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EDITED BY VINCE KOVALICK

Disclosed Ingestion of Loratadine Inherently Anticipates Claim to Metabolite Thereof

Louis M. Troilo

[Judges: Rader (author), Plager, and Bryson]

In Schering Corporation v. Geneva Pharmaceuticals, Inc., No. 02-1516 (Fed. Cir. Aug. 1, 2003), the Federal Circuit affirmed a district court's SJ of invalidity of certain claims of U.S. Patent No. 4,659,716 ("the '716 patent") as being inherently anticipated.

U.S. Patent No. 4,282,233 ("the '233 patent") discloses and claims the antihistamine loratadine, which is the active component of a pharmaceutical that Schering Corporation ("Schering") markets as CLARITIN™. Schering's subsequent '716 patent covers a metabolite of loratadine called descarboethoxyloratadine ("DCL"). Specifically, during the digestion process, the pharmaceutical undergoes a chemical conversion to form a new metabolite compound. Loratadine and its metabolite DCL structurally differ only in that loratadine has a carboethoxy group (-COOEt) on a ring nitrogen, whereas DCL has a hydrogen atom on that ring nitrogen. Unlike conventional antihistamines used at the time Schering launched CLARITIN™, both loratadine and its metabolite DCL are nondrowsy antihistamines.

The '233 patent issued on August 4, 1981, over one year before the earliest priority date of the '716 patent, and, thus, is prior art to the '716 patent under 35 U.S.C. § 102(b). While the '233 patent discloses and claims loratadine, it does not expressly disclose DCL or refer to metabolites of loratadine. Once the '233 patent expired, Geneva Pharmaceuticals, Inc. ("Geneva") and the numerous other Defendants-Appellees sought to market generic versions of loratadine. In doing so, each Appellee sought regulatory approval and submitted an application to the FDA. After receiving notice of the FDA filings, Schering filed suit for infringement of the '716 patent. The parties filed cross motions for SJ on validity issues.

The district court construed claims 1 and 3 of the '716 patent to cover DCL in all its forms, including "metabolized within the human body" and "synthetically produced in a purified and isolated form." Applying that construction, the district court found that the '233 patent did not expressly disclose DCL. However, the district

court found that DCL was necessarily formed as a metabolite by carrying out the process disclosed in the '233 patent. Thus, the '233 patent inherently anticipated claims 1 and 3 of the '716 patent.

On appeal, Schering asserted that inherent anticipation requires recognition in the prior art. The Federal Circuit disagreed, observing that inherent anticipation does not require that a person of ordinary skill in the art at the time would have recognized the inherent disclosure. The Federal Circuit noted that DCL is not formed accidentally or under unusual conditions when loratadine is ingested. Rather, DCL necessarily and inevitably forms from loratadine under normal conditions as a necessary consequence of administering loratadine to patients. Therefore, despite the fact that skilled artisans did not recognize that the prior art '233 patent inherently produced DCL, and despite the fact that the '233 patent does not disclose any compound that is identifiable as DCL, the Court found inherent anticipation.

The Federal Circuit next examined whether Schering's secret tests of loratadine before the critical date placed DCL in the public domain. According to Schering, DCL was not in the public domain such that it could be prior art against the '716 patent because Schering only tested loratadine in secret. The Federal Circuit disagreed, noting that anticipation does not require the actual creation or reduction to practice of the prior art subject matter; anticipation requires only an enabling disclosure. The Court thus ruled that actual administration of loratadine to patients before the critical date of the '716 patent was irrelevant. Rather, the '233 patent suffices as an anticipatory reference if it discloses in an enabling manner the administration of loratadine to patients.

Concerning whether the '233 patent contains an enabling disclosure of DCL, the Federal Circuit noted that this prior art patent need only describe how to make DCL in any form encompassed by a compound claim covering DCL, including DCL as a metabolite in a patient's body. Because the '233 patent discloses administering loratadine to a patient, the inherent result of which is the formation of DCL metabolite, the Federal Circuit held that the '233 patent provides an enabling disclosure for making DCL.

The Federal Circuit noted that its conclusion on inherent anticipation does not preclude patent protection for metabolites of known drugs. Rather, the Court believed that with

proper claiming, patent protection is available for such metabolites. For example, unlike the bare compounds recited in claims 1 and 3 of the '716 patent, the Court indicated that a metabolite may be claimed in its pure and isolated form, or as a pharmaceutical. Alternatively, the patent drafter could claim a method of administering the metabolite or the corresponding pharmaceutical composition. According to the Court, because the '233 patent does not disclose isolation of DCL, it does not provide an enabling disclosure to anticipate such claims. Applying this rationale to the '716 patent, claims 5-13 covering pharmaceutical compositions and claims 14-16 covering methods of treating allergic reactions by administering compounds that include DCL were not found anticipated by the '233

Finally, the Federal Circuit upheld the district court's finding that there was no genuine issue of material fact about whether ingestion of loratadine necessarily produces DCL metabolite. The Federal Circuit found that the district court's conclusion was supported by extensive evidence, including thirteen clinical studies performed by Schering in which all 144 patients involved had measurable amounts of DCL in their systems after ingesting loratadine. This data conforms with Schering's own expert, who testified that no human has been found that does not metabolize loratadine to DCL.

