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Last Month at the Federal Circuit

March 2011

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ABB Inc. v. Cooper Industries, LLC
No. 10-1227 (Fed. Cir. Feb. 17, 2011)
[Appealed from S.D. Tex., Judge Hoyt]

Courts Have Discretion to Limit the Number of Asserted Claims in Complex Patent Suits

In re Katz Interactive Call Processing Patent Litigation
Nos. 09-1450, -1451, -1452, -1468, -1469, 10-1017 (Fed. Cir. Feb. 18, 2011)
[Appealed from C.D. Cal., Judge Klausner]

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[Appealed from D. Del., Judge Robinson]

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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In *In re Katz Interactive Call Processing Patent Litigation*, Nos. 09-1450, -1451, -1452, -1468, -1469, 10-1017 (Fed. Cir. Feb. 18, 2011), the Federal Circuit affirmed, inter alia, the district court's claim selection procedure limiting the number of claims asserted. In this somewhat rare multidistrict litigation patent case, the plaintiff Ronald A. Katz Technology Licensing LP ("Katz") asserted a total of 1,975 claims from 31 patents against 165 defendants ("Defendants"), ranging from banks and shipping companies to cable providers and airlines. The patents were generally directed to telephonic computer interface and processing systems. Katz initially filed 25 separate actions in the Eastern District of Texas and the District of Delaware. Over Katz's objections, Defendants asked the district court to limit the number of asserted claims. The Judicial Panel on Multidistrict Litigation transferred all the cases to the Central District of California for coordinated pretrial proceedings. After initially determining that many claims were duplicative, the district court limited the maximum number of assertable claims but added a proviso permitting Katz to add new claims if they raised nonduplicative issues of infringement or validity. Rather than selecting additional claims, Katz moved the district court to sever and stay the unselected claims on the ground that the district court's order violated its due process rights. The district court denied Katz's motion and Katz appealed. The Federal Circuit found that the district court appropriately placed the burden on Katz to show that the unasserted claims were not duplicative and found no error in the district court's determination that many claims were duplicative. The Court concluded it was both efficient and fair to require Katz to identify nonduplicative claims, and, because Katz failed to make such a showing, it was reasonable for the district court to deny the motion to stay and sever. See the full summary in this issue.

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Looking Ahead

On March 15, 2011, in *In re BP Lubricants USA Inc.*, No. 10-M960 (Fed. Cir. Mar. 15, 2010), the Federal Circuit granted, in part, BP Lubricants USA Inc.'s petition for a writ of mandamus directing the U.S. District Court for the Northern District of Illinois to grant a motion to dismiss a complaint pursuant to the False Marking Statute, 35 U.S.C. § 292. In so doing, the Court held that Fed. R. Civ. P. 9(b)'s particularity requirement applies to false marking claims, and that "a complaint alleging false marking is insufficient when it only asserts conclusory allegations that a defendant is a 'sophisticated company' and 'knew or should have known' that the patent expired." Slip op. at 2. Read the full summary in next month's edition of *Last Month at the Federal Circuit*.

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Federal Question Jurisdiction in DJ Action Depends on the Character of the Threatened Action, Not the Character of the Defense

Corinne L. Miller

Judges: Rader, Lourie, Dyk (author)

[Appealed from S.D. Tex., Judge Hoyt]

In *ABB Inc. v. Cooper Industries, LLC*, No. 10-1227 (Fed. Cir. Feb. 17, 2011), the Federal Circuit reversed the district court's dismissal of a DJ action for lack of subject matter jurisdiction, holding that the case arose under patent laws, and that jurisdiction was conferred by 28 U.S.C. § 1338.

Cooper Industries, LLC and Cooper Power Systems, Inc. (collectively "Cooper") own patents involving electrical equipment containing dielectric fluid. Cooper sued ABB Inc. and ABB Holdings, Inc. (collectively "ABB") for infringement based on ABB's BIOTEMP dielectric fluid. Cooper and ABB settled the lawsuit and entered into a nonexclusive licensing agreement that expressly excluded the right of any third party to make BIOTEMP. ABB thereafter outsourced the manufacture of BIOTEMP to Dow Chemicals ("Dow") and contracted with Dow to indemnify it against claims of infringement by Cooper. Cooper wrote to ABB and Dow, stating that any outsourcing of the manufacture of BIOTEMP would be a material breach of the licensing agreement, and that Cooper would vigorously defend its patent rights.

ABB filed a DJ action seeking a declaration that it did not infringe any valid, enforceable claim of Cooper's patents. Cooper moved to dismiss for lack of subject matter jurisdiction. The district court determined that ABB's complaint was governed by state law because it depended exclusively on interpreting the terms of the licensing agreement, and granted Cooper's motion to dismiss.

"The general rule . . . is that [DJ] jurisdiction exists where the defendant's coercive action arises under federal law. We see no reason to depart from that general principle where the defense is non-federal in nature." Slip op. at 11-12 (citations omitted).

