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§ 20.13 Federal Circuit Decisions

§ 20.13.1 Patents: Claim Construction

*American Medical Systems, Inc. v. Biolitec, Inc.*⁸⁶

Facts: American Medical Systems sued Biolitec for infringement of a patent covering methods and devices for vaporizing tissue using lasers. The district court granted summary judgment of noninfringement because it concluded that the accused device does not perform “photoselective vaporization of tissue” as the district court construed that claim term. The term appears only in the preambles of the asserted patent claims. American Medical Systems appealed.

Held: The preamble to the claim at issue was not a claim limitation, where it was more appropriately characterized as a descriptive name for the set of limitations in the body of the claim, it was not added to distinguish prior art, it did not provide an antecedent basis for terms in the body of the claim, and it did not “embody an essential component of the invention.”

Reasoning: The Federal Circuit reversed, holding that the term “photoselective vaporization of tissue” was not a claim limitation. The panel majority noted that there was no suggestion in the prosecution history that the preamble term was added to distinguish the invention over the prior art, and that the preamble term did not provide a necessary antecedent basis for similar terms (“the tissue”) in the body of the claims. Finally, and most importantly, the majority compared the preamble with the body of the claims and found that it did not supply an essential component of the invention, but was instead more of a descriptive name for an invention that was fully set out in the bodies of the claims. The bodies of the asserted claims described a structurally complete device, and at least the term “photoselective” would either be redundant with, or in conflict with, claim terms.

Judge Dyk dissented, arguing that the Federal Circuit’s precedent did not set out a clear rule as to when a preamble should be construed as limiting and that the cases were internally inconsistent. In Judge Dyk’s view, a rule that all preambles are limiting would make more sense and would better serve the interests of patentees and accused infringers alike by making the scope of patents clearer. In any event, Judge Dyk argued, under existing precedent, the preamble at issue should be construed as a limitation.

86. 618 F.3d 1354 (Fed. Cir. 2010).

§ 20.13.1.1 Patents: False Marking

*Forest Group, Inc. v. Bon Tool Co.*⁸⁷

Facts: Forest Group owned the patent-in-suit, which claimed a novel spring-loaded stilt used in construction. Southland Supply Company sold stilts under a license from Forest Group. Bon Tool bought identical stilts from an unlicensed competitor, and Forest Group sued for infringement. Bon Tool's counterclaims included a claim under the false marking statute, 35 U.S.C. § 292.

In a separate lawsuit involving Forest Group and another party in another district court, the district court granted summary judgment of noninfringement, effectively holding that Forest Group's patent did not cover its own stilts, even though those stilts were marked with the number of Forest Group's patent. Even after that date, however, Forest Group did not alter its design, and continued to place orders to its manufacturer for stilts marked with the patent.

The district court in *Forest Group v. Bon Tool* held that, as of the date of the other district court's summary judgment ruling (November 15, 2007), Forest Group knew that its stilts were falsely marked, and fined Forest Group \$500 for its decision to continue to falsely mark its stilts after that date. Bon Tool appealed, arguing that (1) Forest Group falsely marked its stilts before that date, (2) the fine under the statute should be assessed separately for each falsely marked article, rather than once for a single decision to falsely mark multiple articles, and (3) the district court should have found the case exceptional and awarded attorneys' fees.

Held: The fine in the false marking statute, 35 U.S.C. § 292, of up to \$500, should be assessed on a per-article basis. The burden of proof of intent to deceive the public is a preponderance of the evidence.

Reasoning: The Federal Circuit affirmed the district court's factual finding that Forest Group lacked the requisite knowledge to support a false marking claim before November 15, 2007, and its discretionary decision not to find the case exceptional or award attorney fees. The Federal Circuit reversed, however, on the amount of the fine, holding that the fine in the statute is to be assessed on a per-article basis.

The statute, 35 U.S.C. § 292, provides: "Whoever marks upon, or affixes to, or uses in advertising in connection with *any unpatented article*, [any indication that the article is patented] for the purpose of deceiving the public Shall be fined not more than \$500 for *every such offense*." (emphasis added).

The Federal Circuit panel reasoned that the text of the statute—"any unpatented article" and "every such offense"—clearly indicated that the fine should be imposed for every article falsely marked. The district court thus erred in holding that Forest Group should be fined only once for the one-time decision to mark falsely. The panel rejected Forest Group's arguments based on cases applying the predecessor to the false marking statute under the 1870 Patent Act, noting that Congress changed the statute in 1952. The panel also

87. 590 F.3d 1295 (Fed. Cir. 2009).

rejected a line of post-1952 district court cases applying a time-based approach, imposing fines for every day, week, or month that falsely marked articles were produced, stating that they were “creative attempts to reconcile the statute’s language” with pre-1952 case law, but “[s]ection 292 clearly requires a per article fine.”

