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Last Month at the Federal Circuit

July 2013

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Regents of the University of Minnesota v. AGA Medical Corp.

No. 12-1167 (Fed. Cir. June 3, 2013)

[Appealed from D. Minn., Judge Schiltz]

Final ITC Terminations in Favor of Arbitration Under Section 1337(c) Are Appealable to the Federal Circuit

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[Appealed from ITC]

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[Appealed from D.N.J., Judge Pisano]

Abbreviations

ALJ	Administrative Law Judge
ANDA	Abbreviated New Drug Application
APA	Administrative Procedures Act
APJ	Administrative Patent Judge
Board	Board of Patent Appeals and Interferences
Commissioner	Commissioner of Patents and Trademarks
CIP	Continuation-in-Part
DJ	Declaratory Judgment
DOE	Doctrine of Equivalents
FDA	Food and Drug Administration
IDS	Information Disclosure Statement
ITC	International Trade Commission
JMOL	Judgment as a Matter of Law
MPEP	Manual of Patent Examining Procedure
NDA	New Drug Application
PCT	Patent Cooperation Treaty
PTO	United States Patent and Trademark Office
SJ	Summary Judgment
TTAB	Trademark Trial and Appeal Board

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July 2013

Disclaimer Made During Prosecution of a Predecessor Patent Does Not Carry Forward If the Claim's Substance Has Materially Changed

Sydney R. Kestle*

Judges: Rader, Dyk (author), Wallach
[Appealed from D. Minn., Judge Schiltz]

In *Regents of the University of Minnesota v. AGA Medical Corp.*, No. 12-1167 (Fed. Cir. June 3, 2013), the Federal Circuit affirmed the district court's grants of SJ, holding that U.S. Patent No. 6,077,291 ("the '291 patent") was not infringed and that the asserted claims of U.S. Patent No. 6,077,281 ("the '281 patent") were invalid as anticipated.

Regents of the University of Minnesota ("the University") own the '291 and '281 patents, which protect medical devices for repairing heart defects. Specifically, the '291 and '281 patents describe "transcatheter septal occluders" designed to block holes in the septum. The claimed devices consist of two occluding disks, which attach to one another, collapse, and thread through a catheter into the heart. When the catheter is withdrawn, the disks expand and block the hole.

The University sued AGA Medical Corporation ("AGA") for infringement of both patents. Following a *Markman* hearing, the district court partially granted AGA's motion for SJ of noninfringement as to the '291 patent, stating that no reasonable jury could find AGA's one-piece mesh device infringing. Several months later, the district court granted AGA's motion for SJ of invalidity for claims 1, 4, and 5 of the '281 patent.

On appeal, the Federal Circuit began by addressing whether the district court properly construed the '291 patent to require two concrete disks and held that, indeed, two physically separate disks were required. The Court reasoned that the claim language, the specification, the prosecution history, and the ordinary meaning of the terms mandated such a construction.

"We have held that it is permissible for a patentee to take a different approach to claiming an invention in subsequent patents, either by adding limitations or by altering the claim's format. When the patentee does so, however, we cannot rely on the dubious argument that dissimilar claims present equivalent issues of validity, or that the applicant's disclaimer with respect to one claim would be equally applicable to another claim." Slip op. at 26.

The Court first noted that the claim language supported a separateness requirement. Several of the claims describe "first and second disks" or "first and second occluding disks" that are "affixed,"

“connected,” or “joined” to form a “conjoint” structure. As the Court highlighted, “one does not ordinarily speak of the parts of a unitary structure as being ‘affixed’ or ‘joined’ or ‘connected’ to each other.” Slip op. at 7 (quoting *Regents of the Univ. of Minn. v. AGA Med. Corp.*, 660 F. Supp. 2d 1037, 1044 (D. Minn. 2009)).

In addition, the ’291 patent specification echoed the separateness requirement. It does not teach a single-piece embodiment; rather, it specifically states that “every single embodiment disclosed in the ’291 patent’s drawings and its written description is made up of two separate disks.” *Id.* at 8 (quoting *Regents*, 660 F. Supp. 2d at 1044). The specification also discloses ways of affixing the two disks and describes a possible third piece to be disposed between the two disks. The Court reasoned that these disclosures necessitate an understanding that the device consists of physically distinct structures.

Moreover, the prosecution history similarly emphasized the need for distinct structures. During prosecution, the University distinguished its invention over the prior art by emphasizing the “two disks” that allowed for more advantageous assembly. The ’291 patent was ultimately granted because of the limitation that “*a first membrane is connected to a central portion of a second membrane.*” *Id.* at 10-11 (citation omitted).

Finally, the ordinary meaning of the terms also supported the separateness requirement. Analyzing timely dictionary definitions of “affixed” and “conjoint,” the Court concluded that “when a physical object is described as having been ‘affixed,’ ‘joined,’ ‘connected,’ or ‘conjoin[ed]’ to another object, it means that those objects were previously separate.” *Id.* at 12-13 (alteration in original). The Court discarded the University’s argument that the district court improperly imported process limitations into the claims, stating that “affixed” and “conjoint,” when read in the context of the ’291 patent, properly impose a structural limitation.

This construction indisputably excluded AGA’s device, which was molded from a single tubular piece. AGA’s literature describing the invention as having two disks could not place the accused device within the claims’ scope. Thus, accepting the district court’s claim construction, the Federal Circuit held that AGA’s accused device did not infringe the ’291 patent.

Turning to the validity of the ’281 patent, the Federal Circuit held it invalid as anticipated. Claim 1 of the ’281 patent recites a nontraditional means-plus-function limitation. Under 35 U.S.C. § 112, ¶ 6, the Court evaluated the corresponding structures in the specification and all equivalents thereof. It concluded that the prior art’s radial, umbrella-like frame was an equivalent of the patented device’s peripheral frame structure. The prior art’s “‘springy’ radial frame performed the same function as the peripheral frame structure—mov[ing] [the device] from a compressed to an expanded orientation’—in substantially the same way, with substantially the same result.” *Id.* at 18-19 (alterations in original) (quoting *Regents of the Univ. of Minn. v. AGA Med. Corp.*, 835 F. Supp. 2d 711, 720 (D. Minn. 2011)).

Thus, the primary question remaining on appeal was whether the University disclaimed the prior art construction during the prosecution of a predecessor patent. The Court held that, even though the University “effected a clear and unambiguous disclaimer of [the] radial frame with respect to the [claim] language,” *id.* at 21, the disclaimer did not carry forward to the means-plus-function language used in the ’281 patent.

Even though the predecessor and the ’281 patent shared similar claim language, the substance of each claim’s scope was materially different. Specifically, the limitation requiring “[a] septal defect closure device comprising first and second occluding disks, each disk comprising . . . an elastically deformable frame extending along and attached adjacent to the periphery of the membrane,” was not carried over into the ’281 patent. *Id.* at 26 (alterations in original) (citation omitted). Because the ’281 patent “contain[ed] a different claim limitation than its predecessors and capture[d] different subject matter,” the

disclaimer did not apply. *Id.* at 27. Further, the University did not argue that the radial frame was ineffective during prosecution. Its focus was on distinguishing the prior art based on assembly difficulties. This justification had no relevance on appeal and did not support applying the disclaimer to the '281 patent.

As a final note, the Court dismissed the University's arguments related to "in communication with" and "at least a substantial portion to." While the University "style[d] its arguments as challenges to the district court's application of this claim construction," in reality, the arguments were indirect objections to the claim construction itself. *Id.* at 28. Because those issues were never raised before the district court, they were waived and could not be addressed on appeal.

Accordingly, the Court affirmed the district court's grants of SJ, finding the '291 patent noninfringed and the '281 patent invalid as anticipated.

