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FINNEGAN

LAST MONTH AT THE FEDERAL CIRCUIT

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SPOTLIGHT INFO:

In *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, Nos. 07-1296, -1347 (Fed. Cir. Aug. 19, 2009) (en banc), the Federal Circuit held en banc that 35 U.S.C. § 271(f) cannot apply to method or process patents. The Court held that the word "component," as used in § 271(f), referred to a tangible part of a product, device, or apparatus. Alternatively, the Court concluded that "components" of a method claim included the steps for performing the method or process. Accordingly, because steps for performing a method cannot possibly be "supplied," as required by § 271(f), the Federal Circuit held that § 271(f) cannot apply to method claims. In addition, the Court noted that the legislative history of § 271(f) does not support application of that statute to method claims, and that the presumption against extraterritoriality precludes extending the scope of § 271(f). Judge Newman dissented. See full summary below.

Canadian Law Firm Is Subject to the Jurisdiction of U.S. Federal Courts in Malpractice Claim Based on U.S. Patent Application

Eli Mazour

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

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

In *Touchcom, Inc. v. Bereskin & Parr*, No. 08-1229 (Fed. Cir. Aug. 3, 2009), the Federal Circuit considered whether the act of filing an application for a U.S. patent at the PTO is sufficient to subject the filing attorney to personal jurisdiction in a malpractice claim that is based on that filing. The Court concluded that it is and reversed and remanded the district court's dismissal of the suit based on lack of personal jurisdiction over Bereskin & Parr ("B&P") and H. Samuel Frost.

Touchcom, Inc. and Touchcom Technologies, Inc. (collectively "Touchcom") retained Frost of B&P, a Canadian law firm, to prosecute patent applications in Canada, the United States, and various European countries. Frost filed a Canadian patent application and an application under the Patent Cooperation Treaty ("PCT") in the United Kingdom to obtain patent protection outside of Canada. The PCT application, unlike the Canadian application, did not contain the complete computer source code for the invention because a portion of the source code was unintentionally omitted.

Under the PCT process, a national phase application was filed at the PTO in Alexandria, Virginia. The U.S. application was identical to the PCT application and lacked the omitted portion of the computer source code. Frost transmitted various documents to the PTO before U.S. Patent No. 5,027,282 ("the '282 patent") was issued. Several years later, the U.S. District Court for the Eastern District of Texas held that the '282 patent was invalid for indefiniteness based in large part on the absence of portions of the source code. Touchcom filed a malpractice action against B&P and Frost, which the U.S. District Court for the Eastern District of Virginia dismissed for lack of personal jurisdiction. Touchcom appealed.

On appeal, the Federal Circuit considered whether the district court's exercise of specific jurisdiction over B&P and Frost was proper. The Court reminded that analysis of personal jurisdiction in federal court begins with Fed. R. Civ. P. 4. The Court agreed with the district court that personal jurisdiction is lacking under Fed. R. Civ. P. 4(k)(1)(A), which states that service of process establishes jurisdiction over a defendant "who is subject to the jurisdiction of a court of general jurisdiction in the state where the district court is located." Slip op. at 7 (quoting Fed. R. Civ. P. 4(k)(1)(A)). Specifically, the Court found B&P's and Frost's contacts with Virginia were limited to the filing of a patent application at the PTO and subsequent communications and filings

made in connection with that filing. The Court found that no representative of B&P, including Frost, travelled to Virginia in connection with the patent application or engaged in any conduct in Virginia concerning the interests of Virginia, such as protecting its citizens, businesses, or property. Indeed, the Court found B&P's contacts were limited to long-distance communications with a federal agency that "happens to be located in Virginia . . . ." *Id.* at 10.

"[A] court is entitled to use Rule 4(k)(2) to determine whether it possesses personal jurisdiction over the defendant unless the defendant names a state in which the suit can proceed." Slip op. at 15.

Turning to Rule 4(k)(2), the Court concluded that this rule permits the exercise of jurisdiction over B&P and Frost. Rule 4(k)(2) permits a federal district court to exercise jurisdiction over a foreign defendant if "(1) the plaintiff's claim arises under federal law, (2) the defendant is not subject to jurisdiction in any state's courts of general jurisdiction, and (3) the exercise of personal jurisdiction comports with due process." *Id.* at 7-8 (quoting *Synthes (U.S.A.) v. G.M. dos Reis Jr. Ind. Com. de Equip. Medico*, 563 F.3d 1285, 1294 (Fed. Cir. 2009)).

The Court concluded that, because Touchcom's malpractice claim involved a substantial question of patent law, the district court possessed subject matter jurisdiction under 28 U.S.C. § 1338. Accordingly, the Court concluded that Touchcom's claims necessarily arose under federal law for purposes of Rule 4(k)(2).

Turning to the second requirement of Rule 4(k)(2) that the defendant is not subject to the jurisdiction of any state's courts of general jurisdiction, the Federal Circuit concluded that "a court is entitled to use Rule 4(k)(2) to determine whether it possesses personal jurisdiction over the defendant unless the defendant names a state in which the suit can proceed." *Id.* at 15. In other words, "the defendant is afforded the opportunity to avoid the application of the rule only when it designates a suitable forum in which the plaintiff could have brought suit." *Id.* at 16.

Here, B&P and Frost failed to name any state in which they would be subject to jurisdiction. Thus, the Court found that for purposes of Rule 4(k)(2), Touchcom has made a prima facie showing that B&P and Frost are not subject to the jurisdiction of any state's courts of general jurisdiction. The Court noted, however, that if, on remand, the district court determines that B&P and Frost are subject to personal jurisdiction in another state, or if B&P and Frost designate such a forum, the district court is permitted to transfer the case to that forum.

Finally, to decide whether due process permits the exercise of personal jurisdiction under Rule 4(k)(2), the Court considered whether "(1) defendant has purposefully directed its activities at residents of the forum, (2) the claim arises out of or relates to the defendant's activities with the forum, and (3) assertion of personal jurisdiction is reasonable and fair." *Id.* at 18 (quoting *Synthes (U.S.A.)*, 563 F.3d at 1297). Rule 4(k)(2) "contemplates a defendant's contacts with the entire United States, as opposed to the state in which the district court sits." *Id.* (quoting *Synthes (U.S.A.)*, 563 F.3d at 1295).

The Federal Circuit found that the first factor was satisfied because B&P and Frost purposefully directed their activities at parties in the United States and thus had "minimum contacts" sufficient to satisfy due process. B&P and Frost entered into a contract to obtain a U.S. patent. This contemplated and resulted in seeking and obtaining a property interest from a U.S. agency, the PTO, and therefore, B&P and Frost availed themselves of the laws of the United States. The Court found that the second factor was satisfied because Touchcom's claims of malpractice arose out of Frost filing an allegedly deficient U.S. application with a U.S. agency. Touchcom would not have a claim if Frost had not chosen to file a national phase entry of the PCT application in the United States.

Finally, the Court analyzed whether jurisdiction over B&P and Frost was reasonable and fair, relying on five factors: (1) the burden on the defendant; (2) the forum's interest in adjudicating the dispute; (3) the plaintiff's interest in obtaining convenient and effective relief; (4) the interstate judicial system's interest in obtaining the most efficient resolution of controversies; and (5) the shared interests of the states in furthering fundamental substantive policies.

The Court held with respect to the first factor that the burden for Canadians who are U.S. registered patent agents to defend this case in the United States is minimal. With regard to the second factor, the Court decided that "the United States has an interest in regulating malpractice occurring at the USPTO regardless of the nationalities [of the parties] involved." *Id.* at 21. The Court held that since both U.S. and Canadian courts could equally provide the relief that Touchcom seeks, the third factor is neutral. The Court similarly determined that the fourth and fifth factors do not favor either party.

As a result, the Federal Circuit held that the district court had personal jurisdiction over B&P and Frost, reversed the district court's judgment dismissing Touchcom's complaint for lack of personal jurisdiction, and remanded the case to the district court for further proceedings.

In a dissenting opinion, Judge Prost stated that this case presents one of the "rare situations" in which minimum contacts are present but exercising personal jurisdiction would nevertheless violate due process because "the plaintiff's interest and the state's interest in adjudicating the dispute in the forum are so attenuated that they are clearly outweighed by the burden of subjecting the defendant to litigation within the forum." Prost Dissent at 1 (quoting *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1568 (Fed. Cir. 1994)). Judge Prost disagreed that subjecting B&P and Frost to suit in the United States is a "minimal" burden. Judge Prost noted the burden due to the distance of travel between B&P's office and the district court and the unique burdens placed upon one who must defend oneself in a foreign legal system. Judge Prost disputed the notion that the eligibility to practice before the PTO gives one a special familiarity with U.S. law. Moreover, with regard to the second fairness factor, Judge Prost stated that the United States' interest in regulating malpractice in this case is minimal since neither party is a citizen of the United States and, in general, foreign patent agents are not permitted to represent U.S. citizens.

