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LAST MONTH AT THE FEDERAL CIRCUIT

Table of Contents

Infringement Judgment Reversed Where Expert's Testimony Did Not Address Claim Limitation

Johns Hopkins University v. Datascope Corp.
No. 07-1530 (Fed. Cir. Oct. 2, 2008)
[Appealed from N.D. Md., Judge Quarles]2

Prior Art Patent's Dosage Guidelines Failed to Provide Sufficient Guidance to Prescribe a Treatment Regimen and Did Not Enable Claimed Invention so as to Anticipate Patent-in-Suit

Impax Laboratories, Inc. v. Aventis Pharmaceuticals Inc.
No. 07-1513 (Fed. Cir. Oct. 3, 2008)
[Appealed from D. Del., Judge Farnan]4

Novelty Analysis Is Separate and Distinct from Nonobviousness Analysis

Cohesive Technologies, Inc. v. Waters Corp.
Nos. 08-1029, -1030, -1031, -1032, -1059
(Fed. Cir. Oct. 7, 2008)
[Appealed from D. Mass., Judge Woodlock]5

Claim Amendment Made During Reexamination Neither Impermissibly Broadened nor Substantively Changed Claim Scope

Predicate Logic, Inc. v. Distributive Software, Inc.
No. 07-1539 (Fed. Cir. Oct. 9, 2008)
[Appealed from S.D. Cal., Judge Hayes]8

Substitution of One Known Element for Another Renders Patent Claims Obvious

Asyst Technologies, Inc. v. Emtrak, Inc.
No. 07-1554 (Fed. Cir. Oct. 10, 2008)
[Appealed from N.D. Cal., Judge Fogel]10

Judicial Efficiency and the Policy of Repose Counsels Against Giving Deference on Appeal to PTO's Reissuance of a Patent After a Trial Court Decision

Technology Licensing Corp. v. Videotek, Inc.
Nos. 07-1441, -1463 (Fed. Cir. Oct. 10, 2008)
[Appealed from N.D. Cal.,
Magistrate Judge Seeborg]12

The ITC Does Not Have Statutory Authority to Issue a Limited Exclusion Order Against Downstream Products of Nonrespondents

Kyocera Wireless Corp. v. International Trade Commission
Nos. 07-1493 et al. (Fed. Cir. Oct. 14, 2008)
[Appealed from ITC]15

Hatch-Waxman Reverse Payment Settlement Is Lawful Under Antitrust Laws Since Anticompetitive Effects Were Within the Exclusionary Zone of the Patent

In re Ciprofloxacin Hydrochloride Antitrust Litigation
No. 08-1097 (Fed. Cir. Oct. 15, 2008)
[Appealed from E.D.N.Y., Judge Trager]17

Reweighting Evidence in Reducing Compensatory Damages Award Requires the Option of a New Trial

Minks v. Polaris Industries, Inc.
Nos. 07-1490, -1491 (Fed. Cir. Oct. 17, 2008)
[Appealed from M.D. Fla., Judge Presnell]20

To Anticipate, a Prior Art Reference Must Contain All of the Limitations Arranged or Combined in the Same Way as Recited in the Claim

Net MoneyIN, Inc. v. VeriSign, Inc.
No. 07-1565 (Fed. Cir. Oct. 20, 2008)
[Appealed from D. Ariz., Judge Collins]22

The Grant of a Preliminary Injunction Is Reviewed for Clear Error

Abbott Laboratories v. Sandoz, Inc.
No. 07-1300 (Fed. Cir. Oct. 21, 2008)
[Appealed from N.D. Ill., Judge Coar]24

Insufficient Written Description Under Representative Number of Species Test Where Only One Species Was Identified

In re Alonso
No. 08-1079 (Fed. Cir. Oct. 30, 2008)
[Appealed from Board]26

To Be Patentable Under § 101, a Process Must Be Tied to a Machine or Transform an Article into a Different State or Thing

In re Bilski
No. 07-1130 (Fed. Cir. Oct. 30, 2008) (en banc)
[Appealed from Board]28

SPOTLIGHT INFO:

In *In re Bilski*, No. 07-1130 (Fed. Cir. Oct. 30, 2008) (en banc), the Federal Circuit affirmed the decision of the Board, finding that the method claims in Bernard L. Bilski and Rand A. Warsaw's (collectively "Bilski") patent application were not directed to statutory subject matter under 35 U.S.C. § 101. In doing so, the Court noted that the machine-or-transformation test is the test that should be used to determine whether a process claim is drawn to statutory subject matter. The Court explained that under this test, a claimed process is patentable 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. Judges Mayer, Rader, and Newman filed dissenting opinions, while Judge Dyk filed a concurring opinion. See full summary below.

In *Kyocera Wireless Corp. v. International Trade Commission*, Nos. 07-1493, -1494, -1495, -1496, -1497, -1498, -1499, -1514, -1573, 08-1004, -1009, -1010, -1012, -1013, -1015, -1018, -1019 (Fed. Cir. Oct. 14, 2008), the Federal Circuit, inter alia, vacated the limited exclusion order issued by the ITC and remanded, finding that the ITC lacked authority to issue such an order against downstream products of nonrespondents. The Court explained that the imports of nonrespondents can only be excluded via a general exclusion order. See full summary below.

Infringement Judgment Reversed Where Expert's Testimony Did Not Address Claim Limitation

Larry M. Sandell

Judges: Newman (dissenting), Schall, Zobel (author and District Judge sitting by designation)

[Appealed from N.D. Md., Judge Quarles]

In *Johns Hopkins University v. Datascope Corp.*, No. 07-1530 (Fed. Cir. Oct. 2, 2008), the Federal Circuit concluded in a split decision that the jury's verdict of infringement was not supported by substantial evidence and that the defendant's motion for JMOL should have been granted. Accordingly, the Court reversed the denial of the JMOL motion and remanded for entry of final judgment in favor of Datascope Corporation ("Datascope").

Johns Hopkins University is the owner and Arrow International, Inc. (collectively "Hopkins") is the exclusive licensee of U.S. Patent Nos. 5,766,191 ("the '191 patent"), 6,824,551 ("the '551 patent"), and 7,108,704 ("the '704 patent").

The patents are directed to methods for mechanically fragmenting blood clots and share a common specification. In each of the asserted methods, a fragmentation catheter is introduced into the vascular conduit. Upon deployment, a fragmentation cage or basket at the distal end of the catheter expands to conform to the shape and diameter of the inner lumen of the vascular conduit. After deployment, the fragmentation cage is rotated at a speed high enough to homogenize the thrombotic material obstructing the vascular conduit.

Hopkins sued Datascope, alleging that the use of Datascope's ProLumen device infringes the patents. The infringement claims and Datascope's defense of obviousness were tried to a jury, which found the patents infringed and valid. The district court held a bench trial on Datascope's defenses of inequitable conduct and unclean hands, upholding the enforceability of the three patents. On the issues of infringement and obviousness, Datascope moved for JMOL or, in the alternative, for a new trial, which the district court denied.

On appeal, the Federal Circuit concluded that the jury's verdict of infringement was not supported by substantial evidence and that

Datascope's JMOL motion should have been granted. In the district court, the parties disagreed on the meaning of the phrase "expands to conform to the shape and diameter of the inner lumen" and the term "fragmentation member." The district court construed "fragmentation member" as a means-plus-function term and limited it to the wire cage or basket described in the specification, along with equivalents. As to the disputed "expands to conform" phrase, the district court concluded that "diameter" referred to a "horizontal cross-section" of the vein "regardless of whether it forms a circle," while "shape" referred to the capability of the fragmentation member to "adjust to remain in contact with the sides of the inner lumen along its length." Based on this interpretation, the district court instructed the jury that "expands to conform to the shape and diameter of the inner lumen" means that the "fragmentation member" (in the '191 and '551 patents) or "expandable distal end" (in the '704 patent) "expands and adjusts to remain in contact with the inner lumen in three dimensions along its length and width." Slip op. at 6.

"Here, no reasonable jury could have found that the ProLumen device literally met this limitation [that the device remains in contact with the inner lumen in three dimensions along its length and width] based on [the expert's] opinion, given his contradictory testimony that the device only contacts the vessel in two places." Slip op. at 11.

The Federal Circuit found that, in the place of a cage or basket, the ProLumen device uses a single "S" shaped wire ("S-wire") that is rotated

to break up thrombotic material. The only evidence at trial supporting the contention that the use of the ProLumen device literally meets the "expands to conform" limitation was testimony by Hopkins's expert that the ProLumen fills the lumen in all three dimensions as it rotates. Because all of the asserted claims require that the distal end contact the inner lumen in three dimensions prior to the rotation step, the Court found that the expert's testimony was insufficient. Further, the Court found no evidence that the S-wire makes contact with the inner lumen in three dimensions at any particular instant in time, as the "expands to conform" limitation requires. Rather, Hopkins's expert testified that the ProLumen only contacts the inner lumen at two points. For these reasons, the Court concluded that "no reasonable jury could have found that the ProLumen device literally met" the "expands to conform" limitation and reversed the denial of Datascope's JMOL on the issue of infringement. *Id.* at 11. The Court declined to reach the other issues raised on appeal.

In a dissenting opinion, Judge Newman characterized the Court's opinion as an "independent appellate trial of the factual issues that were decided by the jury and sustained by the district court" and stressed that all reasonable inferences must be made in favor of the verdict. Newman Dissent at 1. In Judge Newman's view, because no fragmentation occurs until the structure is rotated in either the claimed device or the accused device, a reasonable jury could have found that the S-wire is a "fragmentation member." Moreover, Judge Newman agreed with the district court that the jury's finding was not against the clear weight of the evidence. Judge Newman concluded that there was substantial evidence that the "expands to conform" limitation was met, regardless of whether there was also evidence to support Datascope's position. Accordingly, Judge Newman concluded that a reasonable jury could have reached the verdict of infringement.

Prior Art Patent's Dosage Guidelines Failed to Provide Sufficient Guidance to Prescribe a Treatment Regimen and Did Not Enable Claimed Invention so as to Anticipate Patent-in-Suit

Ken M. Motolenich-Salas

Judges: Rader (author), Schall, Zobel (District Judge sitting by designation)

[Appealed from D. Del., Judge Farnan]

In *Impax Laboratories, Inc. v. Aventis Pharmaceuticals Inc.*, No. 07-1513 (Fed. Cir. Oct. 3, 2008), the Federal Circuit held that the district court correctly determined that U.S. Patent No. 5,236,940 ("the '940 patent") was not an enabling prior art reference and therefore did not anticipate U.S. Patent No. 5,527,814 ("the '814 patent") owned by Aventis Pharmaceuticals Inc. ("Aventis").

The '814 patent relates to the use of riluzole to treat Lou Gehrig's disease or amyotrophic lateral sclerosis ("ALS"). Impax Laboratories, Inc. ("Impax") filed an ANDA seeking FDA approval to market generic riluzole. Impax then sued Aventis seeking a DJ of noninfringement, invalidity, and unenforceability. With respect to invalidity, Impax alleged that the '940 patent, which disclosed pharmaceutical compositions useful for the treatment of medical conditions associated with the effects of glutamate, enabled the use of riluzole to treat ALS and therefore qualified as enabling prior art.

The district court found that the disclosure of the '940 patent did not put one of ordinary skill in possession of the invention. As such, the district court determined that Impax did not prove that the '814 patent was anticipated by the '940 patent. *Impax Labs., Inc. v. Aventis Pharms. Inc.*, 333 F. Supp. 2d 265 (D. Del. 2004).