Embodiments Missing from CIP Patent Are Not Restricted from Claim Scope

Vince Kovalick

[Judges: Bryson (author), Newman, and Gajarsa]

In Cordis Corporation v. Medtronic AVE, Inc., No. 02-1457 (Fed. Cir. Aug. 12, 2003), the Federal Circuit reversed the district court's judgment of noninfringement after disagreeing with the district court's claim construction and its application of prosecution history estoppel.

The patents at issue relate to balloon-expandable coronary stents for use in balloon-angioplasty procedures. Cordis Corporation ("Cordis") sued Medtronic AVE, Inc. and several other companies (collectively "Medtronic") for infringement of U.S. Patent Nos. 4,739,762 ("the

'762 patent") and 5,195,984 ("the '984 patent"). Each of the asserted claims recites a "wall surface having a substantially uniform thickness and a plurality of slots formed therein." The district court had construed this limitation to be limited to devices in which the slots are formed by the removal of material. And, because the accused stents have slots that are formed when wire-like material is bent into sinusoidal rings, which are then connected together, the district court granted SI of no literal infringement. The district court also construed the claim phrase "wall surface having a substantially uniform thickness" to mean the thickness of the wall may not vary by more than 0.001 inch. A jury found the accused stents to infringe under the DOE and awarded Cordis \$271 million in damages. On post-trial motions, however, the district court granted JMOL of no infringement, holding that Cordis was barred from asserting equivalence on the foregoing claim limitations.

The Federal Circuit disagreed with the district court's claim constructions. According to the Federal Circuit, nothing about the phrase "slots formed therein" suggests that the slots must be formed by any particular process. The phrase "slots formed therein" describes the physical characteristics of the product, not the method of its manufacture, according to the Court. The specifications of the '762 and '984 patents do not define the "slots formed therein" as openings created by the removal of material from a pre-existing wall surface, even though the preferred embodiment discloses such a configuration.

The district court had based its conclusion on the absence of a particular embodiment from a parent application in a CIP application that led to the patents-in-suit. The district court interpreted this omission of an embodiment as a surrendering of bent-wire or wire mesh-like stents. The Federal Circuit rejected this reasoning, concluding that there may have been several reasons that the patentee choose not to include that embodiment in the CIP application. The Court concluded that a patentee may choose not to carry forward a particular embodiment from a parent patent into a CIP application because that embodiment does not satisfy a limitation that was added to the claims in the CIP. That choice, however, does not mean that the scope of the CIP is limited to the preferred embodiments that were carried forward.

Concerning the claim limitation "substantially uniform thickness," the Federal Circuit con-

cluded that the patent does not set out any numerical standard by which to determine whether the thickness of the wall surface is "substantially uniform." During the prosecution history, applicants distinguished certain prior art by explaining that the wall thickness of the prior art stent varied at different points and ranged from a minimum thickness of 0.0035 inches to a maximum thickness of 0.0045 inches. According to the Federal Circuit, this prosecution history does not disclaim stents that vary in thickness by 0.001 inches or more. The Federal Circuit ruled that the prosecution history overall did not indicate that this one area of distinction was the only distinguishing feature between the claims and the prior art. Moreover, the Federal Circuit concluded that this particular distinction was not a clear and unmistakable disclaimer.

For the same reasons, this prosecution history did not rise to the clear level necessary to support an argument-based estoppel against application of the DOE. Accordingly, the Federal Circuit reversed the judgments of noninfringement and remanded.

Patent Claims Found "Insolubly Indefinite," Hence Invalid

Ningling Wang

[Judges: Linn (author), Lourie, and Gajarsa]

In Honeywell International, Inc. v. International Trade Commission, No. 02-1393 (Fed. Cir. Aug. 26, 2003), the Federal Circuit affirmed the decision of the ITC that the claims at issue were invalid as indefinite under 35 U.S.C. § 112, ¶ 2.

Honeywell International, Inc. ("Honeywell") owns U.S. Patent No. 5,630,976 ("the '976 patent"), which claims a process for manufacturing a multifilament polyester product called polyethylene terephthalate ("PET") yarn. Honeywell complained to the ITC that Hyosung Corporation of Seoul, Korea, and Hyosung (America), Inc. (collectively "Hyosung") were importing PET yarn and PET yarn-containing products that were produced by a process that infringed several claims of the '976 patent. The ITC found that the asserted claims were invalid as indefinite under 35 U.S.C. § 112, ¶ 2, and that the accused polyethylene terephthalate yarns did not infringe.

Claims 1 and 7 of the '976 patent require that solidified yarn must be withdrawn at a cer-

tain speed to form a crystalline, partially oriented yarn with a specified crystallinity and a specified melting-point elevation ("MPE"). Similarly, claim 14 requires that, during the process, the yarn exhibit an MPE within a specified range after the hot drawing.