**Sydney R. Kestle is a Summer Associate at Finnegan.*

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July 2013

Final ITC Terminations in Favor of Arbitration Under Section 1337(c) Are Appealable to the Federal Circuit

Brandon S. Bludau*

Judges: Lourie (dissenting), Bryson, Prost (author)

[Appealed from ITC]

In *InterDigital Communications, LLC v. International Trade Commission*, No. 12-1628 (Fed. Cir. June 7, 2013), the Federal Circuit reversed the ITC's order terminating an investigation as to LG Electronics, Inc., LG Electronics USA, Inc., and LG Electronics Mobilecomm USA, Inc. (collectively "LG") in favor of arbitration per a prior patent license agreement between InterDigital Communications, Inc. (formerly InterDigital Communications, LLC) ("InterDigital") and LG, and remanded to the ITC for further proceedings, explaining that "there is no plausible argument that the parties' dispute in this case arose under their patent license agreement." Slip op. at 2.

InterDigital and LG entered into a patent license agreement ("Agreement") in which InterDigital granted LG for the term of the Agreement a license to certain InterDigital patents with respect to devices designed to operate according to both second ("2G") and third ("3G") generation wireless standards. According to its terms, the Agreement terminated on December 31, 2010. A "survival" clause included in the Agreement provided that at the end of the term of the Agreement, LG will have a "fully paid-up" license for the life of InterDigital's patents for 2G products. The Agreement also permitted either party to submit to arbitration any dispute arising under the Agreement.

The following year, InterDigital amended its complaint with the ITC, asserting that LG violated section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337, by importing wireless devices that infringed patents relating to its 3G wireless technology. LG subsequently moved to terminate the investigation, arguing that its accused 3G products were still covered under the Agreement and that InterDigital's infringement claim was subject to arbitration because it arose under the Agreement. Despite InterDigital's arguments that LG did not have an ongoing license for 3G products under the plain text of the Agreement, the ALJ issued an initial determination granting LG's motion to terminate the investigation as to LG based on the framework for analyzing a motion to stay pending arbitration outlined in *Qualcomm Inc. v. Nokia Corp.*, 466 F.3d 1366 (Fed. Cir. 2006). Under that framework, the ALJ determined that "the parties clearly intended to delegate the question of arbitrability to an arbitrator" and that LG's request for arbitration was not "wholly groundless." Slip op. at 7. The ITC declined to review the ALJ's decision. InterDigital subsequently appealed the ITC's order terminating the investigation as to LG.

"[A] party may appeal an ITC order that is not a final decision on the merits if 'its effect upon appellants is the equivalent of a final determination.'" Slip op. at 13 (quoting *Import Motors, Ltd. v. U.S. Int'l Trade Comm'n*, 530 F.2d 940,

As a threshold matter, the Federal Circuit first addressed whether it had jurisdiction over InterDigital's appeal. Section 1337 lists various ITC determinations for which a party may seek review by the Federal Circuit, namely, a final determination of the ITC under subsection (d), (e), (f), or (g). LG and the ITC argued, however, that the investigation termination was not a final determination under one of the enumerated subsections. Specifically, the ITC terminated the investigation under subsection (c), which permits the ITC to terminate an investigation on the basis of an agreement between the private parties to present the matter for arbitration. The Federal Circuit first looked to precedent from the Court of Customs and Patent Appeals that provided a framework for analyzing whether an ITC order is appealable under section 1337(c). Specifically, the Federal Circuit noted that the proper inquiry as to whether a party may appeal an ITC order that is not a final decision on the merits is if "its effect upon appellants is the equivalent of a final determination." *Id.* at 10 (quoting *Import Motors, Ltd. v. U.S. Int'l Trade Comm'n*, 530 F.2d 940, 944 (C.C.P.A. 1976)). Additionally, the Federal Circuit relied on the general rule that "judicial review will not be precluded on the sole ground that specific procedures for judicial review of a particular agency action are not spelled out in a statute." *Id.* at 13 (quoting *Allied Corp. v. U.S. Int'l Trade Comm'n*, 850 F.2d 1573, 1579 (Fed. Cir. 1988)).

In evaluating whether the ITC order had an effect equivalent to that of a final determination, the Federal Circuit analogized the facts of this case with those of *Farrel Corp. v. U.S. International Trade Commission*, 949 F.2d 1147 (Fed. Cir. 1991), in which the Court found an order terminating an investigation in favor of arbitration to be an appealable final determination because "the dismissal was with prejudice and [the] petitioner [could] not request reopening." Slip op. at 14-15 (alterations in original) (quoting *Farrel*, 949 F.2d at 1151 n.4). Similarly, the Federal Circuit found that "InterDigital will have to await the outcome of the proceeding before the arbitrators to find out whether it can file a new complaint. Until the arbitrators determine whether InterDigital's claims are subject to arbitration, any new complaint InterDigital filed would also be terminated in favor of arbitration." *Id.* at 15. Thus, the Court found that the ITC's "order therefore has 'the same operative effect, in terms of economic impact' as a final determination" and thus is an appealable final determination under 19 U.S.C. § 1337(c). *Id.* (quoting *Import Motors*, 530 F.2d at 945-46).

As to the merits of the ITC's termination, the Federal Circuit noted that the ALJ applied the appropriate framework outlined in *Qualcomm*, in which once it is determined that "the parties to the agreement did clearly and unmistakably intend to delegate the power to decide arbitrability to an arbitrator, then the court should perform a second, more limited inquiry to determine whether the assertion of arbitrability is 'wholly groundless.'" *Id.* at 17 (quoting *Qualcomm*, 466 F.3d at 1371). The Court found, however, that the ALJ did not perform the proper analysis under that framework when he failed to assess the text of the parties' license agreement to determine whether LG's assertion of arbitrability was "wholly groundless." Specifically, the Court explained that in *Qualcomm*, it noted that "[i]n undertaking the 'wholly groundless' inquiry, the district court should look to the scope of the arbitration clause and the precise issues that the moving party asserts are subject to arbitration." *Id.* (quoting *Qualcomm*, 466 F.3d at 1374). After examining the provisions of the Agreement, the Court found LG's assertion of arbitrability to be "wholly groundless" because "the only surviving portion of the grant clause is that portion providing LG with a 'fully paid-up' license for the life of InterDigital's patents for 2G products." *Id.* at 20. The Court further stated that "[t]here simply is no plausible argument that LG's license for 3G products survived the termination of the Agreement." *Id.* Accordingly, the Court reversed the ITC's order terminating the investigation as to LG and remanded to the ITC for further proceedings.

Dissenting-in-part, Judge Lourie agreed that there is no plausible argument that LG could prevail under its patent license agreement. Judge Lourie, however, would dismiss the appeal, because he did not believe that the Court had jurisdiction to entertain the appeal. In his view, the first section of 19 U.S.C. § 1337(c) should be the Court's starting point in determining the subject matter jurisdiction of the Court. According to Judge Lourie, the language of the statute is clear: "[A] termination due to an arbitrability

agreement is a termination 'without . . . a determination.' As it is not a determination, it is also not a 'final determination.'" Lourie Dissent at 2. Judge Lourie also stated that the Court did not have jurisdiction because the ITC's determination was not a final determination under subsection (d), (e), (f), or (g).

**Brandon S. Bludau is a Summer Associate at Finnegan.*

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July 2013

Legally Binding Public Statements May Eliminate Standing for DJ

*Daniel F. Klodowski**

Judges: Dyk (author), Bryson, Moore

[Appealed from S.D.N.Y., Judge Buchwald]

In *Organic Seed Growers & Trade Ass'n v. Monsanto Co.*, No. 12-1298 (Fed. Cir. June 10, 2013), the Federal Circuit held that statements from Monsanto Co. and Monsanto Technology, LLC (collectively "Monsanto") indicating the company would not sue farmers for inadvertent trace usage of its products eliminated the plaintiffs' standing for DJ. Determining there was no remaining case or controversy beyond the scope of Monsanto's assurances, the Court affirmed the district court's dismissal for lack of subject matter jurisdiction.

