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2008 PATENT LAW DECISIONS OF THE FEDERAL CIRCUIT

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I.	Inti	roduction	.750
	A.	Introductory Remarks 1. KSR International Co. v. Teleflex Inc	.750
		1. KSR International Co. v. Teleflex Inc	.751
		2. eBay Inc. v. MercExchange, L.L.C.	.753
		 eBay Inc. v. MercExchange, L.L.C. Diamond v. Diehr and Gottschalk v. Benson 	.753
		4. Gorham Co. v. White	.754
	B.	The U.S. Supreme Court: Quanta Decision	.756
	C.	The Executive Branch: The Rules Promulgated by the	
		U.S. Patent and Trademark Office	.760
	D.	The Legislative Branch: The Patent Reform Act of	
		2007 and the Patent Reform Act of 2008	.762
II.	Dec	cisions Relating to Jurisdiction and Assertability of	
	Cla	ims	.767
	A.	Justiciability 1. Standing	.767
		1. Standing	.767
		2. Mootness	.773
	B.	Subject Matter Jurisdiction	.774
	C.	Declaratory Judgments	.777
		Declaratory Judgments 1. The Federal Circuit's declaratory judgment	
		precedents post- <i>MedImmune</i>	777
		2. Mootness and FDA-listed drugs covered by	
		multiple patents	.780
		3. Sufficient injury	.782
	D.	Appellate Jurisdiction and Reviewability of Judgments	.783
	E.	Personal Jurisdiction	.788
	F.	Res Judicata/Collateral Estoppel	.790
	G.	Res Judicata/Collateral Estoppel Alternative Dispute Resolution	.795
III.	Cla	im Construction	.796
	A.	Claims	.796
		1. Special claims	.796
		2. A or an	.800
	_	3. Plain and ordinary meaning	.802
	B.	Specification	.808
	C.	Prosecution History	.813
	D.	Extrinsic Evidence	
IV.		ringement	.817
	A.	Literal Infringement	.818
	B.	The Doctrine of Equivalents	.823
		1. Amendment-based prosecution history estoppel	.823
		a. The tangentiality exception	.824
		b. The foreseeability exception	.827
		2. Argument-based prosecution history estoppel	.829
	0	3. Other limitations on the Doctrine of Equivalents	.830
	C.	The Reverse Doctrine of Equivalents	.832
	D.	Indirect Infringement Section 271(e)(1): Research Exemption to	.833
	E.	Security 2/1(e)(1): Research Exemption to	000
	Б	Infringement Design Patent Infringement	.030
	F.	Design Patent Infringement	.ð41

2009]

V. Patentability and Validity 843 A. Patentable Subject Matter 843 B. Anticipation 849 1. Patents and printed publications 849 2. Public use and on-sale bar 859 C. Obviousness 865 D. 35 U.S.C. § 112 876 1. Enablement 876 2. Written description 877 3. Definiteness 880 E. Double Patenting 887 VI. Unenforceability 891 A. Inequitable Conduct 891 B. Breach of Duty to Standards Setting Organization 899 C. Improper Inventorship 900 D. Laches 901 VII. Non-Patent Issues 903 A. Alternate Sources of Liability 903 B. Discovery Decisions 905 C. Motions to Transfer 906 VIII. Remedies 909 A. Permanent Injunction 915 C. Damages 920
A. Patentable Subject Matter843B. Anticipation8491. Patents and printed publications8492. Public use and on-sale bar859C. Obviousness865D. 35 U.S.C. § 1128761. Enablement8762. Written description8773. Definiteness880E. Double Patenting887VI. Unenforceability891A. Inequitable Conduct891B. Breach of Duty to Standards Setting Organization899C. Improper Inventorship900D. Laches901VII. Non-Patent Issues903A. Alternate Sources of Liability903B. Discovery Decisions905C. Motions to Transfer906VIII. Remedies909A. Permanent Injunction909B. Preliminary Injunction915C. Damages920
B. Anticipation8491. Patents and printed publications8492. Public use and on-sale bar859C. Obviousness865D. 35 U.S.C. § 1128761. Enablement8762. Written description8773. Definiteness880E. Double Patenting887VI. Unenforceability891A. Inequitable Conduct891B. Breach of Duty to Standards Setting Organization899C. Improper Inventorship900D. Laches901VII. Non-Patent Issues903A. Alternate Sources of Liability903B. Discovery Decisions905C. Motions to Transfer909A. Permanent Injunction909B. Preliminary Injunction915C. Damages920
2. Public use and on-sale bar859C. Obviousness865D. 35 U.S.C. § 1128761. Enablement8762. Written description8773. Definiteness880E. Double Patenting887VI. Unenforceability891A. Inequitable Conduct891B. Breach of Duty to Standards Setting Organization899C. Improper Inventorship900D. Laches901VII. Non-Patent Issues903A. Alternate Sources of Liability903B. Discovery Decisions905C. Motions to Transfer909A. Permanent Injunction909B. Preliminary Injunction915C. Damages920
2. Public use and on-sale bar859C. Obviousness865D. 35 U.S.C. § 1128761. Enablement8762. Written description8773. Definiteness880E. Double Patenting887VI. Unenforceability891A. Inequitable Conduct891B. Breach of Duty to Standards Setting Organization899C. Improper Inventorship900D. Laches901VII. Non-Patent Issues903A. Alternate Sources of Liability903B. Discovery Decisions905C. Motions to Transfer909A. Permanent Injunction909B. Preliminary Injunction915C. Damages920
D. 35 U.S.C. § 112
1. Enablement8762. Written description8773. Definiteness880E. Double Patenting887VI. Unenforceability891A. Inequitable Conduct891B. Breach of Duty to Standards Setting Organization899C. Improper Inventorship900D. Laches901VII. Non-Patent Issues903A. Alternate Sources of Liability903B. Discovery Decisions905C. Motions to Transfer909A. Permanent Injunction909B. Preliminary Injunction915C. Damages920
2. Written description8773. Definiteness880E. Double Patenting887VI. Unenforceability891A. Inequitable Conduct891B. Breach of Duty to Standards Setting Organization899C. Improper Inventorship900D. Laches901VII. Non-Patent Issues903A. Alternate Sources of Liability903B. Discovery Decisions905C. Motions to Transfer909A. Permanent Injunction909B. Preliminary Injunction915C. Damages920
3. Definiteness880E. Double Patenting887VI. Unenforceability891A. Inequitable Conduct891B. Breach of Duty to Standards Setting Organization899C. Improper Inventorship900D. Laches901VII. Non-Patent Issues903A. Alternate Sources of Liability903B. Discovery Decisions905C. Motions to Transfer906VIII. Remedies909A. Permanent Injunction909B. Preliminary Injunction915C. Damages920
E. Double Patenting.887VI. Unenforceability.891A. Inequitable Conduct891B. Breach of Duty to Standards Setting Organization899C. Improper Inventorship900D. Laches901VII. Non-Patent Issues903A. Alternate Sources of Liability.903B. Discovery Decisions905C. Motions to Transfer906VIII. Remedies.909A. Permanent Injunction909B. Preliminary Injunction915C. Damages.920
VI.Unenforceability
B. Breach of Duty to Standards Setting Organization899C. Improper Inventorship900D. Laches901VII. Non-Patent Issues903A. Alternate Sources of Liability903B. Discovery Decisions905C. Motions to Transfer906VIII. Remedies909A. Permanent Injunction909B. Preliminary Injunction915C. Damages920
B. Breach of Duty to Standards Setting Organization899C. Improper Inventorship900D. Laches901VII. Non-Patent Issues903A. Alternate Sources of Liability903B. Discovery Decisions905C. Motions to Transfer906VIII. Remedies909A. Permanent Injunction909B. Preliminary Injunction915C. Damages920
C. Improper Inventorship900D. Laches901VII. Non-Patent Issues903A. Alternate Sources of Liability903B. Discovery Decisions905C. Motions to Transfer906VIII. Remedies909A. Permanent Injunction909B. Preliminary Injunction915C. Damages920
VII. Non-Patent Issues903A. Alternate Sources of Liability903B. Discovery Decisions905C. Motions to Transfer906VIII. Remedies909A. Permanent Injunction909B. Preliminary Injunction915C. Damages920
VII. Non-Patent Issues903A. Alternate Sources of Liability903B. Discovery Decisions905C. Motions to Transfer906VIII. Remedies909A. Permanent Injunction909B. Preliminary Injunction915C. Damages920
A. Alternate Sources of Liability
B. Discovery Decisions905C. Motions to Transfer906VIII. Remedies909A. Permanent Injunction909B. Preliminary Injunction915C. Damages920
C. Motions to Transfer
VIII. Remedies
A. Permanent Injunction
B. Preliminary Injunction
C. Damages
1 Lost profits 020
1. Lost profits
3. Costs
4. Marking
IX. Penalties
A Enhanced Damages for Willful Infringement
B. Award of Attorney Fees
 A. Enhanced Damages for Willful Infringement
A. Administrative Law
B. PTO Procedures937
C. International Trade Commission942
1. Jurisdiction942
2. Scope of authority943

I. INTRODUCTION

A. Introductory Remarks

The United States Supreme Court took a slight breather from patent-law issues in 2008. After issuing three patent-law decisions in 2007 (including *KSR International Co. v. Teleflex Inc.*),¹ the Court

^{1. 550} U.S. 398, 82 U.S.P.Q.2d (BNA) 1385 (2007); *see also* MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 81 U.S.P.Q.2d (BNA) 1225 (2007); Microsoft Corp. v. AT&T Corp., 550 U.S. 437, 82 U.S.P.Q.2d (BNA) 1400 (2007).

issued just one patent-law decision in 2008-Quanta Computer, Inc. v. LG Electronics. Inc.²

Despite the Supreme Court's slower pace, however, the Court's influence loomed large in the United States Court of Appeals for the Federal Circuit in 2008. In a number of cases, the Federal Circuit continued to work through the implications of the Supreme Court's recent precedents, most notably KSR and the Supreme Court's 2006 decision in *eBay Inc. v. MercExchange, L.L.C.*³ The Federal Circuit's continued efforts to apply these cases in different technological and competitive settings may be setting the stage for further elaboration from the Supreme Court on the standard for obviousness and the availability of injunctive relief in patent infringement cases.

The Federal Circuit also, in two en banc decisions, preemptively reevaluated some of its own precedents, considering how they measured up against older (but still binding) Supreme Court case law.⁴ In *In re Bilski*,⁵ the Federal Circuit considered its 35 U.S.C. § 101 patentable-subject-matter jurisprudence against previous Supreme Court decisions such as *Diamond v. Diehr⁶* and *Gottschalk v. Benson.*⁷ And in *Egyptian Goddess, Inc. v. Swisa, Inc.*⁸ the Federal Circuit went back even further in the annals of Supreme Court jurisprudence and revised its own design patent case law in light of the Supreme Court's 1871 decision in Gorham Co. v. White.9

1. KSR International Co. v. Teleflex Inc.

In 2008, the Federal Circuit continued to assess and apply the Supreme Court's 2007 decision in KSR International Co. v. Teleflex Inc., which rejected the Federal Circuit's rigid application of the "teaching, suggestion, or motivation" ("TSM") test in favor of a more flexible approach for determining whether a patent claim is obvious.¹⁰ Using the TSM test, a patent claim was proved obvious if

^{2. 128} S. Ct. 2109, 86 U.S.P.Q.2d (BNA) 1673 (2008); see infra Section I.B (discussing the Court's decision in Quanta).

^{3. 547} U.S. 388, 78 U.S.P.Q.2d (BNA) 1577 (2006).

^{4.} See In re Bilski, 545 F.3d 943, 88 U.S.P.Q.2d (BNA) 1385 (Fed. Cir. 2008); Egyptian Goddess, Inc. v. Swisa, Inc., 543 F.3d 665, 88 U.S.P.Q.2d (BNA) 1658 (Fed. Cir. 2008).

 ^{5. 545} F.3d at 943, 88 U.S.P.Q.2d (BNA) at 1385.
 6. 450 U.S. 185, 209 U.S.P.Q.2d (BNA) 1 (1981).
 7. 409 U.S. 63, 175 U.S.P.Q.2d (BNA) 673 (1972).

⁵⁴³ F.3d at 665, 88 U.S.P.Q.2d (BNA) at 1658. 8

⁸¹ U.S. 511 (1871); see Egyptian Goddess, 543 F.3d at 672, 88 U.S.P.Q.2d (BNA) at 1664 (analyzing the Court's decision in Gorham). For a more detailed discussion of *Egyptian Goddess*, see *infra* Section 1.A.4. 10. 550 U.S. 398, 82 U.S.P.Q.2d (BNA) 1385 (2007).

"'some motivation or suggestion to combine the prior art teachings' can be found in the prior art, the nature of the problem, or the knowledge of a person having ordinary skill in the art."¹¹ In rejecting the Federal Circuit's strict application of the TSM test, the Supreme Court noted that its decision in *Graham v. John Deere Co.*¹² provided for a more expansive and flexible approach to the obviousness question.¹³

Although the Supreme Court did not set forth a particular test in *KSR*, it did offer some guiding principles, such as caution in granting patents "based on the combination of elements found in the prior art" from known methods where the combination yields no more than predictable results.¹⁴ The Federal Circuit in 2008 applied this principle in *Agrizap, Inc. v. Woodstream Corp.*,¹⁵ finding a "textbook case" of obviousness because the asserted claims involved a combination of prior art teachings to yield predictable results.¹⁶ The court applied the same principle to reach a similar conclusion in *Sundance, Inc. v. DeMonte Fabricating Ltd.*¹⁷

In addition, several of the Federal Circuit's cases in 2008 dealt with the ramifications of underlying district court findings that applied the TSM test or *KSR* in the immediate wake of the Supreme Court's decision. In these cases, the court offered additional applications of the directives of *KSR*, such as, "'if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.'"¹⁸ The court also, for example, clarified the post-*KSR* standard for determining obviousness in the context of particular fields of patents, such as those regarding chemical compounds.¹⁹

^{11.} Id. at 407, 82 U.S.P.Q.2d (BNA) at 1391 (citation omitted).

^{12. 383} U.S. 1, 148 U.S.P.Q. (BNA) 459 (1966).

^{13.} KSR Int'l Co., 550 U.S. at 419, 82 U.S.P.Q.2d (BNA) at 1395.

^{14.} Id., 82 U.S.P.Q.2d (BNA) at 1395.

^{15. 520} F.3d 1337, 86 Ù.S.P.Q.2d (BNA) 1110 (Fed. Cir. 2008).

^{16.} *Id.* at 1344, 86 U.S.P.Q.2d (BNA) at 1115. 17. 550 F.3d 1356 (Fed. Čir. 2008) (finding the combination of prior art made the patent obvious).

^{18.} Asyst Techs., Inc. v. Emtrak, Inc., 544 F.3d 1310, 1315, 88 U.S.P.Q.2d (BNA) 1623, 1627 (Fed. Cir. 2008) (quoting *KSR Int'l Co.*, 550 U.S. at 417, 82 U.S.P.Q.2d (BNA) at 1396).

^{19.} See Eisai Co. v. Dr. Reddy's Labs., Ltd., 533 F.3d 1353, 1358, 87 U.S.P.Q.2d (BNA) 1452, 1456 (Fed. Cir. 2008) ("[T]his court consults the counsel of KSR that 'any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." (quoting KSR Int'l Co., 550 U.S. at 420, 82 U.S.P.Q.2d (BNA) at 1397)).

2. eBay Inc. v. MercExchange, L.L.C.

The Federal Circuit also continued in 2008 to delineate the requirements for obtaining injunctive relief upon a finding of infringement in light of the Supreme Court's decision in eBay Inc. v. MercExchange, L.L.C.,²⁰ but left unanswered several questions raised by the 2006 decision. The court expressly left open the question of whether there remained any presumption of irreparable injury upon a finding of patent infringement.²¹ Reviewing the facts of each case presented in detail, the Federal Circuit did not reverse in any of the multiple appeals from the denial of a permanent injunction based on the district court's analysis of the eBay factors,²² and even confirmed that it is within a district court's discretion in appropriate cases to dissolve an injunction granted pre-eBay on the basis that the injunction is no longer equitable in light of that decision.²³ The Federal Circuit did reverse the grant of one permanent injunction, however, where the damages awarded to the plaintiff already included payment of a "market entry fee" that was equivalent to an ongoing royalty payment.²⁴ The court also clarified that the *eBay* decision does not preclude the award of an injunction where the plaintiff does not practice the asserted patents, but that the remaining facts of each particular case must be taken into account.²⁵

3. Diamond v. Diehr and Gottschalk v. Benson

The Federal Circuit in 2008 revisited two Supreme Court cases from over a quarter century ago in its en banc decision in *In re Bilski*,²⁶ clarifying the test for determining what constitutes a patentable process under § 101 and rejecting the court's own tests set forth in

^{20. 547} U.S. 388, 78 U.S.P.Q.2d (BNA) 1577 (2006).

^{21.} Amado v. Microsoft Corp., 517 F.3d 1353, 1359 n.1, 86 U.S.P.Q.2d (BNA) 1090, 1098 n.1 (Fed. Cir. 2008); *see also* Broadcom Corp. v. Qualcomm Inc., 543 F.3d 683, 702, 88 U.S.P.Q.2d (BNA) 1641, 1657 (Fed. Cir. 2008) (explaining that *eBay* did not resolve the issue).

^{22.} Under the factors set forth in *eBay*,

A plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

eBay, 547 U.S. at 391, 78 U.S.P.Q.2d (BNA) at 1578.

^{23.} Amado, 517 F.3d at 1359-62, 86 U.S.P.Q.2d (BNA) at 1094-97 (Fed. Cir. 2008).

^{24.} See Innogenetics, N.V. v. Abbott Labs., 512 F.3d 1363, 1380, 85 U.S.P.Q.2d (BNA) 1641, 1653 (Fed. Cir. 2008) (commenting that the patentee's right to receive royalty payments negates the claim of irreparable injury by the patent infringement).

^{25.} *Id.* at 1379, 85 U.S.P.Q.2d (BNA) at 1653.

^{26. 545} F.3d 943, 88 U.S.P.Q.2d (BNA) 1385 (Fed. Cir. 2008).

State Street Bank & Trust Co. v. Signature Financial Group, Inc.²⁷ and In re Alappat.²⁸ In In re Bilski, the court harkened back to the Supreme Court's decisions in Diamond v. Diehr and Gottschalk v. Benson, which "enunciated a definitive test to determine whether a process claim is tailored narrowly enough to encompass only a particular application of a fundamental principle rather than to pre-empt the principle itself."29 Applying that test. known as the "machine-or-transformation" test, a process is patent-eligible under § 101 if it is tied to a particular machine or apparatus, or it transforms an article into a different state or thing.³⁰

The Federal Circuit's decision left many questions open to future cases. The court, for example, did not set limits of how machine implementation of a process may affect patent-eligibility and did not specify "whether or when recitation of a computer suffices to tie a process claim to a particular machine."³¹ The implications of the Federal Circuit's decision on patent applicants and patent holders will emerge in the courts—including perhaps the Supreme Court—in 2009 and beyond.

4. Gorham Co. v. White

In Egyptian Goddess, Inc. v. Swisa, Inc., the Federal Circuit changed the standard for determining when a design patent is infringed.³² In a unanimous en banc decision, the Federal Circuit aided design patent plaintiffs by abandoning the Federal Circuit's requirement that plaintiffs show the "point of novelty" prong; instead, the Federal Circuit held that design patent plaintiffs need to meet only the "ordinary observer" test,³³ first established by the Supreme Court in 1871 in Gorham Co. v. White.³⁴

A design patent covers the ornamental, rather than the useful, aspects of a product. The "ordinary observer" test from Gorham defines infringement of design patents in terms of whether "in the eve of an ordinary observer . . . two designs are substantially the same," thereby deceiving the observer and "inducing him to purchase

^{27. 149} F.3d 1368, 47 U.S.P.Q.2d (BNA) 1596 (Fed. Cir. 1998).

³³ F.3d 1526, 31 U.S.P.Q.2d (BNA) 1545 (Fed. Cir. 1994). 28.

In re Bilski, 545 F.3d at 954, 88 U.S.P.Q.2d (BNA) at 1385.
 Id. at 955, 88 U.S.P.Q.2d (BNA) at 1391.

^{31.} Id. at 962, 88 U.S.P.Q.2d (BNA) at 1396.

^{32. 543} F.3d 665, 678, 88 U.S.P.Q.2d (BNA) 1658, 1668 (Fed. Cir. 2008) (rejecting the point of novelty test after much discussion and analysis of earlier case law).

^{33.} Id., 88 U.S.P.Q.2d (BNA) at 1668.

^{34. 81} U.S. 511 (1871).

one supposing it to be the other."³⁵ The "ordinary observer" test thus establishes a standard for design patent infringement similar to the "likelihood of confusion" standard for trademark-infringement cases.³⁶

Over time, however, the Federal Circuit added an additional "point of novelty" requirement. A design patent plaintiff now had to prove not only substantial similarity under Gorham's "ordinary observer" test, but also that the accused device contained "substantially the same points of novelty that distinguished the patented design from the prior art."37 The "point of novelty" test was intended to prevent a finding of infringement simply because two products generally looked similar, even though the accused device did not contain the novel design feature or features that allowed the patentee to obtain the patent.³⁸ The "point of novelty" test, however, made proving infringement difficult in many cases because a design patent may have many points of novelty and a defendant could avoid infringement simply by omitting one of them.³⁹

In Egyptian Goddess, the Federal Circuit returned to Gorham, unanimously ruling that the "ordinary observer" is the sole test to determine design patent infringement.⁴⁰ The Federal Circuit, however, tried to prevent findings of infringement based solely on similarity without reference to the novelty that justified the patent: the court required that that the ordinary observer in the Gorham test be someone with knowledge of the prior art.⁴¹ The Federal Circuit said that such familiarity with the prior art will allow a meaningful comparison of the accused devices with the patented claim.⁴² Such an approach, said the court, maintains the "focus on those aspects of a design which render the design different from prior art designs,"43

^{35.} Id. at 528.

^{36.} Egyptian Goddess, 543 F.3d at 682, 88 U.S.P.Q.2d (BNA) at 1671 (noting that an ordinary consumer would not be confused by the similarities between the two products).

^{37.} Goodyear Tire & Rubber Co. v. Hercules Tire & Rubber Co., 162 F.3d 1113, 1118, 48 U.S.P.Q.2d (BNA) 1767, 1770 (Fed. Cir. 1998).

^{38.} See Litton Sys., Inc. v. Whirlpool Corp., 728 F.2d 1423, 1444, 221 U.S.P.Q. (BNA) 97, 109 (Fed. Cir. 1984) (inserting a novelty requirement into previous infringement tests).

^{39.} See Egyptian Goddess, 543 F.3d at 677, 88 U.S.P.Q.2d (BNA) at 1667 (acknowledging the difficulty that the more points of novelty an item possesses, the easier it is for another producer to infringe the patent).

^{40.} Id. at 665, 88 U.S.P.Q.2d (BNA) at 1658.
41. Id. at 677, 88 U.S.P.Q.2d (BNA) at 1667.
42. Id. at 674, 88 U.S.P.Q.2d (BNA) at 1665.
43. Id. at 677, 88 U.S.P.Q.2d (BNA) at 1667 (quoting Sun Hill Indus., Inc. v. Easter Unlimited, Inc., 48 F.3d 1193, 1197, 33 U.S.P.Q.2d (BNA) 1925, 1928 (Fed. Circ. 1005) Cir. 1995)).

while at the same time avoiding "the risk of assigning exaggerated importance to small differences between the claimed and accused designs relating to an insignificant feature simply because that feature can be characterized as a point of novelty."44

The U.S. Supreme Court: Quanta Decision В.

In June 2008, the Supreme Court in Quanta Computer, Inc. v. LG *Electronics, Inc.*⁴⁵ issued a unanimous decision that sought to clarify the law of patent exhaustion.⁴⁶ Specifically, the Court held that the "authorized sale of an article that substantially embodies a patent exhausts the patent holder's rights and prevents the patent holder from invoking patent law to control postsale use of the article."47

The doctrine of patent exhaustion, or the "first-sale doctrine," provides that the initial authorized sale of a patented item terminates ("exhausts") all patent rights to that item.⁴⁸ That is, if a patentee sells a patented article to a purchaser, the purchaser has the rights like any owner of personal property over that particular article-the right to use it, repair it, modify it, discard it, or resell it-unrestricted by any patent rights of the patentee.⁴⁹ A subsequent downstream purchaser of the item, likewise, obtains the same rights to control its disposition.⁵⁰

Before Federal had limited Quanta, the Circuit the patent-exhaustion doctrine in two significant ways. In Mallinckrodt, Inc. v. Medipart, Inc.,⁵¹ the Federal Circuit had held that exhaustion would be triggered—and a patentee's infringement action barred only if the patentee's sale of the patented item was unconditional.⁵² Thus, under the so-called "conditional-sales doctrine," patentees could, to avoid exhaustion, condition sales of patented articles on the purchaser agreeing to conditions, such as field-of-use or single-use restrictions.⁵³ If the purchaser failed to follow those conditions, the patentee could enforce the conditions through a patent infringement

^{44.} Id. at 677, 88 U.S.P.Q.2d (BNA) at 1667-68.

^{45. 128} S. Ct. 2109, 86 U.S.P.Q.2d (BNA) 1673 (2008).

^{46.} *Id.* at 2113, 86 U.S.P.Q.2d (BNA) at 1675. 47. *Id.* at 2122, 86 U.S.P.Q.2d (BNA) at 1682.

^{48.} Id. at 2115, 86 U.S.P.Q.2d (BNA) at 1677.

^{49.} ROBERT L. HARMON, HARMON ON PATENTS: BLACK-LETTER LAW AND COMMENTARY § 31.6 (2007).

^{50.} Id.

^{51. 976} F.2d 700, 24 U.S.P.Q.2d (BNA) 1173 (Fed. Cir. 1992). 52. *Id.* at 706, 24 U.S.P.Q.2d (BNA) at 1178.

^{53.} See id. at 709, 24 U.S.P.Q.2d (BNA) at 1180 (holding that prohibiting a purchaser from reusing a patented medical device was enforceable under patent law).

action (not just through an action under state contract law).⁵⁴ Also, the Federal Circuit had previously held that a patentee's sale of an item would exhaust the patentee's rights only as to a patent's apparatus claims; the patentee would retain all rights under its method claims.55

In Quanta, LG Electronics, Inc. ("LGE") entered into a broad cross-license agreement with Intel, Inc.⁵⁶ LGE licensed to Intel a large portfolio of patents covering aspects of computer systems.⁵⁷ The license agreement authorized Intel to "make, use, sell (directly or indirectly), offer to sell, import or otherwise dispose of" Intel products that practice the LGE patents.⁵⁸ The license agreement explicitly stated that it did not extend a license to any third party to combine licensed products with unlicensed products.⁵⁹ In a separate master agreement, LGE also required Intel to inform its purchasers that Intel's license from LGE did not authorize the purchasers to combine the licensed Intel products with unlicensed non-Intel products.⁶⁰

Quanta Computer, Inc. purchased chips and chipsets from Intel and-despite Intel's warning that Quanta had no license from LGE to combine Intel and non-Intel products-combined them with other components to make computers that infringed LGE's system and method patents.⁶¹ LGE sued Quanta for infringement of its apparatus and method patents.⁶² Quanta raised a patent-exhaustion defense. The district court and the Federal Circuit rejected the defense.⁶³ The Federal Circuit held that the exhaustion defense did not apply to method claims and that, in any event, LGE's license was limited and did not authorize the sale of Intel products for use with non-Intel products.⁶⁴

On review via writ of certiorari, the Supreme Court reversed in a unanimous opinion by Justice Thomas. The Supreme Court

^{54.} Id., 24 U.S.P.Q.2d (BNA) at 1180.

^{54.} *Ia.*, 24 U.S.P.Q.2d (BNA) at 1180. 55. *See* Bandag, Inc. v. Al Bolser's Tire Stores, Inc., 750 F.2d 903, 924, 223 U.S.P.Q.2d (BNA) 982, 992 (Fed. Cir. 1984); *see also* Quanta Computer, Inc. v. LG Elecs., Inc., 128 S. Ct. 2109, 2113, 86 U.S.P.Q.2d (BNA) 1673, 1675 (2008) ("The Court of Appeals for the Federal Circuit held [below] that the doctrine does not apply to method patents at all "). 56. 128 S. Ct. at 2113, 86 U.S.P.Q.2d (BNA) at 1676.

^{57.} *Id.*, 86 U.S.P.Q.2d (BNA) at 1676. 58. *Id.* at 2114, 86 U.S.P.Q.2d (BNA) at 1676.

^{59.} Id., 86 U.S.P.Q.2d (BŇA) at 1676.

^{60.} *Id.*, 86 U.S.P.Q.2d (BNA) at 1676-77.
61. *Id.*, 86 U.S.P.Q.2d (BNA) at 1676-77.
62. *Id.*, 86 U.S.P.Q.2d (BNA) at 1676-77.
62. *Id.*, 86 U.S.P.Q.2d (BNA) at 1676-77.

^{63.} Id. at 2114-15, 86 U.S.P.Q.2d (BNA) at 1677.

^{64.} Id. at 2115, 86 U.S.P.Q.2d (BNA) at 1677.

AMERICAN UNIVERSITY LAW REVIEW [Vol. 58:747

considered three questions: (1) whether the patent-exhaustion doctrine applied to method patents; (2) to what extent a product must embody a patent to trigger exhaustion; and (3) what constitutes an authorized first sale sufficient to trigger exhaustion.⁶⁵

The Court quickly dispensed with the first question, holding that method claims are exhaustible.⁶⁶ The Court stated that it had long held that the exhaustion doctrine applies not only to product claims.67 Moreover, and perhaps more central to the Court's thinking, Justice Thomas pointed out that "[e]liminating exhaustion for method patents would seriously undermine the exhaustion doctrine" because patent drafters could shield items from exhaustion by redrafting apparatus claims as method claims.⁶⁸

The Court then considered "the extent to which a product must embody a patent in order to trigger exhaustion."⁶⁹ The Court relied heavily on the test it articulated in United States v. Univis Lens Co.,⁷⁰ a 1942 decision that, the Court said, "governs this case."⁷¹ In Univis, the Court held that the sale of a product that does not fully practice the patent at issue can still trigger patent exhaustion if its "only reasonable and intended use was to practice the patent and [it] 'embodie[s] essential features of [the] patented invention.'"⁷² The Court determined that the Intel chips and chipsets met this standard and triggered the exhaustion doctrine because they "all but completely practice the patent."73 Although the chips and chipsets were not capable, by themselves, of infringing LGE's patent claims, they nonetheless "substantially embodie[d] the patent because the only step necessary to practice the patent is the application of common processes or the addition of standard parts."⁷⁴ Everything inventive about each patent was embodied in the Intel chips and chipsets; infringement required only a "common and noninventive" final step.⁷⁵

316 U.S. at 249–51, 53 U.S.P.Q.2d (BNA) at 407). 73. Id. at 2120, 86 U.S.P.Q.2d (BNA) at 1680.

^{65.} Id. at 2109, 86 U.S.P.Q.2d (BNA) at 1673.

^{66.} See id. at 2117, 86 U.S.P.Q.2d (BNA) at 1678-79 ("Nothing in this Court's approach to patent exhaustion supports LGE's argument that method patents cannot be exhausted.").

^{67.} See id., 86 U.S.P.Q.2d (BNA) at 1679 (citing United States v. Univis Lens Co., 316 U.S. 241, 53 U.S.P.Q. (BNA) 404 (1942); Ethyl Gasoline Corp. v. United States, 309 U.S. 436, 44 U.S.P.Q. (BNA) 614 (1940)).

^{68.} See id. at 2117-18, 86 U.S.P.Q.2d (BNA) at 1679.

^{69.} Id. at 2118, 86 U.S.P.Q.2d (BNA) at 1679.

 ³¹⁶ U.S. 241, 53 U.S.P.Q.2d (BNA) 404 (1942).
 Quanta, 128 S. Ct. at 2119, 86 U.S.P.Q.2d (BNA) at 1680.

Id., 86 U.S.P.Q.2d (BNA) at 1680 (third alteration in original) (citing Univis, 72.

^{74.} *Id.*, 86 U.S.P.Q.2d (BNA) at 1680. 75. *Id.*, 86 U.S.P.Q.2d (BNA) at 1681.

Finally, the Court considered whether Intel's sale of products to Quanta exhausted LGE's patent rights.⁷⁶ The Court noted that exhaustion is triggered only by a sale authorized by the patent holder, but the Court found that Intel's sales to Quanta were authorized.⁷⁷ Notwithstanding Intel's obligation under the master agreement that it notify purchasers that they did not have a license to combine licensed Intel products with unlicensed non-Intel products, the Court found it dispositive that nothing in the license agreement restricted Intel's right to sell its microprocessors and chipsets to purchasers who intended to combine them with non-Intel parts.⁷⁸ The Court said that the license agreement did not condition Intel's authority to sell its products on whether Intel gave, or Quanta complied with, the notice required under the master agreement.⁷⁹ In short, "[n]o conditions limited Intel's authority to sell products substantially embodying the patents."80

The Court did remark in a footnote that, although the patent-exhaustion doctrine prevented LGE from asserting its patent rights against Quanta, "the authorized nature of the sale to Quanta does not necessarily limit LGE's other *contract* rights."⁸¹ The Court "express[ed] no opinion on whether contract damages might be available even though exhaustion operates to eliminate patent damages."82

Some commentators have suggested that, in the wake of Quanta, a patentee may try to retain patent-law remedies by imposing, in license agreements with manufacturers, conditions on the manufacturers' authority to sell patented items.⁸³ The patentee could then argue that sales in violation of those conditions were unauthorized and that patent exhaustion would not restrict the patentee's remedies.⁸⁴

Quanta did not directly address the continued viability of the Federal Circuit's conditional-sales doctrine, which, as noted above, allows patentees to enforce, through the patent laws, conditions on

84. See id.

Id. at 2121, 86 U.S.P.Q.2d (BNA) at 1681. 76.

^{77.} Id., 86 U.S.P.Q.2d (BŇA) at 1682.

^{78.} Id., 86 U.S.P.Q.2d (BNA) at 1682.

^{79.} *Id.* at 2121–22, 86 U.S.P.Q.2d (BNA) at 1682. 80. *Id.* at 2122, 86 U.S.P.Q.2d (BNA) at 1682.

^{81.} Id. at 2122 n.7, 86 U.S.P.Q.2d (BNA) at 1682 n.7 (emphasis added).

Id., 86 U.S.P.Q.2d (BNA) at 1682 n.7.
 See David J. Cavanaugh & Owen K. Allen, High Court Sees a Lot More Exhaustion, LEGAL TIMES, July 7, 2008, at 14-15 (noting that, in the wake of Quanta, "patent law now provides less certain protection for patentees' efforts to control products after they are sold," and advising patentees that they would be well advised to take care to ensure that "downstream rights are preserved to the fullest extent" in future licensing agreements).

direct purchasers' use of patented items. Although the Solicitor General had broadly asked the Supreme Court to reject the Federal Circuit's conditional-sales precedent,⁸⁵ the Supreme Court did not directly address the issue or even mention the Federal Circuit's decision in *Mallinckrodt*, instead focusing on Intel's status as a licensee whose sales of the patented item were unrestricted by LGE's license agreement.

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

In 2008, the most significant development, with regard to United States Patent and Trademark Office ("USPTO" or "PTO") rules, concerned rules published by the USPTO on August 21, 2007.⁸⁶ These rules would have made a number of controversial revisions relating to patent prosecution. Two key aspects of the revised rules involved limitations on the number of continuation applications and the number of claims in an application.⁸⁷ In particular, the revised rules provided that an applicant seeking to file more than two continuation or continuation-in-part applications, or more than one request for continued examination, must present a showing as to why an amendment, argument, or evidence sought to be entered could not have been previously submitted.⁸⁸ The revised rules also required an applicant to file an examination support document covering all of the claims in any application containing more than five independent claims or twenty-five total claims.⁸⁹

On October 31, 2007, the United States District Court for the Eastern District of Virginia preliminarily enjoined the USPTO from putting its new patent prosecution rules into effect.⁹⁰ On April 1, 2008, the court granted summary judgment in favor of the plaintiffs and voided the USPTO's final rules ("Final Rules") in the two consolidated cases, *Tafas v. Dudas* and *SmithKline Beecham Corp. v. Dudas.*⁹¹ The court determined that the rules were "'not in

^{85.} See Brief for the United States as Amicus Curiae Supporting Petitioners at 18–24, 26–30, Quanta Computer, Inc. v. LG Elecs., Inc., 128 S. Ct. 2109, 86 U.S.P.Q.2d (BNA) 1673 (2009) (No. 06-937).

^{86.} Rules of Practice in Patent Cases, 37 C.F.R. pt. 1 (2008). For background information on the rules adopted in 2007, see generally 72 Fed. Reg. 46,716 (Aug. 21, 2007).

^{87. 72} Fed. Reg. 46,716-44 (Aug. 21, 2007).

^{88.} *Id.* at 46,719–20.

^{89.} *Id.* at 46,721–22.

^{90.} Tafas v. Dudas, 511 F. Supp. 2d 652, 86 U.S.P.Q.2d (BNA) 1548 (E.D. Va. 2007).

^{91.} Tafas v. Dudas, 541 F. Supp. 2d 805, 86 U.S.P.Q.2d (BNA) 1623 (E.D. Va. 2008).

accordance with law' and 'in excess of [the] statutory jurisdiction [and] authority'" of the USPTO.⁹² Contrary to the USPTO's arguments, Senior Judge Cacheris found that the Final Rules were substantive in nature and thus beyond the rulemaking power of the USPTO.⁹³ While the USPTO argued that the rules fell within their rulemaking authority and were procedural in nature, the court found that the Final Rules were not procedural rules and did not relate only to application processing.⁹⁴ Instead, the Final Rules were found to be "substantive rules that change existing law and alter the rights of applicants such as [GlaxoSmithKline] and Tafas under the Patent Act."⁹⁵ The rules "constitute a drastic departure from the terms of the Patent Act as they are presently understood."⁹⁶ This case was appealed to the Federal Circuit, and oral arguments were heard on December 5, 2008.⁹⁷

Unrelated USPTO rules became effective on September 15, 2008.⁹⁸ These rules clarified that "[r]egistration as a patent practitioner does not itself entitle an individual to practice before the Office in trademark matters."⁹⁹ The rules also stated that, as before, any party presenting any paper to the USPTO is certifying that the statements made in such paper, to the best of the party's knowledge, are true, and that such paper is not being submitted frivolously or for any improper purpose.¹⁰⁰ The new rules extended this certification to all papers presented to a hearing officer in a disciplinary proceeding.¹⁰¹ Furthermore, while violations of this section may "jeopardize the probative value of the paper," under the new rules, they no longer threaten the validity of an entire application or of any issued patents or registered trademarks.¹⁰² The old rule (37 C.F.R. § 10.18(b)(1)) stated that with the presentation of any paper to the USPTO, the party presenting such paper was certifying that, to the best of the party's knowledge, all statements made therein were true, and that

^{92.} *Id.* at 811, 86 U.S.P.Q.2d (BNA) at 1627 (citing 5 U.S.C. § 706(2) (2006)).
93. *Id.*, 86 U.S.P.Q.2d (BNA) at 1627.

^{94.} *Id.* at 813, 86 U.S.P.Q.2d (BNA) at 1629. 95. *Id.* at 814, 86 U.S.P.Q.2d (BNA) at 1629.

^{96.} Id., 86 U.S.P.Q.2d (BNA) at 1629.

^{97.} Digital Recording of Oral Argument, Tafas v. Dudas, No. 2008-1352 (Fed. Cir. Dec. 5, 2008), available at http://oralarguments.cafc.uscourts.gov/mp3/2008-1352.mp3.

^{98.} Changes to Representation of Others Before the United States Patent and Trademark Office, 73 Fed. Reg. 47,650 (Aug. 14, 2008) (to be codified at 37 C.F.R. pts. 1, 2, 7, 10, 11, 41).

^{99.} Id. at 47,670 (revising 37 C.F.R. § 11.14(a) (2008)).

^{100.} Id. at 47,652.

^{101.} Id. at 47,653.

^{102.} Id.

violations of the rule "may jeopardize the validity of the application or document, or the validity or enforceability of any patent, trademark registration, or certificate resulting therefrom."¹⁰³ The new rule (37 C.F.R. § 11.18(b)(1)) states that violations of this rule "may jeopardize the probative value of the paper."¹⁰⁴ The new rules also govern the conduct of investigations and disciplinary proceedings before the USPTO.¹⁰⁵ The rules establish the disciplinary jurisdiction of the USPTO and establish explicit grounds for discipline.¹⁰⁶

On June 10, 2008, the USPTO published new rules regarding the formatting and content of appeal briefs.¹⁰⁷ These rules, which were set to take effect on December 10, 2008, were delayed pending review by the Office of Management and Budget.¹⁰⁸

D. The Legislative Branch: The Patent Reform Act of 2007 and the Patent Reform Act of 2008

At the beginning of 2008, congressional patent reform appeared imminent. On September 7, 2007, the House of Representatives easily passed House Bill 1908, the Patent Reform Act of 2007, with a vote of 220 (ayes) to 175 (nays).¹⁰⁹ A somewhat similar reform bill in the Senate, Senate Bill 1145, had already passed the Senate's Committee on the Judiciary on July 19, 2007.¹¹⁰ At the end of 2007, Senator Patrick Leahy, the sponsor of Senate Bill 1145, encouraged the House and Senate to reach a compromise in early 2008 with "the goal of favorable Senate action as early as the floor schedule permits" on a patent reform package.¹¹¹ On January 24, 2008, Senate Bill 1145 was placed on the Senate's legislative calendar.¹¹²

The possibility of passing Senate Bill 1145 disappeared in 2008, however, after facing considerable opposition. Opponents of the bill's provisions included the USPTO,¹¹³ the Bush Administration,¹¹⁴

^{103. 37} C.F.R. § 10.18(b)(1) (2008).

^{104. 73} Fed. Reg. at 47,653.

^{105.} Id.

^{106.} Id.

^{107. 73} Fed. Reg. 32,938 (June 10, 2008)

^{108.}

^{109.}

^{110.}

⁷³ Fed. Reg. 74,972–01 (Dec. 10, 2008). H.R. 1908, 110th Cong. (2007). S. 1145, 110th Cong. (2007). 153 CONG. REC. S15898, S15899 (Dec. 18, 2007) (statement of Sen. Leahy). 111.

^{112.} S. 1145.

^{113.} Donna Young, FDA, Congress To Jointly Form Follow-on Biologics Proposal, BIOWORLD TODAY, Feb. 11, 2008. This article reported on the media statement made by Jon Dudas, Under Secretary of Commerce for Intellectual Property at the USPTO, on Feb. 5, 2008. *Id.* In his statement, Mr. Dudas claimed that the reform package "undermines innovation, particularly in the damages provision" and would be damaging to the biotech industry, universities, and small inventors. Id.

major labor unions (such as the AFL-CIO),¹¹⁵ universities,¹¹⁶ and representatives from the pharmaceutical and biotechnology industries, among others.¹¹⁷ At the end of 2008, Congress ultimately proved unable to institute patent reform.

115. See Letter from Bldg. & Constr. Trade Dep't et al. to U.S. Senator (Feb. 6, 2008), available at http://www.popa.org/pdf/misc/reform1-06feb2008.pdf (voicing opposition of labor unions to provisions on damages, post-grant opposition proceedings, and mandatory publication of applications). 116. See, e.g., Letter from Abbot et al. to John Cornyn, U.S. Senator (Jan. 24, 2008) [hereinafter Abbot letter], available at http://www.patentdocs.typepad.com/patent_docs/files/cornyn_letter.pdf (stating the opinions of Texas employers and U.S. natent holders opposing damages post-grant opposition and volue newsfilter.

116. See, e.g., Letter from Abbot et al. to John Cornyn, U.S. Senator (Jan. 24, 2008) [hereinafter Abbot letter], available at http://www.patentdocs.typepad.com/ patent_docs/files/cornyn_letter.pdf (stating the opinions of Texas employers and U.S. patent holders opposing damages, post-grant opposition, and venue provisions, among others); Letter from Lee T. Todd, Jr., President, Univ. of Kentucky, et al. to Mitch McConnell & Jim Bunning, U.S. Senators (Jan. 23, 2008) [hereinafter Todd letter], available at http://www.patentdocs.typepad.com/patent_docs/files/ mcconnellbunning_letter.pdf (expressing various parties' opinions against damages, post-grant opposition, venue, and applicant quality provisions).

letter], *available at* http://www.patentdocs.typepad.com/patent_docs/files/ mcconnellbunning_letter.pdf (expressing various parties' opinions against damages, post-grant opposition, venue, and applicant quality provisions). 117. See, e.g., Cornyn letter, supra note 116; Todd letter, supra note 116; see also Letter from Adroit Med. et al. to Lamar Alexander & Bob Corker, U.S. Senators (Jan. 29, 2008), *available at* http://www.patentdocs.typepad.com/patent_docs/ files/alexandercorker_letter.pdf (noting concern with damages provisions and post-grant opposition procedures of S. 1145); Letter from AstraZeneca Pharm. LP et al. to Arlen Specter & Robert P. Casey, Jr., U.S. Senators, (Jan. 24, 2008), *available at* http://www.patentdocs.typepad.com/patent_docs/files/spectercasey_letter.pdf (norotesting proposed provisions relating to damages, post-grant opposition,

(protesting proposed provisions relating to damages, post-grant opposition, inequitable conduct, and applicant quality submissions); Letter from Night Operations Sys. et al. to Henry Reid & John Ensign, U.S. Senators (Jan. 23, 2008), *available at* http://www.patentdocs.typepad.com/patent_docs/files/reidensign_ letter.pdf (arguing against damages, post-grant opposition, and venue provisions, among others); Letter from Abbott et al. to Kay Bailey Hutchison, U.S. Senator (Jan. 22, 2008), *available at* http://www.patentdocs.typepad.com/patent_docs/files/ hutchinson_letter.pdf (disagreeing with damages, post-grant opposition, and inequitable conduct provisions); Letter from AbTech Indus, Inc. et al. to John McCain & Jon Kyl, U.S. Senators (Jan. 18, 2008), *available at* http://www.patentdocs.typepad.com/patent_docs/files/mccainkyl_letter.pdf (same); Letter from Amaix et al. to Wayne Allard, U.S. Senator (Dec. 18, 2007), *available at* http://www.patentdocs.typepad.com/patent_docs/files/allard_letter.pdf (same); Letter from The Coca-Cola Co. et al. to Saby Chambliss & Johnny Isakson, U.S. Senators (Dec. 12, 2007), *available at* http://www.patentdocs.typepad.com/ patent_docs/files/chamblissisakson_letter.pdf (same); MEDICAL DEVICE MANUFACTURERS ASSOCIATION, THE PATENT REFORM ACT OF 2007 WILL STIFLE INNOVATION IN MEDICAL TECHNOLOGY (2007), *available at* http://www.medicaldevices.org/public/documents/MDMAPatentReform.pdf

^{114.} Letter from Carlos M. Gutierrez, Sec'y of Commerce, to Patrick Leahy, U.S. Senator (Apr. 3, 2008), available at http://www.ogc.doc.gov/ogc/legreg/letters/110/S1145Apr0308.pdf. In the letter, Mr. Gutierrez expressed the Bush Administration's position on patent reform efforts. The Administration expressed strong opposition to changes in the doctrine of inequitable conduct that would lessen the penalties for such actions without enactment of applicant quality submissions designed to improve application quality. *Id.* at 1. In addition, the Administration stated its "overriding concern" regarding Congress's revisions to the damages statutes, in particular, decreasing the discretion granted to judges in awarding damages. *Id.* at 2; *see also* Letter from Nathaniel F. Wienecke, Assistant Sec'y of Legislation and Intergovernmental Affairs, to Patrick Leahy, U.S. Senator (Feb. 4, 2008), *available at* http://www.ogc.doc.gov/ogc/legreg/letters/110/S1145020408.pdf (detailing opposition to damages provisions in S. 1145, as reported on January 24, 2008, as well as other areas of concern).

Congress has been actively proposing patent reform legislation since at least 2005.¹¹⁸ The reform efforts are designed to institute the most substantial change in the patent laws since the passage of the Patent Act in 1952.¹¹⁹ For example, the goals of reform stated during the 2008 introduction of Senate Bill 1145 were lofty:

(i) to improve patent quality and the patent application process; (ii) to improve and clarify several aspects of patent litigation, including the creation of a less expensive, more expeditious administrative alternative to litigating patent validity issues; and (iii) to make the United States' patent system, where it is useful to do so, more consistent with patent systems throughout the rest of the industrialized world.¹²⁰

To accomplish these goals, the Patent Reform Act of 2007, as proposed in the Senate in 2008 and passed by the House in 2007, provided for the United States to convert from a first-to-invent system to a first-to-file system, thereby harmonizing the U.S. patent system with the rest of the patent systems in the world.¹²¹ In addition, both the Senate and House reform bills would have created an administrative system for challenging patents more quickly and cheaply after their issuance (a "post-grant opposition" proceeding).¹²²

The proposed reform also affected the calculation of reasonable royalty damages.¹²³ House Bill 1908 required that the royalty be

The last time the patent system was significantly changed, the structure of DNA had not been discovered; gasoline was around 27 cents a gallon; and we had not yet sent a man to the moon. . . . [W]e are living in the Information Age, and the products and processes that are being patented are changing as guickly as the times themselves.

Orrin Hatch & Patrick Leahy, Editorial, *Meaningful Patent Reform*, WASH. TIMES, Feb. 15, 2008, at A19; *see also* 1952 Patent Act, Pub. L. No. 82-593, 66 Stat. 792 (1952) (codified as amended in scattered sections of 35 U.S.C.).

120. S. REP. NO. 110-259, pt. 1, at 5.

120. S. KEP. NO. 110-259, pt. 1, at 5. 121. H.R. 1908, 110th Cong. § 3(a) (2007); S. 1145, 110th Cong. § 2(a) (2008). 122. H.R. 1908 § 6; S. 1145 § 5. H.R. 1908 and S. 1145 proposed different post-grant opposition procedures. The House bill had a first window review period during which the patent would not be entitled to a presumption of validity and the burden of proof would be that of preponderance of the evidence rather than clear and convincing evidence. H.R. 1908 § 6(f)(1). The Senate bill proposed two windows S 1145 § 5(c)(1). A patent would not be entitled to a presumption of windows. S. 1145 § 5(c)(1). A patent would not be entitled to a presumption of validity in the first window and the standard of proof would be preponderance of the evidence. *Id.* For the second window, the presumption of validity would exist and invalidity would require proof by clear and convincing evidence. Id.

123. H.R. 1908 § 5(a) (3); S. 1145 § 4(a).

⁽expressing concern over apportionment of damages, post-grant opposition proceedings, PTO rule-making authority, and inequitable conduct provisions). 118. H.R. 2795, 109th Cong. (2005). 119. See S. REP. No. 110-259, pt. 1, at 4 (2008) (statement of Sen. Leahy) ("The

time has come for Congress to reconsider the 50 year old patent statute and how it is currently being applied."). As Senators Orrin Hatch and Patrick Leahy noted shortly after entry of S. 1145 in 2008,

calculated by apportionment or the entire market value rule; only as a last resort could the fact finder use the familiar Georgia Pacific Corp. v. United States Plywood Corp.¹²⁴ factors used to calculate a reasonable royalty.¹²⁵ In Senate Bill 1145, as introduced in 2008, reasonable royalties were to be calculated using the entire market value rule, an established market royalty, or if neither of those provisions were appropriate, through an apportionment method.¹²⁶

A variety of other changes rounded out the reform packages of the Patent Act of 2007, including modification of the current law relating to the best mode requirement,¹²⁷ inequitable conduct,¹²⁸ and venue,¹ as well as the creation of additional disclosure obligations for patent applicants in an effort to increase the quality of patents.¹³⁰

Patent reform has generated a number of divergent views on the best ways to improve the current patent-law system. The most recognized competing factions are technology industries, such as software and semiconductor developers, and the biotechnology and pharmaceutical industries.

In very general terms, the biotechnology and pharmaceutical industries typically favor reform that strengthens the rights of the patent holder. According to researchers, these industries tend to have only a few patents that cover key inventions, and innovation is extremely expensive compared to the cost of copying.¹³¹ As a result, biotechnology and pharmaceutical companies seek to protect their patent rights by discouraging infringement and minimizing mechanisms for challenging their patents.¹³² The biotechnology and pharmaceutical sector has therefore primarily opposed efforts by

^{124.} Ga.-Pac. Corp. v. U.S. Plywood Corp., 318 F. Supp. 1116, 166 U.S.P.Q. (BNA) 235 (S.D.N.Y. 1970).

^{125.} H.R. 1908 § 5(a) (3); see also Ga. Pac. Corp., 318 F. Supp. at 1120, 166 U.S.P.Q. (BNA) at 238 (listing fourteen factors taken from leading cases which can be used to help determine the amount of a reasonable royalty for a patent license).

^{126.} S. 1145 § 4(a).

^{127.} H.R. 1908 § 13.

H.R. 1908 § 12(b); S. 1145 § 12. 128.

^{129.} H.R. 1908 § 11 (a); S. 1145 § 8(a).

^{130.} H.R. 1908 §12 (a); S. 1145 § 11.

^{131.} See Wendy Schact, Patent Reform: Issues in the Biomedical and Software Industries, 27 BIOTECH. L. REP. 153, 156 (2008) (noting that patents could be important to the

²⁷ BIOTECH. L. REP. 153, 156 (2008) (noting that patents could be important to the pharmaceutical industry due the ease in which such products can be replicated). 132. See supra note 117 (listing letters from pharmaceutical and biotechnology companies to members of Congress advocating for the protection of their patent rights in proposed legislation); Donna Young, Analysts Say Patent Reform Will Harm Biotech, Add Costs, BIOWORLD TODAY, Feb. 15, 2008. Biotechnology and pharmaceutical companies also favor lessening the penalty associated with inequitable conduct given the time and expense associated with litigating such claims; congressional attempts to merely codify existing inequitable conduct law have met with resistance from these groups. met with resistance from these groups. Id.

AMERICAN UNIVERSITY LAW REVIEW [Vol. 58:747

Congress to reduce damage awards, which act to deter infringement.¹³³ In addition, post-grant opposition proceedings are viewed unfavorably by the biotechnology and pharmaceutical industry given that the goal of such proceedings is to make invalidation of patents faster and less burdensome to patent challengers.¹³⁴

The high-tech industry, on the other hand, faces different problems. For this sector, companies tend to have a large number of patents that cover relatively minor changes to existing technologies.¹³⁵ The products sold by such companies are the result of a number of prior patented inventions.¹³⁶ As a result, technology companies are concerned with facing damages for infringement that are based on the sale of the total product rather than the contribution to that product made by the (typically small and relatively insignificant) infringing inventive portion of the product.¹³⁷ To combat the problems of "overcompensation" for infringement, technology companies favor apportionment of damages and other methods of cabining the potential damages awards in infringement suits.¹³⁸ In addition, because of the speed at which inventions in the high-tech industry become obsolete, technology companies also favor rapid, streamlined systems for invalidating patents, such as administrative post-grant opposition proceedings with lower burdens of proof.¹³⁶

Despite the contentiousness of patent reform, there is continued interest in 2009 for the reforms proposed by House Bill 1908 and

^{133.} Young, supra note 132.

^{134.} Id.

^{135.} See Schact, supra note 131, at 158 (reporting that new products in software development can embody numerous patentable inventions).

^{136.} Id. at 159.

^{137.} See Coalition for Patent Fairness Thinks Patent Reform Is Near, http://patentbaristas.com/archives/2008/04/02/coalition-for-patent-fairness-thinkspatent-reform-is-near/ (Apr. 2, 2008) (noting that high-tech companies would like to see a lessening of nuisance suits against their companies); *see also* Grant Gross, *Microsoft Asserts Patents, Wants Weaker System*, PC WORLD, May 7, 2007, http://www.pcworld.com/article/131984/microsoft_asserts_patents_wants_weaker_s ystem.html (reporting that Microsoft has argued against the ease in which patent holders can sue infringers resulting in the shut down of product lines which contain a small part of patented equipment or code), *available at* http://www.pcworld.com/article/131984/microsoft_asserts_patents_wants_weaker_s at ystem.html; Coalition for Patent Fairness, http://www.patentfairness.org/ learn/what/ (last visited Mar. 2, 2009) (proposing that damage awards based on common sense standards should be part of comprehensive patent reform legislation).

^{138.} See Gross, supra note 137 (discussing how proposed patent reform legislation, supported by Microsoft, would limit damages based on the number of patents within a product). 139. Id.

Senate Bill 1145.¹⁴⁰ Along with Senate Bill 1145, a revised reform bill-the Patent Reform Act of 2008 (Senate Bill 3600)-was introduced to the Senate in the fall of 2008 for consideration in 2009.¹⁴¹ Like the Patent Reform Act of 2007, the Patent Reform Act of 2008 proposes changes to damages law¹⁴² and creates a post-grant review proceeding.¹⁴³ Elimination of the first-to-invent system¹⁴⁴ and even the "on-sale" and "public use" provisions of 35 U.S.C. § 102 are proposed.¹⁴⁵ Other revisions in Senate Bill 3600 would affect venue,¹⁴⁶ inequitable conduct,¹⁴⁷ and applicant submission standards.¹⁴⁸

II. DECISIONS RELATING TO JURISDICTION AND ASSERTABILITY OF CLAIMS

A. Justiciability

1. Standing

Before a federal court may decide the merits of a case, a plaintiff must first establish that he or she has standing to sue.¹⁴⁹ A patentee's standing to sue for patent infringement is derived from the Patent Act,¹⁵⁰ which states that "[a] patentee shall have remedy by civil action for infringement of his patent."151

^{140.} Obama Supports Patent Reform But Bill May Face Delays, DRUG INDUS. DAILY, Nov. 3, 2008, http://www.fdanews.com/newsletter/article?issueId=12140&articleId= 13. 112187.

^{141.} S. 3600, 110th Cong. (2008); 154 CONG. REC. S9982 (daily ed. Sept. 27, 2008) (statement of Sen. Kyl) (introducing S. 3600 in 2008 "to allow Senators and interested parties the time to consider these alternatives as we prepare for the patent reform debate in the next Congress.")

^{142.} S. $3600 \$ 4(a). The damages provision in S. 3600 focuses on strengthening the "gatekeeper" role of the court. 154 CONG. REC. S9983 (statement of Sen. Kyl). While the damages section of S. 3600 codifies the principle that all relevant factors should be considered in reaching a reasonable royalty (S. $3600 \ \pm 4(a)$), the legislation also provides that certain methods of calculating reasonable royalties, such as standardized measures of damages ("rules of thumb") and royalties paid on such as standardized measures of damages (rules of thumb) and royalities comparable patents, should only be considered in limited circumstances. *Id.* 143. S. $3600 \$ 5. 144. S. $3600 \$ 2(a). 145. S. $3600 \$ 2(b). 146. S. $3600 \$ 8. 147. S. $3600 \$ 8. 147. S. $3600 \$ 8.

^{148.} S. 3600 § 10.

^{149.} See Warth v. Seldin, 422 U.S. 490, 498–99 (1975) (explaining that standing ensures both the party and the dispute are properly before the court and surveying

Article III and prudential standing requirements). 150. 1952 Patent Act, Pub. L. No. 82-593, 66 Stat. 792 (1952) (codified as amended in scattered sections of 35 U.S.C.); *see also* Prima Tek II, L.L.C. v. A-Roo Co., 222 F.3d 1372, 1376, 55 U.S.P.Q.2d (BNA) 1742, 1745 (Fed. Cir. 2000) (determining that appellees had standing to sue as licensees of six U.S. patents). 151. 35 U.S.C. § 281 (2006).

In Akazawa v. Link New Technology International, Inc.,¹⁵² the Federal Circuit addressed the issue of whether a party purporting to own patent rights transferred by way of intestacy has standing to sue.¹⁵³ Any assignment of a patent or an interest in a patent must be in writing.¹⁵⁴ The inventor of the patent at issue in *Akazawa*, however, died intestate without a written will.¹⁵⁵ The inventor's heirs subsequently assigned their interest in the patent to a third party, who then assigned all rights to Akira.¹⁵⁶ When Akira later brought suit against Link New Technology, Link moved for summary judgment on the ground that the initial intestate transfer was not a valid assignment of patent rights.¹⁵⁷ Link reasoned—and the district court agreed-that because no valid assignment had occurred ownership of the patent remained vested in the estate and Akira had no standing to sue.¹⁵⁸

Akira appealed, and the Federal Circuit vacated the district court's decision.¹⁵⁹ The court observed that 35 U.S.C. § 261 is not the only method for transferring ownership of a patent.¹⁶⁰ A change of ownership may also be dictated by operation of law.¹⁶¹ Accordingly, when a patent owner dies, the jurisdiction's law of intestacy will determine who then owns the patent.¹⁶²

Moreover, because state law typically governs patent ownership rather than federal patent law, ownership of the patent at issue required interpretation of Japanese intestacy law.¹⁶³ The Federal Circuit accordingly remanded the case to the trial court with instructions to interpret Japanese law to determine whether Akira had standing to bring suit.¹⁶⁴

The Federal Circuit also had occasion in 2008 to address the reoccurring issue of a patent co-owner's standing to bring suit where the co-owner has failed to join all other owners of the patent. In Lucent Technologies, Inc. v. Gateway, Inc.,¹⁶⁵ Lucent brought suit against Gateway, Dell, and Microsoft for infringement of patents relating to

^{152. 520} F.3d 1354, 86 U.S.P.Q.2d (BNA) 1279 (Fed. Cir. 2008).

^{152. 320} F.3d 1354, 80 C.S.F.Q.2d (BNA) 1273 (Fed. Ch. 2008)
153. Id. at 1355, 86 U.S.P.Q.2d (BNA) at 1280.
154. 35 U.S.C. § 261 (2006).
155. Akazawa, 520 F.3d at 1355, 86 U.S.P.Q.2d (BNA) at 1280.
156. Id., 86 U.S.P.Q.2d (BNA) at 1280.
157. H 20 U.S.P.Q.2d (BNA) at 1280.

Id., 86 U.S.P.Q.2d (BNA) at 1280.
 Id., 86 U.S.P.Q.2d (BNA) at 1280.
 Id., 86 U.S.P.Q.2d (BNA) at 1280.
 Id., 86 U.S.P.Q.2d (BNA) at 1280.

^{160.} Id. at 1356, 86 U.S.P.Q.2d (BNA) at 1281.

^{161.} Id., 86 U.S.P.Q.2d (BNA) at 1281.

^{162.} *Id.* at 1357, 86 U.S.P.Q.2d (BNA) at 1282. 163. *Id.* at 1357–58, 86 U.S.P.Q.2d (BNA) at 1282.

^{164.} Id. at 1358, 86 U.S.P.Q.2d (BNA) at 1283.

^{165. 543} F.3d 710, 88 U.S.P.Q.2d (BNA) 1481 (Fed. Cir. 2008).

MP3 sound encoding.¹⁶⁶ Lucent had developed the patents while party to a joint development agreement with a German company, Fraunhofer Gesellschaft.¹⁶⁷ Lucent, however, had failed to join Fraunhofer to the suit.¹⁶⁸

After the jury found the defendants liable for infringement, the court set aside the verdict and granted the defendants judgment as a matter of law.¹⁶⁹ The court found that, as a matter of law, Fraunhofer was a co-owner of one of the patents-in-suit as a result of the joint development agreement.¹⁷⁰ Because a patent co-owner must join all other owners in order to sue for patent infringement, Lucent lacked standing to assert claims related to this patent against the defendants.¹⁷¹

Lucent appealed, arguing in part that the joint development agreement impermissibly attempted to assign joint ownership to only some of the claims.¹⁷² Because a patentee may only assign title to an entire patent, such a partial assignment would be impermissible.¹⁷³

The Federal Circuit rejected Lucent's interpretation of the joint development agreement and affirmed the district court's ruling.¹⁷⁴ The court noted that while "patent rights cannot be split between claims," an inventor of less than all of the claims in a patent is nevertheless a co-owner of all claims in the patent.¹⁷⁵ Because Lucent had chosen to file its patent applications in a manner that contradicted Lucent's interpretation of the development agreement, Fraunhofer was a co-owner of the patent at issue notwithstanding the terms of that agreement.¹⁷⁶ Accordingly, Lucent lacked standing to assert the patent absent the presence of Fraunhofer.¹⁷⁷

A patentee's failure to join all co-owners may not always be an error of its own making. In DDB Technologies, L.L.C. v. MLB Advanced Media, L.P.,¹⁷⁸ a co-inventor of the patent at issue developed the invention while covered by an employment agreement with Schlumberger Technology Corporation ("Schlumberger").¹⁷⁹ This

^{166.} Id. at 713, 88 U.S.P.Q.2d (BNA) at 1482.

^{167.} Id. at 714-15, 88 U.S.P.Q.2d (BNA) at 1483-84.

^{168.} Id. at 721, 88 U.S.P.Q.2d (BNA) at 1489.

^{169.} *Id.* at 712, 88 U.S.P.Q.2d (BNA) at 1482.
170. *Id.* at 716, 88 U.S.P.Q.2d (BNA) at 1485.

^{171.} Id., 88 U.S.P.Q.2d (BNA) at 1485.

^{172.} Id. at 720, 88 U.S.P.Q.2d (BNA) at 1488.

^{173.} Id., 88 U.S.P.Q.2d (BNA) at 1488.

^{174.} Id. at 722, 88 U.S.P.Q.2d (BNA) at 1489.

^{175.} *Id.* at 721, 88 U.S.P.Q.2d (BNA) at 1489.
176. *Id.* at 722, 88 U.S.P.Q.2d (BNA) at 1489.

^{177.} Id., 88 U.S.P.Q.2d (BNA) at 1489.

^{178. 517} F.3d 1284, 85 U.S.P.Q.2d (BNA) 1942 (Fed. Cir. 2008).

^{179.} Id. at 1286, 85 U.S.P.Q.2d (BNA) at 1944.

employment agreement purported to "grant and assign" to Schlumberger all rights to inventions falling within the scope of inventor's employment.¹⁸⁰ The invention at issue, however, related to the computer simulation of sporting events while Schlumberger was involved in oil wells.¹⁸¹ When the patent owner, DDB Technologies, L.L.C., later sought to enforce the patent against MLB Advanced Media, L.P. ("MLBAM"), MLBAM acquired from Schlumberger all rights and interests that it might have in the patent along with a retroactive license.¹⁸² MLBAM moved to dismiss the action, claiming that DDB had failed to join its purported co-owner, Schlumberger, for the portion of its claim covering the period leading up to the lawsuit and that DDB was legally precluded from suing its purported co-owner, MLBAM, for ongoing infringement.¹⁸³ After finding that the co-inventor's rights to the patent had been automatically divested at the time of invention by the employment agreement, the district court granted MLBAM's motion.¹⁸⁴

A divided panel of the Federal Circuit affirmed in part in a decision that touched on a number of issues relating to an employer's ownership of a device invented during an employee's time of employment.¹⁸⁵ First, Judges Dyk and Clevenger, who made up the majority, determined that interpretation of a contract provision purporting to automatically assign a patent was a matter of federal, rather than state, law.¹⁸⁶ Second, the court differentiated between those employment contracts that automatically grant all rights to future inventions¹⁸⁷ and employment contracts that merely oblige the inventor to grant rights in the future.¹⁸⁸ Third, the court determined that whether the patent at issue fell within the scope of the employment agreement was a matter of state law.¹⁸⁹ Finally, the court applied Federal Circuit law in concluding that the plaintiff should be

expressive grant, an rights in future inventions). 188. *DDB Techs., L.L.C.*, 517 F.3d at 1290, 85 U.S.P.Q.2d (BNA) at 1947; *see also, e.g.*, Arachnid, Inc. v. Merit Indus., Inc., 939 F.2d 1574, 1581, 19 U.S.P.Q.2d (BNA) 1513, 1518 (Fed. Cir. 1991) (finding that where the contract provided that "all rights . . . 'will be assigned' by [inventor] to [client]," the contract merely obliged the inventor to grant rights in the future). 180. DDP Techs. J. L. C. 517 F.3d at 1200, 85 U.S.P.Q.2d (DNA) at 1047.

^{180.} Id. at 1290, 85 U.S.P.Q.2d (BNA) at 1947.

^{180.} Id. at 1290, 85 U.S.P.Q.2d (BNA) at 1947.
181. Id. at 1287, 85 U.S.P.Q.2d (BNA) at 1945.
182. Id. at 1288, 85 U.S.P.Q.2d (BNA) at 1945.
183. Id., 85 U.S.P.Q.2d (BNA) at 1945.
184. Id. at 1288-89, 85 U.S.P.Q.2d (BNA) at 1945-46.
185. Id. at 1289-94, 85 U.S.P.Q.2d (BNA) at 1946-50.
186. Id. at 1289-90, 85 U.S.P.Q.2d (BNA) at 1946-47.
187. Id. at 1290, 85 U.S.P.Q.2d (BNA) at 1947; see also, e.g., FilmTec Corp. v. Allied-Signal, Inc., 939 F.2d 1568, 1573, 19 U.S.P.Q.2d (BNA) 1508, 1512 (Fed. Cir. 1991) (finding that in the contract at issue the investor agroad to grapt and did 1991) (finding that, in the contract at issue, the inventor agreed to grant, and did expressly grant, all rights in future inventions).

^{189.} DDB Techs., L.L.C., 517 F.3d at 1290, 85 U.S.P.Q.2d (BNA) at 1947.

permitted additional discovery on the issue of whether the patents fell within the scope of the employment agreement.¹⁹⁰ The court therefore remanded for further discovery on this issue.¹⁹¹

In dissent, Judge Newman differed with the majority on a number of substantive and procedural issues.¹⁹² According to Judge Newman, the majority had engaged in "grievous overreaching . . . contrary to law and precedent" in finding that federal law controlled the interpretation of the contract merely because standing was involved.¹⁹³ Judge Newman argued that "[s]tate statutory and common law have long been recognized as governing the ownership of patent property."¹⁹⁴ Accordingly, Judge Newman wrote, "There is no authority for preempting state law, no authority for eliminating state law principles of property ownership, no authority for divesting state authority to determine rights and obligations set by employment contract, no authority for rejecting the extensive state precedent of law and procedure governing these issues."195

Judge Newman also disagreed with the majority's holding that DDB could not forcibly join Schlumberger.¹⁹⁶ Judge Newman stated that not only does the provision of Federal Rule of Civil Procedure 19 permitting involuntary joinder make no exception for patent cases,¹⁹⁷ but that it has long been established that involuntary joinder may be used in an infringement action.¹⁹⁸

Finally, Judge Newman was critical of the majority on the issue of whether the employment contract applied as a matter for "jurisdictional discovery."¹⁹⁹ Treating this issue as jurisdictional, according to Judge Newman, directly contradicted the Supreme Court's recent admonition in Arbaugh v. Y & H Corp.²⁰⁰ that the

^{190.} Id. at 1292, 85 U.S.P.Q.2d (BNA) at 1948.

^{191.} Id. at 1293-94, 85 U.S.P.Q.2d (BNA) at 1949-50.

^{192.} *Id.* at 1294, 85 U.S.P.Q.2d (BNA) at 1950 (Newman, J., dissenting).
193. *Id.* at 1296, 85 U.S.P.Q.2d (BNA) at 1951.

^{194.} Id., 85 U.S.P.Q.2d (BŇA) at 1951.

^{195.} Id., 85 U.S.P.Q.2d (BNA) at 1952.

^{196.} *Id.* at 1297–98, 85 U.S.P.Q.2d (BNA) at 1952–53. 197. *Id.* at 1297, 85 U.S.P.Q.2d (BNA) at 1952–53; *see also* FED. R. CIV. P. 19(a) (2) ("If a person has not been joined as required, the court must order that the person be made a party. A person who refuses to join as a plaintiff may be made either a defendant or, in a proper case, an involuntary plaintiff."). 198. DDB Techs., L.L.C., 517 F.3d at 1297–98, 85 U.S.P.Q.2d (BNA) at 1952–53

⁽Newman, J., dissenting); *see also* Indep. Wireless Tel. Co. v. Radio Corp. of Am., 269 U.S. 459, 468–69 (1926); Littlefield v. Perry, 88 U.S. (21 Wall.) 205, 223 (1874).

^{199.} DDB Techs., L.L.C., 517 F.3d at 1298, 85 U.S.P.Q.2d (BNA) at 1953 (Newman, J., dissenting)

Federal Circuit should stop treating threshold facts as jurisdictional unless directed otherwise by Congress.²⁰¹

Standing issues may also arise when the plaintiff is a licensee, rather than the patent owner.²⁰² In order to have constitutional standing to bring an infringement action, the plaintiff must either be the patent owner or an exclusive licensee.²⁰³ "To be an exclusive licensee for standing purposes, a party must have received not only the right to practice the invention within a given territory, but also the patentee's express or implied promise that others shall be excluded from practicing the invention within that territory."204

In Mars, Inc. v. Coin Acceptors, Inc.,205 the Federal Circuit affirmed the district court's denial of leave to amend to add a licensee, MEI, as a co-plaintiff to Mars's patent infringement complaint.²⁰⁶ Mars claimed that MEI had an exclusive license to practice the patents-insuit in the United States and therefore had standing to sue.²⁰⁷ Mars, however, had also granted a second subsidiary a license to practice the patents-in-suit anywhere in the world.²⁰⁸ Accordingly, MEI could not possibly have had an implied, de facto exclusive license and therefore could not be joined as a co-plaintiff in the suit.²⁰⁹

The Federal Circuit also determined that the history of licenses to the patents-at-issue raised additional standing issues. For a portion of the time period for which Mars sought damages, Mars had transferred to MEI title to the patent.²¹⁰ The plaintiff in an infringement action, however, "must be the person or persons in whom the legal title to the patent resided at the time of the

^{201.} DDB Techs., L.L.C., 517 F.3d at 1298-99, 85 U.S.P.Q.2d (BNA) at 1953 (Newman, J., dissenting); see also Arbaugh, 546 U.S. at 511 (observing that when a court dismisses a case for lack of jurisdiction because a threshold fact has not been established the result is an unrefined disposition that should not have a precedential effect).