Allegations of Inequitable Conduct Must Set Forth Particular Factual Bases to Satisfy Rule 9(b)

Mary R. Henninger

Judges: Michel, Linn (author), St. Eve (District Judge sitting by designation)

[Appealed from D. Mass., Judge Lindsay]

In *Exergen Corp. v. Wal-Mart Stores, Inc.*, Nos. 06-1491, 07-1180 (Fed. Cir. Aug. 4, 2009), the Federal Circuit reversed the jury's determination that Exergen Corporation's ("Exergen") U.S. Patent No. 6,047,205 ("the '205 patent") was not invalid; reversed the jury's finding that S.A.A.T. Systems Application of Advanced Technology, Limited and Daiwa Products, Incorporated (collectively "SAAT") willfully infringed Exergen's U.S. Patent Nos. 5,012,813 ("the '813 patent") and 6,292,685 ("the '685 patent"); and reversed the damages that had been awarded to Exergen. In addition, the Federal Circuit affirmed the district court's denial of SAAT's motion for leave to allege inequitable conduct.

Exergen's patents relate to infrared radiation thermometers for measuring human body temperature from a surface of the human body, such as the eardrum or the forehead, to obtain the surface temperature, which is a function of both the internal body temperature and the air temperature. The thermometers calculate the internal body temperature based on equations provided in the patents and display the result in a digital readout. The claims of the '813 and '205 patents are directed to detecting radiation from "biological tissue," whereas the '685 patent claims a thermometer that detects radiation from the skin covering the temporal artery in the temple region. SAAT manufactures

thermometers that detect radiation from the temple and that convert the measured surface reading to the individual's oral temperature. Exergen sued SAAT for infringement of the '813, '205, and '685 patents. SAAT sought leave pursuant to Fed. R. Civ. P. 15(a) to add inequitable conduct as an affirmative defense and counterclaim against the '813 and '685 patents. The district court denied SAAT's motion because SAAT's proposed pleading failed to allege inequitable conduct with particularity under Fed. R. Civ. P. 9(b).

"[T]o plead the 'circumstances' of inequitable conduct with the requisite 'particularity' under Rule 9(b), the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO . . . [and] must include sufficient allegations of underlying facts from which a court may reasonable infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO." Slip op. at 24-25.

The district court construed the term "biological surface tissue" to mean "a living layer of external human tissue having a temperature that can be measured" and "internal temperature" to mean "temperature of the region existing beneath the surface of the biological tissue targeted for measurement." Slip op. at 3-4. The case proceeded to a jury trial on the theory of literal infringement only because Exergen waived any argument that SAAT infringed under the DOE. The jury found that SAAT directly infringed claim 7 of the '813 patent and claims 1 and 3-5 of the '205 patent, and that SAAT actively induced infringement of claims 1 and 27-30 of the '685 patent. The jury also found that the patents were not invalid and that SAAT's infringement was willful. The jury awarded Exergen lost profit damages totaling over $2.5 million. The district court denied SAAT's motion for JMOL on the grounds of noninfringement, invalidity, and absence of lost profits, and Exergen's motion to alter or amend judgment for enhanced damages and prejudgment interest.

SAAT appealed the denial of its motion for leave to amend its answer to allege inequitable conduct and its motion for JMOL, and Exergen cross-appealed the denial of its motion to alter or amend the awarded damages and interest.

SAAT challenged the jury's finding that claims 1-5 of the '205 patent were not anticipated by U.S. Patent No. 4,602,642 ("O'Hara"). At trial, Exergen's expert admitted that O'Hara disclosed all limitations of claim 1 except the third step, namely, "electronically detecting the peak radiation from the multiple areas to obtain a peak temperature signal." *Id.* at 6. On appeal, Exergen focused only on this step to distinguish O'Hara. Exergen first argued that O'Hara heats the probe unit to 98°F and detected this radiation in addition to radiation detected from the patient. The Court rejected this argument, finding that the use of the term "comprising" in claim 1 of the '205 patent did not require detection of radiation solely from the biological tissue. The Court held that O'Hara's detection of radiation from the probe unit upon removal from the chopper unit after having been heated to 98°F and from multiple areas of the biological tissue to obtain a peak temperature did not prevent O'Hara from anticipating.

The Federal Circuit also rejected Exergen's contention that O'Hara detects radiation from a single spot and not "multiple areas." The Court noted that Exergen's expert admitted that O'Hara inherently discloses this limitation because the device necessarily detects radiation from the patient's face, outer ear, and ear canal as the probe unit is moved into position in the ear canal. The Court also stated that the term "biological tissue" is not limited to "ear canal." Because Exergen did not present a separate argument as to the validity of dependent

claims 2-5, the Court held O'Hara anticipated claims 1-5 of the '205 patent and reversed the jury's finding that the claims of the '205 patent are not invalid.

The Federal Circuit also reversed the jury's decision that SAAT directly infringed the '813 patent and actively induced infringement of the '685 patent because SAAT did not directly infringe either patent. First, SAAT's device did not possess "a display for providing an indication of the internal temperature," as recited in claim 7 of the '813 patent. The parties did not dispute that the meaning of "internal temperature" is "temperature of the region existing beneath the surface of the biological tissue targeted for measurement," *id.* at 10, nor did they dispute that, with regard to SAAT's device, the relevant "internal temperature" is the temperature of the temporal artery beneath the skin of the forehead. The Court found that the testimony of Exergen's expert/coinventor made clear that the number shown on the display of the claimed device must be the value of the internal temperature and could not be some other value requiring further (mental) computation before arriving at the internal temperature. The Court held that SAAT's device could not infringe claim 7 of the '813 patent because it measured radiation from the user's forehead and calculated and digitally displayed the user's oral temperature, which did not constitute the "internal temperature" as construed by the district court.

The Federal Circuit also held that no reasonable jury could have found that a user of SAAT's thermometers who followed the accompanying instructions would necessarily have performed the step of "laterally scanning a temperature detector across a forehead," as required by claim 1 of the '685 patent. The parties agreed that "laterally" means "horizontal relative to the human body." *Id.* at 13. The instructions for the ThermoTek thermometer stated, "Scan with the thermometer *around the temple area* (marked as a dotted area in the drawing)." *Id.* at 14. The instructions for the CVS thermometer stated, "Place the thermometer's soft touch tip just outside the eyebrow (in the temple region of the forehead) and slowly *slide upwards* to just below the hairline." *Id.* Exergen argued that the instructions involved at least some horizontal component. But the Court stated that even if it agreed, Exergen's argument ignored the claim language requiring the lateral scan to occur "across the forehead." *Id.* The Federal Circuit also criticized Exergen for telling the jury "to essentially ignore this requirement" when it posited to the jury that scanning within one of the oval patterns in the temple region would achieve substantially the same result as scanning across the forehead. The Court noted that Exergen had expressly waived any argument under the DOE before trial.

The Federal Circuit then found that a customer using SAAT's device would not have infringed claim 27 of the '685 patent or its dependent claims 28-30 because SAAT's device measured the surface temperature of the skin that covers the temporal artery and not the "temperature of the temporal artery through skin," as required by those claims. *Id.* at 17. The '685 patent expressly distinguished skin temperature from core temperature and provided an equation to calculate core temperature when skin and ambient temperatures were known. Since SAAT's device converted the skin temperature measurement to oral temperature and not to the temporal artery temperature, a user of SAAT's device could not infringe claims 27-30 of the '685 patent.

The Federal Circuit then affirmed the denial of SAAT's motion for leave to amend its answer to allege inequitable conduct because SAAT's proposed pleading failed to allege inequitable conduct with particularity under Fed. R. Civ. P. 9(b). The Court held that "in pleading inequitable conduct in patent cases, Rule 9(b) requires identification of the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." *Id.* at 22. Further, the Court held that while "knowledge" and "intent" may be averred generally, a pleading of inequitable conduct under Rule 9(b) must include "sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO." *Id.* at 24-25.

