October 2009

FINNEGAN

LAST MONTH AT THE FEDERAL CIRCUIT

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SPOTLIGHT INFO:

In August 2007, the PTO published its Final Rules, entitled "Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims and Examination of Claims in Patent Applications." 72 Fed. Reg. 46716-46843 (Aug. 21, 2007). The Final Rules included various regulations designed to limit the practice of filing continuation applications and requests for continued examination. The Final Rules provided several restrictions, such as the proposed "Continuation Rule," which would have limited an applicant to only two continuation applications per family as a matter of right. Similarly, the "RCE Rule" would have allowed one request for continued examination per application family as a matter of right. If an applicant wished to file a subsequent continuation application or RCE, however, the applicant would have had to seek permission from the PTO and demonstrate why the additional filing was necessary. In addition, the "Claims Rule" of the Final Rules proposed that an applicant could only file five independent claims and twenty-five total claims per application. If an applicant wished to file more than five independent claims or more than twenty-five total claims, then the applicant would be required to supply information to the PTO about the claimed invention. These Final Rules were intended to become effective in November 2007.

Shortly after the Final Rules were published, however, Dr. Triantafyllos Tafas and GlaxoSmithKline ("GSK") filed motions to enjoin the Final Rules in the Eastern District of Virginia. The district court granted the request and temporarily enjoined the rules, pending the outcome of the litigation. In April 2008, the district court issued a final ruling in favor of Tafas and GSK, holding that the PTO had exceeded its authority, and permanently enjoining the PTO from implementing the Final Rules. In March 2009, on appeal, a divided panel of the Federal Circuit affirmed that judgment in part and reversed it in part. In July 2009, the Federal Circuit vacated the divided-panel decision and agreed to hear the matter en banc. On October 8, 2009, however, GSK and the PTO announced that they would jointly move to dismiss the litigation over the Final Rules. GSK and the PTO filed the joint motion the next day. As a result, the Final Rules will not be implemented, and the patent system that existed before this litigation will remain in place.

Where There Is No Clear Disavowal of Claim Scope, a Patentee's Express Definition of a Claim Term Controls

John W. Cox

Judges: Newman, Lourie (dissenting-in-part), Rader (dissenting-in-part, joining Lourie), Gajarsa (author), Moore

[Appealed from D. Del., Chief Judge Sleet]

In *Martek Biosciences Corp. v. Nutrinova, Inc.*, Nos. 08-1459, -1476 (Fed. Cir. Sept. 3, 2009), the Federal Circuit affirmed the district court's denial of JMOL that the claims of Martek Biosciences Corp.'s ("Martek") U.S. Patent No. 5,340,594 ("the '594 patent") were invalid and that Nutrinova, Inc., Nutrinova Nutrition Specialties and Food Ingredients GmbH, and Lonza, Ltd. (collectively "Lonza") did not infringe claims of U.S. Patent No. 6,410,281 ("the '281 patent"). The Court also found that the district court did not abuse its discretion in excluding Lonza's prior inventorship evidence, and that the district court correctly construed the term "non-chloride sodium salt." Finally, the Federal Circuit reversed the district court's grant of JMOL that the asserted claims of Martek's U.S. Patent No. 6,451,567 ("the '567 patent") were invalid and reversed the district court's construction of the term "animal" in Martek's U.S. Patent No. 5,698,244 ("the '244 patent").

Martek and Lonza make and sell products containing docosahexaenoic acid ("DHA"), an essential omega-3 fatty acid involved in organ development. Because the human body produces limited quantities of DHA, it is desirable to provide supplemental DHA.

Martek asserted that Lonza infringed claims of the '594, '281, '567, and '244 patents, which relate to specified microorganisms that are useful for the commercial production of DHA. Lonza argued that the asserted claims were invalid under 35 U.S.C. §§ 102, 103, and 112. The district court construed the contested claim terms and, based on the construction, Martek stipulated that Lonza did not infringe the asserted claims of the '244 patent, but preserved its right to appeal the court's construction of "animal." A jury then found the

remaining asserted claims infringed and not invalid, and further found that Lonza's infringement of the '281 patent claims was willful. The district court granted Lonza's motion for JMOL that the '567 patent claims were invalid for lack of enablement, and Martek's motion for a permanent injunction. Both parties appealed.

"[B]ecause the patentee explicitly defined 'animal,' [the alleged infringer's] extrinsic evidence is simply irrelevant." Slip op. at 29.

On appeal, Lonza argued that the '594 patent claims were invalid as anticipated by WO 89/00606 and that the jury erred in finding that the application was not prior art against the '594 patent. Lonza argued that substantial evidence did not support the jury's finding that the '594 patent claims were entitled to the priority date of an abandoned application filed in 1988 ("the 1988 application"). Specifically, Lonza argued that two claim limitations, namely, "mixed culture" and "food product," were not described in the 1988 application.

The Federal Circuit found that Martek's expert explained how a person of ordinary skill in the art would recognize that at least one passage in the 1988 application disclosed the process of extracting lipids from a mixed culture of fermenting microorganisms. Accordingly, the Court held that the text of the 1988 application, in light of Martek's expert's testimony, provided substantial evidence to support the finding that the application met the written description requirement for the "mixed culture" limitation.

Noting that a patent claim is not necessarily invalid for lack of written description just because it is broader than the specific examples disclosed, the Court rejected Lonza's argument that the jury could not reasonably rely on the expert's interpretation of the 1988 application because the application did not contain any working examples that consolidated cells from different strains. Further, the Court disagreed with Lonza's argument that the 1988 application taught away from growing the two strains together. The Court found no evidence to suggest that the two strains could not be grown together. Therefore, the Court found substantial evidence to support the jury's finding that the 1988 application adequately described the "mixed culture" limitation of the claims.

Moreover, the Court found that the text of the 1988 application, in light of Martek's expert's testimony, provided substantial evidentiary support for the jury's finding that the 1988 application adequately described the claimed food product comprising extracted lipids and food material. Accordingly, the Court held that substantial evidence supports the jury's finding that the '594 patent claims are entitled to the priority date of the 1988 application and that the district court did not err in denying Lonza's JMOL motion.

Regarding the infringement of the '281 patent claims, the district court construed the claims to require that "the culture medium causes less chemical wearing of the vessel in which the microorganisms are grown as compared to the level of chemical wearing away to a vessel caused by a culture medium comprising sodium chloride as the primary source of sodium." Slip op. at 12 (citation omitted). Lonza argued that Martek failed to prove infringement because it failed to conduct comparative testing to demonstrate that Lonza's culture medium caused "less chemical wear" than a culture medium containing sodium chloride as the primary source of sodium. The Court found that, based on Martek's experts' testimony, the jury could have reasonably concluded that Lonza's culture medium caused less chemical wear than a culture medium containing sodium chloride as the primary source of sodium.

Additionally, Lonza appealed the exclusion of evidence that allegedly showed prior inventorship of the claimed invention. Lonza offered the alleged prior inventor's abandoned patent application and evidence that the examples originally disclosed in the abandoned application were later reproduced, generating the results described in the application. The Court found that the abandoned application failed to establish that the alleged prior inventor reduced the invention to practice, even in view of additional evidence that the Court noted was merely "a post hoc replication of experiments cited in the abandoned application, which does not qualify as evidence from a time prior to or contemporaneous with the alleged prior invention." *Id.* at 19. Because the evidence failed to establish corroboration of the alleged prior inventor's testimony, the Court held that the district court did not abuse its discretion in excluding Lonza's evidence of prior inventorship.

Finally, Lonza argued that the district court misconstrued the '281 patent claim term "non-chloride sodium salt" by allowing that term to include sodium hydroxide. The Court affirmed the district court's construction, finding that the intrinsic and extrinsic evidence supported the construction. Specifically, the prosecution history explicitly stated that sodium hydroxide is a non-chloride sodium salt, and that two treatises taught that sodium hydroxide can be considered a non-chloride sodium salt. The Court further noted that Lonza cited no evidence that sodium hydroxide cannot be considered a non-chloride sodium salt. Moreover, the Court held that Martek committed no clear and unmistakable disavowal of claim scope in light of the prosecution history as a whole.

Turning to Martek's appeal, Martek argued that the district court erred in granting JMOL that all asserted claims of the '567 patent were invalid for lack of enablement. The Federal Circuit held that the district court erred in granting JMOL with respect to the asserted dependent claims because it failed to consider the additional limitations of the dependent claims. Specifically, although the independent claim covered "perhaps 10,000" organisms and the '567 patent disclosed only one such example, the Court found that Lonza failed to present any evidence—much less clear and convincing evidence—that one of ordinary skill in the art must perform undue experimentation to practice the asserted dependent claims. But because the embodiments covered by dependent claims 4 and 5 comprised only twenty-two possibilities, the Court found that the evidence supported the jury's implicit finding that one need not perform undue experimentation to practice these claims. Thus, the Court reversed the district court's grant of JMOL as to claims 4 and 5 of the '567 patent.

Martek also appealed the construction of the term "animal" found in the asserted claims of the '244 patent. In view of the district court's construction, which excluded humans, Martek stipulated that Lonza did not infringe the '244 patent claims. On appeal, the Federal Circuit held that because Martek explicitly defined "animal" in the specification to include humans, that definition controls. The Court also found that Martek had not clearly disavowed itself of humans, even though it had included only nonhuman animals in its preferred embodiments. And the Court found no disavowal in view of isolated statements in the prosecution—that the dissent alleged distinguished between humans and other animals—because the Court failed to find evidence of a clear disclaimer of "humans" from "animal." Further, the Court noted that, because the patentee explicitly defined "animal," Lonza's extrinsic evidence was simply irrelevant.

Judge Lourie, with whom Judge Rader joined, dissented-in-part with respect to the majority's holding that the term "animal" in the claims of the '244 patent includes humans. The dissent acknowledged that the specification defines "animal" to include humans in a single sentence, but reasoned that "[t]his case illustrates the unusual situation in which a purported definition of a claim term in the written description is totally negated by the remainder of the text of the patent." Lourie Dissent at 2. The dissent noted that the specification and claims distinguished between animals and humans in several places. Because the Court is bound to read the claim term in a manner that is consistent with the specification as a whole, the dissent stated that it was clear that one of ordinary skill in the art would conclude that, despite the purported definition in the specification, the term "animal" cannot include humans.

Use of the Term "Comprising" Does Not Render a Claim Anticipated by a Device That Contains Less Than What Is Claimed

Casey L. Dwyer

Judges: Newman (author), Friedman, Mayer

[Appealed from Board]

In *In re Skvorecz*, No. 08-1221 (Fed. Cir. Sept. 3, 2009), the Federal Circuit reversed and remanded the Board's decision rejecting claims 1-5 and 7 in Robert J. Skvorecz's application to reissue U.S. Patent No. 5,996,948 ("the '948 patent") for anticipation based on U.S. Patent No. 5,503,062 ("the '062 patent"), indefiniteness, and failure to comply with the written description requirement.

The '948 patent is directed to a wire chafing stand used for supporting a chafer (i.e., a device for keeping food warm). Specifically, the '948 patent describes a chafing stand wherein the wire legs of the stand are indented so that nested chafing stands can be readily separated. Specifically, the

specification describes a stand whereby the legs have an indent (also called an "offset") located adjacent to the upper ends of the legs, serving to laterally displace each leg relative to the point of attachment of the leg to the upper rim of the stand.

"The protocol of giving claims their broadest reasonable interpretation during examination does not include giving claims a legally incorrect interpretation." Slip op. at 8.

In response to the applicant's request seeking reissuance of claims 1-7 of the '948 patent under 35 U.S.C. § 251, the reissue examiner rejected claims 1-5 and 7 as an improper recapture of surrendered subject matter and claims 1, 2, and 5 as anticipated based on the '062 patent. The Board reversed the rejection based on improper recapture of surrendered subject matter and the anticipation rejection as to claim 5, but sustained the examiner's anticipation rejection as to claims 1 and 2. The Board also entered two new grounds of rejection, rejecting claim 5 for indefiniteness, and claims 1-5 and 7 for failing to comply with the written description requirement.

On appeal, the Federal Circuit first considered the rejections for anticipation. The Board found that the examiner established a prima facie case of anticipation based on the structural similarity between the '948 patent and the '062 patent because the applicant failed to show the claimed invention was not inherently disclosed by the '062 patent. Skvorecz argued that the claims of his patent require that each wire leg has a laterally displacing offset, while the '062 patent discloses a wire leg that does not have an offset that laterally displaces the leg from the rim.

The PTO argued that, under their broadest interpretation, the claims could be construed to include wire legs without offsets. Specifically, the PTO argued that the use of the term "comprising" in claim 1 permits the Skvorecz structure to include legs without offsets, even though the claim stated that "said wire legs" and "each wire leg" had offsets. The Federal Circuit disagreed, finding that the term "comprising" "simply means that the device may contain elements in addition to those explicitly mentioned in the claim." Slip op. at 7-8. The Court noted that the PTO's protocol giving claims their broadest reasonable interpretation during examination "does not include giving claims a legally incorrect interpretation." *Id.* at 8. After warning that the PTO's protocol is "solely an examination expedient, not a rule of claim construction," the Court concluded that the "broadest reasonable interpretation" was incorrectly applied to interpret "comprising" to mean that not all the Skvorecz wire legs need to have offsets. *Id.* In so doing, the Court reminded that the signal "comprising" does not render a claim anticipated by a device that contains less than what is claimed. Accordingly, the Court held that the Board erred in holding that the '062 patent anticipated the '948 patent and reversed the Board's anticipation rejection.

The Federal Circuit next addressed the PTO's argument that dependent claim 5 was indefinite because (1) the phrase "at the separation" lacked antecedent basis in independent claim 1; and (2) the indefiniteness of "at the separation" rendered the term "segments" indefinite, especially because "segments" was not defined in the specification. The Court noted that "[s]ome latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire." *Id.* at 10 (quoting M.P.E.P. § 2173.02). Thus, the Court found that the phrase "at the separation" did not require further antecedent basis and was not indefinite because a person of ordinary skill in the art would understand the claim in view of the specification. The Court instructed the applicant to adopt the Board's suggestion of changing "*the* separation" to "*a* separation," and held that, with this amendment, the claim was not indefinite.

Finally, the Court addressed the PTO's argument that claims 1-5 and 7 did not meet the written description requirement because the claim element "a plurality of offsets located . . . in said first rim" was not described in the specification. Although Figures 12 and 13 showed offsets in the rim, the PTO argued that these were partial figures and did not show every leg's offset and their displacement. The Court rejected the PTO's argument, finding that, in view of the other figures showing the full structure, a person of skill in the art would

understand Figures 12 and 13 as partial structures showing the detail of the offsets. The Court therefore held that the Board erred in finding that the claims failed to meet the written description requirement.

Accordingly, the Federal Circuit reversed the Board's rejections based on anticipation, indefiniteness, and failure to meet the written description requirement and remanded the case for further proceedings.