As a policy matter, the panel remarked on the social costs of false marking, and reasoned that a per-decision fine rather than a per-article fine would render the statute ineffective, as one who falsely marks countless articles for a number of years would not be deterred by a maximum total fine of \$500. The panel was also not moved by Forest Group’s argument that a per-article basis for the fine would encourage a “cottage industry” of false marking litigation. The panel noted that the statute explicitly permits and encourages such litigation, and that any perceived inequities might be remedied by the fact that § 292(a) gives district courts discretion to impose fines of less than \$500: “[i]n the case of inexpensive mass-produced articles, a court has the discretion to determine that a fraction of a penny per article is a proper penalty.”

Pequignot v. Solo Cup Co.⁸⁸

Facts: Solo Cup made disposable cup lids and marked them with the numbers of patents that issued in 1976 and 1986 and expired in 1988 and 2003. Solo made the lids using a stamping process and molds. The molds could be reused for decades, and Solo advised its attorneys that replacing all of the molds upon the expiration of each patent would be costly and burdensome. On advice from its counsel, Solo adopted a policy that it would continue to use molds bearing the numbers of expired patents, but whenever a mold needed to be replaced due to wear or damage, the replacement mold would not bear the numbers of expired patents. Solo also marked several articles—including some that were never covered by patents—with a label indicating that the product “may be covered by one or more U.S. or foreign pending or issued patents. For details, contact www.solocup.com.”

Pequignot, a patent attorney, sued Solo under the false marking statute for both (1) articles bearing the numbers of expired patents, and (2) articles marked with the “may be covered” language that were not, in fact, covered by a patent. Pequignot accused Solo of falsely marking more than 21 billion articles, seeking a fine of \$500 for each article (i.e., \$10.5 trillion), half of which would go to the United States under the statute. The district court granted summary judgment in favor of Solo, reasoning that Solo did not have the requisite intent to deceive because its policy was reasonable and implemented in good faith reliance on the advice of its attorneys. Pequignot appealed.

Held: The phrase “unpatented article” in the false marking statute, 35 U.S.C. § 292(a), includes articles covered by patents that have expired. If one falsely marks an article as patented with knowledge that it is not patented (either in the sense of being covered by an expired patent or never having been covered by a patent at all), that gives rise to an inference that the false marker intended

88. 608 F.3d 1356 (Fed. Cir. 2010).

to deceive the public, but the inference may be rebutted by a preponderance of the evidence, as it was in this case.

Reasoning: The Federal Circuit affirmed. First, the panel rejected Solo's argument that the statutory language "unpatented article" did not apply to products previously covered by patents. The panel found that the language was unambiguous and that falsely marking once-patented articles tends to impose many of the same social costs as falsely marking never-patented articles. Second, the panel affirmed the district court's finding that Solo lacked the requisite intent to deceive the public—as to both the articles bearing the numbers of expired patents and the "may be covered" language. Noting that the false marking statute is a criminal statute, in a sense, court reasoned that the phrase "for the purpose of deceiving the public" requires "a purpose of deceit, rather than simply knowledge that a statement is false." Accordingly, the court held that knowledge that an article is falsely marked can be rebutted by credible evidence that the false marking was not done for the purpose of deceiving the public, which Solo Cup did here by implementing a reasonable policy in good faith reliance on the advice of its counsel. As to the "may be covered" language, the panel held that it was literally true and that Pequignot failed to raise a genuine issue of material fact as to Solo's intent on that point.

The panel also noted that the marking statute, 35 U.S.C. § 287 holds that patentees may not collect damages in an infringement action unless they have either marked their patented articles or proved that the infringer was notified of the infringement.

Stauffer v. Brooks Brothers, Inc.⁸⁹

Facts: Brooks Brothers sold men's bowties, some of which contained an adjustment mechanism, made by a third party. The adjustment mechanism is marked with the numbers of two patents that expired in the 1950s. Stauffer, a patent attorney, bought some of the marked bowties and sued Brooks Brothers under the false marking statute. The district court dismissed the case for lack of standing, holding that Stauffer did not allege that either he or the United States had suffered an injury in fact from the false marking. The federal government moved for leave to intervene, and the district court denied that motion. Stauffer appealed, and the Federal Circuit allowed the government to intervene in the appeal.

Held: The false marking statute, 35 U.S.C. § 292, is a qui tam provision under which "any person" can sue, regardless of whether that person has suffered an injury-in-fact. The constitutionally required injury is supplied by the statute itself, which defines an injury to the United States. In the case below, the district court erred in denying the government's motion to intervene.

Reasoning: Relying heavily on the Supreme Court's decision in *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, 529 U.S. 765 (2000), the Federal Circuit held that Stauffer had standing. The panel reasoned that a qui tam provision, such as the false marking statute, is a statutory

89. 619 F.3d 1321 (Fed. Cir. 2010).

assignment of the United States' rights, and that to have standing Stauffer had to allege that the United States has suffered an injury in fact. Further, Congress defined an injury to the United States by determining that false marking is harmful conduct and by passing the false marking statute prohibiting it. Thus, the panel reasoned, "Stauffer's status arises from his status as 'any person,' and he need not allege more for jurisdictional purposes." An amicus argued that qui tam suits are unconstitutional under the "take care" clause of Article II, § 3 of the Constitution, where the United States assigns its claims without retaining control over the relator's actions, but the panel did not address that argument as it was not raised below or decided by the district court. The panel reversed the dismissal for lack of standing, and remanded for the district court to address the merits. The panel also held that the district court erred in denying the government's motion to intervene, because the government has an interest in the enforcement of its laws, it has an interest in one-half of any fine Stauffer would collect, per 35 U.S.C. § 292(b) ("Any person may sue for the penalty, in which event one-half shall go to the person suing and the other to the use of the United States."), and it would be barred by res judicata from pursuing claims against Brooks Brothers for the same markings if Stauffer lost.