The Organic Seed Growers and Trade Association, joined by a coalition of farmers, seed sellers, and agricultural organizations (collectively "Plaintiffs"), sued Monsanto, seeking DJ of noninfringement, unenforceability, and invalidity with respect to twenty-three of Monsanto's patents ("the patents-in-suit"). The patents-in-suit relate to technologies for genetically modifying seeds. The patents-in-suit include methods of incorporating traits such as glyphosate resistance into plants, thereby allowing crops to survive the application of glyphosate-based herbicides like Monsanto's Roundup product.

The Plaintiffs argued that they faced a significant risk of infringing Monsanto's patents-in-suit, despite their expressed intent to avoid using any Monsanto-developed seeds. Through self-replication, the wind frequently blew glyphosate-resistant seeds from farms to nearby lands. The Plaintiffs cited Monsanto's aggressive litigation strategy in maintaining that lawsuits were likely to follow such forms of inadvertent contamination.

Prior to filing this suit, the Plaintiffs asked Monsanto to sign a covenant not to sue for small amounts of seed contamination. Monsanto refused, explaining through a series of statements that the company will not exercise patent rights where "trace amounts of our patented seeds or traits are present in [a] farmer's fields as a result of inadvertent means," and that "any fear of suit or other action is unreasonable, and any decision not to grow certain crops unjustified." Slip op. at 8 (citations omitted). Monsanto contended that these statements were sufficient to remove any reasonable fear of legal action, so the Plaintiffs lacked standing for a DJ action without the need for Monsanto to issue a signed covenant.

The district court sided with Monsanto, dismissing the suit for lack of subject matter jurisdiction, since the court found no substantial controversy or injury traceable to Monsanto. While the district court concluded it is likely inevitable that trace amounts of windblown seeds from genetically modified plants would travel to the Plaintiffs' farms, it ruled that Monsanto's statements removed the threat of resulting litigation. The district court further found that Monsanto would be legally bound to follow its representations regarding permissible trace contamination.

“[I]t is ‘incumbent on [the declaratory judgment plaintiff] to indicate that it engages in or has sufficiently concrete plans to engage in activities not covered’ by a defendant’s covenant not to sue.” Slip op. at 19-20 (second alteration in original) (quoting *Already, LLC v. Nike, Inc.*, 133 S. Ct. 721, 728 (2013)).

The Federal Circuit affirmed, noting that a DJ plaintiff bears the burden of showing the existence of an actual controversy or threat of harm. The Court held that DJ plaintiffs must have demonstrated a “substantial” risk that the harm will occur, which may prompt [them] to reasonably incur costs to mitigate or avoid that harm.” *Id.* at 10 (alteration in original) (quoting *Clapper v. Amnesty Int’l USA*, 133 S. Ct. 1138, 1150 n.5 (2013)). The Court further observed that “a covenant not to sue a declaratory judgment plaintiff can moot a controversy between the parties.” *Id.* at 14-15.

The Federal Circuit also agreed with the district court that Monsanto’s public statements were legally binding. As the Court reasoned, “[t]aken together, Monsanto’s representations unequivocally disclaim any intent to sue appellant growers, seed sellers, or organizations for inadvertently using or selling ‘trace amounts’ of genetically modified seeds.” *Id.* at 16. The Court defined “trace amounts” as less than one percent of the seeds used or sold by a farm. The Court went on to hold that, “[w]hile Monsanto’s representations are not a covenant not to sue, they have a similar effect.” *Id.* at 17. As a result, the Court held that Monsanto’s statements mooted the controversy within the scope of its representations.

The Federal Circuit observed that, while Monsanto’s statements only offered that the company would not sue farmers inadvertently using trace amounts of its seeds, none of the Plaintiffs alleged that they were acting beyond the scope of Monsanto’s disclaimer. Because none of the Plaintiffs could demonstrate their actions exceeded the conduct permitted by Monsanto, the Court reasoned that “[i]t follows that there is no case or controversy here.” *Id.* at 20. The Federal Circuit also noted that, because Monsanto’s statements were used to defeat DJ, “those representations are binding as a matter of judicial estoppel.” *Id.* at 17.

**Daniel F. Klodowski is a Summer Associate at Finnegan.*

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July 2013

En Banc Court Concludes It Has Jurisdiction over Patent Infringement Determinations When Damages and Willfulness Remain Undecided

Timothy P. McAnulty

Judges: Rader, Newman, Lourie, Dyk, Prost (author), Moore (concurring-in-part and dissenting-in-part), O'Malley (dissenting), Reyna (concurring-in-part and dissenting-in-part), Wallach (dissenting)

[Appealed from D. Del., Judge Robinson]

In *Robert Bosch, LLC v. Pylon Manufacturing Corp.*, Nos. 11-1363, -1364 (Fed. Cir. June 14, 2013), (en banc), the Federal Circuit held that 28 U.S.C. § 1292(c)(2) confers jurisdiction on the Court to hear appeals from patent infringement liability determinations (1) when a trial on damages has not occurred, and (2) when willfulness issues are outstanding and remain undecided.

Robert Bosch, LLC (“Bosch”) sued Pylon Manufacturing Corp. (“Pylon”) for patent infringement, and Pylon later asserted patent infringement claims against Bosch. On a motion by Pylon, the district court bifurcated the issues of liability and damages. The district court also stayed discovery on damages and willfulness issues. After a jury trial on liability and JMOL motions, the district court entered judgment on the liability issues. Bosch appealed and Pylon cross-appealed. Bosch filed a motion to dismiss its appeal and Pylon’s cross-appeal on the ground that the Federal Circuit lacked jurisdiction. The Court denied Bosch’s motion and the parties presented both the substantive and jurisdictional issues before a panel of the Court. After oral argument, the Court sua sponte granted a rehearing en banc to determine if the Court had jurisdiction over the appeal.

Under § 1292(c)(2), an appeal can be taken to the Federal Circuit from a judgment in a patent infringement action that is otherwise appealable except for an accounting. The question before the en banc Court was whether a trial on damages and willfulness is an accounting for purposes of § 1292(c)(2).

The Court first concluded that “an accounting” includes the determination of damages, reasoning that it was clear from the case law and the history of the statute that an accounting includes both the determination of an infringer’s profits as well as a patentee’s damages. The Court noted that in enacting 28 U.S.C. § 227a, the predecessor to § 1292(c)(2), Congress gave the term “accounting” its judicially settled meaning of proceedings before a special master to determine the infringer’s profits and the plaintiff’s damages. The Court stated that “[t]he statute’s interpretation through history is clear.” Slip op. at 13. “An ‘accounting’ in the context of § 1292(c)(2) includes the determination of damages and cannot be limited to a traditional equitable accounting of an infringer’s profits.” *Id.*

“It is clear from the case law and the history of the statute that an accounting includes both the determination of an infringer’s profits as well as a

patentee's damages." Slip op. at 5.

"We also took this case en banc to determine whether § 1292(c)(2) confers jurisdiction on this court to entertain appeals from patent infringement liability determinations when willfulness issues are outstanding and remain undecided. We hold now that it does." *Id.* at 22.

The Court next concluded that an accounting may include a trial on damages, finding that neither the text nor the history of the statute supported Bosch's narrower interpretation to the contrary. The Court based its conclusion on four points. First, Congress expanded jurisdiction over interlocutory appeals from cases in equity to "civil actions for patent infringement which are final except for accounting." *Id.* Second, the issues historically decided in accounting proceedings are the same that are decided in modern damages trials. Third, Congress's reasons for allowing interlocutory appellate jurisdiction over patent cases except for an accounting apply with equal force to a modern damages trial. Fourth, stare decisis weighs in favor of allowing interlocutory appeals where liability has been established and a damages trial remains.

