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2013 Patent Law Decisions of the Federal Circuit

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2013 Patent Law Decisions of the Federal Circuit

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AREA SUMMARIES

2013 PATENT LAW DECISIONS OF THE FEDERAL CIRCUIT*

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^{*} This Area Summary reflects the Authors' current thoughts on the subject matter and should not be attributed, in whole or in part, to Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, any of its attorneys, or any of its clients. This Area Summary is not meant to convey legal opinions or legal advice of any kind. The Authors would like to thank Kevin D. Hawkinson for his assistance in completing this Area Summary. All correspondence regarding this Area Summary should be addressed to Dr. Robert A. Pollock at robert.pollock@finnegan.com.

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INTRODUCTION

The U.S. Court of Appeals for the Federal Circuit's year of decisions in 2013 may be best remembered for the issues not finally decided, the intracourt disputes revealed, and the foundations laid for future changes in the law. In other words, notwithstanding over 100 precedential patent decisions, each with its own important implications to the law, 2013 looked more like a "work in progress" than a final chapter.

The "work in progress" descriptor is particularly apt for the en banc court's decision in *CLS Bank International v. Alice Corp.*,¹ which fell short of its potential to establish conclusive precedent on the patentability of computer software-related inventions. The Federal Circuit held that the patentee's claims to computerized-trading risk management were not patent-eligible subject matters, regardless of

^{1. 717} F.3d 1269 (Fed. Cir.) (en banc) (per curiam), cert. granted, 134 S. Ct. 734 (2013).

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their form as methods, computer-readable media, or systems claims.² However, without a majority opinion, the case failed to provide any precedential reasoning for this and future holdings. In the words of Chief Judge Rader, "though much is published today discussing the proper approach to the patent eligibility inquiry, nothing said today beyond our judgment has the weight of precedent."3 The en banc split clearly portends further disputes and developments, such as the dispute that occurred in Accenture Global Services, GmbH v. Guidewire Software, Inc.⁴ But, another chapter is now guaranteed for CLS Bank, given the U.S. Supreme Court's grant of certiorari.⁵

Another unfolding issue from 2013 involves how invalidation of a patent by the U.S. Patent and Trademark Office (USPTO) can affect a district court's prior judgment. Although the Federal Circuit's position seems to have been cemented as precedent in Fresenius USA, Inc. v. Baxter International, Inc.⁶ (Fresenius II), the opinions dissenting from the panel decision and from the denial of rehearing and rehearing en banc suggest that more is yet to be written. More specifically, the panel in Fresenius II held that post-issuance invalidation by the USPTO removes the court's jurisdiction over an infringement action and effectively vacates any unexecuted damages award.⁷ The case's potential significance is reflected in the parade of horribles raised in multiple dissents to the denial of rehearing and rehearing en banc in Fresenius USA, Inc. v. Baxter International, Inc.⁸ (Fresenius III). Judge O'Malley described the panel's holding as "go[ing] a long way toward rendering district courts meaningless in the resolution of patent infringement disputes . . . by creating a new regime wherein a district court's final adjudication can be undone by later decisions of the [USPTO]."9 Judge Newman went perhaps a step further, decrying the decision as "not only in violation of the Constitution, precedent, and the Federal Rules, but [as] contrary to the purposes of patent law as embodied in the statute and the Constitution."10 Given its potential impact on infringement actions

^{2.} See id. at 1273.

Id. at 1292 n.1 (Rader, C.J., concurring in part and dissenting in part).
 728 F.3d 1336 (Fed. Cir. 2013), *petition for cert. filed*, 82 U.S.L.W. 3469 (U.S. Jan. 31, 2014) (No. 13-918); *see id.* at 1346–48 (Rader, C.J., dissenting) (criticizing) majority for reliance on the CLS Bank plurality opinion).

See CLS Bank, 134 S. Ct. 734.
 721 F.3d 1330 (Fed. Cir.), reh'g and reh'g en banc denied, 733 F.3d 1369 (Fed. Cir. 2013) (per curiam), petition for cert. filed, 82 U.S.L.W. 3540 (U.S. Mar. 5, 2014) (No. 13-1071).

^{7.} Id. at 1332.

^{8. 733} F.3d 1369 (Fed. Cir. 2013) (en banc) (per curiam).

^{9.} *Id.* at 1372 (O'Malley, J., dissenting from denial of rehearing en banc). 10. *Id.* at 1382 (Newman, J., dissenting from denial of rehearing en banc).

generally, it is likely that the *Fresenius* decisions will not be the last time the Federal Circuit addresses the ramifications of post-issuance invalidation by the USPTO.

Another division within the court was exposed by Galderma Laboratories, L.P. v. Tolmar, Inc.,¹¹ in which the majority overturned the district court's judgment that the claimed pharmaceutical formulation was nonobvious.¹² According to Judge Prost's majority opinion, in circumstances where "the claimed invention falls within [the prior art] range," the patent challenger need not show a motivation to select the claimed value; instead, the patentee has a "burden of production \ldots to come forward with evidence that (1) the prior art taught away from the claimed invention; (2) there were new and unexpected results relative to the prior art; or (3) there are other pertinent secondary considerations."13 In other words, where the prior art teaches a variable having a range that brackets the claimed invention, the patentee has a burden to show that the claimed invention was not obvious.¹⁴ Writing in dissent, Judge Newman criticized the panel majority for "distort[ing] the burdens of proof and production, [and] ignor[ing] the applicable standard of proof."¹⁵ In particular, according to Judge Newman, "[t]he district court, unlike the panel majority, correctly recognized that a prima facie showing is not a presumption of obviousness, and does not change the placement of the burden of proof."¹⁶

As Judge Newman noted, the *Galderma* majority was willing to "make[] its own factual findings," foist a burden on the patentee, and reverse the district judgment of nonobviousness.¹⁷ This stands in stark contrast to other 2013 panel decisions that relied on secondary considerations, even in the absence of a presumption of validity, to find nonobviousness.¹⁸ For example, the court in *Galderma* dismissed the unexpected results of increased efficacy without increased side

^{11. 737} F.3d 731 (Fed. Cir. 2013).

^{12.} *Id.* at 741.

^{13.} *Id.* at 738.

^{14.} See id.

^{15.} Id. at 741 (Newman, J., dissenting).

^{16.} Id. at 748.

^{17.} Id. at 741–42.

^{18.} *See, e.g.*, Rambus Inc. v. Rea, 731 F.3d 1248, 1256–58 (Fed. Cir. 2013) (advising the USPTO on remand to reevaluate the obviousness of an invention as a whole); Leo Pharm. Prods., Ltd. v. Rea, 726 F.3d 1346, 1358–59 (Fed. Cir. 2013) (reversing the USPTO's obviousness determination because of objective indicia, such as evidence of unexpected results and commercial success); Apple Inc. v. Int'l Trade Comm'n, 725 F.3d 1356, 1365 (Fed. Cir. 2013) (declaring that objective evidence of secondary considerations must be reviewed before making an obviousness determination).

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effects as an unavailing "difference in degree rather than in kind."19 This holding may be irreconcilable with Leo Pharmaceutical Products, Ltd. v. Rea,²⁰ in which the court found that the reduced degradation of the claimed pharmaceutical composition was a surprising and unexpected result evidencing nonobviousness.²¹ Given the apparent rift, it seems reasonable to expect the Federal Circuit in 2014 to provide-in panel decisions en banc-more thoughts on the burdens of proof and deference to district court factual findings for obviousness.

As for new trends, in the last week of 2013, Kilopass Technology v. Sidense Corp.²² laid a foundation for an increased use of-and a more flexible burden of proof for—fee shifting.²³ The court sided entirely with the accused infringer and held that the suit had been objectively baseless, discussing in detail whether both objective and subjective baselessness must be shown in order to find a case exceptional and award attorneys' fees under 35 U.S.C. § 285.24 After laying out several pages of argument for why proof of subjective bad faith should not be required, the Kilopass panel concluded that precedent prevented eliminating the requirement.²⁵ Importantly, however, Kilopass held that subjective bad faith need not be proven directly.²⁶ Instead, "[o]bjective baselessness alone can create a sufficient inference of bad faith to establish exceptionality under § 285, unless the circumstances as a whole show a lack of recklessness on the patentee's part."27 The potential impact of Kilopass on enabling greater use of fee shifting is significant. As noted by the court, because Kilopass held that objective baselessness alone may be sufficient to support finding a case exceptional, the formal "retention of the subjective bad faith requirement may prove to have little effect [for fee shifting] on this case, as well as many that follow."28

Notably, Kilopass did not occur in a vacuum and may reflect an effort to get in front of an expected change in the law. Prior to the decision, the Supreme Court had granted certiorari in two other cases to address the "exceptional case" standard of 35 U.S.C. § 285 for

Galderma, 737 F.3d at 739. 19.

^{20. 726} F.3d 1346 (Fed. Cir. 2013).

^{21.} Id. at 1358-59.

 ⁷³⁸ F.3d 1302 (Fed. Cir. 2013).
 See id. at 1317–18 (remanding to the district court for a determination of subjective bad faith in light of all the circumstances).

^{24.} See id. at 1309–14.

^{25.} Id. at 1312-14.

^{26.} Id. at 1311.

^{27.} Id. at 1314.

^{28.} Id. (emphasis added).

awarding attorneys' fees to the prevailing party,²⁹ and the U.S. House of Representatives had passed a patent reform bill requiring an award of fees unless the nonprevailing party's positions "were reasonably justified in law and fact" or under circumstances that would "make an award unjust."³⁰ One way or another, *Kilopass* is not the last word on fee shifting.

As evident from the case summaries that follow, there was no shortage of important Federal Circuit opinions in 2013. The dissents and disputes are telling windows into the highest levels of judicial reasoning and part of the evolution of judicial opinion that should, ultimately, lead to consensus. As Justice Cardozo stated, "out of the attrition of diverse minds there is beaten something which has a constancy and uniformity and average value greater than its component elements."³¹ Until then, the landscape on which we practice will remain dynamic.

I. DISTRICT COURT PRACTICE

A. Jurisdiction and Justiciability

Jurisdiction and justiciability are broad preliminary considerations into which the Federal Circuit must inquire before reaching the merits of any case. In 2013, the Federal Circuit addressed several issues that dealt with jurisdiction and justiciability, including whether assignor estoppel creates a federal question to establish subject matter jurisdiction;³² whether state law claims with minimal relation to patent law raise a federal question to establish subject matter jurisdiction under 28 U.S.C. § 1338;³³ whether the Supreme Court has exclusive and original jurisdiction over a case between two states when one state is not a real party in interest;³⁴ whether binding representation not to file suit precludes declaratory judgment;³⁵ and

^{29.} See Octane Fitness, LLC v. Icon Health & Fitness, Inc., 134 S. Ct. 49 (2013); Highmark Inc. v. Allcare Health Mgmt. Sys., Inc., 134 S. Ct. 48 (2013).

^{30.} Innovation Act, H.R. 3309, 113th Cong. § 285 (2013) (as passed by House, Dec. 5, 2013).

^{31.} BENJAMIN N. CARDOZO, THE NATURE OF THE JUDICIAL PROCESS 113 (Quid Pro Law Books 2010) (1921).

^{32.} Semiconductor Energy Lab. Co. v. Nagata, 706 F.3d 1365, 1372 (Fed. Cir. 2013).

^{33.} Forrester Envtl. Servs., Inc. v. Wheelabrator Techs. Inc., 715 F.3d 1329, 1333 (Fed. Cir. 2013).

^{34.} Univ. of Utah v. Max-Planck-Gesellschaft zur Forderung der Wissenschaften E.V., 734 F.3d 1315, 1319 (Fed. Cir. 2013).

^{35.} Organic Seed Growers & Trade Ass'n v. Monsanto Co., 718 F.3d 1350, 1352 (Fed. Cir. 2013), *cert. denied*, 134 S. Ct. 901 (2014).

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whether an appeal after a settlement agreement presents an actual case or controversy.³⁶

1. Subject matter jurisdiction

Federal Circuit jurisdiction over a case depends on the existence of subject matter jurisdiction. This jurisdiction may take the form of a federal question under 28 U.S.C. § 1331 or of original jurisdiction under 28 U.S.C. § 1338. Section 1331 provides that "district courts shall have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States."37 Section 1338 provides that the "district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents."38 In 2013, the Federal Circuit addressed two cases that dealt with subject matter jurisdiction. One addressed the doctrine of assignor estoppel as a federal question and the other addressed false assertions of infringement only tangential to core state law claims under § 1338.

In the first case, Semiconductor Energy Laboratory Co. v. Nagata,³⁹ the Federal Circuit had to determine whether assignor estoppel constituted a federal question under 28 U.S.C. § 1331.40 The defendant, Nagata, was listed as a coinventor on several patents that had been assigned to Semiconductor Energy Laboratory Co., Ltd. ("SEL").⁴¹ When SEL attempted to assert these patents against Samsung, Inc. ("Samsung"), it discovered that Nagata was assisting Samsung in the litigation and had repudiated his signature on the Declarations of Assignment.⁴² Samsung then claimed that the patents were unenforceable due to inequitable conduct regarding the alleged signature problems.⁴³ Although SEL and Samsung eventually settled their dispute in favor of SEL, SEL brought suit against Nagata alleging that the settlement involved significantly less money than it should have due to his testimony.⁴⁴ The suit also set forth several additional state law

^{36.} Allflex USA, Inc. v. Avid Identification Sys., Inc., 704 F.3d 1362, 1363 (Fed. Cir. 2013).

^{37. 28} U.S.C. § 1331 (2012). 38. *Id.* § 1338.

^{39. 706} F.3d 1365 (Fed. Cir. 2013).

^{40. 28} U.S.C. § 1331.

^{41.} Semiconductor Energy, 706 F.3d at 1367.

^{42.} Id.

^{43.} Id.

^{44.} Id. at 1368.

claims that failed to satisfy 28 U.S.C. § 1331.45 Nagata moved to dismiss the case for lack of subject matter jurisdiction.⁴⁶

SEL's only claim purporting to arise under federal law was premised on the doctrine of assignor estoppel.⁴⁷ "Assignor estoppel is an equitable doctrine that prohibits an assignor of a patent or patent application, or one in privity with him, from attacking the validity of that patent when he is sued for infringement by the assignee."48 Assignor estoppel is generally used as a defense to patent infringement.49 The district court granted Nagata's motion to dismiss, finding that assignor estoppel "does not provide a cognizable federal cause of action."50

On appeal, SEL proposed that "assignor estoppel is not merely a defense, but that it embodies fundamental principles of federal patent law and policy by imposing a duty of fair dealing ... on an inventor who assigns intellectual property rights that are protected by the Constitution."51 The Federal Circuit interpreted this argument as an invitation to create a new federal cause of action due to there being no case law precedent or statute cited.⁵² The court declined the invitation and accordingly held that the district court was correct in ruling that SEL's complaint did not invoke federal subject matter jurisdiction based on a claim arising under federal law.⁵³

The Federal Circuit also determined that SEL's state law claims failed to satisfy the subject matter jurisdiction requirements of 28 U.S.C. § 1338(a) because they did not involve substantive federal law.⁵⁴ Because assignor estoppel was not a necessary element of SEL's state law claims, and because the claims did not require the resolution of any disputed substantial question of federal patent law, the court found this issue meritless.⁵⁵ Therefore, the Federal Circuit held that there was no federal subject matter jurisdiction over the claims based on the affirmative assertion of the doctrine of assignor estoppel.⁵⁶

^{45.} Id. at 1367.

^{46.} Id. at 1368.

^{47.} *Id.* at 1369.
48. *Id.* (citing Diamond Scientific Co. v. Ambico, Inc., 848 F.2d 1220, 1224 (Fed. Cir. 1988)).

^{49.} *Id.* 50. Id. at 1368.

^{51.} Id. (omission in original) (internal quotation marks omitted).

^{52.} Id.

^{53.} Id.

^{54.} Id. at 1370.

^{55.} Id. at 1371.

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In the second case about subject matter jurisdiction, Forrester Environmental Services, Inc. v. Wheelabrator Technologies, Inc.,⁵⁷ the Federal Circuit determined that state law claims brought by Forrester Environmental Services, Inc. ("Forrester"), accompanied by a false by Wheelabrator statement made Technologies, Inc. ("Wheelabrator") that the technology at issue was covered by Wheelabrator's patents, were not sufficient to satisfy 28 U.S.C. § 1338.⁵⁸ Forrester and Wheelabrator are competitors in the market for stabilizing heavy metals in incinerator ash and each own patents covering their respective technologies.⁵⁹ Forrester sued Wheelabrator in state court, asserting four state law causes of action based on Wheelabrator's actions regarding a mutual Taiwanese customer: (1) violation of the New Hampshire Consumer Protection Act; (2) tortious interference with a contractual relationship; (3) tortious interference with Forrester's prospective advantage; and (4) trade secret misappropriation.⁶⁰ Forrester alleged that Wheelabrator made false statements to a customer in Taiwan about the scope of Wheelabrator's patents and, in doing so, led the customer to believe that Wheelabrator's patents covered Forrester's products.⁶¹ These misrepresentations allegedly terminated the relationship between Forrester and the customer.⁶²

Because of Forrester's assertions relating to the scope of Wheelabrator's patents, Wheelabrator removed the case to federal court under 28 U.S.C. § 1338.⁶³ Forrester then filed a motion to remand back to state court, alleging a lack of subject matter jurisdiction.⁶⁴ The district court denied the motion and entered summary judgment in favor of Wheelabrator.⁶⁵ On appeal, Forrester contended that the district court lacked subject matter jurisdiction over its state law claims and that, in the alternative, the district court erred on the merits.⁶⁶

Section 1338 gives federal district courts original jurisdiction over civil actions pertaining to patents.⁶⁷

^{57. 715} F.3d 1329 (Fed. Cir. 2013).

^{58.} Id. at 1331, 1336.

^{59.} *Id.* at 1331.

^{60.} *Id.* at 1332.

^{61.} *Id.* 62. *Id.*

^{62.} Ia. 63. Id.

^{64.} *Id.*

^{65.} Id.

^{66.} Id. at 1331.

^{67. 28} U.S.C. § 1338(a) (2012).

[E]ven a cause of action created by state law may "aris[e] under" federal patent law within the meaning of 28 U.S.C. § 1338 if it involves a patent law issue that is "(1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress."68

Wheelabrator argued that Forrester's claims raised a substantial issue of patent law because the Federal Circuit needed to determine the truth or falsity of Wheelabrator's statement in Taiwan about the coverage of its patents before addressing the merits of the state law claims.⁶⁹ Although the Federal Circuit recognized that it had held in the past that state law claims based on allegedly false statements about patents can raise a substantial question of federal law,⁷⁰ the court distinguished this particular set of facts from the prior decisions.⁷¹ The Federal Circuit determined that the previous cases all contained inherent possibilities of future conflict.⁷² However, the possibility of future conflict did not present itself in this case.73 Moreover, Wheelabrator's allegedly inaccurate statements only concerned conduct taking place solely in Taiwan, so there was no possibility that these activities could infringe U.S. patents.⁷⁴ Thus, there was no possibility of inconsistent judgments between state and federal courts because there was no prospect of a future U.S. infringement suit arising out of activity in Taiwan.⁷⁵ Accordingly, the Federal Circuit held that false statements about the scope of patent rights that have no bearing on the outcome of asserted state law claims and that cannot give rise to future disputes do not fall under the jurisdiction of the federal courts.⁷⁶

Original and exclusive jurisdiction 2.

Supreme Court original and exclusive jurisdiction arising under 28 U.S.C. § 1251(a) is another important jurisdictional consideration. Section 1251(a) provides that "[t]he Supreme Court shall have

^{68.} Forrester, 715 F.3d at 1333 (second alteration in original) (quoting Gunn v. Minton, 133 S. Ct. 1059, 1065, 1067 (2013)).

^{69.} Id. at 1334.

^{70.} See id. (citing, for example, Additive Controls & Measurement Sys., Inc. v. Flowdata, 986 F.2d 476 (Fed. Cir. 1993), a case regarding a claim for business disparagement under state law).

^{71.} Id.

^{72.} *Id.* 73. *Id.* 74. *Id.*

^{75.} Id. at 1335.

^{76.} Id.

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original and exclusive jurisdiction of all controversies between two or more States."77

In 2013, the Federal Circuit decided a case that determined whether a suit between two state universities gualified for the Supreme Court's original and exclusive jurisdiction under this section. In University of Utah v. Max-Planck-Gesellschaft zur Forderung der Wissenschaften E.V.,⁷⁸ the Federal Circuit held that where a state university named as a defendant was not the true party in interest, the case did not fall within the purview of the Supreme Court's original and exclusive jurisdiction.⁷⁹ The University of Utah ("UUtah") named several defendants to a suit brought to correct the inventorship of two patents, including the University of Massachusetts ("UMass").80 UMass moved to dismiss the case, arguing that the Supreme Court had exclusive and original jurisdiction over this case under 28 U.S.C. § 1251(a) because it was between two states.⁸¹ After UMass posed this argument, UUtah amended its complaint, dismissing UMass as a named defendant and naming instead four UMass officials.⁸² The named officials then moved to dismiss, but the district court denied their motion, and the defendants appealed.⁸³

To determine whether the exercise of exclusive and original jurisdiction is appropriate, the court must "look beyond the named parties and determine the real party in interest."⁸⁴ A state is a substantial party in interest if the court ruling would directly affect the state and if proper relief could not be granted without the state being a party to the litigation.⁸⁵ "On the other hand, a State with 'some interest of hers [] more or less affected by the decision' but not directly affected by the court's decree is not a real party in interest."⁸⁶ The named defendants argued that although UMass was no longer a named party to the suit, it was the real party in interest because UUtah was seeking to obtain the property of UMass.⁸⁷ They further

87. Id. at 1322.

^{77. 28} U.S.C. § 1251(a) (2012).

^{78. 734} F.3d 1315 (Fed. Cir. 2013).

^{79.} Id. at 1328.

^{80.} Id. at 1317-18.

^{81.} Id. at 1318.

^{82.} Id.

^{83.} Id.

^{84.} *Id.* (citing Illinois v. City of Milwaukee, 406 U.S. 91, 93–94 (1972); *In re* New York, 256 U.S. 490, 500 (1921); *Ex parte* Ayers, 123 U.S. 443, 487 (1887)).

^{85.} *Id.* at 1320–21.

^{86.} Id. at 1321 (alteration in original) (quoting Cunningham v. Macon & Brunswick R.R., 109 U.S. 446, 452 (1883)).

argued that UUtah should not be able to "'plead around' the Supreme Court's exclusive original jurisdiction over disputes between states."88

In procedural questions not unique to patent law, the Federal Circuit applies the law of the regional circuit—in this case, the law of the U.S. Court of Appeals for the First Circuit.⁸⁹ Although the First Circuit had not yet determined what law to apply in such a situation, the Federal Circuit determined that the First Circuit's choice of law was ultimately irrelevant because, under these facts, the outcome would be the same regardless of the standard applied.⁹⁰

Because the First Circuit had not yet addressed the issue, the Federal Circuit considered two alternative standards to apply based on precedent from the U.S. Court of Appeals for the Second Circuit.⁹¹ The first possible standard comes from the majority opinion in Connecticut ex rel. Blumenthal v. Cahill.⁹² Under this standard, the state is considered the real party in interest when its officers are the named party to a dispute and "(1) the alleged injury was caused by actions specifically authorized by State law, and (2) the suit implicates the State's core sovereign interests."93 The named officials in University of Utah were only parties to the first five counts in the complaint.94 Counts one through four sought to correct the inventorship of the patent, and count five sought a declaratory judgment that the asserted inventor was in fact an inventor on the patent.⁹⁵ The Federal Circuit held that a state has no core sovereign interest in the inventorship of patents.⁹⁶ Therefore, under this standard, it held that UMass was not the real party in interest.⁹⁷

The second possible standard that the First Circuit could have applied is from the dissenting opinion in *Cahill*. Under this standard, a state is the real party in interest in a suit when "the effect of the judgment would be to restrain the Government from acting, or to compel it to act."98 The Federal Circuit determined that UMass would not be restrained or required to act if the court ordered the USPTO to

^{88.} Id.

^{89.} Id. at 1319.

^{90.} See id. at 1322, 1328 (noting that even though the First Circuit has never reached this issue, the Supreme Court was unlikely to hear the case even if original jurisdiction was found).

^{91.} See id. at 1322.
92. 217 F.3d 93 (2d Cir. 2000).

^{93.} Univ. of Utah, 734 F.3d. at 1322 (quoting Cahill, 217 F.3d at 99).

^{94.} *Id.* at 1323.

^{95.} Id.

^{96.} Id.

^{97.} Id.

^{98.} Id. (emphasis added) (quoting Cahill, 217 F.3d at 106 (Sotomayor, J., dissenting)).

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correct the inventorship.⁹⁹ Therefore, it concluded that UMass was also not a real party in interest under the second standard.¹⁰⁰

Last, considering a broader interpretation of Supreme Court doctrine, the Federal Circuit concluded that UMass was not a real party in interest because it was not an "indispensable" or "mandatory" party.¹⁰¹ The court determined that the district court could grant UUtah the relief requested without UMass by directing the USPTO to correct the inventorship on the patents.¹⁰² Because this relief would not "deplete the state treasury, compel UMass to act, or instruct UMass how to conform to state law," the Federal Circuit determined that the state was not directly affected by the decision and therefore was not a real party in interest.¹⁰³ Accordingly, under any application of the law the First Circuit could have chosen to apply, UMass was not a real party in interest, and therefore, this case did not fall within the exclusive and original jurisdiction of the Supreme Court.¹⁰⁴

Dissenting, Judge Moore stated that whether a suit implicates the Supreme Court's exclusive original jurisdiction requires a look "behind and beyond the legal form' of the claim to determine 'whether the State is indeed the real party in interest."¹⁰⁵ Judge Moore stated that the majority erred in holding that a patent ownership dispute between two state universities is not a controversy between states as set forth in § 1251(a), and that UUtah should not be allowed to "recast the nature of this dispute by suing the UMass Officials as stand-ins for UMass."¹⁰⁶

Judge Moore further stated that the majority's notion that § 1251(a) did not apply because states have no jurisdiction over patent ownership was at odds with the plain meaning of the statute, which grants the Supreme Court original jurisdiction over all disputes between states.¹⁰⁷ Rather, according to Judge Moore, the concept of core sovereign interest applies to "whether the Supreme Court will decide to exercise its jurisdiction over a dispute, not whether the Court's exclusive original jurisdiction over the controversy exists."¹⁰⁸

99. Id.

^{100.} Id.

^{101.} Id.

^{102.} Id.

^{103.} Id.

^{104.} *Id.* at 1323–25.

^{105.} Id. at 1329 (Moore, J., dissenting).

^{106.} *Id.* 107. *Id.*

^{107.} *Id.* at 1330.

3. Declaratory judgment

The Declaratory Judgment Act provides that, in all cases of actual controversy where there is federal jurisdiction, district courts may preside over actions for the declaration of rights and other legal interests between parties.¹⁰⁹ In 2013, the Federal Circuit considered a case that dealt with a declaratory judgment action brought in the wake of representations by the patentee that an infringement suit would not be filed.

In Organic Seed Growers & Trade Ass'n v. Monsanto Co.,¹¹⁰ the Federal held that Monsanto Co.'s ("Monsanto") binding Circuit representations not to sue mooted the potential controversy in the case and precluded declaratory judgment.111 Monsanto sold transgenic seed that incorporated its patented technologies.¹¹² The appellants in this case, various farmers, seed sellers, and agricultural organizations, were concerned that their seed might inevitably become contaminated by the transgenic seed.¹¹³ This mixing, they feared, could result in Monsanto filing a suit for patent infringement.¹¹⁴ Therefore, the appellants preemptively brought suit against Monsanto for declaratory judgment, alleging that the patents were invalid, unenforceable, and not infringed.¹¹⁵ They also alleged that they were forced to incur substantial costs in creating buffer zones to prevent cross-contamination from neighboring farms growing modified crops.¹¹⁶

Before filing suit, the appellants requested that Monsanto sign a covenant not to sue.¹¹⁷ Monsanto refused their request, claiming that such a covenant was not necessary because Monsanto had no motivation to bring suit for such low levels of accidental infringement.¹¹⁸ Monsanto instead pointed to a portion of its website that stated: "It has never been, nor will it be Monsanto policy to exercise its patent rights where trace amounts of our patented seeds or traits are present in farmer's fields as a result of inadvertent means."¹¹⁹ Monsanto represented to the district court that this

^{109. 28} U.S.C. §§ 2201–2202 (2012).

^{110. 718} F.3d 1350 (Fed. Cir. 2013), cert. denied, 134 S. Ct. 901 (2014).

^{111.} Id. at 1352.

^{112.} Id. at 1353.

^{113.} Id.

^{114.} Id.

^{115.} Id.

^{116.} Id. at 1354.

^{117.} *Id.* 118. *Id.*

^{119.} Id. (quoting a page of Monsanto's website entitled "Monsanto's Commitment: Farmers and Patents").

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statement was meant to assure growers that Monsanto would not bring suit for small quantities of accidental crossover.¹²⁰ Based on these and similar assertions that it did not intend to take action on its transgenic seeds, Monsanto moved to dismiss the case for lack of a substantial case or controversy.¹²¹ In light of these representations, the district court concluded that there was no substantial controversy, no injury, and granted Monsanto's motion to dismiss.¹²²

On appeal, the Federal Circuit determined that "the question in this case [was] not whether the appellants' subjective fear of suit by Monsanto is genuine, but whether they [had] demonstrated a 'substantial risk' that the harm [would] occur, which may prompt [them] to reasonably incur costs to mitigate or avoid that harm."¹²³ Noting that even de minimis infringement could still lead to liability, the court also determined that appellants ran the risk of infringement liability by using contaminated seed for commercial purposes.¹²⁴ However, the Federal Circuit stated that "[d]espite this possibility of infringement, the question is whether Monsanto is correct that its representations moot any potential controversy."¹²⁵ Although the court did not interpret Monsanto's representations as a covenant not to sue, it determined that the representation would nonetheless be binding because of judicial estoppel.¹²⁶ The doctrine of judicial estoppel prevents a party that successfully argues one position from later arguing the opposite position in a case involving the same patent.¹²⁷ The only problem the Federal Circuit found with Monsanto's disclaimer was that it only applies to those who sell or grow "trace," or less than 1%, of seed which, according to the court, comprises the inadvertent contamination with up to 1% of seeds bearing Monsanto's patented traits.¹²⁸ However, because none of the appellants alleged that they were outside the scope of Monsanto's disclaimer, this concern was irrelevant to the present case.¹²⁹ Accordingly, the Federal Circuit concluded that "Monsanto's binding representations remov[ed] any risk of suit against the appellants,"

^{120.} *Id.* at 1357–58. 121. *Id.* at 1352.

^{122.} Id.

^{123.} Id. at 1355 (quoting Clapper v. Amnesty Int'l USA, 133 S. Ct. 1138, 1150 n.5 (2013)).

^{124.} Id. at 1356. 125. Id. at 1357.

^{126.} Id. at 1358.

^{127.} Id.

^{128.} Id. at 1359.

^{129.} Id. at 1359-60.

and therefore the court was without a controversy sufficient to merit a declaratory judgment action.¹³⁰

In another declaratory action case, Arkema Inc. v. Honeywell International, Inc.,¹³¹ the Federal Circuit held that there was sufficient controversy surrounding the two newly issued method patents for a declaratory judgment action where suit had already been brought with regard to patents encompassing the same technology.¹³² Here, the defendant Honeywell International, Inc. ("Honeywell") owned several patents directed toward the refrigerant 1234yf.¹³³ Arkema Inc. ("Arkema") was involved in the manufacturing of these chemicals, and Honeywell filed suit against Arkema for infringing its European patent aimed at that technology.¹³⁴ Arkema then brought suit in the United States for declaratory judgment that Honeywell's composition patents covering 1234yf were invalid and that Arkema's products did not infringe.¹³⁵ Honeywell counterclaimed, alleging that by selling 1234vf in the United States, Arkema infringed on Honeywell composition patents.¹³⁶ While the suit was in discovery, Honeywell obtained two patents covering methods of using 1234yf in automobile air conditioners.¹³⁷ Arkema then sought to supplement its complaint¹³⁸ to include declaratory judgment claims for the two new patents.¹³⁹ The district court denied Arkema's motion on the grounds that there was no justiciable controversy regarding the new patents.¹⁴⁰

On appeal, the Federal Circuit held that this case was "a quintessential example of a situation in which declaratory relief is warranted."141 Arkema had concrete plans to offer 1234yf for sale, and "if Honeywell's view of its patent coverage prevails, then proceeding with its plans would expose Arkema to significant liability."¹⁴² Further, Honeywell had already made it clear that it would enforce its patent rights against Arkema's infringement activity and had previously brought infringement claims against Arkema in

^{130.} *Id.* at 1360–61.

^{131. 706} F.3d 1351 (Fed. Cir. 2013).

^{132.} Id. at 1360.

^{133.} Id. at 1354.

^{134.} Id. at 1355.

^{135.} Id.

^{136.} *Id.* 137. *Id.* at 1354–55.

^{138.} See infra text accompanying notes 247-56 (discussing the portion of this case directed toward leave to amend pleadings).

^{139.} Arkema, 706 F.3d at 1355. 140. Id.

^{141.} Id. at 1357.

^{142.} Id.

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the United States for other patents involving similar technology.¹⁴³ Moreover, in light of testimony by Honeywell's expert that suppliers of 1234yf had already entered into numerous long-term contracts to supply the refrigerant to automobile manufacturers, Arkema was in the "present position of either committing to contracts that could expose it to liability for indirect infringement or abandoning its plans to supply 1234vf to automobile manufacturers in the United States."144 Due to Arkema's exposure to liability regarding the new patents, the certainty of suit by Honeywell regarding those patents, and Arkema's present intent to sell 1234yf for potentially infringing uses, the Federal Circuit reversed the district court and granted declaratory judgment, finding the controversy between the two parties was of sufficient immediacy and reality.¹⁴⁵

Additionally, in 2013, the Federal Circuit considered a case in which the first-to-file rule¹⁴⁶ relating to declaratory judgment actions came into play. In Futurewei Technologies, Inc. v. Acacia Research Corp.,¹⁴⁷ the Federal Circuit held that the first-to-file rule prevents a district court from hearing a second-filed declaratory judgment action when there are no substantial countervailing considerations that support an exception to the rule.¹⁴⁸

Access Co. Ltd. ("Access") and Acacia Patent Acquisition LLC ("APAC"), a wholly owned subsidiary of Acacia Research Group ("Acacia"), signed an exclusive license agreement, whereby APAC granted the sole right to sue for and collect past, present, and future damages and to seek to obtain injunctive or any other relief for infringement of the patents licensed to APAC.¹⁴⁹ The agreement also disclaimed the creation of any third-party beneficiary rights and provided that APAC could not enforce the patents against Access's customers.¹⁵⁰ On December 14, 2009, APAC assigned its interests in the patents to SmartPhone Technologies LLC ("SmartPhone"),

147. 737 F.3d 704 (Fed. Cir. 2013). 148. *Id.* at 708–09.

149. Id. at 705-06.

^{143.} *Id.*

^{144.} Id. at 1359.

^{145.} Id. at 1360 (quoting MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 127 (2007)).

^{146.} Beginning March 16, 2013, the America Invents Act's first-inventor-to-file law came into effect. Leahy-Smith America Invents Act, Pub. L. 112-29, § 35, 125 Stat. 284, 341 (2011) (codified in scattered sections of 35 U.S.C. (2012)). Under this new rule, a patent is granted to the first inventor to file for a patent, regardless of the date of invention. See id. § 3, 125 Stat. at 285–93. Prior to March 16, 2013, the United States operated under a first-to-invent system, in which a patent was granted to the first inventor and not necessarily the first filer. See 35 U.S.C. § 102(a) (2006).

^{150.} Id. at 706.

APAC's wholly owned subsidiary.¹⁵¹ On April 3, 2012, SmartPhone sued Huawei Device USA, Inc. and Futurewei Technologies, Inc. (collectively "Huawei") for infringement.¹⁵² On the following day, Huawei brought suit against SmartPhone seeking declaratory judgment of noninfringement, invalidity, and "enforcement of rights as third-party beneficiary."¹⁵³ Because of the provision disclaiming the rights of third-party beneficiaries, SmartPhone moved to dismiss the complaint, and the district court granted the motion.¹⁵⁴ Huawei appealed the dismissal.¹⁵⁵

On appeal, the Federal Circuit relied heavily on the first-to-file rule in its analysis.¹⁵⁶ The court reasoned that "[w]hen two actions that sufficiently overlap are filed in different federal district courts, one for infringement and the other for declaratory relief, the declaratory judgment action, if filed later, generally is to be stayed, dismissed, or transferred to the forum of the infringement action."¹⁵⁷ The policy behind this theory is "to 'avoid conflicting decisions and promote judicial efficiency."¹⁵⁸ However, exceptions to this rule can be made if it is necessary to effectively and efficiently resolve the dispute.¹⁵⁹

Under this rationale, the Federal Circuit stated that "[f]inding an exception to the first-to-file rule here is unsupported by any substantial countervailing considerations."160 The Federal Circuit determined that the judicial or litigant interests in economy did not favor allowing the claims to proceed in a second-filed declaratory judgment action.¹⁶¹

First, the court determined that "[s]eparating the third-partybeneficiary issue [from the noninfringement and validity issue] cannot serve the objective of efficiency.¹⁶² Next, it determined that having to answer a "California-law question is not enough ... to support an exception to the first-to-file rule."¹⁶³ Because, based on a choice-of-law provision in the agreement, the third-party beneficiary

^{151.} *Id.* 152. *Id.*

^{153.} Id. 154. Id. at 706-07.

^{155.} *Id.* at 707. 156. *Id.*

^{157.} Id. at 708.

^{157.} *Id.* at 706. 158. *Id.* (quoting Merial Ltd. v. Cipla Ltd., 681 F.3d 1283, 1299 (Fed. Cir. 2012)). 159. *Id.* (providing, as examples, "considerations of judicial and litigant economy, and the just and effective disposition of disputes." (quoting Elecs. for Imaging, Inc. v. Coyle, 394 F.3d 1341, 1347 (Fed. Cir. 2005))).

^{160.} *Id.* at 709. 161. *Id.*

^{162.} Id.

^{163.} Id. at 710.

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right would need to be resolved under California law, Acacia argued that this rationale was sufficient to support an exception to the firstto-file rule.¹⁶⁴ The Federal Circuit determined, however, that the Texas court hearing the infringement and validity cases was competent to apply California law to interpret the provision.¹⁶⁵ Accordingly, the Federal Circuit held that, in this case, no exception applied and, therefore, the first-to-file rule prevented the district court from hearing the second-filed declaratory judgment action when there were no substantial countervailing considerations to support an exception to the rule.¹⁶⁶

4. Mootness

Article III of the U.S. Constitution states that the federal judicial power extends only to cases and controversies.¹⁶⁷ The doctrine of mootness deals with the existence (or lack thereof) of a controversy between the parties.¹⁶⁸ Generally, a case will be dismissed for mootness when the parties settle the dispute prior to final adjudication because a controversy no longer exists.¹⁶⁹ In 2013, the Federal Circuit analyzed a unique case under the mootness doctrine where a settlement agreement ended most, but not all, of the claims.

In Allflex USA, Inc. v. Avid Identification Systems, Inc.,¹⁷⁰ the Federal Circuit held that a case is moot if the parties have settled the underlying dispute, regardless of a reservation by the parties to contingently reduce the settlement based on a successful appeal.¹⁷¹ Allflex USA, Inc. ("Allflex") filed suit against Avid Identification Systems, Inc. ("Avid") seeking a declaratory judgment that Avid's inequitable conduct rendered its patents unenforceable and that, therefore, Allflex was not liable for infringement.¹⁷² The district court ruled that Avid and its counsel should be sanctioned under Federal Rule of Civil Procedure 37(c) for failing to disclose a

^{164.} Id. at 709-10.

^{165.} Id. at 710.

^{166.} *Id.* at 709–11.

^{167.} U.S. CONST. art. III, § 2.

^{168.} See Camreta v. Greene, 131 S. Ct. 2020, 2028 (2011) (explaining that "a case remains fit for federal-court adjudication" when "the parties ... have the necessary stake not only at the outset of the litigation [referring to Article III standing], but throughout its course [referring to mootness]" (internal quotation marks omitted)). 169. See, e.g., U.S. Bancorp Mortg. Co. v. Bonner Mall P'ship, 513 U.S. 18, 25

^{(1994) (&}quot;Where mootness results from settlement, however, the losing party has voluntarily forfeited his legal remedy by the ordinary processes of appeal or certiorari⁽...."). 170. 704 F.3d 1362.

^{171.} Id. at 1363.

^{172.} Id.

reexamination proceeding involving the patents at issue.¹⁷³ However, the district court never imposed those sanctions.¹⁷⁴ Subsequently, the district court granted summary judgment in favor of Allflex, finding noninfringement.¹⁷⁵ It also granted partial summary judgment in favor of Allflex, finding inequitable conduct for failing to disclose information about prior public use and offers to sell; however, it found a genuine issue of material fact regarding the intent to deceive.¹⁷⁶

The parties then agreed upon a settlement for all but three issues: the summary judgment order for Allflex in favor of (1)noninfringement; (2) the inequitable conduct claim accompanying a finding of materiality as to the undisclosed information about prior public use and offers for sale; and (3) the ruling that Avid and its counsel should be sanctioned for failing to disclose the existence of reexamination proceedings.¹⁷⁷ The settlement agreement provided that Avid would pay Allflex a lump sum of \$6.55 million, but that lump sum would be reduced by \$50,000 (to only \$6.5 million) if Avid was successful on any of the appealed issues.¹⁷⁸

Unlike most appeals, only one party participated in this appeal.¹⁷⁹ Allflex did not file a response brief on the matter.¹⁸⁰ In its brief, Avid asserted that, despite Allflex's failure to file a responsive brief, Allflex had a continuing interest in the appealed issues.¹⁸¹ The Federal Circuit, however, found that Allflex had no legally cognizable interest in any of the appealed issues.¹⁸² Particularly, Avid had no right to appeal because the district court never entered sanctions and because Avid had not suffered an adverse judgment on the inequitable conduct claim as the case was dismissed without finding the patents unenforceable.¹⁸³ The court noted that a party that receives a judgment decree in its favor may not appeal to obtain a review of the findings it believes to be erroneous if those findings are not critical to the outcome.¹⁸⁴ The Federal Circuit further stated that "where 'the alleged infringer has settled the infringement issue, and no longer professes any

- 175. Id.
- 176. Id.

^{173.} Id. at 1363-64.

^{174.} Id. at 1364.

^{177.} Id.

^{178.} Id. 179. Id. at 1363.

^{180.} Id.

^{181.} Id.

^{182.} Id. at 1366. 183. Id.

^{184.} Id.; see also N.Y. Tel. Co. v. Maltbie, 291 U.S. 645 (1934) (per curiam) (dismissing a suit where the appellant corporation tried to pursue an appeal following).

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interest in... [a] declaratory judgment of invalidity, the case has become moot as a result of the voluntary act of the patentee."¹⁸⁵

The \$50,000 contingency payment was the only remaining evidence Avid put forth in an attempt to avoid the conclusion of mootness.¹⁸⁶ However, the court found that this payment was not an estimation of actual damages.¹⁸⁷ Also, because Avid was never at risk of having to pay monetary damages for the inequitable conduct claim, this amount would not be characterized as a reasonable estimate of a prospective damages award.¹⁸⁸ The Federal Circuit held that Avid failed to show, in light of the one-party appeal, that there was a legitimate, continuing case or controversy, and therefore dismissed the case as moot.189

5. Preemption

Federalism and the preemption doctrine require that a federal law that conflicts with a state law preempt the state law.¹⁹⁰ In Allergan, Inc. v. Athena Cosmetics, Inc., 191 the Federal Circuit held that claims brought under a state health code were not preempted by the Federal Food, Drug, and Cosmetic Act (FDCA) when there was no clear congressional intent to preempt a state law claim of unfair competition.¹⁹² Allergan, Inc. ("Allergan") sued Athena Cosmetics, Inc. ("Athena") for patent infringement and violation of the California Unfair Competition Law ("UCL") for selling hair and evelash growth products without a new drug application approved by either the U.S. Food and Drug Administration (FDA) or the California State Department of Health Services.¹⁹³ Athena moved for judgment on the pleadings, alleging that the FDCA preempted Allergan's unfair competition claim.¹⁹⁴ The district court denied the motion and held that the FDCA did not preempt the UCL claim.¹⁹⁵

^{185.} Allflex, 704 F.3d at 1367 (quoting Aqua Marine Supply v. AIM Machining, Inc., 247 F.3d 1216, 1220 (Fed. Cir. 2001)).

^{186.} Id. at 1366. 187. Id. at 1368.

^{188.} Id.

^{189.} *Id.* at 1369. 190. U.S. CONST. art. VI, cl. 2 ("This Constitution, and the Laws of the United States . . . shall be the supreme Law of the Land "); *see also* Altria Grp., Inc. v. Good, 555 U.S. 70, 543 (2008) ("Consistent with [the Supremacy Clause] command, we have long recognized that state laws that conflict with federal law are without effect." (internal quotation marks omitted)).

^{191. 738} F.3d 1350 (Fed. Cir. 2013).

^{192.} Id. at 1355.

^{193.} Id. at 1353.

^{194.} Id.

^{195.} Id.

On appeal, the parties both agreed that there was no express preemption, so the only issue was implied preemption.¹⁹⁶ Athena argued that the FDCA impliedly preempted the UCL claim because "a state law claim is impliedly preempted if it does not implicate a traditional state law tort principle and exists solely by virtue of a federal statute."197 Allergan responded by arguing that the FDCA does not impliedly preempt its UCL claim because it contains some express preemption provisions, for example, for medical devices and nonprescription drugs, yet it does not contain a similar provision for prescription drugs.¹⁹⁸ Allergan further argued that "there is no implied preemption where simultaneous compliance with state and federal law is possible, and the state law is not an obstacle to the realization of federal goals."¹⁹⁹ Under this theory, Allergan argued that where, as here, the FDCA's requirements paralleled those of the California Health Code, there could be no implied preemption because compliance with both regimes was possible.²⁰⁰ The Federal Circuit agreed with Allergan, finding that Congress's intention is the benchmark of pre-emption analysis.²⁰¹ Because the Federal Circuit could not find a clear purpose by Congress to preempt the state law claim, it held that Allergan's state law UCL claim was not preempted by the FDCA.²⁰²

B. Pleadings

In 2013, the Federal Circuit decided four cases that addressed pleadings. Two of these cases dealt with the sufficiency of pleadings in patent cases, and the other two dealt with leave to amend pleadings in patent cases.