§ 20.13.1.2 Patents: Patent Misuse

*Princo Corp. v. International Trade Commission*⁹⁰

Facts: Philips and Sony were the principal developers of CD-R and CD-RW technology, and of the corresponding standards. A problem arose during development, for which Philips and Sony each had a different solution. Philips's approach was covered by two of its patents (the "Raaymakers patents") and Sony's was covered by its own patent (the "Lagadec patent"). Philips and Sony chose to implement the Raaymakers approach in the technology and standard. Philips and Sony set up a patent pool and offered package licenses. The pool included both the Raaymakers and Lagadec patents. The package licenses included a field-of-use restriction, limiting the licensees to using the licensed patents to produce compact discs according to the standards developed by Philips and Sony.

Princo entered into a package license, but later stopped paying fees and continued to import CD-R and CD-RW products. Philips filed a complaint with the International Trade Commission (ITC), and Princo asserted a defense of patent misuse, under which it alleged several different theories. The ITC found the patent infringed and not invalid. After an appeal to the Federal Circuit in 2005 and a subsequent remand, the ITC rejected Princo's patent misuse defenses. On a second appeal to the Federal Circuit, a panel of the court ordered a remand for the ITC to examine the record to determine whether Philips and Sony agreed to suppress the technology covered by the Lagadec patent and whether that

90. 616 F.3d 1318 (Fed. Cir. 2010) (en banc).

technology could have been commercially viable. After the panel decision, the court granted rehearing en banc to address that issue.

Held: An agreement between two holders of competing patents to commercialize one party's patents and suppress the technology embodied in the other party's patent is not patent misuse. The defense of patent misuse also failed in this case because it is subject to the rule of reason analysis, and the party asserting the claim failed to prove that the alleged agreement had anticompetitive effects because it could not show that the allegedly suppressed technology had a reasonable chance of becoming commercially viable.

Reasoning: The en banc majority held that even if Philips and Sony had agreed to suppress the Lagadec technology, such an arrangement would not constitute patent misuse. The majority began with a general discussion of patent misuse doctrine, noting that it predated modern antitrust doctrine, and that the paradigmatic cases of patent misuse are arrangements involving "leverage" of the patent in a way that broadens its "physical or temporal scope"—such as requiring the purchase of an unpatented product as a condition for obtaining a license to the patent, or requiring royalty payments. The majority surveyed precedent and federal legislation (such as 35 U.S.C. § 271(d), cabining the scope of patent misuse), and noted that a patent gives significant rights to patent holders, including the right to refuse to license at all. The majority reasoned that the conduct prohibited by patent misuse is narrower than that prohibited by antitrust law and that patent misuse is generally restricted to a handful of specific practices addressed in Supreme Court cases.

Against that backdrop, the en banc majority concluded that the alleged agreement was not patent misuse. First, there was no "leverage" involved, as there was no connection between the patent pool licenses and any agreement between Philips and Sony—the pool licenses control what the licensees may do, and the alleged agreement controls what Sony may do. Princo's real complaint was that Sony had not licensed its Lagadec patent for uses outside of the Philips-Sony CD-R and CD-RW standards, which Sony was permitted to do. Philips and Sony were in no sense leveraging the Raaymakers patents, and the facts before the court did not fit within the "handful of specific practices" that precedent recognized as patent misuse.

Second, the majority held that Princo failed to show that the alleged agreement had anticompetitive effects. Where a misuse defense alleges conduct that is not per se anticompetitive, the rule of reason analysis applies, and the party asserting the defense must show anticompetitive effects. The majority noted that joint ventures and pool licenses can have precompetitive effects such as economies of scale and reduction of transaction costs, and that "ancillary restraints" that accompany such arrangements are also assessed under the rule of reason. As Princo failed to show that, in the absence of any agreement between Philips and Sony, the Lagadec technology might have been developed into a commercially viable alternative, its defense failed.

Judge Prost wrote separately, joined by Judge Mayer, to state that she would affirm the ITC's ruling only on the ground that Princo had not met its burden to show that any agreement regarding the Lagadec patent had anticompetitive

effects. Judge Prost would not have addressed the contours of the patent misuse doctrine, and viewed the majority's description of it as too narrow and the dissent's description as too broad.