The Federal Circuit agreed with the district court that SAAT's allegations were deficient with respect to both the particularity of the facts alleged and the reasonableness of the inference of scienter. The Court noted three factual deficiencies. First, SAAT's pleading referred generally to "Exergen, its agents and/or attorneys," and failed to identify the "who" of the material omissions and misrepresentation. That is, the pleadings failed to name a specific individual associated with the filing or prosecution of the application who both knew of the material information and deliberately withheld or misrepresented it. Second, SAAT's pleading failed to identify the "what" and "where" of the material omissions, namely, which claims, and which limitations in those claims, the withheld references were relevant to, and where in those references the material information was found. Third, SAAT's pleading did not explain "why" the withheld information was material and not cumulative, and "how" an examiner would have used this information in assessing the patentability of the claims.

Further, the Federal Circuit found that the facts alleged in SAAT's pleading—that Exergen became aware of the withheld references during the prosecution of its prior applications—did not give rise to a reasonable inference of scienter. SAAT provided no factual basis to infer that any specific individual who owed a duty of disclosure knew of the allegedly material information. The Court stated, "A reference may be many pages long, and its various teachings may be relevant to different applications for different reasons. Thus, one cannot assume that an individual, who generally knew that a reference existed, also knew of the specific material *information* contained in that reference." *Id.* at 27. The Court also found that SAAT did not allege facts sufficient for one to reasonably infer that when the individual made the allegedly false statement to the PTO, that person was also aware of an allegedly contradictory statement on Exergen's website.

As for deceptive intent, while pleading on "information and belief" is permitted under Rule 9(b) when essential information lies uniquely within another party's control, the Court held that the pleading must set forth the specific facts upon which the belief is reasonably based. Here, the Court found that SAAT's pleading provided neither the "information" on which it relied nor any plausible reasons for its "belief." The mere fact that an applicant disclosed a reference during the prosecution of one application but did not disclose it during prosecution of a related application was insufficient to meet the threshold level of deceptive intent required to support an allegation of inequitable conduct. Therefore, SAAT's pleading lacked specific allegations to show that the individual citing the patent during a related prosecution knew of the allegedly material information and deliberately withheld it from the examiner. Accordingly, the Court held that the district court did not abuse its discretion in denying SAAT's motion for leave to add these allegations to SAAT's original answer.

A Drug Formulation Is Obvious If There Are a Finite Number of Options for Making the Formulation

Grace S. Law

Judges: Newman (dissenting), Friedman, Mayer (author)

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

In *Bayer Schering Pharma AG v. Barr Laboratories, Inc.*, No. 08-1282 (Fed. Cir. Aug. 5, 2009), the Federal Circuit affirmed the district court's ruling that U.S. Patent No. 6,787,531 ("the 531 patent") was invalid for obviousness.

Bayer Schering Pharma AG ("Bayer") is the owner of the '531 patent, which covers the oral contraceptive Yasmin®, containing the active ingredient drospirenone. Drospirenone has diuretic and anti-acne properties, which are desirable qualities in an oral contraceptive. However, exposure to acid isomerizes drospirenone into a nondiuretic isomer. In addition, drospirenone is a poorly water soluble hydrophobic composition. Because it will not easily dissolve in liquid, its bioavailability

is degraded. One method of increasing the bioavailability of poorly water soluble drugs is to micronize them. However, micronization also increases a drug's sensitivity to acid. A method of combating the acid-sensitivity problem with an oral drug is to deliver the drug via an enteric-coated pill.

Bayer began developing a micronized form of drospirenone in 1983. Based on in vitro studies of micronized drospirenone, Bayer expected the micronized drug to have reduced bioavailability due to increased acid sensitivity. Therefore, it planned studies using an enterically coated form of drospirenone. In 1988, Bayer also planned studies on other formulations, including a normal or nonenterically coated form of drospirenone. The result of the studies showed that both normal pills and enterically coated pills had the same bioavailability. Bayer therefore developed drospirenone in a normal pill, for which it would eventually receive the '531 patent. During prosecution, Bayer relied on the finding that drospirenone would absorb with a normal pill to overcome an obviousness rejection. The examiner allowed the claims, giving the specific reason that the prior art suggested that micronizing drospirenone would not work.

Barr Laboratories, Incorporated ("Barr") is a generic drug manufacturer that filed an ANDA seeking FDA approval to market a generic version of Yasmin®. Bayer responded to the ANDA by filing suit for patent infringement. The parties agreed that if the '531 patent was valid, Barr infringed various claims of the patent. However, Barr alleged, among other defenses, that the '531 patent was invalid for obviousness. The district court found that the asserted claims were invalid as obvious. It found that it would have been obvious to a person of ordinary skill in pharmaceutical formulation to try a normal pill in formulating drospirenone as an oral contraceptive.

On appeal, Bayer represented that the innovation was to micronize the drospirenone to increase its bioavailability, and that the micronized drospirenone would absorb with a normal pill, against the teachings of the prior art. As to micronization, the Court noted that Bayer's own expert testified that micronization is the first choice solution because it presents the best chance for success. Accordingly, there was adequate support for the district court's conclusion that one of skill would have seen micronization as a viable option.

"[A]n invention would not have been obvious to try when the inventor would have had to try all possibilities in a field unreduced by direction of the prior art." Slip op. at 9.

Regarding enteric coatings, the district court found that the prior art recognized the necessity of using enteric coatings with acid-sensitive drugs, but that enteric coatings also have drawbacks, such as reduced or variable bioavailability. The district court held that it would have been obvious for a person skilled in the art to try a normal pill in formulating drospirenone as a contraceptive. The Federal Circuit agreed. The Court found that while Bayer argued the prior art teaches away from using micronized drospirenone, and Barr argued that the prior art teaches away from using an enteric coating, the parties presented the options available to a pharmaceutical formulator to solve the problem of acid-sensitive but hydrophobic drospirenone.

The district court found that, based on prior art bioavailability testing on spirorenone, a related compound of drospirenone, one of skill in the art would access these studies when formulating drospirenone and be led to believe that drospirenone may absorb in vivo but isomerizes in vitro. Bayer argued that the district court ignored key differences between the two compounds. But the Court found these differences irrelevant because the prior art was not an anticipatory reference. Moreover, the prior art showed that a drug formulator had a viable known option to consider and a reasonable expectation that drospirenone would perform similarly to spirorenone.

The Court also rejected Bayer's argument that the prior art taught away from allowing exposure to the gastric environment, thus suggesting the need for an enteric coating. Barr attacked the merits of the in vitro study, noting that it would not apply to the practice of drospirenone in vivo. The panel majority stated that at this point, a person having ordinary skill in the art must choose between two known, predictable options—delivery of micronized drospirenone by a normal pill or delivery of drospirenone by an enteric-coated pill. The prior art would have funneled the formulator toward these two options. The Court found that the formulator would not have been required to try all possibilities in a field unreduced by the prior art. And the prior art was not vague in pointing toward a general approach or area of exploration. Rather, the prior art guided the formulator precisely to the use of either a normal pill or an enteric-coated pill. The Court concluded that because the selection of micronized drospirenone in a normal pill led to the result anticipated by the prior art, the invention would have been obvious. Accordingly, the Court affirmed the district court's judgment.

Judge Newman dissented, noting that the evidence showed, without contradiction, that it was known that micronized drospirenone rapidly degraded at the acidity of stomach acid and that the Bayer scientists believed that the product required an enteric coating. Judge Newman stated that the majority improperly discounted the testimony of the scientists and ignored the evidence in finding that the invention was obvious to try. Furthermore, Judge Newman noted that contraceptives require complete effectiveness and it was undisputed that it was not reasonably expected that uncoated micronized drospirenone would be 99+% effective as an oral contraceptive. Judge Newman found that the majority's "exercise of judicial expertise to override the clear evidence of how persons of skill in this field actually behaved, is inappropriate." Newman Dissent at 4.

Some New Evidence May Be Presented in the District Court in an Action Under 35 U.S.C. § 145

Mai-Trang D. Dang

Judges: Michel (author), Dyk, Moore (dissenting)

[Appealed from D.D.C., Judge Kennedy]

In *Hyatt v. Doll*, No. 07-1066 (Fed. Cir. Aug. 11, 2009), the Federal Circuit affirmed the district court's grant of SJ sustaining the decision of the Board, which rejected seventy-nine claims of Gilbert P. Hyatt's U.S. Patent Application Serial No. 08/471,702 ("the '702 application") for lack of support by adequate written description. After examining the legislative history and persuasive case law concerning the relevant statute—35 U.S.C. § 145—the Court concluded that the district court properly excluded evidence offered by the inventor because he had a duty to disclose the evidence to the PTO during prosecution but willfully refused.

