³⁹ in light of the claim language was irrelevant because “[t]he scope of this claim is clear; infringement of [defendant’s] product is not. Even if a claim is broad enough to embrace undetectable trace amounts of the claimed invention, ‘breadth is not indefiniteness.’”⁶⁴⁰ Reasoning that the disputed “claim covers a definite chemical structure [and] [t]o a chemist in this field, this claim is plain on its face,” the court held that there was no violation of the definiteness requirement.⁶⁴¹

633. *Id.*, 69 U.S.P.Q.2d (BNA) at 2000.

634. *Id.* at 1376, 69 U.S.P.Q.2d (BNA) at 2002.

635. 365 F.3d 1306, 70 U.S.P.Q.2d (BNA) 1737 (Fed. Cir. 2004), *vacated by* 403 F.3d 1328, 74 U.S.P.Q.2d (BNA) 1398 (Fed. Cir. 2005).

636. *Id.* at 1308, 70 U.S.P.Q.2d (BNA) at 1738.

637. *Id.* at 1314, 70 U.S.P.Q.2d (BNA) at 1743 (citing *Morton Int’l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1469-70, 28 U.S.P.Q.2d (BNA) 1190, 1194 (Fed. Cir. 1993)).

638. *Id.* at 1315, 70 U.S.P.Q.2d (BNA) at 1743. The court’s approach is correct in light of well-established law that infringement involves a two-step process: (1) construing the claim language, which like indefiniteness is a question of law, and (2) applying the construed claims to the accused device, which is a question of fact. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 374, 38 U.S.P.Q.2d 1461, 1464 (1996). The district court’s approach would have collapsed this two prong test for infringement into a strained indefiniteness inquiry, such that if a defendant was uncertain about infringement, the claim necessarily would be invalid as indefinite.

639. *SmithKline Beecham*, 365 F.3d at 1315, 70 U.S.P.Q.2d (BNA) at 1743.

640. *Id.*, 70 U.S.P.Q.2d (BNA) at 1743 (quoting *In re Gardner*, 427 F.2d 786, 788, 166 U.S.P.Q. (BNA) 138, 140 (C.C.P.A. 1970)).

641. *SmithKline Beecham*, 365 F.3d at 1314, 70 U.S.P.Q.2d (BNA) at 1743.

In *Glaxo Group Ltd. v. Apotex, Inc.*,⁶⁴² defendant appealed the decision of the district court that Glaxo's patents were valid and infringed. The asserted claims at issue claimed "[c]efuroxime axetil . . . having a *purity of at least 95%* aside from residual solvents" and "[a] process for preparing a highly pure . . . form of cefuroxime axetil which comprises preparing a *highly pure solution of cefuroxime axetil* and spray drying said solution . . ." ⁶⁴³ Defendant asserted that the district court's construction of "purity" and "pure" in the asserted claims rendered the claims indefinite.⁶⁴⁴ The district court had construed "pure" in the process claim "to mean the absence of impurities, where excipients are not considered to be impurities."⁶⁴⁵ It construed "purity of at least 95%" in the product claim to mean that the cefuroxime axetil must have "no more than 5% degrading, unwanted impurities," where, again, impurities do not include excipients.⁶⁴⁶ According to defendant, a person of ordinary skill in the art would not realize that the product claim covered cefuroxime axetil that had more than five percent of other ingredients, or that the process claim covered a process by which excipients are mixed with cefuroxime axetil.⁶⁴⁷

The Federal Circuit found these arguments to be "disingenuous."⁶⁴⁸ It affirmed the district court's construction of "purity" based on the fact that the specification of the patent containing the product claim "specifically states that the pharmaceutical compositions covered by the invention may contain between 0.1 to 99% of the active ingredient."⁶⁴⁹ "CA formulations with more than 5% other ingredients were thus pointed out to the public in the patent."⁶⁵⁰ The Federal Circuit similarly affirmed the construction of "pure" because the patent containing the process claim disclosed that pharmaceutical compositions of cefuroxime axetil could be produced by spray drying "a suspension of pure amorphous [CA] with the excipients appropriate for said tablets, capsules or granules [and] Glaxo therefore informed the public that combining CA with excipients prior to spray drying was contemplated under the . . . patent."⁶⁵¹ The Federal Circuit found that the patents' detailed disclosures "clearly conveyed to [a person] of ordinary skill in the art that the patentee 'invented what is claimed' and also gave notice to the public of the limits of the invention."⁶⁵²

642. 376 F.3d 1339, 71 U.S.P.Q.2d (BNA) 1801 (Fed. Cir. 2004).

643. *Id.* at 1343, 71 U.S.P.Q.2d (BNA) at 1803.

644. *Id.* at 1348, 71 U.S.P.Q.2d (BNA) at 1806.

645. *Id.* at 1345, 71 U.S.P.Q.2d (BNA) at 1804.

646. *Id.* at 1344-45, 71 U.S.P.Q.2d (BNA) at 1804.

647. *Id.* at 1348, 71 U.S.P.Q.2d (BNA) at 1806-07.

648. *Id.*, 71 U.S.P.Q.2d (BNA) at 1807.

649. *Id.*, 71 U.S.P.Q.2d (BNA) at 1807.

650. *Id.*, 71 U.S.P.Q.2d (BNA) at 1807.

651. *Id.*, 71 U.S.P.Q.2d (BNA) at 1807 (citations and internal quotations omitted).

652. *Id.*, 71 U.S.P.Q.2d (BNA) at 1807 (quoting *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d

E. Design Patent

In *Bernhardt, L.L.C. v. Collezione Europa USA, Inc.*,⁶⁵³ the Federal Circuit addressed, for the first time, the issue of what evidence must be presented to prove infringement of a design patent under the point of novelty test.⁶⁵⁴ Plaintiff sued defendant for infringement of six of its design patents related to furniture designs.⁶⁵⁵ The district court held that Plaintiff had not met its burden of establishing that defendant's designs appropriated the points of novelty of plaintiff's patented designs.⁶⁵⁶ On appeal, the Federal Circuit agreed that it was sufficient for showing the points of novelty for plaintiff to introduce its presentation of the patents-in-suit and their prosecution histories, all of the references cited during prosecution, and its filing of proposed findings of fact and conclusions of law specifying its contentions as to the points of novelty.⁶⁵⁷ The Federal Circuit ruled that, at minimum, a patentee must introduce "the design patent at issue, its prosecution history, and the relevant prior art references cited in the prosecution history," and must proffer, "in some form, its contentions as to points of novelty."⁶⁵⁸ It opined that the contentions as to points of novelty "may be made in any appropriate way, such as in proposed findings of fact."⁶⁵⁹ If the points of novelty can be discerned from these submissions, the Federal Circuit ruled that additional evidence such as expert testimony was not necessary.⁶⁶⁰ The Federal Circuit held that plaintiff had met the minimal evidentiary burden, and that the court was wrong to have declined to determine the points of novelty from plaintiff's submissions and to have concluded, without analysis of the submitted evidence, that Bernhardt did not sufficiently show how defendant's designs appropriated such points of novelty.⁶⁶¹

F. Interference and Priority of Invention

In *Stevens v. Tamai*,⁶⁶² Stevens appealed from the Board's decision granting priority in an interference proceeding to Tamai.⁶⁶³ Tamai was the senior party to the interference, whose application was filed February 15, 1994, and was accorded the benefit of the filing date of the application,

1555, 1563, 19 U.S.P.Q.2d (BNA) 1111, 1116 (Fed. Cir. 1991)).

653. 386 F.3d 1371, 72 U.S.P.Q.2d (BNA) 1901 (Fed. Cir. 2004).

654. *Id.* at 1384, 72 U.S.P.Q.2d (BNA) at 1911.

655. *Id.* at 1373-74, 72 U.S.P.Q.2d (BNA) at 1903.

656. *Id.* at 1384, 72 U.S.P.Q.2d (BNA) at 1911.

657. *Id.*, 72 U.S.P.Q.2d (BNA) at 1911.

658. *Id.*, 72 U.S.P.Q.2d (BNA) at 1911.

659. *Id.*, 72 U.S.P.Q.2d (BNA) at 1911.

660. *Id.*, 72 U.S.P.Q.2d (BNA) at 1911.

661. *Id.* at 1385, 72 U.S.P.Q.2d (BNA) at 1912.

662. 366 F.3d 1325, 70 U.S.P.Q.2d (BNA) 1765 (Fed. Cir. 2004).

663. *Id.* at 1327, 70 U.S.P.Q.2d (BNA) at 1767.

March 29, 1993, to which it was a continuation-in-part (“U.S. patent application”). Stevens’s patent was filed February 7, 1994. During the interference, both Stevens and Tamai filed motions under 37 C.F.R. § 1.633(f) “to be accorded the benefit of the filing date of earlier filed application[s].”⁶⁶⁴ Stevens based his motion on several European applications showing a constructive reduction to practice as early as February 1993.⁶⁶⁵ Tamai’s motion was based on a Patent Cooperation Treaty (“PCT”)⁶⁶⁶ application and an earlier Japanese patent application, both of which were written in Japanese.⁶⁶⁷ The Board granted Stevens’s motion, but partly denied Tamai’s motion with respect to the PCT application on the basis that Tamai did not supply a translation of the PCT application to English in accordance with Rule 637.⁶⁶⁸ The Board still granted Tamai priority, however, on the basis of its Japanese application.⁶⁶⁹

Stevens contended on appeal to the Federal Circuit that the Board erred in granting Tamai’s motion for the benefit of the Japanese application. According to Stevens, 35 U.S.C. § 119⁶⁷⁰ prohibited Tamai from directly claiming the benefit of that application because Tamai failed to obtain the benefit of the intervening PCT application and because the Japanese application was filed more than one year prior to March 29, 1993.⁶⁷¹ It followed, Stevens argued, that Tamai had failed to prove a constructive reduction to practice of the subject matter corresponding to the interference count prior to March 29, 1993, and therefore Stevens should have been awarded priority.

The Federal Circuit agreed with Stevens, holding that “because Tamai failed to prove his entitlement to the benefit of the [intervening] PCT application, it was error for the Board to afford Tamai the benefit of the [earlier] Japanese application.”⁶⁷² It reasoned that because the Japanese application was filed more than one year prior to the filing date of the U.S. parent application, § 119 precluded reliance on that application for priority.

The Federal Circuit rejected Tamai’s arguments that a preliminary

664. *Id.* at 1328, 70 U.S.P.Q.2d (BNA) at 1767 (quoting 37 C.F.R. § 1.633(f) (2003)).

665. *Id.*, 70 U.S.P.Q.2d (BNA) at 1767.

666. Patent Cooperation Treaty, With Regulations, June 19, 1970, 28 U.S.T. 7645.

667. *Stevens*, 366 F.3d at 1328, 70 U.S.P.Q.2d (BNA) at 1767.

668. *Id.* at 1328-29, 70 U.S.P.Q.2d (BNA) at 1768; *see also* 37 C.F.R. § 1.637(f)(2) (2004) (requiring that, for a preliminary motion for benefit of the filing date of an earlier application under § 1.633(f), “[i]f the earlier filed application is not in English, the requirements of § 1.647 must also be met”).

669. *Stevens*, 366 F.3d at 1329, 70 U.S.P.Q.2d (BNA) at 1768.

670. *See* 35 U.S.C. § 119(a) (2000) (granting a patent for invention that was filed “in a foreign country which affords similar privileges in the case of applications filed in the United States” the same rights as if it was filed in the U.S. on that date “if the application in [the U.S.] is filed within twelve months from the earliest date on which such foreign application was filed”).

671. *Stevens*, 366 F.3d at 1330, 70 U.S.P.Q.2d (BNA) at 1769.

672. *Id.*, 70 U.S.P.Q.2d (BNA) at 1769.

motion for benefit under Rule 633 was unnecessary in the first instance because Tamai filed its PCT application with the United States Patent and Trademark Office for the purpose of entering the national stage examination, and according to procedures governing PCT applications, included therein a translation of the Japanese application.⁶⁷³ The Federal Circuit found that the statutes governing PCT applications and the PTO procedural requirements governing interferences “have little to do with one another.”⁶⁷⁴ Tamai relied on 35 U.S.C. § 363, which requires an applicant who seeks the benefit of an international application for his national stage application to submit a copy of the international application and an English translation of that application.⁶⁷⁵ The Federal Circuit noted that Tamai overlooked 35 U.S.C. § 372(b)(3), which permits the PTO to “require a verification of the translation of the international application . . . if the application . . . was filed in a language other than English.”⁶⁷⁶ Thus, the Federal Circuit found that the PTO was “not required to accept an applicant’s transmittal letter requesting entry into the national stage as conclusive proof that a foreign language application contains a particular disclosure.”⁶⁷⁷

The Federal Circuit went on to note that the Rules 633, 637, and 647 governing interference procedures were reasonable to the extent that they placed the burden on the applicant in the best position to know the content of the disclosure and who hopes to benefit from the content of that disclosure to prove its content and to assume the translation costs associated with such proof.⁶⁷⁸ In view of the reasonableness of those rules and the substantial deference to which they are accorded, the Federal Circuit rejected Tamai’s assertion that § 363 “overwhelms the PTO’s interference rules and requires the Board to accord Tamai the benefit of the PCT ‘947 application merely because he completed the requirements for entering the national stage of examination in the United States.”⁶⁷⁹

The Federal Circuit found that the Board’s rejection of Tamai’s argument that the U.S. patent application was the translation of the PCT application was supported by substantial evidence where Tamai’s motion for benefit failed to allege as much, and because Tamai submitted no

673. *Id.* at 1332, 70 U.S.P.Q.2d (BNA) at 1770-71.

674. *Id.*, 70 U.S.P.Q.2d (BNA) at 1771.

675. *See* 35 U.S.C. § 363 (2000) (mandating that “[a]n international application designating the United States shall have the effect . . . of a national application for patent regularly filed”).

676. *Stevens*, 366 F.3d at 1333, 70 U.S.P.Q.2d (BNA) at 1771 (quoting 35 U.S.C. § 372(b)(3) (2000)).

677. *Id.*, 70 U.S.P.Q.2d (BNA) at 1771.

678. *Id.*, 70 U.S.P.Q.2d (BNA) at 1771-72.

679. *Id.* at 1334, 70 U.S.P.Q.2d (BNA) at 1772.

affidavit alleging as much.⁶⁸⁰ Nor did the court agree with Tamai that his submission of a translation with the international application to enter national stage examination under § 371(c)(2) was sufficient to comply with Rules 637(f) and 647, as § 371(c)(2) does not require an affidavit attesting to the accuracy of the translation.⁶⁸¹ In the court's opinion, "compliance with [particular] filing requirements is not sufficient to prove constructive reduction to practice in an interference proceeding."⁶⁸²

Finding Tamai's remaining arguments "either irrelevant or unpersuasive," the court concluded that "the Board did not abuse its discretion in refusing to award Tamai the benefit of [his] PCT application."⁶⁸³ However, because Tamai was not entitled to the benefit of the PCT application, it found that the board also erred in awarding Tamai the benefit of the Japanese application.⁶⁸⁴

G. Patent Term

In *Arnold Partnership v. Dudas*,⁶⁸⁵ the Federal Circuit affirmed the district court's decision that the PTO did not err in its interpretation of 35 U.S.C. § 156 and denial of a patentee's application to extend a patent's term.⁶⁸⁶ Section 156 provides for the extension of a patent's term under certain conditions where the patent claims a drug product that has been subjected to a regulatory review period before its commercial marketing or use, such as that required by the FDA.⁶⁸⁷ The term extension compensates a patent applicant for time lost as a result of the regulatory review period, time which the patent applicant arguably could be profiting from its invention. The statute conditions term extension on the fact that the "product" was not previously approved for commercial marketing.⁶⁸⁸

The patent claims at issue in *Arnold* addressed compositions of hydrocodone and ibuprofen and the method of treating pain with such compositions.⁶⁸⁹ Hydrocodone and ibuprofen had each been previously approved for commercial marketing, in conjunction with other ingredients

680. *Id.*, 70 U.S.P.Q.2d (BNA) at 1772.

681. *Id.*, 70 U.S.P.Q.2d (BNA) at 1772. Compare 35 U.S.C. § 371(c)(2) (2000) (requiring only that a translation is filed and not requiring that an affidavit attesting to the accuracy of a translation is not necessary), with 37 C.F.R. § 1.647 (2004) (requiring, in addition to the translation itself, that an affidavit attesting to the accuracy of such translation also be filed).

682. *Stevens*, 366 F.3d at 1334, 70 U.S.P.Q.2d (BNA) at 1772.

683. *Id.* at 1335, 70 U.S.P.Q.2d (BNA) at 1773.

684. *Id.*, 70 U.S.P.Q.2d (BNA) at 1773.

685. 362 F.3d 1338, 70 U.S.P.Q.2d (BNA) 1311 (Fed. Cir. 2004).

686. *Id.* at 1339, 70 U.S.P.Q.2d (BNA) at 1312.

687. See 35 U.S.C. § 156(a)(4) (2004) (extending the patent term when "the product has been subject to a regulatory review period before its commercial marketing or use").

688. 35 U.S.C. § 156(a)(5)(A) (2004).

689. *Arnold P'ship*, 362 F.3d at 1339, 70 U.S.P.Q.2d (BNA) at 1312.

or alone.⁶⁹⁰ On this basis, the PTO denied the application for patent term extension.⁶⁹¹ The district court affirmed.⁶⁹²

Appellant argued that the statute permits extension of the patent term for a combination drug product when the combination itself previously had not been marketed, and that the drug product should be examined as a whole under the statute, and not on a component-by-component basis.⁶⁹³ The Federal Circuit interpreted § 156 without deference to the district court, but determined that the district court was correct in construing § 156 to require examination of a drug product on a component-by-component basis.⁶⁹⁴ The Federal Circuit particularly emphasized the statute's definition of "product," which means "drug product," which is further defined to mean "the active ingredient of a new drug . . . product . . . including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient."⁶⁹⁵ It found the final phrase, "as a single entity or in combination with another active ingredient," to be determinative.⁶⁹⁶ Under the court's construction, the statute would allow extension of the term of a patent claiming a drug product with two active ingredients, A and B, where either A or B had never been commercially marketed.⁶⁹⁷ But where either A or B had been commercially marketed, no extension would be allowed.⁶⁹⁸

The Federal Circuit refused to give in to Appellant's argument that its construction would conflict with § 156(c), which provides that a patent's term "shall be extended by the time equal to the regulatory review period for the *approved product* which period occurs after the date the patent is issued,"⁶⁹⁹ suggesting that the combination as a whole should be reviewed for prior marketing, since each combination drug product receives only one regulatory review period.⁷⁰⁰ The Federal Circuit found that this argument was based on a "vague implication" that could not overcome the unambiguous language of the rest of the statute.⁷⁰¹ It also refused to change its decision despite its own admission that it does not perfectly overlay with the FDA's practices and regulations, specifically the regulations requiring an NDA for combination drugs, and agreed with the

690. *Id.*, 70 U.S.P.Q.2d (BNA) at 1312.

691. *Id.*, 70 U.S.P.Q.2d (BNA) at 1312.

692. *Id.* at 1340, 70 U.S.P.Q.2d (BNA) at 1313.

693. *Id.* at 1339, 70 U.S.P.Q.2d (BNA) at 1313.

694. *Id.* at 1341, 70 U.S.P.Q.2d (BNA) at 1314.

695. *Id.* at 1341, 70 U.S.P.Q.2d (BNA) at 1314 (quoting 35 U.S.C. § 156(f) (2000)).

696. *Id.*, 70 U.S.P.Q.2d (BNA) at 1314.

697. *Id.*, 70 U.S.P.Q.2d (BNA) at 1314.

698. *Id.*, 70 U.S.P.Q.2d (BNA) at 1314.

699. *Id.* at 1342, 70 U.S.P.Q.2d (BNA) at 1314 (emphasis added) (quoting 35 U.S.C. § 156(c) (2000)).

700. *Id.*, 70 U.S.P.Q.2d (BNA) at 1314.

701. *Id.*, 70 U.S.P.Q.2d (BNA) at 1314.

district court's reasoning for dismissal of the applicant's policy argument that its interpretation would create a financial disincentive to pharmaceutical companies' development of new therapeutic combination drugs.⁷⁰² The Federal Circuit explained that it "must follow the directions of the law, not its own conceptions of the best way to make the law achieve certain policy objectives."⁷⁰³

Lastly, the Federal Circuit addressed the issue of whether the existence of synergism exhibited by a drug combination would call for a different result.⁷⁰⁴ The hydrocodone/ibuprofen drug combination was said to exhibit synergistic effects in that it had a greater analgesic effect yet less harmful side effects than that which could be achieved by its separate components alone.⁷⁰⁵ Finding that "the statutory language [did] not distinguish at all between synergistic and nonsynergistic combinations," the court declined to do so as well.⁷⁰⁶

In *Pfizer Inc. v. Dr. Reddy's Laboratories, Ltd.*,⁷⁰⁷ the Federal Circuit reversed the district court's dismissal of plaintiff's infringement claims.⁷⁰⁸ Plaintiff secured a patent on certain dihydropyridine compounds and their acid addition salts. One such dihydropyridine compound was called amlodipine. Plaintiff later obtained FDA approval of a drug for anti-hypertension and anti-ischemic therapeutic uses in which the active ingredient was an amlodipine besylate salt, and successfully applied for the extension of its patent term under § 156 to compensate for the days consumed by the federal regulatory approval process.⁷⁰⁹ The patent was originally scheduled to expire in early 2003, but as a result of the extension granted to plaintiff, the expiration date was changed to mid-2006. For its patent term extension application, plaintiff identified amlodipine besylate as the product for which it obtained regulatory approval,⁷¹⁰ but as part of the registration of its drug during the FDA approval process, it submitted clinical data obtained from uses of both amlodipine besylate and amlodipine maleate, the latter being just another salt of amlodipine.

Plaintiff accused defendant of patent infringement in response to plaintiff's filing of a New Drug Application proposing to market amlodipine maleate. As part of its NDA, defendant had relied on the clinical data submitted by plaintiff for its amlodipine besylate product.

702. *Id.*, 70 U.S.P.Q.2d (BNA) at 1314-15.

703. *Id.*, 70 U.S.P.Q.2d (BNA) at 1315.

704. *Id.*, 70 U.S.P.Q.2d (BNA) at 1315.

705. *Id.*, 70 U.S.P.Q.2d (BNA) at 1315.

706. *Id.* at 1343, 70 U.S.P.Q.2d (BNA) at 1315.

707. 359 F.3d 1361, 69 U.S.P.Q.2d (BNA) 2016 (Fed. Cir. 2004).

708. *Id.* at 1363, 69 U.S.P.Q.2d (BNA) at 2016.

709. *Id.* at 1364, 69 U.S.P.Q.2d (BNA) at 2017.

710. *Id.*, 69 U.S.P.Q.2d (BNA) at 2017.

Defendant conceded that amlodipine maleate came within the scope of plaintiff's patent claims, but argued that the term extension obtained by plaintiff applied only to protection of amlodipine besylate because that was the compound plaintiff identified in its application for patent term extension.⁷¹¹ Following this reasoning, plaintiff's patent term would have essentially expired for all compounds other than amlodipine besylate.

The Federal Circuit held that the term extension did in fact cover amlodipine maleate. It reasoned that the statutory definition of "drug product" in § 156(f) included "any salt or ester of the active ingredient"⁷¹² and was thus met by both amlodipine besylate and amlodipine maleate, amlodipine being the "active ingredient" in both compositions. Defendant's attempt to market the same drug product for which plaintiff had obtained approval, simply by changing the salt, would exploit the very loophole that the statute's definition of "drug product" foresaw and guarded against. Furthermore, defendant's reliance on the "rights derived" provision of § 156(b), which specifically limits the extension of a patent term to "any use approved for the product," was misguided because that section did not limit the term extension to any specific form of the "product," and thus must be construed to cover the "product" as that word is defined in § 156(f), "including any salt or ester of the active ingredient."⁷¹³ Thus, the court held that the extended term of plaintiff's patent included any salt or ester of amlodipine, and reversed the district court's judgment of noninfringement.

H. *Inventorship*

In *Caterpillar Inc. v. Sturman Industries*,⁷¹⁴ plaintiff sued defendant for alleged violation of Illinois's trade secret statute, breach of a joint development agreement, and unlawful conversion of plaintiff's property.⁷¹⁵ Plaintiff also sought correction of inventorship of two patents issued to defendant, the "329 patent" and the "987 patent."⁷¹⁶ Defendant counterclaimed, seeking correction of inventorship of a third patent issued to plaintiff, the "901 patent," and for fraudulent inducement.⁷¹⁷ The dispute arose out of a joint development agreement entered into by parties through which the parties intended to work together "to develop actuators and driver circuits for Caterpillar's exclusive use in fuel systems for diesel

711. *Id.*, 69 U.S.P.Q.2d (BNA) at 2017.

712. *Id.* at 1366, 69 U.S.P.Q.2d (BNA) at 2019 (quoting 35 U.S.C. § 156(f) (2000)).

713. *Id.*, 69 U.S.P.Q.2d (BNA) at 2019.

714. 387 F.3d 1358, 73 U.S.P.Q.2d (BNA) 1609 (Fed. Cir. 2004).

715. *Id.* at 1364, 73 U.S.P.Q.2d (BNA) at 1613.

716. *Id.*, 73 U.S.P.Q.2d (BNA) at 1613.

717. *Id.*, 73 U.S.P.Q.2d (BNA) at 1613.

engines.”⁷¹⁸ Under the agreement, defendant agreed to assign plaintiff certain intellectual property “made or conceived by [defendant’s] personnel, either alone or with others (a) pursuant to the joint development program or (b) resulting from [plaintiff’s] Proprietary Information.”⁷¹⁹ Plaintiff agreed to pay defendant royalties for its use of any such intellectual property assigned, extending beyond the termination of the agreement.⁷²⁰

The actuators and driver circuits jointly developed by defendant and plaintiff were mainly of a certain type used for “mechanically actuated, electronically controlled unit injectors” (“meuis”).⁷²¹ Defendant assigned his rights to these inventions to plaintiff, and plaintiff subsequently filed applications for patents on them which were granted as the ‘131 and ‘219 patents. One weekend in September 1992, the parties met at a hotel to discuss fuel injector designs and on the second day “brainstormed alternate system designs.”⁷²² The following morning, defendant sketched an idea for an “integrated spool valve employing residual magnetic latching.”⁷²³ This valve comprised a spool-shaped piece that moves back and forth within a cylindrical housing.⁷²⁴ When a current is applied to one side of the cylinder, the spool is magnetically attracted to that side of the cylinder and slides to that side.⁷²⁵ The current is alternatively applied to each side of the housing, making the spool move back and forth from side to side.⁷²⁶ In doing so, the spool opens and closes various channels carrying fluids, and thereby changes the flow of fluids in each repetition.⁷²⁷

When defendant showed his sketch to plaintiff’s employees, plaintiff recognized the potential value of the valve, but rejected the use of the valve design for use in meuis because it would not be suitable for high pressure fuel systems.⁷²⁸ Later, however, plaintiff investigated the valve’s use in another type of fuel injector, the hydraulically actuated, electronically controlled unit injector (“heui”). Plaintiff did not disclose its investigation to defendant.⁷²⁹

In 1993, when the joint development agreement expired, plaintiff attempted to persuade defendant to release plaintiff from its ongoing

718. *Id.* at 1361, 73 U.S.P.Q.2d (BNA) at 1611.

719. *Id.*, 73 U.S.P.Q.2d (BNA) at 1611.

720. *Id.* at 1362, 73 U.S.P.Q.2d (BNA) at 1611.

721. *Id.*, 73 U.S.P.Q.2d (BNA) at 1611.

722. *Id.*, 73 U.S.P.Q.2d (BNA) at 1612.

723. *Id.*, 73 U.S.P.Q.2d (BNA) at 1612.

724. *Id.* at 1363, 73 U.S.P.Q.2d (BNA) at 1612.

725. *Id.*, 73 U.S.P.Q.2d (BNA) at 1612.

726. *Id.*, 73 U.S.P.Q.2d (BNA) at 1612.

727. *Id.*, 73 U.S.P.Q.2d (BNA) at 1612.

728. *Id.*, 73 U.S.P.Q.2d (BNA) at 1612.

729. *Id.*, 73 U.S.P.Q.2d (BNA) at 1612.

royalty obligation for use of intellectual property in exchange for a one-time payment of \$275,000.⁷³⁰ Defendant attempted to get clarification from plaintiff as to the exact intellectual property rights that would be released.⁷³¹ Plaintiff listed the '131 and '219 patents but did not mention the integrated spool valve invention. Defendant agreed to the release.⁷³²

Shortly thereafter, defendant published an article describing the integrated spool valve technology and filed two patent applications based on it.⁷³³ Subsequently, counsel for plaintiff approached defendant to request that he sign a patent application to be filed in the name of plaintiff covering the integrated spool valve.⁷³⁴ The application named defendant a co-inventor, and his signature was therefore necessary to complete the application.⁷³⁵ Defendant refused, stating that he had invented the valve outside the scope of the joint development agreement.⁷³⁶ Plaintiff then proceeded to file two applications based on the technology.⁷³⁷ The first named defendant as an inventor, and as defendant refused to sign it, it was ultimately abandoned.⁷³⁸ The second did not name defendant as an inventor and issued as the '901 patent.⁷³⁹

The district court denied plaintiff's co-inventorship claim to Sturman's '329 and '987 patents. The court held that plaintiff's engineer's alleged contribution to the invention, the selection of the type of steel to be used in the valve, was "merely the exercise of ordinary skill in the art and therefore not a significant addition to the conception" of the inventions.⁷⁴⁰ As part of the development of meuis under the joint development agreement, plaintiff engineers had searched for and found a type of steel that had specific magnetic and physical characteristics that would meet the demands of meui systems, such as "a sixty pound latching force."⁷⁴¹ Although defendant's drawing indicated the use of the particular steel identified by the plaintiff engineers, the court found that the demands of the integrated spool valve did not require the use of such steel.⁷⁴² Furthermore, available publications including a patent issued to defendant prior to the existence of the joint development agreement taught that "substantially any magnetic material"

730. *Id.*, 73 U.S.P.Q.2d (BNA) at 1612.

731. *Id.*, 73 U.S.P.Q.2d (BNA) at 1612.

732. *Id.*, 73 U.S.P.Q.2d (BNA) at 1612.

733. *Id.* at 1363-64, 73 U.S.P.Q.2d (BNA) at 1613.

734. *Id.* at 1364, 73 U.S.P.Q.2d (BNA) at 1613.

735. *Id.*, 73 U.S.P.Q.2d (BNA) at 1613.

736. *Id.*, 73 U.S.P.Q.2d (BNA) at 1613.

737. *Id.*, 73 U.S.P.Q.2d (BNA) at 1613.

738. *Id.*, 73 U.S.P.Q.2d (BNA) at 1613.

739. *Id.*, 73 U.S.P.Q.2d (BNA) at 1613.

740. *Id.* at 1376, 73 U.S.P.Q.2d (BNA) at 1622 (quoting *Caterpillar Inc. v. Sturman Indus., Inc.*, No. 99-1201, slip op. 44 (C.D. Ill. Feb. 6, 2003)).

741. *Caterpillar*, 387 F.3d at 1362, 73 U.S.P.Q.2d (BNA) at 1611.

742. *Id.* at 1376, 73 U.S.P.Q.2d (BNA) at 1623.

would suffice for use in the integrated spool valve.⁷⁴³ Therefore, plaintiff's contribution to the integrated spool valve was not considered a significant addition to the invention.⁷⁴⁴

The Federal Circuit affirmed the district court's conclusion that defendant was the sole inventor of the '329 and '987 patents. Considering the district court's findings of fact, it agreed that the use of the particular steels identified by plaintiff engineers was an "insignificant contribution" which did not support a claim to co-inventorship. Furthermore, because the '329 patent claims did not require either type of steel suggested by the plaintiff engineers, it was legally correct that the engineers were not inventors because its precedent required "that one contribute something to the *claimed* invention."⁷⁴⁵ The Federal Circuit rejected plaintiff's argument that defendant's amendments of the '329 and '987 patents claims to require "material with enough residual magnetism" compelled correction of inventorship.⁷⁴⁶ These limitations, it reasoned, were not specific to the steels identified by plaintiff engineers. Furthermore, when used in the integrated spool valve, defendant's prior patent taught all that was necessary for someone of ordinary skill in the art to select appropriate materials.⁷⁴⁷

As for the '901 patent, all the claims of this patent covered a three-way, dual-solenoid, integrated spool valve used to control the flow of working fluid in a heui. The district court held that, although plaintiff had worked on a three-way integrated spool valve for use in a heui separately from defendant, defendant demonstrated his own prior conception of a three-way version of the valve in a marketing presentation delivered to plaintiff. As for plaintiff's other alleged improvements to the integrated spool valve, the court found that each of these were either an exercise of ordinary skill or disclosed in defendant's sketch. The Federal Circuit found that the district court had clearly erred in its conclusion. Although defendant's presentation had disclosed a three-way valve, it did not refer to an integrated spool valve. Additionally, it found that because a three-way valve was "more complex" than the two-way valve disclosed in defendant's sketch, plaintiff's contribution was "not insignificant in quality

743. *Id.*, 73 U.S.P.Q.2d (BNA) at 1622 (reciting the district court's detailed factual findings, including its observation that public texts also described the magnetic properties of potentially useful materials, that led to its conclusion that Caterpillar's contribution was insignificant).

744. *Id.*, 73 U.S.P.Q.2d (BNA) at 1622.

745. *Id.* at 1378, 73 U.S.P.Q.2d (BNA) at 1623 (emphasis added) (quoting *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1473, 43 U.S.P.Q.2d (BNA) 1935, 1941 (Fed. Cir. 1997)).

746. *Id.*, 73 U.S.P.Q.2d (BNA) at 1623-24.

747. *Id.*, 73 U.S.P.Q.2d (BNA) at 1624.

when measured against the dimension of the full invention.”⁷⁴⁸ Accordingly, because defendant had failed to present clear and convincing evidence of his prior conception of a three-way integrated spool valve, it reversed the district court’s conclusion that defendant was the sole inventor of the ‘901 patent.⁷⁴⁹

In *Eli Lilly and Co. v. Aradigm Corp.*,⁷⁵⁰ plaintiff sued defendant under 35 U.S.C. § 256⁷⁵¹ seeking to have two of its scientists listed as inventors of U.S. Patent No. 5,888,477, owned by defendant.⁷⁵² Following a jury verdict, the district court ordered the PTO to add one of plaintiff’s scientists as an inventor. Defendant appealed this decision.⁷⁵³

Defendant argued that the jury had been provided with erroneous instructions at trial. First, it contended that the jury should have been provided with a construction of one of the claims for which joint inventorship was asserted. The Federal Circuit agreed that “the legal scope of a claim must be known before the contributions of an alleged co-inventor can be compared to that claim to determine whether the correct inventors were named,”⁷⁵⁴ but found that defendant had waived this argument because it had never requested construction of the claims and thereby implicitly conceded that the meanings of the terms therein were clear.⁷⁵⁵ Defendant then argued that the jury verdict form and one of the jury instructions had included “prejudicially paraphrased” descriptions of the claim.⁷⁵⁶ At trial defendant had objected to the paraphrasing, but had not indicated to the district court why such paraphrasing was prejudicial. The Federal Circuit again held that defendant had waived this argument because it failed to indicate what was lacking in the paraphrased

748. *Id.* at 1380, 73 U.S.P.Q.2d (BNA) at 1609 (quoting *Fina Oil*, 123 F.3d at 1473, 43 U.S.P.Q.2d (BNA) at 1935, 1941).

749. *Id.*, 73 U.S.P.Q.2d (BNA) at 1623.

750. 376 F.3d 1352, 71 U.S.P.Q.2d (BNA) 1787 (Fed. Cir. 2004).

751. 35 U.S.C. § 256 (2000) (entitling the Director to issue a certificate correcting an error in naming an inventor, provided that the error was not made with any deceptive intention and on application of all the parties and assignees with proof of the facts).

752. Lilly also sued Aradigm for state law claims of unjust enrichment and breach of contract. *Aradigm*, 376 F.3d at 1368-70, 71 U.S.P.Q.2d (BNA) at 1799-1800.

753. This was a cross-appeal. Lilly appealed the district court’s denial of injunctive relief as a remedy for Aradigm’s breach of contract and unjust infringement claims, for which the jury only awarded Lilly two dollars in nominal damages. *Id.* at 1368-69, 71 U.S.P.Q.2d (BNA) at 1799.

754. *Id.* at 1360, 71 U.S.P.Q.2d (BNA) at 1792.

755. *Id.*, 71 U.S.P.Q.2d (BNA) at 1792.

756. The jury was instructed that “[t]he ‘inventions’ at issue in this case include: . . . that aerosolized lispro produces a relative bioavailability greater than twice that seen after the inhalation of a similar amount of [regular] human insulin.” *Id.*, 71 U.S.P.Q.2d (BNA) at 1792-93. The verdict form also described the invention of claim 6 as “inhaling an aerosolized formulation of insulin lispro into the lungs, which produces a relative bioavailability greater than twice that seen after the inhalation of a similar amount of [regular] insulin.” *Id.*, 71 U.S.P.Q.2d (BNA) at 1793.

description or specify what made it prejudicial:

Generically alleging that the wording of a jury instruction is confusing, without suggesting the logical error the jury might make, does not give the district court the information that it requires to see the alleged error of its ways and to have a meaningful first opportunity to consider changing its course.⁷⁵⁷

Despite concluding that defendant had waived its right to raise its paraphrasing arguments regarding the jury instructions on appeal because its objections were not sufficiently specific, the Federal Circuit applied Seventh Circuit law⁷⁵⁸ and addressed those arguments on their merits. In doing so, the Federal Circuit found that the description of the claimed invention in the verdict form differed from the language of the claim itself only in that the description did not recite as a “distinct first step [the] aerosolizing of lispro” as did the claim.⁷⁵⁹ The description in the verdict form, however, “necessarily encompassed the step of aerosolizing” in that it required that the invention include “inhaling an aerosolized formulation” of lispro.⁷⁶⁰ Turning to the asserted error in the instructions, Aradigm contended that the description given in the instructions had only recited one limitation that was present in the claim at issue. The Federal Circuit found that Seventh Circuit law requires review of the jury instructions as a whole, and that “in light of the verdict form, any alleged error in instruction 20 did not prevent the jury from reasonably discerning the correct message.”⁷⁶¹ Furthermore, the Federal Circuit reasoned, the law of inventorship does not require that an inventor have contributed to the conception of each limitation of any one patent claim.⁷⁶²

Defendant next argued that there was insufficient evidence to support the jury verdict that plaintiff’s scientist was a joint inventor of the ‘477 patent. Plaintiff claimed that its scientist was a joint inventor of the ‘477 patent because he had conveyed to the defendant’s scientists that “aerosolized

757. *Id.* at 1361, 71 U.S.P.Q.2d (BNA) at 1792.

758. *Id.*, 71 U.S.P.Q.2d (BNA) at 1792 (noting that Rule 51 requires objections to state “distinctly the matter objected to and the grounds of the objection”); *see also* *Wilk v. Am. Med. Ass’n*, 719 F.2d 207, 218 (7th Cir. 1983) (dictating the need to look to “the instructions as a whole, in a common sense manner, avoiding fastidiousness, inquiring whether the correct message was conveyed to the jury reasonably well”); *Avern Trust v. Clarke*, 415 F.2d 1238, 1241 (7th Cir. 1969) (“Rule 51 of the Federal Rules of Civil Procedure precludes the assignment of error when no specific objection to an instruction is made.”).

759. *Aradigm*, 376 F.3d at 1361, 71 U.S.P.Q.2d (BNA) at 1792.

760. *Id.*, 71 U.S.P.Q.2d (BNA) at 1792.

761. *Id.*, 71 U.S.P.Q.2d (BNA) at 1793.

762. *Id.* at 1361-62, 71 U.S.P.Q.2d (BNA) at 1793. Aradigm also contested the paraphrasing of the invention in the instructions and the verdict form on the basis that it allowed the jury to find that Lilly’s scientist was a co-inventor when he had contributed “a mere realization about the chemical properties of lispro” already a part of the public domain. *Id.* at 1362, 71 U.S.P.Q.2d (BNA) at 1794.

lispro might be used to produce ‘a relative bioavailability greater than twice that seen after the inhalation of a similar amount of human insulin’” during joint development meetings between Lilly and Aradigm in 1995 and 1996.⁷⁶³ The Federal Circuit held that the jury’s verdict was not sustainable because the jury had not been presented with substantial evidence that this information had ever been communicated by the plaintiff’s scientist. The evidence showed that plaintiff’s scientist had discussed insulin at meetings with defendant, and had suggested to defendant that it try lispro in its aerosol delivery devices. No evidence existed, however, that directly showed that the plaintiff’s scientist had conveyed to defendant that aerosolized lispro should be used “to produce a relative bioavailability greater than twice that seen after inhalation of human insulin.”⁷⁶⁴ The Federal Circuit held that, where the standard for correcting inventorship was a clear and convincing standard, the jury’s verdict could not stand on circumstantial evidence alone.⁷⁶⁵

In its appeal, plaintiff also alleged that the jury instructions were erroneous in that they required plaintiff to prove that its scientist had contributed to the conception of the claimed invention by clear and convincing evidence. Plaintiff argued that joint inventorship disputes under § 256 should be analyzed under the preponderance of the evidence standard where the person allegedly omitted from an issued patent had a co-pending patent application claiming the same subject matter as the issued patent. Plaintiff based its argument on 37 C.F.R. § 1.601 and *Environ Products, Inc. v. Furon Co.*⁷⁶⁶ Section 1.601 provides that a party who does not have the earliest effective filing date in an interference proceeding need only to demonstrate by a preponderance of the evidence that it was the first to invent in order to succeed in the interference if the two patents or applications at issue were co-pending before the PTO.⁷⁶⁷ In this case, the general presumption of patent validity does not apply. In *Environ Products*, the Federal Circuit had held that in a three-way priority contest, between two issued patents and a patent application, all of which had been pending before the PTO at the same time, the parties to the priority contest only needed to prove their claim to original inventorship by a preponderance of the evidence.⁷⁶⁸

The Federal Circuit explained that its holding in *Environ Products* was not binding in this case because the issue there was priority of invention, not correction of inventorship. Furthermore, it did not see a reason to

763. *Id.* at 1363-64, 71 U.S.P.Q.2d (BNA) at 1793.

764. *Id.* at 1364, 71 U.S.P.Q.2d (BNA) at 1794.

765. *Id.*, 71 U.S.P.Q.2d (BNA) at 1795.

766. 215 F.3d 1261, 55 U.S.P.Q.2d (BNA) 1038 (Fed. Cir. 2000).

767. 37 C.F.R. § 1.601 (2005).

768. *Environ Products*, 215 F.3d at 1265, 55 U.S.P.Q.2d at 1041.

extend the holding of *Environ Products* to correction of inventorship cases.

The existence of co-pending applications does throw into question the presumption of validity for the first-filed patent insofar as the presumption involves an issue of timing or priority, namely that the patentee was first to invent. The existence of co-pending applications, however, does not undermine to the same degree the presumption that each of the groups of inventors listed on the patent applications acted independently.⁷⁶⁹

The Federal Circuit found that the clear and convincing burden of proof as applied to joint inventorship disputes was justified because individuals are prone to “reconstructing” the extent of their contribution to the conception of inventions.⁷⁷⁰ Furthermore, the Federal Circuit opined that, unlike a junior party to an interference proceeding, a person alleging non-joinder would benefit from a lower standard of proof without assuming any related risk. A junior party to an interference, on the other hand, risks its own patent claims if it does not successfully demonstrate priority.⁷⁷¹

Furthermore, plaintiff’s argument assumed that its scientist’s patent application claimed the same subject matter as the claims of the ‘477 patent. In a priority dispute interference, however, the preponderance of the evidence standard does not come into play until it has been adjudicated or conceded by the parties that the competing patents or applications do in fact cover the same subject matter.⁷⁷² The Federal Circuit found this to be an additional reason why it could not treat plaintiff’s inventorship claim as the functional equivalent of the priority determination in an interference proceeding.⁷⁷³ For these reasons the court rejected plaintiff’s argument that it deserved a new trial because the jury instruction should have provided that plaintiff could prove joint inventorship by a preponderance of the evidence.

*Linear Technology Corp. v. Impala Linear Corp.*⁷⁷⁴ presented an appeal from a district court’s grant of summary that an alleged inventor’s claim of joint inventorship was not adequately corroborated.⁷⁷⁵ The Federal Circuit began by noting that a party seeking to correct inventorship must establish that it contributed to the conception of the claimed invention “with more than their own testimony concerning the relevant facts.”⁷⁷⁶ The court explained that an alleged inventor must corroborate its inventorship claim

769. *Aradigm*, 376 F.3d at 1366, 71 U.S.P.Q.2d (BNA) at 1797.

770. *Id.* at 1367, 71 U.S.P.Q.2d (BNA) at 1797.

771. *Id.*, 71 U.S.P.Q.2d (BNA) at 1797-98.

772. *Id.*, 71 U.S.P.Q.2d (BNA) at 1798.

773. *Id.*, 71 U.S.P.Q.2d (BNA) at 1798.

774. 379 F.3d 1311, 72 U.S.P.Q.2d (BNA) 1065 (Fed. Cir. 2004).

775. *Id.* at 1327, 72 U.S.P.Q.2d (BNA) at 1076.

776. *Id.*, 72 U.S.P.Q.2d (BNA) at 1076.

with reliable evidence such as: (1) "records made contemporaneously with the inventive process"; (2) "[c]ircumstantial evidence of an independent nature"; and (3) "oral testimony from someone other than the alleged inventor."⁷⁷⁷ After reviewing the alleged inventor's evidence, the court held that the district court "correctly concluded that no reasonable juror could find that [the] inventorship claim was corroborated."⁷⁷⁸

I. Double Patenting

In *Bristol-Myers Squibb Co. v. Pharmachemie B.V.*,⁷⁷⁹ the issue was whether the exclusive licensee could invoke § 121⁷⁸⁰ as a defense to the argument that the claims of the disputed later patent were invalid for double patenting in light of a related earlier patent.⁷⁸¹ The district court granted summary judgment to the exclusive licensee, holding that the "the divisional application that led to the [later] patent was filed as a result of, and consistent with, the restriction requirement issued in 1973."⁷⁸² On appeal, the Federal Circuit explained that its precedent mandates that § 121 is available as a defense to double patenting only if the application for the later patent "was filed as a result of a restriction requirement and is consonant with the restriction requirement."⁷⁸³ After canvassing the prosecution histories of the earlier and later patents, the Federal Circuit determined that:

There was, to say the least, some confusion at various points as to how the various claims should be sorted out for purposes of restriction. But even though at some points restriction requirements were imposed that were similar to, or even identical to, earlier restriction requirements, each requirement was nevertheless separately imposed with respect to each separate application. The record this does not support the inference that any of the various restriction requirements automatically carried forward,

777. *Id.*, 72 U.S.P.Q.2d (BNA) at 1076.

778. *Id.* at 1329, 72 U.S.P.Q.2d (BNA) at 1077.

779. 361 F.3d 1343, 70 U.S.P.Q.2d (BNA) 1097 (Fed. Cir. 2004).

780. Section 121 provides, in pertinent part, as follows:

If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application.

35 U.S.C. § 121 (2000).

781. *Bristol-Myers Squibb*, 361 F.3d at 1344-45, 70 U.S.P.Q.2d (BNA) at 1097.

782. *Id.* at 1348, 70 U.S.P.Q.2d (BNA) at 1100.

783. *Id.*, 70 U.S.P.Q.2d (BNA) at 1100.

in part or in whole, from one application to the next.⁷⁸⁴

Accordingly, the Federal Circuit vacated the grant of summary judgment and remanded to the district court, explaining that given “the complexity of the factual record . . . [w]hether further analysis of the sequence of applications, restriction requirements, and responses by applicants may reveal other grounds for concluding that the protection of Section 121 should be extended . . . is a matter for the district court to address in the first instance.”⁷⁸⁵

In dissent, Judge Newman wrote that regardless of whether the patent applicants complied with the restriction requirements by various applicants, “the issuance of these actions was entirely discretionary with the Commissioner.”⁷⁸⁶ The dissent reasoned that because no dispute existed “that the applicant made the required election for each restriction requirement, and the divisional and continuing applications at issue were accepted by the examiner as properly filed . . . [Section 121] protected the patentee from citation of the earlier patent against the later one.”⁷⁸⁷ The dissent further noted that if the majority’s opinion

require[s] that the minutiae of the various discretionary restriction requirements and the acceptance by the examiners of the applicant’s compliances with those requirements are subject to appellate review, the standard of review is that of the Administrative Procedure Act, not the *de novo* untangling of internal procedures for which my colleagues remand to the district court.⁷⁸⁸

III. INFRINGEMENT

A. Claim Construction

The Federal Circuit’s claim construction landscape during the early part of 2004 was marred by a string of 2-1 decisions. The underlying tension between different claim construction methodologies espoused by different camps of judges came to a head when the Federal Circuit decided to hear en banc the panel’s decision in *Phillips v. AWH Corp.*⁷⁸⁹ This section initially discusses the panel decision in *Phillips* and the subsequent order to

784. *Id.* at 1349, 70 U.S.P.Q.2d (BNA) at 1101.

785. *Id.* at 1350, 70 U.S.P.Q.2d (BNA) at 1101. The court’s remand for further proceedings is curious given the prior decisions holding that, similar to claim construction, double patenting is a question of law subject to *de novo* review. *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 972, 58 U.S.P.Q.2d (BNA) 1869, 1881 (Fed. Cir. 2001) (“[T]he double patenting issue in this case is solely a matter of law.”).

786. *Bristol-Myers Squibb*, 361 F.3d at 1350, 70 U.S.P.Q.2d (BNA) at 1102 (Newman, J., dissenting).

787. *Id.*, 70 U.S.P.Q.2d (BNA) at 1102 (Newman, J., dissenting).

788. *Id.* at 1350-51, 70 U.S.P.Q.2d (BNA) at 1102 (Newman, J., dissenting).

789. 376 F.3d 1382, 71 U.S.P.Q.2d (BNA) 1765 (Fed. Cir. 2004).

hear the case en banc. The section next offers the authors' modest proposal for a claim construction methodology. Given that the Federal Circuit's claim construction jurisprudence does not lend itself to easy classification, the remaining parts of this section groups cases according to the following criteria: (1) cases adopting a broad construction; (2) cases adopting a narrow construction; (3) cases in which the inventors used a "coined term"; (4) means-plus-function limitation cases; and (5) preamble limitations. Finally, this section discusses miscellaneous issues involving claim construction and discuss the various tools that the court employed in 2004 to arrive at its constructions.

1. *Phillips v. AWH Corporation: The panel decision and the en banc order*

Phillips involved the proper construction of the term "baffles" in claims directed to modular wall panels suitable for impact resistance.⁷⁹⁰ At the district court, even though both parties stipulated that "baffles" should be construed as a "means for obstructing, impeding, or checking the flow of something," the district court determined that "the term was ambiguous because 'it does not identify the substance or force the flow of which it is intended to check, impede, or obstruct.'"⁷⁹¹ The district court then reasoned that "the claim language 'does not adequately describe the function of the structure,'" and therefore concluded that "the claim contains means-plus-function language subject to construction under 35 U.S.C. § 112, ¶ 6."⁷⁹² Looking to the specification, the district court held that "every textual reference in the Specification and its diagrams show baffle deployment at an angle other than 90 to the wall faces."⁷⁹³

On appeal, though holding that the district court erred in treating the term "baffle" as a means-plus-function limitation,⁷⁹⁴ the Federal Circuit explained that its "analysis does not end there . . . we must still read the claims in view of the specification and determine whether the patentee has otherwise limited the scope of the claims."⁷⁹⁵ The Federal Circuit started its analysis by noting that "[t]he ordinary meaning of a term must be considered in view of the intrinsic evidence [such as] the claims, the

790. 363 F.3d 1207, 1209-10, 70 U.S.P.Q.2d (BNA) 1417, 1419 (Fed. Cir. 2004).

791. *Id.* at 1210, 70 U.S.P.Q.2d (BNA) at 1419 (quoting *Phillips v. AWH Corp.*, No. 97-MK-212, slip op. at 23 (D. Colo. Nov. 22, 2002)).

792. *Id.*, 70 U.S.P.Q.2d (BNA) at 1418. "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. § 112 (2000)

793. *Phillips*, 363 F.3d at 1210, 70 U.S.P.Q.2d (BNA) at 1418.

794. *Id.* at 1212, 70 U.S.P.Q.2d (BNA) at 1420.