On appeal by Impax, the Federal Circuit remanded for a specific determination on whether the '940 patent enabled a person of ordinary skill in the art to treat ALS with riluzole without regard to the efficacy of such treatment. *Impax Labs., Inc. v. Aventis Pharms. Inc.*, 468 F.3d 1366, 1384 (Fed. Cir. 2006). On remand, the district court concluded that nothing in the '940 patent would direct a skilled artisan to recognize that riluzole could be used to treat ALS, rejecting that "the mere mention of riluzole [was] sufficient to put one skilled in the art in the possession of the claimed invention." *Impax Labs., Inc. v. Aventis Pharms. Inc.*, 496 F. Supp. 2d 428, 432 (D. Del. 2007). In addition, the trial court noted that the dosage guidelines in the disclosure were broad and not specific to any of the hundreds of formulas of the claimed invention or to any of the listed diseases. Finally, the district court also noted the absence of working examples. In view of these findings, the district court found that a skilled artisan would have needed extensive experimentation to link riluzole with the treatment of ALS such that the '940 patent did not enable the claims and thus did not anticipate the '814 patent.

"In sum, each component of the claimed invention—identifying riluzole as a treatment for ALS and devising dosage parameters—would require undue experimentation based on the teachings of the '940 patent." Slip op. at 5.

On appeal, the Federal Circuit noted that the '940 patent's dosage guidelines were broad and general without sufficient direction or guidance to prescribe a treatment regimen. The Court also noted the absence of working examples or anything in the '940 patent that would have led a skilled artisan to identify riluzole as a treatment for ALS. Thus, the Court stated that "each

component of the claimed invention—identifying riluzole as a treatment for ALS and devising dosage parameters—would require undue experimentation based on the teachings of the '940 patent.” Slip op. at 5.

In addition, the Court addressed Impax’s argument that the district court’s silence on remand regarding the initial presumption of enablement to both claimed and unclaimed material in the '940 patent was reversible legal error. The Court stated that the district court correctly placed the burden of proving nonenablement of the '940 patent on the patentee. The Court stated that the district court did not need to specifically articulate its correct burden-shifting framework. As such, the Court affirmed the district court’s holding that the '940 patent was not an enabling prior art reference and did not anticipate the claims of the '814 patent.

Novelty Analysis Is Separate and Distinct from Nonobviousness Analysis

Christine M. Hlavka

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

[Appealed from D. Mass., Judge Woodlock]

In *Cohesive Technologies, Inc. v. Waters Corp.*, Nos. 08-1029, -1030, -1031, -1032, -1059 (Fed. Cir. Oct. 7, 2008), the Federal Circuit affirmed-in-part, reversed-in-part, vacated-in-part, and remanded the district court’s holdings regarding infringement, invalidity, inequitable conduct, and damages.

Cohesive Technologies, Inc. (“Cohesive”) owns U.S. Patent Nos. 5,772,874 (“the '874 patent”) and 5,919,368 (“the '368 patent”), both directed to high-performance liquid chromatography

(“HPLC”) columns. In HPLC, a liquid containing compounds to be separated and measured is passed under pressure through a packed column of chromatographically active particles. The effectiveness of HPLC at separating the compounds from the liquid depends on several variables, including the size and structure of the particles in the column. Each of the '874 and '368 patent claims at issue required the same two key limitations: particles that are “rigid” and have average diameters of “greater than about 30 μm .”

Cohesive brought three related actions against Waters Corporation (“Waters”). The first action alleged that Waters’s 30 μm HPLC columns infringe the '874 patent. The second action alleged that Waters’s 30 μm columns infringe the '368 patent. And the third action alleged that Waters’s 25 μm columns infringed both patents. In the first action, because Waters alleged that the asserted claims were both obvious and anticipated, the district court chose not to submit anticipation to the jury because it considered anticipation to be a subset of obviousness. The court thus sua sponte entered a directed verdict finding that the '874 patent was not anticipated. A jury found that the 30 μm columns infringed the '874 patent and that the '874 patent was not obvious. The district court then held a combined bench trial on damages, willful infringement, and inequitable conduct in the first action, and on preliminary injunction and SJ motions in the second and third actions. The district court entered judgment in favor of Cohesive in the first action and granted Cohesive’s motion for SJ of infringement and no invalidity in the second action. In the third action, the district court granted Waters’s motion for SJ of noninfringement, concluding that the 25 μm columns did not infringe either patent. Both parties appealed.

On appeal, Waters first challenged the district court’s construction of the claim term “rigid.” The district court construed “rigid” as not excluding polymeric particles. Waters argued

that Cohesive had disclaimed polymeric particles during prosecution. The Federal Circuit disagreed, finding that Cohesive had disclaimed only *particular* polymeric particles by distinguishing its particles from the prior art.

The Court also disagreed that the trial evidence was insufficient to permit a reasonable jury to conclude that the particles of its 30 μm columns were rigid. The Court noted that the district court's construction of "rigid" required that the particles exhibit two characteristics. As Cohesive's expert at trial had testified to observing both characteristics in Waters's columns, the Court concluded that there was sufficient evidence to permit a reasonable jury to conclude that Waters's 30 μm columns were rigid. The Court therefore affirmed the district court's construction of "rigid" and its denial of Waters's motion for JMOL of noninfringement of the '874 patent.

"While it is commonly understood that prior art references that anticipate a claim will usually render that claim obvious, it is not necessarily true that a verdict of nonobviousness forecloses anticipation." Slip op. at 14.

Waters next argued that the district court erred in granting JMOL for Cohesive on anticipation rather than allowing the jury to decide the issue. The Federal Circuit agreed, finding that the district court did not make a finding that no reasonable jury could conclude that the asserted references anticipated. The district court characterized the anticipation case as "iffy," which does not foreclose a favorable verdict. The Court noted that novelty and nonobviousness are separate conditions of patentability and separate defenses available in an infringement action. The Court stated, "While it is commonly understood that prior art references that anticipate a claim will usually render that claim obvious, it is not

necessarily true that a verdict of nonobviousness forecloses anticipation." Slip op. at 14. Thus, the Federal Circuit held, a court cannot refuse to submit the issue of anticipation to the jury simply because the accused infringer has also asserted an obviousness defense. It is for the litigants—not the court—to make the strategic decision as to whether to assert one, both, or neither of those defenses in a jury trial. The Court therefore reversed the district court's grant of JMOL on the issue of anticipation.

Finally, Waters asserted that the district court clearly erred by failing to find inequitable conduct. According to Waters, Cohesive committed inequitable conduct by submitting a declaration but failing to disclose that the declarant disagreed with the inventors as to whether the invention generated "turbulent flow." The Federal Circuit noted that the district court had credited Cohesive's testimony that it did not believe the declarant's difference of opinion was material to the ultimate conclusion of his declaration and accordingly found no intent to deceive the PTO. Further, Waters had not cited any independent evidence of specific intent to deceive. The Court therefore affirmed the district court's determination that Waters failed to establish inequitable conduct.

The Federal Circuit next turned to Cohesive's appeal of the district court's grant of SJ of noninfringement by Waters's 25 μm columns. The asserted claims of both patents required that the column particles have average diameters "greater than about 30 μm ." However, because the shape of the particles in an HPLC column is not a uniform sphere, the particles in, for instance, a 25 μm column do not actually have diameters of 25 μm . As a result, the parties disputed the average size of the particles in the accused 25 μm columns—Cohesive alleged an average diameter of 29.01 μm , while Waters asserted an average diameter of 25.22 or 25.16 μm . At trial, the district court construed the language "greater than about 30 μm " to exclude 29.01 μm .

The Federal Circuit held the district court erred in its construction because a court should not construe a claim solely to exclude the accused device and because the district court read the term “about” out of the claim. The Court noted that the term “about” does not have a universal meaning in patent claims. Instead, to construe “about,” a court must focus on the purpose of the limitation in the claimed invention.

Here, the Federal Circuit found that the purpose of the low-end limit on particle size was evident from the specification. The specification taught that the desired flow turbulence could not be attained using particles of nominal average diameters of 20 μm , but could use particles of 50 μm . The specification also stated that particles having nominal average diameters of 50 μm had actual average diameters of 42.39 μm —a variance of 15.22%. As a result, the Court determined that the language “about 30 μm ” should encompass at least 30 $\mu\text{m} \pm 15.22\%$, but not 20 $\mu\text{m} \pm 15.22\%$. That is, particles with actual average diameters of 25.434 μm and larger fell within the claims, but not particles having 23.044 μm actual average diameters and smaller. As to particles having actual average diameters between 23.044 μm and 25.434 μm , the Court found that such particles would fall within the claims if the particles were capable of attaining turbulence. Applying this construction to the facts, the Federal Circuit found that the actual average diameters of Waters’s 25 μm column particles and their ability to attain turbulence were disputed issues of material fact. As a result, the district court’s grant of SJ of no literal infringement was inappropriate, and the Federal Circuit reversed.

The Federal Circuit, however, affirmed the district court’s grant of SJ of noninfringement under the DOE. As the Court explained, though the recitation of numeric ranges in claims does not, by itself, preclude reliance on the DOE, in this

case, “about 30 μm ” already encompassed particle diameters that performed the same function, in the same way, with the same result as the 30 μm particles. Thus, by electing to include the broadening word “about” in the claim, the Federal Circuit concluded that the patentee had already captured what would otherwise be equivalents within the literal scope of the claim. The Court held that “[w]here, as here, a patentee has brought what would otherwise be equivalents of a limitation into the literal scope of the claim, the doctrine of equivalents is unavailable to further broaden the scope of the claim.” *Id.* at 29.

Finally, the Federal Circuit vacated the district court’s lost profits conclusion and remanded for a reconsideration of whether the 25 μm columns and another column are acceptable noninfringing substitutes. The Court also affirmed the district court’s willful infringement determination because the proper construction of “rigid” was a sufficiently close question to foreclose a finding of willfulness. Finally, although the Court agreed that the six-year delay between the jury’s verdict of infringement and the district court’s judgment was unreasonable and unacceptable, the Court denied Cohesive’s request for reassignment on remand, finding no evidence that the district court judge would have substantial difficulty putting his previously expressed views out of his mind.

In his dissent, Judge Mayer disagreed with the majority’s decision to remand the issue of anticipation to the district court. He concluded that if a jury has already determined that an invention is not obvious, it is not possible that the invention could be anticipated by the same references. Accordingly, he would have affirmed the district court’s directed verdict on anticipation.

Claim Amendment Made During Reexamination Neither Impermissibly Broadened nor Substantively Changed Claim Scope

Anita Bhushan

Judges: Newman, Lourie, Linn (author)

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

In *Predicate Logic, Inc. v. Distributive Software, Inc.*, No. 07-1539 (Fed. Cir. Oct. 9, 2008), the Federal Circuit reversed and remanded the district court's grant of SJ of invalidity, holding an amendment made to claim 1 of U.S. Patent No. 5,930,798 ("the '798 patent") during reexamination neither impermissibly broadened nor substantively changed the claim's scope.

Predicate Logic, Inc. ("Predicate") owns the '798 patent, directed to a universal data measurement and analysis method used in software development processes. A single software development project may use many different programming languages that have different metrics, making it difficult to measure and forecast the development process. The '798 patent solves this problem with a universal system for data measurement and analysis. Since software is typically organized hierarchically, the invention of the '798 patent uses a series of predefined rules to generate one or more hierarchical indexes that serve as templates for data collected from all of the project's components. The '798 patent then discloses selectively "instantiating" these hierarchical indexes by populating the index fields with project data and comparing the instantiation results.

Predicate sued Distributive Software, Inc. ("Distributive") for infringement of the '798 patent. In response, Distributive requested, and the PTO granted, an ex parte reexamination

of the patent-in-suit. The district court stayed the litigation pending resolution of the reexamination.

During the reexamination, the examiner issued an examiner's amendment to claim 1 of the '798 patent. Specifically, the examiner amended "instantiating at least one said index" to "first instantiating at least one said index" and "second instantiating at least one said index." The examiner also amended "storing said instantiation of said at least one index" to "storing said first and second instantiations of at least one said index." The claims as amended were allowed.

"Unless a claim granted or confirmed upon reexamination is identical to an original claim, the patent can not be enforced against infringing activity that occurred before the issuance of [the] reexamination certificate." Slip op. at 10-11 (quoting *Bloom Eng'g Co. v. N. Am. Mfg. Co.*, 129 F.3d 1247, 1250 (Fed. Cir. 1997)).