^{202.} See, e.g., Morrow v. Microsoft Corp., 499 F.3d 1332, 1341, 84 U.S.P.Q.2d (BNA) 1377, 1384 (Fed. Cir. 2007) (noting that exclusive license, the exclusive right to license, and the right to sublicense are important aspects of exclusionary rights); Sicom Sys., Ltd. v. Agilent Techs., Inc., 427 F.3d 971, 976, 76 U.S.P.Q.2d (BNA) 1933, 1027 (Seed. Cir. 2007) (obtained that without initial aspects of exclusionary rights); 1937 (Fed. Cir. 2005) (observing that without joinder of patentee, a licensee normally does not have standing to sue).

<sup>normally does not have standing to sue).
203. Mars, Inc. v. Coin Acceptors, Inc., 527 F.3d 1359, 1367, 87 U.S.P.Q.2d (BNA)
1076, 1083 (Fed. Cir. 2008),</sup> *cert. denied*, 129 S. Ct. 653 (2008).
204. *Id.* at 1368, 87 U.S.P.Q.2d (BNA) at 1083 (quoting Rite-Hite Corp. v. Kelley
Co., 56 F.3d 1538, 1552, 35 U.S.P.Q.2d 1065, 1074 (Fed. Cir. 1995)).
205. *Id.* at 1359, 87 U.S.P.Q.2d (BNA) at 1076.
206. *Id.* at 1374, 87 U.S.P.Q.2d (BNA) at 1088.
207. *Id.* at 1367-68, 87 U.S.P.Q.2d (BNA) at 1088.
208. *Id.* at 1368, 87 U.S.P.Q.2d (BNA) at 1083.
209. *Id.* 87 U.S.P.Q.2d (BNA) at 1083.

^{209.} Id., 87 U.S.P.Q.2d (BŇA) at 1083.

^{210.} Because neither Mars nor MEI challenged the district court's determination that MEI lacked standing for this period, the Federal Circuit did not address the issue on appeal. *Id.* at 1372 n.4, 87 U.S.P.Q.2d (BNA) at 1086 n.4.

infringement."²¹¹ Although Mars lacked title for a portion of the relevant period, the Federal Circuit reaffirmed an earlier decision that a patentee who has transferred legal title to another during the time of infringement can under some circumstances cure the resulting jurisdictional defect by reacquiring title to the patent before final judgment.²¹² Here, Mars and MEI had executed an agreement that the district court interpreted as transferring title back to Mars.²¹³ The Federal Circuit disagreed. Applying New York contract law, the court determined that MEI only purported to transfer back to Mars "the right to sue for past infringement."²¹⁴ Under established Federal Circuit precedent, however, such an attempted assignment does not convey either title or standing in an infringement action.²¹⁵ Accordingly. Mars itself lacked standing for the period in which it had transferred ownership to MEL.²¹⁶

2. Mootness

The exercise of federal judicial power pursuant to Article III of the United States Constitution requires the existence of an ongoing case or controversy.²¹⁷ "[F]ederal courts are without power to decide questions that cannot affect the rights of litigants in the case before them."218

In Samsung Electronics Co. v. Rambus, Inc.,²¹⁹ the Federal Circuit had an opportunity to address the effect an offer for full relief has on a court's power to entertain a claim for attorney fees.²²⁰ Samsung sought a declaratory judgment "that the patents at issue were invalid, unenforceable, and not infringed."221 After losing a procedural motion, Rambus filed covenants not to sue, dropped its counterclaims, and offered to pay Samsung's attorney fees in order to avoid having the court publish adverse findings from an earlier, related case.²²² Samsung refused this offer for full relief and persisted

^{211.} Id. at 1370, 87 U.S.P.Q.2d (BNA) at 1084 (quoting Crown Die & Tool Co. v.

^{211.} Id. at 1370, 87 U.S.P.Q.2d (BNA) at 1084 (quoting Crown Die & 1001 Co. v. Nye Tool & Mach. Works, 261 U.S. 24, 40 (1923)).
212. Id. 87 U.S.P.Q.2d (BNA) at 1084-85.
213. Id. at 1363-64, 87 U.S.P.Q.2d (BNA) at 1079-80.
214. Id. at 1371-72, 87 U.S.P.Q.2d (BNA) at 1086.
215. Id. at 1371, 87 U.S.P.Q.2d (BNA) at 1086 (citing Morrow v. Microsoft Corp., 499 F.3d 1332, 1342, 84 U.S.P.Q.2d (BNA) at 1086
216. Id. at 1372, 87 U.S.P.Q.2d (BNA) at 1086

^{216.} Id. at 1372, 87 U.S.P.Q.Žd (BNA) at 1086.

^{217.} Lewis v. Cont'l Bank Corp., 494 U.S. 472, 477 (1990); *see also* Liner v. Jafco, Inc., 375 U.S. 301, 306 n.3 (1964) (noting the Court's lack of jurisdiction to review moot cases).

^{218.} North Carolina v. Rice, 404 U.S. 244, 246 (1971).

^{219.} 523 F.3d 1374, 86 U.S.P.Q.2d (BNA) 1604 (Fed. Cir. 2008).

^{220.} Id. at 1376, 86 U.S.P.Q.2d (BNA) at 1605.

^{221.} Id., 86 U.S.P.Q.2d (BNA) at 1605.

^{222.} Id. at 1377, 86 U.S.P.Q.2d (BNA) at 1605-06.

with its motion for attorney fees, which the trial court denied.²²³ Although the court denied the only relief Samsung sought, it nevertheless found the case exceptional and issued the unpublished spoliation findings from the previous litigation.²²⁴

The Federal Circuit vacated this order and remanded with instructions to dismiss the case.²²⁵ According to the court, "An offer for full relief moots a claim for attorney fees."²²⁶ The court explained that exceptionality is not a separate sanction, but rather is a precondition for the imposition of attorney fees.²²⁷ Accordingly, "[a]fter Rambus offered the entire amount of attorney fees in dispute, the case became moot."228 Because there was no longer an active controversy, the district court's writing constituted an impermissible advisory opinion that the Federal Circuit was required to vacate.229

B. Subject Matter Jurisdiction

The federal district courts have subject matter jurisdiction over "all civil actions arising under the Constitution, laws, or treaties of the United States."²³⁰ Although broad, this grant does not relieve the federal courts from the obligation to ensure that subject matter jurisdiction exists in any particular case.²³¹

In Christianson v. Colt Industries Operating Corp.,232 the Supreme Court established a two-part test for determining whether federal courts have exclusive jurisdiction over a patent case pursuant to 28 U.S.C. § 1338(a).²³³ Under this test, a court must ask whether a well-pleaded complaint establishes either that: (1) "federal patent law creates the cause of action"; or (2) "the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims.⁷²³⁴

^{223.} *Id.*, 86 U.S.P.Q.2d (BNA) at 1606. 224. *Id.*, 86 U.S.P.Q.2d (BNA) at 1606.

^{225.} Id. at 1376, 86 U.S.P.Q.2d (BNA) at 1605.
226. Id. at 1379, 86 U.S.P.Q.2d (BNA) at 1607.
227. Id. at 1379–80, 86 U.S.P.Q.2d (BNA) at 1607.

^{228.} *Id.* at 1380, 86 U.S.P.Q.2d (BNA) at 1607. 229. *Id.*, 86 U.S.P.Q.2d (BNA) at 1608.

^{230. 28} U.S.C. § 1331 (2006); *see* Arbaugh v. Y & H Corp., 546 U.S. 500, 503–16 (2006) (distinguishing between the subject matter jurisdiction of federal courts and the essential elements of a federal claim for relief and ultimately holding that, if Congress did not make a statutory limitation jurisdictional, the courts should not treat it as such).

^{231.} Arbaugh, 546 U.S. at 514 (2006). 232. 486 U.S. 800, 7 U.S.P.Q.2d (BNA) 1109 (1988). 233. Id. at 809, 7 U.S.P.Q.2d (BNA) at 1113.

^{234.} Id., 7 U.S.P.Q.2d (BNA) at 1113.

The answer to the question of whether a court has subject matter jurisdiction over a patent dispute will often be clear.²³⁵ In *ExcelStor* Technology, Inc. v. Papst Licensing GMBH,²³⁶ the plaintiff brought an action in federal district court claiming fraud and breach of contract in relation to a patent licensing agreement.²³⁷ Although these claims arose under state law of contract and fraud, the plaintiff argued that the federal court's exclusive subject matter jurisdiction was triggered by the plaintiff's citation to the "patent exhaustion" doctrine.²³⁸ The district court disagreed and dismissed the complaint for lack of subject matter jurisdiction, stating that patent exhaustion is a defense to patent infringement and not a cause of action sufficient to confer federal jurisdiction over the case.²³⁹ On appeal, the Federal Circuit applied the Christianson two-part test for determining whether jurisdiction exists under § 1338 and affirmed, stating that ExcelStor's claims did not "arise under" the patent laws but merely invoked a defense to a hypothetical claim of patent infringement.²⁴⁰

A court, however, may sometimes find itself facing a close question of whether a certain threshold fact is (1) an element of the claim that must be established on the merits, or (2) a jurisdictional limitation on the court's power to hear the controversy.²⁴¹ Recently, in *Arbaugh*, the Supreme Court provided guidance for determining whether a threshold fact represents a jurisdictional limitation or whether it is simply an element of the claim: "[W]hen Congress does not rank a statutory limitation on coverage as jurisdictional, courts should treat the restriction as nonjurisdictional in character."242

The Federal Circuit first had opportunity to apply Arbaugh in 2008.²⁴³ In Litecubes, L.L.C. v. Northern Lights Products, Inc.,²⁴⁴ the court

^{235.} See, e.g., Fair v. Kohler Die & Specialty Co., 228 U.S. 22, 24-25 (1913) (stating that the plaintiff "obviously... sued upon the patent law," while also observing that "the party who brings a suit is master to decide what law he will rely upon, and therefore does determine whether he will bring a 'suit arising under' the patent or other law of the United States by his declaration or bill"); Pixton v. B&B Plastics, Inc., 291 F.3d 1324, 1327, 62 U.S.P.Q.2d (BNA) 1944, 1946 (Fed. Cir. 2002) (vacating the trial court's order of dismissal for lack of subject matter jurisdiction over an action for patent infringement).

^{236. 541} F.3d 1373, 88 U.S.P.Q.2d (BNA) 1060 (Fed. Cir. 2008).

^{237.} *Id.* at 1375, 88 U.S.P.Q.2d (BNA) at 1061. 238. *Id.* at 1375–76, 88 U.S.P.Q.2d (BNA) at 1061–62.

^{239.} Id. at 1376, 88 U.S.P.Q.2d (BNA) at 1062.

^{240.} *Id.*, 88 U.S.P.Q.2d (BŇA) at 1062. 241. *See* Arbaugh v. Y & H Corp., 546 U.S. 500, 515–16 (2006) ("Whether a disputed matter concerns jurisdiction or the merits (or occasionally both) is sometimes a close question." (quoting Da Silva v. Kinsho Int'l Corp., 229 F.3d 358, 361 (2d Cir. 2000))

^{242.} Id. at 515-16.

^{243.} Cf. Fed. Nat'l Mortgage Ass'n v. United States, 469 F.3d 968, 972-73 (Fed. Cir. 2006) (finding Arbaugh inapplicable).

addressed whether failure to prove that allegedly infringing activity took place in the United States divests the federal courts of subject matter jurisdiction over a patent infringement action.²⁴⁵ The Canadian defendant in Litecubes, GlowProducts.com items ("GlowProducts"), imported novelty from Chinese manufacturers for sale in North America, including the United States.²⁴⁶ The suit proceeded to trial, at which point the jury found GlowProducts liable for willful infringement.²⁴⁷

GlowProducts subsequently filed a motion to dismiss, arguing that its acts of infringement had occurred outside the United States and that the court therefore lacked subject matter jurisdiction.²⁴⁸ The district court accepted GlowProducts' characterization of the issue as jurisdictional, but denied the motion on the ground that sufficient evidence supported the finding that GlowProducts had imported the products into the United States.²⁴⁹

The Federal Circuit subsequently affirmed the denial of the motion to dismiss, but on different grounds than those that the district court found persuasive.²⁵⁰ Noting that "[t]here is no absolute rule prohibiting the extraterritorial reach of federal statutes," the Federal Circuit explained that "[w]hether Congress did extend any particular statute to reach extraterritorial activity is simply a question of statutory interpretation."²⁵¹ Under the rule laid out by the *Arbaugh* Court, however, only those facts clearly identified by Congress as creating a threshold limitation on a statute's scope count as iurisdictional.²⁵² Congress had not so identified the location requirement of 35 U.S.C. § 271.²⁵³ Accordingly, the location of an allegedly infringing act is properly considered an element of the claim for patent infringement rather than a prerequisite for subject matter jurisdiction.²⁵⁴

⁵²³ F.3d 1353, 86 U.S.P.Q.2d (BNA) 1753 (Fed. Cir. 2008). 244.

^{245.} Id. at 1357, 86 U.S.P.Q.2d (BNA) at 1755.
246. Id. at 1358, 86 U.S.P.Q.2d (BNA) at 1756.
247. Id. at 1359, 86 U.S.P.Q.2d (BNA) at 1756.

^{248.} Id., 86 U.S.P.Q.2d (BNA) at 1756. For GlowProducts to be liable for infringement under 35 U.S.C. § 271(a) (2006), it had to have been shown to have either imported into the United States or made, used, offered for sale, or sold LiteCube's invention in the United States. *Litecubes*, 523 F.3d at 1360, 86 U.S.P.Q.2d (BNA) at 1757.

^{249.} *Id.* at 1359, 86 U.S.P.Q.2d (BNA) at 1756–57. 250. *Id.* at 1366, 86 U.S.P.Q.2d (BNA) at 1762.

^{251.} Id. at 1363, 86 U.S.P.Q.2d (BNA) at 1760.
252. Arbaugh v. Y & H Corp., 546 U.S. 500, 516–17 (2006).
253. Litecubes, 523 F.3d at 1363, 86 U.S.P.Q.2d (BNA) at 1759.

^{254.} Id., 86 U.S.P.Q.2d (BNA) at 1759-60. Although Arbaugh provided a bright line answer to this issue, the Federal Circuit nevertheless engaged in an extensive discussion of "whether there is something unique about a limitation that determines

C. Declaratory Judgments

1. The Federal Circuit's declaratory judgment precedents post-MedImmune

In 2008, the Federal Circuit issued several decisions applying the guidance set forth by the Supreme Court in MedImmune, Inc. v. *Genentech*, *Inc.*²⁵⁵ In *MedImmune*, the Supreme Court rejected the Federal Circuit's "reasonable apprehension of suit" test²⁵⁶ and "set forth the correct standard for jurisdiction over a declaratory judgment action."²⁵⁷ In order for a court to have jurisdiction over a declaratory judgment, "the facts alleged, under all the circumstances, [must] show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."²⁵⁸ "In short, 'all the circumstances' must show a controversy."25

In Micron Technology, Inc. v. MOSAID Technologies, Inc.,²⁶⁰ the Federal Circuit applied this "all the circumstances" test and reversed the district court's grant of MOSAID's motion to dismiss for lack of subject matter jurisdiction over Micron's declaratory judgment action.²⁶¹ Micron, a manufacturer of dynamic random access memory ("DRAM"), and its three largest competitors accounted for more than seventy-five percent of worldwide DRAM sales.²⁶² Several years before Micron filed its declaratory judgment complaint, MOSAID, who owned several patents in the DRAM field, sent Micron a number of warning letters strongly encouraging Micron to take a license to these patents.²⁶³ When neither Micron nor its competitors took MOSAID up on its offer, MOSAID brought separate suits against two of Micron's three major DRAM competitors and became involved in a declaratory judgment action with the third.²⁶⁴ All three cases settled when the DRAM manufacturers entered into licensing agreements

the extraterritorial scope of a statute." *Id.* at 1363–66, 86 U.S.P.Q.2d (BNA) at 1760–62. The court concluded there is not. *Id.*, 86 U.S.P.Q.2d (BNA) at 1760.

^{255. 549} U.S. 118, 81 U.S.P.Q.2d (BNA) 1225 (2007).

^{256.} Id. at 132 n.11, 81 U.S.P.Q.2d (BNA) at 1232 n.11.

^{257.} Micron Tech., Inc. v. MOSAID Techs., Inc., 518 F.3d 897, 901, 86 U.S.P.Q.2d (BNA) 1038, 1041 (Fed. Cir. 2008); *see also MedImmune*, 549 U.S. at 127, 81 U.S.P.Q.2d (BNA) at 1229 (establishing a standard for declaratory judgment).

^{258.} MedImmune, 549 U.S. at 127, 81 U.S.P.Q.2d (BNA) at 1229; see also Micron, 518 F.3d at 901, 86 U.S.P.Q.2d (BNA) at 1041 (confirming the standard established in *MedImmune* requiring that "all the circumstances" show a controversy). 259. *Micron*, 518 F.3d at 901, 86 U.S.P.Q.2d (BNA) at 1041.

^{259.} Micron, 518 F.3d at 901, 86 U.S.P.Q.2d (f
260. Id. at 897, 86 U.S.P.Q.2d (BNA) at 1038.
261. Id. at 899, 86 U.S.P.Q.2d (BNA) at 1039.
262. Id., 86 U.S.P.Q.2d (BNA) at 1039.
263. Id., 86 U.S.P.Q.2d (BNA) at 1039.
264. Id., 86 U.S.P.Q.2d (BNA) at 1039.

with MOSAID.²⁶⁵ MOSAID subsequently announced during an analyst conference call "its intent to return to court again soon on these patents promising to be 'unrelenting in the assertion of [its] patent portfolio.""266

Micron, the only remaining major DRAM manufacturer left for MOSAID to target, thereafter filed a declaratory judgment action seeking a declaration of non-infringement.²⁶⁷ The district court, in an order issued prior to the Supreme Court's decision in MedImmune, found no reasonable apprehension of suit and dismissed the action.²⁶⁸

On appeal, the Federal Circuit applied the standard laid out in *MedImmune* and determined there was in fact an actual controversy between the parties: MOSAID had threatened Micron, had sued each of the other leading DRAM chip manufacturers, and had recently made public statements that it intended to continue an aggressive litigation strategy.²⁶⁹

In Cat Tech LLC v. Tubemaster, Inc.,²⁷⁰ the Federal Circuit resolved a question it determined was left open in *MedImmune*.²⁷¹ Prior to MedImmune, the Federal Circuit applied a two-prong test to determine the existence of declaratory judgment authority.²⁷² Under this test:

There must be both (1) an explicit threat or other action by the patentee which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and (2) present activity by the declaratory judgment plaintiff which could constitute infringement, or concrete steps taken by the declaratory judgment plaintiff with the intent to conduct such activity.273

Rather than viewing *MedImmune* as rejecting entirely this two-prong approach, the Cat Tech court found that only the first prongwhether there is a reasonable apprehension of suit-had been overruled.²⁷⁴ The second prong, "whether there has been meaningful preparation to conduct potentially infringing activity," continues to

^{265.} Id., 86 U.S.P.Q.2d (BNA) at 1039.

^{266.} *Id.* at 900, 86 U.S.P.Q.2d (BNA) at 1040. 267. *Id.*, 86 U.S.P.Q.2d (BNA) at 1040.

^{268.} *Id.* at 900, 86 U.S.P.Q.2d (BNA) at 1040. 269. *Id.* at 901, 86 U.S.P.Q.2d (BNA) at 1041.

^{270. 528} F.3d 871, 87 U.S.P.Q.2d (BNA) 1065 (Fed. Cir. 2008).

^{270. 528} F.3d 871, 87 U.S.P.Q.2d (BINA) 1065 (red. CIF. 2006). 271. *Id.*, 87 U.S.P.Q.2d (BNA) 1065. 272. *Id.* at 879, 87 U.S.P.Q.2d (BNA) at 1070 (citing Teva Pharms. USA, Inc. v. Pfizer Inc., 395 F.3d 1324, 1332, 74 U.S.P.Q.2d (BNA) 1088, 1093 (Fed. Cir. 2005)). 273. *Teva Pharms.*, 395 F.3d at 1332, 74 U.S.P.Q.2d (BNA) at 1093. *But see id.* at 1339-42, 74 U.S.P.Q.2d 1088, 1099-101 (Mayer, J., dissenting) (arguing that the Federal Circuit had never before required this test to be satisfied in order for there to be a intelevable case or controversy)

to be a justiciable case or controversy)

^{274.} Cat Tech, 528 F.3d at 879-80, 87 U.S.P.Q.2d (BNA) at 1070-71.

be an "important element" in determining whether jurisdiction exists to issue a declaratory judgment.²⁷⁵ The *Cat Tech* court confirmed that *MedImmune* requires a court to consider the of "totality circumstances," but concluded that "[i]f a declaratory judgment plaintiff has not taken significant, concrete steps to conduct infringing activity, the dispute is neither 'immediate' nor 'real' and the requirements for justiciability have not been met."276

The court accordingly asked "whether there had been 'meaningful preparation' to conduct potentially infringing activity,"277 and concluded there had been.²⁷⁸

Tubemaster had taken all possible steps towards First. manufacturing the devices at issue, generating AutoCAD drawings for each device to the point that the devices were ready for production once a customer order was received.²⁷⁹ Accordingly, the constitutional requirement of "immediacy" was met.²⁸⁰

Second, the court noted that whether a patent dispute is "real" "is often related to the extent to which the technology in question is 'substantially fixed' as opposed to 'fluid and indeterminate' at the time declaratory relief is sought."²⁸¹ Because Tubemaster had taken significant, concrete steps to conduct infringing activity to the point that it did not expect to make "substantial modifications" to its designs after the beginning of production, the court found the reality requirement satisfied.²⁸²

Cat Tech nevertheless argued that because Tubemaster had not yet disclosed or advertised the products to potential customers, no actual controversy yet existed.²⁸³ The Federal Circuit disagreed. Although a lack of such activity may indicate a lack of "immediacy," the court stated that MedImmune commands that all the circumstances be considered when making a justiciability determination.²⁸⁴ Pursuant to this command, "[w]here, as here, there is cogent evidence that a

^{275.} *Id.* at 880, 87 U.S.P.Q.2d (BNA) at 1071. 276. *Id.*, 87 U.S.P.Q.2d (BNA) at 1071.

^{277.} *Id.* at 879, 87 U.S.P.Q.2d (BNA) at 1071 (citing DuPont Merck Pharm. Co. v. Bristol-Myers Squibb Co., 62 F.3d 1397, 1401, 35 U.S.P.Q.2d (BNA) 1718, 1721 (Fed. Cir. 1995); Arrowhead Indus. Water, Inc. v. Ecolochem, Inc., 846 F.2d 731, 736, 6 U.S.P.Q.2d (BNA) 1685, 1689 (Fed. Cir. 1988)).

^{278.} Id. at 881-83, 87 U.S.P.Q.2d (BNA) at 1072-73.

^{279.} Because every order required further customization, Tubemaster could go no further with its preparation. *Id.* at 881–82, 87 U.S.P.Q.2d (BNA) at 1072.
280. *Cat Tech*, 538 F.3d at 882, 87 U.S.P.Q.2d (BNA) at 1072–73.

^{281.} Id. at 882, 87 U.S.P.Q.2d (BNA) at 1073.

Id., 87 U.S.P.Q.2d (BNA) at 1073.
 Id. at 883, 87 U.S.P.Q.2d (BNA) at 1073.
 Id., 87 U.S.P.Q.2d (BNA) at 1073.
 Id., 87 U.S.P.Q.2d (BNA) at 1073 (citing MedImmune, Inc. v. Genetech, Inc., 549 U.S. 118, 127, 81 U.S.P.Q.2d (BNA) 1225, 1229 (2007)).

AMERICAN UNIVERSITY LAW REVIEW [Vol. 58:747

declaratory plaintiff has made meaningful preparation to conduct potentially infringing activity, a showing that the plaintiff has prepared draft sales literature or otherwise disclosed its products to potential customers is not an indispensable prerequisite."285 The court therefore affirmed the district court's grant of declaratory judgment.286

2. Mootness and FDA-listed drugs covered by multiple patents

The Federal Circuit further clarified in Caraco Pharmaceutical Laboratories, Ltd. v. Forest Laboratories, Inc.²⁸⁷ that the issues of standing, ripeness, and mootness would guide its application of the all-thecircumstances test in the pharmaceutical context.²⁸⁸ In *Caraco*, Forest Labs, the manufacturer of the brand name drug Lexapro, brought suit against generic drug manufacturer Caraco for infringement of one of two patents covering Lexapro after Caraco filed an abbreviated new drug application ("ANDA") for Food and Drug Administration ("FDA") approval of a generic version of the drug.² Caraco subsequently sued Forest for a declaratory judgment that the second patent covering Lexapro was either unenforceable or not infringed.²⁹⁰ In response, Forest granted to Caraco a covenant not to sue for infringement of the second patent at issue, but refused to concede that the patent was invalid or not infringed by Caraco's proposed drug.²⁹¹ The district court dismissed the suit on the ground that because there was a covenant not to sue "there's not going to be any loss, there's no threat of lawsuit."292

On appeal, the Federal Circuit applied the all-the-circumstances test and found an actual controversy existed between Caraco and Forest.²⁹³ Although the covenant not to sue eliminated any reasonable apprehension of suit on the patent, it did not render Caraco's declaratory judgment action moot because such an agreement did not remove the regulatory barriers preventing Caraco from marketing its generic version of Lexapro.²⁹⁴

^{285.} Id., 87 U.S.P.Q.2d (BNA) at 1073.

^{286.} Id. at 874, 87 U.S.P.Q.2d (BNA) at 1067.
287. 527 F.3d 1278, 86 U.S.P.Q.2d (BNA) 1289 (Fed. Cir. 2008).

^{288.} Id., 86 U.S.P.Q.2d (BNA) 1289.

^{289.} *Id.* at 1288, 86 U.S.P.Q.2d (BNA) at 1295.
290. *Id.*, 86 U.S.P.Q.2d (BNA) at 1295.

^{291.} Id. at 1289, 86 U.S.P.Q.2d (BNA) at 1296.

^{292.} *Id.* at 1289, 86 U.S.P.Q.2d (BNA) at 1296. (quoting Transcript of Hearing on Motion to Dismiss at 31, *Caraco*, 527 F.3d 1278, 86 U.S.P.Q.2d (BNA) 1289 (No. 2007-

^{1404) (}emphasis added)).

^{293.} Caraco, 527 F.3d at 1282, 86 U.S.P.Q.2d (BNA) at 1290.

^{294.} Id. at 1297, 86 U.S.P.Q.2d (BNA) at 1301.

Under the Hatch-Waxman Act,²⁹⁵ "which governs the [FDA]'s . . . approval of new and generic drugs,"²⁹⁶ Caraco could only begin to market its generic version of Lexapro after either (1) the patents covering the drug expired or (2) all the patents covering Lexapro were found either invalid or not infringed by the ANDA.²⁹⁷

Accordingly, Forest's covenant not to sue did not eliminate the controversy between the parties and the action therefore presented an ongoing Article III case or controversy.²⁹⁸ Indeed, if courts permitted brand name drug manufacturers to moot claims of patent invalidity through covenants not to sue, a manufacturer could, in certain circumstances, prevent its competitors from entering the market until after the potentially invalid patents expired.²⁹⁹

Federal Circuit further clarified Caraco in Janssen The Pharmaceutica, N.V. v. Apotex, Inc.,³⁰⁰ a case which the Federal Circuit acknowledged presented similar facts.³⁰¹ Like the defendant in Caraco, the plaintiff in Janssen brought suit against a generic manufacturer, Apotex, for infringement of one of three patents covering a brand name drug, Risperdal.³⁰² Apotex subsequently sought a declaratory judgment that the remaining two patents covering Risperdal were either invalid or not infringed.³⁰³ Unlike in Caraco, however, Apotex stipulated that the patent on which Janssen

^{295.} Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. §§ 355, 360(cc) (2006), 35 U.S.C. §§ 156, 271, 282 (2006)).

^{296.} *Caraco*, 527 F.3d at 1282, 86 U.S.P.Q.2d (BNA) at 1290. 297. If Caraco had been the first manufacturer to file an ANDA related to 297. If Caraco had been the first manufacturer to file an ANDA related to Lexapro, it could have begun to market its drug if it successfully defended against Forest's pending patent infringement suit. *Id.* at 1287, 86 U.S.P.Q.2d (BNA) at 1294. Under the Hatch-Waxman Act, the first ANDA filer alleging invalidity or noninfringement of the patents covering a drug will obtain a 180-day period of exclusivity if the allegations prove true. *See* 21 U.S.C. § 355(j) (2) (2006). Another manufacturer, however, had both filed an ANDA before Caraco and lost the resulting patent infringement suit, resulting in an injunction barring the manufacturer from marketing its Lexapro bioequivalent. *Caraco*, 527 F.3d at 1286–87, 86 U.S.P.Q.2d (BNA) at 1293–94. Accordingly, the provisions of the Hatch-Waxman Act prevented Caraco from marketing its drug unless it obtained a court Waxman Act prevented Caraco from marketing its drug unless it obtained a court judgment of invalidity or noninfringement. *Id.* at 1287, 86 U.S.P.Q.2d (BNA) at 1295.

Caraco, 527 F.3d at 1297, 86 U.S.P.Q.2d (BNA) at 1301.
 Id. at 1284–85, 86 U.S.P.Q.2d (BNA) at 1292–93.
 540 F.3d 1353, 88 U.S.P.Q.2d (BNA) 1079 (Fed. Cir. 2008).

^{301.} *Id.* at 1360, 88 U.S.P.Q.2d (BNA) at 1085 ("We agree with the parties that if Apotex had not stipulated to the validity of the '663 patent, then *Caraco* would have been controlling."); *id.* at 1361, 88 U.S.P.Q.2d (BNA) at 1085 ("The key difference between *Caraco* and this case is that the harm that gave rise to the jurisdiction over the declaratory judgment claim in Caraco ceased to exist once Apotex stipulated to the validity, in-fringement, and enforceability of the '663 patent."). 302. *Id.* at 1357–58, 88 U.S.P.Q.2d (BNA) at 1083. 303. *Id.* at 1358, 88 U.S.P.Q.2d (BNA) at 1083.

sued was valid and enforceable.³⁰⁴ Janssen moved the court to dismiss Apotex's counterclaims for lack of jurisdiction, and the district court granted the motion.³⁰⁵ The Federal Circuit affirmed.³⁰⁶ According to the Federal Circuit, Apotex's admission that one of the three patents covering Risperdal was valid was sufficient to differentiate the case from *Caraco*.³⁰⁷ Because Apotex, unlike Caraco, "stipulated to the validity, infringement, and enforceability of [one] patent Apotex cannot claim that at the time of the district court's dismissal it was being excluded from selling a noninfringing product by an invalid patent."³⁰⁸ Even if Apotex succeeded on its declaratory judgment claims, it would still be unable to obtain FDA approval until after the remaining patent expired.³⁰⁹

3. Sufficient injury

Although MedImmune eliminated the Federal Circuit's "reasonable apprehension of suit" requirement for establishing declaratory judgment jurisdiction, it did not change the court's "long-standing rule that the existence of a patent is not sufficient to establish declaratory judgment jurisdiction."310 In Prasco, LLC v. Medicis Pharmaceutical Corp.,³¹¹ the Federal Circuit affirmed the dismissal of a declaratory judgment action brought by Prasco against a competitor who had previously brought an infringement suit against it based on an unrelated patent.³¹² Relying on both *Cat Tech* and *Caraco*, the court emphasized that whether an Article III controversy exists cannot be determined through the application of a bright-line rule, but instead requires an analysis of particular facts of the case, including an inquiry into standing, ripeness, and a lack of mootness.³¹³

The court proceeded to provide three examples of ways a patentee can cause an injury sufficient to establish a justiciable controversy: by (1) "creating a reasonable apprehension of an infringement suit"; (2) "demanding the right to royalty payments"; or (3) "creating a

^{304.} Id., 88 U.S.P.Q.2d (BNA) at 1083.

^{305.} Id. at 1359, 88 U.S.P.Q.2d (BNA) at 1083-84.

^{306.} Id. at 1363-64, 88 U.S.P.Q.2d (BNA) at 1087-88.

^{307.} *Id.* at 1360–61, 88 U.S.P.Q.2d (BNA) at 1085–86. 308. *Id.* at 1361, 88 U.S.P.Q.2d (BNA) at 1085–86.

^{309.} Id., 88 U.S.P.Q.2d (BŇA) at 1086.

^{310.} Prasco, LLC v. Medicis Pharm. Corp., 537 F.3d 1329, 1338, 87 U.S.P.Q.2d

⁽BNA) 1675, 1680 (Fed. Cir. 2008).

^{311.} *Id.* at 1329, 87 U.S.P.Q.2d (BNA) at 1675.
312. *Id.* at 1333, 87 U.S.P.Q.2d (BNA) at 1676.

^{313.} Id. at 1336, 87 U.S.P.Q.2d (BNA) at 1678.

barrier to the regulatory approval of a product that is necessary for marketing."314

In Prasco, the patentee had taken no actions at all related to the product at issue.³¹⁵ Accordingly, the Federal Circuit affirmed the trial court's conclusion that Prasco failed to allege "a controversy of sufficient 'immediacy and reality' to create a justiciable controversy."316

D. Appellate Jurisdiction and Reviewability of Judgments

The Federal Circuit has exclusive jurisdiction over any appeal from a final decision of a federal district court if the district court's jurisdiction was based either in whole or in part on 28 U.S.C. § 1338.³¹⁷

Inherent in the court's appellate role is the traditional power to issue a writ of mandamus in the aid of its appellate jurisdiction.³¹⁸ The Federal Circuit therefore has jurisdiction to hear and decide a petition for a writ of mandamus in any case that falls within the purview of § 1338.³¹⁹

The remedy of mandamus, however, "is available only in extraordinary situations to correct a clear abuse of discretion or usurpation of judicial power."³²⁰ Accordingly, a party seeking the writ "bears the burden of proving that it has no other means of attaining the relief desired and that the right to issuance of the writ is 'clear and indisputable."³²¹ Because no other means of attaining the relief desired must be available, the Federal Circuit has emphasized that it may deny the writ even if the request raises an issue that would otherwise qualify as reversible error on direct appeal.³²²

^{314.} Id. at 1339, 87 U.S.P.Q.2d (BNA) at 1680-81.

^{315.} *Id.* at 1340, 87 U.S.P.Q.2d (BNA) at 1681.
316. *Id.* at 1338, 87 U.S.P.Q.2d (BNA) at 1679.

^{317.}

The United States Court of Appeals for the Federal Circuit shall have exclusive jurisdiction . . . of an appeal from a final decision of a district court of the United States . . . if the jurisdiction of that court was based, in whole or in part, on section 1338 of this title

²⁸ U.S.C. § 1295(a) (1) (2006)

^{318.} In re Princo Corp., 478 F.3d 1345, 1351, 81 U.S.P.Q.2d (BNA) 1997, 2001 (Fed. Cir. 2007)

^{319.} *Id.*, 81 U.S.P.Q.2d (BNA) at 2001 (quoting *In re* Newman, 782 F.2d 971, 973, 228 U.S.P.Q (BNA) 450, 452 (Fed. Cir. 1986)).

^{320.} In re Roche Molecular Sys., Inc., 516 F.3d 1003, 1004, 85 U.S.P.Q.2d (BNA) 1843, 1843–44 (Fed. Cir. 2008) (citing *In re* Calmar, Inc., 854 F.2d 461, 464, 7 U.S.P.Q.2d (BNA) 1713, 1715 (Fed. Cir. 1988)).

^{321.} *Id.*, 85 U.S.P.Q.2d (BNA) at 1844 (citation omitted) (quoting Allied Chem. Corp. v. Daiflon, Inc., 449 U.S. 33, 35 (1980)). 322. *Id.*, 85 U.S.P.Q.2d (BNA) at 1844 (citing *In re* Cordis Corp., 769 F.2d 733,

^{737, 226} U.S.P.Q. (BNA) 784, 787 (Fed. Cir. 1985)).

In In re Roche Molecular Systems Inc.,³²³ Roche filed a petition with the Federal Circuit seeking a writ of mandamus directing the district court to enter judgment in its favor.³²⁴ Roche argued the writ was warranted because the plaintiff lacked standing to sue for infringement of the patent at issue.³²⁵ Such an allegation, however, clearly can be, and often is, addressed on appeal.³²⁶ Accordingly, the Federal Circuit denied the petition, finding that Roche had failed to show that the relief it sought could not be obtained after entry of final judgment.³²⁷ Judge Newman dissented, arguing that the writ was warranted because "the posture of the dispute is significantly changed" by the purported error below and to continue the litigation under this purported error "is as inappropriate as it is unnecessary."³²⁸

Of course, an entry of final judgment does not always ensure the Federal Circuit can address an issue raised on appeal. For example, a party wishing to appeal a decision of the district court must file a notice of appeal within the period specified by the Federal Rules of Appellate Procedure.³²⁹ Failure to file a document properly styled as a "notice of appeal," however, will not always be fatal to a party's appeal. For example, in *International Rectifiers Corp. v. IXYS Corp.*, the appellant failed to timely file a properly styled notice of appeal, filing instead a motion to stay the permanent injunction pending appeal.³³¹ The Federal Circuit took the appeal, but first addressed the threshold question of whether it had appellate jurisdiction.³³² Relying on Smith v. Barry,333 the Federal Circuit looked to whether the document filed provided the notice required by Rule 3 of the Federal

^{323.} Id. at 1003, 85 U.S.P.Q.2d (BNA) at 1843. 324. Id. at 1004, 85 U.S.P.Q.2d (BNA) at 1843. 325. Id., 85 U.S.P.Q.2d (BNA) at 1843. 326. See, e.g., Cent. Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Solutions, P.C., 482 F.3d 1347, 82 U.S.P.Q.2d (BNA) 1293 (Fed. Cir. 2007) (addressing on appeal the alleged infringer's allegation that patentees lacked standing because the inventor failed to properly execute a required license). *But see* Sky Techs. LLC v. SAP AG, No. 2:06-CV-440, 2008 WL 4491894, at *1 (Fed. Cir. Sept. 10, 2008) (granting permission to appeal an order that denied the defendant's motion to dismiss for lack of standing where the district court certified the order for permissive appeal on the ground that an immediate appeal "may materially advance the ultimate termination of the litigation"). 327. In re Roche, 516 F.3d at 1004–05, 85 U.S.P.Q.2d (BNA) at 1844. 328. Id. at 1009, 85 U.S.P.Q.2d (BNA) at 1847 (Newman, J., dissenting).

^{329.} See FED. R. APP. P. 4(a)(1)(A) ("In a civil case, except as provided in Rules 4(a)(1)(B), 4(a)(4), and 4(c), the notice of appeal required by Rule 3 must be filed with the district clerk within 30 days after the judgment or order appealed from is entered.")

^{330. 515} F.3d 1354, 85 U.S.P.Q.2d (BNA) 1907 (Fed. Cir. 2008).

^{331.} Id. at 1357, 85 U.S.P.Q.2d (BNA) at 1910.

^{332.} Id., 85 U.S.P.Q.2d (BNA) at 1910.

^{333. 502} U.S. 244, 248-49 (1992).

Rules of Appellate Procedure.³³⁴ Because the appellant's document (a) specified the party or parties taking the appeal, (b) designated the judgment being appealed, and (c) named the court to which the appeal was being taken, the court found the document met the requirements of Rule 3, construed the motion as a notice of appeal, and proceeded to decide the merits of the appeal.³³⁵

In *iLOR, LLC v. Google, Inc.*,336 the Federal Circuit considered a matter of first impression: whether a district court's recitation of the "no just cause for delay" standard of Federal Rule of Civil Procedure 54(b) as to one or more, but not all, claims is sufficient to certify an issue for immediate appeal. The court concluded that it is not.³³⁷ iLOR had sued Google for infringement of its patent and moved for a preliminary injunction, and Google had filed counterclaims seeking a declaratory judgment of non-infringement, invalidity, and unenforceability of the patent.³³⁸ The district court ultimately granted Google's motion for summary judgment of non-infringement and denied iLOR's motion for preliminary injunction.³³⁹ In so doing, it entered an Order which stated, "[T]his Order is FINAL AND APPEALABLE and THERE IS NO JUST CAUSE FOR DELAY."340

On appeal, the Federal Circuit held that the district court's judgment did not dispose of all of Google's counterclaims.³⁴¹ Accordingly, the question of whether the district court had properly certified the decision for immediate appeal remained.³⁴² The district court had not cited Rule 54(b) and had not described any appeal.³⁴³ circumstances justifying immediate Therefore. notwithstanding the district court's use of the "no just reason for delay" language of Rule 54(b), the Federal Circuit adopted the "consensus view" that "bare recitation of the 'no just reason for delay' standard of Rule 54(b) is not sufficient, by itself, to properly certify an issue for immediate appeal."³⁴⁴

- 550 F.3d 1067, 89 U.S.P.Q.2d (BNA) 1097 (Fed. Cir. 2008). 336.
- 337. *Id.* at 1071, 89 U.S.P.Q.2d (BNA) at 1099.
 338. *Id.* at 1069, 89 U.S.P.Q.2d (BNA) at 1098.
- 339. Id. at 1070, 89 U.S.P.Q.2d (BNA) at 1098.
- 340. Id., 89 U.S.P.Q.2d (BNA) at 1099.
- 341. Id. at 1072, 89 U.S.P.Q.2d (BNA) at 1100.
- 342. Id., 89 U.S.P.Q.2d (BŇA) at 1100.
- 343. Id. at 1073, 89 U.S.P.Q.2d (BNA) at 1100-01.
- 344. Id. at 1072, 89 U.S.P.Q.2d (BNA) at 1100.

^{334.} *Int'l Rectifiers Corp.*, 515 F.3d at 1357, 85 U.S.P.Q.2d (BNA) at 1910. 335. *Id.*, 85 U.S.P.Q.2d (BNA) at 1910.

Likewise, a party may be barred from appealing a judgment by the trial court if the party has prevailed below.³⁴⁵ In Symantec Corp. v. Computer Associates International, Inc.,³⁴⁶ the Federal Circuit reiterated the rule that "a properly filed cross-appeal requires that, upon acceptance of appellee's argument, our determination would result in a reversal or modification of the judgment rather than an affirmance."347 The district court had granted Computer Associates ("CA") summary judgment of non-infringement.³⁴⁸ When Symantec appealed, CA cross-appealed the trial court's finding that the doctrine of laches did not bar the scope of Symantec's potential recovery in the event that the court had found CA to have infringed.³⁴⁹ Because acceptance of CA's argument would have had no effect on the district court's judgment of non-infringement, the Federal Circuit dismissed the cross-appeal as improper.³⁵⁰ The court proceeded to review CA's mis-styled laches arguments as an alternative ground for sustaining the judgment.³⁵¹

The Federal Circuit may also find its ability to review the final judgment of the trial court restricted where the dispute, although an actual case or controversy below, becomes moot by the time of appeal. Accordingly, "[w]here the controversy between the parties has ended, the case becomes moot and will be dismissed, 'however convenient it might be to have decided the question' for future cases."352 For example, in Yingbin-Nature (Guangdong) Wood Industry Co. v. International Trade Commission,³⁵³ the International Trade Commission ("ITC") had determined that the appellants' products infringed two separate patents and that this infringement justified a general exclusion order barring importation of the products into the United States.³⁵⁴ The appellants sought Federal Circuit review of the ITC's decision, but only as to a subset of the overall claims it had been found to have infringed.355 Given that these unappealed

^{345.} Symantec Corp. v. Computer Assocs. Int'l, Inc., 522 F.3d 1279, 1294, 86 U.S.P.Q.2d (BNA) 1449, 1457–58 (Fed. Cir. 2008) (citing Bailey v. Dart Container Corp., 292 F.3d 1360, 1362, 63 U.S.P.Q.2d (BNA) 1319, 1319 (Fed. Cir. 2002)).

<sup>Jorp., 292 F.3d 1360, 1362, 63 U.S.P.Q.2d (BNA) 131
346.</sup> *Id.* at 1279, 86 U.S.P.Q.2d (BNA) at 1449.
347. *Id.* at 1294, 86 U.S.P.Q.2d (BNA) at 1457–58.
348. *Id.*, 86 U.S.P.Q.2d (BNA) at 1458.
349. *Id.*, 86 U.S.P.Q.2d (BNA) at 1458.
350. *Id.*, 86 U.S.P.Q.2d (BNA) at 1458.
351. *Id.*, 86 U.S.P.Q.2d (BNA) at 1458.
352. Vinghin Nature (Current depart) Wood Induct (Current depart)

^{351.} Id., 86 U.S.F.Q.2d (BNA) at 1436.
352. Yingbin-Nature (Guangdong) Wood Indus. Co. v. Int'l Trade Comm'n, 535
F.3d 1322, 1329, 87 U.S.P.Q.2d (BNA) 1590, 1595 (Fed. Cir. 2008) (quoting United States v. Alaska S.S. Co., 253 U.S. 113, 116 (1920)).
353. Id. at 1322, 87 U.S.P.Q.2d (BNA) at 1590.
354. Id. at 1325, 87 U.S.P.Q.2d (BNA) at 1592.
355. Id. at 1330, 87 U.S.P.Q.2d (BNA) at 1595.

findings of infringement, standing alone, supported the general exclusion order, the court asked the parties to prepare responses on the issue of mootness.³⁵⁶ After considering the oral arguments, the Federal Circuit concluded that a live controversy still existed.³⁵⁷ Because the patents-in-suit bore different dates of expiration and the finding of infringement challenged on appeal involved a laterexpiring patent, a reversal of the ITC's decision would allow the appellants to begin importing their products at an earlier date.³⁵⁸ Accordingly, this portion of the appeal was not moot.³⁵⁹

Even if a judgment is final and the resulting appeal is timely filed and still presents a live controversy, the court may nevertheless be unable to address the substantive issues on appeal. In Jang v. Boston *Scientific Corp.*,³⁶⁰ the trial court adopted a consent judgment proposed by the parties after a claim construction order adverse to the plaintiff had been issued.³⁶¹ As part of the stipulated judgment, the parties agreed the plaintiff could not prove infringement under the claim construction adopted by the court, but preserved the plaintiff's right to appeal the court's construction.³⁶² On appeal, the Federal Circuit found itself unable to address the substantive issues presented by the parties.³⁶³ Although the court was willing and able to review "stipulated judgments based on claim construction when the judgments were entered with the express purpose of obtaining appellate review of the claim construction," any such judgment "must satisfy the same standards of appellate jurisdiction as any other judgment entered by the district court."364 Accordingly, a stipulated judgment must allow the court "to ascertain the basis for the judgment challenged on appeal."365

The consent judgment at issue in Jang suffered from ambiguities that prevented it from meeting this standard.³⁶⁶ First, the parties had failed to identify which of the multiple claim construction rulings

^{356.} Id. at 1329, 87 U.S.P.Q.2d (BNA) at 1595.
357. Id. at 1331, 87 U.S.P.Q.2d (BNA) at 1596.
358. Id., 87 U.S.P.Q.2d (BNA) at 1596.

^{359.} Id., 87 U.S.P.Q.2d (BNA) at 1596. 360. 532 F.3d 1330, 87 U.S.P.Q.2d (BNA) 1459 (Fed. Cir. 2008).

^{361.} *Id.* at 1332–33, 87 U.S.P.Q.2d (BNA) at 1461. 362. *Id.*, 87 U.S.P.Q.2d (BNA) at 1461.

^{363.} Id. at 1335-36, 87 U.S.P.Q.2d (BNA) at 1463.

^{363.} *Id.* at 1333–36, 67 U.S.P.Q.2d (BNA) at 1462 (citing United States v. Proctor & Gamble Co., 356 U.S. 677 (1958); Oatey Co. v. IPS Corp., 514 F.3d 1271, 1276, 85 U.S.P.Q.2d (BNA) 1791, 1794 (Fed. Cir. 2008); Ventana Med. Sys. Inc. v. Biogenex Labs., Inc., 473 F.3d 1173, 1177, 81 U.S.P.Q.2d (BNA) 1314, 1316 (Fed. Cir. 2008); Ventana Med. Sys. Inc. v. Biogenex Labs., Inc., 473 F.3d 1173, 1177, 81 U.S.P.Q.2d (BNA) 1314, 1316 (Fed. Cir. 2008); Ventana Med. Sys. Inc. v. Biogenex Labs., Inc., 473 F.3d 1275, 1276 Cir. 2006); Generation II Orthotics Inc. v. Med. Tech. Inc., 263 F.3d 1356, 1363, 59 U.S.P.Q.2d (BNA) 1919, 1925 (Fed. Cir. 2001))

^{365.} Id. at 1334-35, 87 U.S.P.Q.2d (BNA) at 1462.

^{366.} Id. at 1335-36, 87 U.S.P.Q.2d (BNA) at 1463.

788 AMERICAN UNIVERSITY LAW REVIEW [Vol. 58:747

affected the issue of infringement.³⁶⁷ Without such an identification, the Federal Circuit concluded, the court risked issuing an advisory opinion that did not actually address the infringement controversy between the parties.³⁶⁸ Second, the parties failed to provide any factual context for the claim construction issues presented.³⁶⁹ Because "a remand for clarification is appropriate where a judgment is ambiguous,"³⁷⁰ the Federal Circuit remanded to the district court for further clarification of these issues.³⁷¹

E. Personal Jurisdiction

Even if the court has jurisdiction over the subject matter of the case, the court may not exercise this power over a particular party unless two criteria are met: (1) "jurisdiction must exist under the forum state's long-arm statute"; and (2) "the assertion of personal jurisdiction must be consistent with the limitations of the due process clause."³⁷² The first inquiry is controlled by the law of the forum while the second inquiry is guided by federal law.³⁷³

In Medical Solutions, Inc. v. C Change Surgical LLC, 374 the Federal Circuit was required to decide whether activities at a trade show constituted a "use" under 35 U.S.C. § 271(a)³⁷⁵ such that personal jurisdiction would be proper under the District of Columbia's longarm statute.³⁷⁶ The court explained that whether a patented item had been "used" is a highly case-specific inquiry, but that "[t]he ordinary meaning of 'use'" is "to put into action or service."³⁷⁷ After noting that a number of trial courts had held that "'the mere demonstration or display of an accused product, even in an obviously commercial atmosphere' is not an act of infringement for purposes of section

^{367.} *Id.* at 1336, 87 U.S.P.Q.2d (BNA) at 1463.
368. *Id.* at 1336–37, 87 U.S.P.Q.2d (BNA) at 1463–64.
369. *Id.* at 1337, 87 U.S.P.Q.2d (BNA) at 1464.

^{370.} Id. at 1335, 87 U.S.P.Q.2d (BNA) at 1463.

^{371.} Id. at 1331, 87 U.S.P.Q.2d (BNA) at 1460.

 ^{372.} Med. Solutions, Inc. v. C Change Surgical LLC, 541 F.3d 1136, 1139,
 88 U.S.P.Q.2d (BNA) 1275, 1277 (Fed. Cir. 2008) (citing Trintec Indus. Inc. v. Pedre Promotional Prods., Inc., 395 F.3d 1275, 1279 73 U.S.P.Q.2d (BNA) 1587, 1589 (Fed. Cir. 2005)). 373. Id. at 1139, 88 U.S.P.Q.2d (BNA) at 1277.

^{374.} *Id.* at 1136, 88 U.S.P.Q.2d (BNA) at 1275. 375. 35 U.S.C. § 271(a) (2006) ("Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention

during the term of the patent therefor, infringes the patent."). 376. *Med. Solutions*, 541 F.3d at 1139, 88 U.S.P.Q.2d (BNA) at 1277. 377. *Id.* at 1141, 88 U.S.P.Q.2d (BNA) at 1278 (quoting NTP, Inc. v. Research In Motion, Ltd., 418 F.3d 1282, 1317, 75 U.S.P.Q.2d (BNA) 1763, 1789 (Fed. Cir. 2005)).

271(a),"³⁷⁸ the court affirmed the trial court's finding that the display and demonstration of aspects of the accused item did not amount to a "use" under § 271.³⁷⁹ Accordingly, personal jurisdiction was lacking, and the trial court had properly dismissed the suit.³⁸⁰

The Federal Circuit also found personal jurisdiction lacking in Avocent Huntsville Corp. v. Aten International Co., Ltd.³⁸¹ In that case, Avocent, an Alabama developer of computer hardware devices, filed a declaratory judgment action against Aten International, a Taiwanese corporation with a California subsidiary.³⁸² The parties did not dispute that Aten International's products were available for sale in Alabama.³⁸³ Relying on that fact, Avocent contended that Aten International should be subject to personal jurisdiction in Alabama.³⁸⁴ The Federal Circuit affirmed the district court's dismissal for lack of personal jurisdiction, finding that Avocent's reliance on the availability of Aten International products in Alabama failed to establish that Aten International either "'purposefully directed its activities at residents of the forum'" or that Avocent's suit "'ar[ose] out of or relate[d] to those activities," as required to satisfy the specific personal jurisdiction standard.³⁸⁵

The Federal Circuit did find sufficient contacts to support the exercise of specific jurisdiction over the defendants in Campbell Pet Co. *v. Miale*.³⁸⁶ In Campbell, the California defendants attended a convention in Seattle, Washington, where they demonstrated their patented products, offered them for sale, and succeeded in taking two orders from out-of-state residents during the course of the convention.³⁸⁷ While at the convention, the defendants confronted several of the plaintiff's employees at the plaintiff's booth and accused them of infringing the defendants' patents.³⁸⁸ Shortly thereafter, Campbell filed suit in the United States District Court for the Western District of Washington seeking a declaratory judgment of

^{378.} Id. at 1140, 88 U.S.P.Q.2d (BNA) at 1278 (quoting Fluid Mgmt. Ltd. v. H.E.R.O. Indus., Ltd., No. 95-5604, 1997 WL 112839, at *4 (N.D. Ill. Mar. 11, 1997)).

^{379.} Id. at 1141, 88 U.S.P.Q.2d (BNA) at 1279.

^{380.} *Id.* at 1142, 88 U.S.P.Q.2d (BNA) at 1279. 381. 552 F.3d 1324, 89 U.S.P.Q.2d (BNA) 1481 (Fed. Cir. 2008).

^{382.} Id. at 1327, 89 U.S.P.Q (BNA) at 1482.

^{383.} Id., 89 U.S.P.Q. (BNA) at 1482.
384. Id. at 133789 U.S.P.Q. (BNA) at 1490.
385. Id. at 1340, 89 U.S.P.Q. (BNA) at 1492 (quoting Breckenridge Pharmaceuticals, Inc. v. Metabolite Laboratories, Inc., 444 F.3d. 1356, 1363, 78 U.S.P.Q.2d 1581, 1585 (Fed. 2006).

^{386. 542} F.3d 879, 881, 88 U.S.P.Q.2d (BNA) 1252, 1254 (Fed. Cir. 2008).

^{387.} Id. at 881-82, 88 U.S.P.Q.2d (BNA) at 1254.

^{388.} Id. at 882, 88 U.S.P.Q.2d (BNA) at 1254.

non-infringement.³⁸⁹ The trial court dismissed the suit, finding that neither general nor specific personal jurisdiction existed over the defendants.³⁹⁰

In order for an exercise of personal jurisdiction to comport with the due process requirements of the U.S. Constitution, three factors must be satisfied: "(1) the non-resident defendant purposely do some act or consummate some transaction in the forum state, (2) the cause of action arise from or be connected with that transaction, and (3) the assumption of jurisdiction by the forum state not offend traditional notions of fair play and substantial justice."391 Applying this analysis, the district court determined that, although the defendants had transacted business in the state, in light of the defendants' conduct at the trade show, the claim of noninfringement was not sufficiently related to the transactions within the state.³⁹² Because the defendants' actions were "akin to submitting cease and desist letters," an exercise of personal jurisdiction would offend traditional notions of fair play and substantial justice.³⁹³

The Federal Circuit reversed and remanded.³⁹⁴ Although under Federal Circuit precedent, a "patentee's act of sending letters to another state claiming infringement and threatening litigation is not sufficient to confer personal jurisdiction in that state," the Federal Circuit held that the situation presented in *Campbell* involved sufficient additional conduct to support the exercise of jurisdiction.³⁹⁵ Specifically, the court found that defendants had done more than serve a verbal notice akin to a cease and desist letter: they attempted to have Campbell removed from the convention and had informed Campbell's customers that Campbell's products infringed the defendants' patents.³⁹⁶

Res Judicata/Collateral Estoppel *F*.

A party may also be barred from litigating a controversy where either claim preclusion or issue preclusion applies.³⁹⁷ "Under the doctrine of claim preclusion, 'a judgment on the merits in a prior suit bars a second suit involving the same parties or their privies based on

^{389.} Id., 88 U.S.P.Q.2d (BNA) at 1254.

^{390.} Id. at 882-83, 88 U.S.P.Q.2d (BNA) at 1254-55.

^{391.} Id., 88 U.S.P.Q.2d (BNA) at 1255.

^{392.} Id. at 883, 88 U.S.P.Q.2d (BNA) at 1255.

^{393.} Id., 88 U.S.P.Q.2d (BNA) at 1255.

^{395.} *Id.*, 68 U.S.P.Q.2d (BIA) at 1255.
394. *Id.* at 889, 88 U.S.P.Q.2d (BNA) at 1260.
395. *Id.* at 885-86, 88 U.S.P.Q.2d (BNA) at 1257.
396. *Id.* at 886, 88 U.S.P.Q.2d (BNA) at 1258.

^{397.} See generally 18 CHARLES ALAN WRIGHT, ARTHUR R. MILLER & EDWARD H. COOPER, FEDERAL PRACTICE AND PROCEDURE § 4402, at 9 (2d ed. 2008).

the same cause of action.³³⁸ Issue preclusion, on the other hand, "bars the relitigation of issues actually adjudicated, and essential to the judgment, in a prior litigation between the same parties."³⁹⁹ Both of these terms fall within the ambit of the doctrine of res judicata.⁴⁰⁰

When a party raises claim preclusion as a bar to subsequent litigation, the Federal Circuit will review the district court's determination under the law of the regional circuit in which the district court sits.⁴⁰¹ In Acumed LLC v. Stryker Corp.,⁴⁰² the Federal Circuit applied the Ninth Circuit's standard for claim preclusion in the context of a patent infringement suit.⁴⁰³ Under Ninth Circuit precedent, claim preclusion applies where: "(1) the same parties, or their privies, were involved in the prior litigation, (2) the prior litigation involved the same claim or cause of action as the later suit. and (3) the prior litigation was terminated by a final judgment on the merits."⁴⁰⁴ In Acumed, the parties contested only the second of these three prongs-whether the prior litigation involved "the same claim or cause of action."405

In a previous lawsuit between the parties in which Stryker had been found to have infringed Acumed's patent, Acumed learned during the discovery phase of the litigation that Stryker had another potentially infringing product currently in development.⁴⁰⁶ Stryker, however, had not yet begun to market or sell the product.⁴⁰⁷ After the close of fact discovery, Stryker began to market this second product.⁴⁰⁸ The court offered to allow Acumed to add an additional infringement claim to cover this new product, but warned Acumed that doing so would necessitate postponing the entire trial for up to one year.⁴⁰⁹ Acumed chose not to incur this delay and declined the court's invitation.⁴¹⁰

^{398.} Acumed LLC v. Stryker Corp., 525 F.3d 1319, 1323, 86 U.S.P.Q.2d (BNA) 1950, 1952 (Fed. Cir. 2008) (quoting Parklane Hosiery Co. v. Shore, 439 U.S. 322, 327 n.5 (1979)).

³²⁷ n.5 (1979)).
399. WRIGHT ET AL., *supra*, note 397 (citing Kaspar Wire Works, Inc. v. Leco Eng'g & Mach., Inc., 575 F.2d 530, 535–536, 198 U.S.P.Q. (BNA) 513, 516 (5th Cir. 1978)).
400. *Acumed*, 525 F.3d at 1323 n.2, 86 U.S.P.Q.2d (BNA) at 1952 n.2.
401. *Id.* at 1323, 86 U.S.P.Q.2d (BNA) at 1952 (citing Media Techs. Licensing, LLC v. Upper Deck Co., 334 F.3d 1366, 1369, 67 U.S.P.Q.2d (BNA) 1374, 1376 (Fed. Cir. 2003).

Cir. 2003))

^{402. 525} F.3d 1319, 86 U.S.P.Q.2d (BNA) 1950. 403. *Id.* at 1323, 86 U.S.P.Q.2d (BNA) 1952.

^{404.} Cent. Delta Water Agency v. United States, 306 F.3d 938, 952 (9th Cir. 2002) (citing Blonder-Tongue Labs. v. Univ. of Ill. Found., 402 U.S. 313, 323–24 (1971)). 405. Acumed, 525 F.3d at 1323, 86 U.S.P.Q.2d (BNA) at 1952.

^{405.} Acumed, 525 F.3d at 1323, 86 U.S.P.Q.2d (
406. Id. at 1322, 86 U.S.P.Q.2d (BNA) at 1951.
407. Id., 86 U.S.P.Q.2d (BNA) at 1951.
408. Id., 86 U.S.P.Q.2d (BNA) at 1951.
409. Id., 86 U.S.P.Q.2d (BNA) at 1951.
410. Id., 86 U.S.P.Q.2d (BNA) at 1951.

Two weeks after the first trial ended with a final judgment of infringement, Acumed initiated a second suit alleging Stryker's newly developed product also infringed the patent.⁴¹¹ The district court presiding over this second case dismissed the action on the ground that this new claim was precluded by the prior judgment. According to the district court, the Federal Circuit's patent-law-specific "essentially-the-same test" for claim preclusion only applies where a claim could not have been litigated in a prior action.⁴¹² The court therefore applied general principles of claim preclusion in reaching its decision.

On appeal, the Federal Circuit rejected this reading of its claim preclusion test and proceeded to explain the proper manner by which the preclusive effect of a previous suit is to be analyzed.⁴¹⁴ In a patent infringement suit, the answer to whether two claims for patent infringement are identical for purposes of claim preclusion is an issue particular to patent law and therefore properly analyzed under Federal Circuit law.⁴¹⁵ "In applying the doctrine of claim preclusion, [the Federal Circuit] is guided by the Restatement (Second) of Judgments,"⁴¹⁶ which instructs a court to look to the transactional facts from which a claim arises.⁴¹⁷ Interpreting Foster v. Hallco Manufacturing Co.⁴¹⁸ and Hallco Manufacturing Co. v. Foster,⁴¹⁹ the court explained that "claim preclusion does not apply unless the accused device in the action before the court is 'essentially the same' as the accused device in a prior action."⁴²⁰ "Accused devices are 'essentially the same' where the differences between them are not 'colorable' or are 'unrelated to the limitations in the claim of the patent.'"421 Furthermore, the court rejected the limitation the district court attempted to impose on the scope of this test, stating that "we find nothing in Hallco or Foster that suggests that the essentially-the-same test does not apply where a claim could have been litigated in a prior

^{411.} Id. at 1323, 86 U.S.P.Q.2d (BNA) at 1952.

^{412.} Id. at 1325, 86 U.S.P.Q.2d (BNA) at 1954.

^{413.} Id., 86 U.S.P.Q.2d (BNA) at 1953.

^{414.} *Id.* at 1323–25, 86 U.S.P.Q.2d (BNA) at 1952–54. 415. *Id.* at 1323, 86 U.S.P.Q.2d (BNA) at 1952.

^{416.} Id. at 1323, 86 U.S.P.Q.2d (BNA) at 1952.

RESTATEMENT (SECOND) OF JUDGMENTS § 24 (1982) (defining a claim for 417 purposes of claim preclusion by the transactional facts from which it arises).

^{418. 947} F.2d 469, 478, 20 U.S.P.Q.2d (BNA) 1241, 1248 (Fed. Cir. 1991).

^{418. 547} F.2d 405, 478, 20 C.5.1.Q.2d (BNA) 1241, 1248 (Fed. Cir. 1951).
419. 256 F.3d 1290, 1294, 59 U.S.P.Q.2d (BNA) 1346, 1348 (Fed. Cir. 2001).
420. Acumed, 525 F.3d at 1324, 86 U.S.P.Q.2d (BNA) at 1953.
421. Id., 86 U.S.P.Q.2d (BNA) at 1953 (citing Foster, 947 F.2d at 479–80, 20 U.S.P.Q.2d (BNA) 1241, 1249; 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)).

action."422 Finding that the defendant had admitted that the two accused devices were not "essentially the same," the Federal Circuit reversed the district court's judgment and remanded for further proceedings.423

In Roche Palo Alto LLC v. Apotex, Inc.,⁴²⁴ the Federal Circuit, relying on Acumed, found the two purportedly infringing devices at issue to be "essentially the same" for purposes of claim preclusion.⁴²⁵ The devices at issue in the different litigation stages in Roche were two generic drug applications targeted at two different variations of Roche's brand name drug.⁴²⁶ During the first phase of the litigation, court rejected Apotex's invalidity and unenforceability the contentions and found that Apotex's first generic drug infringed Roche's drug patent.⁴²⁷ When Roche later brought suit against Apotex for infringement based on the second generic drug, Apotex sought to litigate the validity of the patent a second time, arguing that the generic drug formulations were sufficiently distinct to prevent claim preclusion from applying.⁴²⁸ Both the district court and the Federal Circuit disagreed. Although the drug formulations had differences, the Federal Circuit explained that in order for claim preclusion not to apply, the differences must be related to the claims of the patent at issue.⁴³⁰ Because the drug formulations failed to meet this standard, the defendant's claims that the patent was unenforceable and invalid were barred by the doctrine of claim preclusion.431

The Federal Circuit reiterated this rule in Nasalok Coating Corp. v. *Nylok Corp.*,⁴³² a case involving a trademark dispute.⁴³³ In explaining the "essentially the same" requirement, the court described the policy considerations driving this rule as follows.⁴³⁴ First, "the plaintiff and defendant should be treated equally as to res judicata. If the plaintiff would not be barred from bringing a second infringement suit, the

^{422.} Id. at 1326, 86 U.S.P.Q.2d (BNA) at 1954–55.
423. Id. at 1327, 86 U.S.P.Q.2d (BNA) at 1955.
424. 531 F.3d 1372, 87 U.S.P.Q.2d (BNA) 1308 (Fed. Cir. 2008).

^{425.} Id. at 1379-80, 87 U.S.P.Q.2d (BNA) at 1312-13.

^{426.} *Id.* at 1375–76, 87 U.S.P.Q.2d (BNA) at 1309–10. 427. *Id.* at 1376, 87 U.S.P.Q.2d (BNA) at 1310.

^{428.} Id., 87 U.S.P.Q.2d (BŇA) at 1310.

^{429.} *Id.* at 1380, 87 U.S.P.Q.2d (BNA) at 1313. 430. *Id.* at 1379, 87 U.S.P.Q.2d (BNA) at 1312.

^{431.} *Id.* at 1381, 87 U.S.P.Q.2d (BNA) at 1313–14. 432. 522 F.3d 1320, 86 U.S.P.Q.2d (BNA) 1369 (Fed Cir. 2008); *see* David M. Kelly & Stephanie H. Bald, 2008 Trademark Decisions of the Federal Circuit, 58 AM. U. L. REV. 947, 966 (2009)

^{433.} Id. at 1322, 86 U.S.P.Q.2d (BNA) at 1371.

^{434.} Id. at 1327, 86 U.S.P.Q.2d (BNA) at 1374.

[Vol. 58:747 AMERICAN UNIVERSITY LAW REVIEW

defendant also should not be precluded from challenging patent validity in the second suit."435 Second, "[a]t the time of an infringement suit, it will be difficult to anticipate the new products and future disputes that may later arise between the two parties."436

Claim preclusion may also apply where parties to a controversy previously chose to settle a dispute by contract.⁴³⁷ When such a settlement agreement involves patent issues, the Federal Circuit will have appellate jurisdiction.438 When reviewing a settlement agreement, the Federal Circuit does not apply its own law but instead applies state contract law to interpret the settlement agreement.⁴³⁹

In Howmedica Osteonics Corp. v. Wright Medical Technology, Inc.,⁴⁴⁰ the parties previously entered into a settlement agreement to resolve a patent dispute.⁴⁴¹ This settlement agreement contained a provision that, on its face, provided for release of liability and immunity from future suit to both parties.⁴⁴² When Howmedica later brought suit against Wright for infringement of a patent not at issue in the prior suit, Wright raised the settlement agreement as a defense.443 According to Wright, the language of the settlement agreement was sufficiently broad to collaterally estop Howmedica from bringing any patent infringement suit against Wright that was ripe at the time the settlement agreement was executed.⁴⁴⁴ The Federal Circuit, applying state contract law, determined that the parties only intended the release provision to apply to matters actually in dispute at the time of the contract.⁴⁴⁵ Although the present matter was "ripe" at the time of the agreement and clearly fell within the text of the agreement, New Jersey contract law permits a court to consider extrinsic evidence when interpreting a contract provision.⁴⁴⁶ Accordingly, both the district court and the Federal Circuit proceeded to examine the

^{435.} *Id.*, 86 U.S.P.Q.2d (BNA) at 1374. 436. *Id.*, 86 U.S.P.Q.2d (BNA) at 1375.

^{437.} See, e.g., Marvel Characters, Inc. v. Simon, 310 F.3d 280, 287, 64 U.S.P.Q.2d (BNA) 1891, 1896 (2d Cir. 2002) (explaining that where parties reach a settlement agreement and the court dismisses the dispute with prejudice, the judgment is final

for purposes of res judicata). 438. See 28 U.S.C. § 1295(a) (1) (2006) (granting exclusive jurisdiction to the Court of Appeals for the Federal Circuit where the trial court's jurisdiction was based in whole or in part on 28 U.S.C. § 1338(a)).

^{439.} Howmedica Osteonics Corp. v. Wright Med. Tech. Inc., 540 F.3d 1337, 1347, 88 U.S.P.Q.2d (BNA) 1129, 1136 (Fed. Cir. 2008).
440. Id. at 1337, 88 U.S.P.Q.2d (BNA) at 1129.

^{441.} Id. at 1341-42, 88 U.S.P.Q.2d (BNA) at 1131-32.

^{442.} Id. at 1347-48, 88 U.S.P.Q.2d (BNA) at 1136.

^{443.} *Id.* at 1347, 88 U.S.P.Q.2d (BNA) at 1136. 444. *Id.* at 1342–43, 88 U.S.P.Q.2d (BNA) at 1132.

^{445.} Id. at 1350, 88 U.S.P.Q.2d (BNA) at 1138.

^{446.} Id. at 1348, 88 U.S.P.Q.2d (BNA) at 1136.

intent of the parties, evidenced by their negotiations and a contemporaneous settlement agreement covering a patent dispute in Massachusetts, to conclude that the parties did not intend the agreement to bar the present suit.⁴⁴⁷ As such, Howmedica was not collaterally estopped from initiating the suit.⁴⁴⁸

G. Alternative Dispute Resolution

A court may also decline to exercise jurisdiction where the parties have contracted to have any dispute resolved by alternative dispute resolution.449 Because whether parties to an agreement have contractually bound themselves to settle a dispute through arbitration is not an issue unique to patent law, the Federal Circuit will apply the law of the regional circuit to decide the question.⁴⁵⁰

In DataTreasury Corp. v. Wells Fargo & Co., 451 the trial court refused to dismiss or stay litigation pending arbitration in a patent infringement action.⁴⁵² In DataTreasury, one of Wells Fargo's subsidiaries had previously entered into a patent license agreement with WMR e-Pin LLC ("WMR").⁴⁵³ The license agreement compelled arbitration of any dispute or disagreement "between WMR and Wells Fargo" relating to the license.⁴⁵⁴ WMR subsequently assigned four patents to DataTreasury.⁴⁵⁵ When DataTreasury later brought suit against Wells Fargo for infringement of these patents, Wells Fargo moved to dismiss the suit, arguing that DataTreasury, as an assignee of WMR, was bound by the arbitration clause of the licensing agreement.⁴⁵⁶ The district court denied the motion, and the Federal Circuit affirmed.⁴⁵⁷ Reviewing the issue de novo, the Federal Circuit applied regional circuit law to determine the scope of the licensing agreement.⁴⁵⁸ Because the regional circuit itself would have analyzed the question of arbitrability under the state law governing the contract, the court looked to Minnesota law, which governed the

^{447.} *Id.* at 1349–50, 88 U.S.P.Q.2d (BNA) at 1137–38. 448. *Id.* at 1350, 88 U.S.P.Q.2d (BNA) at 1138.

^{449.} See Cont'l Ins. Co. v. Polish S.S. Co., 346 F.3d 281, 282, 284 (2d Cir. 2003) (compelling parties to a contract to arbitrate a dispute where the contract incorporated an arbitration clause).

^{450.} DataTreasury Corp. v. Wells Fargo & Co., 522 F.3d 1368, 1371–72, 86 U.S.P.Q.2d (BNA) 1440, 1442 (Fed. Cir. 2008).

