

Last Month at the Federal Circuit

March 2006

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- February was inequitable conduct month at the Federal Circuit, as the Court issued four opinions addressing the hazards of failing to disclose not only material prior art references, but also failing to disclose a declarant's relationship to the patentee, *Ferring B.V. v. Barr Laboratories, Inc.*, and failing to disclose that an alleged "discovery" was not supported by clinical evidence but only based on an inventor's insight, *Purdue Pharma L.P. v. Endo Pharmaceuticals Inc.* The Court also held that the "reasonable examiner" test used under the "old" version of PTO Rule 56 for determining the materiality of misstatements or omissions to the PTO did not replace or supplant the new version of Rule 56. *Digital Control, Inc. v. Charles Machine Works.* Lastly, the Court held that a failure to disclose a prior art device to the PTO, where the only evidence of intent is a lack of a good-faith explanation for the nondisclosure, cannot constitute clear and convincing evidence sufficient to support a determination of culpable intent. *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co.*
- On March 1, the Supreme Court ruled in *Illinois Tool Works Inc. v. Independent Ink, Inc.* that the mere fact that a tying product is patented does not support a presumption of market power, thereby eliminating a presumption that had been established in a line of Supreme Court cases extending back to 1947.
- On March 13, 2006, on remand from the Federal Circuit's en banc decision in *Phillips v. AWH*, 415 F.3d 1303 (Fed. Cir. 2005), a jury in the District of Colorado found that the defendants willfully infringed four claims of the asserted patent directed to vandalism-resistant modular wall panels, and awarded Phillips more than \$1.8 million. In a subsequent hearing, the Court will consider whether to grant Phillip's motion to treble the damages. On February 21, 2006, the Supreme Court denied AWH's petition for certiorari on the question of whether "all aspects of a district court's patent claim construction may be reviewed de novo on appeal." *AWH Corp. v. Phillips*, --- S.Ct. ---, 2006 WL 386393, 74 USLW 3464, 74 USLW 3471 (U.S. Feb. 21, 2006) (No. 05-602).
- The winner of the fun appellee name-of-the-month award goes to Guchi Moochie Tackle Company, with runner-up going to The Charles Machine Works (also known as DitchWitch). Neither, however, is quite as fun to say as *Schwing GMBH v. Putzmeister Aktiengesellschaft*, 305 F.3d 1318 (Fed. Cir. 2002).

No Presumption of Market Power When a Tying Product Is Patented

Edward J. Naidich

Justice Stevens delivered the unanimous opinion of the Court. Justice Alito took no part in the decision.

In *Illinois Tool Works Inc. v. Independent Ink, Inc.*, No. 04-1329 (U.S. Mar. 1, 2006), the Supreme Court ruled that the mere fact that a tying product is patented does not support a presumption of market power. The Court vacated the judgment of the Federal Circuit and remanded for further proceedings.

Trident, Inc. and its parent, Illinois Tool Works Inc. (collectively "Trident"),

manufacture and market printing systems that include a patented printhead, a patented ink container, and a specially designed but unpatented ink. Trident sells its systems to original equipment manufacturers ("OEMs"), who agree that they will purchase their ink exclusively from Trident, and that neither they nor their customers will refill the patented containers with ink of any kind.

Independent Ink, Inc. ("Independent") developed an ink with the same chemical composition as the ink sold by petitioners. Independent filed suit against Trident seeking a judgment of noninfringement and invalidity of Trident's patents, and alleging that petitioners were engaged in illegal tying and monopolization under §§ 1 and 2 of the Sherman Act. 15 U.S.C. §§ 1, 2.

After discovery, the district court granted Trident's motion for SJ on the Sherman Act

claims. It rejected Independent’s submission that Trident necessarily had market power in the market for the tying product as a matter of law solely by virtue of the patent on their printhead system, thereby rendering the tying arrangements *per se* violations of the antitrust laws. Finding that Independent had submitted no affirmative evidence defining the relevant market or establishing Trident’s power within it, the district court concluded that Independent could not prevail on either antitrust claim. On appeal, the Federal Circuit reversed the district court’s decision as to Independent’s § 1 claim, finding that it ran contrary to a long chain of Supreme Court decisions.

The Supreme Court vacated the judgment of the Federal Circuit, concluding that the mere fact that a tying product is patented does not support a presumption of market power. The Court noted that “[o]ver the years . . . this Court’s strong disapproval of tying arrangements has substantially diminished. Rather than relying on assumptions, in its

“Congress, the antitrust enforcement agencies, and most economists have all reached the conclusion that a patent does not necessarily confer market power upon the patentee.”
Slip op. at 16.

more recent opinions the Court has required a showing of market power in the tying product.” Slip op. at 5. The Court further explained that the view that tying arrangements may have legitimate business purposes and be procompetitive ultimately prevailed in its jurisprudence. It thereby described the presumption of market power as “a vestige of the Court’s historical distrust of tying arrangements.” *Id.* at 8.