Judge Dyk dissented, joined by Judge Gajarsa. Judge Dyk would have held that the alleged agreement between Philips and Sony constituted patent misuse, and would have remanded for factual findings only on the issue of whether such an agreement existed at all. Judge Dyk viewed precedent of the Supreme Court and the courts of appeals as establishing a patent misuse defense that is broader than antitrust law in the scope of the conduct it prohibits. In Judge Dyk's view of precedent, leveraging is not a necessary element of an antitrust claim or a patent misuse defense where there is an agreement not to compete with the alleged patent. Judge Dyk recited the factual history of the case with an emphasis on how the Raaymakers technology had come to dominate the market for CD-R and CD-RW discs, noting that the royalty rate was between half and two-thirds of the selling price of the discs, and that Sony received a 36 percent cut of the royalties in the CD-RW pool, even though the only "essential" patent it contributed was the Lagadec patent. Judge Dyk viewed the alleged agreement between Philips and Sony as a classic agreement not to compete, "inherently suspect" under antitrust law and patent misuse law. As an "inherently suspect" arrangement, Judge Dyk asserted, the agreement is subject only to "quick look" scrutiny under the rule of reason, and the burden shifts to Philips to offer some plausible precompetitive justification for the restraint. Judge Dyk further disagreed with the majority's holding that Princo's burden was to prove that the Lagadec technology had a reasonable probability of being commercially viable, and criticized the majority's holding as failing to provide adequate protection against suppression of nascent technology.

§ 20.13.1.3 Patents: Written Description Requirement

*Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*⁹¹

Facts: Ariad Pharmaceuticals and others sued Eli Lilly for patent infringement, a jury found infringement and rejected Eli Lilly's invalidity defenses, and the district court denied Eli Lilly's judgment as a matter of law (JMOL) motions. A panel of the Federal Circuit reversed, finding the patent invalid under the written description requirement. The panel's reasoning was that the specification disclosed a "research plan," insufficient to support the broad claims. The inventors were the first to identify transcription factor NF- κ B and to uncover the mechanism by which it activates gene expression underlying the body's immune responses to infection. The inventors recognized that interfering with NF- κ B could reduce the harmful symptoms of certain diseases, and the patent claims all substances that could achieve the desired result of reducing the binding of NF- κ B to NF- κ B recognition sites. The specification did not,

91. 598 F.3d 1336 (Fed. Cir. 2010) (en banc).

however, disclose any such substances. Instead, it hypothesized three types of molecules that might potentially have the desired effect. Under those facts, the panel held, the patent was invalid under the written description requirement. Ariad petitioned for rehearing en banc, arguing that the statute does not contain a written description requirement. The court granted the petition.

Held: 35 U.S.C. § 112 ¶ 1 contains a “written description” requirement, separate from the enablement requirement. The written description requirement applies to original claims as well as claims added or amended during prosecution, and requires that “the description must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed” or “that the inventor had possession of the claimed subject matter as of the filing date.”

Reasoning: Judges of the Federal Circuit had debated for years whether 35 U.S.C. § 112 ¶ 1 contains a “written description” requirement separate from the enablement requirement, and if so, whether it applies to all claims or just original claims. The court divided three times in the previous eight years over whether to sit en banc to address that issue, and the court agreed to do so in *Ariad*.

The en banc majority reaffirmed the Federal Circuit’s earlier precedents holding that the statute contains a separate written description requirement. The majority opinion is largely a restatement of the written description requirement precedents and of the arguments that the requirement’s defenders had deployed in the past.

First, the majority pointed to the text of the statute, reasoning that the comma and the word “and” between the written description language and the enablement language showed that Congress set out two separate requirements. 35 U.S.C. § 112, first paragraph, provides that “The specification shall contain a written description of the invention, *and* of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same” (emphasis added). The majority rejected Eli Lilly’s argument that the written requirement was eliminated when Congress amended the surrounding language in 1836 to require claims for the first time.

Second, the majority cited dicta in Supreme Court opinions—*Evans v. Eaton*, 20 U.S. (7 Wheat.) 356, 433-34 (1822), *Schriber-Schroth Co. v. Cleveland Trust Co.*, 305 U.S. 47, 57 (1938), and *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki*, 535 U.S. 722, 736 (2002) as supporting the existence of a separate written description requirement.

Third, the majority cited *stare decisis*—a reason that had not appeared in previous Federal Circuit opinions upholding the written description requirement—as a reason for preserving the written description requirement. *Stare decisis* has added force in statutory cases, the separate written description requirement had been part of the court’s precedent for at least 40 years, and any change at this point should come from Congress.

Regarding the substance of the written description requirement, the court held that it applies to original claims as well as claims added or amended during prosecution: the text of the statute does not distinguish between the two, and an original claim—while part of the specification—can still fail to adequately

disclose the subject matter that it claims. Further, the court sought to clarify language in its prior opinions that the test is “possession” of the invention by explaining that “‘possession as shown in the disclosure’ is a more complete formation,” and that “the test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art” to determine whether the specification “describe[s] an invention understandable to that skilled artisan and show[s] that the inventor actually invented the invention claimed.”

The majority reaffirmed the panel’s disposition of the case and reversed the district court.

Judge Newman joined the majority, but wrote separately to highlight the consequences of the written description requirement on research universities because it prevents the patenting of basic scientific research.