The Court further held that § 1292(c)(2) confers jurisdiction to entertain appeals from patent infringement liability determinations when willfulness issues are outstanding and remain undecided. The Court noted that the authority of the district court to bifurcate willfulness and infringement issues and the related Seventh Amendment issues were immaterial to its inquiry. Instead, the Court explained that the disposition of the issue turned on whether an "accounting" includes the determination of willfulness. The Court held that it does, basing its decision on the statute itself and cases decided since the enactment of the statute's predecessor. The Court stated that "it is clear that an accounting . . . included the determination of willfulness" and that it was "in no position to change that well settled meaning now." *Id.* at 26.

Judge Moore agreed with the majority's holding that the Court has interlocutory jurisdiction over judgments that are final except for determining damages, but disagreed that this includes jurisdiction over judgments when willful infringement remains outstanding. According to Judge Moore, "[n]o reasonable construction of an 'accounting' can encompass the subjective state-of-mind and objective recklessness inquiries that underpin a willful infringement analysis." Moore Concurrence-in-Part and Dissent-in-Part at 1-2. Judge Moore opined that Congress made clear that an appeal can be had when all that is left is to ascertain the plaintiff's damages and determine the defendant's profits, and that this construction is consistent with the general understanding of the term "accounting." Judge Moore disagreed with the majority's reliance on past cases, stating that none of the cases established that Congress understood an accounting to include the substantive determinations of knowledge, intent, and reasonableness, and further, that none of the cases held that a determination of willfulness is part of an accounting. Judge Moore noted that many cases during the relevant time period gave the term "accounting" its plain and ordinary meaning—the determination of damages. Judge Moore dissented-in-part as there was "no sound basis upon which to twist the statute and introduce such inefficiency into the judicial system." *Id.* at 6-7.

Judge Reyna also agreed with the majority that the Court has interlocutory jurisdiction over judgments that are final except for determining damages, but dissented from the majority's holding that an accounting includes determining willfulness for three reasons. First, according to Judge Reyna, the plain language of § 1292(c)(2) makes no mention of willfulness and does not unambiguously express Congress's intent to exclude willfulness from the finality rule. Second, Judge Reyna reasoned that an accounting bears no relation to the willfulness inquiry, which has little to do with damages and everything to do with liability for infringement. Third, Judge Reyna opined that if § 1292(c)(2) is interpreted to allow an appeal before a determination of willfulness is made, Congress's purpose of avoiding needless expense wrought by piecemeal appeals in patent litigation will be frustrated.

Judge O'Malley dissented, joined by Judge Wallach, disagreeing with both of the majority's

conclusions. Judge O'Malley stated that she did not agree that the scope of the § 1292(c)(2) exception to the final judgment rule "has the astounding breadth the majority affords it today." O'Malley Dissent at 1. According to Judge O'Malley, the majority stretched the statutory provision beyond reasonable bounds, and well beyond anything Congress intended. Judge O'Malley expressed that the appeal should be dismissed because it is a nonfinal judgment over which the Court has no jurisdiction.

According to the dissent, rather than interpreting § 1292(c)(2) narrowly to find limited exceptions to the final judgment rule applicable to all Article III courts, the majority grossly expanded the Court's jurisdictional reach by adopting a broad definition of "an accounting." The dissent stated that the majority asked and answered the wrong question—whether an accounting in 1927, when § 227a was enacted, only permitted consideration of an infringer's profits or also allowed calculation of a patentee's damages.

The dissent opined that the Court instead should have asked whether the 1927 "accounting" proceeding as contemplated in § 1292(c)(2) was the same as or encompassed a jury trial on profits and damages. Judge O'Malley did not find persuasive any of the majority's four reasons for concluding that an "accounting" includes a damages trial.

According to the dissent, the majority's conclusion that an accounting can include a willfulness determination "is even less defensible" than its conclusion that an accounting can include a damages trial. *Id.* at 28. The dissent disagreed with the majority's asking only whether the fact of willfulness was ever considered by special masters when assessing the appropriate measure of an award to a patent holder in a suit in equity, stating that it "is simply not the relevant inquiry." *Id.*

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July 2013

Neither Issue Preclusion nor Claim Preclusion Bar PTO Trademark Challenges Despite District Court Litigation on Dilution and Infringement

*Ellie B. Atkins**

Judges: Lourie, O'Malley, Taranto (author)

[Appealed from TTAB]

In *Levi Strauss & Co. v. Abercrombie & Fitch Trading Co.*, Nos. 12-1495, -1496 (Fed. Cir. June 18, 2013), the Federal Circuit held that district court litigation on trademark infringement and dilution does not preclude challenges to the mark's registration at the PTO, reversing the TTAB and remanding for consideration of the PTO challenges.

Levi Strauss & Company ("Levi") owns multiple federally registered trademarks for the "Arcuate" stitching design used on the back pockets of its jeans, having used the bow-shaped pattern as a source identifier since 1873. In 2005, Abercrombie & Fitch Trading Co. ("Abercrombie") applied to register a "mirror image stitching design" on the Principal Register for use on jackets and on the Supplemental Register for use on clothing, namely, jeans, skirts, and pants. At the PTO, Levi filed an opposition to Abercrombie's application for registration on the Principal Register and a petition of cancellation for Abercrombie's registration on the Supplemental Register, arguing the design was likely to cause confusion and to dilute Levi's mark. Levi then sued Abercrombie in the Northern District of California, alleging that jeans with the "mirror image stitching design," specifically, Abercrombie's "Ruehl" line of jeans, infringed and diluted its trademarked pattern. The PTO stayed the opposition and cancellation proceedings pending resolution of the district court litigation.

In 2009, the district court ruled for Abercrombie on both infringement and dilution, termed the 2009 Judgment on Infringement and the 2009 Judgment on Dilution. Levi appealed the 2009 Judgment on Dilution to the Ninth Circuit Court of Appeals, which reversed and remanded. During the appeal, Abercrombie discontinued its Ruehl brand and filed a new trademark application for the same stitching design to be used on clothing, namely, bottoms for its Gilly Hicks brand. Back at the district court, Levi requested that Abercrombie agree to include its Gilly Hicks line for consideration. Abercrombie refused, and the district court denied Levi's subsequent request to amend its complaint. Levi thus voluntarily dismissed the case, and the district court dismissed Levi's claim for dilution in 2011. Abercrombie then filed for SJ at the PTO, arguing that claim and issue preclusion barred Levi's challenges to Abercrombie's marks. The TTAB granted SJ for Abercrombie, finding issue preclusion but not claim preclusion, and barred Levi's opposition and cancellation proceedings due to the district court litigation.

"Ultimately because the registrations at issue in the PTO cover a much broader range of uses of the Abercrombie mark than were the subject of the district-court litigation, the results of the district-court case do not preclude

Levi Strauss's challenges in the PTO." Slip op. at 2.

In reviewing the TTAB's decision, the Court reversed, holding that neither issue preclusion nor claim preclusion barred Levi's cancellation and opposition proceedings at the PTO. In addressing issue preclusion, the Court held that the 2009 Judgment on Dilution could not support either form of preclusion because the decision was reversed on appeal. "The 2009 Judgment on Dilution is not an extant final judgment on the merits, as required for claim preclusion. And the 2009 district-court findings are not necessary to a resulting judgment, as required for issue preclusion, when, as is true in this case, the only judgment they supported has been reversed." Slip op. at 9. Additionally, the 2011 Judgment on Dilution had no issue-preclusive effect because it was voluntarily dismissed and, thus, "it did not decide any specific issue at all." *Id.* at 10. The only adjudication potentially sufficient for issue preclusion purposes was the 2009 Judgment on Infringement. However, even this did not bar the opposition and cancellation determinations because "[t]he PTO proceedings involve[d] a much broader set of issues than were presented to, or therefore adjudicated in, that court." *Id.* The infringement action only considered specific products, comparing the Ruehl brand of jeans to Levi's protected trademarks. In contrast, the opposition or cancellation proceeding at the PTO involved confusion for any field of use for which Abercrombie sought registration, namely, jeans, skirts, shorts, pants, and jackets. Moreover, the PTO proceedings were not based on the goods' operation in commerce, whereas the infringement action was based in large part on how the goods appeared in the marketplace.

