Last Month at the Federal Circuit

January 2007

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Patent Covering Plavix® Drug Not Anticipated and Grant of Preliminary Injunction Upheld

Aaron M. Raphael

Judges: Lourie (author), Clevenger, Bryson

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

In *Sanofi-Synthelabo v. Apotex, Inc.*, No. 06-1613 (Fed. Cir. Dec. 8, 2006), the Federal Circuit affirmed the district court's grant of a preliminary injunction in favor of Sanofi-Synthelabo, Sanofi-Synthelabo, Inc., and Bristol-Myers Squibb ("BMS") Sanofi Pharmaceuticals Holding Partnership (collectively "Sanofi").

Sanofi markets Plavix®, a platelet aggregation inhibiting agent used to reduce thrombotic events such as heart attacks and strokes. The active ingredient in Plavix® is clopidogrel sulfate, which is covered by Sanofi's U.S. Patent No. 4,847,265 ("the '265 patent"). Apotex Inc. and Apotex Corp. (collectively "Apotex") filed an ANDA to market a generic version of clopidogrel sulfate, which included a Paragraph IV certification alleging invalidity of the '265 patent. In response, Sanofi sued Apotex for infringement, and Apotex counterclaimed that the '265 patent was invalid and unenforceable. The district court granted Sanofi's motion for a preliminary injunction.

On appeal, Apotex argued that claim 2 of U.S. Patent No. 4,529,596 ("the '596 patent") anticipated or rendered obvious claim 3 of the '265 patent, which covers the active ingredient in Plavix®. The Federal Circuit disagreed, noting that claim 3 of the '265 patent consists of the following key limitations: (1) the d-enantiomer, (2) the clopidogrel compound, (3) the bisulfate salt, and (4) substantial separation from the levorotatory isomer. The Court held that claim 2 of the '596 patent did not anticipate claim 3 of the '265 patent because it failed to describe the dextrorotatory or levorotatory enantiomers or any salt.

The Court also rejected Apotex's argument that the two missing limitations, i.e., the d-enantiomer and the bisulfate salt, were inherently disclosed in the '596 patent. The Federal Circuit relied on the district court's findings that the skilled artisan would not have been led to the bisulfate salt because (1) according to expert testimony, a chemist would believe that the hydrochloride salt, not the bisulfate, is the preferred salt for clopidogrel, in light of Example 1 of the '596 patent, which taught preparation of the hydrochloride salt; (2) according to expert testimony, salt formation with a new compound is an unpredictable exercise; and (3) a chemist theoretically had at least fifty different pharmaceutically acceptable salts from which he could have chosen for formulation.

The Federal Circuit also rejected Apotex's argument that *In re May*, 574 F.2d 1082 (C.C.P.A. 1978), *In re Petering*, 301 F.2d 676 (C.C.P.A. 1962), and *In re Schaumann*, 572 F.2d 312 (C.C.P.A. 1978), mandated a finding of anticipation. The Federal Circuit distinguished *May* by noting that the specification of the '596 patent included "no clear statement in the specification that the bisulfate salt is 'especially suitable' for administering compounds of the genus including clopidogrel." Slip op. at 11. In fact, the Court noted that the specification "discloses a number of potentially acceptable salts and discloses the racemate of clopidogrel in Example 1 only as a hydrochloride salt." *Id.* The specification also does not provide "a pattern of preferences," like the disclosures in *Petering* and *Schaumann*, that would limit the genus of claim 2 of the '596 patent to the narrow class of compounds that includes clopidogrel bisulfate.

The Court then turned its attention to Apotex's allegation that the '596 patent rendered claim 3 of the '265 patent obvious. The Court rejected Apotex's contention that preparation of clopidogrel bisulfate would have been obvious to the skilled artisan. The Court found persuasive the district court's finding that "nothing existed in the prior art that would make pursuing the enantiomer of [clopidogrel] an obvious choice, particularly in light of the unpredictability of the pharmaceutical properties of the enantiomers and the potential for enantiomers to racemize in the body." *Id.* at 14. Also supporting nonobviousness was the "extensive time and money Sanofi spent developing the racemate before redirecting its efforts toward the enantiomer, and the unpredictability of salt formation, ..." *Id.* In fact, Apotex's own expert "agreed that salt formation was an unpredictable exercise that would require a chemist 'to engage in experimentation to determine which salt would in fact be suitable.'" *Id.*

Moreover, one of the named inventors tested over twenty salts before arriving at the bisulfate, which had the most desirable properties. *Id.* at 15. The Federal Circuit also found no basis to conclude that the district court erred in considering the unexpected results.

Finally, the Federal Circuit distinguished *In re Adamson*, 275 F.2d 952 (C.C.P.A. 1960), on two grounds. First, unlike the primary reference in *Adamson*, which disclosed the racemic mixtures of the isomers and the acid addition salts, the '596 patent did not disclose the bisulfate salt of the d-enantiomer of clopidogrel. Second, the *Adamson* court found that it would have been expected by the skilled artisan that "enantiomers would have different pharmacological activity and that the toxicity of the *racemate* would lie somewhere between that of its isomers." Slip op. at 16. In contrast, the district court here found that "resolving the racemate was not mere routine experimentation and that it was unexpected that the desirable activity of clopidogrel would be found only in the d-enantiomer." *Id.* at 16-17.

The Federal Circuit then considered the remaining elements of the preliminary injunction test. First, the Federal Circuit rejected Apotex's argument that Sanofi contracted away its right to prove irreparable harm by entering into a settlement agreement to cap damages. The Court also rejected Apotex's assertion that the district court abused its discretion in concluding that Sanofi would suffer irreversible price erosion, relying on the testimony of Sanofi's economics expert and a declaration from a Sanofi executive. The Federal Circuit also did not find any error in the district court's analysis of the remaining evidence that established irreparable harm, including loss of good will, potential reduction in employees, and the discontinuation of clinical trials.