Judge Gajarsa also joined the majority and wrote separately to note that the separate written description serves little purpose except when applied to new or amended claims, but that the text of the statute prohibits restricting its application in that way.

Judges Rader and Linn dissented separately, each joining the other’s opinion. The dissents took issue with all of the reasons the majority gave for preserving the separate written description requirement and for applying it to original claims, and argued that the separate written description requirement—as explained by the majority—conflicts with Federal Circuit precedent on enablement and claim construction.

§ 20.13.1.4 Patents: Remedies

*i4i Limited Partnership v. Microsoft Corp.*⁹²

Facts: i4i accused Microsoft Word’s XML editing capabilities of infringing i4i’s ’449 patent. At trial, i4i’s damages expert testified that an appropriate damages figure would be \$200 million, based on a royalty rate of \$98 and a royalty base of 2.1 million products allegedly used in an infringing manner. i4i’s damages expert derived the royalty rate from a “benchmark” product called XMetaL, which sold for \$499, at a 76.6 percent profit margin for Microsoft, reasoning that approximately 25 percent of Microsoft’s profit margin would be a reasonable royalty rate. i4i’s damages expert derived the royalty base from i4i’s survey expert, who extrapolated from a survey that included approximately 40 substantive questions that he sent to 988 randomly selected businesses, and who only sought to estimate infringing use by businesses. i4i’s damages expert then applied the *Georgia-Pacific* factors to that rate, asserting that the royalty should be between \$96 and \$98. Microsoft countered that the rate was exorbitant, as it had sometimes sold Word for as little as \$97 and paid \$1 million to \$5 million to license other patents, much less than the \$200 million i4i proposed.

92. 589 F.3d 1246 (Fed. Cir. 2009).

Before the case was submitted to the jury, Microsoft did not move for judgment as a matter of law damages. The jury determined that the patent was valid, that Microsoft's Word infringed, that the infringement was willful, and awarded \$200 million in damages. After trial, Microsoft renewed its motions for judgment as a matter of law and moved for a new trial on damages and the court's evidentiary rulings. The district court denied those motions, enhanced the damages award, and entered a permanent injunction against Microsoft, prohibiting further production, use, or marketing of Word with the infringing feature, and against providing any support or assistance concerning the infringing feature. The district court excluded from its injunction users who purchased or licensed Word before the injunction's effective date, and delayed the start of the injunction for 60 days which—the court determined—would be enough time for Microsoft to design a "patch" to disable the infringing feature.

Held: Where a defendant does not file a pre-verdict JMOL motion on damages under Fed. R. Civ. P. 50(a), it waives the right to have the Federal Circuit review whether the award was supported by the evidence—i.e., not "grossly excessive" or "speculative." Instead, the Federal Circuit will only review for whether the award exceeds the maximum amount calculable under the evidence. The Federal Circuit suggested that the distinction may have been dispositive, and, under the more deferential standard, it affirmed the jury's award of \$200 million in damages. The Federal Circuit also affirmed the district court's enhancement of the damages and entry of a permanent injunction against Microsoft.

Reasoning: The Federal Circuit rejected Microsoft's challenges to the admissibility and methodology of i4i's damages expert's testimony, acknowledging that there were weaknesses in his calculations, but explaining that Microsoft's issues were with his conclusions and not his methodology. The court concluded that the testimony was sufficient under Rule 702 and the district court did not abuse its discretion in allowing him to testify. The court also found that the survey expert i4i relied on to calculate the number of infringing business users was sufficient under Rule 702. The court determined that the survey expert's methodology met the minimum standards of relevance and reliability, as both of Microsoft's experts opined that it underestimated the amount of infringing use.

The court first explained that although Microsoft objected to the size of the damages award, it could not reach that question because Microsoft did not file a pre-verdict judgment as a matter of law on damages pursuant to Rule 50. The court suggested that if Microsoft had filed such a motion, "it is true that the outcome might have been different." The court concluded that Microsoft was not entitled to a new trial under the "narrower standard" and "more searching review" of a request for a new trial because the jury's damages award did not exceed the maximum amount calculable from the evidence at trial. The court held that while the damages award was high, it was supported by the evidence at trial. The court also affirmed the district court's grant of a permanent injunction, concluding that the district court had properly applied the four-factor test for entering injunctions, had properly declined to consider consequences to

Microsoft of an injunction, and had properly accommodated the public interest by tailoring the injunction as it had.

ResQNet.com, Inc. v. Lansa, Inc.⁹³

Facts: ResQNet accused Lansa's software of infringing ResQNet's patent. At a bench trial, ResQNet relied on its damages expert, Dr. David, who focused on the first *Georgia-Pacific* factor—royalties received by the patentee from existing licenses—and the second *Georgia-Pacific* factor—comparable licenses. He relied on seven previous ResQNet licenses, five of which did not include the patents-in-suit or claimed technology and instead provided finished software products and source code as well as services such as training, maintenance, marketing, and upgrades. In the five “re-branding” licenses that did not include the patents-in-suit, the companies reserved the right to re-brand ResQNet's products before resale for rates up to 25 percent to 40 percent. The remaining two licenses arose out of litigation over the patents-in-suit. One of those licenses was a lump-sum payment, and another was a straight rate-based license for “substantially less than” 12.5 percent. Dr. David considered some of the remaining *Georgia-Pacific* factors, but opined that “[f]or the most part, the other factors have no real impact here.” Dr. David proposed a reasonable royalty rate of 12.5 percent, explaining that his proposed rate was “somewhere in the middle” of the “re-branding” licenses and the straight rate-based licenses. Lansa did not offer a damages expert in response. The court found that the patent was valid and infringed and awarded damages based on a 12.5 percent hypothetical royalty.