The Court additionally held claim preclusion inapplicable, finding the PTO proceedings and the district court proceedings "[did] not involve the same transactional facts, pragmatically judged." *Id.* at 12. Rather, "all indications are that Levi Strauss's dilution claim, like its infringement claim, was understood as challenging the uses of the stitching design that Abercrombie made on Abercrombie's Ruehl line of clothing, not the full range of uses Abercrombie's registration seeks to cover." *Id.* at 14. The Court also noted, "[A] significant aspect of Abercrombie's defense was that its Ruehl line of jeans and Levi Strauss products were sold in such different channels and at such different prices . . ." *Id.* at 4. The Court further cited its denial to extend the proceedings to also include the Gilly Hicks line as evidence of the district court litigation's narrow focus. The Court reasoned that an alternative ruling would have required owners of famous marks to litigate the entire range of potential uses for the allegedly infringing mark, even those uses that may be necessary for broad PTO registration, but that are irrelevant to the dilution claim. Accordingly, the Court held that neither issue preclusion nor claim preclusion prevented Levi's challenges to Abercrombie's mark, and reversed and remanded the case for further determination of the PTO proceedings.

**Ellie B. Atkins is a Summer Associate at Finnegan.*

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Combination of Drugs Was Obvious to Try When Synergistic Results Were Predictable

Daniel A. Lev

**Judges: Newman (concurring-in-part and dissenting-in-part), Dyk, Prost (author)
[Appealed from E.D. Mich., Judge Cohn]**

In *Novo Nordisk A/S v. Caraco Pharmaceutical Laboratories, Ltd.*, No. 11-1223 (Fed. Cir. June 18, 2013), the Federal Circuit found no error in the district court's finding that the synergistic effects of two Type II diabetes treatments were predictable, thereby rendering the combination obvious. Accordingly, the Court affirmed the district court's holding that claim 4 of U.S. Patent No. 6,677,358 ("the '358 patent") was invalid. The Court also reversed the district court's holding that the '358 patent is unenforceable based on inequitable conduct.

Type II diabetes can be treated with orally administered antidiabetic drugs ("OADs"). Two types of OAD classes at issue in the appeal were insulin secretagogues and insulin sensitizers. Insulin secretagogues work by stimulating insulin release from pancreatic beta cells. Insulin sensitizers reduce insulin resistance by acting on the liver to reduce glucose production and thereby improve insulin sensitivity in muscle and fat tissues. Novo Nordisk A/S and Novo Nordisk Inc. (collectively "Novo") developed repaglinide, a rapid and short-acting insulin secretagogue. Soon after, Novo conducted a clinical trial ("the Moses Study") to assess whether the combination of repaglinide and metformin, a well-known insulin sensitizer, would be more effective than repaglinide alone. The study showed that, when given the combination of repaglinide and metformin, the fasting plasma glucose ("FPG") levels of patients decreased eight times lower than what was typically achieved by metformin alone. This was surprising, because repaglinide on its own actually tended to increase a patient's FPG levels. Therefore, the scientists concluded that the combination therapy yielded a synergistic effect (instead of an additive effect), because the effect of the combination exceeded the sum of the separately administered effects.

During prosecution of the application that resulted in the '358 patent, the examiner rejected the application four times, asserting that the combination therapy would have been obvious to try and that the benefit—specifically, an additive effect from taking both drugs—was predictable. In response, Novo submitted the declaration of Dr. Sturis, a Novo scientist, that presented results of an additional study in obese rats ("Sturis Study") that, when combined with the Moses Study, demonstrated a synergistic effect of repaglinide/metformin combination therapy. Based on this declaration, the PTO issued the '358 patent.

Novo listed the '358 patent in the Orange Book entry for repaglinide. In 2005, Caraco Pharmaceutical Laboratories ("Caraco") filed an ANDA seeking approval to market a generic version. Caraco's ANDA included a certification that the '358 patent was invalid or would not be infringed by selling Caraco's proposed product. In response, Novo sued Caraco, alleging infringement of claim 4 of the '358 patent.

Caraco counterclaimed, asserting, inter alia, that claim 4 would have been obvious and that the '358 patent is unenforceable. After a bench trial, the district court agreed with Caraco on both of those claims. In so doing, the district court considered Novo's argument that the degree of synergistic effect was surprising and unexpected, but ultimately found this argument unpersuasive. Thus, the district court held that Caraco had proven the obviousness of claim 4 by clear and convincing evidence.

On appeal, the Federal Circuit first addressed the district court's obviousness ruling, which Novo challenged on three grounds. First, Novo argued that the district court misallocated the burden of persuasion by forcing Novo to overcome Caraco's "prima facie" case of obviousness with evidence of unexpected results. Second, Novo argued that even if the burdens were properly allocated, Caraco's evidence insufficiently supported the district court's ultimate obviousness findings. Finally, Novo believed that the district court should have deferred to the examiner's original finding that the Sturis and Moses Studies demonstrated unexpected synergy.

“Nothing in the court’s opinion in this case indicates that it reached a premature conclusion on obviousness. To the contrary, after considering the prima facie evidence ‘[b]ut before reaching the ultimate conclusion on the issue of obviousness,’ the court thoroughly evaluated all evidence of unexpected synergy and commercial success.” Slip op. at 13 (alteration in original).

The Federal Circuit rejected Novo's contention that the district court misallocated the burden of persuasion, and declined to reverse on this basis. The Federal Circuit concluded that Novo misinterpreted the role of the burden of persuasion in patent infringement litigation. The Court explained that, although the burden of persuasion remains with the challenger during litigation based on the presumption of validity, "the presumption of validity does not relieve the patentee of any responsibility to set forth evidence in opposition to a challenger's prima facie case which, if left un rebutted, would be sufficient to establish obviousness." Slip op. at 11. Thus, the patentee has two advantages: (1) only the burden of production shifts to the patentee after the challenger makes a prima facie case, and (2) the burden of persuasion by clear and convincing evidence remains with the challenger throughout the litigation.

The Federal Circuit found nothing in the district court's opinion to indicate that it reached a premature conclusion on obviousness. To the contrary, after considering the prima facie evidence but before reaching the ultimate conclusion on the issue of obviousness, the district court thoroughly evaluated all evidence of unexpected synergy and commercial success. It then concluded that, in view of all of this evidence, Caraco had shown by clear and convincing evidence that the combination was obvious. The Court also found that the district court did not invalidate claim 4 due to Novo's failure to prove unexpected results, as Novo alleged. Rather, the district court found that Caraco had established by clear and convincing evidence that the results of the claimed combination therapy were expected and explainable in light of the state of the art as of the critical date.

The Federal Circuit then reviewed the district court's findings and concluded that it was not erroneous for the district court to conclude that the prior art predicted the results found in the Moses and Sturis Studies. Specifically, the Federal Circuit considered the following findings: (1) the closest prior art was combination therapy using metformin and a sulfonylurea, which is another type of insulin secretagogue; (2) that prior art combination therapy was well known to produce beneficial and even synergistic results; and (3) repaglinide was known to be an insulin secretagogue having a similar mechanism of action to the sulfonylurea class of secretagogues, including some short-acting sulfonylurea secretagogues.