Hyatt's application for computer memory architecture is one of several iterations of continuations or CIPs. After several rounds of amendments, Hyatt cancelled all original claims and added 117 new claims, all of which the examiner eventually rejected in a final office action, citing lack of adequate written description and enablement, among other deficiencies. Among Hyatt's notable arguments in his appeal to the Board were: "The '112-1 rejections are *prima facie* erroneous because the disclosure is presumptively valid and correct," and "With the extensive memory disclosure (*e.g.*, Spec. at 99-135) and processor disclosure (*e.g.*, Spec. at 87-98, 214-36) in the instant application, it is unbelievable that the Examiner would object to the disclosure of memory and processor features." Slip op. at 7. Hyatt included in his appeal a table purporting to show support in the specification. The four-column table listed some claim terms under "Representative Terminology," notes the number of occurrences for each term in either the specification or raw source code,

and "Representative Cites Page(s)." With two exceptions, Hyatt did not correlate any evidence submitted with any specific claim limitations.

After the Board affirmed some of the examiner's rejections for lack of adequate written description, Hyatt provided extensive new arguments and citations to the specification in his request for rehearing. The Board denied his request, holding that the new arguments and citations could and should have been presented during the original appeal. In the ensuing district court action under § 145, which provides for the appeal of ex parte proceedings in the PTO to the District of Columbia district court, Hyatt filed his own declaration in support of his opposition to the Director's motion for SJ to affirm the Board's decision. The district court excluded Hyatt's declaration and granted SJ to the Director.

"[W]e have merely reached the unremarkable conclusion that it is unreasonable to believe Congress intended to allow a patent applicant in a § 145 action to introduce new evidence with no regard whatsoever as to his conduct before the PTO, and that, specifically, Congress did not intend that evidence owed, requested and willfully withheld from the PTO must nevertheless be admitted in a § 145 action." Slip op. at 56 (footnote omitted).

Finding a novel issue in the question of whether new evidence is admissible in an action under § 145, the Court first analyzed the legislative origins of the statute and the case law regarding admissibility of evidence. The Court compared the statute in question to its "parallel provision," § 146 governing interferences before the Board. It found that although Congress amended § 146 in 1927 to give weight to PTO proceedings but was silent with regard to evidence under § 145, the same weight should apply in § 145 proceedings. Acknowledging that Supreme Court cases over the past century establish that new evidence *may* be submitted in cases under R.S. § 4915 (a pre-1952 predecessor to §§ 145 and 146), the Court looked to case law in other circuits for guidance on what new evidence may be admissible under § 145. It found that after amendments in 1927, no circuit court allowed a de novo trial under § 4915. Finding no standard in the District of Columbia district court for excluding evidence not submitted in PTO proceedings, the Court found that the case law shows that "the District of Columbia district court will always exclude evidence that was not presented to the PTO due to bad faith or gross negligence and sometimes if the failure to present it was negligent." *Id.* at 34. The Court concluded that "it has been the general practice of federal courts for over eighty years in certain circumstances to exclude evidence which a party could and should have introduced before the Patent Office but did not despite an obligation to do so." *Id.*

Next, the Court examined the application of the APA, noting that the Supreme Court in *Dickinson v. Zurko*, 527 U.S. 150, 165 (1999), held that the Federal Circuit must review fact-finding by the PTO using the framework set forth in the APA. Applying the APA, the Court held that § 145 actions do not meet the APA's provisions for de novo review of factual issues. It also held that § 145 does not specifically provide for a de novo trial in the district court. The Court concluded that "[a] district court is obliged to accept the facts as found by the PTO unless not supported by substantial evidence." Slip op. at 46 (citing *Mazzari v. Rogan*, 323 F.3d 1000, 1005 (Fed. Cir. 2003)). Further, "the district court must defer to the PTO's fact-finding except where appropriately admitted new evidence conflicts with a fact found by the PTO or presents a new factual issue that the PTO did not consider." *Id.* (citing *Mazzari*, 323 F.3d at 1004).

Applying the facts of the instant case, the Court held that Hyatt was obligated to respond to the examiner's written description rejection by explaining where in the specification support for each of the limitations could be found. Because Hyatt could have done so either in response to

the office action rejecting the claims, in his initial appeal to the Board, or anytime in between, the Court found that he had willfully refused to provide evidence in his possession in response to a valid action by the examiner and affirmed the district court. The Court also affirmed the district court's rejection of Hyatt's arguments that his refusal to present the evidence should not bar him from presenting his declaration in the district court. First, it found that the Board's rejections were either identical in "thrust" to the examiner's or responsive to new arguments raised by Hyatt in his appeal brief. Next, it rejected Hyatt's argument that the timing of an earlier, related Federal Circuit decision, *Hyatt v. Dudas*, 492 F.3d 1365 (Fed. Cir. 2007), excused Hyatt's failure to present evidence in this case, because Hyatt was on notice that he had an obligation to rebut the examiner's rejections. The Court also agreed that the Board's reversal of some of the examiner's rejections did not establish that Hyatt acted reasonably.

The Court disavowed adopting a sweeping exclusionary rule, summarizing its holding narrowly: "[W]e have merely reached the unremarkable conclusion that it is unreasonable to believe Congress intended to allow a patent applicant in a § 145 action to introduce new evidence with no regard whatsoever as to his conduct before the PTO, and that, specifically, Congress did not intend that evidence owed, requested and willfully withheld from the PTO must nevertheless be admitted in a § 145 action." Slip op. at 56 (footnote omitted).

In a dissenting opinion, Judge Moore emphasized that Congress contemplated a patent applicant's fundamental right to a "civil action" under the circumstances, not merely an appeal, which may be brought under 35 U.S.C. § 141. In a civil action, the dissent points out, only the Federal Rules of Evidence govern the admissibility of evidence. Further, Judge Moore objected to the majority's characterizations of Hyatt's evidence and noted that the district court found it only negligent, not willfully withheld.

Denial of Attorney Fees Affirmed Where No Useful Purpose Would Be Served by Remand

Stephen C. Bellum

Judges: Schall, Gajarsa (author), Dyk

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

In *Wedgetail, Ltd. v. Huddleston Deluxe, Inc.*, No. 09-1045 (Fed. Cir. Aug. 12, 2009), the Federal Circuit affirmed the district court's denial of attorney fees under 35 U.S.C. § 285.

Wedgetail, Ltd. ("Wedgetail") is the assignee of U.S. Patent No. 6,857,220 ("the '220 patent"), which is directed to fishing lures that simulate swimming motions when dragged through water. Wedgetail sued Huddleston Deluxe, Inc. ("Huddleston") for infringement of the '220 patent. Huddleston, in turn, filed counterclaims of noninfringement and invalidity. After the district court issued its claim construction order, Wedgetail filed a motion to dismiss all claims with prejudice, in which it granted Huddleston a covenant not to sue. Huddleston opposed Wedgetail's motion solely on the ground that Wedgetail's proposed order of dismissal would deprive Huddleston of the opportunity to seek attorney fees as the prevailing party. The district court granted Wedgetail's motion, dismissed all claims with prejudice, and ordered each party to bear its own costs and attorney fees. Huddleston appealed the district court's denial of attorney fees under 35 U.S.C. § 285.

On appeal, the Federal Circuit first reminded that the Court may award reasonable attorney fees to the prevailing party in exceptional cases. The Court cautioned, however, that it has rejected an expansive reading of § 285 and that "only a limited universe of circumstances warrant a finding of exceptionality in a patent case: 'inequitable conduct before the PTO; litigation misconduct; vexatious, unjustified, and otherwise bad faith litigation; a frivolous suit or willful infringement.'" Slip op. at 3 (quoting

Epcon Gas Sys., Inc. v. Bauer Compressors, Inc., 279 F.3d 1022, 1034 (Fed. Cir. 2002)). The Court further stated that, absent litigation misconduct or inequitable conduct before the PTO, it has awarded attorney fees "*only* if both (1) the litigation is brought in subjective bad faith, and (2) the litigation is objectively baseless." *Id.* at 5 (quoting *Brooks Furniture Mfg., Inc. v. Dutailer Int'l, Inc.*, 393 F.3d 1378, 1381 (Fed. Cir. 2005)).