The specification of the '976 patent defines the term "MPE" as "the difference between the specimen melting point (M.P.) and the melting point (M.P.Q.) of a specimen after subsequent rapid liquid nitrogen quenching of an encapsulated [differential scanning calorimeter ("DSC")] sample from the melt." However, the specification does not disclose any method used to prepare the PET-yarn specimen for thermal analysis in the DSC.

The Federal Circuit noted that the calculated MPE for a given sample can vary greatly depending on which method was used to prepare the sample. As of the earliest priority date of the '976 patent, three PET-yarn sample-preparation methods were published, including (1) the "coil method," (2) the "cut method," and (3) the "restrained method." In addition, Honeywell argued that a fourth method of sample preparation, i.e., the "ball method," existed at the time of the invention, but it was not published. The ALI had found that only when using the ball method did the results in MPE of the accused PET-yarn products fall within the claimed ranges of the '976 patent. Therefore, the ITC had concluded that the choice of sample-preparation method was critical to determining whether a particular product is made by a process that infringes the '976 patent.

The Federal Circuit agreed, but neither the claims, the written description, nor the prosecution history of the '976 patent discloses which of the four sample-preparation methods was used.

The Federal Circuit rejected Honeywell's argument that the claim should be construed to read on the "ball method only." Honeywell's proffered construction is supported only by its own expert's declaration and its own confidential document.

The Court also rejected a construction whereby the claims would be satisfied if the MPE falls within the claimed range using any one of the four known sample-preparation methods, concluding that such a construction would not give the public fair notice of the boundaries of the invention.

Finally, the Federal Circuit rejected a construction whereby the claims would be satisfied only if the MPE falls within the claimed range

using each of the four known samplepreparation methods, because Honeywell admitted that such a construction would render the invention inoperable.

Having found the claims invalid for being indefinite, the Court vacated the noninfringement decision as moot.

What Is "About" About?

Mark D. Sweet

[Judges: Mayer (author), Dyk, and Prost]

In *BJ Services Company v. Halliburton Energy Services, Inc.*, No. 02-1496 (Fed. Cir. Aug. 6, 2003), the Federal Circuit affirmed a district court's decision holding a claim of U.S. Patent No. 6,017,855 ("the '855 patent") valid and infringed.

BJ Services Company ("BJ Services") is the owner of the '855 patent, which is directed to a method of fracturing subterranean formations to stimulate oil and gas wells. The sole claim at issue is directed to forming a base fluid by blending together an aqueous fluid and carboxymethyl guar, which has a C* value of about 0.06 percent by weight, adding a crosslinking agent to the base fluid to form a gel, and injecting the gel into at least a portion of a subterranean formation at high pressure to form fractures within the formation.

BJ Services brought suit against Halliburton Energy Services, Inc. ("Halliburton"), claiming that Halliburton infringed the sole claim at issue in the '855 patent. Halliburton argued that the '855 patent was invalid because the claim was indefinite, the specification was not enabling to one of skill in the art, the claim was anticipated, and the '855 patent did not name the proper inventors. A jury found the claim in the '855 patent valid and infringed, and awarded damages to BJ Services.

On appeal, the Federal Circuit held that a reasonable jury could find that the claim in the '855 patent was not invalid for lack of enablement. In response to the argument that the '855 patent does not enable the method and conditions used to measure C*, the Federal Circuit concluded that while the patent was silent about the measurement conditions and while the C* value may vary depending upon the chosen conditions, evidence was presented at trial in the form of the testimony of the inventors of the '855 patent, testimony of a rheology

expert, and excerpts from a textbook to support the jury's conclusion that one of skill in the art would have known how to measure C*.

The Federal Circuit also ruled that a reasonable jury could find that the asserted claim was not invalid for indefiniteness based on the term "about 0.06." The Court relied on experimental results presented by BJ Services that averaged slightly below 0.06 to support the finding of the jury that the term "about" was intended to encompass a range of experimental error.

The Federal Circuit additionally held that the claim of the '855 patent was not anticipated by U.S. Patent No. 5,697,444 to Moorhouse ("Moorhouse"). Moorhouse disclosed a fracturing fluid comprising one or more polymers, preferably carboxymethyl quar, but did not disclose the C* value, which was later measured as 0.077. In the district court, the jury was instructed to give "about 0.06" its plain and ordinary meaning. Because the term "about" was used to encompass experimental error and the jury had before it the typical experimental range, the Federal Circuit held that substantial evidence supports the jury's finding that Moorhouse's C* value of 0.077 does not anticipate the C* value of about 0.06 recited in the claim of the '855 patent.

Finally, the Federal Circuit held that evidence at trial supported the jury's finding that the '855 patent was not invalid for failing to name the proper inventors. The claim at issue was directed to a method of fracturing a subterranean formation using a polymer with a certain C* value. The Federal Circuit ruled that the claim was not to the polymer itself but rather to a method that incorporates that polymer. The evidence at trial indicated that the inventor of the polymer had no knowledge of the method, how the polymer would be used, or the C* value.