On appeal, the Federal Circuit held there was sufficient controversy surrounding infringement to warrant the issuance of a DJ. The Court stated that a specific threat of infringement litigation is not required, and

that Cooper's warning letters to ABB and Dow indicated there was an immediate controversy as to infringement. The Court noted that ABB had an interest in determining whether it would be liable for induced infringement, and whether it would be liable for indemnification based on Dow's liability for infringement. Regarding Cooper's argument that there was no jurisdiction because ABB raised only a state law defense, the Court held that federal question jurisdiction is determined by the character of the threatened action, not the character of the defense. The Court stated that "[t]he general rule . . . is that [DJ] jurisdiction exists where the defendant's coercive action arises under federal law," and that there was "no reason to depart from that general principle where the defense is non-federal in nature." Slip op. at 11-12. The Court held that because Cooper's action for infringement would arise under federal law, the district court had federal question jurisdiction over ABB's DJ action, even if resolution of the case was dependent on ABB's state law defense. The Federal Circuit thus reversed the district court's dismissal for lack of subject matter jurisdiction.

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Courts Have Discretion to Limit the Number of Asserted Claims in Complex Patent Suits

*Andrew J. Ra, Jr.**

Judges: Newman, Lourie, Bryson (author)

[Appealed from C.D. Cal., Judge Klausner]

In *In re Katz Interactive Call Processing Patent Litigation*, Nos. 09-1450, -1451, -1452, -1468, -1469, 10-1017 (Fed. Cir. Feb. 18, 2011), the Federal Circuit affirmed the district court's claim selection procedure limiting the number of claims asserted. With respect to certain asserted claims, the Court affirmed in part grants of SJ of indefiniteness, obviousness, and failure to comply with the written description requirement. For other asserted claims, the Court vacated the district court's grants of SJ of indefiniteness, written description, and noninfringement, and remanded the case for proceedings consistent with its opinion.

In a multidistrict litigation patent case, the plaintiff Ronald A. Katz Technology Licensing LP ("Katz") asserted four groups of patents relating to interactive call processing systems against numerous defendants ("Defendants"). The first group of patents—the "Statistical Interface" group—covered a telephonic interface system for acquiring data from callers and using that data to identify a subset of the group. The second group—the "Conditional Interface Plus" group—covered a telephonic computer interface system capable of handling large volumes of calls and directing them to live-operator or computer-operated stations. The third group—the "Dual Call Mode" group—covered a telephone call processing system for receiving calls for a game or contest that neutralized the advantages gained by repeat callers. Finally, the last group—the "Voice-Data" group—claimed a telephone-computer interface system capable of receiving and identifying digital signals and voice signals from callers.

Katz initially filed 25 separate actions asserting a total of 1,975 claims from 31 patents against 165 defendants that were later consolidated and transferred. Over Katz's objections, Defendants asked the district court to limit the number of asserted claims. After initially determining that many claims were duplicative, the district court limited the maximum number of assertable claims. However, it also added a proviso permitting Katz to add new claims if they "raise[d] issues of infringement/validity that [were] not duplicative" of previously selected claims. Instead of selecting additional claims, Katz moved the court to sever and stay the unselected claims on the ground that the district court's order violated its due process rights. The district court denied Katz's motion. Defendants then jointly moved for SJ on the grounds of

invalidity and noninfringement. Several Defendants also moved individually for SJ on case-specific grounds. The district court held all the claims selected against Defendants to be either invalid or not infringed and entered final judgments in favor of Defendants.

On appeal, the Court addressed the following rulings by the district court: (1) the denial of Katz's motion to stay and sever; (2) SJ for indefiniteness; (3) SJ for failing to satisfy the written description requirement; (4) SJ for obviousness; (5) claim constructions; and (6) SJ of noninfringement for three of the Defendants, U.S. Bancorp and U.S. Bank National Association (collectively "U.S. Bank"), American Airlines, Inc. ("American Airlines"), and DHL Express (USA), Inc. ("DHL").

As to the first issue—the Court affirmed the denial of Katz's motion to stay and sever, and approved the district court's claim selection procedure. In addressing Katz's due process arguments, the Court found the district court appropriately placed the burden on Katz to show that the unasserted claims were not duplicative. "When the claimant is in the best position to narrow the dispute, allocating the production burden to the claimant will benefit the decision-making process and therefore will not offend due process unless the burden allocation unfairly prejudices the claimant's opportunity to present its claim." Slip op. at 11. The Court found no error in the district court's determination that many claims were duplicative and concluded it was both efficient and fair to require Katz to identify nonduplicative claims. Because Katz failed to make any showing that the unasserted claims were nonduplicative, it was reasonable for the district court to deny the motion to stay and sever.