^{451.} *Id.* at 1368, 86 U.S.P.Q.2d (BNA) at 1440. 452. *Id.* at 1371, 86 U.S.P.Q.2d (BNA) at 1442.

^{453.} *Id.* at 1370, 86 U.S.P.Q.2d (BNA) at 1441. 454. *Id.* at 1370–71, 86 U.S.P.Q.2d (BNA) at 1441-42.

^{455.} *Id.* at 1371, 86 U.S.P.Q.2d (BNA) at 1442. 456. *Id.*, 86 U.S.P.Q.2d (BNA) at 1442.

^{457.} *Id.* at 1373, 86 U.S.P.O.2d (BNA) at 1444. 458. *Id.* at 1371, 86 U.S.P.Q.2d (BNA) at 1442.

796 AMERICAN UNIVERSITY LAW REVIEW [Vol. 58:747

contract.⁴⁵⁹ Under Minnesota law, a non-signatory to an arbitration agreement can only enforce an arbitration clause in a limited number of circumstances.⁴⁶⁰ Because Wells Fargo's subsidiary, rather than Wells Fargo, had signed the agreement, and none of the exceptions to third party enforcement applied, the court determined that neither party could be compelled to submit to arbitration.⁴⁶¹ Accordingly, the Federal Circuit affirmed the district court's denial of the defendant's motion to dismiss or stay pending arbitration.⁴⁶²

III. CLAIM CONSTRUCTION

In defining the scope of a patented invention, the claims of a patent are generally given the meaning that they would have to one of "ordinary skill in the art."⁴⁶³ In construing claim terms, courts may consider the claims themselves, the specification, the prosecution history, and extrinsic evidence.⁴⁶⁴

Claims Α.

1. Special claims

Special rules of construction may apply depending on the type of claim or where in the claim a term appears. For example, in TriMed, Inc. v. Stryker Corp., 465 the Federal Circuit considered whether claim language contained a means-plus-function limitation under 35 U.S.C. § 112 para. 6.466 The claim term at issue read "said holes in said plate providing means for allowing the pin to slide axially therein but preventing compression across the fracture, and stabilizing said near end of the pin against displacement in the plane of the plate."467 The Federal Circuit first noted that the "[u]se of the word 'means' creates a presumption that § 112 ¶ 6 applies."468 The presumption is overcome if the claim, in addition to reciting functional language, also "recites sufficient structure for performing the described

^{459.} Id. at 1372, 86 U.S.P.Q.2d (BNA) at 1442-43.

^{460.} See id., 86 U.S.P.Q.2d (BNA) at 1443 (explaining that a non-signatory may be compelled to arbitrate under the theory of (1) incorporation by reference; (2) assumption; (3) agency; (4) veil-piercing/alter ego; (5) equitable estoppel; or (6) third-party beneficiary).

^{461.} Id. at 1372-73, 86 U.S.P.Q.2d (BNA) at 1443-44.

^{462.} Id. at 1373, 86 U.S.P.Q.2d (BNA) at 1444.

^{463.} Phillips v. AWH Corp., 415 F.3d 1303, 1312-13, 75 U.S.P.Q.2d (BNA) 1321, 1326 (Fed. Cir. 2005) (en banc).

^{464.} *Id.* at 1314, 75 U.S.P.Q.2d (BNA) at 1327. 465. 514 F.3d 1256, 85 U.S.P.Q.2d (BNA) 1787 (Fed. Cir. 2008)

^{466.} Id. at 1259-62, 85 U.S.P.Q.2d (BNA) at 1789-91.

^{467.} Id. at 1259, 85 U.S.P.Q.2d (BNA) at 1788 (emphasis in original omitted).

^{468.} Id., 85 U.S.P.Q.2d (BŇA) at 1789.

functions in their entirety."469 Sufficient structure exists if the claim "specifies the exact structure that performs the functions in question without need to resort to other portions of the specification or extrinsic evidence for an adequate understanding of the structure."470

The court identified the function specified in the claim to be "allowing a pin to slide axially through the pin plate while preventing compression across the bone fracture, and stabilizing the exposed end of the pin against displacement in the plane of the plate."471 However, because there was a sufficient structure articulated in the claim—namely. holes—that performed the function. the presumption was overcome, and it was improper to invoke § 112 para. 6.472

The Federal Circuit's opinion in Symantec Corp. v. Computer Associates International, Inc.473 concerned construction of a term in the preamble of the claim.⁴⁷⁴ The patent at issue related to methods "of scanning for and detecting computer viruses."475 The preamble of the claim read: "In a system for transferring digital data for storage in a computer storage medium, a method of screening the data as it is *being transferred*... comprising the steps of:^{*476} The court relied on Catalina Marketing International, Inc. v. Coolsavings.com, Inc.,477 for guideposts in determining whether to construe the preamble as a limitation rather than as merely providing context for the claim.⁴⁷⁸ In Catalina, the Federal Circuit had held that a preamble "generally is not limiting" "[a]bsent clear reliance on the preamble in the prosecution history" to distinguish the prior art, or unless "it is necessary to provide antecedent basis for the body of the claim."⁴⁷⁹ In Symantec, the Federal Circuit recognized that the "as it is being transferred" language had been added to the preamble during prosecution to overcome the prior art, but the court noted that the applicant had also concurrently added another term to the body of the claim to overcome the same prior art.⁴⁸⁰ Thus, there was no clear

^{469.} Id., 85 U.S.P.Q.2d (BNA) at 1789.

^{470.} *Id.* at 1260, 85 U.S.P.Q.2d (BNA) at 1789.
471. *Id.*, 85 U.S.P.Q.2d (BNA) at 1789.
472. *Id.*, 85 U.S.P.Q.2d (BNA) at 1789.

^{473. 522} F.3d 1279, 86 Ù.S.P.Q.2d (BNA) 1449 (Fed. Cir. 2008).

^{474.} *Id.* at 1288, 86 U.S.P.Q.2d (BNA) at 1453. 475. *Id.* at 1286, 86 U.S.P.Q.2d (BNA) at 1451.

^{476.} Id., 86 U.S.P.Q.2d (BNA) at 1452.

^{477. 289} F.3d 801, 62 U.S.P.Q.2d (BNA) 1781 (Fed. Cir. 2002).

^{478.} Symantec, 522 F.3d at 1288-89, 86 U.S.P.Q.2d (BNA) at 1454. 479. Id. at 1288, 86 U.S.P.Q.2d (BNA) at 1454 (citing Catalina, 289 F.3d at 809,

⁶² U.S.P.Q.2d (BNA) at 1785).

^{480.} Id. at 1289, 86 U.S.P.Q.2d (BNA) at 1454.

reliance "on the preamble" language to distinguish the prior art.⁴⁸¹ The Federal Circuit was likewise not persuaded that the difference in language between the added preamble language and the added claim term meant that the preamble language created a distinct limitation.⁴⁸² The court concluded that, in the absence of anything in the specification or prosecution history to indicate a different meaning, it should be assumed that preamble language is duplicative of, or provides context for, the claim term.⁴⁸³

The Federal Circuit separately considered whether the term "computer system" should be limited to a single computer or should be read to include a network of multiple computers.⁴⁸⁴ Finding no support in the specification for a narrow construction of the term, the court construed the term according to its ordinary meaning to one of skill in the computer art, as demonstrated by a dictionary of computing terms.⁴⁸⁵ Notably, the Federal Circuit dismissed testimony by experts regarding how they would construe the term based on their reading of the specification.⁴⁸⁶ Such testimony was "unhelpful" because it gave only an expert's understanding of the term and did not "identify the 'accepted meaning in the field' to one skilled in the art."487

Howmedica Osteonics Corp. v. Wright Medical Technology, Inc. presented a claim construction issue based on tension between a Jepson claim preamble and the body of the claim.⁴⁸⁸ A Jepson claim has a preamble (starting with the word "in") and an improvement clause (starting with the phrase "an improvement comprising" or "the improvement comprising").⁴⁸⁹ The preamble of a Jepson claim limits and defines the scope of the claim.⁴⁶

487. *Id.* at 1291, 86 U.S.P.Q.2d (BNA) at 1455 (quoting Sinorgchem Co., Shandong v. Int'l Trade Comm'n, 511 F.3d 1132, 1137 n.3, 85 U.S.P.Q.2d (BNA) 1415, 1420 n.3 (Fed. Cir. 2007)). 488. 540 F.3d 1337, 1344, 88 U.S.P.Q.2d (BNA) 1129, 1133 (Fed. Cir. 2008).

489. 37 C.F.R. § 1.75(e) (2008); see MANUAL OF PATENT EXAMINING PROCEDURE § 608.01 (m) (2008) ("The preamble of this form of claim is considered to positively and clearly include all the elements or steps recited therein as a part of the claimed combination."); Pentec, Inc. v. Graphic Controls Corp., 776 F.2d 309, 315, 227 U.S.P.Q. (BNA) 766, 770 (Fed. Cir. 1985) (stating that when a Jepson claim is used the "claimed invention consists of the preamble in combination with the improvement").

490. Epson Gas Sys., Inc. v. Bauer Compressors, Inc., 279 F.3d 1022, 1029, 61 U.S.P.Q.2d (BNA) 1470, 1475 (Fed. Cir. 2002).

^{481.} Id., 86 U.S.P.Q.2d (BNA) at 1454 (quoting Catalina, 289 F.3d at 808, 62 U.S.P.Q.2d (BNA) at 1785).

^{482.} *Id.*, 86 U.S.P.Q.2d (BNA) at 1454. 483. *Id.*, 86 U.S.P.Q.2d (BNA) at 1454.

^{484.} Id. at 1290, 86 U.S.P.Q.2d (BNA) at 1455.

^{485.} Id. at 1290-91, 86 U.S.P.Q.2d (BNA) at 1455-56.

^{486.} Id., 86 U.S.P.Q.2d (BNA) at 1455.

In construing a Jepson claim directed to an artificial knee prosthesis, the Federal Circuit considered tension between the preamble and the improvement clause.⁴⁹¹ The preamble of the claim recited that there could be more than one "condylar element" meeting a certain "articulation requirement":

In a knee prosthesis . . . having a femoral component and a tibial component, . . . the femoral component including at least one *condylar element* for confronting and engaging the bearing member to accomplish articulation of the knee prosthesis throughout a range of flexion⁴

The body of the claim (the improvement clause) referred to a singular condylar element that met a certain "geometric requirement": "the anterior-posterior surface profile contour along the condylar element [that has] an essentially constant anterior-posterior articular radius throughout the articular surface area of the condylar element which contacts the bearing member during articulation throughout the primary range of flexion "493

The district court construed the claim to require that, in a femoral component with two condylar elements, both elements needed to meet the geometric requirement.⁴⁹⁴ The Federal Circuit agreed with the district court that the claim term "at least one" should be construed to encompass one or more condylar elements; however, a panel majority disagreed that when there are two condylar elements, both must meet the geometric requirement.⁴⁹⁵ The majority reasoned that if that was the intent, the "more natural way of drafting the claim language . . . would be to require 'each condylar element,' rather than 'the condylar element'" to meet the geometric requirement. Because Wright offered no evidence that the claim should be interpreted by anything other than its plain language, the majority concluded that the claim required only that one condylar element meet the geometric requirement.⁴⁹⁷

Judge Prost dissented, arguing that "the terms 'at least one condylar element' and 'the condylar element' are coextensive in scope", and thus, the two condylar elements must meet both the articulation and the geometric requirements.⁴⁹⁸

^{491.} Howmedica Osteonics Corp., 540 F.3d at 1344, 88 U.S.P.Q.2d (BNA) at 1133.
492. Id. at 1340, 88 U.S.P.Q.2d (BNA) at 1130 (emphasis altered).

^{493.} Id., 88 U.S.P.Q.2d (BNA) at 1130 (emphasis altered).
494. Id. at 1343, 88 U.S.P.Q.2d (BNA) at 1132.
495. Id. at 1344–45, 88 U.S.P.Q.2d (BNA) at 1133–34.

^{496.} Id. at 1344, 88 U.S.P.Q.2d (BNA) at 1133. 497. Id. at 1347, 88 U.S.P.Q.2d (BNA) at 1136.

^{498.} Id. at 1352, 88 U.S.P.Q.2d (BNA) at 1139-40 (Prost, J., dissenting).

2. A or an

The indefinite article "a" or "an" is often construed to mean "one or more."499 In Baldwin Graphic Systems, Inc. v. Siebert, Inc.,500 the Federal Circuit considered construction of the term "a."⁵⁰¹ The patents at issue were systems for cleaning a printing press cylinder using strips of cleaning fabric.⁵⁰² Although the district court had construed "'a pre-soaked fabric roll' to mean 'a single presoaked fabric roll,'" the Federal Circuit disagreed.⁵⁰³ It held that construction of "a" or "an" to mean "one or more" is the general rule and that "exceptions to this rule are extremely limited."⁵⁰⁴ Such exceptions arise only "where the language of the claims themselves, the specification, or the prosecution history necessitate[s] a departure from the rule."⁵⁰⁵ Further, the court held that use of the terms "the" or "said" in subsequent claims to refer back to a claim term containing "a" or "an" does not change application of the rule, but rather "reinvokes that non-singular meaning."506 "Because the initial indefinite article ('a') carries either a singular or plural meaning, any later reference to that same claim element merely reflects the same potential plurality."⁵⁰⁷

In contrast, in TiVo, Inc. v. EchoStar Communications Corp.,⁵⁰⁸ the Federal Circuit construed the term "an" to mean only one.⁵⁰⁹ The dispute concerned patented digital video recorder ("DVR") technology allowing television users to "time-shift" television signals by storing data relating to the transmissions on a hard disk in Motion Picture Expert Group ("MPEG") format and subsequently transforming the data for replay.⁵¹⁰ The claim at issue stated: "wherein said Output Section assembles said video and audio components into an MPEG stream."511

Although the Federal Circuit recognized the general rule that "a" or "an" should be construed to mean "one or more," it noted that

^{499.} See, e.g., KCJ Corp. v. Kinetic Concepts, Inc., 223 F.3d 1351, 1356, 55 U.S.P.Q.2d (BNA) 1835, 1839 (Fed. Cir. 2000) (noting that use of the article "a" is interpreted to limit a specific element to one only where the patentee manifests a clear intent to do so).

^{500. 512} F.3d 1338, 85 U.S.P.Q.2d (BNA) 1503 (Fed. Cir. 2008).

^{501.} *Id.* at 1342, 85 U.S.P.Q.2d (BNA) at 1507. 502. *Id.* at 1340, 85 U.S.P.Q.2d (BNA) at 1504.

^{503.} *Id.* at 1340, 1343, 85 U.S.P.Q.2d (BNA) at 1505, 1507.
504. *Id.* at 1342, 85 U.S.P.Q.2d (BNA) at 1507.
505. *Id.* at 1343, 85 U.S.P.Q.2d (BNA) at 1507.

^{506.} *Id.* at 1342, 85 U.S.P.Q.2d (BNA) at 1507.
507. *Id.* at 1343, 85 U.S.P.Q.2d (BNA) at 1507.
508. 516 F.3d 1290, 85 U.S.P.Q.2d (BNA) 1801 (Fed. Cir. 2008).

^{509.} *Id.* at 1303–04, 85 U.S.P.Q.2d (BNA) at 1811. 510. *Id.* at 1294, 85 U.S.P.Q.2d (BNA) at 1803–04.

^{511.} Id. at 1303, 85 U.S.P.Q.2d (BNA) at 1810.

proper construction "depend[ed] heavily on the context of its use."⁵¹² Relying on earlier and later limitations in the claim, the court concluded that, taken in context, the disputed claim term "clearly indicates that two separate components are assembled into a single stream, not that the video components are assembled into one stream and the audio components into a second stream."⁵¹³ Such a construction was further supported by the specification.⁵¹⁴

Similarly, in Cat Tech LLC v. Tubemaster, Inc.,515 the Federal Circuit held that the precedent construing the article "a" to mean "one or more" was inapplicable to construction of the term "a spacing."516 The term appeared in claims directed to a method for using loading devices to place catalyst particles into a multi-tube chemical reactor.⁵¹⁷ The method required "positioning a plurality of discrete plates" to provide "a spacing" between plates, with the spacing having "a width not greater than the smallest dimension of a single particle to be loaded into the multi-tube reactor."⁵¹⁸ Cat Tech argued that the claim required only one (not all) of the spaces between the plurality of plates to be so narrow.⁵¹⁹

The Federal Circuit acknowledged that "the indefinite article 'a' has been construed to mean 'one or more,'"520 but the court held that Cat Tech's proposed construction would render the "a spacing" limitation meaningless for all practical purposes.⁵²¹ Having just one such "narrow gap between plates would be an exercise in futility because whole catalyst particles would simply fall into the other, wider gaps between the plates."522

Such an interpretation could not be reconciled with certain dependent claims, which specified that the spaces were designed to block whole catalyst particles.⁵²³ Further, the court could find nothing in the specification to support such a construction and instead found that Cat Tech had disclaimed such a construction during prosecution of the parent application.⁵²⁴

^{512.} Id., 85 U.S.P.Q.2d (BNA) at 1811.

^{513.} Id. at 1303, 85 U.S.P.Q.2d (BNA) at 1811.
514. Id. at 1304, 85 U.S.P.Q.2d (BNA) at 1811.
515. 528 F.3d 871, 87 U.S.P.Q.2d (BNA) 1065 (Fed. Cir. 2008).

^{516.} Id. at 886, 87 U.S.P.Q.2d (BNA) at 1976.

^{517.} *Id.* at 874–75, 87 U.S.P.Q.2d (BNA) at 1067. 518. *Id.* at 875, 87 U.S.P.Q.2d (BNA) at 1067.

^{519.} Id. at 884, 87 U.S.P.Q.2d (BNA) at 1074.

^{520.} *Id.* at 886, 87 U.S.P.Q.2d (BNA) at 1074. 521. *Id.* at 885, 87 U.S.P.Q.2d (BNA) at 1076.

^{522.} *Id.*, 87 U.S.P.Q.2d (BNA) at 1075. 523. *Id.*, 87 U.S.P.Q.2d (BNA) at 1075.

^{524.} Id. at 885-86, 87 U.S.P.Q.2d (BNA) at 1075-76.

3. Plain and ordinary meaning

The Federal Circuit has with some frequency given claims their ordinary and customary meaning. For example, in Miken Composites, L.L.C. v. Wilson Sporting Goods Co., 525 the Federal Circuit adopted the ordinary and customary meaning in construing the term "insert" to mean "something inserted or intended for insertion."526 The patentee contended that the limitation was "purely structural" and did not require any specific action—i.e., it was irrelevant "whether an insert is placed into a pre-existing frame or whether a frame is built around it."527 The patentee argued that by requiring insertion, the district court had erred by "importing a process limitation into claims directed to a *product*."⁵²⁸ The Federal Circuit rejected the patentee's argument and affirmed the district court's construction.⁵²⁹ The court noted that "nothing in the claims or specification indicates, explicitly or implicitly, that the inventor used the term in a novel way or intended to impart a novel meaning to it."⁵³⁰ Although the Federal Circuit acknowledged that the ordinary meaning there had "functional attributes," the court stated its construction did not read a process limitation into the claims but was simply a result of the fact that the claim "recites a structural component . . . with certain understood characteristics."531

In Baldwin, by contrast, the Federal Circuit held that a district court had gone beyond the ordinary meaning of claim language and had read a process limitation into an apparatus claim.⁵³² The district court was presented with a claim term-"reduced air content cleaning fabric"—that appeared in both method claims and apparatus claims.⁵³³ The district court construed the term only once to mean "a fabric whose air content has been reduced by some method prior to being wound on a roll."⁵³⁴ The Federal Circuit held that the district court erred.⁵³⁵ The apparatus and method claims were "directed toward different classes of patentable subject matter," and the district court's construction had "blurred an important difference" between

^{525. 515} F.3d 1331, 85 U.S.P.Q.2d (BNA) 1865 (Fed. Cir. 2008).

^{526.} Id. at 1337, 85 U.S.P.Q.2d (BNA) at 1869 (quoting Webster's II New College Dictionary (3d ed. 2005)).

^{527.} Id., 85 U.S.P.Q.2d (BNA) at 1869. 528. Id., 85 U.S.P.Q.2d (BNA) at 1869. 529. Id. at 1338, 85 U.S.P.Q.2d (BNA) at 1870.

^{530.} Id. at 1337, 85 U.S.P.Q.2d (BNA) at 1869.
531. Id. at 1337–38, 85 U.S.P.Q.2d (BNA) at 1870.
532. 512 F.3d 1338, 1346, 85 U.S.P.Q.2d (BNA) 1503, 1509 (Fed. Cir. 2008).
533. Id. at 1344, 85 U.S.P.Q.2d (BNA) at 1508.

^{534.} Id., 85 U.S.P.Q.2d (BNA) at 1508.

^{535.} Id. at 1346, 85 U.S.P.Q.2d (BNA) at 1509.

the two claims.⁵³⁶ The Federal Circuit held that the apparatus claims did not require any particular process or method and did not require the air content to be reduced prior to winding.⁵³⁷ The Federal Circuit also held that the district court erred by construing the *method* claim to require that air content be reduced prior to winding on the roll.⁵³⁸ "[A]lthough a method claim necessarily recites the steps of the method in a particular order, as a general rule the claim is not limited to performance of the steps in the order recited, unless the claim explicitly or implicitly requires a specific order."539 Finding no support in the claims or specification for requiring air content reduction prior to winding and no clear disavowal of claim scope in the prosecution history, the Federal Circuit rejected the district court's construction and remanded the case to the district court.⁵⁴⁰

In DSW, Inc. v. Shoe Pavilion, Inc.,⁵⁴¹ the Federal Circuit also applied the plain and ordinary meaning in interpreting claim language.⁵⁴² The patent at issue in *DSW* was directed to a method for storing and displaying footwear for customer self-selection.⁵⁴³ One step of the method consisted of "selectively positioning a generally vertically disposed, horizontally movably positionable stack divider" between two stacks containing two styles of footwear.544 The district court construed the term to encompass only methods that contain track and roller mechanisms connecting display modules to a support base, which other claims expressly described.545

The Federal Circuit held that the district court improperly imported the "track and roller" limitation from other claims.⁵⁴⁶ The Federal Circuit held that the plain and ordinary meaning of the claim term should control unless it was ambiguous or a special definition was apparent from the intrinsic record.⁵⁴⁷ The Federal Circuit could find no express disclaimer in the prosecution history of other methods of displaying footwear not involving the rolling track mechanism.⁵⁴⁸ Although the preferred embodiment disclosed in the specification included a rolling track mechanism, other embodiments

^{536.} Id. at 1344, 85 U.S.P.Q.2d (BNA) at 1508.

^{537.} Id., 85 U.S.P.Q.2d (BNA) at 1508.

^{538.} *Id.* at 1345, 85 U.S.P.Q.2d (BNA) at 1509. 539. *Id.*, 85 U.S.P.Q.2d (BNA) at 1508.

^{540.} Id. at 1345-46, 85 U.S.P.Q.2d (BNA) at 1508-10.

^{541. 537} F.3d 1342, 87 U.S.P.Q.2d (BNA) 1687 (Fed. Cir. 2008). 542. *Id.* at 1347, 87 U.S.P.Q.2d (BNA) at 1671.

^{543.} *Id.* at 1344, 87 U.S.P.Q.2d (BNA) at 1688–89. 544. *Id.* at 1345 n.1, 87 U.S.P.Q.2d (BNA) at 1690 n.1.

^{545.} Id. at 1345–46, 87 U.S.P.Q.2d (BNA) at 1690.
546. Id. at 1347, 87 U.S.P.Q.2d (BNA) at 1690–91.
547. Id., 87 U.S.P.Q.2d (BNA) at 1691.

^{548.} Id., 87 U.S.P.Q.2d (BNA) at 1691.

included other means to permit the stack dividers to have horizontally movable positions.⁵⁴⁹ Thus, the Federal Circuit concluded that the district court had improperly imported into the claim term a limitation not required by the claims, specification, or prosecution history.⁵⁵⁰

Likewise, in 800 Adept, Inc. v. Murex Securities, Ltd.,551 the Federal Circuit relied on the plain language of the claims.⁵⁵² The patents at issue in 800 Adept related to a method for routing "1-800" telephone calls to a business's location closest to the caller.⁵⁵³ In dispute was the meaning of the method step that required assigning, for each potential caller, a telephone number to which that caller's calls would be routed—"assigning to the physical location of said potential first parties a telephone number of a service location of a second party that will receive calls."⁵⁵⁴ The district court construed the "assigning" limitation to encompass calculations made *during* the telephone call.⁵⁵⁵ The Federal Circuit found such a construction to be flawed.⁵⁵⁶

First, the Federal Circuit found that the plain language of the claims made clear that the assigning step occurred prior to placement of the call and required that a telephone number of a service location be assigned to each potential caller.⁵⁵⁷ In addition, the court found nothing in the claims to suggest that assigning could encompass determining the telephone number of the service location *during the telephone call* based on a stored algorithm.⁵⁵⁸

The written description supported a construction based on the plain language of the claims.⁵⁵⁹ Furthermore, statements made during prosecution in distinguishing the invention from a prior art reference reinforced such a construction.⁵⁶⁰ In considering the prosecution history, the court noted that it did not rely on the doctrine of prosecution disclaimer, which courts use to limit the scope of a claim term "that would otherwise be read broadly."⁵⁶¹

^{549.} Id. at 1348, 87 U.S.P.Q.2d (BNA) at 1691.

^{550.} Id., 87 U.S.P.Q.2d (BNA) at 1691

^{551. 539} F.3d 1354, 88 U.S.P.Q.2d (BNA) 1065 (Fed. Cir. 2008).
552. Id. at 1363, 88 U.S.P.Q.2d (BNA) at 1072.

^{53.} Id. at 1357, 88 U.S.P.Q.2d (BNA) at 1067.
554. Id. at 1359, 88 U.S.P.Q.2d (BNA) at 1069 (emphasis omitted).
555. Id. at 1361, 88 U.S.P.Q.2d (BNA) at 1070-71.

^{556.} *Id.* at 1362, 88 U.S.P.Q.2d (BNA) at 1071. 557. *Id.* at 1363, 88 U.S.P.Q.2d (BNA) at 1072.

^{558.} *Id.*, 88 U.S.P.Q.2d (BNA) at 1072. 559. *Id.*, 88 U.S.P.Q.2d (BNA) at 1072.

^{560.} Id. at 1364, 88 U.S.P.Q.2d (BNA) at 1072-73.

^{561.} Id., 88 U.S.P.Q.2d (BŇA) at 1073.

Rather, the court used the prosecution history simply to support its construction based on the claim language and written description.⁵⁶²

In contrast to the above cases, the Federal Circuit rejected reliance on the ordinary or customary meaning in construing the claim term "binary code" in *Chamberlain Group, Inc. v. Lear Corp.*⁵⁶³ The patent at issue related to a remote-control garage door opening system comprising of a transmitter (generally integrated into the vehicle) and a receiver (usually attached to the device that operates the garage door).⁵⁶⁴ The claim was directed to a transmitter comprising, inter alia, a "binary code generator."⁵⁶⁵ The district court had broadly construed "binary code," based on its ordinary and customary meaning, to "not [be] limited to[] a representation of a base 2 number."⁵⁶⁶ The ordinary meaning of the binary code, according to the district court, could encompass binary numbers (base 2), trinary numbers (base 3), or even decimal numbers (base 10).⁵⁶⁷ Although the Federal Circuit recognized that it is unacceptable to import limitations from the written description into the claims, the appeals court held that the claims and specification required a more narrow interpretation of "binary code" limited to binary numbers.⁵⁶⁸ The court recognized that the written description is highly relevant to claim construction, and the court relied heavily on the specification's use of the term "trinary code," which indicated that "binary code" could not encompass base 3 numbers or any numbers other than base 2 numbers.⁵⁶⁹

Likewise, in Welker Bearing Co. v. PHD, Inc., 570 the Federal Circuit limited the scope of the claim term "mechanism for moving said finger" to the structure disclosed in the patent for performing that function under 35 U.S.C. § 112(6). At issue in that case was the scope of claims in two patents directed to pin clamps that hold a workpiece securely in place during welding and other manufacturing processes.⁵⁷¹ Patent owner Welker Bearing asserted that those patents were infringed by two PHD clamp devices, "Clamp I" and "Clamp II."572

^{562.} Id. at 1365, 88 U.S.P.Q.2d (BNA) at 1074.
563. 516 F.3d 1331, 1337, 86 U.S.P.Q.2d (BNA) 1104, 1108 (Fed. Cir. 2008).
564. Id. at 1333, 86 U.S.P.Q.2d (BNA) at 1105.
565. Id. at 1334, 86 U.S.P.Q.2d (BNA) at 1105.
566. Id. at 1336, 86 U.S.P.Q.2d (BNA) at 1108.
567. Id. at 1336, 86 U.S.P.Q.2d (BNA) at 1108.

^{567.} Id., 86 U.S.P.Q.2d (BNA) at 1107.

^{568.} *Id.* at 1335–39, 86 U.S.P.Q.2d (BNA) at 1107–09. 569. *Id.* at 1335, 1339, 86 U.S.P.Q.2d (BNA) at 1107, 1109.

^{570. 550} F.3d 1090, 89 U.S.P.Q.2d (BNA) 1289 (Fed. Cir. 2008).

^{571.} Id. at 1092, 85 U.S.P.Q.2d (BNA) at 1290-91.

^{572.} Id. at 1094, 85 U.S.P.Q.2d (BNA) at 1292.

Ruling on PHD's motion for summary judgment, the district court construed the claim term "mechanism for moving said finger" as a means-plus-function limitation under 35 U.S.C. § 112(6), and limited its scope to a "rotating central post."⁵⁷³ Based on that ruling, the district court concluded that PHD's Clamp II device did not infringe Welker Bearing's patents.⁵⁷⁴

Reviewing the district court's claim construction, the Federal Circuit reviewed prior decisions construing the word "mechanism" and indicated that whether "mechanism" should be construed under § 112(6) is context specific.⁵⁷⁵ Agreeing with the district court that "mechanism for moving said finger" should be construed as a meansplus-function limitation, the Federal Circuit found it significant that "[n]o adjective endows the claimed 'mechanism' with a physical or structural component."⁵⁷⁶ The Court also found that the remainder of each claim at issue "provides no structural context for determining the characteristics of the 'mechanism' other than to describe its function."577

Turning to whether the district court identified the correct structure disclosed in the specification as corresponding to the claimed function, the Federal Circuit agreed that the patents at issue only identified a single such structure: a rotating central post.⁵⁷⁸ The Court found Welker Bearing's argument that the doctrine of claim differentiation compelled a different conclusion unavailing.

With regard to claim differentiation, this court is aware that claim 1 of the '478 patent recites a rotating element, while claim 1 of the '254 patent does not. This difference between claims in different patents does not change the meaning of these meansplus-function limitations. By statute, this court must follow the directive to construe these limitations according to § $112 \ \P \ 6$. Because both terms share the same specification with the same structure corresponding to the claimed function, this court cannot give these terms any different scope.⁵⁷⁹

Finally, the Federal Circuit rejected Welker Bearing's argument that the Clamp II device could infringe under the doctrine of

^{573.} *Id.*, 85 U.S.P.Q.2d (BNA) at 1293. 574. The district court also granted summary judgment of no infringement as to the Clamp I product on the basis that the record did not show that PHD made, used, sold, or offered for sale the Clamp I device at any time after the patents had issued. Id., 85 U.S.P.Q.2d (BNA) at 1292-93. The Federal Circuit affirmed that finding. Id. at 1095, 85 U.S.P.Q.2d (BNA) at 1293.

^{575.} *Id.* at 1096, 85 U.S.P.Q.2d (BNA) at 1293.
576. *Id.*, 85 U.S.P.Q.2d (BNA) at 1294.
577. *Id.*, 85 U.S.P.Q.2d (BNA) at 1294.
578. *Id.* at 1097, 85 U.S.P.Q.2d (BNA) at 1294.

^{579.} Id. at 1098-99, 85 U.S.P.Q.2d (BNA) at 1295.

equivalents, and clarified that Welker Bearing's argument was one of structural equivalents, rather than the doctrine of equivalents, because Clamp II's structure was well known in the prior art and could not be classified as after-arising technology.⁵⁸⁰ The Court agreed with the district court that the evidence showed Clamp II's structure was not insubstantially different from the claimed rotating central post.581

Notably, in Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc.⁵⁸² the Federal Circuit held that the district court had properly construed "and" to mean "or."583 The lawsuit arose under the Hatch-Waxman Act after Mylan filed an abbreviated new drug application certifying that Ortho-McNeil's patent was invalid or not infringed.⁵⁸⁴ The patent claim at issue contained a specified chemical formula containing several R groups (R1, R2, R3, R4, and R5), wherein "R2, R3, R4, and R5 are independently hydrogen or lower alkyl and R2 and R3 and/or R4 and R5 together may be a group of formula (II).^{"585} The dispute hinged on construction of the term "and": should it be construed to mean "and" (i.e., as conjunctive) so that both limitations must be met (thereby excluding the accused product, topiramate), or should it be construed to mean "or" (i.e., as disjunctive) so that either limitation is sufficient for infringement (thereby implicating topiramate)?⁵⁸⁶

The Federal Circuit determined that, based on the use of "and" in the claim, "and" meant "or" and joined "mutually exclusive possibilities."587 The court looked at the claim term in the context of other claims and noted that to require a conjunctive meaning would render several dependent claims meaningless, contrary to a wellestablished claim construction principle.⁵⁸⁸ Finally, the court examined the specification and concluded that it, too, supported a construction of "and" to mean "or."589 The court concluded that it need not look at extrinsic evidence in construing the claim term because extrinsic evidence is less significant than intrinsic evidence.⁵⁹⁰ While conceding that the primary dictionary definition for "and" is in

^{580.} Id., 85 U.S.P.Q.2d (BNA) at 1296.

^{581.} *Id.* at 1100, 85 U.S.P.Q.2d (BNA) at 1296. 582. 520 F.3d 1358, 86 U.S.P.Q.2d (BNA) 1196 (Fed. Cir. 2008).

^{583.} Id. at 1361, 86 U.S.P.Q.2d (BNA) at 1198.
584. Id. at 1360, 86 U.S.P.Q.2d (BNA) at 1198.
585. Id. at 1361, 86 U.S.P.Q.2d (BNA) at 1199.

^{586.} Id., 86 U.S.P.Q.2d (BNA) at 1199.

^{580.} Id., 80 U.S.F.Q.2d (BNA) at 1199.
587. Id. at 1362, 86 U.S.P.Q.2d (BNA) at 1199.
588. Id., 86 U.S.P.Q.2d (BNA) at 1199 (citing Rambus Inc. v. Infineon Techs. AG, 318 F.3d 1081, 1093, 65 U.S.P.Q.2d (BNA) 1705, 1713 (Fed. Cir. 2003)).

^{589.} Id., 86 U.S.P.Q.2d (BNA) at 1199-200.

^{590.} Id., 86 U.S.P.Q.2d (BNA) at 1200.

the additive sense, the court noted that dictionaries also use "and" to connote alternatives.⁵⁹¹

Finally, the Federal Circuit in O2 Micro International Ltd. v. Beyond Innovation Technology Co.⁵⁹² held that a court's determination that a claim term has its plain and ordinary meaning "may be inadequate when a term has more than one 'ordinary' meaning or when reliance on a term's 'ordinary' meaning does not resolve the parties' dispute."⁵⁹³ The court held that when reliance on the ordinary meaning does not resolve the parties' dispute, it is the court's *duty* to construe the term.⁵⁹⁴

The patents at issue in *O2 Micro* were directed to DC/AC converter circuits, and the claims contained the phrase "only if said feedback signal is above a predetermined threshold."⁵⁹⁵ The parties disputed whether the "only if" limitation applied "at all times without exception" or whether it applied only during "steady state operation."596 The district court declined to construe the phrase, concluding that it had a well-understood definition.⁵⁹⁷ On appeal, the Federal Circuit held that turning to the ordinary meaning did not resolve the parties' dispute because the parties disagreed not about what the words "only if" meant but about when those words applied.598 The district court therefore should have construed the term "to determine what claim scope is appropriate in the context of the patents-in-suit."⁵⁹⁹ By failing to resolve the dispute, the district court improperly left the jury free to consider the parties' claim construction arguments.⁶⁰⁰

B. Specification

The specification is highly relevant to claim construction and is often the "single best guide" to determining the meaning of a claim term to one of ordinary skill in the art.⁶⁰¹ The Federal Circuit frequently relies on the overall invention disclosed in the

^{591.} Id., 86 U.S.P.Q.2d (BNA) at 1200.

^{592. 521} F.3d 1351, 86 U.S.P.Q.2d (BNA) 1304 (Fed. Cir. 2008).
593. *Id.* at 1361, 86 U.S.P.Q.2d (BNA) at 1311.
594. *Id.*, 86 U.S.P.Q.2d (BNA) at 1311.
595. *Id.* at 1264, 1266 (BNA) at 1311.

^{595.} Id. at 1354, 1356, 86 U.S.P.Q.2d (BNA) at 1305, 1307 (emphasis added).

^{596.} *Id.* at 1361, 86 U.S.P.Q.2d (BNA) at 1311. 597. *Id.*, 86 U.S.P.Q.2d (BNA) at 1311.

^{598.} *Id.*, 86 U.S.P.Q.2d (BNA) at 1311. 599. *Id.*, 86 U.S.P.Q.2d (BNA) at 1311.

^{600.} *Id.* at 1362, 86 U.S.P.Q.2d (BNA) at 1311. 601. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315, 75 U.S.P.Q.2d (BNA) 1321, 1326 (Fed. Cir. 2005) (en banc) (citing Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582, 39 U.S.P.Q.2d (BNA) 1573, 1577 (Fed. Cir. 1996)).

specification (and not just specific embodiments) to define the scope of claim terms.

In Netcraft Corp. v. eBay, Inc.,602 the Federal Circuit addressed Internet billing method patents that included the limitation "providing a communications link through equipment of the third party."⁶⁰³ The district court construed the term to require that the third party provide customers with Internet access.⁶⁰⁴ Finding that the claims themselves did not expressly require the third party to provide Internet access, the Federal Circuit turned to the specification.⁶⁰⁵ While it appreciated that the use of the phrase "the present invention" does not automatically limit the meaning of claim terms, the court held that, in this case, the specification's repeated use of "the present invention" in the summary of the invention clearly referred to the invention as a whole and required the third party to provide Internet access.⁶⁰⁶ Furthermore, the abstract and disclosed embodiments supported that construction of the claim term.⁶⁰⁷ Finding the prosecution history to lack clarity, the Federal Circuit concluded that it was less helpful than the specification in construing the claim term.608

In Praxair, Inc. v. ATMI, Inc.,609 the Federal Circuit considered construction of two terms of a patent directed to an apparatus that limits potentially rapid accidental discharges of hazardous gasses from pressurized storage containers.⁶¹⁰ Specifically, it construed the terms "flow restrictor" and "capillary."611

The Federal Circuit rejected defendant ATMI's argument that, based on the specification, the term "flow restrictor" required "severe" restriction of gas flow.⁶¹² The court found that any statements in the specification to that effect pertained only to specific embodiments and not to the full scope of the invention.⁶¹³ Nevertheless, appreciating that the overall objective of the invention was to prevent a hazardous release of gas, the court concluded that the term should be construed to require "a structure that serves to

^{602. 549} F.3d 1394, 89 U.S.P.Q.2d (BNA) 1234 (Fed. Cir. 2008).

^{603.} Id. at 1396, 89 U.S.P.Q.2d (BNA) at 1236 (quoting U.S. Patent No. 5,794,221 (filed July 7, 1995)). 604. *Id.* at 1397, 89 U.S.P.Q.2d (BNA) at 1237.

^{605.} Id., 89 U.S.P.Q.2d (BNA) at 1237.

^{606.} Id. at 1398, 89 U.S.P.Q.2d (BNA) at 1238.
607. Id. at 1398–99, 89 U.S.P.Q.2d (BNA) at 1238.

^{608.} Id. at 1401–02, 89 U.S.P.Q.2d (BNA) at 1240–41.

^{609. 543} F.3d 1306, 88 U.S.P.Q.2d (BNA) 1705 (Fed. Cir. 2008).

^{610.} *Id.* at 1310, 88 U.S.P.Q.2d (BNA) at 1707–08. 611. *Id.* at 1322–28, 88 U.S.P.Q.2d (BNA) at 1717–20.

^{612.} Id. at 1323, 88 U.S.P.Q.2d (BNA) at 1718.

^{613.} Id., 88 U.S.P.Q.2d (BŇA) at 1717.

restrict the rate of flow sufficiently to prevent a hazardous situation."614

810

Similarly, in construing the term "capillary," the Federal Circuit rejected ATMI's argument that the term should be construed to require that the capillaries be uniform.⁶¹⁵ Again looking to the specification, it noted that only specific embodiments discussed uniform capillaries and not the invention as a whole.⁶¹⁶ Moreover, it pointed to the structure of the claims as additional evidence that the term "capillary" did not require uniformity.⁶¹⁷

In *Decisioning.com*, *Inc. v. Federated Department Stores*, *Inc.*,⁶¹⁸ the Federal Circuit relied on the specification to conclude that the term "remote interface," read in light of the specification, should be construed to exclude consumer-owned personal computers.⁶¹⁹ The claim at issue was directed to an automatic account processing system for establishing a financial account for applicants located at a "remote interface."620

In construing the claim term, the majority first noted that the plain and ordinary meaning of "remote interface" is very broad and could, without reference to the specification, cover consumer-owned personal computers.⁶²¹ The court, however, then turned to the specification, focusing on its use of the term "kiosk."622 The preferred embodiment described a remote interface that was housed in a kiosk structure, but alternative embodiments were not so limited and the prosecution history made clear that a remote interface did not have to be housed in a kiosk.⁶²³ The majority, however, concluded that the specification used the term "kiosk" not only to refer to the *housing* for the computer equipment constituting the remote interface, but also, at times, to refer to the "entire 'remote interface' itself."624 These latter uses of "kiosk," combined with the common meaning of "kiosk," suggest that the remote interface is installed in a publicly accessible location.⁶²⁵ Additionally, each example and feature of kiosks described in the specification indicating public accessibility led the majority to conclude that a skilled artisan would recognize that

- 617. Id. at 1326–27, 88 U.S.P.Q.2d (BNA) at 1720.
- 618. 527 F.3d 1300, 86 U.S.P.Q.2d (BNA) 1769 (Fed. Cir. 2008).
 619. *Id.* at 1311, 86 U.S.P.Q.2d (BNA) at 1778.

- 619. *Id.* at 1311, 66 U.S.F.Q.2d (BNA) at 1776.
 620. *Id.* at 1304, 86 U.S.P.Q.2d (BNA) at 1773.
 621. *Id.* at 1308, 86 U.S.P.Q.2d (BNA) at 1776.
 622. *Id.* 86 U.S.P.Q.2d (BNA) at 1776.
 623. *Id.* at 1308–09, 86 U.S.P.Q.2d (BNA) at 1776-77.
 624. *Id.* at 1308, 86 U.S.P.Q.2d (BNA) at 1776.
- 625. Id. at 1310, 86 U.S.P.Q.2d (BNA) at 1777.

^{614.} Id. at 1324, 88 U.S.P.Q.2d (BNA) at 1718.
615. Id. at 1325–26, 88 U.S.P.Q.2d (BNA) at 1719–20.
616. Id., 88 U.S.P.Q.2d (BNA) at 1719.

2009]

"remote interface" required public accessibility and did not encompass a consumer-owned personal computer.⁶²⁶

In his dissent, Judge Linn did not agree with the majority's reading of the specification as using "kiosk" in two different senses: "I cannot subscribe to the majority's seemingly contradictory analysis that the 'remote interface' is not limited to a 'kiosk' except when it is."627 He stated that the majority had "incongruously equate[d] 'remote interface' with 'kiosk' to justify engrafting the 'publicly-accessible' characteristic of kiosks onto the 'remote interface' term."628 Such a construction, according to Judge Linn, "violates fundamental tenets of claim construction precedent."⁶²⁹ He also discerned no disclaimer of consumer-owned personal computers in the specification, and he thus concluded that the term "remote interface" should be given its ordinary, broad meaning.630

In *Oatey v. IPS Corp.*,⁶³¹ the Federal Circuit reaffirmed the principle that claim terms should be construed so as not to exclude embodiments disclosed in the specification unless there is a clear disclaimer in the specification or prosecution history.⁶³² The patented invention in Oatey was directed to a washing machine outlet box with two drain ports designed to satisfy new municipal plumbing codes prohibiting other appliances from sharing the drain port used by washing machines.⁶³³ The claim recited "[a] washing machine outlet box comprising a housing including a bottom wall, [and] first and second juxtaposed drain ports in said bottom wall."634 The district court construed the phrase "first and second juxtaposed drain ports in said bottom wall" specifically to exclude an embodiment described in figure 3 of the patent.⁶³⁵ The district court construed the term to require "two separate physical openings in the bottom wall of the outlet box, as shown in Figure 2, and not a single opening divided by a wall in the attached tailpiece, as shown in Figure 3."636 The Federal Circuit held that, because there was no disclaimer of the figure 3

^{626.} Id., 86 U.S.P.Q.2d (BNA) at 1777-78.

^{627.} Id. at 1317, 86 U.S.P.Q.2d (BNA) at 1783 (Linn, J., concurring-in-part and dissenting-in-part). 628. Id., 86 U.S.P.Q.2d (BNA) at 1783.

^{629.} Id. at 1318, 86 U.S.P.Q.2d (BNA) at 1784.
630. Id., 86 U.S.P.Q.2d (BNA) at 1784.
631. 514 F.3d 1271, 85 U.S.P.Q.2d (BNA) 1791 (Fed. Cir. 2008).

^{632.} Id. at 1276–77, 85 U.S.P.Q.2d (BNA) at 1794–95.
633. Id. at 1272, 85 U.S.P.Q.2d (BNA) at 1792.

Id. at 1275, 85 U.S.P.Q.2d (BNA) at 1793 (quoting U.S. Patent No. 6,148,850 634. (filed Apr. 21, 1999)) (emphasis omitted). 635. Id. at 1275-76, 85 U.S.P.Q.2d (BNA) at 1794.

^{636.} Id., 85 U.S.P.Q.2d (BNA) at 1794 (emphasis added).

structure in the specification or prosecution history, it was improper to exclude it from the scope of the claim.⁶³⁷

812

The Federal Circuit distinguished the *Oatey* case in its later decision in PSN Illinois, LLC v. Ivoclar Vividant, Inc.⁶³⁸ In PSN, the Federal Circuit considered a patent for a method of fabricating porcelain veneer restorations for teeth.⁶³⁹ The claim included an element that required a restoration to be "ready for mounting" on a tooth.⁶⁴⁰ The district court construed the term "ready for mounting" narrowly to mean that all finishing activities prior to mounting on the tooth had been performed (i.e., the element would not be met if any finishing step still needed to be performed).⁶⁴¹ Finding no guidance in the claims themselves and no explicit definition in the specification, the court relied on implicit guidance in the specification to define the meaning of the term.⁶⁴² The Federal Circuit concluded that the district court had erred by giving greater weight to the preferred embodiment (which did not describe finishing steps being performed after this point in the process) than to the summary of the invention (which did describe later finishing steps).⁶⁴³ The court found the decision in Oatey was inapplicable because the court's construction of "ready for mounting" was broader than, and therefore did not exclude, the preferred embodiment.⁶⁴⁴ The court also noted that "Oatey is not a panacea, requiring all claims to cover all embodiments" and that "courts must recognize that disclosed embodiments may be within the scope of other allowed but unasserted claims."645

Although the Federal Circuit has recognized that claims should generally not be construed so as to read in inoperable embodiments. it clarified that principle in *Cordis Corp. v. Medtronic Ave, Inc.*⁶⁴⁶ The case involved a disputed claim pertaining to coronary stents with a wall surface having "'a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member.'"647 The Federal Circuit affirmed the district court's construction of the term "slots" to refer to both "complete slots" and

- 643. Id. at 1166, 86 U.S.P.Q.2d (BNA) at 1897.

Id. at 1277-78, 85 U.S.P.Q.2d (BNA) at 1795. 637.

^{638. 525} F.3d 1159, 86 U.S.P.Q.2d (BNA) 1892 (Fed. Cir. 2008). 639. *Id.* at 1162, 86 U.S.P.Q.2d (BNA) at 1893.

^{640.} Id., 86 U.S.P.Q.2d (BŇA) at 1894.

^{641.} Id. at 1165, 86 U.S.P.Q.2d (BNA) at 1896.

^{642.} Id., 86 U.S.P.Q.2d (BNA) at 1896.

^{643.} *Id.* at 1100, 50 C.3.1.Q.2d (BNA) at 1897.
644. *Id.*, 86 U.S.P.Q.2d (BNA) at 1897.
645. *Id.*, 86 U.S.P.Q.2d (BNA) at 1897.
646. 511 F.3d 1157, 1174, 85 U.S.P.Q.2d (BNA) 1427, 1439 (Fed. Cir. 2008).
647. *Id.* et 4122. 67 U.S.P.Q.2d (BNA) et 1429 (maximum U.S. Pattert No. 4.7

^{647.} Id. at 1173, 85 U.S.P.Q.2d (BNA) at 1438 (quoting U.S. Patent No. 4,739,762 col.11 l.67 to col. 12 l.2 (filed Nov. 3, 1986)).

"half slots."648 According to the Federal Circuit, a construction of the term "slots" to include both "complete slots" and "half slots" was consistent with the written description, which used the term "complete slots" to distinguish from "half slots."649

In so holding, the court rejected the argument that such a construction could not be correct since it covers inoperable embodiments.⁶⁵⁰ The court distinguished between a claim construction that makes all embodiments inoperable—which "should be viewed with extreme skepticism'"-from a construction that might simply cover some inoperable embodiments.⁶⁵¹ The court further noted that construction of other claim terms prevented the claim from covering any inoperable stents.⁶⁵²

C. Prosecution History

In addition to consulting the specification, courts may also rely on the prosecution history in construing claim terms.⁶⁵³ In Board of Regents of the University of Texas System v. BENQ America Corp.,654 the Federal Circuit construed the term "syllabic element"-which appeared in claims directed to a method of communicating by nonverbal transmission using a touch-tone telephone.655 The Federal Circuit held that "syllabic element" should be construed narrowly to mean a one-syllable letter group,656 not, as the patentee contended, a word or part of a word.657

The Federal Circuit found little guidance in the claim language and instead relied on the specification and prosecution history to affirm the construction by the district court.⁶⁵⁸ The Federal Circuit noted that the specification repeatedly distinguished between a "word" and a "syllabic element," demonstrating that the two terms are not coextensive in scope.659 The prosecution history likewise distinguished between "syllabic element" and "word."660 Moreover.

^{648.} Id. at 1173-75, 85 U.S.P.Q.2d (BNA) at 1438-40. 649. Id. at 1174, 85 U.S.P.Q.2d (BNA) at 1438-39. 650. Id., 85 U.S.P.Q.2d (BNA) at 1439. 651. Id., 85 U.S.P.Q.2d (BNA) at 1440 (quoting Talbert Fuel Sys. Patents Co. v. Unocal Corp., 275 F.3d 1371, 1376, 61 U.S.P.Q.2d (BNA) 1363, 1366 (Fed. Cir. 9009) wave for a dama at the parameter for 27 U.S. 909 (2000) 2002), vacated and remanded on other grounds, 537 U.S. 802 (2002)).

^{652.} Id., 85 U.S.P.Q.2d (BNA) at 1439.

^{653.} Phillips v. AWH Corp., 415 F.3d 1303, 1317, 75 U.S.P.Q.2d (BNA) 1321, 1329 (Fed. Cir. 2005) (en banc). 654. 533 F.3d 1362, 87 U.S.P.Q.2d (BNA) 1437 (Fed. Cir. 2008).

^{655.} Id. at 1364–65, 87 U.S.P.Q.2d (BNA) at 1439.

^{656.} Id. at 1367-68, 87 U.S.P.Q.2d (BNA) at 1441.

^{657.} *Id.*, 87 U.S.P.Q.2d (BNA) at 1441. 658. *Id.* at 1368–70, 87 U.S.P.Q.2d (BNA) at 1441–43.

^{659.} Id. at 1368, 87 U.S.P.Q.2d (BNA) at 1442.

^{660.} Id. at 1369-70, 87 U.S.P.Q.2d (BNA) at 1443.

[Vol. 58:747 AMERICAN UNIVERSITY LAW REVIEW

the term "syllabic element" was added during prosecution to overcome an anticipation rejection after the examiner found prior art showing the use of a word-indicating that the claim was narrowed such that "syllabic element" did not include words.⁶⁶¹

The scope of a claim term may be narrowed when the applicant makes a clear disclaimer during prosecution.⁶⁶² In Computer Docking Station Corp. v. Dell, Inc.,663 the patents at issue related to a portable microprocessor.⁶⁶⁴ The Federal Circuit affirmed the district court's construction of the terms "portable computer" and "portable computer microprocessing system" to mean "'a computer without a built-in display or keyboard that is capable of being moved or carried about'"-thus, excluding laptop computers.665

In so holding, the Federal Circuit relied on the doctrine of prosecution disclaimer.⁶⁶⁶ The court noted that the applicant had specifically distinguished its invention from a prior art reference disclosing a laptop computer with a built-in display and keyboard.⁶⁶⁷ Although the applicant distinguished its invention in multiple ways, that did not preclude the court from finding a disavowal when it was clear and unambiguous: "[A] disavowal, if clear and unambiguous, can lie in a single distinction among many."668 In addition to the clear disavowal during prosecution, the court relied on the specification, which also supported such a construction.⁶⁶⁹

Likewise, in Solomon Technologies, Inc. v. International Trade *Commission*, ⁶⁷⁰ the Federal Circuit found that the "prosecution history could not be clearer in showing a disclaimer" of subject matter.⁶⁷¹ Here, the court was reviewing the construction of the term "integral combination of a respective electric motor element and an element of said transmission unit" in a patent directed to a combination motor and transmission device.⁶⁷² The court found that, in response to an anticipation rejection, the patent applicant had clearly

^{661.} Id., 87 U.S.P.Q.2d (BNA) at 1443.
662. Phillips v. AWH Corp., 415 F.3d 1303, 1316, 75 U.S.P.Q.2d (BNA) 1321, 1329 (Fed. Cir. 2005) (en banc).

^{663. 519} F.3d 1366, 86 U.S.P.Q.2d (BNA) 1129 (Fed. Cir. 2008).

^{664.} *Id.* at 1370, 86 U.S.P.Q.2d (BNA) at 1130. 665. *Id.* at 1372–79, 86 U.S.P.Q.2d (BNA) at 1132–36 (emphasis added) (quoting Computer Docking Station Corp. v. Dell, Inc., No. 06-C-32-C, 2006 WL 5999613, at *4 (W.D. Wis. Aug. 16, 2006)). 666. Id. at 1374–75, 86 U.S.P.Q.2d (BNA) at 1134.

^{667.} *Id.* at 1375–77, 86 U.S.P.Q.2d (BNA) at 1135–36.
668. *Id.* at 1377, 86 U.S.P.Q.2d (BNA) at 1136.
669. *Id.* at 1378–79, 86 U.S.P.Q.2d (BNA) at 1137.

^{670. 524} F.3d 1310, 86 U.S.P.Q.2d (BNA) 1805 (Fed. Cir. 2008).

^{671.} Id. at 1313, 86 U.S.P.Q.2d (BNA) at 1808.

^{672.} Id. at 1312-13, 86 U.S.P.Q.2d (BNA) at 1807-08.

2009]

disclaimed devices that use shafts to connect the motor and transmission elements.⁶⁷³

In contrast, the Federal Circuit found only a limited disavowal in *Cohesive Technologies, Inc. v. Waters Corp.*⁶⁷⁴ In *Cohesive*, the claims were directed to a high-performance liquid chromatography apparatus comprising a chromatographic body containing a "'multiplicity of rigid, solid, porous particles."⁶⁷⁵ Based in part on the prosecution history, the Federal Circuit construed "rigid" to not exclude polymeric particles.⁶⁷⁶ The Federal Circuit first recognized that the ordinary meaning of "rigid" does not require that a particle be monomeric and not polymeric.⁶⁷⁷ The Federal Circuit was also unable to discern a clear and unmistakable disavowal of polymeric particles in the prosecution history.⁶⁷⁸ The court agreed that while an expert declaration submitted by the applicant in response to a prior art rejection distinguished the particular particles disclosed in the prior art, the declaration did not disavow *all* polymeric particles.⁶⁷⁹

Finally, in Baldwin Graphic Systems, Inc. v. Siebert, Inc.,680 the Federal Circuit affirmed the district court's construction of the term "sealed sleeve" to be limited to "heat-sealed sleeve" based, in part, on the prosecution history.⁶⁸¹ All references to a "sealed sleeve" in the specification were to a "heat-sealed sleeve," and when the applicant had attempted during prosecution to remove the word "heat" from the specification and thereby broaden the invention's scope, the PTO examiner rejected the changes as impermissibly adding new matter.⁶⁸² Relying on this history, the Federal Circuit held that the term "sealed sleeve" was properly construed as limited to a "heat-sealed sleeve." A broader construction would have caused the claim to have been invalid for lack of support in the initial disclosure.⁶⁸⁴

D. Extrinsic Evidence

Although the Federal Circuit has "emphasized the importance of intrinsic evidence in claim construction," extrinsic evidence may also

^{673.} Id. at 1313, 86 U.S.P.Q.2d (BNA) at 1808.

⁵⁴³ F.3d 1351, 1361, 88 U.S.P.Q.2d (BNA) 1903, 1908-09 (Fed. Cir. 2008). 674.

^{675.} *Id.* at 1358, 88 U.S.P.Q.2d (BNÅ) at 1906 (quoting U.S. Patent No. 5,772,874 col.20 ll.20–34 (filed June 11, 1996)).

^{676.} Id. at 1362, 88 U.S.P.Q.2d (BNA) at 1909.
677. Id. at 1360, 88 U.S.P.Q.2d (BNA) at 1908.
678. Id. at 1360–61, 88 U.S.P.Q.2d (BNA) at 1908–09.

^{679.} Id. at 1361, 88 U.S.P.Q.2d (BNA) at 1908-09.

^{680. 512} F.3d 1338, 85 U.S.P.Q.2d (BNA) 1503 (Fed. Cir. 2008).

^{681.} Id. at 1340, 1344, 85 U.S.P.Q.2d (BNA) at 1505, 1507.

^{682.} Id. at 1340-41, 85 U.S.P.Q.2d (BNA) at 1505. 683. Id. at 1344, 85 U.S.P.Q.2d (BNA) at 1507-08.

^{684.} Id., 85 U.S.P.Q.2d (BŇA) at 1508.

be considered.⁶⁸⁵ The Federal Circuit looked at both intrinsic and extrinsic evidence in construing the claim term "pipeline stage" in Microprocessor Enhancement Corp. v. Texas Instruments Inc.⁶⁸⁶ The patented technology concerned methods for increasing microprocessor efficiency.⁶⁸⁷ The court first looked at the context in which the term was used in the claims and concluded that other terms in the claim indicated that "pipeline stage" was used in a temporal, rather than positional, sense.⁶⁸⁸ The court found the specification to be ambiguous as to the meaning of the term,⁶⁸⁹ but that the prosecution history supported the temporal construction of the claim term.⁶⁹⁰ Finally, the court examined extrinsic evidence—a computer textbook-which the court found "support[ed] the conclusion that the inventor used 'the pipeline stage' in its temporal sense, consistent with the term's ordinary meaning in the computer arts."691

Courts also may rely on dictionaries, provided they are not used to contradict the intrinsic evidence.⁶⁹² In Mangosoft, Inc. v. Oracle Corp.,⁶⁹³ the district court had construed the term "local" as used to describe a computer device in computer networking systems to mean "a computer device (e.g., a hard drive) that is directly attached to a single computer's processor by, for example, the computer's bus."694 Patent owner Mangosoft argued on appeal that the district court's claim construction opinion, which was issued before the Federal Circuit's opinion in *Phillips v. AWH Corp.*, had improperly relied on older case law that promoted the use of technical dictionaries.⁶⁹⁵ The Federal Circuit was unpersuaded.⁶⁹⁶ It noted that *Phillips* "recognized that reference to such sources is not prohibited so long as the ultimate construction given to the claims in question is grounded in the intrinsic evidence."⁶⁹⁷ The court stated that even though the

(Fed. Cir. 2005) (en banc).

^{685.} Phillips v. AWH Corp., 415 F.3d 1303, 1317, 75 U.S.P.Q.2d (BNA) 1321, 1329 (Fed. Cir. 2005) (en banc).

^{686. 520} F.3d 1367, 1377-80, 86 U.S.P.Q.2d (BNA) 1225, 1232-35 (Fed. Cir. 2008). 687. Id. at 1369, 86 U.S.P.Q.2d (BNA) at 1226.

^{688.} Id. at 1378, 86 U.S.P.Q.2d (BNA) at 1233.
689. Id. at 1378–79, 86 U.S.P.Q.2d (BNA) at 1233.
690. Id. at 1378–80, 86 U.S.P.Q.2d (BNA) at 1233–34.

^{691.} Id. at 1380, 86 U.S.P.Q.2d (BNA) at 1235.

^{692.} Phillips v. AWH Corp., 415 F.3d 1303, 1324, 75 U.S.P.Q.2d (BNA) 1321, 1335

^{693. 525} F.3d 1327, 86 U.S.P.Q.2d (BNA) 1939 (Fed. Cir. 2008).

^{694.} Id. at 1329, 86 U.S.P.Q.2d (BNA) at 1941.
695. Id. at 1329–30, 86 U.S.P.Q.2d (BNA) at 1941.

^{696.} *Id.*, 86 U.S.P.Q.2d (BNA) at 1941–42.
697. *Id.* at 1330, 86 U.S.P.Q.2d (BNA) at 1942 (citing *Phillips*, 415 F.3d at 1318, 75 U.S.P.Q.2d (BNA) at 1330).

district court had issued its decision before *Phillips*, its claim construction was "fully consistent with and supported by the intrinsic record—as well as the dictionary—and thus fully comports with our precedent."⁶⁹⁸

Similarly, in *Helmsderfer v. Bobrick Washroom Equipment, Inc.*,⁶⁹⁹ the Federal Circuit affirmed the district court's construction of "partially hidden from view" to mean "hidden from view to some extent but not totally hidden from view" as the term was used to describe the top platform surface in a claim to a wall-mounted diaper changing station.⁷⁰⁰ The Federal Circuit first noted that the specification never used the term "partially hidden from view" to describe the platform top surface and that the term appeared only in the claims.⁷⁰¹ Because there was nothing in the specification to assist in construing the term. the Federal Circuit concluded that the district court was free to look to extrinsic evidence, provided it did not contradict the meaning discerned from the intrinsic record.⁷⁰² According to the Federal Circuit, "[w]hen the intrinsic evidence is silent as to the plain meaning of a term, it is entirely appropriate for the district court to look to dictionaries or other extrinsic sources for context-to aid in arriving at the plain meaning of a claim term."⁷⁰³

IV. INFRINGEMENT

Section 271(a) of the Patent Act provides that "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent."⁷⁰⁴ Determining patent infringement entails two steps: (1) the claims must be construed; and (2) the properly construed claims must be compared to the allegedly infringing device.⁷⁰⁵ This section addresses the Federal Circuit's 2008 cases dealing with the second step.

- 700. Id. at 1380–81, 1384, 87 U.S.P.Q.2d (BNA) at 1217, 1219.
- 701. Id., 87 U.S.P.Q.2d (BNA) at 1217.
- 702. Id. at 1382, 87 U.S.P.Q.2d (BNA) at 1218.
- 703. Id., 87 U.S.P.Q.2d (BNA) at 1218.
- 704. 35 U.S.C. § 271(a) (2006).

^{698.} Id., 86 U.S.P.Q.2d (BNA) at 1942.

^{699. 527} F.3d 1379, 87 Ù.S.P.Q.2d (BNA) 1216 (Fed. Cir. 2008).

^{705.} E.g., Lockwood v. Am. Airlines, Inc., 107 F.3d 1565, 1573, 41 U.P.S.Q.2d (BNA) 1961, 1966 (Fed. Cir. 1997); Markman v. Westview Instruments, Inc., 52 F.3d 967, 976, 34 U.S.P.Q.2d (BNA) 1321, 1326 (Fed. Cir. 1995).

A. Literal Infringement

"Generally, a claim is literally infringed if each properly construed claim element reads on the accused product or process."706 In Johns Hopkins University v. Datascope Corp.,⁷⁰⁷ the Federal Circuit concluded that, despite a jury verdict of infringement and the district court's denial of the accused infringer's motion for judgment as a matter of law ("JMOL"), the accused product did not literally meet each of the claim elements.708

In Datascope, Johns Hopkins University and a licensee alleged that Datascope's ProLumen device infringed patents relating to a catheter system.⁷⁰⁹ Each of the asserted independent claims required introducing, into a vascular conduit, "a fragmentation catheter comprised either of a fragmentation member or an expanding distal end that automatically 'expands to conform to the shape and diameter of the inner lumen' of the vascular conduit."⁷¹⁰ The term "expands to conform to the shape and diameter of the inner lumen" was construed to mean that the fragmentation member or distal end "expands and adjusts to remain in contact with the inner lumen in three dimensions along its length and width."⁷¹¹ The only evidence presented by the plaintiffs to show that the ProLumen literally met the "expands to conform" claim limitation was the testimony of their expert.⁷¹² The expert concluded that "the S-wire in the ProLumen device expands and adjusts to remain in contact with the inner lumen in three dimensions along its length and width."713

The Federal Circuit, in a decision written by District Judge Zobel (sitting by designation), concluded that the expert's opinion was not supported by the facts.⁷¹⁴ On cross-examination, the expert admitted that the ProLumen device contacted the inner lumen at only two points.⁷¹⁵ A video animation relied upon by the expert also showed only two points of contact, and the Federal Circuit said this was unavoidable "[a]s a matter of geometry."716 The Federal Circuit therefore concluded that "no reasonable jury could have found that

^{706.} HERBERT F. SCHWARTZ, PATENT LAW & PRACTICE 160 (4th ed. 2003).
707. 543 F.3d 1342, 88 U.S.P.Q.2d (BNA) 1365 (Fed. Cir. 2008).
708. *Id.* at 1349, 88 U.S.P.Q.2d (BNA) at 1370.
709. *Id.* at 1349, 44 90 U.S.P.Q.2d (BNA) at 1300.

^{709.} *Id.* at 1343–44, 88 U.S.P.Q.2d (BNA) at 1366. 710. *Id.* at 1345, 88 U.S.P.Q.2d (BNA) at 1367 (quoting U.S. Patent No. 5,766,191 col.8 ll.34–42 (filed Feb. 29, 1996)).

^{711.} Id. at 1346, 88 U.S.P.Q.2d (BNA) at 1368.

^{712.} *Id.*, 88 U.S.P.Q.2d (BNA) at 1368. 713. *Id.*, 88 U.S.P.Q.2d (BNA) at 1368.

^{714.} *Id.* at 1348, 88 U.S.P.Q.2d (BNA) at 1369–70. 715. *Id.* at 1347–48, 88 U.S.P.Q.2d (BNA) at 1369.

^{716.} Id. at 1348, 88 U.S.P.Q.2d (BNA) at 1369-70.

the ProLumen device literally met th[e] limitation," and reversed the district court's denial of the defendant's motion for JMOL.⁷¹⁷

Judge Newman's dissent criticized the majority's willingness to rebalance the evidence.⁷¹⁸ Without specifically addressing the claim construction requiring contact "in three dimensions," Judge Newman said plaintiffs' expert's testimony was sufficient to support the jury verdict.⁷¹⁹ "[I]t is not [the Federal Circuit's] province to reweigh the evidence, when there was substantial evidence by which a reasonable jury could have reached its verdict."720

In Technology Licensing Corp. v. Videotek, Inc.,721 the Federal Circuit affirmed a judgment of no literal infringement reached by the district court after a bench trial.⁷²² The patent related to the separation of synchronization signals from video signals.⁷²³ The patent was "directed to methods for sync separation . . . that minimize the effect of noise in the video signal."⁷²⁴ The issue was whether the accused chips produced voltage peaks of synchronization signals that constituted a "clamped sync portion" as required by the claims.⁷²⁵ The trial court found that "it simply cannot be said that the [accused] chips are designed to or do in practice produce a 'clamped sync portion' at the [patented level], even if a few pulses at that level sometimes occur in actual operation."726

On appeal, the plaintiff made two arguments: first, that the trial court had mistakenly excused the defendant's infringement as de minimis ("even if a few pulses at that level sometimes occur in actual operation"); and second, that the trial court improperly required plaintiff to prove intent to infringe.⁷²⁷ The Federal Circuit, however, disagreed with both arguments.⁷²⁸ As to the first argument, the Federal Circuit understood the trial court to have found that "the few pulses that might occur at the [patented] level would not be a

^{717.} Id. at 1349, 88 U.S.P.Q.2d (BNA) at 1370.

^{718.} See id. at 1349-51, 88 U.S.P.Q.2d (BNA) at 1370-72 (Newman, J., dissenting) (concluding that there was, in fact, substantial evidence in support of the jury's verdict, and that it is not the job of the appellate court to replace the trial court's verdict, and that it is not the job of the appendic court to replace verdict due to its own interpretation of the evidence). 719. *Id.* at 1350–51, 88 U.S.P.Q.2d (BNA) at 1371. 720. *Id.* at 1351, 88 U.S.P.Q.2d (BNA) at 1371. 721. 545 F.3d 1316, 88 U.S.P.Q.2d (BNA) 1865 (Fed. Cir. 2008).

Id. at 1336, 88 U.S.P.Q.2d (BNA) at 1880.
 Id. at 1320, 88 U.S.P.Q.2d (BNA) at 1880.
 Id. at 1320, 88 U.S.P.Q.2d (BNA) at 1868.
 Id. at 1321, 88 U.S.P.Q.2d (BNA) at 1868.

^{725.} *Id.* at 1335–36, 88 U.S.P.Q.2d (BNA) at 1880. 726. *Id.* at 1335–36, 88 U.S.P.Q.2d (BNA) at 1880. v. Gennum Corp., No. C 01-04204 RS, 2007 WL 1319528, at *6 (N.D. Cal. May 4, 2007)).

^{727.} Id. at 1336, 88 U.S.P.Q.2d (BNA) at 1880.

^{728.} Id., 88 U.S.P.Q.2d (BŇA) at 1880.

clamped sync portion within the meaning of the claims because the hard clamp circuit does not perform the function of clamping or holding the sync tips to that voltage level."729 The Federal Circuit said the district court did not find "that those few pulses actually would infringe very quickly or briefly."730

The plaintiff's second argument was based on the district court's statement that if any pulses happened at the patented level, "it would be 'a matter of happenstance rather than design."⁷³¹ The plaintiff argued that the court required it to prove intent because of the use of the word "design."732 The Federal Circuit, however, concluded that that statement did not mean that the trial court equated design with intent.⁷³³ Instead, it "was merely part of the evidence considered by the trial court in concluding that the hard clamp circuit does not provide a clamped sync portion."734

In Broadcom Corp. v. International Trade Commission,⁷³⁵ the Federal Circuit addressed when a product's compliance with industry standards could be used to prove infringement.736 Broadcom complained to the International Trade Commission ("ITC") that Qualcomm had imported chipsets that infringed Broadcom's patents.⁷³⁷ Broadcom accused Qualcomm's chipsets in wireless handsets on third-generation wireless networks that use the EV-DO wireless communication standard developed and promoted by Qualcomm.⁷³⁸ Broadcom argued that "under the EV-DO standard, networks *must* implement the Idle State Protocol's Sleep State and that the Sleep State involves powering down a handset's wireless receiver"—which allegedly infringed the patent.739 The Federal Circuit, however, disagreed. It concluded that the EV-DO standard did not require handsets to enter the Sleep State or power down when in the Sleep State: "[t]he EV-DO standard provides that a terminal in the Sleep State 'may shut down part of its subsystems to conserve power' and the terminal 'may shut down processing resources to reduce power consumption.""⁷⁴⁰ Moreover, the Federal Circuit continued, the EV-DO standard specified that "the use of the

^{729.} Id., 88 U.S.P.Q.2d (BNA) at 1880.

^{730.} *Id.*, 88 U.S.P.Q.2d (BNA) at 1880. 731. *Id.*, 88 U.S.P.Q.2d (BNA) at 1880 (quoting *Videotek*, 2007 WL 1319528, at *6).

Id., 88 U.S.P.Q.2d (BNA) at 1880.
 Id., 88 U.S.P.Q.2d (BNA) at 1880.
 Id., 88 U.S.P.Q.2d (BNA) at 1880.
 Id., 88 U.S.P.Q.2d (BNA) at 1880.

^{734.} *Id.*, 66 U.S.F.Q.2d (BNA) at 1660.
735. 542 F.3d 894, 88 U.S.P.Q.2d (BNA) 1289 (Fed. Cir. 2008).
736. *Id.* at 899, 88 U.S.P.Q.2d (BNA) at 1293.
737. *Id.* at 896, 88 U.S.P.Q.2d (BNA) at 1290.

^{738.} *Id.* at 898, 88 U.S.P.Q.2d (BNA) at 1292. 739. *Id.* at 899, 88 U.S.P.Q.2d (BNA) at 1293 (emphasis added).