District Court Improperly Construed Claim Limitation After Jury's Verdict

Vince Kovalick

[Judges: Dyk (author), Schall, and Mayer (dissenting)]

In Hewlett-Packard Co. v. Mustek Systems, Inc., No. 02-1372 (Fed. Cir. Aug. 7, 2003), the Federal Circuit vacated a judgment of infringement of the asserted claims of U.S. Patent No.

5,336,878 ("the '878 patent") and affirmed a judgment of invalidity of the asserted claims of U.S. Patent No. 4,837,635 ("the '635 patent").

Hewlett-Packard Company ("HP") owns the '878 and '635 patents directed to optical-scanner technology. HP sued Mustek Systems, Inc. and Mustek, Inc. (collectively "Mustek") for infringement of five patents, but only the '878 and '635 patents remained on appeal. A jury had found that Mustek literally infringed the claims of both patents. The jury had also found claim 1 of the '635 patent anticipated by a prior art patent ("Cawkell") and claims 1-8 of the '635 patent obvious in view of the prior art. Although the jury had not addressed the issue of infringement under the DOE, and HP had not requested JMOL on this issue, the district court granted JMOL of infringement under the DOE as to certain claims of the '878 patent. The district court also reduced the damages award. Finally, the district court ruled that certain claims of the '878 patent were invalid.

On appeal, the infringement issue turned on the construction of the claim phrase "scan speed indicating means for generating a scan speed signal indicating a selected one of different scan speeds of said displacement means." Although neither party requested a specific construction of this language when the district court first construed the claims, on JMOL, Mustek urged that the district court should construe this limitation as requiring that the user select a specific scanning speed known to the user.

The Federal Circuit ruled that it was improper for the district court to have adapted a new or more detailed claim construction in connection with the JMOL motion. Rather, on JMOL, the issue should have been limited to the guestion of whether substantial evidence supported the verdict under the agreed-upon instruction. In other words, where the parties in the district court elect to provide the jury only with the claim language itself and do not provide an interpretation of the language in light of the specification and the prosecution history, it is too late at the JMOL stage to argue for or adopt a new and more detailed interpretation of the claim language and test the jury's verdict by that new and more detailed interpretation. Accordingly, the Federal Circuit held that the district court's decision was contrary to the undisputed facts and unsupported by substantial evidence because the accused devices do not include a scan-speed selector that, based on the user's selection, generates a scanspeed signal, as required by the district court's original instruction.

The Federal Circuit also vacated the district court's JMOL of infringement under the DOE since no timely motion on this issue had been filed. Moreover, there was no evidence in the record to address the issue of DOE.

Concerning invalidity, the Federal Circuit agreed that Cawkell anticipated claim 1 of the '635 patent and rejected HP's attempts to read limitations into the claims so as to distinguish Cawkell. The obviousness decision was based on the demonstration of a prior art scanner and testimony of three Mustek witnesses who testified that the claimed methods had been publicly performed using the prior art scanner in the same manner as demonstrated to the jury. The Federal Circuit rejected HP's argument that the testimony regarding the use of the prior art scanner was uncorroborated, concluding instead that the testimonial evidence here was sufficiently corroborated by the operation of the device itself, which was made contemporaneously with the alleged prior invention.

Judge Mayer dissented, concluding that the jury's finding of infringement was proper because the claim did not require that a user know what he was selecting, only that a selection be made.

Scope of Claim Terms Broadened by Relying on Ordinary Meaning

Christopher H. Kirkman

[Judges: Gajarsa (author), Newman, and Bryson]

In Anchor Wall Systems, Inc. v. Rockwood Retaining Walls, Inc., No. 02-1592 (Fed. Cir. Aug. 13, 2003), the Federal Circuit affirmed-in-part, reversed-in-part, and vacated-in-part the district court's judgment and remanded the case for further proceedings.

Anchor Wall Systems, Inc. ("Anchor") sued Rockwood Retaining Walls, Inc. and several others (collectively "Rockwood"), alleging infringement of six patents that relate to masonry blocks having interlocking features that allow the blocks to be stacked to form retaining walls.

The district court granted Rockwood's motion for partial SJ of noninfringement. In reaching its decision, the district court narrowly construed

several claim terms, including "back surface," "protrusion," "mate," and "generally parallel," to include limitations from the written description. The district court found no literal infringement and held that because Anchor had amended the claims during prosecution, there was a complete bar to application of the DOE, citing the Federal Circuit's decision in *Festo*. In addition, the district court granted Rockwood's motion to strike the testimony of an expert witness on the grounds that the expert's declarations were untimely and contradicted prior sworn testimony.

On appeal, Anchor argued that the district court had based its partial SJ of noninfringement on an improper construction of the claim terms. The Federal Circuit agreed. For each claim term in question, the Federal Circuit provided a broader construction based on the "ordinary meaning" of the term obtained using a dictionary definition and concluded that nothing in the written description compelled the narrow construction provided by the district court. Accordingly, the Federal Circuit reversed that portion of the district court's decision.