The Court next turned to Novo's third challenge to the district court's obviousness determination—that the district court should have deferred to the PTO's findings that the Moses and Sturis Studies demonstrated

synergy. In support of this argument, Novo relied on the recent holding in *Kappos v. Hyatt*, 132 S. Ct. 1690, 1696 (2012). There, the Supreme Court held that, in cases involving district court review of PTO rejections under 35 U.S.C. § 145, new evidence may be considered and that district courts should not defer to PTO factual findings that are contradicted by the new evidence. The Federal Circuit found that *Hyatt* had no relevance because, here, there was no challenge to a PTO rejection under § 145. Moreover, the Court explained that initial determinations by the PTO in determining whether to grant the application are entitled to no deference in district court infringement proceedings. For these reasons, the Federal Circuit affirmed the district court's obviousness finding.

Next, the Federal Circuit addressed the inequitable conduct determination. Caraco argued that the Sturis declaration and certain representations made by Novo's prosecution counsel, Dr. Bork, constituted inequitable conduct. In particular, Caraco challenged Dr. Sturis's failure to tell the PTO that certain of his reported test results had not been part of his original test protocol. Caraco also challenged Dr. Bork's assertion during prosecution that Dr. Sturis's data provided clear evidence of synergy and his failure to disclose certain e-mails that refuted that statement. Because the district court's decision issued before the Federal Circuit issued its en banc decision in *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011) (en banc), the district court had held the '358 patent unenforceable under either the pre-*Therasense* or post-*Therasense* test for materiality and intent. On appeal, Novo argued that the underlying facts were not material under the post-*Therasense* but-for standard. The Federal Circuit agreed.

Dr. Sturis was accused of failing to notify the PTO that the original test plan did not include his data calculations at 120 minutes. The Federal Circuit found it to be a nonmaterial omission because it did not qualify as "but-for" material. The Court explained that this was not a case in which adverse results were hidden in favor of more positive data, nor did the omission undermine the opinion stated in the declaration. The Court also found that Dr. Bork's statements during prosecution were not material. Important in this determination was that Dr. Bork referred to Dr. Sturis's test results as "evidence" rather than "proof." Therefore, the Federal Circuit reversed the district court's materiality and inequitable conduct findings with regard to both Dr. Sturis and Dr. Bork. The Court did not reach the issue of intent.

Judge Newman, dissenting-in-part, agreed with the majority that neither Dr. Sturis nor Dr. Bork engaged in inequitable conduct, and concurred in the judgment reversing the district court's ruling in that respect. However, in Judge Newman's view, Novo's discovery of the synergistic combination of metformin and repaglinide meets the criteria of patentability, and was incorrectly held to be unpatentable on the ground of obviousness under 35 U.S.C. § 103. Judge Newman noted that "[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." Newman Concurrence-in-Part and Dissent-in-Part at 2. Judge Newman was persuaded by the evidence that the PTO granted the '358 patent based on the synergistic effect that the inventors discovered and established, and that this activity was not suggested in the prior art, was not predictable, and was not obvious.

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A Method for Distributing Copyrighted Products over the Internet Does Not Lack Subject Matter Eligibility

*Boris Lau, Cheng Xu**

Judges: Rader (author), Lourie (concurring), O'Malley
[Appealed from C.D. Cal., Judge Klausner]

In *Ultramercial, Inc. v. Hulu, LLC*, No. 10-1544 (Fed. Cir. June 21, 2013), the Federal Circuit reversed and remanded the district court's judgment that the subject matter of U.S. Patent No. 7,346,545 ("the '545 patent") is not a "process" within the language and meaning of 35 U.S.C. § 101.

The '545 patent claims an eleven-step method for distributing copyrighted products over the Internet where the consumer receives a copyrighted item paid by an advertiser in exchange for viewing the advertisement. Several of these steps require the method being performed through computers, over the Internet, and in a cyber-market environment. Many of the steps also require intricate and complex computer programming.

Ultramercial, Inc. and Ultramercial, LLC (collectively "Ultramercial") sued Hulu, LLC ("Hulu"), YouTube, LLC ("YouTube"), and WildTangent, Inc. ("WildTangent") for infringement of the '545 patent. Hulu and YouTube have been dismissed from the case. WildTangent moved to dismiss the case for failure to state a claim, arguing that the '545 patent lacked patent-eligible subject matter. The district court concluded that the subject matter of the '545 patent is not a "process" within the language and meaning of § 101. Thus, the district court dismissed Ultramercial's claim without formally construing the claims and, further, without requiring defendants to file answers. Ultramercial appealed.

On appeal, the Federal Circuit reversed and remanded the district court's dismissal of Ultramercial's claim, holding that the district court erred in concluding that the '545 patent's subject matter is not considered a "process," one of the subject matter categories listed under § 101.

"The Court has long-recognized that any 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. A court cannot go hunting for abstractions by ignoring the concrete, palpable, tangible limitations of the invention the patentee actually claims. Instead, the relevant inquiry is whether a claim, as a whole, includes *meaningful* limitations restricting it to an application, rather than merely an abstract idea." Slip op. at 15-16.

As an initial matter, the Court addressed the district court's use of Federal Rule of Civil Procedure 12(b)(6) in dismissing Ultramercial's claims, noting that "it will be rare that a patent infringement suit can be dismissed at the pleading stage for lack of patentable subject matter," because every issued patent is presumed to have been issued properly, absent clear and convincing evidence to the contrary. Slip op. at 5. The Court further noted that when Rule 12(b)(6) is used as a defense, dismissal is appropriate only if the factual allegations in the complaint, construed in the light most favorable to the plaintiff, suffice to establish the defense. Therefore, the Court indicated that for a Rule 12(b)(6) dismissal, "the *only* plausible reading of the patent must be that there is clear and convincing evidence of ineligibility. For those reasons, Rule 12(b)(6) dismissal for lack of eligible subject matter will be the exception, not the rule." *Id.* at 6.

The Court held that the district court erred by requiring the patentee to present a claim construction that would show that the claims were subject matter eligible. The Court noted that the claims are presumed to be eligible, and that the district court should have either required the defendant to establish by clear and convincing evidence that the only plausible construction of the patent rendered the subject matter ineligible, or should have adopted a construction most favorable to the patentee.

The Court then turned to the district court's conclusion that the claims are ineligible subject matter, noting that for purposes of the appeal, a construction of the claims most favorable to the patentee will be adopted. The claims recited a method for monetizing and distributing copyrighted products over the Internet, which the Court noted easily satisfies the meaning of a "process" under § 100 and hence falls within an eligible subject matter category. Therefore, the Court also had to decide whether the claim is meaningfully limited to something less than an abstract idea that preempts the use of an abstract concept. While the claimed method involved an abstract idea that advertising can be used as a form of currency, the Court noted that there are also meaningful limitations showing that the patent claim is a specific application of such an idea.

The Court then began to list several meaningful limitations included in the patent claim, noting that many of the steps require intricate and complex computer programming. The Court noted that even without going into the specifics of the patent claim and by just looking at the claim on a general level, the claim cannot be considered an abstract idea and that "it wrenches meaning from the word to label the claimed invention 'abstract.'" *Id.* at 27. Based on the recited steps, the claim involved not an abstract idea, but a very specific application of the idea that advertising could be used to generate money. Moreover, the record showed no evidence that the recited steps of the claim are all token presolution or postsolution steps. Therefore, the Court ruled that the district court erred in deciding that the recited limitations did not limit the abstract idea.

Next, the Court turned to the contention that software programming necessary to facilitate the invention does not deserve patent protection or constitutes abstract subject matter. In *In re Alappat*, 33 F.3d 1526 (Fed. Cir. 1994) (en banc), the Court reasoned that software programming essentially creates a "new machine," because the added programming transforms a general purpose computer into a special purpose computer programmed to perform particular functions pursuant to instructions from program software. The Court noted that this "new machine" could be efficiently claimed in terms of the programming that facilitates a unique function. Moreover, both the Court and the PTO have long recognized that improvements made through interchangeable software or hardware enhancements deserve patent protection.