1. Sufficiency of pleadings

In the first case addressing pleading sufficiency, Hall v. Bed Bath \mathfrak{S} Beyond, Inc.,²⁰³ the Federal Circuit concluded that claim construction is not a necessary element of a complaint alleging patent infringement.²⁰⁴ Hall, an individual inventor, left samples of his packaged invention, the Tote Towel, with Bed Bath and Beyond, Inc.

^{196.} Id. at 1354.

^{197.} Id. at 1354-55 (citing Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001)).

^{198.} Id. at 1355.

^{199.} Id. (relying on Wyeth v. Levine, 129 S. Ct. 1187 (2009)).

^{200.} Id.

^{201.} *Id.* 202. *Id.* at 1355–56.

^{203. 705} F.3d 1357 (Fed. Cir. 2013).

^{204.} Id. at 1372.

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("BB&B").²⁰⁵ Both the package and the towel were marked "patent pending" because a design patent was pending on his invention.²⁰⁶ BB&B then had copies of Hall's Tote Towel manufactured for retail sale by a supplier in Pakistan.²⁰⁷ After Hall's patent issued, Hall sued BB&B.²⁰⁸ BB&B moved to dismiss on the pleadings, alleging that the complaint was insufficient for failing to include allegations of claim construction.²⁰⁹ The district court dismissed all of the claims on the pleadings for failing to include claim construction allegations.²¹⁰ Hall appealed the dismissal.²¹¹

On appeal, arguing that claim construction is an essential element of a patent infringement claim, BB&B relied on precedent from View Engineering, Inc. v. Robotic Vision Systems, Inc.,²¹² in which the court held that a "patent holder, if challenged, must be prepared to demonstrate to both the court and the alleged infringer exactly why it believed before filing the claim that it had a reasonable chance of proving infringement."²¹³ The Federal Circuit, in Hall's case, distinguished this case, stating that it "did not relate to dismissal on the pleadings," but, rather, "concerned a district court's discretion to sanction a patentee under Rule 11 for filing 'baseless counterclaims."²¹⁴ The court distinguished *View Engineering* because that case did not necessitate a claim construction requirement for patent infringement complaints.²¹⁵ Therefore, the Federal Circuit concluded that there was no precedent for requiring claim construction allegations in the pleadings and reversed the dismissal of the patent infringement claim.²¹⁶

In K-Tech Telecommunications, Inc. v. Time Warner Cable Inc.,²¹⁷ the Federal Circuit held that when evaluating complaints alleging direct infringement, district courts must reference Form 18 of the Appendix of Forms to the Federal Rules of Civil Procedure.²¹⁸ K-Tech Telecommunications, Inc. ("K-Tech") owns patents directed at "identifying systems and methods for modifying a major channel

^{205.} Id. at 1361.

^{206.} Id.

^{207.} Id.

^{208.} *Id.* 209. *Id.* at 1362.

^{210.} Id. at 1361-62.

^{211.} *Id.* at 1357. 212. 208 F.3d 981 (Fed. Cir. 2000).

^{213.} Hall, 705 F.3d at 1364.

^{214.} Id.

^{215.} Id.

^{216.} Id.

^{217. 714} F.3d 1277 (Fed. Cir. 2013). 218. Id. at 1279.

number, a minor channel number, and/or a carrier frequency to identify a television program."²¹⁹ In its complaint, K-Tech alleged that Time Warner Cable, Inc. ("TWC") infringed its patents by "making, selling, and offering to sell... systems and methods for modifying a major channel number, a minor channel number, and/or a carrier frequency to identify a television program."²²⁰ The district court dismissed the K-Tech complaint under Federal Rule of Civil Procedure 12(b)(6) because it did not contain the required factual specificity for a patent infringement claim.²²¹

On appeal, K-Tech argued that it complied with Form 18 and that the district court applied the wrong standard.²²² Form 18 requires that a complaint for direct patent infringement include

(1) an allegation of jurisdiction; (2) a statement that the plaintiff owns the patent; (3) a statement that defendant has been infringing the patent "by making, selling, and using [the device] embodying the patent"; (4) a statement that the plaintiff has given the defendant notice of its infringement; and (5) a demand for an injunction and damages.²²³

TWC argued that a complaint's Form 18 sufficiency must be construed in accordance with Supreme Court precedent from Ashcroft v. Iqbal²²⁴ and Bell Atlantic Corp. v. Twombly.²²⁵

The Federal Circuit began its analysis by acknowledging that because the Supreme Court had decided the issue of adequacy of the forms, the court did not have the capacity to criticize.²²⁶ It also stated that it was "required to find that a bare allegation of literal infringement in accordance with Form [18] would be sufficient under Rule 8 to state a claim."²²⁷ Further, the court explained that notice and facial plausibility are the "touchstones" of a pleading analysis under Form 18.²²⁸ In this instance, the district court applied the wrong standard by "requiring that a plaintiff preemptively identify and rebut potential non-infringing alternatives to practicing

227. *Id.* at 1284 (alteration in original) (quoting *McZeal*, 501 F.3d at 1360 (Dyk, J., concurring in part and dissenting in part)).

^{219.} Id. at 1280.

^{220.} *Id.* at 1281–82.

^{221.} *Id.* at 1280.

^{222.} *Id.* at 1282.

^{223.} *Id.* at 1283 (alteration in original) (quoting McZeal v. Spring Nextel Corp., 501 F.3d 1354, 1357 (Fed. Cir. 2007)) (discussing FED. R. CIV. P. Form 18).

^{224. 556} U.S. 662 (2009).

^{225. 550} U.S. 544 (2007); see K-Tech, 714 F.3d at 1282.

^{226.} *K-Tech*, 714 F.3d at 1283 (noting that "[a]ny changes to the Federal Rules of Civil Procedure 'must be obtained by the process of amending the Federal Rules, and not by judicial interpretation'" (quoting Leatherman v. Tarrant Cnty. Narcotics Intelligence & Coordination Unit, 507 U.S. 163, 168 (1993))).

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the claims of an asserted patent."229 The defendants in this case knew what K-Tech's patent claimed, knew what K-Tech asserted their systems did, and knew why K-Tech made those assertions.²³⁰ Therefore, the Federal Circuit found that these allegations were adequate to satisfy the requirements of Form 18, which is all that is required of a plaintiff to satisfy Rule 8.231

Concurring in the result, Judge Wallach disagreed with the majority's dictum that "the Forms control" over the plausibility standard set forth in Iqbal and Twombly.232 Rather, Judge Wallach, who concurred only in the "outcome," argued that these standards should be harmonized such that "plausible allegations conforming to Form 18 are adequate to satisfy the requisite Igbal and Twombly standard."233

2. Leave to amend or supplement pleadings

In the first case addressing leave to amend pleadings, Parallel Networks, LLC v. Abercrombie & Fitch Co.,²³⁴ the Federal Circuit held that, in accordance with the decision in Markman v. Westview Instruments,²³⁵ a district court does not abuse its discretion in denying a motion to supplement pleadings when the amendment would add claims and arguments that could have been brought earlier.236 Plaintiff Parallel Networks, LLC ("Parallel") filed suit against 120 different defendants whose websites "provide applets in response to user requests" and, therefore, allegedly infringed Parallel's patent on an applet called the "Client-Server Communication Using a Limited Capability Client Over a Low-Speed Communication Link."237 The district court ordered an early Markman hearing.238 It then granted summary judgment in favor of noninfringement for most defendants based on the determined claim construction and the fact that Parallel claimed only literal infringement.²³⁹ Shortly thereafter, Parallel moved to amend its complaint to allege infringement based on the

^{229.} Id. at 1284.

^{230.} Id. at 1287.

^{231.} *Id.* 232. *Id.* (Wallach, J., concurring).

^{233.} Id. at 1289.

^{234. 704} F.3d 958 (Fed. Cir. 2013). 235. 52 F.3d 967, 978 (Fed. Cir. 1995) (en banc) (holding that the construction of a patent, including terms of art within its claim, is exclusively within the province of the court).

^{236.} Parallel Networks, 704 F.3d at 971.

^{237.} Id. at 962, 965.

^{238.} Id. at 965.

^{239.} Id.

court's claim constructions.²⁴⁰ The district court denied the motion because Parallel "had ample opportunity to respond, and had in fact responded, to the court's construction," and there was "no basis for granting Parallel another bite at the apple."²⁴¹

Parallel raised two arguments on appeal: first, that the district court failed to address the U.S. Court of Appeals for the Fifth Circuit's "manifest injustice" factor; and second, that the district court did not contemplate four "good cause" factors that would allow Parallel to amend its infringement complaint under Local Patent Rule 3-6(b).²⁴² The Federal Circuit agreed with the district court that Parallel, by its motion to amend its complaint, was improperly trying to posit arguments that it could have made before summary judgment.²⁴³ It elaborated that "claim construction was not an intervening change in the law," that "Parallel chose to pursue a theory that allowed it to accuse a larger number of defendants," and that Parallel could not now, after having lost, "initiate what would amount to a completely new infringement proceeding."²⁴⁴

In summary, the Federal Circuit held that "Parallel ha[d] no good explanation for its failure to bring its new infringement contentions earlier and thus ha[d] brought any perceived prejudice on itself."²⁴⁵ For this reason, the Federal Circuit upheld the district court's decision to deny Parallel's motion to amend its pleadings pursuant to Rule 59(e).²⁴⁶

In the second case, *Arkema Inc. v. Honeywell International, Inc.*, the Federal Circuit determined that courts should grant plaintiffs leave to supplement their complaints and add a declaratory judgment action when there is a sufficient case or controversy for such relief.²⁴⁷ Honeywell International, Inc. ("Honeywell"), the defendant, owned several patents directed toward the refrigerant 1234yf.²⁴⁸ Arkema Inc. ("Arkema") participated in manufacturing 1234yf, and Honeywell sued Arkema for infringing its European patent directed to 1234yf.²⁴⁹ Arkema then brought suit against Honeywell in the United States

^{240.} See id. at 966 (explaining that Parallel filed the motion under Federal Rule of Civil Procedure 59(e)).

^{241.} Id.

^{242.} *Id.* at 970–71.

^{243.} See id. at 971 (suggesting that Rule 59(e) is not the proper way to revisit evidence or arguments that could have been made before summary judgment).

^{244.} Id.

^{245.} Id.

^{246.} *Id.*

^{247. 706} F.3d 1351, 1360 (Fed. Cir. 2013).

^{248.} Id. at 1354.

^{249.} Id. at 1355.

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requesting declaratory judgment that Honeywell's composition patents covering 1234vf were invalid and that its products did not infringe.²⁵⁰ In a counterclaim, Honeywell asserted that Arkema's sales and offers for sale of the accused product constituted infringement of both asserted patents.²⁵¹ Amidst discovery, Honeywell obtained two patents covering methods of using 1234yf in automobile air conditioners.²⁵² Arkema then sought to supplement its complaint to add declaratory judgment claims regarding the two new patents.²⁵³ The district court did not allow Arkema to supplement its complaint because it found that there was no sufficient case or controversy to support an action for declaratory judgment.²⁵⁴

The Federal Circuit reversed the district court, holding that because Honeywell accused Arkema of infringing closely related patents and the associated European patents, there was also a sufficient case or controversy regarding the new patents.²⁵⁵ Thus, because a declaratory judgment action for the new patents was justiciable, the Federal Circuit held that Arkema should have been given leave to supplement its complaint to add these claims.²⁵⁶

C. Preclusion

In 2013, the Federal Circuit had an opportunity to determine two cases on preclusion issues: one on res judicata and the other on collateral estoppel.

1. Res judicata

In the res judicata case, Sanofi-Aventis Deutschland GmbH v. Genentech, Inc.,²⁵⁷ the Federal Circuit held that a U.S. final judgment finding no patent infringement is not sufficient to prevent the patent owner from proceeding in a previously filed foreign arbitration regarding licensing of the patent.²⁵⁸ Sanofi-Aventis Deutschland GmbH ("Sanofi") sued Genentech, Inc. ("Genentech") for patent infringement based on the sale of two pharmaceutical drugs, Rituxan

^{250.} *Id.* 251. *Id.*

^{252.} Id.

^{253.} Id.; see also supra text accompanying notes 141-45 (discussing the declaratory judgment ruling).

^{254.} Arkema, 706 F.3d at 1355.

^{255.} Id. at 1357-60; see also supra notes 141-45 and accompanying text (discussing the declaratory judgment portion of this case).

^{256.} Arkemá, 706 F.3d at 1360.

^{257. 716} F.3d 586 (Fed. Cir. 2013).

^{258.} Id. at 588.

and Avastin.259 The district court found that there was no infringement.260 Before the U.S. lawsuits were filed, however, Genentech contracted to license applications to Behringwerke AG ("Behringwerke").²⁶¹ The agreement, governed by German law, required arbitration to settle disputes between the two parties.²⁶² Behringwerke eventually became Sanofi; however, the licensing agreement and the rights to the patents-in-suit were transferred to another party named Hoechst AG ("Hoechst"), a holding company that owns 85% of Sanofi.²⁶³ Hoechst transferred the patents to Sanofi in October 2008 and then demanded arbitration on the issue of licensing before a European arbitrator pursuant to the licensing agreement.²⁶⁴

The European arbitrator concluded that German substantive law should apply to determine whether Rituxan was a licensed article under the agreement.²⁶⁵ Applying German law, the arbitrator concluded that because Rituxan was made using the enhancer elements of Sanofi's patents, Genentech was liable for damages under the agreement.²⁶⁶ Arbitration proceedings continued to determine the amount of damages.²⁶⁷

While the German arbitration was ongoing, Genentech moved the district court to enjoin Sanofi from continuing with the foreign arbitration.²⁶⁸ The district court denied Genentech's motion, finding that

(1) Genentech has not shown that the parties are the same, as Hoechst is a party to the European arbitration, but is not a party to this litigation, (2) that an injunction would frustrate the policies of [the United States] in favor of enforcement of forum selection clauses in arbitration agreements, and (3) that the injunction would not be in the interest of international comity.²⁶⁹

On appeal, Genentech argued that res judicata mandates that the Federal Circuit ensure foreign arbitrators recognize the decisions of U.S. courts.²⁷⁰ Sanofi, in response, argued that "the strong interest in enforcing forum selection clauses requires the injunction to be denied."271 The Federal Circuit found that Genentech's res judicata

^{259.} Id.

^{260.} Id.

^{261.} *Id.* 262. *Id.* at 589.

^{263.} Id.

^{264.} Id.

^{265.} Id. at 590.

^{266.} Id.

^{267.} Id.

^{268.} Id.

^{269.} Id. (alteration in original) (internal quotation marks omitted).

^{270.} Id. at 591.

^{271.} Id. at 593.

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argument was without merit because it was not arguing that res judicata should be applied to the district court but rather that it should be applied in the foreign arbitration.²⁷² Also, Genentech itself cited a case holding that, "although arbitrators may not ignore res judicata, they 'generally are entitled to determine in the first instance whether to give the prior judicial determination preclusive effect."²⁷³

The Federal Circuit determined that the policy of allowing arbitrators to determine preclusive effect was especially applicable here because there was nothing to suggest that res judicata functions the same way under German law.²⁷⁴ Further, the Federal Circuit made a determination that the issues in the litigation and the arbitration were not the same for res judicata purposes because infringement is not dispositive of a breach of the licensing agreement.²⁷⁵ Therefore, the Federal Circuit held that the U.S. final judgment finding no patent infringement was insufficient to prevent the patent owner from proceeding in the German arbitration.²⁷⁶

2. Collateral estoppel

In 2013, the Federal Circuit heard two cases on collateral estoppel. In the first case, Aspex Eyewear, Inc. v. Zenni Optical Inc.,²⁷⁷ the court held that a plaintiff is collaterally estopped from asserting patent infringement claims based on a prior litigation regarding the same patents that are not materially different from those at issue in the present suit.278

Aspex Eyewear, Inc. ("Aspex") filed suit against Zenni Optical Inc. ("Zenni") for infringement of three patents "directed to clip-on eyewear in which magnets secure the bridge portions of the eyewear."²⁷⁹ Previously, in Aspex Eyewear, Inc. v. Altair Eyewear, Inc.,²⁸⁰ litigation between Aspex and a third party, Altair Eyewear, Inc. ("Altair"), resulted in a finding of noninfringement, involved the

^{272.} Id.

^{273.} Id. at 594 (quoting Collins v. D.R. Horton, Inc., 505 F.3d 874, 880 (9th Cir. 2007)).

^{274.} *Id.* 275. *Id.* at 592–93.

^{276.} Id. at 588.

^{277. 713} F.3d 1377 (Fed. Cir. 2013).
278. *Id.* at 1378–79 (referring to the prior decisions in Aspex Eyewear, Inc. v. Altair Eyewear, Inc., 386 F. Supp. 2d 526 (S.D.N.Y. 2005) (claim construction); Aspex Eyewear, Inc. v. Altair Eyewear, Inc., 485 F. Supp. 2d 310 (S.D.N.Y. 2007) (summary Eyewear, Inc., 2007) (summary Eyewear, 2007) (summary Eyewe judgment of noninfringement); and Aspex Evewear, Inc. v. Altair Evewear, Inc., 288 F. App'x 697 (Fed. Cir. 2008) (affirming in part, reversing in part, and remanding)).

^{279.} Id. at 1379.

^{280. 288} F. App'x 697 (2008).

same three patents, and included many of the same claims.²⁸¹ The Altair court considered the claims at issue, and when its rulings were applied by the district court in the Zenni case, the district court found that "Zenni's accused rimless magnetic clip-on sunglasses were materially indistinguishable from Altair's."282 For this reason, the district court held that collateral estoppel barred the present suit against Zenni.283

In order for collateral estoppel to bar a suit, the party claiming the benefit of the estoppel must show that

(1) the issue at stake is identical to the one involved in the prior proceeding; (2) the issue was actually litigated in the prior proceeding; (3) the determination of the issue in the prior litigation must have been 'a critical and necessary part' of the judgment in the first action; and (4) the party against whom collateral estoppel is asserted must have had a full and fair opportunity to litigate the issue in the prior proceeding.²⁸⁴

Aspex argued that the issue at stake was different than the prior litigation because the claim terms previously considered were not the same claim terms as those now requiring construction.²⁸⁵ Aspex also argued that the claim terms were not properly construed in the prior litigation and that if they were properly construed in this case, Aspex would be entitled to a judgment of infringement against Zenni.²⁸⁶

Zenni responded by arguing that the controlling question was whether the claims at issue could be against Zenni because its glasses were found to be duplicative of Altair's-an issue that was previously litigated to a final judgment of noninfringement.²⁸⁷ The court noted that "Aspex fully litigated the meaning of the term 'retaining mechanism' in the first suit, and that it was finally adjudicated that 'retaining mechanism' as used in these patents requires a rim around the lens, which resulted in a finding of non-infringement."288 Although Aspex asserted that the new claims contained limitations that were not previously considered, the Federal Circuit did not find infringement because every claim against Zenni contained identical terms to those used in the same context against Altair.²⁸⁹ Further,

^{281.} Aspex, 713 F.3d at 1379; see also supra note 278 (mentioning the decisions in the Altair litigation).

^{282.} Aspex, 713 F.3d at 1379. 283. Id.

^{284.} Id. at 1380 (quoting Christo v. Padgett, 223 F.3d 1324, 1339 (11th Cir. 2000)).

^{285.} Id. (explaining that Aspex asserted it was entitled to a new trial for infringement).

^{286.} Id.

^{287.} Id. at 1381.

^{288.} Id. at 1382.

^{289.} Id. at 1381.

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because the district court in this case found that the Zenni and Altair products were materially identical, the Federal Circuit held that "the assertion of different claims in a subsequent suit does not create a new 'issue' to defeat preclusion."²⁹⁰ The Federal Circuit determined that because there was neither a change in circumstance nor any new evidence or materially different arguments than were available to Aspex in the previous litigation, the claims asserted against Zenni were barred under the doctrine of collateral estoppel.²⁹¹

In TecSec, Inc. v. International Business Machines Corp.,²⁹² the Federal Circuit held that collateral estoppel does not apply to prevent relitigation of claim construction when the claim construction is not a critical and necessary part of the prior proceeding.²⁹³ TecSec, Inc. ("TecSec") filed suit against International Business Machines Corp., Inc. ("IBM"), alleging that IBM's Internet servers and software products infringed several of TecSec's patents directed toward computer data security systems.²⁹⁴ After a claim construction order was issued, IBM moved for summary judgment of noninfringement.²⁹⁵ The district court granted IBM's motion, finding noninfringement without relying on the claim constructions at issue in the later litigation.²⁹⁶ As an alternative basis for the ruling in favor of IBM, the district court concluded that "TecSec also had failed to show that IBM's accused systems met the limitations of the asserted claims under the court's claim construction."297 TecSec appealed the grant of summary judgment and the claim construction order, and the Federal Circuit affirmed and remanded without opinion under Federal Circuit Rule 36.²⁹⁸ When proceedings resumed with the remaining defendants on remand, TecSec stipulated that it could not prove infringement under the claim construction adopted by the district court during the proceedings with IBM.²⁹⁹

On appeal, the defendants asserted that the mandate rule barred TecSec from challenging the district court's claim construction because "(1) the district court's constructions were within the scope of its judgment; (2) that judgment was affirmed in the *IBM* appeal; and (3) no issues were reserved for further consideration in the

^{290.} Id.

^{291.} Id. at 1381-82.

^{292. 731} F.3d 1336 (Fed. Cir. 2013).

^{293.} *Id.* at 1343. 294. *Id.* at 1340.

^{294.} *Id.* 134 295. *Id.*

^{296.} Id. at 1341.

^{297.} Id.

^{298.} *Id.* at 1340.

^{299.} Id.

decision in the prior appeal."300 The Federal Circuit disagreed, noting that a Rule 36 judgment merely accepts a lower court's judgment but not necessarily its reasoning.³⁰¹ In the prior proceeding, the district court entered summary judgment on alternative grounds-the first based on a failure of proof regarding acts of infringement by IBM or its customers, and the second based on a failure to show that IBM's software met various claim limitations.³⁰² On this record, the Federal Circuit found that "it cannot be concluded simply on the basis of this court's summary affirmance that we expressly or by necessary implication decided the claim construction issues in the IBM appeal."303

The defendants also asserted that collateral estoppel precluded TecSec from relitigating claim construction.³⁰⁴ In making this argument, the defendants pointed out that the district court construed only the claims that it considered "strictly necessary" to the grant of summary judgment.³⁰⁵ TecSec argued that because the claim constructions were not necessary to the final judgment, collateral estoppel did not apply.³⁰⁶

The Federal Circuit agreed with TecSec that the claim construction ruling was not essential to the judgment.³⁰⁷ In order for collateral estoppel to apply, the party seeking estoppel "must show that the litigated issue was 'actually determined in the prior proceeding' and was a 'critical and necessary part of the decision in the prior proceeding.""308 Additionally, "where the court in the prior suit has determined two issues, either of which could independently support the result, then neither determination is considered essential to the judgment."309 Because the district court's decision regarding IBM's summary judgment was independently predicated on alternative grounds, and therefore was not "critical and necessary" to the prior decision, the Federal Circuit held that collateral estoppel was inapplicable.³¹⁰

^{300.} Id. at 1341.

^{301.} Id. at 1343 (quoting Rates Tech., Inc. v. Mediatrix Telecom, Inc., 688 F.3d 742, 750 (Fed. Cir. 2012)).

^{302.} *Id.* at 1341. 303. *Id.* at 1342.

^{304.} Id. at 1341.

^{305.} Id. at 1343.

^{306.} Id.

^{307.} Id. at 1344.

^{308.} Id. at 1343 (quoting Collins v. Pond Creek Mining Co., 468 F.3d 213, 217 (4th Cir. 2006)).

^{309.} Id. (quoting Ritter v. Mount St. Mary's Coll., 814 F.2d 986, 993 (4th Cir. 1987)) (internal quotation marks omitted).

^{310.} *Id.*

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D. Joinder

Although generally joinder may be either permissive or compulsory, compulsory joinder was the issue addressed by the Federal Circuit in 2013. Compulsory joinder is governed by Federal Rule of Civil Procedure 19 and requires joinder of parties that are necessary and indispensable to the litigation.³¹¹

In University of Utah v. Max-Planck-Gesellschaft zur Forderung der Wissenschaften E.V., the Federal Circuit held that a party is not indispensable when its interests are adequately represented by other defendants, when the court is fully capable of rendering a judgment in the unjoined party's absence, and when there is only a slim possibility that the Supreme Court would accept original jurisdiction over the parties.³¹² The University of Utah ("UUtah") named several defendants in a suit to correct inventorship of two patents, including the University of Massachusetts ("UMass").³¹³ UMass initially relied on an argument that the Supreme Court had exclusive jurisdiction over the case because it was brought between two states.³¹⁴ UUtah, in response, amended its complaint and added four named UMass officials in place of UMass itself.³¹⁵ The remaining defendants then filed a motion under Rule 19 to dismiss the case because of UUtah's failure to join a necessary and indispensable party, UMass.³¹⁶ Although all parties to the suit agreed that UMass should be joined if feasible, the plaintiffs contended that UMass was not an indispensable party and, therefore, was not absolutely required to be joined.³¹⁷

Before addressing the merits of the joinder issue, the Federal Circuit discussed its jurisdiction due to the defendant's requested review under the doctrine of pendant jurisdiction, which is granted only in exceptional circumstances.³¹⁸ However, because the First Circuit has held that a Rule 19 indispensable party must be joined and that a Rule 19 question may be raised for the first time on appeal, the Federal Circuit determined that review for a Rule 19 issue was appropriate.³¹⁹

Because all parties agreed that UMass was a necessary party and that joinder was not feasible, the question before the Federal Circuit

^{311.} FED. R. CIV. P. 19.

^{312. 734} F.3d 1315, 1328 (Fed. Cir. 2013).

^{313.} Id. at 1317–18.

^{314.} *Id.* at 1318.

^{315.} *Id.*

^{316.} *Id.* 317. *Id.* at 1325.

^{318.} *Id.*

^{319.} Id. at 1325-26.

was whether UMass was indispensable.³²⁰ The court, when analyzing indispensability, must "determine whether, in equity and good conscience, the action should proceed among the existing parties or should be dismissed."321

On appeal, both parties relied on Dainippon Screen Manufacturing Co. v. CFMT, Inc.³²² In Dainippon Screen, the district court determined that it lacked personal jurisdiction over CFMT (but not its codefendant parent and exclusive licensee) and dismissed the suit due to its conclusion that, because CFMT was the owner of the patent the manufacturer sought to invalidate, CFMT was an indispensable party under Rule 19(b).³²³ The Federal Circuit in that case reversed the district court's decision because it determined that "prejudice is mitigated when an absent party is adequately represented, and that the presence in the suit of the assignee's parent company and sole owner was adequate representation."³²⁴ The Dainippon Screen court went through four oft-enumerated factors for determining an indispensable party and found that the first two factors (regarding prejudice to an absent party) were inapplicable because of the court's determination that there would be no prejudice to any parties.³²⁵ It also found "the third factor, adequacy of the judgment, to be satisfied because a declaratory judgment did not require an affirmative act by the absent holding company; in other words, relief was not hollow absent joinder."326 The Federal Circuit further determined, with regard to the fourth factor involving an adequate remedy, that when there is a strong showing of the first three factors, little weight need be given to the possibility that another district court might exist in which all parties could be joined.³²⁷

The Federal Circuit held that the present case contained facts that supported finding UMass not to be an indispensable party even more strongly than in *Dainippon Screen*.³²⁸ First, the district court found no prejudice because UMass's interests were adequately represented by the joined defendants, including all other patent owners, each of whom stood to lose its rights if the inventorship was changed.³²⁹ Second, because there was no prejudice, the district court found that

^{320.} Id.

^{321.} *Id.* at 1326 (citing FED. R. CIV. P. 19(b)). 322. 142 F.3d 1266, 1272 (Fed. Cir. 1998).

^{323.} Univ. of Utah, 734 F.3d at 1326 (citing Dainippon Screen, 142 F.3d at 1268-69).

^{324.} Id. (citing Dainippon Screen, 142 F.3d at 1272).

^{325.} Id.

^{326.} Id. (citing Dainippon Screen, 142 F.3d at 1273).

^{327.} Id. (citing Dainippon Screen, 142 F.3d at 1272).

^{328.} Id.

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the second factor carried little weight.³³⁰ Third, the remedy requested, "an order directing the USPTO to correct inventorship would not be insufficient in the absence of UMass, just as findings of invalidity or non-infringement would not have been hollow in Dainippon."³³¹ Finally, with regard to the fourth factor, the district court determined that "the possibility that the Supreme Court would accept original jurisdiction in this case weighs only slightly against UUtah."332 In the end, the district court determined that the fourth factor was significantly outweighed by the first three.³³³

The Federal Circuit agreed that this determination was within the district court's discretion.³³⁴ Therefore, the Federal Circuit held that there was no abuse of discretion when the district court determined that UMass was not an indispensable party.³³⁵

Judge Moore dissented from the majority's holding that UMass was not an indispensable party.³³⁶ Her dissent cited two cases holding that "when a plaintiff brings a declaratory judgment action seeking to invalidate a patent or hold it not infringed, the patentee is both a action."337 necessary and indispensable defendant in that Consequently, Judge Moore would have distinguished Dainippon Screen based on the close relationship and identical interests of the absent and named parties in that suit, and applied the court's general requirement that all co-owners of a patent must be joined in an action affecting that patent.³³⁸

E. Discovery

Discovery refers to the time period in which the parties build their case for trial by gathering relevant facts and witnesses.³³⁹ In 2013, the Federal Circuit addressed several issues related to the discovery period, including when sanctions are appropriate in response to discovery violations, timing and scope of summary judgment, and the content of expert testimony and reports.

^{330.} Id.

^{331.} Id. at 1328.

^{332.} Id.

^{333.} Id.

^{334.} Id.

^{335.} Id.

^{336.} *Id.* at 1331 (Moore, J., dissenting).
337. *Id.* (citing A123 Sys., Inc. v. Hydro-Quebec, 626 F.3d 1213, 1217–19, 1220–22
(Fed. Cir. 2010); Enzo APA & Son, Inc. v. Geapag A.G., 134 F.3d 1090, 1094 (Fed. Cir. 1998)).

^{338.} Id. 339. See FED. R. CIV. P. 26 (governing the various tools parties have at their disposal, such as depositions, interrogatories, and document requests, that can be used to gather information about the pertinent issues).

1. Sanctions

In Alexsam, Inc. v. IDT Corp.,340 the Federal Circuit affirmed that a holding of infringement is an appropriate sanction for discovery violations when previous sanctions fail to secure compliance with a discovery order.³⁴¹ Alexsam, Inc. ("Alexsam") filed suit against IDT Corporation ("IDT"), accusing it of patent infringement.³⁴² At the close of discovery, Alexsam moved for sanctions pursuant to Federal Rule of Civil Procedure 37 alleging that IDT had "failed to disclose information suggesting that the miscellaneous systems infringe Alexsam's patents, in violation of IDT's discovery obligations."³⁴³ The district court granted the motion for sanctions midway through the trial, announcing that the defendant failed to comply with the court order to fully and completely respond to the plaintiff's interrogatories.³⁴⁴ It then declared that the miscellaneous systems were deemed to infringe Alexsam's patents and instructed the jury accordingly.³⁴⁵

The Federal Circuit determined that Fifth Circuit law governed this issue, under which the propriety of severe sanctions depends on factors, including whether willfulness or bad faith is involved, whether the deterrent effect of Rule 37 can be achieved through less drastic means, whether the party was substantially prejudiced in trial preparation, whether the misconduct was attributable to an attorney, and whether the misconduct was an honest misunderstanding of the court's orders.³⁴⁶ For less severe sanctions, such as "deeming certain facts established for purposes of the litigation," the Fifth Circuit only requires "that the sanction be '[j]ust and [f]air,' that it have a 'substantial relationship' to the facts sought to be established by the discovery, and that it meet Rule 37's goals of punishment and deterrence."347 The Federal Circuit concluded that the sanction imposed on IDT fell within the less-severe sanction category and therefore was reviewed under the "just and fair" standard.³⁴⁸ Under this standard, the Fifth Circuit considers five factors:

(1) whether the sanctioned party was warned of the impending sanctions, (2) whether the party made "[e]mpty [p]romises" that it

^{340. 715} F.3d 1336 (Fed. Cir. 2013).
341. *Id.* at 1345.

^{342.} Id. at 1340.

^{343.} Id. 344. Id.

^{345.} Id.

^{346.} See id. at 1342-43 (citing Batson v. Neal Spelce Assocs., 765 F.2d 511, 514 (5th Cir. 1985)).

^{347.} Id. at 1343 (alterations in original) (quoting Chilcutt v. United States, 4 F.3d 1313, 1319–21 (5th Cir. 1993)).

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would "comply with discovery obligations," (3) whether the claim being pursued through discovery was not so "frivolous" that the use of discovery amounted to "an abuse of judicial process," (4) whether the sanctioned party bore some degree of culpability, and (5) whether the court had previously sanctioned the same party.³⁴⁹

In assessing these factors, the Federal Circuit first found that IDT received ample notice of the possibility of sanctions because it was warned that future noncompliance would result in more severe sanctions.³⁵⁰ Second, it found that IDT had made empty promises in the form of misleading, incomplete discovery responses and false representations to the court concerning the extent of its disclosures.³⁵¹ Third, it found that Alexsam's claims were not frivolous, even though the evidence presented to support claims of infringement were insubstantial.³⁵² Fourth, the Federal Circuit found that the failure to disclose the requested information was not innocent because IDT presented no reason why it could not have more closely examined the documents and found that they needed to be disclosed.³⁵³ Finally, IDT had previously been sanctioned for incomplete responses to the same interrogatories.³⁵⁴ Based on these findings, the Federal Circuit found no abuse of discretion on the part of the district court for mandating a finding of infringement as a sanction for failure to comply with the discovery order.355

F. Summary Judgment

In 2013, the Federal Circuit heard two cases about summary judgment. The first case was about the timing of summary judgment motions, and the second case involved the scope of summary judgment orders.

In the first case, *Baron Services, Inc. v. Media Weather Innovations LLC*,³⁵⁶ the Federal Circuit determined that summary judgment was premature when the party opposing the motion did not have access to essential source code or an opportunity to depose essential witnesses.³⁵⁷ Baron Services, Inc. ("Baron") filed suit against Media Weather Innovations LLC ("MWI") for patent infringement of its computerized systems and methods for real-time weather

^{349.} Id. at 1344 (alterations in original) (quoting Chilcutt, 4 F.3d at 1321-24).

^{350.} *Id.* at 1344–45. 351. *Id.* at 1345.

^{352.} Id.

^{353.} *Id.*

^{354.} Id.

^{355.} Id.

^{356. 717} F.3d 907 (Fed. Cir. 2013).

^{357.} *Id.* at 913.

reporting.³⁵⁸ After filing its complaint, Baron served MWI with a request for production of the source code it used in its allegedly infringing device.³⁵⁹ In response, MWI filed for a protective order, which was granted on the ground that the source code might not be relevant to the case because the patent-in-suit, U.S. Patent No. 6,490,525 ("the '525 patent"), claimed no computer-code-based invention.³⁶⁰ MWI attached affidavits from Michael Fannin, a former employee of Baron, and Valerie Ritterbusch, the current president of MWI and a former employee of Baron, to the motion.³⁶¹ Prior to a Markman hearing, MWI filed a motion for summary judgment, attaching a new affidavit by Ritterbusch that asserted that there was no infringement based on her understanding of the claim terms of the '525 patent.³⁶² Baron filed a response opposing the motion, citing Federal Rule of Civil Procedure 56(b) in arguing that "summary judgment was premature because the court had not yet construed the terms... because it had not had the opportunity to review MWI's relevant source code, and because it had yet to depose Ritterbusch and Fannin."363 Baron also filed a motion to compel production of MWI's source code.³⁶⁴ The district court granted MWI's motion for summary judgment and found that claim construction was unnecessary because it only had a "duty" to construe "disputed claim terms."³⁶⁵ It also found that Rule 56(d) was inapplicable because Baron never asked for more time for discovery nor asserted that it could not proceed sufficiently without further discovery.³⁶⁶

"Under Federal Rule of Civil Procedure 56(d), a party opposing a summary judgment motion may request that a district court delay ruling on the motion in order to obtain additional discovery without which 'it cannot present facts essential to justify its opposition."³⁶⁷ The Federal Circuit found that providing Baron an opportunity to reasonably disprove MWI's claims of noninfringement was essential to Baron's opposition.³⁶⁸ Specifically, it found that the opportunity for Baron to examine the source code would have enabled it to

368. Id. at 913.

^{358.} *Id.* at 908. 359. *Id.*

^{360.} Id.

^{361.} *Id.* 362. *Id.* at 910.

^{363.} Id.

^{364.} Id.

^{365.} Id. at 911-12 (emphasis omitted).

^{366.} Id. at 912.

^{367.} Id. (quoting FED. R. CIV. P. 56(d)).

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determine whether MWI's noninfringement claims were viable.³⁶⁹ It also found that deposing Ritterbusch and Fannin was equally important to Baron's opposition of MWI's summary judgment motion because the individuals "possessed personal knowledge of the functionality of the accused products," and "[t]heir affidavits were MWI's primary evidence to support its motion for summary judgment."³⁷⁰ Therefore, the Federal Circuit held that "it was improper for the district court to have refused Baron's request to delay ruling on MWI's summary judgment motion until Baron had the opportunity to access MWI's source code and depose Ritterbusch and Fannin."³⁷¹

Dissenting, Judge Reyna would have affirmed the district court's summary judgment ruling.³⁷² He stated that having made concessions regarding what constituted noninfringing activity, Baron "failed to point to specific ways in which accused products were capable of analysis and/or manipulation that met the claim limitations."³⁷³ Thus, the district court was correct to conclude that "Baron did not have a credible basis to oppose the motion for summary judgment."³⁷⁴ Further, in Judge Reyna's view, the majority took a "highly selective, one-sided perspective of the record," which, among other things, "fail[ed] to take into account Baron's tactics which the district court's broad discretion in case management, Judge Reyna stated that the district court's decision to deny Baron's case management and discovery requests was reasonable.³⁷⁶

In the second summary judgment case, *Charles Machine Works, Inc. v. Vermeer Manufacturing Co.*,³⁷⁷ the Federal Circuit held that Charles Machine Works, Inc. ("CMW") did not have adequate notice that prototypes were within the scope of a summary judgment ruling because the motion and hearing only addressed commercial products.³⁷⁸ CMW sued Vermeer Manufacturing Company ("Vermeer") for infringement of its patent related to a two-pipe drill for boring underground holes based on two different products: (1) commercial products, and (2)

^{369.} Id.

^{370.} Id.

^{371.} Id. 372. Id. at 917 (Reyna, J., dissenting).

^{373.} Id.

^{374.} Id.

^{375.} Id.

^{376.} Id. at 920.

^{377. 723} F.3d 1376 (Fed. Cir. 2013).

^{378.} *Id.* at 1377.

noncommercial prototypes.³⁷⁹ Vermeer moved for summary judgment in regard to both literal infringement and infringement under the doctrine of equivalents.³⁸⁰ The district court granted the motion with regard to all accused products.³⁸¹

CMW appealed, arguing that the district court erred when it granted summary judgment as to Vermeer's prototypes.³⁸² CMW claimed that "Vermeer's motion for summary judgment covered only the accused commercial products," and that "it did not have notice that the court was considering the prototypes."³⁸³ The Federal Circuit agreed with CMW that it had insufficient notice that the summary judgment decision would include the prototypes for three reasons.³⁸⁴ First, Vermeer titled its motion "MOTION FOR SUMMARY JUDGMENT THAT VERMEER'S COMMERCIAL PRODUCTS DO NOT INFRINGE," and presented its argument under the heading "Vermeer's Commercial Products Cannot Infringe Because They Lack a Deflection Shoe Mounted on a Casing or Body."³⁸⁵ Second, "Vermeer's proposed final rulings were again expressly limited to the commercial products," as evidenced by the heading in its brief reading, "GRANT SUMMARY JUDGMENT THAT VERMEER'S COMMERCIAL PRODUCT DOES NOT INFRINGE."386 Third, at the summary judgment hearing, Vermeer explicitly agreed with counsel for CMW that its motion was limited to the commercial products.³⁸⁷ Accordingly, the Federal Circuit held that CMW did not have sufficient notice that the prototypes were within the scope of the summary judgment decision and reversed the district court's finding of summary judgment in relation to the prototypes.³⁸⁸

G. Expert Testimony

Expert testimony is commonly used in patent cases to provide explanations regarding the technical aspects of the asserted patents and accused technology. Expert witnesses who testify must provide an expert report summarizing their findings and methodology.³⁸⁹

384. Id.

^{379.} Id. at 1377-78.

^{380.} Id. at 1378.

^{381.} Id. 382. Id.

^{383.} Id.

^{385.} Id. at 1378-79.

^{386.} *Id.* at 1379. 387. *Id.*

^{388.} Id. at 1381. 389. FED. R. CIV. P. 26(a) (2) (B).

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In Rembrandt Vision Technologies, L.P. v. Johnson & Johnson Vision Care, Inc.,³⁹⁰ the Federal Circuit held that failing to disclose the patentee's expert's testing methodology until cross-examination at trial was an unjustified violation of the rule governing expert reports.³⁹¹ Both Rembrandt Vision Technologies, L.P. ("Rembrandt") and Johnson & Johnson Vision Care, Inc. ("JJVC") manufacture contact lenses.³⁹² Rembrandt owns a patent directed to a "soft gas permeable contact lens"393 and sued IIVC for infringement.³⁹⁴ The issue on appeal was whether "Rembrandt proffered sufficient evidence that the accused contact lenses were 'soft'"-defined as having a Shore D hardness of less than five.³⁹⁵ The only evidence presented by Rembrandt was the testimony of its expert witness, Dr. Thomas Beebe.³⁹⁶ However, [[VC argued that Dr. Beebe's testimony at trial conflicted with the opinions he described in his expert report.397

The expert report described a testing procedure that involved stacking twenty-four of the accused lenses around a stainless steel ball to allow full penetration with a 2.54 millimeter probe.³⁹⁸ On crossexamination, however, Dr. Beebe was questioned about his methods and whether he had tested a sufficiently thick stack of lenses to comply with industry standard testing protocols, which required stacking lenses to a thickness of at least 6 millimeters.³⁹⁹ Confronted with the calculation that twenty-four lenses, each with a thickness of 0.07 millimeters, would have a thickness of only 1.68 millimeters, Dr. Beebe "suddenly changed course in the middle of cross-examination and testified that he did not follow the procedures listed in his expert report," and instead opined that he had cut the lenses into quarters and stacked them on a flat surface before probing them.⁴⁰⁰ This procedure was not in his expert report, and JJVC moved to exclude the testimony.⁴⁰¹

The district court granted IJVC's motion, striking the expert testimony pursuant to Federal Rule of Civil Procedure 37 "because

^{390. 725} F.3d 1377 (Fed. Cir. 2013).

^{391.} Id. at 1381.

^{392.} Id. at 1378.

^{393.} Id. at 1379. 394. Id.

^{395.} Id. 396. Id.

^{397.} Id.

^{398.} Id.

^{399.} Id. at 1380.
400. Id. (quoting Rembrandt Vision Techs., L.P. v. Johnson & Johnson Vision Care, Inc., 282 F.R.D. 655, 659–60 (M.D. Fla. 2012)) (internal quotation marks omitted).

^{401.} Id.

his expert report was 'woefully deficient' to support his trial testimony," and "because nothing in the record established the reliability of the testing methodology he testified to at trial."⁴⁰² Further, because Dr. Beebe's expert testimony was the only evidence presented to prove the lenses were "soft," the district court also granted JJVC's motion for judgment as a matter of law (JMOL).⁴⁰³

On appeal, Rembrandt challenged both the exclusion of Dr. Beebe's testimony as well as the grant of JMOL, arguing that "the mistakes in Dr. Beebe's report were unintended and did not harm JJVC."⁴⁰⁴ JJVC responded by arguing that "regardless of Dr. Beebe's intent, there was no justification for Dr. Beebe's late disclosure of his testing methods," and that his "change in testimony significantly impaired its ability to prepare a noninfringement defense and prepare the case for trial."⁴⁰⁵

The Federal Circuit agreed with JJVC that an "expert witness may not testify to subject matter beyond the scope of the witness's expert report unless the failure to include that information in the report was 'substantially justified or harmless.'"⁴⁰⁶ The court reasoned that there was no substantial justification for the late disclosure because the expert's testimony was at issue in both his deposition and the pretrial briefings which encompassed dispositive motions.⁴⁰⁷ And though JJVC had challenged the adequacy of his Shore D hardness testing methodology prior to trial, Dr. Beebe never attempted to supplement his report.⁴⁰⁸ The Federal Circuit, therefore, held that the district court did not abuse its discretion in excluding Dr. Beebe's testimony pursuant to Rule 37 because it was not "substantially justified or harmless" to fail to disclose testing methodology until cross-examination.⁴⁰⁹

II. FEDERAL CIRCUIT PRACTICE

Each year, the Federal Circuit decides a number of cases pertaining, in whole or in part, to its own Rules of Practice and Procedure. In 2013, the court ruled on the scope of its jurisdiction to hear interlocutory appeals following infringement judgments in

^{402.} Id. (quoting Rembrandt, 282 F.R.D. at 663-67).

^{403.} *Id.*

^{404.} *Id.* at 1381. 405. *Id.*

^{406.} Id. (citing FED. R. CIV. P. 37(c)(1)).

^{407.} Id. at 1382.

^{408.} Id.

^{409.} Id.