^{740.} Id., 88 U.S.P.Q.2d (BNA) at 1293 (emphasis added).

word 'may' instead of 'shall' indicates that a certain feature is not required by the standard."⁷⁴¹ The Federal Circuit therefore affirmed the Commission's finding of non-infringement.⁷⁴² The Federal Circuit did not consider Broadcom's argument that Qualcomm's promotion of the optional features was sufficient to show inducement because the Federal Circuit found that Broadcom had not presented that argument to the administrative law judge at the ITC.⁷⁴³

In Muniauction, Inc. v. Thomson Corp.,744 the Federal Circuit addressed the issue of joint infringement, following up on the court's previous decision in BMC Resources, Inc. v. Paymentech, L.P.,⁷⁴⁵ which "clarified the proper standard for whether a method claim is directly infringed by the combined actions of multiple parties."746 Under BMC *Resources.* "where the actions of multiple parties combine to perform every step of a claimed method, the claim is directly infringed only if one party exercises 'control or direction' over the entire process such that every step is attributable to the controlling party, i.e., the 'mastermind.'"⁷⁴⁷ In *Muniauction*, the issue was whether the actions of a bidder and auctioneer in an electronic system for auctioning financial instruments "may be combined under the law so as to give rise to a finding of direct infringement by the auctioneer."⁷⁴⁸ The Federal Circuit found that it was insufficient that the auctioneer controlled access to its system and instructed bidders on the system's use.⁷⁴⁹ The court held that the auctioneer "neither performed every step of the claimed methods nor had another party perform steps on its behalf, and Muniauction [had] identified no legal theory under which Thomson might be vicariously liable for the actions of the bidders."750

In Zenith Electronics Corp. v. PDI Communications Systems, Inc.,⁷⁵¹ the district court addressed a defense to infringement: implied license.⁷⁵² Plaintiff Zenith owned a patent on wired remote control devices, called "pillow speakers," used to control a television and receive

^{741.} Id., 88 U.S.P.Q.2d (BNA) at 1293.

^{742.} Id. at 908, 88 U.S.P.Q.2d (BNA) at 1299.

^{742.} *Id.* at 906, 66 U.S.F.Q.2d (BNA) at 1255.
743. *Id.* at 900, 88 U.S.P.Q.2d (BNA) at 1293–94.
744. 532 F.3d 1318, 87 U.S.P.Q.2d (BNA) 1350 (Fed. Cir. 2008).
745. 498 F.3d 1373, 84 U.S.P.Q.2d (BNA) 1545 (Fed. Cir. 2007).

^{746.} Muniauction, 532 F.3d at 1329, 87 U.S.P.Q.2d (BNA) at 1357 (citing BMC Res., 498 F.3d at 1380, 84 U.S.P.Q.2d (BNA) at 1549). 747. Id., 87 U.S.P.Q.2d (BNA) at 1358 (citing BMC Res., 498 F.3d at 1380-81,

⁸⁴ U.S.P.Q.2d (BNA) at 1550).

^{748.} Id., 87 U.S.P.Q.2d (BNA) at 1350).
748. Id., 87 U.S.P.Q.2d (BNA) at 1357.
749. Id. at 1330, 87 U.S.P.Q.2d (BNA) at 1358.
750. Id., 87 U.S.P.Q.2d (BNA) at 1358.

^{751. 522} F.3d 1348, 86 Ù.S.P.Q.2d (BNA) 1513 (Fed. Cir. 2008).

^{752.} Id. at 1354, 1360-67, 86 U.S.P.Q.2d (BNA) at 1517, 1521-26.

television audio in hospital rooms.⁷⁵³ Zenith then licensed the patent to three companies that manufactured and distributed the pillow speakers.⁷⁵⁴ Defendant PDI marketed a television that was compatible with Zenith's pillow speakers,⁷⁵⁵ and Zenith sued claiming that PDI directly infringed its patent by testing its televisions with pillow speakers, and indirectly infringed by supplying televisions and encouraging customers to operate them with pillow speakers.⁷⁵⁶ The district court granted PDI's motion for summary judgment based on the licenses between Zenith and the three pillow speaker manufacturers.⁷⁵⁷ The Federal Circuit affirmed.⁷⁵⁸ In an opinion by Judge Schall, the appeals court noted that this case was different than a typical implied-license case.⁷⁵⁹ In an ordinary case, the issue is whether a license is implied by the mere "sale of nonpatented equipment used to practice a patented invention."⁷⁶⁰ A court therefore will, in the typical case, examine whether the unpatented equipment has noninfringing uses and infer an implied license only if the unpatented equipment has no noninfringing uses.⁷⁶¹ In this case, however, the Federal Circuit stated that "the license is not merely implied by virtue of the sale of pillow speakers by [the three manufacturers]."762 Instead, customers purchasing pillow speakers obtained an implied license to use the pillow speakers "derived from the *express licenses* between Zenith and those manufacturers."⁷⁶³ In this situation, where the patent owner had expressly authorized the sale of a device for infringing uses, the traditional inquiry-whether the equipment involved has no noninfringing uses—was irrelevant.⁷⁶⁴

The court next addressed the scope of the implied licenses obtained by the purchasers of pillow speakers—i.e., whether they allowed the customers to use the pillow speakers with non-Zenith

^{753.} *Id.* at 1352, 86 U.S.P.Q.2d (BNA) at 1515. 754. *Id.* at 1353, 86 U.S.P.Q.2d (BNA) at 1516. 755. *Id.* 86 U.S.P.Q.2d (BNA) at 1516.

^{756.} Id., 86 U.S.P.Q.2d (BNA) at 1516.

^{757.} Id. at 1354, 86 U.S.P.Q.2d (BNA) at 1517.
758. Id. at 1362, 86 U.S.P.Q.2d (BNA) at 1523.
759. See id. at 1360-61, 86 U.S.P.Q.2d (BNA) at 1521-22 (analogizing this case to a second Jacobs v. Nintendo of Am., Inc., 370 F.3d 1097, 71 U.S.P.Q.2d (BNA) 1055 (Fed. Cir.

^{2004),} which was not a typical implied-license case). 760. *Id.* at 1360, 86 U.S.P.Q.2d (BNA) at 1522 (quoting Met-Coil Sys., Corp. v. Korners Unlimited, Inc., 803 F.2d 684, 231 U.S.P.Q. (BNA) 474 (Fed. Cir. 1986)) (emphasis added).

^{761.} *Id.*, 86 U.S.P.Q.2d (BNA) at 1521–22.
762. *Id.*, 86 U.S.P.Q.2d (BNA) at 1522.
763. *Id.* at 1361, 86 U.S.P.Q.2d (BNA) at 1522.

^{764.} Id., 86 U.S.P.Q.2d (BŇA) at 1522.

televisions such as PDI's televisions.⁷⁶⁵ The Federal Circuit noted that the express license agreements gave the three manufacturers broad "authorization to 'make, have made, use, sell or otherwise dispose of . . . any pillow speaker unit'" and that "[n]o restrictions are placed on the grants."⁷⁶⁶ The court therefore held that "purchasers of pillow speakers manufactured by [the three companies] obtain[ed] an implied license under [the patent] to use the pillow speakers in combination with any compatible television-not just Zenith televisions,"767 and the appeals court affirmed the district court's grant of summary judgment that the patent was not infringed upon because of the implied license defense.⁷⁶⁸

B. The Doctrine of Equivalents

Under the doctrine of equivalents, "a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention."⁷⁶⁹ Infringement under the doctrine of equivalents may be limited by a number of related doctrines, such as prosecution history estoppel.⁷⁷⁰

1. Amendment-based prosecution history estoppel

"The doctrine of prosecution history estoppel prevents a patent owner from recapturing with the doctrine of equivalents subject matter surrendered to acquire the patent."⁷⁷¹ Under amendmentbased prosecution estoppel history, "[a] patentee's decision to narrow his claims through amendment may be presumed to be a general disclaimer of the territory between the original claim and the amended claim."772 This presumption of surrender, however,

^{765.} See id. at 1361-62, 86 U.S.P.Q.2d (BNA) at 1522 (discussing whether the implied licenses allowed the customers to use the pillow speakers with non-Zenith televisions such as PDI's televisions).

<sup>televisions such as PDI's televisions).
766. Id. at 1362, 86 U.S.P.Q.2d (BNA) at 1523.
767. Id., 86 U.S.P.Q.2d (BNA) at 1523 (emphasis omitted).
768. Id., 86 U.S.P.Q.2d (BNA) at 1522.
769. Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 21, 41 U.S.P.Q.2d (BNA) 1865, 1866 (1997) (citing Graver Tank & Mfg. Co. v. Linde Air Prod. Co., 339 U.S. 605, 609, 85 U.S.P.Q. (BNA) 328, 330 (1950)).
770. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 741, 62
U.S.P. 2d (BNA) 1705 1714 (2002) (citing M/arms Instance, 520 U.S. at 33</sup>

U.S.P.Q.2d (BNA) 1705, 1714 (2002) (citing Warner-Jenkinson, 520 U.S. at 33, 41 U.S.P.Q.2d (BNA) at 1873)).

^{771.} Honeywell Int'l, Inc. v. Hamilton Sundstrand Corp., 523 F.3d 1304, 1312, 86 U.S.P.Q.2d (BNA) 1718, 1724 (Fed. Cir. 2008).
772. *Festo*, 535 U.S. at 740, 62 U.S.P.Q.2d (BNA) at 1713 (citing Exhibit Supply Co.

v. Ace Patents Corp., 315 U.S. 126, 136-37, 52 U.S.P.Q (BNA) 275, 277 (1942).

AMERICAN UNIVERSITY LAW REVIEW

according to Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.,⁷⁷³ can be rebutted if the patentee shows any of the following:

[T]hat the alleged equivalent would have been unforeseeable at the time of the narrowing amendment, that the rationale underlying the narrowing amendment bore no more than a tangential relation to the equivalent in question, or that there was "some other reason" suggesting that the patentee could not reasonably have been expected to have described the alleged equivalent.⁷⁷⁴

The tangentiality exception a.

Federal Circuit addressed the second of these, the The tangentiality exception, in at least three cases during 2008. In Regents of the University of California v. Dakocytomation California, Inc.,⁷⁷⁵ the Federal Circuit rejected the trial court's ruling that prosecution history estoppel barred the plaintiffs' allegations of infringement under the doctrine of equivalents.⁷⁷⁶ The patent at issue was "directed to improved 'methods for identifying and classifying chromosomes' in order to detect chromosomal abnormalities."777 The district court held that the patentees had narrowed the scope of the "blocking nucleic acid" limitation during prosecution.⁷⁷⁸ The district court therefore barred the plaintiffs from asserting that the defendants' peptide nucleic acids ("PNAs") were an equivalent of a "blocking nucleic acid" and granted summary judgment of noninfringement under the doctrine of equivalents.

On appeal, the plaintiffs argued that prosecution history estoppel did not apply because the "nucleic acid" limitation was not narrowed prosecution for a substantial purpose related to during patentability.⁷⁸⁰ Alternatively, they argued that the presumption of surrender was overcome because the rationale for the amendment was only tangentially related to the accused equivalent product.⁷⁸¹

The Federal Circuit concluded that the patentees presumptively surrendered all equivalents of the "blocking nucleic acid" limitation

^{773.} Festo, 535 U.S. 722.

^{774.} Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 344 F.3d 1359, 1369, 68 U.S.P.Q.2d (BNA) 1321, 1327 (Fed. Cir. 2005) (citing *Festo*, 535 U.S. at 740-41, 62 U.S.P.Q.2d (BNA) at 1714).

^{775. 517} F.3d 1364, 85 U.S.P.Q.2d (BNA) 1929 (Fed. Cir. 2008). 776. *Id.* at 1378, 85 U.S.P.Q.2d (BNA) at 1939.

^{777.} Id. at 1368, 85 U.S.P.Q.2d (BNA) at 1930 (quoting U.S. Patent No. 5,447,841 col.1 ll.21-22 (filed Dec. 14, 1990))

^{778.} Id. at 1376, 85 U.S.P.Q.2d (BNA) at 1937.
779. Id., 85 U.S.P.Q.2d (BNA) at 1937.
780. Id., 85 U.S.P.Q.2d (BNA) at 1937.
781. Id., 85 U.S.P.Q.2d (BNA) at 1937.

because they had amended the claim to overcome, at least in part, the examiner's rejections.⁷⁸² The Federal Circuit held that the presumption of surrender was overcome here "because the narrowing amendment was only tangential to the accused PNA equivalent."⁷⁸³ The court found that the prosecution history showed that the patentees' arguments in narrowing the claim focused on the method of blocking, not the type of nucleic acid.⁷⁸⁴ Indeed, the court found that the "nucleic acid" aspect of the claim was "not at issue in the office action rejecting the claims, the Examiner Interview Summary Record, or the patentees' remarks accompanying the amendment."785

The dissenting opinion of Judge Prost disagreed with the majority's application of the presumption of prosecution history estoppel.⁷⁸⁶ The amendment, Judge Prost stated, had more than a simple tangential relationship to the equivalent because it "limits the claims to a method of disabling repetitive sequences by blocking with 'blocking nucleic acids' (i.e., DNA or RNA)."787 Judge Prost stated that the patentees therefore "surrendered any other means of disabling repetitive sequences," but the accused equivalent (PNA) "functions to do exactly that, i.e., to disable repetitive sequences."788

In Lucent Technologies, Inc. v. Gateway, Inc., 789 however, Judge Prost wrote the opinion for the court rejecting the application of the tangentiality exception and holding that prosecution history estoppel barred infringement under the doctrine of equivalents.⁷⁹⁰ The patent at issue related to methods of compressing speech.⁷⁹¹ Plaintiff Lucent argued on appeal that the district court erred in finding that it had not rebutted the presumption of surrender through the tangentiality exception.⁷⁹² More specifically, Lucent argued that the accused equivalent diverged from the claimed invention in that:

[S]teps 1-4 (determining redundancies) are performed once per frame as opposed to once per pulse. This difference . . . is unrelated to the rationale for the amendment, which was to distinguish the claimed invention from the prior art based only on

^{782.} *Id.* at 1377–78, 85 U.S.P.Q.2d (BNA) at 1937–38. 783. *Id.* at 1378, 85 U.S.P.Q.2d (BNA) at 1939.

^{784.} *Id.* at 1381, 85 U.S.P.Q.2d (BNA) at 1941.
785. *Id.* at 1378, 85 U.S.P.Q.2d (BNA) at 1939.
786. *Id.* at 1380, 85 U.S.P.Q.2d (BNA) at 1940 (Prost, J., dissenting).
787. *Id.* at 1381, 85 U.S.P.Q.2d (BNA) at 1941.

^{788.} Id., 85 U.S.P.Q.2d (BŇA) at 1941

^{789. 525} F.3d 1200, 87 U.S.P.Q.2d (BNA) 1001 (Fed. Cir. 2008). 790. *Id.* at 1217, 87 U.S.P.Q.2d (BNA) at 1014–15.

^{791.} Id. at 1204, 87 U.S.P.Q.2d (BNA) at 1004.

^{792.} Id. at 1217, 87 U.S.P.Q.2d (BNA) at 1014.

the performance of step 5 (removing redundancies) during each pulse-forming iteration as opposed to during each frame-based iteration.⁷⁹³

The Federal Circuit again applied *Festo*'s test for the tangential peripheral, or not directly relevant, to the alleged equivalent"⁷⁹⁴—but the court concluded that the plaintiffs had not overcome the presumption of surrender.⁷⁹⁵ The court concluded that the patentee had amended the claims to add "a five-step iterative process for determining and removing redundancies during the pulse-forming loop."⁷⁹⁶ The claimed invention differed from the prior art because the invention determined pitch removal during each pulse-forming iteration.⁷⁹⁷ The alleged equivalent, however, "determine[d] pitch redundancy outside the iterative process for forming each loop," and the court therefore concluded that "the purpose for the amendment is not unrelated [i.e., not tangential] to the alleged equivalent."798

Similarly, in International Rectifier Corp. v. IXYS Corp., 799 the Federal Court held that the tangentiality exception did not apply.⁸⁰⁰ During the prosecution of its patent related to metal-oxide-semiconductor field effect transistors ("MOSFETs"), the patentee added an "adjoining" limitation to overcome the examiner's rejections.⁸⁰¹ The defendant argued that this amendment limited the claim only to MOSFETs devices and therefore precluded it from reaching IXYS's insulated gate bipolar transistors ("IGBTs").802

In response, the patentee argued that prosecution history estoppel did not apply to the "adjoining" limitation because it broadened the claim instead of narrowing it, and alternatively, that the tangential exception applied.⁸⁰³ The Federal Circuit held that the patentee was partially correct that the "adjoining" amendment was broadening in some respects.⁸⁰⁴ In other respects, however, "[t]his term excludes structures that might have been covered by the original claim

^{793.} Id., 87 U.S.P.Q.2d (BNA) at 1014.

^{794.} *Id.* at 1218, 87 U.S.P.Q.2d (BNA) at 1015 (quoting Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 344 F.3d 1359, 1369, 68 U.S.P.Q.2d (BNA) 1321, 1328 (Fed. Cir. 2003) (en banc)). 795. *Id.* at 1218, 87 U.S.P.Q.2d (BNA) at 1015.

^{795.} Id. at 1218, 87 U.S.P.Q.2d (BNA) at 1015.
796. Id., 87 U.S.P.Q.2d (BNA) at 1015.
797. Id., 87 U.S.P.Q.2d (BNA) at 1015.
798. Id., 87 U.S.P.Q.2d (BNA) at 1015.
799. 515 F.3d 1353, 85 U.S.P.Q.2d (BNA) 1907 (Fed. Cir. 2008).
800. Id. at 1359, 85 U.S.P.Q.2d (BNA) at 1912.
801. Id. at 1358, 85 U.S.P.Q.2d (BNA) at 1911.
802. Id., 85 U.S.P.Q.2d (BNA) at 1911.
803. Id. at 1358–59, 85 U.S.P.Q.2d (BNA) at 1911.

^{804.} Id. at 1359, 85 U.S.P.Q.2d (BNA) at 1911.

language," and "[t]he amendment therefore narrowed the scope of the claim."805

As to the tangentiality argument, the Federal Circuit acknowledged that the examiner rejected the original claim because the specification did not support all of its limitations and that the patentee overcame this rejection "by amending the claim to contain only the structural limitations disclosed in the text of the specification," a modification that might not have been required.⁸⁰⁶ Nonetheless, the court concluded that the patentee's decision to narrow the claim "using the limiting term 'adjoining,' whether or not *required* to overcome the rejection, cannot be described as only tangentially related to the equivalency of a structure with a nonadjoining regions."807

The foreseeability exception b.

Honeywell International, Inc. v. Hamilton Sundstrand Corp.⁸⁰⁸ involved both the tangentiality and foreseeability exceptions from Festo. The patent at issue involved "technology to control airflow surge in auxiliary power units or 'APUs.'"809 Honeywell alleged that Sundstrand's APS 3200 infringed claims of three of its patents under the doctrine of equivalents.⁸¹⁰ The district court held that Honeywell had not overcome the presumption of surrender under either the tangentiality or foreseeability exceptions and that prosecution history estoppel therefore precluded application of the doctrine of equivalents.811

The Federal Circuit agreed with the district court. In its tangentiality analysis, the Federal Circuit focused on the patentee's rewriting of dependent claims into independent ones.⁸¹² According to the court, by rewriting the dependent claims (which contained an "IGV limitation") as independent claims, the patentee "'effectively add[ed] the [IGV] limitation to the claimed invention."⁸¹³ The court

808. 523 F.3d 1304, 86 U.S.P.Q.2d (BNA) 1718 (Fed. Cir. 2008). 809. Id. at 1307, 86 U.S.P.Q.2d (BNA) at 1720.

^{805.} Id., 85 U.S.P.Q.2d (BNA) at 1911.

^{806.} Id., 85 U.S.P.Q.2d (BNA) at 1911-12.

^{807.} Id., 85 U.S.P.Q.2d (BNA) at 1912.

^{810.} *Id.* at 1310, 86 U.S.P.Q.2d (BNA) at 1722. 811. *Id.* at 1311, 86 U.S.P.Q.2d (BNA) at 1723.

^{812.} See id. at 1316, 86 U.S.P.Q.2d (BNA) at 1727 (emphasizing the need to assess "the patentee's objectively apparent reason for the narrowing amendment" (quoting Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 344 F.3d 1359, 1369, 68 U.S.P.Q.2d (BNA) 1321, 1328 (Fed. Cir. 2003))). 813. *Id.*, 86 U.S.P.Q.2d (BNA) at 1727 (quoting Honeywell Int'l Inc. v. Hamilton Sundstrand Corp., 370 F.3d 1131, 1144, 71 U.S.P.Q.2d (BNA) 1065, 1074 (Fed. Cir. 9004)).

^{2004)) (}alteration in original).

said that Honeywell had, in essence, amended the claims to add the IGV limitation and that "[b]ecause the alleged equivalent focuses on the IGV limitation, the amendment bore a direct, not merely tangential, relation to the equivalent."814

With respect to foreseeability, the essential inquiry is "whether the alleged equivalent would have been unforeseeable to one of ordinary skill in the art at the time of the amendment."815 By limiting the application of prosecution history estoppel only to unforeseeable equivalents, the exception "ensures that the doctrine [of equivalents] does not capture subject matter that the patent drafter could have foreseen during prosecution and included in the claims."⁸¹⁶ In Honeywell, the Federal Circuit had to decide whether the alleged equivalent—"the use of IGV position to detect high flow and low flow"-was later-developed technology and unforeseeable at the time of the amendments during prosecution.⁸¹⁷ The defendant had not developed the alleged equivalent until eight years after the patent amendments, but the Federal Circuit held that this timing was "ambiguous with respect to the foreseeability criterion" because, for example, the defendant had developed the equivalent quickly after noticing the problem.⁸¹⁸ The court ultimately found that "much of the extrinsic evidence-most notably several prior art references in the record—support[ed] the district court's decision" that the alleged equivalent was foreseeable to a person of ordinary skill at the time of the amendment.⁸¹⁹

In her dissenting opinion, Judge Newman argued that prosecution history estoppel did not apply because the claims were never substantively amended, only changed in form from dependent to independent claims.⁸²⁰ Judge Newman disagreed with the majority's "presumption of surrender to all equivalents of the claim elements and limitations that originated in dependent claims that were never amended and that were not the subject of prosecution history estoppel."821 According to Judge Newman, the majority's holding that "surrender of the entire universe of potential equivalents is presumed

^{814.} Id., 86 U.S.P.Q.2d (BNA) at 1727. 815. Id. at 1312, 86 U.S.P.Q.2d (BNA) at 1724 (quoting Festo, 344 F.3d at 1369, 68 U.S.P.Q.2d (BNA) at 1327).

^{816.} *Id.* at 1313, 86 U.S.P.Q.2d (BNA) at 1725. 817. *Id.*, 86 U.S.P.Q.2d (BŇA) at 1725.

^{818.} Id. at 1314, 86 U.S.P.Q.2d (BNA) at 1726.

^{819.} Id., 86 U.S.P.Q.2d (BNA) at 1726.

^{820.} See id. at 1321, 86. U.S.P.Q.2d (BNA) at 1731 (Newman, J., dissenting) ("Simply presenting claims of varying scope, whether in independent or dependent form, is not a narrowing amendment or argument."). 821. Id. at 1317, 86 U.S.P.Q.2d (BNA) at 1728.

when the original independent claim is cancelled,"822 even though there was no narrowing amendment or limiting argument during prosecution with respect to the dependent claims, "place[d] new constraints on the patentee's access to the doctrine of equivalents."823

With respect to the tangentiality exception, Judge Newman argued that the majority did not review the *reason* for the narrowing amendment and its relation to the accused equivalent as required by Festo.⁸²⁴ According to Judge Newman, "[t]his criterion relates to why an amendment was made; it does not become irrebuttable simply when the accused equivalent concerns the same element that was added by amendment."825

Furthermore, Judge Newman suggested that the majority applied significantly more restrictive criteria for the foreseeability exception than that established by the Supreme Court in *Festo*.⁸²⁶ According to Judge Newman, under Festo, "foreseeability means 'readily known equivalents,' not unknown equivalents developed a decade later."827 The alleged equivalent was not foreseeable because "[i]t was uncontradicted that the [alleged] equivalent was developed years after the [patentee's] application was filed and prosecuted, and only after considerable effort."828

2. Argument-based prosecution history estoppel

"In addition to amendment-based prosecution history estoppel, there can also be argument-based prosecution history estoppel."829 Argument-based prosecution history estoppel can arise when the patentee makes unmistakable statements surrendering claim scope during patent prosecution.⁸³⁰

In Cordis Corp. v. Medtronic AVE, Inc.,⁸³¹ the Federal Circuit engaged in an extensive analysis of argument-based prosecution history estoppel. One of the defendants argued that the district court should have instructed the jury that prosecution history estoppel limited the range of "equivalents of the 'wall surface' limitation."⁸

^{822.} Id., 86 U.S.P.Q.2d (BNA) at 1728.

^{822.} Id., of 0.5.1.4, .2.4 (DA1) at 1720.
823. Id. at 1318, 86 U.S.P.Q.2d (BNA) at 1729.
824. Id. at 1321-22, 86 U.S.P.Q.2d (BNA) at 1731-32.
825. Id. at 1322, 86 U.S.P.Q.2d (BNA) at 1732.

^{826.} Id. at 1318, 86 U.S.P.Q.2d (BNA) at 1729.

^{827.} Id. at 1319, 86 U.S.P.Q.2d (BNA) at 1730 (quoting Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 740, 62 U.S.P.Q.2d (BNA) 1705, 1713 (2002))

^{828.} Id. at 1321, 86 U.S.P.Q.2d (BNA) at 1731.

^{829.} SCHWARTZ, supra note 706, at 168.

^{830.} Id. at 168 n.81.

^{831. 511} F.3d 1157, 85 U.S.P.Q.2d (BNA) 1427 (Fed. Cir. 2008).

^{832.} Id. at 1176, 85 U.S.P.Q.2d (BNA) at 1440.

The appellant relied on *Omega Engineering, Inc. v. Raytek Corp.*,⁸³³ in which the Federal Circuit discussed "the relationship between prosecution disclaimer (limiting claim scope because of statements made by the patentee in prosecution) and argument-based prosecution history estoppel (limiting the scope of the doctrine of equivalents because of statements made by the patentee in prosecution)."834 In Omega, the Federal Circuit stated that both prosecution disclaimer and argument-based estoppel required "clear and unmistakable" disavowing actions or statements during prosecution.835

The Federal Circuit agreed with the district court that the patentee had not made any broad disclaimer regarding the "wall surface" limitation during the prosecution history.⁸³⁶ Instead, the patentee had "simply made explicit the meaning of the term 'wall surface' that was already implicit in the patent."⁸³⁷ A "reference to the 'common cylindrical plane' in the prosecution history therefore did not disclaim any subject matter that was otherwise within the scope of the claim language, but merely explained, in more explicit terms, what the claims already covered."838 Thus, the Federal Circuit held, there was no "clear and unmistakable disavowal of claim scope that would eliminate any equivalents of the 'wall surface' limitation."839

Other limitations on the Doctrine of Equivalents 3.

The doctrine of equivalents is subject to additional limitations besides prosecution history estoppel. For example, "the 'all limitations rule' restricts the application of the doctrine of equivalents if doing so would vitiate a claim limitation."⁸⁴⁰ When considering whether the doctrine of equivalents would vitiate a claim limitation, a court must consider "whether the alleged equivalent can be fairly characterized as an insubstantial change from the claimed subject matter without rendering the pertinent limitation meaningless."841

^{833. 334} F.3d 1314, 67 U.S.P.Q.2d (BNA) 1321 (Fed. Cir. 2003).
834. Cordis, 511 F.3d at 1177, 85 U.S.P.Q.2d (BNA) at 1441.
835. Omega, 334 F.3d at 1325–26, 67 U.S.P.Q.2d (BNA) at 1329.
836. Cordis, 511 F.3d at 1177, 85 U.S.P.Q.2d (BNA) at 1441.

^{837.} *Id.*, 85 U.S.P.Q.2d (BNA) at 1441. 838. *Id.*, 85 U.S.P.Q.2d (BNA) at 1442.

^{839.} Id. at 1178, 85 U.S.P.Q.2d (BNA) at 1442.

^{840.} Carnegie Mellon Univ. v. Hoffmann-La Roche, Inc., 541 F.3d 1115, 1129, 88 U.S.P.Q.2d (BNA) 1233, 1243 (Fed. Cir. 2008) (citing Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 29, 41 U.S.P.Q.2d (BNA) 1865, 1871 (1997)).

^{841.} Id., 88 U.S.P.Q.2d (BNA) at 1243 (citing Freedman Seating Co. v. Am. Seating Co., 420 F.3d 1350, 1359, 76 U.S.P.Q.2d (BNA) 1001, 1008 (Fed. Cir. 2005)).

In Carnegie Mellon University v. Hoffman-La Roche, Inc., the Federal Court held that the "all limitations rule" prevented the patentee's use of the doctrine of equivalents.⁸⁴² The patents related to "novel recombinant plasmids for the enhanced expression of an enzyme" and to "methods for the conditional control of the expression of said enzyme."⁸⁴³ During prosecution, the patentee "specifically chose to limit claim 4 to a recombinant plasmid where the bacterial source [was] *E. coli*."⁸⁴⁴ In litigation, the patentee argued that the defendant's product, which replaced *E. coli* with an enzyme known as Thermus aquaticus ("Taq") was insubstantial and equivalent to the plaintiff's product.⁸⁴⁵ The Federal Circuit, however, concluded that "a finding that *Taq* is an equivalent of *E. coli* would essentially render the 'bacterial source [is] E. coli' claim limitation meaningless, and would thus vitiate that limitation of the claims."⁸⁴⁶ After they "specifically chose" E. coli to be the bacterial source, the plaintiffs "cannot now argue that any bacterial source . . . would infringe that claim."847

In Cohesive Technologies, Inc. v. Waters Corp.,848 the Federal Circuit held that "[w]here . . . a patentee has brought what would otherwise be equivalents of a limitation into the literal scope of the claim, the doctrine of equivalents is unavailable to further broaden the scope of the claim."849 The patents at issue related to High Performance Liquid Chromatography ("HPLC"), which is a "process for separating, identifying, and measuring compounds contained in a liquid."850 The key claim limitation at issue referred to particles "having average diameters of greater than *about* 30 μm."⁸⁵¹ The Federal Court's decision focused on the meaning of the word "about" in the phrase "about 30 µm."⁸⁵²

The patent owner accused the defendant's "30 µm" HPLC columns of being within the scope of equivalents of the "about 30 µm" limitation.⁸⁵³ The Federal Circuit, however, concluded that "the word 'about' in the context of the written description and the claims . . . makes clear [that] 'about 30 µm' encompasses particle diameters that

^{842.} Id. at 1129, 88 U.S.P.Q.2d (BNA) at 1243.

^{842.} *Id.* at 1123, 66 U.S.I. S. Ed. (BIAT) at 1235.
843. *Id.* at 1118, 88 U.S.P.Q.2d (BNA) at 1235.
844. *Id.* at 1129, 88 U.S.P.Q.2d (BNA) at 1243.
845. *Id.* at 1128, 88 U.S.P.Q.2d (BNA) at 1242.

^{846.} Id. at 1129, 88 U.S.P.Q.2d (BNA) at 1243 (alteration in original).

^{847.} *Id.*, 88 U.S.P.Q.2d (BNA) at 1243.
848. 543 F.3d 1351, 88 U.S.P.Q.2d (BNA) 1903 (Fed. Cir. 2008).

^{849.} *Id.* at 1372, 88 U.S.P.Q.2d (BNA) at 1916. 850. *Id.* at 1357–58, 88 U.S.P.Q.2d (BNA) at 1906.

^{851.} *Id.* at 1358, 88 U.S.P.Q.2d (BNA) at 1906 (emphasis added). 852. *See id.* at 1371–72, 88 U.S.P.Q.2d (BNA) at 1916–17 (analyzing the purpose of

the numeric range in the limitation).

perform the same function, in the same way, with the same result as the 30 µm particles."⁸⁵⁴ Thus, such equivalents are already within the literal scope of the claim and the "patentee cannot rely on the doctrine of equivalents to encompass equivalents of equivalents."855

The Reverse Doctrine of Equivalents С.

The mirror image of the doctrine of equivalents is the reverse doctrine of equivalents. The reverse doctrine of equivalents "allows a court to find no infringement even though each element of the patent's claim literally reads on the product or process of the alleged infringer."⁸⁵⁶ It is a factual determination and the test is "whether the apparently literally infringing product or process is so far changed in principle that it performs the same or similar function in a substantially different way."857 The Federal Circuit "has never affirmed a finding of non-infringement under the reverse doctrine of equivalents,"858 and 2008 was no exception.

In Roche Palo Alto LLC v. Apotex, Inc., the defendant Apotex attempted unsuccessfully to invoke the reverse doctrine of equivalents as a defense against infringement.⁸⁵⁹ Plaintiff Roche asserted infringement by Apotex based on a drug formulation covered by an Apotex abbreviated new drug application ("ANDA") that was directed to a generic version of Roche's ACULAR LS drug.⁸⁶⁰ The defendant did not argue that its formulation fell outside of the literal scope of the patent; instead it argued that its formulation did not infringe under the reverse doctrine of equivalents.⁸⁶¹

The defendant argued that:

[A] person of ordinary skill in the art would recognize that the 'principle' of [the asserted patent] is the use of [Octoxynol 40] in an amount sufficient to cause the formation of micelles and thereby provide robust stability to the formulation by preventing interactions between [ketorolac [benzalkonium chloride].⁸⁶² tromethamine] and

According to the defendant, the concentration of Octoxynol 40 in its drug formulation "is far below the concentration required to form

^{854.} Id. at 1372, 88 U.S.P.Q.2d (BNA) at 1916.

^{855.} Id., 88 U.S.P.Q.2d (BŇA) at 1917.

^{856.} SCHWARTZ, *supra* note 706, at 169.

^{857.} Id.

^{858.} Roche Palo Alto, LLC v. Apotex, Inc., 531 F.3d 1372, 1378, 87 U.S.P.Q.2d (BNA) 1308, 1311 (Fed. Cir. 2008).

^{859.} *Id.* at 1378, 87 U.S.P.Q.2d (BNA) at 1311. 860. *Id.* at 1374–76, 87 U.S.P.Q.2d (BNA) at 1309–11.

^{861.} Id. at 1376, 87 U.S.P.Q.2d (BNA) at 1310.

^{862.} Id. at 1378, 87 U.S.P.Q.2d (BNA) at 1311.

micelles."863 According to the defendant, its formulation was "stabilized by a completely different ingredient and mechanism, and a 'substantially different way' functions in from" Roche's formulation.⁸⁶⁴

The Federal Circuit, however, rejected the reverse doctrine of equivalents defense.⁸⁶⁵ The Federal Circuit held that the defendant had failed to properly establish the "principle" or "equitable scope of the claims" in the patented invention.⁸⁶⁶ The Federal Circuit noted that "[t]he 'principle' . . . of the patented invention is determined in light of the specification, prosecution history, and the prior art," but stated that there was "no mention of 'micelle'"-the core of the alleged "principle" of the patent-"in the claims, specification, or prosecution history."867 Furthermore, the specification disclosed a formulation containing the same concentration of Octoxynol 40 as in the alleged infringing formulation.⁸⁶⁸ The Federal Circuit therefore held that the defendant had failed to establish a prima facie case of non-infringement under the reverse doctrine of equivalents, and that the district court had properly granted summary judgment of literal infringement.⁸⁶⁹

D. Indirect Infringement

In 2008, the Federal Circuit also resolved a few cases dealing with Under 35 U.S.C. § 271(b), "'[w]hoever induced infringement. actively induces infringement of a patent shall be liable as an infringer.""870 To prevail on a claim of inducement, "the patentee must show, first that there has been direct infringement, and second that the alleged infringer knowingly induced infringement."871 Two years ago, in DSU Medical Corp. v. JMS Co.,872 the Federal Circuit clarified the meaning of the intent required for induced infringement.⁸⁷³ It "requires more than just intent to cause the acts that produce direct infringement. Beyond that threshold knowledge,

^{863.} Id., 87 U.S.P.Q.2d (BNA) at 1311.

^{864.} *Id.*, 87 U.S.P.Q.2d (BNA) at 1311.
865. *Id.* at 1378–79, 87 U.S.P.Q.2d (BNA) at 1312.
866. *Id.* at 1378, 87 U.S.P.Q.2d (BNA) at 1312.

^{867.} Id., 87 U.S.P.Q.2d (BŇA) at 1312.

^{868.} Id. at 1379, 87 U.S.P.Q.2d (BNA) at 1312.

^{869.} Id., 87 U.S.P.Q.2d (BNA) at 1312.

^{870.} Minn. Mining & Mfg. Co. v. Chemque, Inc., 303 F.3d 1294, 1304–05, 64 U.S.P.Q.2d (BNA) 1270, 1276 (Fed. Cir. 2002) (quoting 35 U.S.C. § 271(b) (2006)).

^{871.} Id., 85 U.S.P.Q.2d (BNA) at 1276-77 (internal citations omitted).

^{872. 471} F.3d 1293, 81 U.S.P.Q.2d (BNA) 1238 (Fed. Cir. 2006) (en banc).

^{873.} Id. at 1306, 81 U.S.P.Q.2d (BNA) at 1247.

AMERICAN UNIVERSITY LAW REVIEW

the inducer must have an affirmative intent to cause direct infringement."874

In Kyocera Wireless Corp. v. International Trade Commission,⁸⁷⁵ the Federal Circuit reiterated the level of intent required for induced infringement.⁸⁷⁶ The ITC's administrative law judge decided the case before the DSU decision, and therefore only required a showing of "the intent to cause the acts that constitute infringement."⁸⁷⁷ The Federal Circuit explained that although proper at the time, this approach was improper after *DSU*.⁸⁷⁸ The court therefore vacated and remanded the ITC's determination of induced infringement.⁸⁷⁹ The Federal Circuit also reiterated that induced infringement requires not only intent to cause the infringing acts, but also "'evidence of culpable conduct, directed to encouraging another's infringement,' i.e., specific intent to encourage infringement."880 The court did, however, note that this specific intent may be shown by circumstantial evidence.881

In Broadcom Corp. v. Qualcomm Inc.,⁸⁸² the Federal Circuit reiterated that circumstantial evidence can be sufficient to show intent for induced infringement.⁸⁸³ The district court had found that Qualcomm directly infringed and induced infringement of certain claims, either literally or under the doctrine of equivalents.⁸⁸⁴ The Federal Circuit agreed with the plaintiff Broadcom that substantial evidence supported the jury's induced-infringement verdict.⁸⁸⁵ The law, the court concluded, did not require direct evidence as defendant Qualcomm argued.⁸⁸⁶ The circumstantial evidence here was enough to establish intent, which under DSU required a showing that the alleged infringer "knew or should have known his actions would induce actual infringements."887 The court noted that Qualcomm did

^{874.} Id., 81 U.S.P.Q.2d (BNA) at 1247 (internal citations omitted).

^{875. 545} F.3d 1340, 89 U.S.P.Q.2d (BNA) 1057 (Fed. Cir. 2008).
876. *Id.* at 1354, 89 U.S.P.Q.2d (BNA) at 1067.

^{876.} Id. at 1354, 89 U.S.P.Q.2d (BNA) at 1067.
877. Id., 89 U.S.P.Q.2d (BNA) at 1067.
878. Id., 89 U.S.P.Q.2d (BNA) at 1067.
879. Id., 89 U.S.P.Q.2d (BNA) at 1067.
880. Id., 89 U.S.P.Q.2d (BNA) at 1067 (quoting DSU Med. Corp. v. JMS Co., 471
F.3d 1293, 1306, 81 U.S.P.Q.2d (BNA) at 1067.

^{881.} *Id.*, 89 U.S.P.Q.2d (BNA) at 1067. 882. 543 F.3d 683, 88 U.S.P.Q.2d (BNA) 1641 (Fed. Cir. 2008). For discussion of this case's implications upon permanent injunctions, see infra notes 1663–1676 and accompanying text. 883. Id. at 699–700, 88 U.S.P.Q.2d (BNA) at 1654–55.

^{884.} *Id.*, 88 U.S.P.Q.2d (BNA) at 1654–55. 885. *Id.* at 700, 88 U.S.P.Q.2d (BNA) at 1655.

^{886.} Id., 88 U.S.P.Q.2d (BNA) at 1655.

^{887.} *Id.* at 699, 88 U.S.P.Q.2d (BNA) at 1654 (quoting DSU Med. Corp. v. JMS Co., 471 F.3d 1293, 1306, 81 U.S.P.Q.2d (BNA) 1238, 1247 (Fed. Cir. 2006) (emphasis added)).

"not dispute that it was on notice of Broadcom's patents and infringement contentions," conceded it "worked closely with its customers to develop and support the accused products," and did not "make changes to those products or give its customers" warnings even after suit was filed.⁸⁸⁸

Qualcomm had also argued that the district court erred by instructing the jury to consider a failure to obtain an opinion of counsel as a factor in determining intent to induce infringement.⁸⁸⁹ Qualcomm argued that the Federal Circuit's decision in In re Seagate⁸⁹⁰ made such an instruction erroneous. According to Qualcomm. because the Federal Circuit held in *Seagate* that willful infringement under 35 U.S.C. § 284 would be determined based on an "objective recklessness" standard and that a defendant had no obligation to obtain opinion of counsel to defeat allegations of willful infringement, there also could be no such obligation for a defendant accused of induced infringement as the Federal Circuit had established in DSU that induced infringement put an even higher burden on the plaintiff—i.e., showing specific intent.⁸⁹¹

The Federal Circuit, however, rejected Qualcomm's assertion that opinion-of-counsel evidence is no longer relevant in determining intent to induce infringement.⁸⁹² According to the court, Qualcomm was correct that a defendant has no affirmative duty to seek an opinion of counsel and that, as the Federal Circuit held in Knorr-Bremse Systeme Fuer Nutzfahrzeuge, GmbH v. Dana Corp.,⁸⁹³ a court may not impose, when a defendant fails to obtain an opinion of counsel, an "adverse inference or evidentiary presumption that such an opinion would have been unfavorable."⁸⁹⁴ The Federal Circuit, however, held that even if an adverse inference or evidentiary presumption was inappropriate, a failure to obtain counsel's opinion could be a factor that a jury could consider in evaluating an alleged infringer's intent.⁸⁹⁵ "Because opinion-of-counsel evidence, along with other factors, may reflect whether the accused infringer 'knew or should have known' that its actions would cause another to directly infringe . . . such evidence remains relevant."896 The court stated that

^{888.} Id. at 700, 88 U.S.P.Q.2d (BNA) at 1655 (internal quotations omitted).

^{889.} Id. at 698–99, 88 U.S.P.Q.2d (BNA) at 1654.

^{890. 497} F.3d 1360, 83 U.S.P.Q.2d (BNA) 1865 (Fed. Cir. 2007) (en banc).

^{891.} Broadcom, 543 F.3d at 699, 88 U.S.P.Q.2d (BNA) at 1654.

^{892.} Id., 88 U.S.P.Q.2d (BNA) at 1654.

³⁸³ F.3d 1337, 72 Ù.S.P.Q.2d (BNA) 1560 (Fed. Cir. 2004) (en banc). 893.

^{894.} Broadcom, 543 F.3d at 699, 88 U.S.P.Q.2d (BNA) at 1654 (quoting Knorr-Bremse, 383 F.3d at 1346, 72 U.S.P.Q.2d (BNA) at 1566).

^{895.} Id. at 699-700, 88 U.S.P.Q.2d (BNA) at 1654-55.

^{896.} Id. at 699, 88 U.S.P.Q.2d (BNA) at 1655.

just as an opinion of counsel can be used by a defendant as exculpatory evidence with respect to intent under DSU, "failures to procure such advice" can be circumstantial evidence used by a plaintiff to show intent to infringe.⁸⁹⁷

The Federal Circuit also was not swayed by Qualcomm's argument based on Seagate. The Federal Circuit held that, whatever effect Seagate's objective recklessness standard may have had to limit the relevance of opinion of counsel with respect to willful infringement, the standard for induced infringement continued to be the "specific intent" standard established in DSU, and on that question, opinion-ofcounsel evidence remained relevant.898

Finally, in another induced-infringement case, Symantec Corp. v. Computer Associates International, Inc.,899 the Federal Circuit reversed a district court's grant of summary judgment of non-infringement. The district court held that the patentee had not established induced infringement because it had not shown direct infringement by third parties.⁹⁰⁰ On appeal, the Federal Circuit vacated and remanded the district court's summary judgment.⁹⁰¹ The court held that even though the plaintiff had not produced evidence that "any particular customer" had directly infringed, the plaintiff had shown that the defendant encouraged customers to use the accused products and that customers could use those products only in an infringing way.⁹⁰² The plaintiff therefore had "produced sufficient circumstantial evidence of direct infringement to create a genuine issue of material fact."903

The Federal Circuit also addressed in 2008 "an important, and previously unresolved, question concerning the scope of liability" under the second form of indirect infringement-contributory infringement under § 271(c).⁹⁰⁴ In Ricoh Co., Ltd. v. Quanta Computer Inc., 550 F.3d 1325 (Fed. Cir. 2008), the accused infringer manufactured an optical disk drive that, for purposes of the appeal, was assumed to contain both (a) components that had no substantial noninfringing use (i.e., separate hardware and embedded software modules that necessarily performed the patented process) and (b) components that did have substantial noninfringing uses.⁹⁰⁵ The

^{897.} Id., 88 U.S.P.Q.2d (BNA) at 1655.

^{898.} Id., 88 U.S.P.Q.2d (BNA) at 1655.

^{899. 522} F.3d. 1279, 86 U.S.P.Q.2d. (BNA) 1449 (Fed. Cir. 2008).
900. *Id.* at 1287, 86 U.S.P.Q.2d (BNA) at 1453.

^{901.} Id. at 1299, 86 U.S.P.Q.2d (BNA) at 1461.

^{902.} Id. at 1293, 86 U.S.P.Q.2d (BNA) at 1457.

^{903.} Id., 86 U.S.P.Q.2d (BNA) at 1457 (emphasis added).

^{904.} Ricoh Co., Ltd. v. Quanta Computer Inc., 550 F.3d 1325, 1336, 89 U.S.P.Q.2d

^{1577, 1585 (}Fed. Cir. 2008)

^{905.} Id., 89 U.S.P.Q.2d (BNA) at 1585.

accused manufacturer could not be held directly liable because only its customers practiced the patented method, but the patent owner sought to hold the manufacturer liable for indirect contributory infringement under § 271(c). Section 271(c) imposes liability on anyone who sells "a component of a patented machine, manufacture, combination, or composition, or a material or apparatus for use in practicing a patented process," if, among other things, the component, material, or apparatus is not "suitable for substantial noninfringing use."906

In a *per curiam* decision, the Federal Circuit held that the accused manufacturer could be held liable for contributory infringement under § 271(c). Even though the ultimate device that the accused manufacturer sold—*i.e.*, the optical disk drive—had substantial noninfringing uses, the Federal Circuit held that the sale of the disk drive could constitute contributory infringement based on the included component that did not have substantial noninfringing uses.⁹⁰⁷ The court stated that under any other rule, evasion of § 271(c) "would become rather easy": a manufacturer that wanted to sell hardware that would be used to infringe a patented process could avoid contributory liability simply by adding additional hardware that also performs another (noninfringing) process.⁹⁰⁸

Judge Gajarsa dissented. He argued that, under the Federal Circuit's prior decision in Hodosh v. Block Drug Co., Inc., 833 F.2d 1575 (Fed. Cir. 1987), the accused manufacturer could be considered, for purposes of § 271(c), to have "sold" only the optical disk drive (which had substantial noninfringing uses) and not the component.⁹⁰⁹ Judge Gajarsa also argued that the facts in *Ricoh* did not rise to the standard for contributory infringement established by the Supreme Court in Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltc., 545 U.S. 913 (2005), which Judge Gajarsa said allowed such liability only where one could "presume an intent that a product [would] be used to infringe another's patent"910 and where there was "more acute fault than the mere understanding that some of one's products will be misused."911

^{906. 35} U.S.C. § 271(c).

^{907. 550} F.3d at 1337-38, 89 U.S.P.Q.2d (BNA) at 1586-87.

^{908.} Id., 89 U.S.P.Q.2d (BNA) at 1586.

^{909.} *Id.* at 1345, 89 U.S.P.Q.2d (BNA) at 1592.
910. *Id.* at 1346, 89 U.S.P.Q.2d (BNA) at 1592.

^{911.} *Id.*, 89 U.S.P.Q.2d (BNA) at 1593 (quoting Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd., 545 U.S. 913, 932-33, 75 U.S.P.Q.2d 1001, 1010 (2005)).

Section 271(e)(1): Research Exemption to Infringement *E*.

The Federal Circuit resolved two cases dealing with 35 U.S.C. § 271(e)(1), the "safe harbor" statute that protects from infringement liability the making, sale, use, or importation of a patented invention "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."⁹¹² In Amgen, Inc. v. International Trade Commission,⁹¹³ Amgen complained to the ITC that Roche's importation of human erythropoietin and derivatives (collectively "EPO") was in violation of section 337 of the Tariff Act of 1930, as amended.⁹¹⁴ Amgen argued that the EPO and the process by which it was made in Europe infringed Amgen's patents.⁹¹⁵ Roche moved for summary judgment, and the Commission granted it, holding that the importation of EPO was protected by the § 271(e)(1) safe harbor.⁹¹⁶ Amgen appealed the Commission's ruling, arguing that the $\S 271(e)(1)$ safe-harbor statute did "not apply to Tariff Act violations based on foreign practice of patented processes," and, moreover, that "not all of the imported EPO was used for the statute's exempt purposes."⁹¹⁷ Amgen argued that the safe-harbor statute did not protect the importation at issue because liability was based, in part, on the infringement of process patents.⁹¹⁸ The safe-harbor statute protects the importation of only "patented invention[s]"; Amgen argued that "a process cannot be imported" and that importation of products produced offshore by an infringing process therefore would not fall within the safe harbor.⁹¹⁹ Amgen also indicated that the Commission had "a long-standing . . . right" to block importation based on offshore practice of U.S. patented process⁹²⁰ and argued that Congress preserved this authority when it enacted § 271(g) in $1988.^{921}$ Amgen cited Congress's statement that the addition of § 271(g) "shall not deprive the patent owner of any remedies available under subsections (a) through (f) of

^{912.} 35 U.S.C. § 271(e)(1) (2006).

^{913. 519} F.3d 1343, 86 U.S.P.Q.2d (BNA) 1188 (Fed. Cir. 2008).
914. Id. at 1344-45, 86 U.S.P.Q.2d (BNA) at 1189; see also Tariff Act of 1930,

¹⁹ U.S.C. § 1337 (2006). 915. *Id.* at 1345, 86 U.S.P.Q.2d (BNA) at 1189. A foreign process can be the basis for U.S. infringement liability under 35 U.S.C. § 271(g), which provides that importing a product "made by a process patented in the United States" constitutes infringement. 35 U.S.C. § 271(g) (2006). 916. Amgen, 519 F.3d at 1345, 86 U.S.P.Q.2d (BNA) at 1189.

^{910.} Allgel, 513 P.St at 1945, 60 C.S. 1.Q.2d (1917. Id., 86 U.S.P.Q.2d (BNA) at 1189.
918. Id., 86 U.S.P.Q.2d (BNA) at 1189.
919. Id. at 1346, 86 U.S.P.Q.2d (BNA) at 1190.

^{920.} Id., 86 U.S.P.Q.2d (BNA) at 1190.

^{921.} Id. at 1347, 86 U.S.P.Q.2d (BNA) at 1190.

section 271 . . . [and] under Section 337 of the Tariff Act of 1930."922 According to Amgen, this showed that although the safe harbor might block process patent infringement when enforced in the district courts under § 271(g), a remedy was retained for processpatent infringement enforced under section 337.923

Judge Newman's majority opinion agreed with the Commission that the safe-harbor statute protected Roche's EPO from section 337 exclusion "not only as to infringement of Amgen's product patents but also as to Amgen's process patents."⁹²⁴ According to the majority, § 271(g)'s legislative history as well as Supreme Court guidance supported the Commission's ruling.⁹²⁵ The majority cited a congressional report directly on this issue, stating that Congress did

not intend that it shall be an act of infringement to import a product which is made by a process patented in the United States "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs."926

The Federal Circuit also cited Supreme Court statements emphasizing Congress's broad purpose "of removing patent-based barriers to proceeding with federal regulatory approval of medically products."927 The court said that this "weigh[ed] heavily against selectively withholding the $\S 271(e)(1)$ exemption depending on whether the infringement action is in the district court or the International Trade Commission."928 That interpretation of this broad policy has extended § 271(e)(1) to "all uses of patented inventions that are reasonably related to the development and submission of any information under the FDCA."929 The Federal Circuit therefore "affirm[ed] the Commission's ruling that the safe harbor statute applies to process patents in actions under Section 337, when the imported product is used for the exempt purposes of § 271(e)(1)."930

With respect to Amgen's second argument—that at least some of the imported EPO was "not exempt because its actual use was not

^{922.} *Id.*, 86 U.S.P.Q.2d (BNA) at 1191 (quoting Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-418, § 9006(c), 102 Stat. 1107, 1567 (1988) (codified at 35 U.S.C. § 272 (2006)). 923. *Id.*, 86 U.S.P.Q.2d (BNA) at 1191.

^{924.} *Id.* at 1348, 86 U.S.P.Q.2d (BNA) at 1191. 925. *Id.*, 86 U.S.P.Q.2d (BNA) at 1191–92.

^{926.} Id., 86 U.S.P.Q.2d (BNA) at 1191-92 (citing S. REP. NO. 100-83, at 48 (1987)).

^{927.} Id., 86 U.S.P.Q.2d (BNA) at 1192.

^{928.} *Id.* at 1348–49, 86 U.S.P.Q.2d (BNA) at 1192. 929. *Id.* at 1348–49, 86 U.S.P.Q.2d (BNA) at 1192. 929. *Id.* at 1348, 86 U.S.P.Q.2d (BNA) at 1192 (quoting Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 202, 74 U.S.P.Q.2d (BNA) 1801, 1805 (2005)).

reasonably related to the development and submission of information"931—the Federal Circuit remanded the case back to the Commission to determine the exempt status of each study in which the EPO was to be used.932

In his dissent, Judge Linn agreed with the majority that $\S 271(e)(1)$ was intended to protect process patents, but he argued that the statute's protection did not extend to block the *Commission's* authority to exclude imports. Judge Linn noted that "§ 271(e)(1) declares that certain activities 'shall not be an act of infringement,'" whereas the plain language of section 337 of the Tariff Act allows the Commission to exclude products even without an act of infringement.⁹³³ Although a separate section, section 1337(a)(1)(B)(i), makes it unlawful to import articles that "infringe a valid and enforceable United States patent,"⁹³⁴ section 1337(a)(1)(B)(ii) prohibits importation of articles that "are made, produced, processed . . . [by] a process covered by the claims of a valid and enforceable United States patent."935 According to Judge Linn, "this difference in language [was] not accidental," and the legislative history showed that process claims are not within the safe-harbor statute.⁹³⁶

In Proveris Scientific Corp. v. Innovasystems, Inc., 937 the Federal Circuit considered whether the § 271(e)(1) safe harbor applied to the importation of products that were not themselves regulated but that were used with regulated devices.⁹³⁸ Plaintiff Proveris sued Innovasystems ("Innova") for infringing its patent related to nasal spray pumps and inhalers.⁹³⁹ Innova's accused device—an Optical Spray Analyzer ("OSA")—is not FDA-regulated, but it is used with a regulated device.⁹⁴⁰ Innova argued that the safe-harbor statute protected the OSA devices because they were "used by third parties solely for the development and submission of information to the

^{931.} Id. at 1349, 86 U.S.P.Q.2d (BNA) at 1192.

^{932.} *Id.* at 1350, 86 U.S.P.Q.2d (BNA) at 1193.
933. *See id.* at 1353, 86 U.S.P.Q.2d (BNA) at 1195 (Linn, J., dissenting) ("19 U.S.C. § 1337(a) (1) (B) (ii) does not require an act of infringement for the Commission to

issue an exclusion order."). 934. Id., 86 U.S.P.Q.2d (BNA) at 1195 (quoting 19 U.S.C. § 1337(a) (1) (B) (i) (2006)) (emphasis added).

^{935.} Id., 86 U.S.P.Q.2d (BNA) at 1195 (quoting § 1337(a) (1) (B) (ii)).
936. Id. at 1353-54, 86 U.S.P.Q.2d (BNA) at 1195-96.
937. 536 F.3d 1256, 87 U.S.P.Q.2d (BNA) 1602 (Fed. Cir. 2008).

^{938.} Id. at 1258, 87 U.S.P.Q.2d (BNA) at 1604.

^{939.} Id., 87 U.S.P.Q.2d (BNA) at 1604.

^{940.} Id. at 1259, 87 U.S.P.Q.2d (BNA) at 1604.

FDA."941 The district court, however, ruled as a matter of law that the safe-harbor statute did not include the OSA devices.⁹⁴²

The Federal Circuit affirmed, noting that one of the purposes of the Hatch-Waxman Act was to eliminate the de facto extension in patent life caused by the fact that other parties could not produce competitive products upon expiration of a patent because such products required FDA pre-market approval, and a competitor ordinarily could not begin that process until after the patent expired.⁹⁴³ Section 271(e)(1) sought to eliminate that distortion "by providing a safe harbor that immunized competitors from infringement on account of making, using, offering to sell, or selling ... a 'patented invention solely for use reasonably related'" to an FDA submission.⁹⁴⁴ "The basic idea behind this provision was to allow competitors to begin the regulatory approval process while the patent was still in force, followed by the market entry immediately upon patent expiration."945

The Federal Circuit concluded that the OSA devices are protected by the § 271(e)(1) safe harbor because they are not subject to the FDA pre-market approval,⁹⁴⁶ and they thus "face[] no regulatory barriers to market entry upon patent expiration."947 The defendant Innova was therefore "not a party who, prior to [§ 271(e)(1)], could be said to have been adversely affected by the [above-mentioned] distortion."948 In short, because Proveris's patented product "is not subject to a required [Federal Drug and Cosmetic Act] approval process, it does not need the safe harbor protection afforded by 35 U.S.C. § 271(e)(1)."949

F. Design Patent Infringement

In Egyptian Goddess, Inc. v. Swisa, Inc.,950 the Federal Circuit reconsidered (in an en banc proceeding) the appropriateness of its point-of-novelty test in design patent cases.⁹⁵¹ The main issue before

^{941.} Id. at 1260, 87 U.S.P.Q.2d (BNA) at 1605.

^{942.} Id., 87 U.S.P.Q.2d (BNA) at 1605. 943. Id. at 1260–61, 87 U.S.P.Q.2d (BNA) at 1605.

^{944.} Id. at 1261, 87 U.S.P.Q.2d (BNA) at 1606 (quoting 35 U.S.C. § 271(e)(1) (2006)).

^{945.} Id. at 1261, 87 U.S.P.Q.2d (BNA) at 1606.

^{946.} Id. at 1265, 87 U.S.P.Q.2d (BNA) at 1609.

^{947.} *Id.*, 87 U.S.P.Q.2d (BNA) at 1609. 948. *Id.*, 87 U.S.P.Q.2d (BNA) at 1609.

^{949.} *Id.* at 1266, 87 U.S.P.Q.2d (BNA) at 1609. 950. 543 F.3d 665, 88 U.S.P.Q.2d (BNA) 1658 (Fed. Cir. 2008) (en banc).

^{951.} Id. at 671, 88 U.S.P.Q.2d (BNA) at 1662-63.

the Court was "whether the 'point of novelty' test should continue to be used as a test for infringement of a design patent."952

The Federal Circuit began by discussing the rule of law for design patent infringement established by the Supreme Court in Gorham Co. *v. White.*⁹⁵³ In that case, the Supreme Court established the "ordinary observer test" as the proper standard to determine infringement of a design patent.⁹⁵⁴ Accordingly,

if, in the eye of an ordinary observer, giving such attention as a purchaser usually gives, two designs are substantially the same, if the resemblance is such as to deceive such an observer, inducing him to purchase one supposing it to be the other, the first one patented is infringed by the other.⁹⁵⁵

The Federal Circuit acknowledged that, since its 1984 case, Litton Systems, Inc. v. Whirlpool Corp.,⁹⁵⁶ it has held that satisfying the ordinaryobserver test is not sufficient to prove similarity.⁹⁵⁷ Rather, the court has also required patentees to satisfy a "point of novelty test," which requires that the accused design "also appropriate the novelty of the claimed design in order to be deemed infringing."958 Thus. in essence, "[f]or a design patent to be infringed . . . no matter how similar two items look, 'the accused device must appropriate the novelty in the patented device which distinguishes it from the prior art.""959 Since its inception, the point-of-novelty test has been used both as "conjunctive" with, and "distinct" from, the ordinary-observer test.⁹⁶⁰

On appeal, the plaintiff urged the Federal Circuit to abandon the point-of-novelty test⁹⁶¹ and replace it with an ordinary-observer test focusing on the "appearance that distinguishes the patented design from the prior art."⁹⁶² The defendant attempted to defend the pointof-novelty test,963 arguing that the Supreme Court had adopted the test in an 1893 decision, Smith v. Whitman Saddle Co.964

^{952.} Id. at 670, 88 U.S.P.Q.2d (BNA) at 1661.

^{953. 81} U.S. 511 (1871).

<sup>615. 51. 61. (1011).
62.</sup> Egyptian Goddess, 542 F.3d at 670, 88 U.S.P.Q.2d (BNA) at 1662.
63. 728 F.2d 1423, 221 U.S.P.Q.2d (BNA) 97 (Fed. Cir. 1984).

^{657.} Egyptian Goddess, 542 F.3d at 670, 88 U.S.P.Q.2d (BNA) at 1662.
958. Id., 88 U.S.P.Q.2d (BNA) at 1662.
959. Id. at 670-71, 88 U.S.P.Q.2d (BNA) at 1662 (quoting Litton, 728 F.2d at 1444, 221 U.S.P.Q.2d (BNA) at 109).

^{960.} *Id.* at 671, 88 U.S.P.Q.2d (BNA) at 1663. 961. *Id.* at 672, 88 U.S.P.Q.2d (BNA) at 1663.

^{962.} *Id.*, 88 U.S.P.Q.2d (BNA) at 1663. 963. *Id.*, 88 U.S.P.Q.2d (BNA) at 1663.

^{964. 148} U.S. 674 (1893).

After a lengthy discussion of *Whitman Saddle*, the Federal Circuit concluded that "[n]othing in the Court's opinion suggested that it was fashioning a separate point of novelty test for infringement."965 The court therefore held that the point-of-novelty test "should no longer be used in the analysis of a claim of design patent infringement [case] . . . [T]he 'ordinary observer' test should be the sole test³⁶⁶ Finally, the Federal Court applied the ordinaryobserver test and affirmed the summary judgment of noninfringement.967

V. PATENTABILITY AND VALIDITY

Every issued patent is presumed to be valid, and each claim of a patent is "presumed valid independently of the validity of other claims."968 This statutory presumption of validity arises because it is assumed that the patent examiner conducted a diligent review of the prior art and verified that all requirements of patentability were met before allowing the claims.⁹⁶⁹ An alleged infringer may overcome the statutory presumption of validity only upon a showing of clear and convincing evidence of invalidity.⁹⁷⁰

A. Patentable Subject Matter

It is a well-known threshold requirement that, in order to qualify for patent protection, an invention must encompass patentable subject matter. The Patent Act 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."⁹⁷¹ Therefore, a patent's validity may be challenged if the claimed subject matter does not fall within one of the four statutory classes listed above.

^{965.} Egyptian Goddess, 543 F.3d at 673, 88 U.S.P.Q.2d (BNA) at 1664–65.
966. Id. at 678, 88 U.S.P.Q.2d (BNA) at 1668.
967. Id. at 680–83, 88 U.S.P.Q.2d (BNA) at 1670–72.

^{968.} 35 U.S.C. § 282 (2006).

^{969.} See Intervet Am., Inc. v. Kee-Vet Labs., Inc., 887 F.2d 1050, 1054, 12 U.S.P.Q.2d (BNA) 1474, 1477 (Fed. Cir. 1989) ("The presumption of validity ... carries with it a presumption the examiner did his duty and knew what claims he was allowing.").

^{970.} See, e.g., Ultra-Tex Surfaces, Inc. v. Hill Bros. Chem. Co., 204 F.3d 1360, 1367, 53 U.S.P.Q.2d (BNA) 1892, 1898 (Fed. Cir. 2000); Robotic Vision Sys., Inc. v. View Eng'g, Inc., 189 F.3d 1370, 1377, 51 U.S.P.Q.2d (BNA) 1948, 1953 (Fed. Cir. 1999); Medtronic Inc. v. Intermedics, Inc., 799 F.2d 734, 741, 230 U.S.P.Q. (BNA) 641, 645 (Fed. Cir. 1986).

^{971. 35} U.S.C. § 101 (2006) (emphasis added).

As the Supreme Court has noted, the broad language of 35 U.S.C. § 101 reflects Congress's intention that patentable subject matter "'include anything under the sun that is made by man.""972

Nevertheless, the Supreme Court's § 101 decisions have imposed some limits. In particular, one may not obtain a patent on laws of nature, physical phenomena, abstract intellectual concepts, or mathematical formulas.⁹⁷³ In 2008, the Federal Circuit issued a key decision that addressed the line between such patent-ineligible principles and patent-eligible subject matter.

The Federal Circuit's en banc decision in *In re Bilski*⁹⁷⁴ clarified the test for determining what constitutes a patentable "process" under § 101, addressing patentability in the context of a prospective business method patent.⁹⁷⁵ Bilski and his co-applicant sought a patent directed to "[i]n essence, . . . a method of hedging risk in the field of commodities trading."⁹⁷⁶ On review, the examiner noted that the applicants had not limited their claims to implementation on a computer and concluded that the claims were not limited by any particular apparatus.⁹⁷⁷ The examiner ultimately rejected all eleven claims as unpatentable under § 101, and the Board of Patent Appeals and Interferences sustained the rejection.978

The Federal Circuit, in a 9-3 decision, affirmed the PTO's rejection of Bilski's claims, holding that the claims were not directed to a patent-eligible "process" under § 101.979 Writing for the majority, Chief Judge Michel explained that, while the Supreme Court has held that a claim is not a patentable "process" if it is drawn to "fundamental principles" (such as "laws of nature, natural phenomena, [or] abstract ideas"), a process may be patentable if it is drawn to a particular "application" of a fundamental principle.⁹⁸⁰ This distinction is designed to prevent the issuance of claims that seek to pre-empt entirely others' use of a law of nature or abstract idea.⁹⁸¹ According to the majority, the Supreme Court, particularly through its decisions in *Diamond v. Dieht*⁹⁸² and *Gottschalk v. Benson*,⁹⁸

975. Id. at 943, 88 U.S.P.Q.2d (BNA) at 1385.

^{972.} Diamond v. Chakrabarty, 447 U.S. 303, 309, 206 U.S.P.Q. (BNA) 193, 197 (1980) (citing S. REP. NO. 82-1979, at 5 (1952)).

^{973.} *Id.*; Parker v. Flook, 437 U.S. 584, 589, 198 U.S.P.Q. (BNA) 193, 201 (1978). 974. 545 F.3d 943, 88 U.S.P.Q. 2d (BNA) 1385 (Fed. Cir. 2008).

^{976.} *Id.* at 949, 88 U.S.P.Q.2d (BNA) at 1387. 977. *Id.* at 950, 88 U.S.P.Q.2d (BNA) at 1388.

^{978.} Id., 88 U.S.P.Q.2d (BNA) at 1388.

^{982. 450} U.S. 185, 209 U.Š.P.Q. (BNA) 1 (1981).

"enunciated a definitive test to determine whether a process claim is tailored narrowly enough to encompass only a particular application of a fundamental principle rather than to pre-empt the principle itself."984 That test is the "machine-or-transformation" test, under which a process is "surely patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing."985

Adopting this test, the court rejected as "inadequate" "several other purported articulations of § 101 tests,"986 including the Freeman-Walter-Abele test,⁹⁸⁷ the "technological arts test,"⁹⁸⁸ and the "useful, concrete, and tangible result" test⁹⁸⁹ set forth in State Street Bank & Trust Co. v. Signature Financial Group, Inc.990 and In re Alappat.991 With respect to the last test, the Federal Circuit noted, without explicitly overruling its decision in State Street,992 that "those portions of our opinions in State Street and AT&T [Corp. v. Excel Communications, Inc.]⁹⁹³ relying solely on a 'useful, concrete and tangible result' analysis should no longer be relied on."994 The Federal Circuit further rejected any "categorical exclusions"-such as for all business

984. In re Bilski, 545 F.3d at 954, 88 U.S.P.Q.2d (BNA) at 1391.
985. Id. at 954, 88 U.S.P.Q.2d (BNA) at 1391 (referencing Benson, 409 U.S. at 70, 175 U.S.P.Q. (BNA) at 676; Diehr, 450 U.S. at 192, 209 U.S.P.Q. (BNA) at 6; Parker v. Flook, 437 U.S. 584, 589 n.9, 198 U.S.P.Q. (BNA) 193, 197 n.9 (1978); Cocrane v. Deener, 94 U.S. 780, 788 (1876)).
986. Id. at 958, 88 U.S.P.Q.2d (BNA) at 1394.
987. Id. at 959, 88 U.S.P.Q.2d (BNA) at 1394. Described and refined in In re Freeman, 573 F.2d 1237, 197 U.S.P.Q. (BNA) 464 (C.C.P.A. 1978), In re Walter, 618 F.2d 758, 205 U.S.P.Q. (BNA) 397 (C.C.P.A. 1980), and In re Abele, 684 F.2d 902, 214 U.S.P.Q. (BNA) 682 (C.C.P.A. 1982), this test required two separate steps: "(1) determining whether the claim recites an 'algorithm' within the meaning of "(1) determining whether the claim recites an 'algorithm' within the meaning of Benson, then (2) determining whether that algorithm is 'applied in any manner to physical elements or process steps.'" In re Bilski, 545 F.3d at 959, 88 U.S.P.Q.2d (BNA) at 959 (citing Abele, 684 F.2d at 905–07, 214 U.S.P.Q. (BNA) at 686).

988. In re Bilski, 545 F.3d at 960, 88 U.S.P.Q.2d (BNA) at 1395. Urged by some amici, the technological arts test would, in the Federal Circuit's view, "be unclear because the meanings of the terms 'technological arts' and 'technology' are both ambiguous and ever-changing. And no such test has ever been explicitly adopted by the Supreme Court, this court, or our predecessor court." *Id.*, 88 U.S.P.Q.2d (BNA) at 1395.

The State Street decision, which involved a claim directed to a data processing 992 system for managing a portfolio of mutual funds, held that claims drawn toward methods of conducting business should be "treated like any other process claims" under § 101. 149 F.3d at 1377, 47 U.S.P.Q.2d (BNA) at 1604. 993. 172 F.3d 1352, 50 U.S.P.Q.2d (BNA) 1447 (Fed. Cir. 1999).

^{983. 409} U.S. 63, 175 U.S.P.Q. (BNA) 673 (1972)

^{984.} In re Bilski, 545 F.3d at 954, 88 U.S.P.Q.2d (BNA) at 1391.

^{989.} Id. at 959–60, 88 U.S.P.Q.2d (BNA) at 1398. 990. 149 F.3d 1368, 47 U.S.P.Q.2d (BNA) 1596 (Fed. Cir. 1998). 991. 33 F.3d 1526, 31 U.S.P.Q.2d (BNA) 1545 (Fed. Cir. 1994).

^{994.} In re Bilski, 545 F.3d at 960 n.19, 88 U.S.P.Q.2d (BNA) at 1395 n.19.

method patents—"beyond those for fundamental principles already identified by the Supreme Court."995

Having concluded that the machine-or-transformation test was the proper test to apply, the Federal Circuit then elaborated upon the "transformation" prong that was at issue in the case.⁹⁹⁶ To qualify as a patent-eligible process under the "transformation" prong, the "transformation must be central to the purpose of the claimed process"⁹⁹⁷ and may not constitute merely "'insignificant postsolution [or extra-solution] activity.'"" In addition, the "article" transformed should be drawn from one of two categories of items: The first (and most "self-evident") category consists of "physical objects or substances" that undergo chemical or physical transformations.⁹⁹⁹ The second category consists of "electronic signals and electronicallymanipulated data" that represent physical objects or substances.¹⁰⁰⁰ As an example of the latter category, the court cited its mixed decision in In re Abele, in which it deemed unpatentable a claim directed to a process of graphically displaying variances in data, but deemed patentable a separate claim specifying that such data constituted "Xray attenuation data produced in a two dimensional field by a computed tomography scanner."¹⁰⁰¹ Thus, because the latter claim encompassed a transformation of raw data into "a particular visual depiction of a physical object" (e.g., a bone or internal organ),¹⁰⁰² it constituted patentable subject matter.

The Federal Circuit held that Bilski's claims did not satisfy the machine-or-transformation test because they did not transform any article to a different state or thing.¹⁰⁰³ The applicants' process, as claimed, involved simply an exchange of legal rights to purchase a

^{995.} Id. at 960, 88 U.S.P.Q.2d (BNA) at 1395.

^{996.} The court declined to elaborate upon the "machine" component of the test. *Id.* at 962, 88 U.S.P.Q.2d (BNA) at 1396 ("As to machine implementation, Applicants themselves admit that the language of claim 1 does not limit any process step to any specific machine or apparatus.... We leave to future cases the elaboration of the precise contours of machine implementation, as well as the answers to particular questions, such as whether or when recitation of a computer suffices to tie a process claim to a particular machine.").