The Court also reminded that, because of the "high level of deference owed to district courts on this issue and the limited circumstances that could qualify as exceptional, the [C]ourt has not imposed a blanket requirement that a district court provide its reasoning in attorney fee cases." *Id.* Instead, the Court has held only that a statement of the district court's reasoning is generally necessary to enable review when a motion for attorney fees is granted or when attorney fees are denied despite the presence of one or more of the circumstances listed above.

Here, the Court concluded that Huddleston directed the Court to nothing in the record that could compel a finding of exceptionality or would otherwise suggest a need for the district court to provide its reasoning. Accordingly, the Court determined that the lack of detailed analysis by the district court did not warrant reversal.

The Court also rejected Huddleston's argument that the district court committed reversible error by failing to entertain a motion for attorney fees under § 285. The Court found that Huddleston's request for attorney fees failed to satisfy Fed. R. Civ. P. 54(d)(2)(B), which sets forth the requirements for filing a motion for attorney fees. Specifically, the Court found that Huddleston did not file a motion for attorney fees with the district court but instead merely requested that the district court set a briefing schedule for such a motion. The Court further found that Huddleston failed to state in its briefing the amount of attorney fees sought. Accordingly, the Court concluded that Huddleston's claim "would appear to fail procedurally." *Id.* at 7.

The Court next considered Huddleston's argument that the filing of a separate motion for attorney fees with the district court would have been futile in light of the district court's order. Huddleston asked the Federal Circuit to treat the district court's order "either as a prejudicial deprivation of Huddleston's right to file a motion or as an erroneous determination that fees are not owed." *Id.* The Federal Circuit found that the record on appeal presented neither any apparent misconduct nor any judicial findings of misconduct on Wedgetail's part. The Court also found that Huddleston had not provided any reason for the Court to believe that Huddleston might successfully present evidence to the district court on remand. For these reasons, the Court concluded that Huddleston "failed to demonstrate either that the district court clearly erred in failing to find this case exceptional or that Huddleston was harmed by the district court's failure to entertain a motion for attorney fees." *Id.* at 8.

Because the Federal Circuit found that the district court's decision, although lacking explanation, was supported by the record, the Court concluded that "[n]o useful purpose would be served by a remand to enable the district court to tell us in express terms what we already know from the record." *Id.* at 9 (alteration in original) (quoting *Consol. Aluminum Corp. v. Foseco Int'l Ltd.*, 910 F.2d 804, 815 (Fed. Cir. 1990)). Accordingly, the Court affirmed the district court's decision not to award attorney fees under § 285.

Specific Identification in the Specification of What the Material Is and Where It Can Be Found Is Sufficient to Constitute Incorporation by Reference of That Material

Sulay D. Jhaveri

Judges: Linn, Dyk (author), Prost

[Appealed from D. Del., Judge Robinson]

In *Callaway Golf Co. v. Acushnet Co.*, No. 09-1076 (Fed. Cir. Aug. 14, 2009), the Federal Circuit reversed the district court's entry of SJ on anticipation and remanded; affirmed the district court's determination that Acushnet

Company ("Acushnet") was not entitled to JMOL that the asserted claims were invalid for obviousness; but vacated the district court's judgment on obviousness and remanded for a new trial.

Callaway Golf Company ("Callaway") is the owner of four patents (collectively "the Sullivan patents") that share nearly identical specifications and contain similar claims to a multilayer polyurethane-covered golf ball. Claim 1 of U.S. Patent No. 6,210,293 ("the '293 patent"), which is generally representative of the asserted claims, recites a golf ball comprising a core, an inner cover made of a blend of low-acid ionomer resins having a Shore D hardness of 60 or more, and an outer cover layer made of a polyurethane material having a Shore D hardness of 64 or less.

"A broader independent claim cannot be nonobvious where a dependent claim stemming from that independent claim is invalid for obviousness." Slip op. at 21-22.

Callaway sued Acushnet for patent infringement based on Acushnet's sales of the Titleist Pro V1, Pro V1*, and Pro V1x golf balls, all of which have a core, an ionomer inner cover, and a polyurethane outer cover. The district court construed the term "cover layer having a Shore D hardness" as measured on the golf ball, not on a sample of the cover layer off the ball. Based on this claim construction, Acushnet stipulated its golf balls infringed the asserted claims. However, Acushnet argued that the Callaway patents were invalid based on anticipation and obviousness, and moved for SJ. With regard to anticipation, Acushnet argued U.S. Patent No. 4,431,193 ("Nesbitt") disclosed a three-piece golf ball meeting all the limitations of the Sullivan claims except the polyurethane outer cover and a blend of ionomers in the inner cover. Acushnet argued that Nesbitt incorporates by reference U.S. Patent No. 4,274,637 ("Molitor '637"), which teaches both polyurethane and ionomer blends as cover materials. Callaway filed a cross-motion for SJ, arguing that Nesbitt did not incorporate Molitor '637.

The district court granted Callaway's motion for SJ, holding that Nesbitt did not describe the use of polyurethane or blends of ionomer resins in Molitor '637 "with sufficient particularity to effectuate an incorporation by reference of those features." Slip op. at 6. With regard to obviousness, Acushnet relied on Nesbitt, Molitor '637, and three other U.S. patents, Nos. 4,674,751 ("Molitor '751"), 5,314,187 ("Proudfit"), and 5,334,673 ("Wu"), arguing that the various separate elements of the Sullivan patents were known in the art. A jury trial limited to the question of obviousness resulted in a verdict concluding that dependent claim 5 of the '293 patent was invalid for obviousness, but the remaining eight claims, including independent claim 4 of the '293 patent, the antecedent claim to claim 5, had not been proven invalid. The district court denied Acushnet's renewed motion for JMOL.

On appeal, Acushnet challenged five major aspects of the district court proceedings. First, Acushnet challenged the district court's claim construction requiring on-the-ball measurements of hardness, citing the specification's reference to an American Society for Testing and Materials ("ASTM") standard that states that the hardness measurement should not be measured on a rounded or curved surface. The Court rejected Acushnet's argument, pointing to disclosures in the specification of hardness measurements taken on intermediate and finished balls, and to testimony from an Acushnet vice president that technical people in the industry deviate from the ASTM method by measuring on the ball. The Court concluded that the district court did not err in its construction requiring on-the-ball measurement.

Second, Acushnet challenged the district court's denial of its JMOL that the asserted Sullivan claims were obvious. Acushnet framed the invention of the Sullivan patents as nothing more than a predictable and "obvious to try" variation of known elements. Callaway argued that the construction was not present in the prior

art, and "produce[s] a synergy and an important new result" over and beyond that which could be expected independently from each prior art element, namely, a true dual-personality ball that is capable of travelling great distances yet does not exhibit diminished playability or durability.

The Federal Circuit found the evidence did not compel a finding that all claim limitations were present in the prior art. The Court noted that since none of the cited references expressly recited the claimed Shore D hardness limitation on a three-piece ball, Acushnet relied on the disclosure of Molitor '751 of a Shore C hardness on a two-piece ball as indirect evidence. But the Court found substantial evidence supported the contrary position. The jury was entitled to determine that the evidence was sufficient to undermine Acushnet's claim that the Shore C hardness present in the prior art would necessarily translate to an on-the-ball Shore D hardness on a three-piece, two-cover ball. The Court therefore concluded that the district court did not err in concluding that substantial evidence supported the jury's implicit resolution of the factual issue in Callaway's favor.

Third, Acushnet challenged the exclusion of evidence in the trial on obviousness. Acushnet sought to have an expert testify about test balls assembled and tested by Acushnet's employees to demonstrate that the Shore D hardness limitations of the asserted claims were inherently met by golf balls made through combination of the prior art. The Court held that the district court properly excluded the expert's testimony because he had not prepared or tested the balls and could not vouch for the reliability of the tests. Next, Acushnet tried to introduce the test evidence, proffering foundational testimony from the Acushnet employee who supervised production of the test balls and delivered them to the independent laboratory for testing. But the district court excluded the evidence presumably under Fed. R. Evid. 403, as it ran a high risk of causing undue prejudice by leading the jury to give Acushnet's obviousness argument excessive weight. The Court found that excluding the evidence here was not an abuse of discretion.

Acushnet also sought to introduce evidence of a parallel inter partes reexamination of the Sullivan patents, wherein the PTO rejected each asserted claim of the Sullivan patents based on essentially the prior art cited by Acushnet in the litigation. The Court found that the district court did not abuse its discretion in excluding the evidence, because the evidence bore little relevance to the jury's independent deliberations on the factual issues underlying the question of obviousness, and the risk of jury confusion if the evidence was introduced was high.