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bifurcated trials,⁴¹⁰ whether a prior failure to cross-appeal terminates an accused infringer's right to challenge validity in the face of a new claim construction,⁴¹¹ and whether a district court gave too much weight to the public's interest of judicial disclosure when unsealing parties' confidential information.412

A. Jurisdiction

In Robert Bosch, LLC v. Pylon Manufacturing Corp.,⁴¹³ the Federal Circuit considered, en banc, whether it has subject matter jurisdiction over appeals from district court infringement liability determinations when damages and willfulness have not yet been adjudicated.⁴¹⁴ In a ruling expected to have significant impact on the economics of patent litigation, the majority of a divided court⁴¹⁵ held that 28 U.S.C. \$1292(c)(2) confers appellate jurisdiction over a finding of patent infringement (1) when a trial on damages has not yet occurred⁴¹⁶ and (2) when willfulness issues are outstanding and remain undecided.⁴¹⁷

In 2008, Robert Bosch, LLC ("Bosch") sued Pylon Manufacturing Corp. ("Pylon") for patent infringement of its windshield wiper blade technology, and Pylon asserted infringement counterclaims against Bosch.⁴¹⁸ Granting Pylon's request to bifurcate infringement liability from damages, the district court similarly bifurcated the issue of willful infringement.419 Accordingly, the district court stayed all discovery on damages and willfulness.⁴²⁰ Following a jury trial on liability and post-trial motions, the district court entered judgment on infringement.⁴²¹ After each party appealed, Bosch moved to dismiss

^{410.} See Robert Bosch, LLC v. Pylon Mfg. Corp., 719 F.3d 1305, 1308, 1318 (Fed. Cir. 2013) (en banc) (asserting that the Federal Circuit took this case en banc sua sponte to consider this question).

^{411.} See Lazare Kaplan Int'l, Inc. v. Photoscribe Techs., Inc., 714 F.3d 1289, 1294 (Fed. Cir. 2013) (holding that the defendant could not address validity on remand because of a failure to file a cross-appeal).

^{412.} See Apple Inc. v. Samsung Elecs. Co. (Apple III), 727 F.3d 1214, 1228–29 (Fed. Cir. 2013) (disagreeing with the district court decision to unseal market research documents). 413. 719 F.3d 1305 (Fed. Cir. 2013) (en banc). 414. *Id.* at 1308.

^{415.} See id. (majority opinion) (Judge Prost joined by Chief Judge Rader as well as Judges Newman, Lourie, and Dyk); id. at 1320 (Moore, J., concurring in part and dissenting in part); id. at 1323 (Reyna, J., concurring in part and dissenting in part) (O'Malley, J., dissenting).

^{416.} *Id.* at 1309. 417. *Id.* at 1317.

^{418.} Robert Bosch, LLC v. Pylon Mfg. Corp., 748 F. Supp. 2d 383, 387 (D. Del. 2010), rev'd, 659 F.3d 1142 (Fed. Cir. 2011).

^{419.} *Robert Bosch*, 719 F.3d at 1308 (quoting Robert Bosch LLC v. Pylon Mfg. Corp., No. CIV.08-542-SLR, 2009 WL 2742750, at *1 (D. Del. Aug. 26, 2009)).

^{420.} Robert Bosch, 719 F.3d at 1308.

^{421.} Id.

both its appeal and Pylon's cross-appeal, arguing that the Federal Circuit lacked jurisdiction over the appeal of infringement liability at that stage of the proceeding because the remaining issues of damages and willfulness were yet to be decided.⁴²² The court denied Bosch's motion as well as its motion for reconsideration.⁴²³ Following oral argument, however, the Federal Circuit sua sponte ordered a rehearing en banc to address the jurisdictional issue.⁴²⁴

Generally, the Federal Circuit's jurisdiction in an appeal is limited to an issue for which there has been a final judgment that ends the litigation on the merits and leaves nothing for the court to do but execute the judgment.⁴²⁵ One patent-specific exception to the final judgment rule, 28 U.S.C. § 1292(c)(2), permits an appeal of nonfinal (interlocutory) decisions.⁴²⁶ This statutory provision grants the Federal Circuit exclusive jurisdiction "of an appeal from a [final] judgment in a civil action for patent infringement which would otherwise be appealable . . . except for an accounting."427 Thus, the question before the en banc court in Bosch was "whether a trial on damages and willfulness is an accounting for the purposes of § 1292(c)(2)."428

Bosch argued that an "accounting" does not include a trial on damages.⁴²⁹ Finding that neither the statute's language nor its legislative history supported Bosch's narrow interpretation, the majority stated that it was "clear from the case law and history of the statute that an accounting includes both the determination of an infringer's profits as well as a patentee's damages."430 The majority relied, in part, on the fact that the meaning of the term "accounting" has evolved over time to include the determination of a patentee's damages and that Congress gave the term this judicially settled meaning when it enacted 1292(c)(2)'s predecessor statute.⁴³¹

The Federal Circuit also rejected Bosch's argument that "an accounting must be limited to a special master's determination of

^{422.} Id.; Robert Bosch LLC v. Pylon Mfg. Corp., 426 F. App'x 912, 913 (Fed. Cir. 2011).

^{423.} Robert Bosch, 719 F.3d at 1308.

^{424.} Id.

^{425. 28} U.S.C. § 1291 (2012) (comprising the federal "final judgment rule").

^{426.} Id. § 1292(c)(2). See generally Alexandra B. Hess et. al., Permissive Interlocutory Appeals at the Court of Appeals for the Federal Circuit: Fifteen Years in Review (1995–2010), 60 Am. U. L. REV. 757 (2011) (tracing the history of the final judgment rule and the 427. 28 U.S.C. § 1292(c) (2) (emphasis added).
428. *Robert Bosch*, 719 F.3d at 1309 ("The disposition of this case turns on the

meaning of 'accounting'").

^{429.} *Id.* 430. *Id.*

^{431.} Id. at 1311–12 (discussing the enactment and legislative history of 28 U.S.C. § 227a (1920), which was recodified at 28 U.S.C. § 1292).

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damages," which is an equitable remedy that "may not include a modern jury trial on damages."432 First, the court noted that in 1948, Congress, rather than eliminating the § 1292 exception to the final judgment rule, "expanded jurisdiction over interlocutory appeals from cases in equity to 'civil actions for patent infringement which are final except for accounting.⁴³³ Because interlocutory appeals were available not only in suits in equity but also in civil actions, the court concluded that the meaning of an "accounting" in § 1292 includes a damages trial.⁴³⁴ Second, the court recognized that past accounting proceedings largely resemble current damage trials.435 Third, the majority noted that the same policy considerationsnotably, the high cost in party and judicial resources of an accounting—that led Congress to initially allow interlocutory appeals in patent cases that are final except for an accounting apply equally to modern damages trials.⁴³⁶ Finally, the court invoked stare decisis, as prior cases permitted interlocutory appeals on infringement issues in cases where damages had not yet been tried.437

Undertaking a similar analysis, the court (without Judges Moore or Reyna) also concluded that, as with damages, an accounting includes willfulness determinations and thus confers appellate jurisdiction to hear interlocutory appeals concerning infringement liability when willfulness determinations remain outstanding.⁴³⁸ The court noted the long-standing practice of determining willfulness as part of an accounting and concluded that Congress did not intend to disturb that practice upon enactment of § 1292(c)'s predecessor.⁴³⁹ Further, the Federal Circuit pointed out that various courts had continued to include willfulness determinations in accountings after Congress had granted interlocutory appeals over cases that were final except for an accounting.⁴⁴⁰

^{432.} Id. at 1313 (internal quotation marks omitted).

^{433.} Id.

^{434.} *Id.*

^{435.} *Id.* 436. *Id.*

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^{437.} *Id.*; *see, e.g., In re* Calmar, Inc., 854 F.2d 461, 464 (Fed. Cir. 1988) (explaining that "the purpose of the legislation . . . allowing interlocutory appeals in patent cases was to *permit* a stay of a damages trial"); Trans-World Mfg. Corp. v. Al Nyman & Sons, Inc., 750 F.2d 1552, 1558 (Fed. Cir. 1984) (noting that the district court ordered and postponed a trial on damages pending appeal from a jury verdict that did not reach the question of damages).

^{438.} Robert Bosch, 719 F.3d at 1317.

^{439.} Id. at 1318.

^{440.} Id.

The majority was careful to limit its decision to bifurcated trials⁴⁴¹ and made clear that it was not determining whether bifurcation of these issues violates the Seventh Amendment.⁴⁴² Significantly, the Federal Circuit noted that district courts have broad discretion with regard to bifurcation.443

While Judges Moore and Reyna, who both wrote opinions concurring in part and dissenting in part, agreed with the majority that the Federal Circuit has appellate jurisdiction over district court judgments that are final except for a determination of damages, both judges dissented from the majority's conclusion that the term "accounting," as used in \S 1292(c)(2), includes a determination of willfulness.⁴⁴⁴ Both opined that the willfulness inquiry bears no relation to an accounting, which is strictly limited to issues of compensation.⁴⁴⁵ Judge O'Malley, joined by Judge Wallach, dissented from the majority's broad interpretation of 1292(c)(2), stating that the majority had "stretche[d] that statutory provision beyond reasonable bounds, and well beyond anything Congress intended."446 In the dissent's view, the term "accounting" in § 1292 only applies to proceedings before special masters or to those instances where all that is left to do is apply the litigated facts to an undisputed set of numbers; it does not encompass a trial on damages or willfulness.⁴⁴⁷ Finally, Judge O'Malley argued that bifurcating infringement and willfulness jury trials may run afoul of the defendant's Seventh Amendment right to a jury trial.⁴⁴⁸

Although the implications of this decision are yet to be realized, the number of motions to bifurcate infringement and damages issues may well increase. Damages trials are risky; they are expensive, timeconsuming, and liability determinations have a substantial reversal

^{441.} Id. at 1320 (stating that 28 U.S.C. § 1292(c) extends to an infringement determination "where the district court has exercised its discretion to bifurcate the issues of damages and willfulness from those of liability").

^{442.} Id. at 1318 ("[W]e did not take this case en banc to determine whether the issues of infringement and willfulness are so interwoven that trying them separately violates the Seventh Amendment. Precedent of this court, nonetheless, indicates that it does not.")

^{443.} Id. at 1319-20 (noting that district court judges are in the best position to make the decision of whether bifurcation is warranted). 444. *Id.* at 1320 (Moore, J., concurring in part and dissenting in part); *id.* at 1323

⁽Reyna, J., concurring in part and dissenting in part).

^{445.} Id. at 1322–23 (Moore, J., concurring in part).
445. Id. at 1322–23 (Moore, J., concurring in part and dissenting in part); id. at 1325 (Reyna, J., concurring in part and dissenting in part).
446. Id. at 1329 (O'Malley, J., dissenting).

^{447.} Id. at 1334-37.

^{448.} Id. at 1345 ("A bifurcation order which requires that two different juries visit the interwoven issues and overlapping facts involving infringement and validity on the one hand and willfulness on the other would violate the defendant's Seventh Amendment right to a jury trial.").

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rate on appeal.⁴⁴⁹ Moreover, the Federal Circuit's express preference for broad district court discretion on bifurcation promises to bolster this practice in matters of patent law adjudication.⁴⁵⁰

In another case implicating the Federal Circuit's subject matter jurisdiction, Wawrzynski v. H.J. Heinz Co.,451 the court considered whether a patent counterclaim may be enough to confer the court with jurisdiction.⁴⁵² In 1997, David Wawrzynski patented a method for dipping and wiping a food article in a specially configured condiment container.⁴⁵³ Wawrzynski presented his patent to H.J. Heinz Company ("Heinz") along with promotional materials and packaging designs, as well as his new idea for a "dual function" product that allowed consumers to either dip food (such as a French fry) into the condiment package or to squeeze out the condiment on its own.⁴⁵⁴ A few months after declining interest in Wawrzynski's product ideas, Heinz released its new "Dip & Squeeze®" packet.455 Wawrzynski sued Heinz in state court, asserting claims relating to this product.⁴⁵⁶ Heinz removed the case to federal district court based on diversity jurisdiction.⁴⁵⁷ Wawrzynski filed an amended complaint, which asserted breach of implied contract and unjust enrichment.⁴⁵⁸

The case was then transferred to the U.S. District Court for the Western District of Pennsylvania, and Heinz filed a counterclaim of invalidity and noninfringement of Wawrzynski's patent.⁴⁵⁹ Wawrzynski filed a motion to dismiss the counterclaims on the ground that his complaint asserted only state law claims, not patent infringement, and thus there was no case or controversy under federal law.⁴⁶⁰ The district court denied the motion.⁴⁶¹ Wawrzynski then filed an answer to the counterclaim, which again stated that he was not suing Heinz for patent infringement and then granted Heinz a covenant not to sue.⁴⁶² Wawrzynski filed a second motion to dismiss

451. 728 F.3d 1374 (Fed. Cir. 2013).

^{449.} Id. at 1316 (majority opinion).

^{450.} See generally id. at 1319–20 ("Finally, we wish to make clear that district courts, in their discretion, may bifurcate willfulness and damages issues from liability issues in any given case. District courts have [this] authority... [and] are best positioned to make [bifurcation] determination[s] on a case-by-case basis.").

^{452.} *Id.* at 1375.

^{453.} Id. at 1376.

^{454.} *Id.*

^{455.} *Id.*

^{456.} *Id.* 457. *Id.*

^{457.} *Ia.* 458. *Id.*

^{459.} Id. at 1376–77.

^{460.} *Id.* at 1377.

^{461.} *Id.*

^{462.} Id.

Heinz's counterclaim, again on the ground that the original complaint made no allegations that implicated the Wawrzynski patent.⁴⁶³ Heinz filed a motion for summary judgment, asserting that federal patent law preempted Wawrzynski's claims.⁴⁶⁴ The district court agreed and granted the motion.465 The district court also granted summary judgment of noninfringement in favor of Heinz after holding that it had jurisdiction to decide the issue.⁴⁶⁶ Wawrzynski appealed, challenging the ruling that his state law claims were preempted by federal patent law, as well as the district court's determination that it had subject matter jurisdiction over Heinz's counterclaim.⁴⁶⁷

Both parties argued that the Federal Circuit had jurisdiction over the matter, albeit for different reasons. Wawrzynski argued that the court had appellate jurisdiction under 28 U.S.C. § 1295 as provided by the Leahy-Smith America Invents Act ("AIA").⁴⁶⁸ Wawrzynski's jurisdictional argument relied on the post-AIA version of § 1295, which grants the court appellate jurisdiction over civil actions where any party asserts a compulsory counterclaim arising under patent law.⁴⁶⁹ Admittedly, Wawrzynski filed his case prior to the AIA's effective date.470 But because Heinz filed its counterclaim of noninfringement after the AIA effective date, Wawrzynski argued that "evolving circumstances" of the case conferred the court with appellate jurisdiction.⁴⁷¹ The Federal Circuit characterized this argument as "creative," but made clear that, for jurisdictional purposes, the only relevant date for post-AIA § 1295 is the date on which the action commences.⁴⁷² Since Wawrzynski's complaint was filed before September 16, 2011, the AIA's effective date, the Federal Circuit concluded that it lacked jurisdiction over his claim.⁴⁷³

Federal Circuit also rejected Heinz's jurisdictional The contentions, which relied on (1) the *pre*AIA version of \S 1295 and (2) the argument that Wawrzynski's complaint, by referring to his patent, asserted a patent claim.⁴⁷⁴ The Federal Circuit disposed of this argument by noting that a district court's federal question

466. Id.

^{463.} See id.

^{464.} Id.

^{465.} Id.

^{467.} *Id.*

^{468.} *Id.* at 1378 (citing Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 19(b), 125 Stat. 284, 331–32 (2011)).

^{469.} Id.; see 28 U.S.C. § 1295(a) (1) (2012).
470. Wawrzynski, 728 F.3d at 1378.

^{471.} Id.

^{472.} Id.

^{473.} Id. at 1379.

^{474.} See id.

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jurisdiction is established under the "well-pleaded complaint rule,"⁴⁷⁵ and that a "sparse background discussion of his patent" is not enough to meet this clearly delineated standard.⁴⁷⁶ The complaint contained no count of patent infringement, lacked the language of a typical patent allegation, did not cite to 35 U.S.C. § 271, and contained a request for relief that recited state law claims rather than a claim for patent infringement.⁴⁷⁷ The court also found credence in Wawrzynski's argument that the complaint put at issue certain ideas and materials that were not found in Wawrzynski's patent.⁴⁷⁸ The Federal Circuit's conclusion was bolstered by the fact that Wawrzynski originally filed his complaint in state court, a fact consistent with the Federal Circuit's determination "that he intended to eschew federal law" in favor of his state law claims.⁴⁷⁹

Before transferring the case to the U.S. Court of Appeals for the Third Circuit, however, the Federal Circuit commented on the merits of the district court's grant of summary judgment.⁴⁸⁰ The Federal Circuit concluded that its jurisdictional analysis "undercut conclusions relied upon by the district court to support its grant of summary judgment of preemption."⁴⁸¹ In addition, the court noted that, given that Wawrzynski conceded that Heinz's product did not infringe and that he provided Heinz with a covenant not to sue, there was no apparent case or controversy to support a judgment on the issue of infringement.⁴⁸²

B. Cross-Appeal

Determining what issues to appeal can present a challenge, especially in view of the Federal Circuit's hard-line approach to its rules of practice. In *Lazare Kaplan International, Inc. v. Photoscribe Technologies, Inc.*,⁴⁸³ a split panel of the Federal Circuit held that a district court could not reopen a patent-validity final judgment on

^{475.} *Id.* at 1379–80 (internal quotation marks omitted) (noting that this rule "makes the plaintiff the 'master of the complaint'" (quoting Caterpillar Inc. v. Williams, 482 U.S. 386, 398–99 (1987))).

^{476.} *Id.* at 1381 (further noting that the complaint only articulated state law counts—namely, allegations for breach of implied contract and unjust enrichment).

^{477.} *Id.* at 1380. 478. *Id.* at 1381.

^{479.} *Id.*

^{480.} See id. at 1381–82 ("[S]ome of the issues underlying our jurisdictional analyses also underlie the district court's summary judgment merits analyses. To fully assess the question of our jurisdiction, we necessarily have analyzed and decided certain of these issues.").

^{481.} *Id.* at 1381.

^{482.} Id.

^{483. 714} F.3d 1289 (Fed. Cir. 2013).

remand under Rule 60(b) when the beneficiary of that ruling failed to file a cross-appeal in an earlier appeal.⁴⁸⁴

Lazare Kaplan International, Inc. ("Lazare Kaplan") sued Photoscribe Technologies, Inc. ("Photoscribe") for infringement of two patents relating to methods for making microinscriptions on gemstones using lasers.⁴⁸⁵ Photoscribe, in turn, filed counterclaims seeking declarations that the patent was invalid.⁴⁸⁶ The district court construed the claim in such a limited way that the inevitable result was a finding of no infringement and of no invalidity as to one of two patents.487 Lazare Kaplan appealed the judgment of noninfringement.488 Photoscribe, however, failed to appeal the judgment as to patent validity.⁴⁸⁹ On appeal for the first time, the Federal Circuit broadened the district court's claim construction of the relevant claim term, vacated its judgment as to noninfringement, and remanded for further proceedings on infringement.⁴⁹⁰ On remand, the district court granted Photoscribe's Federal Rule of Civil Procedure 60(b) motion to vacate the earlier validity judgment, noting that the former decision by the jury was based on a claim construction that had since been reversed.⁴⁹¹ Following a judgment of invalidity on the merits, Lazare Kaplan appealed.⁴⁹²

On appeal for the second time, the majority first decided that Federal Circuit law, and not regional circuit law, applied because the appealed issue "require[d] consistent and uniform application by district courts when handling patent cases."493 Then, the Federal Circuit reversed the district court's grant of relief under Rule 60(b),494 vacated the district court's finding of invalidity, and remanded with instructions to reinstate the court's original judgment

492. See Lazare Kaplan, 714 F.3d at 1292.

^{484.} Id. at 1297.

^{485.} Id. at 1291.

^{486.} Id. 487. See id.

^{488.} Id. at 1292.

^{489.} Id.

^{490.} Lazare Kaplan Int'l, Inc. v. Photoscribe Techs., Inc., 628 F.3d 1359, 1370 (Fed. Cir. 2010).

^{491.} Lazare Kaplan Int'l Inc. v. Photoscribe Techs., Inc., No. 06 CIV. 4005 TPG, 2012 WL 505742, at *4, *8–9 (S.D.N.Y. Feb. 15, 2012) (stating that it "makes no sense" to do otherwise), rev'd in part, vacated in part, 714 F.3d 1289; see also FED. R. CIV. P. 60(b)(5) (providing that a court may grant relief from a final judgment if "it is based on an earlier judgment that has been reversed or vacated").

^{493.} Id. at 1293.

^{494.} Id. at 1297. Although the Federal Circuit reviewed the district court's decision for an abuse of discretion, it afforded the lower court and the law of the regional circuit no deference, as is common practice in reviewing a Rule 60(b) ruling that "turns on substantive issues unique to patent law." Id. at 1293.

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that the patent was "not invalid."⁴⁹⁵ In its analysis, the Federal Circuit concluded that permitting Photoscribe to reopen its invalidity contentions ran afoul of the cross-appeal rule, which the court emphasized was "inveterate and certain."⁴⁹⁶ The majority further noted the well-settled tenet that a party "must file a cross-appeal" when the appealing party seeks to "lessen the rights of its adversary or enlarge its own rights."⁴⁹⁷ Although the cross-appeal rule is usually applied by appellate courts, not district courts, the Federal Circuit found that it nonetheless could be applied to preclude certain arguments in a district court on remand.⁴⁹⁸ Inevitably, the court found that reopening the prior judgment would amount to expanding the rights of Photoscribe or lessening those of Lazare Kaplan—outcomes that the cross-appeal rule was intended to prevent.⁴⁹⁹

The majority also rejected Photoscribe's argument that it was entitled to relief under Federal Rule of Civil Procedure 60(b)(5) and (b)(6).⁵⁰⁰ According to the majority, "[b]oth the cross-appeal rule and Rule $60(b) \dots$ share a common underlying rationale of promoting repose."⁵⁰¹ Allowing for relief in this situation under Rule 60(b), the majority continued, "would allow a movant to circumvent the cross-appeal rule in a manner contrary to its well-established history."⁵⁰²

While the Federal Circuit majority acknowledged that a new claim construction potentially raised new validity issues, the court stated that, absent extraordinary circumstances, "rules are rules, and the cross-appeal rule is firmly established in our law."⁵⁰³ The majority rejected the district court's flawed reasoning that the close interrelation between the issues of invalidity and infringement permitted it to reopen the validity issue absent the prior cross-appeal.⁵⁰⁴ Determining that the district court abused its discretion by granting relief under Rule 60(b), the majority reversed, vacated, and remanded on the issue of validity.⁵⁰⁵ Because the district court failed, however, to reach the issue of infringement, the Federal Circuit again instructed the district court to assess infringement under the claim

^{495.} *Id.* at 1297.

^{496.} Id. at 1293 (quoting Morley Constr. Co. v. Md. Cas. Co., 300 U.S. 185, 191 (1937)).

^{497.} *Id.*

^{498.} *Id.* at 1294–95. 499. *Id.* at 1295–96.

^{500.} *Id.* at 1295–50.

^{501.} *Id.*

^{502.} Id.

^{503.} Id. at 1297.

^{504.} Id. at 1294-95.

^{505.} Id. at 1297.

construction that the Federal Circuit had set forth in the prior appeal and, if necessary, to determine damages.⁵⁰⁶

In dissent, Judge Dyk criticized the majority for failing to adhere to the established principle that claims must be given the same meaning for the purposes of both validity and infringement analysis.⁵⁰⁷ His dissent noted that this was not a situation governed by the traditional cross-appeal rule because Photoscribe was merely seeking to preserve (rather than modify) the rights established by the district court.⁵⁰⁸ As such, Judge Dyk argued that there was no requirement that Photoscribe file a *contingent* cross-appeal and, furthermore, that the majority lacked any support for its conclusion that failure to do so barred Rule 60(b) relief.⁵⁰⁹

C. Motions To Seal Court Records

In a case dubbed by the media as "the Patent Trial of the Century,"⁵¹⁰ Apple, Inc. v. Samsung Electronics Co.⁵¹¹ (Apple III), the Federal Circuit considered whether the unique level of public interest in the matter warranted an altered standard of review with regard to secrecy orders.⁵¹² The court held that where the parties' confidential information is not central to the decision on the merits and the parties' privacy interest is strong, the public interest is minimal, and thus the district court's orders to unseal amounted to an abuse of discretion.⁵¹³

In 2011, Apple, Inc. ("Apple") sued Samsung Electronics Company, Ltd. ("Samsung"), asserting that Samsung's smartphones and tablets infringed Apple's patents and trade dress.⁵¹⁴ In August 2012, a jury returned a verdict for Apple and awarded more than \$1 billion in damages.⁵¹⁵ In light of the extraordinary media interest in the case, the district court judge, Judge Koh, informed the parties

^{506.} Id. at 1298.

^{507.} *Id.* at 1298–99 (Dyk, J., dissenting). 508. *Id.* at 1300.

^{509.} Id. ("[T]he majority identifies no case holding that a failure to file a

contingent cross-appeal bars Rule 60(b) relief."). 510. E.g., Ashby Jones & Jessica E. Vascellaro, *Apple v. Samsung: The Patent Trial* of the Century, WALL ST. J. (July 24, 2012, 1:01 PM), http://online.wsj.com/article/SB 10000872396390443295404577543221814648592.html.

^{511. 727} F.3d 1214 (Fed. Cir. 2013).

^{512.} Id. at 1218.

^{513.} See id. at 1228-29 (elaborating that the disclosure would not be helpful and that Apple clearly demonstrated that it could suffer competitive harm if the pages in question were made available to the public).

^{514.} Id. at 1217.

^{515.} Id.

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that "the whole trial [was] going to be open."⁵¹⁶ As a result, Judge Koh ordered the parties to provide the media with electronic copies of all exhibits used at trial at the end of each day and issued an order unsealing most of the exhibits attached to the parties' pretrial and post-trial motions.⁵¹⁷ Apple and Samsung appealed the unsealing orders with respect to "a small subset of exhibits" containing confidential, detailed, product-specific financial information and market research reports.⁵¹⁸

As an initial matter, the Federal Circuit decided that it had jurisdiction to entertain the appeal of the district court's interlocutory orders under the collateral order doctrine, which permits the appeal of orders affecting rights that would be irretrievably lost absent immediate appeal.⁵¹⁹ In addition, the court determined that regional-that is, the law of the U.S. Court of Appeals for the Ninth Circuit—applied.⁵²⁰

The Federal Circuit reviewed the district court's order to unseal judicial records for abuse of discretion.⁵²¹ Noting the unusual nature of this appeal-in that neither party opposed the other party's request for relief-the court cast its role as arbiter between the parties and the public.522

Beginning its substantive analysis by acknowledging the precept that there is a "common law right of access to judicial records," the Federal Circuit noted that the Ninth Circuit required the parties to demonstrate "compelling reasons" sufficient to outweigh the public interest in order to seal its documents.⁵²³ The district court stated that Apple and Samsung had failed to meet this burden.⁵²⁴ The Federal Circuit, however, determined that the lower court erred in two respects.525

^{516.} *Id.* at 1218 (internal quotation marks omitted).

^{517.} Id. While neither Apple nor Samsung opposed the motions to seal, Reuters America LLC, a nonparty, intervened and filed a successful opposition. Id.

^{518.} Id. at 1218–19.

^{519.} Id. at 1220.

^{520.} Id.

^{521.} Id. at 1221.

^{522.} See id. at 1219, 1221 (stating that "a court must conscientiously balance the competing interests of the public and the party who seeks to keep certain judicial records secret" (internal quotation marks omitted) (quoting Kamakana v. City & Cnty. of Honolulu, 447 F.3d 1172, 1178 (9th Cir. 2006))). While the Federal Circuit denied motions to intervene by various public interest groups, it permitted amicus briefs and allowed selected amici curiae to participate in oral argument. Id. at 1220. 523. Id. at 1221-22.

^{524.} Id. at 1224.

^{525.} See id. at 1225, 1228.

First, the Federal Circuit held that the district court applied the wrong legal standard in its denial of the parties' motions.⁵²⁶ Given that the documents at issue were attached to nondispositive motions, the Federal Circuit stated that the "compelling reasons" test was an improper standard.⁵²⁷ Rather, the district court should have followed the Ninth Circuit's guidance as to nondispositive motions, which requires only a "particularized showing of good cause" to seal discovery documents. 528

Second, the Federal Circuit held that, even under the stricter legal standard, the district court erred in denying the parties' motions to seal the documents because both parties had demonstrated (1) a sufficiently strong privacy interest in sealing the documents, and (2) that public disclosure of the information could cause the parties to suffer competitive harm to their business.⁵²⁹ Finally, the court concluded that the public interest in the disclosure of this information was minimal given that none of these documents were introduced at trial and all were attached to nondispositive motions.⁵³⁰ The Federal Circuit also placed particular emphasis on the fact that the parties, in seeking to seal only limited redactions within what was an already small subset of documents, acted reasonably.⁵³¹ Considering all of these factors, the Federal Circuit held that the district court abused its discretion in refusing to seal the parties' confidential records.⁵³²

III. ADMINISTRATIVE PATENT LAW

The Federal Circuit has jurisdiction over appeals from the Patent Trial and Appeal Board (PTAB or "the Board")⁵³³ as well as the U.S. International Trade Commission (ITC).⁵³⁴ Thus, the Federal Circuit exercises comprehensive appellate review over the final decisions of the primary agencies tasked with adjudicating patent disputes.⁵³⁵ In

^{526.} Id. at 1222-23.

^{527.} Id. at 1222.

^{528.} Id. (internal quotation marks omitted).

^{529.} *Id.* at 1228.
530. *Id.* at 1226, 1228 (stating that while the public policy of disclosure is important, the public interest "does not extend to mere curiosity about the parties' confidential information where that information is not central to a decision on the merits").

^{531.} Id. at 1226.

^{531. 1}a. at 1220. 532. Id. at 1228–29. 533. 28 U.S.C. § 1295(a) (4) (A) (2012). The Board of Patent Appeals and Inferences was renamed the Patent Trial and Appeal Board under the AIA. See Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 7, 125 Stat. 284, 313 (2011). 534. 28 U.S.C. § 1295(a)(6).

^{535.} See id. § 1295(a)(3) (all appeals from the U.S. Court of Federal Claims); id. § 1295(a)(4) (appeals from the PTAB and all appeals from the TTAB and the U.S. Court of International Trade); id. § 1295(a) (6) (appeals from the ITC); id. § 1295(a) (9) (appeals from the Merit Systems Protection Board).

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the future, Federal Circuit review of PTAB decisions will likely increase as parties begin appealing the recently created inter partes and post-grant review trials.536

In 2013, many of the Federal Circuit's written opinions reversed either the PTAB or the ITC for failing to adequately consider secondary indicia of nonobviousness.⁵³⁷ Thus, courts may see an increase in the prevalence of these arguments-and practitioners may likewise see an increase in judicial attention on them-in the near future.

A. PTAB Procedural Challenges—Developing the Law of Post-Grant Review

Federal Circuit opinions often have indirect effects on patent practice in front of the ITC and the USPTO, as rulings in appeals from district court cases sometimes bear on administrative patent trials. Three such important decisions from 2013 are Fresenius II,⁵³⁸ Abbott Laboratories v. Cordis Corp., 539 and Ohio Willow Wood Co. v. Alps South, LLC.⁵⁴⁰

1. USPTO post-judgment patent cancellation: Fresenius USA, Inc. v. Baxter International, Inc.

Because an issued U.S. patent is presumed valid, courts apply a clear and convincing evidence standard in assessing validity.⁵⁴¹ In

^{536.} From September 16, 2012, through April 2, 2014, the PTAB saw 997 inter partes review and 149 transitional covered business method post grant review (CBM) petitions. See Patent Trial and Appeal Board AIA Progress Statistics, USPTO (Apr. 2, 2014), http://www.uspto.gov/ip/boards/bpai/stats/040214_aia_stat_graph.pdf; see also Inter Partes Disputes, USPTO, http://www.uspto.gov/aia_implementation/bpai.jsp (last visited Apr. 29, 2014) (indicating that the procedures for conducting these new proceedings took effect on September 16, 2012). By statute, the final decisions in any of those petitions instituted are appealable to the Federal Circuit. See 28 U.S.C. § 1295(a) (4) (A); see also David L. McCombs et al., Federal Circuit Appeals from the PTAB: A New Game or Just the Same Old Practice?, HAYNES & BOONE LLP 26–27 (2013), http://www.haynesboone.com/files/Uploads/Documents/Fed%20Cir%20Appeals%20 from%20PTAB%20Paper%202122466_16%20(2).pdf (suggesting practitioners should "[a]nticipate [d]elays" at the Federal Circuit and that appeals from the PTAB will lead to "expanded use" of summary affirmances under Federal Circuit Rule 36).

^{537.} See infra Part IV.G. 538. 721 F.3d 1330 (Fed. Cir.), reh'g and reh'g en banc denied, 733 F.3d 1369 (Fed. Cir. 2013) (per curiam), petition for cert. filed, 82 U.S.L.W. 3540 (U.S. Mar. 5, 2014) (No. 13-1071); see infra Part III.A.1.

^{539. 710} F.3d 1318 (Fed. Cir. 2013); see infra Part III.A.2.

^{540. 735} F.3d 1333 (Fed. Cir. 2013); see infra Part III.A.3.

^{541.} See In re Swanson, 540 F.3d 1368, 1377–78 (Fed. Cir. 2008) (contrasting the heightened standard with the lower preponderance of the evidence standard applicable in USPTO reexaminations); Ethicon, Inc. v. Quigg, 849 F.2d 1422, 1426 (Fed. Cir. 1988) (indicating that the party asserting invalidity carries the burden of proof); *see also* 35 U.S.C. § 282(a) (2012) ("A patent shall be presumed valid.").

construing claim terms, courts apply the plain and ordinary meaning of the terms in light of the specification prosecution history.⁵⁴² In contrast, the presumption of validity does not apply before the USPTO, which gives the patent owner an opportunity to amend the claims.⁵⁴³ Further, a "preponderance of the evidence" standard applies.⁵⁴⁴ In addition, in construing claim language, the USPTO applies the "broadest reasonable construction."⁵⁴⁵ Given the different evidentiary standards of the two forums, claims that survive an invalidity challenge in district court litigation may later be found invalid before the USPTO-even based on the same prior art.546

In Fresenius II, a divided Federal Circuit panel held that the USPTO's cancellation of claims is binding in pending infringement litigation and divests litigants from jurisdiction over those claims.⁵⁴⁷ Having previously found the claims invalid, the court vacated an unexecuted money judgment and remanded the case with instructions to dismiss.⁵⁴⁸ Judge Newman dissented.⁵⁴⁹ The ruling provoked a petition for rehearing en banc that the court also denied per curiam,⁵⁵⁰ although not without comment from many of the members of the court.⁵⁵¹

At issue in this case was Baxter International, Inc. and Baxter Healthcare Corporation's (collectively "Baxter") U.S. Patent No.

F.3d 1288, 1304 (Fed. Cir. 2009) (invalidating the patent claims).

549. Fresenius II, 721 F.3d at 1347 (Newman, J., dissenting).

^{542.} Phillips v. AWH Corp., 415 F.3d 1303, 1313–14 (Fed. Cir. 2005) (en banc). 543. See SAP Am. Inc. v. Versata Dev. Grp., 107 U.S.P.Q.2d (BNA) 1097, 1102 (P.T.A.B. 2013) ("The use of the broadest reasonable interpretation encourages patent owners to remove ambiguities and to narrow their claims by amendment, such that the inventor's contribution to the art is expressed in clear, precise and unambiguous terms."); *see, e.g.*, Garmin Int'I, Inc. v. Cuozzo Speed Techs. LLC., No. IPR2012-00001, 2013 WL 2023626, at *3 (P.T.A.B. Jan. 9, 2013) (instituting review). 544. *In re* Caveney, 761 F.2d 671, 674 (Fed. Cir. 1985). 545. 37 C.F.R. § 42,100(b) (2013).

^{546.} See, e.g., Interthinx, Inc. v. Corelogic, Inc., 109 U.S.P.Q.2d (BNA) 1585, 1588– 89 (P.T.A.B. 2014).

^{547.} See Fresenius II, 721 F.3d 1330, 1339–40 (Fed. Cir.), reh'g and reh'g en banc denied, 733 F.3d 1369 (Fed. Cir. 2013) (per curiam), petition for cert. filed, 82 U.S.L.W. 3540 (U.S. Mar. 5, 2014) (No. 13-1071). 548. *Id.* at 1347; *see also* Fresenius USA, Inc. v. Baxter Int'l, Inc. (*Fresenius I*), 582

^{550.} See Fresenius III, 733 F.3d at 1370 (denying the petitions for panel rehearing and rehearing en banc)

^{551.} Compare id. at 1371-72 (Dyk, J., concurring in denial of rehearing en banc) (explaining that precedent shows that a district court's decision is not sufficiently (Cxplaining that precedent shows that a district court's decision is not sufficiently final to bar the preclusive effect of a final judgment by the USPTO), with id. at 1372 (O'Malley, J., dissenting from denial of rehearing en banc) (arguing that the majority's decision allows "a district court's final adjudication [to] be undone by later decisions of the [USPTO]"), and id. at 1382–83 (Newman, J., dissenting from denial of rehearing en banc) (expressing concern that the denial of rehearing en banc "destabilize[d] issued patents" because instead of finality after full litigation, patent validity rested with the USPTO).

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5,247,434 ("the '434 patent"), covering touchscreen interfaces for hemodialysis machines.⁵⁵² In 2003, Fresenius USA, Inc. ("Fresenius") filed a declaratory judgment action challenging the claims of the '434 patent as obvious.⁵⁵³ Baxter counterclaimed and Fresenius stipulated to infringement.⁵⁵⁴ In 2007, the district court entered JMOL in favor of Baxter, holding that Fresenius had failed to carry its burden of proof on the issue of invalidity.⁵⁵⁵ The Federal Circuit affirmed the validity decision in 2009 but remanded to the district court for reconsideration of the post-verdict damage award.⁵⁵⁶ In March 2012, the district court entered a damages award of over \$23 million but stayed execution of the award pending appeal of the USPTO's reexamination of the '434 patent.557

Concurrent with the district court litigation, Fresenius had successfully requested ex parte reexamination of the '434 patent.⁵⁵⁸ In March 2010, the Board of Patent Appeals and Interferences (now the PTAB) affirmed the examiner's rejection of Baxter's claims as obvious.⁵⁵⁹ That decision—directly contrary to the district court's February 2007 holding that the Federal Circuit affirmed in September 2009-was itself affirmed by the Federal Circuit in May 2012.⁵⁶⁰ The Federal Circuit's mandate issued in November 2012, and in April 2013, the USPTO issued a reexamination certificate canceling the '434 patent claims.⁵⁶¹

At the Federal Circuit, the USPTO's cancellation of the '434 patent divested Baxter of jurisdiction.⁵⁶² The 2-1 majority looked to the reexamination statute and its legislative history, and deferred to the USPTO.563

Baxter argued that the district court had already held the claims valid and, thus, issue preclusion applied.⁵⁶⁴ The Federal Circuit, however, held that the unexecuted judgment "was not sufficiently final" so as to preclude application of the intervening invalidity

564. Id. at 1340.

^{552.} Fresenius II, 721 F.3d at 1331-32.

^{553.} Id. at 1332.

^{554.} Id.

^{555.} Id. at 1332-33.

^{556.} *Id.* at 1333. 557. *Id.* at 1334.

^{558.} Id.

^{559.} Id. at 1335; see also supra note 533 (explaining that the AIA replaced the Board of Patent Appeals and Inferences with the PTAB).

^{560.} Fresenius II, 721 F.3d at 1333-35 (citing In re Baxter Int'l, Inc., 678 F.3d 1357 (Fed. Cir. 2012); Fresenius I, 582 F.3d 1288 (Fed. Cir. 2009)).

^{561.} Fresenius II, 721 F.3d at 1335. 562. See id. at 1340–41, 1344–45.

^{563.} See id. at 1339-40.

determination.⁵⁶⁵ In particular, the majority concluded that the litigation on remand had not "merged into a final judgment," meaning "one that ends the litigation on the merits and leaves nothing for the court to do but execute the judgment."566

Addressing the appellee's (and Judge Newman's) argument that action unconstitutionally violated separation-of-powers the principles,⁵⁶⁷ the majority cited Plaut v. Spendthrift Farm, Inc.⁵⁶⁸ as holding that appellate courts must follow the law "in effect at the time" it rules.⁵⁶⁹ Due to the unexecuted judgment, the Federal Circuit found that the case was still pending, vacated, and remanded with instructions to dismiss the district court's judgment in light of the USPTO ruling.570

In her dissent, Judge Newman argued (1) that the majority's holding violated the U.S. Constitution and (2) that the panel incorrectly held the action nonfinal.⁵⁷¹ Judge Newman reasoned that the validity issue was already resolved in the district court litigation and asserted that the ruling was "directly violative of the structure of government."572 She pointed out that nowhere does the reexamination statute mention the USPTO's ability to overrule a district court's judgment and concluded that Congress did not intend to construe it the majority's way.⁵⁷³

The appellants petitioned the Federal Circuit for panel rehearing and rehearing en banc, and the court denied both requests.⁵⁷⁴ The denial sparked three separate divergent commentaries.⁵⁷⁵ Judge Dyk, concurring in the denial of rehearing en banc, defended the panel's

^{565.} Id. at 1341.

^{566.} Id. (quoting Mendenhall v. Barber-Greene Co., 26 F.3d 1573, 1580 (1994)) (internal quotation marks omitted).

^{567.} Fresenius II, 721 F.3d at 1345; see id. at 1348-53 (Newman, I., dissenting) (referencing the majority's decision as an "assault on the principles of separation of powers"). 568. 514 U.S. 211 (1995).

^{569.} *Fresenius II*, 721 F.3d at 1345 (emphasis added) (quoting Thorpe v. Hous. Auth. of the City of Durham, 393 U.S. 268, 281 (1969)).

^{570.} Id. at 1347.

^{571.} Id. at 1347–48 (Newman, J., dissenting).

^{572.} *Id.* 573. *Id.* at 1352.

^{574.} Fresenius III, 733 F.3d 1369, 1370 (Fed. Cir. 2013) (en banc) (per curiam).

^{575.} Compare id. at 1370-71 (Dyk, J., concurring in denial of rehearing en banc) (arguing that the denial of rehearing reflected congressional will, which had recently been reaffirmed in section six of the AIA), with id. at 1372–73 (O'Malley, J., dissenting from denial of rehearing en banc) (stating that the denial of rehearing was a move "toward rendering district courts meaningless in the resolution of patent infringement disputes"), *and id.* at 1382 (Newman, J., dissenting from denial of rehearing en banc) (contending that instead of providing the finality of a full appeal, the denial of rehearing had left the question of patent validity open).

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decision, arguing that a plaintiff should not "be allowed to secure damages for infringement of a patent that has been conclusively found invalid by the [US]PTO."576 Judge O'Malley, also concurring, agreed that the USPTO may rule on the validity of a patent until a judgment award, but stated that the USPTO could not "dislodge the judgment for past infringement awarded to Baxter."577 Reflecting her dissenting panel opinion, Judge Newman's views went further. She wrote in her dissent to the denial of rehearing en banc that "an executive branch agency" cannot "override the judgments of Article III courts, on the same issue and the same premises between the same parties."578

The Fresenius II holding may have important ramifications for USPTO post-grant proceedings. If parties subject to an adverse judgment are still able to invalidate a patent, post-appeal challenges could obviate large damage payments after the district court awards them. Notably, some of the earliest post-grant trials before the USPTO, such as SAP America, Inc. v. Versata Development Group, Inc., 579 have found patent claims unpatentable after final district court judgments.580

2. Construing "contested cases" in the post-grant context: Subpoena power of the district courts for post-grant review in Abbott Laboratories v. Cordis Corp.

Sometimes cases are notable not for what they hold, but for the negative implications of their holding. For example, the Federal Circuit in Abbott Laboratories v. Cordis Corp. held that while subpoenas duces tecum are unavailable under the old inter partes reexamination procedure, they would be available in new post-grant review procedures.581

("Cordis") Cordis Corporation sued Abbott Laboratories ("Abbott") and another company for patent infringement of two

^{576.} Id. at 1370-72 (Dyk, J., concurring in denial of rehearing en banc) (citing John Simmons Co. v. Grier Bros. Co., 258 U.S. 82 (1922); Mendenhall v. Barber-Greene Co., 26 F.3d 1573 (Fed. Cir. 1994)).

^{577.} Id. at 1372–73 (O'Malley, J., dissenting from denial of rehearing en banc).

^{578.} Id. at 1572–75 (O kuman, J., dissenting from denial of rehearing en banc).
579. 107 U.S.P.Q.2d (BNA) 1097 (P.T.A.B. 2013).
580. See, e.g., id. at 1098 (holding that based on the record presented, Versata's claims were unpatentable under 35 U.S.C. § 101). The USPTO issued this final labels. written decision after "[t] he Federal Circuit affirmed the jury's infringement verdict and damages award but vacated and remanded a permanent injunction as overbroad." *Id.* (citing Versata Software Inc. v. SAP Am. Inc., 717 F.3d 1255 (Fed. Cir. 2013), cert. denied, 134 S. Ct. 1013 (2014)); see also infra notes 2325-35, 2418-40 (discussing *Versata* in further detail). 581. 710 F.3d 1318, 1322–26 (Fed. Cir. 2013) (explaining that Congress's 2011

amendment to the Patent Act indicates a legislative intent for 35 U.S.C. § 24 subpoenas to be available to the USPTO).

implantable drug-eluting stent patents.⁵⁸² The defendants subsequently filed requests for inter partes reexamination, which the USPTO granted.⁵⁸³ During the reexamination, Cordis obtained two subpoenas duces tecum from a district court ordering Abbott to produce documents Cordis hoped would evince copying and other secondary considerations supporting the validity of the contested claims.584 The district court complied and ordered Abbott to produce the documents.⁵⁸⁵ Cordis also petitioned the USPTO Director for explicit subpoena authorization, but the USPTO denied the petition.⁵⁸⁶ Abbott moved to quash the subpoenas.⁵⁸⁷ The district court granted the motion, citing the USPTO's denial as persuasive.⁵⁸⁸

As an issue of first impression, the Federal Circuit affirmed the district court's decision granting Abbott's motion to quash the subpoenas duces tecum issued under 35 U.S.C. § 24 for an inter partes reexamination.⁵⁸⁹ The Federal Circuit rejected Cordis's due process claims, indicating that the court was satisfied that the reexamination procedures afforded the parties notice and an opportunity to be heard.⁵⁹⁰ Section 24 makes subpoenas available from the clerk of a U.S. court in "any contested case in the [USPTO]."591 Relying on the plain text of § 24, adjacent statutory provisions, legislative history, and persuasive authority, the Federal Circuit construed the term "contested case" to mean proceedings involving the taking of depositions.⁵⁹² Noting that inter partes reexaminations do not allow for deposition testimony, the Federal Circuit held that the subpoenas were improper under § 24.⁵⁹³ In contrast, the panel held that "[US]PTO regulations providing for

^{582.} Id. at 1320; see also U.S. Patent No. 6,746,773 (filed Sept. 25, 2001); U.S. Patent No. 7,591,844 (filed Nov. 16, 2007).