^{997.} *Id.* at 962, 88 U.S.P.Q.2d (BNA) at 1396. 998. *Id.* at 957 & n.14, 88 U.S.P.Q.2d (BNA) at 1393 & n.14 (citing Diamond v. Diehr, 450 U.S. 185, 191–92, 209 U.S.P.Q. (BNA) 1, 10 (1981)). In addition, the Federal Circuit specified that Diehr further held that "mere field-of-use limitations are generally insufficient to render an otherwise ineligible process claim patent-eligible." Id. at 957, 88 U.S.P.Q.2d (BNA) at 1393.

Id. at 957, 88 U.S.P.Q.2d (BNA) at 1395. 999. *Id.* at 962–63, 88 U.S.P.Q.2d (BNA) at 1396. 1000. *Id.* at 962–63, 88 U.S.P.Q.2d (BNA) at 1397. 1001. *Id.* at 962–63, 88 U.S.P.Q.2d (BNA) at 1397 (citing *In re* Abele, 684 F.2d 902, 908–09, 214 U.S.P.Q. (BNA) 682, 687 (C.C.P.A. 1982)). 1002. *Id.* at 963, 88 U.S.P.Q.2d (BNA) at 1397. 1003. *Id.*, 88 U.S.P.Q.2d (BNA) at 1398.

particular commodity at a particular time and price.¹⁰⁰⁴ As such, it did not involve a patent-eligible transformation under § 101.¹⁰⁰⁵ "Purported transformations or manipulations simply of public or private legal obligations or relationships, business risks, or other such abstractions cannot meet the test because they are not physical objects or substances, and they are not representative of physical objects or substances."1006 This, coupled with the applicants' admission that their claims failed to meet the "machine" prong of the test, rendered Bilski's claims unpatentable under § 101.10

Judge Dyk, joined by Judge Linn, wrote a separate concurrence, which reviewed the legislative history of the patent statute¹⁰⁰⁸ and concluded that, under the statute, the only patent-eligible processes are those concerning other types of patentable subject matter. i.e., manufactures, machines, or compositions of matter.¹⁰⁰⁹ Judge Newman's dissent disagreed with the concurrence's reading of the legislative history to preclude entirely patents on "business method[s]" or "human activity."¹⁰¹⁰ In addition, Judge Newman criticized the majority for "usurp[ing] the legislative role"¹⁰¹¹ and "redefining the word 'process' in the patent statute" in a way that contradicted Supreme Court and Federal Circuit precedent,¹⁰¹² thereby creating uncertainty in the law¹⁰¹³ and threatening to impede technological progress by diminishing inventors' incentives.¹⁰¹⁴

The final two dissents expressed disagreement with the majority's enunciation of the machine-or-transformation test, while nevertheless

^{1004.} Id. at 964, 88 U.S.P.Q.2d (BNA) at 1398.

^{1005.} Id. at 963-64, 88 U.S.P.Q.2d (BNA) at 1398.

^{1006.} Id., 88 U.S.P.Q.2d (BNA) at 1398.

^{1007.} *Id.* at 964, 88 U.S.P.Q.2d (BNA) at 1398. 1008. *Id.* at 966–76, 88 U.S.P.Q.2d (BNA) at 1400–07 (Dyk, J., concurring). 1009. *Id.* at 966, 974, 88 U.S.P.Q.2d (BNA) at 1400, 1407.

^{1010.} Id. at 989, 88 U.S.P.Q.2d (BNA) at 1417 (Newman, J., dissenting); see also id. at 985–89, 88 U.S.P.Q.2d (BNA) at 1414–17 (describing the English Statute of Monopolies and the English common law, and contrasting them with U.S. patent law in order to argue that the English laws do not inform the interpretation of § 101). 1011. *Id.* at 997, 88 U.S.P.Q.2d (BNA) at 1424. 1012. *Id.* at 977, 981, 88 U.S.P.Q.2d (BNA) at 1407, 1411. In particular, according

to Judge Newman, the Supreme Court's decision in *Diehr* "did not propose the 'machine-or-transformation' test" to limit patentable processes under § 101. *Id.* at 981, 88 U.S.P.Q.2d (BNA) at 1411.

^{1013.} See id. at 994-95, 88 U.S.P.Q.2d (BNA) at 1421-22 (arguing that the majority's opinion upset settled expectations and failed to answer numerous questions arising from the machine-or-transformation test, such as what types of transformations may qualify as being "central to the purpose of the claimed process," whether "software instructions implemented on a general purpose computer are deemed 'tied' to a 'particular machine,'" and whether the inventions of *State St.* and AT & T v. Excel would pass the new test). 1014. See id. at 997, 88 U.S.P.Q.2d (BNA) at 1424 ("The court's decision affects

present and future rights and incentives ").

AMERICAN UNIVERSITY LAW REVIEW [Vol. 58:747

agreeing (implicitly or explicitly) that Bilski's claims constituted unpatentable subject matter.¹⁰¹⁵ Judge Mayer dissented on the grounds that the majority opinion did not go far enough to limit patentability under § 101, and he criticized the majority for adopting a test that is "too easily circumvented."¹⁰¹⁶ According to Judge Mayer, "State Street and AT&T should be overruled" because "[a]ffording patent protection to business methods lacks constitutional and statutory support, serves to hinder rather than promote innovation and usurps that which rightfully belongs in the public domain."¹⁰¹⁷ Finally, Judge Rader's dissent argued that the majority should have affirmed the Board's rejection simply "[b]ecause Bilski claims merely an abstract idea."¹⁰¹⁸ This conclusion is supported by a direct reading of Supreme Court precedent, which holds that "the only limits on [patent] eligibility are inventions that embrace natural laws, natural phenomena, and abstract ideas."¹⁰¹⁹ However, wrote Judge Rader, the majority "expands (transforms?) some Supreme Court language into rules that defy the Supreme Court's own rule,"1020 unduly limit the scope of patentable subject matter, and "link[] patent eligibility to the age of iron and steel at a time of subatomic particles and terabytes."1021

The Federal Circuit's order in In re Petrus A.C.M. Nuijten¹⁰²² denied a request to rehear the dispute underlying its 2007 decision in In re *Nuijten*,¹⁰²³ in which the court affirmed the PTO's determination that claims directed to an electromagnetic "signal" were unpatentable under § 101.¹⁰²⁴ Judge Linn, joined by Judges Newman and Rader, dissented from the court's order. Judge Linn would have reheard the case, as it "raise[d] important questions about the relationship between § 101 and § 103."¹⁰²⁵ He also argued that the panel majority

^{1015.} Id. at 998-1011, 88 U.S.P.Q.2d (BNA) at 1424-34 (Mayer, J., dissenting); id. at 1011-15, 88 U.S.P.Q.2d (BNA) at 1434-37 (Rader, J., dissenting).
1016. Id. at 1008, 88 U.S.P.Q.2d (BNA) at 1432 (Mayer, J., dissenting).
1017. Id. at 998, 88 U.S.P.Q.2d (BNA) at 1424. In particular, Judge Mayer wrote, it was "highly unlikely that the framers . . . intended to grant patent protection to methods of conducting business," in light of their keen awareness of the "odious" monopolies on trade that led to the seventeenth-century English Statute of Monopolies. Id. at 998-99, 88 U.S.P.Q.2d (BNA) at 1424-25.
1018. Id. at 1011, 88 U.S.P.Q.2d (BNA) at 1434 (Rader, J., dissenting).
1019. Id. at 1012-13, 88 U.S.P.Q.2d (BNA) at 1435.
1020. Id. at 1013, 88 U.S.P.Q.2d (BNA) at 1436.
1021. Id. at 1011, 88 U.S.P.Q.2d (BNA) at 1434.
1022. 515 F.3d 1361, 85 U.S.P.Q.2d (BNA) at 1434.

^{1022.}

⁵¹⁵ F.3d 1361, 85 U.S.P.Q.2d (BNA) 1927 (Fed. Cir. 2008). 500 F.3d 1346, 84 U.S.P.Q.2d (BNA) 1495 (Fed. Cir. 2007). 1023.

^{1024.} See id. at 1357, 84 U.S.P.Q.2d (BNA) at 1502 (explaining that electromagnetic signals are devoid of matter and they are not "manufacture[s]" under § 101) (alteration in original).

^{1025.} In re Petrus A.C.M. Nuijten, 515 F.3d at 1362, 85 U.S.P.Q.2d (BNA) at 1928.

had too narrowly construed the scope of a § 101 "manufacture" to exclude "'transient or 'fleeting'" things like signals, in conflict with applicable precedent.¹⁰²⁶ Following the Federal Circuit's denial of the petition for rehearing, the Supreme Court denied the appellant's petition for a writ of certiorari.¹⁰²⁷

B. Anticipation

To be patentable, an invention must be "new."¹⁰²⁸ If the claimed subject matter of a patent is not "new," it is said to be "anticipate[d]" by the prior art.¹⁰²⁹ In order to invalidate a claim on the grounds of anticipation, a challenger must establish that every element of the claim was previously described in a single prior art reference, either expressly or inherently.¹⁰³⁰ In contrast with the standard for obviousness, discussed below in Section C, the standard for anticipation is one of strict identity, requiring that the prior reference set forth all claimed elements "arranged as in the claim."1031 Section 102 of the patent statute establishes various ways in which a patent may be invalidated due to anticipation, among which are (1) disclosure in a prior patent or printed publication¹⁰³² and (2) disclosure by public use or sale.¹⁰³³

1. Patents and printed publications

Under § 102 of the patent statute,

[a] person shall be entitled to a patent unless—

(a) the invention was . . . patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

^{1026.} See id. at 1362, 85 U.S.P.Q.2d (BNA) at 1928 (discussing prior decisions' 1026. See 1a. at 1362, 85 U.S.P.Q.2d (BNA) at 1928 (discussing prior decisions broader "framework" for delineating patentable "manufactures," such as those in Diamond v. Chakrabarty, 447 U.S. 303, 309, 206 U.S.P.Q. (BNA) 193, 197 (1980), and In re Breslow, 616 F.2d 516, 205 U.S.P.Q. (BNA) 221 (C.C.P.A. 1980)). 1027. Nuijten v. Dudas, 129 S. Ct. 70 (2008). 1028. See 35 U.S.C. §§ 101–102 (2008) (specifying in § 101 that only a "new and useful" invention—or a "new and useful" improvement upon an invention—is entitled to patent protection (emphasis added)). Section 102 defines various sources of prior art that may negate poyelty, as discussed in further detail below. U & 102

of prior art that may negate novelty, as discussed in further detail below. *Id.* § 102. 1029. EMI Group N. Am. v. Cypress Semiconductor Corp., 268 F.3d 1342, 1350, 60 U.S.P.Q.2d (BNA) 1423, 1429 (Fed. Cir. 2001). 1030. *See id.* at 1350, 60 U.S.P.Q.2d (BNA) at 1429 ("A prior art reference

anticipates a patent claim if the reference discloses, either expressly or inherently, all of the limitations of the claim.") (citing Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 771, 218 U.S.P.Q. 781, 789 (Fed Cir. 1983)).

^{1031.} Connell v. Sears, Roebuck & Co., 722 F.2d 1542, 1548, 220 U.S.P.Q. (BNA) 1031. Connent V. Sears, Roebuck & Co., 722 F.2d 1942, 1948, 220 C.S.P.Q. (BIVA)
103, 198 (Fed. Cir. 1983) (citing Soundscriber Corp. v. United States, 360 F.2d 954, 960, 148 U.S.P.Q. (BNA) 298, 301 (Ct. Cl. 1966)).
1032. 35 U.S.C. § 102 (a) – (b) (2008).
1033. 35 U.S.C. § 102 (b).

(b) the invention was patented or described in a printed publication in this or a foreign country . . . more than one year prior to the date of the application for patent in the United States.¹⁰³⁴

These requirements are "grounded on the principle that once an invention is in the public domain, it is no longer patentable by anyone."¹⁰³⁵ In the case of printed publications, which are not necessarily "published" to the same degree as issued patents, anticipation depends upon whether the particular reference was "publicly available" or "publicly accessible" to interested skilled artisans prior to the "critical date" (i.e., more than one year prior to the date the application was filed).¹⁰³⁶ The determination of whether a document constitutes a printed publication under § 102 is a question of law based upon the underlying facts of each particular case.¹⁰³⁷

In Leggett & Platt Inc. v. VUTEk, Inc., ¹⁰³⁸ the Federal Circuit applied the doctrine of inherent anticipation to affirm summary judgment of invalidity over a previously filed patent. Plaintiff Leggett & Platt ("L&P") instituted an infringement action against defendant VUTEk, a manufacturer of large-scale commercial printers, for alleged infringement of L&P's '518 patent entitled "Method and Apparatus for Ink Jet Printing on Rigid Panels."¹⁰³⁹ VUTEk argued that the asserted '518 claims were anticipated by VUTEk's '823 patent, which described a printer carriage that used UV radiation to set ink after it is deposited on a surface.¹⁰⁴⁰ Although the parties agreed that the '823 reference anticipated numerous limitations of the '518 patent, they disputed whether it disclosed an assembly that is "effective to impinge sufficient UV light on the ink to substantially cure the ink," as required by the '518 patent.¹⁰⁴¹

^{1034. 35} U.S.C. § 102.

^{1035.} In re Hall, 781 F.2d 897, 898, 228 U.S.P.Q. (BNA) 453, 455 (Fed. Cir. 1896) (citing In re Bayer, 568 F.2d 1357, 1361, 196 U.S.P.Q. 670, 675 (C.C.P.A. 1978)).

^{1036.} Bruckelmyer v. Ground Heaters, Inc., 445 F.3d 1374, 1377-78, 78 U.S.P.Q.2d (BNA) 1684, 1687 (Fed. Cir. 2006); *In re* Hall, 781 F.2d at 898-99, 228 U.S.P.Q. (BNA) at 455.

^{1037.} See, e.g., Cooper Cameron Corp. v. Kvaerner Oilfield Prods., Inc., 291 F.3d 1317, 1321, 62 U.S.P.Q.2d (BNA) 1846, 1849 (Fed. Cir. 2002) ("Whether an asserted anticipatory document qualifies as a 'printed publication' under § 102 is a legal conclusion based on underlying factual determinations."); *see also In re* Hall, 781 F.2d at 899, 228 U.S.P.Q. (BNA) at 455 ("The § 102 publication bar is a legal determination based on underlying fact issues, and therefore must be approached on a case-by-case basis."). 1038. 537 F.3d 1349, 87 U.S.P.Q.2d (BNA) 1947 (Fed. Cir. 2008). 1039. *Id.* at 1350, 87 U.S.P.Q.2d (BNA) at 1948. 1040. *Id.* at 1352, 87 U.S.P.Q.2d (BNA) at 1949.

^{1041.} Id. at 1353-54, 87 U.S.P.Q.2d (BNA) at 1950.

In affirming the district court's judgment of invalidity, the Federal Circuit relied on evidence showing that the '823 reference disclosed light emitting diodes ("LEDs") that used UV energy to cure the ink about 75-80% when used as indicated.¹⁰⁴² Under the strict summary judgment standard, the court was unable to hold, as a matter of law, that seventy-five to eighty percent cured constituted "substantially cure[d]" as that term was construed by the district court.¹⁰⁴³ Nevertheless, the Federal Circuit held that, while the '823 reference may not have expressly disclosed LEDs that "substantially cure[d]" ink, "it inherently disclose[d] LEDs that [were] 'effective to' do so."1044 Therefore, the prior art reference anticipated the asserted claims, rendering them invalid.¹⁰⁴⁵

In *Net MoneyIN, Inc. v. Verisign, Inc.*,¹⁰⁴⁶ the Federal Circuit reversed a summary judgment of anticipation on the grounds that the district court had improperly combined elements from two separate examples disclosed within a single prior art reference. The claim at issue recited a payment system for processing credit card transactions over the Internet and comprised five "links" between various participating entities (e.g., between a customer computer and a vending computer, between a customer computer and a payment processing computer).¹⁰⁴⁷ On defendant's motion for summary judgment, the district court concluded that the claim was invalidated by a single prior art reference, the iKP reference, which included all five of the claimed links, albeit in two separately disclosed examples.¹⁰⁴⁸

On appeal, the Federal Circuit ruled that the district court had incorrectly applied the law of anticipation, under which a prior art reference does not anticipate unless it "not only disclose[s] all elements of the claim within the four corners of the document, but... also disclose[s] those elements 'arranged as in the claim.'"1049 This means, the court held,

that unless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the

 ^{1042.} Id. at 1354, 87 U.S.P.Q.2d (BNA) at 1951.

 1043.
 Id. at 1354, 87 U.S.P.Q.2d (BNA) at 1951.

 1044.
 Id. at 1354–55, 87 U.S.P.Q.2d (BNA) at 1951.

^{1045.} Id. at 1356, 87 U.S.P.Q.2d (BNA) at 1953.

^{1046. 545} F.3d 1359, 88 U.S.P.Q.2d (BNA) 1751 (Fed. Cir. 2008). 1047. Id. at 1362, 1368-69, 88 U.S.P.Q.2d (BNA) at 1757-58.

^{1048.} Id. at 1369, 88 U.S.P.Q.2d (BNÅ) at 1758.

^{1049.} Id. at 1369, 88 U.S.P.Q.2d (BNA) at 1758 (citing Connell v. Sears, Roebuck & Co., 722 F.2d 1542, 1548, 220 U.S.P.Q. (BNA) 193, 198 (Fed. Cir. 1983)).

claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102.1056

In the present case, the iKP reference disclosed two separate systems for online credit card payment, neither of which contained all five links combined or arranged in the same way as in the asserted claim.¹⁰⁵¹ Because it was erroneous to combine different elements of the separate systems merely because they all appeared within the same prior art reference, the district court's grant of summary judgment of invalidity was reversed.¹⁰⁵²

In Sanofi-Synthelabo v. Apotex, Inc.,1053 the court affirmed the validity of a patent on a dextrorotatory isomer, where prior patents describing its chemical racemate did not sufficiently disclose or enable the separation of the particular isomer claimed.¹⁰⁵⁴ The patent at issue covered a chemical compound commonly known as clopidogrel bisulfate, which is sold under the brand name Plavix to treat and prevent blood clots.¹⁰⁵⁵ In particular, the asserted claim recited the "dextrorotatory isomer"-one of a pair of stereoisomers of a compound, which is identical to its counterpart (the levo-rotatory isomer) in all aspects except its orientation in three-dimensional space.¹⁰⁵⁶ The racemate—a combination of both stereoisomers—was disclosed in two prior patents as part of a general class of compounds.¹⁰⁵⁷ In response to allegations of infringement, the alleged infringer argued that the prior disclosure of the racemate anticipated the asserted claims, rendering them invalid.¹⁰⁵⁸ The district court held that the prior art's disclosure of a particular genus of compounds did not anticipate the specific isolated stereoisomer claimed, and that the earlier patent did not sufficiently enable one of make ordinary skill to the invention without undue experimentation.¹⁰⁵⁹

The Federal Circuit agreed with the district court's determination that the references did not constitute anticipating disclosures of the detrorotatory isomer, where they contained only general statements that the compounds (including the racemate)

^{1050.} Id. at 1371, 88 U.S.P.Q.2d (BNA) at 1759.

^{1051.} Id., 88 U.S.P.Q.2d (BNA) at 1759.

^{1052.} *Id.* at 1371, 88 U.S.P.Q.2d (BNA) at 1760. 1053. 550 F.3d 1075, 89 U.S.P.Q.2d (BNA) 1370 (Fed. Cir. 2008).

^{1054.} *Id.* at 1084, 89 U.S.P.Q.2d (BNA) at 1375–76. 1055. *Id.* at 1077, 89 U.S.P.Q.2d (BNA) at 1371. 1056. *Id.* at 1077, 1080, 89 U.S.P.Q.2d (BNA) at 1371, 1373.

^{1057.} *Id.* at 1078, 89 U.S.P.Q.2d (BNA) at 1372. 1058. *Id.* at 1083, 89 U.S.P.Q.2d (BNA) at 1375.

^{1059.} Id. at 1084-85, 89 U.S.P.Q.2d (BNA) at 1376-77.

consisted of stereoisomers.1060 As noted in Net MoneyIN, an anticipating reference must disclose all elements of a claim "arranged as in the claim"¹⁰⁶¹ without requiring one of ordinary skill to pick, choose, and combine various elements not directly related to each other in the cited reference.¹⁰⁶² In addition, the Federal Circuit held that the district court did not err when it concluded that the prior art references were not adequately enabling.¹⁰⁶³ Anticipation "requires the specific description as well as enablement of the subject matter at issue."¹⁰⁶⁴ As the court noted, "[a]ny presumption of enablement of prior art does not exclude consideration of whether undue experimentation would be required to achieve enablement."¹⁰⁶⁵ In this case, the evidence established that the process of separating stereoisomers (into their dextrorotatory and levo-rotatory forms) was known to be both difficult and unpredictable, thus requiring substantial experimentation even by those skilled in the art.¹⁰⁶ Therefore, there was no clear error in the district court's finding that the prior art reference would not have enabled a skilled artisan to isolate the dextrorotatory isomer of clopidogrel.¹⁰⁶⁷

Similarly, the court in Impax Laboratories, Inc. v. Aventis Pharmaceuticals, Inc.¹⁰⁶⁸ affirmed the district court's determination that a prior art reference did not anticipate claims directed to a drug treatment, where the reference was not enabling.¹⁰⁶⁹ According to the Federal Circuit, "the trial court's findings properly support[ed] its conclusion that an ordinarily skilled artisan would have needed to experiment unduly to gain possession of the invention."1070 The asserted claims were directed to the use of riluzole to treat amyotrophic lateral sclerosis ("ALS") or Lou Gehrig's disease.¹⁰⁷¹ The record established that the alleged prior art patent, which disclosed several diseases and many thousands of compounds, only made passing reference to riluzole, without discussing its use as a treatment

- 1070. Id. at 1315, 88 U.S.P.Q.2d (BNA) at 1384.
- 1071. Id. at 1314, 88 U.S.P.Q.2d (BNA) at 1382.

^{1060.} Id. at 1084, 89 U.S.P.Q.2d (BNA) at 1375.

^{1061.} *Id.* at 1083, 89 U.S.P.Q.2d (BNA) at 1375 (citing Net MoneyIN, Inc. v. VeriSign, Inc., 545 F.3d 1359, 1369, 88 U.S.P.Q.2d 1751, 1758 (Fed. Cir. 2008)).

^{1062.} *Id.*, 89 U.S.P.Q.2d (BNA) at 1375 (referencing *In re* Arkley, 455 F.2d 586, 587, 172 U.S.P.Q. 524, 526 (C.C.P.A. 1972)).

^{1063.} *Id.* at 1085, 89 U.S.P.Q.2d (BNA) at 1376–77. 1064. *Id.* at 1083, 89 U.S.P.Q.2d (BNA) at 1375. 1065. *Id.* at 1085, 89 U.S.P.Q.2d (BNA) at 1376.

^{1066.} Id., 89 U.S.P.Q.2d (BNA) at 1376.

^{1067.} *Id.*, 89 U.S.P.Q.2d (BNA) at 1376–77. 1068. 545 F.3d 1312, 88 U.S.P.Q.2d (BNA) 1381 (Fed. Cir. 2008). 1069. *Id.* at 1315–16, 88 U.S.P.Q.2d (BNA) at 1384.

for ALS.¹⁰⁷² Moreover, the dosage guidelines in the alleged prior art reference were general and provided insufficient guidance regarding a treatment regimen for ALS.¹⁰⁷³ The reference also failed to provide working examples.¹⁰⁷⁴ Therefore, the Federal Circuit concluded, the reference did not enable a person of ordinary skill in the art to use riluzole as a treatment for ALS, and the patent was not invalid.¹⁰⁷⁵

In PowerOasis, Inc. v. T-Mobile USA Inc., 1076 the Federal Circuit considered whether the presumption of patent validity extends to the question of priority date.¹⁰⁷⁷ PowerOasis asserted two patents that derived from a June 2000 continuation-in-part ("CIP") application, which itself derived from an original application filed in February 1997.¹⁰⁷⁸ The alleged infringer, T-Mobile, argued that the asserted claims were anticipated by the MobileStar Network, which was in public use more than one year prior to the filing of the CIP Because PowerOasis conceded that the MobileStar application. Network included all the limitations of the asserted claims, PowerOasis argued that the claims were entitled to the priority date of the original 1997 application, which predated the MobileStar Network.¹⁰⁷⁹ The district court placed the burden of proof on PowerOasis to establish entitlement to the earlier priority date.¹⁰⁸⁰ After determining that the original patent's written description did not adequately disclose the later-issued CIP claims, the district court granted T-Mobile's motion for summary judgment of invalidity due to anticipation.¹⁰⁸¹

Affirming the decision on appeal, the Federal Circuit rejected PowerOasis's assertion that the presumption of validity should also include a presumption that CIP claims must be accorded the earliest effective filing date.¹⁰⁸² In the present case, the PTO had made no determination regarding the priority date of the claims, either in the context of a rejection or in the context of an interference.¹⁰⁸³ The court explained: "When neither the PTO nor the Board has previously considered priority, there is simply no reason to presume

^{1072.} Id. at 1315-16, 88 U.S.P.Q.2d (BNA) at 1384.

^{1073.} *Id.* at 1316, 88 U.S.P.Q.2d (BNA) at 1384. 1074. *Id.* at 1315–16, 88 U.S.P.Q.2d (BNA) at 1384.

^{1074.} Id. at 1315-10, 66 U.S.P.Q.2d (BNA) at 1384.
1075. Id. at 1316, 88 U.S.P.Q.2d (BNA) at 1384.
1076. 522 F.3d 1299, 86 U.S.P.Q.2d (BNA) at 1385 (Fed. Cir. 2008).
1077. Id. at 1301, 86 U.S.P.Q.2d (BNA) at 1386.
1078. Id. at 1301-02, 86 U.S.P.Q.2d (BNA) at 1386.
1079. Id. at 1302-03, 86 U.S.P.Q.2d (BNA) at 1386.
1079. Id. at 1302-03, 86 U.S.P.Q.2d (BNA) at 1386.

^{1080.} Id. at 1302-05, s6 U.S.P.Q.2d (BNA) at 1380.
1081. Id., 86 U.S.P.Q.2d (BNA) at 1388.
1082. Id. at 1304, 86 U.S.P.Q.2d (BNA) at 1388.
1083. Id. at 1304-05, 86 U.S.P.Q.2d (BNA) at 1388-89.

that claims in a CIP application are entitled to the effective filing date of an earlier filed application."1084

That conclusion, the court explained, did not alter T-Mobile's burden, as the moving party, to prove invalidity by clear and convincing evidence.¹⁰⁸⁵ Because PowerOasis did not dispute that the MobileStar Network was in public use more than one year prior to the filing of the CIP application, and it conceded that the MobileStar Network would constitute § 102(b) prior art if not afforded the earlier filing date, T-Mobile had met its burden.¹⁰⁸⁶ Therefore, "the burden was on PowerOasis to come forward with evidence to the contrary,"¹⁰⁸⁷ i.e., establishing entitlement to an earlier priority date.¹⁰⁸⁸ Upon review of the record, the Federal Circuit agreed with the district court's determination that the asserted claims were not entitled to the earlier filing date because the original written description did not support the later-issued asserted claims.¹⁰⁸⁹

The Federal Circuit reached a similar conclusion in Technology Licensing Corp. v. Videotek, Inc.,¹⁰⁹⁰ when it affirmed the district court's judgment that certain asserted claims were not entitled to an earlier filing date and were therefore invalid over the prior art.¹⁰⁹¹ The court also clarified the burdens of proof raised in PowerOasis, distinguishing between the burden of persuasion ("the ultimate burden assigned to a party who must prove something to a specified degree"), and the burden of production, also known as the burden of "going forward with evidence."¹⁰⁹² Because the patent statute imposes a presumption of validity,

a challenger has the burden of persuasion to show by clear and convincing evidence that the contrary is true. That ultimate burden never shifts, however much the burden of going forward may jump from one party to another as the issues in the case are raised and developed.¹⁰⁹³

Therefore, the court explained,

PowerOasis says nothing more than, and should be understood to say, that once a challenger (the alleged infringer) has introduced sufficient evidence to put at issue whether there is prior art alleged

^{1084.} Id. at 1305, 86 U.S.P.Q.2d (BNA) at 1389.

^{1085.} Id., 86 U.S.P.Q.2d (BNA) at 1389.
1086. Id., 86 U.S.P.Q.2d (BNA) at 1389.
1087. Id., 86 U.S.P.Q.2d (BNA) at 1389.
1088. Id. at 1305–06, 86 U.S.P.Q.2d (BNA) at 1389.
1088. Id. at 1305–06, 86 U.S.P.Q.2d (BNA) at 1389.

^{1089.} Id. at 1306-10, 86 U.S.P.Q.2d (BNA) at 1389-94.

^{1090. 545} F.3d 1316, 88 U.S.P.Q.2d (BNA) 1865 (Fed. Cir. 2008). 1091. *Id.* at 1320, 88 U.S.P.Q.2d (BNA) at 1867–68.

^{1092.} Id. at 1326-27, 88 U.S.P.Q.2d (BNA) at 1873.

^{1093.} Id. at 1329, 88 U.S.P.Q.2d (BNA) at 1874.

to anticipate the claims being asserted, prior art that is dated earlier than the apparent effective date of the asserted patent claim, the patentee has the burden of going forward with evidence and argument to the contrary.¹⁰⁹⁴

In SRI International, Inc. v. Internet Security Systems, Inc., 1095 the Federal Circuit vacated and remanded the district court's summary judgment of invalidity on four SRI patents, because there was insufficient evidence to establish that an SRI prior art paper was publicly accessible-and thus a "printed publication"-under § 102(b).¹⁰⁹⁶ The patents at issue pertained to methods for securing computer systems and detecting suspicious network activity.¹⁰⁹⁷ SRI had described its invention in a paper analyzing the live traffic of TCP/IP gateways—the "Live Traffic" paper.¹⁰⁹⁸ Approximately one year and three months before SRI filed the priority patent application, one of the inventors emailed the Live Traffic paper to a program chair at the Internet Society, which was soliciting papers for an upcoming symposium.¹⁰⁹⁹ The email noted that the Live Traffic paper would also be available on SRI's file transfer protocol ("FTP") server, at a particular FTP address.¹¹⁰⁰ In SRI's later patent infringement action, the defendants moved for summary judgment that all of the patents were invalidated by the prior art Live Traffic paper.¹¹⁰¹ The district court granted the motion, holding that the Live Traffic paper constituted a "printed publication" under § 102(b) and thus anticipated the claims of the patents-in-suit.¹¹⁰²

Vacating and remanding the district court's decision as to the Live Traffic paper,¹¹⁰³ the Federal Circuit held that the record contained insufficient factual support for defendants' assertion that the paper was publicly accessible by virtue of its location on the FTP server.¹¹⁰⁴ Like an uncatalogued graduate thesis stored in a remote library

^{1094.} *Id.* at 1328–29, 88 U.S.P.Q.2d (BNA) at 1874. 1095. 511 F.3d 1186, 85 U.S.P.Q.2d (BNA) 1489 (Fed. Cir. 2008). 1096. *Id.* at 1195, 85 U.S.P.Q.2d (BNA) at 1496.

^{1097.} *Id.* at 1188, 85 U.S.P.Q.2d (BNA) at 1490.

^{1098.} *Id.* at 1188, 1190, 85 U.S.P.Q.2d (BNA) at 1490, 1492. 1099. *Id.* at 1190, 85 U.S.P.Q.2d (BNA) at 1492. 1100. *Id.*, 85 U.S.P.Q.2d (BNA) at 1492.

^{1101.} *Id.* at 1192, 85 U.S.P.Q.2d (BNA) at 1493. 1102. *Id.*, 85 U.S.P.Q.2d (BNA) at 1493.

^{1103.} *Id.* at 1198, 85 U.S.P.Q.2d (BNA) at 1498. The court also affirmed a portion of the district court's decision, in which it granted summary judgment of invalidity as to one of the patents on the grounds that a separate publication—the EMERALD 1997 paper—anticipated the claims. *Id.* at 1192–94, 85 U.S.P.Q.2d (BNA) at 1493– 95.

^{1104.} Id. at 1195, 85 U.S.P.Q.2d (BNA) at 1496.

857

2009]

location,¹¹⁰⁵ the Live Traffic paper was placed on SRI's own FTP server without an index, catalogue, or any other research tools.¹¹⁰⁶ Unlike posters displayed at a publicized professional conference,¹¹⁰⁷ the Live Traffic paper was posted to a proprietary FTP server and known only to a handful of non-SRI individuals charged with peer-reviewing the unfinished paper for future publication.¹¹⁰⁸ It was thus more akin to "posters at a vacant and unpublicized conference."¹¹⁰⁹ Although the record showed seven prior instances in which SRI directed a person to other documents within the same subdirectory, there was "no suggestion" that such individuals could freely navigate through the directory structure¹¹¹⁰ or that they "would—unprompted—look there for an [entirely separate] unpublicized paper with a relatively obscure filename."1111

Judge Moore dissented, arguing that the court should have affirmed the district court's ruling of invalidity based on the Live Traffic paper.¹¹¹² In particular, she argued that the defendants' unrefuted evidence indicated that SRI's FTP server was navigable and used by the cyber security community at the relevant time period.¹¹¹³ She maintained that "[t]his case is quite unlike the uncatalogued, unshelved thesis in a general university library"¹¹¹⁴ because SRI placed the paper on an FTP server used for cyber security, in a subdirectory named for a well-known cyber security project, with a file name that abbreviated an annual cyber security symposium.¹¹¹⁵ Moreover, the factors governing public dissemination-length of time available (seven days), the expertise of the target audience (sophisticated computer scientists who knew how to use the FTP server), reasonable expectation of copying (no confidentiality labels or protective measures to dissuade copying), and ease of copying (simple in FTP tool)—supported the conclusion that the Live Traffic paper was publicly available prior to the critical date.¹¹¹⁶

1105. See In Te Bayer, 508 F.2d 1357, 1358-39, 196 U.S.P.Q. (BNA) 070, 075 (C.C.P.A. 1978) (applicant's uncataloged, unshelved thesis was not a "publication").
1106. Id. at 1196, 85 U.S.P.Q.2d (BNA) at 1496.
1107. See In re Klopfenstein, 380 F.3d 1345, 1347-50, 72 U.S.P.Q.2d (BNA) 1117, 1117-20 (Fed. Cir. 2004) (describing the slide presentation given by applicants at a meeting of the American Association of Cereal Chemists, which was printed and pasted on poster boards to be displayed for the next two-and-a-half days).

- 1111. Id., 85 U.S.P.Q.2d (BNA) at 1497.

^{1105.} See In re Bayer, 568 F.2d 1357, 1358-59, 196 U.S.P.Q. (BNA) 670, 673

^{1108.} *Id.* at 1196–97, 85 U.S.P.Q.2d (BNA) at 1497. 1109. *Id.* at 1197, 85 U.S.P.Q.2d (BNA) at 1497. 1110. *Id.*, 85 U.S.P.Q.2d (BNA) at 1497.

^{1111.} Id., 65 U.S.P.Q.20 (BNA) at 1497.
1112. Id. at 1198, 85 U.S.P.Q.2d (BNA) at 1498 (Moore, J., dissenting in part).
1113. Id. at 1200, 85 U.S.P.Q.2d (BNA) at 1499.
1114. Id. at 1202, 85 U.S.P.Q.2d (BNA) at 1501.
1115. Id. at 1201-02, 85 U.S.P.Q.2d (BNA) at 1500-01.

^{1116.} Id. at 1202-05, 85 U.S.P.Q.2d (BNA) at 1501-03.

AMERICAN UNIVERSITY LAW REVIEW [Vol. 58:747

Another decision discussing the "public accessibility" of a printed publication under § 102 was Kyocera Wireless Corp. v. International Trade Commission,¹¹¹⁷ in which the Federal Circuit disagreed with the International Trade Commission's ("ITC") determination that an alleged prior art reference was not publicly available prior to the critical date.¹¹¹⁸ The prior art at issue was the Global System for Mobile Communications ("GSM") standard, a comprehensive set of technical specifications for a mobile network.¹¹¹⁹ The ITC had concluded that the GSM standard was analogous to the publication in Northern Telecom, Inc. v. Datapoint Corp.,¹¹²⁰ which comprised sensitive documents about a complex military system and was maintained in a restricted-access proprietary library.¹¹²¹ On appeal, however, the Federal Circuit concluded that the record showed wide circulation of the GSM documents prior to the critical date: "publicly available" versions distributed as "consistent sets"; exchange of GSM specifications between U.S. companies and their European subsidiaries; and even the sale of over 25,000 copies of a "GSM bible."1122 Therefore, the GSM standard was "sufficiently accessible, at least to the public interested in the art."1123

Nevertheless, the Federal Circuit affirmed the validity of the patentin-suit under § 102, on the grounds that the GSM standard did not constitute a single anticipating reference.¹¹²⁴ Indeed. the record indicated that the hundreds of specifications making up the GSM standard were authored by various sets of authors at different times and consisted of hundreds of individual specifications, each "stand[ing] as a separate document in its own right."¹¹²⁵ Moreover, the internal cross-references to other parts of the GSM standard did not constitute incorporation by reference so as to warrant consolidation.¹¹²⁶ For those reasons, the Federal Circuit affirmed the ITC's determination that the GSM standard did not anticipate the patent claims under § 102. The court further foreclosed the availability of an obviousness argument, holding that "[t]his court

^{1117. 545} F.3d 1340, 89 U.S.P.Q.2d (BNA) 1057 (Fed. Cir. 2008).
1118. *Id.* at 1345, 85 U.S.P.Q.2d (BNA) at 1060.
1119. *Id.* at 1350, 85 U.S.P.Q.2d (BNA) at 1063–64.

^{1120. 908} F.2d 931, 15 U.S.P.Q.2d (BNA) 1321 (Fed. Cir. 1990).
1121. Kyocera Wireless, 545 F.3d at 1350, 85 U.S.P.Q.2d (BNA) at 1064.

^{1122.} *Id.* at 1350–51, 85 U.S.P.Q.2d (BNA) at 1064. 1123. *Id.* at 1351, 89 U.S.P.Q.2d (BNA) at 1065 (citing *In re* Hall, 781 F.2d 897, 899,

²²⁸ U.S.P.Q. (BNA) 453, 455 (Fed. Cir. 1986)) (internal quotation omitted). 1124. *Id.* at 1352, 89 U.S.P.Q.2d (BNA) at 1065. 1125. *Id.* at 1351, 89 U.S.P.Q.2d (BNA) at 1065.

^{1126.} Id., 89 U.S.P.Q.2d (BNA) at 1065.

need not engage in an obviousness inquiry when [respondent] did not assert relevant obviousness arguments at the proper time."¹¹²⁷

Similarly, where a patent holder raised a new issue of fact on appeal, in *Golden Bridge Technology, Inc. v. Nokia, Inc.*,¹¹²⁸ the Federal Circuit refused to disturb the district court's initial judgment. The asserted claims, which described a mobile communication system using a code division multiple access ("CDMA") scheme, were held invalid by the district court, primarily on the basis of defendant's expert testimony showing the presence of each limitation in a prior art reference.¹¹²⁹ On appeal, the patent holder asserted, for the first time, that the prior art reference failed to disclose a particular "synchronization" limitation.¹¹³⁰ Noting that that patent holder had ample opportunities to present its arguments to the trial court, the Federal Circuit "decline[d] to remand this case to the district court to decide an argument as to what a prior art reference discloses [a fact finding] when that argument, without any justification, is raised for the first time on appeal."¹¹³¹ The court chastised the patent holder: "Appellate courts review district court judgments; we do not find facts."1132

2. Public use and on-sale bar

Section 102(b) of 35 U.S.C. bars the ability to patent an invention that was "in public use or on sale in this country[] more than one year prior to the date of the application for patent in the United States."1133 Therefore, once an inventor publicly uses or sells an invention, she has one year in which to file a patent application. As the Supreme Court has noted, underlying both the public use bar and the on-sale bar is a "reluctance to allow an inventor to remove existing knowledge from public use."¹¹³⁴ The determination of patent validity under § 102(b)'s public use or on-sale bar is a question of law based on underlying facts.¹¹³⁵

In *Pfaff v. Wells Electronics, Inc.*,¹¹³⁶ the Supreme Court set forth a two-pronged test that has been applied to both the public use and on-

^{1127.} Id. at 1352, 89 U.S.P.Q.2d (BNA) at 1066.
1128. 527 F.3d 1318, 87 U.S.P.Q.2d (BNA) 1049 (Fed. Cir. 2008).
1129. Id. at 1320-22, 87 U.S.P.Q.2d (BNA) at 1050.

^{1130.} Id. at 1322, 87 U.S.P.Q.2d (BNA) at 1051.

^{1131.} *Id.* at 1324, 87 U.S.P.Q.2d (BNA) at 1053. 1132. *Id.* at 1323, 87 U.S.P.Q.2d (BNA) at 1053.

³⁵ U.S.C. § 102(b) (2008). 1133.

^{1134.} Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 64, 48 U.S.P.Q.2d (BNA) 1641, 1645 (1998)

^{1135.} Netscape Communs. Corp. v. Konrad, 295 F.3d 1315, 1320, 63 U.S.P.Q.2d (BNA) 1580, 1583 (Fed. Cir. 2002)

^{1136. 525} U.S. 55, 48 U.S.P.Q.2d (BNA) 1641 (1998).

sale bars under § 102(b).¹¹³⁷ Under this test, the on-sale bar invalidates a patent if, prior to the critical date (1) the invention was the subject of a commercial sale or offer for sale; and (2) the invention was ready for patenting.¹¹³⁸ Similarly, the public use bar mandates invalidation if, prior to the critical date, (1) the invention was in public use; and (2) the invention was ready for patenting.¹¹³⁹ A party may show that an invention was "ready for patenting" in at least two ways: (1) by demonstrating that the invention was reduced to practice; or (2) by demonstrating that the inventor had prepared drawings or other written descriptions of the invention that were sufficiently specific to enable one skilled in the art to practice the invention.¹¹⁴⁰

Even in the case of a pre-critical-date public use or sale, however, a patentee may nevertheless avoid invalidation of the patent by establishing that the prior public use or sale was undertaken for the purpose of experimentation, in an effort to "perfect" the invention.¹¹⁴¹ Under this "experimental use" exception, an inventor's limited testing in public does not constitute "public use" for the purpose of § 102(b), so long as the inventor maintains control over the use of the invention¹¹⁴² and does not attempt to profit by it.¹¹⁴³

In E.I. Dupont de Nemours & Co. v. MacDermid Printing Solutions, LLC.¹¹⁴⁴ the Federal Circuit held that the district court abused its

^{1137.} See Invitrogen Corp. v. Biocrest Mfg., L.P., 424 F.3d 1374, 1379, 76 U.S.P.Q.2d (BNA) 1741, 1744 (Fed. Cir. 2005) ("[T]he [*Pfaff*] Court's analysis of the statutory term 'invention,' or the ready for patenting prong, applies to both . . . parts of section 102(b), 'on sale' and 'public use.' Thus, the Supreme Court's 'ready for patenting test' applies to the public use bar under § 102(b)."). 1138. *Pfaff*, 525 U.S. at 67, 48 U.S.P.Q.2d (BNA) at 1646-47.

^{1139.} See Invitrogen, 424 F.3d at 1379, 76 U.S.P.Q.2d (BNA) at 1744 ("A bar under § 102(b) arises where, before the critical date, the invention is in public use and

ready for patenting."). 1140. Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359, 1368, 81 U.S.P.Q.2d (BNA) 1705, 1712 (Fed. Cir. 2007).

^{1141.} *Pfaff*, 525 U.S. at 64–65, 48 U.S.P.Q.2d (BNA) at 1645; *see also* Elizabeth v. Am. Nicholson Pavement Co., 97 U.S. 126, 137 (1877) (holding that an inventor's public use "by way of experiment" does not bar patentability).

^{1142.} See, e.g., Electromotive Div. of Gen. Motors Corp. v. Transp. Sys. Div. of Gen. Elec. Co., 417 F.3d 1203, 1214–15, 75 U.S.P.Q.2d (BNA) 1650, 1658 (Fed. Cir. 2005) ("[C]ontrol and customer awareness ordinarily must be proven if experimentation is to be found."); Lough v. Brunswick Corp., 86 F.3d 1113, 1120, 39 U.S.P.Q.2d (BNA) 1100, 1105 (Fed. Cir. 1996) ("[I]f the inventor has no control over the alleged experiments, he is not experimenting. If he does not inquire about the testing or receive reports concerning the results, similarly, he is not experimenting."); *In re* Hamilton, 882 F.2d 1576, 1581, 11 U.S.P.Q.2d (BNA) 1890, 1894 (Fed. Cir. 1989) ("[T]]he inventor must keep the invention under his own control."). 1143. See Pfaff, 525 U.S. at 65, 48 U.S.P.Q.2d (BNA) at 1645–46 (describing the on-

sale bar, which prevents an invention from being patented if it has been on sale any time before the patent application is filed) (quoting *Elizabeth*, 97 U.S. at 137). 1144. 525 F.3d 1353, 86 U.S.P.Q.2d (BNA) 1732 (Fed. Cir. 2008).

discretion in failing to accord a patent the priority date of the original provisional application, as required by the patent statute.¹¹⁴⁵ In that case, the patentee changed its position over the course of the district court proceedings by asserting an earlier priority date in light of the accused infringer's assertions of invalidity under § 102.¹¹⁴⁶ Nevertheless, the Federal Circuit held that the undisputed facts contained in the prosecution history established that the patent, which derived from a non-provisional application, was entitled to the filing date of the earlier provisional application as a matter of law.¹¹⁴⁷ Because the provisional and non-provisional applications were identical and shared a common inventor, because the nonprovisional was filed within twelve months of the provisional, and finally because the non-provisional explicitly referenced the provisional in the application, 35 U.S.C. § 119(e)(1) of the patent statute mandated that the non-provisional filing be given "the same effect, as to such invention, as though filed on the date of the provisional application."¹¹⁴⁸

In American Seating Co. v. USSC Group, Inc., 1149 the Federal Circuit agreed with the district court's refusal to grant summary judgment of invalidity, over a jury verdict to the contrary, where the prior public use of the invention was experimental.¹¹⁵⁰ The asserted patent was directed to a wheelchair restraint system for use in mass transit vehicles.¹¹⁵¹ The accused infringer, USSC Group, argued that the claims were invalid for being in public use more than one year prior to the December 1996 filing date.¹¹⁵² In particular, USSC pointed to the inventors' failure to obtain formal confidentiality agreements when disclosing the device to others before December 1995.¹¹⁵³

In upholding the district court's denial of USSC's motion for summary judgment, the Federal Circuit held that

the fact that the inventors revealed the prototype to a select group of individuals without a written confidentiality agreement is not dispositive. When access to an invention is clearly limited and controlled by the inventor, depending upon the relationships of

^{1145.} *Id.* at 1354, 86 U.S.P.Q.2d (BNA) at 1734. 1146. *Id.* at 1355–56, 86 U.S.P.Q.2d (BNA) at 1736. 1147. *Id.* at 1358, 86 U.S.P.Q.2d (BNA) at 1741.

^{1148.} *Id.* at 1358, 86 U.S.P.Q.2d (BNA) at 1737 (citing 35 U.S.C. § 119(e)(1) (2008)); *see also id.* at 1359–63, 86 U.S.P.Q.2d (BNA) at 1737–39 (discussing the requirements for a non-provisional application to claim priority over a provisional application).

^{1149. 514} F.3d 1262, 85 U.S.P.Q.2d (BNA) 1683 (Fed. Cir. 2008).

^{1150.} Id. at 1265, 85 U.S.P.Q.2d (BNA) at 1684.

^{1151.} Id., 85 U.S.P.Q.2d (BŇA) at 1684.

^{1152.} Id. at 1267, 85 U.S.P.Q.2d (BNA) at 1685.

^{1153.} Id., 85 U.S.P.Q.2d (BŇA) at 1685.

the observers and the inventor, an understanding of confidentiality can be implied.¹¹⁵⁴

Here, the record established that the inventors had maintained control of the invention throughout the pre-critical-date period.¹¹⁵⁵ The periodic demonstrations to a limited number of friends and colleagues were used to solicit feedback regarding "evolving prototypes" as the invention was being developed.¹¹⁵⁶ All disclosures occurred in an out-of-service bus-indeed, there was no evidence that a prototype was placed in service before December 1995—and the inventors consistently removed the invention from the bus for storage under their control.¹¹⁵⁷ Therefore, these early disclosures fell within the experimental use exception, and the district court appropriately confirmed the jury's verdict that the patent was valid.¹¹⁵⁸

In contrast, the court in Atlanta Attachment Co. v. Leggett & Platt, Inc.¹¹⁵⁹ reversed the district court's judgment applying the experimental use exception and concluded that the claimed invention was invalid for being on sale prior to the critical date.¹¹⁶⁰ Sewing machine manufacturer Atlanta Attachment had developed, in response to a request from potential customer Sealy, Inc., the invention that became the subject of the '603 patent.¹¹⁶¹ The asserted claim of the '603 patent was directed to an automatic gusset ruffler machine for use in producing pillowtop mattresses.¹¹⁶² More than a year prior to the critical date, Atlanta Attachment sent several prototypes to Sealy for testing and approval, along with offers to sell production models to Sealy.¹¹⁶³ Atlanta Attachment also sent an invoice, which Sealy paid, for one prototype that embodied all elements of the asserted claim.¹¹⁶⁴ Although Sealy ultimately decided not to buy the machines, Atlanta Attachment applied for a patent on its invention and later sued Leggett & Platt for patent infringement.1165

Applying the two-pronged test described by the Supreme Court in *Pfaff*, the Federal Circuit held that claimed invention was both (1) the subject of a pre-critical-date commercial offer for sale and (2) ready

^{1154.} *Id.* at 1268, 85 U.S.P.Q.2d (BNA) at 1685–86. 1155. *Id.* at 1267–68, 85 U.S.P.Q.2d (BNA) at 1685–86. 1156. *Id.*, 85 U.S.P.Q.2d (BNA) at 1685–86. 1157. *Id.*, 85 U.S.P.Q.2d (BNA) at 1685–86.

^{1158.} *Id.* at 1268, 85 U.S.P.Q.2d (BNA) at 1686. 1159. 516 F.3d 1361, 85 U.S.P.Q.2d (BNA) 1995 (Fed. Cir. 2008).

^{1160.} Id. at 1363, 85 U.S.P.Q.2d (BNA) at 1996.

^{1161.} Id., at 1363, 65 C.5.1.Q.2d (BNA) at 1996.
1161. Id., 85 U.S.P.Q.2d (BNA) at 1996.
1162. Id., 85 U.S.P.Q.2d (BNA) at 1996.
1163. Id., 85 U.S.P.Q.2d (BNA) at 1997.
1164. Id. at 1363, 1365, 85 U.S.P.Q.2d (BNA) at 1997-98.

^{1165.} Id. at 1364, 85 U.S.P.Q.2d (BNA) at 1997.

for patenting at the time of the offer, thus rendering the asserted claim invalid under the on-sale bar provision of § 102(b).¹¹⁶⁶ In the case of the prototype embodying all elements of the claim, Atlanta Attachment had offered the machine for sale (by sending an invoice) and Sealy had accepted (by paying the invoice). Thus, the invention was the subject of an actual commercial sale, not merely an offer for sale.¹¹⁶⁷ The court also rejected Atlanta Attachment's argument that its sales to Sealy qualified as "experimental use."1168 In giving the prototypes to Sealy to conduct its own testing, Atlanta Attachment relinquished control over the prototypes and the alleged experimentation.¹¹⁶⁹ Moreover, "once there has been a commercial offer, there can be no experimental use exception."¹¹⁷⁰ Finally, the Federal Circuit concluded that the invention was "ready for patenting" under *Pfaff* because it had been reduced to practice at the time of the sale of the prototype, even though other improvements were later made.¹¹⁷¹

In a separate concurrence, Judge Prost called attention to "the confusion in our caselaw" regarding the application of the experimental use doctrine to the two-prong test set forth in *Pfaff*.¹¹⁷² In particular, wrote Judge Prost, the Pfaff decision distinguished between "ready for patenting" (the second prong of the inquiry) and "reduction to practice."¹¹⁷³ Nevertheless, numerous post-Pfaff decisions have held that the experimental use exception is categorically unavailable once the invention is reduced to practice.¹¹⁷⁴ Judge Prost disagreed with this position, noting that "[i]f we were to accept that reduction to practice eliminates availability of the experimental use doctrine as a whole, the continuing viability of that doctrine would exist only between the time an invention is ready for patenting and the time it is reduced to practice."¹¹⁷⁵ This would

863

^{1166.} Id. at 1367, 85 U.S.P.Q.2d (BNA) at 1999.

^{1167.} *Id.* at 1365, 85 U.S.P.Q.2d (BNA) at 1998. 1168. *Id.* at 1366, 85 U.S.P.Q.2d (BNA) at 1999.

^{1169.} Id., 85 U.S.P.Q.2d (BŇA) at 1998. 1170. Id., 85 U.S.P.Q.2d (BNA) at 1999.

^{1170.} Id., 65 U.S.P.Q.2d (BNA) at 1999.
1171. Id. at 1367–68, 85 U.S.P.Q.2d (BNA) at 2000.
1172. Id. at 1368, 85 U.S.P.Q.2d (BNA) at 2000 (Prost, J., concurring).
1173. Id., 85 U.S.P.Q.2d (BNA) at 2000.

^{1173.} *Id.*, 85 U.S.P.Q.2d (BNA) at 2000. 1174. *Id.*, 85 U.S.P.Q.2d (BNA) at 2000–01 (citing Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359, 1371 n.10, 81 U.S.P.Q.2d (BNA) 1705, 1714 n.10 (Fed. Cir. 2007); Allen Eng'g Corp. v. Bartell Indus., Inc., 299 F.3d 1336, 1354, 63 U.S.P.Q.2d (BNA) 1769, 1779 (Fed. Cir. 2002); New Railhead Mfg., L.L.C. v. Vermeer Mfg. Comp. 298 F.3d 1290, 1297, 1299, 63 U.S.P.Q.2d (BNA) 1843, 1850, 1851 (Fed. Cir. 2002); EZ Dock, Inc. v. Schafer Sys., Inc., 276 F.3d 1347, 1357, 61 U.S.P.Q.2d (BNA) 1289, 1296 (Fed. Cir. 2002) (Linn, J., concurring); Zacharin v. United States, 213 F.3d 1366, 1369, 55 U.S.P.Q.2d (BNA) 1047, 1050 (Fed. Cir. 2000)). 1175. Id. at 1368-69, 85 U.S.P.Q.2d (BNA) at 2001.

dramatically restrict inventors' abilities to continue developing an invention.¹¹⁷⁶ Therefore, in her view, even after creating a complete invention that is ready for patenting, inventors "should be able to continue to privately develop any claimed aspect of that invention without risking invalidation, if they conduct development activities in a way that is neither public nor *simply* commercial, even if there is some commercial benefit to the inventor[s] in connection with the experimental use."1177

Notwithstanding Judge Prost's concurrence in Atlanta Attachment, the Federal Circuit issued two additional opinions in 2008 affirming the rule that reduction to practice eliminates the availability of the experimental use exception to the on-sale bar. In re Cygnus Telecommunications Technology, LLC Patent Litigation¹¹⁷⁸ affirmed the district court's ruling of invalidity explicitly "based on this court's law that 'experimental use cannot occur after a reduction to practice.'"¹¹⁷⁹ There, the inventor's own declaration stated that the invention-a computerized call-back system for placing telephone calls from abroad—had been reduced to practice by the time the inventor began charging two "beta testers" a per-minute rate to use the system.¹¹⁸⁰ Other information provided by the inventor further established that the system was functional and embodied all limitations of the claim prior to the sales to the beta testers.¹¹⁸¹ Thus, the district court had correctly declined to apply the experimental use exception, and the patent was invalid under § 102(b).¹¹⁸

Similarly, in In re Omeprazole Patent Litigation,¹¹⁸³ the Federal Circuit reiterated that "experimental use cannot negate a public use when it is shown that the invention was reduced to practice before the experimental use."¹¹⁸⁴ In this matter, which involved patents on the drug omeprazole (the active ingredient in Prilosec), the court concluded that the district court had misapplied the law when it found that the experimental use exception would prevent

^{1176.} Id. at 1369, 85 U.S.P.Q.2d (BNA) at 2001.

^{1170. 10.} at 1309, 85 U.S.P.Q.20 (BNA) at 2001.
1177. Id., 85 U.S.P.Q.2d (BNA) at 2001 (emphasis added).
1178. 536 F.3d 1343, 87 U.S.P.Q.2d (BNA) 1801 (Fed. Cir. 2008).
1179. Id. at 1356, 87 U.S.P.Q.2d (BNA) at 1809 (citing Cont'l Plastic Containers v. Owens Brockway Plastic Prods., Inc., 141 F.3d 1073, 1079, 46 U.S.P.Q.2d (BNA) 1277, 1281 (Fed. Cir. 1998)).
1180. Id. at 1354, 55 - 87 U.S.P.Q.2d (DNA) at 1000.

^{1180.} Id. at 1354-55, 87 U.S.P.Q.2d (BNA) at 1808.

^{1181.} Id., 87 U.S.P.Q.2d (BNA) at 1808.

^{1182.} Id. at 1356, 87 U.S.P.Q.2d (BNA) at 1808-09.

^{1183. 536} F.3d 1361, 87 U.S.P.Q.2d (BNA) 1865 (Fed. Cir. 2008). 1184. *Id.* at 1372, 87 U.S.P.Q.2d (BNA) at 1872 (acknowledging, as a "*But see*," Judge Prost's concurrence in Atlanta Attachment).

invalidation even if the invention had been reduced to practice before or during the experimentation period.¹¹⁸⁵

Nevertheless, the Federal Circuit affirmed the district court's determination that clinical studies investigating the claimed drug formulation did not qualify as invalidating public uses under § 102(b), on the grounds that the drug was not yet ready for patenting at the time of the clinical trials.¹¹⁸⁶ The alleged infringers argued that the claimed drug formulation had been successfully reduced to practice and was therefore "ready for patenting" under Pfaff.¹¹⁸⁷ The district court found otherwise, and the Federal Circuit agreed.¹¹⁸⁸

Although it was undisputed that the formulation had been produced prior to the trials, this "[did] not establish that the [patentees] had determined that the invention would work for its intended purpose" of increasing in vivo drug stability without significantly compromising long-term storage stability.¹¹⁸⁹ Moreover, the fact that the formulation was "more stable" than prior formulations was insufficient to prove that the drug was stable *enough* to be used in treatment.¹¹⁹⁰ Finally, even if it was well-known before the critical date that omeprazole was a safe and effective treatment, the challenge faced by the inventors was not providing safe and effective treatment, but developing a formulation that could be delivered to the small intestine and overcome the drug's sensitivity to the acidic environment-a goal that had not been achieved before the critical date.¹¹⁹¹ Thus, there was no clear error in the district court's finding that the claims were not ready for patenting-and thus not invalidating—under § 102(b).¹¹⁹²

С. Obviousness

In keeping with the goal of limiting patent monopolies to cases of true innovation, the patent statute also bars the patentability of inventions that are obvious. In particular, 35 U.S.C. § 103(a) provides that a claimed invention is unpatentable "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious

^{1185.} Id., 87 U.S.P.Q.2d (BNA) at 1872. 1186. Id. at 1373-75, 87 U.S.P.Q.2d (BNA) at 1873-74.

^{1187.} Id. at 1373, 87 U.S.P.Q.2d (BNA) at 1873.

^{1188.} Id. at 1373-75, 87 U.S.P.Q.2d (BNA) at 1873-75.

^{1189.} Id. at 1373-74, 87 U.S.P.Q.2d (BNA) at 1874-75. 1190. Id. at 1374-75, 87 U.S.P.Q.2d (BNA) at 1874-75.

^{1191.} Id. at 1375, 87 U.S.P.Q.2d (BNA) at 1875.

^{1192.} Id., 87 U.S.P.Q.2d (BŇA) at 1875.

at the time the invention was made to a person having ordinary skill in the art."1193

Obviousness is a legal question, based upon underlying factual determinations.¹¹⁹⁴ The relevant factual inquiries are (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) evidence of secondary factors (also called objective indicia of non-obviousness), such as commercial success, long felt but unsolved needs, and the failure of others.¹¹⁹⁵

In contrast with anticipation, obviousness may be proven by combining elements disclosed in various separate prior art references. In evaluating obviousness based on a combination of references, the Supreme Court has noted that "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does."¹¹⁹⁶ As explained in the Supreme Court's 2007 decision in KSR International Co. v. Teleflex, Inc., ¹¹⁹⁷ obviousness must be assessed in a flexible manner, as the motivation to combine references can be triggered by "any need or problem known in the field of endeavor at the time of invention."¹¹⁹⁸ Nevertheless, a "combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."1199

In deciding KSR, the Supreme Court rejected the Federal Circuit's strict use of the "teaching, suggestion, or motivation" ("TSM") test, under which a patent claim is only found obvious if the prior art, the nature of the problem, or the knowledge of a person of ordinary skill in the art evidences some motivation or suggestion to combine the prior art teachings.¹²⁰⁰

In Cohesive Technologies, Inc. v. Waters Corp., 1201 the Federal Circuit addressed the relationship between the patent-law doctrines of The underlying dispute involved anticipation and obviousness.

^{1193. 35} U.S.C. § 103(a) (2008).

^{1194.} Richardson-Vicks Inc. v. Upjohn Co., 122 F.3d 1476, 1479, 44 U.S.P.Q.2d (BNA) 1181, 1183 (Fed. Cir. 1997) (citing Graham v. John Deere Co., 383 U.S. 1, 17, 148 U.S.P.Q. (BNA) 459, 467 (1966)).

^{1195.} Graham, 383 U.S. at 17-18, 148 U.S.P.Q. (BNA) at 467.

^{1196.} KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398, 418, 82 U.S.P.Q.2d (BNA) 1385, 1396 (2007)

^{1197. 550} U.S. 398, 82 U.S.P.Q.2d (BNA) 1385 (2007).

See id. at 420, 82 U.S.P.Q.2d (BNA) at 1397 (reasserting the applicability of 1198. the Graham analytical framework).

^{1199.} Id. at 416, 82 U.S.P.Q.2d (BNA) at 1389. 1200. Id. at 418–19, 82 U.S.P.Q.2d (BNA) at 1388.

^{1201. 543} F.3d 1351, 88 U.S.P.Q.2d (BNA) 1903 (Fed. Cir. 2008).

patents relating to high-performance liquid chromatography, a process of identifying and separating various chemical compounds in a liquid.¹²⁰² At the jury trial, the alleged infringer, Waters Corp., argued that the asserted claims were anticipated by seven different prior art references.¹²⁰³ Waters also argued that the seven references, either separately or in various combinations, rendered the claims obvious.¹²⁰⁴ Over Waters's objection, the district court submitted obviousness, but not anticipation, to the jury, reasoning that anticipation is "a subset of obviousness."¹²⁰⁵ The jury found, inter alia, that the claims were not obvious over the prior art references.¹²⁰⁶ On appeal, Waters asserted that the district court had erred by granting judgment as a matter of law on the anticipation issue, and the Federal Circuit agreed.¹²⁰⁷

The two-judge majority of the panel held that the district court had erred in refusing to allow the jury to consider anticipation without making the requisite finding that no reasonable jury could have concluded that the references anticipated the claims.¹²⁰⁸ Instead, the district court had characterized Waters's anticipation position as "iffy," which did not foreclose the possibility of a favorable jury verdict.¹²⁰⁹ The majority went on to assert that, "[w]hile it is commonly understood that prior art references that anticipate a claim will usually render that claim obvious, it is not necessarily true that a verdict of nonobviousness forecloses anticipation."1210 Anticipation and obviousness are separate statutory conditions of patentability and involve distinct tests.¹²¹¹ Therefore, the majority refused to accept the dissent's assertion that every anticipated claim is also obvious.¹²¹² The court stated:

1210. Id. at 1364, 88 U.S.P.Q.2d (BNA) at 1911. 1211. Id. at 1363–64, 88 U.S.P.Q.2d (BNA) at 1910–11. 1212. Id. at 1364 n.2, 88 U.S.P.Q.2d (BNA) at 1911 n.2. As an example, the majority posed the following hypothetical:

^{1202.} Id. at 1357-58, 88 U.S.P.Q.2d (BNA) at 1906.

^{1203.} *Id.* at 1358–59, 88 U.S.P.Q.2d (BNA) at 1907. 1204. *Id.* 88 U.S.P.Q.2d (BNA) at 1907.

^{1205.} Id. at 1359, 88 U.S.P.Q.2d (BNA) at 1907.

^{1206.} Id., 88 U.S.P.Q.2d (BNA) at 1907.

^{1207.} *Id.* at 1363, 88 U.S.P.Q.2d (BNA) at 1910. 1208. *Id.*, 88 U.S.P.Q.2d (BNA) at 1910. 1209. *Id.*, 88 U.S.P.Q.2d (BNA) at 1910.

Consider . . . a claim directed toward a particular alloy of metal. The claimed metal alloy may have all the hallmarks of a nonobvious invention there was a long felt but unresolved need for an alloy with the properties of the claimed alloy, others may have tried and failed to produce such an alloy, and, once disclosed, the claimed alloy may have received high praise and seen commercial success. Nevertheless, there may be a centuries-old alchemy textbook that, while not describing any metal alloys, describes a method that, if practiced precisely, actually produces the claimed alloy.

A court cannot refuse to submit the issue of anticipation to the jury simply because the accused infringer has also asserted an obviousness defense. It is for the litigants—not the court—to make the strategic decision as to whether to assert one, both, or neither of these defenses in a jury trial.¹²¹³

The majority therefore reversed the district court's grant of judgment as a matter of law on anticipation and remanded for further proceedings.¹²¹⁴

Judge Mayer dissented from the majority's decision to remand the issue of anticipation to the trial court. He agreed that the tests for establishing obviousness and anticipation are separate and that a district court cannot refuse to submit an anticipation defense to a jury simply because the accused infringer had also presented an obviousness defense.¹²¹⁵ Nevertheless, Judge Mayer maintained that once the jury had already determined that the claims were not obvious, there was no logical reason to remand the case to consider anticipation.¹²¹⁶

The jury here considered all of the allegedly anticipating prior art references, but nonetheless returned a verdict that the asserted claims are non-obvious. If a series of prior art references did not render the claimed invention obvious, how could one of those references contain each and every element of the claimed invention so as to render it anticipated?¹²¹⁷

Therefore, Judge Mayer would have affirmed the district court's directed verdict on anticipation.¹²¹⁸

A series of Federal Circuit decisions in 2008, addressing the Supreme Court's April 2007 decision in KSR,¹²¹⁹ clarified the test for determining obviousness based on a combination of prior art references. The dispute in Agrizap, Inc. v. Woodstream Corp.¹²²⁰ represented a "textbook case of [obviousness] when the asserted claims involve a combination of familiar elements according to known methods that does no more than yield predictable results."1221 The patent at issue was directed to a method and device for

While the prior art alchemy textbook inherently anticipates the claim under § 102, the claim may not be said to be obvious under § 103. Id., 88 U.S.P.Q.2d (BNA) at 1911 n.2.

^{1213.} Id. at 1364–65, 88 U.S.P.Q.2d (BNA) at 1912. 1214. Id. at 1365, 88 U.S.P.Q.2d (BNA) at 1912. 1215. Id. at 1376, 88 U.S.P.Q.2d (BNA) at 1919 (Mayer, J., dissenting).

^{1216.} Id., 88 U.S.P.Q.2d (BNA) at 1919.
1217. Id., 88 U.S.P.Q.2d (BNA) at 1919.
1218. Id. at 1377, 88 U.S.P.Q.2d (BNA) at 1919.
1218. Id. at 1377, 88 U.S.P.Q.2d (BNA) at 1920.
1219. Supra discussion Part I.A.1.

^{1220. 520} F.3d 1337, 86 U.S.P.Q.2d (BNA) 1110 (Fed. Cir. 2008).

^{1221.} Id. at 1344, 86 U.S.P.Q.2d (BNA) at 1115.

electrocuting small rodents, using an electrical resistive switch.¹²²² The undisputed facts showed that a prior art device, the Gopher Zapper, disclosed all elements of the asserted claims, with the exception of the type of switch used: the Gopher Zapper used a mechanical pressure switch, rather than an electrical resistive switch.¹²²³ The use of resistive switches, however, was taught in two prior patents, the Dye and Madsen references, which both described devices for applying electrical current to an external body and were directed toward solving the same problem as the patent-in-suit-the tendency for mechanical switches to malfunction in damp and dirty environments.¹²²⁴ In light of this evidence, the Federal Circuit concluded that the patentee's device was invalid as embodying merely an obvious combination of prior art teachings to yield predictable results.¹²²⁵ Because the objective indicia of non-obviousness were insufficient to overcome such a clear case of obviousness, the Federal Circuit reversed the district court's denial of the accused infringer's motion for judgment as a matter of law as to obviousness.¹²²⁶

In Commonwealth Scientific & Industrial Research Organisation v. Buffalo Technology, Inc., 1227 the Federal Circuit concluded that a genuine issue of material fact existed as to the motivation to combine prior art references to render the patent obvious, and thus, the district court had erred in granting summary judgment in favor of the patentee.¹²²⁸ The patents-in-suit were aimed at addressing a problem affecting indoor wireless local area networks—called the "multipath problem"—in which multiple, echoed signals (caused by radio waves "bouncing" off objects in a room) interfere with the main signal.¹²²⁹ Before the district court, the alleged infringer argued that the claims were obvious in light of several combinations of prior art references.¹²³⁰ Applying the pre-KSR teaching, suggestion, and motivation ("TSM") test, the district court granted summary judgment of non-obviousness, distinguishing between the general motivation to address a problem (which it deemed insignificant to prove obviousness) and a specific motivation to pursue a particular solution to the problem.¹²³¹ The Federal Circuit vacated the district

^{1222.} Id. at 1339-40, 86 U.S.P.Q.2d (BNA) at 1111.

^{1223.} Id. at 1344, 86 U.S.P.Q.2d (BNA) at 1115.

^{1224.} *Id.*, 86 U.S.P.Q.2d (BNA) at 1115. 1225. *Id.*, 86 U.S.P.Q.2d (BNA) at 1115. 1226. *Id.*, 86 U.S.P.Q.2d (BNA) at 1115.

^{1220.} Id., 66 C.S.F.Q.2d (BNA) at 1115.
1227. 542 F.3d 1363, 88 U.S.P.Q.2d (BNA) 1564 (Fed. Cir. 2008).
1228. Id. at 1378, 88 U.S.P.Q.2d (BNA) at 1575.
1229. Id. at 1367, 88 U.S.P.Q.2d (BNA) at 1567.
1230. Id. at 1372-73, 88 U.S.P.Q.2d (BNA) at 1570-71.

^{1231.} Id. at 1373, 88 U.S.P.Q.2d (BNA) at 1571.

court's determination in light of the new analytical framework discussed in KSR.1232

The court explained that the Supreme Court's decision in *KSR* had criticized the Federal Circuit's TSM test for focusing solely on the precise problem that an inventor sought to solve.¹²³³ Rather. the Court ruled in KSR that "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed."1234 Therefore, the alleged infringer had raised a valid argument that all of the relied-upon references addressed a common problem, the "multipath" problem for wireless radio frequency communication systems.¹²³⁵ This, coupled with the patentee's counterargument that the prior art presented a different problem, created a factual issue regarding the motivation to combine references.¹²³⁶ The Federal Circuit accordingly remanded the matter to the district court for further proceedings on the obviousness issue.¹²³⁷

The court in Asyst Technologies, Inc. v. Emtrak, Inc.¹²³⁸ affirmed the trial court's decision to set aside a jury verdict of non-obviousness where the jury improperly failed to consider a piece of relevant prior art. The infringement suit involved a patented system for tracking items, such as silicone semiconductor wafers, in a manufacturing facility.¹²³⁹ The evidence presented at trial demonstrated that one prior art patent, the "Hesser" reference, disclosed "essentially the same structure" as the patent-in-suit.¹²⁴⁰ The sole material difference was that the Hesser reference disclosed that tracking information was communicated over a bus, while the claims of the asserted patent recited communication by way of a multiplexer.¹²⁴¹ The alleged infringers had argued that the Hesser reference, in combination with the well-known interchangeability between a bus and a multiplexer in the relevant prior art, rendered the claims invalid for obviousness.¹²⁴² Following a trial, the jury concluded that the Hesser reference did not constitute relevant prior art and therefore deemed the asserted

^{1232.} Id. at 1374, 88 U.S.P.Q.2d (BNA) at 1572.

^{1233.} Id., 88 U.S.P.Q.2d (BNA) at 1571.

^{1234.} KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398, 420, 82 U.S.P.Q.2d (BNA) 1385, 1389-90 (2007).

^{1235.} *Commonwealth Scientific*, 542 F.3d at 1375, 88 U.S.P.Q.2d (BNA) at 1572. 1236. *Id.* at 1375–76, 88 U.S.P.Q.2d (BNA) at 1572.

^{1237.} *Id.* at 1376, 88 U.S.P.Q.2d (BNA) at 1573. 1238. 544 F.3d 1310, 88 U.S.P.Q.2d (BNA) 1623 (Fed. Cir. 2008).

^{1239.} *Id.* at 1312, 88 U.S.P.Q.2d (BNA) at 1625. 1240. *Id.* at 1314, 88 U.S.P.Q.2d (BNA) at 1626.