"Those seven claims do not run afoul of the rule against purely functional claiming, because the functions of 'processing,' 'receiving,' and 'storing' are coextensive with the structure disclosed, i.e., a general purpose processor." Slip op. at 21.

Although the Court approved the district court's claim selection process, it cautioned that it was not suggesting that such a decision was unreviewable. Rather, "the problem with Katz's position is that [it] made no effort to [show that some of its unselected claims presented unique issues as to liability or damages]. Instead, Katz chose to make the 'all or nothing' argument that the entire claim selection process was flawed from the start That sort of global claim of impropriety is unpersuasive. In complex cases, . . . the district court 'needs to have broad discretion to administer the proceeding.'" *Id.* at 14.

The Court also rejected arguments that the district court violated the statutory presumption that each claim is independently presumed valid. "While different claims are presumed to be of different scope, that does not mean that they necessarily present different questions of validity or infringement." *Id.* at 15.

As to the second issue, indefiniteness, the Court affirmed as to three claims and remanded on the remaining seven. Based on Federal Circuit precedent—that a computer-implemented means-plus-function term is limited to the corresponding structure disclosed in the specification, and the corresponding structure is the algorithm—the district court ruled that the asserted means-plus-function claims were invalid as indefinite because the specifications disclosed only general purpose processors and not the algorithms used to perform the recited functions.

With respect to three of the asserted claims reciting a "processing means . . . for receiving customer

number data entered by a caller and for storing the customer number data . . . and based on a condition coupling an incoming call to the operator terminal,” the Court agreed with the district court. The Court found that the specification failed to disclose an algorithm that corresponded to the “based on a condition coupling an incoming call to the operator terminal” function. “[B]y claiming a processor programmed to perform a specialized function without disclosing the internal structure of that processor in the form of an algorithm, Katz’s claims exhibit the ‘overbreadth inherent in open-ended functional claims.’” *Id.* at 19. In addition, the Court affirmed the district court’s ruling that several claims from the Statistical Interface group were indefinite because they claimed both an apparatus and a method of use.

With respect to the other seven asserted claims, however, the Court concluded that the district court interpreted Federal Circuit precedent too broadly and vacated the ruling on indefiniteness. “Those seven claims do not run afoul of the rule against purely functional claiming, because the functions of ‘processing,’ ‘receiving,’ and ‘storing’ are coextensive with the structure disclosed, i.e., a general purpose processor.” *Id.* at 21.

As to the third issue, written description, the Court affirmed the district court’s ruling invalidating the asserted method claims from the Statistical Interface group for failing to satisfy the written description requirement, but vacated the district court’s decision to invalidate the asserted claims from the Dual Call Mode group.

The Statistical Interface group involved method claims with the steps of “visually displaying customer number data” and “receiving customer number data entered by a caller.” The Court agreed with the district court’s conclusion that the specification had to describe the visual display of customer number data entered by a caller. And, after examining the specification, the Court found that the patents lacked such a description because the specification only described visual displays involving information that was not entered by customers, failing to satisfy the written description requirement.

As for the Dual Call Mode group, the Court vacated the district court’s judgment of invalidity and remanded for construction of the term “operating process format.” The district court found the specification lacked description for a system in which “called number identification signals (DNIS) . . . identif[y] said operating process format.” Katz argued that the specification described such a system by disclosing that DNIS signals correspond to different “call modes,” such as 800 or 900 numbers, and that different call modes are used to identify different “call processing flows.” Based on the district court’s construction of “format,” the Court agreed with Katz that the different call modes disclosed by the specification identified different formats because the specification described asking different questions to and gathering different information from callers who dialed an 800 number as opposed to a 900 number. However, the Court concluded that an open question remained as to what description was actually required because it was possible that “operating process format” could have a narrower construction than “format.” Accordingly, the Court remanded for construction of “operating process format.”

As to the fourth issue, obviousness, the Court affirmed the finding that several of the Voice-Data and Dual Call Mode claims were obvious in light of the prior art. Two prior art references—Yoshizawa (a telephone betting system that allowed callers to place and cancel bets with a registration number) and Szlam (a customer service system that used a voice response system to take orders or transfer calls to agents)—disclosed all the elements of the Voice-Data claims. The Court concluded that combining the two references would have been obvious, even though Yoshizawa called for use under “tight time constraints,” because it also explicitly allowed for use under normal order entry systems. Conversely,

Szlam did not operate under “tight time constraints.” Further, it rejected Katz’s contention that a person of ordinary skill in the art would not be motivated to combine Yoshizawa and Szlam. “A reference can distinguish prior art in order to show the novelty of an invention without teaching away from combining the prior art with the invention disclosed in the reference.” *Id.* at 31.