Res Judicata Applies When Device Accused in Second Suit Remains Unchanged with Respect to Claim Limitations at Issue in First Suit

Stephen L. Keefe

Judges: Michel, Rader (author), Prost

[Appealed from E.D. Va., Judge Davis]

In *Nystrom v. Trex Co.*, No. 09-1026 (Fed. Cir. Sept. 8, 2009), the Federal Circuit affirmed the district court's judgment of noninfringement of U.S. Patent No. 5,474,831 ("the '831 patent") on alternative grounds, holding that plaintiff Ron Nystrom was precluded on res judicata grounds from litigating his infringement claim against Trex Company, Inc. ("Trex"), Home Depot USA, Inc. ("Home Depot"), and Snavely Forest Products Inc. ("Snavely Forest") (collectively "Defendants").

The '831 patent is directed to an outdoor wood-flooring board shaped to shed water from its upper surface while still maintaining a comfortable surface upon which to walk. Trex manufactured a first generation of boards ("Trex I boards") and a second generation of boards ("Trex II boards"). Home Depot and Snavely Forest each distribute Trex boards.

In 2001, Nystrom initiated a suit naming Trex as the sole defendant and alleging that the Trex I boards infringed the '831 patent. The district court entered judgment of noninfringement. On appeal, the Federal Circuit affirmed the district court's constructions of the terms "board" and "manufactured to have," but reversed on the construction of a third claim limitation. On remand, Nystrom attempted to pursue his infringement claim under the DOE, which the district court concluded Nystrom had waived. Nystrom again appealed, and the Federal Circuit affirmed the district court's holding that Nystrom had waived his infringement claim based on the DOE.

Nystrom then filed a second suit in the same district court naming the Defendants and alleging solely that the Trex II boards infringed the '831 patent under the DOE. Trex moved for SJ to bar Nystrom under the doctrine of res judicata from relitigating infringement because the Trex II boards were essentially the same as the Trex I boards. Trex also moved for summary adjudication to prohibit Nystrom from relying on the DOE because of (1) claim vitiation, (2) argument-based estoppel, and (3) amendment-based estoppel. The district court granted SJ on claim vitiation and argument-based estoppel, but denied Trex's motion on res judicata and amendment-based estoppel.

On appeal, the Federal Circuit reminded that, for claim preclusion in a patent case, an accused infringer must show that the accused product or process in the second suit is essentially the same as the accused product or process in the first suit, and that "[c]olorable changes in an infringing device or changes unrelated to the limitations in the claim of the patent would not present a new cause of action." Slip op. at 6 (quoting *Foster v. Hallco Mfg. Co.*, 947 F.2d 469, 480 (Fed. Cir. 1991)).

> "Given that the Trex II boards remain materially identical to the Trex I boards with respect to the pertinent claim limitations at issue, this court cannot under *res judicata* permit Nystrom to have a second bite at the apple." Slip op. at 8-9.

Defendants conceded material differences between the Trex I boards and the Trex II boards, but maintained that the only two limitations leading to the noninfringement judgment in the suit—"board" and "manufactured to have"—are in all material respects the same in the Trex I boards and the Trex II boards.

The Court observed that this case presents "a slightly new angle on claim preclusion," asking "whether the accused infringer may assert claim preclusion when the sole claim limitations at

issue in the first suit remain unchanged in the second suit." *Id.* at 6-7. The Court noted that, although it had previously emphasized that the focus for claim preclusion should be on "material differences" between the two accused devices, it had not addressed directly whether the focus of the "material differences" test is on the claim limitations at issue in each particular case.

Turning to that question, the Court noted that it had already determined in the earlier case that the Trex I boards do not infringe the '831 patent, either literally or, as a result of Nystrom's waiver, by equivalents. The Court observed that for Nystrom to succeed on his infringement claim against the Trex II boards in the second suit, he would have to prove infringement of each claim limitation. The Court noted that the only claim limitations at issue in the first suit were "board" and "manufactured to have," that the constructions for these terms in the second suit were the same as the constructions in the first suit, and that the bases of noninfringement in the first suit were these constructions. The Court explained that "[i]f, therefore, the accused device of the second suit remains unchanged with respect to the corresponding claim limitations at issue in the first suit, then Nystrom has no remaining avenue to pursue his claims now." *Id.* at 7. The Court observed that Nystrom would be attempting to prove infringement of the same claim limitations as to the same features of the accused devices, which is the exact situation that res judicata seeks to prevent. The Court concluded that res judicata thus barred this second attempt to adjudicate the same issues.

The Court pointed out that its analysis assumed the Trex I and Trex II boards to be insubstantially different with respect to the pertinent claim elements. Although Nystrom argued differences in added wood grain and color between the Trex I and Trex II boards, the Court noted that Nystrom's alleged differences fell squarely within the "colorable changes" category. The Court added that simply adding a wood grain and changing the board's color did not materially alter the infringement analysis of the "wood cut from a log" construction of the limitation "board" or the "manufactured utilizing woodworking techniques" construction of the limitation "manufactured to have."

Judge Rader wrote separately to address the doctrine of claim vitiation, reminding that the "all elements" rule established in *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39 n.8 (1997), forecloses resort to the DOE when a limitation would be read completely out of the claim (i.e., would be vitiated). Judge Rader further noted that, nonetheless, the Federal Circuit has warned that an overly broad application of the "all elements" rule may improperly swallow the DOE entirely and limit infringement to "a repeated analysis of literal infringement." Rader Dissent at 2 (quoting *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 149 F.3d 1309, 1317 (Fed. Cir. 1998)). Because claim vitiation limits the DOE, which, by definition, acknowledges that a specific claim limitation is not expressly found in the accused product, in Judge Rader's view, the vitiation doctrine is subsumed within the test for equivalents itself and the "all elements" rule is "simply a circular application of the doctrine of equivalents." *Id.*

Judge Rader went on to explain that while the test for equivalents and vitiation are coterminous, juries decide the test for equivalents as a question of fact, but judges decide vitiation and apply the "all elements" rule as a question of law. Judge Rader noted that although the tests are the same, the testers are different, which could produce different results in application of the same rules.

Structural and Functional Analysis of Disclosed and Prior Art Elements Are Required When Means-Plus-Function Limitations Are at Issue

Jeremy P. Bond

Judges: Newman (concurring), Gajarsa (author), Dyk (concurring)

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

In *Fresenius USA, Inc. v. Baxter International, Inc.*, Nos. 08-1306, -1331 (Fed. Cir. Sept. 10, 2009), the Federal Circuit affirmed the district court's judgment that Fresenius USA, Inc. and Fresenius Medical Care Holdings, Inc. (collectively "Fresenius") failed to provide sufficient evidence of prior art structure to prove that a means-plus-function claim limitation was known in the art, reversed the district court's grant of JMOL as to the remaining claims asserted by

Baxter International, Inc. and Baxter Healthcare Corporation (collectively "Baxter"), vacated the permanent injunction and royalty award it had granted against Fresenius, and remanded.

Baxter owns U.S. Patent Nos. 5,247,434 ("the '434 patent"), 5,744,027 ("the '027 patent"), and 6,284,131 ("the '131 patent"). All three patents are derived from a parent application filed in 1991, and all three disclose and claim a hemodialysis machine integrated with a touch screen user interface.

Fresenius initially brought a DJ action against Baxter on the grounds of invalidity and noninfringement of the '434, '027, and '131 patents. Baxter counterclaimed, alleging infringement of all three patents. The district court granted partial SJ that Fresenius infringed claims of the '131 and '434 patents. Following trial, a jury found all the asserted claims invalid as either anticipated or obvious. The district court overturned the jury's verdict for lack of substantial evidence and granted Baxter's JMOL motion that its asserted claims were not invalid. The district court also found that Fresenius did not present substantial evidence of a motivation to combine the prior art elements to produce the claimed inventions in the '131 and '434 patents.

"Just as a patentee who seeks to prove infringement must provide a structural analysis by demonstrating that the accused device has the identified corresponding structure or an equivalent structure, a challenger who seeks to demonstrate that a means-plus-function limitation was present in the prior art must prove that the corresponding structure—or an equivalent—was present in the prior art." Slip op. at 17.

Following a jury trial on damages, the jury awarded fourteen million dollars to Baxter. The district court granted a permanent injunction against Fresenius and awarded royalties on sales of infringing machines and disposable products linked to the infringing machines. Fresenius appealed the grant of JMOL, entry of the permanent injunction, royalty award, and constructions of specified claim terms. Baxter cross-appealed the jury's determination that the asserted claims of the '027 patent are invalid as anticipated.

On appeal, the Federal Circuit determined that Baxter failed to properly raise the argument that substantial evidence did not support the jury's anticipation determination. The Court noted that Baxter's motions only briefly mentioned the jury's anticipation verdict, and in each motion Baxter relegated its discussion of that verdict to a single footnote. As the Court explained, one specific challenge to an anticipation finding does not preserve all possible challenges to that finding. "If a party fails to raise an argument before the trial court, or presents only a skeletal or undeveloped argument to the trial court, we may deem that argument waived on appeal, and we do so here." Slip op. at 10.

With the exception of claims 26-31 of the '434 patent, the Federal Circuit reversed the JMOL with regard to the asserted claims on evidentiary grounds. With regard to the '027 patent, the district court determined that Fresenius had failed to prove by clear and convincing evidence that claim 11 was obvious because the only relevant expert witness testimony did not discuss the limitations of claim 7, from which claim 11 depended. The Court disagreed because another Fresenius witness had previously discussed those limitations when he testified that claim 7 was anticipated. When assessing the obviousness of claim 11, the jury could have reasonably concluded that the limitations of claim 7 were known in the prior art based on the combined testimony of Fresenius's experts. "In determining whether Fresenius presented substantial evidence to support the jury's verdict that claim 11 is obvious, we must consider all evidence that was before the jury and draw all reasonable inferences from that evidence in the light most favorable to Fresenius." *Id.* at 12.

With regard to the '131 patent, the district court noted that Fresenius's expert, who testified that claim 1 was obvious, did not specifically analyze element (a) of claim 1. Element (a) is written as a Markush group, listing a circulation unit among others. In reversing the district court's finding, the Court pointed out that three witnesses provided testimony that prior art hemodialysis machines contain circulation units. Based on the totality of

the testimony presented by these three witnesses, the jury could have reasonably concluded that the limitations of element (a) were known in the prior art.

Claim 14 of the '131 patent depends from claim 1 and further requires that the touch screen "display a plurality of indicia, each corresponding to a different time-variable hemodialysis parameter." Although the district court noted that an operating manual for a prior art machine disclosed "an indicium corresponding to a time-variable hemodialysis parameter," the district court concluded that Fresenius failed to present any evidence that a "plurality of indicia" was present in the prior art. The Court disagreed because Fresenius provided testimony, using an explanatory demonstrative, that the inventors of the prior art machine had provided for more than one time-variable parameter. The demonstrative indicated that the prior art machine allowed for multiple indicia, each corresponding to a different time-variable hemodialysis parameter. The Court reasoned that the jury could have reasonably credited the testimony and concluded that the relevant limitation was present in the prior art machine.

Baxter additionally asserted that Fresenius failed to demonstrate that a verification limitation of claim 16 existed in the prior art. The Court remained unpersuaded because Fresenius's expert testified that a prior art machine contained the verification limitation, referring to a specific page of an operating manual for support.

Claims 26–31 of the '434 patent contain means-plus-function limitations that require a "means for delivering the dialysate to a dialysate compartment of a hemodialyzer." After stating that a structural analysis is required when means-plus-function limitations are at issue and a functional analysis alone will not suffice, the Court found that Fresenius neither identified the structure in the specification that corresponds to the means for delivering dialysate nor compared it to the structures present in the prior art. The Court explained that, at most, the evidence of record supports a finding that some structures that could perform the claimed function existed in the prior art, and such a finding is insufficient.

The Court also noted an additional reason for affirming the district court's grant of JMOL regarding dependent claim 30. Claim 30 requires a "means for delivering an anticoagulant to a patient," which the jury was instructed requires a microprocessor and stepper motor. However, Fresenius cited no testimony discussing a "stepper motor." While Fresenius contends that an operating manual for a CMS 08 dialysis machine disclosed the necessary structure, Fresenius cited no pages that reference a "stepper motor." The Court independently reviewed the record, noting that the manual briefly mentions a "stepper motor" but does not discuss that structure in the context of the claimed function. "Moreover, even if the CMS 08 manual disclosed a stepper motor for delivering an anticoagulant, it was Fresenius's burden to clearly disclose, discuss, and identify for the jury the supporting evidence upon which it was relying to prove that the claim limitation was present in the prior art." *Id.* at 18.

The Court also reversed the district court's determination that Fresenius had failed to demonstrate the required motivation to combine prior art elements in support of the jury's obviousness determination. Although the district court issued its JMOL opinion before *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), was decided, the Court noted that it remains appropriate post-*KSR* "to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." Slip op. at 20 (quoting *KSR*, 550 U.S. at 418). Thus, the jury's obviousness verdict remains relevant to the Court's review because implicit factual findings underlying the jury's verdict will not be overturned if they are supported by substantial evidence.

In support of its obviousness argument, Fresenius presented a prior art publication by Dr. Rau that disclosed a touch screen interface on an anesthesia-delivery system. The publication mentioned that advancing areas of medicine, such as hemodialysis, could benefit from an improved user interface. Another Fresenius witness, Dr. Phares, also described the ease and prevalence of "integrating a touch screen into some kind of a computer-controlled machine," such as a hemodialysis machine. *Id.* at 21.

Under *KSR*, "if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." *Id.* (quoting *KSR*, 550 U.S. at 417).

The Court reasoned that the jury had implicitly found that the prior art suggested combining a touch screen with a hemodialysis machine. That finding was supported by substantial evidence because a reasonable jury could have concluded that Dr. Rau's publication contained an explicit suggestion to combine the benefits of a touch screen interface with a hemodialysis machine. Based on Dr. Phares's testimony, the jury could also have reasonably concluded that an ordinarily skilled artisan would have known how to make that same combination.

Fresenius asserted several challenges to the district court's injunctive order. However, the Court found that Fresenius had cited no legal error and failed to demonstrate that the district court had made any clearly erroneous factual findings. While the Court concluded that the district court did not abuse its discretion in granting permanent injunctive relief, the injunction was vacated and remanded for the district court to reconsider in light of the partial JMOL reversal. Likewise, the Court vacated the royalty award and remanded for the district court to reconsider whether the previous award was proper in light of the modification of the district court's judgment.

The Court also considered the parties' other arguments and found them unpersuasive. For example, Fresenius asserted that the district court erred in construing several claim terms. The Court declined to consider these arguments because Fresenius failed to clearly explain what result would occur if the Court adopted Fresenius's proposed claim constructions. Moreover, Fresenius unconditionally stipulated to infringement of the asserted claims. The Court reasoned that the infringement judgment cannot be altered by a modified claim construction because Fresenius's stipulation in no way stated or indicated that it was conditioned upon the district court's claim construction.