^{1241.} Id., 88 U.S.P.Q.2d (BNA) at 1626-27.

^{1242.} Id. at 1314-15, 88 U.S.P.Q.2d (BNA) at 1627.

claims non-obvious.¹²⁴³ Following post-trial briefing, the Supreme Court rendered its decision in KSR, and the district court, after hearing additional arguments in light of KSR, set aside the jury verdict and entered judgment of obviousness as a matter of law.¹²⁴⁴

On appeal, the Federal Circuit agreed that the jury had erred in finding that the Hesser reference was not prior art.¹²⁴⁵ Hesser was directly pertinent to the art of tracking articles in a factory.¹²⁴⁶ In fact, the patent holder's own technical expert had acknowledged that the relevant prior art would include the Hesser reference.¹²⁴⁷ Moreover, one of ordinary skill in the art would have been familiar with both buses and multiplexers, each of which had well-known advantages and disadvantages at the time the patent-in-suit was filed.¹²⁴⁸ The court noted KSR's point that "'if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.""1249 Therefore, because the patent holder had presented no evidence to indicate that the multiplexer in its invention operated in an unconventional or unfamiliar way, the Federal Circuit agreed with the district court that it would have been obvious to a skilled artisan to replace Hesser's bus with a multiplexer to arrive at the claimed invention.¹²⁵⁰

As a procedural matter, the court in Asyst Technologies also ruled that the district court did not abuse its discretion in allowing the accused infringer to introduce a new theory of invalidity (based on the Hesser reference).¹²⁵¹ "[T]he change in claim construction resulting from this court's decision on appeal 'changed the rules of the game.^{"1252} It was therefore appropriate for the district court to allow the accused infringer to amend its defenses in light of the new claim construction.¹²⁵³

1251. *Id.* at 1317, 88 U.S.P.Q.2d (BNA) at 1629. 1252. *Id.*, 88 U.S.P.Q.2d (BNA) at 1629 (quoting Johns Hopkins Univ. v. Cellpro, Inc., 152 F.3d 1342, 1357, 47 U.S.P.Q.2d (BNA) 1705, 1715 (Fed. Cir. 1988)). 1253. Id., 88 U.S.P.Q.2d (BNA) at 1629.

^{1243.} Id. at 1313, 88 U.S.P.Q.2d (BNA) at 1625.

^{1244.} *Id.*, 88 U.S.P.Q.2d (BNA) at 1625. 1245. *Id.*, 88 U.S.P.Q.2d (BNA) at 1626. 1246. *Id.*, 88 U.S.P.Q.2d (BNA) at 1626.

^{1247.} Id., 88 U.S.P.Q.2d (BNA) at 1626.
1248. Id. at 1314–15, 88 U.S.P.Q.2d (BNA) at 1627.
1249. Id. at 1315, 88 U.S.P.Q.2d (BNA) at 1627 (quoting KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398, 417, 82 U.S.P.Q.2d (BNA) 1385, 1389 (2007)).

^{1250.} Id., 88 U.S.P.Q.2d (BNA) at 1627. In addition, the secondary considerations asserted by the patent holder were either inapplicable or not attributable to the particular bus/multiplexer substitution that distinguished the patent from Hesser. Id. at 1316, 88 U.S.P.Q.2d (BNA) at 1628.

In *Rentrop v. Spectranetics Corp.*,¹²⁵⁴ however, the Federal Circuit held that a defendant had waived its argument under KSR by not raising the argument in the district court, even though KSR had been decided *after* the jury verdict and post-trial briefing. The court held that the defendant could have raised KSR after the post-trial briefing was completed because the district court judge did not *decide* the posttrial motions for almost four months after the KSR decision.¹²⁵⁵ As the court summarized, "when there is a relevant change in the law before entry of final judgment," a party that fails to notify the district court "waives arguments on appeal that are based on that change of law."¹²⁵⁶

In Erico International Corp. v. Vutec Corp., 1257 the Federal Circuit addressed obviousness in the context of a grant of a preliminary injunction. The dispute arose out of Erico's '994 patent, which disclosed a method of using Erico's popular J-Hook fasteners to support low voltage communication cables.¹²⁵⁸ The asserted claim included a limitation that required "spacing the [J-Hooks] . . . so that the run sags between [the J-Hooks] no more than about 30 cm."¹²⁵⁹ Erico sought a preliminary injunction to prevent the defendant from selling its own version of the J-Hook.¹²⁶⁰ While admitting that it had copied Erico's J-Hook design,¹²⁶¹ the defendant argued that the asserted claim was invalid as obvious over a similar hook device disclosed in "the OBO Betterman" reference, in combination with a 1990 publication by the Electronics Industries Alliance/Telecommunications Industry Association ("EIA/TIA") setting forth proper standards for hanging open-top cable supports.¹²⁶² Nevertheless, the district court granted a preliminary injunction, which the Federal Circuit vacated by a 2-1 panel majority.1263

The majority decision determined that the defendant raised a substantial question of invalidity, thus negating the patent holder's "likelihood of success" on the merits.¹²⁶⁴ As the Federal Circuit explained, "[v]alidity challenges during preliminary injunction proceedings can be successful, that is, they may raise substantial

⁵⁵⁰ F.3d 1112, 89 U.S.P.Q.2d (BNA) 1417 (Fed. Cir. 2008). *Id.* at 1117, 89 U.S.P.Q.2d (BNA) at 1420. 1254.

^{1255.}

Id., 89 U.S.P.Q.2d (BNA) at 1420. 1256.

^{1257. 516} F.3d 1350, 86 U.S.P.Q.2d (BNA) 1030 (Fed. Cir. 2008). 1258. *Id.* at 1351, 86 U.S.P.Q.2d (BNA) at 1031–32.

^{1259.} *Id.* at 1352, 86 U.S.P.Q.2d (BNA) at 1032. 1260. *Id.* at 1351–52, 86 U.S.P.Q.2d (BNA) at 1031.

^{1261.} *Id.* at 1353, 86 U.S.P.Q.2d (BNA) at 1032. 1262. *Id.* at 1354, 86 U.S.P.Q.2d (BNA) at 1033.

^{1263.} Id. at 1351-52, 86 U.S.P.Q.2d (BNA) at 1031.

^{1264.} Id. at 1357, 86 U.S.P.Q.2d (BNA) at 1035.

questions of invalidity, on evidence that would not suffice to support a judgment of invalidity at trial."¹²⁶⁵ Raising a substantial question of invalidity "requires less proof than the clear and convincing standard to show actual invalidity."¹²⁶⁶ Under this lowered standard, the court concluded that the alleged combination of references, supported by the inventor's own testimony, posed a "serious challenge" to the validity of the asserted claim.¹²⁶⁷ The OBO Betterman reference disclosed a hook with downward flaring flanges that were nearly identical to those of Erico's J-Hook.¹²⁶⁸ The EIA/TIA standards set out appropriate circumstances for using an open-top cable support system for communication cables.¹²⁶⁹ Moreover, the inventor had testified that it was common practice for installers of communication cables to pull cable taut in order to reduce sagging to less than 30 cm.¹²⁷⁰ This combination, explained the majority, suggests an "implicit motivation to combine the prior art" to use J-Hooks to meet the claim limitation of 30-cm-or-less cable sag.¹²⁷¹ Thus, a preliminary injunction was not warranted.

Dissenting, Judge Newman argued that the majority applied an incorrect standard to the factor of "likelihood of success on the merits."¹²⁷² The proper inquiry is "not whether there is a 'substantial question'; it is whether the defendants have shown that they are likely to succeed on the merits, on the standards and burdens of proof as would prevail at trial."1273 Moreover, Judge Newman criticized the majority for not explaining how the district court abused its discretion¹²⁷⁴ and for failing to consider the other equitable factors (irreparable harm, the balance of hardships, and the public interest) that are relevant to a preliminary injunction.¹²⁷⁵

The court in *Eisai Co. v. Dr. Reddy's Laboratories, Ltd.*¹²⁷⁶ clarified the post-KSR standard for determining obviousness in the context of patents on chemical compounds. The patent at issue, owned by Eisai, claimed the compound rabeprazole and its salts.¹²⁷⁷ Rabeprazole is part of a class of drugs called proton pump inhibitors, which suppress

- 1269. Id. at 1354, 86 U.S.P.Q.2d (BNA) at 1033.
- 1270. *Id.* at 1356–57, 86 U.S.P.Q.2d (BNA) at 1034–35. 1271. *Id.* at 1356, 86 U.S.P.Q.2d (BNA) at 1034.
- 1272. Id. at 1357, 86 U.S.P.Q.2d (BNA) at 1034.
 1272. Id. at 1357, 86 U.S.P.Q.2d (BNA) at 1035 (Newman, J., dissenting).
 1273. Id. at 1359, 86 U.S.P.Q.2d (BNA) at 1036.
 1274. Id. at 1358, 86 U.S.P.Q.2d (BNA) at 1035.

- 1275. *Id.* at 1358–59, 86 U.S.P.Q.2d (BNA) at 1036. 1276. 533 F.3d 1353, 87 U.S.P.Q.2d (BNA) 1452 (Fed. Cir. 2008).
- 1277. Id. at 1356, 87 U.S.P.Q.2d (BNA) at 1454.

^{1265.} Id. at 1355-56, 86 U.S.P.Q.2d (BNA) at 1034.

^{1266.} *Id.* at 1356, 86 U.S.P.Q.2d (BNA) at 1034. 1267. *Id.*, 86 U.S.P.Q.2d (BNA) at 1034. 1268. *Id.*, 86 U.S.P.Q.2d (BNA) at 1034.

the secretion of gastric acid.¹²⁷⁸ When Dr. Reddy's Laboratories and Teva Pharmaceuticals USA, Inc. filed abbreviated new drug applications ("ANDAs") seeking to produce a generic version of the drug, Eisai initiated a patent infringement lawsuit.¹²⁷⁹ Teva countered by asserting that Eisai's claimed drug compound was obvious in view of EP '726 (claiming lansoprazole, a known anti-ulcer drug), the '431 patent (claiming omeprazole), and an article by Brandstrom, et al.¹²⁸⁰ In particular, Teva focused on the EP '726 patent disclosing lansoprazole, which is structurally identical to rabeprazole, except that lansoprazole has a fluorinated substituent, whereas rabeprazole has a methoxypropoxy substituent.¹²⁸¹ The district court granted Eisai summary judgment of non-obviousness, and Teva appealed.¹²⁸²

The Federal Circuit affirmed the district court's determination that the claims were non-obvious.¹²⁸³ Where the patent claims a chemical compound, an obviousness analysis typically turns on "structural similarities and differences" between the claimed compound and other compounds disclosed in the prior art.¹²⁸⁴ Thus, one may prove obviousness by establishing some motivation for why a skilled artisan would select and then alter a known compound (i.e., lead compound) to arrive at the claimed invention.¹²⁸⁵ The Supreme Court's decision in KSR supports this reasoning, as it noted that "an invention may have been obvious '[w]hen there [was] . . . a design need or market pressure to solve a problem and there [were] . . . a finite number of identified, predictable solutions."1286 "In other words," wrote the Federal Circuit, "post-KSR, a prima facie case of obviousness for a chemical compound still, in general, begins with the reasoned identification of a lead compound."1287

Here, Teva chose to identify lansoprazole as the lead compound in its obviousness theory.¹²⁸⁸ However, one of the most desirable traits of lansoprazole is its ability to cross lipid membranes—a property that is

^{1278.} *Id.*, 87 U.S.P.Q.2d (BNA) at 1454. 1279. *Id.*, 87 U.S.P.Q.2d (BNA) at 1454.

^{1280.} *Id.* at 1357, 87 U.S.P.Q.2d (BNA) at 1455. 1281. *Id.* at 1357–58, 87 U.S.P.Q.2d (BNA) at 1455.

^{1281.} Id. at 1357-56, 87 U.S.P.Q.2d (BNA) at 1453.
1282. Id. at 1356, 87 U.S.P.Q.2d (BNA) at 1454.
1283. Id. at 1362, 87 U.S.P.Q.2d (BNA) at 1459.
1284. Id. at 1356-57, 87 U.S.P.Q.2d (BNA) at 1455 (citing Eli Lilly & Co. v. Zenith Goldline Pharms., Inc., 471 F.3d 1369, 1377, 81 U.S.P.Q.2d (BNA) 1324, 1329 (Fed. Cir. 2006)).

^{1285.} Id. at 1357, 87 U.S.P.Q.2d (BNA) at 1455.

^{1286.} *Id.* at 1359, 87 U.S.P.Q.2d (BNA) at 1456 (citing KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398, 421, 82 U.S.P.Q.2d (BNA) 1385, 1390 (2007)) (alteration in original)

^{1287.} Id., 87 U.S.P.Q.2d (BNA) at 1457.

^{1288.} Id. at 1358-59, 87 U.S.P.Q.2d (BNA) at 1456.

attributable to its fluorinated substituent.¹²⁸⁹ Because the record provided "no discernable reason"¹²⁹⁰ for why a skilled artisan would be motivated to select lansoprazole, only to remove its key feature, Teva failed to establish that the patented claims were obvious.¹²⁹¹

The Federal Circuit's decision in In re DBC¹²⁹² affirmed the PTO's rejection of claims directed to a "nutraceutical composition" from the fruit of the manogsteen tree as obvious over the prior art.¹²⁹³ DBC had obtained a patent on its composition, claiming a mixture of the juice and rind of the mangosteen fruit, combined with at least one other type of fruit or vegetable juice.¹²⁹⁴ On re-examination, the examiner rejected all claims as obvious over a combination of seven references, of which only one (the JP '442 patent) was not before the original examiner who found the claims patentable.¹²⁹⁵ In response. DBC submitted three declarations to show objective indicia of nonobviousness, including the success of XanGo, the commercial embodiment of DBC's invention.¹²⁹⁶ The examiner, however, finalized the rejection, and the Board of Patent Appeals and Interferences affirmed.¹²⁹⁷ On appeal, DBC argued (1) that the Board failed to establish a prima facie case of obviousness based upon a substantial new question of patentability because the JP '442 patent was cumulative prior art and (2) that the Board erred in not giving adequate weight to its evidence of commercial success.¹²⁹⁸

The Federal Circuit affirmed the Board's decision.¹²⁹⁹ Regarding DBC's first argument, the JP '442 reference was not cumulative because it was the only reference that taught the production of a compound with dietary or health benefits (i.e., a "neutraceutical composition" under the patent's definition of the term) combining the bitter mangosteen rind with fruits and fruit juices.¹³⁰⁰ Although one prior art patent disclosed the use of mangosteen rind as a drug, it only disclosed administration via "a syrup, solution, or suspension with a carrier"; it did not disclose a combination of the rind with fruits or fruit juices.¹³⁰¹ Therefore, the PTO correctly

^{1289.} Id. at 1358, 87 U.S.P.Q.2d (BNA) at 1456.

^{1290.} Id., 87 U.S.P.Q.2d (BNA) at 1456. 1291. Id. at 1358–59, 87 U.S.P.Q.2d (BNA) at 1456–57. 1292. 545 F.3d 1373, 89 U.S.P.Q.2d (BNA) 1123 (Fed. Cir. 2008).

^{1293.} Id. at 1376, 89 U.S.P.Q.2d (BNA) at 1125.

^{1294.} *Id.* at 1375–76, 89 U.S.P.Q.2d (BNA) at 1125. 1295. *Id.* at 1376, 89 U.S.P.Q.2d (BNA) at 1125.

^{1296.} Id., 89 U.S.P.Q.2d (BNA) at 1125.

^{1297.} Id., 89 U.S.P.Q.2d (BNA) at 1125-26.

^{1298.} *Id.* at 1377, 89 U.S.P.Q.2d (BNA) at 1126. 1299. *Id.* at 1375, 89 U.S.P.Q.2d (BNA) at 1125. 1300. *Id.* at 1376, 1382, 89 U.S.P.Q.2d (BNA) at 1125, 1130.

^{1301.} Id. at 1382, 89 U.S.P.Q.2d (BNA) at 1130.

876 AMERICAN UNIVERSITY LAW REVIEW [Vol. 58:747

concluded that the JP '442 reference presented a substantial new question of patentability and appropriately rejected the claims.¹³⁰² Regarding DBC's second argument, the Federal Circuit agreed with the PTO that DBC's evidence of commercial success was insufficient to rebut the strong prima facie case of obviousness.¹³⁰³ DBC had merely presented its sales figures without establishing "that the sales were a direct result of the unique characteristics of the claimed invention."1304

D. 35 U.S.C. § 112

1. Enablement

Under the enablement requirement, every patent must describe "the manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same."1305 This statutory mandate is "part of the quid pro quo of the patent bargain"¹³⁰⁶ and is designed to ensure that the public is enriched (by an adequate disclosure of the invention) just as the inventor is enriched (by a limited monopoly to commercialize the invention). It therefore follows that a patent specification must enable the full scope of each and every claim.¹³⁰⁷

Enablement is a question of law, based upon underlying questions of fact.¹³⁰⁸ Moreover, because a patent is presumed valid, a party challenging enablement must prove non-enablement by clear and convincing evidence.¹³⁰⁹

In Sitrick v. Dreamworks, LLC,¹³¹⁰ the Federal Circuit affirmed summary judgment of invalidity due to a lack of enablement, where the scope of the claims was broader than the disclosures in the specifications. The two patents at issue concerned a process for integrating a user's own audio signal or visual image into a pre-

^{1302.} Id. at 1382-83, 89 U.S.P.Q.2d (BNA) at 1130.

^{1303.} Id. at 1384, 89 U.S.P.Q.2d (BNA) at 1132.

^{1304.} *Id.* at 1384, 89 U.S.P.Q.2d (BNA) at 1132 (citing *In re* Huang, 100 F.3d 135, 140, 40 U.S.P.Q.2d (BNA) 1685, 1689 (Fed. Cir. 1996)) (internal quotations omitted).

^{1305. 35} U.S.C. § 112 (2006). 1306. AK Steel Corp. v. Sollac, 344 F.3d 1234, 1244, 68 U.S.P.Q.2d (BNA) 1280, 1287 (Fed. Cir. 2003).

^{1307.} Id. at 1241, 1244, 68 U.S.P.Q.2d (BNA) at 1284, 1287. 1308. Id. at 1238, 68 U.S.P.Q.2d (BNA) at 1283 (citing In re Wands, 858 F.2d 731, 735, 8 U.S.P.Q.2d (BNA) 1400, 1402 (Fed. Cir. 1988)).

^{1309.} Id. at 1238-39, 68 U.S.P.Q.2d (BNA) at 1283. 1310. 516 F.3d 993, 85 U.S.P.Q.2d (BNA) 1826 (Fed. Cir. 2008).

existing audiovisual presentation.¹³¹¹ Defendants' allegedly infringing product, "ReVoice Studio," allowed a user to combine her voice with pre-existing movie images on a DVD.¹³¹² The asserted claims applied to both video games and movies.¹³¹³ Nevertheless, the district court found that the patent specifications did not adequately explain how the invention would function in the context of movies, which, unlike video games, did not use discrete signals for identifying and retrieving particular character images.¹³¹⁴ Thus, the district court adjudged the claims invalid for lack of enablement as to movies.¹³¹⁵

The Federal Circuit affirmed, maintaining that "'[t]he scope of the claims must be less than or equal to the scope of the enablement' to 'ensure[] that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims."¹³¹⁶ Defendants showed, by clear and convincing evidence, that the patents-in-suit did not teach how the patented system would perform certain necessary steps in the context of movies, which did not have easily separable character functions as video games did.¹³¹⁷ In addition, expert testimony clearly established that, as a result of such technical differences, one skilled in the art would not be able to apply the patents' teachings to movies.¹³¹⁸ Therefore, the Federal Circuit held that the district court correctly granted summary judgment of invalidity for lack of enablement.¹³¹⁹

2. Written description

Paragraph one of 35 U.S.C. § 112 also requires "a written description of the invention."¹³²⁰ The Federal Circuit has explained that the written description requirement is separate and distinct from the enablement requirement.¹³²¹ No particular form of disclosure is

35 U.S.C. § 112 (2006). 1320.

2009]

^{1311.} Id. at 995, 85 U.S.P.Q.2d (BNA) at 1827. 1312. Id. at 995, 85 U.S.P.Q.2d (BNA) at 1827. 1313. Id. at 996, 85 U.S.P.Q.2d (BNA) at 1827.

^{1314.} *Id.* at 998, 85 U.S.P.Q.2d (BNA) at 1829. 1315. *Id.* at 996–97, 85 U.S.P.Q.2d (BNA) at 1827.

^{1315.} Id. at 990-97, 65 U.S.P.Q.2d (BNA) at 1827.
1316. Id. at 999, 85 U.S.P.Q.2d (BNA) at 1830 (quoting Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1195-96, 49 U.S.P.Q.2d (BNA) 1671, 1675 (Fed. Cir. 1999)).
1317. Id. at 1000, 85 U.S.P.Q.2d (BNA) at 1831.
1318. Id. at 1000, 85 U.S.P.Q.2d (BNA) at 1831.

^{1318.} Id. at 1000-01, 85 U.S.P.Q.2d (BNA) at 1831.

^{1319.} Id. at 1000, 85 U.S.P.Q.2d (BNA) at 1831.

^{1321.} Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d (BNA) 1111, 1321. vas can mc. v. Manukar, 535 F.20 1353, 1363, 19 0.5.F.Q.20 (BNA) 1111, 1117 (Fed. Cir. 1991); see Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 736, 62 U.S.P.Q.2d (BNA) 1705, 1707 (2002) (listing, as statutory requirements, that the patent application "describe, enable, and set forth the best mode of carrying out the invention"); see also In re Curtis, 354 F.3d 1347, 1357, 69 U.S.P.Q.2d (BNA) 1274, 1282 (Fed. Cir. 2004) ("We interpret 35 U.S.C. § 112, ¶ 1 to

required, but the written description must be sufficient to convey to one of ordinary skill in the art that the patentee was "in possession" of the invention, i.e., that the patentee invented what is claimed.¹³²² Satisfaction of the written description requirement is an issue of fact.¹³²³ The sufficiency of a patent's written description is evaluated as of the filing date of the patent; therefore, the inquiry centers on the original disclosure and the originally filed claims.¹³²⁴

In Carnegie Mellon University v. Hoffmann-LaRoche, Inc.,¹³²⁵ Federal Circuit affirmed summary judgment of invalidity of patents concerning recombinant plasmids, where the patent specifications failed to provide adequate written description support for the full genus of plasmids claimed.¹³²⁶ Discussing its precedent in *Regents of University of California v. Eli Lilly & Co.*,¹³²⁷ the court explained that "to satisfy the written description requirement for a claimed genus, a specification must describe the claimed invention in such a way that a person of skill in the art would understand that the genus that is being claimed has been invented, not just a species of the genus."1328

Contrary to this rule, the facts showed that the asserted claims encompassed an entire genus of recombinant plasmids containing coding sequences of DNA polymerase from any bacterial source, while the more narrow specifications of the patents disclosed solely the polA gene coding sequence from a single bacterial source.¹³²⁹ Particularly in light of record evidence showing that the polA gene varied among different bacterial sources, the court agreed with the district court that this narrow disclosure was insufficient, under Eli Lilly, to support the much broader scope of the claims.¹³³⁰ Thus. the patent holders did not satisfy the written description requirement, and the patents were invalid.¹³³¹

1329. *Id.* at 1125, 88 U.S.P.Q.2d (BNA) at 1240. 1330. *Id.* at 1126, 88 U.S.P.Q.2d (BNA) at 1240.

require a written description requirement separate and apart from the enablement requirement.")

^{1322.} In re Alton, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d (BNA) 1578, 1581 (Fed. Cir. 1996); Vas-Cath, 935 F.2d at 1563–64, 19 U.S.P.Q.2d (BNA) at 1111, 1117; see O'Reilly v. Morse, 56 U.S. 62, 120 (1853) (holding that a patentee "can lawfully claim only what he has invented and described, and if he claims more his patent is void"). 1323. Vas-Cath, 935 F.2d at 1563, 19 U.S.P.Q.2d (BNA) at 1116.

^{1324.} U.S. Steel Corp. v. Phillips Petrol. Co., 865 F.2d 1247, 1251, 9 U.S.P.Q.2d (BNA) 1461, 1464 (Fed. Cir. 1989).

^{1325. 541} F.3d 1115, 88 U.S.P.Q.2d (BNA) 1233 (Fed. Cir. 2008). For discussion of this case's implications on the doctrine of equivalents, see supra notes 840-847 and accompanying text.

^{1326.} *Id.* at 1126, 88 U.S.P.Q.2d (BNA) at 1240. 1327. 119 F.3d 1559 (Fed. Cir. 1997).

^{1328.} Carnegie Mellon, 541 F.3d at 1124, 88 U.S.P.Q.2d (BNA) at 1239.

^{1331.} Id. at 1127, 88 U.S.P.Q.2d (BNA) at 1241.

The court reached a similar result in *In re Alonso*,¹³³² when it affirmed the PTO's rejection of claims directed to the use of human antibodies to treat a rare form of cancer, where the sole antibody described in the specification was not representative of the "densely populated genus" encompassed by the claims.¹³³³ The court held that the PTO's conclusion was supported by substantial evidence.¹³³⁴ Several articles had shown that the type of antibody required for claimed method "var[ied] substantially Alonso's in their composition."1335 Nevertheless, Alonso only disclosed a single antibody. Moreover, the specification failed to teach anything "about the structure, epitope characterization, binding affinity, specificity, or pharmacological properties common to the large family of antibodies implicated by the method."¹³³⁶ It also did not describe the antigens to which the antibodies of the claimed method must bind.1337 Therefore, the PTO correctly rejected the claims for lack of adequate written description of the full claimed genus.

The court's opinion in Commonwealth Scientific & Industrial Research Organisation v. Buffalo Technology (USA), Inc.¹³³⁸ addressed the issue of whether an amendment to a patent application impermissibly added "new matter" to the specification so as to broaden the disclosure beyond what was supported in the written description.1339 As originally filed, the application had described the use of "radio transmissions" to communicate between devices in a wireless local area network.¹³⁴⁰ However, the claims were limited to radio transmissions "in excess of 10 GHz."1341 A later amendment substituted the phrase "radio frequencies" for several references to "in excess of 10 GHz."¹³⁴² This had the effect of "increas[ing] the range of frequencies specifically referenced by [these] passages" to include frequencies between 3 KHz and 300 GHz (the range attributable to "radio frequencies").¹³⁴³

The alleged infringer argued that these amendments improperly broadened the disclosure by adding "new matter" in violation of

- 1333. *Id.* at 1021, 88 U.S.P.Q.2d (BNA) at 1853. 1334. *Id.* at 1020, 88 U.S.P.Q.2d (BNA) at 1852.

- 1335. Id. at 1020, 88 U.S.P.Q.2d (BNA) at 1852.
 1336. Id. at 1022, 88 U.S.P.Q.2d (BNA) at 1853.
 1337. Id. at 1020, 88 U.S.P.Q.2d (BNA) at 1853.
- 1338. 542 F.3d 1363, 88 U.S.P.Q.2d (BNA) 1564 (Fed. Cir. 2008). 1339. *Id.* at 1379, 88 U.S.P.Q.2d (BNA) at 1575.

- Id., 88 U.S.P.Q.2d (BNA) at 1575.
 Id., 88 U.S.P.Q.2d (BNA) at 1575.

⁵⁴⁵ F.3d 1015, 88 U.S.P.Q.2d (BNA) 1849 (Fed. Cir. 2008). 1332.

35 U.S.C. § 132,¹³⁴⁴ and that the disclosure was no longer supported by the original written description, thus rendering the claims invalid under § 112.¹³⁴⁵ The district court disagreed, finding that the invention was described broadly enough in the original written description to encompass systems operating at the larger range of frequencies.¹³⁴⁶

On appeal, the Federal Circuit found no clear error in the district court's determination, holding that "there [was] enough material in the original disclosure" to support the broader reading of the invention.¹³⁴⁷ A close reading of the original application established that the references to a 10 GHz minimum represented "useful embodiments" of the invention, rather than limitations on the claimed subject matter.1348 Moreover, the original specification indicated that the frequency range was not limited to greater than 10 GHz; in fact, there were explicit and implicit references to frequencies as low as 1-3 GHz.¹³⁴⁹ This was further supported by expert testimony, which indicated that a person of ordinary skill would understand that the system permitted continuous transmission at 2–3 GHz.¹³⁵⁰ Therefore, the Federal Circuit affirmed the district court's refusal to invalidate the claims based upon the alleged addition of new matter.¹³⁵¹

Judge Lourie concurred, solely for the purpose of pointing out "a reasonable alternative view" regarding the introduction of new matter.¹³⁵² In light of the full record in the case, Judge Lourie asserted, it would also be reasonable to conclude that the applicants had altered the nature of the specification by their 1995 amendment, thus invalidating the claims.¹³⁵³

3. Definiteness

As a further condition of patentability, 35 U.S.C. § 112 requires a patent to include claims that "particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his

^{1344.} See 35 U.S.C. § 132 (2006) (providing, inter alia, that "[n]o amendment shall introduce new matter into the disclosure of the invention"). 1345. Commonwealth Sci. & Indus. Research Org., 542 F.3d at 1379, 88 U.S.P.Q.2d

⁽BNA) at 1575.

^{1346.} *Id.* at 1380, 88 U.S.P.Q.2d (BNA) at 1576. 1347. *Id.*, 88 U.S.P.Q.2d (BNA) at 1576.

^{1348.} Id., 88 U.S.P.Q.2d (BNA) at 1576.

^{1349.} *Id.* at 1381, 88 U.S.P.Q.2d (BNA) at 1576–77. 1350. *Id.*, 88 U.S.P.Q.2d (BNA) at 1577.

^{1351.} *Id.* at 1382, 88 U.S.P.Q.2d (BNA) at 1578. 1352. *Id.* at 1386, 88 U.S.P.Q.2d (BNA) at 1581 (Lourie, J., concurring).

^{1353.} Id., 88 U.S.P.Q.2d (BNA) at 1581.

invention."¹³⁵⁴ This is referred to as the definiteness requirement, and claims that lack particularity and distinctness are deemed indefinite.¹³⁵⁵ The purpose behind this provision is two-fold: (1) to provide clear warning to others regarding the scope of activities that may constitute infringement and (2) to assist examiners and courts in determining patentability.¹³⁵⁶ Thus, the only patentable claims are those that "clearly distinguish what is claimed from what went before in the art and clearly circumscribe what is foreclosed from future enterprise."1357

Because every claim is presumed to be valid, a claim is indefinite only if it is "not amenable to construction" or "insolubly ambiguous."¹³⁵⁸ A claim is not indefinite simply because "it poses a difficult issue of claim construction."¹³⁵⁹ In the case of means-plusfunction elements, which are limited by statute to "the corresponding structure, material, or acts described in the specification and equivalents thereof,"1360 the specification must provide a person of ordinary skill in the art with enough information to "know and understand what structure corresponds to the means limitation."¹³⁶¹

In Halliburton Energy Services, Inc. v. M-I, LLC, 1362 the Federal Circuit affirmed summary judgment of invalidity for indefiniteness, where the claim term could not be construed from the disclosures in the patent or distinguished from the disclosed prior art.¹³⁶³ The term at issue was "fragile gel," as used in a claim for a method of drilling in oil fields.¹³⁶⁴ Halliburton asserted that the term "fragile gel" referred to a gel that, inter alia: (1) "easily transitions to a liquid state upon the introduction of force (e.g., when drilling starts) and returns to a

^{1354. 35} U.S.C. § 112 (2006).

^{1355.} See United Carbon Co. v. Binney & Smith Co., 317 U.S. 228, 236, 55 U.S.P.Q. (BNA) 381, 385 (1942) ("The statutory requirement of particularity and distinctness in claims is met only when they clearly distinguish what is claimed from what went before in the art and clearly circumscribe what is foreclosed from future

enterprise."). 1356. *Id.*, 55 U.S.P.Q. (BNA) at 385. 1357. *Id.*, 55 U.S.P.Q. (BNA) at 385. 1358. Novo Indus., L.P. v. Micro Molds Corp., 350 F.3d 1348, 1358, 69 U.S.P.Q.2d (2011) 1100 (End. Cir. 2002) (quoting Evyon Research & Eng'g Co. v. United (BNA) 1128, 1135 (Fed. Cir. 2003) (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)); *see* 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) (concluding that Honeywell's patent claims were invalid as indefinite).

<sup>Invalid as indefinite).
1359. Exxon, 265 F.3d at 1375, 60 U.S.P.Q.2d (BNA) at 1276.
1360. 35 U.S.C. § 112 para. 6 (2006).
1361. Biomedino, LLC v. Waters Techs. Corp., 490 F.3d 946, 950, 83 U.S.P.Q.2d (BNA) 1118, 1121 (Fed. Cir. 2007) (quoting Atmel Corp. v. Info. Storage Devices, Inc., 198 F.3d 1374, 1382, 53 U.S.P.Q.2d (BNA) 1225, 1230 (Fed. Cir. 1999)).
1362. 514 F.3d 1244, 85 U.S.P.Q.2d (BNA) 1654 (Fed. Cir. 2008).
1363. d at 1256 85 U.S.P.Q.2d (BNA) at 1658.</sup>

^{1363.} Id. at 1256, 85 U.S.P.Q.2d (BNA) at 1658.

gel when the force is removed (e.g., when drilling stops)" and (2) "is capable of suspending drill cuttings and weighting materials.¹³⁶⁵ The Federal Circuit concluded that neither this proposed definition nor any other construction of the term "fragile gel" could resolve the ambiguity as to its scope in the asserted claims.¹³⁶⁶ Therefore, the court affirmed the district court's judgment of invalidity.¹³⁶⁷

It was not sufficient that the patent specification included a definition of fragile gel that closely tracked the first part of Halliburton's description set forth above.¹³⁶⁸ "Even if a claim term's definition can be reduced to words, the claim is still indefinite if a person of ordinary skill in the art cannot translate the definition into meaningfully precise claim scope."¹³⁶⁹ Here, nothing in the patent sufficiently defined the requisite degree of fragileness as compared to the prior art; that is, "how much more quickly the gels broke when stress was imposed or *how much more* quickly the gels reformed when stress was removed."¹³⁷⁰ Likewise, the patent failed to delineate what degree of suspending capability (i.e., gel strength) was required.¹³⁷¹ Because a variety of factors could affect the liquid-gel transitioning or gel strength in a particular oil well (e.g., geology of the terrain, wellbore size, depth, and angle), an ordinary skilled artisan would be unable to determine, from one oil well to the next, whether a particular drilling fluid would fall within the scope of the claimed invention.¹³⁷² "When a proposed construction requires that an artisan make a separate infringement determination for every set of circumstances in which the composition may be used, and when such determinations are likely to result in differing outcomes (sometimes infringing and sometimes not), that construction is likely to be indefinite."1373

The Federal Circuit also noted that Halliburton's proposed definition was "functional, i.e., the fluid is defined 'by what it does rather than what it is."¹³⁷⁴ As the court explained, the Supreme Court has warned against the "dangers of using only functional claim

^{1365.} Id. at 1250, 85 U.S.P.Q.2d (BNA) at 1659.

^{1366.} *Id.*, 85 U.S.P.Q.2d (BNA) at 1659. 1367. *Id.*, 85 U.S.P.Q.2d (BNA) at 1658.

^{1368.} *Id.* at 1251, 85 U.S.P.Q.2d (BNA) at 1659. 1369. *Id.* 85 U.S.P.Q.2d (BNA) at 1659–60.

^{1370.} Id. at 1253, 85 U.S.P.Q.2d (BNA) at 1661 (emphasis added).
1371. Id. at 1254, 1256, 85 U.S.P.Q.2d (BNA) at 1663.
1372. Id. at 1254–55, 85 U.S.P.Q.2d (BNA) at 1662.
1373. Id. at 1255, 85 U.S.P.Q.2d (BNA) at 1662.
1373. Id. at 1255, 85 U.S.P.Q.2d (BNA) at 1662.

^{1374.} Id., 85 U.S.P.Q.2d (BNA) at 1662 (quoting In re Swinehart, 439 F.2d 210, 212,

¹⁶⁹ U.S.P.Q. (BNA) 226, 228 (C.C.P.A. 1971)).

limitations to distinguish the claimed invention from the prior art."¹³⁷⁵ Although claims are not necessarily indefinite for using functional language, the use of such functional language may fail to clearly delineate the scope of the subject matter claimed, thus rendering the claims indefinite.¹³⁷⁶

Unlike in *Halliburton*, the Federal Circuit in *Microprocessor Enhancement Corp. v. Texas Instruments, Inc.*¹³⁷⁷ reversed the district court's summary judgment of invalidity and held that the claims were not indefinite.¹³⁷⁸ The asserted patent claimed a computer processor architecture and methods for increasing the efficiency of microprocessors.¹³⁷⁹ At the district court, asserted claims one and seven—claiming a "method of executing instructions in a pipelined processor" and a "pipelined processor," respectively—were deemed invalid as indefinite on two grounds: (1) that the claims were insolubly ambiguous for requiring that the same word be construed differently in different portions of one claim; and (2) that the claims impermissibly mixed classes of subject matter (i.e., both method and apparatus) within a single claim.¹³⁸⁰ The Federal Circuit, however, disagreed on both counts, holding that the claims were definite and thus valid.¹³⁸¹

Regarding the use of differing interpretations for the same word within a claim, the court held that the claim was "amenable to construction" and therefore definite.¹³⁸² Although the term could have had one of two meanings, the appropriate meaning was "readily apparent from each occurrence in context," and, as used, the term "was not surrounded by uniform language that require[d] a single interpretation."¹³⁸³ Indeed, although it is generally assumed that a single claim term should be defined consistently throughout all claims of a patent, "the patentee's mere use of a term with an antecedent [such as 'said' or 'the'] *does not require* that both terms

1375. *Id.*, 85 U.S.P.Q.2d (BNA) at 1662 (citing United Carbon Co. v. Binney & Smith Co., 317 U.S. 228, 234, 55 U.S.P.Q. (BNA) 381, 381 (1942); Gen. Elec. Co. v. Wabash Appliance Corp., 304 U.S. 364, 371, 37 U.S.P.Q. (BNA) 466, 469 (1938)).

1381. Id., 86 U.S.P.Q.2d (BŇA) at 1229.

^{1376.} Id., 85 U.S.P.Q.2d (BNA) at 1662–63 (citing Swinehart, 439 F.2d at 212–13, 169 U.S.P.Q. (BNA) at 228).

^{1377. 520} F.3d 1367, 86 U.S.P.Q.2d (BNA) 1225 (Fed. Cir. 2008).

^{1378.} Id. at 1369, 86 U.S.P.Q.2d (BNA) at 1662-63.

^{1379.} Id., 86 U.S.P.Q.2d (BŇA) at 1226.

^{1380.} Id. at 1374, 86 U.S.P.Q.2d (BNA) at 1229.

^{1382.} Id. at 1376, 86 U.S.P.Q.2d (BNA) at 1231–32.

^{1383.} Id., 86 U.S.P.Q.2d (BŇA) at 1232.

AMERICAN UNIVERSITY LAW REVIEW [Vol. 58:747

have the same meaning."¹³⁸⁴ In light of the evidence, the court concluded that the asserted claims were not insolubly ambiguous.¹³⁸⁵

Regarding the mixing of classes of subject matter, although claim one appeared to recite both a method and an apparatus for executing the method, the court determined that the apparatus description actually served as a component of the preamble, rather than a separate claimed component.¹³⁸⁶ Thus, there was no ambiguity as to the scope of the claim, which was "clearly limited to practicing" the claimed method in a pipelined processor possessing the requisite structure."¹³⁸⁷ Conversely, claim seven was not indefinite simply for using functional language in an apparatus claim.¹³⁸⁸ In fact. functional language is explicitly permitted by statute in the context of as were employed here.¹³⁸⁹ means-plus-function limitations. Moreover, the court found, claim seven was limited to an apparatus possessing a certain structure and merely capable of performing certain functions.¹³⁹⁰ Therefore, the claim was not indefinite.¹³⁹¹

In Aristocrat Technologies Australia Pty Ltd. v. International Game Technology,¹³⁹² the court addressed the definiteness requirement in the context of means-plus-function claims directed to a computerimplemented invention.¹³⁹³ The patent-in-suit, the '102 patent, disclosed an electronic slot machine that allowed a user to select her own combinations of winning symbol positions.¹³⁹⁴ Appearing in several places in the asserted claims were the terms "control means" and "game control means," which the parties agreed were meansplus-function terms invoking 35 U.S.C. § 112 para. 6.¹³⁹⁵ The patent owner, Aristocrat, conceded that the only part of the specification describing the structure that performed the functions of the "control means" was a statement that one of ordinary skill in the art could "introduce the methodology on any standard microprocessor base

^{1384.} *Id.* at 1375, 86 U.S.P.Q.2d (BNA) at 1231 (citing Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1342, 60 U.S.P.Q.2d (BNA) 1851 (Fed. Cir. 2001); Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1356–57, 52 U.S.P.Q.2d (BNA) 1029, 1032 (Fed. Cir. 1999)) (emphasis added). 1385. Id., 86 U.S.P.Q.2d (BNA) at 1230.

^{1386.} Id. at 1374-75, 86 Ù.S.P.Q.2d (BNA) at 1230.

^{1387.} Id. at 1375, 86 U.S.P.Q.2d (BNA) at 1230.
1388. Id., 86 U.S.P.Q.2d (BNA) at 1230.
1389. Id., 86 U.S.P.Q.2d (BNA) at 1230.
1389. Id., 86 U.S.P.Q.2d (BNA) at 1230 (citing 35 U.S.C. § 112 (2006); Halliburton Energy Servs., Inc. v. M-I, LLC, 514 F.3d 1244, 1255, 85 U.S.P.Q.2d (BNA) 1654, 1658 (Fed. Cir. 2008)).

^{1390.} Id., 86 Ú.S.P.Q.2d (BNA) at 1230.

^{1390.} Id., 60 C.51.9.2d (BNA) at 1230.
1391. Id., 86 U.S.P.Q.2d (BNA) at 1230.
1392. 521 F.3d 1328, 86 U.S.P.Q.2d (BNA) 1235 (Fed. Cir. 2008).
1393. Id. at 1375, 86 U.S.P.Q.2d (BNA) at 1230.
1394. Id. at 1330, 86 U.S.P.Q.2d (BNA) at 1237.
1395. Id. at 1330, 86 U.S.P.Q.2d (BNA) at 1237.

^{1395.} Id. at 1331, 86 U.S.P.Q.2d (BNA) at 1238.

[sic] gaming machine by means of appropriate programming."1396 The district court held that this constituted an insufficient disclosure of the requisite structure under § 112 and concluded that the claims were invalid for indefiniteness.¹³⁹⁷

The Federal Circuit affirmed the decision, explaining that

[i]n cases involving a computer-implemented invention in which the inventor has invoked means-plus-function claiming, this court has consistently required that the structure disclosed in the specification be more than simply a general purpose computer or microprocessor For a patentee to claim a means for performing a particular function and then to disclose only a general purpose computer as the structure designed to perform that function amounts to pure functional claiming.

Thus, the corresponding structure for a computer-implemented function is "not [a] general purpose computer, or microprocessor, but rather [a] special purpose computer programmed to perform [a] disclosed algorithm."1399

Here, the '102 patent's references to a "standard microprocessor" and "appropriate programming" were insufficient to describe a structure capable of performing the required functions.¹⁴⁰⁰ The specification disclosed no more than a general purpose computer.¹⁴⁰¹ Although Aristocrat "was not required to produce a listing of source code or a highly detailed description of the algorithm to be used," it was required, at the very least, to provide some algorithm that "transform[ed] the general purpose microprocessor [in]to a 'special purpose computer'" to satisfy the corresponding structure requirement for means-plus-function claims.¹⁴⁰² Because it had not, the district court properly adjudged the claims invalid as indefinite.¹⁴⁰³

Two subsequent 2008 decisions reached a similar conclusion. In *Finisar Corp. v. The DirecTV Group, Inc.*¹⁴⁰⁴ the Federal Circuit upheld the district court's determination that a means-plus-function claim directed to scheduling satellite or cable broadcasts was indefinite, where the patent simply recited that "software" performed the disclosed function.¹⁴⁰⁵ The district court correctly noted that this

^{1396.} Id. at 1334, 86 U.S.P.Q.2d (BNA) at 1240 (citation omitted).
1397. Id. at 1333, 86 U.S.P.Q.2d (BNA) at 1239.
1398. Id., 86 U.S.P.Q.2d (BNA) at 1239.
1399. Id., 86 U.S.P.Q.2d (BNA) at 1240 (quoting WMS Gaming, Inc. v. Int'l Game Tech., 184 F.3d 1339, 1349, 51 U.S.P.Q.2d (BNA) 1385, 1391 (Fed. Cir. 1999)).

^{1400.} Id. at 1334, 86 U.S.P.Q.2d (BNA) at 1240.

^{1401.} Id., 86 U.S.P.Q.2d (BŇA) at 1240.

^{1402.} Id. at 1338, 86 U.S.P.Q.2d (BNA) at 1243.
1403. Id., 86 U.S.P.Q.2d (BNA) at 1243.
1404. 523 F.3d 1323, 86 U.S.P.Q.2d (BNA) 1609 (Fed. Cir. 2008).

^{1405.} Id. at 1364, 1366, 86 U.S.P.Q.2d (BNA) at 1611, 1623.

constituted an insufficient disclosure of the purported structure, as it provided no detail about the means to accomplish the function.¹⁴⁰⁶ Because the patent disclosed no algorithm or description of the requisite structure, the claims were invalid for indefiniteness.¹⁴⁰⁷ Likewise, the court in *Net MoneyIN, Inc. v. Verisign, Inc.*¹⁴⁰⁸ affirmed the trial court's judgment of invalidity due to indefiniteness where the specification failed to disclose an algorithm by which the general "bank computer" performed the function of "generating an authorization indicia" for online credit card transactions.¹⁴⁰⁹

In Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.,¹⁴¹⁰ the Federal Circuit reversed a judgment of invalidity due to indefiniteness, where the district court's determination was based upon an incorrect understanding of the law regarding claim definiteness.¹⁴¹¹ In the claims at issue, which were directed to a method of curing tobacco, one limitation required "an airflow sufficient to substantially prevent an anaerobic condition around the vicinity of [the tobacco plants.]"¹⁴¹² The district court determined that the term "anaerobic condition" was indefinite and granted summary judgment for the defendants.1413

Reversing, the Federal Circuit noted that "[w]hen a word of degree is used . . . the patent's specification [must] provide[] some standard for measuring that degree" in order to be deemed definite.¹⁴¹⁴ Because an "anaerobic condition" implies some degree of oxygen deficiency, it was necessary to show, within the patent specification, a standard for measuring that condition.¹⁴¹⁵ The standard, held the court, was clearly established within the patent.¹⁴¹⁶ The claims explicitly referred to curing in an anaerobic environment in order to "substantially prevent the formation of at least one nitrosamine."¹⁴¹⁷ Moreover, the district court had construed the "substantially prevent" term, based upon the intrinsic record, to mean a series of defined

^{1406.} Id. at 1340-41, 86 U.S.P.Q.2d (BNA) at 1623.

^{1407.} Id., 86 U.S.P.Q.2d (BNA) at 1623.

 <sup>1408.
 545</sup> F.3d 1359, 88 U.S.P.Q.2d (BNA) 1751 (Fed. Cir. 2008).

 1409.
 Id. at 1362, 1365–67, 88 U.S.P.Q.2d (BNA) at 1753, 1755, 1757.

 1410.
 537 F.3d 1357, 88 U.S.P.Q.2d (BNA) 1001 (Fed. Cir. 2008).

^{1411.} Id. at 1360–61, 88 U.S.P.Q.2d (BNA) at 1002.

^{1412.} *Id.* at 1360, 1364, 88 U.S.P.Q.2d (BNA) at 1005. 1413. *Id.* at 1360, 88 U.S.P.Q.2d (BNA) at 1002.

^{1414.} *Id.* at 1372, 88 U.S.P.Q.2d (BNA) at 1011 (citing Datamize LLC v. Plumtree Software, Inc., 417 F.3d 1342, 1351, 75 U.S.P.Q.2d (BNA) 1801, 1801 (Fed. Cir. 2005)) (alterations in original). 1415. *Id.* at 1372, 88 U.S.P.Q.2d (BNA) at 1011. 1416. *Id.* at 1360, 88 U.S.P.Q.2d (BNA) at 1002.

^{1417.} Id. at 1372, 88 U.S.P.Q.2d (BNA) at 1012 (citation omitted).

numerical ranges for levels of particular nitrosamine compounds.¹⁴¹⁸ Thus, because one of ordinary skill in the art could ascertain the existence of an "anaerobic condition" by measuring the levels of the various nitrosamines, the term was not insolubly ambiguous.¹⁴¹⁹

"The district court's contrary conclusion," noted the Federal Circuit, "was based on its misunderstanding that claim definiteness requires that a potential infringer be able to determine if a process infringes before practicing the claimed process."¹⁴²⁰ However, this is incorrect under the court's precedent.¹⁴²¹ "The 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."1422 Because the term "anaerobic condition," as construed by the district court, sufficiently delineated the bounds of the claim, it was not indefinite.¹⁴²³

Е. Double Patenting

The judicially created doctrine of obviousness-type double patenting prevents one inventor from obtaining more than one valid patent on essentially the same invention, by precluding attempts to "claim inventions so alike that granting both exclusive rights would effectively extend the life of patent protection."1424 An analysis of double patenting consists of two steps: (1) construing the claims of the two patents to determine the differences; and (2) determining whether the differences render the claims patentably distinct.¹⁴²⁵ "A later patent claim is not patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim."1426

In the examination context, the courts typically use a one-way test, in which "the examiner asks whether the application claims are

^{1418.} Id., 88 U.S.P.Q.2d (BNA) at 1012.

^{1419.} Id., 88 U.S.P.Q.2d (BNA) at 1012.

^{1420.} Id., 88 U.S.P.Q.2d (BNA) at 1012.

^{1420.} Id. at 1372–73, 88 U.S.P.Q.2d (BNA) at 1012. 1422. Id. at 1373, 88 U.S.P.Q.2d (BNA) at 1012 (citing SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1341, 74 U.S.P.Q.2d (BNA) 1398, 1404 (Fed. Cir. 2005), and an Invited an Corp. J. Biographic J. B. 424, F.2d 1274, 1284 (1997); see also Invitrogen Corp. v. Biocrest Mfg., L.P., 424 F.3d 1374, 1384, 76 U.S.P.Q.2d (BNA) 1741, 1747 (Fed. Cir. 2005) (citing same standard). 1423. Star Scientific, 537 F.3d at 1373, 88 U.S.P.Q.2d (BNA) at 1012.

^{1424.} In re Metoprolol Succinate Patent Litig., 494 F.3d 1011, 1016, 83 U.S.P.Q.2d (BNA) 1545, 1548 (Fed. Cir. 2007) (citation omitted).

^{1425.} Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 968, 58 U.S.P.Q.2d (BNA) 1869, 1878 (Fed. Cir. 2001)

^{1426.} Id., 58 U.S.P.Q.2d (BNA) at 1878.

obvious over the patent claims."¹⁴²⁷ In rare circumstances, however, where an applicant has been unable to issue its first-filed application, a two-way test may apply, in which "the examiner also asks whether the patent claims are obvious over the application claims."¹⁴²⁸ The two-way test is "a narrow exception"¹⁴²⁹ that may apply only where "the PTO is solely responsible for . . . delay" that causes a second-filed improvement application to issue prior to a first-filed basic application.¹⁴³⁰ Double patenting is a question of law that is reviewed de novo.¹⁴³¹

In Pfizer, Inc. v. Teva Pharmaceuticals USA Inc.,1432 the Federal Circuit concluded that the district court had erred when it did not hold a patent invalid on the grounds of double patenting.¹⁴³³ The patents-insuit, owned by Pfizer, covered a genus of non-steroidal antiinflammatory compounds that included the compound celocoxib the active ingredient in Pfizer's arthritis drug Celebrex.¹⁴³⁴ During prosecution, Pfizer had responded to the examiner's restriction requirement by electing to pursue only some of its composition claims in the original application (which ultimately issued as the '823 patent), while pursuing the restricted-out composition claims in a divisional application (which became the '165 patent) and the restricted-out method claims in a continuation-in-part application (which became the '068 patent).¹⁴³⁵ In the resulting Hatch-Waxman Act infringement suit, Teva Pharmaceuticals argued that the '068 patent was invalid due to obviousness-type double patenting, because the '165 patent constituted prior art to the '068 patent.¹⁴³⁶ Although the district court determined that the relevant claims of the '068 patent and '165 patent were not patentably distinct, it nonetheless determined that the '068 patent was valid under the "safe-harbor" provision of 35 U.S.C. § 121.1437

On appeal, the Federal Circuit agreed with the trial court that the relevant claims of the two patents were not patentably distinct, because the '068 claims simply recited methods of administering a

^{1427.} In re Berg, 140 F.3d 1428, 1432, 46 U.S.P.Q.2d (BNA) 1226, 1229 (Fed. Cir. 1998).

^{1428.} *Id.* at 1432, 46 U.S.P.Q.2d (BNA) 1429. *Id.*, 46 U.S.P.Q.2d (BNA) at 1229. Id. at 1432, 46 U.S.P.Q.2d (BNA) at 1229.

^{1430.} *Id.* at 1437, 46 U.S.P.Q.2d (BNA) at 1233. 1431. Ga.-Pac. Corp. v. U.S. Gypsum Co., 195 F.3d 1322, 1326, 52 U.S.P.Q.2d (BNA) 1590, 1593 (Fed. Cir. 1999).

^{1432. 518} F.3d 1353, 86 U.S.P.Q.2d (BNA) 1001 (Fed. Cir. 2008). 1433. *Id.* at 1357, 86 U.S.P.Q.2d (BNA) at 1003. 1434. *Id.* at 1356, 86 U.S.P.Q.2d (BNA) at 1003.

^{1435.} Id. at 1357-58, 86 U.S.P.Q.2d (BNA) at 1004.

^{1436.} Id. at 1358, 86 U.S.P.Q.2d (BNA) at 1005.

^{1437.} Id., 86 U.S.P.Q.2d (BNA) at 1005.

"therapeutically-effective amount" of the compounds claimed in the '165 patent and the term "therapeutically-effective amount" appeared in the '165 patent and was stipulated to have identical meaning in both patents.¹⁴³⁸ Nevertheless, the court disagreed with the trial court's conclusion that the '068 patent could claim protection under § 121's so-called safe harbor provision.¹⁴³⁹

Under the safe harbor provision of § 121,

[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.¹⁴⁴⁰

Reviewing the statutory language, the legislative history, and Federal Circuit precedent, the court ultimately concluded that "the protection afforded by section 121 to applications (or patents issued therefrom) filed as a result of a restriction requirement is limited to divisional applications."1441 Not only do both the statute's literal language and the legislative history "refer[] specifically to 'divisional application[s],"¹⁴⁴² but there are also "plausible reasons" why Congress would have limited the safe harbor provision to divisional applications.¹⁴⁴³ In particular, "[i]f the section had included CIPs, which by definition contain new matter, the section might be read as providing the earlier priority date even as to the new matter, contrary to the usual rule that new matter is not entitled to the priority date of the original application."1444 Therefore, the court concluded, because the '068 patent was filed as a continuation-in-part application, rather than as a divisional application, it did not fall under the safe harbor provision, and as a result, it could be-and it was-invalidated by the '165 patent.¹⁴⁴⁵

In *In re Basell Poliolefine Italia S.P.A.*,¹⁴⁴⁶ a majority of the Federal Circuit panel affirmed the Board of Patent Appeals and Interferences' (the "Board") rejection, based on obviousness-type

^{1438.} Id. at 1363, 86 U.S.P.Q.2d (BNA) at 1008.

^{1439.} *Id.* at 1356, 86 U.S.P.Q.2d (BNA) at 1002–03. 1440. *Id.* at 1359, 86 U.S.P.Q.2d (BNA) at 1005.

 ^{1441.} Id. at 1362, 86 U.S.P.Q.2d (BNA) at 1003.

 1441.
 Id. at 1362, 86 U.S.P.Q.2d (BNA) at 1007.

 1442.
 Id. at 1360, 86 U.S.P.Q.2d (BNA) at 1006.

 1443.
 Id. at 1361, 86 U.S.P.Q.2d (BNA) at 1007.

 1444.
 Id., 86 U.S.P.Q.2d (BNA) at 1007.

 1444.
 Id., 86 U.S.P.Q.2d (BNA) at 1007.

^{1445.} Id. at 1362, 86 U.S.P.Q.2d (BNA) at 1007.

^{1446. 547} F.3d 1371, 89 U.S.P.Q.2d (BNA) 1030 (Fed. Cir. 2008).

double patenting, of claims directed to a method of polymerizing unsaturated hydrocarbons.¹⁴⁴⁷ The claims at issue were contained within the '687 patent, which had derived from a 1955 application that was not issued until 2002, following a long series of continuations and divisionals.¹⁴⁴⁸ Shortly after the '687 patent issued, the PTO initiated a Director-ordered reexamination, which reviewed all claims for double patenting, in view of several expired patents issued to one of the '687 inventors, and ultimately concluded that the '687 claims were unpatentable in light of the expired '987 patent.¹⁴⁴⁹ The Board affirmed.1450

The Federal Circuit held, as an initial matter, that the Board did not err in applying a one-way test, rather than a two-way test, for double patenting because the patentees' own actions or inactions were directly responsible for the delay in prosecution.¹⁴⁵¹ In particular, the patentees "did not present any claim resembling the claims at issue until 1964, nine years after . . . fil[ing] the first U.S. application in the chain of priority," and the patentees had repeatedly submitted claims covering other inventions, urged the examiner to declare interferences for unrelated inventions, and filed numerous continuing applications without appeal.¹⁴⁵² The Federal Circuit majority then concluded that the patent claims at issue were not patentably distinct from the claims of the expired '987 patent.¹⁴⁵³ This was because both sets of claims could be read to cover the polymerization of ethylene with alpha-olefins of C_4 to C_6 , using catalysts of titanium halides and aluminum alkyls.¹⁴⁵⁴ Indeed, "the[] claims are both generic and specific to each other in interchangeable ways, involving the same groups of species."¹⁴⁵⁵ Therefore, the court held that the '687 claims were not patentable as a result of double patenting.1456

In dissent, Judge Newman argued that the PTO's reexamination of the '687 claims occurred in violation of reexamination law as it then existed.¹⁴⁵⁷ In particular, prior to November 2, 2002, reexamination "was available only on certain grounds not considered during the

^{1447.} Id. at 1373, 89 U.S.P.Q.2d (BNA) at 1032.

^{1448.} Id., 89 U.S.P.Q.2d (BNA) at 1032.

^{1449.} Id. at 1374, 89 U.S.P.Q.2d (BNA) at 1032.

^{1450.} Id., 89 U.S.P.Q.2d (BNA) at 1032.

^{1451.} Id. at 1376, 89 U.S.P.Q.2d (BNA) at 1034.

^{1452.} Id., 89 U.S.P.Q.2d (BŇA) at 1034.

^{1452.} *Id.* at 1377, 89 U.S.P.Q.2d (BNA) at 1035. 1454. *Id.* at 1377-78, 89 U.S.P.Q.2d (BNA) at 1035.

^{1455.} *Id.* at 1378, 89 U.S.P.Q.2d (BNA) at 1035. 1456. *Id.* at 1373, 89 U.S.P.Q.2d (BNA) at 1031–32.

^{1457.} Id. at 1379, 89 U.S.P.Q.2d (BNA) at 1037.

initial examination."¹⁴⁵⁸ Nevertheless, Judge Newman asserted, the PTO ordered reexamination based on double patenting in June 2002, even though the examiner had already considered the issue of double patenting during the initial examination of the claims.¹⁴⁵⁹ Judge Newman also argued that it was "unfair to chastise [the] patentee[s]" for the delay in issuing the patent, when "most of the delay was agreed by the PTO to be due to its procedures [for interferences]."1460 Finally, Judge Newman argued that the PTO's own findings, as well as expert testimony, establish that the claims of the '687 patent were patentably distinct from those of the '987 patent.1461

VI. UNENFORCEABILITY

A. Inequitable Conduct

A patent applicant's duty of candor and good faith includes the duty to disclose information known to the applicant to be material to patentability.¹⁴⁶² Breach of this duty constitutes inequitable conduct and renders an entire patent unenforceable.¹⁴⁶³ To prove inequitable conduct, an accused infringer must present clear and convincing evidence of at least a threshold level of materiality and intent to deceive the U.S. Patent and Trademark Office ("PTO").¹⁴⁶⁴ Even if this showing is made, however, the district court must balance the equities to determine whether the applicant's conduct was so egregious as to warrant holding the entire patent unenforceable.¹⁴⁶⁵ The district court may thus decline to render the patent unenforceable even in the face of clear and convincing evidence of materiality and intent to deceive.¹⁴⁶⁶ The materiality prong may be proven with evidence that an applicant "made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information."1467 Information is material "when a reasonable examiner would consider

^{1458.} Id. at 1380, 89 U.S.P.Q.2d (BNA) at 1037.

^{1459.} *Id.*, 89 U.S.P.Q.2d (BNA) at 1037. 1460. *Id.* at 1381, 89 U.S.P.Q.2d (BNA) at 1038.

^{1461.} Id. at 1381-82, 89 U.S.P.Q.2d (BNA) at 1038.

^{1462. 37} C.F.R. § 1.56(a) (2009)

^{1463.} Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1365-66, 87 U.S.P.Q.2d (BNA) 1225 (Fed. Cir. 2008).

⁸⁷ U.S.P.Q.2d (BNA) 1225 (red. Cfr. 2008).
1464. *Id.* at 1365, 87 U.S.P.Q.2d (BNA) at 1225.
1465. *Id.* at 1365, 87 U.S.P.Q.2d (BNA) at 1225.
1466. *Id.*, 87 U.S.P.Q.2d (BNA) at 1225.
1467. *Id.* at 1365, 88 U.S.P.Q.2d (BNA) at 1006 (quoting Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359, 1363, 81 U.S.P.Q.2d (BNA) 1705, 1708 (Fed. Cir. 2006)).

it important in deciding whether to allow the application to issue as a patent."¹⁴⁶⁸ "[I]nformation is not material if it is cumulative of other information already disclosed to the PTO."¹⁴⁶⁹

The deceptive intent prong requires that the "applicant had the *specific intent* to . . . mislead[] or deceiv[e] the PTO."¹⁴⁷⁰ Because direct evidence of deceptive intent is often not available, the Federal Circuit has held that intent may be inferred from indirect and circumstantial evidence.¹⁴⁷¹ This indirect and circumstantial evidence must still be clear and convincing, however, and an inference of deceptive intent drawn from such evidence must be "the single most reasonable inference able to be drawn."¹⁴⁷² If the evidence is susceptible of multiple reasonable inferences, a district court must consider all inferences and render a judgment on the evidence "as informed by the range of reasonable inferences."¹⁴⁷³ A district court "errs in overlooking one inference in favor of another equally reasonable inference."¹⁴⁷⁴

In balancing the equities after threshold showings of materiality and deceptive intent, the district court may weigh the substance of the facts underlying those showings and all of the equities of the case.¹⁴⁷⁵ In this balancing, the materiality and intent inquiries are not independent. "The more material the omission or the misrepresentation, the lower [the] level of intent . . . required to establish inequitable conduct, and vice versa."¹⁴⁷⁶

While factual findings on the threshold issues of materiality and intent are reviewed for clear error,¹⁴⁷⁷ the district court's ultimate

1475. Id., 88 U.S.P.Q.2d (BNA) at 1008.

^{1468.} Id. at 1367, 88 U.S.P.Q.2d (BNA) at 1007 (quoting Symantec Corp. v. Computer Assocs. Int'l, Inc., 522 F.3d 1279, 1297, 86 U.S.P.Q.2d (BNA) 1449, 1460 (Fed. Cir. 2008)).

^{1469.} Id., 88 Ú.S.P.Q.2d (BNA) at 1007 (citing Honeywell Int'l Inc. v. Universal Avionics Sys. Corp., 488 F.3d 982, 1000, 82 U.S.P.Q.2d (BNA) 1886, 1900 (Fed. Cir. 2007)).

^{1470.} *Id.* at 1366, 88 U.S.P.Q.2d (BNA) at 1007 (quoting Molins PLC v. Textron, Inc., 48 F.3d 1172, 1181, 33 U.S.P.Q.2d (BNA) 1823, 1829 (Fed. Cir. 1995)) (alterations in original).

^{1471.} *Id.*, 88 U.S.P.Q.2d (BNA) at 1007 (citing *Cargill*, 476 F.3d at 1364, 81 U.S.P.Q.2d (BNA) at 1710).

^{1472.} *Id.*, 88 U.S.P.Q.2d (BNA) at 1007 (citing Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V., 528 F.3d 1365, 1376, 87 U.S.P.Q.2d (BNA) 1225, 1233 (Fed. Cir. 2008)).

^{1473.} Scanner Techs., 528 F.3d at 1376, 87 U.S.P.Q.2d (BNA) at 1233.

^{1474.} Star Scientific, 537 F.3d at 1367, 88 U.S.P.Q.2d (BNA) at 1007 (quoting Scanner Techs., 528 F.3d at 1376, 87 U.S.P.Q.2d (BNA) at 1233).

^{1476.} *Id.*, 88 U.S.P.Q.2d (BNA) at 1008 (quoting Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1256, 43 U.S.P.Q.2d (BNA) 1666, 1668 (Fed. Cir. 1997)).

^{1477.} Reversal for clear error of a district court's determination requires "a 'definite and firm conviction' that a mistake has been made." Monsanto Co. v. Bayer

2009]

determination that an applicant committed inequitable conduct is reviewed for abuse of discretion.¹⁴⁷⁸

In Scanner Technologies Corp. v. ICOS Vision Systems Corp.,¹⁴⁷⁹ the Federal Circuit held that the district court erred in finding materiality because it did not consider all reasonable inferences from the evidence.¹⁴⁸⁰ The applicant had stated in a petition to make special that he made a "rigid comparison" of the claims of the application with the alleged infringing device when, in fact, he had never actually seen the device.¹⁴⁸¹ Reasoning that the applicant's statement suggested that he had seen the device, the district court deemed the applicant to have made a false statement to the PTO.¹⁴⁸² The Federal Circuit found that, although it was reasonable for the district court to infer that "rigid comparison" meant a physical inspection of the infringing device, it was equally reasonable to infer that the applicant had made a comparison using the infringing device's product literature, especially because the applicant cited the literature in its petition.¹⁴⁸³ This alternative inference was also reasonable because product literature may provide just as much information as a physical inspection.¹⁴⁸⁴ Accordingly, the Federal Circuit held that the district court failed to draw all reasonable inferences on the factual findings to show materiality.¹⁴⁸⁵

In Scanner Technologies, the Federal Circuit also reaffirmed that "a false statement that succeeds in expediting the application is, as a matter of law, material for purposes of assessing the issue of inequitable conduct."¹⁴⁸⁶ Inequitable conduct may thus be shown in the absence of a misrepresentation bearing on the patentability of the claims in the application.¹⁴⁸⁷

"An inference of intent to deceive is generally appropriate . . . when (1) highly material information is withheld; (2) 'the applicant knew of the [prior art and] knew or should have known of [its]

Bioscience N.V., 514 F.3d 1229, 1233, 85 U.S.P.Q.2d (BNA) 1582, 1586 (Fed. Cir. 2008) (quoting Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359, 1364, 81 U.S.P.Q.2d (BNA) 1705, 1709 (Fed. Cir. 2007)). 1478. Scanner Techs., 528 F.3d at 1374, 87 U.S.P.Q.2d (BNA) at 1232 (citing Modine

Mfg. Co. v. Allen Group, Inc., 917 F.2d 538, 541, 16 U.S.P.Q.2d (BNA) 1622, 1624 (Fed. Cir. 1990)).

^{1479. 528} F.3d 1365, 87 U.S.P.Q.2d (BNA) 1225 (Fed. Cir. 2008).

^{1480.} *Id.* at 1376, 87 U.S.P.Q.2d (BNA) at 1233. 1481. *Id.*, 87 U.S.P.Q.2d (BNA) at 1233.

^{1481.} Id., 87 U.S.F.Q.2d (BNA) at 1233.
1482. Id., 87 U.S.P.Q.2d (BNA) at 1233.
1483. Id., 87 U.S.P.Q.2d (BNA) at 1233.
1484. Id., 87 U.S.P.Q.2d (BNA) at 1234.
1485. Id. at 1377, 87 U.S.P.Q.2d (BNA) at 1234.
1486. Id. at 1375, 87 U.S.P.Q.2d (BNA) at 1233.
1487. U.S.P.Q.2d (BNA) at 1234.

^{1487.} Id., 87 U.S.P.Q.2d (BNA) at 1233.

materiality . . . ; and (3) the applicant has not provided a credible [good faith] explanation'" for failing to disclose prior art to the PTO.¹⁴⁸⁸ In *Praxair, Inc. v. ATMI, Inc.*,¹⁴⁸⁹ the Federal Circuit affirmed the district court's finding that one patent was unenforceable due to inequitable conduct, concluding that the district court properly inferred deceptive intent.¹⁴⁹⁰ First, the undisclosed prior art was material. The feature ("use of a small, flow-restricting hole") of the prior art devices that the applicant failed to disclose was similar to the use of capillaries to "restrict fluid flow" in the asserted patent.¹⁴⁹¹ Second, intent to deceive was inferred from the high degree of materiality of the prior art to the patent, as confirmed by four statements made in the course of prosecution,¹⁴⁹² the applicant's knowledge of the highly material, undisclosed prior art,1493 and the applicant's lack of a good faith explanation.¹⁴⁹⁴ In particular, the applicant's conclusory testimony that he never intentionally misled the PTO in his career and that he did not knowingly withhold any information during prosecution was "entitled to no weight."1495 Although the applicant provided additional testimony that could at best be interpreted as an explanation that he believed the prior art to be cumulative, this did not provide a sufficient good faith explanation because it was a "[h]indsight construction of reasons why a reference might have been withheld."¹⁴⁹⁶ The applicant did not suggest that he believed the prior art was cumulative at the time of

- 1495. Id. at 1317, 88 U.S.P.Q.2d (BNA) at 1713 (citations omitted).
- 1496. Id. at 1317–18, 88 U.S.P.Q.2d (BNA) at 1713.

^{1488.} Praxair, Inc. v. ATMI, Inc., 543 F.3d 1306, 1313–14, 88 U.S.P.Q.2d (BNA) 1705, 1710 (Fed. Cir. 2008) (quoting Ferring B.V. v. Barr Labs., Inc., 437 F.3d 1181, 1191, 78 U.S.P.Q.2d (BNA) 1161, 1169 (Fed. Cir. 2006)) (alterations in original).