795. *Id.* at 1212-13, 70 U.S.P.Q.2d (BNA) at 1420.

specification, and the prosecution history,”⁷⁹⁶ and observing that a “claim term will not carry its ordinary meaning if the intrinsic evidence shows that the patentee distinguished the term from the prior art on the basis of a particular embodiment, expressly disclaimed subject matter, or described a particular embodiment as important to the invention.”⁷⁹⁷

In examining the intrinsic evidence, the Federal Circuit observed that the “specification is rife with references to impact resistance, especially against projectiles such as bullets and bombs,”⁷⁹⁸ and referred to the specification’s “Disclosure of the Invention” section that stated that baffles are “disposed at such angles that bullets which might penetrate the outer steel panels are deflected.”⁷⁹⁹ The Federal Circuit then explained that:

[T]he specification addresses and distinguishes the prior art, asserting that “[i]n secured facilities, and protective barriers, it is feasible that projectiles may be encountered, such as bullets from high powered guns or bomb fragments.” It continues by stating that “[t]here have not been effective ways of dealing with these powerful impact weapons with inexpensive housing in the prior art.”⁸⁰⁰

Focusing on the figures and diagrams in the asserted patent, the Federal Circuit again emphasized that the patent’s objective was to prevent objects from penetrating through walls because the specification taught that “if bullets ‘were to penetrate the outer steel shell wall, the baffles are disposed at angles which tend to deflect the bullets.’”⁸⁰¹ The Federal Circuit thus held:

From the specification’s explicit descriptions of the invention, we conclude that the patentee regarded his invention as panels providing impact or projectile resistance and that the baffles must be oriented at angles other than 90. Baffles directed at 90 cannot deflect projectiles as described in the [asserted] patent, and in any event, are disclosed in the prior art.⁸⁰²

Addressing the dissent’s argument that its construction was limiting claims to the preferred embodiment, the majority explained that “[i]nspection of the patent shows that baffles angled at other than 90° is the only embodiment disclosed in the patent; its is the invention. It is impossible to derive anything else from the specification.”⁸⁰³

796. *Id.* at 1213, 70 U.S.P.Q.2d (BNA) at 1420.

797. *Id.*, 70 U.S.P.Q.2d (BNA) at 1420 (quoting *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366-67, 62 U.S.P.Q.2d (BNA) 1658, 1662-63 (Fed. Cir. 2002)).

798. *Id.*, 70 U.S.P.Q.2d (BNA) at 1420.

799. *Id.*, 70 U.S.P.Q.2d (BNA) at 1421.

800. *Id.*, 70 U.S.P.Q.2d (BNA) at 1421 (quoting U.S. Patent No. 4,677,798 (issued July 7, 1987)) (citations omitted).

801. *Id.*, 70 U.S.P.Q.2d (BNA) at 1421 (quoting U.S. Patent No. 4,677,798).

802. *Id.*, 70 U.S.P.Q.2d (BNA) at 1421.

803. *Id.* at 1214, 70 U.S.P.Q.2d (BNA) at 1421.

In dissent, Judge Dyk wrote that the majority's opinion "effectively limits the claims to the preferred embodiment, contrary to our recent decision in *Liebel-Flarsheim Co. v. Medrad, Inc.* . . . and numerous other decisions of this court. In doing so, the majority decision attempts to work a major and unfortunate change in our recent claim construction jurisprudence."⁸⁰⁴ The dissent explained that the majority's decision imposed an "additional structural limitation upon the patentee's preferred embodiments that limits baffles to structures 'oriented at angles other than 90°.' This is contrary to the plain meaning, and there is no suggestion that the patentee, acting as his own lexicographer, gave a special meaning to the term baffles."⁸⁰⁵

Addressing the three grounds proffered by the majority opinion, the dissent found that "[n]one is convincing."⁸⁰⁶ With regard to the majority's position that baffles angled at other than 90° was only embodiment disclosed, the dissent noted that the court's jurisprudence has "expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to the embodiment."⁸⁰⁷ With regard to the majority's reasoning that the object of the invention required baffles orientated at angles other than 90°, the dissent reasoned that the specification "merely identifies impact resistance as one of several objectives of the invention."⁸⁰⁸ Again relying on *Liebel-Flarshiem* the dissent noted that the "fact that a patent asserts that an invention achieves several objectives does not require that each of the claims be construed as limited to structures that are capable of achieving all of the objectives."⁸⁰⁹ Finally, with regard to the majority's position that any broader construction of the term "baffles" would read on the prior art, the dissent explained that "[t]he 'axiom' that claims should be construed to preserve validity is not an invitation to narrowly construe ambiguous claim language contrary to its plain meaning."⁸¹⁰

Four months after the panel opinion, the Federal Circuit "determined to

804. *Id.* at 1216, 70 U.S.P.Q.2d (BNA) at 1423 (Dyk, J., dissenting); *see also* *Leibel Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 69 U.S.P.Q.2d (BNA) 1801 (Fed. Cir. 2004) (reversing the district court's order granting summary judgment of noninfringement and rejecting the contention that a patent must be construed as being limited to one embodiment if the patent only describes a single embodiment).

805. *Phillips*, 363 F.3d at 1217, 70 U.S.P.Q.2d (BNA) at 1423 (Dyk, J., dissenting) (quoting *Phillips*, 363 F.3d at 1213, 70 U.S.P.Q.2d (BNA) at 1421 (Lourie, J., writing for the majority)).

806. *Id.*, 70 U.S.P.Q.2d (BNA) at 1424 (Dyk, J., dissenting).

807. *Id.*, 70 U.S.P.Q.2d (BNA) at 1424 (Dyk, J., dissenting) (quoting *Liebel-Flarsheim*, 358 F.3d at 906, 69 U.S.P.Q.2d (BNA) at 1807).

808. *Id.*, 70 U.S.P.Q.2d (BNA) at 1424 (Dyk, J., dissenting).

809. *Id.* at 1217-18, 70 U.S.P.Q.2d (BNA) at 1424 (Dyk, J., dissenting) (quoting *Liebel-Flarsheim*, 358 F.3d at 908, 69 U.S.P.Q.2d (BNA) at 1809).

810. *Id.* at 1218, 70 U.S.P.Q.2d (BNA) at 1425 (Dyk, J., dissenting).

hear th[e] case en banc in order to resolve issues concerning the construction of patent claims raised by the now-vacated panel majority and dissenting opinions.”⁸¹¹ In so doing, the court set forth seven questions for which it invited submission of additional briefs from the parties as well as amicus curae:

Is the public notice function of patent claims better served by referencing primarily to technical and general purpose dictionaries and similar sources to interpret a claim term or by looking primarily to the patentee’s use of the term in the specification? If both sources are to be consulted, in what order?

If dictionaries should serve as the primary source for claim interpretation, should the specification limit the full scope of claim language (as defined by the dictionaries) only when the patentee has acted as his own lexicographer or when the specification reflects a clear disclaimer of claim scope? If so, what language in the specification will satisfy those conditions? What use should be made of general as opposed to technical dictionaries? How does the concept of ordinary meaning apply if there are multiple dictionary definitions of the same term? If the dictionary provides multiple potentially applicable definitions for a term, is it appropriate to look to the specification to determine what definition or definitions should apply?

If the primary source for claim construction should be the specification, what use should be made of dictionaries? Should the range of the ordinary meaning of claim language be limited to the scope of the invention disclosed in the specification, for example, when only a single embodiment is disclosed and no other indications of breadth are disclosed?

Instead of viewing the claim construction methodologies in the majority and dissent of the now-vacated panel decision as alternative, conflicting approaches, should the two approaches be treated as complementary methodologies such that there is a dual restriction on claim scope, and a patentee must satisfy both limiting methodologies in order to establish the claim coverage it seeks?

When, if ever, should claim language be narrowly construed for the sole purpose of avoiding invalidity under, *e.g.*, 35 U.S.C. §§ 102, 103, and 112?

What role should prosecution history and expert testimony by one of ordinary skill in the art play in determining the meaning of the disputed claim terms?

Consistent with the Supreme Court’s decision in *Markman v. Westview Instruments, Inc.* . . . and our *en banc* decision in *Cybor Corp. v. FAS*

811. *Phillips v. AWH Corp.*, 376 F.3d 1382, 1382, 71 U.S.P.Q.2d (BNA) 1765, 1766 (Fed. Cir. 2004).

Technologies, Inc. . . . is it appropriate for this court to accord any deference to any aspect of trial court claim construction rulings? If so, on what aspects, in what circumstances, and to what extent?⁸¹²

Judge Rader concurred with decision to hear the case en banc and suggested that the court receive further commentary on an additional question:

Is claim construction amenable to resolution by resort to strictly algorithmic rules, e.g., specification first, dictionaries first, etc.? Or is claim construction better achieved by using the order or tools relevant in each case to discern the meaning of terms according to the understanding of one of ordinary skill in the art at the time of the invention, thus entrusting trial courts to interpret claims as a contract or statute?⁸¹³

Chief Judge Mayer, however, dissented from the court's decision to hear the case en banc,⁸¹⁴ and in an opinion echoing his earlier dissents in *Markman v. Westview Instruments, Inc.*⁸¹⁵ and *Cybor Corp. v. FAS Technologies, Inc.*,⁸¹⁶ the Chief Judge explained:

Until the court is willing to reconsider its holdings in [*Markman*] . . . and [*Cybor Corp.*] . . . that claim construction is a pure question of law subject to *de novo* review in this court, any attempt to refine the process is futile. Nearly a decade of confusion has resulted from the fiction that claim construction is a matter of law, when it is obvious that it depends on underlying factual determinations which, like all factual questions if disputed, are the province of the trial court, reviewable on appeal for clear error. To pretend otherwise inspires cynicism.⁸¹⁷

While the Federal Circuit's decision to address these seven questions en banc is ambitious in scope and appears a good idea in the abstract, *Phillips* may ultimately present a situation in which the initial en banc order over-promises and the ultimate resolution, if any, under-delivers in terms of resolving the Federal Circuit's fundamental conflicts regarding the mechanics of claim construction. This is especially true because, as explained above, many of the questions on which the court desired briefing were never even raised by the parties in *Phillips*, much less disputed.⁸¹⁸ Indeed, at the district court, the parties stipulated to the construction of the

812. *Id.* at 1383, 71 U.S.P.Q.2d (BNA) at 1766.

813. *Id.* at 1384, 71 U.S.P.Q.2d (BNA) at 1767 (Rader, J., concurring).

814. *Id.*, 71 U.S.P.Q.2d (BNA) at 1767 (Mayer, C.J., dissenting).

815. 52 F.3d 967, 989, 34 U.S.P.Q.2d (BNA) 1321, 1337 (Fed. Cir. 1995) (en banc) (Mayer, J., concurring), *aff'd*, 517 U.S. 370 (1996).

816. 138 F.3d 1448, 1463, 46 U.S.P.Q.2d (BNA) 1169, 1181 (Fed. Cir. 1998) (Mayer, J., concurring).

817. *Phillips*, 376 F.3d at 1384, 71 U.S.P.Q.2d (BNA) at 1767.

818. For example, the role of prosecution history, expert testimony, dictionaries, and deference to district courts in claim construction either played no role in the panel and district court's opinion or received only passing reference.

term “baffles” that ultimately gave rise to the en banc hearing.⁸¹⁹

2. *A modest proposal for a claim construction methodology*

Chief Judge Mayer dissented from the order granting an en banc rehearing in *Phillips*, arguing that “[n]early a decade of confusion has resulted from the fiction that claim construction is a pure question of law” and that a “shuffling” of the Court’s precedent based on that “fiction” would not resolve that confusion.⁸²⁰ We agree with Chief Judge Mayer’s view of the Federal Circuit’s precedent and propose a solution.

It is a staple proposition that claim construction begins with the words of the claims and that claim terms are, in the first instance, to be given their ordinary meanings as they are understood by persons of skill in the art at the time of invention.⁸²¹ The next step, after ascertaining the ordinary meaning, is to review the intrinsic evidence to determine whether the disputed claim terms should receive meanings that differ from the ordinary meanings of the words. We believe that the problem lies in treating the first step as a pure question of law.

The Court has struggled to create a purely *legal* claim construction analysis because the determination of the “ordinary” meaning of a claim term is not a question of law. For example, determining what the term “mosfet” meant to an electrical engineer in 1995 simply is not something that may be determined as a question of law. Rather, it is a question of fact that requires evidence necessary to identify the characteristics of a person of ordinary skill and to determine how such a person understood the term “mosfet” at the relevant time. Various Federal Circuit decisions have vacillated between using specification⁸²² and dictionaries from the relevant time⁸²³ because the Federal Circuit’s jurisprudence is tethered to the idea of claim construction as a pure question of law. But it is not really the role of the specification to define terms as they would ordinarily be understood by a person of skill. Instead the specification functions to teach the new

819. *Phillips v. AWH Corp.*, 363 F.3d 1207, 1210, 70 U.S.P.Q.2d (BNA) 1417, 1419 (discussing *Phillips v. AWH Corp.*, No. 97-MK-212, 2002 U.S. Dist. LEXIS 27298, at *32).

820. *Phillips*, 376 F.3d at 1384, 71 U.S.P.Q.2d (BNA) at 1767 (Mayer, C.J., dissenting).

821. Nathaniel Durrance, *How The Doctrine Of Equivalents May Save Claim Construction*, 33 AIPLA Q. J. 73, 94 (2005) (explaining that the plain meaning of a claim must be determined first and without reference to the offending device).

822. *See, e.g., Nazomi Communications, Inc. v. Arm Holdings, PLC*, 403 F.3d 1364, 74 U.S.P.Q.2d (BNA) 1458 (Fed. Cir. 2005) (“In most cases, the best source for discerning this proper context is the patent specification, wherein the patent applicant describes the invention.”).

823. *See, e.g., Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1309, 51 U.S.P.Q.2d (BNA) 1161, 1168 (Fed. Cir. 1999) (“[I]t is entirely appropriate, perhaps even preferable, for a court to consult trustworthy extrinsic evidence to ensure that the claim construction it is tending to from the patent file is not inconsistent with clearly expressed, plainly apposite, and widely held understandings in the pertinent technical field.”).

invention and to define terms, when necessary, that would not be understood by the person of ordinary skill (at least not understood in the way intended by the inventor). Dictionaries are a more apt tool for determining the ordinary meaning of a term at a relevant time, but they are only one such resource and they often provide inconsistent or conflicting meanings, thereby requiring the court to choose amongst them without making a finding of fact.

A better methodology would be to acknowledge that step one of the claim construction process—ascertaining the ordinary meaning—is a question of fact and allow trial courts to review all relevant evidence, such as dictionaries, expert testimony, and treatises, and make a factual finding as to the ordinary meaning of a disputed term. That finding would be given deference by the court and would serve as a default. The next step in the process, the review of the patent, would remain a question of law reviewed *de novo* by the Federal Circuit Court of Appeals. The trial court would review the intrinsic evidence to determine if the patentee used a disputed term in a way that is inconsistent with the previously ascertained ordinary meaning. This is a question of law because it only requires the court to analyze legal documents (the patent and the prosecution history) to determine the legal significance of the words chosen by the patentee as well as legal significance of the public record in the patent office. For example, the trial court would review the claims to determine if the doctrine of claim differentiation indicates that a particular construction is appropriate. Likewise, the court would review the specification to see if the patentee defined the term (explicitly or implicitly) or if the described purpose of the invention indicates that a particular construction is appropriate or if the patentee indicated that a described element was particularly important to the patented invention. The court would review the prosecution history to see if the patentee or the PTO indicated that a particular term should be given a construction different than the ordinary meaning. This type of analysis of legally operative documents is what courts are trained to do. Courts, however, have no training which would allow them to ascertain the ordinary meanings of words, other than through the review of evidence and the assessment of credibility.

We propose, therefore, that the Federal Circuit adopt a process whereby the district court would ascertain the ordinary meanings of disputed terms as a question of fact and review the patent and the prosecution history as a question of law to ascertain if those documents indicate that a term should receive a particular meaning. Where the ordinary meaning and the meaning derived from the intrinsic evidence are different, the meaning derived from the intrinsic evidence would be adopted as long as the court finds that such an intrinsic meaning exists. If the district court does not

conclude that the intrinsic evidence indicates a particular definition for the term, then the ordinary meaning applies.

3. “Broad construction” cases

In *Chef America, Inc. v. Lamb-Weston, Inc.*,⁸²⁴ the Federal Circuit held that a claim reciting the language, “heating the resulting batter coated dough to a temperature in the range of about 400 degrees F to 850 degrees F . . . means what it says” and required the dough itself, not the oven, to be heated to the stated temperature.⁸²⁵ The disputed claims were directed to the process of producing a “light, flaky dough product.” Plaintiff appealed after the lower court granted summary judgment of noninfringement against it. The Federal Circuit affirmed despite the fact that the district court’s claim construction produced a nonsensical result—the dough would be burned to a crisp if it was heated to 400-850°F.⁸²⁶ The Federal Circuit reasoned that nothing in the specification or the prosecution history suggested that the patentees meant “to” to mean “at,” and a court is not required to redraft claims that, under their only reasonable interpretation make no sense, especially where the patentee himself drafted the claims.⁸²⁷

In fact, according to the Federal Circuit, the prosecution history appeared to indicate that plaintiff intended to use “to” instead of “at,” implying that the dough itself should obtain the specified temperature range rather than the oven in which it would be heated. The temperature range language was added to the claims in response to the examiner’s rejection of them for failing to satisfy the enablement requirement of § 112.⁸²⁸ The original application contained another claim as well as a description in the specification that employed the word “to” to relate the concept of heating dough to the stated temperature range, while in an example, the word “at” took the place of “to.” Thus, the Federal Circuit reasoned that the patentees had a choice between using “to” or “at” and consciously chose “to” when it amended the claim.⁸²⁹

Plaintiff argued that the district court was wrong because it did not construe the claim terms as one of ordinary skill in the art would do. Plaintiff’s position rested on a declaration of its baking expert, in which the expert stated that he would not interpret the claims to require the dough itself to be heated to 450 - 850°F because the resulting product would be “unusable.” The Federal Circuit was not persuaded, explaining that the declaration lacked any explanation of how “to” would be interpreted to

824. 358 F. 3d 1371, 69 U.S.P.Q.2d (BNA) 1857 (Fed. Cir. 2004).

825. *Id.* at 1372, 69 U.S.P.Q.2d (BNA) at 1858.

826. *Id.* at 1373, 69 U.S.P.Q.2d (BNA) at 1859.

827. *Id.* at 1374, 69 U.S.P.Q.2d (BNA) at 1860.

828. *Id.*, 69 U.S.P.Q.2d (BNA) at 1860.

829. *Id.* at 1375, 69 U.S.P.Q. (BNA) at 1860.

mean “at” in the art and thus restated the argument to rewrite the claim simply because the paternal prices would not perform the intended function, which it had already rejected.⁸³⁰

In *Housey Pharmaceuticals, Inc. v. Astrazeneca UK Ltd.*,⁸³¹ plaintiff appealed a district court’s construction of several terms in four of its patents directed to methods for screening substances for protein “inhibitors and activators.” A representative claim included one of the disputed terms, “inhibitor or activator of a protein,” in its preamble as follows: “A method of determining whether a substance is an *inhibitor or activator of a protein* whose production by a cell evokes a responsive change in a phenotypic characteristic other than the level of said protein in said cell per se.”⁸³² The claimed method used two cell lines, one which produced more of the protein of interest and that exhibited a greater phenotypic response to such protein than the other. The district court construed the term “inhibitor or activator of a protein” to mean “a substance that has a greater effect on the phenotype of cells that express the protein of interest at a higher level than on the phenotype of cells that express the protein of interest at a lower level or not at all.”⁸³³ Under this construction, plaintiff stipulated that all four of its patents were invalid and noninfringed. On appeal, however, plaintiff argued that the term “inhibitors or activators” of proteins should have been limited to substances that directly bind to the target protein; the district court’s construction would cover substances that operated to achieve the recited result by both direct and indirect means.

The Federal Circuit affirmed the district court’s broader construction for several reasons, including its finding that the specification expressly defined “inhibitor or activator of a protein” as a substance that yields a positive response to the claimed method, encompassing substances that do not directly bind to the protein of interest.⁸³⁴ Plaintiff attempted to argue that a narrower construction was required under *Athletic Alternatives, Inc. v. Prince Manufacturing, Inc.*,⁸³⁵ which, plaintiff asserted stood for the proposition that the notice function of patent law requires that the narrower meaning prevails in the event of a tie between a broader and narrower meaning. Plaintiff also relied on *Rhine v. Casio, Inc.*,⁸³⁶ which stated that

830. *Id.*, 69 U.S.P.Q. (BNA) at 1860.

831. 366 F.3d 1348, 70 U.S.P.Q.2d (BNA) 1641 (Fed. Cir. 2004).

832. *Id.* at 1350, 70 U.S.P.Q.2d (BNA) at 1642.

833. *Id.* at 1351, 70 U.S.P.Q.2d (BNA) at 1643 (internal quotations omitted).

834. *Id.* at 1352, 70 U.S.P.Q.2d (BNA) at 1644.

835. 73 F.3d 1573, 1581, 37 U.S.P.Q.2d (BNA) 1365, 1372 (Fed. Cir. 1996) (“Where there is an equal choice between a broader and a narrower meaning of a claim, and there is an enabling disclosure that indicates that the applicant is at least entitled to a claim having the narrower meaning, we consider the notice function of the claim to be best served by adopting the narrower meaning.”).

836. 183 F.3d 1342, 51 U.S.P.Q.2d (BNA) 1377 (Fed. Cir. 1999).

“[c]laims should be so construed, if possible, as to sustain their validity.”⁸³⁷

The Federal Circuit found neither of plaintiff’s attempts to invoke canons of construction to support its limited meaning to be persuasive. First, it found that plaintiff misinterpreted *Athletic Alternatives*, characterizing that case as “unusual” and not on point because in that case the patent applicant had made two “*contradictory and irreconcilable* affirmative representations of the contested limitation,”⁸³⁸ and for that reason the court held that the narrower definition should trump the broader one. As for plaintiff’s reliance on *Rhine*, the Federal Circuit said that neither it nor the district court reviewed validity, and therefore plaintiff’s “stipulation of invalidity alone is insufficient to invoke this canon.”⁸³⁹ The Federal Circuit also determined that it was only required to turn to a construction that preserves validity if, after applying “all the available tools of claim construction . . . the claim is still ambiguous.”⁸⁴⁰

In *Fuji Photo Film Co. V. International Trade Commission*,⁸⁴¹ Fuji sought enforcement, modification, and clarification of the International Trade Commission’s (“ITC”) previously issued cease-and-desist and general exclusion orders directed to imported disposable 35-millimeter film cameras that allegedly infringed Fuji’s utility and design patents. The ITC adopted the orders of an Administrative Law Judge (“ALJ”) to whom the case was assigned and Fuji appealed them. Specifically, Fuji appealed the constructions of claims in four of its patents: the ‘168 patent, the ‘087 patent, the ‘495 patent, and the ‘649 patent.

Fuji first asserted error in the ITC’s construction of Claim 1 of Fuji’s ‘168 patent, which contained a limitation directed to the front cover section of a camera. The limitation read:

[A] front cover section which . . . closes said open front of said main case section to cover the majority of said *taking lens* and said *shutter means* and said *film transporting means*, said front cover section being formed with at least one opening for partly receiving therein a member of one of *said means*⁸⁴²

Fuji argued that several named parties’ cameras infringed Claim 1 because they all had front covers with openings which received the film transporting means, the shutter means, or the taking lens.⁸⁴³ The ITC disagreed based on its constructions of “opening” and “said means.”

837. *Id.* at 1345, 51 U.S.P.Q.2d (BNA) at 1379 (internal quotations omitted).

838. *Housey Pharms.*, 366 F.3d at 1356, 70 U.S.P.Q.2d (BNA) at 1647.

839. *Id.*, 70 U.S.P.Q.2d (BNA) at 1647.

840. *Id.*, 70 U.S.P.Q.2d (BNA) at 1647 (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 911, 69 U.S.P.Q.2d (BNA) 1801, 1811 (Fed. Cir. 2004)).

841. 386 F.3d 1095, 72 U.S.P.Q.2d (BNA) 1769 (Fed. Cir. 2004).

842. *Id.* at 1098, 72 U.S.P.Q.2d (BNA) at 1771.

843. *Id.*, 72 U.S.P.Q.2d (BNA) at 1771.

The ITC construed “opening” to mean “hole, breach, or aperture.” Fuji argued that the term should include “[a]n open space serving as a passage or gap,” or “an unobstructed or unoccupied space or place.”⁸⁴⁴ The Federal Circuit agreed with the ITC’s construction, holding that the term “opening” was used throughout the specification to refer to perforations in the surface covering the body of a disposable camera.⁸⁴⁵ Fuji argued that “opening” must be interpreted to include an open space because the specification stated that the lens hole in the front cover was defined by a “circular boss,” that the circular boss consists of a hollow bulge in the front cover section, and that the hollow bulge is “for receiving therein the taking lens.”⁸⁴⁶ The Federal Circuit dismissed this argument because the sentence on which Fuji relied “significantly” did not refer to the circular boss as an “opening.” Thus, the Federal Circuit concluded the sentence did not support Fuji’s argument at all.

The ITC construed “said means” to include the “shutter means” and the “film transporting means,” but not the “taking lens.”⁸⁴⁷ The ITC based its decision on the fact that “taking lens” was not denominated as a “means” in the claim. Fuji disputed this construction, pointing out that other parts of the patent referred to the taking lens as a “means” and discloses cameras in which the taking lens is received by a hole in the camera’s front cover. The Federal Circuit found the plain language of the claim to be dispositive. Because the word “means” was used in reference to two of the three components set forth in the “front cover section” limitation but not the third, and because the same distinction existed in the preamble to the claims, which referred to a “taking lens, shutter means, and film transporting means,” the ITC’s construction was strongly supported.⁸⁴⁸ The Federal Circuit distinguished Fuji’s construction, “which requires that the word ‘means’ be read into a portion of the claim where it is conspicuously absent.”⁸⁴⁹ Furthermore, the Federal Circuit found that the specification did not require a construction different from that which it ascertained from the plain meaning of the claims. Rather, in every embodiment described by the patent, the lens was never the sole element that was partly received by an opening in the camera cover. Therefore, the claim as construed was not at odds with the specification and did not produce a nonsensical result.⁸⁵⁰

The Federal Circuit also rejected Fuji’s argument that the omission of the

844. *Id.*, 72 U.S.P.Q.2d (BNA) at 1771.

845. *Id.*, 72 U.S.P.Q.2d (BNA) at 1771.

846. *Id.*, 72 U.S.P.Q.2d (BNA) at 1771.

847. *Id.* at 1099, 72 U.S.P.Q.2d (BNA) at 1772.

848. *Id.*, 72 U.S.P.Q.2d (BNA) at 1772.

849. *Id.*, 72 U.S.P.Q.2d (BNA) at 1772.

850. *Id.* at 1100, 72 U.S.P.Q.2d (BNA) at 1772.

word “means” after “taking lens” was an inadvertent error. During prosecution, the examiner had made clear that he understood “said means” to refer to two, not three, means when he stated that “said means” “referr[ed] back to the previous two means.”⁸⁵¹ The applicant never disputed this understanding. Therefore, although it explained that “caution must be used in attaching weight to an applicant’s silence in response to an examiner’s statement about claim scope,”⁸⁵² the Federal Circuit characterized the applicant’s failure to correct the examiner’s understanding as well as its failure to correct the claim by amendment or other measure as supporting its decision that the omission of “means” was not inadvertent.⁸⁵³

Fuji argued that because claims depending on Claim 1 referred to “said taking lens means,” and because the phrase “taking lens means” was used twice in the specification, “taking lens” in Claim 1 should be construed as “taking lens means.” The Federal Circuit again disagreed with Fuji, reasoning that although “taking lens means” was used twice in the specification, “taking lens” without the word “means” was used thirteen times. The Federal Circuit thus concluded that there was “no basis for assuming that the use of the term ‘taking lens’ without the term ‘means’ was simply a one-time departure from a contrary usage employed throughout the patent.”⁸⁵⁴ The fact that the “Summary of Invention” section employed the term “taking lens means” and stated that the front cover of the camera has “at least one opening for partially receiving therein a member of at least one of the means” made no difference, as the “Background of the Invention” section referred to the “present invention” as having “a taking lens, a photographic transporting means, [and] an exposure means.”⁸⁵⁵ Furthermore, the Federal Circuit concluded that the inconsistency between Claim 1’s use of “taking lens” and the dependent claims’ use of “taking lens means” could have just as easily been resolved by deleting “means” in the dependent claims as inserting “means” into Claim 1.⁸⁵⁶

851. *Id.*, 72 U.S.P.Q.2d (BNA) at 1772-73.

852. *Id.*, 72 U.S.P.Q.2d (BNA) at 1773.

853. *Id.*, 72 U.S.P.Q.2d (BNA) at 1773. Noting that Fuji’s argument, if successful, would broaden the scope of the claims, the court recited the general rule that “as between the patentee who had a clear opportunity to negotiate broader claims but did not do so, and the public at large, it is the patentee who must bear the cost of its failure to seek protection for particular subject matter.” *Id.*, 72 U.S.P.Q.2d (BNA) at 1773 (internal quotations omitted).

854. *Id.* at 1101, 72 U.S.P.Q.2d (BNA) at 1773.

855. *Id.*, 72 U.S.P.Q.2d (BNA) at 1773.

856. *Id.*, 72 U.S.P.Q.2d (BNA) at 1773. The court also rejected Fuji’s argument that the court’s constructions conflicted with the claim construction adopted in the original investigation of the case. The construction adopted originally was the product of a stipulation made by one of the respondents in the prior case. Because the present case

The Federal Circuit turned next to Fuji's arguments with respect to the construction of the '649 patent. Claim 1 of the '649 patent recited a method for assembling a disposable camera consisting of three essential steps: winding a film taken from a light tight container in a darkroom, loading the film into the camera, and affixing the back cover of the camera.⁸⁵⁷ Although the words "in a darkroom" appeared only in the first of the three steps, the ITC argued that "in a darkroom" should be read into the other two steps as well. It found support for this construction in the specification, in which all embodiments describe the three steps being performed in a darkroom. The Federal Circuit determined that the inclusion of "in a darkroom" in the first step and its omission from other two steps provided strong textual support for Fuji's argument that the second steps are not required to be performed in a darkroom. The Federal Circuit held that the ITC's statement that "there is no suggestion in the '649 patent that the steps 2 and 3 could be performed outside a darkroom . . . ha[d] it backwards."⁸⁵⁸ Rather, "the proper question was whether the specification indicated that the second and third steps cannot be performed outside a darkroom, and thus must be interpreted more narrowly than its language appears to require."⁸⁵⁹ For all statements in the specification which the ITC said supported its construction, the context indicated that the statement was describing a preferred embodiment, not the invention as a whole.

The Federal Circuit also disposed of the theory that the second and third steps must occur in a darkroom because it would be difficult to successfully perform them outside of a darkroom—Fuji's expert testified that the steps could be performed outside of a darkroom so long as the film was protected from light during the processes of loading the camera and securing the back cover.⁸⁶⁰ Furthermore, although the specification referred to the need to avoid exposing the film to light during these steps, the Federal Circuit found nothing in the specification that said the only method of light avoidance is performance of the steps in a darkroom.

In *Bilstad v. Wakalopulos*,⁸⁶¹ Bilstad appealed from a Board of Patent Appeals and Interference judgment in favor of Wakalopulos that found Bilstad's patent application lacked a sufficient written description under § 112.⁸⁶² Bilstad provoked an interference by copying claims of

affected different respondents, none of which were parties to the prior stipulation, the original constructions were not binding. *Id.*, 72 U.S.P.Q.2d (BNA) at 1773-74.

857. *Id.* at 1104, 72 U.S.P.Q.2d (BNA) at 1774-75.

858. *Id.* at 1105, 72 U.S.P.Q.2d (BNA) at 1776.

859. *Id.*, 72 U.S.P.Q.2d (BNA) at 1776.

860. *Id.*, 72 U.S.P.Q.2d (BNA) 1777.

861. 386 F.3d 1116, 72 U.S.P.Q.2d (BNA) 1785 (Fed. Cir. 2004).

862. *Id.* at 1118, 72 U.S.P.Q.2d (BNA) at 1786 (affirming the Board's decision but

Wakalopulos's patent into its patent application. The technology to which the application and patent were directed was an apparatus for sterilizing three-dimensional objects using ionizing radiation without hurting the objects. The relevant portions of the interference count read as follows: "A sterilization apparatus comprising . . . an electron beam tube . . . and a *moveable member manipulating objects in a plurality of directions within the reactive volume* wherein the manipulated objects are sterilized."⁸⁶³ During the interference proceedings, Wakalopulos filed a motion seeking judgment that Bilstad's claim, designated to the interference count was not patentable because it lacked an adequate written description under § 112 for the claim limitation "a moveable member manipulating objects in a plurality of directions within the reactive volume."⁸⁶⁴ After conducting a hearing on Wakalopulos's motion, the Board granted judgment in favor of Wakalopulos. The Board focused on the term "plurality," which it construed to connote an indefinite numerical range from two to infinity. In contrast to the wide range denoted by "plurality" in the count, the written description of Bilstad's application described manipulation in only a "small number of directions."⁸⁶⁵

Bilstad argued on appeal that the Board incorrectly construed plurality. Specifically, it contended that the Board contradicted Federal Circuit precedent by combining dictionary definitions to achieve a range of two to infinity.⁸⁶⁶ The Federal Circuit saw no error in the Board's construction of plurality. Confronted with opposing arguments from the parties as to the meaning of the term, the court found that the Board looked to a dictionary to ascertain the ordinary meaning of plurality, then looked to the written description for context in ascertaining the appropriate meaning of "plurality" found in the dictionary. It then properly determined that the dictionary definitions, Bilstad's proffered definition, and Wakalopulos's proffered definition were all consistent with the written description and construed the term to encompass all of the definitions. The Federal Circuit approved of these steps taken by the Board to derive the correct construction of "plurality," citing precedent stating that "if more than one dictionary definition is consistent with the use of the words in the intrinsic record, the claim terms may be construed to encompass all consistent

remanding the case to the Board in order to apply the correct standard).

863. *Id.* at 1119, 72 U.S.P.Q.2d (BNA) at 1787.

864. *Id.*, 72 U.S.P.Q.2d (BNA) at 1787; *see also* 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, and shall set forth the best mode contemplated by the inventor of carrying out his invention.").

865. *Bilstad*, 386 F.3d at 1122, 72 U.S.P.Q.2d (BNA) at 1789-90.

866. *Id.*, 72 U.S.P.Q.2d (BNA) at 1790.

meanings.”⁸⁶⁷ The fact that the Board’s definition did “little more than incorporate the several distinct [dictionary] definitions into a single one covering the entire scope of ‘plurality’” was not problematic because “the Board did not change the scope of the term or alter the ordinary meanings in any significant way.”⁸⁶⁸

In *Glaxo Group Ltd. v. Apotex, Inc.*,⁸⁶⁹ defendant asserted error in the district court’s construction of “pure” and “having a purity of at least 95%” in plaintiff’s claims directed to a pharmaceutical product and a process of manufacturing such product. The district court’s construction of both terms excluded from consideration of purity “excipients.” Thus, plaintiff’s process claim requiring “a highly pure solution of cefuroxime axetil” was construed to cover processes that used a solution that contains excipients in addition to cefuroxime axetil, and its product claim requiring “cefuroxime axetil . . . having a purity of at least 95%” was construed to cover formulations of cefuroxime axetil with more than five percent other ingredients.⁸⁷⁰

The Federal Circuit affirmed the district court’s constructions of both terms. It proffered three reasons for its decision. First, the Federal Circuit held that the ordinary meaning of “impurity” included “unwanted reaction products formed during synthesis,”⁸⁷¹ and the specification described the types of molecules that are considered impurities consistently with this ordinary meaning. Because “excipients” are “inactive ingredients that are routinely and purposefully added to the active ingredient to enhance the performance of the active ingredient,”⁸⁷² excipients were excluded from the ordinary meaning of impurity.

Second, the Federal Circuit reasoned that if excipients were considered impurities, then one of the patent claims would have to be construed to exclude a preferred embodiment, in violation of the principle that claims “should rarely, if ever” be construed as such.⁸⁷³ Finally, the Federal Circuit found that a construction that would exclude compositions that contained more than five percent of ingredients other than cefuroxime axetil would conflict with the specification of the product patent, which lists pharmaceutical examples which all contained less than ninety-five percent

867. *Id.*, 72 U.S.P.Q.2d (BNA) at 1790 (quoting *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1300, 67 U.S.P.Q.2d (BNA) 1132, 1137 (Fed. Cir. 2003)). The court also found that the definition of “plurality” attributed to it by the Board was consistent with the disclosure of *Wakalopulos’s* patent. *Id.* at 1122-23, 72 U.S.P.Q.2d (BNA) at 1790.

868. *Bilstad*, 386 F.3d at 1123, 72 U.S.P.Q.2d (BNA) at 1790.

869. 376 F.3d 1339, 71 U.S.P.Q.2d (BNA) 1801 (Fed. Cir. 2004).

870. *Id.* at 1344-45, 71 U.S.P.Q.2d (BNA) at 1804.

871. *Id.* at 1347, 71 U.S.P.Q.2d (BNA) at 1806.

872. *Id.*, 71 U.S.P.Q.2d (BNA) at 1806.

873. *Id.*, 71 U.S.P.Q.2d (BNA) at 1806.

cefuroxime axetil.⁸⁷⁴

In *Mars v. H.J. Heinz Co.*,⁸⁷⁵ plaintiff brought suit for infringement of its patent directed to a “dual-textured pet or animal food product comprising [among other things] a soft inner component of a dual texture pet or animal food product *containing a mixture of lipid and solid ingredients.*”⁸⁷⁶ The first issue on appeal was whether “ingredients” should be construed to mean only starting materials. The Federal Circuit held that the term was not so limited. First, the Federal Circuit found that dictionary definitions indicated that the ordinary meaning of “ingredient” could refer to either starting materials or to the components of a mixture after they have been combined.⁸⁷⁷ The Federal Circuit further looked to the claims themselves that were drawn to “a mixture . . . of ingredients.” The context of the term “ingredients” in the claim “strongly suggests that ‘ingredients’ refers to the components after they have been combined to form that ‘mixture.’”⁸⁷⁸ The Federal Circuit referred to its previous decisions in *PIN/NIP, Inc. v. Platte Chemical Co.*⁸⁷⁹ and *Exxon Chemical Patents, Inc. v. Lubrizol Corp.*,⁸⁸⁰ in which it “equated a composition with a mixture and construed the term ‘composition’ to refer to the claimed ingredients *after* they were joined together.”⁸⁸¹ Finally, the Federal Circuit dismissed defendant’s argument that the examples appear to use the term “ingredients” to refer to starting materials by saying that this was “not a sufficient reason . . . to deviate from the ordinary meaning of the claim language,” and furthermore, the statements cited by defendant did not use the term mixture of ingredients.⁸⁸²

The second issue on appeal was whether the correct construction of “containing a mixture of lipid and solid ingredients” was limited to include mixtures containing only solid and lipid ingredients and exclude mixtures containing ingredients in addition to solid and lipid ingredients.⁸⁸³ The Federal Circuit again held that the term was not as narrow as defendant contended, and cited a general purpose dictionary and the Manual Patent Examining Procedure to show that “containing” is open-ended and does not exclude additional, unnamed ingredients. Furthermore, the parties agreed

874. *Id.*, 71 U.S.P.Q.2d (BNA) at 1806.

875. 377 F.3d 1369, 71 U.S.P.Q.2d (BNA) 1837 (Fed. Cir. 2004).

876. *Id.* at 1372, 71 U.S.P.Q.2d (BNA) at 1839.

877. *Id.* at 1374, 71 U.S.P.Q.2d (BNA) at 1740.

878. *Id.*, 71 U.S.P.Q.2d (BNA) at 1740.

879. 304 F.3d 1235, 1244, 64 U.S.P.Q.2d (BNA) 1344, 1350 (Fed. Cir. 2002).

880. 64 F.3d 1553, 1558, 35 U.S.P.Q.2d (BNA) 1801, 1804 (Fed. Cir. 1995) (“The chemical composition exists at the moment the ingredients are mixed together.”).

881. *Mars v. H.J. Heinz Co.*, 377 F.3d 1369, 1374, 71 U.S.P.Q.2d (BNA) 1837, 1841 (Fed. Cir. 2004).

882. *Id.* at 1375, 71 U.S.P.Q.2d (BNA) at 1841.

883. *Id.* at 1374, 71 U.S.P.Q.2d (BNA) at 1841.

that “mixture” means “a portion of matter consisting of two or more components in varying proportions that retain their own properties,” and that nothing within this ordinary meaning of “mixture” barred additional, unnamed ingredients.⁸⁸⁴

The Federal Circuit determined that the district court’s reasons for limiting the term to exclude mixtures containing ingredients in addition to solid and lipid ingredients were lacking. The Federal Circuit reasoned that the district court erred in concluding that the patentee had used the terms “containing” or “mixture” inconsistently with the ordinary, open-ended meanings of these terms. The district court had relied on portions of the specification which provided that the soft inner component should “not exceed 100 wt%’ of lipids and solids and that ‘the most preferred embodiment comprises about 60 wt% solids and 40 wt% lipids.’”⁸⁸⁵ The specification’s full description of “preferable” embodiments, however, allowed for the possibility that the sum weight percent of solids and lipids was less than 100%, where it stated that “[i]t is preferable for the inner portion or component to comprise about 40-90 wt solids and about 10-60 wt lipids,”⁸⁸⁶ and even stated that the “sum of the wt of solids and lipids, in all cases, [does] not *exceed* 100wt.”⁸⁸⁷

Furthermore, it rejected defendant’s argument that the patentee had limited the scope of its claims during prosecution of a related application when it replaced claims requiring an inner component “containing at least an ingredient comprising a lipid, wherein said [inner] component has a total moisture content less than about 25 wt%,” with claims requiring an inner component “containing a mixture of lipid an solid ingredients forming a cream-like matrix . . . and a total moisture content less than about 15wt%.”⁸⁸⁸ Although the amendment narrowed the total moisture content limitation, the Federal Circuit found that “the extent to which additional subject matter, if any, has been surrendered is ambiguous.”⁸⁸⁹

The Federal Circuit also rejected defendant’s claim that the scope of “containing” should be limited to include only the specified ingredients because the patentee used “containing at least” to describe the components of the outer shell of the claimed dual-textured animal food. The Federal Circuit dismissed this argument, reasoning that the phrase “at least” to not be required to make the outer shell limitation open-ended, and instead, it

884. *Id.* at 1376, 71 U.S.P.Q.2d (BNA) at 1842.

885. *Id.* at 1372, 71 U.S.P.Q.2d (BNA) at 1839.

886. *Id.* at 1376, 71 U.S.P.Q.2d (BNA) at 1842 (quoting U.S. Patent No. 6,312,746 (issued Nov. 6, 2001)).

887. *Id.*, 71 U.S.P.Q.2d (BNA) at 1842 (quoting U.S. Patent No. 6,312,746 (issued Nov. 6, 2001)).

888. *Id.* at 1377, 71 U.S.P.Q.2d (BNA) at 1842.

889. *Id.*, 71 U.S.P.Q.2d (BNA) at 1843.

was added to clarify that “not all, but ‘at least’ one, of the listed ingredients must be present in the outer shell.”⁸⁹⁰ In contrast, “at least” was not used in conjunction with the inner component because the inner component was intended to contain both solids and lipids.

For its final argument, defendant contended that the patentee had disclaimed the addition of water in any amount to the starting materials used to make the inner component by its statements in the specification that “it is desirable to provide a palatable edible product without the use of water,” and that “the soft inner portion that is coextruded in the center of the extruded rope does not contain any added water”⁸⁹¹ The Federal Circuit concluded that these statements cited by defendant did not “amount to the ‘clear disclaimer of particular subject matter’ required by [its] precedent to narrow the ordinary meaning of the claim language.”⁸⁹² Furthermore, the Federal Circuit observed other statements in the specification and claims that made clear that water is present in the inner component, including “water activity” and “total moisture content” limitations for the inner component and statements that the inner component has certain “moisture components.”⁸⁹³

Holding that the district court had erred in its construction of Mars’s claims, the Federal Circuit concluded that genuine issues of fact remained as to whether the accused products infringed the patents as properly construed and remanded for further consideration.⁸⁹⁴

In *Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc. (d/b/a Conagra Refrigerated Foods)*,⁸⁹⁵ the patentee appealed a district court’s grant summary judgment of invalidity and unenforceability of its patent covering a “Method of Browning Precooked Whole Muscle Meat Products.”⁸⁹⁶ The district court found the asserted patent claims invalid under 35 U.S.C. § 102(b) based on the invention’s prior sale and public use.⁸⁹⁷ On appeal, the patentee argued that the district court failed to construe the disputed

890. *Id.*, 71 U.S.P.Q.2d at 1843.

891. *Id.* at 1378, 1378 n.6, 71 U.S.P.Q.2d (BNA) at 1844, 1844 n.6.

892. *Id.* at 1378, 72 U.S.P.Q.2d (BNA) at 1843 (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 909, 69 U.S.P.Q.2d (BNA) 1801, 1808 (Fed. Cir. 2004)).

893. *Id.*, 72 U.S.P.Q.2d (BNA) at 1843.

894. *Id.* at 1379, 72 U.S.P.Q.2d (BNA) at 1844.

895. 375 F.3d 1341, 71 U.S.P.Q.2d (BNA) 1705 (Fed. Cir. 2004).

896. *Id.* at 1344, 71 U.S.P.Q.2d (BNA) at 1708. Unitherm and Jennie-O Foods, Inc. together sued Conagra for a variety of claims, including for a declaratory judgment that its patent was invalid and for tortious interference with Unitherm’s prospective economic relationships, and Unitherm separately sued Conagra for violation of § 2 of the Sherman Act (Walker Process claim). Only the court’s judgment with respect to the declaratory judgment of patent invalidity is related to patent law and therefore is the only part of the court’s opinion discussed here. *Id.*, 71 U.S.P.Q.2d (BNA) at 1708.

897. 35 U.S.C. § 102(b) (entitling a person to patent an invention, unless it was “patented or described in a printed publication . . . or in public use . . . more than one year prior to the date of the application for patent.”).

claim terms and incorrectly construed the term “golden brown” according to its plain and ordinary meaning, instead of limiting its scope to the color described in the patent’s five examples.

The Federal Circuit disagreed with the patentee on both counts.⁸⁹⁸ First, the Federal Circuit held that because the patentee failed to identify any “disputed claim terms” in its summary judgment brief or in its brief on appeal other than the term “golden brown,” the district court was free to have construed only that term in granting summary judgment.⁸⁹⁹ The patentee’s generalized contention that the district court should have conducted a Markman hearing did not suffice to show that a genuine issue of material fact precluded summary judgment.⁹⁰⁰ Second, the Federal Circuit found that the district court had properly concluded that the term “golden brown” should be given its plain and ordinary meaning where it had found that (1) the patentee had not acted as its own lexicographer and explicitly defined the term and (2) dictionary definitions of “golden brown” did not conflict with any definition found in, or ascertained by, a reading of the intrinsic evidence.⁹⁰¹ The Federal Circuit labeled patentee’s attempt to limit the meaning of “golden brown” to the color descriptions provided in the patent examples a “violation of our precedent counseling against importing limitations into the claims.”⁹⁰² The Federal Circuit reasoned that the examples represented “neither clear nor explicit disavowal of the common meaning,” and “[i]n fact, [were] . . . precisely what they purport to be: *examples* of Hunter-Lab Color Meter measurements falling within the commonly understood range of ‘golden brown.’”⁹⁰³

*Golight, Inc. v. Wal-Mart Stores, Inc.*⁹⁰⁴ involved claims directed to a remote-controlled portable search light.⁹⁰⁵ While certain unasserted claims expressly recited that the search light rotate through 360 degrees, the disputed claim called for a “horizontal drive means for rotating . . . [a] lamp

898. *Unitherm*, 375 F.3d at 1344, 71 U.S.P.Q.2d (BNA) at 1707.

899. *Id.* at 1346-47, 71 U.S.P.Q.2d (BNA) at 1709.

900. *Id.* at 1349, 71 U.S.P.Q.2d (BNA) at 1712.

901. *Id.* at 1351-52, 71 U.S.P.Q.2d (BNA) at 1712 (citing *Vitronics Corp. v. Conception, Inc.*, 90 F.3d 1576, 1584 n.6 (Fed. Cir. 1996), 39 U.S.P.Q.2d (BNA) 1573, 1578 n. 6, for the proposition that “judges may rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents”).

902. *Id.* at 1351, 71 U.S.P.Q.2d (BNA) at 1713.

903. *Id.*, 71 U.S.P.Q.2d (BNA) at 1713 (emphasis added) (citing *Texas Digital Sys. v. Telegenix, Inc.*, 308 F.3d 1193, 1202-04, 64 U.S.P.Q.2d (BNA) 1812, 1819 (Fed. Cir. 2002) for the proposition that the presumption of ordinary and customary meaning is only rebutted where the patentee “clearly set forth an explicit definition of the term different from its ordinary meaning,” or used “words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope.”).

904. 355 F.3d 1327, 69 U.S.P.Q.2d (BNA) 1481 (Fed. Cir. 2004).

905. *Id.* at 1329, 69 U.S.P.Q.2d (BNA) at 1482.

unit in a horizontal direction.”⁹⁰⁶ The issue before the Federal Circuit was whether this language required a search light to be capable of rotating through 360 degrees.⁹⁰⁷ Conceding that the disputed claim did not recite a 360 degree rotation, defendant argued that such a construction was mandated by the specification and prosecution because “the scope of the claims cannot exceed what is supported by the written description of the patent.”⁹⁰⁸ Seeking support in the specification, defendant relied on a passage stating that a “searchlight apparatus in accordance with the present invention includes a lamp unit mounted in a housing which has a . . . horizontal drive mechanism for rotating the lamp unit in a horizontal direction through at least 360 degrees.”⁹⁰⁹

The Federal Circuit rejected defendant’s analysis of the specification, explaining that although the inventors described their invention as having the ability to rotate through 360 degrees, “this particular advantage is but one feature of the invented search light. The written description describes other significant features as well.”⁹¹⁰ The Federal Circuit then reasoned that the “patentees were not required to include within each of their claims all of these advantages or features described as significant or important in the written description.”⁹¹¹ The Federal Circuit further explained that the specification’s description of lone embodiment as capable of rotating through 360 degrees was not determinative because an “applicant is not necessarily required . . . to describe more embodiments than its preferred one, and we have outright rejected the notion that disclosure of a single embodiment necessarily limits the claims.”⁹¹²

Regarding the prosecution history, defendant argued that the inventors acted as lexicographers requiring that the term “rotating” as used in all the claims be capable of rotating through 360 degrees.⁹¹³ To support its contention, defendant cited to the arguments in which the patentee overcame the prior art by arguing that “the claims in issue have been amended to recite rotation through at least 360 degrees and avoid an incidental disclosure of rotation which could be imputed to Lipman.”⁹¹⁴ The Federal Circuit again found defendant’s argument unconvincing, explaining that “we find no clear or express statement by the patentees giving ‘rotating’ a special meaning” because the patentee’s statements were

906. *Id.* at 1330, 69 U.S.P.Q.2d (BNA) at 1483.

907. *Id.*, 69 U.S.P.Q.2d (BNA) at 1483.

908. *Id.* at 1331, 69 U.S.P.Q.2d (BNA) at 1484.

909. *Id.*, 69 U.S.P.Q.2d (BNA) at 1484.

910. *Id.*, 69 U.S.P.Q.2d (BNA) at 1484.

911. *Id.*, 69 U.S.P.Q.2d (BNA) at 1484.

912. *Id.*, 69 U.S.P.Q.2d (BNA) at 1484 (citing to *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1327, 63 U.S.P.Q.2d (BNA) 1374, 1382-83 (Fed. Cir. 2002)).

913. *Teleflex*, 355 F.3d at 1332, 69 U.S.P.Q.2d (BNA) at 1485.