The Court also found that Yoshizawa and Szlam did not teach away from one of the asserted Voice-Data claims requiring both caller-entered customer numbers and automatic number identification (“ANI”) to obtain account information. Although Szlam only disclosed the use of ANI and Yoshizawa worked in a system that could not utilize ANI, neither reference discouraged the use of both ANI and caller-entered numbers to obtain account information. Finally, the Court determined that Katz could not establish priority over Szlam because it could not point out anything in its specification that disclosed Szlam’s invention—the display of data corresponding to caller-entered signals.

The Court also concluded that asserted claims in the Dual Call Mode group were obvious in light of Szlam and another reference, Student Registration. The asserted claims of the Dual Call Mode group contained a “cue suppression” limitation that used identification signals based on ANI data to avoid prompting callers with previously provided cues. Student Registration described a system that allowed students to use their ID to register for courses and adjusted each response based on a student’s registration status. Although Katz argued that Student Registration lacked the “cue suppression” limitation, the Court concluded otherwise because the registration status acted as an identification signal to elicit the proper response. Since Student Registration disclosed a multifaceted identification technique to suppress cues and Szlam disclosed an ANI-based identification process, the asserted claims were also obvious in light of the two references.

As to the fifth issue, claim construction, the Court found no reversible error in the district court’s claim construction. Although the Court found that the district court inappropriately limited the scope of “acknowledgement number” by importing limitations from a single embodiment, it concluded that the proper construction did not affect any of the district court’s SJ rulings because the asserted claims were found invalid for obviousness. The Court also agreed that Katz’s statements made during reexam to avoid prior art—“[a] password that is composed . . . serves as an access code or PIN, rather than personal identification data”—effectively disclaimed “personal identification data” from all composed passwords. Finally, the Court also affirmed the district court’s construction of “customer number” to mean distinct from a credit card number because Katz could not point out anywhere in the specification that linked the term “customer number” to a credit card number.

As to the sixth, and final, issue, noninfringement, the Court affirmed in part and vacated in part the individual SJs against defendants U.S. Bank, American Airlines, and DHL. For U.S. Bank, the Court reversed the grant of SJ as to the asserted claims of the Statistical Interface and Conditional Interface Plus groups because it was unclear whether the district court’s construction of the DNIS limitation required that the accused system use the full ten-digit called telephone number or some representation. However, it affirmed the grant of SJ of noninfringement for the asserted claim in the Dual Call Mode group because the accused system did not receive calls in the same way as provided in the asserted claim. For American Airlines, the Court vacated the grant of SJ of noninfringement because there was a genuine issue of material fact as to whether the accused device had a “record structure” that stored information representative of caller-entered data. For DHL, the Court declined to address the noninfringement issue because it previously concluded that the asserted claim was invalid.

Finally, although Katz raised additional issues on appeal, the Court declined to address the district court's rulings on claims that were not selected against any of the appellees.

**Andrew Ra is a Law Clerk at Finnegan.*

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Claims to Antibodies with Specific Properties Are Not Always Fully Described by Disclosing the Protein

Adam J. Sibley

Judges: Bryson, Clevenger, Prost (author)

[Appealed from E.D. Tex., Judge Ward]

In *Centocor Ortho Biotech, Inc. v. Abbott Laboratories*, No. 10-1144 (Fed. Cir. Feb. 23, 2011), the Federal Circuit reversed the district court's denial of Abbott Laboratories' ("Abbott") motion for JMOL on invalidity and held that the asserted claims of Centocor Ortho Biotech, Inc.'s ("Centocor") U.S. Patent No. 7,070,775 ("the '775 patent") failed to comply with the written description requirement of 35 U.S.C. § 112.

The '775 patent, issued in 2006, is directed to antibodies to human tumor necrosis factor α ("TNF- α "). For purposes of the appeal, the Federal Circuit explained that antibodies basically consist of two regions: a constant region and a variable region. Changing the variable region can result in an antibody that does not bind to TNF- α or that does not have neutralizing activity. Centocor identified a mouse antibody to human TNF- α , which had high affinity and neutralizing activity ("the A2 mouse antibody"), and produced a "chimeric" antibody containing a mouse variable region and a human constant region. In 1991, Centocor filed a patent application claiming its A2 mouse antibody and chimeric antibody. Subsequently, in 1994, Centocor filed three CIP applications adding new matter, but did not present claims to human variable regions.

Abbott also sought to engineer a fully-human antibody, taking a different path than Centocor. Rather than start from the A2 mouse antibody, Abbott worked directly with human variable regions. By 1995, Abbott had created the therapeutic antibody Humira® and filed a patent application disclosing this fully-human antibody to human TNF- α in 1996. Following the grant of its patent in 2000, Abbott obtained regulatory approval to market Humira® in 2002.

After Abbott received regulatory approval, Centocor filed the '775 patent application claiming, for the first time, fully-human anti-TNF- α antibodies (i.e., antibodies possessing human variable and constant regions). The '775 patent application contained a priority claim to Centocor's earlier-filed patent applications.