Anchor further argued that the district court had erred by concluding that, under *Festo*, an amendment of the asserted claims during prosecution resulted in a complete bar to application of the DOE. The Federal Circuit again agreed and, citing the Supreme Court's rejection of the absolute-bar approach, vacated that portion of the district court's decision.

Finally, Anchor argued that the district court had erred by granting Rockwood's motion to strike the testimony of the expert witness. Applying the law of the Eighth Circuit, the Federal Circuit found that the district court had not abused its discretion and affirmed that portion of the district court's decision.

Alleged Prelitigation Bad-Faith Conduct Does Not Make Case "Exceptional"

James R. Barney

[Judges: Lourie (author), Rader, and Dyk]

In Forest Laboratories, Inc. v. Abbott Laboratories, No. 03-1067 (Fed. Cir. Aug. 7, 2003), the Federal Circuit reversed the district court's award of attorneys' fees and held that the court erred in its finding that the case was exceptional under 35 U.S.C. § 285.

Abbott Laboratories ("Abbott") is the exclusive licensee of U.S. Patent Nos. 4,338,301 ("the '301 patent") and 4,397,839 ("the '839 patent") directed to a lung-surfactant composition for treating respiratory-distress syndrome in premature babies. Abbott developed a commercial product called Survanta® in the 1980s. At about the same time, ONY Inc. ("ONY"), Coplaintiff with Forest Laboratories, Inc. ("Forest"), developed its own product for treating neonatal respiratory-distress syndrome, called calf lungsurfactant extract ("CLSE"). During the development of these products, Abbott and ONY maintained close contact regarding a possible joint development of CLSE. In 1984, Abbott informed ONY that CLSE would likely not be patentable, though Abbott did not specifically mention its own '301 and '839 patents.

In 1991, Survanta® received approval and "orphan drug" status from the FDA, and Abbott then proceeded to market Survanta®. Several years later, Abbott informed ONY and Forest that it had reason to believe that their commercial product, based on CLSE, would infringe the '301 and '839 patents if it were to be marketed. ONY and Forest sued Abbott, seeking a DJ of noninfringement and invalidity of the '301 and '839 patents.

Following a jury trial, the district court granted ONY and Forest a JMOL of noninfringement and also ruled that Abbott was equitably estopped from asserting infringement of the '301 and '839 patents against ONY and Forest because (1) Abbott, by encouraging ONY's and Forest's development of CLSE, had misled them to believe that it would not assert infringement; (2) ONY and Forest reasonably relied on Abbott's misleading conduct; and (3) ONY and Forest would suffer economic and evidentiary prejudice if Abbott were permitted to proceed with its infringement counterclaim.

The district court also found the case to be exceptional under 35 U.S.C. § 285 and awarded attorneys' fees because Abbott, in bad faith, had encouraged ONY to develop CLSE but then later pursued an infringement counterclaim against ONY and Forest in an attempt to prevent their product from reaching the market. Abbott appealed the award of attorneys' fees.

The Federal Circuit explained that an exceptional case under 35 U.S.C. § 285 typically involves inequitable conduct before the PTO, liti-

gation misconduct or bad faith, a frivolous suit, or willful infringement. The Court found, however, that none of those circumstances was present in this case. The Court stressed that a finding of exceptionality has never been based on a patentee's bad-faith business conduct toward an accused infringer prior to litigation, and the Court declined to expand the scope of § 285 in that manner.

The Court recognized that bad-faith litigation can be a basis for a finding of exceptionality. It concluded, however, that Abbott had not engaged in bad-faith litigation. Under § 285, "bad faith" requires not merely misleading prelitigation conduct, but "vexatious, unjustified or frivolous litigation." The Court concluded that the pertinent inquiry was whether Abbott knew or should have known that it would be estopped from asserting the '301 and '839 patents against ONY and Forest yet pursued its infringement counterclaim anyway. The Court ruled that the record did not support the district court's finding that Abbott had knowledge of the events that would ultimately lead to a holding of equitable estoppel.

For all of these reasons, the Court concluded that the district court had erred in its finding that the case was exceptional under 35 U.S.C. § 285 based on Abbott's prelitigation conduct toward ONY and Forest.

35 U.S.C. § 271(g) Does Not Cover Production of Information Used to Make Product

Erin C. DeCarlo

[Judges: Dyk (author), Mayer, and Prost]

In Bayer AG v. Housey Pharmaceuticals, Inc., No. 02-1598 (Fed. Cir. Aug. 22, 2003), the Federal Circuit affirmed the district court's dismissal of Plaintiff Housey Pharmaceuticals, Inc.'s ("Housey") counterclaim for infringement for failure to state a claim.

Housey is the assignee of several patents directed toward "a method of screening for substances which specifically inhibit or activate a particular protein affecting the cultural or morphological characteristics of the cell expressing the protein."