The infringement action resumed after the reexamination proceeding ended. The district court granted Distributive's motion for SJ of invalidity of the '798 patent, holding that the amendments during reexamination substantively changed the claims and improperly broadened the claim scope. First, the district court found that the amendment from "said at least one index" to "at least one said index" broadened the claim scope. The district court reasoned that the original claim required all of the indexes generated in the generating step to be instantiated in the "instantiating" step, but the amended claim did not. The district court concluded that generating four indexes, storing four indexes, instantiating only two

of those indexes, storing the results of those instantiations, and comparing those results would infringe the amended claim, but not the original claim. Accordingly, the district court concluded that the amendment impermissibly broadened the claim scope. Additionally, the district court found that the amendment deleting the “instantiating” step and replacing it with two steps substantively changed the claim by narrowing it and, thus, the ’798 patent could not be enforced against infringing activity that occurred before the issuance of the reexamination certificate.

On appeal, the Federal Circuit held that the district court erred in concluding that the amendment of “said at least one index” to “at least one said index” broadened the claim scope. The Court reasoned that “[i]n analyzing the breadth of the claim before and after amendment, the district court was correct to ask whether any conceivable process would infringe the amended claim, but not infringe the original claim. But the district court’s analysis in considering its hypothetical infringing process was flawed.” Slip op. at 7 (citations omitted). Specifically, the Court found that the hypothetical process infringed both the amended and the original claim.

In finding that the district court’s hypothetical process infringed the original claim, the Federal Circuit reasoned that the hypothetical process met the original claim’s step of “generating . . . at least one hierarchical index” by generating two indexes. The Court emphasized the irrelevance of the hypothetical process’s generation of two additional indexes because they were extraneous and did not affect the infringement analysis since the claim used the open-ended transition phrase “comprising.” Similarly, the “storing said at least one index” limitation of the original claim was met by storing only two indexes regardless of whether the two additional indexes were also stored. The Court also found that the hypothetical process met the remaining steps of the original claim. Thus, the Federal Circuit held that the district court’s hypothetical

infringing process would infringe both the claim as amended and the original claim. The Court, therefore, concluded that the amendment did not broaden the claim scope.

The Federal Circuit also held that the district court incorrectly concluded that the amendment of “instantiating” to “first instantiating” and “second instantiating” substantively changed the claim. In so holding, the Court reasoned that the original claim, like the amended claim, required two “instantiating” steps. The language of the “comparing” step of the original claim, requiring “comparing at least one of the data sets linked to at least one of said instantiated indexes to at least another of the data sets linked to at least another of said instantiated indexes” and the specification’s description of the “instantiating” and “comparing” steps necessitated this result. The district court’s analysis ignored this requirement and erroneously reasoned that the instantiating step in the original claim required only a single instantiation, whereas the corresponding step in the amended claim differed in scope by requiring two instantiations.

The Federal Circuit rejected the district court’s rationale that only one instantiation might occur in the “instantiating” step of the original claim, and that single instantiation would then be compared with a previously stored instantiation generated outside of the claimed process. The Court noted that the “comparing” step of the claim required comparing data sets linked to “one of said instantiated indexes” with data sets linked to “another of said instantiated indexes.” Critically, the use of “said instantiated indexes” indicated that the instantiated indexes found antecedent basis in the claim and thus were generated inside of the claimed process.

The Federal Circuit further rejected as unpersuasive the district court’s rationale that the comparing step might allow a comparison between data sets linked to two different instantiations of the same index rather than two instantiations of different indexes. The Court reasoned that although it agreed that

the “comparing” step in both the original and amended claim permitted a comparison between data sets linked to either multiple instantiations of the same index, single instantiations of multiple indexes, or some combination, the “comparing” step still required that at least two instantiations take place. Because nothing in the amended claim suggested that the “first instantiating” and “second instantiating” steps must be performed on the same index or in data linked to different indexes, the Federal Circuit concluded that the district court’s rationale was unpersuasive. Accordingly, the Federal Circuit held that the amendment of the “instantiating step” to “first instantiating” and “second instantiating” steps did not result in a substantive change to claim 1 of the ‘798 patent. The Court concluded that the original and amended claims were “identical” for purposes of 35 U.S.C. §§ 252 and 307, and thus the ‘798 patent could be enforced against infringing activity that occurred before issuance of the reexamination certificate.

Substitution of One Known Element for Another Renders Patent Claims Obvious

Patricia M. Mitchell

Judges: Michel, Newman, Bryson (author)

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

In *Asyst Technologies, Inc. v. Emtrak, Inc.*, No. 07-1554 (Fed. Cir. Oct. 10, 2008), the Federal Circuit affirmed the district court’s finding that the asserted claims of U.S. Patent No. 5,097,421 (“the ‘421 patent”) are invalid for obviousness.

Asyst Technologies, Inc. (“Asyst”) is the assignee of the ‘421 patent entitled “Intelligent Wafer Carrier.” The ‘421 patent is directed to a system for tracking articles, such as silicon semiconductor wafers, in a manufacturing facility in which the wafers must be processed sequentially at a number of processing stations. The disclosed system includes transportable

containers, which contain wafers that are to be transported between different manufacturing stations and allow the wafers to be maintained in a clean environment.

“[R]eplacing the bus recited in Hesser with a multiplexer is little more than ‘the simple substitution of one known element for another.’” Slip op. at 7 (quoting *KSR Int’l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1740 (2007)).

Asyst sued Jenoptik AG and other parties (collectively “Jenoptik”) for infringement of the ‘421 patent and another patent, U.S. Patent No. 4,974,166 (“the ‘166 patent”). The case had been before the Federal Circuit twice before. The district court first granted SJ of no infringement as to three of the asserted claims because the accused device lacked a simple communications means. On the first appeal, the Federal Circuit reversed the grant of SJ, holding that the trial court had erred in its claim construction. On remand, the trial court again granted SJ of noninfringement as to the claims of the ‘421 patent and dismissed the claims of infringement of the ‘166 patent pursuant to the parties’ agreement. Asyst appealed a second time, and the Federal Circuit affirmed the grant of SJ of no infringement of independent claim 1 of the ‘421 patent, but reversed and remanded with respect to independent claim 2 and dependent claims 11-14. After the second remand, the case was tried to a jury. The jury found claims 2 and 11-14 of the ‘421 patent valid and infringed. Jenoptik then moved for JMOL that the asserted claims were invalid due to obviousness, or alternatively for a new trial. After briefing on the recently decided *KSR International Co. v. Teleflex, Inc.* case, 127 S. Ct. 1727 (2007), the trial court granted JMOL of obviousness in view of U.S. Patent No. 4,588,880 to Hesser (“Hesser”), based in part on *KSR*.

On this third appeal, the Federal Circuit found that the jury's verdict on obviousness was "plainly affected by its conclusion, expressed in the special verdict form, that Hesser was not relevant prior art." Slip op. at 3. The Federal Circuit agreed with the district court that Hesser is "clearly pertinent to the art of tracking workpieces during multiple fabrication steps in a factory, the art to which the '421 patent is directed." *Id.* The Court also found that Asyst's technical expert testified that Hesser was relevant prior art. Accordingly, the Court concluded that the jury erred in finding that Hesser is not prior art.

The Court next considered whether there was substantial evidence that Hesser lacks two limitations of claim 2: a "sensing means for sensing the presence of at least one transportable container," and a "selection means for selecting between respective sensor means of said plurality." The Court rejected Asyst's arguments that Hesser lacked a "sensing means." In doing so, the Court noted similarities in the communication structures disclosed by Hesser and the '421 patent. The Court also relied on an admission by Asyst's expert that Hesser discloses "a section that could be interpreted as sensing the presence of the information carrier." *Id.* at 5. In light of these findings, the Court agreed with the district court that "any implicit finding by the jury that Hesser does not meet the 'sensing means' limitation of the '421 claims was necessarily incorrect." *Id.*

The Court also rejected Asyst's argument that Hesser lacked a "selection means for selecting between respective sensor means of said plurality." Asyst argued that, because Hesser discloses the use of an information bus instead of a multiplexer for communications between a control unit and transportable containers, it does not have any structure that performs "selection" among the containers, but instead indiscriminately transmits information through the bus to all of the transducer stations. The Court agreed with Jenoptik that, in light of *KSR*, the use of a multiplexer instead of a bus did not render the invention of the '421 patent

obvious. The Court relied on the Supreme Court's explanation in *KSR* that, "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.* at 7 (quoting *KSR*, 127 S. Ct. at 1740). The Court found that multiplexers were well known in the art at the time of the '421 patent and that replacing a bus with a multiplexer is "little more than 'the simple substitution of one known element for another.'" *Id.* (quoting *KSR*, 127 S. Ct. at 1740). Thus, the Court concluded that it would be obvious to one of skill in the art to replace the bus in Hesser with a multiplexer in order to obtain the invention of the '421 patent.

The Court next concluded that the jury's finding that one of skill in the art would not have been motivated to combine the system of Hesser with a multiplexer in place of a bus was not supported by substantial evidence. At trial, Jenoptik introduced evidence regarding "the well-known respective advantages of a multiplexer and a bus," and regarding "the circumstances in which one of ordinary skill would have selected one of the two devices over the other." *Id.* at 8. In light of the advantages being well known, the Court rejected Asyst's argument that the saving of battery life in its system, which uses a multiplexer instead of a bus, is an "unexpected result" that renders the asserted claim nonobvious.

The Court also rejected Asyst's argument that the jury's finding of objective indicia of nonobviousness—commercial success, long-felt need, and industry praise—supported its finding that the '421 patent was nonobvious. The Court found that Asyst had failed to link the commercial success and evidence of long-felt need to the substitution of a multiplexer for a bus and, therefore, this evidence could not overcome a strong *prima facie* showing of obviousness.

The Court turned next to dependent claims 11-14, which the district court invalidated in view of Hesser. The Court concluded that, because Asyst had not rebutted Jenoptik's evidence that

Hesser teaches each of the additional limitations in the dependent claims, the district court was justified in overturning the jury's verdict as to those claims.

Finally, the Court concluded that the district court did not abuse its discretion in allowing Jenoptik to assert its invalidity defense based on Hesser after ten years of litigation. The Court rejected Asyst's argument that the delay was prejudicial, and instead found that a change in claim construction resulting from the Court's decision in an earlier appeal "changed the rules of the game," and that therefore Jenoptik was properly permitted to amend its defenses. *Id.* at 12 (quoting *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1357 (Fed. Cir. 1988)).

Judicial Efficiency and the Policy of Repose Counsels Against Giving Deference on Appeal to PTO's Reissuance of a Patent After a Trial Court Decision

Raymond M. Gabriel

Judges: Newman, Plager (author), Schall

[Appealed from N.D. Cal., Magistrate Judge Seeborg]

In *Technology Licensing Corp. v. Videotek, Inc.*, Nos. 07-1441, -1463 (Fed. Cir. Oct. 10, 2008), the Federal Circuit affirmed the trial court's judgment of invalidity of U.S. Patent No. 5,754,250 ("the '250 patent"), rejecting Technology Licensing Corporation's ("TLC") argument that the trial court improperly shifted the burden of persuasion. It also affirmed noninfringement of U.S. Patent No. 5,486,869 ("the '869 patent") in favor of Gennum Corporation ("Gennum"). It affirmed the trial court's conclusion of no inequitable conduct during prosecution of the '250 patent because the alleged omission was cumulative, not material. Finally, the

Court affirmed the validity of the '869 patent, concluding that Gennum did not carry its burden of persuasion.

"It is self-evident that the PTO's subsequent reaffirmation of its earlier position . . . can have no legal effect as such on the already-rendered judgment of a court of competent jurisdiction."
Slip op. at 23.

TLC owns the '250 and '869 patents, which relate to separating synchronization signals, or sync signals, from video signals. To accurately reproduce a transmitted image, circuits referred to as sync separators must precisely extract the sync signal from the composite video signal. This indicates the beginning of information for each line of an image. The first step of the process, called clamping, holds a negative peak of the sync signal to a known voltage. The '250 patent contains claims involving only a single clamp. The '869 patent, on the other hand, claims a sync separator with two separate clamping operations. The '869 patent also describes a sync separator that is able to recover sync signals from different types of video signals.