^{583.} Abbott, 710 F.3d at 1320.

^{584.} Id. at 1321.

^{585.} Id.

^{586.} Id.

^{587.} Id.

^{588.} Id.

^{589.} Id. at 1322, 1328.

^{590.} Id. at 1328 ("We do not believe that, under the facts of this case, excluding compulsory production of testimony in inter partes reexamination proceedings raises a 'serious constitutional problem[].'" (alteration in original) (quoting Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council, 485 U.S. 568, 575, (1988)))

^{591. 35} U.S.C. § 24 (2012). ("The clerk of any United States court for the district wherein testimony is to be taken for use in any contested case in the Patent and Trademark Office, shall, upon the application of any party thereto, issue a subpoena for any witness residing or being within such district, commanding him to appear and testify" (emphasis added)). 592. *Abbott*, 710 F.3d at 1322. 593. *Id.* at 1327.

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depositions in patent proceedings apply exclusively to interferences, derivation proceedings, and the new Board proceedings created by the AIA."594 Thus, the court noted that, under the AIA, Congress had provided for the deposition of affiants in inter partes review proceedings, and the USPTO has interpreted these provisions as authorizing parties to seek § 24 subpoenas.⁵⁹⁵ By implication, subpoenas duces tecum are therefore available in post-grant review proceedings.

3. Estoppel over nonidentical claims—hints for PTAB claim estoppel: Ohio Willow Wood Co. v. Alps South, LLC

After the passage of the AIA and the creation of post-grant review proceedings, parties have sought guidance on how the estoppel provisions of the AIA might apply.⁵⁹⁶ Relatedly, in Ohio Willow Wood Co. v. Alps South, LLC, the Federal Circuit emphasized that collateral estoppel may apply where the patent claims are not identical to those previously held invalid, but the analysis should focus on the issues litigated in the earlier proceeding.⁵⁹⁷ Although this case involved estoppel based on a prior litigation, there is little reason to expect that decisions of the PTAB would use a dissimilar standard.

By way of background, Ohio Willow Wood Company ("OWW") had sued third party Thermo-Ply, Inc. for infringing U.S. Patent No. 7,291,182 ("the '182 patent"), which related to sock-like cushioning for prosthetic limbs.⁵⁹⁸ The district court found the '182 patent invalid as obvious, and the Federal Circuit affirmed this invalidity finding on appeal.⁵⁹⁹ The invalidated '182 patent was a continuation of U.S. Patent No. 5,830,237 ("the '237 patent").600

In an unrelated litigation, OWW sued Alps South, LLC ("Alps") for infringement of the '237 patent.⁶⁰¹ Applying collateral estoppel, the district court granted summary judgment of invalidity for Alps, even though the previously invalidated claims in the '182 patent were not

^{594.} Id.

^{595.} Id. at 1326.

^{596.} See 35 U.S.C. § 315(e)(2) (estopping an inter partes review petitioner from later raising—in court or at the ITC—any issues they "raised or reasonably could have raised")

^{597. 735} F.3d 1333, 1342 (Fed. Cir. 2013). The court also addressed obviousness involving the addition of numerical limitations in dependent claims and inequitable conduct. See infra notes 1492-1511 (obviousness); infra notes 1632–43 (inequitable conduct).

^{598.} Ohio Willow Wood, 735 F.3d at 1336.

^{599.} Id. at 1341.

^{600.} Id.

^{601.} Id.

identical to those in the '237 patent.⁶⁰² The Federal Circuit affirmed, noting that collateral estoppel applies when the distinction between the adjudicated patent claims and the unadjudicated patent claims do not substantially change the question of invalidity.⁶⁰³ Although the previously invalidated claims of the '182 patent used slightly different language to describe substantially the same invention, the mere use of different claim language in the '237 patent did not, in itself, create a new issue of invalidity.⁶⁰⁴ Thus, because OWW did not, for example, explain how the "polymeric" gel in the previously invalidated claims was patently significant as compared to the "block copolymer" gel of the '237 patent claims, the same ruling applied to both.605

B. PTAB Appeals from Examination

In In re Morsa,⁶⁰⁶ the Federal Circuit vacated a Board finding that a prior art reference was enabled and thus anticipated Morsa's patent application, affirmed the Board's obviousness conclusions, and remanded.⁶⁰⁷ The Board had rejected Steve Morsa's argument that the prior art reference lacked enablement because he relied only on attorney argument.⁶⁰⁸ In vacating, the Federal Circuit held that applicants could rely on the disclosure of the reference itself and were not required "to submit affidavits or declarations to challenge the enablement of prior art references."609

In 2001, Morsa applied for a patent to a method and apparatus for getting a benefit-information request from a user, searching a database to match the request, and returning the information to the user.⁶¹⁰ The examiner rejected his application as both anticipated and obvious due to a single prior art reference, the "Peter Martin Associates Press Release," which announced the release of a similar product in 1999.⁶¹¹ On Board appeal, Morsa argued three things: (1) the press release did not qualify as prior art; (2) the press release was not enabling, as its 117 words lacked sufficient detail; and (3) the differences between the press release and the application sufficed to

^{602.} Id. It also held the claims were invalid for obviousness and the parties acted equitably, thus avoiding an inequitable conduct ruling. Id.

^{603.} Id. at 1342 (citing Bourns, Inc. v. United States, 537 F.2d 486, 493 (Ct. Cl. 1976) (per curiam)).

^{604.} *Id.* at 1343. 605. *Id.*

^{606. 713} F.3d 104 (Fed. Cir. 2013), cert. denied, 134 S. Ct. 1317 (2014).

^{607.} Id. at 111.

^{608.} Id. at 110.

^{609.} Id. at 110-11.

^{610.} Id. at 106.

^{611.} Id. at 107.

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support a finding of nonobviousness, particularly in light of relevant objective factors.612

The Board disagreed on all three counts, finding that the press release was prior art, it was presumed enabling, and the rejections were mostly proper.⁶¹³ Specifically, the Board found that Morsa failed to present evidence of objective factors for the Board's consideration.⁶¹⁴ Despite this lack of evidence, the Board found that some of Morsa's claims were patentably distinct.⁶¹⁵

On appeal, the USPTO cited In re Antor Media Corp.⁶¹⁶ to argue that publications used as prior art are presumed enabling.617 The Federal Circuit held that the USPTO improperly presumed the prior art was enabling.618 The court held that an examiner must address an applicant's nonfrivolous argument that the cited prior art is not enabling.⁶¹⁹ Moreover, although an applicant may proffer affidavits or declarations in support of his position, the court declined to require expert testimony in all cases, such as where "a reference appears to not be enabling on its face."620

Because Morsa identified concrete reasons the press release lacked an enabling disclosure, the Board erred.⁶²¹ The Federal Circuit thus vacated the Board's enablement analysis as it related to the anticipation rejection, affirmed in part the Board's ultimate legal conclusions on obviousness, and remanded for further findings regarding anticipation.⁶²²

In one of this year's rare written affirmances of a USPTO appeal,⁶²³ a divided Federal Circuit in In re Hubbell⁶²⁴ affirmed the Board's

- 619. Id. at 110.
- 620. Id.
- 621. Id. at 110–11.
- 622. Id. at 106, 112.

^{612.} Id. at 109 ("Morsa continues to argue here on appeal that the PMA's publication date was after the date of his application."); id. ("Morsa also renews his argument that the PMA is not enabling."); id. at 111 ("The Board considered and rejected Morsa's arguments that objective factors weighed in favor of finding nonobviousness, stating that Morsa had failed to provide evidence of any of the objective factors. Our case law requires the Board to consider evidence of objective factors in any obviousness determination.").

^{613.} Id. at 108-12.

^{614.} Id. at 108.

^{615.} Id. at 108, 112.

^{616. 689} F.3d 1282 (Fed. Cir. 2012).

^{617.} *Morsa*, 713 F.3d at 110. 618. *Id.* at 110–11.

^{623.} The Federal Circuit routinely uses Federal Circuit Rule 36 to affirm USPTO appeals without a written decision, and has done so a number of times this year. See Fed. Cir. R. 36; see, e.g., Voda v. Medtronic, Inc., 541 F. App'x 1003 (Fed. Cir. 2013) (mem.) (per curiam).

^{624. 709} F.3d 1140 (Fed. Cir. 2013).

decision upholding an examiner's final rejection of an application directed to tissue-engineered proteins for obviousness-type double patenting over an issued patent.⁶²⁵ The judicially created doctrine of obviousness-type double patenting bars the issuance of claims that are patentably indistinct from those of an earlier-issued patent.⁶²⁶ The courts designed the doctrine to prevent the unjustified extension of a patent's term and to prevent multiple infringement suits by different assignees asserting essentially the same invention.⁶²⁷

The examiner finally rejected U.S. Patent Application No. 10/650,509 for obviousness-type double patenting in view of U.S. Patent No. 7,601,685 because both were drawn to tissue-regenerative protein matrices for wound healing.628 The application and conflicting patent shared two common inventors but had different inventive entities, owners, and assignees.⁶²⁹ The Board affirmed, rejecting Hubbell's argument that obviousness-type double patenting requires common ownership.630

On appeal, Hubbell argued first that nonidentical inventive entities bar parties from applying obviousness-type double patenting.⁶³¹ Alternatively, he argued that, as a matter of equity, the Board should allow him to obviate the rejection by filing a terminal disclaimer.⁶³²

A majority of the Federal Circuit held that, as stated in the Manual of Patent Examining Procedure ("MPEP"),⁶³³ obviousness-type double patenting does not require common ownership-a position supported by the court's prior case law.⁶³⁴ The majority also held that multiple assignees could still be subject to two separate suits for infringing two distinct sets of claims owned by two different parties.⁶³⁵ The Federal Circuit thus concluded that the Board properly affirmed the examiner's rejection.⁶³⁶ It also rejected a novel argument that the

631. *Id.* at 1145. 632. *Id.*

^{625.} Id. at 1142-43.

^{626.} Id. at 1145.

^{627.} Id. (citing In re Fallaux, 564 F.3d 1313, 1319 (Fed. Cir. 2009); In re Van Ornum, 686 F.2d 937, 943-44 (C.C.P.A. 1982)).

^{628.} Id. at 1142–44.

^{629.} Id. at 1143.

^{630.} Id. at 1144.

^{633.} Id. at 1146 (citing U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 804(I)(A) (8th ed. rev. 9, Oct. 2012)) (stating that while the MPEP is not binding, its provisions "may be given judicial notice to the extent they do not conflict with the statute" (quoting Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 964 (Fed. Cir. 2002))).

^{634.} Id. at 1146–47 (citing In re Fallaux, 564 F.3d 1313 (Fed. Cir. 2009); In re Van Ornum, 686 F.2d 937 (C.C.P.A. 1982)).

^{635.} Id. at 1147.

^{636.} Id. at 1150.

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court should equitably issue a terminal disclaimer at the request of the appellant.⁶³⁷

In dissent, Judge Newman argued that "double patenting does not apply when the application and patent are of separate ownership and have separate inventive entities."⁶³⁸ Judge Newman stated that even as double patenting law has changed, it has always required either common inventorship or common ownership and has always provided the "terminal disclaimer remedy for obviousness-type double patenting."⁶³⁹

In another rare written affirmance of a USPTO decision, the Federal Circuit in *In re Adler*⁶⁴⁰ affirmed the Board's decision upholding the examiner's final rejection as obvious and found that the Board did not rely on new grounds for rejection.⁶⁴¹ Under the Administrative Procedure Act (APA), the USPTO must "provide prior notice to the applicant of all 'matters of fact and law asserted' prior to an appeal hearing before the Board."⁶⁴² Accordingly, "when the Board relies upon a new ground of rejection not relied upon by the examiner, the applicant is entitled to reopen prosecution or to request a rehearing."⁶⁴³ When considering whether the Board issued a new ground of rejection, the ultimate question "is whether [applicants] have had fair opportunity to react to the thrust of the rejection."⁶⁴⁴

Adler's application, which was directed to a system for detecting blood through the walls of the human body (i.e., stomach lining, vessels, etc.), included a swallowable capsule with an in vivo imager.⁶⁴⁵ The examiner rejected the claims as obvious over several prior art references because "[i]t would have been obvious to one of ordinary skill in the art at the time... to incorporate a processor for the colorimetric analysis of video endoscopic data... to determine the presence of blood."⁶⁴⁶ The Board affirmed the rejection and found that in light of these references, it would have been obvious to compare reference values for healthy tissue and blood to determine whether images of the gastrointestinal tract showed a change in the

^{637.} *Id.* at 1149.

^{638.} Id. at 1150-51 (Newman, J., dissenting).

^{639.} *Id.*

^{640. 723} F.3d 1322 (Fed. Cir. 2013).

^{641.} Id. at 1324.

^{642.} *In re* Stepan Co., 660 F.3d 1341, 1345 (Fed. Cir. 2011) (quoting 5 U.S.C. § 554(b)(3) (2006)).

^{643.} In re Leithem, 661 F.3d 1316, 1319 (Fed. Cir. 2011).

^{644.} *Id.* (alteration in original) (quoting *In re* Kronig, 539 F.2d 1300, 1302–03 (C.C.P.A. 1976)).

^{645.} Id. at 1324; see U.S. Patent Application No. 10/097,096 (filed Mar. 14, 2002).

^{646.} Adler, 723 F.3d at 1325 (alteration in original).

level of red color content that correlates to the presence of blood.⁶⁴⁷ Adler argued the Board "failed to appreciate" the multiple comparison steps recited in the claims and that the Board's reasoning constituted improper new grounds for rejection.⁶⁴⁸

In upholding the Board's decision, the Federal Circuit first found that the underlying prior art references disclosed different, but predictable, variations of the combination sought.⁶⁴⁹ The Federal Circuit also found that the Board's reasoning was not a "new ground of rejection" because the examiner made the argument in his answer to the notice of appeal.⁶⁵⁰ Although the Board's explanation of the rejection may have been more detailed than the examiner's, the panel wrote, the additional detail did not amount to a new reason for rejection.⁶⁵¹ Moreover, Adler acknowledged the "new grounds" argument in his reply brief and thus not only "had the opportunity to respond," but also "in fact did respond[] to the thrust of the examiner's basis for rejecting the claims."652 Thus, Adler could not plausibly argue that the Board was introducing a new ground of rejection.⁶⁵³

The Federal Circuit reached a very different decision in In re Biedermann,654 in which it vacated and remanded a Board decision that affirmed the rejection of claims for obviousness where the Board had issued new grounds of rejection.⁶⁵⁵ Biedermann's application disclosed a bone screw with a shank and a holding portion for a rod connecting to other bone screws.656 The connecting rod is retained with a locking screw inserted between two leg portions via ninety-degree oriented flat threads, "sometimes referred to as square threads."⁶⁵⁷ The application described the threads as advantageously "avoid[ing] splaying of the holding portion's legs" and as "easy to produce."658

The examiner rejected the claims as obvious over a combination of three patents—or in the alternative, over two, while inherently teaching a missing element the third provided.⁶⁵⁹ The Board

^{647.} Id. at 1326.

^{648.} Id. at 1326-27.

^{649.} Id. at 1327 (finding that "[t] his is a predictable variation of the combination of" the prior art references).

^{650.} *Id.* at 1327–28.

^{651.} *Id.* at 1328. 652. *Id.*

^{653.} See id.

^{654. 733} F.3d 329 (Fed. Cir. 2013).

^{655.} Id. at 331.

^{656.} Id.

^{657.} Id.

^{658.} Id.

^{659.} Id. at 333-34; see also In re Best, 562 F.2d 1252, 1255 n.4 (C.C.P.A. 1977) ("There is nothing inconsistent in concurrent rejection for obviousness under 35 U.S.C. § 103 and for anticipation under 35 U.S.C. 102.").

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affirmed the rejection over two of the references and, for the first time, referred to a new reference, the Machinery's Handbook, allegedly as a "technical dictionary to confirm the meaning of terms used in the references."⁶⁶⁰ The Board denied the applicant's request for reconsideration, and the applicant appealed.⁶⁶¹

The Federal Circuit vacated the Board's rejection because the Board had found new motivation to combine the prior art, and also because its reliance on the Machinery's Handbook had substantive consequences to the rejection beyond filling in minor evidentiary gaps.⁶⁶² The Federal Circuit found that—whereas the examiner's motivation to combine the Cotrel and Steinbock references focused on the efficiency of a square thread—the Board asserted that the prior patents suggested the use of square threads to avoid splaying of the leg members.⁶⁶³ The Federal Circuit did not agree that the Board was merely reiterating the examiner's rejection in greater detail.⁶⁶⁴ To the contrary, because efficiency and the avoidance of splaying were different grounds forming the bases for different rejections, "the thrust of the rejection" changed when the Board presented its new factual basis.⁶⁶⁵

Regarding the Board's invocation of the Machinery's Handbook, the Federal Circuit determined that citation to and reliance on a new reference will ordinarily be considered tantamount to a new ground of rejection unless the reference is either: found a standard work; is a minor, judicially noticed fact; or is used to fill in the Examiner's evidentiary gaps to support a specific rejection ground.⁶⁶⁶ In this case, however, the Machinery's Handbook permitted the Board to associate the saw-tooth threads of Cotrel with the buttressed and square threads discussed in Steinbock—an association that played an important role in the Board's argument regarding the use of square threads to minimize splaying.⁶⁶⁷ The Federal Circuit thus vacated and remanded the Board's decision.⁶⁶⁸

^{660.} Biedermann, 733 F.3d at 334-35.

^{661.} *Id.* at 335.

^{662.} Id. at 338-39.

^{663.} Id. at 337–38.

^{664.} *Id.* at 338 ("The Board went beyond filling in gaps in the examiner's reasoning because it is not clear that the examiner's reasoning survived in the Board's rejection.").

Board's rejection."). 665. *Id.* at 338–39 (finding that the Board's identification of "machinability" as reason to combine was not the same as the examiner's "efficiency" argument and thus constituted an additional new ground for rejection).

^{666.} Id. at 338 (quoting In re Boon, 439 F.2d 724, 727-28 (C.C.P.A. 1971)).

^{667.} *Id.* at 338–39.

^{668.} Id. at 339.

C. PTAB Appeals from Reexamination

In Leo Pharmaceutical Products, Ltd. v. Rea, the Federal Circuit emphasized the importance of secondary indicia of nonobviousness in reexamination by reversing the Board's weighing of the indicia, obviousness determination, and claim construction.⁶⁶⁹ The examiner reexamined U.S. Patent No. 6,753,013 ("the '013 patent"), which was directed to a storage stable and nonaqueous topical composition comprising a vitamin D analog, a corticosteroid, and a solvent component for the treatment of psoriasis.⁶⁷⁰ The examiner finally rejected the '013 patent as obvious over three prior art references.⁶⁷¹ Leo Pharmaceutical Products, Ltd. ("Leo Pharmaceutical") appealed to the Board.⁶⁷² The Board construed the term "storage stable," relied on the examiner's findings and art, and found that the objective indicia of nonobviousness-unexpected results, commercial success, and "long felt but unsolved need"-did not overcome the rejection.⁶⁷³

The Federal Circuit reversed the Board's construction of "storage stable," finding that the Board erred in narrowing the definition to include only a single example from the specification. However, in a rare twist, the court declined to adopt its own construction by finding it unnecessary for the appeal.⁶⁷⁴ Nevertheless, the Federal Circuit applied the term when reversing the obviousness determination.⁶⁷⁵ The court held that the Board impermissibly used hindsight and incorrectly weighed the objective indicia of nonobviousness.⁶⁷⁶

The Federal Circuit found that the problem (storage stability of vitamin D analogs and corticosteroids in a single formulation) was not known in the art, that "possible approaches to solving the problem were not known or finite," that there was no reasonable expectation of successful results nor any direction in the prior art, and that there was a substantial time gap between the prior art and the filing date.⁶⁷⁷ The court thus reversed, without resorting to remand, and determined that the '013 patent was valid.⁶⁷⁸ Thus, the Federal Circuit again reversed the Board.

^{669. 726} F.3d 1346, 1348 (Fed. Cir. 2013). 670. *Id.* at 1348–49.

^{671.} See id. at 1350-51 ("Then the Board-relying on the examiner's findingsrejected the claims of the '013 patent as obvious over three prior art references.").

^{672.} See id. at 1348, 1350.

^{673.} Id. at 1350-52, 1359.

^{674.} Id. at 1352-53. 675. Id. at 1359.

^{676.} Id.

^{677.} Id. at 1356-57.

^{678.} Id. at 1359.

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In *Smith & Nephew, Inc. v. Rea*,⁶⁷⁹ the Federal Circuit reversed the Board's decision of nonobviousness by finding that no substantial evidence supported the Board's decision.⁶⁸⁰ The panel thus held invalid certain claims of U.S. Patent No. 7,128,744 ("the '744 patent").⁶⁸¹ The '744 patent—directed to a system for using plates to repair bone fractures—was not the first system of bone plates with locking screws.⁶⁸² The patent utilized bone screws and anchors inserted through plates to fix fractured bones and facilitate healing while lessening further fracture propagation.⁶⁸³ Upon reexamination, the examiner found the '744 patent claims obvious.⁶⁸⁴ The Board reversed and held certain claims of the '744 patent valid.⁶⁸⁵

Reversing the Board, the Federal Circuit—agreeing with the examiner—finally invalidated the '744 patent as obvious and provided a detailed analysis of the cited prior art references.⁶⁸⁶ Despite the deferential "substantial evidence" standard of review, the panel found "compelling evidence" of obviousness.⁶⁸⁷

The case turned on whether it would have been obvious to design a bone plate in which all the holes in the head portion were conically tapered and at least partially threaded to engage threaded "locking screws."⁶⁸⁸ The Federal Circuit pointed to four distinct errors made by the Board: first, that it would have been obvious to use a nonlocking screw in a threaded hole to provide compression; second, that the references did not limit the size of countersunk screws and, thus, appropriately shaped screws were obvious; third, that partially threaded holes, regardless of shape, could provide compression; and fourth, that the Board had not considered the Distal Radius Plate and Locking Reconstruction Plate devices when, in fact, the examiner had considered them and they remained part of the record.⁶⁸⁹ The court also discredited declaration testimony of the patent owner's expert, noting that "[e]xpert opinions that are contrary to admissions in the

- 684. *Id.* at 1375.
- 685. *Id.*
- 686. *Id.* at 1375–82. 687. *Id.* at 1380–81.

^{679. 721} F.3d 1371 (Fed. Cir. 2013).

^{680.} Id. at 1373.

^{681.} *Id.*

^{682.} *Id.* at 1374–75.

^{683.} *Id.* at 1373–74.

^{688.} *Id.* at 1374 (explaining that "compression (non-locking) screws draw the bone and the plate together for fracture reduction and quicker healing, while locking screws fix the relative position of the plate and bone," providing stability to weight-bearing bones).

^{689.} Id. at 1377–80.

specification do not create a factual issue."⁶⁹⁰ Thus, the court found the claimed improvements were "no more than the predictable use of prior art elements according to their established functions."⁶⁹¹ Accordingly, despite the substantial evidence standard of review, the Federal Circuit overturned the Board's reversal, reinstituted the results of the reexamination, and held the '744 patent invalid.

And the reversals continued. In *Randall Manufacturing v. Rea*,⁶⁹² an appeal from an inter partes reexamination, the Federal Circuit held that the Board failed to consider many available patents as extrinsic evidence of the level of ordinary skill in the art.⁶⁹³ The court held that the Board also failed to provide a motivation to combine references under 35 U.S.C. § 103, and thus vacated and remanded.⁶⁹⁴

The court determined that the Board, in considering the patentability of claims to ceiling-mounted shipping container partitions, failed to consider the many background references "cited as evidence of the knowledge of one of skill in the art."⁶⁹⁵ Instead, the Board concluded from "the content of the prior art relied upon" that modification of the Aquino reference for ceiling stowage "simply does not follow" and "would [not] have been contemplated" because "there is no need or intent for such a position."⁶⁹⁶

Reviewing the governing legal standards de novo, the Federal Circuit first noted that the Supreme Court in *KSR International Co. v. Teleflex Inc.*⁶⁹⁷ had "criticized a rigid approach to determining obviousness based on the disclosures of individual prior-art references" and, in "[r]ejecting a blinkered focus on individual documents," required parties to look at the prior art in context.⁶⁹⁸ The Federal Circuit admonished the Board for having "[r]un afoul of that basic mandate."⁶⁹⁹ Thus, the Board failed to consider background information to explain the ease with which one skilled in

699. Id.

^{690.} *Id.* at 1380 n.6.

^{691.} *Id.* at 1381 (quoting KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 417 (2007)) (internal quotation marks omitted).

^{692. 733} F.3d 1355 (Fed. Cir. 2013).

^{693.} *Id.* at 1362–63 ("One form of evidence to provide such a foundation, perhaps the most reliable because not litigation-generated, is documentary evidence consisting of prior art in the area.... The Board's failure to consider that evidence—its failure to consider the knowledge of one of skill in the art appropriately—was plainly prejudicial.").

^{694.} *Id.* at 1363.

^{695.} *Id.* at 1356–57, 1361.

^{696.} Id. at 1361 (citations omitted) (internal quotation marks omitted).

^{697. 550} U.S. 398 (2007).

^{698.} Randall, 733 F.3d at 1362 (citation omitted).

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the art could have combined the references to create the invention when it ignored Randall's additional evidence.⁷⁰⁰

The court emphasized the importance of extrinsic evidence to define the level of ordinary skill in the art, and indicated that documentary prior art is "perhaps the most reliable" because it is not generated by litigation.⁷⁰¹ Considering the prior art patents raised by the challenger, for example,

[o]nce it is established that a prevalent, perhaps even predominant, method of stowing a bulkhead panel was to raise it to the ceiling, it is hard to see why one of skill in the art would not have thought to modify Aquino to include this feature-doing so would allow the designer to achieve the other advantages of the Aquino assembly while using a stowage strategy that was very familiar in the industry.⁷⁰²

In contrast, the Federal Circuit affirmed the Board-both in various Rule 36 affirmances and also in written opinions. In Rexnord Industries, LLC v. Kappos,⁷⁰³ the Federal Circuit affirmed the Board's determination of no anticipation but reversed its determination of obviousness in an appeal from an inter partes patent reexamination.⁷⁰⁴ The patent at issue, U.S. Patent No. 6,523,680 ("the '680 patent"), claimed a mechanical conveyor belt formed of rows of belt modules interlinked by transverse rods.⁷⁰⁵ Generally, plastic webs between belt modules prevent pinching of fingers or other small objects between modules.⁷⁰⁶ The '680 patent illustrates this limitation with a figure showing an "[e]xample space" of "less than 10 mm."707

The patent owner, Habasit Belting, Inc. ("Habasit"), sued Rexnord Industries, LLC ("Rexnord") for infringement.⁷⁰⁸ Rexnord responded by requesting inter partes reexamination of the '680 patent, and the district court stayed proceedings pending its completion.⁷⁰⁹ On reexamination, Rexnord argued, among other things, that a less than 10 millimeter space was inherent in several

^{700.} Id. In a footnote, the Federal Circuit noted that although the examiner never made this argument, it was Randall's right as the appellee to defend the examiner's rejection on any ground presented in the record. Id. at 1363 n.3.

^{701.} Id. at 1362–63.

^{702.} *Id.* at 1363. 703. 705 F.3d 1347 (Fed. Cir. 2013).

^{704.} Id. at 1348.

^{705.} Id.

^{706.} Id.

^{707.} Id. at 1349.

^{708.} Id. at 1348.

^{709.} Id.

cited references.⁷¹⁰ The examiner found all claims invalid as anticipated and obvious, particularly because the references showed a space small enough to prevent pinching, and taught all other claim elements save the "less than 10 mm" space limitation.⁷¹¹

Habasit appealed to the Board, emphasizing that no reference taught the 10 millimeter maximum space and that some references showed belts with no space at all.⁷¹² Rexnord responded that one reference taught a web portion that partially covered those gaps, but the Board reversed by finding the claims neither anticipated nor obvious because no reference explicitly discussed the feature.⁷¹³ Rexnord requested a rehearing, emphasizing that several cited references inherently taught a space of less than 10 millimeters and that the creation of a space in the claimed range was "a mere design choice" in view of previously cited art.⁷¹⁴ Standing by the '680 patent's validity, the Board concluded that it did not need to address Rexnord's "new theory" because it was raised for the first time in the request for rehearing.715

The Federal Circuit reversed the Board, holding that Rexnord's "new theory" had previously been presented during reexamination.⁷¹⁶ Moreover, as an appellee, Rexnord could defend on any ground supported by the record, regardless of whether the appellant had raised the argument.⁷¹⁷ Finding that the references relied upon by the appellee had been presented during reexamination, the Federal Circuit allowed the appellee to raise the arguments on appeal and reversed the Board's decision that the claims were not obvious.⁷¹⁸ Agreeing that the "less than 10 mm space" limitation was not inherent in the prior art, the Federal Circuit affirmed the Board's decision that the claims were not anticipated.⁷¹⁹

But there were other reversals as well. In *Rambus Inc. v. Rea*,⁷²⁰ the Federal Circuit reviewed an invalidity decision made by the Board during reexamination proceedings.⁷²¹ Affirming the Board's claim

^{710.} Id. at 1354.

^{711.} *Id.* at 1353. 712. *Id.* at 1353–54.

^{713.} Id. at 1354.

^{714.} Id. at 1354–55 (internal quotation marks omitted).

^{715.} Id. at 1355. 716. Id. at 1355-56.

^{717.} Id. at 1356. 718. Id.

^{719.} Id.

^{720. 731} F.3d 1248 (Fed. Cir. 2013).

^{721.} Id. at 1250–51.

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construction and vacating the Board's obviousness decision, the Federal Circuit panel remanded for further proceedings.⁷²²

U.S. Patent No. 6,260,097 ("the '097 patent"), which was directed to dynamic random-access memory with a synchronous data transfer memory system, facilitated data transfer at twice the traditional rate.⁷²³ The '097 patent did this by alternating between the rising and falling edge of a digital clock signal (i.e., working on both the 1's and 0's, as they entered both the "on" and "off" states).⁷²⁴ Thus, every clock cycle of alternating current would yield *two* data transfers, rather than the traditional one, and thereby double data transfer speed.⁷²⁵ The USPTO initiated reexamination and found the '097 patent invalid over two references, an unexamined Japanese patent application and an Intel system manual and specification.⁷²⁶ The Board upheld the decision and Rambus Inc. ("Rambus") appealed.⁷²⁷

The Federal Circuit identified numerous errors in the Board's obviousness decision that required reversal.⁷²⁸ First, the Board erroneously applied a burden of proof requiring Rambus to affirmatively present evidence that skilled artisans would have been unable to modify a prior art reference.⁷²⁹ Second, the Board supplied novel reasons for combining art relied on in the reexamination.⁷³⁰ Unlike the situation in In re Adler,⁷³¹ these findings went beyond merely a more detailed discussion of the examiner's arguments and thus constituted new fact-finding in violation of the prior notice requirement imposed by 5 U.S.C. \S 554(b)(3).⁷³² Section 554(b)(3) requires the USPTO to provide notice to applicants of "all matters of fact and law" before it.733 Lastly, the Board improperly ruled that Rambus's objective evidence lacked the requisite nexus with the claimed invention merely because it "related to unclaimed features," such as the precise clock speed of a commercial embodiment.⁷³⁴

^{722.} *Id.* at 1255.

^{723.} *Id.* at 1250–51. 724. *Id.* at 1251.

^{725.} Id.

^{726.} *Id.*

^{727.} Id.

^{728.} Id. at 1255.

^{729.} Id. ("That was legal error.").

^{730.} Id.

^{731.} See 723 F.3d 1322, 1328 (Fed. Cir. 2013) (finding that the Board's explanation may be more in depth than the examiner's without violating the prior notice requirement); see supra text accompanying notes 640–53.

^{732.} Rambus, 731 F.3d at 1255.

^{733. 5} U.S.C. § 554(b)(3) (2012); accord Rambus, 731 F.3d at 1255.

^{734.} Rambus, 731 F.3d at 1256.

However, the Federal Circuit upheld the anticipation decision of the Board.⁷³⁵ The panel analyzed the construction of the terms "external clock signal" and "write request," and agreed with the USPTO's construction.⁷³⁶ Because the court agreed with the construction, it upheld the anticipation arguments.⁷³⁷ The Federal Circuit reversed, remanded, and instructed the Board to carefully consider the objective evidence of nonobviousness on Rambus's patented design as a whole.⁷³⁸

In Institut Pasteur v. Focarino,739 the Federal Circuit again held that the Board failed to adequately consider relevant objective indicia of nonobviousness and reversed or remanded the Board's decisions with respect to two of three Institut Pasteur patents found invalid during inter partes reexamination.⁷⁴⁰ As the Federal Circuit noted, Institut Pasteur researchers discovered highly specific group I intron-encoded ("GIIE") endonucleases encoded in the intervening sequences of yeast mitochondrial DNA, and in the early 1990s pioneered the use of these enzymes to modify targeted genetic sequences in eukaryotic cells.⁷⁴¹ Recognizing the usefulness of this approach, Institut Pasteur filed a series of patent applications directed to methods and tools for site-directed manipulation of eukaryotic chromosomes.742 The resulting patents at issue-U.S. Patent Nos. 7,309,605 ("the '605 patent"), 6,610,545 ("the '545 patent"), and 6,833,252 ("the '252 patent")-all claimed priority to a 1992 application and all simultaneously expired on May 6, 2012.743

In 2009, Precision BioSciences, Inc. filed requests for inter partes reexamination of four Institut Pasteur patents, including the three at issue in this appeal.⁷⁴⁴ The USPTO granted the reexamination, and the examiner invalidated a number of Institut Pasteur's claims under 35 U.S.C. § 103 for obviousness.⁷⁴⁵ The rejections were based on two scientific journal articles disclosing the use of a GIIE endonuclease to transfer DNA from a plasmid to a nonchromosomal DNA in prokaryotic (bacterial) cells.⁷⁴⁶ The examiner held that it would have

- 738. Id. at 1258.
- 739. 738 F.3d 1337 (Fed. Cir. 2013). 740. *Id.* at 1338–39.
- 741. Id. at 1339.
- 742. Id. at 1340.
- 743. Id. at 1338, 1340.
- 744. Id. at 1341.
- 745. Id. at 1339, 1341.
- 746. Id. at 1342.

^{735.} *Id*. at 1254.

^{736.} *Id.* at 1252–54. 737. *Id.*

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been obvious to substitute eukaryotic chromosomal DNA for prokaryotic DNA and thus invalidated Institut Pasteur's claims.⁷⁴⁷ On appeal, the Board affirmed, finding the claimed inventions were "obvious extensions of [the] two prior-art references."⁷⁴⁸ The Board discounted objective secondary evidence of industry praise, copying, and licensing as not outweighing "the strong case of obviousness."749

With respect to the '605 patent, the Federal Circuit noted that the patent expired and Institut Pasteur only presented substantively amended claims.⁷⁵⁰ Because the USPTO could not issue claims of substantially different scope after the term of the '605 patent had expired, the court held that the appeal of that patent was moot.⁷⁵¹

Turning to the '545 patent, the Federal Circuit held that the Board erred in concluding that a person of ordinary skill in the relevant art would have expected that a GIIE endonuclease would successfully promote targeted gene transfer in eukaryotic cells, thus providing motivation to try and rendering the variation obvious under § 103.752 Relying on KSR, the court stated that the Board "failed to give proper consideration to at least two categories of evidence"-(1) teaching away in the prior art and (2) industry praise and licensing.⁷⁵³ Regarding the former, neither the Board nor the opposing party could refute the clear teaching that the use of GIIE to create doublestranded breaks in chromosomal DNA could be highly toxic to eukaryotic cells.⁷⁵⁴ Absent such evidence, no person of ordinary skill in the art would have expected success.⁷⁵⁵ Likewise, the strong evidence of industry praise, acceptance, copying, and licensing overcame the Board's opinion that the claims were obvious.756

Finally, the court noted that the parties agreed that the claims of the '252 patent required less than the claims of the '545 patent, and thus applied the same reasoning to the broader claims of the '252 patent.⁷⁵⁷ The court added that "[t]he Board identified only a single reason that one of ordinary skill in the art would have attempted" the claims at issue-to apply the GIIE-based methods to mammalian (and

749. Id. (internal quotation marks omitted).

751. Id.

- 753. Id. 754. Id. at 1345.
- 755. Id. at 1346.
- 756. Id. at 1344, 1347-48.
- 757. Id. at 1348.

^{747.} *Id.* at 1341.748. *Id.* at 1338.

^{750.} Id. at 1343.

^{752.} Id. at 1344.

theoretically, eventually human) cells.⁷⁵⁸ Finding this motivation broad, conclusory, and rebutted under the discussion of the narrower '545 patent claims, the court remanded the '252 patent to the Board for further consideration of the objective-indicia evidence.759

Thus, the Board (1) dismissed the appeal on the '605 patent as moot; (2) reversed the Board on the '545 patent; (3) vacated the appeal decision on one of the three patents at issue; and (4) remanded for further proceedings on whether motivation existed "at the relevant time" to combine and to fully consider the secondary indicia previously presented.⁷⁶⁰

D. PTAB Appeals from Interferences

In Sanofi-Aventis v. Pfizer Inc.,⁷⁶¹ the Federal Circuit affirmed in full one of the two interference proceedings meriting a published opinion in 2013.762 The court framed the issue on appeal as whether Pfizer Inc. ("Pfizer"), the junior party, had established conception and reduction to practice of cDNA encoding regulatory cytokine interleukin 13 ("IL-13") before Sanofi-Aventis's ("Sanofi") priority date.⁷⁶³ The Board held that Pfizer had overcome that heavy burden and the Federal Circuit affirmed.⁷⁶⁴

The Board found that Pfizer had isolated cDNA encoding IL-13, identified its structural characteristics, and appreciated that it encoded the full-length sequence prior to the critical date.⁷⁶⁵ And although Pfizer's original sequence analysis contained a number of errors-including one that changed the amino acid sequence of the encoded polypeptide-the Board held that Pfizer had established conception and reduction to practice before Sanofi's priority date.⁷⁶⁶

Sanofi argued that Fiers v. Revel⁷⁶⁷ and Burroughs Wellcome Co. v. Barr Laboratories, Inc.⁷⁶⁸ established that the conception of DNA required the party to possess the full and correct nucleotide sequence per se.⁷⁶⁹ The Federal Circuit, however, indicated that the entire chemical structure, such as a complete nucleotide or protein sequence, was not

- 761. 733 F.3d 1364 (Fed. Cir. 2013).
- 762. *Id.* at 1369. 763. *Id.* at 1366.
- 764. Id. at 1369.
- 765. Id. at 1368.
- 766. *Id.* at 1367. 767. 984 F.2d 1164 (Fed. Cir. 1993).
- 768. 40 F.3d 1223 (Fed. Cir. 1994).
- 769. Pfizer, 733 F.3d at 1368.

^{758.} Id. at 1348–49.

^{759.} Id. at 1348.

^{760.} Id. at 1349-50.

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always necessary to establish conception.⁷⁷⁰ In particular, the court pointed to *Enzo Biochem, Inc. v. Gen-Probe Inc.*,⁷⁷¹ in which the court upheld claims to DNA probes deposited with the ATCC, a global nonprofit bioresource center, even though the party had not determined the nucleotide sequences.⁷⁷² Thus, the court held that a full, correct sequence is not an absolute requirement for conception of an isolated DNA "[w]hen the subject matter is a DNA segment, [and] conception requires possession and appreciation of the DNA segment that is claimed."⁷⁷³

Agreeing with the Board, the Federal Circuit found that Pfizer had satisfied the articulated standard and sufficiently characterized the IL-13 cDNA "so as to distinguish it from other materials, and to define how to obtain it."⁷⁷⁴ The Federal Circuit thus affirmed the Board's ruling that Pfizer had carried the heavy burden of a junior party in an interference proceeding and awarded priority to Pfizer.⁷⁷⁵

E. Patent Appeals from the U.S. International Trade Commission

The ITC enforces cross-border intellectual property disputes through section 337 of the Tariff Act of 1930.⁷⁷⁶ The ITC conducts trial-like "investigations" involving substantive patent, trademark, copyright, and trade secret disputes, among other common law unfair trade practices.⁷⁷⁷ In recent years, the forum has been home to many high-profile disputes over mobile phone technology informally dubbed the "smartphone patent wars."⁷⁷⁸ A number of those cases came to a head in 2013, thus inching closer to final resolution. The ITC in 2013 reviewed five key appeals from the smartphone patent wars, an important ruling on domestic industry,

^{770.} *Id.* at 1368–69.

^{771. 323} F.3d 956 (Fed. Cir. 2002).

^{772.} Id. at 966-70; see also Pfizer, 733 F.3d at 1368.

^{773.} Pfizer, 733 F.3d at 1369.

^{774.} *Id.* (quoting Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1206 (Fed. Cir. 1991)) (internal quotation marks omitted).

^{775.} Id.

^{776.} *See* 19 U.S.C. § 1337 (2012) (forbidding unfair methods of competition and unfair acts in the importation of articles into the United States, including the importation of articles that infringe value and enforceable U.S. patents).

^{777.} See id. § 1337(b)–(c) (highlighting that if the ITC finds a violation during the investigation, it may forbid the articles concerned from entering the United States).

^{778.} See, e.g., Smartphone Patent Wars, WIKIPEDIA, http://en.wikipedia.org/wiki/Smart phone_patent_wars (last updated Apr. 23, 2014, 11:12 PM) (providing a surprisingly detailed listing and account of the many claims between players in the global smartphone industry); see also Suzanne Cunningham, Mobile Patent Suits, THOMSON REUTERS (Aug. 17, 2011), http://blog.thomsonreuters.com/index.php/mobile-patent -suits-graphic-of-the-day (providing a definitive—though now outdated—graphical representation of the smartphone patent wars, which appeared in a number of national daily newspapers).

and another highly anticipated ruling finding induced infringement unavailable where the underlying infringement occurs domestically. The court's induced infringement ruling provides clarity but bodes ill for parties seeking to assert method claims under a theory of induced domestic infringement.779

In the first of the cell phone cases, InterDigital Communications, LLC v. International Trade Commission⁷⁸⁰ (InterDigital II), the Federal Circuit denied a petition for panel rehearing and rehearing en banc concerning the domestic industry requirement of section 337 of the Tariff Act of 1930.⁷⁸¹ In doing so, the court found that a party's patent licensing activities alone may satisfy this requirement, even if no domestic industry manufactures the patent-protected articles.⁷⁸²

As background, by statute, any importer found competing unfairly with a "domestic industry" can have its imports excluded from the United States and, in some cases, seized and forfeited.⁷⁸³ The domestic industry requirement "with respect to articles protected by the patent"784 can be satisfied by showing that there exists in the United States "(A) significant investment in plant and equipment; (B) significant employment of labor or capital; or (C) substantial investment in its exploitation, including engineering, research and development, or licensing."785

In this case, InterDigital Communications, LLC and InterDigital Technology Corporation (collectively "InterDigital") filed an ITC complaint alleging Nokia Inc. and Nokia Corporation (collectively "Nokia") infringed two patents.786 The action was instituted, and the ITC affirmed the administrative law judge's ("ALJ") finding of no infringement.⁷⁸⁷ In InterDigital Communications, LLC v. International Trade Commission⁷⁸⁸ (InterDigital I), the Federal Circuit reversed the ITC, holding that the patents infringed and that the ITC erred by

^{779.} See Suprema, Inc. v. Int'l Trade Comm'n, 742 F.3d 1350, 1375-76 (Fed. Cir. 2013) (Reyna, J., concurring in part and dissenting in part) (finding that the majority holding creates loopholes that enable foreign competitors to infringe domestic patents).

^{780. 707} F.3d 1295 (Fed. Cir. 2013) (en banc) (per curiam).

^{781.} Id. at 1297–98.

^{782.} *Id.* 783. *See id.* at 1300 (citing 19 U.S.C. § 1337(a)(2)-(3)(2012)); *see also* 19 U.S.C. § 1337(d) (exclusion from entry); 19 U.S.C. § 1337(i) (seizure and forfeiture).

^{784.} *InterDigital II*, 707 F.3d at 1298 (internal quotation marks omitted).
785. 19 U.S.C. § 1337(a) (3).

^{786.} InterDigital Commc'ns, LLC v. Int'l Trade Comm'n (InterDigital I), 690 F.3d 1318, 1323 (Fed. Cir. 2012), reh'g and reh'g en banc denied, 707 F.3d 1295, and cert. denied, 134 S. Ct. 469 (2013).

^{787.} Id. at 1324.

^{788. 690} F.3d 1318 (Fed. Cir. 2012), reh'g and reh'g en banc denied, 707 F.3d 1295 (Fed. Cir. 2013) (per curiam), and cert. denied, 134 S. Ct. 469 (2013).

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incorrectly construing claim terms.⁷⁸⁹ The court dismissed Nokia's argument that InterDigital did not satisfy the domestic industry requirement, instead finding that InterDigital's patent-licensing activities alone sufficed.⁷⁹⁰ Nokia petitioned for panel rehearing and rehearing en banc on a single issue: whether InterDigital's licensing alone satisfied section 337's domestic industry requirement.⁷⁹¹

The Federal Circuit denied the petition and analyzed the text of the domestic industry requirement of subsections 337(a)(2) and (3).⁷⁹² Focusing on the phrase "with respect to the articles protected by the patent" in section 337(a)(3), the court found that any "substantial investment" under section 337(a)(3)(C) "means that the engineering, research and development, or licensing activities must pertain to products that are covered by the patent that is being asserted."⁷⁹³ In this case, the court found that InterDigital's extensive licensing activities were a "classic case for the application of subparagraph (C)," as InterDigital "licenses its wireless technology and patents to significant handset and device manufacturers throughout the world," granting them significant revenue streams, salaries, and benefits for InterDigital employees doing the licensing work in the United States.794

Considering the legislative history, the court noted that Congress had considered proposals to expand the overall coverage of section 337 to American industries that did not manufacture products stateside (or at all) but were engaged in engineering, research, development, or licensing of technology other manufacturers could use.⁷⁹⁵ The resulting bill was a compromise that "retained the industry requirement but made clear that it would not be necessary for a complainant to prove that patent-protected goods were being produced in this country."⁷⁹⁶ The court distinguished the cases cited by Nokia and concluded that section 337 is satisfied regardless of whether the party manufactures the patented product-so long as the party seeking relief has a substantial investment in the protected patent to satisfy the domestic industry requirement.