^{1489. 543} F.3d 1306, 88 Ú.S.P.Q.2d (BNA) 1705 (Fed. Cir. 2008)

^{1490.} *Id.* at 1318, 88 U.S.P.Q.2d (BNA) at 1713. The Federal Circuit reversed the district court's finding of inequitable conduct as to the '609 patent for failure to prove deceptive intent. *See id.* at 1318–19, 88 U.S.P.Q.2d (BNA) at 1713–14 (finding that the statements indicating deceptive intent concerning the other patent were made after the issuance a "notice of allowability indicating that all claims of the '609 patent would be issued")

^{1491.} *Id.* at 1314, 88 U.S.P.Q.2d (BNA) at 1710–11. 1492. *Id.* at 1315–16, 88 U.S.P.Q.2d (BNA) at 1711–12 ("(1) The prior art did not teach the claimed 'extreme limitation in flow' used 'to provide a commercially practical container' that prevents 'the catastrophic discharge' of toxic contents; (2) Existing safety measures were limited to 'highly complex methods' and 'elaborate systems;' (3) There was no indication in the prior art to use 'severe flow restriction' to overcome[] the problems of delivering highly toxic fluids from portable containers"; and (4) "[N]one of the prior art comes close to disclosing a restriction in the flow path from a pressurized container that has a diameter that does not exceed 0.2 mm." (quoting Praxair, Inc. v. ATMI, Inc., 445 F. Supp. 2d 473, 480 n.8 (D. Del. 2006)) (alterations in original))

^{1493.} *Id.* at 1316–17, 88 U.S.P.Q.2d (BNA) at 1712–13. 1494. *Id.* at 1317–18, 88 U.S.P.Q.2d (BNA) at 1713.

prosecution, and the applicant never stated that cumulativeness was the reason he failed to disclose the prior art.¹⁴⁹⁷

Judge Lourie dissented regarding the inequitable conduct holding because the majority inferred intent but cited no evidence of intent to deceive, thereby "incorrectly conflat[ing] intent with materiality Non-citation of a reference does not necessarily justify an inference of intent to deceive."1498

In Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc., 1499 the Federal Circuit affirmed the district court's finding of intent to deceive in the patentee's failure to disclose that the half-life comparisons between the claimed compound and the prior art were at different dosages.¹⁵⁰⁰ On a prior appeal, the Federal Circuit remanded the question of deceptive intent, holding that the district court had failed to consider the reasonable inference that the failure to disclose different dosages in the applicant's declaration may have been due to mere inadvertence, if making a comparison at different dosages was indeed reasonable.¹⁵⁰¹ On remand, the district court again found intent to deceive.¹⁵⁰² In its second appeal, the patentee presented a different justification for its failure to disclose the use of different dosages in its half-life comparisons. The patentee argued that the dosage information was not material because the half-life comparisons using different dosages were intended to show a difference in properties, which was relevant to-and in response toan obviousness rejection.¹⁵⁰³ The half-life comparisons were not intended to address the anticipation rejection, for which comparisons using equivalent dosages would be relevant.¹⁵⁰⁴ The Federal Circuit rejected this argument, relying in part on the patentee's failure to "delineate between evidence intended to address the anticipation rejection and evidence intended to address the obviousness rejection."¹⁵⁰⁵ The court concluded that the district court properly found that the half-life comparisons were directed to both the anticipation and obviousness rejections, and "to the extent that they

^{1497.} Id., 88 U.S.P.Q.2d (BNA) at 1713. 1498. Id. at 1329, 88 U.S.P.Q.2d (BNA) at 1722 (Lourie, J., dissenting) (citing M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co., Inc., 439 F.3d 1335, 1342-43, M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co., Inc., 439 F.
78 U.S.P.Q.2d (BNA) 1229, 1236 (Fed. Cir. 2006)).
1499. 525 F.3d 1334, 87 U.S.P.Q.2d (BNA) 1110 (Fed. Cir. 2008).
1500. *Id.* at 1346, 87 U.S.P.Q.2d (BNA) at 1120.
1501. *Id.* at 1342, 87 U.S.P.Q.2d (BNA) at 1116–17.
1502. *Id.* at 1346, 87 U.S.P.Q.2d (BNA) at 1117.
1503. *Id.*, 87 U.S.P.Q.2d (BNA) at 1117.
1504. *Id.* at 1344, 87 U.S.P.Q.2d (BNA) at 1118.
1505. *Id.* at 1346, 87 U.S.P.Q.2d (BNA) at 1119–20.

were intended to address the anticipation rejection, the failure to disclose dosage information evidenced intent to deceive."¹⁵⁰⁶

Judge Rader dissented, noting that inequitable conduct "has taken on a new life as a litigation tactic" that allows a trial court to dispose of a case "without the rigors of claim construction and other patent doctrines."1507 In numerous cases, including Aventis, the district court has "elected to try [inequitable conduct] in advance of the issues of infringement and validity."¹⁵⁰⁸ Citing the Federal Circuit's Kingsdown Medical Consultants, Ltd. v. Hollister Inc. opinion, ¹⁵⁰⁹ Judge Rader noted that inequitable conduct is "not a remedy for every mistake, blunder, or fault in the patent procurement process."1510 In Aventis. the omission of dosage information was evidence of neglect, rather than culpable intent, because data were not concealed in the declaration but rather submitted without mention of the different doses.¹⁵¹¹ Furthermore, the chemist who made the declaration explained that the different dosage "did not come to his mind."¹⁵¹² Such negligence did "not rise to the level of intent to deceive."¹⁵¹³

In Monsanto Co. v. Bayer Bioscience N.V.,¹⁵¹⁴ the Federal Circuit affirmed the district court's holding that the patentee's '565 patent was unenforceable for inequitable conduct.¹⁵¹⁵ The Federal Circuit held that the failure to disclose notes related to a prior art abstract was material because the patentee made statements about the abstract in support of patentability that "directly contradict[ed]" the notes.¹⁵¹⁶ In reaching this conclusion, the Federal Circuit noted that it "do[es] not suggest that all internal documents of potential relevance must be submitted to the PTO as a matter of course."¹⁵¹⁷ An inference of deceptive intent was also proper because the prosecuting

^{1506.} Id., 87 U.S.P.Q.2d (BNA) at 1120.

^{1507.} Id. at 1349–50, 87 U.S.P.Q.2d (BNA) at 1122 (Rader, J., dissenting).
1508. Id. at 1350, 87 U.S.P.Q.2d (BNA) at 1122–23 (citing Frazier v. Roessel Cine Photo Tech, Inc., 417 F.3d 1230, 75 U.S.P.Q.2d (BNA) 1822 (Fed. Cir. 2005); Semiconductor Energy Lab. Co. v. Samsung Elecs. Co., 204 F.3d 1368, 54 U.S.P.Q.2d (BNA) 1001 (Fed. Cir. 2000)).

^{1509.} Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 876, 9 U.S.P.Q.2d (BNA) 1384, 1392 (Fed. Cir. 1988) (en banc).
1510. Aventis, 525 F.3d at 1350, 87 U.S.P.Q.2d (BNA) at 1123 (Rader, J.,

dissenting). 1511. Id. at 1351, 87 U.S.P.Q.2d (BNA) at 1124.

^{1512.} Id. at 1351-52, 87 U.S.P.Q.2d (BNA) at 1124.

^{1513.} *Id.*, 87 U.S.P.Q.2d (BNA) at 1124. 1514. 514 F.3d 1229, 85 U.S.P.Q.2d (BNA) 1582 (Fed. Cir. 2008).

^{1515.} Id. at 1231, 85 U.S.P.Q.2d (BNA) at 1584.

^{1516.} Id. at 1240, 85 U.S.P.Q.2d (BNÁ) at 1591. The notes were taken by a Bayer employee while in front of a poster for which the prior art abstract was made. Id. at 1235, 85 U.S.P.Q.2d (BNA) at 1587. The poster contained much more information than the prior art abstract itself. Id. at 1235, 85 U.S.P.Q.2d (BNA) at 1587. 1517. Id. at 1240, 85 U.S.P.Q.2d (BNA) at 1591.

attorney was admittedly aware of the notes during prosecution, had discussed the notes with their author, and had conceded that the notes would have been important to the Examiner if they contained reliable information.¹⁵¹⁸ His explanation that he did not understand the notes after discussing them with the notes' author lacked credibility.¹⁵¹⁹ The Federal Circuit also affirmed the district court's holding that the patentee's three other patents were unenforceable for inequitable conduct.¹⁵²⁰ Although the patentee dismissed its infringement claims under these three patents and covenanted not to sue the defendant for infringement, the district court properly retained jurisdiction to rule on attorney fees and to make findings of inequitable conduct.¹⁵²¹

In Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.,¹⁵²² the Federal Circuit found that the district court's factual findings on deceptive intent were clearly erroneous, and reversed the judgment of unenforceability.¹⁵²³ The prosecuting attorney had received a letter that potentially disclosed prior art, yet had concluded that the content was not material to the patent application he was preparing.¹⁵²⁴ Shortly after filing the patent application, the patentee replaced the attorney.¹⁵²⁵ The defendant theorized that the patentee replaced its attorney because of concerns about the need to disclose the letter to the PTO.¹⁵²⁶ However, because there was no evidence indicating that the patentee even knew the contents of the letter or that the letter was the reason that the patentee changed attorneys, the Federal Circuit concluded that the district court had clearly erred in accepting the theory that the patentees replaced the prosecuting attorney in order to prevent disclosure of the letter to the PTO.¹⁵²⁷ The fact that the applicant did not provide a credible alternative explanation for the attorney's replacement was not sufficient to warrant an inference of deceptive intent.¹⁵²⁸

^{1518.} *Id.* at 1241, 85 U.S.P.Q.2d (BNA) at 1592. 1519. *Id.*, 85 U.S.P.Q.2d (BNA) at 1592.

^{1520.} *Id.* at 1243, 85 U.S.P.Q.2d (BNA) at 1593. 1521. *Id.* at 1242–43, 85 U.S.P.Q.2d (BNA) at 1592–93 (citing Highway Equip. Co., Inc. v. FECO, Ltd., 469 F.3d 1027, 1033 n.1, 81 U.S.P.Q.2d (BNA) 1120, 1124 n.1 (Fed. Cir. 2006))

^{1522. 537} F.3d 1357, 88 U.S.P.Q.2d (BNA) 1001 (Fed. Cir. 2008).
1523. *Id.* at 1360, 88 U.S.P.Q.2d (BNA) at 1002.
1524. *Id.* at 1361–62, 88 U.S.P.Q.2d (BNA) at 1003.

^{1525.} Id. at 1363, 88 U.S.P.Q.2d (BNA) at 1004.

^{1525.} Id. at 1305, 66 C.51.9.2d (BNA) at 1005.
1526. Id. at 1367, 88 U.S.P.Q.2d (BNA) at 1008.
1527. Id. at 1367-69, 88 U.S.P.Q.2d (BNA) at 1008-09.
1528. Id. at 1368, 88 U.S.P.Q.2d (BNA) at 1008 (citing M. Eagles Tool Warehouse,
1529. The transformation of the t Inc. v. Fisher Tooling Co., Inc., 439 F.3d 1335, 1341, 78 U.S.P.Q.2d (BNA) 1229, 1235 (Fed. Cir. 2006)).

In Research Corp. Technologies, Inc. v. Microsoft Corp.,¹⁵²⁹ the Federal Circuit reversed the district court's finding of inequitable conduct because of the district court's erroneous analysis of the deceptive intent prong and failure to consider materiality.¹⁵³⁰ On materiality. the Federal Circuit held that the patentees' failure to disclose one of the inventors' experiments was not material because: (1) the inventors had no obligation to report experiments that occurred after filing of the patent application; (2) the experiments were not necessary to practice the patented invention; and (3) the inventor performed the experiments as part of her continuing doctoral thesis, and not to accomplish the objective of the patents.¹⁵³¹ In its discussion of materiality, the Federal Circuit also noted that the inventor published the experiments in question, and publication "is an act inconsistent with an intent to conceal data from the USPTO."1532 On the issue of intent to deceive, the Federal Circuit held that the district court's analysis was clearly erroneous because the district court improperly focused on the inventor's stated views at trial regarding the purposes of the patent system.¹⁵³³ Such views and motives for applying for a patent are "generally irrelevant to a proper determination of inequitable conduct."1534

In Eisai Co. v. Dr. Reddy's Laboratories, Ltd., 1535 the Federal Circuit affirmed the judgment of the district court that the alleged infringers had failed to prove the patent unenforceable for inequitable conduct.¹⁵³⁶ The patentee's failure to disclose its own co-pending application for a compound it considered separately patentable was not material because, even if disclosure of the application led to a provisional obviousness-type double-patenting rejection, applicants routinely overcome such rejections.¹⁵³⁷ The district court's finding that the materiality of this potential situation was low was therefore proper.¹⁵³⁸ The alleged infringer's theory that the patentee intended to deceive the PTO by filing its two patent applications separately was also properly rejected by the district court as evidence not rising to the level of inequitable conduct.¹⁵³⁹ A separate filing, "while not

^{1529.} 536 F.3d 1247, 87 U.S.P.Q.2d (BNA) 1519 (Fed. Cir. 2008).

^{1530.} *Id.* at 1252, 87 U.S.P.Q.2d (BNA) at 1524. 1531. *Id.* at 1252–53, 87 U.S.P.Q.2d (BNA) at 1523–24.

^{1532.} *Id.* at 1252, 87 U.S.P.Q.2d (BNA) at 1523. 1533. *Id.* at 1253, 87 U.S.P.Q.2d (BNA) at 1524.

^{1534.} Id., 87 U.S.P.Q.2d (BNA) at 1524.

^{1535. 533} F.3d 1353, 87 U.S.P.Q.2d (BNA) 1452 (Fed. Cir. 2008).

<sup>Isole J. J. at 1355, 87 U.S.P.Q.2d (BNA) at 1454.
Id. at 1360, 87 U.S.P.Q.2d (BNA) at 1454.
Id. at 1360, 87 U.S.P.Q.2d (BNA) at 1457–58.
Id., 87 U.S.P.Q.2d (BNA) at 1458.</sup>

^{1539.} Id. at 1361, 87 U.S.P.Q.2d (BNA) at 1458.

completely forthcoming," was not deemed an attempt to hide from the PTO because similar applications are usually assigned to the same examiner in the same art unit.¹⁵⁴⁰

In Symantec Corp. v. Computer Associates International, Inc.,¹⁵⁴¹ the Federal Circuit affirmed the district court's findings that the accused infringer failed to prove the materiality prong for inequitable conduct.¹⁵⁴² First, the Federal Circuit held that an inventor's declaration that he was "an original, first and joint inventor" was not false simply because the inventor could not identify his contribution precisely fourteen years later.¹⁵⁴³ The inventor and his co-inventor both testified in general terms that the inventor had come up with the idea for the invention.¹⁵⁴⁴ Second, the Federal Circuit held that the inventor's declaration that he had practiced in the field of computer software for ten years and become intimately familiar with the state of the art was not a misrepresentation simply because he was "a marketing person" and lacked technical expertise.1545 As the Federal Circuit noted, the "mere fact that he was not a technical person does nothing to refute" his familiarity with the state of the art.1546 Third, the Federal Circuit concluded that the inventor's declaration that he reviewed and understood the contents of the specification, including the claims, when he did not fully understand the language of the claim contents, was not misleading.¹⁵⁴⁷ A "failure to understand the *meaning* of the claims," on the other hand, would "likely be considered material."1548

B. Breach of Duty to Standards Setting Organization

Breach of the duty to disclose relevant intellectual property rights to a standards-setting organization ("SSO") before the adoption of a standard may also result in an unenforceability finding.¹⁵⁴⁹ The

^{1540.} Id., 87 U.S.P.Q.2d (BNA) at 1458.

^{1541. 522} F.3d 1279, 86 U.S.P.Q.2d (BNA) 1449 (Fed. Cir. 2008). 1542. *Id.* at 1296–98, 86 U.S.P.Q.2d (BNA) at 1459–61.

^{1543.} Id. at 1297, 86 U.S.P.Q.2d (BNA) at 1460 (citation omitted).

^{1544.} Id., 86 U.S.P.Q.2d (BNA) at 1460.

^{1545.} *Id.* at 1297–98, 86 U.S.P.Q.2d (BNA) at 1460–61. 1546. *Id.* at 1298, 86 U.S.P.Q.2d (BNA) at 1460–61.

^{1547.} Id., 86 U.S.P.Q.2d (BŇA) at 1461.

^{1548.} *Id.*, 86 U.S.P.Q.2d (BNA) at 1461 (quoting Symantec Corp. v. Computer Assocs. Int'l, Inc., No. 02-CV-73740-DT, 2008 WL 3950254, at *7 (E.D. Mich. Aug. 31, 2006)) (emphasis added).

^{1549.} See, e.g., Qualcomm Inc. v. Broadcom Corp., 548 F.3d 1004, 1010, 89 U.S.P.Q.2d (BNA) 1321, 1325 (Fed. Cir. 2008) (explaining the need for this disclosure to avoid "patent hold-up" which occurs when a patent holder fails to disclosure its the advector of the disclosure to the disclose intellectual property rights to an SSO "prior to the adoption of a standard" and, therefore, prevents "industry participants from implementing the standard").

AMERICAN UNIVERSITY LAW REVIEW

existence of a disclosure duty is "a legal question with factual underpinnings."1550

In Qualcomm Inc. v. Broadcom Corp.,¹⁵⁵¹ the Federal Circuit affirmed the district court's unenforceability judgment, finding that the plaintiff breached its duty to disclose its patents to a video compression SSO known as the Joint Video Team ("JVT").1552 Although the language of the JVT policy did not expressly require disclosure by all JVT participants in all circumstances, and only explicitly required disclosure of members submitting technical proposals, the Federal Circuit concluded that participants understood the policy to impose a disclosure duty on all participants.¹⁵⁵³ Turning to the scope of the disclosure duty, the Federal Circuit affirmed the district court's finding that the duty required JVT participants to disclose patents that "reasonably might be necessary" to practice the standard.¹⁵⁵⁴ Finding that the plaintiff had breached that disclosure duty, the Federal Circuit addressed the question of whether the district court was within its authority to order the patents unenforceable against the world.¹⁵⁵⁵ Although the district court had correctly concluded that the patents were unenforceable, the Federal Circuit concluded that its remedy ordering the patents unenforceable against the world was too broad and remanded the judgment with instructions to hold the patents unenforceable only against products that comply with the standard.¹⁵⁵⁶

C. Improper Inventorship

To show co-inventorship, the alleged co-inventor must "prove his contribution to the conception of the claims by clear and convincing evidence."1557 An alleged co-inventor's testimony alone is insufficient

^{1550.} Id. at 1012, 89 U.S.P.Q.2d (BNA) at 1326 (citing Rambus Inc. v. Infineon Techs. AG, 318 F.3d 1081, 1087 n.3, 65 U.S.P.Q.2d (BNA) 1705, 1709 n.3 (Fed. Cir. 2003)).

^{1551. 548} F.3d 1004, 89 U.S.P.Q.2d (BNA) 1321 (Fed. Cir. 2008). For discussion of this case's implications regarding the award of attorney fees, see infra notes 1842-

¹⁸⁵⁸ and accompanying text. 1552. *Id.* at 1008, 89 U.S.P.Q.2d (BNA) at 1323. 1553. *Id.* at 1013–16, 89 U.S.P.Q.2d (BNA) at 1328–29. 1554. *Id.* at 1017–18, 89 U.S.P.Q.2d (BNA) at 1330 (citation omitted). By not disclosing these patents prior to the adoption of the standard, a patentee that has patent protection covering the standard can keep industry participants from using the standard unless they entered a license agreement. Id. at 1020, 89 U.S.P.Q.2d (BNA) at 1325.

^{1555.} Id. at 1019, 1024-26, 89 U.S.P.Q.2d (BNA) at 1326, 1335.

^{1556.} *Id.* at 1027, 89 U.S.P.Q.2d (BNA) at 1337–38. 1557. Symantec Corp. v. Computer Assocs. Int'l, Inc., 522 F.3d 1279, 1295, 86 U.S.P.Q.2d (BNA) 1449, 1459 (Fed. Cir. 2008) (citing Ethicon, Inc. v. U.S. Surgical Corp., 135 F.3d 1456, 1461, 45 U.S.P.Q.2d (BNA) 1545, 1548 (Fed. Cir. 1008) 1998)).

evidence unless it is sufficiently corroborated.¹⁵⁵⁸ Whether an alleged co-inventor's testimony is sufficiently corroborated is evaluated using a "rule of reason analysis," which in turn requires an evaluation of all relevant evidence.1559

In Symantec Corp. v. Computer Associates International, Inc., 1560 the alleged co-inventor sought to corroborate his declaration with the named inventor's notes, which reflected a conversation between the named inventor and the alleged co-inventor.¹⁵⁶¹ However, the Federal Circuit held that the alleged co-inventor's declaration lacked the requisite corroboration because the notes at most reflected only that the two had a discussion of the then-current state of the art and did not establish any contribution to the invention by the alleged coinventor.1562

D. Laches

The laches defense, when established, bars a patentee's claims for damages incurred prior to suit.¹⁵⁶³ In order to invoke the defense of laches, a defendant must prove: "(1) [that] the plaintiff delayed filing suit for an unreasonable and inexcusable length of time from the time the plaintiff knew or reasonably should have known of its claim against the defendant; and (2) [that] the delay operated to the prejudice or injury of the defendant."1564

A rebuttable presumption of laches arises when the patentee delays filing suit for more than six years after the date the patentee knew or should have known of the alleged infringer's activity.¹⁵⁶⁵ If the alleged infringer shows that the patentee's delay in filing suit exceeds six years, then the burden shifts to the patentee to rebut the presumption by raising a genuine issue of material fact regarding either the reasonableness of its delay or the lack of prejudice to the

^{1558.} Id., 86 U.S.P.Q.2d (BNA) at 1459 (citing Ethicon, 135 F.3d at 1461, 45 U.S.P.Q.2d (BNA) at 1548).

^{1559.} *Id.*, 86 U.S.P.Q.2d (BNA) at 1459 (quoting Gemstar-TV Guide Int'l, Inc. v. Int'l Trade Comm'n, 383 F.3d 1352, 1382, 72 U.S.P.Q.2d (BNA) 1609, 1631 (Fed. Cir. 2004))

^{1560. 522} F.3d 1279, 86 U.S.P.Q.2d (BNA) 1449 (Fed. Cir. 2008).

^{1561.} *Id.* at 1295–96, 86 U.S.P.Q.2d (BNA) at 1459. 1562. *Id.* at 1296, 86 U.S.P.Q.2d (BNA) at 1459.

^{1563.} *Id.* at 1294, 86 U.S.P.Q.2d (BNA) at 1458. 1564. *Id.* at 1294, 86 U.S.P.Q.2d (BNA) at 1458. 1564. *Id.* at 1294, 86 U.S.P.Q.2d (BNA) at 1458 (citing A.C. Aukerman Co. v. R.L. Chaides Constr. Co., 960 F.2d 1020, 1032, 22 U.S.P.Q.2d (BNA) 1321, 1328 (Fed. Cir. 1992) (en banc)) (internal quotations omitted) (alterations in original). 1565. *Id.*, 86 U.S.P.Q.2d (BNA) at 1458 (citing *Aukerman*, 960 F.2d at 1035–36,

²² U.S.P.Q.2d (BNA) at 1331).

alleged infringer.¹⁵⁶⁶ Once the patentee makes such a showing, the burden shifts back to the alleged infringer to prove the elements of laches by a preponderance of the evidence.¹⁵⁶⁷ The Federal Circuit reviews the district court's determination on laches for an abuse of discretion.1568

In Serdarevic v. Advanced Medical Optics, Inc., 1569 the Federal Circuit affirmed the district court's grant of summary judgment that the plaintiff's inventorship claim was barred by laches.¹⁵⁷⁰ The plaintiff filed an action asserting inventorship eight years after learning of the existence of the patents, thereby giving rise to a presumption of laches.¹⁵⁷¹ The plaintiff contended that laches should not bar her claim because her suit was filed within six years of the issuance of the reexamination certificate for one of the patents.¹⁵⁷² The Federal Circuit held that this "other litigation" excuse for the delay in filing suit did not prevent the application of the presumption of laches because the plaintiff was not engaged in the "other litigation," which may have excused her delay.¹⁵⁷³ In addition, the plaintiff did not identify any way in which the reexamination proceeding changed her inventorship claim.¹⁵⁷⁴

The plaintiff attempted to rebut the laches presumption by justifying the delay in filing suit.¹⁵⁷⁵ In particular, the plaintiff claimed that she was unfamiliar with the U.S. patent system.¹⁵⁷⁶ The Federal Circuit affirmed the district court's finding that the plaintiff's unfamiliarity with the U.S. patent system was not sufficient evidence to rebut the presumption of an unreasonable delay because she was represented by patent counsel who could have enabled her to file suit.1577

Finally, the plaintiff's attempt to preclude the application of laches through an unclean hands claim also failed. The plaintiff was unable

1569. 532 F.3d 1352, 87 U.S.P.Q.2d (BNA) 1481 (Fed. Cir. 2008).

1572. Id., 87 U.S.P.Q.2d (BNA) at 1484.

1576. *Id.*, 87 U.S.P.Q.2d (BNA) at 1485. 1577. *Id.*, 87 U.S.P.Q.2d (BNA) at 1485.

^{1566.} Wanlass v. Gen. Elec. Co., 148 F.3d 1334, 1337, 46 U.S.P.Q.2d (BNA) 1915, 1917 (Fed. Cir. 1998) (citing Aukerman, 960 F.2d at 1035-38, 22 U.S.P.Q.2d (BNA) at 1331-33).

^{1567.} Aukerman, 960 F.2d at 1038, 22 U.S.P.Q.2d (BNA) at 1323–33. 1568. Id. at 1039, 22 U.S.P.Q.2d (BNA) at 1333.

^{1570.} *Id.* at 1356, 87 U.S.P.Q.2d (BNA) at 1482. 1571. *Id.* at 1358, 87 U.S.P.Q.2d (BNA) at 1484.

^{1573.} Id. at 1359, 87 U.S.P.Q.2d (BNA) at 1485.

^{1574.} *Id.*, 87 U.S.P.Q.2d (BNA) at 1485. 1575. *Id.* at 1360, 87 U.S.P.Q.2d (BNA) at 1485.

to show that the defendant had engaged in "particularly egregious conduct" and was responsible for plaintiff's delay in bringing suit.¹⁵⁷⁸

In Symantec, the Federal Circuit held that the district court did not err in dismissing a laches defense.¹⁵⁷⁹ The court reasoned that—even if the plaintiff knew about an earlier product that was later rebranded to be the infringing product-there was no evidence that the earlier product was the same or similar to the product in suit, and "laches would only apply if the products were the same or similar."¹⁵⁸⁰ The Federal Circuit also held that the plaintiff's earlier warning letter alleging willful infringement by the earlier product, which was sent before the defendant re-branded the earlier product, did not necessarily assume or concede that the two products were similar for purposes of the laches period of delay.¹⁵⁸¹

VII. NON-PATENT ISSUES

A. Alternate Sources of Liability

In In re Ciprofloxacin Hydrochloride Antitrust Litigation,¹⁵⁸² the Federal Circuit held that the district court did not err in concluding that settlement agreements between the patent holders, brand-name manufacturers of the drug, and generic manufacturers to resolve Hatch-Waxman Act cases did not violate section 1 of the Sherman Act,¹⁵⁸³ which prohibits "unreasonable restraints" of trade.¹⁵⁸⁴ In the settlement agreements, the patent holder agreed to make payments to the generic manufacturers ("reverse payments"), who in turn agreed not to challenge the validity of the patent or to market a generic version of the drug containing the patented compound until after the patent expired.¹⁵⁸⁵ The Federal Circuit concluded that the district court properly applied a "rule of reason analysis"¹⁵⁸⁶ to

^{1578.} Id. at 1361, 87 U.S.P.Q.2d (BNA) at 1486-87 (citation omitted).

^{Isro. J. M. at 1801, 67 C.S. 142.2d (BIAT) at 1405 Charles on Charle} 1980)).

^{1581.} Id., 86 U.S.P.Q.2d (BNA) at 1458–59.
1582. 544 F.3d 1323, 88 U.S.P.Q.2d (BNA) 1801 (Fed. Cir. 2008).
1583. Id. at 1333, 88 U.S.P.Q.2d (BNA) at 1808.

^{1584.} *Id.* at 1331, 88 U.S.P.Q.2d (BNA) at 1807 (quoting State Oil Co. v. Khan, 522 U.S. 3, 10 (1997)).

^{1585.} Id. at 1328-29, 88 U.S.P.Q.2d (BNA) at 1804.

^{1586.} *Id.* at 1332, 88 U.S.P.Q.2d (BNA) at 1807. The "rule of reason" analysis is a three-step process. First, the plaintiff must show that the "challenged action had an actual adverse effect on competition as a whole in the relevant market." The burden then "shifts to the defendant to establish the pro-competitive redeeming virtues of the action." Finally, if defendant carries its burden, the plaintiff must "show that the

determine whether the settlement agreements were unlawful and properly found that plaintiffs had failed to show that the "[a]greements had an anti-competitive effect on the market... beyond that permitted by the patent."1587

The Federal Circuit observed that long-standing judicial policy favors settlement.¹⁵⁸⁸ A settlement that protects a patent holder's legal right to a monopoly over the manufacture and distribution of the patented invention is not unlawful, even though it may have some adverse effects on competition.1589

The Federal Circuit emphasized that the "essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent."¹⁵⁹⁰ The court thus agreed with the United States Courts of Appeals for the Second and Eleventh Circuits that, in the absence of sham litigation or fraud before the PTO, the court "need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment."1591

In Dominant Semiconductors SDN. BHD. v. Osram GMBH,¹⁵⁹² the Federal Circuit affirmed the district court's grant of summary judgment dismissing the alleged infringer plaintiff's claims for unfair competition, intentional interference with contractual relations, interference with prospective economic advantage, and trade libel.¹⁵⁹³ The bases for plaintiff's claims were its contentions that the defendant made false and misleading public infringement allegations about the plaintiff's products and that the defendant filed its patent infringement complaint before the ITC in bad faith.¹⁵⁹⁴ A plaintiff seeking to prove bad faith must prove that the allegations were objectively baseless, such that "no reasonable litigant could reasonably expect success on the merits."1595 "[A]n objectively reasonable effort to litigate cannot be sham regardless of subjective

1591. Id., 88 U.S.P.Q.2d (BŇA) at 1810.

same pro-competitive effect could be achieved through an alternative means . . . less restrictive of competition." *Id.*, 88 U.S.P.Q.2d (BNA) at 1807 (quoting Clorox Co. v. Sterling Winthrop, Inc., 117 F.3d 50, 56, 43 U.S.P.Q.2d (BNA) 1161, 1165 (2d Cir. 1997))

^{1587.} Id., 88 U.S.P.Q.2d (BNA) at 1807 (citation omitted).

^{1507.} Id., 66 U.S.F. Q.2d (BIVA) at 1607 (Citation onlined).
1588. In re Ciprofloxacin Hydrochlorine Antitrust Litig., 544 F.3d 1323, 1333, 88 U.S.P.Q.2d (BNA) 1801, 1808 (Fed. Cir. 2008) (citing Flex-Foot, Inc. v. CRP, Inc., 238 F.3d 1362, 1368, 57 U.S.P.Q.2d (BNA) 1635, 1640 (Fed. Cir. 2001)).
1589. Id. at 1337, 88 U.S.P.Q.2d (BNA) at 1811 (citing In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 208 (2d Cir. 2006)).
1590. Id. at 1336, 88 U.S.P.Q.2d (BNA) at 1810.
1501. Id. at U.S.P.Q.2d (BNA) at 1810.

^{1591.} Id., 88 U.S.P.Q.2d (BNA) at 1810.
1592. 524 F.3d 1254, 86 U.S.P.Q.2d (BNA) 1480 (Fed. Cir. 2008).
1593. Id. at 1255-56, 86 U.S.P.Q.2d (BNA) at 1481.
1594. Id. at 1258, 86 U.S.P.Q.2d (BNA) at 1483.
1595. Id. at 1260, 86 U.S.P.Q.2d (BNA) at 1485 (quoting GP Indus., Inc. v. Eran Indus., Inc., 500 F.3d 1369, 1374, 84 U.S.P.Q.2d (BNA) 1604, 1607 (Fed. Cir. 2007)).

intent."¹⁵⁹⁶ The Federal Circuit further suggested that "a successful outcome of the underlying litigation refutes a conclusion that the litigation was objectively baseless at the outset."¹⁵⁹⁷ The defendant's evidence of success in its patent infringement claims before the ITC thus provided sufficient proof that its infringement claims were not objectively baseless.¹⁵⁹⁸

B. Discovery Decisions

"Under the Federal Rules of Civil Procedure, the parties must be afforded adequate time for general discovery before being required to respond to a motion for summary judgment."1599 A showing of necessity and diligence otherwise required for a Rule 56(f) request for additional discovery does not apply when parties do not initially have adequate opportunity for discovery.¹⁶⁰⁰ In Metropolitan Life Insurance Co. v. Bancorp Services, L.L.C.,¹⁶⁰¹ the Federal Circuit held that the district court erred in denying the patentee's Rule 56(f) motion seeking additional discovery. The district court erroneously reasoned that the patentee had not proven that the defendant's deponents would testify contrary to their declarations if deposed.¹⁶⁰³ However, the appropriate fact to consider was that the patentee had not been afforded a reasonable opportunity to conduct discovery.¹⁶⁰⁴ Where, as in this case, there has not been an adequate initial opportunity for discovery, a Rule 56(f) request for additional discovery need not be accompanied by a strict showing of necessity and diligence.¹⁶⁰⁵ The Federal Circuit remanded to permit reasonable discovery by the patentee to proceed.¹⁶⁰⁶

^{1596.} Id. at 1261, 86 U.S.P.Q.2d (BNA) at 1485 (quoting Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 57, 26 U.S.P.Q.2d (BNA) 1641, 1645 (1993)).

^{1597.} Id., 86 U.S.P.Q.2d (BNA) at 1485 (citing Prof'l Real Estate Investors, 508 U.S. at 62, 26 U.S.P.Q.2d (BNA) at 1647).

^{1598.} Id. at 1263, 86 U.S.P.Q.2d (BNA) at 1487.

^{1599.} Metro. Life Ins. Co. v. Bancorp Servs., L.L.C., 527 F.3d 1330, 1336, 87 U.S.P.Q.2d (BNA) 1140, 1144 (Fed. Cir. 2008) (quoting Iverson v. Johnson Gas Appliance Co., 172 F.3d 524, 530 (8th Cir. 1997)).

^{1600.} *Id.* at 1337, 87 U.S.P.Q.2d (BNA) at 1144 (citing *Iverson*, 172 F.3d at 530). 1601. 527 F.3d 1330, 87 U.S.P.Q.2d (BNA) 1140 (Fed. Cir. 2008). 1602. *Id.* at 1332, 87 U.S.P.Q.2d (BNA) at 1141.

^{1602.} Id. at 1337, 87 U.S.P.Q.2d (BNA) at 1145.
1604. Id. at 1337–38, 87 U.S.P.Q.2d (BNA) at 1145.
1605. Id. at 1337, 87 U.S.P.Q.2d (BNA) at 1145 (citing Exigent Tech., Inc. v. Atrana Solutions, Inc., 442 F.3d 1301, 1311, 78 U.S.P.Q.2d (BNA) 1321, 1327–28 (Fed. Cir. 9000). 2006)).

^{1606.} Id. at 1338, 87 U.S.P.Q.2d (BNA) at 1146.

AMERICAN UNIVERSITY LAW REVIEW

C. Motions to Transfer

On petition for a writ of mandamus in In re TS Tech USA Corp.,¹⁶⁰⁷ the Federal Circuit ordered the district court to transfer venue of a patent infringement case filed in the United States District Court for the Eastern District of Texas to the United States District Court for the Southern District of Ohio. In September 2007, plaintiff Lear Corporation filed suit against TS Tech in the Eastern District of Texas for infringement of a patent relating to pivotally attached vehicle headrest assemblies.¹⁶⁰⁸ Lear's complaint alleged that TS Tech had been making and selling infringing headrest assemblies to Honda, and that TS Tech induced Honda to infringe the patent by incorporating the headrest assemblies into Honda vehicles, which are sold throughout the United States, including in the Eastern District of Texas.¹⁶⁰

In December 2007, TS Tech filed a motion to transfer venue for convenience to the Southern District of Ohio, under 28 U.S.C. § 1404(a).¹⁶¹⁰ In support of transfer, TS Tech argued that the physical and documentary evidence was mainly located in Ohio and the key witnesses all lived in Ohio, Michigan, and Canada, and that none of the parties were either incorporated in Texas or had any offices in the Eastern District of Texas.¹⁶¹¹ Lear opposed, arguing that the Eastern District of Texas was the proper venue because several Honda vehicles containing the allegedly infringing headrest assemblies had been sold in Texas.¹⁶¹² In September 2008, the district court denied transfer, finding that TS Tech failed to demonstrate that the inconvenience to the parties and witnesses clearly outweighed the deference entitled to Lear's choice of forum, and that because several Honda vehicles containing the allegedly infringing headrests had been sold in the venue, the Eastern District of Texas had a "substantial interest" in adjudicating the case.¹⁶¹³

TS Tech petitioned the Federal Circuit for a writ of mandamus ordering the district court to transfer the case.¹⁶¹⁴ Relying on the Fifth Circuit's recent en banc decision granting a similar petition for a writ of mandamus in *In re Volkswagen of America, Inc.*,¹⁶¹⁵ the Federal

^{1607. 551} F.3d 1315, 89 U.S.P.Q.2d (BNA) 1567 (Fed. Cir. 2008).

^{1608.} *Id.* at 1318, 89 U.S.P.Q.2d (BNA) at 1568. 1609. *Id.*, 89 U.S.P.Q.2d (BNA) at 1568.

^{1609.} *Id.*, 89 U.S.P.Q.2d (BNA) at 1568.
1610. *Id.*, 89 U.S.P.Q.2d (BNA) at 1568.
1611. *Id.*, 89 U.S.P.Q.2d (BNA) at 1568.
1612. *Id.*, 89 U.S.P.Q.2d (BNA) at 1568.
1613. *Id.*, 89 U.S.P.Q.2d (BNA) at 1568.
1614. *Id.*, 89 U.S.P.Q.2d (BNA) at 1568.
1614. *Id.*, 89 U.S.P.Q.2d (BNA) at 1568.

^{1615. 545} F.3d 304, 89 U.S.P.Q.2d (BNA) 1501 (5th Cir. 2008) (en banc).

Circuit granted TS Tech's petition, finding that under the circumstances, the district court's decision not to transfer was a "clear abuse of discretion" that produced a "patently erroneous result" and therefore justified the extraordinary writ.¹⁶¹⁶

The Federal Circuit confirmed that regional circuit law governs whether a motion to transfer a patent infringement case under § 1404(a) should be granted, and that under Fifth Circuit law, a motion to transfer venue should be granted upon a showing that the transferee venue is "clearly more convenient" than the venue chosen by the plaintiffs.¹⁶¹⁷ From *Volkswagen*, the court identified both "public" and "private" factors, taken from forum non conveniens law, to consider when ruling on a motion to transfer under § 1404(a).¹⁶¹⁸

Applying those factors, the Federal Circuit held that the district court applied some of the relevant factors correctly, but that overall the analysis "contained several key errors."¹⁶¹⁹ The district court's first error was to give too much weight to Lear's choice of forum.¹⁶²⁰ As the Fifth Circuit had explained in Volkswagen, "the plaintiff's choice of venue corresponds to the burden that a moving party must meet in order to demonstrate that the transferee venue is a clearly more convenient venue," but it is not a separate factor to be considered in favor of the plaintiff on a motion for transfer.¹⁶²¹

The district court's second error, according to the Federal Circuit, was that it "ignored Fifth Circuit precedent in assessing the cost of attendance for witnesses."¹⁶²² The Fifth Circuit has adopted a "100mile" rule "which requires that '[w]hen the distance between an existing venue for trial of a matter and a proposed venue under § 1404(a) is more than 100 miles, the factor of inconvenience to witnesses increases in direct relationship to the additional distance to

^{1616.} In re TS Tech, 551 F.3d at 1319, 1322, 89 U.S.P.Q.2d (BNA) at 1569, 1570 (recounting the high burden that must be met for the granting of a writ of mandmus and finding that the petitioner had met that standard). 1617. *Id.*, at 1319, 89 U.S.P.Q.2d (BNA) at 1568.

^{1617.} Id., at 1515, 65 U.S.F.Q.2d (BIVA) at 1506. 1618. Id., 89 U.S.P.Q.2d (BNA) at 1568-69. "The 'private' interest factors include: (1) the relative ease of access to sources of proof; (2) the availability of compulsory process to secure the attendance of witnesses; (3) the cost of attendance for willing witnesses; and (4) all other practical problems that make a trial easy, expeditious, and inexpensive." *Id.*, 89 U.S.P.Q.2d (BNA) at 1569 (citing Piper Aircraft Co. v. Reyno, 454 U.S. 235, 241 n.6 (1981)). "The 'public' interest factors to be considered are (1) the administrative difficulties flowing from court congestion; (2) the local interest in having localized interests decided at home; (3) the familiarity of the forum with the law that will govern the case; and (4) the avoidance of unnecessary problems of conflicts of laws [or in] the application of foreign law." *Id.*, 89
U.S.P.Q.2d (BNA) at 1569 (quoting *Volkswagen*, 545 F.3d at 315).
1619. *Id.* at 1320, 89 U.S.P.Q.2d (BNA) at 1569.
1620. *Id.*, 89 U.S.P.Q.2d (BNA) at 1569.
1621. *Id.*, 89 U.S.P.Q.2d (BNA) at 1569.
1622. *Id.*, 89 U.S.P.Q.2d (BNA) at 1569.

be traveled."¹⁶²³ The Federal Circuit noted that witnesses would need to travel approximately 900 more miles to attend trial in the Eastern District of Texas than to do so in the Southern District of Ohio.¹⁶²⁴

The third error identified by the Federal Circuit was the district court's determination that the "relative ease to access of sources of proof" factor was neutral because "many of the documents were stored electronically."¹⁶²⁵ Again following the Fifth Circuit's *Volkswagen* opinion, the Federal Circuit concluded that because all of the physical evidence, including the headrests and the documentary evidence, were far more convenient to the Southern District of Ohio, the district court's conclusion that this factor was neutral was error.¹⁶²⁶

Finally, the Federal Circuit identified the district court's determination that the Eastern District of Texas had a "substantial interest" in having the case heard locally as a fourth error in the court's analysis.¹⁶²⁷ Based on the facts presented, the Federal Circuit concluded that "there is no relevant connection between the actions giving rise to this case and the Eastern District of Texas. . . . [T]he vehicles containing TS Tech's allegedly infringing headrest assemblies were sold throughout the United States and thus the citizens of the Eastern District of Texas have no more or less of a meaningful connection to this case than any other venue."¹⁶²⁸ The Federal Circuit therefore concluded that "[b]ecause the district court's errors here are essentially identical [to the errors identified by the Fifth Circuit in *Volkswagen*], we hold that TS Tech has demonstrated a clear and indisputable right to a writ."¹⁶²⁹

In addition, the Federal Circuit clarified that TS Tech was not required to seek reconsideration of the district court's denial of its transfer motion before seeking a writ of mandamus because TS Tech has no reasonable expectation that the district court would reverse its prior ruling and because interlocutory review of a denial of a motion to transfer is unavailable under 28 U.S.C. § 1292 (b).¹⁶³⁰

^{1623.} *Id.*, 89 U.S.P.Q.2d (BNA) at 1569 (quoting *In re Volkswagen AG*, 371 F.3d 201, 204-05 (5th Cir. 2004)).

^{1624.} *Id.*, 89 U.S.P.Q.2d (BNA) at 1569.

^{1625.} Id. at 1320-21, 89 U.S.P.Q.2d (BNA) at 1570.

^{1626.} Id. at 1321, 89 U.S.P.Q.2d (BNA) at 1570.

^{1627.} *Id.*, 89 U.S.P.Q.2d (BNA) at 1570.

^{1628.} Id. 89 U.S.P.Q.2d (BNA) at 1570. 1629. Id. at 1322, 89 U.S.P.Q.2d (BNA) at 1570.

^{1629.} *Id.* at 1522, 89 U.S.P.Q.2d (BNA) at 1571.

^{1050.} *Iu.*, 69 U.S.F.Q.20 (DNA) at 1571.

VIII. REMEDIES

A. Permanent Injunction

In the 2006 eBay Inc. v. MercExchange, L.L.C.¹⁶³¹ decision, the Supreme Court confirmed that a patentee-plaintiff must satisfy the following four-factor test before a court may grant a permanent injunction:

(1) that [the plaintiff] has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.¹⁶

The Federal Circuit continued to refine the application of *eBay* to different factual circumstances in 2008. In Innogenetics, N.V. v. Abbott Laboratories,¹⁶³³ Innogenetics brought an action against Abbott for infringement of its patent relating to diagnostic tools that detected and classified hepatitis C virus genotypes which facilitated customizing treatments of patients with varying genotypes.¹⁶³⁴ At the infringement trial, Innogenetics' damages expert proposed an upfront "market entry fee" payment of \$5.8 million and a running royalty of five to ten euros per test on the 190,000 tests Abbott had sold up to that point.¹⁶³⁵ At the conclusion of the evidence, the jury trial found in favor of Innogenetics, and the court entered judgment of infringement and reasonable royalties in the amount of \$7 million.¹⁶³⁶

Innogenetics moved for a permanent injunction.¹⁶³⁷ In granting Innogenetics a permanent injunction in addition to the \$7 million damages award, the district court stated, "[i]t would denigrate the value of plaintiff's patent rights to allow defendant to continue to sell plaintiff's invention as its own in exchange for the same fee it would have paid without the lawsuit."¹⁶³⁸

On appeal, the Federal Circuit vacated the district court's grant of a permanent injunction prohibiting the future sales of Abbott's

^{1631. 547} U.S. 388, 78 U.S.P.Q.2d (BNA) 1577 (2006).

^{1632.} *Id.* at 391, 78 U.S.P.Q.2d (BNA) at 1578 (citing Weinberger v. Romero-Barcelo, 456 U.S. 305, 311–313 (1982); Amoco Prod. Co. v. Gambell, 480 U.S. 531, 542 (1987))

^{1633. 512} F.3d 1363, 85 U.S.P.Q.2d (BNA) 1641 (Fed. Cir. 2008).

^{1634.} *Id.* at 1368, 85 U.S.P.Q.2d (BNA) at 1644.
1635. *Id.* at 1380, 85 U.S.P.Q.2d (BNA) at 1653.
1636. *Id.*, 87 U.S.P.Q.2d (BNA) at 1653.
1637. *Id.* at 1650. 77 U.S.P.Q.2d (DNA) at 1653.

^{1637.} Id. at 1369, 87 U.S.P.Q.2d (BNA) at 1645.

genotyping assay kits, finding that the lower court's ruling was an abuse of discretion. Counsel for Innogenetics argued that the jury's damages calculation was a royalty for Abbott's past infringement only.1639

The Federal Circuit rejected this argument, finding on review of the trial record that, during the damages portion of the trial, Innogenetics' damages expert factored in the cost of a license that would allow Abbott to continue selling the infringing product—and concluded that the jury's award "include[d] both an up-front payment and an *ongoing* royalty payment."1640 The court held that "[w]hen a patentee requests and receives such compensation, it cannot be heard to complain that it will be irreparably harmed by future sales" and that "this factor greatly outweighs the other eBay factors in this case."1641 The court also noted that "[i]njunctive relief ought not to act as a form of 'extra damages' to compensate for litigation costs" and that "[i]f litigation costs were a factor, injunctive relief would be warranted in every litigated patent case."1642 The Federal Circuit remanded the case to the district court to "delineate the terms of the compulsory license."1643

In Amado v. Microsoft Corp., 1644 plaintiff Amado filed a suit against Microsoft for infringement of his patent relating to a software program that combines the functionalities of spreadsheet and database software.¹⁶⁴⁵ Following a 2005 jury verdict that Amado's patent was valid and infringed, the district court granted Amado's motion for a permanent injunction but stayed the injunction until "[s]even days after the resolution or abandonment of any appeal."¹⁶⁴⁶ The district court rejected Amado's motion to enforce the stay seven days after the mandate issued and, instead, interpreted the term "appeal" to include a petition for certiorari.¹⁶⁴⁷ The district court granted Microsoft's request for an extension of the stay following the Supreme Court's denial of certiorari.¹⁶⁴⁸ Microsoft then moved for permanent dissolution of the permanent injunction, arguing that the "Supreme Court's recent decision in eBay made the grant of

1646. Id., 86 U.S.P.Q.2d (BŇA) at 1092.

^{1639.} Id. at 1380, 87 U.S.P.Q.2d (BNA) at 1653.

<sup>Id40. Id. at 1380, 85 U.S.P.Q.2d (BNA) at 1653.
Id41. Id., 85 U.S.P.Q.2d (BNA) at 1653.
I642. Id. at 1380 n.8, 86 U.S.P.Q.2d (BNA) at 1654 (citations omitted).</sup>

^{1643.} Id. at 1381, 85 U.S.P.Q.2d (BNA) at 1654.

^{1644. 517} F.3d 1353, 86 U.S.P.Q.2d (BNA) 1090 (Fed. Cir. 2008).

^{1645.} Id. at 1356, 86 U.S.P.Q.2d (BNA) at 1092.

^{1647.} Id. at 1357, 86 U.S.P.Q.2d (BNA) at 1093.

^{1648.} Id., 86 U.S.P.Q.2d (BŇA) at 1093.

injunction inappropriate."¹⁶⁴⁹ After applying the four-factor test for injunctive relief, the district court found "both an absence of irreparable harm and that the public interest would be disserved by granting an injunction," and therefore dissolved the permanent injunction.¹⁶⁵⁰

Amado appealed, arguing that the "mandate rule foreclosed Microsoft from challenging the injunction or the district court from modifying it."1651 Although it agreed that the mandate rule would have foreclosed Microsoft from challenging the initial entry of the permanent injunction, the Federal Circuit rejected Amado's argument that the district court abused its discretion when it modified the stay of the injunction once it was incorporated into the mandate from the Federal Circuit's 2006 order.¹⁶⁵² The court noted that "district courts possess broad equitable authority to modify injunctions" and concluded that there was no abuse of discretion when the district court reconsidered the permanent injunction in light of *eBay* and, ultimately, decided to dissolve the injunction when it determined that it was "no longer equitable under the circumstances."¹⁶⁵³ The court also noted that it did not reach the argument of "whether there remains a rebuttable presumption of irreparable harm following a judgment of validity and infringement following *eBay*" because the district court in this case was "within its discretion to find an *absence* of irreparable harm based on the evidence presented at trial."1654

In Voda v. Cordis Corp.,¹⁶⁵⁵ plaintiff Voda alleged that Cordis had infringed three of its patents relating to catheter designs for interventional cardiology.¹⁶⁵⁶ After the district court found that Voda's patents were not invalid and were infringed, Voda moved for a permanent injunction.¹⁶⁵⁷ Rather than attempting to prove irreparable injury to himself, Voda attempted to show the effect Cordis's infringement had on its exclusive licensee of the patents-insuit.¹⁶⁵⁸ The district court denied Voda's motion for a permanent injunction, finding that Voda had failed to demonstrate irreparable

^{1649.} Id. at 1359, 86 U.S.P.Q.2d (BNA) at 1094.

^{1650.} *Id.*, 86 U.S.P.Q.2d (BNA) at 1095. 1651. *Id.*, 86 U.S.P.Q.2d (BNA) at 1095.

^{1652.} Id. at 1358, 86 U.S.P.Q.2d (BNA) at 1094. The Federal Circuit's 2006 order affirming the district court's final judgment, *Amado v. Microsoft Corp.*, 185 F. App'x 953 (Fed. Cir. 2006) (per curiam), is also referred to as *Amado I*.

^{1653.} Id. at 1358-61, 86 U.S.P.Q.2d (BNA) at 1094-96.

^{1654.} Id. at 1359 n.1, 86 U.S.P.Q.2d (BNA) at 1095 n.1.

^{1655. 536} F.3d 1311, 87 U.S.P.Q.2d (BNA) 1742 (Fed. Cir. 2008).
1656. *Id.* at 1315, 87 U.S.P.Q.2d (BNA) at 1744–45.
1657. *Id.* at 1315, 87 U.S.P.Q.2d (BNA) at 1745.

^{1658.} Id. at 1329, 87 U.S.P.Q.2d (BNA) at 1755-56.

injury and failed to show that monetary damages were inadequate to compensate for Cordis's infringement.¹⁶⁵⁹ Voda appealed the district court's denial of the permanent injunction.¹⁶⁶⁰ The Federal Circuit affirmed the denial of a permanent injunction, finding that Voda's attempt to proof of injury to his exclusive licensee, rather than to himself, did not provide a basis for entry of a permanent injunction.¹⁶⁶¹ While affirming the denial of a permanent injunction of the facts of Voda, however, the court noted that "patent owners that license their patents rather than practice them 'may be able to satisfy the traditional four-factor test' for a permanent injunction."¹⁶⁶²

In Broadcom Corp. v. Qualcomm Inc., 1663 plaintiff Broadcom filed an action against Qualcomm for infringement of three of its patents relating to baseband chips designed to work in cell phones on 3G networks.¹⁶⁶⁴ A jury found that Broadcom's patents were infringed and not invalid, and awarded Broadcom damages.¹⁶⁶⁵ Subsequently, the district court held a bench trial on the issue of injunctive relief.¹⁶⁶⁶ In support of its motion for an injunction, Broadcom put forth evidence that it would be irreparably injured because it has a general policy not to license its patents and that monetary damages were insufficient because it would not have agreed to enter a licensing agreement with its direct competitor for strategic business reasons.¹⁶⁶⁷

At the conclusion of the bench trial, the district court entered a permanent injunction against Qualcomm on all patents.¹⁶⁶⁸ The permanent injunction barred Qualcomm's future sales of products using Broadcom's patents but included a "sunset" provision that allowed "continued sales pursuant to a mandatory royalty through January 31, 2009."¹⁶⁶⁹ In its analysis of the *eBay* factors, the district court found that (1) Broadcom had demonstrated irreparable harm because, even though it did not practice the claimed inventions, the competition for "design wins" in the baseband marketplace could

^{1659.} Id., 87 U.S.P.Q.2d (BNA) at 1755-56.

^{1660.} Id. at 1315, 87 U.S.P.Q.2d (BNA) at 1745.

^{1661.} Id. at 1329, 87 U.S.P.Q.2d (BNA) at 1756.

Ide2. Id., 87 U.S.P.Q.2d (BNA) at 1756 (quoting eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 393, 78 U.S.P.Q. (BNA) 1577, 1579 (2006)).
 1663. 543 F.3d 683, 88 U.S.P.Q.2d (BNA) 1641 (Fed. Cir. 2008). For discussion of

this case's implications regarding indirect infringement, see supra notes 882-889 and accompanying text.

^{1664.} *Id.* at 686, 88 U.S.P.Q.2d (BNA) at 1644. 1665. *Id.* at 687, 88 U.S.P.Q.2d (BNA) at 1644. 1666. *Id.* 88 U.S.P.Q.2d (BNA) at 1645. 1667. *Id.* at 702–04, 88 U.S.P.Q.2d (BNA) at 1656–58.

^{1668.} Id. at 687, 88 U.S.P.Q.2d (BNA) at 1645.

^{1669.} Id., 88 U.S.P.Q.2d (BNA) at 1645.

have a competitive effect on firms;¹⁶⁷⁰ (2) the lack of adequate remedy at law weighed in favor of an injunction with respect to all of the infringed patents;¹⁶⁷¹ (3) the permanent injunction would harm Qualcomm, but held that "with a sunset provision which ameliorates the negative effects on Qualcomm, the balance of hardships favors Broadcom";¹⁶⁷² and (4) an immediate permanent injunction would adversely affect the public, network carriers, and handset manufacturers, but that the sunset provisions "balance[] the policy of protecting the patentee's rights against the desirability of avoiding immediate market disruptions."1673

The Federal Circuit affirmed the grant of a permanent injunction, noting that the "district court provided a well-reasoned and comprehensive opinion addressing injunctive relief."¹⁶⁷⁴ The court held that Broadcom demonstrated irreparable harm, "despite the fact that it does not currently practice the claimed inventions," when it showed that Qualcomm competes indirectly with Broadcom in the baseband chip market.¹⁶⁷⁵ The court distinguished this ruling from a prior decision: whereas in Voda the alleged harm was to an "exclusive licensee," in this case Broadcom did not "rely on harm to others, but rather allege[d] that its own commercial activities will be irreparably injured by Qualcomm's infringing activity."1676

Likewise, in Acumed LLC v. Stryker Corporation,¹⁶⁷⁷ the Federal Circuit affirmed a district court's decision to grant an injunction despite the defendant's arguments that the eBav factors did not warrant one. Acumed asserted a patent directed to a proximal humeral nail ("PHN")-a type of orthopedic nail used for the treatment of fractures of the upper arm-against one of Stryker's PHN products.¹⁶⁷⁸ In 2005, a jury found willful infringement and awarded damages, and in early 2006, the district court issued a permanent injunction.¹⁶⁷⁹

While Stryker's appeal was pending in 2006, however, the Supreme Court decided eBay,¹⁶⁸⁰ and the Federal Circuit, in addition to affirming the jury's verdict and damages award, remanded the case to

^{1670.} Id. at 702-03, 88 U.S.P.Q.2d (BNA) at 1656-57.

^{1671.} Id. at 703–04, 88 U.S.P.Q.2d (BNA) at 1657–58. 1672. Id. at 704, 88 U.S.P.Q.2d (BNA) at 1658.

^{1673.} Id., 88 U.S.P.Q.2d (BNA) at 1658 (alteration in original) (citations omitted).

^{1674.} *Id.* at 702, 88 U.S.P.Q.2d (BNA) at 1656. 1675. *Id.* at 703, 88 U.S.P.Q.2d (BNA) at 1657.

^{1676.} *Id.*, 88 U.S.P.Q.2d (BNA) at 1657. 1677. 551 F.3d 1323, 89 U.S.P.Q.2d (BNA) 1612 (Fed. Cir. 2008).

^{1678.} Id. at 1326, 89 U.S.P.Q.2d (BNA) at 1613. 1679. Id., 89 U.S.P.Q.2d (BŇA) at 1613.

^{1680.} eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 78 U.S.P.Q.2d (BNA) 1577 (2006).

the district court for reconsideration of the four-factor test for injunctive relief in light of *eBay*.¹⁶⁸¹

On remand, defendant Stryker responded to Acumed's motion for a permanent injunction by submitting an opposition memorandum supported by the declarations of five physicians attesting to their use of Stryker's product, and stating that it was less prone to nail "backout" than Acumed's competing product.¹⁶⁸² Stryker also argued that Acumed's prior licensing of the asserted patent barred a finding of irreparable injury.¹⁶⁸³

The district court rejected Stryker's arguments and again issued a permanent injunction.¹⁶⁸⁴ On appeal, the Federal Circuit concluded that the district court's findings and determination were not an abuse of discretion. First, the Federal Circuit rejected Stryker's argument that Acumed's prior licensing of the asserted patent precluded findings of irreparable injury and no adequate remedy at law: "While the fact that a patentee has previously chosen to license the patent may indicate that a reasonable royalty does compensate for an infringement, that is but one factor for the district court to consider."1685 The court confirmed the district court's analysis that the addition of Stryker as a licensee could still cause Acumed irreparable harm, stating that:

[a]dding a new competitor to the market may create an irreparable harm that the prior licenses did not. In this case, the fact that Acumed licensed the [asserted] patent under two particular sets of circumstances does not mean that the district court abused its discretion in not holding that Acumed must now grant a further license to Stryker and receive only a royalty as compensation.¹⁶⁸⁶

Second, the court rejected Stryker's arguments that the balance of hardships counseled against an injunction because the evidence showed an injunction would cause a hardship for Stryker's customers and patients and because Stryker had made significant expenditures in designing and manufacturing its infringing product.¹⁶⁸⁷ "As a preliminary matter, the balance of hardship is only between a plaintiff and a defendant, and thus the effect on customers and patients alleged by Stryker is irrelevant under this prong of the

^{1681.} Acumed LLC v. Stryker Corp., 483 F.3d 800, 811, 82 U.S.P.Q.2d (BNA) 1481, 1489 (Fed. Cir. 2007)

^{1682.} Acumed, 551 F.3d at 1326, 1331, 89 U.S.P.Q.2d (BNA) at 1613, 1617.

^{1683.} Id. at 1327-28, 89 U.S.P.Q.2d (BNA) at 1614.

^{1684.} Id., 89 U.S.P.Q.2d (BNA) at 1614-1615.

^{1685.} *Id.* at 1328, 89 U.S.P.Q.2d (BNA) at 1614. 1686. *Id.* at 1329, 89 U.S.P.Q.2d (BNA) at 1615.

^{1687.} Id. at 1329-30, 89 U.S.P.Q.2d (BNA) at 1615-1616.

injunction test."1688 The court also stated, "We also see no abuse of discretion in the court's decision not to consider Stryker's expenses in designing and marketing the [accused product], since those are expenses related to an infringing product."1689

Finally, the Federal Circuit confirmed that the district court had not abused its discretion when it concluded that the public interest did not preclude an injunction.¹⁶⁹⁰ The court concluded that the district court's findings that there was "considerable dispute" at trial about whether Stryker's evidence of a public health issue regarding screw back-out with Acumed's competing product was the product of "biased experts," and that Stryker had not proven that there was any public health problem with Acumed's product were not an abuse of discretion.¹⁶⁹¹

However, while affirming the district court's ruling, the Federal Circuit expressed that this presented a close case.¹⁶⁹⁷ The court specifically indicated that its affirmance took into account that its review was under the abuse of discretion standard:

Ultimately, this was a close case, especially with regard to the irreparable harm and lack of adequate remedy at law prongs of the four-factor test, in view of past licenses having been granted, and the public interest prong, in light of testimony that the accused product was a medically superior one. Nonetheless, the standard of review, viz., abuse of discretion, compels our decision to affirm the district court.¹⁶⁹³

B. Preliminary Injunction

A preliminary injunction is entered before trial to protect a party's rights while an infringement trial is pending. Preliminary injunctions require an examination of the following four factors: (1) likelihood of success on the merits, (2) harm to the moving party if the injunction is not granted, (3) the balance of hardships, and (4) the impact of the injunction on the public interest.¹⁶⁹⁴

^{1688.} *Id.* at 1330, 89 U.S.P.Q.2d (BNA) at 1616 (citing eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391, 78 U.S.P.Q.2d (BNA) 1577, 1578 (2006)).

^{1689.} Id. at 1330, 89 U.S.P.Q.2d (BNA) at 1616 (citing Windsurfing Int'l, Inc. v. AMF, Inc., 782 F.2d 995, 1003 n.12, 228 U.S.P.Q. (BNA) 562, 567 (Fed. Cir. 1986)).
1690. Id. at 1330-31, 89 U.S.P.Q.2d (BNA) at 1616-1617.

^{1691.} *Id.*, 89 U.S.P.Q.2d (BNA) at 1616-1617. 1692. *Id.* at 1332, 89 U.S.P.Q.2d (BNA) at 1617.

^{1693.} Id., 89 U.S.P.Q.2d (BNA) at 1617.

^{1694.} See Nutrition 21 v. United States, 930 F.2d 867, 869, 18 U.S.P.Q.2d (BNA) 1347, 1348–49 (Fed. Cir. 1991) ("Whether a preliminary injunction should issue turns upon four factors: (1) the probability that the movant will succeed on the merits; (2) the threat of irreparable harm to the movant should a preliminary injunction be denied; (3) the balance between this harm and the harm that granting

In Abbott Laboratories v. Sandoz, Inc.,1695 plaintiff Abbott brought an infringement action against Sandoz for infringement of its patents involving its extended release formulations of one its brand name antibiotic drugs.¹⁶⁹⁶ In granting Abbott a preliminary injunction against Sandoz, the district court found that (1) Abbott had demonstrated a reasonable likelihood of proving infringement of its patents;¹⁶⁹⁷ (2) Abbott would suffer irreparable harm despite the existence of generic producers already in this market because the generic producers "do not negate the market share and revenue loss upon Sandoz['s] entry while the litigation proceeds";¹⁶⁹⁸ (3) the balance of hardships weighed in favor of Abbott because "Abbott will lose much more if this Court did not enjoin Sandoz's infringing conduct than if the Court enjoins Sandoz and it is subsequently found that the '718 patent is invalid or unenforceable";¹⁶⁹⁹ and (4) while the public interest may be served by the availability of less expensive forms of successful medicines, the court also recognized "the public interest in creating beneficial and useful products and the cost involved in that process" and, thus, enforcing the Abbott Laboratories patent would also serve the public interest.¹⁷⁰⁰

On appeal, Sandoz argued that the district court had abused its discretion by granting the preliminary injunction because Sandoz had raised a "substantial question" as to the validity of the patent at issue as well as Abbott's "inequitable conduct" in obtaining the patents.¹⁷⁰¹

Affirming the grant of preliminary injunction,¹⁷⁰² a panel majority of the Federal Circuit found that the district court had not abused its discretion in granting a preliminary injunction against Sandoz.

The correct standard is not whether a substantial question has been raised, but whether the patentee is likely to succeed on the merits, upon application of the standards of proof that will prevail at trial. The question is not whether the patent is vulnerable; the

the injunction will cause to the other parties litigant; and (4) the public interest.") (quoting Pretty Punch Shoppettes, Inc. v. Hauk, 844 F.2d 782, 783, 6 U.S.P.Q.2d (duoting Freity Funch Shoppenes, Inc. 7. Flaux, 677 Fize 762, (BNA) 1563, 1564 (Fed. Cir. 1988)). 1695. 544 F.3d 1341, 89 U.S.P.Q.2d (BNA) 1161 (Fed. Cir. 2008). 1696. *Id.* at 1343–44, 89 U.S.P.Q.2d (BNA) at 1164–65. 1697. *Id.* at 1361, 89 U.S.P.Q.2d (BNA) at 1179.

^{1698.} Id. at 1361–62, 89 U.S.P.Q.2d (BNA) at 1179.

^{1699.} *Id.* at 1362, 89 U.S.P.Q.2d (BNA) at 1179. 1700. *Id.* 89 U.S.P.Q.2d (BNA) at 1179-80.

^{1701.} Abbott Labs. v. Sandoz, Inc., 544 F.3d 1341, 1345, 89 U.S.P.Q.2d (BNA) 1161, 1166 (Fed. Cir. 2008) ("Sandoz assigns legal error to the district court's rulings that Abbott is likely to prevail on the issues of validity, infringement, and inequitable conduct, and states that the district court abused its discretion in balancing the equities and granting the injunction.").

^{1702.} Id. at 1371, 89 U.S.P.Q.2d (BNA) at 1186.

question is who is likely to prevail in the end, considered with equitable factors that relate to whether the status quo should or should not be preserved while the trial is ongoing. The presentation of sufficient evidence to show the likelihood of prevailing on the merits is quite different from the presentation of substantial evidence to show vulnerability.¹⁷⁰³

The majority opinion also provided an overview of the law granting preliminary injunction to address the issues raised by Judge Gajarsa's dissent.¹⁷⁰⁴ Writing for the majority, Judge Newman noted that "[no] circuit has held that it suffices to raise a 'substantial question'" as to whether or not a defendant is likely to prevail on the merits.¹⁷⁰⁵ The court went on to hold that "[r]aising a substantial question may avoid dismissal on the pleadings, but contrary to the view of the dissent, establishing that there is an issue for trial is not the same as establishing the likelihood of prevailing at trial."¹⁷⁰⁶

In his dissent, Judge Gajarsa found that there was "no legal basis for the granting of the preliminary injunction and its issuance is an abuse of discretion."¹⁷⁰⁷ Judge Gajarsa focused on the preliminary injunction factor of "a reasonable likelihood of success on the merits" and argued that there were "substantial questions of both validity and enforceability of the '718 patent preventing a finding of likelihood of success on the merits."1708 The dissent found that the district court erred when it failed to "properly consider and weigh the ample evidence produced by Sandoz that clearly established a substantial question of invalidity and rendered the patent vulnerable to an invalidity challenge at trial."¹⁷⁰⁹ Furthermore, the dissent argued that the district court had abused its discretion by finding the "concededly false statement" made by Abbott to be immaterial and thus failing to find a substantial question of inequitable conduct on Abbott's part.¹⁷¹⁰

In Judkins v. HT Window Fashion Corp.,¹⁷¹¹ the Federal Circuit affirmed the district court's denial of a motion for preliminary injunction based on a Lanham Act counterclaim.¹⁷¹² The patents at issue in Judkins involved a process for manufacturing window coverings.¹⁷¹³ On HT's motion for a preliminary injunction, HT

^{1703.} *Id.* at 1364, 89 U.S.P.Q.2d (BNA) at 1180-81. 1704. *Id.* at 1363-68, 89 U.S.P.Q.2d (BNA) at 1180-84.

^{1705.} Id. at 1368, 89 U.S.P.Q.2d (BNA) at 1184.

^{1706.} *Id.* at 1369, 89 U.S.P.Q.2d (BNA) at 1184. 1707. *Id.* at 1371, 89 U.S.P.Q.2d (BNA) at 1186.

^{1708.} Id. at 1381, 89 U.S.P.Q.2d (BNA) at 1194.
1709. Id. at 1372, 89 U.S.P.Q.2d (BNA) at 1187.
1710. Id. at 1379–81, 89 U.S.P.Q.2d (BNA) at 1193.

^{1711. 529} F.3d 1334, 86 U.S.P.Q.2d (BNA) 1352 (Fed. Cir. 2008).

^{1712.} Id. at 1336, 86 U.S.P.Q.2d (BNA) at 1354.

^{1713.} Id., 86 U.S.P.Q.2d (BŇA) at 1354.

alleged that Judkins had "violated section 43(a) of the Lanham Act¹⁷¹⁴ by sending HT's customers and potential customers letters stating that an HT product infringed its patents" and that Judkins had acted in bad faith because he knew that his patent was unenforceable.¹⁷¹⁵

The district court denied HT's motion for preliminary injunction holding that "HT could not establish bad faith or overcome the presumption of the patent's validity by clear and convincing evidence and therefore could not show the requisite likelihood of success on the merits."1716

The Federal Circuit affirmed the district court's denial of HT's request for a preliminary injunction.¹⁷¹⁷ Plaintiff Judkins obtained his '120 patent for the process after the Board of Patent Appeals and Interferences granted priority for his patent application over a patent assigned to a competitor and soon filed a suit against HT for infringement of its '120 patent.¹⁷¹⁸ The court rejected HT's argument that the district court had erred when it failed to find that an earlier settlement was collusive and thus indicative of bad faith on Judkins assertion of the '120 patent; instead, the court deferred to the court's judgment and declined to make an assumption on the district court's diligence.¹⁷¹⁹ The court also rejected HT's arguments that the district court clearly erred by questioning the substance of the finding in an earlier litigation, applying a presumption of validity, and failing to use the "objective baselessness" standard of bad faith.¹⁷²⁰

The Federal Circuit reversed the district court's denial of a preliminary injunction in E.I. du Pont de Nemours & Co. v. MacDermid Printing Solutions, L.L.C.¹⁷²¹ The patents at issue in DuPont were directed to a process for preparing a flexographic printing plate from a photosensitive element for use in the process.¹⁷²² In opposition to DuPont's motion for a preliminary injunction, defendant MacDermid argued that DuPont could not show a likelihood of success on the merits because DuPont's patent "was invalid under Section 102(b) because the invention was on sale or in public use before the critical date . . . of February 27, 2001, or one year before the filing date of the

- 1720. *Id.* at 1341–42, 86 U.S.P.Q.2d (BNA) at 1357–59. 1721. 525 F.3d 1353, 1354, 86 U.S.P.Q.2d (BNA) 1732, 1734 (Fed. Cir. 2008)
- [hereinafter DuPont].

^{1714. 15} U.S.C. § 1125(a) (2006). 1715. *Id.*, 86 U.S.P.Q.2d (BNA) at 1354.

^{1716.} *Id.* at 1337, 86 U.S.P.Q.2d (BNA) at 1355. 1717. *Id.* at 1344-45, 86 U.S.P.Q.2d (BNA) at 1361.

^{1718.} Id. at 1337, 86 U.S.P.Q.2d (BNA) at 1355.

^{1719.} Id. at 1341, 86 U.S.P.Q.2d (BNA) at 1358.

^{1722.} Id. at 1354, 86 U.S.P.Q.2d (BNA) at 1734.

non-provisional application."¹⁷²³ The district court agreed and denied DuPont's motion for a preliminary injunction because DuPont had not shown that MacDermid's asserted invalidity defenses lacked substantial merit.1724

On appeal of the preliminary injunction, the Federal Circuit found that the district court had abused its discretion in finding that a "substantial question" as to the validity of the patent existed because the "non-provisional application was entitled to the filing date of the provisional application as a matter of law."¹⁷²⁵ The court vacated and remanded the case for consideration because the district court had not reached "the parties' remaining arguments as to validity and enforceability as well as the remaining preliminary injunction factors."1726

In Proctor & Gamble Co. v. Kraft Foods Global, Inc.,¹⁷²⁷ Proctor & Gamble ("P & G") filed an action against Kraft for infringement of its patent for a plastic container, intended to replace conventional metal cans for marketing and storing ground coffee, and moved for a preliminary injunction.¹⁷²⁸ While the motion for preliminary injunction was pending, the district court granted Kraft's motion to stay, effectively denying P & G's motion for preliminary injunction.¹⁷²⁹ P & G appealed.¹⁷³⁰ The Federal Circuit reversed, finding that the lower court had "abused its discretion by effectively denying P & G's motion for a preliminary injunction without considering and balancing the required factors."¹⁷³¹ The Federal Circuit rejected the district court's refusal to hear P & G's arguments regarding likelihood of success without first construing the claims, as well as its refusal to consider arguments regarding irreparable harm and the balance of hardships on the basis that such arguments would only be considered if Kraft's motion for a stay were not granted.¹⁷³² The court remanded the matter to the district court for a full evaluation of the preliminary injunction factors.¹⁷³³

- 1728. Id. at *1, 89 U.S.P.Q.2d (BNA) at 1086.
- 1729. *Id.* at *1, 89 U.S.P.Q.2d (BNA) at 1086–87. 1730. *Id.* at *2, 89 U.S.P.Q.2d (BNA) at 1087.
- 1731. Id. at *4, 89 U.S.P.Q.2d (BNA) at 1088. 1732. Id., 89 U.S.P.Q.2d (BNA) at 1088-89.

^{1723.} *Id.* at 1355, 86 U.S.P.Q.2d (BNA) at 1735. 1724. *Id.* at 1357, 86 U.S.P.Q.2d (BNA) at 1736. 1725. *Id.* at 1358, 86 U.S.P.Q.2d (BNA) at 1737.

^{1726.} Id. at 1354, 86 U.S.P.Q.2d (BNA) at 1734.

No. 2008-1105, 2008 WL 5101824, 89 U.S.P.Q.2d (BNA) 1085 (Fed. Cir. Dec. 1727. 5, 2008).

^{1733.} Id. at *6, 89 U.S.P.Q.2d (BNA) at 1090.

AMERICAN UNIVERSITY LAW REVIEW

C. Damages

In TiVo, Inc. v. Echostar Communications Corp., 1734 plaintiff TiVo brought a suit against Echostar in the Eastern District of Texas for infringement of claims related to its patent on technology that enables television users to "time-shift" television signals thereby enabling users to digitally record and replay the program on the user's television set.¹⁷³⁵ The district court entered judgment on the jury award of \$73,991,964 in damages for TiVo (\$32,663,906 in lost profits and \$41,328,058 in reasonable royalties), and Echostar appealed.¹⁷³⁶ Even though it reversed the verdict of infringement as to two of the four claims on which the jury had found infringement, the Federal Circuit affirmed the damages awarded by the district court "[b]ecause the damages calculation at trial was not predicated on the infringement of particular claims, and because we have upheld the jury's verdict that all of the accused devices infringe the software claims."¹⁷³⁷ The Federal Circuit also noted that the district court's injunction was stayed pending the appeal and, once the appeal becomes final, the district court can make a determination of additional damages that TiVo may have sustained while the stay of the permanent injunction has been in effect.¹⁷³⁸

1. Lost profits

In order for a patent owner to recover lost profits as opposed to a reasonable royalty, the patent owner must "prove a causal relation between the infringement and its loss of profits. The patent owner must show that 'but for' the infringement, it would have made the infringer's sales."1739

In American Seating Co. v. USSC Group, Inc.,¹⁷⁴⁰ American Seating filed an action against USSC alleging that two of USSC's wheelchair tie-down devices, the VPRo I and the VPRo II, infringed its patent for a wheelchair restraint system for use in mass transit vehicles.¹⁷⁴¹ The jury returned a verdict including an award of lost profits from convoyed sales of non-patented products to American Seating. The district court granted in part USSC's motion for remittitur by setting

^{1734. 516} F.3d 1290, 85 U.S.P.Q.2d (BNA) 1801 (Fed Cir. 2008).