In a concurring opinion, Judge Dyk asked whether the district court could, in its discretion, stay further proceedings pending the outcome of a reexamination before the PTO. Judge Dyk noted that while Fresenius had not established the invalidity of claims 26-31 of the '434 patent, those claims on their face were of dubious validity in light of the Court's holding that the asserted claims of the '131 patent and the '027 patent are invalid. Judge Newman responded to Judge Dyk's concurrence in a separate concurring opinion because she was concerned about distorting the role of reexamination. While a strong supporter of the principle of reexamination, Judge Newman stated that staying the action at this late stage would entail several years of additional delay. Judge Newman pointed out that the PTO had yet to finally decide the reexamination, which remains subject to judicial review on the same issues of validity that have already been litigated.

Federal Circuit Vacates $358 Million Jury Award in Microsoft Infringement Case

Judy W. Chung

Judges: Michel (author), Newman, Lourie

[Appealed from S.D. Cal., Judge Huff]

In *Lucent Technologies, Inc. v. Gateway, Inc.*, Nos. 08-1485, -1487, -1495 (Fed. Cir. Sept. 11, 2009), the Federal Circuit affirmed the district court's denial of Microsoft Corporation's ("Microsoft") JMOL motion for noninfringement, reversed the district court's denial of Microsoft's JMOL motion regarding damages, vacated the damages award, and remanded for a new trial on damages.

Lucent Technologies, Inc. ("Lucent") owns U.S. Patent No. 4,763,356 ("the '356 patent"), directed to a method of entering information into fields on a computer screen without using a keyboard. In 2002, Lucent asserted the '356 patent against Microsoft and others in three separate infringement suits, which were later consolidated. Microsoft challenged Lucent's infringement contentions, contending among other defenses that the '356 patent was invalid as anticipated and obvious, and, even if valid, Microsoft's sales of its products did not infringe the '356 patent. The jury found Microsoft liable as to its Microsoft Money, Microsoft Outlook, and Windows Mobile products. The verdict, without distinguishing among the three products or between inducement and contributory infringement, awarded a single lump sum of $357,693,056.18 to Lucent.

The parties filed numerous post-trial motions, including Microsoft's renewed motions seeking JMOL that the '356 patent is anticipated and obvious, and seeking to overturn the jury's

damages award. The district court found substantial evidence in the record to support the jury's findings and denied Microsoft's motions. Microsoft appealed the denial and Lucent cross-appealed the district court's SJ of noninfringement of certain claims of the '356 patent.

On appeal, the Court first considered the district court's denial of Microsoft's JMOL motion on obviousness. Applying the district court's claim construction, which was not appealed, the Court considered whether claim 19 of the '356 patent would have been obvious over a 1984 magazine article describing the use of computer touch screens. The parties and their experts disagreed about whether the article described three of the limitations of claim 19 and whether a fourth limitation would have been obvious from the article. Specifically, the parties differed about whether the article disclosed the limitations of (1) "inserting in said one field information that is derived as a result of said user operating said displayed tool," which the district court construed to mean "inserting in a particular field information that is derived as a result of the user operating the displayed tool"; (2) a "tool adapted to allow said user to compose said information," which the district court construed to mean "a graphical keyboard tool or a graphical number keypad tool, which allows the user to compose information by pointing to the display keys of that tool"; (3) "concurrently displaying a predefined tool associated with said one of said fields," which the district court construed to mean "displaying at the same time, as by a window overlaying the form"; and (4) the step of "indicating a particular one of said information fields into which information is to be inserted," which Microsoft's expert conceded the article does not teach.

The Federal Circuit concluded that it was reasonable for the jury to have concluded that the prior art article describes a computer system that does not disclose or use these four limitations required by claim 19. Accordingly, the Court concluded that the district court did not err in denying Microsoft's motion for JMOL concerning the validity of claim 19 of the '356 patent.

Similarly, the Federal Circuit concluded that the district court did not err in denying Microsoft's motion for JMOL that claim 21 of the '356 patent would have been obvious in view of the prior art article. Claim 21 requires that "the step of displaying said pattern includes the step of displaying one or more of said information fields as a bit-mapped-graphics field," which the Court concluded would not have been obvious from the article, either standing alone or when combined with other prior art references.

"Although our law states certain mandatory conditions for applying the entire market value rule, courts must nevertheless be cognizant of a fundamental relationship between the entire market value rule and the calculation of a running royalty damages award. Simply put, the base used in a running royalty calculation can always be the value of the entire commercial embodiment, as long as the magnitude of the rate is within an acceptable range (as determined by the evidence)." Slip op. at 61.

Turning to indirect infringement, the Court considered Microsoft's arguments that (1) Lucent did not prove direct infringement, a necessary predicate for proving indirect infringement; (2) Lucent did not prove contributory infringement because the products have substantial noninfringing uses; and (3) Lucent cannot prove inducement because the products are merely capable of inducing and Microsoft was not shown to have the requisite intent to induce.

With regard to direct infringement, the Court agreed that Lucent's direct evidence of direct infringement was limited, but found circumstantial evidence adequate to permit a jury to find that at least one person, other than Lucent's expert, had performed the claimed method. The Court concluded that Lucent's circumstantial evidence of infringement was "something less than the weight of the evidence," yet was just "more than a mere scintilla," thus satisfying the requirements for a finding of direct infringement. Slip op. at 23 (quoting *Consolo v. Fed. Maritime Comm'n*, 383 U.S. 607, 620 (1996); *Consol. Edison Co. v.*

NLRB, 305 U.S. 197, 229 (1938)). The Court also disagreed with Microsoft's argument that the evidence required a jury to conclude that Microsoft Outlook does not contain a "composition tool."

Regarding contributory infringement, the issue at bar was reduced to whether the "material or apparatus" required by the patent is the entire software package or just the particular tool (e.g., the calendar date-picker) that performs the claimed method. The date-picker tool is suitable only for an infringing use, while the software package as a whole is capable of substantial noninfringing use. The Federal Circuit concluded that "[i]nclusion of the date-picker feature within a larger program does not change the date-picker's ability to infringe," and that a jury could reasonably conclude that Microsoft intended users to use the tool, and that the only intended use of the tool infringed the '356 patent. *Id.* at 27. The Federal Circuit also rejected Microsoft's argument that, under the Supreme Court's holding in *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437 (2007), 35 U.S.C. § 271(c) does not apply because "[Microsoft's] products are not a 'material or apparatus' as the statute requires for contributory infringement of patent methods." Slip op. at 27. The Court observed that the Supreme Court in *Microsoft* did not address the meaning of "material or apparatus" in § 271(c).

With regard to inducing infringement, while the Court agreed with Microsoft that the evidence of Microsoft's intent to induce infringement was not strong, the Court was not persuaded that the jury was unreasonable in finding Microsoft possessed the requisite intent to induce at least one user of its products to infringe the claimed methods. For these reasons, the Court affirmed the district court's denial of Microsoft's motion for JMOL that Microsoft did not induce infringement of the '356 patent.

Turning next to damages, the Court first observed that the total dollar value of the sales of accused software products was $8 billion. Microsoft challenged the jury's award of a lump-sum royalty payment of $357,693,056.18 on the grounds that (1) the jury should not have applied the entire market value rule to the value of Microsoft's three software products; and (2) for method claims, *Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263 (Fed. Cir. 2004), requires that damages be limited to the proven number of instances of actual infringing use. Although the Court rejected both arguments as presented by Microsoft, the Court agreed that substantial evidence did not support the jury's damages award. Further, to the extent the jury relied on an entire market value calculation to arrive at the lump-sum damages amount, the Court concluded that the award is not supported by substantial evidence and is against the clear weight of the evidence.

In so concluding, the Court first determined whether substantial evidence supported a lump-sum, paid-in-full royalty of approximately $358 million for Microsoft's indirect infringement of the '356 patent. To do this, the Court determined whether substantial evidence supported the jury's implicit finding that Microsoft would have agreed to, at the time of the hypothetical negotiation, a lump-sum, paid-in-full royalty of that amount. Focusing its analysis on Microsoft Outlook and the relevant *Georgia-Pacific* factors, the Court concluded it did not. Specifically, the Court concluded that the second *Georgia-Pacific* factor, the rates paid by the licensee for the use of other patents comparable to the patent-in-suit, weighed strongly against the jury's award because there was little evidentiary basis for awarding roughly three to four times the average amount in the lump-sum agreements in evidence.

The Court also found that *Georgia-Pacific* factors 10 (the nature of the patented invention, the character of the commercial embodiment of it as owned and produced by the licensor, and the benefits to those who have used the invention) and 13 (the portion of realizable profit that should be credited to the invention as distinguished from nonpatented elements, the manufacturing process, business risks, or significant features or improvements added by the infringer) weigh against the damages award because "most of the realizable profit must be credited to non-patented elements," as the date-picker feature does not constitute a substantial portion of the value of Outlook. Slip op. at 49. Moreover, the Court found that *Georgia-Pacific* factor 11 (the extent to which the infringer has made use of the invention; any evidence probative of the value of that use) weighs against the jury's award because the record was "conspicuously devoid of any data about how often consumers use the patented date-picker invention." *Id.* at 52.

After reviewing these and other *Georgia-Pacific* factors, the Court was left with the "unmistakable conclusion that the jury's damages award is not supported by substantial evidence, but is based mainly on speculation or guesswork." *Id.* at 54.

The Federal Circuit next considered Microsoft's argument that the damages award must be reversed because the jury erroneously applied the entire market value rule. The Court concluded that, assuming the jury did apply the entire market value rule, its application amounted to legal error for two reasons. First, Lucent did not prove that the patented method of the '356 patent was the basis, or even a substantial basis, of the consumer demand for the Outlook product. Second, the Court found that the methodology used by Lucent's damages expert did not comport with the purpose of damages law or the entire market value rule primarily because he "tried to reach the damages number he would have obtained had he used the price of the entire computer as a royalty base." *Id.* at 60.

For these reasons, the Court vacated the jury's damages award and remanded for a new trial on damages.

With regard to Lucent's cross-appeal, the Federal Circuit affirmed the district court's SJ of noninfringement of certain apparatus claims of the '356 patent containing means-plus-function elements not found in claims 19 and 21 because Lucent did not identify algorithms or analyze source code used in the accused programs.

In sum, the Federal Circuit affirmed the district court's denial of Microsoft's JMOL motion for noninfringement, reversed the district court's denial of Microsoft's JMOL motion regarding damages, vacated the damages award, and remanded for a new trial on damages.

35 U.S.C. § 121 Safe Harbor from Double Patenting Rejections Does Not Apply to Continuation Applications

Elizabeth E. Mathiesen

Judges: Mayer, Clevenger, Schall (author)

[Appealed from D. Mass., Judge Young]

In *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, Nos. 09-1020, -1096 (Fed. Cir. Sept. 15, 2009), the Federal Circuit held that the safe harbor against double patenting rejections of divisional applications provided by 35 U.S.C. § 121 did not apply to continuation applications. The Court held that in limited circumstances, both the patentee and a patent challenger may rely on evidence produced after the effective priority date but before the actual filing date of a patent to support or rebut a finding of no obviousness-type double patenting ("OTDP"). Finally, the Court affirmed the majority of the district court's holdings of infringement and no invalidity for indefiniteness or anticipation.

Amgen Inc. ("Amgen") is the owner of a family of patents directed to recombinant erythropoietin ("EPO"), a protein useful in treating blood disorders such as anemia. F. Hoffman-La Roche Ltd., Roche Diagnostics GmbH, and Hoffman-La Roche Inc. (collectively "Roche") makes MIRCERA®, a recombinant EPO polypeptide covalently linked to polyethylene glycol ("PEG"). Roche manufactures MIRCERA® overseas, but has sought to market it in the United States. In response, Amgen sought a DJ that, if imported into the United States, MIRCERA® would infringe the claims of at least five of Amgen's patents: U.S. Patent Nos. 5,441,868 ("the '868 patent"), 5,547,933 ("the '933 patent"), 5,618,698 ("the '698 patent"), 5,756,349 ("the '349 patent"), and 5,955,422 ("the '422 patent"). These patents all descend as continuations from a single parent application, which issued as U.S. Patent No. 4,703,008 ("the '008 patent").

The '008 patent was subject to a six-way restriction requirement between the following groups of inventions: polypeptides, DNA, plasmids, cells, pharmaceutical compositions, and assays. Claims to DNA were elected and issued in the '008 patent. During the pendency of the application that issued as the '008 patent, two continuation applications were filed and led to additional continuation applications that issued as the five patents-in-suit. The patents-in-suit may be divided into two groups: the "product patents" (the '933 and '422 patents, containing product and product-by-process claims) and the "process patents" (the '868, '698, and '349 patents, claiming methods of producing recombinant EPO). None of the patents claim the subject matter claimed in the '008 patent—DNA and cells containing the DNA.

Amgen brought a DJ action against Roche in Massachusetts, alleging that MIRCERA® would infringe Amgen's five EPO patents. The case was decided by a combination of SJ, jury trial, and JMOL, and the district court entered judgment that

the '349 patent was neither invalid nor infringed, and that the remaining four patents were valid and infringed. The district court granted Amgen declaratory relief and permanently enjoined Roche from marketing MIRCERA® in the United States.

"[T]he § 121 safe harbor provision does not protect continuation applications or patents descending from only continuation applications." Slip op. at 15.

Roche appealed the district court's findings that none of the claims were invalid for OTDP and that claim 1 of the '422 patent was neither anticipated nor indefinite and infringed. Roche also challenged the jury's verdict that the '933, '868, and '698 patents were literally infringed. Amgen cross-appealed from the district court's holding and the jury's verdict that some of the asserted claims were not infringed.

The Federal Circuit vacated the district court's grant of SJ to Amgen of no invalidity for OTDP, vacated the district court's grant of JMOL of no infringement of claim 7 of the '349 patent, remanded these issues to the district court for a new trial, and affirmed all other judgments.

35 U.S.C. § 121 provides a safe harbor against double patenting rejections for divisional applications filed as a result of a restriction requirement. The Federal Circuit, citing their holding in *Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*, 518 F.3d 1353 (Fed. Cir. 2008), held that § 121 does not apply to continuation applications. The Court held that "[t]he statute on its face applies only to divisional applications, and a continuation application, like a continuation-in-part application, is not a divisional application." Slip op. at 15-16 (footnote omitted). The Court recognized that Amgen's applications may have satisfied all the substantive requirements of a divisional application, but refused to grant the patents the benefits accorded to divisional applications. *Id.* at 16-17 (quoting *Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1382 (Fed. Cir. 2003) ("Given the potential windfall [a] patent term extension could provide to a patentee, this court applies a strict test for application of § 121." (alteration in original))). The Court distinguished this case from situations where a divisional application is properly filed in response to a restriction requirement and continuation applications are filed off the divisional application. Those continuations of divisional applications will continue to receive the benefit of the § 121 safe harbor from double patenting rejections. Accordingly, the Court vacated the district court's SJ holding of no OTDP of the '933, '422, and '349 patents over the claims of the '008, '868, and '698 patents, and remanded for a new trial on this issue.