Both patents resulted from a chain of continuation and CIP applications. The inventor filed the first patent application, Serial No. 837,323 ("the '323 application") on February 28, 1992. The '869 patent eventually issued from a continuation application. Before the '869 patent issued, the inventor filed a CIP application on June 22, 1995. The '250 patent later issued from another CIP application derived from the 1995 CIP application.

TLC filed a complaint against Videotek, Inc. ("Videotek"), alleging infringement of the '869 and the '250 patents for sync separator chips supplied by Gennum to Videotek. Videotek filed a third-party complaint against

Gennum seeking indemnification. TLC and Videotek settled, leaving only the dispute between TLC and Gennum. Gennum manufactured chips with both one- and two-clamp circuits. The trial court found Gennum's one-clamp chips infringed the asserted claims of the '250 patent. But it held the '250 patent invalid as anticipated, rejecting TLC's argument that the patent was entitled to the filing date of the '323 application. It also found neither the one- nor two-clamp chips infringed the asserted claims of the '869 patent. Finally, it rejected Gennum's challenge to the validity of claim 31 on the ground that it did not meet the written description, enablement, and indefiniteness requirements of 35 U.S.C. § 112.

The Federal Circuit first addressed TLC's appeal of the invalidity judgment of claim 33 of the '250 patent. TLC did not dispute that chips made by Elantec, which were described in data sheets published in May and November 1993, contained all the limitations of the asserted claims of the '250 patent. These data sheets were published after the filing date of the '323 application, but more than one year before the filing date of the application that resulted in the '250 patent. The issue for the Court was whether the Elantec chips were prior art. Thus, the Court addressed whether claim 33, and particularly the "other circuit" limitation, was adequately described by the '323 application and therefore entitled to the benefit of the '323 application's 1992 filing date.

On appeal, TLC argued that the trial court erred by shifting the burden of proof to TLC to show the '250 patent was entitled to the earlier filing date of the '323 application. TLC contended that the burden of persuasion should have remained on the challenger. On the other hand, Gennum argued that the Court's decision in *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299 (Fed. Cir. 2008), relieved Gennum of that burden.

Based on its reading of *PowerOasis*, Gennum argued that the risk of nonpersuasion falls on the patentee, contending that the patentee has the burden of proving entitlement to the earlier effective filing date. The Court noted Gennum

was not alone in reading *PowerOasis* to have modified the traditional burdens rule so that the patentee has the burden of persuasion to prove it was entitled to the earlier filing date. In the Court's view, however, *PowerOasis* did not extend so far. "[O]nce a challenger (the alleged infringer) has introduced sufficient evidence to put at issue whether there is prior art alleged to anticipate the claims being asserted, . . . the patentee has the burden of going forward with evidence and argument to the contrary." Slip op. at 18-19.

Turning to the trial court's opinion, the Federal Circuit found that the trial court did not improperly shift the burden of persuasion on TLC. The Court interpreted the trial court's opinion as concluding that, after giving TLC's evidence due weight, Gennum's evidence and arguments were sufficient to conclude by clear and convincing evidence that the '323 application did not provide adequate written support for claim 33.

On the burden issue, TLC also argued that the trial court gave no deference to the PTO's decision to approve the claim. The prior art at issue was before the examiner, but nothing in the record indicated the PTO determined claim 33 was or was not entitled to the '323 application filing date. Therefore, absent express evidence by the examiner, the overall assessment of the evidence by the trial court subsumed the deference question. Moreover, the Federal Circuit assumed the trial court properly included the PTO's expertise in its calculations because TLC produced no evidence to the contrary on appeal.

The Court also addressed the effect that the reissuance of the '250 patent, subsequent to the decision by the trial court, had on the appeal. It was self-evident to the Court that the PTO's reissuance of a patent can have no legal effect on an already rendered judgment of a court of competent jurisdiction, but the question of deference on appeal remained. The Court further concluded it would give no deference on appeal to a patent reissued subsequent to a trial court's decision. "[J]udicial efficiency and the

policy of repose” counseled the Court against adding an additional deference factor or asking the trial court to reopen the entire invalidity question to reweigh additional deference. *Id.* at 23. In the Court’s view, the judicial process would be “held hostage to the timing of” further PTO review. *Id.* Thus, only the record before the Court on appeal would be consulted without deference to the later reissue decision.

Finally, the Court addressed the merits of the trial court’s determination that the ’323 application does not provide adequate written description support for the “other circuit” limitation of claim 33. TLC argued that two resistors in a figure of the ’323 application provided adequate description support for the “other circuit” limitation in claim 33. The text of the written description, however, made no mention of one resistor and only briefly referred to the other in passing. In contrast, the ’250 patent contained new matter describing resistors in a new figure that corresponded to the “other circuit.” Furthermore, although the inventor identified subject matter from the ’323 application that corresponded to another limitation of claim 33, the only support that he acknowledged for the “other circuit” limitation was the new matter added in 1995.

The Federal Circuit rejected TLC’s argument that the two resistors in the written description of the ’323 application provided adequate support for the “other circuit.” First, the Court noted, comparing the figure in the ’323 application with the figure in the ’250 patent did not address whether the ’323 application itself had sufficient written description for claim 33. Next, the Court noted that the trial court was not persuaded that the inventor had possession of the claimed “other circuit” in 1992 when he filed the ’323 application. Based on the entire record before it, the trial court concluded that a person skilled in the art would not understand the ’323 application to show the inventor had actually invented the claimed subject matter as of 1992. The Court affirmed the trial court’s finding that claim 33 and its dependent claims were not entitled to the benefit of the 1992 filing date and the resultant finding of invalidity.

The Court next turned to the infringement judgment of the asserted claims of the ’869 patent. TLC argued that the trial court erred as a matter of law in excusing infringement by Gennum as de minimis. The Federal Circuit rejected this argument, finding that the trial court concluded Gennum’s chips did not infringe because they did not satisfy the limitations of the claims, not that the chips would infringe but only very quickly or briefly. Accordingly, the Court affirmed the trial court’s judgment of no infringement.

The Court then addressed Gennum’s appeal of the finding of no inequitable conduct during the prosecution of the ’250 patent by failure to disclose certain prior art to the PTO. The trial court concluded, and the Federal Circuit agreed, this prior art was cumulative and thus not material. Gennum, however, urged the Court “to hold that an anticipatory prior art reference is material as a matter of law, regardless of whether it was cumulative to other prior art of record in the patent application.” *Id.* at 33. Gennum suggested that the Court could modify the PTO rule regarding cumulative references because it was promulgated pursuant to the judicially created doctrine of inequitable conduct. The Court rejected the argument, stating it was bound to follow its own precedent: “[A] cumulative reference is not material for purposes of inequitable conduct.” *Id.* at 34. Therefore, the Court affirmed the conclusion of no inequitable conduct.

Finally, the Federal Circuit addressed Gennum’s appeal of the trial court’s holding that claim 31 of the ’869 patent was not invalid for indefiniteness. The parties agreed that the claim was written in means-plus-function language. But Gennum argued that the ’869 patent failed to disclose adequate structure in the specification because the claimed circuit element was only shown as a black box with no details of its inner circuitry. The Federal Circuit rejected Gennum’s argument, noting Gennum failed to prove a person skilled in the art would not have recognized the black box as a known structure. Accordingly, the Federal Circuit affirmed the trial court’s finding that the claim was not invalid for indefiniteness.

The ITC Does Not Have Statutory Authority to Issue a Limited Exclusion Order Against Downstream Products of Nonrespondents

Judy W. Chung

Judges: Rader (author), Bryson, Linn

[Appealed from ITC]

In *Kyocera Wireless Corp. v. International Trade Commission*, Nos. 07-1493 et al. (Fed. Cir. Oct. 14, 2008), the Federal Circuit affirmed the ITC's claim construction, its determination of validity as to anticipation and obviousness, and its finding of no direct infringement. The Court, however, vacated and remanded the ITC's finding of induced infringement. It also vacated and remanded the limited exclusion order ("LEO") issued by the ITC, finding that the ITC lacked authority to issue an LEO against downstream products of nonrespondents.

Broadcom Corporation ("Broadcom") owns U.S. Patent No. 6,714,983 ("the '983 patent") directed to a mobile computing device that can communicate with wireless networks and operate in a reduced power mode to extend battery life. Broadcom filed a complaint in the ITC naming Qualcomm Incorporated ("Qualcomm") as the sole respondent, alleging that certain Qualcomm chips and chipsets infringed the '983 patent. The parties disagreed with the construction of the term "different" in the claim phrase "communication circuitry . . . being adapted to use a first wireless communication and a second wireless communication different from the first wireless communication." Qualcomm argued for a broad construction, but the ITC rejected that construction and construed "a first wireless communication and a second wireless communication different from the first wireless communication" as "refer[ring] to two different methods of communication." Slip op. at 5 (alteration in original). The ITC also rejected Qualcomm's anticipation and obviousness

arguments. In addition, although the ITC found no direct infringement by Qualcomm, it found that Qualcomm was liable for induced infringement.

"Section 337 permits exclusion of the imports of non-respondents only via a general exclusion order, and then too, only by satisfying the heightened requirements of 1337(d)(2)(A) or (B)." Slip op. at 30.

The ITC issued an LEO excluding handheld wireless devices that include certain Qualcomm chips and chipsets that are programmed to enable certain power-saving features covered by the '983 patent. Qualcomm appealed. Qualcomm's customers and wireless network operators, who were not named in Broadcom's complaint, also appealed. The customers included wireless device manufacturers whose products were subject to the LEO and the wireless network operators included those parties whose networks depended on products subject to the LEO. The Federal Circuit consolidated the appeals.

On appeal, the Federal Circuit started with claim construction. It affirmed the ITC's construction that "different" first and second wireless communications referred to two different communication methods, relying on the context of the claim as a whole and the specification. It rejected Qualcomm's contention that the construction of the same claim term in *Sorensen v. ITC*, 427 F.3d 1375 (Fed. Cir. 2005), required a broad construction of the term "different." The Court explained that its broad interpretation of the term "different" in *Sorensen* was based on its analysis of the context of the different claims and the intrinsic record in that case, and therefore, *Sorensen* did not create a categorical rule that the term "different" without further qualification must mean "any difference."

The Federal Circuit next addressed Qualcomm's anticipation arguments. Qualcomm first argued that three prior art patents anticipated the claims of the '983 patent. The Federal Circuit noted that Qualcomm's arguments with respect to these references turned on Qualcomm's construction of the term "different." Because the Court had already rejected that construction, it affirmed the ITC's finding that the three patent references did not anticipate the '983 patent claims. Second, Qualcomm argued that the Global System for Mobile Communications ("GSM") standard anticipated the '983 patent claims. The ITC found that Qualcomm had not shown that the GSM standard was a "printed publication" under 35 U.S.C. § 102 and that because the standard included separate GSM specifications, the specifications did not together constitute a single reference for § 102 purposes. The Federal Circuit rejected the ITC's finding that the GSM standard was not publicly available, explaining that GSM specifications were widely distributed without any restriction. However, the Court agreed with the ITC that the GSM standard was not a single reference as required for anticipation because it comprised different specifications authored by different authors at different times.

Qualcomm also challenged the ITC's determination with respect to obviousness. The ITC had rejected Qualcomm's obviousness arguments, finding that Qualcomm waived this defense by failing to raise it in a timely manner. Qualcomm argued that it never had the opportunity to present evidence under the proper legal standard because the Supreme Court's decision in *KSR International Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007), was decided after the ITC's determination of liability. The Federal Circuit rejected this argument, affirming the ITC's determination that Qualcomm waived this defense by failing to set forth an obviousness analysis until after an initial determination by the ALJ.