The Federal Circuit also found that the district court did not err in balancing the hardships because Apotex's harms were "almost entirely preventable" and were the result of its own decision to launch its generic product before a decision. The Federal Circuit also concluded that the fourth factor, the public interest, weighed in favor of Sanofi. The Court found persuasive that the "significant 'public interest in encouraging investment in drug development and protecting the exclusionary rights conveyed in valid pharmaceutical patents' tips the scales in favor of Sanofi." *Id.* at 24.

Apotex also alleged that the district court erred by precluding Apotex from proffering evidence of unclean hands by counsel for BMS and Sanofi during settlement negotiations. *Id.* The Federal Circuit rejected Apotex's allegation, noting that any fraud or perjury committed by BMS or Sanofi during the settlement negotiations was unrelated to the infringement and validity of the '265 patent. Accordingly, the Court found no abuse of discretion in the grant of the preliminary injunction.

A Case "Arises Under" Section 1338(a) and Confers Jurisdiction on the Federal Circuit Only If Patent Law Is a Necessary Element of the Complaint

Leila R. Abdi

Judges: Mayer, Bryson, Linn (author)

[Appealed from E.D. Mich., Judge Tarnow]

In *Thompson v. Microsoft Corp.*, No. 06-1073 (Fed. Cir. Dec. 8, 2006), the Federal Circuit held that it lacked jurisdiction under 28 U.S.C. § 1338(a) to hear the appeal and transferred the case to the U.S. Court of Appeals for the Sixth Circuit.

> "Because inventorship is not necessary to the success of Thompson's unjust enrichment claim, and because 'a claim supported by alternative theories in the complaint may not form the basis for [section] 1338(a) jurisdiction unless patent law is essential to each of those theories,' Thompson's well-pleaded complaint does not establish that the right to relief necessarily depends on resolution of a substantial question of federal patent law." Slip op. at 7 (citation omitted).

Robert Thompson conceived and developed software to create programmable and extensible folders for data storage, which he referred to as "SmartFolders." Thompson encountered a problem while developing the software and posted a question seeking assistance to a computer forum. A representative of Microsoft's Developer Relations Group contacted him to help him resolve it, and another member of Microsoft's Developer Relations Group later contacted him about comarketing opportunities. In response, Thompson developed a version of SmartFolders for Microsoft's upcoming Windows NT operating system. According to Thompson, he shared the technology with Microsoft with the understanding that Microsoft would not appropriate the software for its own use, but they did not enter into any nondisclosure agreement.

Thompson alleges that Microsoft publicly discussed his SmartFolders technology at the OLE 2.0 Conference in May 1993 and claimed it as a Microsoft product. In May 1994, Microsoft filed a patent application for programmable folder technology, which later became U.S. Patent Nos. 5,682,532 and 5,771,384.

In August 2000, Thompson filed a one-count complaint for unjust enrichment against Microsoft in Michigan state court. Thompson alleged misappropriation,

patenting, and use of Thompson's IP. Alleging diversity jurisdiction under 28 U.S.C. § 1332 and federal question jurisdiction under 28 U.S.C. § 1338(a), Microsoft removed the action to federal district court. Thompson then filed an amended complaint, alleging only unjust enrichment under Michigan state law. In its answer, Microsoft urged that Thompson's claim was preempted by federal law.

The district court denied Microsoft's motion for SJ in January 2002 and stayed the case in September of that year, pending the outcome of an interlocutory appeal to the Federal Circuit in *Ultra-Precision Manufacturing, Ltd. v. Ford Motor Co.*, 338 F.3d 1353 (Fed. Cir. 2003). *Ultra-Precision* related to whether an unjust-enrichment claim under Michigan law was preempted by federal patent law; however, the Federal Circuit dismissed the interlocutory appeal for lack of jurisdiction without consideration of the preemption issue. In October 2003, the district court lifted the stay in the present case, and Microsoft renewed its motion for SJ in June 2004. The case was stayed again, however, pending the Federal Circuit's decision in the appeal from final judgment entered in *Ultra-Precision*. In June 2005, the Federal Circuit held that the unjust-enrichment claim as pleaded in *Ultra-Precision* was preempted by federal law and affirmed the district court's decision on that issue. The Court stated that the appellant's complaint did not plead that the appellee received any incremental benefit over and above the benefit the general public received from ideas placed in the public domain.

After the decision in *Ultra-Precision*, Thompson conceded in his supplemental brief in the district court that a substantial part of the original damages claim was preempted by federal law. The district court granted Thompson's subsequent motion to treat the amended complaint as having included a request for "incremental benefit" damages. The district court then, however, held that the case was preempted by federal law, granted Microsoft's motion for SJ, and dismissed Thompson's claim for unjust enrichment. Thompson appealed to the Federal Circuit, alleging his claim involved a substantial question of patent law under 28 U.S.C. § 1338(a) and that the Federal Circuit had jurisdiction.

On appeal, the Federal Circuit first considered whether it had jurisdiction over the appeal, specifically, whether this was a case that arose under patent law such that the jurisdiction of the district court was based at least "in part" on § 1338(a). The Court determined that the state law of Michigan, not federal patent law, creates Thompson's unjust-enrichment claim and, therefore, the relevant question was whether patent law was a necessary element of Thompson's unjust-enrichment claim.

The Federal Circuit observed that Thompson's pleading related to Microsoft's being unjustly enriched by its misappropriation, patenting, and use of proprietary information. Inventorship and patents being obtained were not necessary to the success of Thompson's unjust-enrichment claim, and patent law was not essential to alternative theories in the complaint. Furthermore, the Court stated that Microsoft's defense on preemption grounds did not provide the Court jurisdiction either. Thus, the Court held that it lacked jurisdiction to hear the case and transferred it to the U.S. Court of Appeals for the Sixth Circuit.