914. *Id.*, 69 U.S.P.Q.2d (BNA) at 1485.

subject “to multiple reasonable interpretations.”⁹¹⁵ In particular, the Federal Circuit explained that the patentee’s statements could be understood “to distinguish only those claims that explicitly recited a 360 degrees limitation,” and thus concluded that that statements “do not rise to level of a clear disavowal of scope with respect to” the disputed claim.⁹¹⁶

The majority opinion also rejected defendant’s argument that the claims must require a 360 degree rotation because the claims were written in means plus function format pursuant to § 112, ¶ 6.⁹¹⁷ Focusing on the functional language, the majority reasoned that “the function of the ‘horizontal drive means’ is ‘rotating said lamp unit in a horizontal direction’” and nothing in such language requires a 360 degree rotation.⁹¹⁸ Then looking to the structure corresponding to the recited function, the majority noted that although the assembly structure “may be capable of rotating through 360 degrees, we see nothing in the written description that compels limiting the function to only this degree of rotation, or to rotation through any particular angle at all.”⁹¹⁹

In dissent, Judge Archer construed the claim language as requiring rotation through 360 degrees because the claims were written in means plus function format, and the only “structure in the specification which describes the horizontal rotating means expressly states that it is ‘free to rotate through greater than 360 degrees in either direction.’”⁹²⁰ The dissent thus reasoned that “only devices capable of rotating through 360 degrees and their equivalents are covered by this claim limitation; a device incapable of rotating through 360 degrees is not.”⁹²¹ In addition to the specification, the dissent noted that the patentee distinguished his claims from the prior art by arguing that the prior art reference “would not be rotatable so as to be able to sweep *through 360 degrees or greater as achieved by applicants’ invention.*”⁹²² In light of these arguments, the dissent concluded that the applicants “defined ‘rotate’ . . . to require that the horizontal drive means for rotating be capable of rotation through 360 degrees.”⁹²³

*International Rectifier Corp. v. Ixys Corp.*⁹²⁴ involved claims directed to metal-oxide-silicon field effect transistors (“MOSFET”) devices having a

915. *Id.*, 69 U.S.P.Q.2d (BNA) at 1485.

916. *Id.* at 1333, 69 U.S.P.Q.2d (BNA) at 1485.

917. 35 U.S.C. § 112, ¶ 6 (2000); *Teleflex*, 355 F.3d at 1333, 69 U.S.P.Q.2d (BNA) at 1486.

918. *Teleflex*, 355 F.3d at 1333-34, 69 U.S.P.Q.2d (BNA) at 1486.

919. *Id.* at 1334, 69 U.S.P.Q.2d (BNA) at 1486.

920. *Id.* at 1341, 69 U.S.P.Q.2d (BNA) at 1492.

921. *Id.*, 69 U.S.P.Q.2d (BNA) at 1492.

922. *Id.*, 69 U.S.P.Q.2d (BNA) at 1492 (emphasis added).

923. *Id.*, 69 U.S.P.Q.2d (BNA) at 1492.

924. 361 F.3d 1363, 70 U.S.P.Q.2d (BNA) 1209 (Fed. Cir. 2004).

limitation reciting “at least [a] first base region being a cellular polygonal region . . . and [a] first source region having the shape of an annular ring disposed within [the] cellular polygonal first base region.”⁹²⁵ On appeal, the claim terms in dispute were “polygonal” and “annular.”⁹²⁶

With respect to “polygonal,” the issue on appeal was whether the district court properly construed the term to mean that the “corners of the polygonal regions may take the form of spherical junctions (i.e., round) after processing and are not necessarily formed by straight lines intersecting at a point to form a well defined angle.”⁹²⁷ In particular, defendant argued that the district court improperly departed from the ordinary and customary meaning of polygonal, which would require that the polygon corners have straight lines joining together in well-defined angles.⁹²⁸

The Federal Circuit began its analysis “with an examination of the possible dictionary definitions of the word ‘polygon.’”⁹²⁹ Having reviewed different versions of *Webster’s Third New International Dictionary*,⁹³⁰ the Federal Circuit reasoned that “[b]y necessity, the boundary of a closed plane figure will also include multiple included angles formed at the intersection of the straight lines.”⁹³¹ The Federal Circuit next looked to the specification to determine “whether the patentee acted as his own lexicographer, or otherwise disavowed or disclaimed the full scope of the ordinary and customary meaning of [polygonal].”⁹³² In so doing, the Federal Circuit reasoned that the “depictions and descriptions of the patents are consistent with the ordinary definition of the word ‘polygon.’”⁹³³ The Federal Circuit therefore held that the construction allowing the polygonal corners to be round rather than formed by straight edges was erroneous.⁹³⁴

In reaching its construction, the Federal Circuit rejected plaintiff’s argument that a person of ordinary skill in the art would understand that the processing techniques for MOSFET transistors would “necessarily blur[] the outline of the regions.”⁹³⁵ The court explained that “[w]hile [the plaintiff] is correct that the meaning of claim terms must be considered from the perspective of one of ordinary skill in the art, that does not mean

925. *Id.* at 1367, 70 U.S.P.Q.2d (BNA) at 1212.

926. A third claim term on appeal was “adjoining.” *Id.*, 70 U.S.P.Q.2d (BNA) at 1212.

927. *Id.* at 1370, 70 U.S.P.Q.2d (BNA) at 1214.

928. *Id.*, 70 U.S.P.Q.2d (BNA) at 1214.

929. *Id.*, 70 U.S.P.Q.2d (BNA) at 1214.

930. *Id.*, 70 U.S.P.Q.2d (BNA) at 1214.

931. *Id.* at 1371, 70 U.S.P.Q.2d (BNA) at 1214.

932. *Id.*, 70 U.S.P.Q.2d (BNA) at 1215.

933. *Id.*, 70 U.S.P.Q.2d (BNA) at 1215. The court also noted that “neither party argues that anything in the prosecution history affects the scope of the any of the disputed claim terms.” *Id.*, 70 U.S.P.Q.2d (BNA) at 1215.

934. *Id.*, 70 U.S.P.Q.2d (BNA) at 1215.

935. *Id.*, 70 U.S.P.Q.2d (BNA) at 1215.

that the inventor's choice of words may be ignored."⁹³⁶ The Federal Circuit thus concluded that nothing in the intrinsic evidence "suggest[s] that the recognition of these diffusion effects by those skilled in the art warrants the re-definition of the term polygon to mean anything other than 'a closed plane figure bounded by straight lines.'"⁹³⁷

With respect to the term "annular," the issue was whether the district court's construction of the term as encompassing shapes not ordinarily considered to be annular, such as hexagonal and ovals shapes, was overly broad.⁹³⁸ Though observing that the dictionaries indicated that the term's ordinary meaning is "of or relating to an area formed by two concentric circular regions,"⁹³⁹ the Federal Circuit determined that the patentee acted as a lexicographer and expressly defined "annular" to include more than just circular shapes.⁹⁴⁰ Specifically, the Federal Circuit reasoned that the inventor "deviated from th[e] ordinary and customary meaning, and used the word 'annular' to describe structures that are . . . polygonal. In particular, [the specifications] illustrate[] base and source regions of concentric squares and . . . of concentric hexagons."⁹⁴¹ The text accompanying these figures refers to these shapes as 'rings.'"⁹⁴² Given such statements in the specification, the Federal Circuit held that "the patentee acted as his own lexicographer, and the patentee's definition trumps the ordinary and customary meaning that otherwise would have attached."⁹⁴³

*SmithKline Beecham Corp. v. Apotex Corp.*⁹⁴⁴ involved a claim covering the chemical compound "crystalline paroxetine hydrochloride hemihydrate" ("PHC hemihydrate") having antidepressant properties.⁹⁴⁵ Relying on the patent specification's discussion of "the superior handling properties of the hemihydrate form that improve the manufacture of PHC," the district court construed the claim as limited to "commercially significant amounts of PHC hemihydrate."⁹⁴⁶

Reversing this construction on appeal, the Federal Circuit began its analysis by noting that claim construction requires courts "to place the claim language in its proper technological and temporal context."⁹⁴⁷

936. *Id.*, 70 U.S.P.Q.2d (BNA) at 1215.

937. *Id.*, 70 U.S.P.Q.2d (BNA) at 1215.

938. *Id.* at 1372, 70 U.S.P.Q.2d (BNA) at 1215-16.

939. *Id.* at 1373, 70 U.S.P.Q.2d (BNA) at 1216.

940. *Id.*, 70 U.S.P.Q.2d (BNA) at 1216.

941. *Id.*, 70 U.S.P.Q.2d (BNA) at 1216.

942. *Id.*, 70 U.S.P.Q.2d (BNA) at 1216.

943. *Id.*, 70 U.S.P.Q.2d (BNA) at 1216.

944. 365 F.3d 1306, 70 U.S.P.Q.2d (BNA) 1737 (Fed. Cir. 2004).

945. *Id.* at 1308, 70 U.S.P.Q.2d (BNA) at 1739.

946. *Id.* at 1313, 70 U.S.P.Q.2d (BNA) at 1742.

947. *Id.*, 70 U.S.P.Q.2d (BNA) at 1742.

Turning to the claim itself, the court explained that the “language is not ambiguous, but rather describes a very specific compound. The record repeatedly shows that artisans in this area of technology at the time of invention would have understood that the claim embraces PHC hemihydrate without further limitation.”⁹⁴⁸ With regard to the remaining intrinsic evidence, the Federal Circuit explained that the specification does not “redefine the compound in terms of its commercial properties, but emphasize[s] that the new compound exhibits favorable characteristics.”⁹⁴⁹ The Federal Circuit thus concluded that “[a] description of characteristics does not redefine a compound with an established and unambiguous structural definition.”⁹⁵⁰ The Federal Circuit reached the same conclusion upon review of the prosecution history, noting that “nothing in the prosecution history . . . defines the invention in terms of commercially significant quantities.”⁹⁵¹

The Federal Circuit also addressed the district court’s public policy consideration that absent a “commercially significant quantity” limitation, the claim would cover trace amounts of the claimed compound thereby producing “absurd results” that would “not serve any policy of patent law” by precluding “attempts to make prior art PHC anhydrate compound.”⁹⁵² The Federal Circuit explained that claim construction “is not a policy-driven inquiry,” and claim scope cannot “be broadened or narrowed based on abstract policy considerations regarding the effect of a particular claim meaning.”⁹⁵³

In *Home Diagnostics, Inc. v. Lifescan, Inc.*,⁹⁵⁴ the issue was whether the phrase “upon detection of a suitable stable endpoint” in claims directed to measuring glucose concentration in a blood sample was limited to use of “predetermined timing methods,” as required by the district court’s construction.⁹⁵⁵ In reversing the construction below the Federal Circuit began by noting that the “claim language itself governs the meaning of the claim.”⁹⁵⁶ Focusing on the context of the claim language, the court reasoned that the disputed phrase “does not explicitly require a predetermined time for the reaction, but instead measures the endpoint by

948. *Id.*, 70 U.S.P.Q.2d (BNA) at 1742.

949. *Id.*, 70 U.S.P.Q.2d (BNA) at 1742.

950. *Id.*, 70 U.S.P.Q.2d (BNA) at 1742.

951. *Id.*, 70 U.S.P.Q.2d (BNA) at 1742.

952. *Id.* at 1313-14, 70 U.S.P.Q.2d (BNA) at 1742.

953. *Id.* at 1314, 70 U.S.P.Q.2d (BNA) at 1742. This reasoning appears to provide a clear answer to one of the en banc questions to be addressed in *Phillips*. Namely, whether claim language should “be narrowly construed for the sole purpose of avoiding invalidity under, e.g., 35 U.S.C. §§ 102, 103 and 112.” *Phillips v. AWH Corp.*, 376 F.3d 1382, 1383, 71 U.S.P.Q.2d (BNA) 1765, 1766 (Fed. Cir. 2004).

954. 381 F.3d 1352, 72 U.S.P.Q.2d (BNA) 1276 (Fed. Cir. 2004).

955. *Id.* at 1354-55, 72 U.S.P.Q.2d (BNA) at 1278.

956. *Id.* at 1355, 72 U.S.P.Q.2d (BNA) at 1278.

the stability of reflectance . . . [and] emphasizes that the method does not require any determination of a starting point for application of the blood sample to the matrix.”⁹⁵⁷ Thus, based on the claim language, the Federal Circuit determined that the claim “limits the endpoint by reference to suitable stability in the reflectance readings, not by reference to a predetermined time.”⁹⁵⁸

Turning to the remaining intrinsic evidence, the Federal Circuit determined that the specification supported its construction because, “[i]n discussing the invention as a whole,” the specification provides examples illustrating “that a ‘suitably stable endpoint’ varies between unspecified points in time.”⁹⁵⁹ The Federal Circuit also observed that although the predetermined timing method was the only embodiment disclosed in the patent, “the specification limits its discussion of predetermined timing methods to preferred embodiments.”⁹⁶⁰ Explaining that “the applicant’s choice to describe only a single embodiment does not mean that the patent clearly and unambiguously disavowed other embodiments,” the Federal Circuit determined that the district court erroneously “plac[ed] too much emphasis on the specification’s discussion of the preferred embodiments, rather than the meaning of the claims themselves.”⁹⁶¹

The Federal Circuit also noted that the prosecution history established that the claims were not limited to a predetermined timing method because claim language in related patent applications evolved from “‘predetermined time period’ to ‘predetermined incubation period’ to ‘suitably stable endpoint’” thus showing that the patentee “purposefully sought in the [asserted] patent claim scope broader than the predetermined timing method.”⁹⁶² In addition, the Federal Circuit used prior art cited during prosecution of the disputed claims as a tool to underscore that persons of ordinary skill in the art would understand the claim language to be broader than use of predetermined timing methods.

In *Lighting World, Inc. v. Birchwood Lighting, Inc.*,⁹⁶³ an issue on appeal was whether the claim phrase “a plurality of lamp supports . . . for engaging and supporting . . . fluorescent lamps”⁹⁶⁴ was properly construed by the district court as limited only to structures providing support from below.⁹⁶⁵ The Federal Circuit reversed this construction, explaining that

957. *Id.* at 1356, 72 U.S.P.Q.2d (BNA) at 1279.

958. *Id.*, 72 U.S.P.Q.2d (BNA) at 1279.

959. *Id.* at 1356-57, 72 U.S.P.Q.2d (BNA) at 1279.

960. *Id.* at 1357, 72 U.S.P.Q.2d (BNA) at 1279.

961. *Id.*, 72 U.S.P.Q.2d (BNA) at 1279.

962. *Id.* at 1358, 72 U.S.P.Q.2d (BNA) at 1280.

963. 382 F.3d 1354, 72 U.S.P.Q.2d (BNA) 1344 (Fed. Cir. 2004).

964. *Id.* at 1363, 72 U.S.P.Q.2d (BNA) at 1346.

965. *Id.* at 1364, 72 U.S.P.Q.2d (BNA) at 1346.

although the intrinsic evidence clearly shows that the lamp supports may provide support from below, nothing in the intrinsic evidence restricts the claims solely to such an embodiment.⁹⁶⁶ In particular, the Federal Circuit explained that the disputed claim language “is not by its terms limited to supports that engage and support the lamps from below, and there is no language in the written description that limits the term ‘supporting and engaging’ to support and engagement from below.”⁹⁶⁷ The Federal Circuit further explained that although the asserted patent contained several figures “show[ing] lamp supports that provide support from below the lamps, the scope of the claims is not limited to particular embodiments depicted in the figures or described in the written description.”⁹⁶⁸ The court further elaborated that

[t]he ordinary meaning of the terms “supporting and engaging” includes more than support or engagement from below, and the fact that the patentee has not included figures depicting support and engagement from other orientations is not sufficient to limit the claim language to the particular orientation depicted in the figures.⁹⁶⁹

The Federal Circuit also noted that several figures in the asserted patent depicted a device that “appears to clip around the lamps and thus provides support and engagement for the lamps that would be effective in other lamp orientations.”⁹⁷⁰ In so doing, the Federal Circuit rejected defendant’s argument that such a clip was unclaimed and thus dedicated to the public, explaining that this “argument misses the relevance of the clip”⁹⁷¹ because plaintiff “does not point to the clip as a claimed feature, but instead refers to the clip to show that its use of the terms ‘supporting and engaging’ was not meant to be limited to support and engagement from below.”⁹⁷²

In *In re Bigio*,⁹⁷³ the question was whether the Board properly construed the term “hair brush” as including “not only brushes that may be used for human hair on [a] scalp, but also brushes that may be used for hairs on other parts of animal bodies (e.g., human facial hair . . . or pet hair).”⁹⁷⁴ The Federal Circuit began its analysis by noting that the “PTO gives a disputed claim term its broadest reasonable interpretation during patent prosecution The ‘broadest reasonable interpretation’ rule recognizes that ‘before a patent is granted the claims are readily amended as part of the

966. *Id.*, 72 U.S.P.Q.2d (BNA) at 1346-47.

967. *Id.* at 1365, 72 U.S.P.Q.2d (BNA) at 1353.

968. *Id.*, 72 U.S.P.Q.2d (BNA) at 1353.

969. *Id.*, 72 U.S.P.Q.2d (BNA) at 1353.

970. *Id.*, 72 U.S.P.Q.2d (BNA) at 1353.

971. *Id.*, 72 U.S.P.Q.2d (BNA) at 1353.

972. *Id.*, 72 U.S.P.Q.2d (BNA) at 1353.

973. 381 F.3d 1320, 72 U.S.P.Q.2d (BNA) 1209 (Fed. Cir. 2004).

974. *Id.* at 1323-24, 72 U.S.P.Q.2d (BNA) at 1210.

examination process.”⁹⁷⁵ In affirming the PTO’s construction, the Federal Circuit examined the claim language and determined that “the word ‘hair’ preceding ‘brush’ throughout the body of the claim does not alone limit the claim to brushes for scalp hair. At best, the word ‘hair’ carries the meaning that the claimed invention involves brushing some kind of hair.”⁹⁷⁶ Regarding the specification, the Federal Circuit held that the PTO correctly declined to import limitations from the specification that would limit the claims only to scalp hair because “[a]bsent claim language carrying a narrow meaning, the PTO should only limit the claim based on the specification or prosecution history when those sources expressly disclaim the broader definition.”⁹⁷⁷ Accordingly, the Federal Circuit held that because “the term ‘hair brush’ alone does not specify the kind of hair to be groomed by the claimed invention . . . the term may reasonably encompass not only scalp hair brushes but also facial hair brushes.”⁹⁷⁸

In *In re American Academy of Science Tech Center*,⁹⁷⁹ the owner of a patent directed to a computer network sought review of the Board’s decision upholding an examiner’s rejection of all claims as anticipated by several references.⁹⁸⁰ The patented network distributed the processing of user applications among several computers, in contrast to a system in which one mainframe computer processed user applications and was connected to several “dumb terminals” with which users would interface.⁹⁸¹

The claims under consideration required a “plurality of independent, not necessarily uniform, general purpose user computers” that are “connected to a data center computer.”⁹⁸² The claims also recited the “user application program” to “indirectly issu[e] data base calls.”⁹⁸³ One of the four references relied upon by the examiner and the Board described a system in which several mainframe computers interfaced with a single database.⁹⁸⁴ Another disclosed the networking of several personal computers to a database computer that is connected to a database.⁹⁸⁵ The examiner found that the mainframe computer in the first reference and the personal computers of the second reference anticipated the “general purpose user computers” element of the claims.⁹⁸⁶

975. *Id.* at 1324, 72 U.S.P.Q.2d (BNA) at 1211 (quoting *Burlington Indus. v. Quigg*, 822 F.2d 1581, 1583, 3 U.S.P.Q.2d (BNA) 1436, 1438 (Fed. Cir. 1987)).

976. *Id.*, 72 U.S.P.Q.2d (BNA) at 1211.

977. *Id.* at 1325, 72 U.S.P.Q.2d (BNA) at 1211.

978. *Id.*, 72 U.S.P.Q.2d (BNA) at 1211.

979. 367 F.3d 1359, 70 U.S.P.Q.2d (BNA) 1827 (Fed. Cir. 2004).

980. *Id.* at 1361, 70 U.S.P.Q.2d (BNA) at 1828.

981. *Id.*, 70 U.S.P.Q.2d (BNA) at 1828.

982. *Id.* at 1362, 70 U.S.P.Q.2d (BNA) at 1829.

983. *Id.*, 70 U.S.P.Q.2d (BNA) at 1829.

984. *Id.*, 70 U.S.P.Q.2d (BNA) at 1829.

985. *Id.*, 70 U.S.P.Q.2d (BNA) at 1829.

986. *Id.*, 70 U.S.P.Q.2d (BNA) at 1829.

On appeal, American Academy argued that “user computer” should be limited to refer only to single-user computers, pointing to the Background of the Invention section of the specification that points to deficiencies with multi-user computers such as mainframes.⁹⁸⁷ The Federal Circuit disagreed with American Academy’s characterization. Although the Background highlighted the problems inherent in performing all the processing necessary to run multiple user applications at a central computer, the Federal Circuit also noted that the specification did not “disclaim” the networking of mainframes to a central computer that performs the function of database access.⁹⁸⁸ The Federal Circuit opined that the Background section appeared to allow such a configuration and that “[i]n such a case, several less expensive mainframe computers could be used to manage the processing of an increasing number of user applications while the overhead associated with communication among processors would be limited to communications related to the storage and retrieval of data.”⁹⁸⁹

American Academy countered that by describing the invention as including a “plurality of user stations each dedicated to servicing a user (which could be a person, another device, or machine),” the definition of “user computer” could not include “multi-user computers.”⁹⁹⁰ The Federal Circuit nevertheless agreed with the PTO that “machine” could include a mainframe computer, that statements in the specification that distinguished “user computer” from a data center computer in terms of function, and that indicated that a “variety of configurations” could be used to enable the user computer to serve its function suggested that a construction of “user computer” that would include multi-user computers would not be unreasonably broad.⁹⁹¹

The Federal Circuit also refused to find any fault with the Board’s decision to discredit declarations submitted by American Academy which ostensibly supported its construction of “user computer.”⁹⁹² The Federal Circuit explained that the Board was entitled to conclude that the lack of factual corroboration warranted discounting the opinions expressed therein.⁹⁹³

987. *Id.* at 1365, 70 U.S.P.Q.2d (BNA) at 1832.

988. *Id.* at 1366, 70 U.S.P.Q.2d (BNA) at 1832.

989. *Id.*, 70 U.S.P.Q.2d (BNA) at 1832.

990. *Id.*, 70 U.S.P.Q.2d (BNA) at 1832.

991. *Id.* at 1367, 70 U.S.P.Q.2d (BNA) at 1832.

992. *Id.* at 1368, 70 U.S.P.Q.2d (BNA) at 1833.

993. *Id.*, 70 U.S.P.Q.2d (BNA) at 1833-34. The Federal Circuit also rejected American Academy’s argument that the prosecution history supported its construction. During prosecution of the application that matured into the patent, the applicant described a reference cited by the PTO as including remote transaction terminals and a host computer which processed the transactions. Neither the applicant nor the examiner referred to the host computer as a “user computer,” and American Academy argued that this was evidence that the user computer was limited to serving one user. The Federal Circuit, however, said

Finally, the Federal Circuit refused to find that the Board's construction of "user computer" was fatally inconsistent with the construction adopted by the district court during American Academy's litigation against an accused infringer.⁹⁹⁴ The district court had construed "user computer" to mean "a computer that serves one user at a time."⁹⁹⁵ The Federal Circuit opined that the Board is "required to use a different standard for construing claims than that used by district courts," in that it must "give claims their broadest reasonable interpretation during examination."⁹⁹⁶

American Academy also contended that the Board's construction of the term "indirectly issuing" to mean "requiring only that a request from the host computer go through some other component before it is sent to the database"⁹⁹⁷ was erroneous. American Academy urged that the term should be limited in its meaning to "a user computer application program issuing a call for data as though from resident storage, coupled with an intermediate step redirecting the call to the remote data center computer."⁹⁹⁸ American Academy pointed to the specification's description of the preferred embodiment in which a "data base simulator program" enabled an application program running at a user station to request storage or retrieval of data from a data center as though it were requesting data from a data base that resided on the user station.⁹⁹⁹

The Federal Circuit rejected this argument, stating that its precedent "caution[s] against reading limitations into a claim from the preferred embodiment described in the specification, even if it is the only embodiment described, absent clear disclaimer in the specification."¹⁰⁰⁰ The Federal Circuit found no such clear disclaimer in the specification here.¹⁰⁰¹ Rather, it again found that the specification described the invention in broad terms and lucidly identified the data base simulator as "a preferred embodiment, and just one of the 'variety of conventional protocol procedures.'"¹⁰⁰² Thus, the Federal Circuit did not find that "indirectly

that the applicant *distinguished* the cited reference on the basis that the application programs were run on the host computer instead of the remote terminals, likening the disclosed system to that of the "dumb terminal" configuration that the invention was intended to replace. Thus, the court found, this was the reason why it would not have made sense for the applicant to refer to the host computer as a "user computer." *Id.* at 1368-69, 70 U.S.P.Q.2d (BNA) at 1833-34.

994. *Id.* at 1369, 70 U.S.P.Q.2d (BNA) at 1834.

995. *Id.*, 70 U.S.P.Q.2d (BNA) at 1834.

996. *Id.*, 70 U.S.P.Q.2d (BNA) at 1834.

997. *Id.*, 70 U.S.P.Q.2d (BNA) at 1834.

998. *Id.*, 70 U.S.P.Q.2d (BNA) at 1834.

999. *Id.*, 70 U.S.P.Q.2d (BNA) at 1834 (citing U.S. Patent No. 4,714,989 (issued Dec. 22, 1987)).

1000. *Id.*, 70 U.S.P.Q.2d (BNA) at 1834 (citing *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906, 69 U.S.P.Q.2d (BNA) 1801, 1807 (Fed. Cir. 2004)).

1001. *Id.*, 70 U.S.P.Q.2d (BNA) at 1834.

1002. *Id.* at 1370, 70 U.S.P.Q.2d at 1834.

issuing” was limited to the use of a data base simulator.¹⁰⁰³

In *Nystrom v. Trex Co.*,¹⁰⁰⁴ plaintiff appealed the district court’s construction of disputed claim terms in its patent directed to wooden planks used in the construction of outdoor decks.¹⁰⁰⁵ The disputed claim terms construed by the Federal Circuit included “board,” “manufactured to,” and “convex top surface.”¹⁰⁰⁶

The Federal Circuit construed “board” as used in the claims to require “an elongated, flat piece of wood or other rigid material.”¹⁰⁰⁷ The Federal Circuit rejected defendant’s proposed construction, adopted by the district court, which would further limit “board” to mean “a piece of elongated construction material made from wood cut from a log.”¹⁰⁰⁸ Defendant manufactures decking planks “made from composites of wood fibers and recycled plastic.”¹⁰⁰⁹ Defendant argued that both dictionary definitions of “board” and the prosecution history supported its limited construction.¹⁰¹⁰

Beginning its claim construction analysis with the words of the claim, the Federal Circuit found that although some dictionaries included definitions of “board” that limited the term to planks of wood cut from a log, others did not.¹⁰¹¹ Thus, the Federal Circuit found that “these definitions show[ed] that the ordinary meaning of the word ‘board’ encompasses both a piece of cut wood or sawn timber and a similarly-shaped item made of a rigid material.”¹⁰¹² Furthermore, the Federal Circuit held that plaintiff had not disclaimed boards made from materials other than logs, as he described his invention as “a decking board which is shaped to shed water from its upper surface, and which also yields a superior product *when cut from a log.*”¹⁰¹³ The Federal Circuit concluded the phrase “when cut from a log” to implicitly recognize that the invention’s boards may be cut from a material other than a log. Finally, the Federal Circuit found support for its broader construction in the claims themselves where some claims were expressly limited to “wood decking board[s]” having “curved growth rings.”¹⁰¹⁴

The Federal Circuit also found no support for defendant’s proposed

1003. *Id.*, 70 U.S.P.Q.2d (BNA) at 1835.

1004. 374 F.3d 1105, 71 U.S.P.Q.2d (BNA) 1241 (Fed. Cir. 2004).

1005. *Id.* at 1107, 71 U.S.P.Q.2d (BNA) at 1243.

1006. *Id.* at 1108-09, 71 U.S.P.Q.2d (BNA) at 1243-44.

1007. *Id.* at 1113, 71 U.S.P.Q.2d (BNA) at 1247.

1008. *Id.* at 1110, 71 U.S.P.Q.2d (BNA) at 1245.

1009. *Id.* at 1109, 71 U.S.P.Q.2d (BNA) at 1244.

1010. *Id.* at 1111, 71 U.S.P.Q.2d (BNA) at 1245.

1011. *Id.* at 1111-12, 71 U.S.P.Q.2d (BNA) at 1246.

1012. *Id.* at 1112, 71 U.S.P.Q.2d (BNA) at 1246.

1013. *Id.*, 71 U.S.P.Q.2d (BNA) at 1246 (emphasis in original).

1014. *Id.*, 71 U.S.P.Q.2d (BNA) at 1246-47 (citing U.S. Patent No. 5,474,831 (issued Dec. 12, 1995)).

construction in the prosecution history.¹⁰¹⁵ Defendant pointed to a statement made by plaintiff in overcoming an obviousness rejection that a cited reference “[was] clearly not concerned with materials made from wood.”¹⁰¹⁶ Rather than a disclaimer, the Federal Circuit interpreted that statement to be simply “an argument against the examiner’s obviousness rejection.”¹⁰¹⁷ Specifically, the Federal Circuit found that the argument was made to show why there was no motivation to combine the cited reference with another cited reference and therefore the argument was “insufficient to restrict the scope of [plaintiff]’s claims.”¹⁰¹⁸

The Federal Circuit next turned to the definition of “manufactured to have.”¹⁰¹⁹ The district court restricted this term to “a manufacturing process utilizing woodworking techniques” based on the statements in the specification that “‘the advantages of the invention’ were achieved through ‘cutting or milling and the like.’”¹⁰²⁰ In light of its construction of “board,” the Federal Circuit found no reason to limit “manufactured to have” to woodworking techniques.¹⁰²¹ Furthermore, it noted that even the district court acknowledged that the “cutting or milling” language was used to describe a preferred embodiment. The Federal Circuit therefore held that “manufactured to have” in the context of the claims at issue meant that “the convex top surface is shaped by manufacturing.”¹⁰²²

Finally, the Federal Circuit analyzed the meaning of “convex top surface.”¹⁰²³ The district court again limited this term on the basis of statements made during prosecution, holding that the term meant “an upper surface with an outward curve that has a ratio of its radius of curvature to width of the board between 4:1 to 6:1.”¹⁰²⁴ The statements relied upon by the district court were made in a supplemental amendment to one particular claim, of the patent Claim 16. Plaintiff indicated in conjunction with that amendment that it had tried several different radii of curvature and discovered that a ratio of radius of curvature to width of the board of about 5:1 “produced the desired result, *i.e.* it shed water and did not produce an uneven sensation to someone standing on it.”¹⁰²⁵ Plaintiff noted that the basic objectives of the invention could be met by boards with curvature to width ratios within a “narrow” range of 4:1 to about 6:1, but that “anything

1015. *Id.* at 1112-13, 71 U.S.P.Q.2d (BNA) at 1247.

1016. *Id.* at 1113, 71 U.S.P.Q.2d (BNA) at 1247.

1017. *Id.*, 71 U.S.P.Q.2d (BNA) at 1247.

1018. *Id.*, 71 U.S.P.Q.2d (BNA) at 1247.

1019. *Id.* at 1113-14, 71 U.S.P.Q.2d (BNA) at 1247-48.

1020. *Id.*, 71 U.S.P.Q.2d (BNA) at 1247-48.

1021. *Id.* at 1114, 71 U.S.P.Q.2d (BNA) at 1248.

1022. *Id.*, 71 U.S.P.Q.2d (BNA) at 1248.

1023. *Id.*, 71 U.S.P.Q.2d (BNA) at 1248.

1024. *Id.*, 71 U.S.P.Q.2d (BNA) at 1248.

1025. *Id.* at 1115, 71 U.S.P.Q.2d (BNA) at 1248-49.

much outside this range does not provide satisfactory performance and/or is not acceptable to the consumer.”¹⁰²⁶

The Federal Circuit held that the dictionary definition of “convex” is “having a surface or boundary that curves or bulges outward, as the exterior of a sphere,” and that this definition was consistent with the specification.¹⁰²⁷ Plaintiff’s statements during prosecution relied upon by the district court, it found, were only directed to Claim 16 and were not intended to limit “convex” in every instance that term was used within the entire patent.¹⁰²⁸ It also reasoned that the district court had ignored the fact that Claim 16 already contained the limitation that required “said top surface having a radius of curvature that is approximately five times as great as the width of the board” prior to the amendment involving the statements at issue.¹⁰²⁹

4. “Narrow construction” cases

In *Microsoft Corp. v. Multi-Tech Systems, Inc.*,¹⁰³⁰ Multi-Tech sued Net2Phone for infringing three of its patents directed to systems and methods for simultaneously transmitting voice and/or computer data to a remote site over a telephone line, (the ‘649, ‘647, and ‘532 patents).¹⁰³¹ Six months later, Microsoft brought an action in the same court against Multi-Tech to invalidate the same patents Multi-Tech was asserting against Net2Phone, and Multi-Tech countersued Microsoft for infringement. The court issued a single Markman order construing the claim terms in dispute in the two cases and entered final judgment of non-infringement against Multi-Tech in both cases where Multi-Tech conceded that neither Microsoft nor Net2Phone’s accused systems met the limitations of the asserted claims as the court had construed them. Multi-Tech then appealed the district court’s claim construction and Microsoft’s invalidity claims were stayed pending the Federal Circuit’s resolution of claim construction and infringement issues.

For its argument, Multi-Tech first addressed the district court’s construction of claim limitations referring to the “sending,” “transmitting,” and “receiving” of data packets, which limited those activities to the transmission of data packets over a direct point-to-point telephone line connection, and as such did not cover transmission over a packet-switched

1026. *Id.*, 71 U.S.P.Q.2d (BNA) at 1249.

1027. *Id.*, 71 U.S.P.Q.2d (BNA) at 1248 (citing AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 402 (4th ed. 2000)).

1028. *Id.*, 71 U.S.P.Q.2d (BNA) at 1249.

1029. *Id.*, 71 U.S.P.Q.2d (BNA) at 1249.

1030. 357 F.3d 1340, 69 U.S.P.Q.2d (BNA) 1815 (Fed. Cir. 2004).

1031. *Id.* at 1342, 1344, 69 U.S.P.Q.2d (BNA) at 1816, 1819.

network such as the Internet.¹⁰³² The Federal Circuit agreed with the district court's construction. Although only one of the claims at issue explicitly stated that the transmission of data packets must occur "over a telephone line," the specification, identical for all patents at issue, "repeatedly and consistently describe[d] the local and remote systems of the claimed inventions as communicating directly over a telephone line."¹⁰³³ All of the specification's preferred embodiments described hardware components that "communicat[ed] over a standard telephone line," and it disclosed that the system "allows the user to connect to remote locations equipped with similar system or with modems, facsimile machines, or standard telephones over a single analog telephone line."¹⁰³⁴ The Federal Circuit particularly emphasized that statements describing transmission over a telephone line were found in the Summary of Invention section of the specification and were not limited to preferred embodiments.¹⁰³⁵

Multi-Tech attempted to argue that its descriptions of the claimed inventions were limited to just the "ends" of the communication system, but the Federal Circuit rejected this argument because the description referred to the transfer of data packets "over" and "through" telephone lines about two dozen times. Thus, the Federal Circuit could not avoid the "inescapable conclusion" that communications contemplated by Multi-Tech's patents occurred directly over telephone lines.

As further support for its construction, the Federal Circuit pointed to the prosecution history of one of the three patents, in which Multi-Tech had summarized its invention as part of its response to an examiner's office action rejecting its claims as obvious over prior art. Multi-Tech's summary described its invention as a system which operates "over a standard telephone line," one that "establishes a point-to-point connection between the telephone equipment on each end of the line," and in which "packets [are transmitted] across a POTS [(“plain old telephone service”).”¹⁰³⁶ Multi-Tech argued, however, that these statements were made during prosecution of only one of the patents at issue, and not during prosecution of the other two.¹⁰³⁷ Therefore, Multi-Tech contended that the statements were inapplicable to the construction of the claims belonging to its two remaining patents at issue, one of which was issued before the statements

1032. *Id.* at 1346, 69 U.S.P.Q.2d (BNA) at 1820.

1033. *Id.* at 1348, 69 U.S.P.Q.2d (BNA) at 1821.

1034. *Id.*, 69 U.S.P.Q.2d (BNA) at 1821 (quoting U.S. Patent No. 5,452,289 (issued Sept. 19, 1995)).

1035. *Id.*, 69 U.S.P.Q.2d (BNA) at 1821.

1036. *Id.*, 69 U.S.P.Q.2d (BNA) at 1822.

1037. *Id.* at 1350, 69 U.S.P.Q.2d (BNA) at 1823.

were even made.¹⁰³⁸ The Federal Circuit disagreed,¹⁰³⁹ Holding that the statements made during prosecution of the '649 patent were also "pertinent" to the construction of the claims in both the '627 and '532 patents because all three patents shared the same specification, and therefore represented Multi-Tech's own understanding of the inventions disclosed in all three patents.¹⁰⁴⁰ Even though the examiner of the applications giving rise to the '627 and '532 patents did not rely on the statements made during prosecution of the '649 patent, the Federal Circuit had on numerous occasions held that the patentee's own statements were relevant to claim interpretation regardless of whether or not the examiner relied upon them in issuing the patent.¹⁰⁴¹ According to the Federal Circuit, "[w]e take the patentee at its word and will not construe the scope of the '649 patent's claims more broadly than the patentee itself clearly envisioned."¹⁰⁴²

Even though its resolution of the medium of transmission issue disposed of the need for the Federal Circuit to proceed to construe other claim limitations, it went on to construe the terms "multiplexing," "headers," "speaker phone" and "digitizing" in the interest of judicial efficiency.¹⁰⁴³ The district court had concluded that Multi-Tech acted as its own lexicographer and construed the term "multiplexing" in accordance with Multi-tech's definition to be "the combining of voice data ("V-data") and conventional data ("C-data") for transmission through the same channel by dynamically changing the time allocations for transmission of each type of data, such that V-data has higher priority over C-data and C-data is substituted for silence packets which are detected and discarded."¹⁰⁴⁴ Multi-Tech argued that the district court's construction improperly imported limitations from the specification into the claims.¹⁰⁴⁵ Although it agreed that it had "acted as its own lexicographer" in this instance, Multi-Tech disagreed with the district court's construction to the extent that it limited "multiplexing" to require the prioritization of V-data over C-data and the substitution of C-data for silence packets.¹⁰⁴⁶ The Federal Circuit only partly agreed with Multi-Tech, holding that the district court improperly construed "multiplexing" to require detection and discarding of silence packets and the transmission of computer data packets during

1038. *Id.*, 69 U.S.P.Q.2d (BNA) at 1823.

1039. *Id.*, 69 U.S.P.Q.2d (BNA) at 1823.

1040. *Id.*, 69 U.S.P.Q.2d (BNA) at 1823.

1041. *Id.*, 69 U.S.P.Q.2d (BNA) at 1823.

1042. *Id.*, 69 U.S.P.Q.2d (BNA) at 1823.

1043. *Id.* at 1351, 69 U.S.P.Q.2d (BNA) at 1824.

1044. *Id.* at 1345, 69 U.S.P.Q.2d (BNA) at 1819 (quoting U.S. Patent No. 5,452,289 (issued Sept. 19, 1995)).

1045. *Id.* at 1351, 69 U.S.P.Q.2d (BNA) at 1824.

1046. *Id.*, 69 U.S.P.Q.2d (BNA) at 1824.

periods of silence because those features were described only in association with preferred embodiments of the invention. They were nowhere described as “necessary for the multiplexing function.”¹⁰⁴⁷ Furthermore, these features were separately claimed in independent claims not at issue, and thus the doctrine of claim differentiation weighed against their limitation of independent claims reciting only “multiplexing.” Because the specification provided that V-data was prioritized over C-data “to ensure the integrity of the real-time voice transmission,” and because the Federal Circuit considered maintaining such integrity to be “central to the functioning of the claimed inventions,” the term “multiplexing” must be defined to require such prioritization.¹⁰⁴⁸

The Federal Circuit next addressed the term “headers.” Several claims at issue recited limitations in which “headers” were placed on or otherwise associated with various data packets transmitted in the systems. Multi-Tech argued that “headers” should be given its ordinary meaning and be defined as “information structures that precede units of data, such as packets.”¹⁰⁴⁹ The district court, however, required that “headers” attached to voice data packets identify whether the packets contained speech or silence, and Microsoft further argued on appeal that computer data packet headers must identify packet type and packet length. The Federal Circuit took yet a fourth view. Starting with the presumption that “headers” carried its own ordinary meaning of “information structure[s] that precede[] and identif[y] the information that follows,” the court next looked to the claim language and found that it separately referred to “headers” associated with voice data packets and those headers associated with computer data packets.¹⁰⁵⁰ Furthermore, the specification explained that the voice data packets used different headers than computer data packets so that sites receiving the data could distinguish between the two types of data packets, and that such distinction was necessary to enable prioritization. Thus, it held that “headers” required information identifying whether the packets that followed them contained voice or computer data. But further limitation of the term advanced by the district court and Microsoft was inappropriate, as the asserted limitations were found only in conjunction with the preferred embodiments disclosed by the patents and were merely illustrative of how the headers could be configured. Thus, “headers” did not need to identify the type and length of the computer data packets or whether the voice packets contained speech or silence.

The Federal Circuit next addressed the terms “hands-free speaker

1047. *Id.* at 1351-52, 69 U.S.P.Q.2d (BNA) at 1824.

1048. *Id.* at 1351, 69 U.S.P.Q.2d (BNA) at 1824.

1049. *Id.* at 1352, 69 U.S.P.Q.2d (BNA) at 1824-25.

1050. *Id.* at 1352-53, 69 U.S.P.Q.2d (BNA) at 1825.

phone,” “full-duplex speaker phone,” and “full-duplex hands-free speaker phone.” The district court had limited the “hands-free” speaker phones to those speaker phones with the traditional telephone hardware, including a handset and headset. Multi-Tech argued that the hands-free phones were not limited to any structure beyond a speaker and a microphone and the Federal Circuit agreed. Neither the claims nor the specification described any particular physical housing for the hands-free phones, and the specification repeatedly described the hands-free interface as simply a microphone and a speaker. Furthermore, claims dependent on those that merely recited “hands free speaker phone” required headset hardware. Finally, the court concluded that to require more structure than just a speaker and a microphone would “impermissibly exclude a preferred embodiment from the claim limitation.”¹⁰⁵¹

The Federal Circuit did, however, follow the district court’s lead in requiring “speaker phone” limitations to require the use of “echo cancellation.” The specification “clearly mandate[d] the use of acoustical and line echo cancellation” where it provided that the “‘use of the speaker and microphone *necessitates* the use of an acoustical echo cancellation algorithm to prevent feedback from destroying the voice signals,” and that “‘a line echo cancellation algorithm is *needed* no matter which telephone interface . . . is used.”¹⁰⁵²

Finally, the Federal Circuit affirmed the district court’s construction of the term “digitizing” where it found that the parties did not dispute its construction: Multi-Tech argued that the district court improperly construed it as necessarily being performed by “the codec circuit” that was disclosed in the preferred embodiments of the specification, while Microsoft responded that the court did not interpret the term to require such performance by the codec circuit.¹⁰⁵³

In *Searfoss v. Pioneer Consolidated Corp.*,¹⁰⁵⁴ plaintiff appealed the decision of the district court to grant summary judgment of non-infringement.¹⁰⁵⁵ Plaintiff sued for infringement of its patent related to moveable cover systems for trucks. Plaintiff sued exclusively under the doctrine of equivalents and did not allege literal infringement.

The district court found that defendant’s truck covers did not infringe because they did not meet at least two elements of the asserted claim. The first, “actuation means for connecting said tension bail to said extension assembly and applying a downward force through said tension bail center

1051. *Id.* at 1353-54, 69 U.S.P.Q.2d (BNA) at 1825-26.

1052. *Id.* at 1354, 69 U.S.P.Q.2d (BNA) at 1826.

1053. *Id.*, 69 U.S.P.Q.2d (BNA) at 1826.

1054. 374 F.3d 1142, 71 U.S.P.Q.2d (BNA) 1517 (Fed. Cir. 2004).

1055. *Id.* at 1144, 71 U.S.P.Q.2d (BNA) at 1518.

section to said cover,”¹⁰⁵⁶ had been construed by the court in its Markman order to be a means-plus-function term with two claimed functions: (1) to connect the tension bail and extension assembly, and (2) to apply a downward force through the tension bail to the cover.¹⁰⁵⁷ The district court further construed the “connecting” function to require in the context of the asserted claim a “direct pivotal connection” between the extension assembly and the tension bail such that “connecting” was synonymous with “attaching.”¹⁰⁵⁸ Thus, it held, this claim term excluded means in which the tension bail and extension assembly were indirectly connected, and especially excluded means in which they were tangentially connected through the cover, “because one function of the actuation means is to apply downward force to the cover and a construction of actuation means to include cover would be ‘nonsensical.’”¹⁰⁵⁹

The district court also held that a “direct pivotal connection” was required to perform the second function of the actuation means, to apply a downward force through the tension bail cover. It rejected plaintiff’s argument that the downward force was merely gravity¹⁰⁶⁰ because the actuation means was “described in relation to its function of applying downward force” and therefore “there must be some relation between the actuation means and the downward force.”¹⁰⁶¹ Furthermore, the court looked to the claim language that stated that the downward force is substantially reduced while the cover is winding back on its reel, and the court found that “the direct pivotal connections between the tension bail and the extension assembly are what makes this possible.”¹⁰⁶²

The court held that no reasonable jury could find that the asserted claims were infringed under the doctrine of equivalents¹⁰⁶³ because the defendant’s system did not contain an equivalent of an “actuation means.” Plaintiff appealed both the construction of the asserted claim and the court’s decision to grant summary judgment based on that construction.¹⁰⁶⁴

The Federal Circuit began its analysis by first stating that the “actuation means” term was not a means-plus-function term as construed by the district court at all, but rather, because the claim specifically recited the structure that performed the claimed function the presumption resulting

1056. *Id.* at 1145, 71 U.S.P.Q.2d (BNA) at 1519.

1057. *Id.* at 1146, 71 U.S.P.Q.2d (BNA) at 1519.

1058. *Id.*, 71 U.S.P.Q.2d (BNA) at 1519-20.

1059. *Id.* at 1147, 71 U.S.P.Q.2d (BNA) at 1520 (quoting *Searfoss v. Pioneer Consol. Corp.*, No. 99-CV-76394-DT, 2002 U.S. Dist. LEXIS 27471, at 6-7 (E.D. Mich. Sept. 13, 2002)).

1060. *Id.*, 71 U.S.P.Q.2d (BNA) at 1520.

1061. *Id.*, 71 U.S.P.Q.2d (BNA) at 1520.

1062. *Id.*, 71 U.S.P.Q.2d (BNA) at 1520.

1063. *Id.* at 1148, 71 U.S.P.Q.2d (BNA) at 1520-21.

1064. *Id.*, 71 U.S.P.Q.2d (BNA) at 1521.

from the use of the word “means” had been overcome.¹⁰⁶⁵ The Federal Circuit held, however, that this error was harmless because, as both parties agreed, the scope of the claim would have been identical had it been construed under a means-plus-function term or under the doctrine of equivalents.¹⁰⁶⁶

Next the Federal Circuit turned to the district court’s construction of “connecting.” Plaintiff argued that neither defendant nor the district court had pointed to anything in the specification to overcome the heavy presumption that “connecting” should be construed in accordance with its ordinary meaning derived from several non-technical dictionaries to encompass both direct and indirect connections. Citing the general law that “what the claim terms would mean to laymen is irrelevant,” the Federal Circuit concluded that what the district court had done was proper.¹⁰⁶⁷ The Federal Circuit determined that the district court had “acknowledged the competing general dictionary definitions of ‘connect’” but had also consulted the written description “as it must.”¹⁰⁶⁸ There, the Federal Circuit agreed with the district court, it was evident that “as used in claim 3, the term ‘connecting’ refers to a ‘direct pivotal connection between the tension bail and the extension assembly’ because the patent referred to the term ‘connecting’ as synonymous with ‘attaching.’”¹⁰⁶⁹

The Federal Circuit found support for this decision in the fact that all relevant figures of the patent showed a direct connection between the legs of the tension bail and those of the extension assembly, and that the specification made reference to such direct connections throughout.¹⁰⁷⁰ Furthermore, the Federal Circuit agreed with the district court that any construction which would permit a connection “through the cover” would be problematic because the cover would then be part of the actuation means, and therefore would apply a downward force to itself according to the rest of the claim language.

In *Novartis Pharmaceuticals Corp. v. Abbott Laboratories*,¹⁰⁷¹ plaintiff sued defendant for infringement of two patents directed to compositions of cyclosporine, a compound used to prevent organ rejection in transplant patients.¹⁰⁷² One of the claimed compositions at issue comprised three

1065. *Id.*, 71 U.S.P.Q.2d (BNA) at 1521. The description of the structure which overcame this presumption is as follows: “said actuation means including first and second pivot connections respectively between said first and second tension bail legs and a midpoint t on said respective first and second extension bail legs.” *Id.*, 71 U.S.P.Q.2d (BNA) at 1521.

1066. *Id.*, 71 U.S.P.Q.2d (BNA) at 1521.

1067. *Id.* at 1149-50, 71 U.S.P.Q.2d (BNA) at 1522.

1068. *Id.*, 71 U.S.P.Q.2d (BNA) at 1522.

1069. *Id.* at 1150, 71 U.S.P.Q.2d (BNA) at 1522.

1070. *Id.*, 71 U.S.P.Q.2d (BNA) at 1522.

1071. 375 F.3d 1328, 71 U.S.P.Q.2d (BNA) 1650 (Fed. Cir. 2004).

1072. *Id.* at 1330, 71 U.S.P.Q.2d (BNA) at 1652.

components in addition to the active cyclosporine ingredient: (1) “a hydrophilic component,” (2) a “lipophilic component,” and (3) “a hydrophilic surfactant.”¹⁰⁷³ The district court granted defendant’s post-verdict motion for a JMOL that it did not infringe this particular patent claim, and plaintiff appealed. Specifically, plaintiff argued that the district court had too narrowly construed the term “lipophilic component” to exclude lipophilic components which acted as “surfactants.”¹⁰⁷⁴

The district court had held that the patent disavowed lipophilic components that acted as surfactants in stating that “[s]uitable components for use as lipophilic phase include any pharmaceutically acceptable solvent which is non-miscible with the selected hydrophilic phase Such solvents will appropriately be devoid or substantially devoid of surfactant function.”¹⁰⁷⁵ The court found further support for its decision from the fact that the claim listed three excipients: a hydrophilic component, a lipophilic component, and a surfactant, and as such, suggested that each component was separate and distinct.¹⁰⁷⁶ Finally, support was found in the prosecution history of the patent, which the jury found that defendant did not infringe, where the patentee had acknowledged a distinction between surfactants and lipophilic components.¹⁰⁷⁷ In granting its JMOL, the district court also had held that, as a matter of law, a jury could not find that defendant’s product infringed under the doctrine of equivalents because of the “specific exclusion principle.”¹⁰⁷⁸

Plaintiff pointed out on appeal that parts of the specification taught that a surfactant may form “part of” the lipophilic phase, and that these teachings contradicted the district court’s findings that a surfactant can form no part of the lipophilic component. The Federal Circuit agreed with plaintiff on this point, but found that the specification’s teaching that a surfactant or a mixture of surfactants can form “part of” the lipophilic phase necessarily implies that the other part of the lipophilic phase must not be a surfactant.¹⁰⁷⁹ Plaintiff’s expert’s opinion that the specification’s disclosure indicated that a surfactant “could function alone” as the solvent of the lipophilic phase was found to “directly contradict[] the express teaching of the specification, and [could] not be used to give [the Court] appropriate

1073. *Id.* at 1330-31, 71 U.S.P.Q.2d (BNA) at 1652-53.

1074. *Id.* at 1335, 71 U.S.P.Q.2d (BNA) at 1656.

1075. *Id.* at 1331, 71 U.S.P.Q.2d (BNA) at 1653 (quoting U.S. Patent No. 5,342,625 (issued Aug. 30, 1994)).

1076. *Id.*, 71 U.S.P.Q.2d (BNA) at 1653.

1077. *Id.*, 71 U.S.P.Q.2d (BNA) at 1653.

1078. *Id.* at 1337, 71 U.S.P.Q.2d (BNA) at 1658.

1079. *Id.*, 71 U.S.P.Q.2d (BNA) at 1658. For example, the patent provided that if a surfactant forms a part of the lipophilic phase, it does so as a “co-solvent.” *Id.*, 71 U.S.P.Q.2d (BNA) at 1658.

guidance to reach the correct claim construction.”¹⁰⁸⁰ Thus, in view of the intrinsic evidence, the Federal Circuit held that “lipophilic component” must be construed to require a non-surfactant component.