The patented technology is premised upon the notion that if a protein of interest is

expressed by a cell line, that cell line changes in at least one identifiable way. Therefore, a cell line that expresses a high level of the protein of interest can be identified and developed. In this way, if a disease is linked to a specific protein, according to the patented method, agents can be identified that will either increase or decrease the activity of the protein. Claim 1 of U.S. Patent No. 4,980,281, for example, is directed toward a method of determining whether a substance is an inhibitor or activator of a protein whose production by a cell evokes a responsive change in a phenotypic characteristic other than the level of said protein in said cell per se.

In the district court, Defendants Bayer AG and Bayer Corporation (collectively "Bayer") sought a DJ of invalidity, unenforceability, and noninfringement of the Housey patents. Housey counterclaimed for infringement, alleging that Bayer both induced others to infringe Housey's patents and directly infringed the method claims under 35 U.S.C. § 271(g). According to Housey, Bayer used Housey's patented process to make the characterization of a pharmacologically active agent. Using this characterization, Bayer then allegedly produced a drug product, and 35 U.S.C. § 271(g) prevented such activity. The district court, however, agreed with Bayer and dismissed Housey's counterclaim.

On appeal, Housey argued that the information produced by the process was a product protected under § 271(g). Bayer countered that the statute only applied to manufactured products, and information is not a manufactured product. The Federal Circuit affirmed the district court's judgment that the statute only applies to physical goods, not intangible information. The Court determined that other provisions of the statute, including exceptions for situations wherein products are materially changed by a subsequent process or wherein products become a trivial and nonessential component of another product, indicated a statutory intent to protect only physical goods.

The Court also reviewed the legislative history of the statute and found nothing that contemplated protecting intangible products produced by a patented process. Thus, in light of this legislative silence, the Court refused to expand the scope of coverage contemplated by § 271 to include "information," when Congress could do so expressly if it so chose.

Accordingly, the Court held that in order for a product to have been made by a patented

process in the United States, as required by 35 U.S.C. § 271(g), it must be a physical article that was manufactured. The production of information is not covered.

Alternatively, Housey argued that its infringement counterclaim additionally encompassed a pharmaceutical composition (i.e., the drug itself) containing an activator or inhibitor of a protein, where the activating or inhibiting effect was discovered through the use of Housey's patented method. Thus, according to Housey, the drug itself was produced by the patented product and fell within the protection afforded by § 271(q).

Citing Bio-Technology General Corp. v. Genentech, Inc., 80 F.3d 1553, 1561 (Fed. Cir. 1996), the Court noted that the proximity of the product produced to the patented process should be determined on a case-by-case basis. In this case, the Court found that the patented process is not used in the actual synthesis of the physical drug product because the information derived from the process is not an actual step in manufacturing the drug. Therefore, the drug product was not made by a process patented in the United States, as required by § 271(g).

Accordingly, the Federal Circuit found that neither the method-of-use claims nor the drug-product claims were protected under § 271(g) and affirmed the district court's dismissal of Housey's infringement counterclaim for failure to state a claim.

Claims to "Electronic Multifunction Card" Are Not Limited to Card Size

Kenneth M. Lesch

[Judges: Dyk (author), Clevenger, and Linn]

In *E-Pass Technologies v. 3Com Corporation*, No. 02-1593 (Fed. Cir. Aug. 20, 2003), the Federal Circuit rejected the district court's claim construction of the phrase "electronic multifunction card" and reversed its SJ of noninfringement. The Federal Circuit remanded the case with a broader claim construction and ruled that under this new claim construction, the Plaintiff, E-Pass Technologies ("E-Pass"), may be able to prove infringement of its patent claims by 3Com Corporation ("3Com").

E-Pass is the assignee of U.S. Patent No. 5,726,311 ("the '311 patent") directed to a

method for substituting multiple credit cards with a single, electronic multifunction card. E-Pass accused 3Com's "Palm Pilot" device of infringing claim 1 of the '311 patent. The claim language in dispute was the phrase "electronic multi-function card," which the district court construed to mean a device having the standard credit-card dimensions according to the American National Standards Institute ("ANSI"), i.e., 3.375 inches long, 2.215 inches high, and 0.030 inches thick. The district court granted 3Com's motion for SJ of noninfringement because the accused Palm Pilot is substantially larger than a standard credit card and no reasonable jury would find infringement under the DOE.

In construing claim 1, the Federal Circuit first consulted a dictionary to determine the ordinary meaning of the term "card." That dictionary defines "card" as a "flat, stiff, usually small and rectangular piece of material," but does not provide specific dimensions. The Federal Circuit also concluded that the phrase "electronic multifunction card" and the claim in its entirety do not suggest any size limitations. Further, the Federal Circuit concluded that the ANSI standard does not intend to provide a definition for all cards or electronic multifunction cards.

The Federal Circuit found error in the district court's reliance on the patent specification to limit the card size. The '311 patent states that "the simple form of the electronic multi-function card . . . has the outer dimensions of usual credit or check cards," and "[credit] cards . . . normally have standardized dimensions." While the district court concluded that these teachings limited the scope of the invention, the Federal Circuit concluded that these teachings showed that only some embodiments might have certain size limitations.