Induced Infringement Requires Specific Intent to Encourage Another's Infringement

David C. Hoffman

Judges: Rader (author), Schall, Linn

[Appealed from N.D. Cal., Judge Jensen]

In *DSU Medical Corp. v. JMS Co.*, Nos. 04-1620, 05-1048, -1052 (Fed. Cir. Dec. 13, 2006), the Federal Circuit affirmed the district court's ruling that ITL Corporation Pty, Ltd. ("ITL") was not liable for contributory infringement because it did not contribute to acts of infringement in the United States. In an en banc section of the opinion, the Court also addressed the requisite intent required for a finding of induced infringement.

DSU Medical Corporation and Medisystems Corporation (collectively "DSU") own U.S. Patent No. 5,112,311 ("the '311 patent") and have an exclusive license to U.S. Patent No. 5,266,072 ("the '072 patent"), both of which are directed to a guarded, winged-needle assembly intended to prevent accidental needle-stick injuries. Specifically, the '311 patent claims a "slotted, locking guard for shielding a needle, and a winged needle assembly including a needle, a winged needle hub, and a slotted, locking guard."

ITL, an Australian company, manufactures the allegedly infringing device in Malaysia and Singapore, marketing its product under the name "Platypus™ Needle Guard." The Platypus needle guard is a small piece of plastic in the form of an open clamshell. During use, the halves of the clamshell close to form the needle guard. Under the terms of the '311 patent as construed by the district court, the Platypus needle guard only infringes in its closed-shell configuration. JMS Company, Limited ("JMS") is a Japanese medical supply company that distributes Platypus needle guards worldwide.

DSU sued JMS and ITL for infringement of the '311 and the '072 patents. Following a claim construction hearing, the district court granted SJ of noninfringement on multiple claims. The district court also granted SJ of infringement of claims 46, 47, 49, 52, and 53 of the '311 patent. After a jury trial, the district court entered a

final judgment finding claims 46, 47, and 50-52 of the '311 patent were invalid as obvious, but that JMS infringed claims 49, 53, and 54 of the '311 patent and that ITL was not liable for contributory infringement. DSU appealed, and JMU and ITL cross-appealed.

> "[I]nducement requires evidence of culpable conduct, directed to encouraging another's infringement, not merely that the inducer had knowledge of the direct infringer's activities." Slip op. at 18.

On appeal, the Federal Circuit affirmed the trial court's holding that ITL was not liable for contributory infringement. The Federal Circuit noted that ITL only contributed to placing the Platypus needle guards into the infringing closed-shell configuration in Malaysia, not in the United States. Explaining that 35 U.S.C. § 271(c) has a territorial limitation requiring contributory acts to occur in the United States, the Court stated that it could not reverse a jury verdict of noninfringement on mere inferences that the Platypus needle guard units sold in the United States were put into the infringing closed-shell configuration. The Court found that the record did not show that the Platypus needle guards ITL shipped into the United States in the open-shell configuration were ever put into an infringing configuration, i.e., closed-shell. As a result, the trial court did not abuse its discretion in denying DSU's motion for new trial on ITL's contributory infringement.

Next, DSU argued that the district court erred in instructing the jury that the alleged inducer, JMS, must have the specific intent to encourage another's infringement, and not merely knowledge of the acts alleged to constitute infringement. The Federal Circuit addressed this portion of the opinion en banc. Noting that the Supreme Court in *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 125 S. Ct. 2764, 2779 (2005), "validate[d] this court's articulation of the state of mind requirement for inducement" in the copyright context, the Court held that liability for inducement requires more than just intent to cause the acts that produce direct infringement, but also "an affirmative intent to cause direct infringement." Slip op. at 18. In other words, the Court explained, inducement requires that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement. Accordingly, the Federal Circuit upheld the district court's instruction, finding that liability for inducement requires "evidence of culpable conduct, directed to encouraging another's infringement, not merely that the inducer had knowledge of the direct infringer's activities." *Id*.

Chief Judge Michel and Judge Mayer, in concurring opinions, wrote separately to state that they did not consider it necessary to address the issue of intent en banc. Because there was no actual conflict in the Court's existing case law, there was no need for the full court to intervene. Such intervention should be reserved for "real conflicts" and "cases of exceptional importance." Finally, they wrote to make clear that the Federal Circuit did not set forth a new standard regarding what satisfies the "knowledge of the patent" requirement in cases filed under 35 U.S.C. § 271(b).

Doctrine of Equivalents Cannot Expand Claim Scope to Cover Devices Antithetical to the Limitations of the Claim

Kenie Ho

Judges: Newman, Mayer, Rader (author)

[Appealed from D. Nev., Judge Pro]

In *Planet Bingo, LLC v. GameTech International, Inc.*, No. 05-1476 (Fed. Cir. Dec. 13, 2006), the Federal Circuit affirmed the district court's holdings of noninfringement for claims 3 and 6-9 of U.S. Patent No. 5,482,289 ("the '289 patent"), invalidity of claims 2 and 5 of the '289 patent, and noninfringement of claims 1, 4, 7, 8, 11, 12, 15, 16, 19, 21, 24, 25, 28, 32, and 35-39 of U.S. Patent No. 5,727,786 ("the '786 patent").