The Federal Circuit turned next to the ITC's infringement rulings. The ITC found that Qualcomm did not directly infringe the '983 patent, but found that it had induced infringement. Specifically, it found that Qualcomm induced infringement by its customers by, inter alia, providing them with software, training them, and recommending that they implement battery-saving features. The Federal Circuit affirmed the ITC's finding of no direct infringement, noting that there was substantial evidence for the ITC to conclude that Broadcom failed to establish direct infringement by Qualcomm. The Court, however, vacated and remanded the ITC's determination of induced infringement. It noted that the ITC's initial determination was issued prior to its decision in *DSU Medical Corp. v. JMS Co.*, which clarified that the specific intent necessary for a finding of induced infringement "requires more than just intent to cause the acts that produce direct infringement" and that "the inducer must have an affirmative intent to cause direct infringement." 471 F.3d 1293, 1306 (Fed. Cir. 2006). The Court noted that the current record fell short of the necessary intent showing for inducement—that Qualcomm possessed a specific intent to cause infringement of Broadcom's '983 patent.

Finally, with respect to the LEO, Qualcomm and the third-party manufacturers and carriers argued that the ITC exceeded its statutory authority by issuing an LEO that excluded imports of downstream manufacturers that were not named in Broadcom's complaint. Specifically, they argued that the LEOs issued by the ITC may only exclude products of named parties. On the other hand, Broadcom and the ITC contended that the ITC has authority to issue an LEO that excludes all articles that are determined to violate 35 U.S.C. § 1337, regardless of the identity of the importer. The Federal Circuit agreed with Qualcomm and the other appellants, and vacated the LEO.

The Court explained that because the ITC is a creature of statute, its authority must be found in the enabling statute. The Court found that § 1337 provides for two types of exclusion orders that the ITC may issue: (1) general exclusion orders (“GEOs”) and (2) LEOs. It noted that § 1337(d)(2) provides that the default exclusion remedy is an LEO and that a GEO is only appropriate under two exceptional circumstances. Specifically, the ITC may issue a GEO under either subsection d(2)(A) if it is “necessary to prevent circumvention of an exclusion order limited to products of named persons” or under subsection d(2)(b) if “there is a pattern of violation of this section and it is difficult to identify the source of infringing products.” Slip op. at 25. By implication, reasoned the Court, an LEO is both “an exclusion order limited to products of named persons,” and one where the complainant has not demonstrated “a pattern of violation of this section and [difficulty in identifying] the source of infringing products.” *Id.* Thus, the Court concluded that “on its face, the statutory context limit[ed] LEOs to named respondents that the Commission finds in violation of Section 337,” and that in order to obtain an exclusion order against nonrespondents, a complainant must seek a GEO and satisfy the heightened burdens imposed by § 1337. *Id.* at 25-26.

Further, the Federal Circuit found that Broadcom knew the identity of third-party handset manufacturers whose products contained Qualcomm’s chips or chipsets, and that Broadcom appeared to have made a strategic decision in not naming the third-party handset manufacturers in its complaint. Therefore, the Federal Circuit reasoned that Broadcom opted to forgo the full advantage of obtaining an LEO that would exclude the known third-party handset manufacturers.

Finally, citing to its decision in *Fuji Photo Film Co. v. ITC*, 474 F.3d 1281, 1286 (Fed. Cir. 2007), the Federal Circuit reiterated its holding that LEOs “only apply to the specific parties before the

Commission in the investigation.” Slip op. at 29. Accordingly, the Federal Circuit vacated the LEO and remanded, noting that the ITC could reconsider its enforcement options on remand.

Hatch-Waxman Reverse Payment Settlement Is Lawful Under Antitrust Laws Since Anticompetitive Effects Were Within the Exclusionary Zone of the Patent

Krista E. Bianco

Judges: Schall, Prost (author), Ward (District Judge sitting by designation)

[Appealed from E.D.N.Y., Judge Trager]

In *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, No. 08-1097 (Fed. Cir. Oct. 15, 2008), the Federal Circuit affirmed the district court’s grant of SJ, holding that reverse payment settlement agreements were not in violation of section 1 of the Sherman Act. The Court also affirmed the district court’s dismissal of state antitrust claims.

Bayer AG and Bayer Corporation (collectively “Bayer”) own U.S. Patent No. 4,670,444 (“the ‘444 patent”), directed to ciprofloxacin hydrochloride, the active ingredient in Cipro® (“Cipro”). The FDA approved marketing Cipro in October 1987 and granted an additional six-month period of marketing exclusivity after the ‘444 patent expired on December 9, 2003. In October 1991, Barr Laboratories, Inc. (“Barr”) filed an ANDA containing a Paragraph IV certification asserting that the ‘444 patent was invalid and unenforceable. In January 1992, Bayer sued Barr for patent infringement. Before trial, the parties settled their suit. Under the settlement agreement, Barr agreed not to challenge the validity or enforceability of

the '444 patent in exchange for a settlement payment. In addition, Bayer entered into a supply agreement with Barr where Bayer agreed to either supply Barr with Cipro for sale or make quarterly payments (referred to as reverse or exclusion payments) to Barr until December 31, 2003, in return for Barr agreeing not to manufacture, or have manufactured, a generic version of Cipro in the United States.

In 2000 and 2001, direct and indirect purchasers of Cipro and advocacy groups (collectively "purchasers") filed several antitrust actions in federal courts against Bayer, Barr, and the other generic manufacturer parties to the settlement agreements, challenging the agreements. The suits were consolidated in the Eastern District of New York. The purchasers alleged that the settlement agreements constituted an illegal market allocation in violation of sections 1 and 2 of the Sherman Act and various state antitrust and consumer protection laws. The district court granted Bayer and the generic manufacturers' motion for SJ, finding that the agreements did not have anticompetitive effects under section 1 of the Sherman Act. The district court also granted Bayer's motion to dismiss the state law antitrust claims, finding the claims preempted by federal patent law.

"Settlement of patent claims by agreement between the parties—including exchange of consideration—rather than by litigation is not precluded by the Sherman Act even though it may have some adverse effects on competition." Slip op. at 14.

On appeal, the Court affirmed the district court's finding that the agreements were not an unreasonable restraint on competition in violation of section 1 of the Sherman Act. The Court rejected the purchasers' argument that the district court should have concluded that the agreements were per se unlawful or should have applied a proper rule of reason analysis.

The Court first found the agreements not to be per se unlawful since there was no basis for the district court to confidently predict that the agreements at issue would be found to be unlawful under a rule of reason analysis.

Next, applying the law of the Second Circuit, the Court stated that the starting point in a rule of reason analysis is to define the relevant market and to determine whether Bayer possesses market power in the relevant market. The Court held that the district court undertook a full rule of reason analysis. The district court first determined that the relevant market is ciprofloxacin and that Bayer had market power within the market. The district court then determined that there was no evidence that the agreements created a bottleneck on challenges to the '444 patent or otherwise restrained competition outside the exclusionary zone of the patent. The district court concluded that the purchasers had failed to demonstrate that the agreements had an anticompetitive effect on the market for ciprofloxacin beyond that permitted by the '444 patent, thus failing to meet their burden under the first step of the rule of reason analysis.

Addressing the purchasers' argument that the district court erred in concluding the agreements were within the exclusionary zone of the '444 patent and in essence per se legal, the Court concluded that the district court did not find the agreements to be per se legal, but rather simply recognized that any adverse anticompetitive effects within the scope of the '444 patent could not be redressed by antitrust law. The Court noted that a patent is an exception to the general rule against monopolies and to the right of access to a free and open market. The Court held that the essence of the agreements was to exclude Barr from profiting from the patented invention, a right within Bayer's rights as a patentee. Noting the long-standing policy in the law in favor of settlements, the Court stated that "[s]ettlement of patent claims by agreement between the parties—including exchange of consideration—rather than by litigation is not precluded by the Sherman Act even though it may have some adverse effects on competition." Slip op. at 14.

The Court also held that provisions not to challenge the validity of the '444 patent did not render the agreements violative of the antitrust laws. Since settlements in patent cases frequently provide that the alleged infringer will not challenge the validity of the patent, the mere fact that the agreements insulated Bayer from patent validity challenges by Barr was not in itself an antitrust violation. The Court noted that four other generic manufacturers filed Paragraph IV ANDAs and initiated challenges to the validity of the '444 patent.

Next, the Court addressed the purchasers' argument that the Court should adopt the legal standards applied by other regional circuits and government agencies in evaluating agreements involving exclusion payments in the context of the Hatch-Waxman Act. The purchasers asserted that the other legal standards provide for greater antitrust scrutiny of agreements than the standard adopted by the district court. The Court found the district court's analysis to be sound since the district court considered whether there was evidence of sham litigation or fraud before the PTO and whether any anticompetitive effects of the agreements were outside the exclusionary zone of the '444 patent. The Court distinguished the Sixth Circuit's decision in *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003), wherein the Sixth Circuit found a reverse payment agreement to be a per se violation of antitrust laws. The Court concluded that the *In re Cardizem* agreement clearly had anticompetitive effects outside the exclusion zone of the patent. There, in addition to a reverse payment, the settlement agreement included an agreement by the generic manufacturer to not relinquish its 180-day exclusivity period, thereby delaying the entry of other generic manufacturers. The agreement also required that the generic manufacturer would not market noninfringing versions of the generic drug.

Reviewing the analytical approach followed by the Second and Eleventh Circuits, the Court concluded that in cases such as this, wherein

all anticompetitive effects of the settlement agreement are within the exclusionary power of the patent, the outcome is the same whether the court begins its analysis under antitrust law by applying a rule of reason approach to evaluate the anticompetitive effects or under patent law by analyzing the right to exclude afforded by the patent. "The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent." Slip op. at 19. The Court further agreed with the Second and Eleventh Circuits and the district court that, in the absence of evidence of fraud before the PTO or sham litigation, the court need not consider the validity of the patent in the antitrust analysis. The Court rejected the FTC and Solicitor General's arguments that an evaluation of the validity of the patent is necessary in an antitrust analysis. The Court noted that patents hold a statutory presumption of validity. Thus, the Court held that the district court correctly concluded that there is no legal basis for restricting the right of a patentee to choose its preferred means of enforcement and no support for the notion that the Hatch-Waxman Act was intended to thwart settlements.

The Court next rejected the purchasers' assertion that the district court erred in finding that other generic companies could still challenge the '444 patent and their incentive to challenge the patent would grow with the chance that the patent would be held invalid, rendering any anticompetitive effects of the agreements short-lived. According to the purchasers, the incentives to initiate and vigorously challenge a patent under the Hatch-Waxman Act are significantly reduced because of the effort, time, and expense of filing a Paragraph IV ANDA. The Court noted that while the Hatch-Waxman Act creates certain burdens for generic manufacturers, it also provides significant benefits. Thus, the Court held that the district court reasonably concluded that the incentive to mount a challenge would increase with the chance that the '444 patent would be held invalid. The Court also held that the district court

did not err in not considering evidence showing that the agreements preserved Barr's claim to the 180-day exclusivity period since that theory had already been addressed in the first district court opinion denying the purchasers' motions for partial SJ.

Finally, the Court affirmed the district court's dismissal of the purchasers' state antitrust claims. The purchasers argued that federal patent law does not preempt state law monopolization claims when the patent was procured by fraud. The Court noted that the record is not clear whether the district court considered case law cited by the purchasers concerning their preemption argument, but since the Court agreed with the district court's determination that no fraud had occurred, it held that the district court's dismissal of the state antitrust claims was not erroneous.

Reweighting Evidence in Reducing Compensatory Damages Award Requires the Option of a New Trial

Michel E. Souaya

Judges: Newman, Plager, Gajarsa (author)

[Appealed from M.D. Fla., Judge Presnell]

In *Minks v. Polaris Industries, Inc.*, Nos. 07-1490, -1491 (Fed. Cir. Oct. 17, 2008), the Federal Circuit vacated a district court's judgment reducing the jury's damages award without offering the plaintiff the option of a new trial. The Court also held that the jury instruction regarding actual notice of infringement was erroneous and prejudicial to the plaintiff. Finally, the Court affirmed the award of attorneys' fees and the jury's verdicts of infringement and willfulness.