Shortly after the issuance of the '775 patent, Centocor sued Abbott, alleging that Abbott's therapeutic

antibody Humira® infringed several claims of the '775 patent. After a jury verdict finding all of the asserted claims valid and willfully infringed, and awarding Centocor \$1.67 billion in damages, the district court granted Abbott's motion for JMOL of no willful infringement but denied its motions for JMOL on noninfringement and invalidity.

On appeal, the Federal Circuit noted that the pivotal issue was whether the '775 patent provides adequate written description for the claimed human variable regions. The Court explained that Centocor must rely on a priority date from an earlier-filed application because it first sought claims to human variable regions and fully-human antibodies in the '775 patent application filed in 2002. At that time, Abbott had already discovered and patented a fully-human antibody to TNF- α that had high affinity and neutralizing activity. Since Centocor had relied on the 1994 CIP applications, the Court examined them to determine whether the written description supported an antibody to human TNF- α with (1) a human constant region, (2) a human variable region, (3) high affinity for human TNF- α , (4) neutralizing activity, and (5) the ability to bind to TNF- α in the same place as Centocor's A2 mouse antibody ("A2 specificity").

“Claiming antibodies with specific properties, e.g., an antibody that binds to human TNF- α with A2 specificity, can result in a claim that does not meet written description even if the human TNF- α protein is disclosed because antibodies with those properties have not been adequately described.”
Slip op. at 20.

The Federal Circuit found that the CIP specifications did not describe a single antibody that satisfies the claim limitations or disclose any relevant identifying characteristics for fully-human antibodies or even a single human variable region. In addition, the Court determined that the specifications failed to disclose any relationship between the human TNF- α protein, the known mouse variable region that satisfies the critical claim limitations, and potential human variable regions that would satisfy the claim limitations. “At bottom, the asserted claims constitute a wish list of properties that a fully-human, therapeutic TNF- α antibody should have: high affinity, neutralizing activity, and the ability to bind in the same place as the mouse A2 antibody.” Slip op. at 17. The Court thus found that the specifications, at best, describe a plan for making fully-human antibodies, but that a mere wish or plan for obtaining the claimed invention was not sufficient for written description purposes. Accordingly, the Court held that because Centocor had not invented a fully-human, high affinity, neutralizing A2 specific antibody in 1994, a reasonable jury could not conclude that Centocor possessed one.

The Court also rejected Centocor's argument that *Noelle v. Lederman*, 355 F.3d 1343 (Fed. Cir. 2004), and the PTO written description guidelines support the view that fully disclosing the human TNF- α protein provides adequate written description for any antibody that binds to it. As explained by the Federal Circuit, the PTO guidelines example permits an applicant to “claim an antibody to novel protein X without describing the antibody when (1) the applicant fully discloses the novel protein and (2) generating the claimed antibody is so routine that possessing the protein places the applicant in possession of an antibody.” Slip op. at 19. The Court also explained that while *Noelle* suggests that written description for certain antibody claims can be satisfied by disclosing a well-characterized antigen, that reasoning applies to the disclosure of newly characterized antigens where creation of the antibodies is routine.

The Federal Circuit noted that unlike the example in the PTO guidelines and the invention claimed in *Noelle*, the human TNF- α protein and antibodies to that protein were not novel; rather, they were known

in the literature. The claimed invention is a class of antibodies containing a human variable region that has particularly desirable therapeutic properties. The Court explained that “[c]laiming antibodies with specific properties, e.g., an antibody that binds to human TNF- α with A2 specificity, can result in a claim that does not meet written description even if the human TNF- α protein is disclosed because antibodies with those properties have not been adequately described.” *Id.* at 20. Importantly, the Court found that obtaining a high affinity, neutralizing, A2 specific antibody with a human variable region was not possible in 1994 using “conventional,” “routine,” “well developed and mature” technology. *Id.* (citation omitted). Thus, unlike the antibody example in the PTO guidelines, the Federal Circuit concluded that the simple possession of the known TNF- α protein did not place Centocor in possession of the claimed antibodies.

Accordingly, the Federal Circuit found the asserted claims of the '775 patent invalid for lack of written description and reversed the judgment of the district court.

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Specification Limits the Invention Even in the Absence of Explicit Claim Language

Sheetal S. Patel

Judges: Newman, Friedman (*dubitante*), Lourie (author)

[Appealed from N.D. Cal., Senior Judge Whyte]

In *Hologic, Inc. v. SenoRx, Inc.*, No. 10-1235 (Fed. Cir. Feb. 24, 2011), the Federal Circuit reversed the district court's SJ finding of invalidity because it was based on an erroneous claim construction.