In so doing, the Court discussed the holding in *Takeda Pharmaceutical Co. v. Doll*, 561 F.3d 1372 (Fed. Cir. 2009) (evidence generated up to the filing date of the later-filed application of alternative processes to make a product may be used to support a position that product and process claims are patentably distinct and therefore not subject to an OTDP rejection). The Court stated that a patent challenger may not use evidence produced after the filing date of the first-filed patent to support a prima facie case of OTDP (i.e., evidence that no alternative processes exist). However, should a patentee rely on post-filing date evidence to show the existence of alternative processes, the challenger may then also use post-filing date evidence to rebut the patentee's assertions.

The Court then addressed the question of whether the process patent claims were invalid for OTDP over the '008 patent. The Court agreed with the district court's claim construction and held that the process claims required the step of producing and isolating a glycosylated EPO polypeptide with a specific biological activity. The Court held that a person of ordinary skill in the art would not have a reasonable expectation of success in producing this protein based on the claims of the '008 patent. The Court relied on expert testimony that the '008 patent claims did not teach which, if any, host cells would produce EPO with the carbohydrate structure necessary for its in vivo function and that no one had successfully produced a recombinant glycoprotein with in vivo biological activity where the carbohydrate structures were important for biological activity. Accordingly, the Federal Circuit affirmed the district court's finding of no invalidity of claims 1 and 2 of the '868 patent and claims 6-9 of the '698 patent for OTDP.

The Federal Circuit affirmed the district court's holding that the product patent claims were not invalid for anticipation by prior art teaching EPO protein purified from urine. The Court

acknowledged that an old product is not patentable, even if made by a new process, but pointed out that a new product may be patented by reciting source or process limitations, so long as the product is new and unobvious. The district court construed the claims to include the source limitation "wherein said erythropoietin is purified from mammalian cells grown in culture," and relied on expert testimony that demonstrated that EPO purified from mammalian cells could be distinguished from urinary EPO based on its carbohydrate content. The Court found that this distinction was sufficient to impart novelty on the claimed products.

The Federal Circuit affirmed the district court's finding that the patents were not invalid for indefiniteness, holding that the definitions of EPO and the source limitations in the claims were definite because the product-by-process nature of the product claims allowed Amgen to define the claimed product by the source. The Court opined that "to call the process limitation indefinite in this situation would defeat one of the purposes of product-by-process claims, namely permitting product-by-process claims reciting new products lacking physical description." Slip op. at 55-56.

The Court affirmed the district court's findings of literal infringement of some of the asserted product and process claims, holding that the addition of PEG to recombinant EPO was simply the addition of an element, not a fundamental chemical transformation. Therefore, pegylation is not a transformation of the EPO polypeptide structure that would exclude it from the scope of the product claims. With regard to the process claims, the Court evaluated infringement under 35 U.S.C. § 271(g) (prohibiting the importation of a product made by a process patented in the United States). Specifically, the Court addressed whether MIRCERA® is materially changed by subsequent processes prior to importation. Stating that "[i]n the biotechnology context, a significant change in a protein's structure and/or properties would constitute a material change," *id.* at 65, the Court looked to Amgen's specification and claims for a recitation of the protein's structure and function. The Court found that the structure and functional differences between the product produced by Amgen's claimed processes were not material because MIRCERA® still contains EPO, the structure of EPO remains intact, and MIRCERA® possesses the same functionality as the EPO product produced by the processes of Amgen's claims. Accordingly, the Court affirmed the district court's holding of infringement of both the product and process patents.

The Court also affirmed the district court's JMOL overturning a jury's verdict of infringement under the DOE for a subset of the asserted product claims, holding that Amgen had failed to identify limitation by limitation the equivalent function-way-result. In particular, the Court found that the record lacked particularized testimony and linking argument as to the insubstantiality of the differences between a therapeutic efficacy limitation in the claims and the actual therapeutic efficacy of MIRCERA®. Accordingly, the Court affirmed the district court's holding of no infringement of claims 9, 11, 12, and 14 of the '933 patent.

The Court vacated the district court's JMOL holding of no infringement overturning a jury's verdict of infringement of claim 7 of the '349 patent, holding that a reasonable jury could have found this claim infringed because evidence was produced that Roche's actual production process met the limitations of the claims. The Court remanded to the district court for a new trial.

On remand, the district court will reconsider the OTDP of the '933, '422, and '349 patent claims over the '008, '868, and '698 patent claims, and the infringement of claim 7 of the '349 patent. Because the Court upheld the majority of the infringement rulings, the permanent injunction remains in place.

Claims to Methods of Optimizing Therapeutic Efficacy Are Patent-Eligible Subject Matter Under 35 U.S.C. § 101

David Albagli

Judges: Michel, Lourie (author), Clark (District Judge sitting by designation)

[Appealed from S.D. Cal., Judge Houston]

In *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, No. 08-1403 (Fed. Cir. Sept. 16, 2009), the Federal Circuit reversed the district court's grant of SJ of invalidity and

held that the asserted claims of U.S. Patent Nos. 6,355,623 ("the '623 patent") and 6,680,302 ("the '302 patent") were drawn to statutory subject matter and therefore not invalid under 35 U.S.C. § 101.

"The inventive nature of the claimed methods stems not from preemption of all use of these natural processes, but from the application of a natural phenomenon in a series of transformative steps comprising particular methods of treatment." Slip op. at 22.

The patents claim methods for calibrating the dosage of thiopurine drugs used for treating certain autoimmune diseases. 6-mercaptopurine ("6-MP") and the prodrug azathiopurine, which first converts to 6-MP in the body, are converted to various metabolites, including 6-methyl-mercaptopurine ("6-MMP") and 6-thioguanine ("6-TG"). The claimed methods involve measuring these metabolites to optimize therapeutic efficacy while minimizing toxicity.

The methods typically include two steps: (1) "administering" a drug that provides 6-TG to a subject, and (2) "determining" the levels of the drug's metabolites, 6-TG and/or 6-MMP, in the subject. The claims further recite that the metabolite levels are compared to predetermined metabolite levels, "wherein" the measured levels "indicate a need" to vary the amount of drug to be administered to maximize efficacy and minimize toxicity.

Prometheus Laboratories, Inc. ("Prometheus") marketed a test that used the claimed methods. Mayo Collaborative Services and Mayo Clinic Rochester (collectively "Mayo") purchased and used Prometheus's test, but in 2004, Mayo announced that it would make a test measuring the same metabolites for its own use and sale. Prometheus brought a suit for patent infringement, asserting certain claims of the '623 and '302 patents. After Prometheus filed the lawsuit, Mayo rescinded its announcement and has still not launched its test.

The parties filed cross-motions for SJ regarding infringement of claim 7 of the '623 patent. The district court construed "indicates a need" to mean "a warning that an adjustment in dosage may be required." Slip op. at 4. Mayo then moved for SJ of invalidity under 35 U.S.C. § 101. Mayo argued that the claims recite unpatentable subject matter because the correlations between metabolite levels and efficacy and toxicity are natural phenomena, and the claims wholly preempt use of the natural phenomena. The district court granted SJ of invalidity, finding that the administering and determining steps were merely data-gathering steps for the correlation, and that the final step, construed to be a "warning," was only a mental step. The district court also concluded that the inventors did not "invent" the claimed correlation but merely observed the relationship between the metabolites and therapeutic efficacy and toxicity. Thus, according to the district court, the claims covered the correlation itself and impermissibly wholly preempted the correlation.

On appeal, the Federal Circuit noted that while the Supreme Court has construed § 101 broadly, § 101 is not unlimited and does not embrace every discovery. The Supreme Court has held that a claim to a process is not patent-eligible if it claims laws of nature, natural phenomena, and abstract ideas. Although claims to a fundamental principle are unpatentable, an application of a law of nature may be deserving of patent protection. Thus, the Federal Circuit stated that the key issue for patentability on the present facts was whether a claim is drawn to a fundamental principle or an application of a fundamental principle.

The Federal Circuit then referred to its "definitive test" regarding statutory subject matter set forth in *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc), *cert. granted*, 129 S. Ct. 2735 (June 1, 2009). The machine-or-transformation test states, "A claimed process is surely patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing." Slip op. at 8. The Court further highlighted that the use of a machine or transformation of an article must impose meaningful limits on the claim and must not be insignificant extra-solution activity or merely a data-gathering step. If steps of a method represent data gathering rather than being "central" to the purpose of the process, then the patentee likely cannot rely on the data-gathering steps to prove

that the claimed process is transformative and thus drawn to patentable subject matter.

The Federal Circuit concluded that the claimed methods of treatment are patentable subject matter because they transform an article into a different state or thing, and the transformation is central to the purpose of the claimed process. The Court held that the transformation was of the human body following administration of a drug and the various chemical and physical changes of the drug's metabolites that enable their concentrations to be determined. Because the claimed methods met the transformation prong under *Bilski*, the Court did not consider whether they also met the machine prong.

The Court did not consider the disputed claims as merely claiming natural correlations and data-gathering steps. The Court noted that methods of treatment are always transformative when a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition. When administering thiopurine drugs, the body necessarily undergoes a transformation, and the effect on the body after metabolizing the artificially administered drugs is the entire purpose of administering the drugs. Here, the transformation was the result of the physical administration of a drug to a subject to transform—i.e., treat—the subject, which is itself not a natural process. Thus, the Court held that the administering step was a significant transformative element of the claimed method.

Even though some claims did not recite a transforming step, the Federal Circuit held that all the claims were nonetheless patentable because the determining step, which was present in each of the asserted claims, was also transformative and central to the invention. Determining the level of metabolites in a patient necessarily involves a transformation. Some form of manipulation was necessary to extract the metabolites from a sample and determine their concentration. The Court rejected Mayo's argument that this was simply a data-gathering step for use of the correlations. The Court found that the transformation was central to the purpose of the claims since the determining step was a significant part of the claimed method of treatment. Thus, by working a chemical and physical transformation on physical substances, the Court held that the determining step sufficiently confined the patent monopoly within definite bounds.

The Federal Circuit then stated that the administering and determining steps are not insignificant extra-solution activity or mere data gathering. The Court noted that although these steps gather useful data, these steps were not "'merely' for the purpose of gathering data." *Id.* at 18. The steps were part of a treatment protocol, and they were transformative.

Next, the Federal Circuit agreed with the district court that the final "wherein" clauses were mental steps and not patent-eligible per se. But the Court noted that a subsequent mental step does not, by itself, negate the transformative nature of prior steps. The data obtained in the administering and determining steps for use in the mental step were obtained by steps well within the realm of patentable subject matter. As the Court noted in *Bilski*, even though a fundmental principle itself is not patent-eligible, processes incorporating a fundamental principle may be patent-eligible. Thus, it is irrelevant that any individual step by itself would be unpatentable under § 101. Here, when viewing the treatment methods as a whole, the Court found that Prometheus invented a series of transformative steps that optimizes efficacy and reduces toxicity of a method of treatment for particular diseases using particular drugs.

Finally, the Federal Circuit held that the district court erred in finding that the claims wholly preempt the use of correlations between metabolite levels and efficacy or toxicity. The Court found that the claims cover transformative methods of treatment, which are a particular application of natural processes, and not simply the correlation itself. Regardless, the Court noted that because the claims met the machine-or-transformation test, they did not preempt a fundamental principle. Thus, the Court held that "[t]he inventive nature of the claimed methods stem[med] not from preemption of all use of these natural processes, but from the application of a natural phenomenon in a series of transformative steps comprising particular methods of treatment." *Id.* at 22.

Judgment of No Direct Infringement Reversed in Part Due to Application of Disclaimer Inconsistent with Claim Construction Order

Jessica A. Keesee

Judges: Prost (author), Gajarsa, Bryson (concurring-in-part and dissenting-in-part)

[Appealed from N.D. Ohio, Judge Gaughan]

In *Vita-Mix Corp. v. Basic Holding, Inc.*, Nos. 08-1479, -1517 (Fed. Cir. Sept. 16, 2009), the Federal Circuit vacated and remanded the district court's judgment of no direct infringement and affirmed the judgment of no contributory infringement, no inducement of infringement, and no trademark infringement. The Court vacated and remanded the judgment of invalidity based on anticipation, obviousness, or lack of enablement. The Court also affirmed the judgment of no inequitable conduct and no laches.

Vita-Mix Corporation ("Vita-Mix") is the assignee of U.S. Patent No. 5,302,021 ("the '021 patent"). The sole claim of the '021 patent is directed to a method of preventing the formation of air pockets around the moving blades of a consumer food blender. The method involves inserting a plunger into the body of the blender to block the air channel that creates air pockets when ingredients are blended.

In 2006, Vita-Mix sued Basic Holding, Inc. ("Basic") and affiliated companies. Vita-Mix alleged infringement of the '021 patent by dozens of Basic's blender models and trademark infringement by the Blender Solutions™ 5000 model. Basic responded by filing DJ counterclaims of noninfringement, invalidity, and inequitable conduct. The district court resolved on SJ the entire dispute between the parties. Vita-Mix appealed on the issues of patent and trademark infringement. Basic cross-appealed on the issues of no invalidity, inequitable conduct, and laches.

On appeal, Vita-Mix contended that the district court erred in finding no direct infringement based, in part, on applying to the accused device a claim construction inconsistent with its claim construction order. The district court determined during claim construction that Vita-Mix expressly disclaimed any stirring operation that breaks up or dislodges air pockets after they have begun to form, and that Vita-Mix limited the scope of the claimed invention to positioning the plunger such that it prevents air pockets from forming. The prior art disclosed blenders with structurally similar stirring wands that were used to break up or dislodge air pockets.

In its cross-motion for SJ, Basic argued that its accused line of smoothie makers did not infringe because the stir stick was used to stir the contents of the blender, and the patentee disclaimed stirring. Vita-Mix's infringement theory, by contrast, was that it was the positioning of the stir stick, not the stirring action, that prevented air pockets from forming. In its order granting SJ of no infringement, the district court held that the patentee disclaimed "all stirring." The district court disposed of the two allegations of direct infringement by Basic for lack of direct evidence and proceeded to grant Basic's motion for SJ for no infringement, which served as the basis for granting SJ of no contributory infringement and no inducement as well.

The Federal Circuit observed that disclaiming "all stirring, regardless of whether and how the stirring acts on air pockets, ignores the nature of the distinction between a positioning that prevents air pockets from forming and an operation that breaks up air pockets after they have begun to form." Slip op. at 9. Thus, the Federal Circuit agreed with Vita-Mix that the district court's disclaimer finding on SJ appears inconsistent with the district court's earlier claim construction and that the earlier claim construction is correct.