^{1735.} Id. at 1294, 85 U.S.P.Q.2d (BNA) at 1803.

^{1736.} *Id.*, 85 U.S.P.Q.2d (BNA) at 1804. 1737. *Id.* at 1312, 85 U.S.P.Q.2d (BNA) at 1817.

^{1737.} Id. at 1512, 65 C.S.I.Q.2d (BNA) at 1617.
1738. Id., 85 U.S.P.Q.2d (BNA) at 1817.
1739. BIC Leisure Prods., Inc. v. Windsurfing Int'l, Inc., 1 F.3d 1214, 1218, 27 U.S.P.Q.2d (BNA) 1671, 1674 (Fed. Cir. 1993).
1740. 514 F.3d 1262, 85 U.S.P.Q.2d (BNA) 1683 (Fed. Cir. 2008).

^{1741.} Id. at 1265-66, 85 U.S.P.Q.2d (BNA) at 1684.

aside a portion of the verdict related to convoyed sales, because "the record evidence, viewed in the light most favorable to American Seating, was insufficient as a matter of law for the jury to find that the patented tie-down system and unpatented passenger seats were part of a single functional unit."¹⁷⁴² The district court reduced the original jury award of \$2,326,129 in lost profits to \$676,850.¹⁷⁴³ American Seating appealed the district court's decision setting aside a portion of the jury's verdict and USSC cross-appealed the district court's confirmation of the "jury's award of lost profit damages for sales of the non-infringing VPRo II."1744

The Federal Circuit affirmed the

trial court's conclusions that American Seating failed as a matter of law to meet its burden of establishing a functional relationship between passenger seats and the patented restraint system, and the jury properly awarded damages for lost profits on USSC's deliveries of the VPRo II predicated upon offers to sell the infringing VPRo I.¹⁷⁴⁵

The court also noted that "[b]ecause it is clear that no interrelated or functional relationship inheres between the seats and the tie-down restraint system on a passenger bus, the district court was correct that the jury had no basis to conclude that lost profits on collateral sales of passenger seats were due American Seating."1746

Waters Corp.,¹⁷⁴⁷ In Cohesive Technologies, Inc. v. Cohesive Technologies brought three related actions accusing Waters of infringing its patents relating to high-performance liquid chromatography ("HLPC"), a process for separating, identifying, and measuring compounds contained in a liquid.¹⁷⁴⁸ Following a bench trial, the district court concluded that Cohesive was not entitled to lost profits as a result of infringement, because Waters had acceptable noninfringing substitutes.¹⁷⁴⁹ The Federal Circuit vacated the lower court's ruling that Cohesive was not entitled to lost profits because it was "unclear whether the other product available, standing alone, would have been an acceptable substitute."1750 Specifically, the Federal Circuit did not understand what the district court meant in its differentiation between a "fully-acceptable substitute" and a

^{1742.} Id. at 1268-69, 85 U.S.P.Q.2d (BNA) at 1686.

^{1743.} *Id.* at 1266, 85 U.S.P.Q.2d (BNA) at 1684. 1744. *Id.* at 1269–70, 85 U.S.P.Q.2d (BNA) at 1687–88.

^{1745.} *Id.* at 1268, 85 U.S.P.Q.2d (BNA) at 1686.
1746. *Id.* at 1269, 85 U.S.P.Q.2d (BNA) at 1687.
1747. 543 F.3d 1351, 88 U.S.P.Q.2d (BNA) 1903 (Fed. Cir. 2008).

^{1747. 543} F.3d 1351, 88 U.S.P.Q.2d (BNA) 1903 (Fed. 1748. *Id.* at 1357–58, 88 U.S.P.Q.2d (BNA) at 1905–06.

^{1749.} Id. at 1372, 88 U.S.P.Q.2d (BNA) at 1917.

^{1750.} Id. at 1357, 88 U.S.P.Q.2d (BNA) at 1906.

"reasonably acceptable substitute."¹⁷⁵¹ The court remanded for "reconsideration based upon its determination of (1) whether the 25 mm columns infringe under the correct claim construction; and (2) whether the 2.1 x 20 mm columns are acceptable noninfringing substitutes."1752

2. Reasonable royalty

922

In Monsanto Co. v. David, 1753 Monsanto brought an infringement action against David, a commercial farmer, for infringement of its patents involving genes used in soybean seeds.¹⁷⁵⁴ Monsanto claimed that David had planted soybean seeds with the patented genes in 2003 that were improperly saved from the previous year's harvest.¹⁷⁵⁵ The district court entered judgment against David for willfully infringing Monsanto's patent and for breach of the technology agreement by planting saved seed from the prior year's harvest and awarded Monsanto reasonable royalty damages of \$226,214.40.1756 David appealed the district court's judgment.¹⁷⁵

The Federal Circuit upheld the district court's reasonable royalty calculation of \$55.04 per infringing seed unit but vacated the district court's calculation of seed density of 107.5 pounds per acre.¹⁷⁵⁸ The Federal Circuit found it significant that there was confusion concerning the 120 pound per acre density estimate that David had offered during his trial testimony.¹⁷⁵⁹ Based on the transcript and David's "extensive previous testimony," which showed that David had never estimated planting the Monsanto seed at more than seventy-five pounds per acre, the Federal Circuit concluded that the 120 pound density figure that David referenced was for conventional seed, not seed utilizing Monsanto's patented genes.¹⁷⁶⁰ While noting the district court's "difficult task of determining the total soybean acreage planted by David in 2003 and the density of seed used in those fields" in order to assess the number of infringing seed units planted by David, the court nevertheless found that the district court's determination was "clearly erroneous" because it had based its

^{1751.} Id. at 1373, 88 U.S.P.Q.2d (BNA) at 1917.

^{1752.} Id. at 1373-74, 88 U.S.P.Q.2d (BNA) at 1917-18.

^{1753. 516} F.3d 1009, 85 U.S.P.Q.2d (BNA) 1963 (Fed. Cir. 2008). 1754. *Id.* at 1011–12, 85 U.S.P.Q.2d (BNA) at 1965–66.

^{1755.} *Id.* at 1011 12, 05 C.P.Q.2d (BNA) at 1966.
1756. *Id.* at 1013, 85 U.S.P.Q.2d (BNA) at 1966.
1757. *Id.*, 85 U.S.P.Q.2d (BNA) at 1966.
1758. *Id.* at 1019–20, 85 U.S.P.Q.2d (BNA) at 1971.
1758. *Id.* at 1019–20, 85 U.S.P.Q.2d (BNA) at 1971.

^{1759.} Id. at 1019, 85 U.S.P.Q.2d (BNA) at 1971.

^{1760.} Id., 85 U.S.P.Q.2d (BŇA) at 1970-71.

calculation on the use of an anomalous 120 pound density figure.¹⁷⁶¹ Thus, the Federal Circuit vacated the district court's ruling on this issue and remanded for further fact-finding concerning the soybean density issue.¹⁷⁶²

In *Amado v. Microsoft Corp.*,¹⁷⁶³ the district court awarded plaintiff Amado a post-verdict royalty equivalent to \$0.12 per infringing unit for products sold during the stay of a permanent injunction against Microsoft.¹⁷⁶⁴ The district court reached \$0.12 by trebling the preverdict reasonable royalty of \$0.04, reasoning that post-verdict sales should be considered willful infringement.¹⁷⁶⁵ Reviewing the award on appeal, the Federal Circuit noted that willfulness "is not the inquiry when the infringement is permitted by a court-ordered stav."¹⁷⁶⁶ The court vacated the district court's award because it "did not expressly consider that Microsoft's infringing sales took place following the grant of an injunction that was stayed."¹⁷⁶⁷ The Federal Circuit remanded the matter for reconsideration because the court was "unable to determine whether the district court's award of \$0.12 was a reasonable exercise of its discretion."1768

In addition, Microsoft argued that any damages awarded to Amado must be adjusted in light of *Microsoft Corp. v. AT & T Corp.*,¹⁷⁶⁹ which held "that liability under 35 U.S.C. § 271(f) does not extend to the installation of software onto a computer abroad when the copies of that software are made abroad, because in such case the copies are not 'supplied' from the United States within the meaning of that statute."¹⁷⁷⁰ Based on AT & T, Microsoft argued that "[a]ny damages awarded to Amado should . . . be limited to products manufactured and or sold in the United Sates."¹⁷⁷¹ Though the Federal Circuit concluded that "Microsoft is entitled to assert the AT & T decision," the court was "unable to determine whether the infringing products sold by Microsoft were provided in such a way as to not be 'supplied from the United States' as required to extinguish § 271(f) liability."¹⁷⁷² Thus, the Federal Circuit remanded to the district court "to decide

- 1762. Id. at 1019, 85 U.S.P.Q.2d (BNA) at 1971. 1763. 517 F.3d 1353, 86 U.S.P.Q.2d (BNA) 1090 (Fed. Cir. 2008).
- 1764. Id. at 1362, 86 U.S.P.Q.2d (BNA) at 1097.
- 1765. *Id.* at 1361, 86 U.S.P.Q.2d (BNA) at 1096. 1766. *Id.* at 1362, 86 U.S.P.Q.2d (BNA) at 1097.
- 1767. Id., 86 U.S.P.Q.2d (BNA) at 1097.
- 1768. Id., 86 U.S.P.Q.2d (BNA) at 1097.
 1769. 550 U.S. 437, 82 U.S.P.Q.2d (BNA) 1400 (2007).
 1770. Amado, 517 F.3d at 1363, 86 U.S.P.Q.2d (BNA) at 1098.
- 1771. Id., 86 U.S.P.Q.2d (BNA) at 1098.
- 1772. Id. at 1364, 86 U.S.P.Q.2d (BNA) at 1098.

^{1761.} Id. at 1018-19, 85 U.S.P.Q.2d (BNA) at 1970.

the applicability of AT & T' along with its reconsideration of the "proper disbursement of funds from escrow."¹⁷⁷³

3. Costs

In Zenith Electronics Corp. v. PDI Communications Systems. Inc.,¹⁷⁷⁴ plaintiff Zenith brought an action against PDI for infringement of its patents relating to televisions and wired remote controls used in hospital rooms.¹⁷⁷⁵ Among its other summary judgment rulings, the district court denied PDI's motion for costs without further explanation and PDI cross-appealed.¹⁷⁷⁶ The Federal Circuit agreed with PDI that "Seventh Circuit law requires the district court to provide some explanation of its decision regarding costs."¹⁷⁷⁷ However, the court noted that because the court vacated and remanded several of the district court's summary judgment rulings, it was "in no position to opine on whether PDI should ultimately be deemed the prevailing party for purposes of recovering costs."¹⁷⁷⁸ The court held that PDI could move again for costs and that the district court's "conclusion on that issue should be accompanied by an explanation in accordance with *Krocka*[v. City of Chicago]¹⁷⁷⁹."¹⁷⁸⁰

4. Marking

In Wine Railway Appliance Co. v. Enterprise Railway Equipment Co.,¹⁷⁸¹ the Supreme Court held that "under the predecessor statute to the notice provision of 35 U.S.C. § 287, a patentee who fails to mark his patented article with the appropriate patent number could only recover damages for infringement occurring after actual notice was provided the infringer."¹⁷⁸² In DSW, Inc. v. Shoe Pavilion, Inc.,¹⁷⁸³ the Federal Circuit held that the district court misapplied Wine Railway because it failed to recognize "that a patentee may indeed recover damages for infringement that continues after actual notice is provided."1784

- 1776. Id. at 1351–52, 86 U.S.P.Q.2d (BNA) at 1513 (Fed. Cir. 2008).
 1777. Id. at 1351–52, 86 U.S.P.Q.2d (BNA) at 1514–15.
 1776. Id. at 1352, 86 U.S.P.Q.2d (BNA) at 1515.
 1777. Id. at 1367, 86 U.S.P.Q.2d (BNA) at 1527.

- 1778. *Id.*, 86 U.S.P.Q.2d (BNA) at 1527. 1779. 203 F.3d 507 (7th Cir. 2000).
- 1780. Zenith, 522 F.3d at 1367, 86 U.S.P.Q.2d (BNA) at 1527.
- 1781. 297 U.S. 387, 28 U.S.P.Q. (BNA) 299 (1936).
- 1782. DSW, Inc. v. Shoe Pavilion, Inc., 537 F.3d 1342, 1348, 87 U.S.P.Q.2d (BNA)
- 1687, 1692 (Fed. Cir. 2008)
- 1783. 537 F.3d 1342, 87 Ú.S.P.Q.2d (BNA) 1687 (Fed. Cir. 2008).
- 1784. Id. at 1348, 87 U.S.P.Q.2d (BNA) at 1692.

^{1773.} Id., 86 U.S.P.Q.2d (BNA) at 1098.

DSW brought an action against Shoe Pavilion for infringement of its patents for a system of storing and displaying a large selection of footwear for customer self-service.¹⁷⁸⁵ The district court granted summary judgment for Shoe Pavilion, citing Wine Railway and holding that "no damages for infringement are recoverable by a plaintiff unless the infringing activity continues after notice is provided to the infringer."¹⁷⁸⁶ The district court excused post-notice infringement because "Shoe Pavilion took reasonable steps and timely removed all of the infringing shoe displays."¹⁷⁸⁷ The Federal Circuit reversed the district court's holding, stating that the trial court had "erred in concluding that Shoe Pavilion's reasonable steps and good faith efforts to bring its infringing activity to a timely end equated to an immediate cessation."¹⁷⁸⁸ The court held that the "district misapplied the standard expressed by the Supreme Court in Wine Railway"¹⁷⁸⁹ and that "a patentee may indeed recover damages for infringement that continues after actual notice is provided" regardless of how diligently the infringer takes steps to stop infringing.¹⁷⁹⁰ The court reiterated that "the law offers an infringer no exception to liability for the time it takes to terminate infringing activities, no matter how expeditious and reasonable its efforts."1791

IX. PENALTIES

A. Enhanced Damages for Willful Infringement

Patent infringement is a strict liability offense; therefore, the nature of the offense is only relevant in determining whether enhanced damages are warranted.¹⁷⁹² The Patent Act does not provide any standard for the award of enhanced damages.¹⁷⁹³ Accordingly, the Federal Circuit has held that an award of enhanced damages requires a showing of willful infringement.¹⁷⁹⁴

In 2007, the Federal Circuit, sitting en banc, overruled its earlier precedent and changed the standard for a finding of willful infringement "from one of an affirmative duty of care to one of

^{1785.} *Id.* at 1344, 87 U.S.P.Q.2d (BNA) at 1688. 1786. *Id.*, 87 U.S.P.Q.2d (BNA) at 1690.

^{1787.} Id., 87 U.S.P.Q.2d (BNA) at 1690.

^{1788.} *Id.* at 1348, 87 U.S.P.Q.2d (BNA) at 1692. 1789. *Id.*, 87 U.S.P.Q.2d (BNA) at 1692.

^{1790.} Id., 87 U.S.P.Q.2d (BNA) at 1692.
1791. Id., 87 U.S.P.Q.2d (BNA) at 1692.
1792. In re Seagate Tech., LLC, 497 F.3d 1360, 1368, 83 U.S.P.Q.2d (BNA) 1865,

^{1868 (}Fed. Cir. 2007) (en banc).

^{1793.} Id. at 1368 n.3, 83 U.S.P.Q.2d (BNA) at 1868 n.3. 1794. Id. at 1368, 83 U.S.P.Q.2d (BNA) at 1868.

objective recklessness."¹⁷⁹⁵ Thus, to support an award of enhanced damages, the plaintiff must prove by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent.¹⁷⁹⁶

In Minks v. Polaris Industries, Inc., 1797 the Federal Circuit considered whether a jury's finding of willfulness in a trial that occurred before In re Seagate Technology, LLC¹⁷⁹⁸ must be reversed in light of that decision, and concluded that it did not.¹⁷⁹⁹ In *Minks*, the owner of a patent directed to an electronic governor system for internal combustion engines sued Polaris Industries, a manufacturer of allterrain vehicles ("ATVs"), for infringement.¹⁸⁰⁰ Approximately one year before filing suit—and after the parties had exchanged several communications regarding Minks's patent rights-Minks sent a letter informing Polaris of its belief that Polaris's ATVs infringed Minks's patent.¹⁸⁰¹ At the conclusion of the evidence at trial, the jury was given a willfulness instruction that Polaris argued on appeal was plain error in light of *Seagate*, but to which Polaris did not object at trial.¹⁸⁰² The jury found that Polaris willfully infringed Minks's patent.¹⁸⁰³ The district court subsequently granted enhanced damages and attorney fees.¹⁸⁰⁴

When a jury instruction is not objected to at trial, the appeals court will review the instruction only for "plain error."¹⁸⁰⁵ The Federal Circuit in Minks applied the regional circuit's plain error review standard:

Under [the United States Court of Appeals for the Eleventh Circuit's] plain error review, an appellate court must not correct an error the defendant failed to raise in the district court unless there is (1) error, (2) that is plain, and (3) that affects substantial rights. If all three of those conditions are met, the court may exercise its discretion to notice a forfeited error but only if (4) the error

^{1795.} Minks v. Polaris Indus., Inc., 546 F.3d 1364, 1380, 89 U.S.P.Q.2d (BNA) 1102, 1114 (Fed. Cir. 2008).

^{1796.} Seagate, 497 F.3d at 1371, , 83 U.S.P.Q.2d (BNA) 1865, 1870.

^{1797.} 546 F.3d 1364, 89 U.S.P.Q.2d (BNA) 1102 (Fed. Cir. 2008).

^{1798.} 497 F.3d 1360, 1368, 83 U.S.P.Q.2d (BNA) 1865, 1868 (Fed. Cir. 2007) (en banc).

^{1799.} Id. at 1379–81, 89 U.S.P.Q.2d (BNA) at 1114–15.

^{1800.} *Id.* at 1367–69, 89 U.S.P.Q.2d (BNA) at 1104–06. 1801. *Id.* at 1369, 89 U.S.P.Q.2d (BNA) at 1106.

^{1802.} *Id.* at 1379, 89 U.S.P.Q.2d (BNA) at 1114. 1803. *Id.* at 1369, 89 U.S.P.Q.2d (BNA) at 1106.

^{1804.} Id., 89 U.S.P.Q.2d (BNA) at 1106. However, the district court subsequently granted Polaris's motion for a reduction in damages and reduced Minks's original award. Id., 89 U.S.P.Q.2d (BNA) at 1106.

^{1805.} Id. at 1379, 89 U.S.P.Q.2d (BNA) at 1114.

seriously affects the fairness, integrity, or public reputation of judicial proceedings.¹⁸⁰⁶

Affirming the jury's finding of willfulness, the Federal Circuit concluded that it did not need to decide whether the instruction given to the jury constituted plain error, because Polaris failed to offer any argument or to cite any evidence to establish that any alleged error affected its substantial rights or affected the fairness, integrity, or public reputation of judicial proceedings—the third and fourth elements of the Eleventh Circuit's plain error standard.¹⁸⁰⁷ Specifically, Polaris made no argument that the jury would not have found willfulness if it was instructed differently, arguing instead that the jury's willfulness finding "affected its substantial rights because it resulted in the imposition of enhanced damages and attorney fees."1808 The Federal Circuit also stated that it did not think Polaris could have shown that the alleged error in the jury instruction affected its substantial rights because the trial court's order granting enhanced damages stated that it was "fairly clear" that deliberate copying had taken place and that "the case was not close."¹⁸⁰⁹ Based on that record, the Federal Circuit stated "it appears that error in the jury instruction was not prejudicial because the jury may very well have arrived at the same result."¹⁸¹⁰ The Federal Circuit also stated that there had been no argument that the outcome of the case might "seriously affect[] the fairness, integrity, or public reputation of judicial proceedings," and affirmed the jury's willfulness verdict.¹⁸¹¹

B. Award of Attorney Fees

Section 285 of the Patent Act provides that "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party."¹⁸¹² Under that section, the trial court must first determine whether the particular case is "exceptional," а determination that must be based on clear and convincing evidence.¹⁸¹³ If the court finds that it is, the trial court must then

^{1806.} Id. at 1379-80, 89 U.S.P.Q.2d (BNA) at 1114 (quoting United States v. LeCroy, 441 F.3d 914, 930 (11th Cir. 2006)). 1807. Id. at 1380-81, 89 U.S.P.Q.2d (BNA) at 1114-15.

^{1808.} Id., 89 U.S.P.Q.2d (BNA) at 1115.

^{1809.} *Id.* at 1381, 89 U.S.P.Q.2d (BNA) at 1115 (quoting Minks v. Polaris Indus., Inc., No. 6:05-cv-1894-Orl-31KRS, 2007 WL 788418, at *1 (M.D. Fla. Mar. 14, 2007)). 1810. Id. at 1381, 89 U.S.P.Q.2d (BNA) at 1115.

^{1811.} Id., 89 U.S.P.Q.2d (BNA) at 1115 (quoting United States v. LeCroy, 441 F.3d 914, 930 (11th Cir. 2006)) (alteration in original).

^{1812. 35} U.S.C. § 285 (2006)

^{1813.} Forest Labs., Inc. v. Abbott Labs., 339 F.3d 1324, 1327, 67 U.S.P.Q.2d (BNA) 1682, 1684 (Fed. Cir. 2003) (quoting 35 U.S.C. § 285 (2006)).

determine, as a matter of discretion, whether to award attorney fees.¹⁸¹⁴ However, "[i]n order to provide a basis for meaningful review" of the decision to award attorney fees under section 285, the court of appeals requires the trial court not only to make the ultimate finding that the case is exceptional, "but also to articulate the more particular factual findings from which the finding of 'exceptional circumstances' follows."1815

In Innovation Technologies, Inc. v. Splash! Medical Devices, LLC,¹⁸¹⁶ the Federal Circuit vacated and remanded an award of attorney fees under § 285 because the district court did not provide sufficient factual findings to allow for appellate review.¹⁸¹⁷ In that case, more than one year after filing suit and following extensive discovery (but prior to a *Markman v. Westview Instruments. Inc.*¹⁸¹⁸ hearing). Innovation executed a covenant not to sue Splash on the patent at issue and moved to dismiss its infringement suit with prejudice.¹⁸¹⁹ Splash subsequently moved for attorney fees pursuant to § 285. The district court granted the motion in a one-paragraph order stating in relevant part:

This case qualifies as an "exceptional" case under 35 U.S.C. § 285 justifying an award of attorney's fees to Splash as the prevailing party. Splash has shown by clear and convincing evidence that Innovation knew or, on reasonable investigation, should have known, that its claims of infringement were baseless. It appears to me that the lawsuit was filed solely for the *purpose* of harassing a small competitor.¹⁸²⁰

The Federal Circuit held that "[t]he three conclusory statements quoted above-which merely stated that this is an exceptional case, that Innovation knew or should have known that its claims of infringement were 'baseless,' and that it 'appear[ed]' that the suit was filed 'solely' to 'harass' a small competitor," were inadequate to allow the Federal Circuit to perform its review function.¹⁸²¹

On remand, the district court was provided with latitude to select the bases for its conclusion that the case was exceptional:

U.S.P.Q. 821, 824 (Fed. Cir. 1985) (quoting Hughes v. Novi Am., Inc., 724 F.2d 122, 124, 220 U.S.P.Q. (BNA) 707, 709 (Fed. Cir. 1984)). 1816. 528 F.3d 1348, 87 U.S.P.Q.2d (BNA) 1222 (Fed. Cir. 2008).

- 1817. *Id.* at 1351–52, 87 U.S.P.Q.2d (BNA) at 1224. 1818. 517 U.S. 370 (1996).

^{1814.} See id. at 1329, 67 U.S.P.Q.2d (BNA) at 1686 (noting the "limited circumstance in which an award of attorney fees is appropriate"). 1815. Reactive Metals & Alloys Corp. v. ESM, Inc., 769 F.2d 1578, 1582, 226

^{1819.} Id. at 1350, 87 U.S.P.Q.2d (BNA) at 1223.

^{1820.} *Id.*, 87 U.S.P.Q.2d (BNA) at 1223 (quoting Order Granting Splash's Motion for Attorney's Fees, No. 07-1424 (C.A. Fed. Mar. 22, 2007)) (emphasis added). 1821. Id. at 1351, 87 U.S.P.Q.2d (BNA) at 1224.

Of course, the district court need not necessarily make findings on all of [the points raised by the parties]. Findings on those issues upon which the court bases its new determination of the "exceptional case" issue are all that is required. The detail necessary . . . is a matter largely within the district court's discretion. $^{\scriptscriptstyle 1822}$

If the district court awards attorney fees based on its exceptional case finding, it must also explain the reasons for the conclusion that such an award is warranted.¹⁸²³

Over a dissenting opinion, the Federal Circuit held that the trial court's findings of inequitable conduct and litigation misconduct could justify an exceptional case finding in Nilssen v. Osram Sylvania, Inc.¹⁸²⁴ In a 2000 complaint, Nilssen accused Osram of infringing twenty-six patents relating to fluorescent light bulbs and ballasts used in combination with fluorescent light bulbs.¹⁸²⁵ Over the next five years, Nilssen informally removed several of those patents from the case while attempting to assert additional patents through a variety of means, all without formally releasing Osram from infringement liability on any of the patents.¹⁸²⁶ By the time of trial, Nilssen formally reduced the number of patents being asserted to eleven.¹⁸²⁷

Following a bench trial on inequitable conduct, the district court held that the asserted patents were unenforceable because Nilssen had misclaimed small entity status and improperly paid small entity maintenance fees, failed to disclose to the patent examiner litigation related to the patent applications, misclaimed the priority of earlier filing dates, withheld material prior art, and submitted misleading affidavits to the Patent and Trademark Office.¹⁸²⁸ In a 2007 decision, the Federal Circuit affirmed the district court's inequitable conduct ruling.1829

In addition, Nilssen engaged in litigation conduct, which the district court found was relevant to the exceptional case finding. Nilssen had refused to provide a witness for a deposition absent a court instruction to do so, claiming that its own unverified interrogatory responses had no legal effect at trial, claimed reliance on tax counsel's advice as a defense to inequitable conduct after

^{1822.} Id. at 1352, 87 U.S.P.Q.2d (BNA) at 1224.

^{1823.} *Id.*, 87 U.S.P.Q.2d (BNA) at 1224. 1824. 528 F.3d 1352, 1361, 87 U.S.P.Q.2d (BNA) 1161, 1167 (Fed. Cir. 2008).

^{1825.} *Id.* at 1354, 87 U.S.P.Q.2d (BNÅ) at 1162. 1826. *Id.* at 1354–55, 87 U.S.P.Q.2d (BNÅ) at 1162.

^{1827.} Id. at 1355, 87 U.S.P.Q.2d (BNA) at 1162–63. 1828. Id. at 1356, 87 U.S.P.Q.2d (BNA) at 1163.

^{1829.} Nilssen v. Osram Sylvania, Inc., 504 F.3d 1223, 1235–36, 84 U.S.P.Q.2d (BNA)

^{1811, 1820 (}Fed. Cir. 2007).

having asserted attorney-client privilege over such advice, and had produced documents late.¹⁸³⁰

On Osram's post-trial motion for attorney fees, the district court concluded that the case was exceptional and awarded Osram its attorney fees.¹⁸³¹ The district court identified three reasons for finding exceptionality: "Nilssen's inequitable conduct, the frivolous nature of the lawsuit, and [Nilssen's] litigation misconduct."¹⁸³²

In reviewing the district court's exceptional case determination, the Federal Circuit first clarified that there is no per se rule of exceptionality in cases involving inequitable conduct but, in appropriate cases, a finding of inequitable conduct can constitute a basis for the award of attorney fees.¹⁸³³ The Court then rejected appellant Nilssen's argument that the district court's exceptional case finding should be reversed because Nilssen's inequitable conduct was "benign," stating "[i]f certain conduct has been held to be inequitable, and we have affirmed the district court's conclusion that it was here, it is hence per se not benign."1834

The Court explained that the inequitable conduct determination was not the sole basis for the district court's award of attorney fees and that the findings regarding Nilssen's litigation misconduct also supported the exceptional case finding.¹⁸³⁵ The Federal Circuit declined to independently address Nilssen's arguments that each instance of litigation misconduct found by the district court was either harmless oversight of a litigation formality or a permissibly rough litigation tactic.

As an appellate court, we are ill-suited to weigh such evidence. All of the instances described above are context-specific, and the district court found that, taken in context, they amounted to litigation misconduct [W]e are not left with the firm conviction that a mistake was committed. Furthermore, it ill behooves an appellate court to overrule a trial judge concerning litigation misconduct when the litigation occurred in front of the trial judge, not the appellate court.¹⁸

Finally, the Court stated that the abuse of discretion standard of review was central to its decision to affirm the district court's grant of attorney fees.¹⁸³⁷

^{1830.} Nilssen, 528 F.3d at 1355–56, 87 U.S.P.Q.2d (BNA) at 1163. 1831. Id. at 1356, 87 U.S.P.Q.2d (BNA) at 1163.

^{1832.} Id., 87 U.S.P.Q.2d (BŇA) at 1163.

^{1833.} Id. at 1358, 87 U.S.P.Q.2d (BNA) at 1164.

^{1834.} *Id.*, 87 U.S.P.Q.2d (BNA) at 1164–65. 1835. *Id.*, 87 U.S.P.Q.2d (BNA) at 1165.

^{1836.} Id. at 1359, 87 U.S.P.Q.2d (BNA) at 1165.

^{1837.} Id. at 1360, 87 U.S.P.Q.2d (BNA) at 1166.

Dissenting, Judge Newman stated that the majority's decision "promotes unexceptional trial procedures and non-culpable prosecution errors into an 'exceptional case' of such severity as to warrant the award of attorney fees."1838 First citing the "American Rule" that "one should not be penalized for merely defending or prosecuting a lawsuit," her opinion reviewed in detail the Federal Circuit's 2007 decision upholding the finding of inequitable conduct and argued that the findings in that opinion did not justify the majority's conclusion.¹⁸³⁹ Judge Newman also argued that the panel majority's analysis was a departure from Federal Circuit precedent because the majority held that "the nature of the grounds on which inequitable conduct [is] found is not relevant to the attorney fee determination."¹⁸⁴⁰ Her dissent concluded that the panel majority's holding "enlarges the scope of 'exceptional case' to include less than egregious aspects of patent prosecution and litigation practice, with no evidence or charge of bad faith or prejudice."¹⁸⁴¹

In Qualcomm Inc. v. Broadcom Corp.,¹⁸⁴² the Federal Circuit held that Qualcomm's litigation misconduct, standing alone, was sufficient to justify an award of attorney fees under § 285.¹⁸⁴³ In response to Qualcomm's complaint of patent infringement alleging that Broadcom products, which utilized the H.264 video compression standard, infringed patents owned by Qualcomm, Broadcom raised a defense that Qualcomm's patents were unenforceable because Qualcomm failed to disclose the patents to a Joint Video Team ("JVT") standards-setting organization during discussions leading to the adoption of the H.264 video compression standard.¹⁸⁴⁴ Throughout discovery and the trial, Qualcomm represented that it did not participate in the JVT during the development of the relevant standard and, therefore, had no duty to disclose its patents to that body.¹⁸⁴⁵ During cross-examination on one of the last days of the

^{1838.} Id. at 1361, 87 U.S.P.Q.2d (BNA) at 1167. 1839. See id. at 1361–63, 87 U.S.P.Q.2d (BNA) at 1167–68 (quoting Summit Valley Indus., Inc. v. Local 112, United Bhd. of Carpenters, 456 U.S. 717, 724 (1982)) (stating that the majority had truncated its explanation of the underlying facts).

^{1840.} Id. at 1364, 87 U.S.P.Q.2d (BNA) at 1169. 1841. Id. at 1365, 87 U.S.P.Q.2d (BNA) at 1169.

^{1842. 548} F.3d 1004, 89 U.S.P.Q.2d (BNA) 1321 (Fed. Cir. 2008). For discussion of this case's implications regarding breach of duty to a standards setting organization, see supra notes 1551-1556.

^{1843.} See id. at 1027, 89 U.S.P.Q.2d (BNA) at 1337-38 (concluding that Broadcom should receive attorney fees related to the exceptional case determination).

^{1844.} See id. at 1008–09, 89 U.S.P.Q.2d (BNA) at 1323–24 (summarizing the district court's conclusion that Qualcomm's patent was unenforceable because of its inequitable conduct).

^{1845.} Id. at 1009, 89 U.S.P.Q.2d (BNA) at 1324.

infringement trial, however, a Qualcomm witness acknowledged that she possessed emails relating to the JVT that Qualcomm previously claimed did not exist.¹⁸⁴⁶ Ultimately, it was revealed that Qualcomm possessed over 200,000 pages of emails and electronic documents demonstrating that Qualcomm had participated in the JVT from as early as January 2002.¹⁸⁴⁷ The district court later concluded that Qualcomm "knowingly attempted in trial to continue the concealment of evidence."¹⁸⁴⁸ It also determined, based on the lateproduced evidence, that Qualcomm engaged in a "carefully orchestrated plan . . . to achieve its goal of holding hostage the entire industry desiring to practice the H.264 standard" by concealing from the JVT the existence of the asserted patents, and held numerous Qualcomm patents unenforceable.¹⁸⁴⁹

Following trial, the district court granted Broadcom's motion for attorney fees, basing its exceptional case determination both on Qualcomm's "bad faith participation" in the JVT and Qualcomm's "litigation misconduct . . . during discovery, motions practice, trial, and post-trial proceedings."1850

On appeal, Qualcomm argued that the district court's grant of attorney fees should be vacated because it was based in part on Qualcomm's bad faith participation in the JVT and that "a patentee's bad faith business conduct toward an accused infringer prior to litigation" should not be factored into an award of attorney fees under § 285.1851 The Federal Circuit held that the district court's findings regarding Qualcomm's bad faith participation in the JVT were not clearly erroneous, and that the district court's litigation misconduct findings were sufficient standing alone to support the determination.¹⁸⁵² Accordingly, exceptional case "in the circumstances of the present case it was not error for the district court to additionally consider the related JVT misconduct, which was an important predicate to understanding and evaluating the litigation misconduct."1853

^{1846.} Id., 89 U.S.P.Q.2d (BNA) at 1324.

^{1847.} *Id.*, 89 U.S.P.Q.2d (BNA) at 1324. 1848. *Id.*, 89 U.S.P.Q.2d (BNA) at 1324 (quoting Order on Remedy for Finding of Waiver, Qualcomm Inc. v. Broadcom Corp., 539 F. Supp. 2d 1214, 1245 (S.D. Cal.

<sup>Walver, Qualconnin Inc. V. Broadconn Colp., 353 F. Supp. 2d 1214, 1243 (S.D. Cal. 2007) (Civ. No. 05-CV-1958-B(BLM))).
1849. Id. at 1009–10, 89 U.S.P.Q.2d (BNA) at 1324.
1850. Id. at 1010, 89 U.S.P.Q.2d (BNA) at 1324–25 (quoting Qualcomm Inc. v. Broadcom Corp., No. 05-CV-1958, 2007 WL 2261799 at *2 (S.D. Cal. Aug. 6, 2007)).
1051. Id. at 1020 27 200 U.S.P.Q.2d (DNA) at 1327.</sup>

^{1851.} Id. at 1026–27, 89 U.S.P.Q.2d (BNA) at 1337. 1852. Id. at 1027, 89 U.S.P.Q.2d (BNA) at 1337.

^{1853.} Id., 89 U.S.P.Q.2d (BNA) at 1337.

In Minks v. Polaris Industries, Inc., 1854 based on a jury's finding of willful infringement, the district court determined that the case was exceptional under § 285 and awarded Minks attorney fees.¹⁸⁵⁵ The district court determined that a "reasonable fee" was \$234,663.00, but awarded only half that amount on the basis that Minks's damages theory was "economic nonsense" and that the reduction was warranted to offset "the great deal of time during trial [that] was wasted by Plaintiff attempting to evade the basic laws of economics and common sense."1856

On Minks's appeal of the reduced attorney fees award, the Federal Circuit affirmed.¹⁸⁵⁷ "[W]e detect no abuse of discretion in the award of attorney fees. Even on appeal, Minks remains unable or unwilling to articulate a coherent damages theory."¹⁸⁵⁸

Finally, in Takeda Chemical Industries, Ltd. v. Mylan Labs., Inc., 1859 the Federal Circuit affirmed the district court's finding of an exceptional case and award of \$16,800,000 in attorney fees against generic drug manufacturer defendants. The court found no abuse of discretion in the district court's finding that the totality of circumstances, including the lack of a good faith basis for Paragraph IV ANDA certifications and numerous instances of litigation misconduct, merited the award.¹⁸⁶⁰

The district court's award was supported in part by the fact that defendants Alphapharm Pty., Ltd. and Genpharm, Inc. (collectively, "Alphapharm") and Mylan Laboratories, Inc.. Mylan Pharmaceuticals, Inc., and UDL Laboratories, Inc. (collectively, "Mylan") had changed their invalidity arguments from those initially presented in their Paragraph IV certification letters.¹⁸⁶¹ In particular, the district court found Alphapharm's certification letter to be "baseless" and Mylan's to have been "filed in bad faith and with no reasonable basis "¹⁸⁶² On appeal, defendant-appellants were joined in amicus curiae by the Generic Pharmaceutical Association, in arguing that "ANDA filers should be allowed to litigate the best available theories at trial," regardless of whether the theories were

^{1854. 546} F.3d 1364, 89 U.S.P.Q.2d (BNA) 1102 (Fed. Cir. 2008).

^{1855.} Id. at 1375, 89 U.S.P.Q.2d (BNA) at 1110.

^{1856.} *Id.*, 89 U.S.P.Q.2d (BNA) at 1110 (quoting Order, Minks v. Polaris Indus., Inc., No. 6:05-cv-1894-Orl-31KRS, 2007 WL 1725211, at *2 (M.D. Fla. 2007)).

^{1857.} Id., 89 U.S.P.Q.2d (BNA) at 1110. 1858. Id., 89 U.S.P.Q.2d (BNA) at 1110.

^{1859. 549} F. 3d 1381, 89 U.S.P.Q.2d (BNA) 1218 (Fed. Cir. 2008).

^{1860.} Id. at 1384, 89 U.S.P.Q.2d (BNÀ) at 1220.

^{1861.} Id., 89 U.S.P.Q.2d (BNA) at 1220.

^{1862.} Id. at 1385, 89 U.S.P.Q.2d (BNA) at 1221 (internal quotations omitted).

initially included in the certification letters.¹⁸⁶³ Amicus and the defendant-appellants argued that affirming the district court's decision would "have a chilling effect on future ANDA patent challenges."1864

The Federal Circuit found this "chilling" argument unpersuasive. The court noted that, in making a Paragraph IV certification, ANDA filers are required by statute to "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid."¹⁸⁶⁵ The court did not find that the district court's opinion had limited ANDA filers to only those theories of invalidity raised in certification letters.¹⁸⁶⁶ The district court's finding of an exceptional case was supported by the specific circumstances of the case, namely certification "baseless letters compounded with litigation misconduct."1867

X. REVIEW OF ADMINISTRATIVE ACTIONS

A. Administrative Law

Congress established the inter partes reexamination procedure in the American Inventors Protection Act of 1999 ("AIPA").¹⁸⁶⁸ Inter partes reexamination allows third parties to have an expanded role in the reexamination of issued patents by allowing the third party "to participate in the reexamination by submitting written comments addressing issues raised in the patent owner's response to an office action, appealing a decision in favor of patentability, and participating as a party to an appeal taken by the patent owner."¹⁸⁶⁹ The AIPA includes the following provision establishing its effective date: "Subject to subsection (b), this subtitle and the amendments made by this subtitle shall take effect on the date of the enactment of this Act and shall apply to any patent that issues from an original application filed in the United States on or after that date."1870

In *Cooper Technologies Co. v. Dudas*,¹⁸⁷¹ the Federal Circuit considered the meaning of the phrase "original application" in § 4608 of AIPA.¹⁸⁷²

^{1863.} Id. at 1386, 89 U.S.P.Q.2d (BNA) at 1222.

^{1864.} Id., 89 U.S.P.Q.2d (BŇA) at 1222.

^{1865.} Id. at 1390, 89 U.S.P.Q.2d (BNA) at 1225 (quoting 21 U.S.C. § 355(j)(2)(B)(iv)(II)(2006).

^{1866.} *Id.*, 89 U.S.P.Q.2d (BNA) at 1225. 1867. *Id.*, 89 U.S.P.Q.2d (BNA) at 1225.

^{1868.} Pub. L. No. 106-113, §§ 4001-4808, 113 Stat. 1501, 1501A-552 to -591 (1999).

^{1869.} Cooper Techs. Co. v. Dudas, 536 F.3d 1330, 1332, 87 U.S.P.Q.2d (BNA) 1705, 1706 (Fed. Cir. 2008).

^{1870. § 4608, 113} Stat. at 1501A-572 (emphasis added).

^{1871.} Cooper, 536 F.3d at 1330, 87 U.S.P.Q.2d (BNA) at 1705.

The Federal Circuit concluded that the PTO interpretation of "original application" as encompassing "utility, plant and design applications, including first filed applications, continuations, divisionals, continuations-in-part, continued prosecution applications and the national stage phase of international applications" is reasonable and is entitled to *Chevron*¹⁸⁷³ deference.¹⁸⁷⁴

In Cooper, third party Thomas & Betts Corporation requested an inter partes reexamination of U.S. Patent No. 6,984,791 owned by appellant Cooper Technologies Company.¹⁸⁷⁵ Cooper responded that inter partes reexamination was not available because the original application that resulted in the '791 patent was filed before November 29, 1999, the effective date of the AIPA.¹⁸⁷⁶ The PTO determined that the application resulting in the '791 patent, though a continuation of an earlier application, was an "original application" for the purposes of the AIPA and, thus, was subject to inter partes reexamination.¹⁸⁷⁷ The reexamination went forward over Cooper's objection and the Patent Office issued an initial office action rejecting all claims of the patent as invalid.¹⁸⁷⁸

Cooper sued the Director of the PTO in U.S. district court.¹⁸⁷⁹ The district court found that the PTO's interpretation was "fully consistent with the term [original application]'s established meaning in patent law" and granted summary judgment in favor of the PTO.¹⁸⁸⁰ The district court, however, declined to address the question of the level of deference accorded to the PTO's interpretation of "original

^{1872.} Id. at 1335-37, 87 U.S.P.Q.2d (BNA) at 1709-11.

^{1873.} In *Chevron U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 842 (1984), the Supreme Court set forth the legal analysis for determining whether to grant deference to a government agency's interpretation of its own statutory mandate. under *Chevron*, a reviewing court must first ask "whether Congress has directly spoken to the precise question at issue." *Id.* If Congress has done so, the inquiry is at an end; the court "must give effect to the unambiguously expressed intent of Congress." *Id.* at 843. If, however, "the statute in question is ambiguous and the agency's interpretation is reasonable," Cathedral Candle Co. v. U.S. Int'l Trade Comm'n, 400 F.3d 1352, 1361 (Fed. Cir. 2005), "a court must defer to the agency's construction of a statute governing agency conduct." *Id*

construction of a statute governing agency conduct." *Id.* 1874. *Cooper*, 536 F.3d at 1331-32, 87 U.S.P.Q.2d (BNA) at 1706 (quoting Rules to Implement Inter Partes Reexamination Proceedings, 65 Fed. Reg. 76,756, 76,757 (Dec. 7, 2000)).

⁽Dec. 1, 2007).
1875. Id. at 1334, 87 U.S.P.Q.2d (BNA) at 1708.
1876. Id., 87 U.S.P.Q.2d (BNA) at 1708.
1877. Id., 87 U.S.P.Q.2d (BNA) at 1708.
1879. Id. 2014 (BNA) at 1708.

^{1877.} Id., 87 U.S.F.Q.2d (BNA) at 1708.
1878. Id., 87 U.S.P.Q.2d (BNA) at 1708.
1879. Id., 87 U.S.P.Q.2d (BNA) at 1708.
1880. Id., 87 U.S.P.Q.2d (BNA) at 1708 (quoting Cooper Techs. Co. v. Dudas, No. 1:07-CV-853, 2007 WL 4233467, at *4, 85 U.S.P.Q.2d 1465, 1468-69 (E.D. Va. Nov. 30, 2007)).

application," finding instead that the outcome would be the same regardless of the level of deference owed to the PTO.¹⁸⁸¹

On appeal, the Federal Circuit addressed the appropriate level of deference for the PTO's interpretation of the AIPA.¹⁸⁸² The Federal Circuit found that, because the PTO was merely clarifying or explaining existing law, its reading of the term "original application" was "interpretative" rather than "substantive" and, therefore, within the PTO's authority under 35 U.S.C. § 2.¹⁸⁸³ Because the PTO was acting within its authority to administer statutory provisions relating to the "conduct of proceedings in the Office," the Court found that the PTO's interpretation was entitled to analysis under the *Chevron* framework.¹⁸⁸⁴ Finding that Congress had not directly spoken on the issue—that the PTO expressly interpreted "original application" shortly after the AIPA was enacted and that Congress did not amend the "original application" language when it amended the AIPA-the Federal Circuit determined that the PTO's interpretation of section 4608 was permissible.¹⁸⁸⁵

In Technology Licensing Corp. v. Videotek, Inc., 1886 the Federal Circuit also considered the level of deference owed to a determination of the PTO.¹⁸⁸⁷ In the lower court, Technology Licensing Corp. ("TLC") filed a complaint against Videotek, Inc. alleging infringement of two TLC patents.¹⁸⁸⁸ A magistrate judge found that the asserted claim of one patent was indefinite and of the other patent was valid but not infringed.¹⁸⁸⁹ Both parties appealed the magistrate's ruling to the Federal Circuit.¹⁸⁹⁰ TLC separately filed a reissue application regarding one of the asserted patents, U.S. Patent No. 5,754,250.¹⁸⁹¹ After the oral argument but before the Federal Circuit issued its opinion, the PTO reissued the '250 patent with the original claims unchanged.¹⁸⁹² The Court declined to consider the effect of the PTO's grant of a reissue,¹⁸⁹³ finding instead that "judicial efficiency

- 1881. *Id.*, 87 U.S.P.Q.2d (BNA) at 1708. 1882. *Id.* at 1335, 87 U.S.P.Q.2d (BNA) at 1709.
- 1883. *Id.* at 1336, 87 U.S.P.O.2d (BNA) at 1710 (quoting Animal Legal Def. Fund v. Quigg, 932 F.2d 920, 927, 18 U.S.P.Q.2d 1677, 1683 (Fed. Cir. 1991)).

- 1885. *Id.* at 1340–43, 87 U.S.P.Q.2d (BNA) at 1713–15.
- 545 F.3d 1316, 88 U.S.P.Q.2d (BNA) 1865 (Fed. Cir. 2008). *Id.* at 1330–31, 88 U.S.P.Q.2d (BNA) at 1875–76. 1886.
- 1887.
- 1888. *Id.* at 1323, 88 U.S.P.Q.2d (BNA) at 1870. 1889. *Id.* at 1323–24, 88 U.S.P.Q.2d (BNA) at 1870–72.
- 1890. *Id.* at 1325, 88 U.S.P.Q.2d (BNA) at 1872. 1891. *Id.* at 1330, 88 U.S.P.Q.2d (BNA) at 1875.
- 1892. Id., 88 U.S.P.Q.2d (BNA) at 1865.
- 1893. Id. at 1331, 88 U.S.P.Q.2d (BNA) at 1876.

^{1884.} *Id.* at 1337, 87 U.S.P.Q.2d (BNA) at 1710 (quoting 35 U.S.C. § 2(a)(2)(A) (2006)).

and the policy of repose counsels against our re-weighing of the evidence to add an additional deference-thumb to the scale, or, even more disruptive, our asking the trial court to reopen the entire invalidity question to reweigh the intangible worth of additional deference."1894

In In re Swanson,¹⁸⁹⁵ the Federal Circuit reviewed de novo the PTO's Board of Patent Appeals and Interferences' (the "Board") interpretation of 35 U.S.C. § 303(a), which permits the PTO to grant a reexamination request only if it determines that "a substantial new question of patentability affecting any claim of the patent concerned is raised by the request."¹⁸⁹⁶ While the PTO's "interpretation of statutory provisions concerning 'the conduct of proceedings in the Office'" may be owed deference, the Board's statutory interpretation is entitled to none.¹⁸⁹⁷

B. PTO Procedures

In re Swanson also considered the scope of 35 U.S.C. § 303(a) for the first time since a 2002 amendment specifying that "[t]he existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office."1898 The Federal Circuit determined that, under amended § 303(a) as revised, a "substantial new question of patentability" could exist even if a federal court had previously considered the question.¹⁸⁹⁹ "[A] 'substantial new question of patentability' refers to a question which has never been considered by the PTO."¹⁹⁰⁰

In prior infringement litigation between Abbott Laboratories, an exclusive licensee of Mr. Swanson's patent, and Syntron Bioresearch, Inc., the alleged infringer, both the district court and the Federal Circuit had determined that a prior art reference known as "Deutsch" did not anticipate asserted claims of a patent-in-suit.¹⁹⁰¹ Despite the rulings of the Article III courts, the Federal Circuit held that the

^{1894.} Id., 88 U.S.P.Q.2d (BNA) at 1876.

^{1895. 540} F.3d 1368, 88 U.S.P.Q.2d (BNA) 1196 (Fed. Cir. 2008). 1896. *Id.* at 1374–75, 88 U.S.P.Q.2d (BNA) at 1200–01 (quoting 35 U.S.C. § 303(a) (2006)).

<sup>(2000)).
1897.</sup> Id. at 1374 n.3, 88 U.S.P.Q.2d (BNA) at 1206 n.3 (quoting 35 U.S.C. § 2(b) (2) (A) (2006)) (distinguishing Cooper Techs. Co. v. Dudas, 536 F.3d 1330, 87 U.S.P.Q.2d (BNA) 1705 (Fed. Cir. 2008)).
1898. Id. at 1376, 88 U.S.P.Q.2d (BNA) at 1204 (quoting 35 U.S.C. § 303(a)

^{(2006)).}

^{1899.} *Id.* at 1379, 88 U.S.P.Q.2d (BNA) at 1204.

^{1900.} Id., 88 U.S.P.Q.2d (BNA) at 1204.

^{1901.} Id. at 1373, 88 U.S.P.Q.2d (BNA) at 1199.

question of whether Deutsch was an anticipatory reference could still raise a substantial new question of patentability sufficient to initiate a reexamination.¹⁹⁰² The Federal Circuit stated that a "court's final judgment and the examiner's rejection are not duplicative-they are differing proceedings with different evidentiary standards for validity."¹⁹⁰³ In civil litigation, a challenger must prove invalidity by clear and convincing evidence.¹⁹⁰⁴ During patent examinations and reexaminations, however, an applicant need only prove validity by a preponderance of the evidence.¹⁹⁰⁵ Thus, the fact that an Article III court had determined the validity of the asserted claims did not preclude the PTO from coming to a contrary conclusion under its own, different evidentiary standards for determining validity.¹⁹⁰⁶

Nor was the fact that the examiner had already considered the Deutsch reference during the initial examination a bar to the PTO considering the reference again on re-examination.¹⁹⁰⁷ The initial examiner relied upon Deutsch only as a secondary reference in an obviousness rejection of a broader claim.¹⁹⁰⁸

In light of the extremely limited purpose for which the examiner considered Deutsch in the initial examination, the Board is correct that the issue of whether Deutsch anticipates the method disclosed in claims 22, 23, and 25 was a substantial new question of patentability, never before addressed by the PTO.¹⁹⁰⁹

In Burandt v. Dudas,¹⁹¹⁰ the Federal Circuit affirmed the district court's grant of summary judgment in favor of the Director of the PTO, where the Director's decision to deny a patent holder's request for reinstatement of his patent after failure to pay the maintenance "neither arbitrary or capricious, nor an abuse of fee was discretion."¹⁹¹¹ By operation of an assignment agreement, inventor Burandt assigned the patent at issue to his employer, Investment Rarities, Inc. ("IRI").¹⁹¹² IRI failed to pay the first of three statutorily

^{1902.} Id. at 1379, 88 U.S.P.Q.2d (BNA) at 1204.
1903. Id., 88 U.S.P.Q.2d (BNA) at 1204.
1904. See id., 88 U.S.P.Q.2d (BNA) at 1204 (recalling that in an earlier court proceeding, "Syntron had the burden of proving by clear and convincing evidence that the '484 patent was invalid"). 1905. See id., 88 U.S.P.Q.2d (BNA) at 1204 (noting that in the examiner's

proceedings, a preponderance of evidence supported invalidity). 1906. *Id.* at 1377–79, 88 U.S.P.Q.2d (BNA) at 1203–04.

^{1907.} See id. at 1381, 88 U.S.P.Q.2d (BNA) at 1205 (agreeing with the Board that a substantial new question of patentability had been raised under § 303(a)). 1908. *Id.*, 88 U.S.P.Q.2d (BNA) at 1205. 1909. *Id.*, 88 U.S.P.Q.2d (BNA) at 1206. 1910. 528 F.3d 1329, 87 U.S.P.Q.2d (BNA) 1134 (Fed. Cir. 2008).

^{1911.} Id. at 1336, 87 U.S.P.Q.2d (BNA) at 1139-40.

^{1912.} Id. at 1330, 87 U.S.P.Q.2d (BNA) at 1135.

mandated maintenance fees.¹⁹¹³ Consequently, the patent expired.¹⁹¹⁴ Seven years later, Burandt, who had been suffering from a mental illness, contacted the PTO and learned that his patent had expired.¹⁹¹⁵ Burandt gained legal title to the expired patent and sought to reinstate it by sending a maintenance fee payment to the PTO.¹⁹¹⁶ The PTO denied Mr. Burandt's attempts to reinstate his patent.¹⁹¹⁷ The district court granted summary judgment in favor of the Director of the PTO.¹⁹¹⁸

Section 41(c)(1) of 35 U.S.C. provides that "[t]he Director may accept payment of any maintenance fee . . . at any time after the sixmonth grace period if the delay is shown to the satisfaction of the Director to have been unavoidable."¹⁹¹⁹ "[I]n determining whether a delay in paying a maintenance fee was unavoidable, one looks to whether the party responsible for payment of the maintenance fee exercised the due care of a reasonably prudent person."¹⁹²⁰ The district court noted that IRI was responsible for the payment of maintenance fees and there was no evidence that IRI had exercised due care in paying the maintenance fee.¹⁹²¹ Reviewing the Director's action under an arbitrary and capricious standard, the Federal Circuit agreed.¹⁹²² Burandt's mental illness and destitute financial condition were irrelevant to the inquiry, because IRI, not Burandt, was the legal owner of the patent at the time the maintenance fees were due.¹⁹²³

In Aristocrat Technologies Australia Pty Ltd. v. International Game Technology,¹⁹²⁴ appellant Aristocrat Technologies Australia Pty Ltd. filed the national stage application of an international patent cooperation treaty application one day late.¹⁹²⁵ As a result, the PTO notified Aristocrat that the application had been abandoned.¹⁹²⁶ Aristocrat filed a petition to revive the application pursuant to

^{1913.} Id. at 1331, 87 U.S.P.Q.2d (BNA) at 1136.

^{1913.} Id. at 1331, 87 U.S.P.Q.2d (BNA) at 1136.
1914. Id., 87 U.S.P.Q.2d (BNA) at 1136.
1915. Id., 87 U.S.P.Q.2d (BNA) at 1136.
1916. Id., 87 U.S.P.Q.2d (BNA) at 1136.
1917. Id. at 1331, 87 U.S.P.Q.2d (BNA) at 1136.
1918. Id., 87 U.S.P.Q.2d (BNA) at 1136 (citing Burandt v. Dudas, 496 F. Supp. 2d 643, 653 (E.D. Va. 2007)).

^{1919. 35} U.S.C. § 41(c)(1) (2006). 1920. Burandt, 528 F.3d at 1333, 87 U.S.P.Q.2d (BNA) at 1137 (quoting Ray v. Lehman, 55 F.3d 606, 609, 34 U.S.P.Q.2d 1786, 1787 (Fed. Cir. 1995)).

^{1921.} Id. at 1331-32, 87 U.S.P.Q.2d (BNA) at 1136.

^{1922.} Id. at 1332-33, 1336, 87 U.S.P.Q.2d (BNA) at 1137, 1139.

^{1923.} Id. at 1335, 87 U.S.P.Q.2d (BNA) at 1139

^{1924. 543} F.3d 657, 88 U.S.P.Q.2d (BNA) 1458 (Fed. Cir. 2008).

^{1925.} Id. at 659, 88 U.S.P.Q.2d (BNA) at 1459.

^{1926.} Id., 88 U.S.P.Q.2d (BNA) at 1459.

37 C.F.R. § 1.137(a),¹⁹²⁷ which the PTO granted because the delay in filing was "unintentional."1928

Shortly after the revived application issued as U.S. Patent No. 7,056,215,¹⁹²⁹ Aristocrat filed suit against International Game Technology and IGT (collectively "IGT") for infringement of the patent.¹⁹³⁰ IGT asserted that the '215 patent was invalid because it had been "improperly revived" by the PTO because the PTO required Aristocrat to show only "unintentional delay" instead of "unavoidable" delay, which IGT asserted was the proper standard.¹⁹³¹ The district court agreed and granted summary judgment in IGT's favor. 1932

The Federal Circuit considered only the threshold issue of whether "improper revival" of an abandoned patent application could be asserted as an invalidity defense in a suit involving the infringement or validity of a patent.¹⁹³³ Overturning the district court's holding, the Federal Circuit "conclude[d] that 'improper revival' is not a cognizable defense in an action involving the validity or infringement of a patent."¹⁹³⁴ Not only was "improper revival" not a recognized defense under 35 U.S.C. § 282 (which catalogues "defenses available in an action involving the validity or infringement of a patent"),¹⁹³⁵ but the court noted that "[t]here is good reason not to permit procedural irregularities during prosecution, such as the one at issue here, to provide a basis for invalidity. Once a patent has issued, the procedural minutiae of prosecution have little relevance to the metes and bounds of the patentee's right to exclude."1936

Although it declined to find patents invalid for "procedural irregularit[ies]" in Aristocrat, the Federal Circuit stressed that any irregularity during prosecution that involves inequitable conduct are "redressible under that framework."1937

In In re DBC,¹⁹³⁸ the Federal Circuit affirmed a final decision of the Board of Patent Appeals and Interferences, rejecting as obvious claims directed to a "nutraceutical composition" from the fruit of the

³⁷ C.F.R. § 1.137(a) (2008). 1927.

^{1928.} Aristocrat, 543 F.3d at 659-60, 88 U.S.P.Q.2d (BNA) at 1460.

^{1929.} *Id.* at 659, 88 U.S.P.Q.2d (BNA) at 1459. 1930. *Id.* at 660, 88 U.S.P.Q.2d (BNA) at 1458.

^{1930.} Id. at 660, 88 U.S.P.Q.2d (BNA) at 1458.
1931. Id., 88 U.S.P.Q.2d (BNA) at 1460 (quoting Aristocrat Techs. Austl. Pty Ltd. v. Int'l Game Tech., 491 F. Supp. 2d 916, 924–29 (N.D. Cal. 2007)).
1932. Id., 88 U.S.P.Q.2d (BNA) at 1460.
1933. Id. at 660–61, 88 U.S.P.Q.2d (BNA) at 1461.
1934. Id. at 659, 88 U.S.P.Q.2d (BNA) at 1459.
1935. Id. at 661–62, 88 U.S.P.Q.2d (BNA) at 1461.
1936. Id. at 663, 88 U.S.P.Q.2d (BNA) at 1462.
1937. Id., 88 U.S.P.Q.2d (BNA) at 1462.
1937. Id., 88 U.S.P.Q.2d (BNA) at 1462.
1938. Id. St.S.P.Q.2d (BNA) at 1462.

^{1938. 545} F.3d 1373, 89 U.S.P.Q.2d (BNA) 1123 (Fed. Cir. 2008).

mangosteen tree.¹⁹³⁹ Appellant DBC raised for the first time, on appeal to the Federal Circuit, the issue of whether two members of the panel that heard DBC's appeal from the patent examiner's rejection had been appointed in violation of the Appointments Clause¹⁹⁴⁰ of the Constitution.¹⁹⁴¹ However, by not "rais[ing] its objection to the manner of appointment to the Board itself," DBC waived the issue.¹⁹⁴² A party must object to an agency before attacking the agency action in court because "it gives [the] agency an opportunity to correct its own mistakes" and "it promotes judicial efficiency."¹⁹⁴³

Nor did the Federal Circuit entertain the merits of the constitutionality of the appointment of the administrative patent judges under the Appointments Clause—an issue raised by Professor John F. Duffy of the George Washington University Law School in a 2007 law review article.¹⁹⁴⁴ Duffy contended that legislation that delegated the power to appoint administrative patent judges to the Director of the PTO instead of the Secretary of Commerce was unconstitutional under the Appointments Clause of the Constitution, because that power is reserved to "the President alone, in the Courts of Law, or in the Heads of Departments."1945 The court, however, remarked that Professor Duffy's article was "not an intervening change in law or facts, nor was it based on any legal or factual propositions that were not knowable to DBC when it was proceeding before the Board."¹⁹⁴⁶ For that reason, there was nothing that prevented DBC from raising the issue to the Board on its own.¹⁹⁴⁷ Moreover, the court found there was no cause to rule on the merits where DBC had not challenged the propriety or competence of the administrative patent law judges and where Congress had already passed remedial legislation re-delegating the power of appointment to the Secretary of the Treasury.¹⁹⁴⁸

Finally, the Federal Circuit in Hyatt v. Dudas, 1949 addressed how specific the Board of Patent Appeals and Interferences (BPAI) must

^{1939.} Id. at 1382-83, 89 U.S.P.Q.2d (BNA) at 1130.

^{1940.} Id. at 1377, 89 U.S.P.Q.2d (BNA) at 1126.

^{1941.} U.S. CONST. art. II, § 2, cl. 2. 1942. 545 F.3d. at 1378, 89 U.S.P.Q.2d (BNA) at 1127.

^{1943.} Id. at 1378-79, 89 U.S.P.Q.2d (BNA) at 1127-28 (quoting Woodford v. Ngo, 548 U.S. 81, 89 (2006)). 1944. John F. Duffy, Are Administrative Patent Judges Constitutional?, 2007 PATENTLY-O

^{1944.} John F. Duny, Are Administrative Faten Judges Constitutional?, 2007 FAT.
PAT. L.J. 21, 21, http://www.patentlyo.com/lawjournal/files/Duffy.BPAI.pdf.
1945. Duffy, supra note 1944, at 21 (citing U.S. CONST. art. II, § 2, cl. 2).
1946. In re DBC, 545 F.3d at 1380, 89 U.S.P.Q.2d (BNA) at 1128.
1947. Id., 89 U.S.P.Q.2d (BNA) at 1128.
1948. Id. at 1380–81, 89 U.S.P.Q.2d (BNA) at 1129.
1949. December 200 U.S.P.Q.2d (BNA) at 1129.

^{1949. 551} F.3d 1307, 89 U.S.P.Q.2d (BNA) 1465 (Fed. Cir. 2008).

be when addressing groups of claims in patent applications. In Hyatt, the BPAI had been confronted with 2,400 claims in twelve related applications from inventor Gilbert Hyatt.¹⁹⁵⁰ The PTO examiner had rejected all of the claims, most commonly based on the written description requirement of 35 U.S.C. § 112(1).¹⁹⁵¹ On appeal, the BPAI did not review each claim independently, but simply reviewed twenty-one of the claims that Hyatt had discussed in the "Summary of the Invention" sections of his briefs to the BPAI.¹⁹⁵² On the basis of this review of twenty-one claims, the BPAI affirmed the examiner's rejections of all claims.¹⁹⁵³ The Federal Circuit held the BAPI's method was erroneous and in violation of PTO Rule 1.192(c)(7).¹⁹⁵⁴ That rule allows the BPAI, when addressing multiple claims, to select and review just one representative claim for each "ground of rejection."1955 The Federal Circuit, on the contrary, held that a "ground of rejection" could not simply be "the statutory requirement for patentability that a claim fails to meet" but had to be "the precise reason why the claim fails that requirement."¹⁹⁵⁶ Thus, the court held that the BPAI could not consider as a group claims rejected for lack of written description "unless the claims share a common limitation that lacks written description support."1957

C. International Trade Commission

1. Jurisdiction

In Amgen, Inc. v. International Trade Commission,¹⁹⁵⁸ the International Trade Commission ("ITC") ruled that it did not have jurisdiction to investigate and resolve charges of infringement where the imported drug, under development and subject to the 35 U.S.C. § 271(e) safeharbor statute, had not been sold in the United States and was not the subject of an existing contract for sale.¹⁹⁵⁹ Recognizing that "[t]he Commission's assignment is to prevent and remedy unfair acts flowing from infringement," the Federal Circuit reversed the ITC's

^{1950.} Id. at 1309, 89 U.S.P.Q.2d (BNA) at 1466.

^{1951.} Id., 89 U.S.P.Q.2d (BNA) at 1466.

^{1952.} *Id.* Hyatt first sought review in the United States District Court for the District of Columbia, with that court finding that the BPAI's method to be erroneous. Hyatt v. Dudas, Nos. 04-1802, 04-1138, 04-1139, and 05-0310, 2006 WL 2521242 (D.D.C. Aug. 30, 2006). 1953. *Id.*, 89 U.S.P.Q.2d (BNA) at 1467.

^{1953.} Id., 65 C.S.I. Q. Zu (BNA) at 1407.
1954. Hyatt, 551 F.3d at 1309, 89 U.S.P.Q.2d (BNA) at 1467.
1955. Id. at 1311, 89 U.S.P.Q.2d (BNA) at 1468 (citing 37 C.F.R. § 1.192(c) (7)).
1956. Id. at 1312, 89 U.S.P.Q.2d (BNA) at 1469.
1957. Id. at 1313, 89 U.S.P.Q.2d (BNA) at 1469.
1958. Id. at 1313, 89 U.S.P.Q.2d (BNA) at 1469.

^{1958. 519} F.3d 1343, 86 U.S.P.Q.2d (BNA) 1188 (Fed. Cir. 2008).

^{1959.} Id. at 1345, 86 U.S.P.Q.2d (BNA) at 1190.

determination.¹⁹⁶⁰ The ITC's jurisdiction is "properly invoked" "[w]hen it has been shown that infringing acts are reasonably likely to occur."¹⁹⁶¹

2. Scope of authority

Upon finding a violation of 19 U.S.C. § 1337, the ITC has the authority to issue two types of exclusion orders: a limited exclusion order ("LEO"), directed to products imported by a respondent, or a general exclusion order ("GEO"), directed to all infringing articles, regardless of whether the importer is a party to the investigation.¹⁹⁶² The ITC has long used LEOs to exclude not only a respondent's infringing article, but also any downstream product (whether or not manufactured or imported by that respondent) that incorporates the infringing article.¹⁹⁶³

In Kyocera Wireless Corp. v. International Trade Commission, 1964 complainant Broadcom Corporation sought an LEO against infringing baseband processor chips manufactured by Qualcomm Corporation, the only named respondent in this investigation, as well as cellular telephones, PDAs and other wireless communications devices that contained the infringing chips.¹⁹⁶⁵ After having found a violation of § 1337 in the liability phase of the investigation, the ITC addressed the appropriate remedy in a separate phase.¹⁹⁶⁶ Companies with a stake in the outcome of the investigation, including downstream manufacturers of infringing products, like cell phone manufacturers and wireless service providers, intervened to argue against an exclusion order that extended to downstream products.¹⁹⁶⁷ Following hearings on the appropriate remedy, the ITC issued an LEO excluding

[h]andheld wireless communications devices, including cellular telephone handsets and PDAs, containing Qualcomm baseband processor chips or chipsets that are programmed to enable the

^{1960.} *Id.* at 1352–53, 86 U.S.P.Q.2d (BNA) at 1194–95 (emphasis added). 1961. *Id.* at 1352, 86 U.S.P.Q.2d (BNA) at 1194.

^{1962. 19} U.S.C. § 1337(d) (2006).

^{1963.} See, e.g., Elec. Connectors, USITC Pub. 2981, Inv. No. 337-TA-374 (July 1996) (issuing a limited exclusion order to prohibit the unlicensed importation of infringing products); Microsphere Adhesives, USITC Pub. 2949, Inv. No. 337-TA-366 (Jan. 1996) (ruling that a limited exclusion order should cover downstream products that contain infringing components in order to ensure proper relief); Aramid Fiber, USITC Pub. 1824, Inv. No. 337-TA-194 (Mar. 1984) (stating that a protective order should be issued in order to avoid serious harm to a party).

^{1964. 545} F.3d 1340, 89 U.S.P.Q.2d (BNA) 1057 (Fed. Cir. 2008).
1965. *Id.* at 1345, 89 U.S.P.Q.2d (BNA) at 1059–60.
1966. *Id.* at 1346, 89 U.S.P.Q.2d (BNA) at 1060.

^{1967.} Id., 89 U.S.P.Q.2d (BNA) at 1061.

[Vol. 58:747

power saving features covered by claims 1, 4, 8, 9, or 11 of U.S. Patent No. 6,714,983, wherein the chips or chipsets are manufactured abroad by behalf of Qualcomm or on Incorporated.¹⁹⁶⁸

The Federal Circuit determined that the ITC had exceeded its statutory authority by issuing an LEO that excludes from the United States downstream products of manufacturers that were not named as respondents in the investigation.¹⁹⁶⁹ According to the Federal Circuit, 19 U.S.C. § 1337(d), the statute from which the ITC derives its authority to exclude articles that infringe on a valid U.S. patent, "permits LEOs to exclude only the violating products of named respondents."¹⁹⁷⁰

Section 1337(d) provides the following:

(d) Exclusion of articles from entry

(1) If the Commission determines, as a result of an investigation under this section, that there is a violation of this section, it shall direct the articles concerned, imported by any person violating the provision of this section, be excluded from entry into the United States . . .

(2) The authority of the Commission to order an exclusion from entry of articles shall be limited to persons determined by the Commission to be violating this section unless the Commission determines that-

(A) a general exclusion from entry of articles is necessary to prevent circumvention of an exclusion order limited to products of named person; or

(B) there is a pattern of violation of this section and it is difficult to identify the source of infringing products.¹⁹⁷¹

Analyzing § 1337(d) under the Supreme Court's familiar Chevron framework,¹⁹⁷² the Federal Circuit determined that the statute "speaks unambiguously to the precise question at issue in this case."¹⁹⁷³ In order to give meaning to each of the statute's clauses, LEOs must be limited to "named respondents that the Commission finds in

^{1968.} Id., 89 U.S.P.Q.2d (BNA) at 1060-61 (quoting Baseband Processor Chips, USITC Inv. No. 337-TA-543 (June 2007)).

^{1969.} Id. at 1345, 89 U.S.P.Q.2d (BNÁ) at 1060.

^{1970.} Id. at 1358, 89 U.S.P.Q.2d (BNA) at 1070 (emphasis added).
1971. 19 U.S.C. § 1337(d) (2006).
1972. See supra note 1873 (summarizing the test for whether to grant deference to an agency's interpretation of its own statutory mandate).

^{1973.} Kyocera, 545 F.3d at 1358, 89 U.S.P.Q.2d (BNA) at 1070.

violation of section 337."¹⁹⁷⁴ Doing otherwise would render superfluous the sections of the statute concerning GEOs.¹⁹⁷⁵

The Federal Circuit rejected the Commission and Broadcom's argument that so limiting the scope of the remedy under a LEO would allow "unnamed, difficult-to-identify importers of infringing articles" to escape enforcement.¹⁹⁷⁶ A party fearing circumvention of an LEO can seek a GEO, as long as the party is able to meet the heightened requirements of § 1337(d) (2) (Å) or (B).¹⁹⁷⁷ The Federal Circuit noted that Broadcom's "strategic decision" to name only chipmaker Qualcomm as a respondent, even though Broadcom knew the identities of the handset manufacturers who incorporated those chips, put the company in a difficult position to argue about the danger of unknown infringers circumventing an LEO.¹⁹⁷⁸ Broadcom did not seek a GEO, so it was not entitled to the exclusion of "downstream products" of those who are not "persons determined . . . to be violating [Section 337]."1979

^{1974.} Id. at 1356, 89 U.S.P.Q.2d (BNA) at 1068.

^{1975.} See id. (discussing the distinct circumstances in which LEOs and GEOs should be applied).

^{1976.} *Id.* at 1357, 89 U.S.P.Q.2d (BNA) at 1069. 1977. *Id.*, 89 U.S.P.Q.2d (BNA) at 1069. 1978. *Id.*, 89 U.S.P.Q.2d (BNA) at 1069.

^{1979.} Id. at 1357-58, 89 U.S.P.Q.2d (BNA) at 1070.