As the Court explained, the presumption that a patent confers market power arose outside the

antitrust context as part of the patent misuse doctrine, which provides a defense to patent infringement when a patentee ties the purchase of unpatented goods to the sale of a patented good. The presumption that a patent confers market power then migrated from patent law to antitrust law in *International Salt Co. v. United States*, 332 U.S. 392 (1947).

In 1988, Congress amended the Patent Code to eliminate the patent-equals-market-power presumption in the patent misuse context. See 35 U.S.C. § 271(d)(5). The Court noted that although the 1988 amendment only expressly refers to the patent misuse context, and not to the antitrust laws, the amendment “certainly invites a reappraisal of the *per se* rule announced in *International Salt*.” Slip op. at 12.

The Court reasoned that if Congress intended to eliminate the presumption in the patent misuse context, it would be absurd to maintain the presumption under the antitrust laws, which can make the conduct at issue a federal crime punishable by up to ten years in prison. The Court further stated that “given the fact that the patent misuse doctrine provided the basis for the market power presumption, it would be anomalous to preserve the presumption in antitrust after Congress has eliminated its foundation.” *Id.* at 13. Thus, the Court concluded that while some tying arrangements involving patented products “are still unlawful, such as those that are the product of a true monopoly or a marketwide conspiracy, . . . that conclusion must be supported by proof of power in the relevant market rather than by a mere presumption thereof.” *Id.*

Independent further argued (i) that the Court should endorse a rebuttable presumption that patentees possess market power when they condition the purchase of a patented product on an agreement to buy unpatented goods

exclusively from the patentee, or (ii) that the Court should recognize a presumption of market power when a tying arrangement involves the purchase of unpatented goods over a period of time, a so-called “requirements tie.” The Court rejected both of these proposed alternatives, concluding that “the lesson to be learned from *International Salt* and the academic commentary is the same: Many tying arrangements, even those involving patents and requirements ties, are fully consistent with a free, competitive market.” *Id.* at 16. The Court elaborated that “Congress, the antitrust enforcement agencies, and most economists have all reached the conclusion that a patent does not necessarily confer market power upon the patentee.” *Id.* The Court therefore held that in all cases involving a tying arrangement, the plaintiff must prove that the defendant has market power in the tying product. It then remanded the case to allow Independent an opportunity to develop and introduce evidence defining the relevant market and proving that Trident possesses power within it.

There Is Little Basis to Infer Intent to Deceive When Materiality Is Low

Robert E. McBride

Judges: Gajarsa, Plager (author), Linn

In *Purdue Pharma L.P. v. Endo Pharmaceuticals Inc.*, Nos. 04-1189, -1347, -1357 (Fed. Cir. Feb. 1, 2006), the Federal Circuit withdrew its previous holding, vacated the district court’s holding that certain OxyContin® patents were unenforceable due to inequitable conduct, and remanded the case for further consideration regarding a determination of inequitable conduct. The Federal Circuit also affirmed the district court’s infringement holding.

Purdue Pharma L.P. and other related companies (collectively “Purdue”) asserted three patents directed to controlled release oxycodone medications for treatment of moderate to severe pain against Endo Pharmaceuticals Inc. and a related company (collectively “Endo”). The specification of each patent states: “It has now been *surprisingly discovered* that the presently claimed controlled release oxycodone formulations acceptably control pain over a substantially narrower, approximately four-fold [range] . . . in approximately 90% of patients. This is in sharp contrast to the approximately eight-fold range required for approximately 90% of patients for opioid analgesics in general.” Slip op. at 4, quoting U.S. Patent No. 5,549,912 (emphasis added).

In September 2000, Endo filed an ANDA with the FDA seeking approval to make and sell a generic version of Purdue’s OxyContin® formulation. By that time, Purdue had listed the three patents-in-suit in the Orange Book as covering OxyContin®. In October 2000, Purdue filed suit on the basis of Endo’s ANDA filing.

During the trial, Dr. Kaiko, a named inventor, testified that his “insight” led to the discovery of the reduced dosage range.

Using his knowledge of opioids and oxycodone, he “envisioned” a four-fold dosage range in 90% of patients. Despite the absence of any clinical results to support this claim, Purdue repeatedly relied on the “discovery” of that reduced dosage range during the prosecution of the patents-in-suit to distinguish the invention from other prior art opioids. Moreover, Purdue used language

“Purdue’s failure to disclose to the PTO that the asserted four-fold dosage range of the claimed oxycodone formulation was based on insight rather than experimental data does not rise to such a high level of materiality.” Slip op. at 19.

suggesting the existence of clinical results supporting the reduced dosage range.