The '289 and '786 patents claim alternative methods of playing bingo by coupling traditional bingo numbers with additional "indicia" or "markings," such as colors or shading patterns. These additional designations overlay a bingo game matrix to provide more winning combinations for more prizes. The designations come into play either with markings on the bingo balls, as in the '289 patent, or with a marked bingo flashboard, as in the '786 patent. GameTech International, Inc. ("GameTech") offers a version of bingo, "Rainbow Bingo," that includes an additional layer of markings, with different colors assigned to the columns of a bingo matrix, and jewels or coins assigned to the rows.

Planet Bingo, LLC ("Planet Bingo"), the exclusive licensee of the '289 and '786 patents, sued GameTech, alleging that "Rainbow Bingo" infringed both patents. At the *Markman* hearing, a magistrate judge construed fourteen claim limitations in favor of GameTech. The district court later adopted this claim construction to support SJ of noninfringement. Specifically, the district court held that the '289 and '786 patent claims required the winning combinations of the additional markings be predetermined before the start of the bingo game, whereas the accused device assigned specific winning combinations after drawing the first bingo ball.

Separately, the district court considered GameTech's counterclaim of invalidity in a motion *in limine* and found that claims 2 and 5 of the '289 patent were anticipated by an antecedent game known as "HOTBALL."

On appeal, the Federal Circuit affirmed the district court's grant of SJ of noninfringement of both patents. The Court rejected Planet Bingo's argument that the claim limitation "predetermined winning combination" merely required that the participants in the game know, before the start of play, the predetermined rules for winning. Noting that claim language governs claim meaning, the Court explained that, in this instance, the claim language recited a "predetermined winning combination," not "predetermined rules," for identifying a winning combination. Further, the claim preamble called for "a game" of bingo, and thus specified that each individual bingo game had a different predetermined winning combination.

"The specification often supplies the critical context to construe the claim language." Slip op. at 7.

The Federal Circuit also noted that the specification supplies the context to construe the claim language. Here, the specification repeatedly explained that the game determined the "winning combination" before the first bingo ball was drawn, thereby indicating the meaning of "predetermined." Additionally, the various embodiments in the specification for the '289 and '786 patents always provided the winning combination before the start of each bingo game. Finally, the summary of the invention for the '786 patent stated "a predetermined group of bingo numbers" was selected "at the beginning of each game." Accordingly, because the accused device did not determine a winning combination until after the drawing of the first ball (i.e., after game start), it did not literally infringe.

Turning to the DOE, the Federal Circuit explained that the patentee bears the burden of showing that the accused method performs substantially the same step, in substantially the same way, with substantially the same result. While the DOE cannot expand to eliminate a claim element entirely, it does provide additional coverage in the event of an unforeseeable change. In this instance, however, the patents contained a distinct limitation requiring the winning combination be determined before the start of a game. Thus, the DOE cannot be used to expand claim scope to cover winning combinations determined after the start of a game. To do so would have eliminated the claim element entirely and allowed recapture of subject matter excluded by a deliberate and foreseeable claim-drafting decision of the patentee.

In its analysis, the Federal Circuit factually distinguished the present case from cited precedent where the disputed differences with the accused device were less foreseeable at the time the patent at issue was drafted. Further, those cases only dealt with questions of small variations in the degree of achieving a claim limitation. In contrast, the application of the DOE in this case would change "before" to "after," a more marked difference. The Court refused to apply the DOE where the accused device contained the antithesis of the claimed structure.

Next, the Federal Circuit affirmed the district court's holding that claims 2 and 5 of the '289 patent were anticipated by the prior art bingo game HOTBALL. A claim is anticipated and, thus, invalid if each and every limitation of a claim is found, expressly or inherently, in a single prior art reference. HOTBALL required that either a player or bingo hall operator pick a number before the start of the game that, if drawn as the final component of a bingo combination, gave the winner an additional progressive prize associated with that number ("the HOTBALL number"). Planet Bingo argued, however, that HOTBALL did not disclose the precise elements of a winning combination before the first ball was drawn, as required by claims 2 and 5 of the '289 patent. Specifically, Planet Bingo argued that a progressive jackpot in HOTBALL is not based on a "predetermined winning combination" but rather on a player's ability to guess the last number needed for a bingo win. Rejecting Planet Bingo's arguments, the Federal Circuit explained that the predetermined winning combination in the claims of the '289 patent did not require the player to know the numbers that will form the predetermined winning combination. Thus, the HOTBALL game anticipated claims 2 and 5 of the '289 patent.

Patentee Must Show Prima Facie Infringement for Each Accused Product Before Burden Shifts to Accused Infringer to Offer Contrary Evidence

Mary B. Rucker

Judges: Mayer, Clevenger, Bryson (author)

[Appealed from E.D. Mich., Judge O'Meara]

In *L&W, Inc. v. Shertech, Inc.*, Nos. 06-1065, -1097 (Fed. Cir. Dec. 14, 2006), the Federal Circuit vacated and remanded a SJ ruling of infringement of claim 7 of U.S. Patent No. 5,670,264 ("the '264 patent"), but affirmed a jury verdict finding claim 7 valid and claim 10 invalid.

L&W, Inc. ("L&W") sued Shertech, Inc. and Steven W. Sheridan (collectively "Shertech") seeking a DJ that its line of automotive heat shields did not infringe

Shertech's '264 patent and that the '264 patent was invalid and unenforceable. Following cross-motions for SJ, the district court entered SJ of infringement. A jury found all of the asserted claims invalid with the exception of claim 7. The district court denied L&W's motions for a new trial or JMOL regarding claim 7, denied Shertech's motions for a new trial or JMOL regarding claim 10, and entered judgment of infringement against L&W.

The manufacturing steps L&W uses in producing its heat shields include stacking thin metal sheets, crimping or hemming the edges of the sheets to hold them together, pressing dimples or embossments into the stack of metal sheets, and pressing the stack into its final form. The district court held that the metal layers that make up the heat shields covered by claim 7 required "standoffs" and that this term means "a projection that either separates or has the potential to separate." Neither party disputed this construction.