Reminding that direct infringement can be proven by circumstantial evidence, the Court further concluded that the district court erred as a matter of law in disposing of the direct infringement claims by requiring direct evidence of infringement by either Basic or by Basic's customers. Specifically, the Court found circumstantial evidence as to whether users tend to insert the stir stick into the pitcher without stirring, and under such conditions, whether the accused device would necessarily infringe created a genuine issue of material fact regarding whether employees and customers of Basic engaged in acts of direct infringement.

Turning to the grant of SJ of no contributory infringement, the Court reasoned that since the accused devices were undisputedly capable of noninfringing use, the question of contributory infringement turned on whether the noninfringing

use was substantial. Adopting the opinion of Vita-Mix's expert and assuming that customer use of the accused device directly infringes, unless the stir stick is used to break up air pockets or is in contact with the sides of the pitcher, the Court held that no reasonable jury could find that using the stir stick to stir is an insubstantial use of the accused device. Accordingly, the Court affirmed the district court's grant of SJ of no contributory infringement.

Next, affirming the grant of SJ of no inducement, the Court found the record devoid of direct or circumstantial evidence of Basic's intent to encourage customers to infringe the '021 patent.

"To find that the patentee disclaimed all stirring, regardless of whether and how the stirring acts on air pockets, ignores the nature of the distinction between a positioning that prevents air pockets from forming and an operation that breaks up air pockets after they have begun to form." Slip op. at 9.

The Court found that the product instructions did not evidence a specific intent to encourage infringement, since they either taught a stirring action—which Basic could have reasonably believed was noninfringing—or evidenced an intent to discourage infringement. Looking to product design, the Court held that although the "default" vertical position of the stir stick may lead to infringing use under certain conditions, there was no evidence that Basic intended users to maintain the stir stick in the default position.

The Court next reviewed the grant of SJ of no trademark infringement under Sixth Circuit law. Vita-Mix claimed common law trademark protection for the number 5000. Although Vita-Mix had federal trademark protection for the mark "VITA-MIX," it had not registered the mark "Vita-Mix 5000" or the number "5000" itself, and had never marked the number "5000" in commerce. Under Sixth Circuit law, an unregistered mark is entitled to protection as a trademark if it is inherently distinctive or has acquired secondary meaning. The Court found that there was no evidence in the record that the number "5000" had any secondary meaning, apart from its appearance in conjunction with the "VITA-MIX" mark within the designation "Vita-Mix® 5000," and functioned only to distinguish the blender from previous Vita-Mix products on the market. Further, the Court found no evidence of record that Basic used the designation "5000" as a trademark in its sale of the Blender Solutions™ 5000 product. The Court concluded that no reasonable jury could find that either Vita-Mix's or Basic's use of the designation "5000" is a protectable mark, and, therefore, Vita-Mix could not make a prima facie case of trademark infringement as a matter of law.

The Federal Circuit next considered the grant of SJ of invalidity in favor of Vita-Mix. Having determined the district court's application of a claim construction that excludes "all stirring" inconsistent with the original claim construction order, the Court remanded the issue for reconsideration under proper construction.

With regard to the grant of SJ of no inequitable conduct by Vita-Mix, the Court found that Basic made no genuine showing of deceptive intent. Basic's charge on appeal was that the inventor of the '021 patent made a false statement in a declaration when he distinguished low-powered prior art blenders as incapable of forming air pockets around the blades and submitted a declaration to the PTO that the cited prior art reference was irrelevant as it disclosed a low-powered blender. On appeal, Basic offered additional prior art evidence that the inventor's statement was false. The Court, however, found that regardless of whether the statement is actually false, the inventor believed the statement to be true at the time it was made.

Finally, the Court affirmed the grant of SJ of no laches after finding that, although Vita-Mix was aware of Basic's accused blenders and waited over five years before bringing suit, such delay did not give rise to the presumption of laches.

For these reasons, the Court affirmed the judgments of no inducement, no contributory infringement, and no trademark infringement; vacated and remanded the judgments of no invalidity for anticipation, obviousness, or lack of enablement; and affirmed the judgments of no inequitable conduct and no laches.

Judge Bryson, dissenting-in-part, disagreed with the majority's judgment upholding the SJ rulings on inducement of infringement and contributory

infringement. In Judge Bryson's view, Vita-Mix introduced enough evidence to overcome Basic's SJ motion. Specifically, with regard to inducement, for example, Judge Bryson pointed to Vita-Mix's expert report, which states that, in normal operation, the accused device will practice the claimed invention and that Basic's instructions for using the blenders did not direct users to avoid using the device in the default mode, i.e., when the stick is inserted but not being used to stir the contents of the blender.

Judge Bryson also looked to evidence of Basic's videotaped television demonstration of the operation of the accused device, which depicted periods of time in which the operator did not use the stir stick or even touch it, instead leaving the stir stick in the default position during operation. Judge Bryson argued that a fact-finder could regard that advertising demonstration as a form of instruction on the use of the device that entailed using it, at least in part, in an infringing manner. Judge Bryson also pointed to some of Basic's instructions arguably giving specific directions to use the accused device in the default manner for some purposes.

Regarding contributory infringement, Judge Bryson looked to whether the accused device can be used for substantial noninfringing purposes. In Judge Bryson's view, the fact that the stir stick can be used in a noninfringing manner does not overcome the evidence offered by Vita-Mix that customers who use the Basic device with the stir stick inserted would infringe in a large percentage of instances and that the device had no substantial use that did not entail at least some period of infringement.

Patentee Who Retains Substantial Rights in Patent Must Join Exclusive Licensee in Infringement Suit Despite Terms of License

Adam M. Breier

Judges: Lourie (author), Rader, Clark (District Judge sitting by designation)

[Appealed from D. Mass., Judge Stearns]

In *AsymmetRx, Inc. v. Biocare Medical, LLC*, No. 09-1094 (Fed. Cir. Sept. 18, 2009), the Federal Circuit raised sua sponte the issue of lack of standing of plaintiff AsymmetRx, Inc. ("AsymmetRx"), and on this basis vacated the district court's grant of SJ to defendant Biocare Medical, LLC ("Biocare").

The President and Fellows of Harvard College ("Harvard") own U.S. Patent Nos. 6,946,256 ("the '256 patent") and 7,030,227 ("the '227 patent"), which relate to p63 antibodies and methods for using them to detect malignant carcinoma. Harvard entered into a license agreement with Biocare ("the Biocare License") to make, use, and sell the p63 antibodies. The Biocare License stated that it did not include a license under any U.S. or foreign patents. The '256 and '227 patents were pending but had not issued before the effective date of the Biocare License. The Biocare License also defined a limited field of use, the life science research market, but did not actually limit the license grant to that field.

> "When viewing the retention of the right to sue in conjunction with all of the other rights retained by Harvard, it is clear that Harvard conveyed less than all substantial rights under the '256 and '227 patents. While any of these restrictions alone might not have been destructive of the transfer of all substantial rights, their totality is sufficient to do so." Slip op. at 12.

A few years later, Harvard entered into an agreement with AsymmetRx ("the AsymmetRx License") that also concerned the p63 antibodies. Under the AsymmetRx License, AsymmetRx received "an exclusive commercial license" under the '256 and '227 patents, and "a license" to use the p63 antibodies. The AsymmetRx License was limited to a field defined as the "[s]ale of clinical and diagnostic products and services based on detecting p63 expression or mutation." Slip op. at 2-3 (alteration in original). Under the license, Harvard reserved certain rights and imposed certain obligations on AsymmetRx. Moreover, AsymmetRx could enforce the patents in an infringement action as long as AsymmetRx still had an exclusive license at the time the action was commenced.

AsymmetRx sued Biocare for patent infringement, alleging that Biocare's sale of the p63 antibodies violated AsymmetRx's exclusive rights in the commercial diagnostic field. The district court granted Biocare's motion for SJ and found that the Biocare License was not limited to the life sciences research market, and that the Biocare License excluded only rights to any materials covered by patents already in existence when Biocare received its license.

On appeal, the Federal Circuit first addressed sua sponte the antecedent question of whether AsymmetRx had the statutory right to bring an action for infringement without joining the patent owner, Harvard. A suit for infringement ordinarily must be brought by a party holding legal title to the patent. The Court noted that a mere license that gave the licensee no title in the patent did not give the licensee right to sue at law in his own name for an infringement.

Noting that the critical determination regarding a party's ability to sue in its own name is whether an agreement transferring patent rights to that party is, in effect, an assignment or a mere license, the Court proceeded to examine whether the agreement transferred all substantial rights to the patents and whether the surrounding circumstances indicated an intent to do so.

The Court found that although the AsymmetRx License effected a broad conveyance of rights to AsymmetRx, Harvard retained substantial interests under the '256 and '227 patents, including the right to sue for infringement. Harvard also retained the right to make and use the p63 antibodies for its own academic research purposes, as well as the right to provide the p63 antibodies to nonprofit or governmental institutions for academic research purposes. In addition, Harvard retained a great deal of control over aspects of the licensed products within the commercial diagnostic field and over sublicenses. The agreement also specified that AsymmetRx was to cooperate with Harvard to maintain the patent rights, so as to enable Harvard to apply for, to prosecute, and to maintain patent applications and patents in Harvard's name. The Court found that retention of all of those rights was inconsistent with an assignment of the patents. Moreover, although AsymmetRx had the option to initiate a suit for infringement, it did not enjoy the right to indulge infringements, which normally accompanies a complete conveyance of the right to sue. Finally, if AsymmetRx did commence an infringement action, it was obligated to consider Harvard's views and Harvard's approval was necessary for any settlement of suit. Harvard may elect to join as a party in that action and, if Harvard does join such an action, it jointly controls the suit with AsymmetRx.

In short, the Court held that Harvard did not convey the entire right to enforce the patents to AsymmetRx. Thus, the Court concluded that AsymmetRx must be considered a licensee, not an assignee, and that it did not have a sufficient interest in the patents to sue, on its own, for infringement as a "patentee." The Court held that Harvard, by retaining the various rights to its patents, must join in any infringement suit its licensee chooses to bring.

The Court also stated that the policies underlying Fed. R. Civ. P. 19 argue for Harvard's joinder in this case. The disposition of AsymmetRx's suit against Biocare could either prejudice Harvard's interests or expose Biocare to the risk of multiple litigations. Under the Biocare License, the Court noted that Harvard was obligated to help Biocare defend against any infringement suit by a third party. By granting licenses to two parties involving the same subject matter, Harvard had potentially put itself in the conflicting position of having to aid two licensees opposed to each other. Complicating matters was the fact that Harvard was continuing to accept royalty payments from Biocare for the allegedly infringing sales. Thus, joinder of Harvard would permit the relationships between AsymmetRx, Biocare, and Harvard to all be resolved at the same time as well as solve the standing problem.

Written Description and Prosecution History May Trump the Plain Language of the Claims and the Doctrine of Claim Differentiation During Claim Construction

Matthew R. Van Eman

Judges: Lourie (author), Rader, Moore

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

In *Edwards Lifesciences LLC v. Cook Inc.*, No. 09-1006 (Fed. Cir. Sept. 22, 2009), the Federal Circuit affirmed the district court's grant of SJ of

noninfringement in favor of the defendants Cook Incorporated and W.L. Gore and Associates, Inc. (collectively "Cook"). The Federal Circuit determined that the district court had correctly construed certain claim terms and correctly determined that Cook's devices did not infringe under the district court's claim constructions.

Plaintiffs Edwards Lifesciences LLC and Endogad Research PTY Limited (collectively "Edwards") own four patents, which are related and share a common specification. The patents relate to intraluminal grafts for treating diseases of the blood vessels. Each of the asserted claims recite two of the following structures: a "graft," a "graft body," or a "graft structure," a "bifurcated base structure," and a "bifurcated base graft structure." Further, in each of the claims, the two elements were "anchored," "attached," "attachable," or "dockable" to each other while inside a vessel. The court construed those terms (1) to be intraluminal, (2) to require wires, (3) to require that those wires be malleable, and (4) to preclude resilience from such wires. The district court determined that the Cook devices did not infringe because the devices did not contain malleable wires, as the claims required.

"[C]laim differentiation is a rule of thumb that does not trump the clear import of the specification." Slip op. at 16.

On appeal, the Federal Circuit agreed with the district court that, in light of the specification, the claimed "graft" devices must all be intraluminal. The Court noted that, although the construction of a claim term is usually controlled by its ordinary meaning, an alternative meaning is appropriate if the patentee distinguished that term from prior art on the basis of a particular embodiment, expressly disclaimed subject matter, described a particular embodiment as important to the invention, or acted as its own lexicographer in defining a claim term. The Federal Circuit recognized that the terms "graft" and "intraluminal graft" were consistently used interchangeably. Further, the only devices described in the specification were intraluminal, supporting an interpretation that is consistent with that description. Moreover, the Court stated, "[W]hen the preferred embodiment is described in the specification as the invention itself, the claims are not necessarily entitled to a scope broader than that embodiment." Slip op. at 12 (quoting *Chimie v. PPG Indus. Inc.*, 402 F.3d 1371, 1379 (Fed. Cir. 2005)). Here, the specification frequently described an "intraluminal graft" as "the present invention" or "this invention," indicating an intent to limit the invention to intraluminal devices. *Id.*

The Federal Circuit also found that the claim language itself supported the district court's construction. The Court recognized that certain claims required that the grafts be attachable "while inside of a vessel," but noted that traditional vascular grafts are not implanted "inside of a vessel," and "intraluminal" specifically means "inside of a vessel." Therefore, the Federal Circuit found that the claims supported the district court's interpretation that a "graft body" must be intraluminal rather than being part of a traditional vascular graft.

Finally, the Court agreed that claim differentiation did not require that "graft" be read differently from "intraluminal graft." Although certain claims recited a "second graft . . . adapted to be intravascularly inserted into a lumen of [a] first graft," the intravascular insertion and the "intraluminal grafts" were not redundant. A device could theoretically be "intravascularly inserted" but ultimately reside outside of the vessel, such as inside the heart. Further, the Federal Circuit found that the doctrine of claim differentiation did not require the district court to give the "graft" devices their broadest possible meaning if the specification did not demand it. Although Edwards pointed to certain amendments made during prosecution to urge a broader claim construction, the Court found the accompanying remarks and inventors' statements indicated that the devices must be intraluminal.

The Federal Circuit then agreed that the claims required the devices to include wires because the devices were intraluminal and because each of the claims recited an attachment that required wires. In reaching this conclusion, the Court noted that the parties had agreed at trial that intraluminal devices required wires. Moreover, every embodiment described in the specification and shown in the drawings included wires. In addition, every claim also required that the two graft components be "anchored," "attached," "attachable," or "dockable" to each other, and the parties agreed that only wires performed that function. In addition, the Federal Circuit disagreed with Edwards's argument that because certain

dependent claims recited "a wire structure," the doctrine of claim differentiation required the Court to find that the independent claims did not require wires. The Court stated that "claim differentiation is a rule of thumb that does not trump the clear import of the specification," and the specification and the parties' agreement in the district court made it clear that the claimed graft devices required wires. *Id.* at 16.