^{789.} Id. at 1330; see also John R. Magnus & Sheridan S. McKinney, 2012 International Trade Law Decisions of the Federal Circuit, 62 AM. U. L. REV. 963, 980-91 (2013) (analyzing *InterDigital I* in further detail). 790. *InterDigital I*, 690 F.3d at 1329–30.

^{791.} InterDigital II, 707 F.3d at 1297.

^{792.} Id. at 1296–97; see 19 U.S.C. § 1337(a) (2)–(3) (2012). 793. InterDigital II, 707 F.3d at 1297–98.

^{794.} Id. at 1298–99.

^{795.} Id. at 1300.

^{796.} Id. at 1301-02.

Judge Newman dissented.⁷⁹⁷ She found that "[t]he purpose of the licensing amendment to [s]ection 337 was to enlarge the benefit and incentive to domestic industry by giving licensors" ITC access, but that the "amendment did not eliminate the domestic industry requirement."⁷⁹⁸ She argued that the decisions Nokia cited, as well as others, conflicted with the majority's ruling, and would have held that the domestic industry requirement cannot be met by licensing alone.⁷⁹⁹

In another appeal from the same case, *InterDigital Communications*, *LLC v. International Trade Commission*⁸⁰⁰ (*InterDigital III*), the Federal Circuit reversed the ITC's order terminating an investigation in favor of arbitration pursuant to a prior patent license agreement between the parties and remanded to the ITC for further proceedings.⁸⁰¹ Importantly, the Federal Circuit delved into the scope of jurisdiction on appeal from an administrative agency.

InterDigital Communications, Inc., InterDigital Technology Corporation, and IPR Licensing, Inc. (collectively "InterDigital") licensed with LG Electronics, Inc., LG Electronics USA, Inc., and LG Electronics Mobilecomm USA, Inc. (collectively "LG").⁸⁰² The licenses at issue covered certain InterDigital patents on devices operating second- and third-generation (2G and 3G) wireless standards.⁸⁰³ The license terminated on the last day of 2010, but included a survival clause that provided LG with a "fully paid-up" license for the remainder of the life of InterDigital's patents for all 2G products and allowed either party to resolve disputes via arbitration.⁸⁰⁴ In 2011, InterDigital amended its ITC complaint, asserting that LG was importing wireless devices infringing patents related to its 3G wireless technology.⁸⁰⁵

Invoking the arbitration clause, LG moved to terminate.⁸⁰⁶ Over InterDigital's objections, the ALJ applied *Qualcomm Inc. v. Nokia Corp.*⁸⁰⁷ and granted LG's motion to terminate as to LG based on staying cases pending arbitration.⁸⁰⁸ Under *Qualcomm*, unless an assertion of arbitrability is "wholly groundless," a lower court presented

^{797.} Id. at 1304 (Newman, J., dissenting from denial of rehearing).

^{798.} Id.

^{799.} Id. at 1314–18.

^{800. 718} F.3d 1336 (Fed. Cir. 2013).

^{801.} Id. at 1338.

^{802.} Id.

^{803.} Id. at 1338–39.

^{804.} Id. at 1339 (emphasis omitted).

^{805.} Id. at 1340.

^{806.} Id.

^{807. 466} F.3d 1366, 1371 (Fed. Cir. 2006).

^{808.} InterDigital III, 718 F.3d at 1340.

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with a motion to stay pending arbitration should first determine whether the parties delegated arbitrability decisions to the arbitrator.⁸⁰⁹ The ALJ in InterDigital III held that the parties "clearly intended to delegate the guestion of arbitrability to an arbitrator."810 The ITC declined to review the ALJ's decision and InterDigital appealed.⁸¹¹

The Federal Circuit first needed to determine whether it had jurisdiction over an ITC termination that the ITC itself did not consider a final determination.⁸¹² Looking to precedent from its precursor, the U.S. Court of Customs and Patent Appeals, the panel first asked whether the decision's "effect upon appellants is the equivalent of a final determination."813 By analogizing to Farrel Corp. v. U.S. International Trade Commission,⁸¹⁴ the Federal Circuit found the arbitration appealable because the petitioner could not request reopening.⁸¹⁵ Conversely, if InterDigital filed a new complaint before the arbitrators determined whether the claims were subject to arbitration, any new complaint would be terminated in favor of arbitration.⁸¹⁶ In the interim, LG could continue to import its allegedly infringing devices.⁸¹⁷ Thus, the ITC's ruling had "the same operative effect, in terms of economic impact' as a final determination."818

On the merits, the Federal Circuit first generally approved of the Qualcomm framework applied by the ITC ALJ, agreeing that the parties clearly and unmistakably agreed to be bound by the arbitration clause in the license.⁸¹⁹ The court found, however, that the ALJ erred by finding LG's assertion of arbitrability was not "wholly groundless."820 To the contrary, upon analyzing the agreement, the court found LG's assertion of arbitrability under the agreement was wholly groundless because there was "no plausible argument that LG's license for 3G products survived the termination of the Agreement."821

Qualcomm, 466 F.3d at 1371. 809.

^{810.} InterDigital III, 718 F.3d at 1340.

^{811.} Id. at 1341.

^{812.} Id. 813. Id. at 1343 (quoting Import Motors, Ltd. v. U.S. Int'l Trade Comm'n, 530 F.2d 940, 944 (C.C.P.A. 1976)).

^{814. 949} F.2d 1147 (Fed. Cir. 1991).

^{815.} InterDigital III, 718 F.3d at 1344-45.

^{816.} Id.

^{817.} Id. at 1345.

^{818.} Id. (quoting Imperial Motors, 530 F.2d at 945-46).

^{819.} Id. at 1346.

^{820.} Id.

^{821.} Id. at 1347.

Judge Lourie dissented in part.⁸²² He agreed that there was no plausible argument for LG prevailing on the license but contended that the appeal should have been dismissed on jurisdictional grounds.⁸²³ He would have held that the court was without jurisdiction because the language of section 337 was clear and indicated that a termination in light of an arbitration agreement was "without . . . a determination."824

Apple Inc. v. International Trade Commission⁸²⁵ presented a different, if relevant, smartphone-related dispute. There, the Federal Circuit partially reversed, and thus remanded, an ITC holding that Googleowned Motorola Mobility, Inc. ("Motorola") infringed certain claims of Apple's U.S. Patent No. 7,663,607 ("the '607 patent"), but affirmed the ITC's finding of noninfringement of a second Apple patent, U.S. Patent No. 7,812,828 ("the '828 patent").826

On Apple's '607 patent, the Federal Circuit affirmed the ITC's determination that claims 1 through 7 were anticipated by the prior art but reversed and remanded the ITC on claim 10 over anticipation and obviousness.⁸²⁷ Previously, the ITC had investigated whether intervenor Motorola had infringed various claims of the two Apple smartphone touchscreen patents; the ITC had concluded that a prior art patent anticipated the asserted claims of the first '607 patent despite Apple's arguing conception prior to the prior art's filing date.⁸²⁸ Here, however, the court held that Motorola (the intervenor in the appeal) did not infringe the '828 patent and therefore affirmed the decision on that second patent.829

In the appeal, the Federal Circuit first held that the prior art could claim conception to an earlier provisional patent application, and thus qualified as prior art against the first Apple patent, the '607 patent.⁸³⁰ The court agreed that claims 1 through 7 were anticipated by the '607 patent, noting how similar the scanning algorithms were.⁸³¹ But the Federal Circuit reversed the ITC's decision on claim 10 of the '607 patent, finding that the ITC erred in holding a prior art reference incorporated by reference another patent.⁸³² Thus, the Federal Circuit

^{822.} *Id.* (Lourie, J., dissenting). 823. *Id.* at 1347–48.

^{824.} Id. at 1348 (quoting 19 U.S.C. § 1337(c) (2012)).

^{825. 725} F.3d 1356 (Fed. Cir. 2013).

^{826.} Id. at 1367-68.

^{827.} Id. at 1363, 1367.

^{828.} Id. at 1360-61. 829. Id. at 1368.

^{830.} Id. at 1363.

^{831.} Id.

^{832.} Id.

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found that the ITC had lacked substantial evidence to determine the patentability of claim 10, and remanded for further proceedings.⁸³³

While the Federal Circuit agreed with the ITC's finding that a separate reference did not anticipate claim 10, the court vacated the ITC's decision that the first Apple patent, the '607 patent, would have been obvious in light of the reference combined with an unexamined Japanese patent application.⁸³⁴ Apple asserted, and the Federal Circuit again agreed, that the ITC improperly ignored objective secondary considerations, and that "[t]his error was not harmless."⁸³⁵

Lastly, the Federal Circuit vacated the ITC's decision that Motorola did not infringe the second Apple patent, the '828 patent.⁸³⁶ The court first overturned the ITC's construction of the term "mathematically fitting an ellipse" and instead agreed with Apple's construction.⁸³⁷ Thus, the court vacated and remanded the ITC's decision on the '828 patent.⁸³⁸

Judge Reyna, concurring in part and dissenting in part, argued that, based on priority dates, the decision should have been remanded on anticipation.⁸³⁹ He further dissented to the majority's remand of the ultimate legal question of obviousness.⁸⁴⁰ He would have determined that claim 10 was not obvious as a matter of law, as "[o]bviousness is not shown when prior art gives only 'general guidance as to the particular form of the claimed invention or how to achieve it.'"⁸⁴¹ Judge Reyna, however, agreed that the ITC erred in not analyzing the objective evidence of "industry praise, copying, and commercial success."⁸⁴²

The previous case was not the only appeal from the ITC involving Motorola and mobile phones in 2013. Microsoft Corporation ("Microsoft") and Motorola both cross-appealed the results of another ITC investigation concerning mobile phone patent infringement. Specifically, Microsoft and Motorola each appealed from separate parts of a mixed ITC decision Microsoft brought over multiple patents.⁸⁴³ The ITC found violations of 19 U.S.C. § 1337

^{833.} *Id.* at 1367.

^{834.} Id. at 1364–65.

^{835.} *Id.* at 1366.

^{836.} Id. at 1368.

^{837.} Id. at 1367–68.

^{838.} Id. at 1368.

^{839.} Id. at 1376–77 (Reyna, J., concurring in part and dissenting in part).

^{840.} Id. at 1368–69.

^{841.} *Id.* at 1368–69, 1374 (quoting *In re* Rosuvastatin Calcium Patent Litig., 703 F.3d 511, 518 (Fed. Cir. 2012)).

^{842.} *Id.* at 1369.

^{843.} See Microsoft Corp. v. Int'l Trade Comm'n, 731 F.3d 1354, 1357 & n.1 (Fed. Cir. 2013).

over some of the patents, but no violation on others.⁸⁴⁴ In the first appeal, Microsoft Corp. v. International Trade Commission,⁸⁴⁵ the Federal Circuit handed Motorola (here an intervening party) a nearcomplete win. The court affirmed the ITC's findings of no violation by Motorola on three patents.⁸⁴⁶ However, the court partly reversed the ITC on a fourth patent because it found that the ITC incorrectly construed the claims.847

In 2010, Microsoft asked, and the ITC agreed, to investigate Motorola, whose mobile phones and tablets were claimed to infringe on nine Microsoft mobile device patents, four of which were relevant to this first appeal.⁸⁴⁸ The ALJ found otherwise, holding that the accused products did not infringe any of the four patents and that Microsoft had failed to prove the existence of a domestic industry supporting its claim against those products.⁸⁴⁹ Specifically, the ALJ concluded that Microsoft failed to show that the devices it used to demonstrate domestic industry actually implemented three of the patents.⁸⁵⁰ The ITC upheld the ALI's decision in full, and Microsoft appealed.851

The Federal Circuit affirmed the ITC's finding of noninfringement of one patent and affirmed that Microsoft failed to show a domestic industry with respect to two others.⁸⁵² The Federal Circuit agreed that Microsoft had substantially invested in its operating system and that the operating system was vitally important to mobile phones on which it runs.⁸⁵³ But that was not enough.⁸⁵⁴ The court found that 19 U.S.C. § 337 "unmistakably requires that the domestic company's substantial investments relate to actual 'articles protected by the patent."⁸⁵⁵ Here, the ITC cited substantial evidence supporting a finding that Microsoft did not meet this standard, whether through research and development or other investments.⁸⁵⁶

In the sole reversed issue, the Federal Circuit held that the ITC relied on a claim construction that improperly imposed "extraneous

- 848. Id.

851. Id.

- 853. Id. at 1361.
- 854. Id.

856. Id. at 1362.

^{844.} Id. at 1357.

^{845. 731} F.3d 1354 (Fed. Cir. 2013).

^{846.} *Id.* at 1357. 847. *Id.*

^{849.} Id. at 1357–58.

^{850.} Id. at 1358.

^{852.} Id. at 1368.

^{855.} Id. at 1361–62 (quoting 19 U.S.C. § 1337(a) (2)–(3) (2012)).

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restrictions" on the claim.⁸⁵⁷ The court was thus required to reverse the noninfringement finding "as to the main group of accused products," where no alternative grounds were advanced to support it.⁸⁵⁸ The court remanded, asking the ITC to reach the additional requirements for indirect infringement.⁸⁵⁹ The court stated that, on remand, the ITC should also address "the effect of infringement findings-direct infringement already established, indirect infringement possibly to be found on remand-on whether there [was] a section 337 violation and what remedy [was] appropriate."860

In the related cross-appeal, Motorola Mobility, LLC v. International Trade Commission,⁸⁶¹ Motorola argued that the ITC erred when it held the asserted claims of two of the other patents at issue valid.⁸⁶² A unanimous panel, however, disagreed with Motorola and affirmed the ITC's determination that Motorola violated § 337, and, additionally, that substantial evidence supported the ITC's ruling on the patents' validity.⁸⁶³

Motorola appealed the ITC's ruling on only one of the nine patents involved in the investigation-U.S. Patent No. 6,370,566 ("the '566 patent").⁸⁶⁴ The appeal involved an issue of claim construction-one that was never squarely addressed by either party-regarding the meaning of "synchronization component configured to synchronize."865 Specifically, Motorola argued that Apple's Newton MessagePad did have a synchronization component software that facilitated communication comprising and synchronization, as required by the '566 patent, and thus anticipated the asserted claims.⁸⁶⁶ Applying the ordinary meaning of the phrase, the Federal Circuit held that the transitive verb required more than whatever software would be needed for a mobile device to work in the first place.867

The ALJ held that a device manual or underlying device that was largely silent on any additional synchronization software did not inherently anticipate the claim.⁸⁶⁸ The Federal Circuit, applying the

860. Id.

^{857.} Id. at 1367.

^{858.} Id. at 1367-68.

^{859.} Id. at 1368.

^{861. 737} F.3d 1345 (Fed. Cir. 2013).

^{862.} Id. at 1347.

^{863.} Id. at 1346. The panel consisted of Chief Judge Randall Rader, Judge Sharon Prost, and Judge Richard Taranto. Id.

^{864.} Id. at 1346-47.

^{865.} Id. at 1349. 866. Id. at 1348-49.

^{867.} Id. at 1349.

^{868.} Id.

substantial evidence standard of review, deferred to the presiding judge's consideration of the testimony and evidence.⁸⁶⁹ Motorola's obviousness argument was similarly unavailing, as it only relied on one expert witness's admissions.⁸⁷⁰ The presiding ALJ found that the analysis was "conclusory and generalized," and rejected it, and the Federal Circuit deferred to that ruling.⁸⁷¹ Thus, Motorola failed to persuade the Federal Circuit that the ALJ erred in finding no inherent anticipation or obviousness and holding the '566 patent valid.⁸⁷²

In Motiva, LLC v. International Trade Commission,873 the Federal Circuit affirmed the ITC's decision that Nintendo Co., Ltd. and Nintendo of America, Inc. (collectively "Nintendo") did not violate § 337 because Motiva, LLC ("Motiva") lacked the economic prong of the domestic industry requirement, and thus standing, to bring a claim before the ITC.⁸⁷⁴ Motiva owns two patents related to systems for exercise and physical rehabilitation that guide user movements by interactive and sensory feedback similar to (Motiva claimed) the Nintendo Wii.⁸⁷⁵ From 2003 to 2007, Motiva made substantial investments to commercialize the technology but never got past the prototyping stage before ending all development activities in 2007.⁸⁷⁶ In 2008, Motiva sued Nintendo for infringement in district court; that court stayed the litigation pending the outcome of a reexamination on one of the patents at issue.877 Two years later, Motiva filed its complaint with the ITC.⁸⁷⁸ Nintendo then moved for summary judgment, arguing that Motiva lacked a domestic industry to protect.⁸⁷⁹ The ALJ granted summary judgment, and Motiva appealed.⁸⁸⁰

Motiva argued that its investment in litigation against Nintendo satisfied the economic prong of the domestic industry requirement because the threat of removing the Wii from the market through litigation was key to developing a "product-driven licensing business" that would encourage partners to incorporate its patented technology into a successful product.⁸⁸¹ The Federal Circuit, however, found that given the FTC's substantial evidence to the contrary, "[t]here [was]

^{869.} Id. at 1350–51.
870. Id. at 1350.
871. Id.
872. Id. at 1351.
873. 716 F.3d 596 (Fed. Cir. 2013).
874. Id. at 597, 601.
875. Id. at 597.
876. Id. at 598–99.
877. Id. at 597.
878. Id.
879. Id.
879. Id.
880. Id. at 598.

^{881.} *Id.* at 600.

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simply no reasonable likelihood that, after successful litigation against Nintendo, Motiva's patented technology would have been licensed by partners who would have incorporated it into 'goods practicing the patents."⁸⁸² Because lacking the economic prong of the domestic industry requirement jurisdictionally bars a party from bringing or maintaining an ITC action, the Federal Circuit affirmed the ITC's decision that Nintendo did not violate § 337.883

Last but certainly not least, in Suprema Inc. v. International Trade Commission,⁸⁸⁴ a Federal Circuit panel ruled unequivocally that the ITC may not grant exclusion orders for induced patent infringement where the required underlying act of direct infringement occurs after importation.⁸⁸⁵ The ruling may make it harder to enforce computer program patents in the ITC—for instance, where the imported device or software does not directly infringe the method without the actions of an end user or other later implementer.

This case arose from two claims appealed from an ITC investigation regarding biometric fingerprint scanners that Suprema, Inc., a Korean company, imported and that Mentalix, Inc. ("Mentalix"), an American company, purchased and used postimport.⁸⁸⁶ Cross Match Technologies, Inc. ("Cross Match"), a crossappellant and intervenor, averred that the parties infringed three Cross Match patents.⁸⁸⁷ Relevant to the first appeal, the ITC, agreeing with the ALJ, found that Mentalix directly infringed a claim of one patent by using its own software with imported Suprema scanners.⁸⁸⁸ It also found for the first time that Suprema induced that infringement.⁸⁸⁹ The ITC thus issued a limited exclusion order preventing those scanners from entering the United States.⁸⁹⁰

The Federal Circuit panel vacated and remanded for a much narrower limited exclusion order.⁸⁹¹ Judge O'Malley wrote that, to the contrary, "an exclusion order based on [patent or copyright infringement] may not be predicated on a theory of induced infringement where no direct infringement occurs until post-

^{882.} Id. at 601 (quoting InterDigital II, 707 F.3d 1295, 1299 (Fed. Cir. 2013) (en banc) (per curiam)).

^{883.} *Id.* 884. 742 F.3d 1350 (Fed. Cir. 2013).

^{885.} Id. at 1353.

^{886.} Id. at 1352–53, 1355.

^{887.} Id. at 1353, 1355; see U.S. Patent No. 7,203,344 (filed Jan. 16, 2003); U.S. Patent No. 7,277,562 (filed Aug. 1, 2003); U.S. Patent No. 5,900,993 (filed May 9, 1997).

^{888.} Suprema, 742 F.3d at 1355-56. The software, for those curious, is called FedSubmit. Id. at 1355.

^{889.} Id. at 1355.

^{890.} Id. at 1353.

^{891.} Id. at 1368.

importation.^{**892} The panel upheld an exclusion order over the products that directly infringed some of the claims at issue but remanded to the ITC to tailor the newer, more limited order.^{***}

Analyzing the statutory history and case law surrounding both 19 U.S.C. § 1337(a)(1)(B)(i) and 35 U.S.C. § 271(b), the panel concluded that induced infringement is not complete—and thus does not occur—until (1) a party culpably induces infringement and (2) an underlying direct infringement occurs.⁸⁹⁴ Because the act of direct infringement did not occur until *after* the importation, the court reasoned, the ITC has no authority to exclude articles that do not yet induce infringement.⁸⁹⁵

Judge Reyna dissented in part on the main point, taking a broader view of the relevant statutes. He argued that the majority overlooked the congressional purpose of § 337 as well as "the long established agency practice" of investigating based on induced infringement.⁸⁹⁶ He also argued that the majority overlooked related precedent by the Federal Circuit to do so.⁸⁹⁷ Thus, he concluded that "the majority has created a fissure in the dam of the U.S. border through which circumvention of [s]ection 337 will ensue, thereby harming holders of U.S. patents."⁸⁹⁸ He would have allowed induced infringement of method claims to premise an ITC exclusion order.⁸⁹⁹

IV. PATENTABILITY AND VALIDITY

In 2013, the Federal Circuit decided many cases that impacted the standards and precedent for patentability and validity determinations. These included the highly anticipated en banc decision in *CLS Bank International v. Alice Corp.*, which addressed whether computer-implemented method and system claims are patent-eligible subject matter under 35 U.S.C. § 101.⁹⁰⁰ Other significant decisions addressed written description under 35 U.S.C.

^{892.} *Id.* at 1353.

^{893.} *Id.* at 1352–53.

^{894.} *Id.* at 1360.

^{895.} Id. at 1360–61.

^{896.} *Id.* at 1372–73 & n.2 (Reyna, J., concurring in part and dissenting in part) (collecting cases that highlight the traditional stance held by the ITC to conduct unfair trade investigations where induced infringement is apparent).

^{897.} *Id.* at 1373 & n.4 (citing as authority ERBE Elektromedizin GmbH v. Int'l Trade Comm'n, 566 F.3d 1028 (Fed. Cir. 2009); Kyocera Wireless Corp. v. Int'l Trade Comm'n, 545 F.3d 1340 (Fed. Cir. 2008); and Alloc, Inc. v. Int'l Trade Comm'n, 342 F.3d 1361 (Fed. Cir. 2003)).

^{898.} Id. at 1372.

^{899.} Id. at 1377.

^{900. 717} F.3d 1269, 1273 (Fed. Cir.) (en banc) (per curiam), cert. granted, 134 S. Ct. 734 (2013).

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§ 112,⁹⁰¹ the on-sale and public-use bars,⁹⁰² and obviousness under 35 U.S.C. § 103.903

A. Patentable Subject Matter

The threshold question for patentability is whether the invention is patent-eligible subject matter. Patent-eligible subject matter is broadly defined in 35 U.S.C. § 101 as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."904 The three judicially defined categorical exceptions are "laws of nature, physical phenomena, and abstract ideas."905 As reflected in the 2013 Federal Circuit cases discussed below, determining whether a claim falls within one of the judicially created exceptions, and therefore is not patentable subject matter, has proven complicated for both the USPTO and the courts.

The leading 2013 Federal Circuit case on patentable subject matter was CLS Bank International v. Alice Corp.⁹⁰⁶ Contrary to the original panel decision,⁹⁰⁷ the en banc Federal Circuit affirmed the district court's holding that claims directed to methods, computer-readable media, and systems for computerized trading risk management were not eligible subject matters.⁹⁰⁸ No majority was reached, however, as to the rationale.909

^{901.} See In re Bimeda Research & Dev. Ltd., 724 F.3d 1320, 1324 (Fed. Cir. 2013) (affirming the Board's decision that a medical patent lacked written description support); Novozymes A/S v. DuPont Nutrition Biosciences APS, 723 F.3d 1336, 1346 (Fed. Cir. 2013) (holding that "no reasonable jury would find that the claims of the . patent meet the written description requirement of § 112"), *cert. denied*, 134 S. Ct. 1501 (2014); *see also infra* text accompanying notes 1160–91 (discussing these cases).

^{902.} See Hamilton Beach Brands v. Sunbeam Prods., Inc., 726 F.3d 1370, 1374 (Fed. Cir. 2013) (agreeing that a transaction with a foreign supplier before patenting was a sale for purposes of the on-sale doctrine); Dey, L.P. v. Sunovion, 715 F.3d 1351, 1353 (Fed. Cir. 2013) (deciding that one parties' claimed trials were not a public use to prevent another from patenting a similar formulation); see also infra text accompanying notes 1253–1304 (discussing these cases).

^{903.} See Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd., 719 F.3d 1346, 1348 (Fed. Cir. 2013) (affirming the district court's conclusion that combing two pharmaceuticals was "obvious" and thus invalidating the patent); Soverain Software LLC v. Newegg Inc., 705 F.3d 1333, 1336–37 (Fed. Cir. 2013) (reexamining a question of obviousness removed from the jury by the district court); see also infra text accompanying notes 1306–46, 1400–31 (discussing these cases). 904. 35 U.S.C. § 101 (2012).

^{905.} Bilski v. Kappos, 130 S. Ct. 3218, 3225 (2010) (quoting Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980)). 906. 717 F.3d 1269 (Fed. Cir.) (en banc) (per curiam), *cert. granted*, 134 S.

Ct. 734 (2013).

^{907.} CLS Bank Int'l v. Alice Corp., 685 F.3d 1341, 1343 (Fed. Cir.) (holding that the claims were patent-eligible subject matter), vacated en banc, 484 F. App'x 559 (Fed. Cir. 2012).

^{908.} CLS Bank, 717 F.3d at 1273.

^{909.} See id. (indicating that the court was "equally divided").

Alice Corporation Pty. Ltd. ("Alice") owned the patents-in-suit, which include U.S. Patent Nos. 5,970,479 ("the '479 patent"); 6,912,510 ("the '510 patent"); 7,149,720 ("the '720 patent"); and 7,725,375 ("the '375 patent").⁹¹⁰ The four patents share substantially the same specifications and are directed to "the management of risk relating to specified, yet unknown, future events."911 They "recite methods of exchanging obligations" (e.g., debt) between parties, "data processing systems," and "computer-readable media containing a program code for directing an exchange of obligations" that enables a trusted third party to settle obligations between first and second parties without a "settlement risk."912

CLS Bank International and CLS Services Ltd. (collectively "CLS "seeking a declaratory judgment of Bank") sued Alice. noninfringement, invalidity, and unenforceability as to the '479, '510, and '720 patents."913 Alice counterclaimed for infringement.914 CLS Bank subsequently moved for summary judgment, contending (among other things) that the asserted claims were invalid under 35 U.S.C. § 101.915 Alice filed cross motions for summary judgment.916 Both parties' motions were denied without prejudice so that they could be refiled after certiorari was granted by the Supreme Court in In re Bilski.⁹¹⁷

After the Supreme Court's decision in Bilski v. Kappos,918 the parties renewed their respective §101 summary judgment motions, including invalidity contentions for the '375 patent that had been added to the case.⁹¹⁹ The district court granted CLS Bank's motion and denied Alice's cross motion, holding that the asserted claims were not directed to patent-eligible subject matter.⁹²⁰ Alice appealed, and a Federal Circuit panel reversed, holding that the claims were directed to patentable subject matter.921

^{910.} Id. at 1274 (Lourie, J., concurring).

^{911.} Id. (internal quotation marks omitted).

^{912.} *Id.* 913. *Id.*

^{914.} Id. 915. Id. at 1275.

^{916.} Id.

^{917. 545} F.3d 943 (Fed. Cir. 2008) (en banc), cert. granted sub nom. Bilski v. Doll,

¹²⁹ S. Ct. 2735 (2009); *CLS Bank*, 717 F.3d at 1275. 918. 130 S. Ct. 3218, 3227–29 (2010) (rejecting the Federal Circuit's "machine-ortransformation" test as the only test to determine process-patent eligibility and recognizing that "business methods" are not categorically excluded from the scope of patentable subject matter under 35 U.S.C. § 101).

^{919.} CLS Bank, 717 F.3d at 1275 (Lourie, J., concurring).

^{920.} Id.

^{921.} Id. at 1273.

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On rehearing en banc, a majority of the Federal Circuit held that the asserted method and computer-readable media claims were not patentable subject matter under § 101, and thus affirmed the district court's grant of summary judgment to CLS Bank.⁹²² However, there was no majority opinion addressing the reasoning.⁹²³ "An equally divided" Federal Circuit affirmed the district court's finding that the system claims were not patent eligible.⁹²⁴ As Chief Judge Rader noted, "though much is published today discussing the proper approach to the patent eligibility inquiry, nothing said today beyond our judgment has the weight of precedent."⁹²⁵

Judge Lourie's concurrence, which Judges Dyk, Prost, Reyna, and Wallach joined, constitutes the case's plurality opinion.⁹²⁶ Before reviewing foundational § 101 precedent, Judge Lourie explained the basic steps in a patent-eligibility analysis.⁹²⁷ First, if the claimed invention is not "a process, machine, manufacture, or composition of matter," it is ineligible under § 101.⁹²⁸ Second, if the invention fits into one of these categories, the court must determine whether the claim is ineligible as a law of nature, natural phenomenon, or abstract idea.⁹²⁹ Claims must pass both tests to satisfy § 101.⁹³⁰

For his analysis of subject-matter eligibility, Judge Lourie first looked at the asserted method claims, finding claim 33 of the '479 patent representative.⁹³¹ This claim recites "[a] method of exchanging obligations as between parties," with steps that include "creating a shadow credit record," "obtaining from each exchange institution a start-of-day balance," "adjusting each respective party's shadow credit record or shadow debit record," and "instructing ones of the exchange institutions to exchange credits or debits."⁹³² Essentially, claim 33 is a method of reducing risk by facilitating trades between different parties.⁹³³ Alice and CLS Bank also agreed that, though not expressly stated in the claim, certain steps are computer implemented.⁹³⁴

As Judge Lourie stated, because the claim "plainly recites a process," the question is whether it "amounts to no more than a

^{922.} Id. (majority decision).

^{923.} See id.

^{924.} Id.

^{925.} Id. at 1292 n.1 (Rader, C.J., concurring in part and dissenting in part).

^{926.} Id. at 1273 (Lourie, J., concurring).

^{927.} See id. at 1276.

^{928.} Id. at 1277 (citing 35 U.S.C. § 101 (2012)).

^{929.} Id.

^{930.} *Id.*

^{931.} *Id.* at 1285. 932. *Id.*

^{933.} *Id.* at 1286.

^{934.} Id. at 1285.

patent-ineligible abstract idea."935 Judge Lourie found a method of reducing settlement risk by facilitating trades to be "a 'disembodied' concept" that, standing alone, is not patent eligible.⁹³⁶

Turning to the specified steps, Judge Lourie considered whether they added "significantly more" such that the process was not just an abstract idea.937 According to Judge Lourie, the steps of creating and maintaining shadow records, and integrating those records into exchange institution accounts, added no substantive value to the claim.⁹³⁸ Consequently, the claim was not patent-eligible subject matter.939

Judge Lourie specifically dismissed the implicit requirement for computer implementation as taking the claim beyond an abstract idea.⁹⁴⁰ According to Judge Lourie, "[u]nless the claims require a computer to perform operations that are not merely accelerated calculations, a computer does not itself confer patent eligibility."941 Computer implementation in this case thus failed to "materially narrow[] the claims relative to the abstract idea they embrace[d]."⁹⁴² The steps of creating credit records and providing end-of-day instructions were similarly rejected as failing to move the claim beyond an abstract idea.⁹⁴³ These were viewed as "no more than the necessary tracking activities" and "trivial limitations" that did not significantly narrow the abstract idea.⁹⁴⁴

In addition to the method claims, the patents-in-suit included computer-readable medium claims, also known as "Beauregard claims,"945 and system claims that expressly included a data storage unit and a computer.⁹⁴⁶ While recognizing that both "nominally recite[]" physical devices that would not require consideration of their "abstractness" as in the case of processes, Judge Lourie's view was that a § 101 analysis calls for examination of the actual claim language rather than drafting formalities.947 Applying this perspective, Judge Lourie found that both types of claims were really

^{935.} Id. at 1285-86.

^{936.} Id. at 1286 (quoting In re Alappat, 33 F.3d 1526, 1544 (Fed. Cir. 1994) (en banc)).

^{937.} Id. (internal quotation marks omitted).

^{938.} Id.

^{939.} Id. at 1287.

^{940.} Id. at 1286.

^{941.} Id.

^{942.} Id.

^{943.} Id. at 1286-87.

^{944.} Id. at 1287.

These claims are named after In re Beauregard, 53 F.3d 1583 (Fed. Cir. 1995). 945. *CLS Bank*, 717 F.3d at 1287 (Lourie, J., concurring). 946. *CLS Bank*, 717 F.3d at 1287, 1289 (Lourie, J., concurring). 947. *Id.* at 1288.

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method claims in disguise.⁹⁴⁸ Rather than providing any significant added "inventive concept," he viewed the system claims as no more than an abstract idea with computer implementation.⁹⁴⁹ In his view, abstract method claims do not become patent-eligible simply by integrating them with machines, computer language, or other patenteligible requirements without adding some inventive concept.950

Chief Judge Rader, concurring in part and dissenting in part, provided a detailed analysis of § 101 and its history.⁹⁵¹ After noting that the standard for patent-eligible subject matter was intentionally drafted broadly and that its judicial exceptions are limited,⁹⁵² he concluded that the relevant inquiry is whether a claim as a whole includes "meaningful limitations" that restrict it to an application from merely an abstract idea.⁹⁵³ The "as a whole" perspective is necessary because "[a]ny claim can be stripped down, simplified, generalized, or paraphrased to remove all of its concrete limitations, until at its core, something that could be characterized as an abstract idea is revealed."954 It would be improper for courts to venture for abstractions by dissecting and manufacturing the claims as the court wishes, all while disregarding the actual claim language and its limitations as written by the patentee.⁹⁵⁵ In this light, he would have affirmed the district court's finding that the method and media claims were not patent eligible, but reversed to find that the system claims were patent eligible.⁹⁵⁶

In drawing a line between claims that do and do not include such "meaningful limitations," Chief Judge Rader identified useful "guideposts" within Supreme Court precedent.⁹⁵⁷ On the one hand, "a claim is not meaningfully limited if it merely describes an abstract idea or simply adds 'apply it.'"958 Likewise, a claim is not meaningfully limited if it preempts all practical applications of an abstract idea, "contains only insignificant or token pre- or postsolution activity," or "if its purported limitations provide no real

^{948.} Id. at 1288, 1291.

^{949.} Id. at 1291.

^{950.} Id. at 1292.

^{951.} See id. at 1292, 1294–1305 (Rader, C.J., concurring in part and dissenting in part).
952. See id. at 1294–97.

^{953.} Id. at 1299 (emphasis omitted). Chief Judge Rader also provided "additional reflections" in which he counseled that "[w]hen all else fails, consult the statute!" Id. at 1333–36 (Rader, C.J., additional reflections).

^{954.} Id. at 1298 (Rader, C.J., concurring in part and dissenting in part).

^{955.} Id.

^{956.} Id. at 1292.

^{957.} Id. at 1299-1300.

^{958.} Id. (quoting Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1297 (2012)).

direction, cover all possible ways to achieve the provided result, or are overly-generalized."⁹⁵⁹ On the other hand, a process claim will be meaningfully limited (and patent-eligible subject matter) if its implementation requires a particular machine or provides a transformation of matter, or adds limitations (other than insignificant pre- or post-solution activity) essential to the invention.⁹⁶⁰

According to Chief Judge Rader, computer-specific limitations may, but do not necessarily, provide meaningful limitations to an abstract idea such that it becomes patent-eligible subject matter.⁹⁶¹

The key to this inquiry is whether the claims tie the otherwise abstract idea to a *specific way* of doing something with a computer, or a *specific computer* for doing something; if so, they likely will be patent eligible, unlike claims directed to *nothing more than the idea* of doing that thing on a computer.⁹⁶²

After reiterating that judicial exceptions to the broad scope of § 101 must be narrow and applying the presumption of validity under 35 U.S.C. § 282,⁹⁶³ Chief Judge Rader found that the asserted system claims recite "complex interrelated machine components that would squarely fit within the terms of [s]ection 101 and involve nothing theoretical, highly generalized, or otherwise abstract."964 Relying on detailed explanations in the patent specification for the computer system, including numerous flow charts, Chief Judge Rader found that the system limitations were integral and not mere post-solution activities.⁹⁶⁵ Nor, in his view, did the system claims preempt all methods of an abstract idea, which could be implemented without the specified data processing systems.⁹⁶⁶ To the contrary, the claims were "indistinguishable" from the patent-eligible subject matter in Diamond v. Diehr,⁹⁶⁷ when the abstract idea was "integrated into a system utilizing machines."968 For at least these reasons, Chief Judge Rader, joined by Judges Moore, Linn, and O'Malley, would have reversed the district court's determination that the system claims were patent-ineligible subject matter.⁹⁶⁹

^{959.} Id. at 1300–01.

^{960.} *Id.* at 1301.

^{961.} Id. at 1302.

^{962.} Id.

^{963.} Id. at 1304–05.

^{964.} Id. at 1306.

^{965.} *Id.* at 1307–08.

^{966.} *Id.* at 1309–10.

^{967. 450} U.S. 175 (1981).

^{968.} CLS Bank, 717 F.3d at 1311 (Rader, C.J., concurring in part and dissenting in part).

^{969.} *Id.* at 1313.

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As for the asserted method claims, Chief Judge Rader found that they recited no more than long-used, general steps "inherent in the concept of an escrow."970 Limiting the abstract escrow idea to a particular field of use does not make them patent eligible.⁹⁷¹ Thus, Judges Rader and Moore would have affirmed the district court's conclusion that the method and media claims were patent ineligible.⁹⁷² Judges Linn and O'Malley wrote separately with regard to these latter claims.⁹⁷³ While dispute remains regarding the patent eligibility of the claims, Chief Judge Rader, joined by Judges Moore, Linn, and O'Malley, sought remand for additional proceedings.⁹⁷⁴

Judge Moore, dissenting in part, further addressed the system claims and reiterated that she would have reversed the district court to find them patent-eligible subject matter.⁹⁷⁵ The focus of Judge Moore's opinion answered the rhetorical question: "if meaningfully tying a method to a machine can be an important indication of patent-eligibility, how can a claim to the *machine itself*, with all its structural and functional limitations, not be patent-eligible?"⁹⁷⁶ She observed that her colleagues who affirmed the invalidity of these claims "erroneously appl[ied] Prometheus's 'inventive concept' language by stripping away all known elements from the asserted system claims and analyzing only whether what remains, as opposed to the claim as a whole, [was] an abstract idea."977

Judge Moore looked to the language of the claims as a whole to assess their patent eligibility.⁹⁷⁸ She noted the multiple structural components (a computer, a first-party device, and a data storage device) and configurations to perform specific functions, and found that "[1]ooking at these hardware and software elements, it is impossible to conclude that this claim is merely an abstract idea."979 She also differentiated between patent-eligible subject matter and claims that meet all the requirements for patentability.980

Judge Moore cautioned that "if all of these claims, including the system claims, are not patent-eligible, this case is the death of

^{970.} Id. at 1312.

^{971.} *Id.* at 1312–13.972. *Id.* at 1313.

^{973.} Id. 974. Id.

^{975.} Id. at 1314 (Moore, J., dissenting in part).

^{976.} Id.

^{977.} Id. at 1315 (referencing Mayo Collaborative Servs. v. Prometheus Labs., Inc.,

¹³² S. Ct. 1289 (2012)).

^{978.} Id. at 1317.

^{979.} Id. at 1319–20.

^{980.} Id. at 1320-21.

hundreds of thousands of patents, including all business method, financial system, and software patents as well as many computer implemented and telecommunications patents."981 In her view, "[w]hen you walk up to the § 101 gate holding a computer in your arms (or software for that matter), you should not be rejected because your computer is an abstract idea."982

Judge Newman, concurring in part and dissenting in part, observed that the court's irresolution concerning § 101 "affects not only this court and the trial courts, but also [US]PTO examiners and agency tribunals, and all who invent and invest in new technology."⁹⁸³ The inconsistent precedent "demonstrates that an all-purpose bright-line rule for the threshold portal of section 101 is as unavailable as it is unnecessary."984 She specifically disagreed with using § 101 to determine whether a technical advance is patentable, and thought that it should not be used to resolve the policy question of "the public's right to study the scientific and technologic knowledge contained in patents."985

In view of the Federal Circuit's inability to define the scope of patent-eligible subject matter, Judge Newman proposed "returning to the time-tested principles of patent law" by holding that (1) the scope of patent-eligible subject matter is, as stated in §101, without consideration of abstractness or preemption; (2) patent eligibility does not depend on the form of the claim (e.g., whether drafted as a method or system); and (3) experimental use of patented information, whether "for basic or applied purposes," is not barred.986

Judges Linn and O'Malley, in their dissenting opinion, argued the claims should "rise and fall" together because they all contain the same meaningful limitation-a computer-based implementationthat renders them patent eligible.987 Thus, Judges Linn and O'Malley would have held that the method and media claims were patent eligible, just as they had for the asserted system claims.988

Shortly after CLS Bank, the Federal Circuit in Ultramercial, Inc. v. Hulu, LLC⁹⁸⁹ reversed and remanded the district court's judgment that the subject matter of U.S. Patent No. 7,346,545 ("the '545

^{981.} Id. at 1313.

^{982.} Id. at 1321.

^{983.} Id. (Newman, J., concurring in part and dissenting in part).

^{984.} Id.

^{985.} Id.

^{986.} Id. at 1322.

^{987.} *Id.* at 1327 (Linn, J., dissenting). 988. *Id.* at 1333.

^{989. 722} F.3d 1335 (Fed. Cir. 2013), *petition for cert. filed sub nom*. WildTangent, Inc. v. Ultramercial, LLC, 82 U.S.L.W. 3107 (U.S. Aug. 23, 2013) (No. 13-255).

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patent") was not a patent-eligible process under 35 U.S.C. § 101.⁹⁹⁰ The '545 patent claims an eleven-step method for Internet distribution of copyrighted products.⁹⁹¹ Ultramercial, Inc. and Ultramercial, LLC (collectively "Ultramercial") sued Hulu, LLC ("Hulu"), YouTube, LLC ("YouTube"), and WildTangent, Inc. ("WildTangent") for infringement of the '545 patent.⁹⁹² After Hulu and YouTube were dismissed from the case, WildTangent filed a motion to dismiss the case for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6).⁹⁹³ The district court granted WildTangent's motion to dismiss, concluding that the '545 patent did not claim patentable subject matter.⁹⁹⁴

Chief Judge Rader, writing on behalf of the Federal Circuit, addressed several preliminary issues raised by the district court in dismissing Ultramercial's complaint "without formally construing the claims and, further, without requiring defendants to file answers."⁹⁹⁵ The court explained that, because of the presumption of validity and the factual issues underlying a § 101 analysis, "it will be rare that a patent infringement suit can be dismissed at the pleading stage for lack of patentable subject matter."⁹⁹⁶ Further, while there is no established requirement for construing claims before addressing subject matter eligibility, "claim construction should be required" where factual issues are in dispute.⁹⁹⁷ Finally, the court explained that while "[c]onstruing every asserted claim and then conducting a § 101 analysis may not be a wise use of judicial resources," subject matter eligibility must be evaluated for each claim.⁹⁹⁸

With the foregoing preliminary considerations in mind, the Federal Circuit held that the district court erred in concluding the patentee was required to present claim construction showing that the claims were patent eligible.⁹⁹⁹ The Federal Circuit noted that the claims were presumed to be patent eligible, and that the district court should have either "required the defendant to establish that the only plausible construction was one that, by clear and convincing evidence rendered the subject matter ineligible," or should have "adopted a

^{990.} *Id.* at 1337.

^{991.} Id. at 1337-38.

^{992.} *Id.* 993. *Id.* at 1338.

^{994.} *Id.*

^{995.} *Id.*

^{996.} *Id.*

^{997.} *Id.* at 1339.

^{998.} Id. at 1340.

^{999.} Id. at 1349.

construction most favorable to the patentee."¹⁰⁰⁰ The court further held that for the dismissal under Rule 12(b)(6) to have been proper, "the complaint and patent must by themselves show clear and convincing evidence that the claim is not directed to an application of an abstract idea, but to a disembodied abstract idea itself."1001

Looking at the many steps recited in the claims, the court found that they "require intricate and complex computer programming ... performed through computers, on the internet, and in a cybermarket environment."¹⁰⁰² The court concluded that the district court erred in stripping these limitations from the claims and instead imagining some "core" of the invention.¹⁰⁰³ Rather than being an abstract idea, the court found, looking at a figure from the patent specification, that the claims were directed to "a specific application of a method implemented by several computer systems, operating in tandem, over a computer network."¹⁰⁰⁴ Accordingly, the district court had erred in deciding that the recited limitations did not meaningfully limit the abstract idea.¹⁰⁰⁵

The Federal Circuit also rejected the contention that software programming is ineligible subject matter or otherwise undeserving of patent protection.¹⁰⁰⁶ In this regard, it cited its prior decision in In re Alappat,¹⁰⁰⁷ in which the court reasoned that software programming essentially creates a patentable "new machine," a special purpose computer programmed to implement the specific software instructions.¹⁰⁰⁸ The court further noted that the Federal Circuit and the USPTO have long recognized that improvements to digital "through interchangeable software computers or hardware enhancements deserve patent protection."1009

Noting first that "the claims in this case [were] not highly generalized" and that the recited "steps [were] not inherent in the idea of monetizing advertising," the court addressed the breadth of the claims in not specifying a particular method for delivering the advertising content to the consumer.¹⁰¹⁰ The court held that a claim is not an "abstract idea" merely because it is broad or lacks of

^{1000.} Id.

^{1001.} Id.

^{1002.} Id. at 1350. 1003. Id.

^{1004.} Id. 1005. Id. at 1353.