Hologic, Inc. ("Hologic") owns U.S. Patent No. 6,482,142 ("the '142 patent"), which discloses a balloon brachytherapy device with a means for providing a predetermined asymmetric isodose profile within a target tissue. Balloon brachytherapy is a type of radiation therapy in which a balloon is inserted into the body at or near a tumor or other proliferative tissue disease site. Hologic brought suit against SenoRx, Inc. ("SenoRx") alleging that SenoRx's balloon brachytherapy device infringed its patents. SenoRx conceded infringement of claims 1 and 8 of the '142 patent but argued that the asserted claims were invalid.

The district court construed the following language in claim 1, "the radiation source further being asymmetrically located and arranged within the expandable surface to provide predetermined asymmetric isodose curves with respect to the apparatus volume," to require that the radiation source be "located and arranged inside the expandable surface so as not to be concentric with the expandable outer surface," and did not limit the claimed asymmetry to asymmetry about the longitudinal axis as Hologic had argued. The district court similarly construed "predetermined asymmetric isodose curves" in both claims to mean "isodose curves determined before radiation is administered which are not substantially the same shape as the apparatus volume and/or not concentric with the apparatus volume."

Additionally, the district court denied SenoRx's motion for SJ of invalidity based on the inoperability of language in claim 1 that required a radiation source disposed completely within the expandable outer surface but also spaced apart from the apparatus volume, finding that the intended meaning of the claim was that the source was located within the balloon but spaced apart from its surface. Additionally, based on its claim constructions, the district court granted SenoRx's motion for SJ of invalidity of claim 1 of the '142 patent, as anticipated by the prior art, but denied SenoRx's motion with respect to claim 8. At trial, however, the jury, instructed by the district court as to its claim constructions, found claim 8 anticipated and obvious in light of the prior art, and the district court subsequently entered judgment for SenoRx.

On appeal, the Federal Circuit found that the district court erred by not limiting claim 1 to situations in which asymmetry was achieved by displacing the radiation source from the longitudinal axis. First, the Court noted that asymmetry is a relative concept that can only exist in relation to some reference. “Here, claim 1 does not specify a reference for the asymmetry of the radiation source’s placement within the expandable surface; however, the specification makes clear what the inventors contemplated as their invention.” Slip op. at 13. Specifically, the Federal Circuit explained that each description of the invention contemplating the placement of a radiation source described displacement from the longitudinal axis of the balloon. Further, while there was one sentence in the specification that did not specify any reference for its asymmetry, the Court rejected SenoRx’s argument that it supported the broader reading of claim 1. In particular, the Court found that the sentence was the first in a paragraph that included two descriptions of asymmetry about the longitudinal axis and, thus, was simply a prelude to those descriptions, and consistent with the rest of the specification.

“Here, claim 1 does not specify a reference for the asymmetry of the radiation source’s placement within the expandable surface; however, the specification makes clear what the inventors contemplated as their invention.” Slip op. at 13.

Second, the Federal Circuit rejected the district court’s conclusion that claim differentiation between claims 1 and 6 supported its claim constructions. In so doing, the Court also rejected Hologic’s argument that looking to other terms is only appropriate when the comparison is between an independent claim and the claims that depend from it. Here, claim 6 referred to a plurality of radiation sources and allowed for some of those sources to be on the longitudinal axis while some are displaced by the changed shape of at least one of the “elongate members” or lumens. The Federal Circuit indicated that claim 1, however, did not refer to “elongate members” and thus may require less specificity in explaining the shape and location of sources with respect to each other. The Court then noted that “[d]ifferent terms or phrases in separate claims may be construed to cover the same subject matter where the written description and prosecution history indicate that such a reading . . . is proper.” *Id.* at 15-16 (alterations in original) (citation omitted). In this instance, the Court found that although the claims were worded sufficiently differently, there was no indication that this particular difference should result in an entirely different reading of the asymmetry of the radiation source in claim 1 that was not called for by the plain language of the claim and was not otherwise supported by the specification.

The Federal Circuit also rejected SenoRx’s argument that certain figures in the ’142 patent showed asymmetry with respect to the apparatus volume, but not with respect to the longitudinal axis. Ultimately, the Court found that the specification, including the figures, consistently and exclusively shows radiation sources located asymmetrically about the longitudinal axis, and because that was clearly what the inventors of the ’142 patent conceived, claim 1 was properly construed as referencing radiation sources that are located and arranged so as not to be on the longitudinal axis of the expandable surface.

Additionally, the Federal Circuit rejected SenoRx’s alternative argument that, even under Hologic’s proposed claim construction, the ’142 patent was invalid as anticipated. The Court declined to find on appeal, based on a single figure in a prior art reference upon which SenoRx relied, that the reference disclosed asymmetry about the longitudinal axis, as a matter of law.

Finally, the Federal Circuit agreed with the district court that claim 1 was not invalid as inoperable and not

enabled. Specifically, “although ‘apparatus volume’ was an odd choice of language to describe what the inventor intended to describe, its use was consistent in the claim, in accordance with use in the prosecution history, and it results in coverage of the embodiments disclosed.” *Id.* at 18-19 (citation omitted).