Third, the Federal Circuit found that the wires required by the claims must be malleable because the inventors disclaimed the use of resilient, or self-expanding, wires. The Court noted that the inventors had disparaged prior art resilient wires in their "background art" section of the specification. Therefore, when the claims were read in light of the specification, a person of ordinary skill in the art would understand that the invention required malleable, rather than resilient, wires.

Further, although the inventors canceled claims during prosecution that required "malleable wires" and replaced them with claims requiring only "wires," the inventors conducted the prosecution as if the wires were required to be malleable. For example, in attempting to distinguish over certain prior art, Edwards stated that the written description expressly taught wires that were malleable and not self-expanding. Thus, the change in claim language did not affect the breadth of the claims because the inventors' statements indicated that the claims remained narrow.

Fourth, the Federal Circuit agreed that, in the context of the specification, malleable wires and resilient wires were mutually exclusive. The specification defined "malleable" to exclude any substantial resilience, and the Court found that that definition must override any ordinary meaning of the word "malleable" that might allow for substantial resilience.

Based on this construction, the Federal Circuit affirmed the grant of SJ of noninfringement for the accused Cook devices. The Court found that the wires in the accused devices were primarily resilient, self-expanding wires and therefore were not malleable, as required by the court's claim construction. In addition, the Court affirmed the district court's grant of SJ of noninfringement under the DOE because the inventors had disclaimed resilient wires and therefore could not use the DOE to recapture the disclaimed scope.

Absent Evidence of Cataloging Date, a Reference Registered at the Copyright Office and Cataloged in Commercial Databases May Not Be "Publicly Accessible" Prior Art

Nishla Keiser

Judges: Gajarsa, Linn, Prost (author)

[Appealed from Board]

In *In re Lister*, No. 09-1060 (Fed. Cir. Sept. 22, 2009), the Federal Circuit vacated and remanded the Board's decision that a prior art reference registered with the U.S. Copyright Office ("Copyright Office") and listed in the Westlaw and Dialog databases was publicly accessible for the purposes of 35 U.S.C. § 102(b).

More than two years before Dr. Richard Lister filed an application with the PTO on a method for playing golf, he described the method in a manuscript, submitted the manuscript to the Copyright Office, and received a certificate of registration. In the most recent final rejection of the application, the examiner rejected the pending claims as anticipated by Dr. Lister's manuscript ("the Lister manuscript") under 35 U.S.C. § 102(a) and (b).

Dr. Lister appealed to the Board, which reversed the § 102(a) rejection because that subsection requires description in a printed publication prior to the date of invention, and "[Dr.] Lister could not have disclosed his own invention before he invented it." Slip op. at 3 (alteration in original). Regarding § 102(b), the Board concluded that the copyright registration for the manuscript was issued more than one year prior to Dr. Lister's application date. The Board further found that the manuscript was publicly accessible through the Copyright Office, and affirmed the § 102(b) rejection.

On appeal, the Court evaluated whether the Lister manuscript met the requirements for a "printed publication." The Court first noted that a reference must have been sufficiently accessible to the public interested in the art in order to qualify as a printed publication bar under § 102(b). The Court stated that a reference is publicly accessible if it was "disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable

diligence, can locate it." *Id.* at 6 (quoting *Kyocera Wireless Corp. v. Int'l Trade Comm'n*, 545 F.3d 1340, 1350 (2008)). The Court explained that it must consider all facts and circumstances surrounding the disclosure and determine whether an interested researcher would have been sufficiently capable of finding the reference and examining its contents.

The parties agreed that the manuscript disclosed the claimed invention, that the Copyright Office issued a certificate of registration for the Lister manuscript more than two years before the application filing date, and that the Copyright Office maintained a copy of the manuscript in Washington, DC. It was also undisputed that a copy of the manuscript was available upon request to be inspected by the public and that, absent limited special circumstances, the Copyright Office would neither provide copies of the manuscript nor permit individuals inspecting the document to make copies themselves. However, the parties disputed when, and if, the manuscript was listed in a catalog or index that would have allowed an interested researcher to locate the reference.

"[I]n this case the government has not identified any evidence . . . with regard to database updates. Absent such evidence, we have no basis to conclude that the manuscript was publicly accessible prior to the critical date." Slip op. at 16.

The Court first considered whether the manuscript was available for inspection, and disagreed with Dr. Lister's first argument that the burden of traveling to Washington, DC, and navigating the Copyright Office's procedures would preclude a finding of general availability. The Court found that any member of the public who submits a proper request is capable of gaining access to the manuscript, and that a reference can be publicly accessible, even if significant travel is required. Further, the Court held that it is not necessary to show that anyone actually inspected the reference once accessibility is shown. Finally, the Court agreed with the Board's conclusion that an interested researcher would be able to gain and retain an understanding of the invention upon inspection of the manuscript and without any need to obtain a copy.

After establishing that the Lister manuscript was available for inspection, the Federal Circuit considered whether anyone would have been able to learn of its existence and potential relevance prior to the critical date. The Court first addressed Dr. Lister's argument that the catalogs and databases relied upon by the Board were not sufficiently searchable to lead an interested researcher to the manuscript. In particular, the Court noted that there were three relevant databases: the Copyright Office's automated catalog, Westlaw, and Dialog. The Copyright Office's catalog was searchable only by author's last name or the first word of the work's title, while Westlaw and Dialog obtained data from the Copyright Office and allowed for keyword searches of the full titles but not the full texts of the works.

Regarding the Copyright Office's catalog, the Court found that neither searching by author nor the first word in the title ("Advanced") would guide a researcher interested in his golfing method to the manuscript. But the Court found that because the Westlaw and Dialog databases permit searching of titles by keyword, a reasonably diligent researcher could have found the manuscript by searching for the word "golf" in combination with the word "handicap." Thus, the Court decided that the Lister manuscript was publicly accessible as of the date that it was included in either Westlaw or Dialog.

Finally, the Court addressed whether the Lister manuscript was publicly accessible in Westlaw or Dialog more than one year prior to the critical date. According to M.P.E.P. § 2128, absent evidence of the public posting date, disclosures on the Internet or on an on-line database cannot be relied upon as prior art under 35 U.S.C. § 102(a) or (b) if the publication itself does not include a publication date or retrieval date. The Court rejected the government's arguments regarding the Lister manuscript's public posting date.

The Court rejected the government's reliance on Dr. Lister's IDS statement that "[t]he information contained in [the commercial] databases comes *directly* from the Library of Congress." *Id.* at 15. According to the Court, the word "directly" did not

indicate that the manuscript was listed in Westlaw or Dialog shortly after the Copyright Office issued Dr. Lister's certificate of registration, as asserted by the government. The Court reasoned that Westlaw or Dialog could acquire the catalog information "directly" ten years after it was first generated for the Copyright Office catalog. Further, the Court noted that there was no other evidence regarding the timing or process used by Westlaw or Dialog to incorporate the Copyright Office's information. Absent such evidence, the Court determined that it could not conclude that the manuscript was publicly accessible prior to the critical date.

The Court also rejected the government's argument that it made a prima facie showing that the manuscript was included in the commercial databases shortly after the Copyright Office granted the certificate of registration that justified shifting the burden to Dr. Lister to present evidence to the contrary. The Court found that all the evidence showed was that, at some point in time, the commercial databases incorporated the Copyright Office's automated catalog information about the Lister manuscript into their own databases. The Court concluded that, absent any evidence pertaining to the general practices of Westlaw and Dialog regarding the timing of updates from the Copyright Office, the government's presumption that the manuscript was added to Westlaw and Dialog prior to the critical date would be pure speculation. Accordingly, the Court ruled that the Board erred in affirming the § 102(b) rejection.

Genuine Issues of Material Fact Preclude SJ on Breach of a Nondisclosure Agreement Due to Misuse of Confidential Information

Ceyda A. Maisami

Judges: Schall, Plager, Moore (author)

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

In *Kara Technology Inc. v. Stamps.com, Inc.*, Nos. 09-1027, -1028 (Fed. Cir. Sept. 24, 2009), the Federal Circuit vacated-in-part, reversed-in-part, and remanded the district court's decision that Stamps.com, Inc. ("Stamps") did not infringe various claims of U.S. Patent Nos. 6,505,179 ("the '179 patent") and 6,735,575 ("the '575 patent"), owned by Kara Technology Incorporated ("Kara"), with its Pre-Version 5 ("Pre-V5") or Versions 5 and later ("V5") products, and that Stamps did not breach its nondisclosure agreement ("NDA") with Kara.

Kara owns the '179 and '575 patents relating to apparatuses and methods of creating and verifying the authenticity of documents, such as postage. The patents concern technology that allows a customer to print a secured document (such as a stamp or an airline ticket) at home using preprinted label sheets. Stamps approached Kara to collaborate on Kara's PC-based stamp technology, and in May 2000, they signed an NDA requiring Stamps to "keep secret and not disclose . . . and not use for its own use in any capacity whatsoever any Confidential Information for any purpose other than for the purpose for which such information was disclosed." Slip op. at 3-4 (alteration in original) (citing NDA, ¶¶ 1, 3). Further, the NDA specifically provided that Stamps was not permitted to "make written, electronic, or photostatic copies or excerpts of or summaries of Confidential Information" without prior written consent from Kara. *Id.* at 4 (citing NDA, ¶ 5).

In July 2000, Stamps indicated it was no longer interested in pursuing a business relationship with Kara. In October 2001, Stamps announced that the U.S. Postal Service had approved beta testing of its PC-based postage product. The Pre-V5 product was launched commercially in July 2002 and the V5 line was launched in June 2005. In 2004, Kara brought suit against Stamps, alleging infringement and breach of contract.

Following a jury trial, the jury found that neither the Pre-V5 nor the V5 line of products infringed the asserted claims. The district court then entered judgment, holding that Stamps was the prevailing party. Kara subsequently filed a renewed JMOL motion that Stamps' Pre-V5 product infringed claim 42 of the '575 patent and claims 36, 38, and 42 of the '179 patent, a motion for a new trial, a motion to strike the part of the July 16 judgment stating that Stamps was the prevailing party, and a motion to dismiss Stamps' invalidity and unenforceability counterclaims. In September 2008, the district court denied the motions for a new trial and renewed JMOL, but granted the motion to strike the reference to Stamps as a prevailing party, entered judgment for Kara on the counterclaim of unenforceability, and dismissed the invalidity counterclaims without prejudice.

On appeal, the Federal Circuit vacated the judgment of noninfringement, concluding that the district court erred in construing the claims. The Court held that "[t]he central dispute concerns the meaning of the underlined language describing the creation and validation of the security indicia," and "whether the security indicia must be created and validated under control of a key contained in the preestablished data." *Id.* at 7. The Federal Court further added, "The disputed terms and phrases require that the information or data contained in the preestablished data be used to create and validate the security indicia, but contrary to the district court's determination and Stamps.com's arguments, they do not require a key or cryptographic key in the preestablished data." *Id.* at 10. The Court then remanded the proceedings to the district court for further proceedings because "we do not . . . believe it would be appropriate to rule as a matter of law on the issue of the Pre-V5 infringement in the first instance in light of alternative arguments of noninfringement that Stamps.com presented to the jury." *Id.* at 11-12.

The Court next analyzed whether the district court erred by granting the SJ motion, finding that the statute of limitations for the contract claim had run because the claim was barred by the four-year statute of limitations under the applicable state law (Texas state law), or, in the alternative, that the NDA did not protect Kara's trade secrets. The Court stated that, assuming arguendo that the statute of limitations had not run, all alleged "confidential" information was in the public domain. Thus, Stamps could not have breached the NDA by copying and retaining the information learned through its business dealings with Kara.

Kara alleged two separate breaches of the NDA. The first was based on Stamps' admitted note-taking during a May 2000 business meeting, in violation of paragraph 5 of the NDA. The second was based on Stamps' alleged use of Kara's confidential information to develop Stamps' PC-based postage products, in violation of paragraph 3 of the NDA. In agreeing with the district court that the note-taking breach is barred by the statute of limitations, the Federal Circuit stated, "There is no real dispute that Kara knew or should have known of this breach at the time it occurred, as the meeting was attended by several of Kara's employees, including its President and Chief Operating Officer. Kara did not file its complaint until October 22, 2004, and therefore any claim based on this breach is barred by Texas's four-year statute of limitations." *Id.* at 13.

Finally, the Federal Circuit reversed the district court's grant of SJ on the breach of contract claim and remanded for further proceedings because "there are material issues of fact in dispute regarding breach of the NDA due to misuse of the confidential information." *Id.* at 15. The Federal Circuit further added that material factual disputes existed concerning what was disclosed at a presentation by Kara employees and what one skilled in the art would have understood from Kara's exhibit at a stamp expo. *Id.* The Federal Court further stated, "Because we conclude that the district court erred when construing the claims, we vacate the judgment of noninfringement and remand. Because the district court erred by granting [SJ] on the breach of contract claim when there exist disputes of material fact on Stamps.com's alleged misuse of information, we reverse and remand." *Id.* at 16.

Patent Claiming a Method of Treatment Was Not Enabled Where It Failed to Establish Utility

Jared D. Schuettenhelm

Judges: Mayer, Gajarsa (dissenting), Dyk (author)

[Appealed from D.N.J., Judge Pisano, and D. Del., Judge Robinson]

In *In re '318 Patent Infringement Litigation*, Nos. 08-1594, 09-1070, -1088 (Fed. Cir. Sept. 25, 2009), the Federal Circuit affirmed the district court's judgment against Janssen Pharmaceutica N.V., Janssen L.P., and Synaptech, Inc. (collectively "Janssen"), holding that the claims of U.S. Patent No. 4,663,318 ("the '318 patent") were invalid for lack of enablement.

The '318 patent claims a method for treating Alzheimer's disease with galanthamine. At the time the '318 patent application was filed in 1986, researchers had observed a correlation between Alzheimer's disease and reduced levels of the neurotransmitter acetylcholine in the brain. During neurotransmission, acetylcholine is released by a transmitting neuron and binds to receptors

on a receiving neuron. Galanthamine inhibits acetylcholinesterase, an enzyme that breaks down acetylcholine. Accordingly, acetylcholinesterase inhibitors such as galanthamine increase the amount of acetylcholine available for binding to receptors on receiving neurons.

The specification of the '318 patent application was just over one page in length and provided short summaries of six scientific papers in which galanthamine had been administered to humans or animals. The Court found that the specification did not provide analysis or insight connecting the results of any of these six studies to galanthamine's potential to treat Alzheimer's disease in humans.