Plaintiff also argued that “lipophilic phase” had been unnecessarily limited to require “that the lipophilic component must be immiscible with the hydrophilic phase in the absence of surfactants.”¹⁰⁸¹ The specification provided only that “suitable components for use as lipophilic phase” may include solvents that were nonmiscible with the hydrophilic phase.¹⁰⁸² The Federal Circuit agreed with Novartis that this teaching did not require that the entire lipophilic phase be nonmiscible, rather that only one of its components should be immiscible.¹⁰⁸³

In *On-Line Technologies, Inc. v. Bodenseewerk Perkin-Elmer GMBH*,¹⁰⁸⁴ plaintiff appealed the district court’s claim construction and resultant grant of summary judgment of non-infringement of its patent claims directed to an improvement of a gas cell.¹⁰⁸⁵ The gas cells contemplated by the patent were used in infrared spectrometers to house gas samples for testing their composition.¹⁰⁸⁶ In the infrared spectrometer, an infrared light beam is passed through the gas in the gas cell and a detector on the other side measures the absorption of the light by the gas.¹⁰⁸⁷ Plaintiff’s invention improved the accuracy of the absorption reading by achieving a longer light path of the beam in the gas cell while simultaneously reducing the effects of astigmatism and light beam diffusion that had until then prohibited effective lengthening of the beam.¹⁰⁸⁸ Plaintiff sued defendant for selling devices that allegedly infringed its patent.¹⁰⁸⁹

At the district court level, defendant was granted summary judgment of non-infringement because its devices had objective mirrors with toroidal surfaces, not “substantially spherical” surfaces “having a cylindrical component added thereto” as required by the asserted claim.¹⁰⁹⁰ The district court held that toroidal surfaces were excluded from the scope of the claims because the patent’s specification described the contour of the spherical objective mirrors as “approaching toroidal,” and interpreted this statement to mean that the contemplated mirrors were not actually

1080. *Id.* at 1335-36, 71 U.S.P.Q.2d (BNA) at 1656.

1081. *Id.* at 1336-37, 71 U.S.P.Q.2d (BNA) at 1657.

1082. *Id.* at 1331, 71 U.S.P.Q.2d (BNA) at 1653 (quoting U.S. Patent No. 5,342,625 (issued Aug. 30, 1994)).

1083. *Id.* at 1337, 71 U.S.P.Q.2d (BNA) at 1653.

1084. 386 F.3d 1133, 73 U.S.P.Q.2d (BNA) 1116 (Fed. Cir. 2004).

1085. *Id.* at 1135-36, 73 U.S.P.Q.2d (BNA) at 1117-18.

1086. *Id.*, 73 U.S.P.Q.2d (BNA) at 1117-18.

1087. *Id.* at 1135, 73 U.S.P.Q.2d (BNA) at 1117.

1088. *Id.*, 73 U.S.P.Q.2d (BNA) at 1117-18.

1089. *Id.*, 73 U.S.P.Q.2d (BNA) at 1118.

1090. *Id.* at 1136-37, 73 U.S.P.Q.2d (BNA) at 1118-19.

toroidal.¹⁰⁹¹ In addition, extrinsic evidence was characterized as establishing that “spherical objective mirrors with cylindrical corrections are not the same as toroidal objective mirrors.”¹⁰⁹² The court further found that because the specification disclosed toroidal surfaces but did not claim them, the dedication-disclosure rule mandated that plaintiff could not use the doctrine of equivalents to cover defendant’s toroidal mirrors.¹⁰⁹³

On appeal, the Federal Circuit held that the term “substantially spherical . . . having a cylindrical component added thereto” has no “precise and generally understood meaning in the art as applied to reflective surfaces.” The Federal Circuit therefore searched the specification for guidance as to the term’s meaning. There, it found that the descriptions of the preferred embodiments referred to the curved surfaces as toroidal surfaces and used the same language that was used in the asserted claim. This explicit equation between a toroidal surface and a substantially spherical surface having a cylindrical component added thereto “made clear” that for purposes of the patent, a toroidal surface was included within the scope of the claim. The Federal Circuit went on to state that even if the specification had not been so explicit in its equation, the reference in the description of the preferred embodiment to toroidal surfaces would give rise to a “very strong inference” that the claim included such surfaces within its scope. This was due to the court’s precedent that claims should rarely if ever be construed to exclude the preferred embodiments.

The Federal Circuit disagreed with the district court’s interpretation of “approaching toroidal.” Considered in conjunction with the preferred embodiments’ explicit reference to toroidal surfaces, the Federal Circuit considered it clear that “approaching toroidal” did not intend to exclude surfaces that were actually toroidal. To substantiate this point, the Federal Circuit pointed to evidence that it was considered impossible to make any surface perfectly toroidal, and to the fact that the specification and claims described characteristics and functions of surfaces which were consistent with those of a toroidal surface.¹⁰⁹⁴ Thus, Federal Circuit held that the district court construed the disputed claim too narrowly and vacated the

1091. *Id.* at 1137, 73 U.S.P.Q.2d (BNA) at 1119.

1092. *Id.*, 73 U.S.P.Q.2d (BNA) at 1119.

1093. *Id.*, 73 U.S.P.Q.2d (BNA) at 1119.

1094. *Id.* at 1138-39, 73 U.S.P.Q.2d (BNA) at 1120-21. The Federal Circuit in any event disagreed with Perkin-Elmer’s characterization of the extrinsic evidence and found that it instead supported the construction advanced by On-Line. Specifically, it found that Perkin-Elmer’s evidence demonstrating a technical, mathematical distinction between a toroid and a spherocylinder was refuted by On-Line’s expert’s testimony that a person of ordinary skill in the art would understand the disputed claim language to describe the toroidal surfaces used by On-Line and Perkin-Elmer’s products as opposed to having the meaning attributed to the term by mathematicians. *Id.*, 73 U.S.P.Q.2d (BNA) at 1120-21.

grant of summary judgment.¹⁰⁹⁵

In *C.R. Bard, Inc. v. United States Surgical Corp.*,¹⁰⁹⁶ plaintiff sued for direct infringement and inducement of infringement of its patent directed to a surgical mesh implant used to repair hernias.¹⁰⁹⁷ The asserted claim required “a hollow plug” wherein “the surface of said hollow plug [is] conformable,” and “said hollow plug [is] extremely pliable.”¹⁰⁹⁸ In its claim construction order, the district court construed the asserted claim to require “pre-formed pleats.” The Federal Circuit affirmed this construction. In an opinion written by Judge Michel, the Federal Circuit explained that the pleating limitation was required because the patent’s specification, particularly the Abstract and Summary of the Invention sections, consistently described the plug as having pleats.¹⁰⁹⁹ Although Bard argued that *Texas Digital Systems, Inc. v. Telegenix, Inc.*¹¹⁰⁰ required the court to look to dictionary definitions to determine the ordinary and customary meaning of the claim terms, the court rejected any interpretation of *Texas Digital* that would have it disregard the intrinsic record.¹¹⁰¹ It acknowledged that two lines of claim construction cases exist. One, outlined in *Bell Atlantic Network Services, Inc. v. Covad Communications Group, Inc.*¹¹⁰² and *Vitronics Corp. v. Conceptiontronic, Inc.*,¹¹⁰³ “indicates that the intrinsic record is the primary source for determining claim meaning.”¹¹⁰⁴ A second, outlined in *Texas Digital*, “suggests that the intrinsic record, except for the claims, should be consulted only after the ordinary and customary meaning of claim terms to persons skilled in the pertinent art is determined,” and which “emphasizes technical and general-usage dictionaries in determining the ordinary meaning.”¹¹⁰⁵ But even the latter line of cases, the Federal Circuit said,

does not require, or even allow, the Court to disregard the intrinsic record. Instead, these cases merely suggest a methodology that emphasizes the use of dictionaries and claim that if courts adopt this methodology, claim terms “will be more accurately determined” and improperly narrow constructions “will be more easily avoided.”¹¹⁰⁶

The Federal Circuit deliberately refrained from settling the law on the

1095. *Id.* at 1140, 73 U.S.P.Q.2d (BNA) at 1121-22.

1096. 388 F.3d 858, 73 U.S.P.Q.2d (BNA) 1011 (Fed. Cir. 2004).

1097. *Id.* at 861, 73 U.S.P.Q.2d (BNA) at 1013.

1098. *Id.* at 860, 73 U.S.P.Q.2d (BNA) at 1013.

1099. *Id.*, 73 U.S.P.Q.2d (BNA) at 1013.

1100. 308 F.3d 1193, 64 U.S.P.Q.2d (BNA) 1812 (Fed. Cir. 2002).

1101. *C.R. Bard, Inc.*, 388 F.3d at 862, 73 U.S.P.Q.2d (BNA) at 1014.

1102. 262 F.3d 1258, 59 U.S.P.Q.2d (BNA) 1865 (Fed. Cir. 2001).

1103. 90 F.3d 1576, 39 U.S.P.Q.2d (BNA) 1573 (Fed. Cir. 1996).

1104. *C.R. Bard, Inc.*, 388 F.3d at 861, 73 U.S.P.Q.2d (BNA) at 1014.

1105. *Id.* at 862, 73 U.S.P.Q.2d (BNA) at 1014.

1106. *Id.* at 862-63, 73 U.S.P.Q.2d (BNA) at 1015 (quoting *Tex. Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1205, 64 U.S.P.Q.2d (BNA) 1812, 1820 (Fed. Cir. 2002)).

issue of the “relationship between ordinary and customary meaning, dictionary definitions and the intrinsic record,” explaining that it would affirm the district court’s construction under the standard set forth by either the *Texas Digital* or the *Bell Atlantic* line of cases.¹¹⁰⁷ Beginning by consulting the ordinary and customary meaning of the claim terms as requested by plaintiff, the Federal Circuit determined that plaintiff’s proffered general-use dictionary definitions of “conformable” and “pliable” were unhelpful. The Federal Circuit found definitions of “conformable” and “pliable” to be inapposite because the controlling issue was how “plug” should be construed. The Federal Circuit also questioned the need to consult the dictionary to derive the ordinary meanings of “conformable” or “pliable” because these terms were commonplace. Finally, the Federal Circuit said, referring to *Texas Digital*, “even under the cases [plaintiff] cite[d], the ordinary and customary meaning of a term does not govern if the intrinsic record contains clear lexicography or disavowal of claim scope.”¹¹⁰⁸

The Federal Circuit next explained how the patent’s specification required that the claim be limited to pleated plugs. The Summary of Invention and Abstract both described the invention as being an implant or plug having a pleated surface. It indicated that although “a statement’s location is not determinative” statements that describe the invention as a whole, rather than statements that describe only preferred embodiments, are more likely to support a limiting definition of a claim term and are more likely found in certain locations such as the Summary of Invention section of a patent.¹¹⁰⁹

Plaintiff attempted to argue that statements indicating that the plugs of the invention were pleated were merely “passing references,” by citing *Liebel-Flarsheim Co. v. Medrad, Inc.*,¹¹¹⁰ but the court found that in the present case the patentee “explicitly defines the inventive plug as ‘having’ or ‘including a pleated surface.’”¹¹¹¹ By “defines,” the Federal Circuit stated that it did not mean that the inventors acted as “lexicographers and redefined words differently from their ordinary meaning in the art.”¹¹¹² Instead, the Federal Circuit said it used the term “merely to denote that the specification makes clear at various points that the claimed invention is

1107. See *id.* at 863, 73 U.S.P.Q.2d (BNA) at 1015 (predicting that a resolution to the debate over whether dictionaries may be considered intrinsic evidence would soon be forthcoming). The court was referring to its decision to rehear *Phillips v. AWH Corp.*, 376 F.3d 1382, 71 U.S.P.Q.2d (BNA) 1765 (Fed. Cir. 2004) (en banc). *Id.*, 73 U.S.P.Q.2d (BNA) at 1015.

1108. *Id.*, 73 U.S.P.Q.2d (BNA) at 1015.

1109. *Id.* at 864, 73 U.S.P.Q.2d (BNA) at 1016.

1110. 358 F.3d 898, 69 U.S.P.Q.2d (BNA) 1801 (Fed. Cir. 2004).

1111. *C.R. Bard, Inc.*, 388 F.3d at 864-65, 73 U.S.P.Q.2d (BNA) at 1017.

1112. *Id.* at 864 n.3, 73 U.S.P.Q.2d (BNA) at 1020 n.3.

narrower than the claim language might imply based on a reading of the specification as a whole.”¹¹¹³

Plaintiff also contended that the statements referring to pleating did not define the terms “conformable” or “pliable” as requiring pleating, but again the court found that the focus on these terms was beside the point as the patent described the plug or implant to have pleats.¹¹¹⁴ Plaintiff also argued that because the patent’s descriptions of preferred embodiments did not describe the implant as pleated, the claim cannot be limited to pleated plugs because that construction would counter the general rule that claims should not be construed to exclude preferred embodiments. The Federal Circuit held that the description of the preferred embodiment relied upon by plaintiff unsurprisingly omitted reference to pleating because the description focused on the “filler body” of the implant, which was only one aspect of the claimed invention.¹¹¹⁵ Additionally, because the patent “globally defined the plug as having a pleated surface, the term ‘pleated’ need not be repeated each time a term describing some other aspect of the plug is used.”¹¹¹⁶ Thus, the Federal Circuit held that the failure of the applicant to insert “pleated” before “implant” in the description of the preferred embodiment did not mean that a non-pleated plug was disclosed.¹¹¹⁷

Even though the Federal Circuit found that the specification sufficiently demonstrated that the claimed plug must be pleated, it went on to demonstrate that the prosecution history confirmed its analysis. The Federal Circuit determined that during prosecution, the applicants had overcome at least two rejections by referring to the pleated feature of its invention. First, the applicants overcame a prior art reference by stating that the implant disclosed in reference “does not contain pleats.” Second, the applicants overcame an indefiniteness rejection by stating that the “compressibility” of its plug derives from the configuration of the mesh fabric of which it was comprised, not the mesh fabric itself. Third, in an interview summary, the applicants restated their position that the prior art reference was not invalidating because it did not contain pleats and that it was “the texturing of the implant which permits the claimed plug to conform to irregularities in the shape of the defect without kinking or buckling.”¹¹¹⁸ (The court construed the applicants’ emphasis on the configuration and texturing of the mesh fabric to implicate pleating.)¹¹¹⁹

1113. *Id.*, 73 U.S.P.Q.2d (BNA) at 1020 n.3.

1114. *Id.* at 864-65, 73 U.S.P.Q.2d (BNA) at 1016-17.

1115. *Id.*, 73 U.S.P.Q.2d (BNA) at 1016-17.

1116. *Id.*, 73 U.S.P.Q.2d (BNA) at 1016-17.

1117. *Id.*, 73 U.S.P.Q.2d (BNA) at 1016-17.

1118. *Id.* at 867, 73 U.S.P.Q.2d (BNA) at 1018.

1119. *Id.*, 73 U.S.P.Q.2d (BNA) at 1018.

Similar arguments were made during reexamination of the patent. Some of the applicants' arguments that its claims required pleating during prosecution and reexamination were not clearly made with reference to the asserted claim at issue, and the Federal Circuit acknowledged that it would be "improper" to rely on these arguments as the sole basis for limiting the asserted claim to require pleating. During reexamination, however, the Federal Circuit reasoned that the examiner had rejected the asserted claim and one other claim over a prior art reference on the basis that these claims did not require pleating, and the patentee responded by saying "[a]s explained in the specification . . . the surface of the inventive plug is *pleated*."¹¹²⁰ The Federal Circuit found this to be an unequivocal statement constituting a clear disclaimer of claim scope.¹¹²¹

In *W.E. Hall Co. v. Atlanta Corrugating, L.L.C.*,¹¹²² the Federal Circuit held that the ordinary and customary meanings of claim terms must stand if the written description and prosecution history are ambiguous as to whether the patentee used the terms in an inconsistent manner.¹¹²³ Plaintiff sued for infringement of its patent on a metal "Hydraulically Efficient Ribbed Pipe" for use in storm drain and sewer applications. Claim one of the patent recited pipe of "single piece construction . . . consisting essentially of . . . ribs defining a corresponding plurality of open channels" formed in the material that becomes the pipe wall.¹¹²⁴ The district court held that defendant's pipe did not infringe because it found the "open channel" requirement was not met by the accused channels, which were closed with metal inserts. Nor could the district court understand how a "single piece construction" might include multiple pieces. It thus rejected plaintiff's position that the prosecution history required a departure from the ordinary and customary meaning of the claim terms.¹¹²⁵ The district court further rejected plaintiff's theory as to the partially open transition term "consisting essentially of." Although it agreed that this term permits additional elements that do not materially affect the basic and novel properties of an invention, the Federal Circuit held that its presence in the asserted claim did not extend the claim's scope to include defendant's metal inserts, which materially affected cost, hydraulic efficiency, and corrosion—all of which Hall stated were the novel and basic properties of the invention.¹¹²⁶

The Federal Circuit readily concluded that the district court correctly

1120. *Id.* at 861, 73 U.S.P.Q.2d (BNA) at 1013.

1121. *Id.* at 868, 73 U.S.P.Q.2d (BNA) at 1019.

1122. 370 F.3d 1343, 71 U.S.P.Q.2d (BNA) 1135 (Fed. Cir. 2004).

1123. *Id.* at 1353, 71 U.S.P.Q.2d (BNA) at 1142.

1124. *Id.* at 1346, 71 U.S.P.Q.2d (BNA) at 1136.

1125. *Id.* at 1349, 71 U.S.P.Q.2d (BNA) at 1139.

1126. *Id.*, 71 U.S.P.Q.2d (BNA) at 1139.

construed the claims. It began by stating the general rule that where the inventor does not act as his own lexicographer within the four corners of the intrinsic evidence, the appellate court must rely on the plain and ordinary meaning of these terms.¹¹²⁷ The Federal Circuit then reasoned that, according to general use dictionaries, the term “open” means “[n]ot shut in or confined, not surrounded by barriers,” and that “single piece” was clear in meaning without resorting to a dictionary.¹¹²⁸ Further, the Federal Circuit noted nothing in the specification or the prosecution history clearly suggests that plaintiff intended to use these terms in a manner other than according to their ordinary meanings.¹¹²⁹

The Federal Circuit then rejected defendant’s plea to read “open channels” as meaning those that are free from reinforcing inserts, and “single piece construction” to mean that only a single element contributing to the structural integrity of the pipe.¹¹³⁰ The Federal Circuit pointed out that, while plaintiff focused on the reinforcing elements of the prior art Nyssen pipe during prosecution, the record does not dispositively show that the company intended to use the disputed terms in any manner inconsistent with their ordinary meanings. Further, the Federal Circuit added that, while some statements from the prosecution history might be read to support plaintiff’s theory as to the “single piece construction” language, because this dialogue is not necessarily inconsistent with the term’s ordinary meaning, the district court was correct in using the ordinary meaning.¹¹³¹

In *Kinik Co. v. International Trade Commission*,¹¹³² the issue was whether claims directed to a perform made from a “mixture containing a liquid binder, powdered matrix material, and abrasive particles”¹¹³³ were limited to mixtures containing a larger volume of liquid binder concentration than powdered matrix material.¹¹³⁴ Recognizing case law stating that, “while claims are to be interpreted in light of the specification . . . it does not follow that limitation from the specification may be read into the claims,”¹¹³⁵ the Federal Circuit explained that such

1127. *Id.*, 71 U.S.P.Q.2d (BNA) at 1139 (citing *Vitronics Corp. v. Conceptronic Inc.*, 90 F.3d 1576, 1582, 39 U.S.P.Q.2d (BNA) 1573, 1576 (Fed. Cir. 1996)).

1128. *Id.* at 1350, 71 U.S.P.Q.2d (BNA) at 1140.

1129. *W.E. Hall Co. v. Atlanta Corrugating, L.L.C.*, 370 F.3d 1343, 71 U.S.P.Q.2d (BNA) 1135 (Fed. Cir. 2004).

1130. *Id.* at 1351, 71 U.S.P.Q.2d (BNA) at 1140.

1131. *Id.* at 1351, 71 U.S.P.Q.2d (BNA) at 1140.

1132. 362 F.3d 1359, 70 U.S.P.Q.2d (BNA) 1300 (Fed. Cir. 2004).

1133. *Id.* at 1363, 70 U.S.P.Q.2d (BNA) at 1302.

1134. *Id.*, 70 U.S.P.Q.2d (BNA) at 1302.

1135. *Id.* at 1364, 70 U.S.P.Q.2d (BNA) at 1304 (citing *Sjolund v. Musland*, 847 F.2d 1573, 1581, 6 U.S.P.Q.2d (BNA) 2020, 2027 (Fed. Cir. 1988) and *Texas Instruments, Inc. v. U.S. Int’l Trade Comm’n*, 805 F.2d 1558, 1563, 231 U.S.P.Q. (BNA) 833, 835 (Fed. Cir. 1986)).

“precedent does not hold that claims are not limited by what is described and enabled. Patent claims are directed to the invention set forth in the specification.”¹¹³⁶

Reviewing the specification of the disputed patent, the court noted that the claimed invention was “described with specificity . . . and this specificity was illustrated in the examples.”¹¹³⁷ In particular, the Federal Circuit observed that the specification “states that the prior art performs having low binder volume are hard, stiff, and brittle. . . . The inventor’s discussion of the disadvantages of the low binder prior art sheds light on the scope of the invention.”¹¹³⁸ The Federal Circuit further explained that “[e]ven the broadest descriptive test in the [] specification describes only mixtures where binder volume exceeds matrix powder volume.”¹¹³⁹ Additionally, the Federal Circuit determined that the prosecution history confirmed its reading of the specification because “[d]uring prosecution the same specificity—the excess volume of liquid binder over matrix powder in the perform mixture—was emphasized as a material distinction from the prior art.”¹¹⁴⁰ Accordingly, the Federal Circuit held that the claimed mixture required a greater volume of liquid binder than powdered matrix because “[c]laims cannot be construed as encompassing prior art that was distinguished in the specification and disclaimed during prosecution.”¹¹⁴¹

Finally, addressing an ALJ’s reasoning that the term “mixture” should be construed consistent with dictionary definitions, the Federal Circuit explained that the “issue, however, is not one dictionary definition of a common word, but meaning of ‘mixture’ as used in the patent documents The words of patent claims have the meaning and scope with which they are used in the specification and prosecution history.”¹¹⁴²

*Astrazeneca AB v. Mutual Pharmaceutical Co.*¹¹⁴³ involved the proper construction of the term “solubilizer.”¹¹⁴⁴ Although the parties agreed that the ordinary meaning of “solubilizer” encompassed surfacants, co-solvents, and complexation agents, defendant argued that the term’s use in the intrinsic evidence required that it be construed as limited only to surfacants.¹¹⁴⁵ While the district court rejected defendant’s effort to curtail the term’s ordinary meaning, the court reversed. However, in so doing, the

1136. *Id.*, 70 U.S.P.Q.2d (BNA) at 1304.

1137. *Id.* at 1365, 70 U.S.P.Q.2d (BNA) at 1304.

1138. *W.E. Hall Co. v. Atlanta Corrugating, L.L.C.*, 370 F.3d 1343, 1365, 71 U.S.P.Q.2d (BNA) 1135, 1304 (Fed. Cir. 2004).

1139. *Id.*, 71 U.S.P.Q.2d (BNA) at 1304.

1140. *Id.*, 71 U.S.P.Q.2d (BNA) at 1304.

1141. *Id.*, 71 U.S.P.Q.2d (BNA) at 1304.

1142. *Id.*, 71 U.S.P.Q.2d (BNA) at 1304 (citation omitted).

1143. 384 F.3d 1333, 72 U.S.P.Q.2d (BNA) 1726 (Fed. Cir. 2004).

1144. *Id.* at 1135-36, 72 U.S.P.Q.2d (BNA) at 1727-29.

1145. *Id.* at 1336, 72 U.S.P.Q.2d (BNA) at 1728.

court directly acknowledged that “[t]he district court’s lengthy and careful opinions relied extensively on our recent case law, which is unfortunately complex and inconsistent.”¹¹⁴⁶

The Federal Circuit began by addressing the competing theories of claim construction that have emerged in its jurisprudence. The Federal Circuit first noted that:

A long line of cases indicates that evidence intrinsic to the patent—particularly the patent’s specification, including the inventors’ statutorily-required written description of the invention—is the primary source for determining claim meaning. We have embraced that position frequently Indeed, that proposition has been accepted in patent law for many years [T]he goal of claim construction is to determine what an ordinary artisan would deem the invention claimed by the patent, taking the claims together with the rest of the specification. Under this approach to claim construction, evidence extrinsic to the patent is useful insofar as it ‘can shed useful light on the relevant art—and thus better allow a court to place itself in the shoes of a person of ordinary skill in the art’ reading the claims alongside the rest of the specification.¹¹⁴⁷

The Federal Circuit also observed that at the same time:

Language in some of our recent cases suggests that the intrinsic record, except for the claims, should be consulted only after the ordinary and customary meaning of the claim terms to persons skilled in the art is determined. The language in these cases emphasizes the use of technical and general-usage dictionaries in determining the ordinary meaning. Under this approach, where the ordinary meaning of a claim is evidence, the inventor’s written description of the invention, for example, is relevant only insofar as it provides clear lexicography or disavowal of the ordinary meaning.¹¹⁴⁸

The Federal Circuit then explained that the “question becomes whether the intrinsic evidence takes priority in our construction of the claim term ‘solubilizer,’ or if instead the ordinary meaning of the term, as determined from sources such as treatises and dictionaries, controls our construction in the absence of intrinsic evidence of clear lexicography or disavowal.”¹¹⁴⁹ The Federal Circuit, however, determined that it need not “decide which approach is proper as a matter of law” because, even under plaintiff’s proposed approach, the intrinsic evidence “clearly binds [plaintiff] to a narrower definition of ‘solubilizer’ than the extrinsic evidence would

1146. *Id.*, 72 U.S.P.Q.2d (BNA) at 1728.

1147. *Id.* at 1336-37, 72 U.S.P.Q.2d (BNA) at 1728-29 (citations omitted).

1148. *Id.* at 1337, 72 U.S.P.Q.2d (BNA) at 1729 (citing *Tex. Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 64 U.S.P.Q.2d (BNA) 1812 (Fed. Cir. 2002) (citations omitted)).

1149. *Id.* at 1337-38, 72 U.S.P.Q.2d (BNA) at 1729.

support.”¹¹⁵⁰

After reviewing the specification, the Federal Circuit reasoned that both the Background of the Invention and the Description of the Invention establish that the inventors used “solubilizer” as limited only to surfacants.¹¹⁵¹ In particular, the Federal Circuit explained that the specification statement that “[t]he solubilizers suitable according to the invention are defined below,” and then stated that “[t]he solubilizers suitable for the preparations according to the invention are semi-solid or liquid non-ionic surface active agents [i.e., surfacants]”¹¹⁵² Rejecting plaintiff’s argument that such statements referred to the preferred embodiment, the court explained that “[w]e might agree if the specification stated, for example, ‘a solubilizer’ . . . but in fact the specification definitively states ‘the solubilizers suitable for the preparations according to the invention.’”¹¹⁵³ The Federal Circuit further elaborated that while plaintiff “seems to suggest that lexicography requires a statement in the form ‘I define ___ to mean __,’ . . . such rigid formalism is not required.”¹¹⁵⁴

The Federal Circuit also held that the specification disavowed coverage of nonsurfactant solubilizers, explaining that the “inventors’ lexicography alone works an implicit disavowal . . . the rest of the specification goes further.”¹¹⁵⁵ Again rejecting the argument that such statements of disavowal simply addressed features of the preferred embodiment, the Federal Circuit explained that:

[Plaintiff] seems to suggest that clear disavowal requires an “expression of manifest exclusion or restriction” in the form of “my invention does not include ___.” But again, such rigid formalism is not required: Where the general summary or description of the invention describes a feature of the invention . . . and criticizes other products . . . that lack that feature, this operates as a clear disavowal of these other products (and processes using these products).¹¹⁵⁶

The Federal Circuit also stated that “while it is of course improper to limit the claims to the particular preferred embodiments described in the specification, the patentee’s choice of preferred embodiments can shed

1150. *Id.* at 1338, 72 U.S.P.Q.2d (BNA) at 1729-30.

1151. *Id.*, 72 U.S.P.Q.2d (BNA) at 1729-30.

1152. *Id.* at 1339, 72 U.S.P.Q.2d (BNA) at 1730.

1153. *Id.*, 72 U.S.P.Q.2d (BNA) at 1730.

1154. *Id.*, 72 U.S.P.Q.2d (BNA) at 1730.

1155. *Id.* at 1340, 72 U.S.P.Q.2d (BNA) at 1731.

1156. *See id.*, 72 U.S.P.Q.2d (BNA) at 1731 (citing its decision in *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 58 U.S.P.Q.2d (BNA) 1059 (Fed. Cir. 2001) in support of this proposition and explaining that even its seemingly countervailing decision in *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 63 U.S.P.Q.2d (BNA) 1374 (Fed. Cir. 2002) cited *SciMed* with approval).

light on the intended scope of the claims.”¹¹⁵⁷ The Federal Circuit then determined that the “fact that all of the solubilizers listed in the specification and used in the working examples were surfactants adds further support to the conclusion that the term ‘solubilizer’ . . . should be limited, according to the definition employed in the specification, to surfactants.”¹¹⁵⁸

In *Gaus v. Conair Corp.*,¹¹⁵⁹ the disputed language was “an electrical operating unit and a pair of spaced-apart electrically exposed conductive probe networks” in claims directed to circuit devices for use in appliances such as hair dryers.¹¹⁶⁰ The issue before the Federal Circuit was whether the “electrical operating unit” was properly construed as being separate from the “conductive probe networks.”¹¹⁶¹ Starting with the claims themselves, the Federal Circuit reasoned that “the clear implication of the claim language is that the pair of probe networks is a distinct component, separate from the electrical operating unit.”¹¹⁶²

Having surveyed the specification, the Federal Circuit determined that “[n]othing in the descriptions of these two components suggests that their structures or functions overlap. To the contrary, the specification plainly describes the two components as separate.”¹¹⁶³ In particular, the Federal Circuit found it significant that “the specification describes one of the principal advantages of the claimed invention in a way that excludes the electrical operating unit from serving as part of the pair of probe networks.”¹¹⁶⁴ The specification distinguished prior art devices that triggered a protective circuit only when there was direct contact between water and the power supply, and taught that the claimed invention “protects the user from . . . a shock . . . by arranging for the protective circuit to be separate from the voltage-carrying components of the appliance.”¹¹⁶⁵

Rejecting plaintiff’s argument that such discussion in the specification was directed to a preferred embodiment, the Federal Circuit noted that the specification states that “‘according to the invention’ the protective circuit’ accomplishes this disconnection before the user can be connected to voltage-carrying exposed parts via the fluid which has entered the

1157. *Id.* at 1341, 72 U.S.P.Q.2d (BNA) at 1731.

1158. *See id.*, 72 U.S.P.Q.2d (BNA) at 1731 (explaining that, in addition to the specification, prosecution history may be looked at in making a claim construction determination).

1159. 363 F.3d 1284, 70 U.S.P.Q.2d (BNA) 1380 (Fed. Cir. 2004).

1160. *Id.* at 1288, 70 U.S.P.Q.2d (BNA) at 1382.

1161. *Id.*, 70 U.S.P.Q.2d (BNA) at 1382.

1162. *Id.*, 70 U.S.P.Q.2d (BNA) at 1382.

1163. *Id.*, 70 U.S.P.Q.2d (BNA) at 1382.

1164. *Id.* at 1289, 70 U.S.P.Q.2d (BNA) at 1383.

1165. *Id.*, 70 U.S.P.Q.2d (BNA) at 1383.

housing.”¹¹⁶⁶ The Federal Circuit thus held that “[t]he specification . . . demonstrates that the invention itself requires that the user can be completely protected from shock, in contrast to prior art devices that exposed the user to a brief, non-lethal shock.”¹¹⁶⁷

In *Novartis Pharmaceuticals Corp. v. Eon Labs Manufacturing, Inc.*,¹¹⁶⁸ the issue was whether the claim term “hydrosol” was “limited to medicinal products prepared outside of the body or whether it also include[d] products formed . . . after a particular medicinal product has been ingested.”¹¹⁶⁹ Because the parties did not “suggest[] that hydrosol has a specialized meaning inconsistent with the ordinary dictionary definition,”¹¹⁷⁰ the court began its analysis by examining general purpose dictionary definitions.¹¹⁷¹ After reviewing various dictionaries, the Federal Circuit observed that it was presented with two competing definitions: one definition “include[s] a dispersion of solid particles in aqueous colloidal solution formed in a patient’s stomach” and another definition is “limited to medicinal preparation consisting of dispersion of solid particles in an aqueous colloidal solution formed outside the body.”¹¹⁷²

Faced with these competing dictionary definitions, the Federal Circuit explained that well-settled precedent provides that a court “need not arbitrarily pick and choose from the various accepted definitions of a word to decide which meaning was intended as the word is used in a given claim. [Rather t]he subject matter, the context, etc., will more often than not lead to the correct conclusion.”¹¹⁷³ The Federal Circuit then turned to the specification and observed that the claimed “hydrosol” is described strictly “in terms of a pharmaceutical composition and makes no mention of the term in any other context.”¹¹⁷⁴ In particular, the Federal Circuit noted the specification “repeatedly describes the invention as a ‘pharmaceutical composition,’”¹¹⁷⁵ and distinguishes the claimed “hydrosol” from the prior art “on the ground that ‘it was never [previously] proposed to use pharmacologically active agent particles in an aqueous hydrosol form for intravenous injection purposes.’”¹¹⁷⁶ The Federal Circuit thus concluded

1166. *Id.* at 1290, 70 U.S.P.Q.2d (BNA) at 1384.

1167. *Id.*, 70 U.S.P.Q.2d (BNA) at 1384.

1168. 363 F.3d 1306, 70 U.S.P.Q.2d (BNA) 1438 (Fed. Cir. 2004).

1169. *Id.* at 1308, 70 U.S.P.Q.2d (BNA) at 1439.

1170. *Id.*, 70 U.S.P.Q.2d (BNA) at 1439.

1171. *Id.*, 70 U.S.P.Q.2d (BNA) at 1439.

1172. *Id.* at 1310, 70 U.S.P.Q.2d (BNA) at 1441.

1173. *Id.*, 70 U.S.P.Q.2d (BNA) at 1441 (quoting *Liebscher v. Boothroyd*, 258 F.2d 948, 951, 119 U.S.P.Q. (BNA) 133, 135 (C.C.P.A. 1958)).

1174. *Novartis Pharm. Corp. v. Eon Labs Mfg., Inc.*, 363 F.3d 1306, 1310, 70 U.S.P.Q.2d (BNA) 1438, 1441 (Fed. Cir. 2004).

1175. *Id.*, 70 U.S.P.Q.2d (BNA) at 1441.

1176. *Id.*, 70 U.S.P.Q.2d (BNA) at 1441 (quoting U.S. Patent No. 5,389,382 (issued Feb. 14, 1995)).

that “[b]ecause an injectable hydrosol must necessarily be prepared outside the body, these statements further support adoption of more limited definition of ‘hydrosol’ as a medicinal preparation prepared outside the body.”¹¹⁷⁷

The Federal Circuit further determined that the prosecution history also required that the claimed “hydrosol” be limited to preparation outside the body because the patentee’s arguments to overcome the prior art “clearly suggest[] that the hydrosol is a ‘pharmaceutical composition’ that can be injected into a patient.”¹¹⁷⁸ While noting that none of the statements in the intrinsic evidence “is an explicit disclaimer of subject matter sufficient to vary the scope of the claim from its ordinary meaning, these statements are helpful in guiding us to choose between competing dictionary definitions of a claim term.”¹¹⁷⁹

In reaching its construction, the Federal Circuit distinguished its prior decision in *Zenith Laboratories, Inc. v. Bristol-Myers Squibb Co.*,¹¹⁸⁰ in which the court held that claimed subject matter was not limited to a pre-ingested form, because “the plain meaning of the claim language was clear and there was no express or implied pre-ingestion limitation.”¹¹⁸¹ The Federal Circuit also distinguished its decision in *Schering Corp. v. Geneva Pharmaceuticals, Inc.*,¹¹⁸² involving circumstances in which the parties agreed that the claimed metabolite was formed in a patients body following ingestion.¹¹⁸³

In dissent, Judge Clevenger criticized the majority’s reliance on “multiple dictionaries to find an ambiguity in the meaning of ‘hydrosol’ as claimed.”¹¹⁸⁴ In particular, the dissent explained that it was “at a loss to understand why this dictionary search creates an ambiguity” and that the “majority’s decision depends entirely on a suspect secondary meaning for ‘medicine’ found in only a single dictionary,” especially when the disputed term was hydrosol.¹¹⁸⁵ Accordingly, the dissent reasoned that it would have followed “our settled law to allow the term its full breadth, unless the patentee had made an explicit disclaimer or clear disavowal of scope to alter the ordinary broad meaning of the term.”¹¹⁸⁶

In *Norian Corp. v. Stryker Corp.*,¹¹⁸⁷ the Federal Circuit affirmed the

1177. *Id.* at 1310-11, 70 U.S.P.Q.2d (BNA) at 1441-42.

1178. *Id.*, 70 U.S.P.Q.2d (BNA) at 1441-42.

1179. *Id.*, 70 U.S.P.Q.2d (BNA) at 1441-42.

1180. 19 F.3d 1418, 30 U.S.P.Q.2d (BNA) 1285 (Fed. Cir. 1994).

1181. *Novartis Pharm. Corp.*, 363 F.3d at 1311, 70 U.S.P.Q.2d (BNA) at 1442.

1182. 339 F.3d 1373, 67 U.S.P.Q.2d (BNA) 1664 (Fed. Cir. 2003).

1183. *Novartis Pharm. Corp.*, 363 F.3d at 1311, 70 U.S.P.Q.2d (BNA) at 1442.

1184. *Id.* at 1313, 70 U.S.P.Q.2d (BNA) at 1444 (Clevenger, J., dissenting).

1185. *Id.* at 1315, 70 U.S.P.Q.2d (BNA) at 1446 (Clevenger, J., dissenting).

1186. *Id.* at 1314, 70 U.S.P.Q.2d (BNA) at 1445 (Clevenger, J., dissenting).

1187. 363 F.3d 1321, 70 U.S.P.Q.2d (BNA) 1508 (Fed. Cir. 2004).

construction of the term “phosphoric acid source” to mean an “acidic chemical that acts as a source of phosphate.”¹¹⁸⁸ While noting that the “most natural reading of the [claim language] . . . would be a source of phosphoric acid,”¹¹⁸⁹ the court explained that:

The meaning of a technical term in a patent claim is determined in accordance with its usage in the specification, elaborated if appropriate by the prosecution history and with due consideration to usage in the field of invention A technical term is not properly removed from its context in order to seek its meaning Whether a term appearing in a patent claim is subject to limitations beyond its abstract general meaning is determined in the context of the invention described in the specification, the prosecution history, and the prior art.¹¹⁹⁰

The Federal Circuit thus affirmed the district court’s construction because it “accord[ed] with the chemical descriptions in the specification,” and “[n]o contradictory information appears in the patent prosecution.”¹¹⁹¹

*Alza Corp. v. Mylan Laboratories, Inc.*¹¹⁹² involved the issue of whether the term “skin permeable form” should be construed to cover fentanyl that can pass through skin including fentanyl citrate solutions.¹¹⁹³ Noting that the claim term “is not plain on its face to one of ordinary skill in the art,” the Federal Circuit proceeded to review the remaining intrinsic evidence to determine the term’s meaning.¹¹⁹⁴ Referring to the specification’s statement that the inventors “have discovered that fentanyl citrate . . . has such a low skin permeability that it is not at all suitable for transdermal delivery even with the use of permeation enhances. Instead . . . the drug should be incorporated in the transdermal therapeutic system in the form of the base,”¹¹⁹⁵ the Federal Circuit reasoned that fentanyl citrate “is not a skin permeable form of fentanyl in the context of the invention of the [asserted] patent.”¹¹⁹⁶ The Federal Circuit then determined that the prosecution history confirmed that the claim term did not include fentanyl citrate based on the inventors’ argument distinguishing the prior art as “suggest[ing] the production of a diffusion matrix containing fentanyl citrate, which we specifically stated in the [asserted] patent was unsuitable for transdermal delivery.”¹¹⁹⁷ Accordingly, the Federal Circuit held that “[b]oth the prosecution history and the specification disclaimed fentanyl citrate

1188. *Id.* at 1325, 70 U.S.P.Q.2d (BNA) at 1511.

1189. *Id.* at 1325-26, 70 U.S.P.Q.2d (BNA) at 1511-12.

1190. *Id.* at 1326, 70 U.S.P.Q.2d (BNA) at 1512.

1191. *Id.*, 70 U.S.P.Q.2d (BNA) at 1512.

1192. 391 F.3d 1365, 73 U.S.P.Q.2d (BNA) 1161 (Fed. Cir. 2004).

1193. *Id.* at 1370-71, 73 U.S.P.Q.2d (BNA) at 1164.

1194. *Id.* at 1370, 73 U.S.P.Q.2d (BNA) at 1163-64.

1195. *Id.*, 73 U.S.P.Q.2d (BNA) at 1163-64.

1196. *Id.*, 73 U.S.P.Q.2d (BNA) at 1163-64.

1197. *Id.* at 1371, 73 U.S.P.Q.2d (BNA) at 1164.

because it was unsuitable for transdermal administration and therefore not a ‘skin permeable form’ of fentanyl.”¹¹⁹⁸

5. “Coined terms” cases

In 2004, the Federal Circuit rendered several opinions extending the court’s holding in *J.T. Eaton & Co. v. Atlantic Past & Glue Co.*¹¹⁹⁹ that if a “dispositive claim limitation is a term unknown to those of ordinary skill in the art at the time the application was filed[, i]t thus fell on the applicants, as a duty, to provide a precise definition for . . . the limitation.”¹²⁰⁰

In *Goldenberg v. Cytogen, Inc.*,¹²⁰¹ the Federal Circuit noted that though a heavy presumption exists that terms carry their ordinary meaning as would be understood by one of ordinary skill in the art, such a presumption is inapplicable when “a claim term has no ordinary and customary meaning, [and] a court must resort to the remaining intrinsic evidence—the written description and the prosecution history—to obtain the meaning of that term.”¹²⁰² The Federal Circuit began its analysis by noting that the “parties agree that the term ‘marker substance’ has no accepted meaning to one of ordinary skill in the art, and we find no reason to disagree with their conclusion. Accordingly we construe [the term] only as broadly as provided for by the patent itself.”¹²⁰³ In affirming the district court’s construction of “intra-cellular marker substance” to mean an “antigen existing within a body cell,”¹²⁰⁴ the Federal Circuit reasoned that the patent disclosed twenty-six different antigens, all of which were described as “suitable . . . marker substances.”¹²⁰⁵ The Federal Circuit thus determined that, at minimum, the “patent clearly regards ‘antigens’ as falling within the scope of ‘marker substances.’”¹²⁰⁶

The Federal Circuit then explained that the prosecution history supports the district court’s construction by “further reveal[ing] the inventor’s understanding of the term ‘marker substance’ as synonymous with ‘antigen.’”¹²⁰⁷ In particular, the Federal Circuit pointed to the applicant’s argument that “[t]he method and compositions claimed in the present application relate to antibodies to intracellular tumor-associated antigens.”¹²⁰⁸ The Federal Circuit thus concluded that “[b]ecause neither

1198. *Id.*, 73 U.S.P.Q.2d (BNA) at 1164.

1199. 106 F.3d 1563, 41 U.S.P.Q.2d (BNA) 1641 (Fed. Cir. 1997).

1200. *Id.* at 1570, 41 U.S.P.Q.2d (BNA) at 1646.

1201. 373 F.3d 1158, 71 U.S.P.Q.2d (BNA) 1255 (Fed. Cir. 2004).

1202. *Id.* at 1164, 71 U.S.P.Q.2d (BNA) at 1259.

1203. *Id.*, 71 U.S.P.Q.2d (BNA) at 1260.

1204. *Id.*, 71 U.S.P.Q.2d (BNA) at 1259.

1205. *Id.* at 1165, 71 U.S.P.Q.2d (BNA) at 1260.

1206. *Id.*, 71 U.S.P.Q.2d (BNA) at 1260.

1207. *Id.*, 71 U.S.P.Q.2d (BNA) at 1260.

1208. *Id.*, 71 U.S.P.Q.2d (BNA) at 1260.

the patent specification nor the prosecution history supports the breadth of the construction that [plaintiff] desires, we affirm the district court's claim construction"¹²⁰⁹

In *Irdeto Access, Inc. v. Echostar Satellite Corp.*,¹²¹⁰ the Federal Circuit addressed the proper construction of the term "group key."¹²¹¹ Challenging the district court's construction of the term to mean "a key associated with a subset of the total subscriber base,"¹²¹² plaintiff contended that such a construction was contrary to the "heavy presumption that [the claims] mean what they say," and thus "proffer[ed] definitions from a general-usage dictionary to show that nothing in the 'ordinary meaning' of the claim terms requires limiting 'group' to fewer than all subscribers."¹²¹³ Nonetheless, based on the applicants statements during prosecution that "the claims have certain 'key' modifiers which have no accepted meaning in the art . . . [and] that the modifiers for key [such as group] . . . are very adequately described in the specification,"¹²¹⁴ the Federal Circuit rejected the argument.¹²¹⁵ The Federal Circuit instead agreed with defendant's position that "there can be no such 'heavy presumption' where a disputed term lacks an accepted meaning in the art."¹²¹⁶ Citing to its decision in *J.T. Eaton*, the Federal Circuit explained that "absent such an accepted meaning, we construe a claim term only as broadly as provided for by the patent itself. The duty thus falls on the patent applicant to provide a precise definition for the disputed term."¹²¹⁷ The Federal Circuit further explained that: "[W]here evidence such as expert testimony or technical dictionaries demonstrates that artisans would attach a special meaning to a claim term or would attach no meaning at all to the claim term independent of the specification[,] 'general usage dictionaries are rendered irrelevant with respect to that term.'"¹²¹⁸ The Federal Circuit thus reasoned that "[h]aving conceded that the 'key' modifiers have no accepted meaning in the art, the

1209. *Id.*, 71 U.S.P.Q.2d (BNA) at 1260. In affirming, the court also clarified that "molecular sub-units, such as those present in the HCG antigen, qualify as antigens under this construction." *Id.*, 71 U.S.P.Q.2d (BNA) at 1260. Based on this clarification, the court reversed the grant of summary judgement of no infringement under the doctrine of equivalents. *Id.* at 1169, 71 U.S.P.Q.2d (BNA) at 1263.

1210. 383 F.3d 1295, 72 U.S.P.Q.2d (BNA) 1678 (Fed. Cir. 2004). The authors' law firm represented plaintiff in the case.

1211. *Id.* at 1300, 72 U.S.P.Q.2d (BNA) at 1682.

1212. *Id.*, 72 U.S.P.Q.2d (BNA) at 1682.

1213. *Id.*, 72 U.S.P.Q.2d (BNA) at 1682 (quoting *Lieble-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 913, 69 U.S.P.Q.2d (BNA) 1801, 1813 (Fed. Cir. 2004)).

1214. *Id.* at 1298, 72 U.S.P.Q.2d (BNA) at 1681.

1215. *Id.* at 1300, 72 U.S.P.Q.2d (BNA) at 1682.

1216. *Id.*, 72 U.S.P.Q.2d (BNA) at 1682.

1217. *Id.*, 72 U.S.P.Q.2d (BNA) at 1682 (citing *J.T. Eaton & Co. v. Atl. Paste & Glue Co.*, 106 F.3d 1563, 1570, 41 U.S.P.Q.2d (BNA) 1641, 1646-47 (Fed. Cir. 1997)).

1218. *Id.*, 72 U.S.P.Q.2d (BNA) at 1682 (quoting *Vanderlande Indus. Nederland B.V. v. Int'l Trade Comm'n*, 366 F.3d 1311, 1321, 70 U.S.P.Q.2d (BNA) 1696, 1704 (Fed. Cir. 2004)).

applicant expressly directed the public to the specification to discern that meaning and thus measure the scope of the claimed invention.”¹²¹⁹

Seeking to mitigate the impact of the prosecution history, plaintiff argued that the applicant’s statement that certain terms were adequately described in the specification “does not transform every aspect of the preferred embodiment into a claim limitation,” and identified portions of the specification that used language such as “may” and “for example” when describing the term “group key.”¹²²⁰ The Federal Circuit, however, rejected this argument as well, explaining that “the specification consistently equates group with a *subset* of all subscribers.”¹²²¹ Relying on its decision in *Bell Atlantic Network Services, Inc. v. Covad Communications Group, Inc.*,¹²²² holding that “the specification may define claim terms ‘by implication’ such that the meaning may be ‘found in or ascertained by reading of the patent documents,’”¹²²³ the Federal Circuit concluded that:

[W]hile the specification does not contain any statements of explicit disavowal or words of manifest exclusion, it repeatedly, consistently, and exclusively uses “group” to denote fewer than all subscribers, manifesting the patentee’s clear intent to so limit the term. The specification also contains no affirmative indication that group can consist of all subscribers within the system. A reasonable competitor reading the patent could only understand “group” to refer to a subset of all subscribers.¹²²⁴

In reaching this conclusion, the Federal Circuit rejected plaintiff’s argument that “only statements of ‘clear disclaimer’ in language indicating ‘manifest exclusion or restriction’ can overcome the ‘heavy presumption’ in favor of ordinary meaning.”¹²²⁵ In so doing, the Federal Circuit distinguished cases such as *Leibel-Flarshiem Co. v. Medrad, Inc.*,¹²²⁶ *Brookhill-Wilk I, L.L.C. v. Intuitive Surgical, Inc.*,¹²²⁷ and *Teleflex Inc. v. Ficosa North America Corp.*¹²²⁸ on the basis that such cases did not

involve[] a situation where the applicant admitted that certain claim terms lacked any agreed upon meaning in the art . . . and unequivocally directed the patent examiner, as well as the public, to the specification as

1219. *Id.* at 1303, 72 U.S.P.Q.2d (BNA) at 1684.

1220. *Id.* at 1300, 72 U.S.P.Q.2d (BNA) at 1683.

1221. *See id.* at 1301, 72 U.S.P.Q.2d (BNA) at 1683 (explaining that “[n]owhere does the specification contemplate a single group made up of the entire subscriber base.”).

1222. 262 F.3d 1258, 59 U.S.P.Q.2d (BNA) 1865 (Fed. Cir. 2001).

1223. *Id.* at 1268, 59 U.S.P.Q.2d (BNA) at 1870-71 (quoting *Vitronics Corp. v. Conception, Inc.*, 90 F.3d 1576, 1582 n.6, 39 U.S.P.Q.2d (BNA) 1573, 1578 n.3 (Fed. Cir. 1996)).

1224. *Irdeto Access, Inc.*, 383 F.3d at 1303, 72 U.S.P.Q.2d (BNA) at 1684.

1225. *Id.* at 1301, 72 U.S.P.Q.2d (BNA) at 1684.

1226. 358 F.3d 898, 69 U.S.P.Q.2d (BNA) 1801 (Fed. Cir. 2004).

1227. 334 F.3d 1294, 67 U.S.P.Q.2d (BNA) 1132 (Fed. Cir. 2003).

1228. 299 F.3d 1313, 63 U.S.P.Q.2d (BNA) 1374 (Fed. Cir. 2002).

the complete source of meaning for the disputed terms Patentee's clear intent to rely on the four corners of his patent to define fully the terms at issue thus takes this case out of the "heavy presumption" regime of our cases.¹²²⁹

6. *Means-plus-function claims*

a. *Determining whether a claim limitation invokes the means-plus-function format of 35 U.S.C. § 112, ¶ 6*

One of the Federal Circuit's most consistent areas of jurisprudence is its practice of strictly enforcing the rule that a claim term without the word "means" carries a heavy presumption that it is not a means-plus-function limitation under § 112, ¶ 6.¹²³⁰ As the Federal Circuit explained in 2004, "it is not surprising that we have seldom held that a limitation not using the term 'means' must be considered to be in means-plus-function form. In fact, we have identified only one published opinion since [1996] in which we have done so."¹²³¹

In *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*,¹²³² the Federal Circuit reversed the district court's construction of the phrase "determining a condition of the heart from among a plurality of conditions of the heart."¹²³³ Agreeing with plaintiff's contentions that the claim preamble's recitation of "the method comprising the steps of"¹²³⁴ does not invoke a means-plus-function analysis, the Federal Circuit held that

Method claims necessarily recite steps of the method, and the preamble words that "the method comprises the steps of" do not automatically convert each ensuing step into the form of § 112[,] ¶ 6. Nor does the preamble usage "steps of" create a presumption that each ensuing step is in step-plus-function form; to the contrary, the absence of the signal "step for" creates the contrary presumption.¹²³⁵

In *Linear Technology Corp. v. Impala Linear Corp.*,¹²³⁶ the Federal Circuit addressed the issue of whether the terms "circuit" and "circuitry" failed to connote sufficient structure such that the terms should be construed as means-plus-function limitations.¹²³⁷ Reversing the construction of these terms pursuant to § 112, ¶ 6, the Federal Circuit

1229. *Irdeto Access, Inc.*, 383 F.3d at 1302-03, 72 U.S.P.Q.2d (BNA) at 1684.