On appeal, Shertech argued that L&W's acknowledged infringement of the "standoffs" limitation in a patent application that L&W filed, which according to Shertech, discloses a multilayer heat shield that would form air gaps between the embossed metal layers at an elevated temperature. While the Court acknowledged that the application stated that undulations will cause the metal layers of some embossed heat shields to separate at elevated temperatures, it held that L&W did not admit that their accused heat shields contained similar undulations or operated at the same elevated temperatures as those referred to in the application.

Further, the Court found that general statements about heat-shield structure and performance made by Shertech's expert lacked the specificity necessary to establish that the metal layers of L&W's accused heat shields have separations sufficient to satisfy the "standoffs" limitations. Moreover, the Court questioned the significance of an experiment performed by Shertech's expert because of the differences between the experimental design and L&W's accused heat shields.

In addition, Shertech's expert analyzed only one of the sixteen L&W accused heat shields and stated that the device he analyzed was typical of all sixteen. Shertech argued that it was L&W's obligation to refute the assumption that the analyzed device was typical of all sixteen if it genuinely believed there were relevant distinctions among the accused devices. The Court disagreed, holding that Shertech could not assume that all of L&W's products were like the one analyzed and then shift the burden to L&W to prove the contrary. Instead, "[w]hen a patentee with the burden of proof seeks summary judgment of infringement, it must make a prima facie showing of infringement as to each accused device before the burden shifts to the accused infringer to offer contrary evidence." Slip op. at 9. Accordingly, the Court vacated and remanded the SJ of infringement of claim 7.

L&W also appealed the validity verdict of claim 7 and Shertech cross-appealed the invalidity verdict of claim 10. In particular, both parties argued that it was inconsistent for the jury to find independent claim 7 valid while finding claim 10, which depends from claim 7, invalid. While L&W asserted that claims 7 and 10 should both be found invalid, Shertech asserted that both should be held valid. The Court, however, concluded that both parties waived their objections to the inconsistency because neither party objected before the jury was discharged or immediately thereafter. In so finding, the Federal Circuit applied the Sixth Circuit's procedural law and policy whereby "a party waives its objection to inconsistency in a jury's verdict if the party had an adequate opportunity to object but failed to do so." *Id*. at 11.

The Federal Circuit also stated that the Sixth Circuit would likely reject that a "plain error" exception applies to the waiver rule to avoid "misuse of procedural rules to obtain a new trial when inconsistencies are most efficiently resolved by the original jury." *Id.* at 12. The Court explained that the rule promotes judicial efficiency in allowing the original jury to resolve the inconsistency and that each party had an adequate opportunity to object. The Court also reasoned that lawyers should be aware of the possibility that use of Fed. R. Civ. P. 49 for specific factual findings from the jury could result in inconsistent responses. The Court noted the verdict in this case was simple, the inconsistency should have been obvious, and the parties could have objected before the court discharged the jury or immediately thereafter.

Commercial Offer Before Critical Date Is Not Sufficient to Satisfy On-Sale Bar

Joyce Craig-Rient

Judges: Newman, Friedman, Dyk (author)

[Appealed from N.D. Cal., Chief Judge Walker]

In *Plumtree Software, Inc. v. Datamize, LLC*, No. 06-1017 (Fed. Cir. Dec. 18, 2006), the Federal Circuit affirmed that Plumtree Software, Inc. ("Plumtree") showed a reasonable apprehension of suit as required to establish DJ jurisdiction but vacated the grant of SJ that Datamize, LLC's ("Datamize") patents were invalid pursuant to the on-sale bar doctrine of 35 U.S.C. § 102(b).

Plumtree sued Datamize for DJ of noninfringement of two patents, U.S. Patent Nos. 6,460,040 ("the '040

patent") and 6,658,418 ("the '418 patent"). The patents disclose a computer program, or "authoring tool," used to create other software. The inventive technology can be used for interactive electronic kiosks, such as those used at ski resorts to provide information about ski conditions. The invention encompasses both the method of creating the kiosk software and the authoring tool for creating that software, but does not encompass the kiosk itself.

Plumtree filed a motion for SJ that the patents were invalid under the on-sale bar doctrine because the methods of the patent claims had been on sale or offered for sale more than one year before the date the patent applications were filed. Datamize, in turn, filed a motion to dismiss for lack of subject matter jurisdiction, alleging that Plumtree had not established a "reasonable apprehension" that Datamize would sue for infringement of the two patents.

This was not the first lawsuit between the parties related to the kiosk technology. In 2002, Datamize sued Plumtree in the U.S. District Court for the District of Montana ("Montana action"), alleging infringement of U.S. Patent No. 6,014,137 ("the '137 patent"), the parent of the '040 and '418 patents. At the same time, Datamize sent a letter to Plumtree warning that Plumtree will infringe the claims in a continuation patent application to the '137 patent upon its issuance. That application later issued as the '040 patent. Plumtree filed a motion to dismiss the Montana action but also filed a DJ action in California ("first California action"), seeking judgment that it did not infringe the '137 patent. Datamize then counterclaimed for infringement. In July 2003, the district court dismissed the Montana action for lack of personal jurisdiction. In a third lawsuit ("Texas action"), Datamize sued nine defendants for infringement of the '040 and '418 patents but did not include Plumtree. Datamize did, however, list Plumtree's products in response to an interrogatory seeking a list of products embodying the inventions claimed in the '040 and '418 patents.

In July 2004, the district court in the first California action granted Plumtree's SJ motion and held the '137 patent invalid for indefiniteness. The same day, Plumtree filed the present DJ action with regard to the '040 and '418 patents ("second California action"). Plumtree filed a motion for SJ that the patents were invalid under the on-sale bar. Datamize subsequently filed a motion to dismiss for lack of subject matter jurisdiction.