The district court had also incorrectly concluded that the purpose of the claimed card was to perform the functions of various credit cardsized cards and inferred from this that the claimed multipurpose card should therefore be the same size. The Federal Circuit rejected this reasoning, noting that claimed inventions may have several purposes, but that should not limit the claims.

The Federal Circuit therefore reversed the grant of SJ of noninfringement as being based on an incorrect claim construction and remanded for further proceedings.

Personal Jurisdiction Proper over Out-of-State Defendants in DJ Action

Kevin M. Rosenbaum

[Judges: Gajarsa (author), Rader, and Bryson]

In Electronics for Imaging, Inc. v. Coyle, No. 02-1536 (Fed. Cir. Aug. 18, 2003), the Federal Circuit reversed a district court's dismissal of Electronics for Imaging, Inc.'s ("EFI") complaint for declaratory and injunctive relief and remanded that personal jurisdiction over Jan R. Coyle and Kolbet Labs (collectively "Defendants") would be proper.

On December 9, 1997, Jan R. Coyle, a Nevada resident, filed U.S. Patent Application No. 08/987,212 ("the '212 application"), which issued as U.S. Patent No. 6,337,746 ("the '746 patent") on January 8, 2002. The '212 application concerned an interface card for coupling a computer to an external device.

EFI, a Delaware corporation with its principal place of business in Foster City, California, develops, manufactures, and sells print controllers, which are devices that control printers and copiers. EFI believes that Coyle does business as Kolbet Labs, a Nevada corporation. In late 1999 or early 2000, Coyle solicited EFI and proposed that EFI purchase Defendants' technology related to an interface card for controlling printers and copiers. On or about January 28, 2000, EFI and Kolbet Labs entered into a mutual nondisclosure agreement ("NDA"), which Coyle signed as "owner" of Kolbet Labs.

After signing the NDA, Defendants provided information regarding their technology to EFI. At several different times around May and June 2000, Coyle's attorney in California, Newton Lee, sent EFI various documents relating to the progress of the '212 application, including copies of selected parts of the '212 application. In September 2001, Coyle informed EFI by telephone that the claims of the '212 application had been allowed by the PTO, alleged that the allowed patent claims covered EFI's print controllers, and continued to report further new developments in his technology.

On December 11, 2001, before the '746 patent issued, EFI filed a complaint for declaratory and injunctive relief against Defendants in the United States District Court for the Northern District of California. EFI's complaint alleged that

(1) EFI did not misappropriate any trade-secret information belonging to Defendants by sales of its print controllers or otherwise, and (2) EFI did not breach any NDA with Defendants. After the '746 patent issued, EFI amended its complaint to allege that the claims of the '746 patent were invalid. Defendants moved to dismiss the amended complaint for lack of personal jurisdiction.

The district court, applying Ninth Circuit law, granted Defendants' motion holding that EFI had failed to show that Defendants had purposefully directed their activities at California, thereby failing to establish that Defendants had the "minimum contacts" in California necessary to justify the exercise of jurisdiction over Defendants.

On appeal, the Federal Circuit first determined that the district court had erred in applying the law of personal jurisdiction of the Ninth Circuit to all three claims in the complaint. The Court held that Ninth Circuit law governs for personal jurisdiction of the declaratory claims of nonmisappropriation of trade secrets and nonbreach of contract because these claims do not present questions that are intimately involved with the substance of the patent laws. However, Federal Circuit law applies to personal jurisdiction for the patent-invalidity claim because this question is intimately involved with the substance of the patent laws.

In determining whether the district court could assert specific personal jurisdiction over Defendants, the Court considered whether the forum state's long-arm statute permits service of process, and whether the assertion of jurisdiction would be inconsistent with due process. Because California's long-arm statute permits service of process to the limits of the due-process clauses of the federal Constitution, the personal-jurisdiction analysis is whether the jurisdiction comports with federal due process.

In finding that personal jurisdiction would be proper for the patent-invalidity claim, the Federal Circuit considered whether (1) the Defendants purposefully directed their activities at residents of the forum state, (2) the claim arises out of or relates to the Defendants' activities with the forum state, and (3) assertion of personal jurisdiction is reasonable and fair. The first two factors correspond to the "minimum contacts" prong and the third factor with the "fair play and substantial justice" prong of Supreme Court precedents on jurisdiction.

Applying the first factor, the Court determined Defendants' contacts were "purposefully

directed" at California because Coyle hired two California law firms to prosecute the '212 application, Coyle hired a California attorney who contacted EFI at various times to report on the progress of the pending application, Coyle telephoned EFI in California at various times between approximately late 1999 (or early 2000) and fall of 2001 regarding the subject matter of the technology covered by the patent application, and two representatives of Defendants visited EFI's facility in California for the purpose of demonstrating the technology underlying what later issued as the '746 patent.

Applying the second factor, the Court held that the contacts with California made by Coyle and Kolbet Labs clearly arise out of or are related to EFI's claim that the '746 patent is invalid.