1230. See 35 U.S.C. § 112, ¶ 6 (2000) (stating that, in the specification of a patent application, the means of performing a function can be an element of the specification).

1231. *Lighting World, Inc. v. Birchwood Lighting, Inc.*, 382 F.3d 1354, 1362, 72 U.S.P.Q.2d (BNA) 1344, 1351 (Fed. Cir. 2004).

1232. 381 F.3d 1371, 72 U.S.P.Q.2d (BNA) 1333 (Fed. Cir. 2004).

1233. *Id.* at 1375, 72 U.S.P.Q.2d (BNA) at 1335.

1234. *Id.* at 1381, 72 U.S.P.Q.2d (BNA) at 1340.

1235. *Id.* at 1382, 72 U.S.P.Q.2d (BNA) at 1341.

1236. 379 F.3d 1311, 72 U.S.P.Q.2d (BNA) 1065 (Fed. Cir. 2004).

1237. *Id.* at 1319, 72 U.S.P.Q.2d (BNA) at 1069.

explained that the district court legally erred by failing to impose on the party advocating a means-plus-function construction the burden “demonstrating that the claim fails to ‘recite sufficiently definite structure’ or recites a ‘function without reciting sufficient structure for performing that function.’”¹²³⁸ The Federal Circuit noted that to “determine whether a claim term recites sufficient structure, we examine whether it has an understood meaning in the art,”¹²³⁹ and concluded that the “[t]echnical dictionaries, which are evidence of the understandings of persons of skill in the technical arts, plainly indicate that the term ‘circuit’ connotes structure.”¹²⁴⁰ The Federal Circuit also reasoned that viewing the claim language in context confirmed that the term “circuit” connoted sufficient structure because claims recited the “respective objectives or operations” for each circuit.¹²⁴¹ In addition, the Federal Circuit observed that an expert declaration from plaintiff’s expert demonstrated “[t]hat persons of ordinary skill in the art would understand the structural arrangements of circuit components from the term ‘circuit’ coupled with the qualifying language of [the] claim[s].”¹²⁴² Accordingly, the Federal Circuit held that

because the term “circuit” is used in each of the disputed limitations of [the] claims . . . with a recitation of the respective circuit’s operation in sufficient detail to suggest structure to persons of ordinary skill in the art, the “circuit” and “circuitry” limitations of such claims are not means-plus-function limitations.¹²⁴³

The decision in *Linear Technology* appears to comport with the decision in *Apex Inc. v. Raritan Computer, Inc.*,¹²⁴⁴ in which the Federal Circuit held that the term “circuit” preceded by “an appropriate identifier such as ‘interface,’ ‘programming’ and ‘logic,’ certainly identifies some structural meaning to one of ordinary skill in the art” so as to preclude invocation of § 112, ¶ 6 absent the word “means.”¹²⁴⁵ The Federal Circuit’s holding that the term “circuit” for performing a certain function provides sufficient structure is difficult to reconcile with its reasoning in *Personalized Media Communications, L.L.C. v. International Trade Commission*,¹²⁴⁶ which posited that § 112, ¶ 6 would be applicable for “generic structural term[s]

1238. *Id.*, 72 U.S.P.Q.2d (BNA) at 1070 (quoting *Watts v. XL Sys., Inc.*, 232 F.3d 877, 880, 56 U.S.P.Q.2d (BNA) 1836, 1838 (Fed. Cir. 2000)).

1239. *Id.* at 1320, 72 U.S.P.Q.2d (BNA) at 1070 (quoting *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1369, 62 U.S.P.Q.2d (BNA) 1658, 1665 (Fed. Cir. 2002)).

1240. *Id.*, 72 U.S.P.Q.2d (BNA) at 1070.

1241. *Id.*, 72 U.S.P.Q.2d (BNA) at 1070.

1242. *Id.*, 72 U.S.P.Q.2d (BNA) at 1071.

1243. *Id.* at 1320-21, 72 U.S.P.Q.2d (BNA) at 1071.

1244. 325 F.3d 1364, 1371-72, 66 U.S.P.Q.2d (BNA) 1444, 1451 (Fed. Cir. 2003).

1245. *Id.* at 1373, 66 U.S.P.Q.2d (BNA) at 1451. However, the court expressly noted that “we do not find it necessary to hold that the term ‘circuit’ by itself always connotes sufficient structure.” *Id.*, 66 U.S.P.Q.2d (BNA) at 1451.

1246. 161 F.3d 696, 48 U.S.P.Q.2d (BNA) 1880 (Fed. Cir. 1998).

such as ‘means,’ ‘element,’ or ‘device.’”¹²⁴⁷

In *Lighting World, Inc. v. Birchwood Lighting, Inc.*,¹²⁴⁸ an issue on appeal was whether the claim term “connector assembly” was a means-plus-function limitation under § 112, ¶ 6.¹²⁴⁹ The Federal Circuit began its analysis by observing that its “precedent provides that ‘[a] claim limitation that actually uses the word ‘means’ invokes a rebuttable presumption that § 112, ¶ 6 applies. By contrast, a claim term that does not use ‘means’ will trigger the rebuttable presumption that § 112, ¶ 6 does not apply.”¹²⁵⁰ The Federal Circuit then explained that “[t]he presumption that a limitation lacking the term ‘means’ is not subject to section 112, ¶ 6 can be overcome if it is demonstrated that ‘the claim term fails to recite sufficiently definite structure or else recites function without reciting sufficient structure for performing that function,’”¹²⁵¹ and noted that its “cases make clear . . . that the presumption flowing from the absence of the term ‘means’ is a strong one that is not readily overcome.”¹²⁵² The Federal Circuit further reasoned that “[t]he task of determining whether [a] limitation in question should be regarded as a means-plus-function limitation, like all claim construction issues, is a question of law for the court, even though it is a question on which evidence from experts may be relevant.”¹²⁵³ The Federal Circuit thus explained that “even when expert evidence has been offered with respect to the issue of claim construction, we must determine whether that evidence comports with the intrinsic evidence in the case.”¹²⁵⁴

Turning to the claim language and record before it, the Federal Circuit observed that defendant introduced an expert declaration urging that the means-plus-function format should be invoked because “the term ‘connector’ encompasses ‘at least a single infinity of possible devices’ and that the term ‘would not provide [those] of ordinary skill in the lighting fixture art with sufficient structural information . . . as to what device or component would read on the claim element.”¹²⁵⁵ The Federal Circuit, however, explained that the expert declaration failed to

address the central issue in determining whether section 112[,] ¶ 6 applies. Implicit in [defendant’s expert] declaration is the premise that in order to be regarded as structural for purposes of section 112[,] ¶ 6, a

1247. *Id.* at 704, 48 U.S.P.Q.2d (BNA) at 1887.

1248. 382 F.3d 1354, 72 U.S.P.Q.2d (BNA) 1344 (Fed. Cir. 2004).

1249. *Id.* at 1358, 72 U.S.P.Q.2d (BNA) at 1348.

1250. *Id.*, 72 U.S.P.Q.2d (BNA) at 1348 (quoting *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1369, 62 U.S.P.Q.2d (BNA) 1658, 1664 (Fed. Cir. 2002)).

1251. *Id.*, 72 U.S.P.Q.2d (BNA) at 1348 (quoting *CCS Fitness, Inc.*, 288 F.3d at 1369, 62 U.S.P.Q.2d (BNA) at 1664 (internal quotations omitted)).

1252. *Id.*, 72 U.S.P.Q.2d (BNA) at 1348.

1253. *Id.*, 72 U.S.P.Q.2d (BNA) at 1348.

1254. *Id.* at 1359, 72 U.S.P.Q.2d (BNA) at 1349.

1255. *Id.*, 72 U.S.P.Q.2d (BNA) at 1349.

claim limitation must identify a specific structure and not use a generic term that includes a wide variety of structures.¹²⁵⁶

The Federal Circuit rejected defendant's approach as "unduly restrictive,"¹²⁵⁷ explaining that precedent does not "require[] the claim term to denote a specific structure;"¹²⁵⁸ rather, it is sufficient "if the claim term is used in common parlance or by persons of skill in the pertinent art to designate structure, even if the term identifies a broad class of structures by their function."¹²⁵⁹

The Federal Circuit thus explained that the proper inquiry was whether the term "connector assembly" would be understood by a person skilled in the art "to describe structure, as opposed to a term that is simply a nonce word or a verbal construct that is not recognized as the name of structure and is simply a substitute for the term 'means for.'"¹²⁶⁰ The Federal Circuit then noted that its precedent instructs that relevant dictionaries can be consulted "to determine if a disputed term has achieved recognition as a noun denoting structure, even if the noun is derived from the function performed."¹²⁶¹ After examining the dictionary definitions of the words "connector" and "assembly," the Federal Circuit concluded that:

While the terms "connector" and "connector assembly" are certainly broad, and may in the end include any structure that performs the role of connecting . . . [t]hose terms are routinely treated as structural by patent practitioners and courts, and we conclude that there is no reason to treat the term "connector assembly" any differently for purposes of section 112[.], ¶ 6. The consequence of defining the term "connector assembly" free of the constraints of section 112[.], ¶ 6 may be to render the claim more vulnerable to attack for invalidity, but that is a risk that a claim drafter assumes by choosing broad structural terms rather than choosing

1256. *Id.*, 72 U.S.P.Q.2d (BNA) at 1349.

1257. *Id.*, 72 U.S.P.Q.2d (BNA) at 1349.

1258. *Id.*, 72 U.S.P.Q.2d (BNA) at 1349.

1259. *Id.* at 1359-60, 72 U.S.P.Q.2d (BNA) at 1349. The court canvassed its precedent in which it held that broad claim language lacking the word "means" did not invoke § 112, ¶ 6. *See id.* at 1360 (discussing *Greenberg v. Ethicon Endo-Surgery, Inc.*, 91 F.3d 1580, 39 U.S.P.Q.2d (BNA) 1783 (Fed. Cir. 1996), which held that the phrase "denote mechanism" was not a means-plus-function limitation; *Personalized Media Communications, L.L.C. v. Int'l Trade Comm'n*, 161 F.3d 696, 48 U.S.P.Q.2d (BNA) 1880 (Fed. Cir. 1998), which held that the phrase "digital detector" was not a means-plus-function limitation; *Al-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 50 U.S.P.Q.2d (BNA) 1161 (Fed. Cir. 1999), which held that the phrase "eyeglass hanger member" was not a means-plus-function limitation; *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 62 U.S.P.Q.2d (BNA) 1658 (Fed. Cir. 2002), which held that the phrase "reciprocating member" was not a means-plus-function limitation; *Watts v. XL Sys., Inc.*, 232 F.3d 877, 56 U.S.P.Q.2d (BNA) (Fed. Cir. 2000), which held that the phrase "sealing connected joints" was not a means-plus-function limitation).

1260. *Id.*, 72 U.S.P.Q.2d at 1350.

1261. *Id.*, 72 U.S.P.Q.2d at 1350.

to claim in means-plus-function format under section 112 [,] ¶ 6.¹²⁶²

The Federal Circuit further added that in light of its rules for determining whether a claim term without the word “means” invokes § 112, ¶ 6, “it is not surprising that we have seldom held that a limitation not using the term ‘means’ must be considered to be in means-plus-function form. In fact, we have identified only one published opinion since [1996] in which we have done so.”¹²⁶³

In *Phillips v. AWH Corp.*,¹²⁶⁴ the Federal Circuit reversed a construction of the term “baffles” as a means-plus-function limitation.¹²⁶⁵ The Federal Circuit noted that “use of the word ‘means’ creates a presumption that § 112, ¶ 6 applies,” while absence of “the word ‘means’ creates a presumption that § 112, ¶ 6 does not apply.”¹²⁶⁶ The Federal Circuit then explained that the disputed claim term “does not expressly use the word ‘means’”¹²⁶⁷ and “the word ‘baffle’ is a sufficient recitation of structure, which carries its ordinary meaning of ‘something for deflecting, checking, or otherwise regulating flow.’”¹²⁶⁸ The Federal Circuit further elaborated that “[s]imply because the claims do not identify the matter upon which the baffle acts does not, by itself, rebut that presumption or render the term subject to means-plus-function treatment. Our case law has focused on the structure of claim terms when determining whether § 112, ¶ 6 applies.”¹²⁶⁹

b. Determining the recited function and corresponding structure

NOMOS Corp. v. Brainlab USA, Inc.,¹²⁷⁰ presented a means-plus-function claim related to a system for identifying the precise position of a cancerous lesion in a patient’s body when the patient is positioned on a treatment table of a radiation therapy device.¹²⁷¹ The claim at issue recited as one of its limitations “a means for generating at least one ultrasound image of the lesion in the patient’s body.”¹²⁷² The question was whether this claim covered an accused infringer’s device which is also used for identifying the position of lesion in a patient’s body for purposes of administering radiation therapy, where the allegedly infringing device used a hand-held ultrasound probe, rather than a probe that was fixed to the

1262. *Id.* at 1361-62, 72 U.S.P.Q.2d at 1351.

1263. *Id.* at 1362, 72 U.S.P.Q.2d at 1351.

1264. 363 F.3d 1207, 70 U.S.P.Q.2d (BNA) 1417 (Fed. Cir. 2004).

1265. *Id.* at 1211-12, 70 U.S.P.Q.2d at 1420.

1266. *Id.* at 1212, 70 U.S.P.Q.2d at 1420.

1267. *Id.*, 70 U.S.P.Q.2d at 1420.

1268. *Id.*, 70 U.S.P.Q.2d at 1420 (citing WEBSTER’S THIRD NEW INTERNATIONAL DICTIONARY 162 (1993)).

1269. *Id.*, 70 U.S.P.Q.2d at 1420.

1270. 357 F.3d 1364, 69 U.S.P.Q.2d (BNA) 1853 (Fed. Cir. 2004).

1271. *Id.* at 1366, 69 U.S.P.Q.2d at 1855.

1272. *Id.* at 1366, 69 U.S.P.Q.2d at 1855.

treatment table.

The district court construed the means-plus-function limitation to require an ultrasound probe that was fixed by a bracket or fixation device that maintains the ultrasound probe perpendicular to the treatment table. Applying this construction, the accused device did not infringe. On appeal the Federal Circuit agreed with this construction because the only embodiment described by the patent's specification included a fixed device and described the probe as "disposed on" or "secured to" the treatment table. Furthermore, the patent stated that "the means for generating the ultrasound image may be an ultrasound probe, *including* a means for mounting the ultrasound probe to a radiation therapy device."¹²⁷³ The Federal Circuit also found it clear that "in order to generate ultrasound image[s] the ultrasound probe must be mounted to the treatment table by a fixation device" because the patent stated that the "[u]ltra sound probe . . . is *mounted* so that it can be moved upwardly and downwardly with respect to bracket 423, so that ultrasound probe 422 may be brought into contact with the patient's body 302 *in order to generate ultrasound image 421.*"¹²⁷⁴

Plaintiff countered that claim 1 should not be construed to require a fixed probe because claim 3, dependant upon claim 1, expressly required a "means for mounting," and therefore the concept of claim differentiation prevented the court from reading a mounting requirement into claim 1. The Federal Circuit explained, however, that it was not reading limitations from a dependant claim into the independent claim; it found the fixed probe requirement by looking to the written description, not claim 3. Also, it opined that the claim differentiation concept was a "guide, not a rigid rule," and would not outweigh the provisions of § 112.¹²⁷⁵ Having thus agreed with the district court interpretation of the claims, the Federal Circuit held that the accused device did not infringe because it fashioned a hand held probe. It further concluded that because the accused device antedated the patent, there could be no resort to infringement under the doctrine of equivalents of this means- plus-function claim.

In *TI Group Automotive Systems (North America), Inc. v. VDO North America, L.L.C.*,¹²⁷⁶ plaintiff appealed the district court's granting of defendant's post-verdict motion for a JMOL of non-infringement.¹²⁷⁷ Defendant cross-appealed the district court's denial of its motion for a JMOL of invalidity. The patent at issue was directed to a fuel pump

1273. *Id.* at 1368, 69 U.S.P.Q.2d at 1856.

1274. *Id.*, 69 U.S.P.Q.2d at 1856.

1275. *Id.*, 69 U.S.P.Q.2d at 1856.

1276. 375 F.3d 1126, 71 U.S.P.Q.2d (BNA) 1328 (Fed. Cir. 2004).

1277. *Id.* at 1132, 71 U.S.P.Q.2d at 1333.

assembly technology.¹²⁷⁸ Four claim terms were at issue in the appeal and cross-appeal. First, plaintiff argued that the district court's understanding of "fuel reservoir" as "the portion of the apparatus for pumping fuel in which fuel is collected and retained apart from fuel in the fuel tank" was too narrow.¹²⁷⁹ The Federal Circuit held that the written description amply supported the district court's definition, because each dictionary definition of "reservoir" implicates "some sort of containment of liquid."¹²⁸⁰ Thus, contrary to plaintiff's proffered construction "in the context of this invention," the fuel in the "fuel reservoir" was contained apart from the fuel in the "fuel tank."¹²⁸¹

The second claim term at issue was "pumping means." Plaintiff argued that the district court erred by construing this term as a means-plus-function limitation under § 112, ¶ 6.¹²⁸² The Federal Circuit agreed, finding that, although the term was presumed to be a means-plus-function limitation because it used the word "means," the presumption was overcome because the claim limitation recited not only the means but also its structure, location, and operation.¹²⁸³ The district court therefore erred by incorporating other limitations from the specification that were not necessary to perform the function recited in the limitation "to pump fuel into the reservoir."¹²⁸⁴

With respect to the same claim element, plaintiff argued that the district court had again too narrowly construed "within" in "pumping means for pumping fuel into the reservoir, said means being located *within* the reservoir in the region of the opening" to require the pumping means to be located inside the reservoir. On this point, plaintiff and defendant offered competing dictionary definitions, plaintiff arguing that "within" should be construed to mean "in the limits or compass of, not beyond," and defendant arguing that "within" should be construed to mean "in the inner part or interior of."¹²⁸⁵ The Federal Circuit ultimately upheld the district court's

1278. *Id.* at 1130, 71 U.S.P.Q.2d at 1331.

1279. *Id.* at 1134, 71 U.S.P.Q.2d at 1334.

1280. *Id.*, 71 U.S.P.Q.2d at 1334-35.

1281. *Id.*, 71 U.S.P.Q.2d at 1335. The independent claim at issue in the appeal recited: "2. Apparatus for pumping fuel from a *fuel tank* to an engine comprising: (a) a supply port for carrying fuel from the apparatus to the engine; (b) a *fuel reservoir* which includes an opening for connecting the interior of the reservoir to the interior of the *fuel tank* . . ." *Id.* at 1131, 71 U.S.P.Q.2d at 1332 (emphasis added).

1282. *Id.* at 1135, 71 U.S.P.Q.2d at 1335.

1283. *Id.*, 71 U.S.P.Q.2d at 1335. The court found that the portions of the claim limitation which recited "including a nozzle and a venturi tube in alignment with the nozzle," "being located within the reservoir in the region of the opening," and "the passage of fuel out of the nozzle and through the venturi tube causing fuel to be entrained through the opening into the interior of the reservoir," recited the structure, location, and operation of the "pumping means," respectively.

1284. *Id.*, 71 U.S.P.Q.2d at 1335.

1285. *Id.* at 1136, 71 U.S.P.Q.2d at 1335-36.

construction because plaintiff's proffered construction was not so different from defendant's, where "in ordinary and customary usage, what is not outside is on the inside."¹²⁸⁶

The Federal Circuit also addressed defendant's arguments supporting its construction, on the inner side. Defendant argued that the patent's drawings show the pumping means located inside the reservoir, that plaintiff's construction ignored the "primary . . . and most relevant" definition of "within," and that plaintiff's statements during prosecution of a Japanese counterpart application confirmed that "within" was intended to mean "inside."¹²⁸⁷ The Federal Circuit found the first two arguments unpersuasive because it had previously held that drawings alone do not operate to limit the claims to the specific configuration depicted and because "a patentee is entitled to a definition that encompasses all consistent meanings."¹²⁸⁸ As for defendant's third argument, the Federal Circuit "declined to comment, . . . and note[d] only that 'the varying legal and procedural requirements for obtaining a patent protection in foreign countries might render consideration of certain types of representations inappropriate' for consideration in a claim construction analysis of a United States counterpart."¹²⁸⁹

As for the fifth term at issue, "opening for connecting the interior of the reservoir to the interior of the fuel tank," the Federal Circuit construed it to require "that there be a hole, passage, or aperture for joining or linking the interior of the reservoir to the exterior of the reservoir."¹²⁹⁰ It found that the district court had erred in additionally requiring that the aperture be "disposed adjacent to both the interior of the reservoir and the interior of the fuel tank" because nothing in the ordinary meaning of the term nor in the written description required such limitations.¹²⁹¹

Finally, the Federal Circuit found error in the district court's construction of a limitation in a dependent claim that the opening for connecting, defined above, is "at the bottom of the reservoir" to mean that the opening must be in the "bottom surface of the reservoir."¹²⁹² Rather, the Federal Circuit held, the ordinary and customary meaning of "bottom of the reservoir" is "the lower or lowest part of the reservoir," and was not restricted to only the reservoir's bottom surface.¹²⁹³

1286. *Id.*, 71 U.S.P.Q.2d at 1336.

1287. *Id.*, 71 U.S.P.Q.2d at 1336.

1288. *Id.*, 71 U.S.P.Q.2d at 1336.

1289. *Id.*, 71 U.S.P.Q.2d at 1336 (citing *Caterpillar Tractor Co. v. Berco, S.p.A.*, 714 F.2d 1110, 1116, 219 U.S.P.Q. (BNA) 185, 188 (Fed. Cir. 1983)).

1290. *Id.* at 1138, 71 U.S.P.Q.2d at 1337.

1291. *Id.*, 71 U.S.P.Q.2d at 1337.

1292. *Id.*, 71 U.S.P.Q.2d at 1338.

1293. *Id.*, 71 U.S.P.Q.2d at 1338.

Defendant's "pumping means" was located on the fuel tank side of the opening that divides the fuel tank from the reservoir; it was not "located within the reservoir" as required by the claims. Therefore, the Federal Circuit affirmed the district court's judgment granting of defendant's post-verdict motion for a JMOL of non-infringement.¹²⁹⁴ Having found that the claims were too narrowly construed by the district court, it also vacated the district court's opinion that the patent was valid and remanded the invalidity question for the court's reconsideration under the properly construed claims.¹²⁹⁵

In *Frank's Casing Crew & Rental Tools, Inc. v. Weatherford International, Inc.*,¹²⁹⁶ plaintiff appealed the district court's grant of summary judgment of non-infringement.¹²⁹⁷ The patent was directed to a remotely controlled device for handling sections of well casing to be lowered into a well after drilling. The patented device included a "stabbing apparatus" mounted on a derrick which had "at least three major interconnectable subassemblies" that could be disassembled to facilitate transport, among other things, and an "extendable boom" which contained jaws on one end to engage the casing.¹²⁹⁸ The boom was "hydraulically movable in an up-and-down pivoting motion or in a side-to-side motion, or both such motions simultaneously."¹²⁹⁹ In the preferred embodiment, a hydraulic piston and cylinder subassembly "which [was] connected to the boom through a plate structure" called a "lift plate" was used to raise and lower the boom holding the casing section.¹³⁰⁰

The asserted claims recited the following limitation, which the district court, the parties, and the Federal Circuit agreed was a means-plus-function limitation.¹³⁰¹ The means were for: "selectively pivoting said boom about said horizontal axis to raise and lower the second end of said boom which carries said jaws, and to elevate said boom to a location where it extends in a generally vertical direction."¹³⁰²

The district court held that the structure corresponding to this "means for selectively pivoting" term necessarily included the lift plate to which the boom was attached, rather than merely the piston and cylinder subassembly as plaintiff contended.¹³⁰³ The Federal Circuit affirmed the district court's

1294. *Id.* at 1139, 71 U.S.P.Q.2d at 1338.

1295. *Id.* at 1139-40, 71 U.S.P.Q.2d at 1339.

1296. 389 F.3d 1370, 73 U.S.P.Q.2d (BNA) 1065 (Fed. Cir. 2004).

1297. *Id.* at 1376, 73 U.S.P.Q.2d (BNA) at 1068.

1298. *Id.* at 1372, 73 U.S.P.Q.2d (BNA) at 1066.

1299. *Id.*, 73 U.S.P.Q.2d (BNA) at 1066.

1300. *Id.*, 73 U.S.P.Q.2d (BNA) at 1066.

1301. *Id.* at 1375, 73 U.S.P.Q.2d (BNA) at 1067.

1302. *Id.*, 73 U.S.P.Q.2d (BNA) at 1067.

1303. *Id.*, 73 U.S.P.Q.2d (BNA) at 1067.

construction.¹³⁰⁴ Although the piston and cylinder subassembly occasionally was described without mention of the lift plate, the court found that “the only embodiment showing use of the piston and cylinder subassembly discloses a direct connection to the lift plate.”¹³⁰⁵ Furthermore, the Federal Circuit held that the applicant’s statement during prosecution that the “lifting cylinder ‘*simply cannot be used*’ when directly connected to the boom” in distinguishing the invention from the prior art “underscored the essentiality of the lift plate to the claimed function.”¹³⁰⁶

The Federal Circuit also established that the principle requiring that the “same terms appearing in different portions of the claims should be given the same meaning” extended to terms appearing in related claims and that this principle supported the more limited construction advanced by defendant and arrived at by the district court.¹³⁰⁷ The Federal Circuit explained that other claims besides the asserted one contained the same means-plus-function limitation but also required a “yawing” function, meaning side-to-side movement.¹³⁰⁸ Because (1) the lift plate was essential for performing a yawing function, (2) the identical means-plus-function term found in the asserted claim was found in claims requiring yawing, and (3) the specification gave no reason why the terms should be interpreted differently in the various claims, the district court found that the structure, which corresponded to the means-plus-function term in the asserted claim, required a lift plate.¹³⁰⁹

In reviewing the district court’s grant of summary judgment of non-infringement, the Federal Circuit agreed that the accused device, which achieved pivoting by an under-mounted hydraulic cylinder, satisfied the requirement that an identity of function exist in order to infringe a means-plus-function claim. The Federal Circuit, however, concluded that the accused device represented a “distinct structural approach” to performing that function.¹³¹⁰ Furthermore, because defendant’s accused device was in use before the filing of the patent, the Federal Circuit concluded that it did not need to engage in a separate analysis under the doctrine of equivalents.¹³¹¹ It therefore affirmed the grant of summary judgment of non-infringement.¹³¹²

In *Linear Tech. Corp. v. Impala Linear Corp.*,¹³¹³ an issue on appeal was

1304. *Id.* at 1379-80, 73 U.S.P.Q.2d (BNA) at 1071.

1305. *Id.* at 1377, 73 U.S.P.Q.2d (BNA) at 1069.

1306. *Id.*, 73 U.S.P.Q.2d (BNA) at 1069.

1307. *Id.*, 73 U.S.P.Q.2d (BNA) at 1069.

1308. *Id.* at 1374, 73 U.S.P.Q.2d (BNA) at 1067.

1309. *Id.* at 1377-78, 73 U.S.P.Q.2d (BNA) at 1069-70.

1310. *Id.* at 1378, 73 U.S.P.Q.2d (BNA) at 1070.

1311. *Id.* at 1379, 73 U.S.P.Q.2d (BNA) at 1070.

1312. *Id.*, 73 U.S.P.Q.2d (BNA) at 1070.

1313. 379 F.3d 1311, 72 U.S.P.Q.2d (BNA) 1065 (Fed. Cir. 2004).

the determination of the proper structure corresponding to the claim phrase “a second means for generating a first control signal during a first state of circuit operation.”¹³¹⁴ The Federal Circuit explained that construing a means-plus-function limitation entails a two-step process.¹³¹⁵ First, a court must identify the recited function within the means-plus-function limitation.¹³¹⁶ Second, a court must examine the written description to determine the structure that corresponds to and performs the recited function.¹³¹⁷ The Federal Circuit further noted that “[p]roper application of § 112 ¶ 6 generally reads the claim element to embrace distinct and alternative described structures for performing the claimed function.”¹³¹⁸ Having identified the corresponding structure, the court explained that simply because a “disputed term is not limited to a single structure does not disqualify it as corresponding structure, as long as the class of structures is identifiable by a person of ordinary skill in the art.”¹³¹⁹

*Versa Corp. v. Ag-Bag International Ltd.*¹³²⁰ involved the proper construction of the term “means for creating air channels.”¹³²¹ The Federal Circuit began by noting that construction of a means-plus-function limitation “includes identifying the claimed function and determining the corresponding structure or acts disclosed in the specification.”¹³²² Examining the claim language, the court reasoned that the dispute centered on “whether flutes must be included in the structures that perform this function.”¹³²³ Though noting that “[i]n most places the specification describes that invention as including both flutes and perforated pipe,” the Federal Circuit observed that: “the specification also points out that both structures are not required, stating: ‘[I]t is believed that sufficient air will be present to achieve decomposition with either the channels . . . or the perforated pipe . . . although it is preferred that both the flutes . . . and the pipe . . . be utilized.’”¹³²⁴ The Federal Circuit relied on precedent providing that “[w]hen multiple embodiments in the specification correspond to the claimed function, proper application of § 112, ¶ 6 generally reads the claim

1314. *Id.* at 1321, 72 U.S.P.Q.2d (BNA) at 1071.

1315. *Id.* at 1322, 72 U.S.P.Q.2d (BNA) at 1071-72.

1316. *Id.*, 72 U.S.P.Q.2d (BNA) at 1071.

1317. *Id.*, 72 U.S.P.Q.2d (BNA) at 1072.

1318. *Id.*, 72 U.S.P.Q.2d (BNA) at 1072 (quoting *Creo Prods., Inc. v. Presstek, Inc.*, 305 F.3d 1337, 1346, 64 U.S.P.Q.2d (BNA) 1385, 1396 (Fed. Cir. 2002)).

1319. *Id.*, 72 U.S.P.Q.2d (BNA) at 1072.

1320. 392 F.3d 1325, 73 U.S.P.O.2d (BNA) 1191 (Fed. Cir. 2004).

1321. *Id.* at 1327, 73 U.S.P.O.2d (BNA) at 1192.

1322. *Id.* at 1328, 73 U.S.P.Q.2d (BNA) at 1193 (quoting *IMS Tech., Inc. v. Haas Automation, Inc.*, 206 F.3d 1422, 1430, 54 U.S.P.Q.2D (BNA) 1129, 1137 (Fed. Cir. 2000)).

1323. *Id.*, 73 U.S.P.Q.2d (BNA) at 1193.

1324. *Id.* at 1328-29, 73 U.S.P.Q.2d (BNA) at 1193.

element to embrace each of those embodiments.”¹³²⁵ Based on this precedent, the Federal Circuit concluded that “in light of this disclosure, flutes are not essential.”¹³²⁶

In dissent, Judge Newman explained that:

This case does not present a new question, and it should not have a new answer. The question is, can a patent claim clause written in means-plus-function form be construed, as a matter of law, literally to cover a device that is not the invention described in the specification, that is not shown in any of the drawings, that was not examined for patentability, that was excluded by prosecution arguments, and that is not an asserted equivalent. Statute and precedent require that the question be answered in the negative.¹³²⁷

The dissent further characterized the majority opinion as requiring that “the description of the invention, the prosecution history, and the prior art, must give way to a claim construction that covers an invention that the applicant foresaw but chose not to describe and prosecute.”¹³²⁸

c. Preamble limitations

*Poly-America, L.P. v. GSE Lining Technology, Inc.*¹³²⁹ presented the issue of whether the term “blown-film” appearing in the claim preamble was a claim limitation.¹³³⁰ Instructing that “[n]o litmus test defines when a preamble limits claim scope,”¹³³¹ the Federal Circuit identified two circumstances in which a term in the preamble operates as a claim limitation: (1) when the preamble “recites essential structure or steps, or if it is ‘necessary to give life, meaning, and vitality’ to the claim,”¹³³² and (2) when the preamble recites “additional structure or steps underscored as important by the specification.”¹³³³ The Federal Circuit then determined that “blown-film” was a claim limitation because the “specification is replete with references to the invention as a ‘blown-film’ liner, including

1325. *Id.* at 1329, 73 U.S.P.Q.2d (BNA) at 1193 (quoting *Micro Chem. Inc. v. Great Plains Chem. Co.*, 194 F.3d 1250, 1258, 52 U.S.P.Q.2d (BNA) 1258, 1266 (Fed. Cir. 1999)).

1326. *Id.*, 73 U.S.P.O.2d (BNA) at 1193.

1327. *Id.* at 1331, 73 U.S.P.O.2d (BNA) at 1195.

1328. *Id.*, 73 U.S.P.Q.2d (BNA) at 1195.

1329. 383 F.3d 1303, 72 U.S.P.O.2d (BNA) 1685 (Fed. Cir. 2004).

1330. *Id.* at 1309-10, 72 U.S.P.O.2d (BNA) at 1689.

1331. *Id.* at 1309, 72 U.S.P.Q.2d (BNA) at 1689 (quoting *Catalina Mktg. Int’l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808, 62 U.S.P.Q.2d (BNA) 1781, 1788 (Fed. Cir. 2002)).

1332. *Id.* at 1309-10, 72 U.S.P.Q.2d (BNA) at 1689 (quoting *Pitney Bowes, Inc. v. Hewlett-Packard, Co.*, 182 F.3d 1298, 1305, 51 U.S.P.Q.2d (BNA) 1161, 1169 (Fed. Cir. 1999)).

1333. *Id.* at 1310, 72 U.S.P.Q.2d (BNA) at 1689 (quoting *Catalina Mktg. Int’l, Inc.*, 289 F.3d at 808, 62 U.S.P.Q.2d (BNA) at 1788).

the title of the patent itself and the ‘Summary of the Invention.’”¹³³⁴ The Federal Circuit further reasoned that the specification also repeatedly uses the term “blown-film” to describe the preferred embodiments and “the entire preamble ‘blown-film textured liner’ is restated in each of the patent’s seven claims.”¹³³⁵ Accordingly, the Federal Circuit held that “the inventor considered that the ‘blown-film’ preamble language represented an important characteristic of the claimed invention.”¹³³⁶

In *Intirtool, Ltd. v. Texar Corp.*,¹³³⁷ the district court held that plaintiff’s patent covering punch pliers for use in punching holes in overlapping sheets of metal was invalid for failing to satisfy the written description requirement.¹³³⁸ The sole independent claim of the patent recited as its preamble “handheld punch pliers for simultaneously punching and connecting overlapping sheet metal” such as the corners of overlapping ceiling tile grids.¹³³⁹ Furthermore, Figure Six of the patent illustrated the result of operation of the pliers in which “the portion of the metal not cut by the punching operation bends back down and flat with the metal surface so as to securely connect the two pieces of metal.”¹³⁴⁰ The district court found that the written description did not support the claims because clear and convincing evidence showed that the pliers described by the specification punched holes through overlapping sheets of metal but did not connect the sheets, and *Intirtool* admitted that its pliers did not function in the way illustrated by Figure Six.

On appeal, the Federal Circuit reversed the judgment of invalidity, explaining that the district court erred by interpreting the preamble of the independent claim as a limitation. The Federal Circuit held that the preamble added nothing to the remainder of the claim, which described the punch pliers in “complete and exacting structural detail.”¹³⁴¹ Furthermore, although the specification discussed “a connecting tab [that] remains securely connected to the parent sheet metal,” the court reasoned that the preamble did not recite “any additional structure or steps underscored as important by the specification.”¹³⁴² Moreover, any statements made during prosecution that the punch pliers “simultaneously punched and connected” metal sheets were merely referring to the benefits or features of the claimed invention, which were not patentably significant. Finally, the Federal

1334. *Id.*, 72 U.S.P.O.2d (BNA) at 1689.

1335. *Id.*, 72 U.S.P.O.2d (BNA) at 1689.

1336. *Id.*, 72 U.S.P.Q.2d (BNA) at 1689.

1337. 369 F.3d 1289, 70 U.S.P.O.2d (BNA) 1780 (Fed. Cir. 2004).

1338. *Id.* at 1293, 70 U.S.P.O.2d (BNA) at 1782.

1339. *Id.* at 1294, 70 U.S.P.O.2d (BNA) at 1783.

1340. *Id.* at 1296, 70 U.S.P.O.2d (BNA) at 1785.

1341. *Id.* at 1295, 70 U.S.P.O.2d (BNA) at 1784.

1342. *Id.* at 1290, 70 U.S.P.Q.2d (BNA) at 1780.

Circuit concluded that the district court erroneously construed claim language reciting “bending the sheet metal plug formed by said cut substantially at an imaginary cord on the uncut sheet metal between the ends of said semicircular shaped cut” to require a “crimping effect” bending back the uncut portion of the holes as demonstrated in Figure Six.¹³⁴³ It opined that the claim term was not restricted to the embodiment described by the figure, and therefore the court’s reliance on its erroneous construction rendered its finding of invalidity clearly erroneous.¹³⁴⁴

In *Metabolite Laboratories, Inc. v. Laboratory Corp. of America*,¹³⁴⁵ the licensee of a patent directed to a method of detecting vitamin deficiencies was held liable for indirect infringement in recommending an infringing test to physicians.¹³⁴⁶ The claimed method involved screening of body fluids for increased levels of homocysteine, an amino acid that is metabolized with the assistance of both vitamins B12 and folic acid and thus appears in elevated levels in a person or animal who suffers from a deficiency of either vitamin.¹³⁴⁷ This method was called the “total homocysteine test” and identified a deficiency of either vitamin, but it did not indicate in which vitamin a patient was deficient. Metabolite’s claims were also directed to a “total homocysteine-methylmalonic acid” test, which, through the use of methylmalonic acid, identified the particular vitamin that was deficient.¹³⁴⁸

Metabolite licensed the patented method to LabCorp, a laboratory testing company, who originally performed the total homocysteine assays. In 1998, LabCorp switched to a total homocysteine assay developed by Abbott Laboratories and discontinued paying royalties to Metabolite for its total homocysteine test. Pursuant to a jury verdict, LabCorp was found to have willfully infringed Metabolite’s patent.

LabCorp’s primary non-infringement argument on appeal rested on the construction of the claimed step of “[c]orrelating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.”¹³⁴⁹ LabCorp argued that this correlating step should be construed to require a showing of a separate hematologic or neuropsychiatric symptom to confirm the “correlation.” The Federal Circuit disagreed, explaining that the claim only required correlation between an elevated level of total homocysteine and a deficiency of cobalamin or folate. It found no further required correlation, nor anything about confirmation of

1343. *Id.* at 1296, 70 U.S.P.O.2d (BNA) at 1785.

1344. *Id.*, 70 U.S.P.Q.2d (BNA) at 1785.

1345. 370 F.3d 1354, 71 U.S.P.Q.2d (BNA) 1081 (Fed. Cir. 2004).

1346. *Id.* at 1371, 71 U.S.P.Q.2d (BNA) at 1094.

1347. *Id.* at 1358, 71 U.S.P.Q.2d (BNA) at 1084.

1348. *Id.*, 71 U.S.P.Q.2d (BNA) at 1084.

1349. *Id.* at 1359, 71 U.S.P.Q.2d (BNA) at 1084.

such correlation.

The Federal Circuit found support for this interpretation in the patent's preamble, "[a] method for detecting a deficiency of cobalamin or folate," which it characterized as restating that the invention was a method of detecting vitamin deficiency, and it did not relate such deficiency to any specific "abnormality."¹³⁵⁰ The Federal Circuit found further support in the prosecution history, in which the examiner characterized the preamble as stating the intended use of the invention. Finally, although the Federal Circuit discussed the relationship between elevated homocysteine levels and either clinical or hematological symptoms, it nevertheless found support in the patent's specification, which acknowledged that the described method could show vitamin deficiencies that exist without any clinical symptoms.

The Federal Circuit also rejected LabCorp's argument that, since only twenty percent of assays have elevated levels of homocysteine, only that percentage could form the basis for a damages award. LabCorp itself had urged the district court to define "correlating" to include either a mutual or reciprocal relationship, the court observed. The Federal Circuit declined "the invitation to apply a different claim construction for computation of damages than for infringement liability."¹³⁵¹

7. *Miscellaneous claim construction issues*

The Federal Circuit reinforced its approach to "words of approximation" in *Liquid Dynamics Corp. v. Vaughan Co.*,¹³⁵² where it held that a claim reciting the term "substantial" and "substantially" did not require perfection with respect to the specific parameters that the terms modified.¹³⁵³ Plaintiff brought an action against defendant alleging that its slurry tanks infringed plaintiff's patent covering an apparatus for storing and uniformly mixing the liquid and solid components of waste that comprise slurries in preparation for the slurry's treatment and/or use as a fertilizer or other agents. The claims at issue were drawn to an apparatus for stirring slurries in slurry tanks and required as part of its limitations that certain flow generating means be positioned in a certain way for generating:

substantial helical flow path of the liquid and solid components [with the components] traveling outwardly . . . from the center portion of the tank . . . then upwardly . . . then inwardly . . . then downwardly . . . and then outwardly . . . , the liquid and solid components continuing to travel in the helical path as the entire body of liquid and solid components

1350. *Id.* at 1362, 71 U.S.P.Q.2d (BNA) at 1086.

1351. *Id.* at 1364, 71 U.S.P.O.2d (BNA) at 1088.

1352. 355 F.3d 1361, 69 U.S.P.O.2d (BNA) 1595 (Fed. Cir. 2004).

1353. *Id.* at 1368, 69 U.S.P.Q.2d (BNA) at 1600.

continues to rotate.¹³⁵⁴

The district court accepted defendant's proposed construction of this "substantial helical flow path" limitation to require "a helical flow path" rather than a "largely or generally spiral-like flow path" as plaintiff would have it, because the district court understood the plain claim language to require "a flow path that emanates from the tank center and returns to the center after one rotation," and because two of the patent's figures illustrated a "perfectly helical flow."¹³⁵⁵ Applying this construction, the district court ruled that defendant did not infringe plaintiff's patent and granted defendant's motion for summary judgment of non-infringement.

The Federal Circuit vacated the district court's grant of summary judgment, finding error in its construction. According to the Federal Circuit, courts are to examine intrinsic evidence of record before resorting to extrinsic evidence, and they are to examine intrinsic evidence "in seriatim." It explained that a court is to start with the claim terms' ordinary meaning as understood by one of ordinary skill in the art, and a court is to resort to the written description "when the claim language itself lacks sufficient clarity to determine the scope of the claims."¹³⁵⁶ In light of the its previous decisions construing "words of approximation" such as "substantial(ly)" to require something less than perfection, the Federal Circuit found the plain language of the claims at issue to be clear and not contradicted by anything in the written description—"substantial helical flow path." Such description required neither a perfectly helical flow nor a flow that returns to the center in exactly one rotation, a pattern demonstrated by a flow path that was none other than perfectly helical.

In *Vanderlande Industries Nederland v. International Trade Commission*,¹³⁵⁷ the Federal Circuit reviewed the International Trade Commission's decision that certain imported machinery infringed the claims of a U.S. patent directed to "sortation systems," i.e., mechanical systems for sorting items such as packages.¹³⁵⁸ The meanings of two claim terms were disputed: "glide surface surrounding said [slat] wall" and "glide surface having substantially the same configuration as said outer surface of said slat."¹³⁵⁹

Plaintiff argued that the proper construction of the first term required the glide surface to contact the outer surface of the slat *on all sides*. The Federal Circuit held that it did not. Although it was evident that the glide surface in the preferred embodiment contacted the outer surface of the slat

1354. *Id.* at 1364, 69 U.S.P.O.2d (BNA) at 1597.

1355. *Id.* at 1366, 69 U.S.P.O.2d (BNA) at 1598.

1356. *Id.* at 1367, 69 U.S.P.O.2d (BNA) at 1600.

1357. 366 F.3d 1311, 70 U.S.P.O.2d (BNA) 1696 (Fed. Cir. 2004).

1358. *Id.* at 1312, 70 U.S.P.O.2d (BNA) at 1697.

1359. *Id.* at 1317, 70 U.S.P.O.2d (BNA) at 1701.

at various points on all sides, there also existed points of no contact on each side in the same embodiment. Furthermore, the Summary of Invention section of the patent allowed for one or more sides to not have contact with the slat because it stated that the invention includes embodiments with contact “*between at least one edge* of each slat and an engaging portion of the glide surface of the diverter shoe.”¹³⁶⁰ The Summary section also described a contact point on the *bottom* of the slat without describing a similar point of contact on the *top*. Even though the Summary of Invention section suggested that these embodiments lacking contact on all sides were not preferable, embodiments contact on all sides “[e]ll within the disclosure of the invention, indicating that the patent requires a broader meaning” of the disputed term than the one offered by Vanderlande.¹³⁶¹

The Federal Circuit rejected plaintiff’s argument that the patentee’s statements to the European Patent Office during prosecution of a European counterpart to the patent restricted the scope of the claims to cover glide surfaces that contacted all sides of the outer surface of the slat. The applicants for the European counterpart stated that the claimed invention could be distinguished from a prior art device because the prior art device did not have a glide surface that would “surround” the slats. Their argument was that because the structure in the prior art that corresponded to the claimed “glide surface” was located below the top wall of the slat, it would not “surround” the slats. But the Federal Circuit agreed with the tribunal below that this distinction had “nothing to do with whether or where the ‘glide surface’ contacts the slot,” and therefore did not preclude a broader construction.¹³⁶²

Finally, plaintiff proffered a general-usage dictionary as proof that “glide surface” should be understood as having contact on all sides. It specifically relied on the dictionary’s definition of the noun “glide” and an illustrative example of the word which showed a circular metal button attached to the bottom of furniture legs in which the button completely contacted both the furniture leg and the floor. Apart from its conclusion that plaintiff’s argument consisted of a “shaky syllogism,” the Federal Circuit dismissed it for several reasons. First, plaintiff misapprehended the function of claim construction analysis of arriving at the construction the terms would be given by “a person skilled in the relevant art” by resorting to a general usage dictionary when the testimony of experts and the patent’s inventors showed that “glide surface” had no recognized meaning in the relevant art. “A general usage dictionary cannot overcome credible art-specific evidence

1360. *Id.* at 1320, 70 U.S.P.O.2d (BNA) at 1703.

1361. *Id.*, 70 U.S.P.O.2d (BNA) at 1703.

1362. *Id.*, 70 U.S.P.Q.2d (BNA) at 1703.

of the meaning or lack of meaning of a claim term.”¹³⁶³ Second, plaintiff relied on the definition of “glide,” “only one word in a two-word claim term.”¹³⁶⁴ Finally, the dictionary definition proffered was “entirely eclipsed” by the patent’s written description which provided “detailed, art specific examples of glide surfaces . . . including embodiments in which the glide surface does not contact every side of the slat.”¹³⁶⁵ Thus, the Federal Circuit concluded that a “glide surface” has “some contact, but not necessarily complete contact, with the outer surface of the slat, and that need not contact all sides of the slat.”¹³⁶⁶ This construction differed slightly from that given to the term by the ITC because it required some contact; whereas the ITC’s construction would conceivably cover “no contact” technologies which the Federal Circuit believed were well beyond the scope of the disclosure.

Turning to the second disputed claim term, “the glide surface having substantially the same configuration as said outer surface of said slat,” the Federal Circuit decided whether it was error for the ITC to not construe this term and whether the plaintiff’s proffered construction, “that the glide surface of the shoe must largely, but not necessarily wholly, resemble the configuration of the outer surface of the slat in every, or largely every, relevant respect,” was correct.¹³⁶⁷

Again, the Federal Circuit found defects in plaintiff’s position. First, there was no requirement that the ITC formally construe this claim because it was not in dispute when the ALJ originally construed the claims. Moreover, the ALJ was “plainly attentive to the critical words ‘substantially the same configuration’” in view of its statement that “substantially is considered to be a ‘broadening usage’ that must be given reasonable scope; such words must be viewed by the decision maker as they would be understood by persons experienced in the field of the invention.”¹³⁶⁸ Third, plaintiff did not show how its proffered definition was significantly different from the ALJ’s explanation of the effect of the word substantially.

In *Scanner Technologies Corp. v. ICOS Vision System Corp., N.V.*,¹³⁶⁹

1363. *Id.* at 1321, 70 U.S.P.O.2d (BNA) at 1704.

1364. *Id.*, 70 U.S.P.Q.2d (BNA) at 1704.

1365. *Id.* at 1322, 70 U.S.P.Q.2d (BNA) at 1704. The Court also dismissed Vanderlande’s argument that the content of a mediation statement drafted by the patent owner and licensee supported its contact-with-all-sides construction because it was ambiguous, and in any event, “was at most a theory advanced in a proceeding to mediate a separate litigation, upon which [the Court places] little—if any weight in claim construction.” Furthermore, the content of the statement would be inadmissible in a patent suit in federal district court under Federal Rule of Evidence 408.

1366. *Id.*, 70 U.S.P.O.2d (BNA) at 1705.

1367. *Id.* at 1323, 70 U.S.P.O.2d (BNA) at 1705.

1368. *Id.*, 70 U.S.P.Q.2d (BNA) at 1705.

1369. 365 F.3d 1299, 70 U.S.P.Q.2d (BNA) 1900 (Fed. Cir. 2004).

the court addressed the issue of whether the district court erred in construing the term “an illumination apparatus” as limited to an apparatus containing only a single illumination source.¹³⁷⁰ The Federal Circuit recounted long-standing precedent that it “has repeatedly emphasized that an indefinite article ‘a’ or ‘an’ in patent parlance carries the meaning of ‘one or more’ in open-ended claims containing the transitional phrase ‘comprising.’” Based on this precedent, the Federal Circuit held that the disputed term “is properly construed to encompass one or more illumination sources because the patentee has not evinced a clear intent to limit the article ‘an’ to a single illumination source in either the claims or the specification”¹³⁷¹

Addressing defendant’s argument that both the disputed claim and the specification “call out other limitations with multiple components, e.g., ‘first camera’ to take a ‘first image’ and ‘second camera’ to take ‘a second image,’”¹³⁷² the court explained that:

we do not agree that the failure to specifically refer to a “first illumination apparatus” and a “second illumination apparatus” evinces a clear intent on the part of the patentee that the term be limited to a single illumination source. Indeed, the very use of the article “an” indicates, at least presumptively, that the patentees intended the claim language “an illumination apparatus” to mean one or more illumination sources, and thus to cover implicitly “a first illumination apparatus” and subsequent “illumination apparatuses” where they exist. To limit the claim term “an illumination apparatus” to one illumination source, we require much stronger evidence of the patentees’ intent than strained extrapolation from the language employed by the patentees in other claim limitations.¹³⁷³

The Federal Circuit thus concluded that when a “comprising” claim “includes the article ‘a’ or ‘an,’ and the specification is at best inconclusive on the patentee’s intent to limit that article to a single element or step, [the court does not] find a ‘clear intent’ to so limit the claims.”¹³⁷⁴

In reaching its construction, the Federal Circuit distinguished its prior decisions in *Insituform Technologies, Inc. v. Cat Contracting, Inc.*¹³⁷⁵ and *North American Vaccine, Inc. v. American Cyanamid Co.*,¹³⁷⁶ in which the Federal Circuit held that use of the pronoun “a” limited the claim term to the singular form, as isolated cases involving unique sets of

1370. *Id.* at 1304, 70 U.S.P.O.2d (BNA) at 1904.

1371. *Id.*, 70 U.S.P.O.2d (BNA) at 1904.

1372. *Id.*, 70 U.S.P.O.2d (BNA) at 1904.

1373. *Id.*, 70 U.S.P.O.2d (BNA) at 1904.

1374. *Id.* at 1305, 70 U.S.P.Q.2d (BNA) at 1905.

1375. 99 F.3d 1098, 40 U.S.P.Q.2d (BNA) 1602 (Fed. Cir. 1996).