The Court then addressed the issue of the '545 patent not outlining any specific detailed mechanism for delivering the media content to the consumer. The Court noted that this lack of specificity does not make the patent claim abstract. As long as the patent discloses sufficient information to allow a person of ordinary skill in the art to practice the invention and to satisfy the written description requirement, the disclosure does not have to provide detailed information for every step in the process. In addition, written description and enablement are conditions that must be met for patentability, and not for subject matter

eligibility.

The Court then distinguished this case from *CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1373 (Fed. Cir. 2011), a case involving a patent describing a method and system for detecting fraud in credit card transactions. The Court noted that, unlike the patent claims in *CyberSource*, the claims here require, among other things, controlled interaction with a consumer over an Internet website, which is “something far removed from *purely* mental steps.” Slip op. at 32-33.

Accordingly, the Court reversed the district court’s dismissal of Ultramercial’s patent claims for lack of subject matter and remanded for further proceedings.

In a concurring opinion, Judge Lourie agreed with the Court’s reversal of the judgment on appeal and its remand for further proceedings. While he agreed with the Court that no formal claim construction is needed to interpret the claims at this stage, Judge Lourie would have followed a two-step inquiry, derived from *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), for determination of patent eligibility under § 101. Specifically, a court has to determine (1) whether the claimed invention falls within the four classes defined by § 101; and (2) whether the exceptions to subject matter eligibility apply to the invention. *CLS Bank Int’l v. Alice Corp.*, 2013 WL 1920941, at *9 (Fed. Cir. May 10, 2013). In terms of abstractness, Judge Lourie would have determined whether the claim bears any risk of preempting an abstract idea by analyzing the fundamental concept embedded in the claim and then determining whether there are additional limitations to narrow the claim not to cover the full abstract idea.

**Boris Lau and Cheng Xu are Summer Associates at Finnegan.*

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Good-Faith Belief of Invalidity May Negate Intent for Inducement

Matthew J. Luneack*

Judges: Newman (concurring-in-part and dissenting-in-part), Prost (author), O'Malley (concurring-in-part and dissenting-in-part)

[Appealed from E.D. Tex., Magistrate Judge Everingham]

In *Commil USA, LLC v. Cisco Systems, Inc.*, No. 12-1042 (Fed. Cir. June 25, 2013), the Federal Circuit affirmed the district court's grant of a new trial, vacated the jury's verdict on induced infringement, and remanded for a new trial. Specifically, the Court held that as a defense to an induced infringement claim, Cisco Systems, Inc. ("Cisco") should have been allowed to present evidence showing its good-faith belief of invalidity.

Commil USA, LLC ("Commil") owns U.S. Patent No. 6,430,395 ("the '395 patent"), covering a method of providing mobile devices traveling throughout a network area with faster and more reliable transfers from one base station to another. Commil sued Cisco, alleging certain Cisco WiFi access points and controllers infringed the claims of the '395 patent. Following an initial trial in which the jury found Cisco liable for direct infringement but not for induced infringement, the district court granted Commil's motion for a partial new trial on the issues of induced infringement and damages. The district court found that Cisco's counsel's inflammatory statements during trial may have had a prejudicial effect on the jury, influencing the outcome.

Prior to the second trial, Cisco proffered evidence showing its good-faith belief that the '395 patent was invalid. The district court excluded the evidence but did not issue a written opinion explaining its reasoning. Based on jury instructions imposing liability for inducers that were at least negligent to the fact that their actions would induce infringement, the jury held Cisco liable and awarded Commil \$63.7 million in damages.

On appeal, Cisco raised two main arguments. First, Cisco argued that the jury instruction on inducement was erroneous in light of the Supreme Court's decision in *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060 (2011), because it allowed the jury to find inducement based on mere negligence. Second, Cisco contended that the district court improperly excluded evidence of its good-faith belief of invalidity, which would have shown it lacked the requisite intent for induced infringement.

Cisco also challenged the district court's grant of a partial new trial and its construction of the claimed term "short-range communication protocol."

"It is axiomatic that one cannot infringe an invalid patent. Accordingly, one could be aware of a patent and induce another to perform the steps of the patent claim, but have a good-faith belief that the patent is not valid. Under

those circumstances, it can hardly be said that the alleged inducer intended to induce infringement. Thus, a good-faith belief of invalidity is evidence that may negate the specific intent to encourage another's infringement, which is required for induced infringement." Slip op. at 10 (citing *Prima Tek II, L.L.C. v. Polypap, S.A.R.L.*, 412 F.3d 1284, 1291 (Fed. Cir. 2005); *Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1580 (Fed. Cir. 1983)).

The Federal Circuit held that the jury instruction on induced infringement in the second trial was erroneous as a matter of law and prejudiced the outcome. The district court instructed the jury that it could find inducement if "Cisco actually intended to cause the acts that constitute direct infringement and . . . *knew or should have known* that its actions would induce actual infringement." Slip op. at 6 (emphasis added) (citation omitted). Although the language used by the district court reflected the proper standard for induced infringement at the time it was given, the Supreme Court subsequently changed the level of culpability required, enabling Cisco's appeal. Now, under *Global-Tech*, induced infringement requires *knowledge* that the induced acts constitute patent infringement. This knowledge requirement is satisfied by a showing of actual knowledge or willful blindness, neither of which can be found on facts supporting only recklessness or negligence on the part of the inducer. Because the jury instruction allowed Cisco to be held liable based on mere negligence where knowledge is required, it could have changed the result. Therefore, the Court vacated the jury's verdict on induced infringement and remanded for a new trial.

The Federal Circuit next addressed whether the jury should have been allowed to consider the evidence of Cisco's good-faith belief of invalidity. The Court reasoned that there was "no principled distinction between a good-faith belief of invalidity and a good-faith belief of non-infringement for the purpose of whether a defendant possessed the specific intent to induce infringement of a patent." *Id.* at 10. An invalid patent cannot be infringed, so if accused inducers believe a patent is invalid, they cannot also *intend* to induce infringement. Therefore, since the Court has found good-faith belief of noninfringement to be relevant evidence, which may show an accused inducer lacked the requisite intent to be held liable, good-faith belief of invalidity should also be considered relevant.

Cisco challenged the district court's grant of a partial new trial, arguing that there was no basis to grant a new trial and that separating the issue of whether Cisco had a good-faith belief of invalidity from the issue of whether the patent claims are valid violated the Seventh Amendment. Due to the potential jury bias, the Federal Circuit found the district court had not abused its discretion in granting a new trial because of the inflammatory references to ethnicity and religion made by Cisco's counsel. Additionally, the Court held that patent infringement and invalidity are two distinct issues, and that a jury could decide whether Cisco had a good-faith belief of invalidity without deciding "whether the underlying position was meritorious." *Id.* at 17.

Lastly, Cisco argued for a narrower construction of the term "short-range communication protocol." Cisco contended that the term should be limited to only the specific short-range protocols listed in the '395 patent. The Federal Circuit dismissed this argument because it lacked merit.

Accordingly, the Federal Circuit affirmed the district court's original grant of a new trial, vacated the jury's induced infringement verdict, and remanded for a new trial. Although Cisco also appealed the district court's findings regarding validity, infringement, and damages, the Court left these issues for the district court to decide on remand.