The district court in the second California action held that DJ jurisdiction was proper because a "case or controversy" existed with regard to both patents. Specifically, the district found that the totality of the circumstances, including (1) the Montana action, (2) the Texas action, and (3) the letter referencing the patent application that later issued as the '040 patent, was sufficient to cause Plumtree to have a reasonable apprehension of suit. With regard to the SJ motion, the district court held both patents invalid under the on-sale bar of § 102(b). The district court found that Datamize's predecessor in interest offered in January 1995 to provide its interactive kiosk system to the sponsors of a ski industry trade show in exchange for waiver of a sponsorship fee. It further found that this offer occurred prior to the critical date of February 27, 1995, and was made in exchange for valuable consideration. Moreover, it concluded that the kiosk embodied all of the claims of the '040 and '418 patents. For these reasons, the district court granted SJ of invalidity in favor of Plumtree.

> "Performing the steps of the patented method for a commercial purpose is clearly an attempt to profit from the commercial use of an invention. Consequently, performing the patented method for commercial purposes before the critical date constitutes a sale under § 102(b)." Slip op. at 18.

On appeal, the Federal Circuit affirmed the district court's holding that DJ jurisdiction was proper. Despite Datamize's argument that, because the DJ action was filed more than two years after the '137 patent infringement action, the passage of time had dissipated any reasonable apprehension of suit, the Court explained that, absent a covenant not to sue, a reasonable apprehension may be eliminated only in narrow circumstances not present in this case. Applying its reasoning from *Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953 (Fed. Cir. 1987), the Federal Circuit concluded that, between the two lawsuits, Datamize continued to engage in a course of conduct that demonstrated a willingness to protect its technology. Thus, Plumtree had a reasonable apprehension of suit.

With regard to the on-sale bar, the Federal Circuit vacated the district court's grant of SJ and remanded for further proceedings. The Court rejected Datamize's argument that waiver of the $10,000 sponsorship fee did not constitute consideration, and concluded that it could not sustain the district court's invalidity decision because the kiosk system itself is not patented. The Federal Circuit discounted the district court's reliance on testimony that the kiosk itself embodied all claims of the patents-in-suit. Rather, the Court applied the test from *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55 (1998), under which invalidity under the on-sale bar requires (1) that the product be the subject of a commercial offer for sale, and (2) that the invention be ready for patenting. The Court noted that the first prong of the *Pfaff* test could be established if Plumtree could show that either (1) Datamize's predecessor made a commercial offer to perform the patented method before the critical date, or (2) it actually performed the patented method for a promise of future compensation. The Court concluded that Plumtree failed to demonstrate facts sufficient to satisfy either option.

With regard to the first option, a commercial offer for sale, the Federal Circuit found that there existed a commercial offer before the critical date because there was a binding contract between Datamize's predecessor and the ski industry association. The Court concluded, however, that, because the agreement between the parties did not require Datamize's predecessor to provide the kiosk system software or perform the patented method, SJ based on this commercial offer theory was not appropriate.

Turning to the second option, performing the patented process, the Court concluded that Plumtree could prevail on SJ only if it demonstrated that Datamize's predecessor in fact performed each of the steps of the patented process before the critical date pursuant to the contract. The Court found that the kiosk system intended for use at the trade show was not completed until after February 27, 1995, and Plumtree did not establish performance of each of the steps of the patented process prior to that date. Thus, the Federal Circuit concluded that the record does not support SJ.

Structurally Similar Chemical Compounds Alone Do Not Render a Compound Obvious

Nicole L. M. Valtz

Judges: Rader (author), Schall, Gajarsa

[Appealed from S.D. Ind., Judge Young]

In *Eli Lilly & Co. v. Zenith Goldline Pharmaceuticals, Inc.*, Nos. 05-1396, -1429, -1430 (Fed. Cir. Dec. 26, 2006), the Federal Circuit affirmed the district court's holding that the asserted claims of U.S. Patent No. 5,229,382 ("the '382 patent") were valid, enforceable, and infringed.

Eli Lilly and Company ("Lilly") owns the '382 patent, which discloses olanzapine and its use to treat schizophrenia. Lilly had previously discovered other drugs in the same family of thienobenzodiazepines, including clozapine, flumezapine, ethyl flumezapine, and ethyl olanzapine ("Compound '222"). In fact, Lilly marketed clozapine as the first "atypical" antipsychotic drug in the late 1960s; however, it was withdrawn in 1975 following the discovery that it caused a potentially fatal blood disorder in one percent of patients. Fourteen years later, no better drug had been developed, and the FDA reapproved the use of clozapine in combination with careful blood monitoring.

In 1996, Lilly began marketing olanzapine as Zyprexa®. Olanzapine differs from other members of the thienobenzodiazepine family in two critical respects. First, olanzapine has a hydrogen atom substituted on the benzene ring, rather than a chlorine atom (as found in clozapine) or a fluorine atom (as found in flumezapine). This halogen substitution, sometimes referred to as the "neuroleptic substituent," was an electron-withdrawing group widely believed to be responsible for the antipsychotic activity of clozapine, flumezapine, and other antipsychotics before the discovery of olanzapine. Second, the thiophene ring of olanzapine is substituted with a methyl group, rather than an ethyl group, as found on ethyl flumezapine and ethyl olanzapine (both of which did not reach the market because they cause significant side effects).

> "[P]atentability for a chemical compound does not depend only on structural similarity. This court will not ignore a relevant property of a compound in the obviousness calculus." Slip op. at 11 (citation omitted).