Held: The district court's damages award relied on speculative and unreliable evidence “divorced from proof of economic harm linked to the claimed invention” and was inconsistent with the court's damages law. The court explained that the majority of the licenses relied on had “no relationship to the claimed invention” and did not justify the plaintiff's proposed double-digit royalty rate.

Reasoning: The Federal Circuit vacated the district court's damages award and remanded for a determination of damages. The court criticized two parts of ResQNet's damages expert's analysis: (1) the “extremely” high rates in the re-branding licenses compared with the license on the claimed technology and (2) the unconvincing reasons he gave for considering the bundling licenses. The court explained that he offered “little or no evidence of a link between the re-branding licenses and the claimed invention” and that the district court “made no effort to link certain licenses to the infringed patent.” The court asserted that he did not attempt to show that the re-branding agreements embodied the claimed technology or to show demand for the patented technology. Instead, the court found that Dr. David's downward shift from the re-branding licenses was “an admission that his calculations are speculative without any relation to actual market rates.”

93. 594 F.3d 860 (Fed. Cir. 2010) (per curiam).

The court also noted that the district court appeared to be influenced by Lansa's decision not to use a damages expert, but explained that it was ResQNet's burden—not Lansa's—to persuade the court with legally sufficient evidence regarding the reasonable royalty. The court also explained that the most reliable evidence in the case was the litigation straight-rate license on the patents-in-suit, and stated that “[o]n other occasions, this court has acknowledged that the hypothetical reasonable royalty calculation occurs before litigation and that litigation itself can skew the results of the hypothetical negotiation.”

In a dissent, Judge Newman criticized the majority's decision, asserting that it created a new rule that no licenses involving the patented technology could be considered if the patents themselves were not directly licensed or if the licenses included subject matter in addition to that which was infringed.

§ 20.13.1.5 Patents: Appellate Jurisdiction of the Federal Circuit

*Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc.*⁹⁴

Facts: CTI owned a patent on a method of detecting vitamin deficiencies by assaying homocysteine levels. Metabolite had a nonexclusive license and a right to sublicense. Metabolite granted LabCorp a sublicense to the patented method and to related “know-how technology” which included software to implement and automate the patented method. LabCorp's license allowed it to terminate the agreement if “a more cost effective commercial alternative is available that does not infringe a valid and enforceable claim” of the licensed patent.

When LabCorp stopped paying royalties and started using an alternative assay, Metabolite sued for breach of the license and CTI sued for patent infringement. Metabolite was found liable, and the court entered an injunction. LabCorp then outsourced the assay to a company that was separately licensed to the patent by CTI. Metabolite filed a post-judgment motion asserting that LabCorp's outsourcing violated the injunction.

LabCorp filed a separate declaratory judgment suit—the case from which this appeal came—seeking a judgment that it had not violated the license agreement with Metabolite.

Ruling on the post-judgment rulings in the first case, the district court held that its judgment did not cover LabCorp's outsourcing, and that whether that was a breach was a matter that should be resolved in LabCorp's separate declaratory judgment suit.

In the declaratory judgment suit, the district court ruled in favor of LabCorp, holding that the judgment in the prior case had effectively terminated the license agreement, and LabCorp had no further obligations to Metabolite with respect to the homocysteine assay. Metabolite appealed to the Federal

94. 599 F.3d 1277 (Fed. Cir. 2010).

Circuit, and LabCorp filed a motion to dismiss or, alternatively, to transfer the case to the Tenth Circuit.

Held: The Federal Circuit did not have jurisdiction over an appeal from a dispute involving failure to pay royalty fees, where the infringement question underlying the breach of contract claim was decided in a previous case before the complaint in the current case was filed, and all that remained were questions of state contract law.

Reasoning: The panel majority ruled that it did not have jurisdiction, and transferred the case to the Tenth Circuit. The Federal Circuit has exclusive jurisdiction over appeals from district court judgments, where the district court's jurisdiction was based "in whole or in part" on the statute that gives district courts "original jurisdiction of any civil action arising under any Act of Congress relating to patents." 28 U.S.C. §§ 1295(a)(1), 1338(a). A case "arise[s] under" patent law if either (1) patent law creates the cause of action or (2) a question of patent law is a necessary element of one of the claims.

Although the breach of contract claims in the initial suit fit that description, in this case the question of infringement had already been resolved by the prior lawsuit. Thus, at the time the complaint was filed, the only issue in actual dispute was the contract law question of whether the license was terminated. Jurisdiction is generally addressed as of the time the complaint is filed, and because the infringement question had been resolved at that time, the case did not "arise under" patent law, and the Federal Circuit thus lacked jurisdiction over the resulting appeal. The suit was properly in federal court under the federal courts' diversity jurisdiction, so the proper remedy was to transfer the case to the Tenth Circuit.