^{1006.} Id.

³³ F.3d 1526 (Fed. Cir. 1994) (en banc). 1007.

^{1008.} Ultramercial, 722 F.3d at 1353.

^{1009.} Id.

^{1010.} Id.

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specificity.¹⁰¹¹ Moreover, § 101 is not the right tool to address these concerns, which are properly addressed under 35 U.S.C. § 112.1012

Finally, the court rejected the argument that the claims were to "a mathematical algorithm, a series of purely mental steps, or any similarly abstract concept."¹⁰¹³ The court distinguished the unpatentable mental steps addressed in CyberSource Corp. v. Retail Decisions, Inc.,¹⁰¹⁴ because the claims in Ultramercial "require[d], among other things, controlled interaction with a consumer over an Internet website," which is "something far removed from *purely* mental steps."¹⁰¹⁵

In a concurring opinion, Judge Lourie agreed with the court's reversal of the judgment on appeal and its remand for further proceedings, but explained that he would have followed the two-step inquiry outlined in CLS Bank,1016 which was derived from Mayo Collaborative Services v. Prometheus Laboratories, Inc.,¹⁰¹⁷ to determine patent eligibility under § 101.¹⁰¹⁸ Specifically, the court first determines whether the claimed invention fits within one of the four statutorily defined classes enumerated in § 101 and second determines whether any exceptions to subject-matter eligibility apply.¹⁰¹⁹

The next Federal Circuit case addressing § 101 was Accenture Global Services, GmbH v. Guidewire Software, Inc., where the Federal Circuit affirmed the district court's grant of summary judgment and held the system claims at issue patent ineligible under § 101.¹⁰²⁰ Accenture Services, GmbH and Accenture, LLP (collectively Global "Accenture") had sued Guidewire Software, Inc. ("Guidewire") for infringement of U.S. Patent No. 7,013,284 ("the '284 patent"), which discloses a computer program, including various data and controller components, directed to insurance-related tasks.¹⁰²¹ Guidewire asserted several affirmative defenses in response and moved for summary judgment, asserting that the claims were patent-ineligible subject matter.¹⁰²² In granting Guidewire's motion after the Supreme

1016. See supra text accompanying notes 927-30 (summarizing the two-step inquiry Judge Lourie outlined in CLS Bank).

1019. Id. at 1354–55 (quoting CLS Bank, 717 F.3d at 1281–82). 1020. 728 F.3d 1336, 1337–38 (Fed. Cir. 2013), petition for cert. filed, 82 U.S.L.W.

^{1011.} *Id.* 1012. *Id.* at 1353–54.

^{1013.} Id. at 1354.

^{1014. 654} F.3d 1366, 1373 (Fed. Cir. 2011).

^{1015.} Ultramercial, 722 F.3d at 1354.

^{1017. 132} S. Ct. 1289 (2012).

^{1018.} Ultramercial, 722 F.3d at 1354 (Lourie, J., concurring).

^{3469 (}U.S. Jan. 31, 2014) (No. 13-918).

^{1021.} *Id.* at 1337–39. 1022. *Id.* at 1339–40.

Court decided Bilski,¹⁰²³ the district court held that the '284 patent recited concepts for organizing data, not specific devices or systems, and merely limiting the claims to the insurance industry did not make them patent eligible.¹⁰²⁴

Accenture appealed the district court's holding only with respect to the system claims and not the court's judgment invalidating the method claims.¹⁰²⁵ However, the Federal Circuit affirmed the district court's finding of patent ineligibility as to the system claims both because the claims failed to offer any meaningful limitations beyond that found in the method claims and because, when viewed separately from the other claims, as directed in Mayo and the plurality opinion in CLS Bank, they failed to recite patent-eligible subject matter.¹⁰²⁶

The court's analysis focused on comparing the "substantive limitations" of the method and system claims to determine whether "the system claim offer[ed] a 'meaningful limitation' to the abstract method claim, which ha[d] already been adjudicated to be patentineligible."1027 Ultimately, the court concluded that "[b]ecause the system claim and method claim contain only 'minor differences in terminology [but] require performance of the same basic process,' they should rise or fall together."1028

According to the court, it was undisputed that system claim 1 "include[d] virtually the same limitations and many of the same software components as the patent-ineligible method claims."1029 Accenture relied on additional limitations in the system claims to differentiate from the method claims.¹⁰³⁰ The court looked to the patent specification and the method of claim 8 to conclude that each of these limitations was "present in the method claims, albeit without a specific reference to those components by name."¹⁰³¹ The court explained that, while system claims are not always found patentineligible because similar method claims are, a finding of ineligibility is inescapable when the two claim types appear in the same patent and contain the same insignificant meaningful limitations.¹⁰³²

^{1023.} Id. at 1340.

^{1024.} Id.

^{1025.} Id.

^{1026.} Id. at 1342.

^{1027.} Id. (quoting CLS Bank Int'l v. Alice Corp., 717 F.3d 1269, 1291 (Fed. Cir.) (en banc) (per curiam) (Lourie, J., concurring), cert. granted, 134 S. Ct. 734 (2013)). 1028. Id. at 1344 (second alteration in original) (citation omitted) (quoting CLS Bank, 717 F.3d at 1291 (Lourie, J., concurring)).

^{1029.} *Id.* at 1342. 1030. *Id.*

^{1031.} Id.

^{1032.} Id. at 1344.

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The court also addressed the system claims independently of the method claims and further found them to be invalid under § 101 because they "fail[ed] to include limitations that set them apart from the abstract idea of handling insurance-related information."¹⁰³³ In reaching this conclusion, the court found that the system claims, at their core, merely claimed the abstract idea of generating and organizing insurance-related tasks.¹⁰³⁴ Using this "abstract idea of the claim" as a starting point, the court conducted a preemption analysis, looking for "additional substantive limitations" that "narrow, confine, or otherwise tie down the claim," to determine whether the claim, in practical terms, attempts to cover the abstract idea itself.¹⁰³⁵

According to the court, Accenture argued that the system claim was not an abstract idea because the claim "appl[ied] it in a computer environment and within the insurance industry."1036 These limitations were rejected as not able to "narrow, confine, or otherwise tie down the claim," or otherwise "provide additional substantive limitations to avoid preempting the abstract idea" of the system claims.¹⁰³⁷ First, citing to Bancorp Services, L.L.C. v. Sun Life Assurance Co. of Canada (U.S.),¹⁰³⁸ the court noted that "simply implementing an abstract concept on a computer, without meaningful limitations to that concept, does not transform a patent-ineligible claim into a patent-eligible one."1039 Second, citing to Bilski, the court explained that "limiting the application of an abstract idea to one field of use does not necessarily guard against preempting all uses of the abstract idea."1040

Lastly, the court dismissed Accenture's argument that relied on the complexity of the specification, including its detailed implementation guidelines.¹⁰⁴¹ The court explained that the important inquiry is the claim, not the specification, and that the intricacies of the implementing software and the detail recited in the specification will not transform a claim reciting merely an abstract idea into patenteligible subject matter.¹⁰⁴²

^{1033.} Id.

^{1034.} Id.

^{1035.} Id. at 1344-45 (quoting CLS Bank Int'l v. Alice Corp., 717 F.3d 1269, 1282 (Fed. Cir.) (en banc) (per curiam) (Lourie, J., concurring), cert. granted, 134 S. Ct. 734 (2013)).

^{1036.} Id. at 1345.

^{1037.} Id. (internal quotation marks omitted) (quoting CLS Bank, 717 F.3d at 1282 (Lourie, J., concurring)). 1038. 687 F.3d 1266 (Fed. Cir. 2012), petition for cert. filed, 82 U.S.L.W. 3319 (U.S.

Nov. 8, 2013) (No. 13-584).

^{1039.} Accenture Global Servs., 728 F.3d at 1345 (citing Bancorp, 687 F.3d at 1280).

^{1040.} Id. (citing Bilski v. Kappos, 130 S. Ct. 3218, 3231 (2010)).

^{1041.} Id.

^{1042.} Id.

Chief Judge Rader dissented, stating that "[a] court cannot go hunting for abstractions by ignoring the concrete, palpable, tangible limitations of the invention the patentee actually claims," which he contended the majority had done.¹⁰⁴³ Chief Judge Rader, acknowledging the majority's reliance on the plurality opinion in CLS Bank, insisted that no part of the CLS Bank decision was precedential.¹⁰⁴⁴ Contending that the Federal Circuit should have relied on Supreme Court and other Federal Circuit precedent, Chief Judge Rader opined that the system claims were patent-eligible subject matter because they "offer 'significantly more' than the purported abstract idea and meaningfully limit the claims' scope."1045 Chief Judge Rader argued, in particular, that the claims did not preempt an abstract idea because (1) "someone can 'generate tasks based on rules to be completed upon the occurrence of an event' [as recited in the claims] in a number of ways without infringing the claims"; and (2) specific computer components are required that do not prevent performing the method as mental steps.¹⁰⁴⁶

B. Indefiniteness

Compliance with 35 U.S.C. § 112(b)¹⁰⁴⁷ requires that the specification "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention."¹⁰⁴⁸ The definiteness requirement serves to ensure that the claims, as viewed through the lens of the written description, adequately disclose to the public the scope of the patentee's right to exclude.¹⁰⁴⁹ Indefiniteness, a question of law that is reviewed de novo on appeal, requires an

^{1043.} *Id.* at 1346 (Rader, C.J., dissenting) (internal quotation marks omitted) (quoting Ultramercial, Inc. v. Hulu, LLC, 722 F.3d 1335, 1344 (Fed. Cir. 2013)). 1044. *Id.* at 1346–47.

^{1045.} *Id.* at 1347–48 (citation omitted) (quoting Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1293 (2012)).

^{1046.} *Id.* at 1348 (quoting CLS Bank Int'l v. Alice Corp., 717 F.3d 1269, 1277 (Fed. Cir.) (en banc) (per curiam) (Lourie, J., concurring), *cert. granted*, 134 S. Ct. 734 (2013)).

⁽endate) (per edutal) (Eourie, J., concurring), *eth. granua*, 151. 64. 151. (2017). 1047. Although the AIA replaced the second paragraph of 35 U.S.C. § 112 (2006) with 35 U.S.C. § 112(b) (2012), the pre-AIA version applies to patents issued prior to September 16, 2012. Biosig Instruments, Inc. v. Nautilus, Inc., 715 F.3d 891, 897 (Fed. Cir. 2013), *cert. granted*, 134 S. Ct. 896 (2014). *Compare* 35 U.S.C. § 112 (2006) ("The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the *applicant* regards as his invention (emphasis added)), *with* 35 U.S.C. § 112(b) (2012) ("The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the *inventor or a joint inventor* regards as the invention." (emphasis added)).

^{1048. 35} U.S.C. § 112(b) (2012).

^{1049.} Honeywell Int'l, Inc. v. Int'l Trade Comm'n, 341 F.3d 1332, 1338 (Fed. Cir. 2003).

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accused infringer to "demonstrate by clear and convincing evidence that one of ordinary skill in the relevant art could not discern the boundaries of the claim based on the claim language, the specification, the prosecution history, and the knowledge in the relevant art."1050 Three cases addressed by the Federal Circuit in 2013 resulted in different conclusions as to the indefiniteness of the claim term in dispute.

In Biosig Instruments, Inc. v. Nautilus, Inc., 1051 the Federal Circuit reversed and remanded the district court's grant of summary judgment of invalidity for indefiniteness.¹⁰⁵² The patent-in-suit, U.S. Patent No. 5,337,753 ("the '753 patent"), assigned to Biosig Instruments, Inc. ("Biosig"), discloses a heart-rate monitor used with exercise equipment.¹⁰⁵³ Nautilus, Inc. ("Nautilus") twice requested ex parte reexamination of the '753 patent over certain prior art, but the USPTO confirmed its patentability.¹⁰⁵⁴ Biosig then sued Nautilus, alleging infringement of the '753 patent.¹⁰⁵⁵ Nautilus moved for summary judgment on infringement and indefiniteness, which the district court granted as to indefiniteness.¹⁰⁵⁶ Specifically, the district court found that the claim term "spaced relationship" was not distinctly and particularly claimed as required by 35 U.S.C. § 112(b).¹⁰⁵⁷

On appeal, the Federal Circuit reversed the district court's grant of summary judgment finding that the claims were indefinite.¹⁰⁵⁸ According to the Federal Circuit, because the claim term "spaced relationship" was amenable to construction-indeed, was actually construed by the district court-indefiniteness would require evidence that a person of ordinary skill in the art would find the term "insolubly ambiguous" or, in other words, "that it fails to provide sufficient clarity delineating the bounds of the claim to one skilled in the art."¹⁰⁵⁹ Looking to the intrinsic evidence, the court found that

^{1050.} Wellman, Inc. v. Eastman Chem. Co., 642 F.3d 1355, 1365-66 (Fed. Cir. 2011) (internal quotation marks omitted) (quoting Haemonetics Corp. v. Baxter Healthcare Corp., 607 F.3d 776, 783 (Fed. Cir. 2010)). 1051. 715 F.3d 891 (Fed. Cir. 2013), *cert. granted*, 134 S. Ct. 896 (2014). 1052. *Id.* at 893.

^{1053.} Id.

^{1054.} Id. at 896.

^{1055.} Id. A third reexamination proceeding was instituted by Nautilus, but the USPTO denied the request, finding that there were no substantial new questions of patentability raised by the request. Id. at 897.

^{1056.} *Id.* at 896–97. 1057. *Id.* at 897.

^{1058.} Id. at 893.

^{1059.} Id. at 898-99.

such boundaries were provided, and stated that "[n]othing more rigorous is required under § 112, [paragraph] 2."1060

The district court construed "spaced relationship" as "a defined relationship between the live electrode and the common electrode on one side of the cylindrical bar and the same or a different defined relationship between the live electrode and the common electrode on the other side of the cylindrical bar."¹⁰⁶¹ While recognizing that the specification lacked specific parameters defining "spaced relationship," the court noted that its upper and lower boundaries were provided with "sufficient clarity" to a person of ordinary skill.¹⁰⁶² The court noted, in particular, that the electrode spacing had an upper bound based on "the width of a user's hands because claim 1 requires the live and common electrodes to independently detect electrical signals at two distinct points of a hand," and a lower bound because "it is not feasible that the distance between the live and common electrodes be infinitesimally small."¹⁰⁶³ The court further found that a skilled artisan could determine the bounds of the "spaced relationship" by reference to the function of the claimed device.¹⁰⁶⁴ The fact that some experimentation is required to determine the claim scope carries "little weight" for indefiniteness.¹⁰⁶⁵

The Federal Circuit distinguished Halliburton Energy Services, Inc. v. M-I *LLC*,¹⁰⁶⁶ which Nautilus relied upon, because "the 'upper bound' that was lacking in Halliburton is found here."1067 Instead, the court deemed the issues analogous to Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 1068 because, as in that case, the bounds of the claim term could be determined by those skilled in the art in view of variables disclosed in the intrinsic record.¹⁰⁶⁹ Accordingly, the court found that the disputed term "spaced relationship" was not "insolubly ambiguous."¹⁰⁷⁰

Finally, the Federal Circuit addressed the district court's decision and Nautilus's arguments on appeal pertaining to "drafting or defining claims in relation to their functions."¹⁰⁷¹ The Federal Circuit explained that the district court examined the term "spaced

^{1060.} Id. at 901.

^{1061.} *Id.* at 899. 1062. *Id.*

^{1063.} Id.

^{1064.} Id. at 901.

^{1065.} Id. at 902.

^{1066. 514} F.3d 1244 (Fed. Cir. 2008).

^{1067.} Biosig Instruments, 715 F.3d at 903 (citing Halliburton Energy, 514 F.3d at 1253).

⁶⁵⁵ F.3d 1364 (Fed. Cir. 2011). 1068.

^{1069.} Biosig Instruments, 715 F.3d at 903 (citing Star Scientific, 655 F.3d at 1373-74).

^{1070.} Id.

^{1071.} Id. at 903-04.

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relationship" in a "vacuum," choosing to ignore the functional aspects of the claim-specifically, how the "spaced relationship' contributes to the removal of noise signals, such as EMG signals, and the overall capabilities of the claimed heart rate monitor."¹⁰⁷² Thus, the Federal Circuit determined that the district court's failure to consider Biosig's evidence on the basis that it merely spoke to the "function of the claim," was error.¹⁰⁷³

The court similarly found unpersuasive Nautilus's related contention that the claims at issue were invalid because they claimed both an apparatus and a method of use.¹⁰⁷⁴ The court concluded that the '753 patent was not indefinite and did not fall within its holding in IPXL Holdings, L.L.C. v. Amazon.com, Inc.¹⁰⁷⁵ because the '753 patent recited apparatus claims with functional limitations.¹⁰⁷⁶

Judge Schall concurred and would have reached the same result with a more restricted analysis.¹⁰⁷⁷ He agreed with the majority's conclusion that neither of the two grounds for indefiniteness-(1) that the claim was not amenable to construction or (2) that it was construed but failed sufficiently delineate its metes and bounds-was present.¹⁰⁷⁸ to However, in his view, the court did not need to address anything more than whether these grounds were present and whether Nautilus's reliance on Halliburton and IPXL Holdings was justified.¹⁰⁷⁹

Judge Schall was concerned that the majority's "analysis proceed[ed] as if the 'spaced relationship' limitation itself-rather than other limitations of claim 1-included a functional requirement to remove EMG signals," which Judge Schall believed the parties to the appeal and the district court also presumed.¹⁰⁸⁰ Judge Schall opined that the court "should not address a functional limitation included neither in the 'spaced relationship' limitation itself nor in the district court's construction of that limitation," and that by considering other points in claim 1, the court addressed an issue that was not on appeal.¹⁰⁸¹

- 1073. Id.
- 1074. Id.
- 430 F.3d 1377 (Fed. Cir. 2005). 1075.
- 1076. Biosig Instruments, 715 F.3d at 904.
- 1077. Id. at 905 (Schall, J., concurring). 1078. Id.
- 1079. Id. at 905-06.
- 1080. Id. at 906.
- 1081. Id.

^{1072.} Id. at 904.

In *Teva Pharmaceuticals USA*, *Inc. v. Sandoz*, *Inc.*,¹⁰⁸² the Federal Circuit affirmed the district court's holding that one group of claims was valid and infringed, but reversed and remanded the judgment that the second set of claims was valid.¹⁰⁸³ In considering infringement, the Federal Circuit further found that the patentee's argument during prosecution did not constitute prosecution disclaimer that disavowed claim scope.¹⁰⁸⁴

Sandoz, Inc. ("Sandoz") and Mylan Pharmaceuticals Inc. ("Mylan"), the two defendants in the case, submitted Abbreviated New Drug Applications ("ANDA") for approval to market generic versions of Teva Pharmaceuticals USA, Inc.'s ("Teva") Copaxone[®] drug product indicated to treat multiple sclerosis.¹⁰⁸⁵ The patents at issue included claims to "copolymer-1," which is comprised of individual polymers of different molecular weights, and methods of making copolymer-1.¹⁰⁸⁶

At issue regarding indefiniteness was the fact that the molecular weight could be measured in various ways.¹⁰⁸⁷ First, it could be described as an average molecular weight, such as "the peak average molecular weight (M_p), number average molecular weight (M_n), and weight average molecular weight (M_w)."¹⁰⁸⁸ This average approach was used in claim 1 of U.S. Patent No. 5,981,589, which is representative of the "Group I" claims at issue.¹⁰⁸⁹ Second, the molecular weight could be described as the fraction of molecules falling within a set range.¹⁰⁹⁰ The second approach is reflected in claim 1 of U.S. Patent No. 6,054,430, which is representative of the "Group II" claims on appeal.¹⁰⁹¹ The district court had construed "molecular weight" in both groups of *claims* to mean the M_p .¹⁰⁹²

In holding that the Group I claims were indefinite, the Federal Circuit found them ambiguous as to which measurement of average molecular weight was to be used.¹⁰⁹³ The court looked to the prosecution history to address this ambiguity, but found that Teva's arguments were inconsistent—sometimes Teva relied on M_p and at

^{1082. 723} F.3d 1363 (Fed. Cir. 2013), cert. granted, 82 U.S.L.W. 3562 (U.S. Mar. 31, 2014) (No. 13-854).
1083. Id. at 1366.
1084. Id. at 1375.
1085. Id. at 1367.
1086. Id.
1088. Id.
1089. Id. at 1366-67 & n.1.
1090. Id. at 1366-67 & n.1.
1092. Id. at 1367.
1093. Id. at 1367.

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other times on M_{w} .¹⁰⁹⁴ According to the court, the ambiguity was not resolved by the specification because the method described, "Size Exclusion Chromatography," was not limited to providing M_{p} , and the results depicted graphically in the specification were closer to M_{w} .¹⁰⁹⁵ For these reasons, the court found the Group I claims indefinite.¹⁰⁹⁶ However, the Federal Circuit agreed with Teva and the district court that the Group II claims, which referred to exact molecular weight distributions and not average values, were not ambiguous and therefore not indefinite.¹⁰⁹⁷

In Ibormeith IP, LLC v. Mercedes-Benz USA, LLC,1098 the Federal Circuit affirmed the district court's grant of summary judgment of indefiniteness.¹⁰⁹⁹ Ibormeith IP, LLC ("Ibormeith") is the assignee of U.S. Patent No. 6,313,749 ("the '749 patent"), which "addresses the monitoring of conditions affecting, or behavior reflecting, a vehicle driver's sleepiness and the issuing of a warning to the driver before the driving is unduly impaired."¹¹⁰⁰ Ibormeith sued Mercedes-Benz USA, LLC and Daimler AG (collectively "Mercedes") for infringement.¹¹⁰¹ Mercedes filed a motion for summary judgment, arguing that the means-plus-function "computational means" limitations were indefinite.¹¹⁰² While Ibormeith argued that the required structure included algorithms found in the specification, the district court disagreed and granted summary judgment for Mercedes.¹¹⁰³

On appeal, the Federal Circuit looked to whether the algorithm was adequately disclosed in the '749 patent because the "price" for using means-plus-function claiming under 35 U.S.C. § 112(f) "is that the claim be tied to a structure defined with sufficient particularity in the specification."¹¹⁰⁴ The Federal Circuit agreed with the district court and found that the disclosed algorithm did not adequately define the structure, and that the claim was therefore indefinite.¹¹⁰⁵

Discussing the relevant portions of the specification, the Federal Circuit found that "there is no disclosure of even a single concrete relationship between the various factors that are used to compute an

1103. Id.

^{1094.} Id.

^{1095.} *Id.*

^{1096.} *Id.* 1097. *Id.* at 1368–70.

^{1098. 732} F.3d 1376 (Fed. Cir. 2013).

^{1099.} *Id.* at 1377.

^{1000.} *Id.* at 1100. *Id.*

^{1101.} Id. at 1378.

^{1102.} Id.

^{1104.} Id. at 1379.

^{1105.} Id. at 1379–80.

outcome to warn of driver drowsiness."¹¹⁰⁶ Rather, Ibormeith's expert described Table 10—which discloses definitions related to the "Sleep Propensity Algorithm"-in the specification as providing an algorithm "template" and stated that one would need to determine, among other things, which factors to use and how to use them.¹¹⁰⁷ The court took these contentions of breadth, which apparently were necessary for Ibormeith's infringement position, as binding admissions that doomed the validity of the claims.¹¹⁰⁸

The court explained that even if Table 10 could be interpreted as simply incorporating all of the listed factors a skilled artisan would consider appropriate, "[s]uch a reading of Table 10 leaves the disclosure without an algorithm whose terms are defined and understandable."1109 Moreover, the court noted, Table 10 merely listed factors without explaining how to weigh them to arrive at a computed warning indicator.¹¹¹⁰ Finally, Ibormeith could not rely on other disclosures in the specification to provide the requisite structure because, at most, it provided information one "skill[ed] in the art *could* use to design his or her own method of weighting."¹¹¹¹ In sum, the court held that an algorithm with no limits on how to calculate, combine, or weigh values is insufficient in making the claim's bounds understandable.¹¹¹²

C. Enablement

The enablement requirement, as set forth in 35 U.S.C. \S 112(a) requires that the specification "enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same."1113 Enablement is a determination made as of the filing date of the patent application,¹¹¹⁴ and it "is satisfied when one skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation."1115 While the statute does not explicitly use the term "undue experimentation," this standard is well established.¹¹¹⁶

^{1106.} *Id.* at 1381. 1107. *Id.*

^{1108.} Id.

^{1109.} Id.

^{1110.} Id. at 1382.

^{1111.} Id. 1112. Id.

^{1113. 35} U.S.C. § 112(a) (2012).

^{1114.} Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1254 (Fed. Cir. 2004).

^{1115.} AK Steel Corp. v. Sollac & Ugine, 344 F.3d 1234, 1244 (Fed. Cir. 2003). 1116. *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

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In Cephalon Inc. v. Watson Pharmaceuticals, Inc.,¹¹¹⁷ the Federal Circuit reversed the district court's holding that the asserted patents were invalid for lack of enablement.¹¹¹⁸ The court found that the infringement defendants, Watson Pharmaceuticals Inc. and Watson Pharma, Inc. (collectively "Watson"), failed to show that undue experimentation was required to practice the claimed invention.¹¹¹⁹

U.S. Patent Nos. 6,200,604 and 6,974,590 (collectively "the Khankari patents") cover methods for administration of a fentanyl tablet and the use of an additional pH-adjusting substance in combination with an effervescent agent via mucosal delivery.¹¹²⁰ Cephalon Inc. and CIMA Labs, Inc. (collectively "Cephalon") hold the New Drug Application (NDA) for fentanyl buccal tablets, Fentora[®], for cancer pain treatment.¹¹²¹

Watson filed an ANDA seeking to market a generic version of Fentora^{®,1122} In turn, Cephalon sued Watson for infringement of the Khankari patents.¹¹²³ After a bench trial, the district court concluded that Cephalon did not meet its burden of proving that Watson's ANDA products infringed.¹¹²⁴ The district court further held that Watson established that the Khankari patents were invalid for lack of enablement because they did not contain directions for formulating and coadministering two separate dosage forms in order to achieve an effervescent reaction.¹¹²⁵ The district court found that "undue experimentation" would be required given the lack of such disclosure.¹¹²⁶

In reversing on nonenablement, the Federal Circuit first noted that the district court erred as to the burden of proof it applied when it found that Watson's prima facie case was not rebutted by Cephalon.¹¹²⁷ The court explained that, because of the presumption of validity, the challenger alone bears the burden of proof, as there is no burden shifting for enablement.¹¹²⁸ The question, instead, was whether Watson had "prov[ed] lack of enablement by clear and convincing evidence."¹¹²⁹ The court determined that Watson had not.¹¹³⁰

^{1117. 707} F.3d 1330 (Fed. Cir. 2013).

^{1118.} Id. at 1333 (reversing as to nonenablement; affirming as to noninfringement).

^{1119.} Id. at 1332–33.

^{1120.} *Id.* 1121. *Id.* at 1331, 1335.

^{1122.} Id.

^{1123.} Id.

^{1124.} Id.

^{1125.} Id. at 1337.

^{1126.} Id.

^{1127.} *Id.* 1128. *Id.* at 1337–38.

^{1129.} Id. at 1337.

^{1130.} Id. at 1338.

Watson's nonenablement evidence was principally based on expert testimony that co-administration "would be very difficult and complicated."1131 Notwithstanding the district court's determination that such testimony was credible, the Federal Circuit found it to be "largely unsupported" and stated that it "carrie[d] little weight in this analysis."¹¹³² Such an "*ipse dixit*... cannot be enough to constitute clear and convincing evidence."1133

The Federal Circuit also found that the district court erred in focusing on the admission by Cephalon's expert that some experimentation may be necessary to practice the claimed invention.¹¹³⁴ Experimentation, even if extensive, may be permissible "if it is merely routine, or if the specification in question provides a reasonable amount of guidance."¹¹³⁵ Accordingly, the potential need for clinical experimentation was not, on its own, dispositive of the case.¹¹³⁶

In view of this standard, the Federal Circuit found that Watson failed to meet its burden to establish the amount of experimentation necessary to determine the formulation of the two doses in order to achieve the proper effervescent reaction.¹¹³⁷ Watson's unsubstantiated test "that experimentation would be difficult and complicated" was insufficient to show that the required experimentation would be excessive.¹¹³⁸ Accordingly, the Federal Circuit reversed the district court's conclusion to the contrary as erroneous.¹¹³⁹

In Wyeth & Cordis Corp. v. Abbott Laboratories, 1140 the Federal Circuit affirmed the district court's summary judgment of invalidity for nonenablement.¹¹⁴¹ Wyeth and Cordis Corporation ("Wyeth") sued Abbott Laboratories, Abbott Cardiovascular Systems, Inc., Abbott Laboratories, Inc., Medtronic Inc., Medtronic Vascular, Inc., Medtronic USA, Inc., Boston Scientific Corporation, and Boston Scientific Scimed, Inc. (collectively "the defendants") for infringement of patents related to methods of treating or preventing restenosis by administering rapamycin.¹¹⁴² The district court adopted Wyeth's proposed construction of the term "rapamycin" as meaning

^{1131.} Id. (internal quotation marks omitted).

^{1132.} Id.

^{1133.} *Id.* 1134. *Id.*

^{1135.} Id. at 1339 (quoting PPG Indus., Inc. v. Guardian Indus., Corp., 75 F.3d 1558,

^{1564 (}Fed. Cir. 1996)).

^{1136.} Id. 1137. Id.

^{1138.} Id.

^{1139.} *Id.* at 1339–40. 1140. 720 F.3d 1380 (Fed. Cir. 2013).

^{1141.} Id. at 1382.

^{1142.} Id. at 1380, 1383.

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"a compound containing a macrocyclic triene ring structure produced by *Streptomyces hygroscopicus*, having immunosuppressive and anti-restenotic effects."¹¹⁴³ Notably, while "rapamycin" encompasses a class of compounds, the parties agreed that the specifications of the patents-in-suit disclosed only one species, sirolimus.¹¹⁴⁴ In view of this construction, the district court granted summary judgment in favor of the defendants and found that the patents-in-suit were invalid "for nonenablement and lack of written description."¹¹⁴⁵

The Federal Circuit articulated the issue on appeal as "whether practicing the full scope of the claims require[d] excessive—and thus undue—experimentation."¹¹⁴⁶ Agreeing with the district court's decision, the Federal Circuit concluded that there was no genuine issue of material fact that practicing the claims at issue would require excessive experimentation.¹¹⁴⁷ In particular, the Federal Circuit noted the broad nature of the claims at issue and stated that, "[u]nder the district court's unchallenged construction of 'rapamycin,' the invention is a new method of use of a known compound (sirolimus) *and* any other compounds that meet the construction's structural and functional requirements."¹¹⁴⁸

Although Wyeth's assertions that four other compounds similar to sirolimus were known and that a person of ordinary skill would have known the rapamycin compounds to have an upper weight limit were taken as true for summary judgment purposes, the Federal Circuit nevertheless found that more than routine experimentation would be required.¹¹⁴⁹ First, even with a molecular weight limitation, there would still be "at least tens of thousands of candidates," yet there was no indication of how to modify sirolimus.¹¹⁵⁰ Second, it would be necessary to synthesize and test each candidate because their pharmacologic properties are unpredictable.¹¹⁵¹ The court found that the testing alone, without considering the synthesis work, would have been undue and noted that "Wyeth's expert conceded that it would take technicians weeks" of testing for each compound.¹¹⁵²

In holding that undue experimentation would be required, the court described the specification as only providing a starting point from which

^{1143.} Id. at 1383 (internal quotation marks omitted).

^{1144.} Id. at 1382.

^{1145.} *Id.* at 1383.

^{1146.} *Id.* at 1384. 1147. *Id.* at 1385.

^{1147.} *Ia.* at 1565. 1148. *Id.*

^{1149.} *Id*.

^{1150.} Id.

^{1151.} Id.

^{1152.} Id. at 1385-86.

to begin further research in an uncertain field.¹¹⁵³ Without guidance or predictions about which modifications of sirolimus would lead to an active compound, the court concluded that "[t]he resulting need to engage in a systematic screening process for each of the many rapamycin candidate compounds is excessive experimentation."1154

D. Written Description

35 U.S.C. § 112(a) mandates that a patent application's "specification . . . contain a written description of the invention."¹¹⁵⁵ "[T]he test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date."¹¹⁵⁶ Possession is shown by describing the invention with all its claim limitations, including using "descriptive means [such] as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention."1157 While the written description requirement does not require examples or actual reduction to practice, the level of detail required to satisfy it will depend largely on the nature of the claim and the technology's complexity.¹¹⁵⁸ A "mere wish or plan," however, to obtain the claimed invention is insufficient to satisfy the written description requirement.1159

In In re Bimeda Research & Development Ltd.,¹¹⁶⁰ the Federal Circuit affirmed the Board's decision that certain claims introduced in the course of ex parte reexamination were not supported by a sufficient written description.¹¹⁶¹ U.S. Patent No. 6,506,400 ("the '400 patent"), owned by Bimeda Research & Development Limited ("Bimeda"), is directed to methods for preventing inflammation of a cow's udder tissue.¹¹⁶² Ex parte reexamination was ordered by the USPTO "to reevaluate patentability in light of prior art teachings of teat seal formulations utilizing a physical barrier in conjunction with certain antiinfective agents such as antibiotics and the antiseptic acriflavine."1163 During reexamination, Bimeda cancelled certain

^{1153.} Id. at 1386.

^{1154.} Id.

^{1155.} 35 U.S.C. § 112(a) (2012).

^{1156.} Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).

^{1157.} Lockwood v. Am. Airlines, Inc., 107 F.3d 1565, 1572 (Fed. Cir. 1997).

^{1158.} Ariad, 598 F.3d at 1351.

^{1159.} Centocor Ortho Biotech, Inc. v. Abbott Labs., 636 F.3d 1341, 1348 (Fed. Cir. 2011) (quoting Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1566 (Fed. Cir. 1997)) (internal quotation marks omitted).

^{1160. 724} F.3d 1320 (Fed. Cir. 2013). 1161. *Id.* at 1321.

^{1162.} Id.

^{1163.} Id. at 1321-22.

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original claims and added new claims, which recited use of "an acriflavine-free" formulation.¹¹⁶⁴ The examiner rejected these new claims on the ground that the '400 patent, which did not mention acriflavine, did not demonstrate possession of an acriflavine-free composition.¹¹⁶⁵ The Board affirmed "because the disclosure did not describe[] a formulation excluding a specific species of the anti-infective genus," i.e., acriflavine, "while permitting others to be present."¹¹⁶⁶ "Rather, the Board found, the '400 patent described inventions that were free of entire classes of agents such as antibiotics."1167

On appeal, the Federal Circuit found substantial evidence supporting the Board's conclusions due to general inconsistencies contained in the disclosure.¹¹⁶⁸ Walking through the patent specification, the court identified repeated disclosure of an antibioticfree method and stated that "the summary of the invention describes the invention's 'non-antibiotic approach' to preventing mastitis," and that "[t]he remainder of the disclosure similarly distinguishes the invention due to its ability to prevent mastitis without using antibiotics."1169 The court found that "[t]he specification thus leaves no room for argument that the inventor possessed a formulation that excludes only acriflavine while permitting the use of antibiotics."1170

Chief Judge Rader concurred, emphasizing—what he considered a problematic alternate rationale presented by the Board-that the patentee failed to demonstrate a formula excluding acriflavine as an antiinfective.¹¹⁷¹ He was of the opinion that, by declining to address the issue of negative claiming, the Board essentially required the patentee to demonstrate possession of something it specifically claims not to possess in order to satisfy written description.¹¹⁷²

In Novozymes A/S v. DuPont Nutrition Biosciences APS,¹¹⁷³ the Federal Circuit affirmed, over Chief Judge Rader's dissent, the district court's [MOL that the claims were invalid for an inadequate written description.¹¹⁷⁴ Plaintiffs Novozymes A/S and Novozymes North America, Inc. (collectively "Novozymes") and Defendants DuPont Nutrition Biosciences APS, Genencor International Wisconsin, Inc.,

^{1164.} Id.

^{1165.} *Id.*

^{1166.} Id. at 1323 (alteration in original) (internal quotation marks omitted).

^{1167.} *Id.* 1168. *Id.*

^{1169.} Id.

^{1170.} Id. at 1324.

^{1171.} *Id.* (Rader, C.J., concurring). 1172. *Id.* at 1324–25.

^{1173. 723} F.3d 1336 (Fed. Cir. 2013), cert. denied, 134 S. Ct. 1801 (2014).

^{1174.} Id. at 1338; see id. at 1351 (Rader, C.J., concurring).

Danisco US Inc., and Danisco USA Inc. (collectively "DuPont") are preparations used in commercial competitors for enzyme applications, such as ethanol production.¹¹⁷⁵ Novozymes sued DuPont for infringement of U.S. Patent No. 7,713,723 ("the '723 patent"), directed to modified enzymes possessing improved function and stability under harsh environmental conditions.¹¹⁷⁶ During the trial, the jury concluded that the '723 patent was not invalid for enablement or lack of written description and awarded Novozymes damages.¹¹⁷⁷ The district court, however, granted DuPont's post-trial motion for JMOL, finding the '723 patent invalid under 35 U.S.C. § 112 for failure to satisfy the written description requirement.¹¹⁷⁸

At issue was whether claims in the '723 patent, added when the application for the '723 patent was filed in 2009, were supported by the provisional application filed in 2000 ("the 2000 application").¹¹⁷⁹ Novozymes argued that the jury's determination-finding the claims not invalid for lack of written description-was sufficiently supported since each claim limitation was expressly disclosed in the 2000 application.¹¹⁸⁰ Novozymes further argued that the district court improperly discounted expert testimony that "a person of ordinary skill in the art would have had no difficulty deriving the claimed invention from the disclosure of the 2000 application."¹¹⁸¹ The Federal Circuit rejected these arguments.

The Federal Circuit agreed that the 2000 application contained each individual limitation claimed in the '723 patent, but rejected this as insufficient because the 2000 application did not disclose any specific variant, beyond the enormous number of potential variants, that satisfied the claim.1182 The court contrasted the claims and the specification, noting that while "the claims... narrowly recite specific alpha-amylase variants," the specification merely provides "generalized guidance" toward potential variants that could lead to the desired result.¹¹⁸³ Looking at each claim as "an integrated whole rather than as a collection of independent limitations," the court found neither any "blaze marks" to lead a person of ordinary skill toward the proper variants, nor even one variant falling within the claims.¹¹⁸⁴

^{1175.} Id. at 1337-38 (majority opinion).

^{1176.} Id. at 1338.

^{1177.} *Id.* at 1338, 1342. 1178. *Id.* at 1342.

^{1179.} Id. at 1342-43.

^{1180.} Id. at 1345.

^{1181.} *Id.* 1182. *Id.* at 1348. 1183. Id. at 1346.

^{1184.} Id. at 1349.

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Criticizing Novozymes's expert for using hindsight to find support for the claim limitations, the Federal Circuit explained that written description support is viewed "from the proper vantage point of one with no foreknowledge of the specific compound."1185 The court reasoned that, based only on the 2000 application, a person of ordinary skill would have understood that Novozymes predicted a variation at position 239 would lead to the desired thermostability, but "not that [Novozymes] possessed or had definitively identified any such mutations that would do so."1186

Addressing Novozymes's argument that one of ordinary skill would have known how to test every possible variant at position 239, the court explained that the pertinent question was "whether the 2000 application disclose[d] the [variants] to him, specifically, as something [the] appellants actually invented."¹¹⁸⁷ The 2000 application provided the "roadmap" for creating candidate variants in the search for thermostability.¹¹⁸⁸ But because "[a] patent... is not a reward for the search, but compensation for its successful conclusion[,] ... the written description requirement prohibits a patentee from leaving it to the ... industry to complete an unfinished invention."¹¹⁸⁹

Chief Judge Rader dissented because, in his view, the jury's verdict on the factual question of written description "deserve[d] significant deference" and was supported by substantial evidence.¹¹⁹⁰ He pointed to disclosure in the specification supporting the '723 patent claims and noted that "the jury received expert testimony, heard from skilled protein engineers, reviewed visual aids and publication excerpts, and examined the patent document as guided by those skilled in the art[] over an eight day trial."¹¹⁹¹

In Synthes USA, LLC v. Spinal Kinetics, Inc., 1192 the Federal Circuit affirmed the jury's verdict of lack of written description and the district court's denial of a request for attorneys' fees.¹¹⁹³ Synthes USA, LLC ("Synthes") filed suit against Spinal Kinetics, Inc. ("SK"), alleging that SK infringed claims 29 through 31 of Synthes's U.S.

^{1185.} Id. (quoting In re Ruschig, 379 F.2d 990, 995 (C.C.P.A. 1967)) (internal quotation marks omitted).

^{1186.} *Id.* at 1350.

^{1187.} *Id.* (quoting *Ruschig*, 379 F.2d at 995) (internal quotation marks omitted). 1188. *Id.*

^{1189.} Id. (quoting Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1353 (Fed. Cir. 2010) (en banc)) (internal quotation marks omitted).

^{1190.} Id. at 1351 (Rader, C.J., dissenting).

^{1191.} Id. at 1351–52.

^{1192. 734} F.3d 1332 (Fed. Cir. 2013).

^{1193.} Id. at 1334-35.

Patent No. 7,429,270 ("the '270 patent").1194 "The '270 patent is directed to an 'Intervertebral Implant,' which is a prosthetic device designed to replace a diseased or degenerated disc located between adjacent vertebrae of the human spine."1195

At trial, the jury held that SK did not infringe and that SK proved "that claim 29, and consequently claims 30 and 31, were invalid for lack of written description support."¹¹⁹⁶ In response to Synthes's motion for [MOL, the district court affirmed the jury's verdict of invalidity for lack of a sufficient written description for two phrases, "plate including a plurality of openings" and "wherein the core is substantially cylindrical."1197 Synthes appealed, and SK cross-appealed.1198

On appeal, the Federal Circuit agreed with the district court that "substantial evidence supported the jury verdict that the term 'plate including a plurality of openings' lacked written description support."1199 In this regard, the Federal Circuit noted the breadth of the claims in view of the district court's construction and that broad language was added to the claims during prosecution.¹²⁰⁰ The court stated that, although broadening claims in order to capture a competitor's product during prosecution is not improper, any such claims must remain supported by the written description.¹²⁰¹ A claim is sufficiently supported by the written description when one skilled in the art would be led to believe the inventor in fact "ha[d] possession of the claimed subject matter as of the filing date."1202

The Federal Circuit found that the written description "never discloses anything broader than using grooves to anchor the fiber system to the cover plates."¹²⁰³ The court stated that the jury did not believe "grooves" constituted an adequate disclosure and, "when all reasonable inferences are drawn in favor of the jury verdict, we must affirm that decision."¹²⁰⁴ Further, "SK presented testimony regarding the plurality of openings limitation."¹²⁰⁵ The court held that, based on this testimony, "it would not be evident that peripheral grooves on the cover plates would disclose to skilled artisans that internal slots

^{1194.} Id.

^{1195.} Id. at 1335.

^{1196.} *Id.* at 1340. 1197. *Id.*

^{1198.} Id.

^{1199.} *Id.* 1200. *Id.* at 1341.

^{1201.} Id.

^{1202.} Id. (alteration in original) (quoting Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc)). 1203. *Id.* at 1342.

^{1204.} Id.

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would serve the same function."¹²⁰⁶ The court explained that whether the written description requirement has been met is a question of fact based on the "nature and scope of the claims" and the "complexity and predictability of the relevant technology."¹²⁰⁷ Thus, the court concluded that the jury's reliance on the evidence and expert testimony properly supported the finding "that the '270 patent's written description [did] not support the broad plurality of openings limitation."1208

Judge Taranto disagreed with the majority and believed that SK failed to show by clear and convincing evidence that the asserted claims were invalid for lack of written description.¹²⁰⁹ Judge Taranto opined that SK offered no clear and convincing proof that the difference between the "openings" of the claims and the grooves of the written description is one that (in the eyes of skilled artisans) has any effect, let alone an effect that is difficult to predict, on fulfillment of the identified purposes of the claims at issue.¹²¹⁰

E. Best Mode

The best mode requirement can be understood as a statutory exchange through which the inventor obtains a temporary right to exclude others from the claimed invention, and in exchange for this right, the public receives enrichment through the knowledge conferred by the inventor through the patent system.¹²¹¹ The requirement is articulated in 35 U.S.C. § 112(a): "[t]he specification . . . shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention."¹²¹² The purpose of the best mode requirement is to ensure an inventor will only obtain a patent if the embodiment of the invention actually conceived has been made available to the public.¹²¹³

A two-pronged analysis is used to determine compliance with the best mode requirement.¹²¹⁴ First, the court engages in a subjective inquiry, looking at the state of mind of the inventor at the time the application was filed to determine whether the inventor had a preferred mode of carrying out the invention.¹²¹⁵ Second, if the

^{1206.} Id. at 1343.

^{1207.} Id. at 1344 (quoting Ariad, 598 F.3d at 1351).

^{1208.} Id.

^{1209.} Id. at 1346 (Taranto, J., dissenting).

^{1210.} Id.

^{1211.} Eli Lilly & Co. v. Barr Labs. Inc., 251 F.3d 955, 963 (Fed. Cir. 2001).

^{1212. 35} U.S.C. § 112(a) (2012). 1213. *In re* Gay, 309 F.2d 769, 772 (C.C.P.A. 1962).

^{1214.} Pfizer, Inc. v. Teva Pharm. USA, Inc., 518 F.3d 1353, 1364 (Fed. Cir. 2008).