Accordingly, the Federal Circuit reversed the district court’s grant of SJ of invalidity of claim 1 and the district court’s judgment of invalidity of claim 8, remanded for further proceedings, and awarded costs to Hologic.

Judge Friedman, in an opinion *dubitante*, disagreed with the majority’s construction of claim 1. As he explained, independent claims 2 and 6 shed light on the meaning of claim 1 because they both explicitly refer to “solid radiation sources,” or “a radiation source,” followed in each instance by the words “with respect to a longitudinal axis through the apparatus volume.” In Judge Friedman’s view, the use of the term “a longitudinal axis” in those two claims shows that “when the patentee wanted the claim to include that limitation he knew how to do so, *i.e.*, by explicitly including those words.” Friedman *op. dubitante* at 2. Thus, Judge Friedman would find that the district court correctly construed claim 1 as not including the “longitudinal axis” limitation because the patentee did not include that limitation in the claim.

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March 2011

Burden of Proof for Infringement Under the DOE Is Not Heightened in Cases of Separate Patentability

Shana K. Cyr

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

[Appealed from D. Del., Judge Robinson]

In *Siemens Medical Solutions USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.*, Nos. 10-1145, -1177 (Fed. Cir. Feb. 24, 2011), the Federal Circuit affirmed the district court's denial of a motion by Saint-Gobain Ceramics & Plastics, Inc. ("Saint-Gobain") for JMOL or a new trial based on erroneous jury instructions and excluded evidence. The Court also vacated and remanded on the issue of damages.

Siemens Medical Solutions USA, Inc. ("Siemens") owns U.S. Patent No. 4,958,080 ("the '080 patent"), which is directed to radiation detectors comprising a lutetium oxyorthosilicate ("LSO") crystal. The radiation detectors are used in positron emission tomography ("PET") scanners. Siemens sued Saint-Gobain for contributory and induced infringement of the '080 patent based on Saint-Gobain's sale of lutetium-yttrium orthosilicate ("LYSO") crystals to Philips Medical Systems ("Philips") for use in PET scanners.

Saint-Gobain moved for JMOL or a new trial after the jury awarded Siemens \$52.3 million in damages for infringement under the DOE. The district court denied Saint-Gobain's motion but reduced the jury award to over \$44.9 million, because the sale of some of the scanner products was "wholly speculative." The parties appealed and cross-appealed.

Saint-Gobain challenged the district court's jury instructions with regard to the burden of proof; its jury instructions with regard to the presumption of validity of U.S. Patent No. 6,624,420 ("the '420 patent"), which is licensed to Saint-Gobain; its decision to exclude certain evidence; and its decision to permit the jury to consider lost profit damages. Siemens argued that the damages challenged the district court's reduction of the jury's damages award.

On appeal, the Federal Circuit took each of Saint-Gobain's and Siemens's challenges in turn. With regard to the jury instructions, the Court held that the district court did not err in instructing that infringement may be proved by a preponderance of the evidence, even in cases of separate patentability. The Court reasoned that "separate patentability, while potentially relevant to the

equivalence issue and deserving of due weight in the infringement analysis, does not merit a heightened evidentiary burden.” Slip op. at 15. The Court noted that finding equivalence does not constructively invalidate a separate patent for being obvious, because of the validity presumption and the differences between equivalence and obviousness.

“[S]eparate patentability, while potentially relevant to the equivalence issue and deserving of due weight in the infringement analysis, does not merit a heightened evidentiary burden.” Slip op. at 15.

The Federal Circuit also held that the district court did not err in not instructing the jury that the '420 patent was presumed valid. The Court reasoned that the '080 patent's validity was not at issue and that an infringement verdict would not affect the '420 patent's validity. The Court further noted that the instructional video and subsequent testimony provided the jury with notice of the validity presumption.

With regard to the excluded evidence, the Federal Circuit held that the district court did not err in excluding U.S. Patent No. 6,323,489 (“the '489 patent”). The Court reasoned that Saint-Gobain used their *license* of the '489 patent as evidence, and only after the trial did Saint-Gobain argue that the '489 patent was relevant to the patentability of LYSO crystals. The Court noted that any error associated with the district court's ruling was harmless, because the '489 patent would have been largely cumulative of evidence of record, and because the jury was presented with a text reference to the issuance of the '489 patent and an image of the patent itself.

The Federal Circuit also held that the district court did not err in excluding testimony by Saint-Gobain's expert regarding the use of LYSO crystals in other applications, because the expert could not testify on matters not disclosed in his expert report or deposition, and could not rely on testing that was not disclosed during discovery.

With regard to lost profits damages, the Federal Circuit held that the district court did not err in permitting the jury to make an award as it was based on substantial evidence.