1376. 7 F.3d 1571, 28 U.S.P.Q.2d (BNA) 1333 (Fed. Cir. 1993).

circumstances.¹³⁷⁷ The Federal Circuit explained that in *Insituform* where the disputed term was “a cup,” “neither the specification nor the drawings discloses the use of more than one cup,” and in fact repeatedly described or depicted ‘the cup.’”¹³⁷⁸ The Federal Circuit also distinguished *North American Vaccine* as inapposite because the claims in that case did not invoke the open phrase “comprising.” Accordingly, the court concluded that: “Indeed, it [is] the very use of the transition ‘comprising’ in conjunction with the article ‘a’ or ‘an’ that creates the presumption that the article is construed to mean one or more elements or steps, unless there is evidence of clear intent to limit the claims.”¹³⁷⁹

*Norian Corp. v. Stryker Corp.*¹³⁸⁰ involved claims directed to kits used to prepare calcium minerals where the disputed language was the phrase “consisting of.”¹³⁸¹ Noting that this transitional phrase “is a term of patent convention meaning that the claimed invention contains only what is expressly set forth in the claims,”¹³⁸² the Federal Circuit reasoned that the phrase “does not limit aspects unrelated to the invention [and i]t is thus necessary to determine what is limited by the ‘consisting of’ phrase.”¹³⁸³ Having analyzed the disputed claim, the Federal Circuit concluded that “[w]hile the term ‘consisting of’ permits no other chemicals in the [claimed] kit [for preparing a calcium mineral], a spatula is not part of the invention that is described.”¹³⁸⁴

In dissent, Judge Schall reasoned that the majority opinion “errs in holding that [plaintiff’s] use of the phrase ‘consisting of’ limits only chemical, but not mechanical components.”¹³⁸⁵ The dissent explained that “[o]ur case law makes it clear that ‘closed’ transition phrases such as consisting of are understood to exclude any elements, steps, or ingredients not specified in the claim.”¹³⁸⁶ The dissent further noted that plaintiff “even recognized that a kit can include mechanical items, such as packaging, by stating in [the] claims . . . that ‘said dry ingredients and

1377. *Scanner Techs. Corp.*, 365 F.3d at 1304-06, 70 U.S.P.Q.2d (BNA) at 1904-05.

1378. *Id.* at 1304, 70 U.S.P.O.2d (BNA) at 1904.

1379. *Id.* at 1305-06, 70 U.S.P.O.2d (BNA) at 1904-05.

1380. 363 F.3d 1321, 70 U.S.P.O.2d (BNA) 1508 (Fed. Cir. 2004).

1381. *Id.* at 1331, 70 U.S.P.O.2d (BNA) at 1516.

1382. *Id.*, 70 U.S.P.O.2d (BNA) at 1516.

1383. *Id.*, 70 U.S.P.O.2d (BNA) at 1516.

1384. *Id.*, 70 U.S.P.O.2d (BNA) at 1516.

1385. *Id.* at 1334, 70 U.S.P.Q.2d (BNA) at 1519 (Scholl, J., concurring in part, dissenting in part).

1386. *Id.*, 70 U.S.P.Q.2d (BNA) at 1518 (Scholl, J., concurring in part, dissenting in part) (quoting *AFG Indus., Inc. v. Cardinal IG Co.*, 239 F.3d 1239, 1245, 59 U.S.P.Q.2d 1776 (Fed. Cir. 2001)). A significant thrust of the dissenting opinion was that plaintiff’s use of “consisting of” and its statements during prosecution provided notice to competitors that the claims only covered the elements expressly recited in the claims. *Id.* at 1335-36, 70 U.S.P.Q.2d (BNA) at 1519-20 (Scholl, J., concurring in part, dissenting in part).

solution are present in separate containers.”¹³⁸⁷

The topic of waiver in the context of claim construction has become much more prevalent in Federal Circuit jurisprudence, yet a cohesive framework for resolving the issue continues to prove elusive.¹³⁸⁸ In *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*,¹³⁸⁹ defendant argued that plaintiff failed to preserve its right to appeal a district court’s claim construction because it “did not make a formal objection when the jury was instructed on the claim construction.”¹³⁹⁰ In response, plaintiff contended that “the claim construction was decided at the *Markman* hearing, and was not a proper subject of trial objection under [Federal Rule of Civil Procedure] 51.”¹³⁹¹ Crediting the position advanced by plaintiff, the Federal Circuit explained that:

When the claim construction is resolved pre-trial, and the patentee presented the same position in the *Markman* proceeding as is now pressed, a further objection to the district court’s pre-trial ruling may indeed have been not only futile but unnecessary. In this case the court claim construction resulted from a hearing at which all parties’ positions were presented, and . . . extensively argued Objection under Rule 51 was not required to preserve the right to appeal the *Markman* ruling.¹³⁹²

In *Koito Manufacturing Co. v. Turn-Key-Tech., L.L.C.*,¹³⁹³ the Federal Circuit adopted a seemingly contrary position, holding that the patentee waived its right to challenge the district court’s claim construction by failing to object to the construction during trial even though the construction was rendered pre-trial in two *Markman* orders.¹³⁹⁴ The Federal Circuit explained that the patentee:

did not, however, preserve its claim construction argument at trial and also did not object to the jury’s instruction on this claim term. Because it failed to preserve its rights, [patentee] is not permitted to contest the

1387. *Id.* at 1335, 70 U.S.P.Q.2d (BNA) at 1519 Scholl, J., concurring in part, dissenting in part).

1388. One of the first decisions in this area was *Key Pharm. v. Hercon Labs. Corp.*, 161 F.3d 709, 48 U.S.P.Q.2d (BNA) 1911 (Fed. Cir. 1998), in which the accused infringer changed its positions on claim construction on appeal and even argued that the claim constructions it advanced at trial were in error. The court recognized the defendant’s about-face as a clear strategy to “salvage its invalidity case,” and ruled that a party is prohibited from asserting a position on appeal that is inconsistent with a position it advocated at trial by the law of waiver and judicial estoppel. The court, out of an “abundance of fairness,” however, declined to stop the defendant in the case at hand because it had not explicitly set forth this rule before. Since then, there have been a series of cases in which the court has addressed waiver of a party’s right to argue claim construction on appeal, yet no cohesive rule has emerged.

1389. 381 F.3d 1371, 72 U.S.P.Q.2d (BNA) 1333 (Fed. Cir. 2004).

1390. *Id.* at 1380, 72 U.S.P.Q.2d (BNA) at 1339.

1391. *Id.*, 72 U.S.P.Q.2d (BNA) at 1340.

1392. *Id.* at 1381, 72 U.S.P.Q.2d (BNA) at 1340.

1393. 381 F.3d 1142, 72 U.S.P.O.2d (BNA) 1190 (Fed. Cir. 2004).

1394. *Id.* at 1150, 72 U.S.P.Q.2d (BNA) at 1196.

construction . . . If [patentee] had wanted a different construction . . . it should have objected at trial.¹³⁹⁵

In *Gaus v. Conair Corp.*,¹³⁹⁶ the Federal Circuit rejected plaintiff's argument that the defendant waived its right to advance a claim construction on appeal that differed in scope from the proffered construction at the district court, explaining that: "While the two formulations employ somewhat different language, they embody the same concept—that the probe network must contain two conductive elements that are separate or independent from the voltage—carrying portions of the hairdryer. We find no change in position on [defendant's] part, and thus no waiver."¹³⁹⁷ This holding appears to be a caveat to the court's prior instruction that a party is not prevented from "clarifying" the original scope of its claim construction, suggesting that a proffered construction on appeal does not have to mimic *en hac verba* the construction urged at the district court.

8. *Various tools of claim construction*

a. *Use of related prosecution histories*

In *Goldenberg v. Cytogen, Inc.*,¹³⁹⁸ the Federal Circuit addressed propriety of using the prosecution history of second patent for construing claims of a first patent in circumstances when such claims were rejected on double patenting grounds over the second patent.¹³⁹⁹ The Federal Circuit reasoned that such reliance is entirely appropriate because the prosecution history and content of the second patent "constitute[] part of the prosecution history of the . . . application [for the first patent]."¹⁴⁰⁰ Analogizing to an earlier decision providing that "prior art cited in a patent or cited in the prosecution history of the patent constitutes prior art,"¹⁴⁰¹ the Federal Circuit reasoned that statements made to overcome a double patenting rejection by distinguishing one from another application are part of the intrinsic evidence of the first patent.¹⁴⁰²

The Federal Circuit also addressed whether a district court correctly relied on added matter in a second application which was a continuation-in-part of a first application when construing claims that issued from the first

1395. *Id.*, 72 U.S.P.Q.2d (BNA) at 1196.

1396. 363 F.3d 1284, 70 U.S.P.O.2d (BNA) 1380 (Fed. Cir. 2004).

1397. *Id.* at 1288, 70 U.S.P.Q.2d (BNA) at 1383.

1398. 373 F.3d 1158, 71 U.S.P.Q.2d (BNA) 1255 (Fed. Cir. 2004).

1399. *Id.* at 1166-67, 71 U.S.P.Q.2d (BNA) at 1261-62.

1400. *Id.* at 1167, 71 U.S.P.Q.2d (BNA) at 1261.

1401. *Id.*, 71 U.S.P.Q.2d (BNA) at 1261-62 (quoting *Kumar v. Ovonic Battery Co.*, 351 F.3d 1364, 1368, 69 U.S.P.Q.2d (BNA) 1220, 1224 (Fed. Cir. 2003)).

1402. *Id.*, 71 U.S.P.Q.2d (BNA) at 1261-62.

application.¹⁴⁰³ The Federal Circuit explained that such reliance is incorrect because the “the relevant passages from the [second application] . . . were added during the continuation-in-part These passages are therefore new matter added to the content of the [second application] subsequent to when it was distinguished from the [first application].”¹⁴⁰⁴ Thus, “[w]hile the content of the [second application] at the time it was distinguished from the [first application] constitutes part of the prosecution history of the [first application], subsequently added material is not similarly incorporated.”¹⁴⁰⁵

The Federal Circuit elucidated its reasoning by explaining that

[i]n the absence of an incorporation into the intrinsic evidence, this court’s precedent takes a narrow view on when a related patent or its prosecution history is available to construe the claims of a patent at issue and draws a distinct line between patents that have a familial relationship and those that do not.¹⁴⁰⁶

While noting that its earlier holding in *Microsoft Corp. v. Multi-Tech Systems, Inc.*¹⁴⁰⁷ permitted “reliance on statements made subsequent to the issuance of a patent when construing its claims where the statements were made in connection with continued prosecution of sibling applications,”¹⁴⁰⁸ the Federal Circuit determined that decision to be inapposite because:

The [first application] and [second application] were filed separately and therefore lack the formal relationship necessary for free license to use the contents of the [second patent] and prosecution history when construing the claims of [the first patent] While the [second application] was distinguished from the scope of the [first] application’s claims, the relevant passages from the [second patent] relied on by the district court are new matter added by the . . . continuation-in-part application. Consequently, the passages are not part of the intrinsic evidence of the [second patent]. Absent a formal relationship or incorporation during prosecution, the new-matter content of the [second patent] is not available to construe the claims of the [first patent].¹⁴⁰⁹

b. Use of prior art cited in prosecution histories

In 2004, the Federal Circuit also placed an increased weight on prior art cited during prosecution in construing disputed claim terms. The Federal

1403. *Id.* at 1166-67, 71 U.S.P.Q.2d (BNA) at 1261.

1404. *Id.* at 1167, 71 U.S.P.Q.2d (BNA) at 1262.

1405. *Id.*, 71 U.S.P.Q.2d (BNA) at 1262.

1406. *Id.*, 71 U.S.P.Q.2d (BNA) at 1262.

1407. 357 F.3d 1340, 1350, 69 U.S.P.Q.2d (BNA) 1815, 1819 (Fed. Cir. 2004); *see also supra* notes 1030-1053 and accompanying text (providing a detailed discussion of the *Microsoft Corp.* case).

1408. *Goldenberg*, 373 F.3d at 1167, 71 U.S.P.Q.2d (BNA) at 1261-62.

1409. *Id.* at 1167-68, 71 U.S.P.Q.2d (BNA) 1262.

Circuit had previously held that “[w]hen 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 proper construction of the term, because it may indicate not only the meaning of the claim terms to persons of ordinary skill in the art, but also that the patentee intended to adopt that meaning.”¹⁴¹⁰

In *Goldenberg v. Cytogen, Inc.*, the Federal Circuit held that the prosecution history and content of a patent which was cited as the basis for a double patenting rejection was properly considered in construing the disputed claims of a different patent because such subject matter “formed the basis of the examiner’s rejection of the [disputed claims] on double-patenting grounds.”¹⁴¹¹

Similarly, in *Home Diagnostics, Inc. v. Lifescan, Inc.*,¹⁴¹² the Federal Circuit referenced cited prior art to determine that, at the time of the invention, persons of ordinary skill in the art would have understood the claimed phrase “upon detection of a suitably stable endpoint” to be broader than use of a predetermined timing method.¹⁴¹³ Analyzing two patents cited during prosecution, the Federal Circuit observed that the prior art “discloses both an endpoint-seeking methodology and a predetermined-timing methodology,”¹⁴¹⁴ and therefore concluded that persons of ordinary skill in the art would have understood the phrase to encompass any method for calculating glucose concentration “without an error of clinical significance.”

c. Expert testimony

In *Goldenberg v. Cytogen, Inc.*, the Federal Circuit addressed a district court’s decision to permit expert testimony during a summary judgment hearing at which claim construction issues were also argued.¹⁴¹⁵ Citing its past decisions, the Federal Circuit noted that “[a]lthough expert testimony and declarations are useful to confirm that the construed meaning is

1410. *Arthur A. Collins, Inc. v. N. Telecom Ltd.*, 216 F.3d 1042, 1045, 55 U.S.P.Q.2d 1143, 1146 (Fed. Cir. 2000); *accord* *Kumar v. Ovonic Battery Co.*, 351 F.3d 1364, 1368, 69 U.S.P.Q.2d (BNA) 1220, 1224 (Fed. Cir. 2003) (“[P]rior art cited in a patent or cited in the prosecution history of a patent constitutes intrinsic evidence.”).

1411. *Goldenberg*, 373 F.3d at 1167, 71 U.S.P.Q.2d (BNA) at 1261. The court’s analysis analogized to the decision in *Kumar*, 351 F.3d at 1368, 69 U.S.P.Q.2d at 1224.

1412. 381 F.3d 1352, 72 U.S.P.Q.2d 1276 (Fed. Cir. 2004).

1413. *Id.* at 1358, 72 U.S.P.Q.2d at 1280-81.

1414. *Id.*, 72 U.S.P.Q.2d at 1280-81.

1415. *Goldenberg*, 373 F.3d at 1166, 71 U.S.P.Q.2d (BNA) at 1261. Judge Probst wrote a dissenting opinion, reasoning that nothing in the intrinsic evidence proscribed the “intracellular marker substance” from including portions of an antigen located inside a cell. *Id.* at 1170, 71 U.S.P.Q.2d (BNA) at 1264 (Probst, J., dissenting). In particular, the dissent opined that “the prosecution history can hardly be characterized as definitional of the term ‘marker substance,’ and cannot be used, in my view, as a basis to conclude that ‘marker substance’ corresponds to an antigen, and not portions thereof.” *Id.* at 1171, 71 U.S.P.Q.2d (BNA) at 1264-65 (Probst, J., dissenting).

consistent with the denotation ascribed by those in the field of the art, such extrinsic evidence cannot be used to vary the plain language of the patent document.”¹⁴¹⁶ The Federal Circuit then explained that the district court’s construction of the disputed terms “was consistent with that required by the intrinsic evidence, and the district court’s use of the expert testimony therefore falls within the permissible first clause of the above-quoted language.”¹⁴¹⁷ The Federal Circuit further clarified that “there is no prohibition on a district court’s ability to *hear* expert testimony.”¹⁴¹⁸

B. *Literal Infringement*

In *AFG Industries, Inc. v. Cardinal IG Co.*,¹⁴¹⁹ plaintiff for infringement of its patent claiming a glass window bearing a reflective coating to reduce transfer of heat through the glass.¹⁴²⁰ The only existing patent claim required a “5-layered transparent coating” composed of alternating “layers” of zinc oxide and silver. In a previous appeal by patentee,¹⁴²¹ the Federal Circuit had construed the term “layer” to mean “a thickness of a material of substantially uniform chemical composition, but excluding interlayers having a thickness not to substantially affect the optical properties of the coating.”¹⁴²² The Federal Circuit then remanded the case back to the district court for a determination of whether defendant’s accused low-emissivity glass product infringed the claim under the Federal Circuit’s construction. Defendant’s accused product was produced by moving a piece of glass through sequential “coating zones” in which the thickness of certain materials such as zinc oxide and silver were deposited by “magnetron sputter deposition” on the glass. To increase the thickness of certain coatings on the glass, the material was deposited twice or more on the glass in consecutive depositions. As a result of this process, defendant’s accused product had a central zinc coating which had been formed by three separate “depositions.” The district court held that this central zinc oxide coating was comprised of three separate “layers” as that term was defined by the Federal Circuit. Furthermore, certain of defendant’s products had titanium dioxide between its layers of zinc oxide and silver. For these reasons, the district court held that the product did not display the five-layer structure claimed by the patent.

1416. *Id.* at 1167, 71 U.S.P.Q.2d (BNA) at 1261 (quoting *Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1332, 67 U.S.P.Q.2d 1321, 1338 (Fed. Cir. 2003)).

1417. *Id.* at 1166, 71 U.S.P.Q.2d at 1261.

1418. *Id.*, 71 U.S.P.Q.2d at 1261.

1419. 375 F.3d 1367, 71 U.S.P.Q.2d (BNA) 1678 (Fed. Cir. 2004).

1420. *Id.* at 1369, 71 U.S.P.Q.2d (BNA) at 1679.

1421. *See id.* at 1370, 71 U.S.P.Q.2d (BNA) at 1680 (noting that this litigation was originally filed in 1996 and had already been appealed to and remanded by the Federal Circuit twice before this decision was rendered).

1422. *Id.*, 71 U.S.P.Q.2d (BNA) 1680.

On appeal, the Federal Circuit held that the district court had improperly relied on the method of manufacture of the defendant's product in determining whether that product infringed the "pure product claim."¹⁴²³ Under its construction of the term "layer," the Federal Circuit found that defendant's successive depositions of zinc oxide might form one "layer" as required by the patent so long as the successive depositions did not have an "optical effect different than that of a single deposition of the same thickness."¹⁴²⁴ Thus, "multiple depositions [were] only relevant if they affect the structure and optical properties."¹⁴²⁵

The Federal Circuit vacated the district court's grant of summary judgment and reviewed the record to determine whether a genuine issue of material fact remained as to infringement. Based on a defendant's internal document describing its products as containing five layers, and results of secondary ion mass spectroscopy studies of defendant's products which showed no interface between successive depositions of zinc oxide, the Federal Circuit held that such a genuine issue of material fact did exist and remanded the case back to the district court.¹⁴²⁶

In *International Rectifier*, plaintiff argued that because the parties stipulated to a simulated shape of an accused device, the issue of infringement was a matter of law that hinged on claim construction.¹⁴²⁷ The Federal Circuit explained in *General Mills Inc. v. Hunt-Wesson, Inc.*¹⁴²⁸ that the "question of literal infringement collapses into claim construction and is amenable to summary judgment" was limited to cases in which the parties and the district court agreed how competing claims constructions would apply to the undisputed structure of the accused device.¹⁴²⁹ The Federal Circuit held that such reasoning does not apply when "the structure of [accused] product has been stipulated to, not the factual determination of whether that product meets one or another claim construction."¹⁴³⁰ The Federal Circuit vacated summary judgment because "factual issues exist as to whether the [accused] devices" included the

1423. *Id.* at 1373, 71 U.S.P.Q.2d (BNA) at 1683.

1424. *Id.*, 71 U.S.P.Q.2d (BNA) at 1683.

1425. *Id.*, 71 U.S.P.Q.2d (BNA) at 1683.

1426. The court vacated the district court's grant of summary judgment on the alternative ground that at least some of Cardinal's accused products contained a layer of titanium dioxide in between alternating layers of silver and zinc oxide. *Id.* at 1374, 71 U.S.P.Q.2d (BNA) at 1684-85. It instructed the trial court to examine separately and distinctly each category of Cardinal's accused products and to determine whether the titanium oxide would affect the optical properties of the coating. *Id.*, 71 U.S.P.Q.2d (BNA) at 1685.

1427. *Int'l Rectifier Corp. v. IXYS Corp.*, 361 F.3d 1363, 1374-75, 70 U.S.P.Q.2d (BNA) 1209, 1218 (Fed. Cir. 2004).

1428. 103 F.3d 978, 41 U.S.P.Q.2d (BNA) 1440 (Fed. Cir. 1997).

1429. *Id.* at 983, 41 U.S.P.Q.2d (BNA) at 1445.

1430. *Int'l Rectifier Corp.*, 361 F.3d at 1375, 70 U.S.P.Q.2d (BNA) at 1218.

disputed claim limitations.¹⁴³¹

In *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*,¹⁴³² the Federal Circuit reversed the district court's claim construction and remanded for new trial on infringement explaining that: "It is well established that when an incorrect jury instruction—such as an incorrect claim construction—removes from the jury a basis on which the jury could reasonably have reached a different verdict, the verdict should not stand."¹⁴³³

In *Golden Blount, Inc. v. Robert H. Peterson Co.*,¹⁴³⁴ the Federal Circuit reversed a finding of infringement following a bench trial because the district court "did not provide any findings of fact or analysis to support its conclusion."¹⁴³⁵ The Federal Circuit noted that the district court's opinion lacked any "expla[nation] how the limitations of the claim, as construed, compare to the allegedly infringing device."¹⁴³⁶ Explaining that while Federal Rule of Civil Procedure 52(a) "'does not require detailed findings on every factual issue raised,' the district court opinion 'must include as many of the subsidiary facts as are necessary to disclose . . . the steps by which the trial court determined factual issues and reached its ultimate conclusions.'"¹⁴³⁷ The Federal Circuit therefore vacated the judgment below "[b]ecause the district court's sparse opinion provides this court with only bald conclusions for review, we conclude that the district court's judgment as to [issues of infringement] . . . is insufficient under Rule 52(a)."¹⁴³⁸

In *Globetrotter Software, Inc. v. Elan Computer Group, Inc.*,¹⁴³⁹ the Federal Circuit reversed a grant of summary judgment of non-infringement when the record contained "expert reports and other evidence [that] were both highly technical and confusing."¹⁴⁴⁰ Citing its prior case law regarding disposition of technical issues on summary judgment, the court instructed that "[i]t is not our task, nor is it the task of the district court, to attempt to interpret confusing or general testimony to determine whether a [claim] has been made out, particularly at the summary judgment

1431. *Id.*, 70 U.S.P.Q.2d (BNA) at 1218.

1432. 381 F.3d 1371, 72 U.S.P.Q.2d (BNA) 1333 (Fed. Cir. 2004).

1433. *Id.* at 1383, 72 U.S.P.Q.2d (BNA) at 1341.

1434. 365 F.3d 1054, 70 U.S.P.Q.2d (BNA) 1624 (Fed. Cir. 2004).

1435. *Id.* at 1060, 70 U.S.P.Q.2d (BNA) at 1628.

1436. *Id.*, 70 U.S.P.Q.2d (BNA) at 1628.

1437. *Id.*, 70 U.S.P.Q.2d (BNA) at 1628 (quoting *Atlantic Thermoplastics Co. v. Faytex Corp.*, 5 F.3d 1477, 1478-79, 28 U.S.P.Q.2d (BNA) 1343, 1343-44 (Fed. Cir. 1993)).

1438. *Id.* at 1061, 70 U.S.P.Q.2d (BNA) at 1629. Dissenting from the majority opinion's holding on this issue, Judge Newman explained that the defendant "did not challenge the specificity of the district court's infringement analysis, and did not appeal this aspect." *Id.* at 1063, 70 U.S.P.Q.2d (BNA) at 1630 (Newman, J., dissenting).

1439. 362 F.3d 1367, 70 U.S.P.Q.2d (BNA) 1161 (Fed. Cir. 2004).

1440. *Id.* at 1378, 70 U.S.P.Q.2d (BNA) at 1169.

stage.”¹⁴⁴¹

In *Centricut, L.L.C. v. Esab Group, Inc.*,¹⁴⁴² the central issue was whether a patentee’s failure to proffer any expert testimony on infringement resulted in an absence of proof.¹⁴⁴³ On appeal, the alleged infringer argued that the patentee failed to carry its burden of proof on the infringement because it did not show how the accused devices satisfied the claimed “work-function limitation.”¹⁴⁴⁴ The Federal Circuit first explained that only expert testimony in the record was from the alleged infringer’s expert who testified that the patentee’s various evidence of infringement was not reliable and not an accurate representation of the accused product.¹⁴⁴⁵ The Federal Circuit then noted that each of the patentee’s theories of infringement “suffer[ed] from the same deficiency: none is supported by expert testimony.”¹⁴⁴⁶ In so doing, the Federal Circuit explained that “[i]n many patent cases expert testimony will not be necessary because the technology will ‘easily understandable without the need for expert explanatory testimony,’” however, the Federal Circuit concluded that “there is no claim that this is such case. Indeed, in this case the technology was complex.”¹⁴⁴⁷ The Federal Circuit further elaborated that:

We do not state a per se rule that expert testimony is required to prove infringement when the art is complex. Suffice it to say that in a case involving complex technology, where the accused infringer offers expert testimony negating infringement, the patentee cannot satisfy its burden of proof by relying only on testimony from those who are admittedly not expert in the field. That is what happened here, and the patentee thus failed to satisfy its burden of proof. This case stands as an apt example of what may befall a patent law plaintiff who presents complex subject matter without inputs from experts qualified on the relevant points in issue when the accused infringer has negated infringement with its own expert.¹⁴⁴⁸

C. Infringement Under the Doctrine of Equivalents

I. Festo

In *Honeywell International Inc. v. Hamilton Sundstrand Corp.*,¹⁴⁴⁹

1441. *Id.*, 70 U.S.P.Q.2d (BNA) at 1169 (quoting *Schumer v. Lab. Computer Sys.*, 308 F.3d 1304, 1316, 64 U.S.P.Q.2d (BNA) 1832, 1843 (Fed. Cir. 2002)).

1442. 390 F.3d 1361, 73 U.S.P.Q.2d (BNA) 1135 (Fed. Cir. 2004).

1443. *Id.* at 1363, 73 U.S.P.Q.2d (BNA) at 1135.

1444. *Id.* at 1367, 73 U.S.P.Q.2d (BNA) at 1139.

1445. *Id.* at 1367-68, 73 U.S.P.Q.2d (BNA) at 1139.

1446. *Id.* at 1369, 73 U.S.P.Q.2d (BNA) at 1140.

1447. *Id.*, 73 U.S.P.Q.2d (BNA) at 1140.

1448. *Id.* at 1370, 73 U.S.P.Q.2d (BNA) at 1141.

1449. 370 F.3d 1131, 71 U.S.P.Q.2d (BNA) 1065 (Fed. Cir. 2004).

plaintiff for infringement of its patents directed to an aircraft auxiliary power unit (“APU”).¹⁴⁵⁰ Each of the asserted patent claims required the APU to include “inlet guide vanes” and required the operation of a “surge bleed valve,” a valve that vents excess air in a main air duct within the APU’s air compressor, to be a function of the position of the inlet guide vanes.¹⁴⁵¹ Defendant’s accused device contained inlet guide vanes, but operation of its surge bleed valve was a function of temperature, rather than the position of the inlet guide vanes. However, the accused device had a feature in which operation of its surge bleed valve would be blocked during extreme conditions, and this blocking mechanism was a function of the position of the guide vanes.

As part of its post-verdict motion for a JMOL of non-infringement and on appeal, defendant argued that its APU device could not be held to have infringed the patents under the doctrine of equivalents because the asserted claims were narrowed by amendment and that prosecution history estoppel barred all equivalents for the inlet guide vane limitation under *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*¹⁴⁵² During prosecution, the claims at issue were originally dependent on other claims that did not contain the inlet guide vane limitation. The original independent claims were rejected as obvious over the prior art, and the claims asserted against defendant were amended to expressly incorporate the limitations of the rejected claims.¹⁴⁵³ The district court held that because the claims were “merely rewritten into independent form, the elements at issue were not amended and patentee did not give up an embodiment of the invention with the inlet guide vane” limitation.¹⁴⁵⁴ In contrast, the Federal Circuit held that an amendment that rewrites a dependent claim into independent form and surrenders the original independent claims constitutes a narrowing amendment that may give rise to an estoppel if it is made to secure the patent.¹⁴⁵⁵ It rejected the patentee’s argument that “although it surrendered its broader independent claims, there is no presumption of surrender because the scope of the rewritten claims themselves has not been narrowed.”¹⁴⁵⁶ The Supreme Court, it explained, had already considered this argument in *Festo* and had stated that “rewriting a dependent claim in independent form creates a presumptive surrender if the amendment is ‘made to secure the patent.’”¹⁴⁵⁷ Furthermore, the Federal Circuit had

1450. *Id.* at 1133-34, 71 U.S.P.Q.2d (BNA) at 1066.

1451. *Id.* at 1134-35, 71 U.S.P.Q.2d (BNA) at 1066-67.

1452. *Id.* at 1138-39, 71 U.S.P.Q.2d (BNA) at 1069.

1453. *Id.* at 1137, 71 U.S.P.Q.2d (BNA) at 1068.

1454. *Id.* at 1138, 71 U.S.P.Q.2d (BNA) at 1069 (internal quotations omitted).

1455. *Id.* at 1141, 71 U.S.P.Q.2d (BNA) at 1071-72.

1456. *Id.*, 71 U.S.P.Q.2d (BNA) at 1072.

1457. *Id.* at 1142, 71 U.S.P.Q.2d (BNA) at 1072 (citing *Festo Corp. v. Shoketsu Kinzoku*

consistently applied this rule in its post-*Festo* decisions. Having found that the patentee had presumptively surrendered all equivalents of the inlet guide vane limitation, the Federal Circuit remanded the decision of whether Honeywell had rebutted this presumption to the district court.¹⁴⁵⁸

In *Novartis Pharmaceuticals Corp. v. Abbott Laboratories*,¹⁴⁵⁹ the Federal Circuit found that under the correct construction, the “lipophilic phase” could include one or more “surfactants,” so long as the lipophilic component also contains at least one non-surfactant lipophilic excipient, which was capable of dissolving cyclosporine.¹⁴⁶⁰ Defendant’s accused product contained a component called “Span 80” which was both a lipophilic excipient and a surfactant.¹⁴⁶¹ Because the accused product contained no non-surfactant components that would meet the requirements of a “lipophilic phase,” the court held that the product did not literally infringe the asserted claim.¹⁴⁶²

Novartis argued that Defendant’s product infringed the claim under the doctrine of equivalents because, as its experts testified, Span 80 “ ‘does not exhibit the amphiphilic function of a surfactant’ nor does it ‘function as a surfactant . . . but, rather, . . . it functions as the lipophilic component.’ ”¹⁴⁶³ The Federal circuit, however, found that the specification expressly acknowledged that Span 80 was a surfactant, and therefore, Novartis was precluded from arguing that Span 80 was an equivalent to a non-surfactant required by the claim as construed.¹⁴⁶⁴

The Federal Circuit distinguished the case at hand from that of the Supreme Court in *Graver Tank & Manufacturing Co. v. Linde Air Products Co.*,¹⁴⁶⁵ and its own case *Wright Medical Technology, Inc. v. Osteonics Corp.*¹⁴⁶⁶ In *Graver Tank* and *Wright Medical*, the Federal Circuit explained, “the fact that certain claimed limitations in the element at issue were missing in the accused product did not change the fact that the element, albeit different from that expressly claimed, was indeed present in the accused product.”¹⁴⁶⁷ In contrast, the Federal Circuit found that the “lipophilic component” element could not be met under the doctrine of equivalents by Span 80, a surfactant, because inclusion of a chemical

Kogyo Kabushiki Co., 535 U.S. 722, 736, 62 U.S.P.Q.2d (BNA) 1705, 1707 (2002) (internal quotations omitted).

1458. *Id.* at 1146, 71 U.S.P.Q.2d (BNA) at 1075.

1459. 375 F.3d 1328, 71 U.S.P.Q.2d (BNA) 1650 (Fed. Cir. 2004).

1460. *Id.* at 1337, 71 U.S.P.Q.2d (BNA) at 1657.

1461. *Id.*, 71 U.S.P.Q.2d (BNA) at 1657.

1462. *Id.*, 71 U.S.P.Q.2d (BNA) at 1657.

1463. *Id.*, 71 U.S.P.Q.2d (BNA) at 1657.

1464. *Id.*, 71 U.S.P.Q.2d (BNA) at 1657.

1465. 339 U.S. 605, 85 U.S.P.Q. 328 (1950).

1466. 122 F.3d 1440, 43 U.S.P.Q.2d 1837 (Fed. Cir. 1997).

1467. *Novartis Pharm. Corp.*, 375 F.3d at 1339, 71 U.S.P.Q.2d (BNA) at 1659.

composition made entirely of surfactants would be inconsistent with the construction of “lipophilic component.”¹⁴⁶⁸

In *Insituform Technologies, Inc. v. Cat Contracting Inc.*,¹⁴⁶⁹ plaintiff sued for infringement of its patent on a process for repairing underground sewer pipes.¹⁴⁷⁰ The claimed method involved installing a liner into a pipe by applying “vacuum cups” to windows cut into the liner in order to draw a resin through the liner.¹⁴⁷¹ Originally, the asserted claim as filed contained no limit to the number of vacuum cups used in the method.¹⁴⁷² During prosecution of the patent, however, the applicants amended the claim to specify that the method used a single cup.¹⁴⁷³ The defendants’ accused method at issue used multiple vacuum cups.¹⁴⁷⁴

Following a lengthy procedural history,¹⁴⁷⁵ the Federal Circuit considered whether the plaintiffs were barred by prosecution history estoppel from asserting infringement under the doctrine of equivalents after *Festo II* and *Festo III*.¹⁴⁷⁶ Plaintiff argued that the reason for its amendment of the claim to require a single vacuum cup had only a tangential relationship to the accused equivalent, and that therefore, the presumption of prosecution history estoppel was rebutted.¹⁴⁷⁷ The Federal Circuit agreed.¹⁴⁷⁸ It found that plaintiff made clear the applicants had made the amendment at issue in order to overcome a § 103 rejection to show that its process did not have the disadvantage of the prior art of

1468. *Id.*, 71 U.S.P.Q.2d (BNA) at 1659.

1469. 385 F.3d 1360, 72 U.S.P.Q.2d (BNA) 1870 (Fed. Cir. 2004).

1470. *Id.* at 1362, 72 U.S.P.Q.2d (BNA) at 1872.

1471. *Id.* at 1362-63, 72 U.S.P.Q.2d (BNA) at 1872-73.

1472. *Id.* at 1366, 72 U.S.P.Q.2d (BNA) at 1876.

1473. *Id.*, 72 U.S.P.Q.2d (BNA) at 1876.

1474. *Id.* at 1363, 72 U.S.P.Q.2d (BNA) at 1873.

1475. *See id.* at 1363-67, 72 U.S.P.Q.2d (BNA) at 1873-76 (involving an initial grant of judgment notwithstanding the verdict (“JNOV”) by the United States District Court for the Southern District of Texas, a subsequent retrial to the bench and finding of patent infringement and an initial appeal by defendants and cross-appeal by plaintiffs to the Court of Appeals for the Federal Circuit). The Court of Appeals affirmed the JNOV order but vacated and remanded the decision on other grounds. The District Court again found for the plaintiffs, and defendants appealed. The Court of Appeals affirmed in part, reversed in part, vacated in part, and remanded. An initial petition for a writ of certiorari to the Supreme Court was denied. After two remands, the District Court entered final liability judgment and another appeal ensued. The Court of Appeals for the Federal Circuit then reversed in part, vacated in part, and remanded. The District Court entered final judgment for plaintiffs and defendants again appealed. The Court of Appeals for the Federal Circuit again reversed in part, vacated in part, and remanded. Petition for writ of certiorari to the Supreme Court was granted, and judgment was vacated and remanded to the Court of Appeals for the Federal Circuit. The Federal Circuit initially reinstated the appeal, vacated, and remanded. However, following a petition for rehearing and response, the Federal Circuit decided the case on the merits.

1476. *Id.* at 1367, 72 U.S.P.Q.2d (BNA) at 1876.

1477. *Id.*, 72 U.S.P.Q.2d at 1876-77.

1478. *Id.*, 72 U.S.P.Q.2d at 1876-77.

having a large compressor at the end of the liner.¹⁴⁷⁹ The Federal Circuit held that there was “no indication anywhere in the prosecution history of any relationship between the narrowing amendment and a multiple cup process.”¹⁴⁸⁰ Therefore, the Federal Circuit concluded that the plaintiffs successfully rebutted the presumption that they were estopped from seeking to extend their claims to the accused process under the doctrine of equivalents.¹⁴⁸¹

2. *Dedication-disclosure rule*

In *Johnson & Johnston v. R.E. Service Co.*,¹⁴⁸² the Federal Circuit formally pronounced the disclosure-dedication rule, holding that

when a patent drafter discloses but declines to claim subject matter . . . this action dedicates that unclaimed subject matter to the public. Application of the doctrine of equivalents to recapture subject matter deliberately left unclaimed would “conflict with the primacy of the claims in defining the scope of the patentee’s exclusive right.”¹⁴⁸³

In 2004, the Federal Circuit addressed the disclosure dedication rule for the first time since its decision in en banc decision in *Johnson & Johnston*.

*PSC Computers Products, Inc. v. Foxconn International, Inc.*¹⁴⁸⁴ presented the Federal Circuit’s first opportunity to elaborate on the dedication-disclosure rule¹⁴⁸⁵ *PSC Computers* involved a claim directed to a “resilient metal strap” for securing a heat sink clip to a microchip.¹⁴⁸⁶ The asserted patent also provided that “the elongated strap . . . is made of a resilient metal such as stainless steel although other resilient materials may be suitable for the strap,” and that “other prior art devices use molded plastic and/or metal parts that must be cast or forged.”¹⁴⁸⁷ The parties both sold competing heat sink clips, with plaintiff’s clip made of metal and defendant’s clip made of plastic.¹⁴⁸⁸ At the district court, plaintiff conceded no literal infringement, and the court then granted summary judgment of non-infringement under the doctrine of equivalents reasoning that the dedication-disclosure rule precluded claims from

1479. *Id.* at 1370, 72 U.S.P.Q.2d (BNA) at 1879.

1480. *Id.*, 72 U.S.P.Q.2d (BNA) at 1879.

1481. *Id.* at 1370-71, 72 U.S.P.Q.2d (BNA) at 1879.

1482. 285 F.3d 1046, 62 U.S.P.Q.2d (BNA) 1225 (Fed. Cir. 2002) (en banc).

1483. *Id.* at 1054, 62 U.S.P.Q.2d (BNA) at 1230 (quoting *Sage Prods. Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1424, 44 U.S.P.Q.2d (BNA) 1103, 1107 (Fed. Cir. 1997)). This articulation of the rule follows the court’s decision in *Maxwell v. J. Baker, Inc.*, 86 F.3d 1098, 1106-08, 39 U.S.P.Q.2d (BNA) 1001, 1008-10 (Fed. Cir. 1996).

1484. 355 F.3d 1353, 69 U.S.P.Q.2d (BNA) 1460 (Fed. Cir. 2004).

1485. *Id.* at 1355-56, 69 U.S.P.Q.2d (BNA) at 1463.

1486. *Id.* at 1355, 69 U.S.P.Q.2d (BNA) at 1461.

1487. *Id.* at 1356, 69 U.S.P.Q.2d (BNA) at 1462.

1488. *Id.*, 69 U.S.P.Q.2d (BNA) at 1462.

extending to plastic clips.¹⁴⁸⁹

On appeal, the Federal Circuit identified the two questions presented for review: “(1) How specific must a disclosure in a written description be to dedicate matter to the public? and (2) Was the [patent’s] written description sufficiently specific to dedicate plastic parts to the public?”¹⁴⁹⁰ Addressing the first question, the Federal Circuit first observed that similar to claim language that is interpreted from the perspective of one of ordinary skill in the art, “[i]t thus follows as a matter of logic that, in the absence of a compelling reason to do otherwise, the written description must also be interpreted according to the understanding of one of ordinary skill in the art.”¹⁴⁹¹ The Federal Circuit then answered the first question by explaining that “that if one of ordinary skill in the art can understand the unclaimed disclosed teaching upon reading the written description, the alternative matter disclosed has been dedicated to the public.”¹⁴⁹² The Federal Circuit further noted that “any generic reference in a written specification” does not necessarily result in dedication to the public, rather “[t]he disclosure must be of such specificity that one of ordinary skill in the art could identify the subject matter that had been disclosed and not claimed.”¹⁴⁹³ In enunciating this rule for evaluating the dedication-disclosure rule, the Federal Circuit adopted a standard closely resembling the test for compliance with the written description requirement:

We thus hold that if one of ordinary skill in the art can understand the unclaimed disclosed teaching upon reading the written description, the alternative matter disclosed has been dedicated to the public. This “disclosure-dedication” rule does not mean that any generic reference in a written specification necessarily dedicates all members of that particular genus to the public. The disclosure must be of such specificity that one of ordinary skill in the art could identify the subject matter that had been disclosed and not claimed.¹⁴⁹⁴

Addressing the second question, the Federal Circuit stated that “*generic* disclosure[s]” would not suffice to trigger the dedication-disclosure rule, and held that the patent’s reference that ““other resilient materials may be suitable for the strap”” was not enough to effect a dedication of all resilient materials other than metal.¹⁴⁹⁵ The Federal Circuit, however, explained that the specific disclosure that “[o]ther prior art devices use molded plastic and/or metal parts that must be case or forged” worked a dedication of the

1489. *Id.* at 1355, 69 U.S.P.Q.2d (BNA) at 1461-62.

1490. *Id.* at 1358, 69 U.S.P.Q.2d (BNA) at 1463.

1491. *Id.* at 1359, 69 U.S.P.Q.2d (BNA) at 1465.

1492. *Id.* at 1360, 69 U.S.P.Q.2d (BNA) at 1465.

1493. *Id.*, 69 U.S.P.Q.2d (BNA) at 1465.

1494. *Id.*, 69 U.S.P.Q.2d (BNA) at 1465.

1495. *Id.*, 69 U.S.P.Q.2d (BNA) at 1465 (citation omitted).

alternative use of plastic parts to the public.¹⁴⁹⁶ The Federal Circuit noted that one skilled in the art having read this disclosure

could reasonably conclude from this language . . . that plastic clip parts could be substituted for metal clip parts. [Plaintiff] was thus obliged to either claim plastic parts in addition to metal parts . . . or to not claim them and dedicate the use of plastic parts to the public.¹⁴⁹⁷

The court thus affirmed summary judgment, holding that the use of plastic clips was dedicated to the public.¹⁴⁹⁸

The Federal Circuit again addressed the scope and application of the disclosure-dedication rule in *Toro Co. v. White Consolidated Industries, Inc.*¹⁴⁹⁹ *Toro* involved a patent in which the specification disclosed both a replaceable ring cover and a unitary cover for a vacuum blower, but the claims were directed only to a permanently affixed cover (i.e., a unitary cover).¹⁵⁰⁰ Plaintiff appealed the district court's holding that the disclosure-dedication rule precluded infringement under the doctrine of equivalents.¹⁵⁰¹

The Federal Circuit initially noted that its precedent did not "explicitly articulate[] a standard for reviewing the application of the disclosure-dedication rule."¹⁵⁰² Explaining that the disclosure-dedication rule, like the prosecution history estoppel, limits the permissible scope under the doctrine of equivalents, the court reasoned that both rules should be analyzed under the same standard.¹⁵⁰³ Given the prosecution history estoppel presents a question of law, the court held that "the disclosure-dedication rule . . . presents a question of law, subject to de novo review."¹⁵⁰⁴

To avoid application of the disclosure-dedication rule, plaintiff first argued that "failure to claim . . . a cover with a replaceable ring, was wholly unintentional and that the disclosure-dedication rule should not apply as a matter of law."¹⁵⁰⁵ The court rejected that argument, explaining that "intent is not part of the *Johnson & Johnston* disclosure-dedication

1496. *Id.*, 69 U.S.P.Q.2d (BNA) at 1465 (citation omitted).

1497. *Id.*, 69 U.S.P.Q.2d (BNA) at 1465.

1498. *Id.* at 1361, 69 U.S.P.Q.2d (BNA) at 1466.

1499. 383 F.3d 1326, 72 U.S.P.Q.2d (BNA) 1449 (Fed. Cir. 2004).

1500. *Id.* at 1331, 72 U.S.P.Q.2d (BNA) at 1452.

1501. *Id.* at 1331-32, 72 U.S.P.Q.2d (BNA) at 1453.

1502. *Id.* at 1330, 72 U.S.P.Q.2d (BNA) at 1452.

1503. *Id.* at 1331, 72 U.S.P.Q.2d (BNA) at 1452.

1504. *Id.*, 72 U.S.P.Q.2d (BNA) at 1452. The opinion's holding that application of the disclosure-dedication rule presents a question of law is internally inconsistent with the opinion's subsequent reasoning that "[i]n the present case, the district court found no genuine issue of material fact in concluding that the disclosure of a replaceable ring would have been apparent to one of ordinary skill in the art." *Id.* at 1334, 72 U.S.P.Q.2d (BNA) at 1455. If the disclosure-dedication rule is a question of law, it is unclear why affordance of a district court opinion would be based on the absence of a genuine issue of material fact.

1505. *Id.* at 1332, 72 U.S.P.Q.2d (BNA) at 1453.

analysis. The language of *Johnson & Johnston* is clear: “The patentee’s subjective intent is irrelevant to determining whether unclaimed subject matter has been disclosed and therefore dedicated to the public.”¹⁵⁰⁶

The plaintiff also argued that “the level of disclosure of a replaceable ring in the . . . patent [was] insufficient, as a matter of law, to trigger the disclosure-dedication rule.”¹⁵⁰⁷ In doing so, plaintiff contended that the degree of disclosure necessary to trigger the rule must satisfy the written description standard under § 112, ¶ 1.¹⁵⁰⁸ The Federal Circuit also rejected this argument, reasoning that “the disclosure-dedication rule does not impose a § 112 requirement on the disclosed but unclaimed subject matter. The standards articulated in § 112 are directed to the claimed invention, not to disclosures in the written description that may implicate the disclosure-dedication rule.”¹⁵⁰⁹ While acknowledging the court’s earlier decision in *PSC Computer Products, Inc. v. Foxconn International*¹⁵¹⁰ holding that subject matter is dedicated to the public “if one of ordinary skill in the art can understand the unclaimed disclosed teaching upon reading the written description,”¹⁵¹¹ the court explained that “disclosures implicating the disclosure-dedication rule need not directly relate to the description of the claimed invention or be contained in the ‘Detailed Description of the Invention’ section of the patent, but may appear merely in the portion of the patent describing the ‘Background of the Invention.’”¹⁵¹²

Plaintiff further argued that the Federal Circuit’s decision in an earlier appeal held that the disputed patent did not describe any structure other than an attached ring, which precluded application of the disclosure-dedication rule to removable rings.¹⁵¹³ The Federal Circuit rejected this argument too, explaining that its earlier decision “did not analyze the written description of the . . . patent for disclosed but unclaimed subject matter Rather, in that decision, this court construed a claim term and in that context concluded that the specification did not support [Plaintiff’s] proposed claim construction.”¹⁵¹⁴ The Federal Circuit further opined that “[m]aterial that is explicitly disclaimed in the specification—like the disclaimer of a removable ring in this case—is disclosed for purposes of

1506. *Id.* at 1333, 72 U.S.P.Q.2d (BNA) at 1453 (quoting *Johnson & Johnston v. R.E. Serv. Co.*, 285 F.3d 1046, 1053 n.1, 62 U.S.P.Q.2d (BNA) 1225, 1230 n.1 (Fed. Cir. 2002)).

1507. *Id.*, 72 U.S.P.Q.2d (BNA) at 1453.

1508. *Id.*, 72 U.S.P.Q.2d (BNA) at 1454.

1509. *Id.* at 1334, 72 U.S.P.Q.2d (BNA) at 1454.

1510. 355 F.3d 1353, 69 U.S.P.Q.2d (BNA) 1460 (Fed. Cir. 2004).

1511. *Toro Co.*, 383 F.3d at 1334, 72 U.S.P.Q.2d (BNA) at 1454 (quoting *PSC Computer Prods., Inc.*, 355 F.3d at 1360, 69 U.S.P.Q.2d (BNA) at 1465).

1512. *Id.*, 72 U.S.P.Q.2d (BNA) at 1455 (citations omitted).

1513. *Id.* at 1336, 72 U.S.P.Q.2d (BNA) at 1456.

1514. *Id.*, 72 U.S.P.Q.2d (BNA) at 1456.

the disclosure-dedication rule, but it cannot be encompassed within the scope of the claims.”¹⁵¹⁵

3. *Prosecution history estoppel*

In two parallel cases decided on the same day by the Federal Circuit, *Glaxo Wellcome, Inc. v. Impax Laboratories, Inc.*,¹⁵¹⁶ and *SmithKline Beecham Corp. v. Excel Pharmaceuticals, Inc.*,¹⁵¹⁷ Glaxo Wellcome sued pharmaceutical companies for infringement of its patent when they filed Abbreviated New Drug Applications with the FDA proposing generic substitutes for the drugs covered by the patent.¹⁵¹⁸ The patented technology was a sustained release form of the anti-depression and anti-smoking drug, bupropion hydrochloride. The claims were drawn to bupropion hydrochloride compounded with hydroxypropyl methylcellulose (“HPMC”), the latter ingredient being key for achieving sustained release. In their motions for summary judgment, the accused infringers argued that their generic compounds did not contain HPMC, but rather contained different agents that achieved sustained release, hydroxypropyl cellulose (“HPC”) and poly-vinyl alcohol (“PVC”). Moreover, they contended that Glaxo could not attempt to extend its patent to reach their formulations under the doctrine of prosecution history estoppel because Glaxo limited its claims to require HPMC in response to a rejection by an examiner during prosecution. In response, Glaxo explained that it had amended its claims to recite HPMC “to distinguish the sustained release agent in its invention from other disclosed excipients in the application.”¹⁵¹⁹

Both district courts and the Federal Circuit agreed with the defendants. The following factors weighed in the Federal Circuit’s decision. First, the patent examiner required Glaxo during prosecution to restrict its claims to include HPMC, because recitation of HPMC was “critical” to distinguish the claims from the prior art, namely the instant release formulations of bupropion hydrochloride that were known.¹⁵²⁰ The examiner also required recitation of HPMC in order to satisfy the enablement requirement, because the application recited only HPMC as a sustained release agent, the application did not enable one with ordinary skill in the art to make other sustained release formulations.¹⁵²¹ Under *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*,¹⁵²² restriction of the claims to formulations that

1515. *Id.*, 72 U.S.P.Q.2d (BNA) at 1456.

1516. 356 F.3d 1348, 69 U.S.P.Q.2d (BNA) 1705 (Fed. Cir. 2004).

1517. 356 F.3d 1357, 69 U.S.P.Q.2d (BNA) 1712 (Fed. Cir. 2004).

1518. *Glaxo Wellcome, Inc.*, 356 F.3d at 1351, 69 U.S.P.Q.2d (BNA) at 1707; *SmithKline Beecham Corp.*, 356 F.3d at 1359, 69 U.S.P.Q.2d (BNA) at 1713.

1519. *Glaxo Wellcome, Inc.*, 356 F.3d at 1352, 69 U.S.P.Q.2d (BNA) at 1708.

1520. *Id.*, 69 U.S.P.Q.2d (BNA) at 1708 (citation omitted).

1521. *Id.*, 69 U.S.P.Q.2d (BNA) at 1708.

1522. 535 U.S. 722, 62 U.S.P.Q.2d (BNA) 1705 (2002).

required HPMC created a presumption that Glaxo gave up its claim to equivalents of HPMC. Glaxo failed to rebut this presumption and thus could not support its infringement claims against the defendants, whose accused formulation did not include HPMC.