Floyd M. Minks sued Polaris Industries, Inc. ("Polaris") for infringement of U.S. Patent No. 4,664,080 ("the '080 patent"). The '080 patent is directed to an electronic system designed to limit the speed of an all-terrain vehicle when

it is operated in the reverse direction—i.e., a reverse speed limiter. The system inhibits ignition according to engine speed. After trial in which the jury found willful infringement and awarded damages of \$1,294,620.91, the district court reduced the award to \$55,809.60 (after doubling). The court also awarded attorneys' fees of \$117,316.50, which was about half the amount Minks requested. Minks appealed the reduction in damages, as well as the amount of attorneys' fees awarded. He also asserted on appeal that the jury instruction as to the date Polaris received actual notice of the alleged infringement was erroneous. Polaris cross-appealed from the denial of its JMOL motion on noninfringement and from the jury's finding of willfulness. Polaris also appealed the enhancement of damages and grant of attorneys' fees on the ground that the jury instruction on willfulness was plain error under *In re Seagate Technology, LLC*, 174 F.3d 1360 (Fed. Cir. 2007) (en banc).

"[T]he district court's reduction of compensatory damages necessarily amounted to an assessment of the sufficiency of the evidence, and as such, the option of a new trial was required." Slip op. at 11.

On appeal, the Federal Circuit first considered whether the Seventh Amendment required the district court to offer Minks the option of a new trial in lieu of accepting the reduced damages award. Applying Eleventh Circuit law, the Court found that it did. The Court first noted that in *Hetzel v. Prince William County*, 523 U.S. 208, 211 (1998), the Supreme Court held that a district court reducing an excessive jury award must offer the plaintiff the option of a new trial if the reduction is premised on a finding that the factual record does not support the award.

In the Eleventh Circuit, however, when a jury's award is premised on "legal error," a court may reduce the award and enter an absolute

judgment in the amount sufficient to correct the legal error without offering the plaintiff the option of a new trial.

The Federal Circuit concluded that, because the district court identified no legal principle that would limit the amount of reasonable royalty, its reduction of the jury's compensatory damages award was governed squarely by *Hetzel*. The Court found that the district court "necessarily engaged in an independent review of the evidence and substituted its conclusion for that of the jury on the factual issue of compensatory damages." Slip op. at 10. Rather than consider the amount of a reasonable royalty supported by the evidence, the Court concluded that "the district court's exercise of discretion to assess the evidence and overturn the jury's verdict upon a determination that it is excessive may only result in the order of a new trial, either unqualified or conditioned on Minks' refusal to accept a reduction." *Id.* at 13. Accordingly, the Court vacated the district court's order reducing the jury's compensatory damages award and remanded for a new trial on damages.

In doing so, the Court noted that its previous decision in *Tronzo v. Biomet*, 236 F.3d 1342 (Fed. Cir. 2001) ("*Tronzo II*"), could be distinguished and did not compel a contrary result. In *Tronzo II*, which was also decided under Eleventh Circuit law, the Court affirmed a reduction of a jury's compensatory damages award without offering the plaintiff a new trial. In that case, the Court concluded that the district court was under no obligation to offer a new trial because the plaintiff had adduced no evidence to support its damages assessment. Thus, the Court found that, unlike here, the district court did not reweigh any evidence and the reduction in damages had been made on purely legal grounds. Thus, the option of a new trial was not necessary in *Tronzo II* under Eleventh Circuit law.

The Federal Circuit next affirmed the award of attorneys' fees. Because the Court found that Minks was unable or unwilling to articulate a coherent damages theory, even on appeal, the

Court concluded that the award of attorneys' fees was not an abuse of the district court's discretion.

The Court then reviewed the jury instruction for actual notice de novo for legal error. The district court gave the following instruction for actual notice: "The date notice was given is the date on which Minks communicated to Polaris a specific charge that one of its products may infringe claim two of the '080 patent." Minks objected to this instruction on the ground that it precludes a jury from finding notice prior to discovery of Polaris's infringement. Minks thus requested the following instruction: "The date notice was given is the date on which Minks communicated to Polaris a specific charge that one of its products infringed or would infringe claim two of the '080 patent."

The Court agreed with Minks that the given instruction did not fairly and correctly state the issues and the law, and that the jury should have been more clearly instructed that it was permitted to find notice prior to the date Minks discovered Polaris's infringement. According to the Court, a specific charge of infringement does not require the patentee to make an "unqualified" charge of infringement. Rather, plaintiff may satisfy the statutory notice requirement merely by making a qualified charge of infringement. Thus, a letter to Polaris written by Minks prior to his discovery of infringement, in which he described the elements of an infringing device, constituted a qualified charge of infringement possibly sufficient to fulfill the statutory notice requirement.

The Court next considered the question of infringement of claim 2 of the '080 patent, which is a means-plus-function claim. Polaris argued that the accused devices do not perform an identical function to the claimed function because the accused devices sense the frequency of an alternator's AC output rather than its peak voltage. The Court rejected this argument, noting that the function for which the accused device must be identical is the function

specified in the claim, which made no such distinction. Because it was undisputed that the accused device performed the claimed function of “inhibit[ing] ignition responsive to the speed of said engine,” the Federal Circuit found that the district court’s denial of Polaris’s motion was not improper.

With regard to structure, Polaris argued that the accused frequency-sensitive devices do not contain components equivalent to a voltage divider and a switching transistor and, thus, the frequency-sensing circuitry of the accused devices cannot be equivalent as a matter of law. The Court rejected this argument, noting that differences in physical structure alone are not determinative of § 112, ¶ 6 equivalence. Rather, the Court reiterated that, “once identity of function is established, the test for infringement is whether the structure of the accused device performs in substantially the same way to achieve substantially the same result” as the disclosed structure. Slip op. at 24.

The Court agreed with the district court that the jury’s verdict of infringement was supported by substantial evidence that the accused devices meet claim 2 of the ‘080 patent. Specifically, the Court found that both expert testimony and the ‘080 patent itself indicated that a person of ordinary skill would know that circuitry responsive to the frequency of an AC current is interchangeable with circuitry responsive to the voltage of an AC current. The Court concluded, therefore, that the record constituted substantial evidence upon which a reasonable jury could conclude that the accused devices perform the requisite function in substantially the same way—sensing the frequency of the alternator’s AC output rather than the voltage of that output—to achieve an identical result—interrupting the engine ignition. Accordingly, the Court affirmed the district court’s denial of Polaris’s JMOL motion on infringement.

Finally, the Federal Circuit affirmed the district court’s denial of Polaris’s motion for JMOL on the charge of willfulness. Polaris argued that the jury instruction on willful infringement was plain error

because it applied a negligence standard instead of one of objective recklessness, contrary to the Court’s opinion in *In re Seagate*. The Court rejected this argument, citing Polaris’s failure to proffer any evidence that it had been prejudiced by the error. Noting the district court’s finding that Polaris had deliberately copied Minks’s design, the Court concluded that the mistaken instruction was not prejudicial. According to the Court, Polaris’s deliberate act of copying would have satisfied either the negligence or the recklessness standard and the jury would have arrived at the same result under either instruction.

To Anticipate, a Prior Art Reference Must Contain All of the Limitations Arranged or Combined in the Same Way as Recited in the Claim

Susan Y. Tull

Judges: Linn (author), Clevenger, Moore

[Appealed from D. Ariz., Judge Collins]

In *Net MoneyIN, Inc. v. VeriSign, Inc.*, No. 07-1565 (Fed. Cir. Oct. 20, 2008), the Federal Circuit affirmed-in-part and reversed-in-part the district court’s judgments in favor of defendant VeriSign, Inc. (“VeriSign”). The Court affirmed that claims 1, 13, and 14 of U.S. Patent No. 5,822,737 (“the ‘737 patent”) and claim 1 of U.S. Patent No. 5,963,917 (“the ‘917 patent”) are invalid under 35 U.S.C. § 112, ¶ 2. The Court also affirmed the district court’s denial of plaintiff Net MoneyIN, Inc.’s (“Net MoneyIN”) motion to amend its complaint. The Court, however, reversed the district court’s grant of SJ that claim 23 of the ‘737 patent is invalid under 35 U.S.C. § 102(a) because the district court applied an incorrect standard of law.

Net MoneyIN’s patents are directed to systems for processing credit card transactions over the Internet and for addressing security concerns related to these transactions. The prior art for

processing online transactions involved four entities: the customer, merchant, merchant's bank, and issuing bank. In addition to imposing a heavy financial burden on merchants, these conventional models also required customers to convey confidential information over the Internet to unknown merchants. Net MoneyIN's patents added a fifth entity to this model, a financial processing entity that (1) received credit card account information and an amount to be charged from the customer when an order was placed; (2) sought authorization from the card issuer over the existing bank network; and (3) notified both the customer and the merchant of authorization. Of note, the '737 patent recited a bank computer that included means for generating an authorization indicia while the '917 patent recited a financial processing computer that included means for receiving customer account and amount data from both the customer and merchant computers.

“We thus hold that unless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102.”
Slip op. at 17-18.

Net MoneyIN sued VeriSign, among others, for infringement of the '737 and '917 patents. As part of its construction of the claim terms, the district court invalidated claims 1, 13, and 14 of the '737 patent and claim 1 of the '917 patent, which contain limitations in means-plus-function format, as lacking corresponding structure and, thus, indefinite under 35 U.S.C. § 112, ¶ 2.

Following claim construction, the district court denied Net MoneyIN's motion for leave to amend its complaint to add a claim for induced infringement, and granted VeriSign's motion for SJ that it did not induce infringement of Net MoneyIN's patents. The district court also granted VeriSign's motion for SJ of invalidity of claim 23 of the '737 patent under U.S.C. § 102(a), as anticipated. The district court then entered final judgment in favor of VeriSign and Net MoneyIN appealed.

On appeal, the Federal Circuit first addressed the district court's ruling on indefiniteness under 35 U.S.C. § 112, ¶ 2. Noting that claims 1, 13, and 14 of the '737 patent rise and fall together, the Court focused on claim 1 alone. Net MoneyIN argued that means-plus-function language was not present in claim 1 of the '737 patent, and alternatively, that if such language were present, the specification recited sufficient structure to make the claim definite. The Court disagreed. The claim's use of the word "means" and recital of a function triggered the presumption of means-plus-function under 35 U.S.C. § 112, ¶ 6 and the Court found that Net MoneyIN failed to rebut this presumption. Claim 1 of the '737 patent is directed to a financial transaction system comprising, among other things, "a first bank computer" including "means for generating an authorization indicia." Net MoneyIN contended that a "bank computer" was a commonly known structure for generating authorization indicia. The Court rejected this argument because the bank computer is not linked in the claim as the "means" for generating an authorization indicia. Rather, the bank computer is recited as "including" those means. Slip op. at 9. Because the Court concluded that the claimed generating means is a subset of the bank computer, it required recitation of structure that is a component of the bank computer to rebut the presumption. The Court reiterated its holding in *Aristocrat Technologies Australia Pty Ltd v. International Game Technologies*, 521 F.3d 1328, 1333 (Fed. Cir. 2008), that, "in a means-plus-function claim in which the disclosed

structure is a computer, or microprocessor, programmed to carry out an algorithm, the disclosed structure is not the general purpose computer, but rather the special purpose computer programmed to perform the disclosed algorithm.” Slip op. at 10-11 (internal quotation marks omitted). Here, because the Court found no disclosure of an algorithm by which a general purpose bank computer generates an authorization indicia, the Court affirmed the district court’s conclusion that claims 1, 13, and 14 of the ’737 patent are invalid.