Fourth, Acushnet argued that it should have been granted JMOL or a new trial based on inconsistent jury verdicts. The jury ruled dependent claim 5 of the '293 patent invalid for obviousness while finding all other asserted claims, including independent claim 4 from which claim 5 depends, not invalid. The Court noted that "[a] broader independent claim cannot be nonobvious where a dependent claim stemming from that independent claim is invalid for obviousness." *Id.* at 21-22. Callaway argued that the verdict is not irreconcilably inconsistent because claim 5 of the '293 patent lacks a "blend" limitation, whereas the other claims require the inner cover to contain a "blend" of ionomer resins, and the jury could have rationally concluded that the "blend" claims were not obvious even if claim 5, lacking a "blend" limitation, was obvious.

The Court noted that the district court's rejection of Callaway's theory was proper because reconciliation of inconsistent verdicts must be consistent with the evidence and theories adduced at trial. And at trial, no party asserted any patentable difference among the asserted claims before the jury or otherwise meaningfully distinguished between the claims on the basis of the "blend" limitation. However, the Court noted that the district court's reasoning that the inconsistency was "harmless" in light of Acushnet's stipulation of infringement was flawed. The Court cited Third Circuit law that "where a reading of the verdicts that would solve the apparent inconsistency proves impossible and the evidence might support either of the two inconsistent verdicts, 'the appropriate remedy is ordinarily, not simply to accept one verdict and dismiss the other, but to order an entirely new trial.'" *Id.* at 23 (citation omitted). Accordingly, the Court vacated the judgment of the district court and remanded for a new trial on obviousness.

Finally, Acushnet argued that the district court erred in holding that Nesbitt did not incorporate Molitor '637. The Court considered the relevant passage of Nesbitt describing the materials that may be used in the cover layers of the Nesbitt golf ball. The passage referred to Molitor '637, which teaches that many foamable materials, including both polyurethane and ionomer-resin blends, may be used as golf ball cover materials. The Court examined the disclosure in Nesbitt indicating that layers of the golf ball may be made from a "natural or synthetic polymeric material," including all of the foamable polymeric materials described in Molitor '637. The Court noted that polyurethane is a foamable composition. Accordingly, the Court held that Nesbitt incorporates by reference the potential cover layer materials described in Molitor '637, including polyurethane and ionomer-resin blends, and reversed SJ to Callaway and remanded for further proceedings. The Court noted that nothing precludes the district court from permitting Callaway to file a new motion for SJ on that issue, if the district court thinks it appropriate.

En Banc Court Holds That § 271(f) Does Not Apply to Method Patents

Melanie R. Grover

Judges: Newman, Mayer, Lourie (author). Part C.2 was heard en banc before Michel, Newman (dissenting), Mayer, Lourie (author), Rader, Schall, Bryson, Gajarsa, Linn, Dyk, Prost, Moore.

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

In *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, Nos. 07-1296, -1347 (Fed. Cir. Aug. 19, 2009) (en banc), the Federal Circuit held en banc that 35 U.S.C. § 271(f) cannot apply to method or process patents. Additionally, a panel of the Federal Circuit reversed the district court's SJ of invalidity, reinstating the jury's verdict of validity, held that inequitable conduct arguments could not be asserted on remand, affirmed the district court's limit on damages to only those products that actually performed the patented method, and declined to reassign the case to a different judge on remand.

Cardiac Pacemakers, Inc. ("Cardiac") is the exclusive licensee of U.S. Patent No. 4,407,288 ("the '288 patent"), which claims a method of heart stimulation using an implantable heart stimulator capable of detecting heart arrhythmias. Cardiac sued St. Jude Medical, Inc. ("St. Jude") for infringement of the '288 patent, among others. After a jury trial, the jury found the '288 patent valid and enforceable but not infringed, rejecting St. Jude's arguments that it was obvious and unenforceable for inequitable conduct. But the district court granted St. Jude's JMOL on invalidity and also granted a conditional new trial on obviousness and inequitable conduct should the JMOL decision be reversed. The district court also denied Cardiac's JMOL for infringement.

Cardiac appealed, and a panel of the Federal Circuit reversed the district court, holding that the court had exceeded its discretionary authority by granting St. Jude's JMOL and reversing the district court's claim construction of one claim term. The panel remanded the case to the district court for a new trial on infringement and reassessment of damages. During the remanded trial, the district court allowed St. Jude to argue new invalidity and unenforceability defenses. At the conclusion of the remanded trial, the district court granted Cardiac's SJ motion for infringement and held that Cardiac's potential damages included the sale of infringing devices exported from the United States to other countries under 35 U.S.C. § 271(f). But the district court also granted St. Jude's SJ motion for anticipation and limited damages to products that actually performed the method steps. Cardiac and St. Jude both appealed these rulings.

On appeal, a panel of the Federal Circuit found that the district court improperly allowed St. Jude to present invalidity arguments during the remanded trial. Prior Federal Circuit panels had expressly limited the remanded trial to an assessment of infringement, calculation of any damages, and any directly related new

issues. The Court stated that while a changed claim construction may permit new anticipation arguments, the changed term must have been an element missing from the prior art. The Court found that the term at issue was uncontested at trial and never served as a basis for distinguishing the prior art. Thus, the Court reinstated the jury's verdict of nonobviousness because the jury's verdict of validity could not have depended on the erroneous construction of the claim.

The Federal Circuit also found that the district court improperly allowed St. Jude to make inequitable conduct arguments on remand. The Court concluded that St. Jude had either failed to pursue their arguments at trial or failed to appeal the arguments, and had therefore waived them. In addition, the Court found that St. Jude had entered into a stipulation with Cardiac that precluded it from pursuing its remaining viable inequitable conduct argument. With all of St. Jude's inequitable conduct arguments either waived or covered by the stipulation, the Court reinstated the jury's verdict of enforceability.

The Court then turned to the district court's rulings on damages. First, the Court affirmed the district court's ruling that damages could only apply to products that actually performed the claimed method, and not to products with the mere capability to practice the method. Cardiac argued that *Stryker Corp. v. Intermedics Orthopedics, Inc.*, 96 F.3d 1409 (Fed. Cir. 1996), indicated that a plaintiff could receive damages on sales of an infringing product that lacked a required element, so long as the element was capable of being supplied. The Federal Circuit disagreed, distinguishing *Stryker* on its facts. The Court stated that in *Stryker*, the plaintiff sought lost profits on a patented apparatus and the entire apparatus was supplied during surgery. In the present case, Cardiac sought royalties on a patented method, and all the elements of the method could not be supplied until a device actually performs all of the steps. Therefore, the Court reasoned, Cardiac could only receive infringement damages on those devices that actually performed the patented method.

Finally, the Court turned to the district court's ruling that § 271(f) applied to method claims, the only issue heard en banc. Although the district court based its decision on *Union Carbide Chemicals & Plastics Technology Corp. v. Shell Oil Co.*, 425 F.3d 1366 (Fed. Cir. 2005), which held that § 271(f) applied to method claims, the Court noted that *Union Carbide* and its predecessors were decided before the Supreme Court examined and gave direction on § 271(f) in *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437 (2007). The Court stated that the Supreme Court's decision in *Microsoft* sent a clear message that the territorial limits of patents should not be lightly breached.

"[B]ecause one cannot supply the step of a method, Section 271(f) cannot apply to method or process patents." Slip op. at 27.

First, the Federal Circuit looked to the definition of the word "component," as used in § 271(f). The Court stated that "a component of a tangible product, device, or apparatus is a tangible part of the product, device, or apparatus, whereas a component of a method or process is a step in that method or process," slip op. at 23, and "not the physical components used in performance of the method," *id.* at 25. The Federal Circuit rejected Cardiac's argument that a component of a process may encompass the apparatus that performs the process. In doing so, the Court pointed to the language of § 271(c), where Congress contrasts a component of a patented machine with a material or apparatus for use in practicing a patented process, to show that Congress clearly believed that a component was separate and distinct from a material or apparatus for use in practicing a patented process.

Having found that the components of a method are the steps of the method, the Federal Circuit concluded that § 271(f)'s requirement that components be supplied from the United States eliminates method patents from its reach. The Court stated that the word "supply" implies the transfer of a physical object and "[s]upplying an

intangible step is thus a physical impossibility." *Id.* at 26. The Court reasoned that the legislative history of § 271(f) supports this conclusion because Congress was focused on closing the loophole, presented by the Supreme Court's decision in *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518 (1972), that shipping an unassembled patented product abroad for later assembly avoids patent infringement. "The legislative history of Section 271(f) is almost completely devoid of any reference to the protection of method patents and the Supreme Court has advised us that it is Congress's right, not the courts', to extend the statute beyond the *Deepsouth* problem it was designed to fix." Slip op. at 27.