The Federal Circuit also rejected Glaxo's argument that it did not "narrow" its claims when it added HPMC, as required in order for the *Festo* presumption to arise, because at the same time it added HPMC limitation to its claims, it deleted another limitation, one requiring a specific shelf life of the compound. The court rejected this argument because the HPMC limitation was not an entirely new limitation that replaced the shelf life limitation.¹⁵²³ Rather, the preamble of the claims as originally filed already recited the phrase "sustained release tablet," and the preamble limited the claims under *Catalina Marketing International, Inc. v. Coolsavings.com, Inc.*,¹⁵²⁴ because it recited the "essential structure or steps, or if it is necessary to give life, meaning and vitality to the claim."¹⁵²⁵

Second, contrary to Glaxo's contentions, the Federal Circuit found that the examiner had not required Glaxo to recite HPMC in its claims in order to distinguish the claims from other disclosed excipients. Rather, the examiner found that the disclosed sustained release agent, HPMC, distinguished the invention that was the subject of Glaxo's application from the prior art, and therefore found recitation of the sustained release agent to be critical to the patentability of the invention.¹⁵²⁶

Glaxo also failed to rebut the presumption that it threw away its right to claim other sustained release compounds. It attempted to dispel the *Festo* presumption by claiming that HPC was an unforeseeable equivalent. Under *Festo*, the presumption can be rebutted if the patentee shows that the alleged equivalent was unforeseeable at the time of the amendment of the claims that gave rise to the presumption. Glaxo argued that if it were to have limited its claims to HPMC, PVC, and/or HPC formulations, the claims would have been rejected for including new matter, as HPC was not disclosed in the application. Citing the Supreme Court's decision in *Festo*, Glaxo urged that the patentee's ability to claim an alleged equivalent was a "hallmark of the unforeseeability excuse."¹⁵²⁷ The Federal Circuit rejected and criticized this interpretation of the Supreme Court's decision. It opined that new matter prohibitions are not directly germane to the issue of

1523. *Glaxo Wellcome, Inc.*, 356 F.3d at 1353, 69 U.S.P.Q.2d (BNA) at 1709.

1524. 289 F.3d 801, 808, 62 U.S.P.Q.2d (BNA) 1781, 1784-85 (Fed. Cir. 2002).

1525. *Glaxo Wellcome, Inc.*, 356 F.3d at 1353, 69 U.S.P.Q.2d (BNA) at 1708-09 (internal quotation omitted).

1526. *Id.* at 1352, 69 U.S.P.Q.2d (BNA) at 1708.

1527. *Id.* at 1354, 69 U.S.P.Q.2d (BNA) at 1709 (citing *Festo Corp.*, 535 U.S. 722, 62 U.S.P.Q.2d (BNA) 1705).

infringement under the doctrine of equivalents and pointed out the fact that what it termed “the quintessential example of an enforceable equivalent, after-arising technology” would always be new matter.¹⁵²⁸ Furthermore, Glaxo took the Supreme Court’s words out of context: the Federal Circuit found no sympathy in *Festo* for patentees who fail to claim readily known equivalents at the time of application. Instead, the question was whether Glaxo could have foreseen sustained release agents for bupropion hydrochloride other than HPMC at the time of filing or amendment.¹⁵²⁹ In the case of HPC, included by Impax in its formulation, there existed ample evidence that HPC was used as a release agent at the time the claims were amended. In contrast, there was not enough evidence of record to decide in the *SmithKline* case whether PVA was a foreseeable and claimable sustained release compound for bupropion hydrochloride.¹⁵³⁰ Thus, the Federal Circuit affirmed the lower court’s decision in *Glaxo*,¹⁵³¹ and remanded the decision in *SmithKline*.¹⁵³²

*Gaus v. Conair Corp.*¹⁵³³ presented an appeal from a jury verdict of infringement under the doctrine of equivalents involving an accused device that used a single component to perform the function of two claim elements.¹⁵³⁴ Plaintiff argued that the jury verdict was correct in light of the court’s precedent that equivalency can be established even when “separate claim limitations are combined into a single component of the accused device.”¹⁵³⁵ The Federal Circuit, however, noted that its precedent makes clear that “[a] particular structure can be deemed outside the reach of the doctrine of equivalents because that structure is clearly excluded from the claims whether the exclusion is express or implied.”¹⁵³⁶

1528. *Id.*, 69 U.S.P.Q.2d (BNA) at 1709.

1529. *Id.* at 1355, 69 U.S.P.Q.2d (BNA) at 1710.

1530. *SmithKline Beecham Corp.*, 356 F.3d at 1365, 69 U.S.P.Q.2d (BNA) at 1718.

1531. *Glaxo Wellcome, Inc.*, 356 F.3d at 1357, 69 U.S.P.Q.2d (BNA) at 1712.

1532. *SmithKline Beecham Corp.*, 356 F.3d at 1365, 69 U.S.P.Q.2d (BNA) at 1718. An additional argument raised by Glaxo in *Glaxo Wellcome, Inc.*, but not in *SmithKline Beecham Corp.*, centered on claim one of the asserted patent which recited HPMC as a limitation as originally filed. Glaxo argued that because HPMC was not added as limitation to Claim one in response to an office action, the doctrine of prosecution history estoppel would not apply to the enforcement of Claim one; therefore, Glaxo could reach equivalents to HPMC through that claim. The Federal Circuit was not persuaded. It explained that the *Festo* bar to invocation of the doctrine of equivalents applies to all claims containing the same limitation to ensure consistent interpretation of the same claim terms in the same patent, and there was no reason to diverge from the line in this case. It reasoned that Claim one recitation was not added in response to an examiner’s rejection because it already existed at the time of filing. There was nothing to say that the examiner considered recitation of HPMC to be less critical to claim one’s patentability than other claims.

1533. 363 F.3d 1284, 70 U.S.P.Q.2d (BNA) 1380 (Fed. Cir. 2004).

1534. *Id.* at 1291, 70 U.S.P.Q.2d (BNA) at 1385.

1535. *Id.*, 70 U.S.P.Q.2d (BNA) at 1385 (quoting *Dolly, Inc. v. Spalding & Evenflo Cos.*, 16 F.3d 394, 399, 29 U.S.P.Q.2d 1767, 1770 (Fed. Cir. 1994)).

1536. *Id.*, 70 U.S.P.Q.2d (BNA) at 1385 (quoting *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1345, 58 U.S.P.Q.2d (BNA) 1059, 1066 (Fed. Cir.

Noting that the patent “criticized prior art in which the protective device relied on the fluid coming in contact with the voltage-carrying portions of the system,”¹⁵³⁷ the Federal Circuit concluded that the patentee “disavowed coverage of devices in which the two components are separate . . . the patentee cannot reclaim that surrendered coverage by invoking the doctrine of equivalents.”¹⁵³⁸

In *Lighting World, Inc. v. Birchwood Lighting, Inc.*,¹⁵³⁹ the plaintiff appealed a grant of the JMOL of no infringement under the doctrine of equivalents, arguing that the district court incorrectly required “evidence as to the level of ordinary skill in the art as part of [the] proof of infringement under the doctrine of equivalents.”¹⁵⁴⁰ The Federal Circuit affirmed the judgment below, noting that the “‘vantage point of one of ordinary skill in the relevant art provides the perspective for assessing the substantiality of the differences’ between the claimed invention and the accused device.”¹⁵⁴¹ The Federal Circuit further elaborated that “the requirement that equivalence be evaluated from the perspective of one of ordinary skill in the art applies whether equivalence is misused by the ‘function-way-result’ test or by the ‘insubstantial difference’ test.”¹⁵⁴²

D. Indirect Infringement

In *Insituform Technologies, Inc. v. Cat Contracting Inc.*,¹⁵⁴³ the Federal Circuit acknowledged that the standard for determining whether a party has the requisite intent in order to qualify as an inducer of infringement under § 271 was ambiguous.¹⁵⁴⁴ Specifically, it stated that “there is a lack of clarity concerning whether the required intent must be merely to induce the specific acts or additionally to cause an infringement.”¹⁵⁴⁵ It cited *Manville Sales Corp. v. Paramount Systems, Inc.*¹⁵⁴⁶ for the proposition that “[t]he plaintiff has the burden of showing that the alleged infringer’s actions induced infringing acts *and* that he knew or should have known his actions would induce actual infringements”¹⁵⁴⁷ and *Hewlett-Packard Co. v.*

2001)).

1537. *Id.*, 70 U.S.P.Q.2d (BNA) at 1385.

1538. *Id.*, 70 U.S.P.Q.2d (BNA) at 1386.

1539. 382 F.3d 1354, 72 U.S.P.Q.2d (BNA) 1344 (Fed. Cir. 2004).

1540. *Id.* at 1357, 72 U.S.P.Q.2d (BNA) at 1347.

1541. *Id.*, 72 U.S.P.Q.2d (BNA) at 1347 (quoting *Hilton Davis Chem. Co. v. Warner-Jenkinson Co.*, 62 F.3d 1512, 1519, 35 U.S.P.Q.2d (BNA) 1641, 1646 (Fed. Cir. 1995)).

1542. *Id.*, 72 U.S.P.Q.2d (BNA) at 1347 (quoting *Hilton Davis Chem. Co.*, 62 F.3d at 1518-19, 35 U.S.P.Q.2d at 1645-46).

1543. 385 F.3d 1360, 72 U.S.P.Q.2d (BNA) 1870 (Fed. Cir. 2004).

1544. *Id.* at 1377-78, 72 U.S.P.Q.2d (BNA) at 1884.

1545. *Id.* at 1378, 72 U.S.P.Q.2d (BNA) at 1884.

1546. 917 F.2d 544, 553, 16 U.S.P.Q.2d (BNA) 1587, 1594 (Fed. Cir. 1990).

1547. *Insituform Techs., Inc.*, 385 F.3d at 1378, 72 U.S.P.Q.2d (BNA) at 1884.

*Bausch & Lomb, Inc.*¹⁵⁴⁸ for the proposition that “[p]roof of actual intent to cause the acts which constitute the infringement is a necessary prerequisite to finding active inducement.”¹⁵⁴⁹ The Federal Circuit refrained from settling the law on this issue, however, because it found that the lower court’s holding that defendants were liable for inducing infringement should be upheld under either standard.

Defendants Firstliner and CAT were in the business of rehabilitating and restructuring pipes. Firstliner oversaw the marketing of its “trenchless” procedure for pipe rehabilitation to potential licensees, and sold pipe liners and related materials to CAT and its licensees.¹⁵⁵⁰ The district court held defendants CAT and Firstliner liable for induced infringement of Insituform’s patented process of fixing underground pipes by installing a liner into the pipe. The district court based its decision on the fact that CAT and Firstliner’s licensee, in responding to a questionnaire, indicated that it used the infringing process and that Firstliner representatives provided directives to teach the licensee how to implement the process.¹⁵⁵¹ Reviewing the decision of the district court under the clearly erroneous standard, the Federal Circuit held that there was evidence in the record to support the district court’s finding of induced infringement, and it was “not left with the definite and firm conviction that a mistake has been committed.”¹⁵⁵²

*Pellegrini v. Analog Devices, Inc.*¹⁵⁵³ presented a matter of first impression for the Federal Circuit.¹⁵⁵⁴ Plaintiff appealed the district court’s granting of summary judgment in favor of Analog with respect to Pelligrini’s claims of infringement under 35 U.S.C. § 271(f)(1).¹⁵⁵⁵ Plaintiff held a patent directed to “brushless motor drive circuits,” and defendant, headquartered in the United States, designed circuit chips that either alone or in combination with other components, ostensibly fell within the scope of the patent claims. All of defendant’s circuit chips, however, were manufactured outside of the United States, and most of

1548. 909 F.2d 1464, 1469, 15 U.S.P.Q.2d (BNA) 1525, 1529 (Fed. Cir. 1990).

1549. *Insituform Techs., Inc.*, 385 F.3d at 1378, 72 U.S.P.Q.2d (BNA) at 1884.

1550. *Id.* at 1363, 72 U.S.P.Q.2d (BNA) at 1873.

1551. *Id.* at 1378, 72 U.S.P.Q.2d (BNA) at 1885.

1552. *Id.*, 72 U.S.P.Q.2d (BNA) at 1885.

1553. 375 F.3d 1113, 71 U.S.P.Q.2d (BNA) 1630 (Fed. Cir. 2004).

1554. *Id.* at 1115-16, 71 U.S.P.Q.2d (BNA) at 1632.

1555. *Id.* at 1116, 71 U.S.P.Q.2d (BNA) at 1632. 35 U.S.C. § 271(f)(1) reads:

Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, such a manner as to actively induce the combination of such components outside the United States in a manner that would infringe the patent if such combination occurred within the United States shall be liable as an infringer.

35 U.S.C. § 271(f)(1) (2000).

them were sold and shipped to customers outside of the United States. Plaintiff claimed that defendant's chips which were manufactured and sold abroad were "supplie[d] or cause[d] to be supplied in or from the United States" in violation of § 271 because they were designed in the United States and produced and sold according to instructions emanating from the United States.¹⁵⁵⁶

The Federal Circuit affirmed the decision of the district court. It found that § 271 (f)(1) "is clear on its face," applying "only where components of a patented invention are physically present in the United States."¹⁵⁵⁷ It found further support for its decision in its previous cases stating that the "tort" of patent infringement occurs where the offending act is committed, and not where the injury lies. Thus, it held that the "'suppl[y]ing] or caus[ing] to be supplied' in § 271(f)(1) clearly refers to physical supply of components, not simply to the supply of instructions or corporate oversight."¹⁵⁵⁸

Plaintiff argued that the court's location requirement would result in a "seemingly contradictory construction of §271(f)(1)"¹⁵⁵⁹ in that the combination of components outside the United States cannot occur if the components are inside the United States.¹⁵⁶⁰ Plaintiff additionally argued that boilerplate language in defendant's commercial invoices, admittedly included to demonstrate compliance with U.S. export laws, proved that defendant in fact did supply components from the United States, or at least prevented Analog from denying that fact to escape liability under U.S. patent laws.

The Federal Circuit rejected both of these arguments. First, it held that its construction of § 271(f)(1) would result in no inconsistency because it was obvious that § 271(f) contemplates an intervening sale or exportation between the time the components exist in their uncombined state within the United States and the time the components are combined outside of the United States. Second, the Federal Circuit determined that compliance with the export laws was not an issue before the court, and the fact that defendant notes on its invoices that its commodities were exported from the United States simply "does not stand up against the uncontested fact that no [accused] chips were exported from the United States."¹⁵⁶¹

In *Dynacore Holdings Corp. v. U.S. Philips Corp.*¹⁵⁶² the Federal Circuit addressed circumstances under which a party could be held liable for

1556. *Pellegrini*, 375 F.3d at 1115, 71 U.S.P.Q.2d (BNA) at 1631.

1557. *Id.* at 1117, 71 U.S.P.Q.2d (BNA) at 1633.

1558. *Id.* at 1118, 71 U.S.P.Q.2d (BNA) at 1633.

1559. *Id.* at 1117, 71 U.S.P.Q.2d (BNA) at 1633 (citation omitted).

1560. *Id.*, 71 U.S.P.Q.2d (BNA) at 1633.

1561. *Id.* at 1118, 71 U.S.P.Q.2d (BNA) at 1634.

1562. 363 F.3d 1263, 70 U.S.P.Q.2d (BNA) 1369 (Fed. Cir. 2004).

indirect infringement.¹⁵⁶³ The Federal Circuit explained that “[i]n order to prove vicarious liability for indirect infringement, a plaintiff who demonstrates direct infringement must also establish that the defendant possessed the requisite knowledge or intent to be held liable.”¹⁵⁶⁴ The Federal Circuit further noted “[a] defendant’s liability for indirect infringement must relate to the identified instances of direct infringement. Plaintiffs who identify *individual* acts of direct infringement must restrict their theories of vicarious liability—and tie their claims for damages or injunctive relief—to *the identified act*.”¹⁵⁶⁵

In *Linear Technology Corp. v. Impala Linear Corp.*,¹⁵⁶⁶ plaintiff appealed a grant of summary judgment holding that defendant was not liable for contributory infringement of claims directed to controlling a switching voltage regulator.¹⁵⁶⁷ While noting that “the evidentiary showing in this case may be sparse and not altogether clear,” the court vacated the grant of summary judgment reasoning that a genuine issue of fact existed as to whether defendant was liable for contributory infringement.¹⁵⁶⁸ In particular, the Federal Circuit noted that the record contains evidence that defendant’s products used by third parties “may have circuitry that prevents reversal of inductor current,” and evidence that defendant’s customers may “directly infringe by using [defendant’s] parts to prevent current reversal.”¹⁵⁶⁹

In *Metabolite Laboratories, Inc. v. Laboratory Corp. of America*,¹⁵⁷⁰ the Federal Circuit upheld the jury’s verdict that defendant indirectly infringed

1563. *Id.* at 1272, 70 U.S.P.Q.2d (BNA) at 1375.

1564. *Id.* at 1273-74, 70 U.S.P.Q.2d (BNA) at 1376 (citing *Hewlett-Packard Co. v. Bausch & Lomb*, 909 F.2d 1464, 1469, 15 U.S.P.Q.2d (BNA) 1525, 1529 (Fed. Cir. 1990)). *Dynacore* and its citation to *Hewlett-Packard* continues a schism in the court’s jurisprudence on whether induced infringement requires “proof of actual intent to cause the acts which constitute the infringement,” *Hewlett-Packard Co.*, 909 F.2d at 1469, 15 U.S.P.Q.2d (BNA) at 1529, or a “showing that the alleged infringer’s actions induced infringing acts and that he knew or should have known his actions would induce infringement.” *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553, 16 U.S.P.Q.2d (BNA) 1587, 1594 (Fed. Cir. 1990). *See also* *Fuji Photo Film Co. v. Jazz Photo Corp.*, 394 F.3d 1368, 1377, 73 U.S.P.Q.2d (BNA) 1678, 1686 (Fed. Cir. 2005) (acknowledging without resolving the “lack of clarity” in this issue).

1565. *Dynacore*, 363 F.3d at 1274, 70 U.S.P.Q.2d (BNA) at 1377. The court affirmed summary judgment of non-infringement, explaining that

[i]t is well settled that an expert’s unsupported conclusion on the ultimate issue of infringement is insufficient to raise a genuine issue of material fact, and that a party may not avoid that rule simply by framing the expert’s conclusion as an assertion that a particular critical claim limitation is found in the accused device.

Id. at 1278, 70 U.S.P.Q.2d (BNA) at 1379.

1566. 379 F.3d 1311, 72 U.S.P.Q.2d (BNA) 1065 (Fed. Cir. 2004).

1567. *Id.* at 1326, 72 U.S.P.Q.2d (BNA) at 1075.

1568. *Id.*, 72 U.S.P.Q.2d (BNA) at 1075.

1569. *Id.*, 72 U.S.P.Q.2d (BNA) at 1075.

1570. 370 F.3d 1354, 71 U.S.P.Q.2d (BNA) 1081 (Fed. Cir. 2004).

plaintiff's patented method of detecting vitamin deficiencies.¹⁵⁷¹ The claimed method comprised the steps of (1) assaying a body fluid for an elevated level of total homocysteine and (2) correlating an elevated level of total homocysteine with a deficiency of certain vitamins. In its primary non-infringement argument, defendant asserted that the doctors to which it provided the accused assay were not shown to have performed the second correlating step. The Federal Circuit disagreed. It found "substantial evidence" supporting the jury's verdict where it was shown that physicians receiving total assays performed the step and an inventor testified to the effect that "it would be malpractice" for a doctor to receive the assay and then not determine the deficiency.¹⁵⁷² The Federal Circuit held that the record did not need to contain direct evidence that every physician performed the "correlating" step in order to support the verdict. Rather, it opined that circumstantial evidence is "not only sufficient, but may also be more certain, satisfying and persuasive than direct evidence."¹⁵⁷³

The Federal Circuit also found that a reasonable jury could find that defendant had the requisite intent to induce infringement under § 271(b) where defendant's articles stated that elevated total homocysteine correlated to particular vitamin deficiencies, and further recommended treatment of such deficiency with vitamin supplements.¹⁵⁷⁴

E. Willful Infringement

The Federal Circuit's en banc decision in *Knorr-Bremse Systeme Fuer Nutzfahrezeuge GMBH v. Dana Corp.* ("*Knorr-Bremse*")¹⁵⁷⁵ addressed the long-debated issue of whether an adverse inference is properly drawn by a factfinder in determining willful infringement when a defendant either does not rely on an opinion of counsel or fails to obtain such an opinion.¹⁵⁷⁶ The factual posture of the case involved an appeal from a finding of willful infringement, in which one defendant argued that "an adverse inference should not have been drawn from [the] withholding . . . of an opinion of counsel concerning the patent issues, and from the failure of [another defendant] to obtain its own opinion of counsel."¹⁵⁷⁷ The majority opinion addressed four specific questions for which it requested additional briefing from the parties and invited submission of amicus curiae briefs.¹⁵⁷⁸

1571. *Id.* at 1357, 71 U.S.P.Q.2d (BNA) at 1083.

1572. *Id.* at 1364, 71 U.S.P.Q.2d (BNA) at 1088.

1573. *Id.* at 1365, 71 U.S.P.Q.2d (BNA) at 1088 (quoting *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1272, 229 U.S.P.Q. (BNA) 805, 813 (Fed. Cir. 1986)).

1574. *Id.*, 71 U.S.P.Q.2d (BNA) at 1088.

1575. 383 F.3d 1337, 72 U.S.P.Q.2d (BNA) 1560 (Fed. Cir. 2004).

1576. *Id.*, 72 U.S.P.Q.2d (BNA) at 1560.

1577. *Id.* at 1340, 72 U.S.P.Q.2d (BNA) at 1562.

1578. *Id.* at 1341, 72 U.S.P.Q.2d (BNA) at 1562.

Before reaching the specific questions, however, the Federal Circuit observed that the “concept of ‘willful infringement’ is not simply a conduit for enhancement of damages; it is a statement that patent infringement, like other civil wrongs, is disfavored, and intentional disregard of legal rights warrants deterrence.”¹⁵⁷⁹ Noting that “[f]undamental to determination of willful infringement is the duty to act in accordance with law,”¹⁵⁸⁰ the Federal Circuit explained a finding of willful infringement is predicated “on consideration of the totality of the circumstances . . . and may include contributions of several factors.”¹⁵⁸¹

The Federal Circuit also traced the evolution of the adverse inference in the context of determining willful infringement.¹⁵⁸² In particular, the court addressed its decision in *Underwater Devices, Inc. v. Morrison-Knudsen Co.*,¹⁵⁸³ which involved a defendant who was advised by its attorney to “continue to refuse even to discuss the payment of a royalty” because “[c]ourts, in recent years, have—in patent infringement cases—found the patents claimed to be infringed upon invalid in approximately 80% of the cases.”¹⁵⁸⁴ The court explained that based on the record evincing “flagrant disregard of presumptively valid patents,”¹⁵⁸⁵ the *Underwater Devices* court held that “where, as here, a potential infringer has actual notice of another’s patent rights, he has an affirmative duty to exercise due care to determine whether or not he is infringing,’ including ‘the duty to seek and obtain competent legal advice.’”¹⁵⁸⁶

The Federal Circuit then noted that the issue of privilege first arose in *Kloster Speedsteel AB v. Crucible Inc.*,¹⁵⁸⁷ in which the defendant had “not even asserted that it sought advice of counsel when notified of the allowed claims,”¹⁵⁸⁸ and the court held that the defendant’s “silence on the subject, in alleged reliance on the attorney-client privilege, would warrant the conclusion that it either obtained no advice of counsel or did so and was advised that its . . . accused products would be an infringement of valid U.S. patents.”¹⁵⁸⁹ The court explained that the propriety of using an

1579. *Id.* at 1342, 72 U.S.P.Q.2d (BNA) at 1564.

1580. *Id.* at 1343, 72 U.S.P.Q.2d (BNA) at 1564.

1581. *Id.* at 1342-43, 72 U.S.P.Q.2d (BNA) at 1564 (citing *Gustafson, Inc. v. Intersystems Indus. Prods.*, 897 F.2d 508, 510, 13 U.S.P.Q.2d (BNA) 1972, 1973 (Fed. Cir. 1990)).

1582. *Id.* at 1343, 72 U.S.P.Q.2d (BNA) at 1564.

1583. 717 F.2d 1380, 219 U.S.P.Q. (BNA) 569 (Fed. Cir. 1983).

1584. *Knorr-Bremse Systeme Fuer Nutzfahrezeuge GMBH*, 383 F.3d at 1343, 72 U.S.P.Q.2d (BNA) at 1564 (quoting *Underwater Devices*, 717 F.2d at 1385, 219 U.S.P.Q. (BNA) at 572).

1585. *Knorr-Bremse Systeme Fuer Nutzfahrezeuge GMBH*, 383 F.3d at 1343, 72 U.S.P.Q.2d (BNA) at 1564.

1586. *Id.*, 72 U.S.P.Q.2d (BNA) at 1564 (quoting *Underwater Devices*, 717 F.2d at 1389-90, 219 U.S.P.Q. (BNA) at 576).

1587. 793 F.2d 1565, 230 U.S.P.Q. (BNA) 160 (Fed. Cir. 1986).

1588. *Id.* at 1580, 230 U.S.P.Q. (BNA) at 173.

1589. *Id.*, 230 U.S.P.Q. (BNA) at 173.

adverse inference was reinforced in *Fromson v. Western Litho Plate & Supply Co.*,¹⁵⁹⁰ in which the court held that “a court must be free to infer that either no opinion was obtained or, if an opinion were obtained, it was contrary to the infringer’s desire to initiate or continue its use of the patentee’s invention.”¹⁵⁹¹ Having canvassed the history of the adverse inference, the court concluded that while those decisions did not “focus . . . on attorney-client relationships, but on disrespect for law . . . [T]he implementation of this precedent has resulted in inappropriate burdens on the attorney-client relationship.”¹⁵⁹²

Turning to the questions before it, the Federal Circuit first addressed the issue of: “When the attorney-client privilege and/or work-product privilege is invoked by defendant in an infringement suit, is it appropriate for the trier of fact to draw an adverse inference with respect to willful infringement?”¹⁵⁹³ The court simply stated that “[t]he answer is ‘no,’” explaining that “[a]lthough the duty to respect the law is undiminished, no adverse inference shall arise from invocation of the attorney-client and/or work product privilege.”¹⁵⁹⁴ Citing to the Supreme Court’s instruction that the attorney-client privilege is “the oldest of the privileges for confidential communications known to common law,”¹⁵⁹⁵ and that its purpose “encourag[es] full and frank communication between attorneys and their clients and thereby promot[es] broader public interests in the observance of law and administration of justice,”¹⁵⁹⁶ the Federal Circuit explained:

Although this court has never suggested that opinions of counsel concerning patents are not privileged, the inference that withheld opinions are adverse to the client’s actions can distort the attorney-client relationship, in derogation of the foundations of that relationship. We conclude that a special rule affecting attorney-client relationships in patent cases is not warranted . . . There should be no risk of liability in disclosures to and from counsel in patent matters; such risk can intrude upon full communication and ultimately the public interest in encouraging open and confident relationships between client and attorney.¹⁵⁹⁷

1590. 853 F.2d 1568, 7 U.S.P.Q.2d (BNA) 1606 (Fed. Cir. 1988).

1591. *Id.* at 1572-73, 7 U.S.P.Q.2d (BNA) at 1611.

1592. *Knorr-Bremse Systeme Fuer Nutzfahrezeuge GMBH*, 383 F.3d at 1343, 72 U.S.P.Q.2d (BNA) at 1564.

1593. *Id.* at 1344, 72 U.S.P.Q.2d (BNA) at 1565.

1594. *Id.*, 72 U.S.P.Q.2d (BNA) at 1565.

1595. *Id.*, 72 U.S.P.Q.2d (BNA) at 1565 (quoting *Upjohn Co. v. United States*, 449 U.S. 383, 389 (1981)).

1596. *Id.*, 72 U.S.P.Q.2d (BNA) at 1565 (quoting *Upjohn*, 449 U.S. at 389).

1597. *Id.*, 72 U.S.P.Q.2d (BNA) at 1565 (citations omitted). In so doing, the court noted that “[t]here is precedent for the drawing of adverse inferences in circumstances other than those involving attorney-client relationships,” such as a party’s refusal to produce documents or its destruction of documents. *Id.* at 1345, 72 U.S.P.Q.2d (BNA) at 1565.

The Federal Circuit thus concluded that while a “defendant may of course choose to waive the privilege and produce the advice of counsel . . . [such action] shall no longer entail an adverse inference as to the nature of the advice.”¹⁵⁹⁸

The second question before the court was “[w]hen the defendant had not obtained legal advice, is it appropriate to draw an adverse inference with respect to willful infringement?”¹⁵⁹⁹ The Federal Circuit again answered the question “no,” explaining that the issue “is not of privilege, but whether there is a legal duty upon a potential infringer to consult with counsel, such that failure to do so will provide an inference or evidentiary presumption that such opinion would have been negative.”¹⁶⁰⁰

The Federal Circuit reasoned that together with its “holding that it is inappropriate to draw an adverse inference that undisclosed legal advice for which attorney-client privilege is claimed was unfavorable, we also hold that it is inappropriate to draw a similar adverse inference from failure to consult counsel.”¹⁶⁰¹ The court further reasoned that “[a]lthough there continues to be ‘an affirmative duty of due care to avoid infringement of the known patent rights of others’ . . . the failure to obtain an exculpatory opinion of counsel shall no longer provide an adverse inference or evidentiary presumption that such an opinion would have been unfavorable.”¹⁶⁰²

The third question addressed by the Federal Circuit was “[i]f the court concludes that the law should be changed, and the adverse inference withdrawn as applied to this case, what are the consequences for this case?”¹⁶⁰³ Answering the question, the court explained that “[b]ecause elimination of the adverse inference as drawn by the district court is a material change in the totality of the circumstances, a fresh weighing of the evidence is required to determine whether the defendants committed willful infringement.”¹⁶⁰⁴ The court did so despite the district court’s analysis of

1598. *Id.*, 72 U.S.P.Q.2d (BNA) at 1566.

1599. *Id.*, 72 U.S.P.Q.2d (BNA) at 1566.

1600. *Id.*, 72 U.S.P.Q.2d (BNA) at 1566.

1601. *Id.*, 72 U.S.P.Q.2d (BNA) at 1566.

1602. *Id.* at 1345-46, 72 U.S.P.Q.2d (BNA) at 1566 (quoting *L.A. Gear Inc., v. Thom McAn Shoe Co.*, 988 F.2d 1117, 1127, 25 U.S.P.Q.2d (BNA) 1913, 1924 (Fed. Cir. 1993)). The court’s answers to questions one and two give rise to another question: under what circumstances can a plaintiff introduce into evidence that a defendant obtained an opinion on which it did not rely or that defendant did not obtain any opinion at all? Put differently, it is difficult to imagine any reason why a plaintiff would refer to an opinion that a defendant did not rely upon for any reason other than to have the factfinder draw a negative inference. The court’s opinion noted that certain amicus curiae raised the issue, but it declined to address the issue because it was “not raised by this case, was not before the district court, and has not been briefed on this appeal.” *Id.* at 1347, 72 U.S.P.Q.2d (BNA) at 1567.

1603. *Id.* at 1346, 72 U.S.P.Q.2d (BNA) at 1566.

1604. *Id.*, 72 U.S.P.Q.2d (BNA) at 1567.

other factors supporting a finding of willfulness.¹⁶⁰⁵

The last question before the Federal Circuit was whether “the existence of a substantial defense to infringement [should] be sufficient to defeat liability for willful infringement even if no legal advice has been secured?”¹⁶⁰⁶ The Federal Circuit also answered this question in the negative, observing that its “[p]recedent includes this factor with other factors to be considered among the totality of circumstances, stressing the ‘theme of whether a prudent person would have sound reason to believe that the patent was not infringed or was invalid or unenforceable, and would be so held if litigated.’”¹⁶⁰⁷ The Federal Circuit explained that “accord[ing] each factor the weight warranted by its strength in the particular case . . . [is] preferable to abstracting any factor for per se treatment, for this greater flexibility enables the trier of fact to fit the decision to all the circumstances.”¹⁶⁰⁸

Writing separately, Judge Dyk concurred-in-part and dissented-in-part, explaining that he joined the “majority opinion insofar as it eliminates an adverse inference” but dissented to the extent that the majority’s opinion may be read to reaffirm the *Underwater Devices* holding.¹⁶⁰⁹ In dissent, Judge Dyk observed that “[t]here is a substantial question as to whether the due care requirement is consistent with the Supreme Court cases holding that punitive damages can only be awarded in situations where the conduct is reprehensible.”¹⁶¹⁰ Judge Dyk further noted that the court’s own precedent “often recognized that enhanced damages . . . are a form of punitive damages . . . [that] are awarded to punish reprehensible behavior, referred to in this context as willful infringement.”¹⁶¹¹ Accordingly, Judge Dyk reasoned that

a potential infringer’s mere failure to engage in due care is not itself reprehensible conduct. To hold that it is effectively shifts the burden of proof on the issue of willfulness from the patentee to the infringer, which must show that its infringement is not willful by showing that it exercised due care.¹⁶¹²

In *Norian Corp. v. Stryker Corp.*,¹⁶¹³ the plaintiff appealed the district court’s grant of a JMOL that there was no willful infringement, arguing

1605. *Id.*, 72 U.S.P.Q.2d (BNA) at 1567.

1606. *Id.* at 1347, 72 U.S.P.Q.2d (BNA) at 1567.

1607. *Id.*, 72 U.S.P.Q.2d (BNA) at 1567 (quoting *SRI, Int’l, Inc. v. Advanced Tech. Labs. Inc.*, 127 F.3d 1462, 1465, 44 U.S.P.Q.2d (BNA) 1422, 1424 (Fed. Cir. 1997)).

1608. *Id.*, 72 U.S.P.Q.2d (BNA) at 1567.

1609. *Id.* at 1348, 72 U.S.P.Q.2d (BNA) at 1568.

1610. *Id.*, 72 U.S.P.Q.2d (BNA) at 1568 (citing *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003) and *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559 (1996)).

1611. *Id.*, 72 U.S.P.Q.2d (BNA) at 1568.

1612. *Id.* at 1349, 72 U.S.P.Q.2d (BNA) at 1569.

1613. 363 F.3d 1321, 70 U.S.P.Q.2d (BNA) 1508 (Fed. Cir. 2004).

that willfulness could be found by a jury because the evidence showed that defendant had knowledge of the asserted patent and that defendant “provided no evidence that it had relied on an opinion of counsel that its activities were not infringing.”¹⁶¹⁴ Foreshadowing its en banc decision in *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GMBH v. Dana Corp.*,¹⁶¹⁵ the Federal Circuit rejected plaintiffs’ argument and explained that:

[A]bsent an initial presentation of evidence on the [willfulness] issue by [plaintiff], this burden of coming forward in defense did not arise. There is no evidentiary presumption that every infringement is willful. Willful infringement is not established by the simple fact of infringement, even though [defendant] stipulated that it had knowledge of [defendant’s] patents.¹⁶¹⁶

In *Insituform Technologies, Inc. v. Cat Contracting Inc.*,¹⁶¹⁷ the district court had held that certain defendants’ infringement was willful “due to a complete absence of competent advice regarding possible infringement of the ‘012 patent and a flagrant display of deliberate misconduct by [the defendants] throughout this proceeding.”¹⁶¹⁸ The Federal Circuit vacated this decision in light of its decision in *Knorr-Bremse*.¹⁶¹⁹ The court in *Knorr-Bremse* held that “the failure to obtain an exculpatory opinion of counsel shall no longer provide an adverse inference or evidentiary presumption that such an opinion would have been unfavorable.”¹⁶²⁰ Because the district court in *Insituform* relied upon such an inference in deciding that the defendants’ infringement was willful, and elimination of this inference would materially change the totality of the circumstances the district court was required to consider in making its willfulness determination, the court could not uphold the district court’s decision and remanded the case for further proceedings.¹⁶²¹

In *Glaxo Group Ltd. v. Apotex, Inc.*,¹⁶²² the Federal Circuit held that the mere filing of an abbreviated new drug application (“ANDA”) cannot constitute an act of willful infringement compensable by attorney’s fees.¹⁶²³ Apotex had filed an ANDA seeking FDA approval of a generic version of

1614. *Id.* at 1332, 70 U.S.P.Q.2d (BNA) at 1517.

1615. 383 F.3d 1337, 72 U.S.P.Q.2d (BNA) 1560 (Fed. Cir. 2004) (en banc).

1616. *Norian Corp.*, 363 F.3d at 1332, 70 U.S.P.Q.2d (BNA) at 1517.

1617. 385 F.3d 1360, 72 U.S.P.Q.2d (BNA) 1870 (Fed. Cir. 2004).

1618. *Id.* at 1377, 72 U.S.P.Q.2d (BNA) at 1884 (emphasis omitted).

1619. *See id.* at 1377, 72 U.S.P.Q.2d (BNA) at 1884 (citing *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GMBH v. Dana Corp.*, 383 F.3d 1337 (2004) holding that failing to attain an attorney’s exculpatory opinion “shall no longer provide an adverse inference or presumption that such an opinion would have been unfavorable.”).

1620. *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GMBH*, 383 F.3d at 1346, 72 U.S.P.Q.2d (BNA) at 1566.

1621. *Id.*, 72 U.S.P.Q.2d (BNA) at 1567.

1622. 376 F.3d 1339, 71 U.S.P.Q.2d (BNA) 1801 (Fed. Cir. 2004).

1623. *Id.* at 1342, 71 U.S.P.Q.2d (BNA) at 1802.

Ceftin®, an orally administered antibiotic. Glaxo brought a declaratory action against Apotex alleging that its ANDA infringed two of Glaxo's patents covering Ceftin® under § 271(e)(2)(A).¹⁶²⁴ The district court found that Apotex's ANDA infringed Glaxo's patents and that Apotex's infringement was willful because it did not exercise due care, relying heavily on the fact that Apotex did not receive an opinion from patent counsel. The Federal Circuit reversed. It reasoned that infringement under § 271(e)(2)(A) was a "highly artificial" act of infringement which results in only a very limited set of consequences set forth in § 271(e)(4).¹⁶²⁵ It noted that under the statutorily limited list of available remedies, a court could only award money damages if commercial activity had actually occurred in the United States or if the product had been imported. It described 35 U.S.C. § 285¹⁶²⁶ as an "exception" to these limits in that it permits attorneys' fees to be awarded to the prevailing party in exceptional cases.¹⁶²⁷

Although a "myriad of factual circumstances" may give rise to the § 285 exception, the Federal Circuit found that such circumstances were not present in this case.¹⁶²⁸ Apotex had not engaged in any litigation misconduct nor included any certification in its ANDA under 21 U.S.C. § 355(j)(2)(A)¹⁶²⁹ that commercial marketing of the subject drug would not infringe any valid, unexpired patent.¹⁶³⁰ It contrasted these facts to those in *Yamanuchi Pharmaceutical Co. v. Danbury Pharmacal*,¹⁶³¹ in which the Federal Circuit determined that a "baseless and 'wholly unjustified'" certification combined with litigation misconduct, warranted a finding of willfulness.¹⁶³² Under these circumstances, the Federal Circuit concluded that the district court had abused its discretion in finding willful infringement.¹⁶³³

1624. See 35 U.S.C. § 271(e)(2)(A)(2000) ("It shall be an act of infringement to submit[:](A) an application under Section 505(j) of the Federal Food, Drug, and Cosmetic Act . . . for a drug claimed in a patent or the use of which is claimed in a patent, . . . [i]f the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.").

1625. *Glaxo Group Ltd.*, 376 F.3d at 1349, 71 U.S.P.Q.2d (BNA) at 1808.

1626. 35 U.S.C. § 285 (2000).

1627. *Glaxo Group Ltd.*, 376 F.3d at 1350, 71 U.S.P.Q.2d (BNA) at 1808.

1628. *Id.* at 1350-51, 71 U.S.P.Q.2d (BNA) at 1808-09.

1629. 21 U.S.C. § 355(j)(2)(A) (2000).

1630. *Glaxo Group Ltd.*, 376 F.3d at 1344, 71 U.S.P.Q.2d (BNA) at 1809. The omission was due to the fact that Glaxo had not listed its patents in the Orange Book because at the time its patent applications were filed, antibiotics were excepted from such listing under a now-repealed section of the FDCA. *Id.*, 71 U.S.P.Q.2d (BNA) at 1803-04.

1631. 231 F.3d 1339, 1346, 56 U.S.P.Q.2d (BNA) 1641, 1646 (Fed. Cir. 2000).

1632. *Glaxo Group Ltd.*, 376 F.3d at 1350, 71 U.S.P.Q.2d (BNA) at 1808.

1633. *Id.* at 1351, 71 U.S.P.Q.2d (BNA) at 1809.

IV. INEQUITABLE CONDUCT AND OTHER DEFENSES

A. *Inequitable Conduct*

In *Intirtool, Ltd. v. Texar Corp.*,¹⁶³⁴ the district court held that the patentee had engaged in inequitable conduct during prosecution of its patent covering punch pliers by “repeatedly stat[ing], and indeed stress[ing], that the described tool simultaneously punched holes and connected ceiling grids, knowing that this assertion was false.”¹⁶³⁵ Specifically, the district court found “clear and convincing evidence” that the claimed punch pliers punched holes in overlapping sheets of metal but did not connect the sheets.¹⁶³⁶ The Federal Circuit reversed, holding that the repeated statements were “not clearly incorrect,” because, as the district court had found, a loose connection was established through use of the pliers. Furthermore, the statements regarding “punching and connecting” referred merely to the features described in the preamble of the patent’s sole independent claim.¹⁶³⁷ For these reasons, the Federal Circuit found that patentee’s conduct during prosecution neither rose to the required level of materiality to support a finding of inequitable conduct nor were its statements false.¹⁶³⁸ Therefore, it held that the district court clearly erred in its findings that plaintiff’s statements were material misrepresentations and abused its discretion in ruling that Intirtool had engaged in inequitable conduct.¹⁶³⁹

*Monsanto Co. v. Bayer Bioscience N.V.*¹⁶⁴⁰ presented an appeal from a grant of summary judgment that defendant procured the disputed patent through inequitable conduct.¹⁶⁴¹ In particular, the district court held that in order to overcome a rejection for lack of enablement, the defendant submitted a false declaration with intent to deceive the PTO by omitting negative test results concerning the claimed method for producing a protein toxic to insects.¹⁶⁴²

The Federal Circuit began its analysis by noting that to “hold a patent unenforceable for inequitable conduct, a court must find, by clear and convincing evidence, that the applicant omitted or misrepresented material facts with the intention of misleading or deceiving the patent examiner.”¹⁶⁴³ On the issue of falsity of the declaration, plaintiff argued that the district

1634. 369 F.3d 1289, 70 U.S.P.Q.2d (BNA) 1780 (Fed. Cir. 2004).

1635. *Id.* at 1296, 70 U.S.P.Q.2d (BNA) at 1785.

1636. *Id.* at 1294, 70 U.S.P.Q.2d (BNA) at 1783.

1637. *Id.* at 1296-97, 70 U.S.P.Q.2d (BNA) at 1785.

1638. *Id.* at 1297, 70 U.S.P.Q.2d (BNA) at 1785.

1639. *Id.*, 70 U.S.P.Q.2d (BNA) at 1785.

1640. 363 F.3d 1235, 70 U.S.P.Q.2d (BNA) 1257 (Fed. Cir. 2004).

1641. *Id.* at 1237, 70 U.S.P.Q.2d (BNA) at 1259.

1642. *Id.*, 70 U.S.P.Q.2d (BNA) at 1259.

1643. *Id.* at 1239, 70 U.S.P.Q.2d (BNA) at 1260.

court correctly held that defendant's assertion in its declaration that it knew of no negative test results was clearly false.¹⁶⁴⁴ Defendant by contrast, argued that the "omitted test results were not 'negative' with respect to the question that the patent examiner was seeking to answer," but rather "showed that those tests led to no reliable conclusion."¹⁶⁴⁵ Noting that at summary judgment "the evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor,"¹⁶⁴⁶ the Federal Circuit determined that the district court erroneously resolved the disputed issue of falsity in favor of defendant because such a decision:

[R]equired the court to reject the explanation provided in [defendant's] affidavit. If the [district] court were to credit [defendant's] affidavit, it could find that the test results withheld from the PTO were not negative and [the defendant's] statement to the PTO that he know of no contrary results was true.¹⁶⁴⁷

Accordingly, the Federal Circuit held that a material issue of fact existed concerning the truth of the defendant's declaration.¹⁶⁴⁸

Relying on the court's earlier decision in *Paragon Podiatry Laboratory, Inc. v. KLM Laboratories, Inc.*,¹⁶⁴⁹ plaintiff argued that defendant's litigation affidavit was "insufficient to raise a genuine issue of material fact as to falsity."¹⁶⁵⁰ The Federal Circuit, however, determined that *Pargaon* was markedly different from the case before it, explaining that in *Paragon* "there was no question that the submission to the PTO was false and that the false representations were material; the only issue was whether the false and material representations were submitted with an intent to deceive."¹⁶⁵¹ The Federal Circuit then reasoned that, by contrast, the record before it contained disputes of material fact concerning both "the issue of intent" and "whether [defendant's] declaration was false or misleading at all."¹⁶⁵² Specifically, the Federal Circuit observed that because defendant's affidavit "described in detail each of the allegedly negative test results and explained why those test results, in [defendant's] view, were not inconsistent with the declaration . . . submitted to the PTO," the record contained a disputed issue of fact for the factfinder to resolve.¹⁶⁵³

The Federal Circuit further explained that even if no genuine issue

1644. *Id.*, 70 U.S.P.Q.2d (BNA) at 1260.

1645. *Id.*, 70 U.S.P.Q.2d (BNA) at 1260-61.

1646. *Id.* at 1240, 70 U.S.P.Q.2d (BNA) at 1261 (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986)).

1647. *Id.*, 70 U.S.P.Q.2d (BNA) at 1261.

1648. *Id.*, 70 U.S.P.Q.2d (BNA) at 1261.

1649. 984 F.2d 1182, 25 U.S.P.Q.2d (BNA) 1561 (Fed. Cir. 1993).

1650. *Monsanto Co.*, 363 F.3d at 1240, 70 U.S.P.Q.2d (BNA) at 1261.

1651. *Id.*, 70 U.S.P.Q.2d (BNA) at 1261.

1652. *Id.* at 1241, 70 U.S.P.Q.2d (BNA) at 1261.

1653. *Id.*, 70 U.S.P.Q.2d (BNA) at 1261.

existed concerning the falsity of defendant's declaration, a triable issue remained regarding defendant's intent to deceive the PTO.¹⁶⁵⁴ The court opined:

[A]lthough the intent element of fraud or inequitable conduct may be proven by a showing of acts the natural consequence of which were presumably intended by the actor, this requires the fact finder to evaluate all the facts and circumstances in each case. Such an evaluation is rarely enabled in summary proceedings.¹⁶⁵⁵

Noting that defendant's statement that it "did not intend to deceive the PTO was based on [its] detailed explanation of [its] interpretation of the disputed results,"¹⁶⁵⁶ the court thus concluded that defendant had "at least state[d] facts supporting a plausible justification or excuse for the misrepresentation."¹⁶⁵⁷

Finally, the Federal Circuit addressed the district court's determination that "the circumstances surrounding the declaration provided convincing evidence that [defendant's] declaration was submitted with the intention of misleading the PTO,"¹⁶⁵⁸ particularly in light of "the threat that without the declaration the examiner would limit the claims"¹⁶⁵⁹ and defendant's status "as a small enterprise with limited resources . . . pursuing a survival strategy."¹⁶⁶⁰ Though agreeing that "circumstances surrounding the submission of the declaration are certainly relevant to the inquiry into intent,"¹⁶⁶¹ the court concluded that: "[T]he small size of the applicants' company and the applicants' presumed incentive to obtain broad patent protection for their inventions did not give rise to such a compelling inference of deceptive intent as to justify the entry of summary judgment on the issue."¹⁶⁶²

In *Alza Corp. v. Mylan Laboratories, Inc.*,¹⁶⁶³ defendant appealed the district court's finding of no inequitable conduct.¹⁶⁶⁴ Defendant argued that an inventor committed inequitable conduct by submitting a declaration to the PTO containing statements that were misleading and inconsistent with actual test results.¹⁶⁶⁵ The district court found that the statement at issue on

1654. *Id.*, 70 U.S.P.Q.2d (BNA) at 1262.

1655. *Id.*, 70 U.S.P.Q.2d (BNA) at 1262 (quoting *Paragon Podiatry Lab., Inc.*, 984 F.2d at 1190, 25 U.S.P.Q.2d (BNA) at 1567).

1656. *Id.*, 70 U.S.P.Q.2d (BNA) at 1262.

1657. *Id.*, 70 U.S.P.Q.2d (BNA) at 1262 (quoting *Paragon Podiatry Lab., Inc.*, 984 F.2d at 1191, 25 U.S.P.Q.2d (BNA) at 1569).

1658. *Id.*, 70 U.S.P.Q.2d (BNA) at 1262.

1659. *Id.*, 70 U.S.P.Q.2d (BNA) at 1262.

1660. *Id.*, 70 U.S.P.Q.2d (BNA) at 1262.

1661. *Id.*, 70 U.S.P.Q.2d (BNA) at 1262.

1662. *Id.* at 1241-42, 70 U.S.P.Q.2d (BNA) at 1262.

1663. 391 F.3d 1365, 73 U.S.P.Q.2d (BNA) 1161 (Fed. Cir. 2004).

1664. *Id.* at 1373, 73 U.S.P.Q.2d (BNA) at 1167.

1665. *Id.*, 73 U.S.P.Q.2d (BNA) at 1167.

appeal “was literally true” but “had the potential to mislead the examiner.”¹⁶⁶⁶ However, the district court reasoned that “in light of all the circumstances,” it could not find that the inventor “acted with the requisite intent when he failed to point out that the data he submitted to the patent examiner included values that would suggest that one could also achieve an adequate flux in a transdermal system that used a sufficiently large fentanyl citrate.”¹⁶⁶⁷ Reviewing the record evidence, the court held that the district court did not commit clear error or abuse its discretion.¹⁶⁶⁸

B. Antitrust

In *Monsanto Co. v. McFarling*,¹⁶⁶⁹ plaintiff appealed the district court’s grant of summary judgment denying its claim that defendant committed patent misuse by tying patented products of first generation soybean seeds to unpatented second generation soybean seeds.¹⁶⁷⁰ The Federal Circuit explained that “in evaluating a patent misuse defense, ‘[t]he key inquiry is whether, by imposing conditions that derive their force from the patent, the patentee has impermissibly broadened the scope of the patent grant with anticompetitive effect.’”¹⁶⁷¹ The Federal Circuit then explained that a tying agreement may serve as a form of patent misuse if a licensor “conditions the license on a patent licensee’s purchase of an unpatented material for use in the invention.”¹⁶⁷²

In vacating the grant of summary judgment, the Federal Circuit reasoned that defendant “does not raise a typical tying allegation and the mere recitation of the word ‘tying’ is not sufficient to state a patent misuse defense.”¹⁶⁷³ Noting that the “licensed and patented product (the first generation seeds) and the good made by the licensed product (the second generation seeds) are nearly identical copies,”¹⁶⁷⁴ the court declined “to hold that [defendant’s] raw exercise of its right to exclude from the patented invention by itself is a ‘tying’ arrangement that exceeds the scope of the patent grant.”¹⁶⁷⁵

1666. *Id.*, 73 U.S.P.Q.2d (BNA) at 1167.

1667. *Id.* at 1373-74, 73 U.S.P.Q.2d (BNA) at 1167.

1668. *Id.* at 1374, 73 U.S.P.Q.2d (BNA) at 1167. In dissent, Judge Dyk reasoned that “[t]here would seem to be no basis for finding the statement ‘literally true.’” *Id.* at 1376, 73 U.S.P.Q.2d (BNA) at 1169 (Dyk, J., dissenting).

1669. 363 F.3d 1336, 70 U.S.P.Q.2d (BNA) 1481 (Fed. Cir. 2004).

1670. *Id.* at 1341, 70 U.S.P.Q.2d (BNA) at 1484.

1671. *Id.* at 1341, 70 U.S.P.Q.2d (BNA) at 1484 (quoting *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1372, 48 U.S.P.Q.2d (BNA) 1225, 1248 (Fed. Cir. 1998)).

1672. *Id.*, 70 U.S.P.Q.2d (BNA) at 1484.

1673. *Id.* at 1342, 70 U.S.P.Q.2d (BNA) at 1485.

1674. *Id.* at 1343, 70 U.S.P.Q.2d (BNA) at 1486.

1675. *Id.* at 1342, 70 U.S.P.Q.2d (BNA) at 1485.