Judge Newman concurred-in-part, joining the opinion as to vacating and remanding the induced infringement judgment and upholding the grant of a partial new trial, but disagreeing with the change in law regarding good-faith belief of invalidity. Judge Newman expressed that a good-faith belief of invalidity is a defense to willfulness of infringement but is not a defense to the fact of infringement of a valid patent, whether direct or indirect. Likening liability for induced infringement to joint tortfeasance,

Judge Newman stated that “[a] mistake of law, even if made in good faith, does not absolve a tortfeasor.” Newman Concurrence-in-Part and Dissent-in-Part at 3. Thus, according to Judge Newman, “whether there is infringement in fact does not depend on the belief of the accused infringer that it might succeed in invalidating the patent. Such a belief, even if held in good faith, does not negate infringement of a valid and enforceable patent.” *Id.* at 4.

Judge O’Malley also concurred-in-part, joining the opinion as to vacating the induced infringement judgment and as to the relevance of an accused inducer’s good-faith belief of invalidity. Judge O’Malley further agreed that the district court had not abused its discretion in granting a new trial, but did not believe that the partial retrial comported with the Seventh Amendment. Not only did the issues of validity and induced infringement overlap, causing potential confusion according to Judge O’Malley, but it was also possible that the inappropriate statements by Cisco’s counsel affected the jury’s validity determination as well. Judge O’Malley also dissented from “the majority’s refusal to address . . . whether Commil did or ever could prove the third-party direct infringement which is a necessary predicate to Commil’s induced infringement claim.” O’Malley Concurrence-in-Part and Dissent-in-Part at 3.

**Matthew J. Luneack is a Summer Associate at Finnegan.*

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Synthesizing and Screening Tens of Thousands of Candidate Compounds Constitutes Undue Experimentation

Corinne L. Miller

Judges: Moore (author), Bryson, Wallach

[Appealed from D.N.J., Judge Pisano]

In *Wyeth v. Abbott Laboratories*, Nos. 12-1223, -1224 (Fed. Cir. June 26, 2013), the Federal Circuit affirmed the district court's SJ of invalidity for nonenablement, holding that there was no genuine issue of material fact that the specification does not enable one of ordinary skill to practice the asserted claims without undue experimentation.

U.S. Patent Nos. 5,516,781 and 5,563,146 (collectively "the patents-in-suit") relate to methods of treating or preventing restenosis—the renarrowing of an artery—by administering rapamycin. Generally, "rapamycin" may refer to a class of compounds; however, the parties agreed that the shared specification of the patents-in-suit discloses only one rapamycin species called sirolimus.

In two separate actions, Wyeth and Cordis Corporation (collectively "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 "Defendants") for infringement of the patents-in-suit. Defendants market stent products that elute everolimus and zotarolimus, two drugs that have the same macrocyclic ring as sirolimus but different substituents at the C-42 position. The district court adopted Wyeth's proposed construction of "rapamycin" as "a compound containing a macrocyclic triene ring structure produced by *Streptomyces hygroscopicus*, having immunosuppressive and anti-restenotic effects," and based in part on that construction, granted Defendants' joint motions for SJ of invalidity for nonenablement and lack of written description. Slip op. at 4-5 (citation omitted).

The central issue on appeal, as articulated by the Court, was whether practicing the full scope of the claims requires excessive—and thus undue—experimentation. Agreeing with the district court, the Court concluded that there was no genuine dispute that practicing the full scope of the claims, measured at the time of filing, would require excessive experimentation. The Court noted that the scope of the claims-at-issue was broad and, "[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." *Id.* at 7. The Court further agreed that there was no genuine dispute that the specification's guidance was limited to disclosures of the immunosuppressive and antirestenotic properties of sirolimus and assays to screen for those properties.

"In sum, there is no genuine dispute that practicing the full scope of the

claims would require synthesizing and screening *each* of at least tens of thousands of compounds.” Slip op. at 8.

For purposes of SJ, the Court accepted as true Wyeth’s claims about the state of the art and Wyeth’s expert testimony that one of ordinary skill in the art would have understood that potential rapamycin compounds should have molecular weights below 1,200 Daltons in order to be permeable across cell membranes. The Court also accepted as true that one of ordinary skill could routinely use the assays disclosed in the specification to determine immunosuppressive and antirestenotic effects in candidate compounds. Even accepting all of this as true, the Court found no genuine dispute that practicing the full scope of the claims would require more than routine experimentation for two reasons. “First, there is no dispute that, even if potential rapamycin compounds must have a molecular weight below 1,200 Daltons, there are still at least tens of thousands of candidates.” *Id.* at 8. Specifically, the Court noted, the specification is silent about how to structurally modify sirolimus, let alone in a way that would preserve the recited utility. “Second, there is no genuine dispute that it would be necessary to first synthesize and then screen *each* candidate compound using the assays disclosed in the specification to determine whether it has immunosuppressive and antirestenotic effects.” *Id.* The Court noted there was no evidence in the record that any particular substitutions outside of the macrocyclic ring are preferable.

The Court then addressed whether having to synthesize and screen each of at least tens of thousands of candidate compounds constitutes undue experimentation. The Court concluded that in this instance, it did, stating that “[u]ndue experimentation is a matter of degree.” *Id.* at 8-9 (citing *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1253 (Fed. Cir. 2004)). Relying on its precedent describing limits on permissible experimentation in the context of enablement, the Court found that the specification here disclosed only a starting point for further iterative research in an unpredictable and poorly understood field. The Court reasoned that synthesizing candidate compounds derived from sirolimus could, itself, require a complicated and lengthy series of experiments in synthetic organic chemistry. Specifically, the Court determined that, “[e]ven putting the challenges of synthesis aside, one of ordinary skill would need to assay each of at least tens of thousands of candidates,” each of which Wyeth’s expert conceded would take weeks to complete. *Id.* at 10. Accordingly, the Court affirmed the district court’s grant of SJ of invalidity, concluding that “[t]he resulting need to engage in a systematic screening process for each of the many rapamycin candidate compounds is excessive experimentation.” *Id.*

The Federal Circuit noted that because it found the patents-in-suit invalid for lack of enablement, it need not address the written description issues raised in Wyeth’s appeal.

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Looking Ahead

On July 2, 2013, in *Fresenius USA, Inc. v. Baxter International, Inc.*, Nos. 12-1334, -1335 (Fed. Cir. July 2, 2013), the Federal Circuit considered the effect of parallel PTO proceedings on a district court's subject matter jurisdiction. The relevant chronology was as follows: (1) the district court held on SJ that certain patent claims were valid; (2) between the time of that ruling and the time final judgment was entered, the PTO, during reexamination, found the claims invalid and the Board affirmed; (3) the district court then entered final judgment enforcing the claims; and (4) a day later, the Federal Circuit affirmed the PTO's determination of invalidity. In the instant appeal, the Federal Circuit explained that, because of the PTO decision, Baxter International, Inc. no longer had a cause of action. The Court went on to explain that the district court's SJ ruling does not count as a final decision for res judicata purposes because it did not conclude the case as a whole. Judge Newman, in a lengthy dissent, explained that the majority ruling amounted to an unconstitutional violation of separation of powers.

Read the full summary in the next edition of *Last Month at the Federal Circuit*.

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Spotlight Info

In *Ultramercial, Inc. v. Hulu, LLC*, No. 10-1544 (Fed. Cir. June 21, 2013), the Federal Circuit reversed and remanded the district court's judgment that the subject matter of U.S. Patent No. 7,346,545 ("the '545 patent") is not a "process" within the language and meaning of 35 U.S.C. § 101. The Federal Circuit noted that the claims recite a method for monetizing and distributing copyrighted products over the Internet, which the Court noted easily satisfies the meaning of a "process" under § 101 and hence falls within an eligible subject matter category. The Court also had to decide whether the claim is meaningfully limited to something less than an abstract idea that preempts the use of an abstract concept. In finding the claimed steps require intricate and complex computer programming, the Court noted that the claim involved not an abstract idea, but a very specific application of the idea. See this month's edition of *Last Month at the Federal Circuit* for a full summary of this decision.

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