Regarding the third factor, the Court held that Defendants were unable to demonstrate that it would be unreasonable for the district court to exercise jurisdiction over them for the following reasons: it would not impose much of a geographic burden for Nevada defendants to litigate in California; California has a substantial interest in protecting its residents from unwarranted claims of patent infringement; EFI has an interest in protecting itself from patent infringement, even though Coyle has filed a complaint against EFI in the District Court for the District of Nevada because the still-pending Nevada case can be consolidated with the current action; and, finally, there is no conflict between the interests of California and Nevada in furthering their own respective substantive laws because federal patent law would govern the patentinvalidity claim irrespective of the forum.

Applying Ninth Circuit law, the Court also held that personal jurisdiction would be proper for the breach of contract claim. Defendants had purposefully availed themselves of the laws of California because the confidentiality principles of the NDA governed Defendants' repeated communications with and solicitation of EFI's business in California, and the NDA itself envisioned and governed such communications and included a California choice-of-law clause. As for the second part of the personal jurisdiction inquiry, whether a particular claim arises out of forum-related activities, the Ninth Circuit requires that "but for" Defendant's contacts with the forum, EFI's claims against Defendants would not have arisen. The Court held that but for Defendants' contacts with California, EFI would not be seeking a judicial declaration that it did

not breach the NDA's confidentiality principles.

Similarly, the Court concluded that the district court's exercise of jurisdiction over Defendants regarding the nonmisappropriation of trade secrets claim would comport with due process. The Court held that Defendants purposefully availed themselves of the privilege of conducting activities in California, thereby invoking the benefits and protections of the laws of California.

Each Patent Claim Need Not Address Every Problem with Prior Art Stated in Specification

Vince Kovalick

[Judges: Plager (author), Bryson, and Prost]

In Resonate Inc. v. Alteon Websystems, Inc., No. 02-1201 (Fed. Cir. Aug. 5, 2003), the Federal Circuit vacated the district court's claim construction and remanded for further proceedings after construing the claims.

Resonate, Inc. ("Resonate") owns U.S. Patent No. 5,774,660 ("the '660 patent") directed to an Internet server. Resonate sued Alteon Websystems, Inc. ("Alteon") for infringement of the '660 patent. After the district court construed the claims, Resonate stipulated that it could not prevail on infringement, and the district court entered final judgment of noninfringement in favor of Alteon. The '660 patent concerns a load-balancing approach for web-server access. In particular, a router determines what type of information the client is requesting and then selects a server to handle the request based on the content requested. The claimconstruction dispute centered on whether the claim language was "transmitting the requested resource to the client," specifically, whether the claim at issue required a dated transmission path from a selected server back to a client to bypass a load-balancer router. The district court construed this phrase to mean "transmitting outbound data packets from the server directly to the client using the connection with the client which was transferred to the server, causing the outbound data to bypass the load balancer."

In the accused devices, all data is transmitted from the selected server to the client through the load-balancer router. Thus, under

the district court's construction, the accused devices do not infringe.

The Federal Circuit concluded that the claim language itself fails to specify whether the data must pass through or bypass the load balancer. Thus, by the plain language of the claim, any transmission path from the selected server to the client appears to be within the scope of the claim. Alteon argued that the claimed connection would be understood by those of ordinary skill in the art to occur in the TCP/IP Internet context, which would bypass the load balancer. The Federal Circuit rejected this argument, however, because nothing in the claim defined the limitations in terms of the TCP/IP protocol.

The Federal Circuit also rejected Alteon's argument that the specification required the bypass feature. The Federal Circuit reviewed the specification and noted that it set out two different problems in the prior art that the claimed invention overcame. The Court characterized the issue as follows: when the written description sets out two different problems present in

the prior art, is it necessary that the invention claimed, and thus each and every claim in the patent, address both problems? According to the Federal Circuit, the answer is no. Likewise, the Federal Circuit rejected any attempts by Alteon to read the preferred embodiment, which did indeed bypass the load balancer, into the claims.

Accordingly, the Federal Circuit vacated the judgment of noninfringement and remanded for further proceedings.

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In Last month at The Federal Circuit, certain terms, titles, and names of federal agencies that are frequently referred to in text, appear in abbreviated forms or as acronyms. These abbreviated forms and acronyms are listed below.

ALJ	Administrative Law Judge
ANDA	Abbreviated New Drug Application
APA	Administrative Procedures Act
A DI	Administrative Datant Ludge

Administrative Patent Judge APJ

Board of Patent Appeals and Interferences **Board** Commissioner of Patents and Trademarks Commissioner

Continuation-in-Part CIP Declaratory Judgment DJ Doctrine of Equivalents DOE Food & Drug Administration **FDA IDS** Information Disclosure Statement

IΡ **Intellectual Property** ITC **International Trade Commission**

Judgment as a Matter of Law **IMOL**

Manual of Patent Examining Procedure **MPEP**

PCT **Patent Cooperation Treaty**

PTO United States Patent and Trademark Office SEC Securities and Exchange Commission

Summary Judgment SI SM Special Master