The Federal Circuit next considered whether claim 1 of the ’917 patent is indefinite. The district court construed the function specifying that both the amount data and the account data must come from both the customer computer and the merchant computer. Net MoneyIN argued that the financial processing center received the data from either the customer computer, the merchant computer, or both computers. The Court concluded that Net MoneyIN’s proffered construction was different from, and broader in scope than, the construction it asserted in the district court. Because Net MoneyIN’s new construction was not proper on appeal, the Court affirmed the district court’s construction of this claim. Because Net MoneyIN conceded that, under the district court’s construction, no structure is disclosed in the specification to perform the claimed function, the Federal Circuit affirmed that claim 1 of the ’917 patent is invalid.

Turning to claim 23 of the ’737 patent, the Federal Circuit clarified that, “unless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102.” *Id.* at 17-18. The prior art at issue disclosed two protocols for processing Internet credit card transactions. Neither protocol contained all of the elements arranged or combined in the same manner as the ’737 patent. The Court concluded that the district court erred in combining parts of the separate protocols shown in the reference to find claim 23 anticipated. Accordingly, the

Court reversed the district court’s grant of SJ of invalidity.

Finally, the Court reviewed the district court’s denial of Net MoneyIN’s motion to amend its complaint. The Court held that, because VeriSign did not consent—either implicitly or explicitly—to litigate inducement, the district court possessed the discretion to deny Net MoneyIN’s motion. Because it found no abuse of the district court’s discretion, the Court affirmed the denial of the motion to amend.

The Grant of a Preliminary Injunction Is Reviewed for Clear Error

Matthew R. Van Eman

Judges: Newman (author), Archer (concurring), Gajarsa (dissenting)

[Appealed from N.D. Ill., Judge Coar]

In *Abbott Laboratories v. Sandoz, Inc.*, No. 07-1300 (Fed. Cir. Oct. 21, 2008), the Federal Circuit affirmed the district court’s grant of a preliminary injunction barring Sandoz, Inc. (“Sandoz”) from selling a generic form of extended release clarithromycin pending final resolution of the case.

The suit relates to extended release formulations of clarithromycin. Sandoz filed an ANDA, which the FDA approved in 2005. Abbott Laboratories (“Abbott”), who markets the drug under the brand name Biaxin®XL, filed suit, charging Sandoz with infringing U.S. Patent No. 6,010,718 (“the ’718 patent”) and U.S. Patent No. 6,551,616 (“the ’616 patent”). The ’718 patent claims an extended release formulation comprising an erythromycin derivative and a pharmaceutically acceptable polymer. The ’616 patent is a CIP of the ’718 patent, which claims a method of reducing gastrointestinal side effects.

The district court considered the factors relevant to the grant or denial of a preliminary injunction

and found that Abbott was likely to prevail on Sandoz's challenges based on patent invalidity in view of the prior art, unenforceability based on inequitable conduct during prosecution, and noninfringement. In addition, the district court determined that each of the equitable factors weighed in Abbott's favor.

"The question is not whether the patent is vulnerable; the question is who is likely to prevail in the end, considered with equitable factors that relate to whether the status quo should or should not be preserved while the trial is ongoing." Slip op. at 41.

On appeal, the Federal Circuit found that the district court did not clearly err in its determination that Sandoz would not likely succeed in establishing invalidity based on anticipation or obviousness. The Court found no error in the district court's conclusion that Sandoz would not likely succeed in establishing anticipation, as the prior art reference neither described the product of the '718 patent claims nor enabled the pharmacokinetic properties that are set forth in the claims. With respect to obviousness, the prior art references provided various controlled release formulations including clarithromycin, as well as the same polymeric carriers used in controlled release dosage forms for drugs other than clarithromycin. The district court found, and the Federal Circuit agreed, that "Sandoz had not produced evidence indicating that the [pharmacokinetic] limitations [of the patent claims] were disclosed in the prior art or were inherent to the structural limitations of the prior art compositions." Slip op. at 16. Regarding Sandoz's argument that the claimed invention was obvious to try, the Court held that *KSR International Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007), did not create a presumption that all experimentation in fields where there is already a background of useful knowledge is "obvious to try," without considering the nature of the science or technology. Rather, the Court held

that each case must be decided in its particular context, including the characteristics of the science or technology, the nature of the known choices, the specificity or generality of the prior art, and the predictability of results in the area of interest. The Court also noted that "knowledge of the goal does not render its achievement obvious." Slip op. at 19. Accordingly, the Federal Circuit affirmed the district court's ruling, holding that it appropriately applied the KSR standard of whether the patents-in-suit represented an "identified, predictable solution" and "anticipated success" to the problem of producing extended release formulations having the pharmacokinetic properties in the claims. *Id.* at 19-20.

The Federal Circuit further found that the district court had not erred in its analysis of Sandoz's challenges based on inequitable conduct. The Federal Circuit agreed with the district court that Sandoz did not establish that the various types of data that Abbott failed to submit to the PTO during prosecution were material under either Rule 56 or the reasonable examiner standard. Moreover, Sandoz did not present any independent evidence of intent to deceive, and the Court noted that materiality, even if found, does not establish intent. Thus, the Court found that the district court did not abuse its discretion in holding that the patents-in-suit were not likely to be held unenforceable due to inequitable conduct.

Regarding noninfringement, the Federal Circuit found no error in the district court's claim construction of "pharmaceutically acceptable polymer," which was based on the Federal Circuit's prior construction of the phrase in *Abbott Laboratories v. Andrx Pharmaceuticals, Inc.*, 473 F.3d 1196 (Fed. Cir. 2007). The district court found that Abbott demonstrated a substantial likelihood that the maltodextrin found in Sandoz's product satisfied this limitation. Accordingly, the Court affirmed the district court's ruling that Abbott had shown a reasonable likelihood of proving infringement.

The Federal Circuit also found that the district court properly concluded that the equitable factors each weighed in favor of granting the

preliminary injunction. Specifically, the Federal Circuit agreed with the district court's conclusion that damages for infringement, if Abbott should ultimately prevail in the litigation, did not negate the market share and revenue loss caused by Sandoz's market entry during the proceedings. In addition, the Federal Circuit agreed that the balance of hardships weigh in Abbott's favor, concluding that "Abbott will lose much more if [the] Court did not enjoin Sandoz's infringing conduct than if the Court enjoins Sandoz and it is subsequently found that the '718 patent is invalid or unenforceable." Slip op. at 38 (quoting *Abbott Labs. v. Sandoz, Inc.*, 500 F. Supp. 2d 807, 845 (N.D. Ill. 2007)). Finally, as to the public interest, the district court acknowledged that public interest favors less expensive drugs. The district court also recognized that shifting market benefits to the infringer while litigation is pending for patents that are likely to withstand the attack adversely affects the incentive for discovery and development of new products. Thus, the Federal Circuit held that the district court did not abuse its discretion in weighing the legal probabilities and equities and granting preliminary injunction.

Judge Gajarsa dissented, focusing on the court's treatment of the likelihood of success factor in the preliminary injunction analysis. Specifically, Judge Gajarsa stated that the district court had erred because, under Federal Circuit precedent, "[i]n resisting a preliminary injunction, however, one need not make out a case of actual invalidity. Vulnerability is the issue at the preliminary injunction stages, while validity is the issue at trial." Gajarsa Dissent at 2 (quoting *Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1335 (Fed. Cir. 2006)). Further, Judge Gajarsa stated that "when the alleged infringer raises a substantial question regarding validity, a preliminary injunction cannot issue because the patentee has failed to demonstrate a likelihood of success on the merits." *Id.* at 4. Here, Judge Gajarsa would find that the district court committed reversible error because Sandoz had raised substantial questions as to obviousness and enforceability of the claims that were the basis for the preliminary injunction.

In a section of the opinion in which concurring Judge Archer did not join, Judge Newman addressed the dissent's arguments as to the proper standard of review of the grant of a preliminary injunction in patent cases. Judge Newman summarized the standard as applied in each circuit and by the Supreme Court, explaining that each reviewed the grant of a preliminary injunction for an abuse of discretion, and that "[t]he correct standard is not whether a substantial question has been raised, but whether the patentee is likely to succeed on the merits." Slip op. at 41. In addition, Judge Newman stated that the dissent relied on recent Federal Circuit decisions that are not clearly established precedent, and if there is a conflict between more recent holdings and prior Federal Circuit decisions, the Court must follow the holdings of the earlier decisions. If the Court believes a different standard should apply to patent cases, that change must be made en banc.

Insufficient Written Description Under Representative Number of Species Test Where Only One Species Was Identified

Mary R. Henninger

Judges: Michel, Mayer, Stearns (author and District Judge sitting by designation)

[Appealed from Board]

In *In re Alonso*, No. 08-1079 (Fed. Cir. Oct. 30, 2008), the Federal Circuit affirmed the Board's decision sustaining the examiner's rejection of claim 92 of U.S. Patent Application No. 08/469,749 ("the '749 application") for lack of adequate written description.

Claim 92 of the '749 application was directed to a method of treating neurofibrosarcoma, a rare cancer of the sheath of a peripheral nerve, using human monoclonal antibodies targeted to a patient's tumor. In Example 1, the '749

application described preparing a tumor cell suspension from a tumor sample, sensitizing human spleen cells with the tumor cells, fusing the sensitized spleen cells with a cell line to create hybridomas, and screening for hybridomas that secrete monoclonal antibodies specifically reactive to the tumor cells. Example 2 of the '749 application further described treating a patient with neurofibrosarcoma using monoclonal antibodies obtained by this method using cells isolated from the patient's own tumor.

“[A] patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species other than those specifically enumerated.” Slip op. at 7 (citation omitted).

The examiner rejected claim 92 as lacking adequate written description support for the broad genus of antibodies encompassed by the claim language. The Board affirmed the rejection, finding the single antibody described in the specification to be insufficiently representative to provide adequate written description support for the genus of antibodies claimed. The Court also noted that the Board relied on two scientific articles that confirmed the hypothesis that the antibodies required to perform Alonso's claimed method vary substantially in their composition.

The Court found that the Board's factual findings for lack of written description were supported by substantial evidence. The Court relied on its previous holding in *Noelle v. Lederman*, 355 F.3d 1343, 1350 (Fed. Cir. 2004), that “a patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated.” Slip op. at 7. The Court also

found that Alonso failed to distinguish the facts of *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2002), by arguing that he had reduced his method to practice and identified the resulting compound. The Court stated that, “while it is true that Rochester disclosed no compounds that worked with the claimed method, the one compound disclosed by Alonso cannot be said to be representative of a densely populated genus.” Slip op. at 8. The Court also dismissed Alonso's argument that the Board's findings as to the sufficiency of description and enablement were at odds since the Board had reversed the examiner's rejection of claim 92 for lack of enablement. The Court restated that, while the written description and enablement requirements usually rise and fall together, each serves discrete legal requirements, and that an invention may be enabled even though it has not been described.

The Court also noted that the specification of the '749 application does not characterize the antigens to which the monoclonal antibodies must bind, and only discloses the molecular weight of the one antigen identified in the specification. The Court further stated that the specification taught nothing about the structure, epitope characterization, binding affinity, specificity, or pharmacological properties common to the large family of antibodies implicated by the method. Relying on prior written description case law, the Federal Circuit held that this was insufficient.

Alonso also argued that there was a well-known correlation between the structure and function of the antibodies generated by the treatment method described in the '749 application. However, since Alonso did not raise the structure-function correlation argument in the proceedings before the Board, the Federal Circuit did not consider the argument on appeal.

To Be Patentable Under § 101, a Process Must Be Tied to a Machine or Transform an Article into a Different State or Thing

Erika H. Arner

Judges: Michel (author), Newman (dissenting), Mayer (dissenting), Lourie, Rader (dissenting), Schall, Bryson, Gajarsa, Linn, Dyk (concurring), Prost, Moore

[Appealed from Board]

In *In re Bilski*, No. 07-1130 (Fed. Cir. Oct. 30, 2008) (en banc), the Federal Circuit affirmed the decision of the Board, finding that the method claims in Bernard L. Bilski and Rand A. Warsaw's (collectively "Bilski") patent application were not directed to statutory subject matter under 35 U.S.C. § 101. In doing so, the Court noted that the machine-or-transformation test is the test that should be used to determine whether a process claim is drawn to statutory subject matter. The Court explained that under this test, a claimed process is patentable 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.