C. Pre-Emption

*Globetrotter Software, Inc. v. Elan Computer Group, Inc.*¹⁶⁷⁶ presented an issue of whether federal patent law preempted state-law tort claims in circumstances in which defendant could not establish that plaintiff's claims of infringement were objectively baseless.¹⁶⁷⁷ Noting that, as a general matter, state-law claims "can survive federal preemption only to the extent that those claims are based on a showing of 'bad faith' action in asserting infringement,"¹⁶⁷⁸ the court explained that "federal patent laws thus bar state-law liability for communications concerning alleged infringement so long as those communications are not made in 'bad faith.'"¹⁶⁷⁹ After canvassing the Supreme Court's and Federal Circuit's jurisprudence concerning the bad faith standard,¹⁶⁸⁰ the court determined that:

[T]he objectively baseless standard . . . applies to state-law claims based on communications alleging that a patent holder has engaged in wrongful conduct by asserting claims of patent infringement A plaintiff claiming that a patent holder has engaged in wrongful conduct by asserting claims of patent infringement must establish that the claims of infringement were objectively baseless.¹⁶⁸¹

Turning to the record below, the court affirmed the grant of summary judgment that defendant's state-law tort claims were preempted by the patent laws, noting that defendant "made no effort to establish that the claims asserted by [plaintiff] with respect to [two asserted] patents were objectively baseless, either because those patents were obviously invalid or plainly not infringed."¹⁶⁸² With regard to a third asserted patent, the court concluded that plaintiff's infringement claim "was not objectively baseless, as is amply demonstrated by our reversal of that grant of summary judgment [of noninfringement]."¹⁶⁸³

1676. 362 F.3d 1367, 70 U.S.P.Q.2d (BNA) 1161 (Fed. Cir. 2004).

1677. *Id.* at 1374-75, 70 U.S.P.Q.2d (BNA) at 1166-67.

1678. *Id.* at 1374, 70 U.S.P.Q.2d (BNA) at 1166 (citing *Zenith Elecs. Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1355, 51 U.S.P.Q.2d (BNA) 1337, 1349 (Fed. Cir. 1999)).

1679. *Id.* at 1374-75, 70 U.S.P.Q.2d (BNA) at 1166-67.

1680. The court specifically addressed the Supreme Court's decision in *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.*, in which the Court held that a "lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." 508 U.S. 49, 60, 26 U.S.P.Q.2d (BNA) 1641, 1648 (1993). The court likewise noted its holding in *Golan v. Pingel Enterprises, Inc.*, that "[t]o show bad faith in [the patentee's] actions, [plaintiff] must offer clear and convincing evidence that [patentee] had no reasonable basis to believe that the [accused device] infringed [the] patents." 310 F.3d 1360, 1371, 64 U.S.P.Q.2d (BNA) 1911, 1918 (Fed. Cir. 2002). The court also noted its decision in *Hunter Douglas, Inc. v. Harmonic Design, Inc.*, providing that federal law preempts state law claims that punish "publicizing a patent in the marketplace unless the plaintiff can show that the patentholder acted in bad faith." 153 F.3d 1318, 1336, 47 U.S.P.Q.2d (BNA) 1769, 1774 (Fed. Cir. 1998).

1681. *Globetrotter Software, Inc.*, 362 F.3d at 1377, 70 U.S.P.Q.2d (BNA) at 1169.

1682. *Id.* at 1375, 70 U.S.P.Q.2d (BNA) at 1167.

1683. *Id.*, 70 U.S.P.Q.2d (BNA) at 1167; *see also id.* at 1376, 70 U.S.P.Q.2d (BNA) at

D. License

In *Jacobs v. Nintendo of America, Inc.*,¹⁶⁸⁴ plaintiff sued for infringement of its patent covering a “tilt sensitive” video game control box.¹⁶⁸⁵ Plaintiff had previously sued defendant’s supplier of certain “accelerometer” components of the claimed control box, Analog Devices, Inc., for inducement and contributory infringement of the same patent. That litigation ended when plaintiff and Analog entered into a settlement agreement providing Analog a license “to make, use, sell, import and export components . . . for use in tilt-sensitive control boxes,” and by which plaintiff covenanted not to sue Analog for “any cause of action having as an element the infringement of the ‘958 patent by Analog or any other party, whether occurring in the past, present or in the future.”¹⁶⁸⁶ Defendant asserted that it was protected from suit by plaintiff’s agreement with Analog. The Federal Circuit agreed, reasoning that basic contract law principles prevent a party who assigns a right in exchange for consideration from acting to undermine the commercial value of that right.¹⁶⁸⁷ Thus, plaintiff could not prevent Analog’s customers from making infringing control boxes after granting Analog the right to sell components of those control boxes.

Plaintiff argued that defendant could only raise the license as a defense if the court determined that Analog’s accelerometer components had no noninfringing uses. Plaintiff’s argument referred to previous Federal Circuit decisions discussing the Court’s view that a patentee’s (or licensee’s) sale of an article that has no noninfringing uses may carry with it an implied license to use the article in an infringing manner.¹⁶⁸⁸ However, the Federal Circuit found these cases to be irrelevant, because there was no need to make a determination as to whether plaintiff had given Analog the right to sell components to be used in infringing devices. The settlement agreement conclusively allowed Analog to sell its accelerometers to be used in infringing control boxes because plaintiff could not prevent anyone from making non-infringing devices. Thus, the agreement would only make sense if it was understood to permit the sale of components to be made in infringing devices.¹⁶⁸⁹

1168 (finding that where claim is not objectively baseless, the court cannot examine litigant’s subjective motives and therefore cannot establish bad faith).

1684. 370 F.3d 1097, 71 U.S.P.Q.2d (BNA) 1055 (Fed. Cir. 2004). The authors’ law firm represented defendant in this case.

1685. *Id.* at 1098, 71 U.S.P.Q.2d (BNA) at 1055.

1686. *Id.* at 1098-99, 71 U.S.P.Q.2d (BNA) at 1055-56.

1687. *Id.* at 1101, 71 U.S.P.Q.2d (BNA) at 1057.

1688. *Id.* at 1100, 71 U.S.P.Q.2d (BNA) at 1057 (citing *Met-Coil Sys. Corp. v. Korners Unlimited, Inc.*, 803 F.2d 684, 686, 231 U.S.P.Q.2d (BNA) 474, 476 (Fed. Cir. 1986)).

1689. *Id.*, 71 U.S.P.Q.2d (BNA) at 1057.

Plaintiff next offered three separate interpretations of the license agreement that would permit suit against defendant. First, plaintiff contended the agreement granted Analog a “bare license” that consisted merely of the right not to be sued for making, using, or selling the accelerometers. But the Federal Circuit found that if it were to adopt plaintiff’s construction of the license provision of the settlement agreement, then the additional “covenant not to sue” provision would be completely redundant. Furthermore, the license provided Analog the right to sell accelerometers “for use in tilt-sensitive control boxes.”¹⁶⁹⁰ This language went far beyond the grant of a bare license. Second, plaintiff argued that the license should be interpreted to grant Analog the right to make and sell infringing control boxes on its own (rather than the accelerometer components). The Federal Circuit found it unlikely, however, that Analog would have bargained for the right to build infringing control boxes on its own because it was not in the business of making game controllers. As its last attempt, plaintiff broadly argued that the license afforded Analog the right to sell accelerometers to anyone without fear of suit, but simply did not shield its customers from suit. The Federal Circuit again rejected this argument asking why Analog would have “contracted for the right to manufacture and sell a product knowing that its customers would be unable to use the product for the bargained-for purpose.”¹⁶⁹¹ Thus, the Federal Circuit affirmed the district court’s holding that plaintiff was precluded from suing defendant for its manufacture and sale of tilt-sensitive control boxes that incorporated Analog’s accelerometers.¹⁶⁹²

E. Settlement

*Unova, Inc. v. Acer Inc.*¹⁶⁹³ involved an appeal from a district court’s grant of summary judgment holding that a settlement agreement between plaintiff and a third party worked to release defendant from patent infringement liability where the defendant had acquired the third party subsequent to the settlement agreement.¹⁶⁹⁴ As an initial matter, the Federal Circuit noted that “[s]ettlement agreements are governed by the generally applicable law of contracts”¹⁶⁹⁵ and that “[a] contract must be so interpreted as to give effect to the mutual intention of the parties as it existed at the time of contracting.”¹⁶⁹⁶ Reviewing the applicable California

1690. *Id.* at 1101, 71 U.S.P.Q.2d (BNA) at 1058.

1691. *Id.*, 71 U.S.P.Q.2d (BNA) at 1058.

1692. *Id.* at 1102, 71 U.S.P.Q.2d (BNA) at 1058.

1693. 363 F.3d 1278, 70 U.S.P.Q.2d (BNA) 1464 (Fed. Cir. 2004).

1694. *Id.* at 1279-80, 70 U.S.P.Q.2d (BNA) at 1465-66.

1695. *Id.* at 1281, 70 U.S.P.Q.2d (BNA) at 1466.

1696. *Id.*, 70 U.S.P.Q.2d (BNA) at 1466 (quoting CAL. CIV. CODE § 1636 (Deering 2004)).

contract law, the Federal Circuit determined that “courts have held that a third party’s rights under a release agreement are predicated upon the contracting parties’ intent to benefit him and that the third party bears the burden of showing that the contracting parties intended to release him.”¹⁶⁹⁷

Having reviewed the settlement agreement, the Federal Circuit determined that the plaintiff and third party “did not intend to release [defendant] from liability for infringement arising from events that occurred before it became [third party’s] parent” company.¹⁶⁹⁸ In particular, the Federal Circuit observed that “release provision itself is most sensibly read as not releasing [defendant] from liability for infringement prior to its acquisition of [the third party]” because the provision stated that the plaintiff “‘hereby releases [the third party], its parents, and its subsidiaries’ from all claims that related to ‘an allegation of infringement of any Smart Battery Patents.’”¹⁶⁹⁹ The Federal Circuit explained that it construed the provision to mean that as of the signing date the defendant released the third party, its parents, and subsidiaries from liability for prior infringement.¹⁷⁰⁰ Accordingly, the Federal Circuit concluded that because the defendant was not the third party’s parent “on that date,” it “is not entitled to the benefit of the release.”¹⁷⁰¹

Addressing the defendant’s argument that such an interpretation would render the term “parent” to be a nullity because the third party did not have any parent companies on the date the settlement agreement was signed, the Federal Circuit explained that it would “not interpret the release provision contrary to the plain meaning of its language or contrary to common sense. The release agreement is written in the present tense . . . and refers to acts of past infringement; thus it most naturally does not refer to [third party’s] future parents.”¹⁷⁰² The Federal Circuit further noted that when the parties to the settlement agreement intended to refer to future entities, they did so expressly and “the fact that they did not similarly modify the term ‘parents’ suggests that they did not seek to release [the third party’s] future parents.”¹⁷⁰³

F. Miscellaneous Defenses

In *National Steel Car, Ltd. v. Canadian Pacific Railway, Ltd.*,¹⁷⁰⁴ the Federal Circuit confronted an issue that only two federal courts had ever

1697. *Id.*, 70 U.S.P.Q.2d (BNA) at 1466.

1698. *Id.* at 1282, 70 U.S.P.Q.2d (BNA) at 1467.

1699. *Id.*, 70 U.S.P.Q.2d (BNA) at 1467.

1700. *Id.*, 70 U.S.P.Q.2d (BNA) at 1467.

1701. *Id.*, 70 U.S.P.Q.2d (BNA) at 1467.

1702. *Id.*, 70 U.S.P.Q.2d (BNA) at 1467.

1703. *Id.*, 70 U.S.P.Q.2d (BNA) at 1467.

1704. 357 F.3d 1319, 69 U.S.P.Q.2d (BNA) 1641 (Fed. Cir. 2004).

before addressed: what is the scope of the “temporary presence” exemption to liability for infringement in 35 U.S.C. § 272?¹⁷⁰⁵ National Steel sued Canadian Pacific Railway (“CPR”) for infringement of its patent directed to a type of railway car and moved for a preliminary injunction.¹⁷⁰⁶ The district court granted National Steel’s motion, finding that CPR had conceded that the asserted claims read on its railway cars and that its defenses to infringement lacked substantial merit.¹⁷⁰⁷ As one of these defenses, CPR contended that its actions were exempt from liability under § 272’s “temporary presence” exception to infringement liability.¹⁷⁰⁸ Under this statute, never before interpreted by the Federal Circuit, the use of any invention in “certain foreign-owned” vehicles entering the United States “temporarily or accidentally” is not an act of infringement under certain conditions.¹⁷⁰⁹

To prove that its use of the accused railcars was exempted under this statute, CPR brought forth evidence that it was a Canadian company and that its rail cars operated on rail lines that, for the most part, it owned in Canada and the United States to deliver lumber from Canada to the United States.¹⁷¹⁰ The district court held that these facts were insufficient to raise a substantial question of whether CPR was liable for infringement.¹⁷¹¹ The Federal Circuit disagreed. First, it disagreed with the district court’s reasoning that the rail car invention was not used in a foreign-owned vehicle because the trains that pulled the cars were owned and operated by U.S. companies in the United States.¹⁷¹² The Federal Circuit looked to Congress’s definition of “vehicle” in the Dictionary Act, 1 U.S.C. § 4,¹⁷¹³ which it said controlled its interpretation of the term, and found that the district court had construed that term in § 272 too narrowly.¹⁷¹⁴ Rather, a vehicle for purposes of § 272 “includes every description of carriage or other artificial contrivance used, or capable of being used, as a means of transportation on land,” carriage being defined in Webster’s Dictionary as

1705. *Id.* at 1329, 69 U.S.P.Q.2d (BNA) at 1648. 35 U.S.C. § 272 states:

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

35 U.S.C. § 272 (2000).

1706. *Nat’l Steel Car, Ltd.*, 357 F.3d at 1322, 69 U.S.P.Q.2d (BNA) at 1642.

1707. *Id.* at 1324, 69 U.S.P.Q.2d (BNA) at 1645.

1708. *Id.*, 69 U.S.P.Q.2d (BNA) at 1645.

1709. *Id.* at 1326, 69 U.S.P.Q.2d (BNA) at 1646.

1710. *Id.* at 1323-24, 69 U.S.P.Q.2d (BNA) at 1644-45.

1711. *Id.* at 1328-29, 69 U.S.P.Q.2d (BNA) at 1647-48.

1712. *Id.* at 1328, 69 U.S.P.Q.2d (BNA) at 1648.

1713. *Id.*, 69 U.S.P.Q.2d (BNA) at 1648.

1714. *Id.*, 69 U.S.P.Q.2d (BNA) at 1648.

“means of conveyance,” “a wheeled vehicle for people, or a wheeled support carrying a burden such as a gun carriage.”¹⁷¹⁵ Therefore, the court concluded, the railcars were vehicles for purposes of the exemption.¹⁷¹⁶

The Federal Circuit next turned to the issue of whether CPR’s railcars were only entering the United States “temporarily” for purposes of satisfying § 272’s requirements.¹⁷¹⁷ Resorting to the legislative history behind the statute which indicated that it was promulgated to facilitate international commerce that would otherwise be overburdened by conflicting patent laws regulating transportation vessels, it held that entering “temporarily” should be defined to mean “entering for a period of time of finite duration with the sole purpose of engaging in international commerce.”¹⁷¹⁸ Contrary to the urgings of National Steel Car, the Federal Circuit found the following factors irrelevant to this inquiry: the magnitude of the benefit derived by the accused infringer as a result of the use of the vehicle in the United States and the burden imposed on the patent holder as a result of the exemption.¹⁷¹⁹ Also dismissed was National Steel Car’s argument that CPR should not be able to claim the benefit of the exemption because there existed testimony that their cars occasionally are “grabbed” by the U.S. railway without permission and used for domestic commerce.¹⁷²⁰ This evidence did not show that the cars entered with the “purpose to engage in commerce other than international commerce.”¹⁷²¹

Finally, the Federal Circuit addressed the question of what the requirement that the invention be “used exclusively for the needs of the . . . vehicle” meant.¹⁷²² The court disagreed with the district court’s narrow interpretation that the invention at issue should exclude inventions “pertaining to the construction of the vehicle.”¹⁷²³ It found no distinction in the statute between “propulsive needs” and “structural needs,” therefore the district court was wrong in its reasoning that because the invention at issue defined the structure of the rail car, rather than an aspect of the locomotive’s propulsion system, the use of the invention did not fall within the scope of § 272.¹⁷²⁴ Rather, looking again to the legislative history, the court found that the Supreme Court case which the statute had codified, as well as the Paris Convention Treaty after which the statute was modeled,

1715. *Id.*, 69 U.S.P.Q.2d (BNA) at 1648 (internal quotations omitted).

1716. *Id.*, 69 U.S.P.Q.2d (BNA) at 1648.

1717. *Id.*, 69 U.S.P.Q.2d (BNA) at 1649.

1718. *Id.*, 69 U.S.P.Q.2d (BNA) at 1650.

1719. *Id.* at 1329, 69 U.S.P.Q.2d (BNA) at 1650.

1720. *Id.* at 1332, 69 U.S.P.Q.2d (BNA) at 1651.

1721. *Id.*, 69 U.S.P.Q.2d (BNA) at 1651.

1722. *Id.*, 69 U.S.P.Q.2d (BNA) at 1651.

1723. *Id.* at 1332-33, 69 U.S.P.Q.2d (BNA) at 1650-51.

1724. *Id.*, 69 U.S.P.Q.2d (BNA) at 1650-51.

both expressly extended the scope of noninfringing uses to inventions used in the construction of vehicles.¹⁷²⁵ Therefore, the train cars at issue satisfied this requirement.¹⁷²⁶

Finally, the court found error in the district court's finding that CPR was precluded from benefiting from the statutory exemption because, allegedly, both CPR and the supplier of the accused cars that it used had sold the cars in the United States.¹⁷²⁷ As for the alleged sales by the supplier, the statute only exempts sales in the United States by those that temporarily enter the United States, and not third parties.¹⁷²⁸ Therefore, the supplier's sales did not bar CPR from using this defense.¹⁷²⁹ Second, as for the alleged sales by CPR to United States companies, the district court itself recognized that there had been no decision regarding the ownership of the cars—the only finding was that CPR “may” engage in such conduct.¹⁷³⁰ This was insufficient to deprive CPR of its § 272¹⁷³¹ defense.¹⁷³²

In *Vanderlande Industries Nederland v. International Trade Commission*,¹⁷³³ the Federal Circuit reviewed the ITC's ruling that Vanderlande Industries Nederland and Vanderlande Industries, Inc. (“Vanderlande”) had “engaged in unfair methods of competition and unfair acts” in violation of § 337 of the Tariff Act of 1930 by importing and selling a “sortation system” that infringed a U.S. patent.¹⁷³⁴ Vanderlande contested the ITC's ruling on the basis that the patent owner and exclusive licensee (“Complainants”) were equitably estopped from asserting the patent against Vanderlande.¹⁷³⁵ Specifically, Vanderlande argued that the Complainants misled Vanderlande by (1) their delay in filing suit despite their knowledge that Vanderlande had contracted to build the accused sorting systems in Europe and the United States, and by (2) their participation in the construction of a United Parcel Service sorting facility in which Vanderlande was installing the accused system.¹⁷³⁶

Despite these allegations, the Federal Circuit held that Vanderlande did not fulfill the first element of equitable estoppel requiring that “the patentee, who usually must have knowledge of the true facts, communicates something in a misleading way, either by words, conduct or

1725. *Id.* at 1333, 69 U.S.P.Q.2d (BNA) at 1651.

1726. *Id.*, 69 U.S.P.Q.2d (BNA) at 1651.

1727. *Id.*, 69 U.S.P.Q.2d (BNA) at 1652.

1728. *Id.*, 69 U.S.P.Q.2d (BNA) at 1652.

1729. *Id.* at 1334, 69 U.S.P.Q.2d (BNA) at 1652.

1730. *Id.*, 69 U.S.P.Q.2d (BNA) at 1652.

1731. *Id.*, 69 U.S.P.Q.2d (BNA) at 1653.

1732. *Id.*, 69 U.S.P.Q.2d (BNA) at 1653.

1733. 366 F.3d 1311, 70 U.S.P.Q.2d (BNA) 1696 (Fed. Cir. 2004).

1734. *Id.*, 70 U.S.P.Q.2d (BNA) at 1698.

1735. *Id.* at 1324, 70 U.S.P.Q.2d (BNA) at 1706.

1736. *Id.*, 70 U.S.P.Q.2d (BNA) at 1706.

silence.”¹⁷³⁷ The Complainants had twice warned Vanderlande by letter that it may infringe their patent if it built its sorting system in the United States, and such “warnings of potential infringement . . . are precisely the opposite of the sort of conduct needed to give rise to equitable estoppel.”¹⁷³⁸ Furthermore, the Complainants had only waited nine months after confirming that Vanderlande was using an infringing system at the United States Parcel facility before filed a complaint with the ITC.¹⁷³⁹

In *Intirtool, Ltd. v. Texar Corp.*,¹⁷⁴⁰ Intirtool owned a patent on punch pliers and supplied these pliers to Texar, who resold them to retailers.¹⁷⁴¹ In 1993, Texar informed Intirtool that, although it was “perfectly satisfied” with Intirtool, it could get very similar pliers from a competing supplier for a lower cost. Texar therefore requested that Intirtool match the lower price. When Intirtool refused, Texar at a later, unspecified date, turned to the competitor for its supply. Intirtool did not pursue enforcement of its patent against Texar until 2000. The District Court for the Eastern District of Texas found that Intirtool should have known from its 1993 conversation with Texar that Texar was “going to continue to sell the punch pliers but would acquire them from another vendor,” and held that, as a result of Intirtool’s delay in filing suit until 2000, Intirtool’s pre-filing damages were barred. The Federal Circuit reversed.¹⁷⁴² Although it found that a presumption of laches arises “where a patentee delays bringing suit for more than six years after the date the patentee knew or should have known of the alleged infringer’s activity,”¹⁷⁴³ it found that Texar’s notice to Intirtool that it contemplated the possibility of reselling competing tools at a future date was not sufficient to give Intirtool actual or constructive knowledge of an act of infringement.¹⁷⁴⁴ Rather, at the time of that conversation, Texar was still Intirtool’s “perfectly satisfied” customer. Therefore, the laches clock did not start ticking as a result of the 1993 conversation between Intirtool and Texar, and because there was no evidence that Intirtool should have known that Texar had ever acted on its plan, the laches clock did not start ticking at all. Therefore, the Federal Circuit held that the district court’s determination that Intirtool should have known that it had an infringement claim more than six years prior to the date it filed suit against Texar was an abuse of discretion.¹⁷⁴⁵

1737. *Id.*, 70 U.S.P.Q.2d (BNA) at 1706.

1738. *Id.* at 1325, 70 U.S.P.Q.2d (BNA) at 1706.

1739. *Id.*, 70 U.S.P.Q.2d (BNA) at 1707.

1740. 369 F.3d 1289, 70 U.S.P.Q.2d (BNA) 1780 (Fed. Cir. 2004).

1741. *Id.* at 1292-93, 70 U.S.P.Q.2d (BNA) at 1782-83.

1742. *Id.* at 1298, 70 U.S.P.Q.2d (BNA) at 1786.

1743. *Id.* at 1297, 70 U.S.P.Q.2d (BNA) at 1786 (internal quotations omitted).

1744. *Id.* at 1297-1298, 70 U.S.P.Q.2d (BNA) 1785-86.

1745. *Id.* at 1298, 70 U.S.P.Q.2d (BNA) at 1786.

V. REMEDIES

A. *Permanent Injunction*

*International Rectifier Corp. v. Samsung Electronics Co.*¹⁷⁴⁶ involved an appeal from contempt proceedings following entry of a permanent injunction.¹⁷⁴⁷ At the district court, the parties stipulated to a consent judgment and an injunction that resolved all infringement issues concerning defendant's product but reserved the issue of infringement regarding products made by defendant for a third party according to the third party's specifications.¹⁷⁴⁸ Tracking the language of § 271(a),¹⁷⁴⁹ the permanent injunction prohibited defendant "from making, using, offering for sale or selling in or importing into the United States the components, devices or products infringing any claim of [the asserted patent]."¹⁷⁵⁰ Two years after entry of the permanent injunction, plaintiff initiated contempt proceedings against defendant and the third party for violating the injunction through sales of third party-designed and defendant-manufactured devices in the United States.¹⁷⁵¹ Thus, the primary issue on appeal was whether defendant's and third party's conduct violated the district court's order.¹⁷⁵²

The Federal Circuit started its analysis by noting that "[a] court may grant an injunction in a patent infringement case 'in accordance with the principles of equity to prevent the violation of any right secured by the patent, on such terms as the court deems reasonable.'"¹⁷⁵³ The Federal Circuit explained that "it is well known that United States patent laws 'do not, and were not intended to, operate beyond the limits of the United States,'"¹⁷⁵⁴ and that "it is not an infringement to make or use a patented product outside of the United States."¹⁷⁵⁵ The Federal Circuit then reasoned that because no dispute existed that defendant's actions did not occur within the United States, its actions do not violate either the language of the permanent injunction or the applicable patent law precedent.¹⁷⁵⁶

1746. 361 F.3d 1355, 70 U.S.P.Q.2d (BNA) 1124 (Fed. Cir. 2004).

1747. *Id.* at 1357, 70 U.S.P.Q.2d (BNA) at 1125.

1748. *Id.* at 1358, 70 U.S.P.Q.2d (BNA) at 1126.

1749. 35 U.S.C. § 271(a) (2000) ("Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefore, infringes the patent.")

1750. *Int'l Rectifier Corp.*, 361 F.3d at 1360, 70 U.S.P.Q.2d (BNA) at 1127.

1751. *Id.* at 1358, 70 U.S.P.Q.2d (BNA) at 1126.

1752. *Id.* at 1359, 70 U.S.P.Q.2d (BNA) at 1127.

1753. *Id.*, 70 U.S.P.Q.2d (BNA) at 1127 (quoting 35 U.S.C. § 283 (2000)).

1754. *Id.* at 1360, 70 U.S.P.Q.2d (BNA) at 1128 (quoting *Brown v. Duchesne*, 60 U.S. 183, 195, (1856)).

1755. *Id.*, 70 U.S.P.Q.2d (BNA) at 1128 (quoting *Rotec Indus., Inc. v. Mitsubishi Corp.*, 215 F.3d 1246, 1251, 55 U.S.P.Q.2d (BNA) 1001, 1004 (Fed. Cir. 2000)).

1756. *Id.* at 1361, 70 U.S.P.Q.2d (BNA) at 1128.

Then addressing plaintiff's theory that the defendant's and third party's agreement to subvert a permanent injunction was tantamount to infringement of the patent, the Federal Circuit held that such an argument "has no basis in law."¹⁷⁵⁷ The court further reasoned that even if the third party imported an infringing device, such conduct would not violate the permanent injunction because there was no basis for attributing the third party's conduct to the defendant.¹⁷⁵⁸ Rather, the Federal Circuit explained that "[t]he only occasion when a person not a party may be punished is when he has helped to bring about . . . an act of a party. This means that the non-party must either abet the defendant, or must be legally identified with him."¹⁷⁵⁹ Based on the record, the Federal Circuit concluded that the only arrangement between defendant and third party was a fabrication agreement for the manufacture and shipment of devices outside the United States, and there was no evidence that defendant exercised any control over the third party nor was defendant related to the third party.¹⁷⁶⁰

In *International Rectifier Corp. v. IXYS Corp.*,¹⁷⁶¹ the issue was whether a permanent injunction order "prohibiting infringement by 'any device covered by one or more of Claims 1 through 5'"¹⁷⁶² of the disputed patent was overly broad given the requirements of Federal Rule of Civil Procedure 65(d).¹⁷⁶³ The Federal Circuit noted that, as a general matter, "broad injunctions that merely instruct that enjoined party not to violate a statute" are contrary to the policy of Rule 65(d) because "[s]uch injunctions increase the likelihood of unwarranted contempt proceedings for acts unlike or unrelated to those originally judged unlawful."¹⁷⁶⁴ The Federal Circuit explained that in the patent infringement context, it "has rejected as

1757. *Id.*, 70 U.S.P.Q.2d (BNA) at 1128.

1758. *Id.*, 70 U.S.P.Q.2d (BNA) at 1128 (citing *Tegal Corp. v. Tokyo Electron Co.*, 248 F.3d 1376, 1379, 58 U.S.P.Q.2d (BNA) 1791, 1793 (Fed. Cir. 2001). In *Tegal*, the Federal Circuit explained that "courts have held parties in contempt based on the conduct of others, but in that circumstance they have required proof that the party subject to contempt sanctions had control over those who engaged in the conduct proscribed by the injunction." 248 F.3d at 1379, 58 U.S.P.Q.2d (BNA) at 1793.

1759. *Int'l Rectifier Corp.*, 361 F.3d at 1362, 70 U.S.P.Q.2d (BNA) at 1128 (quoting *Additive Controls & Mgmt. Sys., Inc. v. Flowdata, Inc.*, 96 F.3d 1390, 1394, 40 U.S.P.Q.2d (BNA) 1106, 1109 (Fed. Cir. 1996)).

1760. *Id.*, 70 U.S.P.Q.2d (BNA) at 1128.

1761. 383 F.3d 1312, 72 U.S.P.Q.2d (BNA) 1571 (Fed. Cir. 2004).

1762. *Id.* at 1316, 72 U.S.P.Q.2d (BNA) at 1574.

1763. *Id.* at 1315, 72 U.S.P.Q.2d (BNA) at 1573. Rule 65(d) provides:

Every order granting an injunction and every restraining order shall set forth the reasons for its issuance; shall be specific in terms; shall describe in reasonable detail, and not by reference to the complaint or other document, the acts or acts sought to be restrained; and is binding only upon the parties to the action, their officers, agents, servants, employees, and attorneys, and upon those persons in active concert or participation with them who receive actual notice of the order by personal service or otherwise.

FED. R. CIV. P. 65(d).

1764. *Int'l Rectifier Corp.*, 383 F.3d at 1316, 72 U.S.P.Q.2d (BNA) at 1574.

overly broad a permanent injunction that simply prohibits future infringement of a patent.”¹⁷⁶⁵ Discussing its decision in *Additive Controls & Measurement Systems, Inc. v. Flowdata, Inc.*,¹⁷⁶⁶ the court explained that it vacated a permanent injunction order because:

[I]t lacked specific terms and a reasonably detailed description of the acts sought to be restrained. Furthermore, the order failed to state which acts constituted infringement or to expressly limit its prohibition to the manufacture, use, or sale of the specific device found to infringe, or devices no more than colorably different from the infringing device.¹⁷⁶⁷

Analogizing the circumstances in *Additive Controls* to the permanent injunction order on appeal, the court explained that “[o]n its face the injunction applies to many more devices than those actually adjudicated. Indeed, by its terms the injunction applies to ‘any device’ made or sold by [defendant] that is within the scope of the patent claims.”¹⁷⁶⁸ The Federal Circuit further reasoned that the

actual scope of the injunction cannot be that expansive . . . because this court has held that “contempt proceedings . . . are available only with respect to devices previously admitted or adjudged to infringe, and to other devices which are no more than colorably different therefrom and which clearly are infringements of the patent.”¹⁷⁶⁹

The court thus concluded that “the only acts the injunction may prohibit are infringement of the patent by the adjudicated devices and infringement by devices not more than colorably different from the adjudicated devices” and “to comply with Rule 65(d), the injunction should explicitly proscribe those specific acts.”¹⁷⁷⁰

B. Damages

1. Lost profits

In *Juicy Whip, Inc. v. Orange Bang, Inc.*,¹⁷⁷¹ the plaintiff appealed the district court decision denying its claim for lost profits, arguing that there was a functional relationship between a patented device and an unpatented material requiring application of the entire market value rule.¹⁷⁷² Vacating the district court’s order, the Federal Circuit explained that:

1765. *Id.*, 72 U.S.P.Q.2d (BNA) at 1574.

1766. 986 F.2d 476, 25 U.S.P.Q.2d (BNA) 1798 (Fed. Cir. 1993).

1767. *Int’l Rectifier Corp.*, 383 F.3d at 1316, 72 U.S.P.Q.2d (BNA) at 1574 (internal citations omitted) (citing *Additive Controls*, 986 F.2d at 479-80, 25 U.S.P.Q.2d (BNA) at 1801).

1768. *Id.*, 72 U.S.P.Q.2d (BNA) at 1574.

1769. *Id.*, 72 U.S.P.Q.2d (BNA) at 1574 (quoting *KSM Fastening Sys., Inc. v. H.A. Jones Co.*, 776 F.2d 1522, 1526, 227 U.S.P.Q. (BNA) 676, 679 (Fed. Cir. 1985)).

1770. *Id.*, 72 U.S.P.Q.2d (BNA) at 1574.

1771. 382 F.3d 1367, 72 U.S.P.Q.2d (BNA) 1385 (Fed. Cir. 2004).

1772. *Id.* at 1371, 72 U.S.P.Q.2d (BNA) at 1387.

The entire market value rule was a principle of patent damages that defined a patentee's ability to recover lost profits on unpatented components typically sold with a patented item . . . "[T]he rule has been extended to allow inclusion of physically separate unpatented components normally sold with a patented components" with the caveat that both were "considered to be components of a single assembly or parts of a complete machine, or they together constitute a functional unit."¹⁷⁷³

Based on the record evidence, the court determined that the patented device and unpatented material "are in fact analogous to parts of a single assembly or a complete machine, as the [unpatented material] functions together with the [patented product] to produce the visual appearance that is central to [plaintiff's patent]."¹⁷⁷⁴ The court further reasoned that "[d]espite some limited interchangeability . . . the two items do 'function together to achieve one result.'"¹⁷⁷⁵

In *Poly-America, L.P. v. GSE Lining Technology, Inc.*¹⁷⁷⁶ plaintiff sought to recover lost profits based on its sister company's sales.¹⁷⁷⁷ While noting that "the recovery of lost profits by a patentee is not limited to the situation in which the patentee is selling the patented device", the Federal Circuit rejected plaintiff's attempt to extend the reach of lost profits and made clear that "the patentee needs to have been selling some item, the profits of which have been lost due to infringing sales, in order to claim damages consisting of lost profits."¹⁷⁷⁸ The Federal Circuit explained that plaintiff and its sister corporation "may not enjoy the advantages of their separate corporate structure and, at the same time avoid the consequential limitations of that structure—in this case, the inability of the patent holder to claim lost profits of its non-exclusive licensee."¹⁷⁷⁹ Accordingly, the Federal Circuit held that although plaintiff "may have the right to sue under its patents, both as an owner and as a back-licensee, it can recover only its own lost profits, not [its sister company's]."¹⁷⁸⁰

2. Reasonable royalty

In *Golight, Inc. v. Wal-Mart Stores, Inc.*,¹⁷⁸¹ defendant challenged an assessed royalty rate as "unreasonable as a matter of law" because it would

1773. *Id.*, 72 U.S.P.Q.2d (BNA) at 1387 (quoting *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1543, 35 U.S.P.Q.2d (BNA) 1065, 1073 (Fed. Cir. 1995)).

1774. *Id.* at 1372, 72 U.S.P.Q.2d (BNA) at 1387.

1775. *Id.*, 72 U.S.P.Q.2d (BNA) at 1387 (quoting *Rite-Hite*, 56 F.3d at 1551, 35 U.S.P.Q.2d (BNA) at 1073).

1776. 383 F.3d 1303, 72 U.S.P.Q.2d (BNA) 1685 (Fed. Cir. 2004).

1777. *Id.* at 1310, 72 U.S.P.Q.2d (BNA) at 1690.

1778. *Id.* at 1311, 72 U.S.P.Q.2d (BNA) at 1690.

1779. *Id.*, 72 U.S.P.Q.2d (BNA) at 1690.

1780. *Id.*, 72 U.S.P.Q.2d (BNA) at 1690.

1781. 355 F.3d 1327, 69 U.S.P.Q.2d (BNA) 1481 (Fed. Cir. 2004).

have required defendant to sell the product below cost and defendant could not have raised its prices to account for the royalty because it was “already selling the products at a loss.”¹⁷⁸² The Federal Circuit rejected defendant’s challenge, explaining that “[t]here is no rule that a royalty be no higher than the infringer’s net profit margin.”¹⁷⁸³ The Federal Circuit further noted that defendant’s evidence “establishes no more than what it might have preferred to pay, which is not the test for damages.”¹⁷⁸⁴

In *Monsanto Co. v. Ralph*,¹⁷⁸⁵ the Federal Circuit again declined to overturn the jury’s award of a reasonable royalty on the ground that defendant would not have “negotiate[d] a royalty in excess of [its] anticipated profit.”¹⁷⁸⁶ The Federal Circuit explained that “although an infringer’s anticipated profit from use of the patented invention is ‘[a]mong the factors to be considered in determining’ a reasonable royalty . . . the law does not require that an infringer be permitted to make a profit.”¹⁷⁸⁷

In *Norian Corp. v. Stryker Corp.*,¹⁷⁸⁸ the Federal Circuit again affirmed that upon finding of infringement, a plaintiff is entitled to at least a reasonable royalty pursuant to § 284,¹⁷⁸⁹ if such damages are sought.¹⁷⁹⁰ At trial, the plaintiff’s expert testified that a reasonable royalty would have been fifteen percent, while defendant’s expert testified that such a royalty would have been three percent.¹⁷⁹¹ The district court then entered judgment on the jury’s finding that no amount of damages had been proven.¹⁷⁹² In reversing this judgment, the Federal Circuit explained that § 284 requires that “damages to a successful claimant in a patent infringement suit shall not be less than a reasonable royalty.”¹⁷⁹³

3. Enhanced damages

In *Juicy Whip, Inc. v. Orange Bang, Inc.*,¹⁷⁹⁴ the Federal Circuit affirmed

1782. *Id.* at 1338, 69 U.S.P.Q.2d (BNA) at 1489-90.

1783. *Id.*, 69 U.S.P.Q.2d (BNA) at 1490 (quoting *State Indus., Inc. v. Mor-Flo Indus., Inc.*, 883 F.2d 1573, 1580, 12 U.S.P.Q.2d (BNA) 1026, 1031 (Fed. Cir. 1989)).

1784. *Id.*, 69 U.S.P.Q.2d (BNA) at 1490.

1785. 382 F.3d 1374, 72 U.S.P.Q.2d (BNA) 1515 (Fed. Cir. 2004).

1786. *Id.* at 1384, 72 U.S.P.Q.2d (BNA) at 1522.

1787. *Id.*, 72 U.S.P.Q.2d (BNA) at 1522 (internal citations omitted) (quoting *Georgia-Pac. Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1120, 166 U.S.P.Q. (BNA) 235, 238 (S.D.N.Y. 1970)).

1788. 363 F.3d 1321, 70 U.S.P.Q.2d (BNA) 1508 (Fed. Cir. 2004).

1789. Section 284 provides, in pertinent part, that a court shall award a successful claimant “damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention.” 35 U.S.C. § 284 (2000).

1790. *Norian Corp.*, 363 F.3d at 1333, 70 U.S.P.Q.2d (BNA) at 1517. Of course, a plaintiff can choose not to plead damages resulting from infringement, and seek only an injunction.

1791. *Id.*, 70 U.S.P.Q.2d (BNA) at 1517.

1792. *Id.*, 70 U.S.P.Q.2d (BNA) at 1517.

1793. *Id.*, 70 U.S.P.Q.2d (BNA) at 1517.

1794. 382 F.3d 1367, 72 U.S.P.Q.2d (BNA) 1385 (Fed. Cir. 2004).

the denial of enhanced damages and attorney's fees explaining that its precedent makes "clear that 'a finding of willful infringement merely *authorizes*, but does not *mandate* an award of increased damages."¹⁷⁹⁵ The Federal Circuit also noted that the district court "properly considered the various factors relating to attorney fees, including 'the degree of culpability of the infringer, the closeness of the question, [and] litigation behavior."¹⁷⁹⁶

4. *Attorney's fees and costs*

In *Lighting World, Inc. v. Birchwood Lighting, Inc.*,¹⁷⁹⁷ the Federal Circuit affirmed the denial of attorney's fees to the defendant based on plaintiff's alleged litigation misconduct, explaining that it "decline[s] to second-guess the district court's judgment" because "[t]he district judge is in a far better position to assess that matter than we are, and nothing presented to us on appeal indicates that the district court's assessment is so clearly flawed as to justify our overturning the district court's holding on that issue."¹⁷⁹⁸ The Federal Circuit also declined to accept defendant's argument that it was entitled to attorney's fees based on an inequitable conduct theory that was raised solely in the context of a request for attorney's fees.¹⁷⁹⁹ The Federal Circuit explained that based on defendant's "belated raising of the inequitable conduct issue and the exacting standard applicable to attorney fee requests, we hold that the district court did not err in denying [defendant's] fee application."¹⁸⁰⁰

*Inland Steel Co. v. LTV Steel Co.*¹⁸⁰¹ involved an appeal from a denial of defendant's request for attorney fees and costs based on the court's determination that the defendant was not a prevailing party in circumstances in which the asserted patent was found invalid during re-examination before the PTO.¹⁸⁰² The question before the Federal Circuit was "whether [defendant] is a 'prevailing party' and thus potentially eligible for the award of attorney fees and costs."¹⁸⁰³ The Federal Circuit first observed that it applies its own law "to define the meaning of prevailing party in the context of patent litigation."¹⁸⁰⁴ The Federal Circuit then stated that "to be a prevailing party, one must 'receive at least some

1795. *Id.* at 1373, 72 U.S.P.Q.2d (BNA) at 1388-89 (quoting *Modine Mfg. Co. v. Allen Group, Inc.*, 917 F.2d 538, 543 (Fed. Cir. 1990)).

1796. *Id.*, 72 U.S.P.Q.2d (BNA) at 1389 (quoting *Superior Fireplace Co. v. Majestic Prods. Co.*, 270 F.3d 1358, 1378 (Fed. Cir. 2001)).

1797. 382 F.3d 1354, 72 U.S.P.Q.2d (BNA) 1344 (Fed. Cir. 2004).

1798. *Id.* at 1366, 72 U.S.P.Q.2d (BNA) at 1354-55.

1799. *Id.* at 1366-67, 72 U.S.P.Q.2d (BNA) at 1355.

1800. *Id.* at 1367, 72 U.S.P.Q.2d (BNA) at 1355.

1801. 364 F.3d 1318, 70 U.S.P.Q.2d 1472 (Fed. Cir. 2004).

1802. *Id.* at 1319, 70 U.S.P.Q.2d at 1473.

1803. *Id.* at 1319-20, 70 U.S.P.Q.2d at 1474.

1804. *Id.* at 1320, 70 U.S.P.Q.2d at 1474 (quoting *Manindra Milling Corp. v. Ogilvie Mills, Inc.*, 76 F.3d 1178, 1181, 37 U.S.P.Q.2d 1707, 1710 (Fed. Cir. 1996)).

relief on the merits,' which 'alters . . . the legal relationship of the parties.'"¹⁸⁰⁵ The Federal Circuit held that in light of district court entry of judgment of non-infringement and dismissal of invalidity counterclaims as moot, defendant "is a prevailing party on a claim adjudicated by the district court, even though it initially prevailed on the issue of invalidity in a different forum."¹⁸⁰⁶ Accordingly, the Federal Circuit remanded back to the district court to determine whether attorney's fees and costs should be awarded given defendant's status as the prevailing party.¹⁸⁰⁷

In *Power Mosfet Technologies, L.L.C. v. Siemens AG*,¹⁸⁰⁸ the Federal Circuit held that a party who had all claims asserted against it dismissed with prejudice was a prevailing party for purposes of Federal Rule of Civil Procedure 54(d)(1).¹⁸⁰⁹ The court explained that it applies its own law to determine whether a party is prevailing, and explained that, under its law, a "dismissal of a claim with prejudice . . . is a judgment on the merits."¹⁸¹⁰

*Stephens v. Tech International*¹⁸¹¹ involved an appeal from a district court's grant of attorney's fees to defendant under § 285.¹⁸¹² The district court based its award on findings that plaintiff's infringement suit was frivolous and in bad faith and its notification of a separate patent application constituted litigation misconduct.¹⁸¹³ On appeal, the Federal Circuit began its analysis by noting that exceptional cases under § 285 typically involve "inequitable conduct before the PTO, litigation misconduct, vexatious and otherwise bad faith litigation, frivolous suit or willful infringement."¹⁸¹⁴ The Federal Circuit then explained that "[a] frivolous infringement suit is one which the patentee knew or, on reasonable investigation, should have known was baseless."¹⁸¹⁵

Reviewing the record, the Federal Circuit held that the district court erred in concluding that plaintiff's suit was frivolous.¹⁸¹⁶ In particular, the Federal Circuit reasoned that plaintiff's theories of claim construction and infringement under the doctrine of equivalents were consistent with the intrinsic evidence, expert testimony, and precedent.¹⁸¹⁷ The court also held

1805. *Id.*, 70 U.S.P.Q.2d at 1474 (quoting *Former Employees of Motorola Ceramic Prods. v. United States*, 336 F.3d 1360, 1364 (Fed. Cir. 2003) (quoting *Buckhannon Bd. & Care Home, Inc. v. W. Va. Dep't of Health & Human Res.*, 532 U.S. 598, 603-05 (2001))).

1806. *Id.*, 70 U.S.P.Q.2d at 1474-75.

1807. *Id.* at 1321, 70 U.S.P.Q.2d at 1475.

1808. 378 F.3d 1396, 72 U.S.P.Q.2d (BNA) 1129 (Fed. Cir. 2004).

1809. *Id.* at 1415-16, 72 U.S.P.Q.2d (BNA) at 1142.

1810. *Id.* at 1416, 72 U.S.P.Q.2d (BNA) at 1142.

1811. 393 F.3d 1269, 73 U.S.P.Q.2d (BNA) 1369 (Fed. Cir. 2004).

1812. *Id.* at 1273, 73 U.S.P.Q.2d (BNA) at 1372.

1813. *Id.*, 73 U.S.P.Q.2d (BNA) at 1372.

1814. *Id.*, 73 U.S.P.Q.2d (BNA) at 1372.

1815. *Id.* at 1273-74, 73 U.S.P.Q.2d (BNA) at 1372 (quoting *Haynes Int'l, Inc. v. Jessup Steel Co.*, 8 F.3d 1573, 1579, 28 U.S.P.Q.2d 1652, 1657 (Fed. Cir. 1993)).

1816. *Id.* at 1274, 73 U.S.P.Q.2d (BNA) at 1373.

1817. *Id.* at 1274-75, 73 U.S.P.Q.2d (BNA) at 1373-74.

that notifying defendant of pending application was not litigation misconduct, but was well within plaintiff's rights under 35 U.S.C. § 154.¹⁸¹⁸

5. *Pre-filing investigation under Rule 11*

The Federal Circuit's decision in *Q-Pharma, Inc. v. Andrew Jergens Co.*¹⁸¹⁹ relaxed the standard for a pre-filing investigation from the court's prior decision in *View Engineering Inc. v. Robotic Vision Systems, Inc.*¹⁸²⁰ *Q-Pharma* involved an appeal from a district court's denial of Rule 11¹⁸²¹ sanctions and attorney's fees after plaintiff voluntarily dismissed its claim of infringement and agreed not to sue defendant in the future for infringement of the asserted patent.¹⁸²² On appeal, defendant argued that the district court abused its discretion by failing to award sanctions given that plaintiff's pre-suit claim construction was frivolous, plaintiff's reliance on defendant's advertisements were not reasonable, and that plaintiff did not take reasonable steps to test the accused product to determine whether it was infringing.¹⁸²³

Holding that the district court did not abuse its discretion, the Federal Circuit explained that "[i]n the context of patent infringement actions, we have interpreted Rule 11 to require, at a minimum, that an attorney interpret the asserted patent claims and compare the accused device with those claims before filing a claim alleging infringement."¹⁸²⁴ Attempting to demonstrate that the district court abused its discretion by failing to levy sanctions, defendant first argued that plaintiff never possessed a formal pre-filing claim chart.¹⁸²⁵ Rejecting this argument, the Federal Circuit explained that "a claim chart is not a requirement of a pre-filing infringement analysis, as the owner, inventor, and/or drafter of a patent ought to have a clear idea of what the patent covers without the formality of a claim chart."¹⁸²⁶

The defendant also argued that sanctions were appropriate because plaintiff's pre-filing claim construction analysis was frivolous.¹⁸²⁷ The Federal Circuit again rejected defendant's argument, reasoning that claim construction is "not always an exact science, and it is not unusual for the parties to offer competing definitions of even the simplest claim

1818. *Id.* at 1276, 73 U.S.P.Q.2d (BNA) at 1374.

1819. 360 F.3d 1295, 70 U.S.P.Q.2d (BNA) 1001 (Fed. Cir. 2004).

1820. 208 F.3d 981, 986, 54 U.S.P.Q.2d 1179, 1183 (Fed. Cir. 2000).

1821. FED. R. CIV. P. 11.

1822. *Q-Pharma, Inc.*, 360 F.3d at 1297-98, 70 U.S.P.Q.2d (BNA) at 1002-03.

1823. *Id.* at 1300, 70 U.S.P.Q.2d (BNA) at 1004.

1824. *Id.* at 1300-01, 70 U.S.P.Q.2d (BNA) at 1005.

1825. *Id.* at 1301, 70 U.S.P.Q.2d (BNA) at 1005.

1826. *Id.*, 70 U.S.P.Q.2d (BNA) at 1005.

1827. *Id.*, 70 U.S.P.Q.2d (BNA) at 1005.

language.”¹⁸²⁸ The court thus concluded that defendant’s pre-filing construction was not frivolous because it “followed the standard canons of claim construction and was reasonably supported by the intrinsic record.”¹⁸²⁹

Defendant next contended that plaintiff’s pre-filing infringement analysis was inadequate because it was premised only on plaintiff’s advertising statements and did not include actual testing of the physical product.¹⁸³⁰ The Federal Circuit explained that while plaintiff could have conducted a more thorough investigation, the reliance on advertising statements and product ingredients provided a sufficient basis for filing suit.¹⁸³¹

Defendant also contended that the suit was frivolous because plaintiff should have known that the asserted claims were invalid in light of letters from potential licensees questioning their validity.¹⁸³² The Federal Circuit rejected this contention, observing that plaintiff

reasonably believed its patent to be valid in light of the statutory presumption of validity . . . as well as licenses that several companies took under the patent. The . . . letters from accused infringers questioning the validity of the [asserted] patent do not negate [defendant’s] legal and factual bases for believing the patent to be valid.¹⁸³³

The Federal Circuit then distinguished its prior decision in *View Engineering* from the circumstances on appeal. While explaining that *View Engineering* “makes clear that reliance on advertising as a basis for filing an infringement suit is not sufficient under Rule 11,”¹⁸³⁴ the court limited that decision to its facts by noting that “sanctions were warranted because the patentee had not performed any claim construction analysis or an infringement analysis prior to filing its counterclaim for infringement.”¹⁸³⁵ By contrast, the court explained that defendant relied on both its claim construction analysis and plaintiff’s advertisement information.¹⁸³⁶ The court further explained that

our case law makes clear that the key factor in determining whether a patentee performed a reasonable pre-filing inquiry is the presence of an infringement analysis . . . [a]nd an infringement analysis can simply consist of a good faith, informed comparison of the claims of a patent

1828. *Id.*, 70 U.S.P.Q.2d (BNA) at 1005.

1829. *Id.*, 70 U.S.P.Q.2d (BNA) at 1005.

1830. *Id.* at 1301-02, 70 U.S.P.Q.2d (BNA) at 1005.

1831. *Id.*, 70 U.S.P.Q.2d (BNA) at 1005-06.

1832. *Id.* at 1303, 70 U.S.P.Q.2d (BNA) at 1006.

1833. *Id.*, 70 U.S.P.Q.2d (BNA) at 1006.

1834. *Id.* at 1302, 70 U.S.P.Q.2d (BNA) at 1006.

1835. *Id.*, 70 U.S.P.Q.2d (BNA) at 1006.

1836. *Id.*, 70 U.S.P.Q.2d (BNA) at 1006.

against the accused subject matter.¹⁸³⁷

Defendant also argued that the district court abused its discretion in denying attorney's fees.¹⁸³⁸ The Federal Circuit affirmed the district court's denial based on the same reasoning as it affirmed the court's denial of sanctions.¹⁸³⁹ The Federal Circuit further reasoned that attorney's fees were properly denied because "we fail to see how a changed legal theory that leads to the voluntary dismissal of a lawsuit can amount to bad faith litigation."¹⁸⁴⁰

1837. *Id.*, 70 U.S.P.Q.2d (BNA) at 1006.

1838. *Id.* at 1303, 70 U.S.P.Q.2d (BNA) at 1007.

1839. *Id.* at 1304, 70 U.S.P.Q.2d (BNA) at 1007.

1840. *Id.*, 70 U.S.P.Q.2d (BNA) at 1007.