^{1215.} Id.

inventor possessed a best mode, the court must determine whether the written description disclosed the best mode such that a person skilled in the art could practice it.¹²¹⁶ This determination is an objective inquiry focused on the scope of the claimed invention and the level of skill in the art.¹²¹⁷ While a defense for patent infringement based on a best mode violation has been eliminated by statute for cases commenced on or after September 16, 2011, this change is not otherwise retroactive for earlier-filed litigations.¹²¹⁸

In Ateliers de la Haute-Garonne v. Broetje Automation USA Inc.,¹²¹⁹ the Federal Circuit reversed the district court's entry of summary judgment for failure to disclose the best mode, affirmed that U.S. Patent No. 5,011,339 ("the '339 patent") was not abandoned, and remanded for further infringement proceedings.¹²²⁰ Ateliers de la Haute-Garonne and F2C2 Systems S.A.S. (collectively "AHG") sued Broetje Automation USA Inc. and Bröetje Automation GmbH (collectively "Broetje"), alleging, among other things, infringement of the '339 patent and U.S. Patent No. 5,143,216 ("the '216 patent").¹²²¹ Both the '339 patent and the '216 patent claim priority to a French application "and relate to the dispensing of objects such as rivets through a pressurized tube with grooves along its inner surface, to provide a rapid and smooth supply of properly positioned rivets for such uses as the assembly of metal parts of aircraft."1222

The district court granted Broetje's motion for summary judgment on best mode, which was based on inventor testimony that the tube required an odd number of grooves.¹²²³ The district court found that neither the '339 patent nor the '216 patent affirmatively identified an odd number of grooves as being a better design feature than an even number of grooves, and that "a person of ordinary skill" in the art would not be able to ascertain that by reading the specification.¹²²⁴ Ultimately, the district court concluded that the '339 patent and the '216 patent "are so objectively inadequate as to effectively conceal the best mode from the public, such that a reasonable jury could not find in AHG's favor with respect to Broetje's 'odd number' theory."1225

^{1216.} *Id.* 1217. *Id.*

^{1218.} See Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 15, 125 Stat. 284,

^{328 (2011) (}codified at 35 U.S.C. § 282(b)(3)(A) (2012)).

^{1219. 717} F.3d 1351 (Fed. Cir. 2013). 1220. Id. at 1352–53.

^{1221.} Id.

^{1222.} Id. at 1353.

^{1223.} Id. at 1355–56.

^{1224.} Id. at 1356.

^{1225.} Id. (internal quotation marks omitted).

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The district court did not decide the remaining issues in the complaint, but did reject Broetje's argument that AHG abandoned the '339 patent for failure to pay the issue fee.¹²²⁶

On appeal, the Federal Circuit addressed the standard for invalidating a patent for lack of best mode.¹²²⁷ Over the dissent of Judge Prost, the court explained that, contrary to Broetje's argument, binding precedent held that intentional concealment is required.¹²²⁸ Applying this standard, the Federal Circuit found that the district court erred as a matter of law in stating that intentional concealment was not required.¹²²⁹

The Federal Circuit further explained that the best mode requirement is satisfied when the preferred mode is disclosed, even if not specifically identified as such.¹²³⁰ The court found that, at the time the patent application was filed, "the inventors primarily used a three-groove tube," as was shown in the embodiments of the tube in the drawings included in the original specification.¹²³¹ Further, the court found no evidence in the record that the inventors knew of or concealed a better mode.¹²³² While recognizing that a five-groove tube was ultimately used for commercialization, the three-groove tube was considered to be the best embodiment at the time of the patent application's filing.¹²³³ The inventor's testimony regarding the need for an odd number of grooves was also seen as consistent with the '339 and '216 patents' disclosure of three grooves.¹²³⁴ Accordingly, the court concluded that disclosure of a three-groove tube sufficiently "enable[d] a person skilled in the art to practice the best mode" of the claimed invention.1235

Judge Prost dissented for two principal reasons. First, she felt that the majority's decision was "based on an error of law," was "not in accord with [Federal Circuit] precedent regarding intent in a best

^{1226.} Id. at 1353.

^{1227.} See id. at 1356-57.

^{1228.} See id. at 1357–58 & n.3 (invoking *In re* Gay, 309 F.2d 769, 772 (C.C.P.A. 1962), as setting forth "[t]he requirement that a best mode violation requires intentional concealment" and discrediting Judge Prost's arguments to the contrary); see also id. at 1360 n.1 (Prost, J., dissenting) (asserting that the court is bound by *In re* Sherwood, 613 F.2d 809 (C.C.P.A. 1980), not *Gay*). See generally S. Corp. v. United States, 690 F.2d 1368, 1369 (Fed. Cir. 1982) (en banc) (indicating that decisions of the U.S. Court of Customs and Patent Appeals, the Federal Circuit's predecessor, are binding precedent for the Federal Circuit).

^{1229.} Âteliers de la Haute-Garonne, 717 F.3d at 1358.

^{1230.} Id.

^{1231.} Id.

^{1232.} *Id.* at 1358–59. 1233. *Id.*

^{1234.} Id. at 1358.

^{1235.} Id. at 1359.

mode analysis[,] and misconstrue[d] as legal error the district court's reasonable conclusion."¹²³⁶ Her interpretation of precedent indicated that intentional concealment is not required.¹²³⁷ Second, Judge Prost viewed the best mode as having been concealed because the inventors "buried it amongst many embodiments that they knew did not work."1238 Thus, Judge Prost reasoned, the disclosure was "not an adequate guide that one of ordinary skill in the art could follow to determine the best mode for the invention."1239

F. Anticipation and Statutory Bars

To anticipate a claim and render it invalid, a single prior art reference must expressly or inherently disclose each and every element as set forth in the claim.¹²⁴⁰ The prior art reference must guide one skilled in the art or unambiguously disclose the claimed invention without the need to combine various disclosures.¹²⁴¹ Further, the elements must be arranged as required by the claim, but identity of terminology is not required.¹²⁴²

In Rambus Inc. v. Rea, the Federal Circuit affirmed the Board's claim construction and finding of anticipation, vacated the Board's obviousness decision, and remanded for further proceedings.¹²⁴³ The claims at issue related to synchronous data transfer at double the rate of a clock signal through transferal of data on both the rising and falling edges of the clock signal.¹²⁴⁴ On appeal, the Federal Circuit first addressed the anticipation issue, which rested on whether the Board properly construed (1) "external clock signal" to require that the clock be periodic only during "data input phases," and not periodic during "all system operations"; and (2) "write request" as not limited to multiple-bit requests.¹²⁴⁵ The Federal Circuit agreed with the USPTO's constructions because nothing in the record limited the language to require a different construction.¹²⁴⁶

^{1236.} Id. at 1359-60 (Prost, J., dissenting).

^{1237.} Id. at 1360 & nn.1-3.

^{1238.} Id. at 1361.

^{1239.} *Id.* at 1362. 1240. Karsten Mfg. Corp. v. Cleveland Golf Co., 242 F.3d 1376, 1383 (Fed. Cir. 2001).

^{1241.} In re Arkley, 455 F.2d 586, 587 (C.C.P.A. 1972).

^{1242.} *In re* Bond, 910 F.2d 831, 832 (Fed. Cir. 1990) (per curiam). 1243. 731 F.3d 1248, 1250 (Fed. Cir. 2013); *see supra* text accompanying notes 720– 38 (explaining the reasoning behind the Federal Circuit's decision to vacate the TTAB's obviousness determination); infra notes 1457–76 (discussing the court's reasoning surrounding its obviousness analysis).

^{1244.} Rambus, 731 F.3d at 1250.

^{1245.} Id. at 1252-53.

^{1246.} Id. at 1252-54.

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The "external clock signal" limitation was at issue because the prior art reference taught a method of transferring data during each halfcycle of an external clock, using two internal clock signals tied, respectively, to the rising and falling edge of the external clock.¹²⁴⁷ Rambus argued that, in contrast to the USPTO's construction, "external clock signal" should be construed as being continuously periodic because, among other reasons, the claims require all operations to be synchronized with the clock signal and "the specification only discloses a periodic clock signal."¹²⁴⁸ In affirming the USPTO's construction, the Federal Circuit opined that, "while the 'external clock signal' must be periodic during data transfer, nothing in the claim language[, specification, or file history] requires the signal to be periodic for all time."1249

Regarding the USPTO's construction of "write request," the Federal Circuit agreed with the Board that it could contain a single bit, and was not limited to a multiple-bit request.¹²⁵⁰ The court looked to the specification and preferred embodiment therein, and found it consistent with a single-bit request, noting that "[a] claim construction that excludes the preferred embodiment is rarely, if ever, correct and would require highly persuasive evidentiary support."¹²⁵¹ Accordingly, because it affirmed the claim constructions and saw no facts in dispute, the Federal Circuit affirmed the Board's anticipation determination.1252

In Hamilton Beach Brands, Inc. v. Sunbeam Products, Inc., 1253 the Federal Circuit affirmed the district court's holding that the asserted claims were invalid for violating the public-use and on-sale bar provisions of 35 U.S.C. § 102(b).¹²⁵⁴ Hamilton Beach Brands, Inc. ("Hamilton Beach") is assignee of U.S. Patent No. 7,947,928 ("the '928 patent"), which discloses a portable slow cooker with clips used to seal the detachable lid.¹²⁵⁵ Hamilton Beach sued Sunbeam Products, Inc. ("Sunbeam") for infringement, and Sunbeam moved for summary judgment of invalidity for anticipation.¹²⁵⁶ The district

1254. Id. at 1379.

^{1247.} *Id.* at 1251–53. 1248. *Id.* at 1252.

^{1249.} Id.

^{1250.} Id. at 1253.

^{1251.} Id. (quoting Adams Respiratory Therapeutics, Inc. v. Perrigo Co., 616 F.3d 1283, 1290, (Fed. Cir. 2010)) (internal quotation marks omitted).

^{1252.} See id. at 1254.

⁷²⁶ F.3d 1370 (Fed. Cir. 2013). 1253.

^{1255.} Id. at 1371-72.

^{1256.} Id. at 1373-74.

court granted Sunbeam's motion, finding the claims invalid under the on-sale and public-use bars of § 102(b).¹²⁵⁷

At issue on appeal was whether Hamilton Beach's transaction with its foreign supplier, more than one year before the '928 patent's filing date, constituted an offer for sale.¹²⁵⁸ More specifically, the Federal Circuit considered the transaction in light of Pfaff v. Wells *Electronics, Inc.*,¹²⁵⁹ under which "[t]he on-sale bar applies when two conditions are satisfied before the critical date: (1) the claimed invention must be the subject of a commercial offer for sale; and (2) the invention must be ready for patenting."¹²⁶⁰ The court concluded that the asserted claims were invalid under the § 102(b) on-sale bar because the transaction "was an offer for sale of a product that anticipated the asserted claims" when the invention was ready for patenting.¹²⁶¹ As foundation for its opinion, the court made a number of general statements regarding the on-sale bar, including that the on-sale bar does not have a "supplier exception" and that an offer directed to the United States made by a foreign entity qualifies as an invalidating activity.¹²⁶²

Addressing the first prong of *Pfaff*, Hamilton Beach argued that the first condition was not met because there was no binding contract before the § 102(b) critical date.¹²⁶³ The Federal Circuit dismissed this argument, focusing on the "pre-critical" date *offer*, which could have been accepted as being sufficient for the first element of the on-sale bar even without a binding contract.¹²⁶⁴ Accordingly, the court determined that the first prong of *Pfaff* was met.¹²⁶⁵

Turning to the second prong of *Pfaff*, Hamilton Beach argued that the district court erred by failing to do an element-by-element analysis of the precritical date prototype and product samples, which Hamilton Beach contended did not meet all the claim limitations.¹²⁶⁶ Hamilton Beach further argued that it had not been able to perfect a product meeting all the claim limitations until after the critical date.¹²⁶⁷ The Federal Circuit, however, concluded that the district

^{1257.} *Id.* at 1374 (applying the 2006 version of § 102, even though it was amended by the AIA, because the case was filed before the AIA amendments became effective).

^{1258.} *Id.* at 1374–75.

^{1259. 525} U.S. 55 (1998).

^{1260.} Hamilton Beach Brands, 726 F.3d at 1374 (citing Pfaff, 525 U.S. at 67).

^{1261.} *Id.*

^{1262.} Id. at 1375.

^{1263.} *Id.* at 1377.

^{1264.} *Id.*

^{1265.} *Id.*

^{1266.} Id. at 1378.

^{1267.} Id.

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court did not err in finding that the product was ready for patenting.¹²⁶⁸ The court also found that Hamilton Beach conceded that it possessed, before the critical date, at least one working prototype of the slow cooker that met all of the claim limitations.¹²⁶⁹ The court disregarded Hamilton Beach's argument that some of the prototypes did not work as intended, explaining that "fine-tuning' of an invention after the critical date does not mean that the invention was not ready for patenting."¹²⁷⁰ Therefore, the Federal Circuit affirmed the district court's finding that the asserted claims were invalid under § 102(b) and did not reach the remaining issues.¹²⁷¹

In dissent, Judge Reyna focused on the Supreme Court's instructions in *Pfaff* that the on-sale bar applies to *commercial* offers.¹²⁷² He opined that the majority, without reviewing whether the offer was commercial in nature, erroneously "extended the no-supplierexception rule to a case without considering whether the purchase order was placed for purely experimental purposes."¹²⁷³ According to Judge Reyna, Federal Circuit precedent for applying a "no-supplierexception rule involved offers or sales that unquestionably met the Supreme Court's requirement that the offer be part of a 'commercial' offer or sale."¹²⁷⁴ Judge Reyna maintained that, for the experimental-use exception to remain viable, the Federal Circuit must not neglect to consider the Supreme Court's express requirement for a commercial offer for sale when invoking the no-supplier-exception rule.¹²⁷⁵ Judge Reyna concluded that his "greatest concern[]" was that the majority's holding would cause a single offer to buy for purely experimental purposes to trigger the on-sale bar and render the experimental-use exception worthless for future innovators.¹²⁷⁶

In Dey, L.P. v. Sunovion Pharmaceuticals, Inc.,¹²⁷⁷ the Federal Circuit reversed and remanded the district court's grant of summary judgment because it found that Sunovion Pharmaceuticals, Inc. ("Sunovion") had not established that use in a pharmaceutical clinical trial constituted a public use of Dey, L.P., Dey, Inc., and Mylan, Inc.'s (collectively "Dey") inventions under 35 U.S.C.

- 1270. *Id.*
- 1271. Id.
- 1272. *Id.* (Reyna, J., dissenting). 1273. *Id.* at 1380.
- 1274. Id.
- 1275. Id. at 1381.
- 1276. Id.
- 1277. 715 F.3d 1351 (Fed. Cir. 2013).

^{1268.} Id.

^{1269.} *Id.* at 1379.

§ 102(b).¹²⁷⁸ The parties' patents and products at issue concern the treatment of obstructive pulmonary disease by formulating formoterol in an aqueous solution and administering it via a nebulizer.¹²⁷⁹ In response to Dey's suit alleging patent infringement, Sunovion argued on summary judgment, and the district court agreed, that some of Dey's patents were invalid in light of a Sunovion clinical trial using Sunovion's own product, which constituted a prior public use of Dey's inventions.¹²⁸⁰ The parties stipulated that Dey's asserted claims would be anticipated by the formulation of Batch 3501A—a clinical trial batch that was identical to the formulation Sunovion ultimately marketed—used in Sunovion's clinical trial if it was in "public use."¹²⁸¹

During the clinical study in question ("Study 50"), three different formoterol dosages were used: "Batches 3501A, 3501B, and 3501C."¹²⁸² While the participants were given limited information about the study, they were not provided specific information about the formulation of Batch 3501A.¹²⁸³ The participants signed a consent form stating that the medications "must be taken only by the person for whom it was intended," that subjects would have to log how they used the drugs, and that they would return unused medications at the conclusion of the study.¹²⁸⁴ While participants could discuss the study with their doctors and others, test administrators were required to sign a formal confidentiality agreement.¹²⁸⁵

On appeal, the Federal Circuit disagreed that Sunovion was entitled to summary judgment of invalidity because two material issues of fact, both of which related to whether the clinical trial constituted a "public use" of Batch 3501A, remained in dispute.¹²⁸⁶ First, the Federal Circuit did not agree with the district court "that the use of Batch 3501A by Study 50 participants was indisputably open and free."¹²⁸⁷ The court explained that losing some Batch 3501A vials and allowing participants to self-administer the medication at home "d[id] not preclude a reasonable jury from concluding that the use of Batch 3501A was sufficiently controlled

^{1278.} Id. at 1352–53 (citing 305 U.S.C. § 102(b) (2006)).

^{1279.} Id. at 1353.

^{1280.} *Id.* at 1354. 1281. *Id.* at 1353–54.

^{1281.} *Id.* at 1353–54. 1282. *Id.* at 1353.

^{1282.} *Id.* at 1355.

^{1284.} Id.

^{1285.} Id.

^{1286.} Id. at 1356.

^{1287.} Id.

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and restricted, rather than unfettered and public."¹²⁸⁸ Second, the Federal Circuit disagreed that the lack of control over confidentiality obligations in Study 50 dictated that summary judgment was appropriate.¹²⁸⁹ The court reasoned that the absence of a formal obligation of secrecy on the study subjects did not automatically transform Sunovion's clinical trial into a public use because the court has never required a formal confidentiality agreement to show nonpublic use; in the absence of such an agreement, the court "simply ask[s] whether there were 'circumstances creating a similar expectation of secrecy."¹²⁹⁰

The Federal Circuit addressed several of what it described as the district court's "misconceptions" about "public use."1291 Noting that the district court had considered significant the lack of any control by Dey over Sunovion's clinical studies and the absence of any confidential obligation to Dey by the participants, the Federal Circuit explained that "public use" does not necessarily follow from use by a third party not having an obligation to the inventor.¹²⁹² Instead, secret use by a third party may not constitute a public use, and the court "measure[s] the adequacy of the confidentiality guarantees by looking to the party in control of the allegedly invalidating prior use," which, in third-party use cases, is the third party.¹²⁹³ Thus, the court explained that "a secret third-party use is not invalidating."¹²⁹⁴ Applying these standards, the court concluded that because "a reasonable jury could conclude" that there was an expectation of confidentiality in Study 50, albeit not to the inventors, summary judgment was inappropriate.¹²⁹⁵

The Federal Circuit also addressed the district court's conclusion, and Sunovion's arguments, that use at home by the Study 50 participants of Batch 3501A was key and that it was immaterial whether the study participants understood the formulation's composition.¹²⁹⁶ According to the Federal Circuit, "[t]hese arguments take the cited precedent out of context and stretch it too far."¹²⁹⁷ The court explained that the district court erred in

^{1288.} *Id.*

^{1289.} *Id.* at 1357.

^{1290.} *Id.* (quoting Invitrogen Corp. v. Biocrest Mfg., L.P., 424 F.3d 1374, 1382 (Fed. Cir. 2005)).

^{1291.} *Id.* at 1358–60.

^{1292.} *Id.* at 1358.

^{1293.} *Id.* 1294. *Id.* at 1358–59.

^{1294.} *Id.* at 1358–55. 1295. *Id.* at 1359–60.

^{1296.} *Id.* at 1359. 00.

^{1297.} Id.

dismissing the participants' limited knowledge of Batch 3501A's formulation and sidestepping disputed factual questions about the nature of the alleged public use.¹²⁹⁸ For this reason, the court held that "a reasonable jury could conclude that if members of the public are not informed of, and cannot readily discern, the claimed features of the invention in the allegedly invalidating prior art, the public has not been put in possession of those features."1299

Judge Newman dissented from the court's decision to remand the case and would have held that the clinical trial was not an invalidating "public use."1300 She would not have remanded due to the absence of facts in dispute or facts that required a finding that these trials were a public use.¹³⁰¹ Instead, she would have merely reversed the district court, as "[t]he issue requires resolution, not perpetuation."¹³⁰²

G. Obviousness

An invention is obvious as a matter of law "if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art."¹³⁰³ Several factual inquiries underlie this determination, including the scope and content of the prior art, the level of ordinary skill in the field of the invention, the differences between the claimed invention and the prior art, and any objective evidence of nonobviousness.¹³⁰⁴ Relevant objective evidence of nonobviousness, or "secondary considerations," includes "commercial success, long felt but unsolved needs, failure of others," and unexpected results.¹³⁰⁵

In Soverain Software LLC v. Newegg Inc., 1306 the Federal Circuit reversed the district court's validity determination, finding all asserted claims in

^{1298.} Id.

^{1299.} Id.

^{1300.} Id. at 1360 (Newman, J., dissenting).

^{1301.} Id. at 1361.

^{1302.} Id. 1303. 35 U.S.C. § 103(a) (2012).

^{1304.} Graham v. John Deere Co., 383 U.S. 1, 17–18 (1966); *see also* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 406–07 (2007) ("If a court, or patent examiner, conducts this [factual] analysis and concludes the claimed subject matter was obvious, the

claim is invalid under § 103."). 1305. Graham, 383 U.S. at 406; accord KSR, 550 U.S. at 406; see, e.g., In re Soni, 54 F.3d 746, 750 (Fed. Cir. 1995) (explaining how a patent applicant would make a showing of "unexpected results" in proving the obviousness of a patent the applicant allegedly infringed upon).

^{1306. 705} F.3d 1333 (Fed. Cir.), modified on reh'g, 728 F.3d 1332 (Fed. Cir. 2013) (per curiam).

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three of Soverain Software LLC's ("Soverain") patents obvious in view of the prior art.¹³⁰⁷ Soverain filed a patent infringement suit against Newegg Inc. ("Newegg"), alleging infringement of U.S. Patent Nos. 5,715,314 ("the '314 patent"); 5,909,492 ("the '492 patent"); and 7,272,639 ("the '639 patent").¹³⁰⁸ The patents pertained "to electronic commerce, wherein a merchant's products are offered and purchased online."¹³⁰⁹ After the jury returned a verdict finding infringement of the '314 and '492 patents, "the district court granted Soverain's motion for JMOL of infringement of the '639 patent."¹³¹⁰ Concluding that there was insufficient evidence and a possibility of confusion, the district court declined to allow the jury to determine the issue of obviousness.¹³¹¹ Instead, the district court found that the asserted claims were not invalid.¹³¹²

On appeal, the Federal Circuit addressed the district court's removal of obviousness—a question of law—from the jury and concluded that the district court did not violate the right to a jury trial.¹³¹³ The Federal Circuit then turned its focus to whether the district court correctly determined the question of obviousness, which the court reviewed de novo.¹³¹⁴

The asserted claims of the '314 patent and the '492 patent ("the shopping cart claims") are directed to a network-based sales system, wherein a buyer designates products for purchase by placing them in a "shopping cart," and a request for payment is initiated after a buyer requests to check out.¹³¹⁵ The claims indicate that each selected product is identified by a shopping cart "message" comprising a "product identifier."¹³¹⁶ The Federal Circuit determined that the "product identifier" message of the asserted claims was patently indistinguishable from the message in the CompuServe Mall system, the primary prior art reference, as both commands designated a specific product for placement in the buyer's personal holding file.¹³¹⁷ Moreover, the court determined that the "product identifier" term had no special meaning or designated format requirements.¹³¹⁸

 1307.
 Id. at 1347.

 1308.
 Id. at 1334–35.

 1309.
 Id. at 1335.

 1310.
 Id. at 1336.

 1311.
 Id.

 1312.
 Id.

 1313.
 Id. at 1336–37.

 1314.
 Id. at 1337.

 1315.
 Id.

 1316.
 Id. at 1338.

 1317.
 Id. at 1339.

 1318.
 Id.

Soverain argued that its system was superior to the prior art because it could be used with the Internet.¹³¹⁹ The court, relying on Muniauction, Inc. v. Thomson Corp., ¹³²⁰ held that "a person of ordinary skill could have adapted the CompuServe order command to known browser capabilities when these capabilities became commonplace" and that it was obvious to do so.¹³²¹ Ultimately, the court concluded that the shopping cart claims were obvious in light of the CompuServe Mall system.¹³²²

The remaining asserted claims of the '492 patent-the so-called "hypertext statement claims"-regarded the online shopping system outlined in the patents, in which the server computer sends transaction statements to the client computer per a request from the client computer.¹³²³ The Federal Circuit held that the distinction Soverain offered between the hypertext statement claims and prior art "[wa]s not a limitation on the claims other than a commonplace Internet capability to facilitate on-line transactions."¹³²⁴ The court distinguished Muniauction, which held that "it was obvious to 'apply[] the use of the Internet to existing electronic processes at a time when doing so was commonplace,"1325 whereas here, using hypertext to communicate a "statement document" or "transaction detail document" was an acceptable and familiar usage of Internet technology within existing processes.¹³²⁶ Accordingly, the court held that the hypertext statement claims were also obvious.¹³²⁷

The court then turned to the asserted "session identifier claims" of the '639 patent, which disclosed "methods of processing service requests from a client to a server system through a network."¹³²⁸ As to the term "session identifier," the parties stipulated to the following: "'a text string that identifies a session,' wherein a 'session' is a 'series of requests and responses to perform a complete task or set of tasks between a client and a server system."¹³²⁹ In light of the agreed-upon claim construction, the

^{1319.} Id. at 1340.

^{1320. 532} F.3d 1318 (Fed. Cir. 2008).

^{1321.} Soverain Software, 705 F.3d at 1340 (footnote omitted) (agreeing that "conducting previously known methods through an Internet web browser [is] obvious because it amount[s] to no more than applying the use of the Internet to existing electronic processes at a time when doing so was commonplace" (quoting Muniauction, 532 F.3d at 1327) (internal quotation marks omitted)).

^{1322.} *Id.* at 1341. 1323. *Id.* at 1342 (internal quotation marks omitted).

^{1324.} Id. at 1343.

^{1325.} Id. at 1343–44 (alteration in original) (quoting Muniauction, 532 F.3d at 1327).

^{1326.} Id. at 1344.

^{1327.} Id.

^{1328.} Id. (internal quotation marks omitted).

^{1329.} Id. at 1345.

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court found no distinction between the claimed "session identifier," the "credential identifier," or the "transaction identifier" as used in the asserted prior art references.¹³³⁰ Thus, the court held that the session identifier claims were also obvious.¹³³¹

As for secondary considerations of nonobviousness, Soverain argued that its software, which allegedly corresponded to the asserted claims, enjoyed "widespread recognition in the general media" and had been "widely licensed."¹³³² Nonetheless, the court agreed with Newegg that Soverain had not established a nexus between the software and the patents.¹³³³ Moreover, the court indicated that the software did not achieve widespread acceptance in the industry and was "abandoned by almost all of its original licensees."¹³³⁴ Accordingly, the Federal Circuit reversed the judgments of validity and vacated the judgments of infringement and damages.¹³³⁵

Approximately seven months later, the Federal Circuit granted the parties' request for rehearing to clarify its rulings on claims 34 and 35 of the '314 patent.¹³³⁶ On rehearing, the Federal Circuit criticized the district court for directing its substantive analysis to limitations in claim 34 and for its failure to discuss any limitation of claim 35 in relation to either validity or infringement.¹³³⁷ The court further noted that the parties directed their efforts only to claim 34, as "[c]laim 35 was not briefed on this appeal, and was not mentioned in the argument of the appeal."¹³³⁸ Indeed, the court indicated that it "treated claim 34 as 'representative' of the shopping cart claims in suit, and held claim 34 invalid."1339 Additionally, although Soverain submitted supplemental briefing, the court found that it did not provide any new information concerning the specific limitation of claim 35.1340 Thus, the court "confirm[ed] that claim 34 [was] representative of the 'shopping cart' claims, including claim 35, and concluded that dependent claim 35 [was] invalid on the ground of obviousness."¹³⁴¹

1333. Id.

- 1335. Id. at 1347.
- 1336. Soverain Software LLC v. Newegg, Inc., 728 F.3d 1332, 1333 (Fed. Cir. 2013) (per curiam).

^{1330.} Id. at 1346.

^{1331.} Id.

^{1332.} *Id.*

^{1334.} *Id.*

^{1337.} See id. at 1334.

^{1338.} Id. at 1334-35.

^{1339.} *Id.* at 1335.

^{1340.} Id.

^{1341.} *Id.* at 1136.

In Bayer Healthcare Pharmaceuticals, Inc. v. Watson Pharmaceuticals, Inc.,1342 the Federal Circuit reversed the district court's entry of summary judgment that the asserted claims of U.S. Patent No. RE37,564 ("the '564 patent") were not invalid for obviousness.¹³⁴³ The '564 patent related to pharmaceutical formulations and dosing regimens for combined oral contraceptive ("COC") products, which are commonly known as birth control pills.¹³⁴⁴ Bayer Healthcare Pharmaceuticals, Inc. and Bayer Schering Pharma AG (collectively "Bayer") developed low-dose COC synthetic а estrogen ethinylestradiol ("EE") and the synthetic progestin drospirenone ("DRSP").¹³⁴⁵ Whereas early COCs were dosed on a 21/7 schedule, in which patients would take the medication for twenty-one days followed by seven pill-free days, Bayer designed its formulation to be administered with a reduced pill-free interval comprising twentythree or twenty-four days of medication, followed by four or five days without.¹³⁴⁶ Bayer's commercial embodiment of these regimens of the '564 patent were marketed under the name YAZ[®].¹³⁴⁷

Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., Sandoz, Inc., Lupin Ltd., and Lupin Pharmaceuticals, Inc. (collectively "the defendants") filed ANDAs to market generic versions of YAZ[®].¹³⁴⁸ In response, Bayer sued, alleging infringement of claims 13 and 15 of the '564 patent.1349 The defendants conceded infringement but counterclaimed that the asserted claims were invalid for obviousness.¹³⁵⁰ The parties filed cross motions for summary judgment on the issue of obviousness.¹³⁵¹ The district court granted Bayer's motion, concluding that the asserted claims were not invalid.¹³⁵²

On appeal, the Federal Circuit determined that the asserted claims of the '564 patent were obvious at the time of invention in light of six prior art references.¹³⁵³ The defendants argued that one of the references disclosed a low-dose COC combining EE and DRSP in the dosage ranges encompassing those of the recited claims.¹³⁵⁴ The defendants further argued that the remaining references provided

^{1342. 713} F.3d 1369 (Fed. Cir. 2013).

^{1343.} Id. at 1370-71.

^{1344.} Id. at 1371.

^{1345.} Id. at 1370-71. 1346. Id. at 1371-72.

^{1347.} *Id.* at 1372. 1348. *Id.* at 1370, 1372.

^{1349.} Id. at 1372.

^{1350.} Id.

^{1351.} *Id.* 1352. *Id.* at 1372–73.

^{1353.} Id. at 1373-74.

^{1354.} Id. at 1374.

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motivation to combine the low-dose COC with a reduced pill-free interval by identifying the problem of missed-pill conceptions, and suggested a shortened pill-free interval as a solution.¹³⁵⁵ Agreeing with the defendants, the court reasoned that "the cited prior art references set forth every limitation required by the asserted claims and provide express motivation to combine those teachings to derive the claimed COC products."¹³⁵⁶ The court continued:

[W]ith every limitation of the asserted claims thus disclosed in the cited references, the question, as the district court recognized, becomes whether a person of ordinary skill in the art would have been motivated to combine those teachings to derive the claimed subject matter with a reasonable expectation of success.¹³⁵⁷

The court concluded that based on the prior art's recommendations to use the 24/4 and 23/5 dosing regimens, which would minimize the risks of escape ovulation, someone of ordinary skill in the art would have been led to implement such a shortened pill-free interval for use with known low-dose COCs, as the asserted claims stated.¹³⁵⁸

The Federal Circuit then found Bayer's evidence of secondary indicia of nonobviousness legally insufficient.¹³⁵⁹ As to unexpected results, the court found that the data Bayer relied upon confirmed that administering additional active pills to generate a shortened pillfree interval resulted in additional follicular suppression, which even Bayer's expert agreed was "common sense."¹³⁶⁰ The court found that Bayer's evidence of expert skepticism did not show surprise by FDA experts but merely "reflect[ed] attention to the FDA's normal duties ensuring the safety and efficacy of new drugs by requiring actual data to corroborate statements in a new drug application."1361 The court also rejected Bayer's evidence of industry praise, including Bayer's citations to its own efficacy studies and an article by the first-named inventor of the '564 patent that characterized the 24/4 COC regimen as an "innovative strategy."¹³⁶² The court found that "[s]uch bare journal citations and self-referential commendation [fell] well short of demonstrating true industry praise," and that "industry praise of what was clearly rendered obvious by published references is not a persuasive secondary consideration."1363 Finally, the court rejected Bayer's evidence

- 1355. Id.
- 1356. Id.
- 1357. *Id.* at 1375.
- 1358. *Id.* at 1376. 1359. *Id.* at 1377.

- 1361. *Id.*
- 1362. Id.
- 1363. Id.

^{1360.} *Id.*

of copying as not probative in the ANDA context because the FDA requires a showing of bioequivalence for approval.¹³⁶⁴

The patents at issue in Allergan, Inc. v. Sandoz Inc.¹³⁶⁵ related to Allergan, Inc.'s ("Allergan") drug Combigan[®], a combination brimonidine and timolol eye-drop product used to treat glaucoma.¹³⁶⁶ U.S. Patent No. 7,323,463 ("the '463 patent") was directed to a composition comprising the two active ingredients, whereas asserted claim 4 of U.S. Patent No. 7,030,149 ("the '149 patent") related to reducing the number of daily doses of the drug combination from three to two without a corresponding loss of efficacy.¹³⁶⁷ Sandoz Inc. ("Sandoz") and several other companies filed ANDAs directed to Allergan's Combigan[®].¹³⁶⁸ In response, Allergan filed infringement actions.¹³⁶⁹ On appeal, the Federal Circuit reversed the district court's finding that the '463 patent was not invalid as obvious, and affirmed the finding that claim 4 of the '149 patent would not have been obvious.1370

With respect to the '463 patent, the Federal Circuit noted that the topical administration of timolol and brimonidine, the '463 patent's two active ingredients, to the eye was taught in the prior art, and that compositions of the two drugs at the claimed concentration were commercially available for this purpose at the time of the invention.¹³⁷¹ Further noting that a prior art reference provided an express motivation to combine the two drugs in order to increase patient compliance, the court found that a person of ordinary skill would have been motivated to develop a fixed combination of brimonidine and timolol with a reasonable expectation of success.¹³⁷² Responding to the district court's finding of no motivation to combine because the FDA did not consider patient compliance in its approval decisions, the court stated that although FDA approval may be relevant to the obviousness inquiry, "[m]otivation to combine may be found in many different places and forms."1373 Thus, there is no

^{1364.} Id.

^{1365. 726} F.3d 1286 (Fed. Cir. 2013), cert. denied, 82 U.S.L.W. 3458 (U.S. Mar. 31, 2014) (No. 13-889).

^{1366.} *Id.* at 1289. 1367. *Id.* at 1288–89.

^{1368.} Id. at 1288.

^{1369.} Id.

^{1370.} Id.

^{1371.} Id. at 1290-91. 1372. Id. at 1291–92.

^{1373.} Id. at 1292.

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requirement that the motivation to develop the claimed invention be related to FDA approval.¹³⁷⁴

Although the Federal Circuit noted that formulation science entails some degree of unpredictability, it nevertheless found a reasonable expectation of success in light of the prior art teaching to administer brimonidine and timolol solutions together.¹³⁷⁵ The court accepted the district court's factual findings regarding teaching away, long-felt need, and unexpected results; however, the Federal Circuit found these factors insufficient to render the claimed invention nonobvious.¹³⁷⁶ With respect to unexpected results, the court agreed that an increase of efficacy was unexpected but held that this finding did not outweigh the analysis that motivation to combine brimonidine and timolol existed for increased patient compliance.¹³⁷⁷ Accordingly, the court "conclud[ed] that the claims of the '463 patent [were] invalid as obvious."1378

Having found the '463 patent claims invalid, the Federal Circuit noted that claim 4 of the '149 patent added an additional limitation that reduced the daily doses of brimonidine "from 3 to 2 times a day without loss of efficacy."¹³⁷⁹ The court acknowledged that when brimonidine is dosed twice-instead of three times a day-a loss of efficacy occurs in the afternoon, which is referred to as the "afternoon trough."¹³⁸⁰ And although the prior art showed that brimonidine and timolol could be co-administered twice daily, it did "not show that there was no loss of efficacy associated with that treatment."¹³⁸¹ Thus, Sandoz provided no evidence in the prior art to support a finding that the addition of timolol would alleviate the loss of efficacy and thus failed to establish obviousness.¹³⁸²

Finally, addressing Allergan's arguments that the district court erred in construing claims 1 through 3 of the '149 patent, the Federal Circuit found no error.¹³⁸³ Specifically, "[t]he district court construed the term 'administered in separate compositions' to require that serial administration of brimonidine and timolol be compared to the fixedcombination product."¹³⁸⁴ Looking to the plain language of the claim,

^{1374.} Id.

^{1375.} Id.

^{1376.} Id. at 1293.

^{1377.} Id. 1378. Id.

^{1379.} Id. (emphasis omitted). 1380. Id. at 1294.

^{1381.} Id.

¹³⁸⁹ Id

^{1383.} Id. at 1294-95.

^{1384.} Id. at 1295.

the Federal Circuit agreed with the district court that the term "contemplates that administration of both compositions to the same eye be compared to the combination product."¹³⁸⁵

Judge Dyk, who concurred in part and dissented in part, also agreed with the district court's claim construction and joined in the majority's holding that the '463 patent was obvious but would have found claim 4 of the '149 patent obvious.¹³⁸⁶ Judge Dyk opined that the majority's opinion hinged on the determination "that claim 4 was not obvious because it claims the result of twice-a-day dosing avoiding a loss of efficacy in the afternoon."¹³⁸⁷ But according to Judge Dyk, avoiding a loss of efficacy was a result of the claimed method, not a separate step.¹³⁸⁸ He was therefore of the opinion that the court should follow its precedent in *Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc.*,¹³⁸⁹ and recognize "that '[n]ewly discovered results of known processes directed to the same purpose are not patentable."¹³⁹⁰

In *Novo Nordisk A/S v. Caraco Pharmaceutical Laboratories, Ltd.*,¹³⁹¹ the Federal Circuit found no error in the district court's finding that U.S. Patent No. 6,677,358 ("the '358 patent") was invalid as obvious.¹³⁹² Accordingly, the Federal Circuit affirmed the district court's holding that claim 4 of the '358 patent was invalid.¹³⁹³ The Federal Circuit, however, reversed the district court's holding of unenforceability on the basis of inequitable conduct.¹³⁹⁴

The '358 patent includes a method claim for treating Type II diabetes using repaglinide and metformin.¹³⁹⁵ After investigating repaglinide, Novo Nordisk A/S and Novo Nordisk Inc. (collectively "Novo") conducted a study ("the Moses Study") "to determine whether repaglinide might be more effective when administered in combination therapy with metformin."¹³⁹⁶ The Moses Study found that the combination of metformin and repaglinide "reduced [fasting blood glucose] to levels more than eight times lower than what was

^{1385.} Id.

^{1386.} Id. (Dyk, J., concurring in part and dissenting in part).

^{1387.} Id. at 1296 (internal quotation marks omitted).

^{1388.} Id.

^{1389. 246} F.3d 1368 (Fed. Cir. 2001).

^{1390.} *Allergan*, 726 F.3d at 1296 (Dyk, J., concurring in part and dissenting in part) (alteration in original) (quoting *Bristol-Myers Squibb*, 246 F.3d at 1376).

^{1391. 719} F.3d 1346 (Fed. Cir. 2013).

^{1392.} Id. at 1348, 1359–60.

^{1393.} *Id.* at 1359–60.

^{1394.} *Id.*; *see infra* text accompanying notes 1579–96 (discussing inequitable conduct generally as well as *Novo Nordisk*'s inequitable conduct analysis).

^{1395.} *Novo Nordisk*, 719 F.3d at 1348–49.

^{1396.} *Id.* at 1349.

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typically achieved by metformin alone."¹³⁹⁷ Based on the results from the Moses Study, Novo filed a patent application for methods of treatment using a repaglinide/metformin combination.¹³⁹⁸ In response to the examiner's obviousness rejection, Novo submitted, via a declaration from one of its scientists, Dr. Sturis, the results of an additional study in obese rats that, when combined with the Moses Study, demonstrated a synergistic effect of repaglinide/metformin combination therapy.¹³⁹⁹ Based on this declaration, the USPTO issued the '358 patent.¹⁴⁰⁰

In response to an ANDA filed by Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") to market a generic version of repaglinide, Novo filed suit and asserted infringement of claim 4 of the '358 patent.¹⁴⁰¹ The district court found the claim invalid as obvious and unenforceable due to inequitable conduct.¹⁴⁰²

The Federal Circuit first considered the district court's obviousness ruling, which Novo challenged on the following three grounds: (1) the district court's misallocation of the burden of persuasion; (2) the evidence presented by Caraco was insufficient to support the district court's obviousness conclusion; and (3) the district court's failure to afford deference to the examiner's original finding.¹⁴⁰³ The Federal Circuit rejected Novo's contention that, in employing language referring to Novo's attempt to overcome Caraco's prima facie case of obviousness, the district court inappropriately shifted the burden of persuasion in contravention of 35 U.S.C. § 282.¹⁴⁰⁴ While the court agreed that "the burden of persuasion remains with the challenger" because of the presumption of validity, it stated that this "does not relieve the patentee of any responsibility to set forth evidence in opposition to a challenger's prima facie case which, if left unrebutted, would be sufficient to establish obviousness."¹⁴⁰⁵

More specifically, the district court had found that, unless rebutted, Caraco presented evidence "sufficient to establish that the repaglinide/metformin combination was obvious to try, and that a person of ordinary skill in the art would have reasonably expected the combination would yield success in the form of beneficial, and even

1397. Id.

^{1398.} Id.

^{1399.} Id. at 1350–51.

^{1400.} *Id.* at 1351.

^{1401.} Id.

^{1402.} Id.

^{1403.} Id. at 1352.

^{1404.} *Id.* at 1352–54.

^{1405.} *Id.* at 1353.

synergistic, results."¹⁴⁰⁶ After reaching that conclusion, the district court next appropriately considered "whether Novo's countervailing secondary consideration evidence of unexpected synergy (i.e., its 'attempt to prove unexpected results') was sufficient to 'overcome' Caraco's prima facie case."¹⁴⁰⁷ The court concluded that the use of the words "overcome" and "prima facie" did not necessarily shift the onus of the burden of persuasion.¹⁴⁰⁸ Indeed, "as long as the court reserved its ultimate conclusion on validity until after it considered the evidence from both sides, this language simply reflect[ed] the court's shift of the burden of production once the court determined that the challenger has established a prima facie case of obviousness."1409

Addressing Novo's argument regarding the expectation of results, the court found that the district court did not err in holding that the combination of metformin and repaglinide would predictably show synergy because synergy was known to occur when metformin was combined with sulfonylurea-a compound with similar properties and a similar mechanism of action to repaglinide.¹⁴¹⁰ The Federal Circuit concluded that "Caraco proved by clear and convincing evidence that an artisan would have expected the level of synergy Novo found when it combined metformin and repaglinide."1411

The Federal Circuit was also not persuaded by Novo's argument, which relied on Kappos v. Hyatt,¹⁴¹² that the district court should have given deference to the examiner's finding of synergy in the clinical trials.¹⁴¹³ The court stated that *Hyatt* was irrelevant, as it involved a 35 U.S.C. § 145 action directly challenging a USPTO rejection, whereas here the plaintiff was challenging an issued patent under the Hatch-Waxman Act.¹⁴¹⁴ Instead, while an issued patent has a presumption of validity that must be overcome by clear and convincing evidence, "[n]o decision of the Supreme Court or this court has ever suggested that there is an added burden to overcome [US]PTO findings in district court infringement proceedings."1415

^{1406.} Id.

^{1407.} *Id.* 1408. *Id.*

^{1409.} Id. at 1354.

^{1410.} Id. at 1355.

^{1411.} Id. at 1356. 1412. 132 S. Ct. 1690 (2012).

^{1413.} See Novo Nordisk, 719 F.3d at 1356-57 (rejecting Novo's assertion that Hyatt requires district courts to defer to an examiner's findings when no new evidence is presented at trial (citing Hyatt, 132 S. Ct. at 1696)). 1414. Id.

^{1415.} Id. at 1357.

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Judge Newman, who concurred in part and dissented in part, agreed with the majority in finding no inequitable conduct but dissented on the basis of obviousness.¹⁴¹⁶ According to Judge Newman, "[t]he question is not whether it would have been obvious to look for synergistic combinations; the question is whether it was obvious that the combination of metformin and repaglinide would exhibit synergism and that the combination would be 800% more effective than the additive effect of the components separately."1417 Judge Newman, persuaded by the evidence that the USPTO granted the '358 patent based on the synergistic effects demonstrated in clinical studies, noted that the prior art did not show that all sulfonylurea compounds showed a synergistic effect in combination with metformin.¹⁴¹⁸ Judge Newman thus believed that the synergistic effects demonstrated for the claimed combination "was not suggested in the prior art, was not predictable, and was not obvious."1419

In *Smith & Nephew, Inc. v. Rea*, the Federal Circuit reversed the Board's decision holding that certain claims of U.S. Patent No. 7,128,744 ("the '744 patent") were nonobvious.¹⁴²⁰ Synthes (U.S.A.) ("Synthes"), a medical device company, owns the '744 patent, which "is directed to a system for using plates to repair bone fractures in long bones."¹⁴²¹ The "bone plate" is attached to the bone by "bone anchors" inserted through the plate's predrilled holes.¹⁴²² The dispute centered "on the structure of the holes in the plate through which the screws are inserted."¹⁴²³ Additionally, the '744 patent "claims priority to a provisional application filed on September 13, 1999."¹⁴²⁴

On reexamination requested by Smith & Nephew, Inc. ("Smith & Nephew"), the USPTO examiner rejected all fifty-five claims as obvious due to numerous prior art references, including a 1997 article by N.P. Haas ("the Haas article") and Synthes devices from the 1990s ("the Synthes devices").¹⁴²⁵ The Haas article disclosed a plate with "only conically tapered, threaded holes in the shaft and head portions of the plate."¹⁴²⁶ The Synthes devices consisted of a Distal Radius Plate for wrist

^{1416.} Id. at 1360 (Newman, J., concurring in part and dissenting in part).

^{1417.} Id.

^{1418.} *Id.* at 1362.

^{1419.} *Id.*

^{1420. 721} F.3d 1371, 1373 (Fed. Cir. 2013); *see supra* text accompanying notes 679–91 (discussing the reasons behind the Federal Circuit's reversal of the USPTO despite the deferential standard of review).

^{1421.} Smith & Nephew, 721 F.3d at 1373.

^{1422.} Id.

^{1423.} Id.

^{1424.} Id.

^{1425.} *Id.* at 1373–75.