"[A]t the end of the day, the specification, even read in the light of the knowledge of those skilled in the art, does no more than state a hypothesis and propose testing to determine the accuracy of that hypothesis. That is not sufficient." Slip op. at 16.

During prosecution, the examiner rejected the claims in the '318 patent application as obvious in light of the cited animal studies. In response, the inventor stated that because the brains of the animals in the cited studies were normal rather than having physiological changes similar to Alzheimer's disease, the studies had no relevance to Alzheimer's disease. As a result, the inventor stated that it would be "baseless" to predict that galanthamine would be useful to treat Alzheimer's disease from these studies. The inventor then stated that "experiments [are] underway using animal models which are expected to show that treatment with galanthamine does result in an improvement in the condition of those suffering from Alzheimer's disease." Slip op. at 7 (alteration in original) (citation omitted). Because the inventor did not learn the results of the animal testing experiments until after the '318 patent had issued, the results were never submitted to the PTO.

In 2005, several generic drug manufacturers filed ANDAs and Paragraph IV certifications with the FDA, seeking approval to market generic versions of galanthamine. Janssen sued each manufacturer for infringing the '318 patent and the actions were subsequently consolidated. The defendants conceded infringement of claims 1 and 4, but asserted that the '318 patent was invalid based on anticipation, obviousness, and lack of enablement. After a bench trial, the district court held that the patent was neither anticipated nor obvious, but that it was invalid for lack of enablement.

On appeal, the Federal Circuit noted the close relationship between enablement and utility. The Court stated that, "[i]f a patent claim fails to meet the utility requirement because it is not useful or operative, then it also fails to meet the how-to-use aspect of the enablement requirement." *Id.* at 10 (emphasis omitted) (quoting *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1358 (Fed. Cir. 1999)). The Court observed that the utility requirement prevents mere ideas from being patented. In addition, the Court noted that the utility requirement prevents the patenting of mere research proposals or an invention that is simply an object of research.

The Federal Circuit also observed that patent applications claiming new methods of treatment typically demonstrate utility by providing test results. But the Court affirmed that such testing need not be conducted by the inventor. Further, human trials are not necessary to support the utility of a therapeutic invention. Instead, in vitro test results for a claimed pharmaceutical compound, combined with animal test results for a structurally similar compound, may provide a reasonable correlation sufficient to satisfy the utility requirement.

Here, the Court found that neither in vitro test results nor animal test results involving the use of galanthamine to treat Alzheimer's-like conditions were provided. In addition, because the proposed animal test results were not available at the time of the application, they could not be used to establish enablement. Janssen argued, however, that the specification established utility by analytic reasoning. Janssen asserted that the prior art tests summarized in the specification would lead one skilled in the art to infer that galanthamine affected the ability of acetylcholine to bind to receptors in the brain. Since these receptors involve the ability to learn, Janssen argued that the specification suggested that galanthamine could have beneficial effects on learning.

The Federal Circuit was not persuaded by these arguments, noting that these insights were not

described in the specification. The Court also found that there was no evidence that a person skilled in the art would infer galanthamine's utility from the specification, even if such inferences could substitute for an explicit description of utility.

Moreover, the Court found the testimony of Janssen's expert witnesses fell far short of demonstrating that a person of ordinary skill in the art would have recognized that the specification conveyed the required assertion of a credible utility. The Court also noted the inventor's testimony revealed that an ordinary skilled artisan would not have viewed the patent's disclosure as describing the utility of galantamine as a treatment for Alzheimer's disease.

Accordingly, the Court found that "at the end of the day, the specification, even read in the light of the knowledge of those skilled in the art, does no more than state a hypothesis and propose testing to determine the accuracy of that hypothesis." *Id.* at 16. This was insufficient to establish utility. As a result, the Federal Circuit held that the '318 patent did not satisfy the enablement requirement because it did not establish utility.

Judge Gajarsa dissented, stating that that the district court did not undertake the required legal analysis to determine whether an ordinary skilled artisan reading the patent would understand it to reveal a credible utility for the invention. Further, Judge Gajarsa found that the district court failed to make the factual findings necessary to support the ultimate legal conclusion regarding enablement. Judge Gajarsa noted the majority's finding that where the record would not support a finding of utility, the absence of findings by the district court on the issue of whether a person skilled in the art could infer utility from the prior art described in the specification was not error. In response, Judge Gajarsa stated that because there was evidence of record that supported a conclusion that the '318 patent claims were not invalid, it was inappropriate for the Court to weigh the evidence and make contrary factual findings, especially in the absence of any consideration by the district court of numerous prior art references that were specifically discussed in the patent. Thus, Judge Gajarsa would have vacated the judgment and remanded the case to the district court to make the required factual findings and perform the necessary legal analysis.

Failure to Provide Unpublished Information About Less Similar Compounds Is Not Inequitable Conduct

Wesley B. Derrick

Judges: Newman (author), Rader, Prost

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

In *AstraZeneca Pharmaceuticals LP v. Teva Pharmaceuticals USA, Inc.*, Nos. 08-1480, -1481 (Fed. Cir. Sept. 25, 2009), the Federal Circuit affirmed the district court's SJ that appellants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively "Teva") and Sandoz, Inc. ("Sandoz") had not presented evidence sufficient for a reasonable jury to find that, during prosecution of the subject patent application, AstraZeneca Pharmaceuticals LP and AstraZeneca UK Limited ("AstraZeneca") had misrepresented or omitted material fact with intent to mislead the patent examiner.

The patent at issue, U.S. Patent No. 4,879,288 ("the '288 patent"), assigned to AstraZeneca, claims the antipsychotic drug quetiapine (marketed under the brand name "SEROQUEL®"). The claimed drug is an "atypical" antipsychotic, lacking undesirable side effects associated with "typical" antipsychotics, such as involuntary body movements including torsion spasms, muscle spasms and dystonia of the face, neck, or back with protrusion of the tongue, and tonic spasms of the limbs (dyskinesia). The '288 patent expires on September 26, 2011.

Teva and Sandoz, both generic drug manufacturers, each filed an ANDA seeking FDA approval to market a generic version of Seroquel®. AstraZeneca responded by filing suit against both for patent infringement. The suits were consolidated in the U.S. District Court for the District of New Jersey. The district court granted SJ that there was no inequitable conduct during prosecution.

On appeal, Teva and Sandoz only challenged the SJ of no inequitable conduct. The Federal Circuit noted that "[a]lthough the premises of inequitable conduct require findings based on all the evidence, . . . a motion for summary judgment

may be granted when, drawing all reasonable factual inferences in favor of the non-movant, the evidence is such that the non-movant can not prevail." Slip op. at 3 (quoting *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 547 (Fed. Cir. 1998)). As stated by the Court, the issue in the case "relate[d] to the extent to which the patent applicant, having fully disclosed the relevant prior art and having provided comparative data to the satisfaction of the patent examiner, must also present any additional unpublished information in the applicant's possession concerning other less structurally similar compounds, and must also synthesize additional compounds for comparative testing." *Id.* at 4. According to the Court, both the materiality of withheld information and deceptive intent must be separately proved and, if both are proved, materiality and deceptive intent are balanced by the court, with cognizance of the underlying facts, to determine whether there was inequitable conduct. Finally, the Court stated that if a district court finds there was inequitable conduct, it may, in its discretion, declare the patent unenforceable.

"The law is clear that 'inequitable conduct requires not intent to withhold, but rather intent to deceive. Intent to deceive cannot be inferred simply from the decision to withhold [information] where the reasons given for the withholding are plausible.'" Slip. op. at 16 (alteration in original) (quoting *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1367 (Fed. Cir. 2003)).

The Court noted that the prior art references at issue had been presented to the PTO in AstraZeneca's Information Disclosure Statement ("IDS"), which had been submitted before the examiner's first Office Action. Four compounds listed in the prior art references identified in the IDS were relevant compounds. The compounds included Compound 21076, Compound 24028 ("Schmutz B"), perlapine ("Schmutz I"), and fluperlapine. Although AstraZeneca possessed internal test data for these compounds, as well as for many other compounds, it did not include this internal data in the IDS.

Teva and Sandoz argued that AstraZeneca's data showed that some prior art compounds potentially exhibited atypical antipsychotic activity, and that this information should have been reported to the patent examiner.

The Court examined whether the information allegedly withheld could establish the fact of materiality and whether there was evidence of intentional withholding of the information. Noting that there are several standards for establishing materiality, the Court addressed the most frequently employed test, which questions "whether a reasonable examiner would have considered the information important in deciding whether to grant the patent, even when the omitted information does not negate patentability." *Id.* at 10. The Court considered the argument by Teva and Sandoz that AstraZeneca misrepresented that the atypical properties of quetiapine were unexpected, presenting only internal test data from compounds that were typical while omitting internal test data from those that were potentially atypical. It also considered the argument by AstraZeneca that it performed the comparison requested by the examiner, and that it never represented that quetiapine's atypical properties made it completely unique, noting it identified the references describing the compounds that are allegedly atypical antipsychotics.

The Court concluded that "[n]o relevant reference [was] asserted to have been withheld." *Id.* at 11. The Court further noted that various references indicate that certain prior art compounds were known to be atyptical antipsychotics. Further, noting that the examiner made his prima facie obviousness rejection with all the references before him, the Court addressed the contentions that AstraZeneca falsely stated that generating test data on relevant prior art compounds would be very expensive, and that AstraZeneca should have submitted its existing test data for these compounds because their structures are equally close to quetiapine. The Court rejected the notion that AstraZeneca falsely stated that generating test data on the relevant prior art compounds would be very expensive. Specifically, the Court noted that, in this case, there was no evidence that if such tests had been conducted, it would have been material to patentability, as no showing was made that structural similarity between the compounds would establish that the prior art compounds would have atypical properties.

Regarding the determination of which compounds are more structurally similar, the Court stated that precedent suggests ascertaining the common elements of the claimed invention and the prior art. In this case, that was concluded to be the core structure. Thus, once the core structure was identified, the similarity of appended side chains must then be considered. The Court found this process consistent with what was asserted by AstraZeneca, not disputed by the examiner, and led to its conclusions that AstraZeneca's substitution of references was not a material misrepresentation, and the nonprovision of data on the less structurally similar Compound 24028 was not a material omission.

The Court then rejected Teva and Sandoz's argument that AstraZeneca's submission of its internal test data along with its internal test data of prior art references was an implied misrepresentation because it omitted other internal test data, including that for fluperlapine, perlapine, Compound 21076, and Compound 24028. The Court noted that AstraZeneca had not asserted that no prior art compound was atypical, but that the structurally closest prior art compounds, as required by the examiner, did not possess the same properties as quetiapine.

The Court then addressed whether Teva and Sandoz could establish the intent to deceive required for a finding of inequitable conduct by clear and convincing evidence. It first dismissed as incorrect that a high level of materiality allowed for a proportionately lesser showing of intent to deceive. The Court set forth that the only evidence of intent offered was AstraZeneca's internal knowledge that certain compounds of this structural class were atypical, and that it did not include this information in the IDS. The Court stated that the law was clear that inequitable conduct requires more than an intent to withhold, but rather required an intent to deceive. The Court further stated that intent to deceive cannot be inferred simply from the decision to withhold information where the reasons for withholding the information are plausible, as in this case, where the examiner focused on the other structurally closest compounds.

Finally, the Court agreed with the district court's conclusion that the Appellants had not provided evidence sufficient to establish the threshold facts of material withholding with intent to deceive and affirmed the district court's grant of SJ.

Communications from the Government, Reinforced by Its Representations to the Federal Circuit, Can Establish the Applicability of § 1498(a)

Aaron J. Capron

Judges: Newman (author), Prost, Moore

[Appealed from E.D. Mo., Judge Perry]

In *Advanced Software Design Corp. v. Federal Reserve Bank of St. Louis*, No. 08-1152 (Fed. Cir. Sept. 30, 2009), the Federal Circuit affirmed the district court's grant of SJ dismissing certain counts of a patent infringement suit brought by Advanced Software Design Corporation and its founder, Calin A. Sandru (collectively "Advanced Software"). The Court determined that the allegedly infringing acts relevant to this appeal were for the United States, and with its authorization and consent, and thus could only be pursued in the Court of Federal Claims under 28 U.S.C. § 1498(a).

Advanced Software sued Fiserv, Inc. ("Fiserv") and three regional Federal Reserve Banks, alleging infringement of U.S. Patent Nos. 6,792,110, 6,549,624, and 6,233,340, all of which relate to a method for detecting fraudulent bank checks.

The technology charged with infringement is called seal encoding technology, which places check identifying data in a seal on the face of a check when the check is printed. Using software programmed with the encryption system, a bank at which the check is processed after its deposit can decode the seal and compare the decoded information to the information on the check. Any discrepancy will alert the bank to a possible altered or counterfeit check. Because the procedure involves both encoding, which takes place when the checks are issued, and decoding and verification, the technology depends on participation by the check issuer and the bank that processes the check after its deposit. As concerns the involvement of the United States, the assertions of infringement arise from the use of this system with checks issued by the U.S. Department of the Treasury ("Treasury").

Prior to adoption of the seal encoding system, the Treasury and its Financial Management Service ("FMS") would have to verify each deposited,

Treasury-issued check. By the time a fraudulent check was identified by the Treasury, a perpetrator would already have received the funds from a bank of first deposit, leaving the bank or Federal Reserve Bank to bear the loss. With the seal encoding system, Federal Reserve Banks, without any verification by the Treasury, could detect fraudulent checks, thereby preventing funds from being transferred to the perpetrator.

Fiserv and one of the Federal Reserve Banks negotiated a contract to conduct a pilot project using the seal encoding technology. While not a party to the contract, the Treasury participated in the pilot program by printing the encoded checks and had discussions with the Federal Reserve Bank to modify the language of the contract to reflect the joint project.

"The communications from the United States to the Federal Reserve Banks, reinforced by the request by the United States to intervene in the district court and its representations to this [C]ourt that the accused activities are 'for the United States' and with its authorization or consent, established the applicability of §1498(a)." Slip op. at 8.

Based on these facts, the district court granted defendants' SJ motion, dismissing the infringement claims that were based on Treasury checks and ruling that the alleged acts of infringement were "for the United States" and could only be litigated in the Court of Federal Claims. Based on this dismissal, the district court also denied as moot the United States' motions to intervene and for SJ on the grounds that the accused acts were for the United States.

On appeal, the Federal Circuit first observed that the coverage of § 1498 should be broad so as not to limit the government's freedom. While the statute removes the threat of an injunction, it requires the government—not a third party—to be liable for an infringing use. When the alleged infringement is by the third-party nongovernment entity, the statute states that the accused activity is "for the United States" if it was conducted (1) for the government, and (2) with the authorization or consent of the government.