Judge Dyk dissented, arguing that the Federal Circuit had jurisdiction because (1) the case raised the question of the res judicata effect of a prior judgment arising under the patent laws, and (2) in his view, the contract claims before the court still rested on a substantial question of patent law.

§ 20.13.1.6 Patents: Jurisdiction Under the Hatch-Waxman Act

*Novo Nordisk A/S v. Caraco Pharmaceutical Laboratories, Ltd.*⁹⁵

Facts: The FDA approved Novo's drug repaglinide (brand name PRANDIN) for three uses: (1) by itself, (2) in combination with metformin, and (3) in combination with thiazolidinediones. The Orange Book listed two patents for PRANDIN, one by itself (the '035 patent) and one in combination with metformin (the '358 patent). The '035 patent expired in 2009, but the '358 patent did not expire until 2018. The FDA assigned the '358 patent the use

95. 601 F.3d 1359 (Fed. Cir. 2010).

code “U-546—USE of repaglinide in combination with metformin to lower blood glucose.”

Caraco filed an ANDA for repaglinide, filing a Paragraph III certification for the '035 patent and a Paragraph IV certification for the '358 patent. Novo then initiated an infringement action against Caraco. Caraco stipulated that its ANDA would infringe the '358 patent if it included a label for repaglinide in combination with metformin. Caraco then submitted an amended ANDA with a Paragraph IV certification for the '358 patent and a Section viii Statement declaring that Caraco was not seeking approval for the repaglinide-metformin combination therapy. The FDA indicated that it would approve Caraco's proposed carve-out label, and Novo requested reconsideration on the grounds that allowing the carve-out would render the drug less safe and effective.

Novo then updated the use code narrative for the '358 patent, and the FDA substituted the new use code “U-968—A method for improving glycemic control in adults with type 2 diabetes mellitus.” The FDA then denied Caraco's Section viii Statement because its proposed carve-out label overlapped with the new use code. Caraco then amended its answer in the infringement lawsuit to add a counterclaim under 21 U.S.C. § 355(j)(5)(C)(ii), requesting an order requiring Novo to change the use code for the '358 patent in reference to PRANDIN from U-968 back to U-546. The district court granted Caraco summary judgment on its counterclaim and granted an injunction ordering Novo to amend its use code.

Held: 21 U.S.C. § 355(j)(5)(C)(ii)(I), the counterclaim provision of the Hatch-Waxman Act, did not provide an ANDA filer with a basis to challenge an overbroad use code listing in the Orange Book. The Hatch-Waxman Act authorized a counterclaim only if the listed patent did not claim *any* approved methods of using the listed drug. Thus, the court reasoned, Caraco, the Abbreviated New Drug Application (ANDA) filer, did not have a statutory basis to assert a counterclaim for injunctive relief against Novo, which listed a use code broader than but including the patented method.

Reasoning: The Hatch-Waxman Act provides a limited counterclaim to a generic manufacturer in a Paragraph IV infringement action. The Act authorizes the generic manufacturer to assert a counterclaim “*on the ground that the patent does not claim* either (aa) the drug for which the application was approved; or (bb) *an approved method of using the drug.*” 21 U.S.C. § 355(j)(5)(C)(ii) (I) (emphases added). The Federal Circuit recognized that the counterclaim provision was enacted to correct an issue raised in an earlier Federal Circuit case—*Mylan*—where an ANDA filer was powerless to sue to correct inaccurate Orange Book listings. But the court concluded that the counterclaim provision's language was unambiguous, as the statute only authorized a counterclaim when the patent did not claim “*an approved method.*” Thus, the court reasoned, the Act authorized a counterclaim only if the listed patent did not claim *any* approved methods of using the listed drug. The court explained that this was consistent with the legislative history, which merely demonstrated that it was resolving the specific issue in *Mylan* and did not address the factual issue in the present case.

The court suggested that Paragraph IV litigation should resolve issues where an ANDA filer's method does not actually infringe the listed patent.

The Federal Circuit further found that the statute did not allow for an order compelling the patent holder to change its use code narrative. Instead, it allowed for the correction or deletion of "patent information," which only included the patent number and expiration date. The court explained that this was consistent with the language as used in the statute. The court recognized that the FDA promulgated a regulation concerning "Submission of Patent Information" prior to the enactment of the counterclaim provision that included the patent number, expiration date, use code narrative, and other information. But the court explained that the counterclaim provision did not mention the FDA regulations and did not suggest that it was adopting a meaning broader than the statutory definition. Thus, the court reversed the district court's decision and vacated the injunction.