The Federal Circuit also rejected Cardiac's argument that a statement in the legislative history indicated that Congress understood "components" to apply also to method patents. The Court reasoned that a statement by one private proponent of a pending bill in Congress cannot override the clear language of the statute and the context in which it was enacted. In addition, to support its holding that § 271(f) does not apply to method patents, the Court pointed to the presumption against extraterritoriality and the narrow view of § 271(f) taken by the Supreme Court in *Microsoft*. The Court stated that the presumption compelled them not to extend the reach of § 271(f) to method patents.

Finally, the Federal Circuit expressly overruled the decision in *Union Carbide*, as well as any other decisions, that § 271(f) applies to method patents. Because the patent at issue in the present case was a method patent, the Federal Circuit reversed the district court and held that Cardiac could not receive any damages for sales of devices outside the United States.

In the dissent, Judge Newman disagreed with the Court's holding that all process patents fall outside the scope of § 271(f). Judge Newman stated that the text of the statute is not ambiguous, the term "patented invention" applies to all patent-eligible subject matter, and Congress explicitly states a specific statutory class when it intends to single one out. The dissent concluded that because Congress did not single out process patents but used the term "patented invention" in § 271(f), the statute must cover process patents as well as the other statutory classes. The dissent further noted that the original language of § 271(f) expressly listed "a patented machine, manufacture, or composition of matter," but this was changed to "patented invention" in the final version. Citing the statutory construction rule that "[w]here Congress includes limiting language in an earlier version of a bill but deletes it prior to enactment, it may be presumed that the limitation was not intended," Judge Newman concluded that Congress intended § 271(f) to apply to process patents. Newman Dissent at 9-10.

Judge Newman then examined how § 271(f) applies to process components. First, she stated that a process may involve both product and process aspects. "It appears that the heart stimulator is supplied from the United States and combined with process steps that are taught from the United States and performed abroad." *Id.* at 12. The dissent noted this issue was not brought out in the appeal. Next, Judge Newman made an analogy between coinfringement and § 271(f). Judge Newman reasoned that the holding in *BMC Resources, Inc. v. Paymentech, L.P.*, 498 F.3d 1373 (Fed. Cir. 2007), that in some cases the practice of steps of a patented method by two parties can be combined, whereby the party that performs earlier steps "supplies" this component to the party that performs the later steps, was "commensurate with the application of § 271(f) to processes that are partly performed in the United States." Newman Dissent at 14. This precedent, she asserted, does not support a conclusion that it is a physical impossibility to read § 271(f) as applying to processes.

Finally, Judge Newman addressed the sovereignty issue of extraterritoriality. Using the example of a patented process that is practiced so that some steps are performed in the United States and others offshore, she opined that the "purloiner of the patented process may escape liability everywhere," and that the legislators could not have intended to enable avoidance of process patents by this ploy.

Id. at 15. Judge Newman concluded that for process patents, the majority opinion reopened the loophole exposed by *Deepsouth* and overreached by dumping the statute entirely in an overreaction to the facts of one case.

Foreclosure Under State Law May Transfer Patent Ownership Without a Writing

Bart A. Gerstenblith

Judges: Michel, Bryson, Spencer (Chief District Judge sitting by designation, author)

[Appealed from the E.D. Tex., Judge Folsom]

In *Sky Technologies LLC v. SAP AG*, No. 08-1606 (Fed. Cir. Aug. 20, 2009), the Federal Circuit affirmed the district court's judgment that Sky Technologies LLC ("Sky") had standing to bring a patent infringement suit because patent ownership was properly transferred by operation of state foreclosure law.

Sky had obtained ownership of several U.S. patents from Cross Atlantic Capital Partners, Inc. ("XACP") through a foreclosure sale without any written agreement, after Ozro, Inc. ("Ozro"), who had purchased the patent from the original owner, used the patents to secure loans from XACP but later faulted.

Upon obtaining an ownership interest, Sky later filed a patent infringement suit against SAP AG and SAP America, Inc. (collectively "SAP"). SAP moved to dismiss Sky's complaint for lack of standing. The district court ultimately held that the patents-in-suit were transferred from Ozro to XACP through the foreclosure proceedings because XACP properly complied with the Massachusetts Uniform Commercial Code ("UCC") foreclosure requirements by placing the patent collateral up for sale at a public auction and notifying Ozro of the sale. Thus, when XACP assigned the patents-in-suit to Sky, Sky became vested with all rights, title, and interest in the patents and the chain-of-title had not been broken from Ozro to Sky. Sky thus had standing to bring suit.

> "[A]ssignment is not the only method by which to transfer patent ownership. . . . [F]oreclosure under state law may transfer patent ownership." Slip op. at 9.

On appeal, the Federal Circuit considered whether Sky had properly obtained title to the patents-in-suit via the foreclosure process, as there had been no written transfer between Ozro and XACP, and as a result, whether Sky had standing to sue.

The Federal Circuit first considered whether state or federal law should apply. The Court observed that, while patent ownership is determined by state, not federal, law, "the question of whether a patent assignment clause creates an automatic assignment or merely an obligation to assign is intimately bound up with the question of standing in patent cases," and is thus "treated . . . as a matter of federal law." Slip op. at 7-8 (quoting *DDB Techs., L.L.C. v. MLB Advanced Media, L.P.*, 517 F.3d 1284, 1290 (Fed. Cir. 2008)). Accordingly, federal law is typically used to determine the validity and terms of an assignment, but state law controls any transfer of patent ownership by operation of law not deemed an assignment. *Id.* at 8.

Second, the Court noted that even though an assignment must be in writing, "[t]here is nothing that limits assignment as the only means for transferring patent ownership. . . . [O]wnership of a patent may be changed by operation of law." *Id.* (quoting *Akazawa v. Link New Tech. Int'l, Inc.*, 520 F.3d 1354, 1356 (Fed. Cir. 2008)). In *Akazawa*, the Federal Circuit held that "passage of title through intestacy is not an assignment, and therefore did not require a writing." *Id.* at 9 (citing *Akazawa*, 520 F.3d at 1358). Further, if the controlling state or foreign intestacy law passed title of the patent to the heirs of the inventor upon his death, then all subsequent transfers were valid. *Id.* Thus, while an assignment must be in writing, "assignment is not the only method by which to transfer patent ownership. . . . [F]oreclosure under state law may transfer patent ownership." *Id.*

Third, the Federal Circuit concluded that title was transferred by operation of Massachusetts law. Specifically, because XACP foreclosed on the patents-in-suit in conformity with the provisions of the Massachusetts UCC, XACP obtained title to the patents through the foreclosure sale. The Court rejected SAP's argument that 35 U.S.C. § 154 limited the ownership of patents to three categories of individuals—the patentee, his heirs, or his assigns—because § 154 does not restrict patent ownership to these three classes of individuals, and the statutory language "fails to specifically address *transfers* of patent ownership." *Id.* at 11. The Court also rejected SAP's argument that the Massachusetts UCC required a writing to transfer any patent collateral, whether the transfer is by assignment or operation of law, because the plain language of the UCC provision recognized that a writing is permissible but not required.

Fourth, the Court rejected SAP's federal preemption argument because 35 U.S.C. § 261 "speaks only to assignments of patents; there exists no federal statute requiring a writing for all conveyances of patent ownership." *Id.* at 12. Thus, "no federal law preempts the use of the Massachusetts UCC foreclosure provisions to transfer patent ownership by operation of law." *Id.*

Finally, the Federal Circuit concluded that public policy weighed in favor of permitting transfers of patent ownership through operation of law without a writing. First, if foreclosure on security interests secured by patent collateral could not transfer ownership to the secured creditor, a large number of patent titles presently subject to security interests may be invalidated. Second, by restricting transfer of patent ownership only to assignments, the value of patents could significantly diminish because patent owners would be limited in their ability to use patents as collateral or pledged security. Third, it would be impractical to require secured parties to seek written assignments following foreclosure from businesses that may have ceased to exist.

Accordingly, the Federal Circuit affirmed the district court's finding that Sky had standing to bring suit.