Zenith Goldline Pharmaceuticals, Inc. (now IVAX Pharmaceuticals, Inc., "IVAX"), Dr. Reddy's Laboratories, Ltd. ("DRL"), and Teva Pharmaceuticals USA, Inc. ("Teva") each filed an ANDA for a generic version of Zyprexa®, thereby conceding infringement. Lilly sued. The district court held that the defendants did not prove by clear and convincing evidence that the claims of the '382 patent were invalid as anticipated or obvious.

On appeal, the Federal Circuit first agreed with the district court that the claims of the '382 patent were not anticipated by a cited reference ("*Chakrabarti*") disclosing millions of compounds in the same general family of thienobenzodiazepines. The Court rejected IVAX's argument that *Chakrabarti*'s disclosure of compounds in the thienobenzodiazepine family anticipated claim 1, to olanzapine, because it did not spell out "a definite and limited class of compounds" that enabled one of ordinary skill in the art to "at once envisage" each member of the limited class. In distinguishing the present case from the cited case law, the Court noted that *Chakrabarti* disclosed millions of compounds, with sixty compounds specifically examined. None of the preferred compounds resembled olanzapine, and the preferred compounds all had a fluorine or chlorine substituent on the benzene ring, rather than a hydrogen, as found in olanzapine. After describing other differences between olanzapine and the prior art compounds, the Court concluded that there was no anticipation because (1) the cited reference preferred complete compounds, not individual substituents; (2) there was no generic disclosure encompassing olanzapine; and (3) there was no suggestion to modify the closest described compound into a preferred compound.

Turning to obviousness, the Federal Circuit first agreed with the district court that claims to olanzapine are not

obvious because the prior art taught away from antipsychotics that lack a halogen substituent on the benzene ring. The Court explained that, for a chemical compound, a prima facie case of obviousness requires the prior art to have "structural similarity" to the claimed compound and provide a reason or motivation to make the inventive compound. Lilly's own prior art patent, U.S. Patent No. 4,115,574 ("the '574 patent") disclosed Compound '222, which, like olanzapine, has a hydrogen atom rather than a halogen substituent. However, the Federal Circuit noted that the '574 patent expressed a preference for a halogen-containing compound, and that the "prior art references at the time of this invention taught away from using a non-halogenated compound as a substituent in the benzene ring, exactly where olanzapine has a hydrogen atom." Slip op. at 11.

The Federal Circuit also agreed with the district court's determination that a person of ordinary skill in the art would not have chosen Compound '222 as a starting compound to further modify, because it did not contain the neuroleptic halogen substituent. In addition, Compound '222 has an ethyl group substitution where olanzapine has a methyl group; the Court found no motivation to modify this substituent in the prior art. Going further, the Court found that the art taught away from selection of Compound '222 as a lead compound. The '574 patent did not provide any biological data for Compound '222, but instead indicated that halogen-substituted compounds were preferred, and described the fluorine-substituted ethyl flumezapine as "particularly active." *Id*. at 12. Other art taught that substitution with fluorine or chlorine increased antipsychotic activity and reported that Compound '222 was less active than clozapine, the benchmark for this class of compounds.

The Federal Circuit also rejected IVAX's argument that olanzapine is rendered obvious by Compound '222, because structurally, olanzapine is the adjacent homolog of Compound '222. The Court emphasized that the "patentability for a chemical compound does not depend only on structural similarity." *Id*. at 11. If a "relevant property" of a compound is "unexpected and significant," that property cannot be overlooked, regardless of how structurally similar the compounds may be, but can render the inventive compound nonobvious. *Id.* Here, although there is some structural similarity of olanzapine to the prior art, olanzapine exhibits "unexpected beneficial properties," which must be accounted for in the analysis and lead to nonobviousness.

The Federal Circuit also explained that the prior art did not provide motivation to make the modifications required to reach olanzapine. The Federal Circuit dismissed the argument that olanzapine was "bracketed" by two compounds in the prior art with similar structures: combining Compound '222's hydrogen-substituted benzene ring and flumezapine's methyl substitution on the thiophene ring generates the structure of olanzapine, thereby making olanzapine prima facie obvious. Structural similarity is not controlling in this case, and the prior art did not contain any suggestion to make these modifications. Mere identification in the prior art of each component of a composition does not render the combination obvious; the law requires some motivation to select and combine the references to reach the claimed invention.

Even if a prima facie case of obviousness could be established, the Federal Circuit held it would be overcome by Lilly's extensive secondary considerations. "The record shows a long-felt need for a safer, less toxic, and more effective clozapine-like drug; a decade (or more) of failure to find a replacement for clozapine; a reasonable amount of commercial success for olanzapine; and a number of awards for olanzapine as indicators of industry acclaim." *Id.* at 14.

The Federal Circuit next upheld the district court's finding that Lilly's clinical trials of olanzapine were an experimental, rather than public use, and therefore, negated any statutory bar under § 102(b). The Court emphasized that a use which occurs in the open will not trigger a statutory bar when undertaken to experiment on or with the claimed invention. Here, phase I clinical trials were performed to test the safety and efficacy of olanzapine. The trials were conducted in the Lilly clinic, with restricted access, security, and confining the volunteers' movements. The Court concluded that because Lilly had "tailored its tests to their experimental drug safety and efficacy purpose, adequately monitored for results, and maintained confidentiality," the trial court did not err in finding no public use. *Id.* at 16.