Bilski filed a patent application with claims directed to a method for hedging risk in the field of commodities trading. Claim 1 recites "[a] method for managing the consumption risk costs of a commodity sold by a commodity provider at a fixed price comprising the steps of . . . initiating a series of transactions between said commodity provider and consumers of said commodity"; "identifying market participants for said commodity having a counter-risk position to said consumers"; and "initiating a series of transactions between said commodity provider and said market participants." Slip op. at 2.

The examiner rejected Bilski's claims under § 101, reasoning that they were not directed to the "technological arts" and that they were not limited by any specific apparatus. *Id.* at 3. On appeal, the

Board held that the examiner erred to the extent he relied on a "technological arts" test because the case law did not support such a test. It noted that the examiner's requirement of a specific apparatus was also erroneous. Nonetheless, the Board sustained the examiner's rejection, finding that the claims were directed to an abstract idea ineligible for patent protection. Bilski appealed.

On appeal, a panel heard oral argument on October 1, 2007. Prior to disposition by the panel, however, the Federal Circuit sua sponte ordered an en banc review. In its order, the Federal Circuit posed five questions for supplemental briefing by the parties and amici:

(1) Whether claim 1 of Bilski's application claims patent-eligible subject matter under 35 U.S.C. § 101?

(2) What standard should govern in determining whether a process is patent-eligible subject matter under § 101?

(3) Whether the claimed subject matter is not patent-eligible because it constitutes an abstract idea or mental process; when does a claim that contains both mental and physical steps create patent-eligible subject matter?

(4) Whether a method or process must result in a physical transformation of an article or be tied to a machine to be patent-eligible subject matter under § 101?

"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 10.

(5) Whether it is appropriate to reconsider *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998), and *AT&T Corp. v. Excel Communications, Inc.*, 172 F.3d 1352 (Fed. Cir. 1999), in this case and, if so, whether those cases should be overruled in any respect?

The Federal Circuit began its analysis with the language of the statute, noting that § 101 recites four categories of patent-eligible subject matter: processes, machines, manufactures, and compositions of matter. The Court observed that the issue here involved what the term “process” in § 101 meant, and how to determine whether a given method claim recites a process that complies with § 101. The Court rejected the dictionary definition of the term “process,” noting that the Supreme Court has held that the meaning of “process” as used in § 101 is narrower than its ordinary meaning. Specifically, the Court noted that a claim is not a patent-eligible “process” if it claims laws of nature, natural phenomena, or abstract ideas, which the Court characterized as “fundamental principles.” Slip op. at 6-7. The Court explained that a process claim that incorporates a “fundamental principle” may be patented only if it recites a particular application of the fundamental principle. It added that the “machine-or-transformation test” is the “definitive test” for determining when a process claim encompasses only a particular application of a fundamental principle. *Id.* at 10. According to this test, “[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.” *Id.*

The Court acknowledged arguments by *Bilski* and several amici that the Supreme Court did not intend the machine-or-transformation test to be the sole test for patentable processes. The Court, however, noted that its reliance on this test as the applicable test for § 101 analysis was “sound.” *Id.* at 14. It added that the Supreme Court or the Federal Circuit may need to change the test

because “future developments in technology and the sciences may present difficult challenges to the machine-or-transformation test, just as the widespread use of computers and the advent of the Internet has begun to challenge it in the past decade.” *Id.* at 14-15. But for now, it declined to depart from this test.

The Federal Circuit also reiterated two other important aspects of the Supreme Court’s § 101 jurisprudence. First, the Court noted whether a claimed process is novel or nonobvious is irrelevant to the § 101 analysis. And, second, it is inappropriate to determine the patent-eligibility of a claim as a whole based on whether selected limitations constitute patent-eligible subject matter.

“Patents granted in the wake of *State Street* have ranged from the somewhat ridiculous to the truly absurd.” Mayer Dissent at 12.

The Federal Circuit next addressed the issue of whether several other purported articulations of § 101 tests were valid and useful, and rejected all of them. It started with the *Freeman-Walter-Abele* test, which requires determining whether the claim recites an “algorithm” and then determining whether the algorithm is “applied” in any manner to physical elements or process steps. The Court found that this test was inadequate in light of its opinion here and that it had previously recognized that a claim failing that test may nonetheless be patent-eligible. Similarly, the Court concluded that the “useful, concrete and tangible result” test associated with *State Street* was inadequate. It explained that “while looking for ‘a useful, concrete and tangible result’ may in many instances provide useful indications of whether a claim is drawn to a fundamental principle or a practical application of such a principle, that inquiry is insufficient to determine whether a claim is patent-eligible under § 101.” *Id.* at 20.

“[T]he full reach of today’s change of law is not clear Uncertainty is the enemy of innovation. These new uncertainties not only diminish the incentives available to new enterprise, but disrupt the settled expectations of those who relied on the law as it existed.” Newman Dissent at 2.

The Court also declined to adopt the “technological arts test” urged by some amici. It reasoned that the contours of such a test would be unclear because the meanings of the terms “technological arts” and “technology” were both ambiguous and ever-changing. The Court likewise rejected calls for categorical exclusions. In so doing, the Court reaffirmed its conclusion in *State Street* that the so-called “business method exception” is unlawful and that “business method claims . . . are ‘subject to the same legal requirements for patentability as applied to any other process or method.’” *Id.* at 21 (quoting *State Street*, 149 F.3d at 1375-76). The Court also declined to adopt a test that would allow claims that recite “physical steps” without any connection to a particular machine or apparatus. *Id.* at 23.

Having rejected these other tests, the Federal Circuit provided additional guidance on how to perform the § 101 analysis using the machine-or-transformation test. In so doing, the Court drew heavily from *Parker v. Flook*, 437 U.S. 584 (1978), and *Gottschalk v. Benson*, 409 U.S. 63 (1972). The Court explained that the machine-or-transformation test is a two-branched inquiry; an applicant may show that a process claim satisfies § 101 either by showing that his claim is tied to a particular machine, or by showing that his claim transforms an article. The Court noted that “the use of a specific machine or transformation of an article must impose meaningful limits on the claim’s scope to impart patent-eligibility,” and that “the involvement of the machine or transformation in the claimed process must not merely be

insignificant extra-solution activity.” Slip op. at 24. As to machine implementation, the Court explained that because *Bilski* admitted that the language of claim 1 did not limit any process step to any specific machine or apparatus, issues specific to the machine-implementation part of the test were not before it. Thus, the Court left for another day whether and when the recitation of a computer alone would suffice to tie a process claim to a particular machine. With respect to the transformation part of the test, the Court noted that a claimed process is patent-eligible if it transforms an article into a different state or thing. It explained that the transformation must be central to the purpose of the claimed process and that the main aspect of the transformation test that required clarification was what sorts of things constitute “articles” such that their transformation is sufficient to impart eligibility under § 101.

The Court observed that it was virtually self-evident that a process for chemical or physical transformation of physical objects or substances is statutory. It noted, however, that “the raw materials of many information-age processes . . . are electronic signals and electronically-manipulated data” and “so-called business methods” that involve the “manipulation of even more abstract constructs such as legal obligations, organizational relationships, and business risks.” *Id.* at 25. It questioned which, if any, of these processes qualified as a transformation or reduction of any article into a different state or thing constituting patent-eligible subject matter. It noted that its case law has taken a measured approach to this question and that it saw no reason to expand the boundaries of what constitutes patent-eligible transformations of articles. It explained that “[s]o long as the claimed process is limited to a practical application of a fundamental principle to transform specific data, and the claim is limited to a visual depiction that represents specific physical objects or substances, there is no danger that the scope of the claim would wholly pre-empt all uses of the principle.” *Id.* at 26.

Finally, the Court applied the principles mentioned above to *Bilski*’s claims to determine whether those

claims satisfied the machine-or-transformation test. The Court held that the claimed process did not transform any article to a different state or thing. It explained that mere manipulations of legal obligations or relationships, business risks, or “other such abstractions” could not meet the transformation prong of the test because they were not and did not represent physical objects or substances. *Id.* at 28. In addition, the Court noted that because *Bilski* admitted that the claims did not involve a machine or an apparatus, that prong was also not satisfied. Accordingly, the Court concluded that *Bilski*’s claims were not drawn to patent-eligible subject matter under § 101 and affirmed the decision of the Board.

“Because [the majority] links patent eligibility to the age of iron and steel at a time of subatomic particles and terabytes, I must respectfully dissent.” Rader Dissent at 1.

Judge Dyk, joined by Judge Linn, filed a concurring opinion to document statutory support for the majority’s opinion, analyzing the history of the patent statute beginning with the Patent Act of 1793 and its English underpinnings. He disagreed with the dissenters that the majority “usurp[ed] the legislative role.” Dyk Concurrence at 1. Following a review of patents issued under the English Statute of Monopolies and the legislative histories of the 1793 and 1952 Patent Acts, Judge Dyk noted that “the uniform assumption was that the only processes that were patentable were processes for using or creating manufactures, machines, and compositions of matter.” *Id.* at 2. He concluded that the history of § 101 fully supported the majority’s holding that *Bilski*’s claims do not recite patentable subject matter.

Judge Newman dissented. She observed that the exclusion of certain process inventions was

contrary to the statute and precedent, and ignored the constitutional mandate. She explained that by limiting patent eligibility to those processes that satisfy the machine-or-transformation test, the majority contravened the Supreme Court’s refusal to so hold in *Benson* and *Flook*. Newman Dissent at 6-7. She also examined the English origins and legislative history of the 1793 Patent Act, concluding that nothing in the statute supported demoting processes to “second-class status” behind the other categories of patentable subject matter. *Id.* at 26. To avoid a sure disincentive to innovation-based commerce, Judge Newman concluded that the law permitted patenting any process invention “that is not clearly a ‘fundamental truth, law of nature, or abstract idea.’” *Id.* at 40.

Judge Mayer also dissented, arguing that the majority did not go far enough. He explained that the Court should have overruled *State Street* and *AT&T*. According to him, affording patent protection to business methods lacks constitutional and statutory support, and retards innovation. Judge Mayer also listed patents granted since *State Street* ranging “from the somewhat ridiculous to the truly absurd” and noted the “thundering chorus of criticism” that ensued. Mayer Dissent at 12-13. He urged adopting a “technological arts” test that would exclude from patent eligibility any process that draws its inventive concept from disciplines such as business, law, sociology, or psychology. *Id.* at 23.

Finally, Judge Rader also dissented, arguing that the majority created a new circuitous judge-made test in contravention of Supreme Court precedent. He explained that § 101 broadly grants patent eligibility to “any” process, subject to the other conditions for patentability. Rader Dissent at 2. According to him, the majority should have merely noted that *Bilski* is attempting to patent an abstract idea and that nothing more was needed.

WASHINGTON, DC
ATLANTA, GA
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PALO ALTO, CA
RESTON, VA
BRUSSELS
SHANGHAI
TAIPEI
TOKYO



Contacts



Esther H. Lim
Editor-in-Chief
202.408.4121
esther.lim@finnegan.com



Naveen Modi
Assistant Editor
202.408.4065
naveen.modi@finnegan.com



Tina E. Hulse
Assistant Editor
650.849.6665
tina.hulse@finnegan.com



Joyce Craig
Assistant Editor
202.408.6013
joyce.craig@finnegan.com

Abbreviations

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

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Looking Ahead

On April 1, 2008, Judge Cacheris struck down the highly controversial PTO rules that limited the number of claims and continuation applications that may be filed. Judge Cacheris found the rules to be substantive in nature and, thus, beyond the PTO's rulemaking authority. See *Tafas v. Dudas*, No. 1:07cv846 (E.D. Va. 2007). The PTO appealed. See *Tafas v. Dudas*, No. 08-1352 (Fed. Cir. May 13, 2008). The appeal has been fully briefed. Many amici curiae have also filed briefs. The Federal Circuit heard oral argument on December 5, 2008, and is expected to rule sometime next year.