Trademark Is Obtained Fraudulently Under the Lanham Act Only If Applicant Makes a False, Material Representation with Intent to Deceive

Linda K. McLeod and Anna S. Balichina

Judges: Michel (author), Dyk, Moore

[Appealed from TTAB]

In *In re Bose Corp.*, No. 08-1448 (Fed. Cir. Aug. 31, 2009), the Federal Circuit held that a trademark is obtained fraudulently under the Lanham Act only if the applicant or registrant knowingly makes a false, material representation with intent to deceive the PTO.

Hexawave, Inc. ("Hexawave") filed a use-based application to register the mark HEXAWAVE for a variety of electronic goods it claimed to be using in commerce. Bose Corporation ("Bose") opposed Hexawave's application based on fraud and likelihood of confusion with Bose's registered WAVE marks for a variety of electronic goods. Hexawave filed a counterclaim to cancel Bose's registration on the ground of fraud and presented evidence that Bose obtained a renewal of its registration for the mark WAVE in 2001 by claiming that it was still using the mark in connection with the goods listed in its registration, despite knowing that it had not manufactured or sold two of the goods listed in the registration (audio tape recorders and players) since 1997. Bose insisted that its renewal application was based on its honest, good-faith belief that its receipt, repair, and return of its previously sold audio tape recorders and players bearing the WAVE mark in 2001 was

sufficient to support renewal of its registration. Bose did not relabel or make any alterations to the products, apart from the technical repairs.

"There is no fraud if a false misrepresentation is occasioned by an honest misunderstanding or inadvertence without a willful intent to deceive." Slip op. at 10 (citing *Smith Int'l, Inc. v. Olin Corp.*, 209 USPQ 1033, 1043 (TTAB 1981)).

Relying on the Federal Circuit's decision in *Torres v. Cantine Torresella S.r.l.*, 808 F.2d 46 (Fed. Cir. 1986), and following the decisions in a series of cases beginning with the 2003 decision in *Medinol Ltd. v. Neuro Vasx, Inc.*, 67 USPQ2d 1205 (TTAB 2003), TTAB held that specific intent to commit fraud is not required, and that fraud occurs when an applicant or registrant makes a false, material misrepresentation that the applicant or registrant *knew or should have known* was false. To avoid a finding of fraud, TTAB explained, Bose must prove that its declaration of continued use, though false, was made with a reasonable and honest belief that it was true. TTAB concluded that it was unreasonable for Bose to believe that its repair services constituted continued use of its mark sufficient to maintain its registration. Additionally, TTAB reasoned that Bose's repair services did not constitute a trademark use because Bose no longer owned the goods. TTAB ultimately ordered cancellation of Bose's registration for the WAVE mark in its entirety.

The Federal Circuit reversed TTAB's fraud decision, signaling a strong limitation to the strict rule of fraud under *Medinol*. The Court reaffirmed decisions of its predecessor court, the Court of Customs and Patent Appeals, which prohibit an applicant from making *knowingly* inaccurate or *knowingly* misleading statements. Absent requisite intent to mislead the PTO, the Court held, "[E]ven a material misrepresentation would not qualify as fraud under the Lanham Act warranting cancellation." Slip op. at 4.

Analyzing TTAB's *Medinol* decision and its progeny, the Federal Circuit acknowledged that TTAB had correctly found a material legal distinction between a false representation and a fraudulent one, the latter involving an intent to deceive, whereas the former may be occasioned by a misunderstanding, an inadvertence, a mere negligent omission, or the like. The Court also agreed with TTAB that, in determining whether a trademark registration was obtained fraudulently, the appropriate inquiry is not the registrant's subjective intent but rather the objective manifestations of that intent, and that intent must often be inferred from the circumstances and related statement made.

But the Court stressed that evidence of intent to deceive and fraud must be clear and convincing, and that inferences drawn from lesser evidence cannot satisfy the deceptive intent requirement for proving fraud. The Court specifically rejected the principle holding in TTAB's *Medinol* line of cases, namely, that a trademark applicant commits fraud in procuring a registration when it makes material representations of fact in its declaration that it knows or should know to be false or misleading.

The Court stated that "[b]y equating 'should have known' of the falsity with a subjective intent, the Board erroneously lowered the fraud standard to a simple negligence standard." *Id.* at 6. The Court reiterated its precedent in *Symbol Technologies, Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1582 (Fed. Cir. 1991), holding that "[m]ere negligence is not sufficient to infer fraud or dishonesty." Slip op. at 6 (alteration in original). Rather, "a finding that particular conduct amounts to 'gross negligence' does not of itself justify an inference of intent to deceive." *Id.* (quoting *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1998) (en banc)). The principle that the standard for finding intent to deceive is stricter than the standard for negligence or gross negligence, even though announced in patent inequitable conduct cases, applies with equal force to trademark fraud cases. After all, an allegation of

fraud in a trademark case, as in any other case, should not be taken lightly. Thus, the Court held that "a trademark is obtained fraudulently under the Lanham Act only if the applicant or registrant *knowingly* makes a false, material representation with the *intent to deceive* the PTO." *Id.* at 6-7 (emphases added).

The PTO argued that under *Torres*, making a submission to the PTO with reckless disregard of its truth or falsity satisfies the "intent to deceive" requirement. The Federal Circuit stated that it did not have to resolve this issue because, before Bose's counsel submitted the renewal declaration in 2001, neither the PTO nor any court had held that repairing and shipping repaired goods did not satisfy the "use in commerce" requirement. The Court concluded that even if it were to "assume that reckless disregard qualifies, there is no basis for finding [Bose's] conduct reckless." *Id.* at 9 n.2.

The Court also dismissed TTAB's reliance on *Torres* to justify the "should have known" standard. Although the Court recognized that *Torres* did use the phrase "knows or should know" in finding an intent to deceive and fraud before the PTO, it stated that TTAB read *Torres* too broadly. The Court cautioned that one should not focus on the phrase "should know" and ignore the facts of the case. As the Court noted, Torres admitted that he made false statements to the PTO about trademark usage when he filed his renewal application.

In this case, the Court found that Bose's general counsel knew that the company had stopped manufacturing and selling audio tape recorders and players at the time the Section 8/9 renewal was filed. Thus, the Court concluded that Bose's statement in the renewal application that the WAVE mark was in "use in commerce" for such goods was a material, false misrepresentation to the PTO. The Court noted, however, that Bose's counsel testified under oath that he believed that repairing previously sold audio tape recorders and players under the WAVE mark satisfied the "use in commerce" requirement at the time he signed the renewal application. Whether such belief was reasonable, the Court said, was not part of the analysis. Rather, the Court held that "[t]here is no fraud if a false misrepresentation is occasioned by an honest misunderstanding or inadvertence without a willful intent to deceive." *Id.* at 10 (citing *Smith Int'l, Inc. v. Olin Corp.*, 209 USPQ 1033, 1043 (TTAB 1981)).

The Court concluded that Bose did not commit fraud in renewing its registration and that TTAB erred in canceling the mark in its entirety. The Court, however, held that, since Bose no longer used the mark on audio tape recorders and players, the registration had to be restricted to reflect commercial reality and therefore remanded the case to TTAB for appropriate proceedings.

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Abbreviations

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

Looking Ahead

On September 11, 2009, the Federal Circuit vacated a jury's $358 million award against Microsoft Corporation ("Microsoft") in *Lucent Technologies, Inc. v. Gateway, Inc.*, No. 08-1485 (Fed. Cir. Sept. 11, 2009). While the Court affirmed the jury's patent validity and infringement verdicts, the Court held that the jury's lump-sum royalty payment lacked sufficient evidentiary support. Although the Court acknowledged that it rarely finds a jury's damages award lacks substantial evidence, the Court found that the jury's award here was "based mainly on speculation or guesswork." Accordingly, the Federal Circuit vacated the damages award and remanded for a new trial on damages.

On September 16, 2009, the Federal Circuit reversed the district court's grant of SJ of invalidity under 35 U.S.C. § 101 in *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, No. 08-1403 (Fed. Cir. Sept. 16, 2009). Applying the machine-or-transformation test of *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc), the Court held that the claimed method for calibrating the proper dosage for treating autoimmune diseases constituted patentable subject matter. Specifically, the Court found that "[t]he transformation is of the human body following administration of a drug and the various chemical and physical changes of the drug's metabolites that enable their concentrations to be determined." Slip op. at 14-15. Thus, the Court found the claims satisfied § 101 and reversed the district court's judgment.

See next month's edition for full summaries of these cases.