The Federal Circuit first considered the second prong—whether the accused activity was conducted with the authorization or consent of the government. While failing to include an explicit contractual authorization or consent of the government, the record provided a correspondence between officials at the Treasury and the Federal Reserve Banks regarding the participation of the Treasury in adopting the seal encoding technology. In correspondence to one of the Federal Reserve Banks, the Commissioner of Treasury FMS stated that, depending on the outcome of the pilot program, the FMS intended to implement the seal encoding technology in their production of checks. The government, in its brief as amicus curiae on this appeal, stated that this correspondence constitutes express authorization or consent to the Federal Reserve Banks to make use of the seal encoding technology. The government pointed out that the Deputy Commissioner of FMS confirmed this authorization in a declaration to the district court. Relying on precedent holding that "'authorization or consent' on the part of the [g]overnment may be given in many ways," the Federal Circuit agreed with the district court that authorization or consent by the government was achieved based on the Treasury's correspondence and unequivocal statements in the declaration. Slip op. at 11 (quoting *Hughes Aircraft Co. v. United States*, 534 F.2d 889, 901 (Ct. Cl. 1976)).

The Federal Circuit also noted that the United States made several representations in its amicus curiae brief, its motion to participate in oral argument before the Court, and during oral argument, which were fully in accord with the conclusion of the district court. In the motion to participate, the government stated that it "has an interest in preventing any interference with its fiscal agent, the Federal Reserve Banks, in performing work for the government." *Id.* Further, during oral argument, the government provided authorization, if it had not done so already, for the allegedly infringing acts of the third parties and consented to liability under § 1498, relieving the third parties of any liability.

The Court next considered the first prong—whether the accused activity was conducted for the government. First, the Court noted that § 1498 does not require the government to be a party to any contract, but may apply to activities by "any person, firm, or corporation" for the benefit of the government. The Court also stated that, to be a beneficiary for the purpose of § 1498, it was not necessary to be the sole beneficiary. Acknowledging national interest in averting fraud using Treasury checks and saving Treasury resources by adopting this efficient technology, the Federal Circuit agreed with the district court that there were significant benefits to the United States.

The Court, disagreeing with Advanced Software's arguments that the government only received an incidental benefit, held that the benefits to the government of using the seal encoding technology on Treasury checks were not mere incidental effects. It reasoned that the seal encoding technology for Treasury checks required the Treasury's participation in every encoded Treasury check. Accordingly, because of the significant benefits received by the Treasury, the Court determined that the accused activity was conducted for the government.

Accordingly, the Federal Circuit discerned no error in the district court's ruling that the Federal Reserve Banks acted for the government when they contracted to adopt technology to detect fraudulent Treasury checks. Thus, the Court affirmed the district court's ruling that § 1498 applies to the counts involving Treasury checks.

Plaintiff Lacked Standing to Sue for Patent Infringement Where an Inventor Validly Transferred His Title to a Third Party Before Reducing It to Practice

Sean A. O'Donnell

Judges: Linn (author), Prost, Moore

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

In *Board of Trustees of Leland Stanford Junior University v. Roche Molecular Systems, Inc.*, Nos. 08-1509, -1510 (Fed. Cir. Sept. 30, 2009), the Federal Circuit affirmed the district court's ruling that the counterclaim of ownership by cross-appellants Roche Molecular Systems, Inc., Roche Diagnostics Corporation, and Roche Diagnostic Operations, Inc. (collectively "Roche") was barred by California statutes of limitation, but claims for infringement by appellant Board of Trustees of the Leland Stanford Junior University ("Stanford") failed for lack of standing due to Stanford's defective title in the patents-in-suit.

The patents-in-suit, U.S. Patent Nos. 5,968,730 ("the '730 patent"), 6,503,705 ("the '705 patent"), and 7,129,041 ("the '041 patent"), claim methods for quantifying the Human Immunodeficiency Virus ("HIV") in human blood samples and correlating those measurements with the therapeutic effectiveness of antiretroviral drugs. The claimed methods use polymerase chain reaction ("PCR") to measure ribonucleic acid ("RNA") from HIV in the blood plasma of humans taking such drugs. All three patents descend from a common parent. Three Stanford researchers—Mark Holodniy, Thomas Merigan, and David Katzenstein—are named inventors on all three patents.

Stanford sued Roche in the Northern District of California on October 14, 2005, alleging infringement. Roche answered and counterclaimed against Stanford, Merigan, and Holodniy, asserting, inter alia, that Stanford lacked standing and that Roche possessed ownership, license, and/or shop rights to the patents through Roche's acquisition of Cetus's PCR assets. Roche pleaded its ownership theory as a DJ counterclaim, an affirmative defense, and a challenge to Stanford's standing to sue for infringement.

The parties cross-moved for SJ on Roche's rights. The district court construed Roche's pleading under Fed. R. Civ. P. 8(c) as a counterclaim but not as an affirmative defense. The district court held that (1) Roche's ownership claims were barred by California statutes of limitation, laches, and the Bayh-Dole Act ("the Act"); (2) Roche's license claims failed because Stanford never consented to Roche's acquisition of Cetus's patent licenses; and (3) Roche lacked shop rights. Roche petitioned for a writ of mandamus to vacate the ruling, but the Court denied it.

After a *Markman* hearing, the district court construed certain claim terms, whereupon Roche

moved for SJ that the asserted claims were invalid as obvious. The district court ruled in Roche's favor. Stanford appealed the district court's claim construction and invalidity holding, and Roche cross-appealed the judgment regarding the parties' respective rights in the patents.

On appeal, Stanford challenged the propriety of Roche's cross-appeal on grounds that Roche's license arguments did not seek to modify the judgment below and therefore were not the proper subject of a cross-appeal. The Court disagreed. Reasoning that Stanford's appeal of the district court judgment applies only to the asserted claims of the patents-in-suit and that Roche's ownership and license arguments apply to the patents as a whole, the Court held that Roche's motion sought to enlarge its own rights under the judgment, and such efforts are the proper subject of a cross-appeal.

Before the district court, Roche had tried to defeat Stanford's suit based on Stanford's defective title and to obtain a judgment that it owned Holodniy's interest in the patents-in-suit. The Court agreed with the district court that California's statutes of limitation barred Roche's counterclaim for a judgment of ownership, but rejected the district court's holding that such determination defeated Roche's ownership and standing defenses. The Court held that, pursuant to Rule 8(c)(2), the district court abused its discretion by striking Roche's affirmative defense that Stanford has defective title to the patents-in-suit. According to the Court, Rule 8(c)(2) generally favors defendants by construing responsive pleadings liberally to maximize the defendant's available legal theories, and it allows a party to plead alternative statements. The district court was thus obligated to consider Roche's counterclaim and defenses.

The Court also held that California law allows a party to raise a defense at any time, even if a claim would be barred by a statute of limitations. Thus, California's statutes of limitation regarding ownership disputes would not bar Roche's defense of ownership. The Court also found Stanford's assertions of laches defective for similar reasons. As for Stanford's equitable estoppel claims, the Court held that they failed for lack of evidence that Roche made any misrepresentations or concealed any facts about ownership. The Court noted that Roche's defense challenging Stanford's standing due to defective title was critical, stating, "It is well settled that questions of standing can be raised at any time and are not foreclosed by, or subject to, statutes of limitation." Slip op. at 10.

According to the Court, the substantive question of who owns the patents-in-suit turned on whether the relevant patent assignment clauses created an automatic assignment or a mere obligation to assign. Holodniy signed multiple contracts regarding the invention rights in dispute. The Copyright and Patent Agreement ("CPA") with Stanford, for example, states that Holodniy "agree[s] to assign or confirm in writing to Stanford and/or Sponsors" the rights to inventions he may conceive or actually reduce to practice. *Id.* at 11 (emphasis omitted). The Court held that this language shows only an agreement to assign Holodniy's invention rights at some future time, so Stanford did not obtain title to Holodniy's inventions at the time of signing nor at the time of invention. The Visitor's Confidentiality Agreement ("VCA") with Cetus, meanwhile, recites, "I will assign and do hereby assign to CETUS, my right, title, and interest in each of the ideas, inventions and improvements." *Id.* at 12 (emphasis omitted). According to the Court, such language served to immediately transfer to Cetus equitable title in Holodniy's inventions. In addition, legal title vested in Cetus on May 4, 1992, when the parent application for the inventions was filed. Thus, the Court determined that Holodniy had no rights to transfer when he subsequently tried to assign them to Stanford on May 4, 1995.

The Court gave little consideration to Stanford's assertions that a genuine factual dispute existed regarding whether the patents arose as a consequence of Holodniy's access to Cetus's facilities, as required under the VCA. According to the Court, it is undisputed that Holodniy received from Cetus a PCR protocol, equipment for HIV RNA extraction, and access to necessary equipment that he used to develop the HIV RNA assay. Moreover, even if Holodniy conceived and reduced to practice the invention after departing Cetus, this event took place no later than the application date of May 14, 1992, and his research was still directly related to the collaboration with Cetus. Accordingly, the Court held Holodniy's later attempt to transfer title to Stanford in 1995 was still defective.

The Court also rejected Stanford's argument that it was a bona fide purchaser under 35 U.S.C. § 261 on grounds that Stanford had constructive notice of Cetus's claims to Holodniy's invention. According to the Court, a bona fide purchaser is one who purchases legal title to property in good faith for valuable consideration and without notice (constructive or actual) of any other claim of interest. The Court found that Stanford received constructive notice of Cetus's interest at least through Holodniy's employment by Stanford, and that, because Holodniy executed the VCA, his knowledge of it was imputed to his employer. Moreover, the Court also found that Stanford had similar notice through Holodniy's supervisor, who directed Holodniy to work with Cetus and executed agreements of his own that transferred intellectual property rights to Cetus. Although Stanford asserted that Holodniy signed the VCA solely on his own behalf, not Stanford's, the Court found that this argument missed the point. According to the Court, the VCA indicates that Holodniy was acting as an independent contractor with respect to Cetus, not with respect to Stanford, and that "Holodniy [had] signed away his *individual* rights as an inventor, not Stanford's." *Id.* at 15-16.

The Court overruled the district court's holding that the Act negated Holodniy's assignment to Cetus and that it empowered Stanford to take complete title to the inventions. The Court noted that 35 U.S.C. §§ 200, 202 allow the government to take title to "subject inventions" under certain circumstances, or the "contractor" universities or inventors to retain ownership if the government does not. Citing prior rulings, however, the Court held that nothing in the statutes, regulations, or Federal Circuit case law indicates that title is automatically forfeited when the Act's provisions are violated. At most, the Act would provide the government with a discretionary option to Holodniy's rights. Concerning Stanford's rights, the Court held that its election of title under the Act also did not have "the power to void any prior, otherwise valid assignments of patent rights." *Id.* at 17. Critically, Stanford's claim of title under the Act occurred after Holodniy's valid transfer of rights to Cetus (six years after), and the Court explained that such election cannot give Stanford superior title to a prior valid assignment.

The Court saw no merit in Stanford's argument that Cal. Bus. & Prof. Code § 16600 (2009) voids the VCA. The Court noted that under section 16600, every contract is void to the extent that it restrains anyone "from engaging in a lawful profession, trade, or business of any kind." *Id.* at 19. The Court found that Stanford provided no evidence that the VCA restrained Holodniy from engaging in any profession; rather, the record shows that Holodniy continued his research, published articles, and further developed the technology after ending his work at Cetus. Moreover, the Court held that section 16600 applies to restrictions on departing employees, not to assignments of patent rights.

The Court applied California statutory limitations law to determine that a four-year deadline applies to Roche's DJ action requesting a judgment that it owns the patents-in-suit. Noting that such ownership disputes are normally a matter of state law, the Court held that Cal. Civ. Proc. Code §§ 337(1) and 343 (2009) apply to Roche's claims and both set a limit of four years. The Court stated that tolling begins for a DJ action when the corresponding claim for damages or injunction accrues, but tolling is delayed until the plaintiff discovers, or has reason to discover, the cause of action. The Court agreed with the district court that Roche's claim accrued no later than April 2000. The Court found that Stanford's slide presentation to Roche on April 6, 2000, asserted Stanford's ownership of the HIV RNA assays, indicated that applications descending from the parent were pending, and stated that Stanford was offering licenses to Roche for the relevant patents (including those yet to issue). The Court reasoned that these representations directly contradicted the transfer of rights manifested in the VCA and therefore put Roche on notice that Stanford was claiming rights to Holodniy's inventions.

The Court rejected Roche's argument that the cause of action for patent ownership does not accrue until each patent issues. The Court distinguished *Stark v. Advanced Magnetics, Inc.*, 29 F.3d 1570, 1576 (Fed. Cir. 1994), which held otherwise and was cited by Roche, on grounds that the applications at issue in *Stark* were secret and the challenging party thus lacked actual knowledge. Roche, by comparison, had explicit notice that Stanford intended to secure additional patents to the same subject matter at least through the April 2000 slide presentation. Moreover, the Court found that the principle stated in *Stark*, that each patent is a separate

chose in action, concerned whether an action for infringement could be brought before a patent issues, not whether a party had to wait until a patent issued to challenge ownership. Consequently, the Court found *Stark* inapplicable in this case.

The Court also rejected Roche's argument that its holding in *DDB Technologies, L.L.C. v. MLB Advanced Media, L.P.*, 517 F.3d 1284 (Fed. Cir. 2008), precludes application of state statutes of limitation to patent ownership claims. The Court distinguished *DDB* on grounds that its holding applied in the limited instance where applicable state law prevents an assignor from urging estoppel or waiver against an assignee. Finding no such California law, the Court upheld the district court's decision that the California statutes of limitation apply to Roche's claims, and that the statutes bar Roche's claims of ownership in the patents-in-suit.

Finally, the Court held that Stanford's inability to establish that it possessed Holodniy's interest in the patents-in-suit still undermined Stanford's right to assert its cause of action against Roche, despite the running of the statute of limitations against Roche's claim of ownership. The Court reasoned that Stanford could not establish that it perfected ownership and, consequently, joinder of all plaintiffs in the suit, regardless of whether Roche could demonstrate its ownership. According to the Court, Stanford therefore lacked standing to sue Roche, the district court lacked jurisdiction over Stanford's infringement claim, and the district court should not have addressed the validity of the patents. Accordingly, the Court vacated the district court's finding of invalidity and remanded the case for dismissal due to lack of standing.

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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

Looking Ahead

On October 13, 2009, the Federal Circuit ordered rehearing en banc in *Princo Corp. v. ITC*, No. 07-1386. The Court vacated its April 20, 2009, opinion and directed the parties to file new briefs "addressing primarily those issues originally decided in Section II of the [vacated] opinion." In Section II, the Court addressed Princo Corporation's contention that the ITC erred by failing to find patent misuse, either as a result of tying or as a result of an agreement between Sony and U.S. Philips Corporation ("Philips") concerning the availability of a patent in the context of a "patent pool" covering CD-R and CD-RW technology. In its April 2009 order, the Federal Circuit remanded this issue to the ITC for a determination of whether Sony and Philips had, in fact, entered into such an agreement. The order granting rehearing en banc did not set a date for oral argument.