Regarding Siemen's cross-appeal, the Federal Circuit held that the district court did not err in reducing the jury's damages award as the evidence did *not* suggest that Philips *sold* the additional scanners. The Court held, however, that the district court erred by failing to consider *any* damages on the additional scanners, because the evidence indicated that Philips *made* them. The Federal Circuit stated that a district court that “eliminates a lost profits award with regard to a portion of the infringing devices . . . must then determine an appropriate measure of damages for that portion.” *Id.* at 32. The Court vacated and remanded on the issue of damages from the additional scanners that were made.

In a dissenting opinion, Judge Prost stated that the jury instructions should have addressed the overlap between the tests for obviousness and equivalence. Specifically, Judge Prost stated that the district court erred in not instructing the jury that it could find equivalence if, and only if, the state of the art had advanced from the time of the '420 patent's invention to the time of the alleged infringement.

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March 2011

In a Split Decision, Federal Circuit Denies Petition for Rehearing En Banc, Declining to Review Panel Decision Requiring Direct Evidence of Intervening Rights for Prosecution Laches Defense

Amanda K. Murphy

Judges: Rader, Newman, Lourie, Bryson, Gajarsa, Linn, Dyk, Prost, Moore, O'Malley

Dissenting opinions filed by Judges Prost, with whom Gajarsa, Moore, and O'Malley join, and Dyk

[Appealed from D. Del., Judge Robinson]

In *Cancer Research Technology Ltd. v. Barr Laboratories, Inc.*, No. 10-1204 (Fed. Cir. Feb. 28, 2011), the Federal Circuit, in a 5-5 vote, denied Barr Laboratories, Inc.'s ("Barr") petition for rehearing en banc of panel decision *Cancer Research Technology Ltd. v. Barr Laboratories, Inc.*, No. 10-1204 (Fed. Cir. Nov. 9, 2010) ("panel decision"), which reversed the district court's finding of prosecution laches and inequitable conduct.

Cancer Research Technology Limited ("Cancer Research") owns U.S. Patent No. 5,260,291 ("the '291 patent"), which claims a genus of compounds and methods for treating cancer by administering those compounds. The original application that led to the '291 patent was filed in August 1982. The examiner rejected the application for lack of utility. Rather than respond to the office action, the applicant instead filed a continuation application. The examiner again issued a utility rejection, and the applicant again filed a continuation application. This process was repeated nine more times. Cancer Research eventually took over prosecution and substantively responded to the utility rejection by arguing that the animal tests in the original application were adequate to establish utility in humans. The PTO agreed and the '291 patent subsequently issued.

"Where 'the purpose and result of the conduct of the inventor were unduly to postpone the time when the public could enjoy the free use of the invention,' equity bars the inventor from seeking to exclude the public from the claimed subject matter." Prost Dissent at 3.

Barr filed an ANDA with a Paragraph IV certification challenging the validity of the '291 patent. Cancer

Research sued Barr for patent infringement and the district court held the '291 patent unenforceable for prosecution laches and inequitable conduct. On appeal, the Federal Circuit reversed, holding that prosecution laches requires a finding of prejudice, which in turn requires a demonstration of intervening rights. Barr filed a petition for rehearing en banc of the Court's November 9, 2010, decision and the Court denied the petition.

Judge Prost, with whom Judges Gajarsa, Moore, and O'Malley joined, dissented. According to the dissent, the panel majority's decision narrowed the equitable doctrine of prosecution laches by requiring direct evidence of intervening rights. In Judge Prost's opinion, the majority's decision established a rigid rule that "surely discounts the relevant concerns that may arise" when patents are not prosecuted in a timely manner. Prost Dissent at 3. According to the dissent, the majority's decision was contrary to Supreme Court precedent, which distinguishes prosecution laches and intervening rights as independent defenses. Judge Prost further stated that the rigidity of the majority's rule was of particular concern because the Supreme Court has repeatedly cautioned against excessive formalism in application of the patent laws. Instead, the majority should have applied a flexible "totality of the circumstances" test for prosecution laches in order to accommodate the different ways in which the public might be harmed by a delay in the patent monopoly. Thus, Judge Prost concluded that en banc review should have been granted to prevent the harm done by the panel majority to the equitable doctrine of prosecution laches.

Judge Dyk wrote a separate dissent in which he agreed with Judge Prost's opinion that a defendant need not show evidence of intervening rights to establish a prosecution laches defense. However, Judge Dyk disagreed with the other dissenting judges that the proper test should be a "totality of the circumstances" test, since such a test "is really no test at all." Dyk Dissent at 1. According to Judge Dyk, the Supreme Court has not required the use of a "totality of the circumstances test" for prosecution laches, and such a test would be unadvisable because it will not provide patent prosecutors with sufficient guidance as to when they risk a defense of prosecution laches. Thus, Judge Dyk concluded that the Court should have granted en banc review to provide such guidance.

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