^{1426.} Id. at 1374–75.

fractures with all anchor holes partially threaded and designed for use with either locking or nonlocking screws, and a Locking Reconstruction Plate for jaw fractures with anchor holes having threaded lower portions and unthreaded, conically flared upper portions that allowed for countersunk screws.¹⁴²⁷

The examiner concluded that combining the Haas article with any of the references cited taught the claimed invention.¹⁴²⁸ He also adopted Smith & Nephew's argument that there was a motivation to combine the references because having all screw holes threaded would provide the option of using either locking or compression screws.¹⁴²⁹ Synthes appealed to the Board, which upheld the rejections of thirty-one of the claims and reversed the rejections of twenty-four of the claims.¹⁴³⁰ The Board concluded that "[t]he prior art references did not teach or suggest the exclusive use of conical, partially threaded holes in a condylar buttress plate because it was not believed that those holes could be used with non-locking screws to provide compression."¹⁴³¹

On appeal, the Federal Circuit reversed the Board's decision that the twenty-four claims were nonobvious, finding "several problems with the Board's analysis."¹⁴³² While acknowledging that the "substantial evidence standard of review" required that the court give deference to the Board's findings of fact, the Federal Circuit noted that the Board's factual findings, which were largely undisputed, were not at issue in the case.¹⁴³³ Instead, the case centered on the analytical errors in the Board's decision about the obviousness of including only threaded holes in the head portion of the condylar plate.¹⁴³⁴ The Federal Circuit reasoned that,

[g]iven the compelling evidence that it would have been obvious to modify any one of the three primary references to have only threaded holes in the head portion, the sole remaining feature that distinguishes the plate system of claim 1 from the prior art condylar plate systems using partially threaded holes is the fully conical shape of the holes in the plate recited in claim 1. And that feature is found in the secondary reference, [the] Haas [article].¹⁴³⁵

^{1427.} Id. at 1375.

^{1428.} Id.

^{1429.} Id.

^{1430.} Id. at 1373 (upholding claims 24-31 and 33-55 and reversing claims 1-23 and 32).

^{1431.} Id. at 1377.

^{1432.} *Id.* at 1377–80, 1382.

^{1433.} *Id.* at 1380 (quoting *In re* Gartside, 203 F.3d 1305, 1316 (Fed. Cir. 2000)) (internal quotation marks omitted).

^{1434.} Id.

^{1435.} Id.

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The remaining question before the Federal Circuit was whether it would "have been obvious to a person of ordinary skill in the art to combine the partially threaded holes . . . with the partially threaded, conical holes," which were both disclosed in the prior art.¹⁴³⁶ The Federal Circuit found that this case fell into "the Supreme Court's characterization of obviousness as entailing an improvement that is no 'more than the predictable use of prior art elements according to their established functions."¹⁴³⁷ The Federal Circuit concluded that the patentability of the invention at issue turned on the structure of the holes-which was well known in the art-not the nature of the screws used with those holes.¹⁴³⁸ Accordingly, the Federal Circuit reversed the part of the Board's decision upholding any of the patent's claims.¹⁴³⁹

In Leo Pharmaceutical Products, Ltd. v. Rea, the Federal Circuit reversed the Board's claim construction and obviousness determinations.¹⁴⁴⁰ U.S. Patent No. 6,753,013 ("the '013 patent") is owned by Leo Pharmaceutical and directed to "storage stable" compositions for the treatment of psoriasis comprising a combination of at least one vitamin D analog, a corticosteroid, and a solvent selected from a particular group of nonaqueous solvents.¹⁴⁴¹

Relying on the examiner's findings, the Board rejected several "claims of the '013 patent as obvious over three prior art references: U.S. Patent No. 4,083,974 (Turi); U.S. Patent No. 4,610,978 (Dikstein); and WO 94/13353 (Serup)."1442 Finally, the Board determined that the evidence presented in support of objective indicia of nonobviousness was insufficient.1443

The Federal Circuit found that the Board's construction of "storage stable" was impermissibly narrow, as it failed to encompass "a composition that maintains its stability during its shelf life for its intended use as an approved pharmaceutical product for sale and home use by ordinary customers."1444 Although the court declined to adopt a specific construction, a broad understanding of "storage stability" was key to its finding that the '013 patent was not simply a

^{1436.} Id.

^{1437.} Id. at 1381 (quoting KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 417 (2007)).

^{1438.} Id. at 1381-82.

^{1439.} Id. at 1382.

^{1440. 726} F.3d 1346, 1348 (Fed. Cir. 2013); see supra text accompanying notes 669-78 (providing an overview of this case).

^{1441.} Leo Pharm., 726 F.3d at 1348–49. 1442. Id. at 1350–51 (rejecting claims 1, 2, 4–8, 14, 16–19, 21, 23, 39–91, and 143–146).

^{1443.} Id. at 1351.

^{1444.} Id. at 1352.

combination of elements found in the prior art.¹⁴⁴⁵ In particular, the court noted that the inventors of the '013 patent "recognized and solved a problem with the storage stability of certain formulations—a problem that the prior art did not recognize and a problem that was not solved for over a decade."¹⁴⁴⁶

Discussing the teaching away in the prior art, the Federal Circuit explained that while "Dikstein and Serup attempt[ed] the combination of a vitamin D analog with a corticosteroid, neither disclose[d] or addresse[d] the stability problems of combining vitamin D analogs and corticosteroids into one pharmaceutical formulation."¹⁴⁴⁷ Because the prior art did not disclose stability issues, there was no motivation "to improve upon either Dikstein or Serup using Turi."¹⁴⁴⁸ The court, guided by hindsight, concluded that the Board erred by folding the obviousness analysis into a combination of elements analysis.¹⁴⁴⁹ The record included numerous reasons suggesting why "a person of ordinary skill in the art would not have been motivated to try" the claimed invention of the '013 patent, let alone make it.¹⁴⁵⁰ Accordingly,

[i]n light of the lack of expectation of a successful result, the failure of the prior art to provide direction, and the substantial number of intervening years between the publication of the prior art and the '013 patent's filing date, this invention is not simply a case of picking and choosing from a list in order to achieve a compatible and non-deleterious preparation as the Board suggests.¹⁴⁵¹

The Federal Circuit also found extensive evidence of unexpected results that, together with the entire obviousness analysis, presented a compelling case of nonobviousness.¹⁴⁵² The court reasoned that the comparative data of the Dikstein and Serup formulations provided strong evidence during reexamination "that the '013 patent's combination of known elements yield[ed] more than just predictable results."¹⁴⁵³ Additionally, the court found persuasive evidence that Leo Pharmaceutical's Taclonex[®] ointment, which embodied the elements of the '013 patent, was "the first FDA-approved drug to combine vitamin D and corticosteroids into a single formulation"

^{1445.} *Id.* at 1352–53.

^{1446.} *Id.* at 1353.

^{1447.} *Id.* at 1354.

^{1448.} Id.

^{1449.} Id.

^{1450.} *Id.* at 1354–55.

^{1451.} Id. at 1357 (internal quotation marks omitted).

^{1452.} Id. at 1358.

^{1453.} Id.

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product and enjoyed commercial success.¹⁴⁵⁴ The court further noted "evidence of long felt but unresolved need."¹⁴⁵⁵ Specifically, more than twenty-two years had passed since Turi was published and fourteen years since Dikstein was published, yet Leo Pharmaceutical was the first to provide a single formulation comprising a vitamin D analog and a corticosteroid.¹⁴⁵⁶

In *Rambus Inc. v. Rea*, the Federal Circuit reviewed an invalidity decision made by the Board during reexamination proceedings.¹⁴⁵⁷ The Federal Circuit affirmed the Board's claim construction, affirmed the Board's finding of anticipation, vacated the Board's obviousness decision, and remanded for further proceedings.¹⁴⁵⁸

U.S. Patent No. 6,260,097 ("the '097 patent") solves the problem of data-transfer bottlenecks by using a synchronous memory system to transfer data.¹⁴⁵⁹ The USPTO initiated an inter partes reexamination of the '097 patent claims and found that the reexamined claims were not patentable over "Unexamined Japanese Patent Application No. 56-88987 (Inagaki) and the Intel iAPX system manual and specification (iAPX)."¹⁴⁶⁰ The examiner rejected certain claims as anticipated by Inagaki and as obvious in light of iAPX in combination with Inagaki.¹⁴⁶¹ The Board affirmed the rejections, and Rambus appealed.¹⁴⁶²

Turning to obviousness, the Federal Circuit considered the Board's holding that the reexamined claims would have been obvious in view of iAPX in combination with Inagaki.¹⁴⁶³ Rambus argued that the Board committed multiple errors, and the Federal Circuit agreed.¹⁴⁶⁴ First, the Federal Circuit found that the Board erroneously placed the burden on Rambus to show nonobviousness.¹⁴⁶⁵ The court explained that "[i]n reexamination proceedings, 'a preponderance of the evidence must show nonpatentability before the [US]PTO may reject the claims of a patent application."¹⁴⁶⁶ Accordingly, because the Board improperly concluded that Rambus had not demonstrated

^{1454.} Id.

^{1455.} Id. at 1359 (emphasis omitted).

^{1456.} *Id.*

^{1457. 731} F.3d 1248, 1250–51 (Fed. Cir. 2013).

^{1458.} *Id.* at 1252–55; *see supra* text accompanying notes 720–38, 1243–52 (discussing the court's reasoning for vacating the TTAB's obviousness decision and affirming the Board's finding of anticipation).

^{1459.} Rambus, 731 F.3d at 1250.

^{1460.} *Id.* at 1251.

^{1461.} Id.

^{1462.} *Id.*

^{1463.} *Id.* at 1254.

^{1464.} *Id.* at 1254–56.

^{1465.} *Id.* at 1255.

^{1466.} Id. (quoting Ethicon, Inc. v. Quigg, 849 F.2d 1422, 1427, 1156 (Fed. Cir. 1988)).

nonobviousness, the Federal Circuit determined that the Board committed legal error.1467

The Federal Circuit also found that in supplying novel reasons for combining the art relied on during reexamination, the Board exceeded its limited role in reviewing an examiner's decisions.¹⁴⁶⁸ The Federal Circuit explained that the APA ensures that the Board may not rely on different grounds than the examiner when making rejections.¹⁴⁶⁹ According to the court, the ultimate issue is whether the USPTO provided the appellant "a fair opportunity to react to the thrust of the rejection."1470 According to the Federal Circuit, the Board erred by providing its own reasoning for combining the prior art.¹⁴⁷¹ Without considering the merits of the Board's findings regarding the motivation to combine, the Federal Circuit decided that since "[t]he Board has a procedure for issuing a new ground of rejection in appeals of *inter partes* reexaminations," the court could "not let the Board shortcut this procedure and deprive appellants of their due process rights."1472

Considering the Board's treatment of secondary considerations, the Federal Circuit first held that the Board erred in finding that Rambus's evidence "lacked a nexus because it related to unclaimed features."1473 The court emphasized that "[o]bjective evidence of nonobviousness need only be 'reasonably commensurate with the scope of the claims," a standard that "do[es] not require a patentee to produce objective evidence of nonobviousness for every potential embodiment of the claim."¹⁴⁷⁴ The court noted that while objective evidence of nonobviousness has an insufficient nexus if it relates only "to a feature that was known in the prior art," obviousness will turn on whether the invention viewed in its entirety would have been obvious.¹⁴⁷⁵ The Federal Circuit declined to make such factual determinations on appeal and instead instructed the Board to carefully consider the objective evidence of nonobviousness on remand.1476

^{1467.} *Id.* 1468. *Id.*

^{1469.} Id.

^{1470.} Id. (quoting In re Jung, 637 F.3d 1356, 1365 (Fed. Cir. 2011)) (internal quotation marks omitted).

^{1471.} Id. at 1256.

^{1472.} Id.

^{1473.} Id.

^{1474.} Id. at 1257 (quoting In re Huai-Hung Kao, 639 F.3d 1057, 1068 (Fed. Cir. 2011)).

^{1475.} Id. at 1257–58 (citation omitted) (internal quotation marks omitted).

^{1476.} Id. at 1258.

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In *MeadWestVaco Corp. v. Rexam Beauty & Closures, Inc.*,¹⁴⁷⁷ the Federal Circuit affirmed in part and vacated in part the district court's decision regarding validity and infringement, and remanded for further proceedings.¹⁴⁷⁸ Specifically, the Federal Circuit affirmed the district court's claim constructions, denial of a motion to exclude expert testimony, and finding of infringement, but vacated the district court's summary judgment of nonobviousness and remanded on that issue.¹⁴⁷⁹ The court further found that Rexam Beauty and Closures, Inc. and Rexam Dispensing Systems S.A.S. (collectively "Rexam") as well as Valois of America, Inc. and Valois S.A.S. (collectively "Valois") "waived their indefiniteness arguments by failing to pursue them at trial."¹⁴⁸⁰

U.S. Patent Nos. 7,718,132 ("the '132 patent") and 7,722,819 ("the '819 patent"), which are assigned to MeadWestVaco Corporation and MeadWestVaco Calmar, Inc. (collectively "MWV"), are directed to an "invisible" dip tube for perfume that enhances the appearance of the perfume bottle by disappearing when immersed in liquid.¹⁴⁸¹ Both the '132 and '819 patents include claims specific to fragrance dispensers ("the fragrance-specific claims").¹⁴⁸² The '132 patent, which is a continuation of the '819 patent, includes additional claims directed to generic dispensers ("the generic dispenser claims").¹⁴⁸³

MWV sued Rexam and Valois for infringement of both patents, and in response, Rexam and Valois alleged declaratory judgment counterclaims of invalidity and noninfringement.¹⁴⁸⁴ Ruling on the parties' summary judgment motions, the district court granted MWV's motion for summary judgment of nonobviousness and denied Rexam and Valois's motion for summary judgment of indefiniteness.¹⁴⁸⁵ The district court also found that Rexam and Valois infringed the '132 patent's generic dispenser claims and entered a permanent injunction against both parties.¹⁴⁸⁶ Rexam and Valois appealed.¹⁴⁸⁷

On appeal, the Federal Circuit noted that, whereas obviousness must be analyzed on a claim-by-claim basis, the district court's analysis

^{1477. 731} F.3d 1258 (Fed. Cir. 2013).

^{1478.} Id. at 1261.

^{1479.} *Id.* 1480. *Id.*

^{1481.} *Id.* at 1261–62.

^{1482.} *Id.* at 1262.

^{1483.} Id.

^{1484.} Id. at 1263.

^{1485.} Id.

^{1486.} Id.

^{1487.} Id.

did not distinguish between the fragrance-specific claims and the generic dispenser claims.¹⁴⁸⁸ The court found that MWV's objective evidence of nonobviousness was not "commensurate in scope with the claims."1489

In addition to not distinguishing between the fragrance-specific claims and the generic dispenser claims, the Federal Circuit found that the district court also erred by resolving material issues of fact in favor of the moving party, MWV, which the Federal Circuit noted was "inappropriate at the summary judgment stage."¹⁴⁹⁰ The Federal Circuit held that the evidence presented by Valois "created material issues of fact inappropriate for resolution on summary judgment" and therefore vacated and remanded for a trial on the issue of obviousness.¹⁴⁹¹

In Ohio Willow Wood Co. v. Alps South, LLC, the Federal Circuit affirmed the district court's finding that OWW was collaterally estopped from challenging the invalidity of certain asserted claims of U.S. Patent No. 5,830,237 ("the '237 patent"), and that other asserted claims of the '237 patent were invalid for obviousness.¹⁴⁹² However, the Federal Circuit reversed the district court's grant of summary judgment of no inequitable conduct.1493

The '237 patent is directed to cushioning devices with a gel and fabric liner for covering amputated limbs.¹⁴⁹⁴ OWW sued Alps for infringement of the '237 patent, and the district court stayed the '237 patent litigation pending resolution of two consecutive ex parte reexamination proceedings initiated by Alps.¹⁴⁹⁵ During the first reexamination proceeding, OWW overcame Alps's primary reference, a prior art gel liner manufactured by Silipos, Inc. ("Silipos"), by showing that the gel of Silipos's product bled through the fabric liner to the exterior surface and amending its claims to clarify that the gel remained only on the interior lining of its invention.¹⁴⁹⁶ The second ex parte reexamination initiated by Alps was based on another Silipos product, the "Single Socket Gel Liner" ("SSGL").¹⁴⁹⁷ Alps alleged that the SSGL product did not allow any

^{1488.} Id. at 1264.

^{1489.} Id. at 1264-65 (quoting Asyst Techs., Inc. v. Emtrak, Inc., 544 F.3d 1310, 1316 (Fed. Cir. 2008)).

^{1490.} Id. at 1265.

^{1491.} Id.

^{1492. 735} F.3d 1333, 1377 (Fed. Cir. 2013). 1493. *Id.*; *see infra* notes 1632–43 (discussing the court's inequitable conduct analysis); see also supra Part III.A.3 (analyzing the court's analysis regarding estoppel over nonidentical claims). 1494. *Ohio Willow Wood*, 735 F.3d at 1337.

^{1495.} Id.

^{1496.} Id. at 1337-38.

^{1497.} Id. at 1338.

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gel to bleed through to the exterior surface.¹⁴⁹⁸ In support of its allegation, Alps provided "testimony from Mr. Jean-Paul Comtesse, who had been affiliated with Silipos and involved in the development" of both prior art Silipos products.¹⁴⁹⁹ The examiner rejected the '237 patent claims as obvious in view of the SSGL product.¹⁵⁰⁰ The Board sided with OWW and reversed, finding that Mr. Comtesse was an interested third party and, therefore, his uncorroborated testimony was inadmissible and insufficient to sustain the examiner's rejection.¹⁵⁰¹

During the stay of the '237 patent litigation, OWW instituted another infringement action based on a related patent, U.S. Patent No. 7,291,182 ("the '182 patent").¹⁵⁰² In the '182 patent litigation, the district court found the '182 patent's claims invalid for obviousness on summary judgment, and the Federal Circuit subsequently affirmed this decision on appeal.¹⁵⁰³ The stay in the '237 patent litigation was lifted, and the parties filed motions for summary judgment.¹⁵⁰⁴ The district court granted summary judgment to Alps with respect to validity, finding the asserted claims of the '237 patent invalid either due to the collateral-estoppel effect of the '182 patent litigation or due to obviousness.¹⁵⁰⁵ In addition, the court ruled in favor of OWW's motion for summary judgment of no inequitable conduct.¹⁵⁰⁶ Both parties appealed the district court's summary judgment decisions.¹⁵⁰⁷

On appeal, the Federal Circuit affirmed the district court's grant of summary judgment of obviousness for dependent claims that placed numerical limits on "the 'gel composition' and 'fabric' of independent claim 1 of the '237 patent." 1508 The court held that the addition of the numerical limits was nothing more than "the exercise of routine skill," as "[e]ach of the features were well-known in the prior art and their use would have been predictable by one of ordinary skill in the art."1509 Moreover, the record presented

^{1498.} Id.

^{1499.} Id.

^{1500.} Id. at 1339–40.

^{1501.} *Id.* at 1340–41. 1502. *Id.* at 1341.

^{1503.} Id. (citing Ohio Willow Wood Co. v. Thermo-Ply, Inc., No. 9:07-CV-274, 2009

WL 6499349 (E.D. Tex. Nov. 20, 2009), aff'd per curiam, 440 F. App'x 926 (Fed. Cir. 2011) (mem.)). 1504. Id.

^{1505.} Id.

^{1506.} Id.; see infra notes 1632-43.

^{1507.} Ohio Willow Wood, 735 F.3d at 1341.

^{1508.} Id. at 1343–44.

^{1509.} Id. at 1344.

evidence of prior art devices employing features alleged to be missing from the prior art, which the court determined demonstrated a motivation to combine.¹⁵¹⁰ Finally, the court held that because OWW's evidence of secondary indicia of nonobviousness applied equally to the prior art SSGL product, OWW had failed to establish a nexus with the patented invention and thus had failed to overcome the prima facie finding of obviousness.¹⁵¹¹

In Galderma Laboratories, L.P. v. Tolmar, Inc., a split panel of the Federal Circuit reversed the district court, holding the claims in the patents-in-suit invalid as obvious.¹⁵¹² Galderma Laboratories, L.P., Galderma S.A., and Galderma Research and Development, S.N.C. (collectively "Galderma") own the patents-in-suit directed to composition claims and method claims for treating acne embodied in its topical medication Differin® Gel.¹⁵¹³ Tolmar, Inc. ("Tolmar") filed an ANDA seeking approval to market a generic version of Galderma's Differin[®] Gel, 0.3%, containing 0.3% by weight adapalene.¹⁵¹⁴ In response, Galderma sued Tolmar for infringing the patents-in-suit.¹⁵¹⁵ Before the district court, Tolmar alleged obviousness primarily based on prior art that showed, among other things, that 0.1% and 0.03% adapalene products were suitable for the treatment of acne and were well tolerated, and that 0.3% adapalene was useful for other indications without tolerability issues.¹⁵¹⁶ After a bench trial, the district court found in favor of Galderma.¹⁵¹⁷ While the district court ruled against Tolmar on several issues, obviousness was the sole issue on appeal.¹⁵¹⁸

In reversing the lower court's decision, the Federal Circuit noted that the district court erred in its obviousness inquiry when it required Tolmar to provide motivation in the prior art to raise the concentration of adapalene to the claimed 0.3% product.¹⁵¹⁹ Rather, the court pointed to the wording of 35 U.S.C. § 103 to show that Tolmar only had to demonstrate that "the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill

^{1510.} Id.

^{1511.} Id.

^{1512. 737} F.3d 731, 734 (Fed. Cir. 2013). 1513. *Id*.

^{1514.} Id.

^{1515.} Id.

^{1516.} *Id.* at 734–35. 1517. *Id.* at 734.

^{1518.} Id.

^{1519.} Id. at 737.

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in the art to which the claimed invention pertains."¹⁵²⁰ Here, because Tolmar established that the prior art taught a range that included the claimed invention and the prior art commercial embodiment, the court explained that the central issue was determining whether motivation existed to choose the 0.3% adapalene composition in "the disclosed range."¹⁵²¹ Over the dissent of Judge Newman, the court held that the burden of production fell to Galderma to prove that "(1) the prior art taught away from the claimed invention; (2) there were new and unexpected results relative to the prior art; or (3) there [we]re other pertinent secondary considerations."¹⁵²² In this light, the court found that Tolmar had demonstrated that the claimed 0.3% adapalene composition was within the prior art's range of concentrations for the treatment and moved on to consider whether Galderma had shown the claimed invention nonobvious based on teaching away, unexpected results, or other secondary considerations.¹⁵²³

Addressing the first question, the Federal Circuit reversed the district court's factual findings to hold that the prior art did not teach away from the claimed invention.¹⁵²⁴ The district court found as a factual matter that the prior art taught away from the 0.3% because of dose-dependent increases in side effects.¹⁵²⁵ Although the Federal Circuit did not dispute the associated finding that 0.1% was taught by the prior art to be an optimal concentration, it held that this did not constitute "teaching away" and that the district court erred in finding to the contrary.¹⁵²⁶

Instead, according to the *Galderma* majority, the prior art did not teach away because there was no evidence that raising the concentration to 0.3% would be "unproductive" and no indication that the side effects would be too great to deter the development of a product with 0.3% adapalene.¹⁵²⁷ In other words, "[a] teaching that a composition may be optimal or standard does not criticize, discredit, or otherwise discourage investigation into other compositions" and thus cannot teach away.¹⁵²⁸

With respect to the second question of unexpected results, the Federal Circuit agreed with the district court that the 0.1% and 0.3%

^{1520.} Id. (quoting 35 U.S.C. § 103 (2012)).

^{1521.} *Id.* at 737–38. 1522. *Id.* at 738.

^{1522.} *Id.* at 758. 1523. *Id.*

^{1524.} *Id.* at 738–39.

^{1525.} Id. at 738.

^{1526.} Id.

^{1527.} Id. at 739.

^{1528.} Id.

adapalene tolerability was similar and that this "was unexpected in view of the prior art, since a skilled artisan would have expected that tripling the concentration of adapalene would have resulted in a clinically significant increase in side effects."¹⁵²⁹ However, according to the court, this unexpected result was not "probative of nonobviousness."¹⁵³⁰ Instead, the court found that the unexpected result was a difference "in degree rather than kind" and not indicative of nonobviousness because "the modification of the percentage is within the capabilities of one skilled in the art at the time.^{*1531} Given this reasoning, the court held that "the comparable tolerability of 0.1% and 0.3% adapalene does not indicate that the asserted claims are non-obvious."1532

Addressing the third question of the presence of pertinent secondary considerations, the Federal Circuit rejected the district court's reliance on commercial success evidenced by generic copying and market share.¹⁵³³ Although it recognized that the copying was motivated by profit, the court dismissed this evidence because it did not show the drug's commercial success relative to the prior art, nor did it reveal whether "the commercial success of the branded drug [was] 'due to the merits of the claimed invention beyond what was readily available in the prior art."¹⁵³⁴ The court also dismissed the evidence of commercial success based on market share, stating that "[w]here market entry by others was precluded [due to blocking patents]"-as it saw the case-"the inference of nonobviousness of [the asserted claims], from evidence of commercial success, is weak."¹⁵³⁵ Accordingly, the court found "minimal probative value" in the commercial success of Differin® Gel, 0.3%.¹⁵³⁶

In her dissent, Judge Newman acknowledged the closeness of the obviousness inquiry but still disapproved of the majority's "scant attention to the district court's analysis" and that the majority instead made its "own findings[] and appl[ied] flawed procedural and substantive law."¹⁵³⁷ This dissent criticized the panel majority in particular for "distort[ing] the burdens of proof and production," and for "ignor[ing] the applicable

^{1529.} *Id.* 1530. *Id.*

^{1531.} Id.

^{1532.} *Id.* 1533. *Id.* at 740.

^{1534.} Id. (quoting J.T. Eaton & Co. v. Atl. Paste & Glue Co., 106 F.3d 1563, 1571 (Fed. Cir. 1997)).

^{1535.} Id. (alterations in original) (quoting Merck & Co. v. Teva Pharm. USA, Inc., 395 F.3d 1364, 1377 (Fed. Cir. 2005)) (internal quotation marks omitted). 1536. *Id.* at 740–41 (quoting *Merck & Co.*, 395 F.3d at 1376).

^{1537.} Id. at 741 (Newman, J., dissenting).

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standard of proof."1538 According to Judge Newman, "[t]he district court, unlike the panel majority, correctly recognized that a prima facie showing is not a presumption of obviousness, and does not change the placement of the burden of proof."1539

Moreover, in Judge Newman's view, the majority acknowledged but did not apply the validity presumption.¹⁵⁴⁰ Specifically, she viewed the majority's decision as improperly relieving Tolmar from its burden of persuasion simply because Tolmar showed that the invention was within a disclosed range in the prior art.¹⁵⁴¹ Thus, the majority's ruling, according to Judge Newman, allowed "small differences [that] may have large consequences or benefits," and was particularly worrisome in light of a newly adopted "first-to-file law with its pressures for early filing, possibly before all embodiments have been fully explored."1542

On the facts, Judge Newman found that the district court's "findings well support the conclusion that invalidity on the ground of obviousness was not established by clear and convincing evidence."1543 Therefore, given the heavy burden litigants face in overcoming a district court's factual findings, Judge Newman would have affirmed the district court's holding of nonobviousness.¹⁵⁴⁴

H. Double Patenting

The doctrine of double patenting seeks to prevent the unjustified extension of patent exclusivity beyond the term of a patent.¹⁵⁴⁵ There are two types of double patenting: (1) same-invention-type double patenting and (2) obviousness-type double patenting.¹⁵⁴⁶ Thus, "[a] double patenting rejection precludes one person from obtaining more than one valid patent for either (a) the 'same invention,' or (b) an 'obvious' modification of the same invention."1547

In St. Jude Medical, Inc. v. Access Closure, Inc., 1548 the Federal Circuit reversed and remanded the district court's application of the 35 U.S.C. § 121's safe-harbor provision to protect asserted patents from invalidity

^{1538.} Id.

^{1539.} Id. at 748.

^{1540.} Id. at 749. 1541. Id.

^{1542.} *Id.* at 749–50. 1543. *Id.* at 742.

^{1544.} Id. at 749.

^{1545.} Boehringer Ingelheim Int'l GmbH v. Barr Labs., Inc., 592 F.3d 1340, 1346 (Fed. Cir. 2010).

^{1546.} Id.

^{1547.} In re Longi, 759 F.2d 887, 892 (Fed. Cir. 1985).

^{1548. 729} F.3d 1369 (Fed. Cir. 2013).

due to double patenting and sought to clarify the requirement that the patent must maintain consonance in order for the safe-harbor provision to be applicable.¹⁵⁴⁹ St. Jude Medical, Inc. and St. Jude Medical Puerto Rico, LLC (collectively "St. Jude") own U.S. Patent No. 7,008,439 ("the Janzen patent"), which "relate[s] to methods and devices for sealing a vascular puncture."¹⁵⁵⁰ During prosecution of the Janzen patent's grandparent application, the examiner required restriction of the application under 35 U.S.C. § 121 to Group I (device) or Group II (method) and an election of Species A, B, or C, which were each related to different apparatuses.¹⁵⁵¹ In response, the applicant elected Group I, Species B.¹⁵⁵²

Subsequently, "the applicant filed U.S. Patent Application No. 08/318,380 ('the parent application') as a divisional of the grandparent application."1553 In response to a similar restriction and election requirement, the applicant again elected Group I, Species B.¹⁵⁵⁴ Before the parent application issued, the applicant filed the Janzen application as a continuation of the parent application.¹⁵⁵⁵ To provoke an interference, "the applicant canceled the original claims and copied both device and method claims from a different patent."¹⁵⁵⁶ The applicant prevailed in the interference, and the application issued as the Janzen patent with both device and method claims.¹⁵⁵⁷ The applicant also filed another continuation based on the parent application, which issued as U.S. Patent No. 5,725,498 ("the sibling patent").¹⁵⁵⁸ Notably, as a result of the interference proceeding, the sibling patent issued earlier than the Janzen patent.¹⁵⁵⁹ Similar to the Janzen patent, U.S. Patent Nos. 5,275,616 and 5,716,375 (collectively "the Fowler patents") are similar to the Janzen patent but disclose a balloon catheter that positions the plug close to the vascular puncture.¹⁵⁶⁰

St. Jude sued Access Closure, Inc. ("ACI"), alleging infringement of the Janzen and Fowler patents.¹⁵⁶¹ The jury found that ACI had infringed claims 7 and 8 of the Janzen patent, but that claims 7, 8,

 ^{1549.} Id. at 1371, 1377.

 1550.
 Id. at 1371.

 1551.
 Id. at 1373.

 1552.
 Id.

 1553.
 Id. at 1373-74.

 1554.
 Id. at 1374.

 1555.
 Id.

 1556.
 Id.

 1557.
 Id.

 1558.
 Id.

 1559.
 Id.

 1559.
 Id.

 1550.
 Id.

 1558.
 Id.

 1559.
 Id.

 1560.
 Id. at 1371, 1374.

^{1561.} Id. at 1375.

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and 9 of the Janzen patent were invalid for double patenting.¹⁵⁶² The district court deemed "the jury's double patenting finding an 'advisory opinion'" and, after a bench trial, determined that the safeharbor provision prevented the claims of the Janzen patent from being invalidated, thereby overturning the jury's verdict.¹⁵⁶³

On appeal, ACI contended that, contrary to the district court's ruling, the Janzen patent violated the consonance requirement, which "derives from the safe harbor's 'as a result of' requirement and specifies that the line of demarcation between the independent and distinct inventions that prompted the restriction requirement be maintained."¹⁵⁶⁴ The Federal Circuit agreed with ACI, explaining that consonance prevents the challenged patent (the Janzen patent), the reference patent (the sibling patent), and the restricted patent (the grandparent application) from claiming the same inventions.¹⁵⁶⁵ The Federal Circuit found that the examiner placed two restrictions on the grandparent application: a device/method restriction and a restriction resulting from the elections of species.¹⁵⁶⁶ These restrictions then defined the "line of demarcation" relevant to the consonance requirement.¹⁵⁶⁷

After determining the line of demarcation, the Federal Circuit next determined whether that line had been violated by considering whether the Janzen patent, the sibling patent, or the grandparent application claimed the same restricted inventions.¹⁵⁶⁸ The court found that the line of demarcation was maintained with respect to the grandparent application but not with respect to the sibling patent.¹⁵⁶⁹ The court explained that "the sibling application was not filed 'as a result' of the restriction since it pursued a claim generic to all of the Species in Group II, and therefore overlapped Group II, Species C found in the Janzen patent."¹⁵⁷⁰ Consequently, the court found the safe-harbor provision inapplicable because the Janzen patent and the sibling patent lacked consonance.¹⁵⁷¹ Accordingly, the

^{1562.} *Id.* 1563. *Id.*

^{1564.} Id. at 1377 (quoting Gerber Garment Tech., Inc. v. Lectra Sys., Inc., 916 F.2d 683, 688 (Fed. Cir. 1990)) (internal quotation marks omitted). 1565. Id.

^{1566.} Id. at 1379.

^{1567.} Id.

^{1568.} Id.

^{1569.} Id.

^{1570.} Id. at 1380.

^{1571.} Id.

Federal Circuit reversed and held claims 7 through 9 of the Janzen patent invalid for double patenting.¹⁵⁷²

Because the court found these claims invalid for double patenting, it concluded that the claim construction issues on appeal were moot.¹⁵⁷³ The Federal Circuit also saw "no error in the district court's legal conclusion of nonobviousness" as to the Fowler patents and therefore affirmed the denial of ACI's renewed motion for IMOL.¹⁵⁷⁴

In a concurring opinion, Judge Lourie stated that he agreed with the majority in all respects but would have invalidated the Janzen patent based on different reasoning.¹⁵⁷⁵ Specifically, he focused on the fact that the Janzen and sibling patents did not maintain consonance with the original restriction requirement.¹⁵⁷⁶ Iudge "The restriction requirement required Lourie further stated: dividing claims to devices from claims to methods, and the Janzen patent contains both device and method claims. It is the opposite of consonant."1577 Judge Lourie would not have considered the requirement for election of species, as he believed that the majority opinion "overcomplicate[d]" the matter by "commingl[ing]" the two different practices.1578

Ι. **Unenforceability**

Although a patent may otherwise be valid and meet the requirements of patentability, a patentee's conduct can render a patent unenforceable. An inequitable conduct claim must provide clear and convincing evidence of both "misrepresented or omitted information material to patentability" and "specific intent to mislead or deceive the [US]PTO."1579 Further, the Federal Circuit's en banc decision in Therasense, Inc. v. Becton, Dickinson & Co.¹⁵⁸⁰ requires proof of "but-for materiality"-that is, the USPTO would have rejected the claim "but-for" the applicant's failure to disclose the prior art.¹⁵⁸¹ If a court grants an equitable conduct claim, the entire patent is unenforceable, unlike validity defenses, which are claim-specific.¹⁵⁸²

^{1572.} Id. 1573. Id.

^{1574.} Id. at 1380-82.

^{1575.} Id. at 1382 (Lourie, J., concurring).

^{1576.} Id. at 1382–83.

^{1577.} Id. at 1383.

^{1578.} Id. at 1383-84.

^{1579.} In re Rosuvastatin Calcium Patent Litig., 703 F.3d 511, 519 (Fed. Cir. 2012).

^{1580. 649} F.3d 1276 (Fed. Cir. 2011) (en banc).

^{1581.} Id. at 1291.

^{1582.} Id. at 1288.

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In Novo Nordisk A/S, the Federal Circuit reversed the district court's finding of inequitable conduct.¹⁵⁸³ The Federal Circuit concluded that the representations and omissions were not material under Therasense's "but for" standard.¹⁵⁸⁴ As recited by the Federal Circuit, the district court found inequitable conduct based on the fact that Dr. Sturis, a declarant during prosecution, omitted information regarding his testing protocol and relevance of the rat data he reported to treating human patients.¹⁵⁸⁵ Specifically, Dr. Sturis described the data as showing "significant synergy" based on a statistical analysis from data at a 120-minute test interval, while the data as a whole were less statistically significant and only showed "synergistic effects."1586 The defendant, Caraco, accused Dr. Sturis of failing to inform the USPTO that his original test protocol only included the analysis resulting in the less favorable statistical significance and did not include his calculations for the 120-minute interval showing more favorable statistical significance.¹⁵⁸⁷ The district court agreed with Caraco's accusation that Dr. Sturis withheld from the USPTO his opinion that the data did not provide evidence of synergy in humans.¹⁵⁸⁸

However, the Federal Circuit found these omissions to be immaterial.¹⁵⁸⁹ The court distinguished Dr. Sturis's failure to disclose that the more favorable data were a post hoc analysis from "a case where a declarant hid adverse test results from the [US]PTO in favor of more promising data selected post hoc."¹⁵⁹⁰ Nor did the court find Dr. Sturis's representations false.¹⁵⁹¹ Regarding the relevance of the rat data to synergy in humans, the court found that Dr. Sturis was clear that his results were only suggestive of synergy, particularly because any reasonable examiner would not find that a study conducted on animals definitively proves synergy in humans.¹⁵⁹²

The district court also based its inequitable conduct determination on what it found to be material misrepresentations by prosecution counsel, Dr. Bork, when submitting the Sturis declaration.¹⁵⁹³ The

1584. Novo Nordisk, 719 F.3d at 1358–59.

^{1583.} Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd., 719 F.3d 1346, 1357 (Fed. Cir. 2013); *see supra* text accompanying notes 1391–11.

^{1585.} Id. at 1358.

^{1586.} Id. at 1350.

^{1587.} Id. at 1357–59.

^{1588.} Id. at 1358.

^{1589.} Id. at 1358-59.

^{1590.} Id. at 1358.

^{1591.} Id.

^{1592.} Id.

^{1593.} *Id.* at 1359.

statements at issue included that "the data presented in the Declaration of Dr. Sturis, provides *clear evidence of synergy*," which the district court found inconsistent with the declaration failing to definitively prove synergy in humans.¹⁵⁹⁴ The Federal Circuit found Dr. Bork's statements "troubling, but not material."¹⁵⁹⁵ According to the court, the statements were not material because they "employed carefully-chosen language which tracked the qualified nature of Dr. Sturis's opinions."1596

In Network Signatures, Inc. v. State Farm Mutual Automobile Insurance Co.,¹⁵⁹⁷ the Federal Circuit held that the USPTO Director did not act contrary to law or abuse his discretion by excusing the delayed payment of maintenance fees and that standards for inequitable conduct were not met.¹⁵⁹⁸ Accordingly, the court reversed and remanded the case back to the district court for further consideration on the merits of the complaint.¹⁵⁹⁹

The Naval Research Laboratory ("NRL") allowed its U.S. Patent No. 5,511,122 ("the '122 patent") to lapse by not paying the 7.5-year maintenance fee after perceiving a lack of commercial interest in the patent.¹⁶⁰⁰ Two weeks after the payment lapse, Network Signatures, Inc. ("Network Signatures") contacted the NRL and requested a license to the '122 patent.¹⁶⁰¹ The NRL immediately submitted the USPTO's standard form to petition for unintentional delayed payment and revival, which includes the statement that "[t]he delay in payment of the maintenance fee to this patent was unintentional."1602 The USPTO granted the petition, and the NRL issued the license to Network Signatures.¹⁶⁰³ Network Signatures subsequently sued State Farm Mutual Automobile Insurance Company ("State Farm") for infringement of the '122 patent.¹⁶⁰⁴ State Farm responded by moving for summary judgment on the ground that the NRL engaged in inequitable conduct by falsely representing to the USPTO that its nonpayment was "unintentional."¹⁶⁰⁵

The district court concluded that the criteria of inequitable conduct were met and granted summary judgment.¹⁶⁰⁶ Specifically,

^{1594.} Id.

^{1595.} Id.

^{1596.} *Id.* 1597. 731 F.3d 1239 (Fed. Cir. 2013).

^{1598.} Id. at 1240.

^{1599.} Id. at 1244.

^{1600.} Id. at 1240-41. 1601. Id. at 1241.

^{1602.} Id. (alteration in original) (quoting 37 C.F.R. § 1.378(c) (3) (2011)). 1603. Id.

^{1604.} Id.

^{1605.} Id.

^{1606.} Id. at 1240.

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the district court concluded that the NRL's counsel had intended to deceive the USPTO regarding the lapsed payment by using the USPTO's standard unintentional delay form without explanation of the reasons for the delay.¹⁶⁰⁷

On appeal, the Federal Circuit reversed.¹⁶⁰⁸ The court did not agree that using the USPTO's standard form without specifying the cause of the delay constituted a "material misrepresentation with intent to deceive."¹⁶⁰⁹ The court specifically noted that the statute had been amended to relax the standard for accepting late payments to include "unintentional," not merely "unavoidable," delays.¹⁶¹⁰ The court further noted that the regulation governing late maintenance fee payment, 37 C.F.R. § 1.378(a), "requires only a statement that the delay was 'unintentional," and that the USPTO's standard form requires no additional information for the "unintentional" delay.¹⁶¹¹ Accordingly, the Federal Circuit concluded that the NRL's use of the standard form, which required no explanation, did not constitute "clear and convincing evidence of withholding of material information with the intent to deceive the [USPTO]."¹⁶¹²

Judge Clevenger dissented.¹⁶¹³ He would have held that the district court correctly granted summary judgment on materiality but not on the issue of intent because material facts regarding the NRL's intent were in dispute.¹⁶¹⁴ In his view, State Farm established that the USPTO would have denied the NRL's petition.¹⁶¹⁵ Judge Clevenger therefore would have remanded on the issue of intent to provide State Farm an opportunity to produce evidence that the NRL "knew the information was material and made a deliberate decision to withhold it from the [US]PTO."¹⁶¹⁶

In *Intellect Wireless, Inc. v. HTC Corp.*,¹⁶¹⁷ the Federal Circuit affirmed the district court's judgment that U.S. Patent Nos. 7,266,186 ("the '186 patent") and 7,310,416 ("the '416 patent") were unenforceable due to inequitable conduct.¹⁶¹⁸ Intellect Wireless, Inc. ("Intellect") asserted that both patents related to wireless transmission of caller

^{1607.} *Id.* at 1241–42.

^{1608.} *Id.* at 1244.

^{1609.} *Id.* at 1242.

^{1610.} *Id.* at 1242–43. 1611. *Id.* at 1243.

^{1612.} *Id*.

^{1613.} Id. at 1244 (Clevenger, J., dissenting).

^{1614.} *Id.*

^{1615.} *Id.* at 1244–45.

^{1616.} *Id.* at 1247.

^{1617. 732} F.3d 1339 (Fed. Cir. 2013).

^{1618.} *Id.* at 1341.

identification (ID) information-specifically, providing caller ID information over a wireless network and displaying the ID on the cell phone screen.¹⁶¹⁹

Intellect brought an infringement suit against HTC Corporation and HTC America, Inc. (collectively "HTC").¹⁶²⁰ After trial, the district court held that HTC proved inequitable conduct because Daniel Henderson, the sole inventor, submitted a Rule 131 declaration-to overcome a prior art reference during prosecutionwhich contained false statements that were neither withdrawn, called to the attention of the USPTO, nor fully corrected, and because Mr. Henderson acted with the requisite intent to deceive.¹⁶²¹

On appeal, the Federal Circuit determined that it was "undisputed that Mr. Henderson's original declaration was unmistakably false" in representing that the claimed invention had been reduced to practice and explained that, "[a]bsent curing, this alone establishes materiality."¹⁶²² While Mr. Henderson had submitted a revised declaration lacking statements about the alleged reduction to practice, the court held that "the revised declaration did not cure the misconduct because it never expressly negated the false references to actual reduction to practice in the original declaration" and did not "advise the [US]PTO of Mr. Henderson's misrepresentations,"1623 which is required under Rohm & Haas Co. v. Chrystal Chemical Co.¹⁶²⁴ The court also explained that "Therasense in no way modified Rohm & Hass's holding that the materiality prong of inequitable conduct is met when an applicant files a false affidavit and fails to cure the misconduct."¹⁶²⁵ To the contrary, Therasense expressly affirmed the holding in Rohm & Haas that filing a false affidavit is material misconduct.¹⁶²⁶

The Federal Circuit also held that the district court did not err in its finding on intent.¹⁶²⁷ The court reasoned that the district court could infer an intent to deceive when Mr. Henderson submitted an

^{1619.} Id.

^{1620.} Id.

^{1621.} Id. at 1341-42.

^{1622.} Id. at 1342.

^{1623.} *Id.* at 1343. 1624. *See* 722 F.2d 1556, 1572 (Fed. Cir. 1983) (providing that in order for an applicant to cure a material misrepresentation, the applicant must "expressly advise the [US]PTO of its existence, stating specifically wherein it resides"); accord Intellect Wireless, 732 F.3d at 1343 (noting that Federal Circuit precedent "clearly requires" that a declaration "openly advise" the USPTO of the misrepresentations (citing Rohm & Haas, 722 F.2d at 1572)).

^{1625.} *Intellect Wireless*, 732 F.3d at 1344. 1626. *Id.* (citing Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1292 (Fed. Cir. 2011) (en banc)).

^{1627.} Id. at 1345.

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affidavit with fabricated information.¹⁶²⁸ The court found the inference stronger in this case because "Henderson engaged in a pattern of deceit" by making false statements regarding reduction to practice to obtain claims in several related patents.¹⁶²⁹ Further, the Federal Circuit found sufficient evidence of intent based on the original declaration containing "completely false statements" and the replacement declaration that failed to "expressly admit[] the earlier falsity."¹⁶³⁰ Finally, the Federal Circuit held that the district court did not commit error by rejecting Henderson's explanation as not credible, noting that appellate courts generally should not reverse credibility determinations by lower courts.¹⁶³¹

In Ohio Willow Wood Co., the Federal Circuit reversed and remanded the district court's grant of summary judgment of no inequitable conduct.¹⁶³² In reversing the district court, the Federal Circuit found that summary judgment of no inequitable conduct was precluded by genuine issues of material fact regarding OWW's conduct during the second reexamination.¹⁶³³ The Federal Circuit viewed the materiality question as turning on whether the Board would have credited Mr. Comtesse's testimony (which the Board did not) but-for information withheld or misrepresented by OWW.¹⁶³⁴ Applying the "rule of reason" test, the Federal Circuit first held that "a reasonable finder of fact could conclude that OWW had withheld material evidence" that would have corroborated Mr. Comtesse's testimony and affected the Board's determination.¹⁶³⁵ The Federal Circuit further found, agreeing with Alps, that OWW had overstated Mr. Comtesse's interest in the dispute and thereby undermined his credibility before the Board.¹⁶³⁶ The Federal Circuit concluded that "OWW's counsel was aware that Mr. Comtesse's level of interest was critical to convincing the [Board] to reverse the examiner's final rejection."¹⁶³⁷ Analogizing OWW's misrepresentations to filing a false affidavit, the court found OWW's conduct could have been material