In a concurrence, Judge Clevenger expressed concern that Paragraph IV litigation might not resolve the issue in this case because Caraco could not assert that its proposed labeling (which was required to cover all three methods) would not infringe the '358 patent. He suggested that the FDA "gummed up the works" by requiring a single broad indication for repaglinide, but that it was Congress's burden—and not the court's—to address the issue raised in the case, for which there was no statutory resolution. In a dissent, Judge Dyk argued that the majority's interpretation was contrary to the manifest purpose of the counterclaim provision of the Hatch-Waxman Act—namely, "to prevent manipulative practices by patent holders." In a dissent from the denial of the petition for rehearing en banc, Judge Gajarsa—joined by Judge Dyk—asserted that the majority's interpretation was incorrect, that "pioneering drug manufacturers now have every incentive to follow Novo's lead and draft exceedingly broad use codes thereby insulating themselves from generic competition and rendering Section viii a dead letter," and that Caraco would be unable to prevail in a Paragraph IV litigation because its label would include information regarding the patented combination even though the patent concededly did not cover the use for which Caraco sought to market the drug.⁹⁶

Teva Pharmaceuticals USA, Inc. v. Eisai Co.⁹⁷

Facts: Eisai, which holds the NDA for donepezil (marketed as Aricept(R)), listed five patents for Aricept(R) in the Orange Book. Ranbaxy filed the first ANDA for the generic form of donepezil, filing both Paragraph III and IV certifications. Teva subsequently filed two separate ANDAs for generic donepezil. Teva's first ANDA had the same Paragraph III and IV certifications as Ranbaxy. Teva subsequently amended its first ANDA to change its Paragraph III certification to a Paragraph IV certification. Teva's second ANDA was filed by Gate, a division of Teva. The second ANDA was for a different generic form of donepezil than the first ANDA. The Gate ANDA originally included only Paragraph III

96. *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 615 F.3d 1374 (Fed. Cir. 2010).

97. 620 F.3d 1341 (Fed. Cir. 2010).

certifications, but those were later changed to Paragraph IV certifications. Eisai timely sued Teva and Gate for infringement of one of the listed patents—the '841 patent—pursuant to 35 U.S.C. § 271(e)(2). The infringement actions were consolidated, Teva and Gate stipulated that their generic form of donepezil would infringe the '871 patent unless the patent was invalid or infringed, and Eisai obtained a preliminary injunction.

Teva and Gate later filed a declaratory judgment that they would not infringe the four remaining patents listed in the Orange Book for Aricept(R), which Eisai had never sought to enforce. Prior to the filing of the declaratory judgment action, Eisai filed statutory disclaimers for two of the listed patents—the '321 and '864 patents—which had the effect of cancelling the patent claims. After the declaratory judgment action was filed, the parties negotiated a covenant-not-to-sue for the remaining two patents listed in the Orange Book—the '911 and '760 patents. Eisai asserted that the statutory disclaimers and covenant-not-to-sue meant that there was no justiciable controversy between the parties. Teva and Gate responded that they were suffering an injury cognizable under Article III because the four patents remained listed in the Orange Book, so FDA approval of the Gate ANDA could not occur until the exclusivity period had run for the first-filer on the four patents—Ranbaxy. The district court dismissed the declaratory judgment action.

Held: An actual controversy existed because the ANDA filer could not market its product until it obtained approval from the FDA, which it could not obtain until it succeeded in litigation, even though the New Drug Application (NDA) filer did not seek to enforce four of the five patents listed in the Orange Book and instead filed terminal disclaimers and covenants-not-to-sue on them. Further, the district court abused its discretion in declining to hear the matter under the Declaratory Judgment Act, as there were no typical factors that would warrant the exercise of discretion.

Reasoning: The Federal Circuit held that there was an actual controversy in the case. It first noted that an ANDA filer can bring suit under the Declaratory Judgment Act, 28 U.S.C. § 2201, against the holder of an NDA. It explained that the case presented an actual controversy because a favorable judgment would eliminate the potential for Eisai to exclude Teva from the market, as Teva still needed a court judgment of invalidity or noninfringement to obtain FDA approval and enter the market. The court reasoned that the separate preliminary injunction against the '841 patent did not affect the actual controversy, as the injunction was merely preliminary and the underlying litigation was ongoing. The court explained that the parties' stipulation after the appeal was filed that the injunction would remain in effect until expiration of the '841 patent (November 2010) did not alter its analysis because it did not affect jurisdiction at the outset of the appeal and because after that date the remaining four patents would bar Teva's entry into the market after November 2010.

The court further held that the district court abused its discretion when it refused to entertain the suit under the Declaratory Judgment Act. The Federal Circuit explained that the district court erroneously concluded that there was no subject matter jurisdiction, one of the factors it considered in declining to

entertain the case. Further, the court held that the district court's exercise of discretion was not supported by the facts. The Federal Circuit held that the record did not support the district court's conclusion that Teva's filing of multiple ANDAs—one under Gate's name—was improper gamesmanship. Instead, the Federal Circuit reasoned, nothing in the Hatch-Waxman Act bars a company from filing multiple ANDAs covering different formulations of the same drug and nothing was improper about filing the ANDAs under different corporate names, particularly since the filing decision was made at the FDA's request. The court explained that this case presented none of the typical factors, such as duplicity, that might warrant the exercise of discretion to decline jurisdiction.