Finally, the Federal Circuit considered and rejected DRL's assertion that the '382 patent should be declared unenforceable due to inequitable conduct. First, when the PTO questioned Lilly about blood cholesterol levels in dog studies, Lilly did not disclose to the PTO its statements to the Swedish Board about the hematotoxic effects of olanzapine in these studies. Because the hematotoxicity findings were "believed not to have clinical relevance to humans," the Court concluded that Lilly did not fail to disclose information to the PTO. Second, the Federal Circuit did not find that the declaration of a Lilly physician was false, or that certain information was withheld from the PTO with an intent to deceive. On a third inequitable conduct charge, the Court concluded that Lilly's nondisclosure of *Chakrabarti* and the '574 patent was neither a material omission nor done with the intent to deceive, where another Lilly patent with an identical specification was disclosed and *Chakrabarti* was cited by the examiner during prosecution.

General Statements in Specification Describing Improvement over Prior Art Did Not Act as Disclaimer

Hayley S. Weimer

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

[Appealed from D. Ariz., Judge Collins]

In *Ventana Medical Systems, Inc. v. BioGenex Laboratories, Inc.*, No. 06-1074 (Fed. Cir. Dec. 29, 2006), the Federal Circuit vacated a judgment of noninfringement due to the district court's error in claim construction.

U.S. Patent No. 6,352,861 ("the '861 patent") relates to automated apparatuses and methods used to perform a variety of biological assays. It stems from the same patent application as six other patents assigned to Ventana Medical Systems, Inc. ("Ventana"), all of which share a common specification. These patents each claim various features and methods related to the common specification. The claims of the '861 patent relate to automatic dispensing systems that employ bar code-labeled reagent containers and/or slides.

BioGenex Laboratories, Inc. ("BioGenex") manufactures and sells automated staining devices. Ventana filed suit against BioGenex alleging infringement of various claims of the '861 patent. After the district court construed the claim term "dispensing" and other terms, Ventana stipulated to a judgment of noninfringement.

On appeal, the sole issue was the proper construction of "dispensing" in the asserted claims. The district court's narrow construction required "direct dispensing," which meant that the "reagent is dispensed directly from the reagent container" onto the slide, without the use of an intermediate transport. Moreover, the district court held that the inventors disclaimed the "sip and spit" method of dispensing, which utilized an intermediate transport, during the prosecution of an ancestor application.

The Federal Circuit agreed with Ventana that nothing in the record suggested such a narrow construction of "dispensing." Specifically, the claims themselves did not contain language that could be read to limit the term "dispensing" to "direct dispensing." Notably, BioGenex agreed at oral argument that the word "onto" in the claims did not exclude the "sip and spit" method of dispensing from the ordinary meaning of dispensing. Nor did the Federal Circuit find anything in the specification to justify a narrow construction.

While the Federal Circuit has held that the specification may, in some cases, reveal an intentional disclaimer of claim scope, this was not such a case. BioGenex pointed only to general statements by the inventors relating to improvement upon prior art. The Federal Circuit held that "[s]uch general statements, without more, will not be interpreted to disclaim every feature of every prior art device." Slip op. at 10. Moreover, the fact that the specification discloses embodiments relating to direct dispensing did not mean that the method claims at issue were limited to the disclosed embodiments. In addition, each claim does not cover every feature disclosed in the specification, so it is improper to limit the claim to other, unclaimed features. Merely because the preferred embodiments contain a "direct dispensing" feature did not mean that the inventors were required to claim this feature in the '861 patent.

> "BioGenex points to only general statements by the inventors indicating that the invention is intended to improve upon prior art automated staining methods . . . . Such general statements, without more, will not be interpreted to disclaim every feature of every prior art device discussed in the 'BACKGROUND ART' section of the patent." Slip op. at 10.

Further, BioGenex raised the doctrine of prosecution disclaimer, but the Court explained that this doctrine does not generally apply when the claim term in the descendant patent uses different language. In this case, the claim language at issue did not mirror the allegedly disclaiming statements in the prosecution of an ancestor of the '861 patent. Therefore, that alleged disclaimer did not apply to the claims of the '861 patent. The prosecution history of the '861 patent also supported a broad construction of "dispensing." Moreover, the prosecution histories of later-issued patents did not inform the proper construction of "dispensing" in the '861 patent because, like the ancestors of the '861 patent, the language used in the later-issued patents was not identical to the claim language in the '861 patent, and, as such, was not relevant. Thus, due to the district court's error in claim construction, the Federal Circuit vacated the judgment of noninfringement and remanded.

Judge Lourie dissented, focusing instead on the specification for a narrow reading of "dispensing." He pointed to the abstract, the summary of the invention, the detailed disclosure of the invention, and the figures, which he asserted broadly disclosed the overall invention of all seven patents that stem from the same specification and require "direct dispensing."

Abbreviations | Acronyms

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 & Drug Administration
IDS	Information Disclosure Statement
IP	Intellectual Property
ITC	International Trade Commission
JMOL	Judgment as a Matter of Law
MPEP	Manual of Patent Examining Procedure
PCT	Patent Cooperation Treaty
PTO	United States Patent and Trademark Office
SEC	Securities and Exchange Commission
SJ	Summary Judgment
SM	Special Master

Looking Ahead

- On February 21, 2007, the Supreme Court will hear arguments in *Microsoft Corp. v. AT & T Corp.*, No. 05-1056. The questions presented in the case are (1) whether digital software code may be considered a "component[] of a patented invention" within the meaning of § 271(f)(1), and if so, (2) whether copies of such a component made in a foreign country are "supplie[d] . . . from the United States."

  On January 26, 2007, the Federal Circuit ordered an en banc hearing in *In re Seagate Technology, LLC*, Misc. Docket No. 830, to consider (1) whether a party's assertion of the advice of counsel defense to willful infringement should extend wavier of the attorney-client privilege to communications with that party's trial counsel; (2) what impact should the waiver have on work product; and (3) should the duty of care under *Underwater Devices, Inc. v. Morrison-Knudsen Co.*, 717 F.2d 1380 (Fed. Cir. 1983), be reevaluated. Briefing is scheduled to begin in February.

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