While the trial court found that Endo's proposed generic drug product would infringe Purdue's patents, it also held Purdue's patents unenforceable due to inequitable conduct during prosecution of the patents. The district court found that Purdue's failure to inform the PTO that its reduced dosage "discovery" supported only by Dr. Kaiko's insight without any supportive clinical results constituted a failure to disclose material information that was inconsistent with arguments for patentability. The district court then inferred intent to deceive the PTO from the high materiality of the omission and Purdue's inability to prove its reduced dosage claim from existing clinical trials. After weighing materiality and intent, the district court held the patents unenforceable due to inequitable conduct.

In its initial decision, *Purdue Pharma L.P. v. Endo Pharmaceuticals Inc.*, 410 F.3d 690 (Fed. Cir. 2005), the Federal Circuit affirmed the district court's holding that the patents were unenforceable due to inequitable conduct. In that decision, the Court held that Purdue's failure to disclose that the invention was not supported by clinical studies, despite its implications to the contrary, was material. The Court further held that intent to mislead could be inferred from Purdue's statements in the context in which they were made and the clear pattern of misdirection evident throughout the prosecution of the patents.

In reconsidering its earlier decision on petition for rehearing, the Federal Circuit withdrew its previous decision, vacated the district court's holding of inequitable conduct, and remanded the case for further consideration on the issue of inequitable conduct. According to the

Court, Purdue did not make an affirmative misrepresentation. Though the requisite intent to deceive required for a finding of inequitable conduct may be inferred in some cases when a patentee has withheld highly material information such as a key prior art reference and knew or should have known of its materiality, Purdue's failure to disclose to the PTO that its discovery was based on insight rather than experimental data did not rise to such a high level of materiality. The Court further explained that Purdue's admitted inability to prove to the FDA with experimental results that OxyContin® was a more efficiently titratable analgesic than opioids did not necessarily conflict with Purdue's statements to the PTO regarding discovery of a reduced dosage range. The quantum of proof necessary for FDA approval is significantly higher than that required by the PTO. Citing these errors in the trial court's intent analysis, the Federal Circuit remanded the case for the district court to reconsider its intent finding and, if the trial court still finds a threshold level of intent to deceive, to reweigh its materiality and intent findings to determine whether the sanction of inequitable conduct is warranted.

The Federal Circuit also affirmed the trial court's judgment of infringement despite the Court's finding that the trial court erroneously construed the claims. The trial court impermissibly imported a limitation that the invention acceptably control pain for 90% of patients over a four-fold dosage range into the claim because Purdue described the four-fold dosage range "as a property of, or a result of administering," not "a necessary feature" of the claimed oxycodone formulation. Endo did not challenge that other limitations are met. Therefore, the Court affirmed the infringement determination.

Importation of Limitations from the Specification into Claims Is Improper

Kristin L. Menon

Judges: Clevenger, Rader (author), Dyk

In *Varco, L.P. v. Pason Systems USA Corp.*, No. 05-1136 (Fed. Cir. Feb. 1, 2006), the Federal Circuit held that the district court abused its discretion in denying Varco, L.P.’s (“Varco”) motion for a preliminary injunction because it construed disputed claim terms too narrowly.

The only claim at issue, independent method claim 14 of Varco’s U.S. Patent No. 5,474,142 (“the ’142 patent”), claims the automatic regulation of the release of a drill string of a drilling rig. The ’142 patent describes using signals from up to four parameters to automatically control the release of the drill string. Before the automatic regulation begins, an operator manually sets a desired threshold value for each of the chosen parameters. When two parameters are selected to control the drilling operation, one parameter primarily controls, and the other controls only if the signal crosses the manually preset undesirable threshold to prevent conflicts in control.

In deciding Varco’s motion for a preliminary injunction, the district court construed two disputed claim terms. The district court relied on the specification and the applicant’s arguments in prosecution to construe the first disputed term, “selecting,” to require two manual steps by the operator of the drilling rig, and it relied on the preferred embodiment to construe the second disputed term, “relaying,” to require pneumatically operated valves. Because an operator of Pason Systems USA Corporation’s (“Pason”) accused device

selects the controlling parameters via a computer screen interface and the device does not use pneumatic valves, the district court held that Varco had not shown a likelihood of success in proving infringement and denied Varco’s motion for a preliminary injunction.

On appeal, the Federal Circuit held that the district court erred in construing both disputed claim terms too narrowly. With regard to the district court’s construction that the “selecting” step is limited to manual operation, the Federal Circuit highlighted that the preamble indicates the opposite, stating that the method is for “automatically regulating” the drill release. The Court explained that the manual steps described in the specification, and relied upon by the district court, are precursors to, not a part of, the selected regulator’s automatic regulation. The Federal Circuit also relied on claim differentiation to demonstrate the error in the district court’s construction. Moreover, the prosecution history confirms that the claimed “selecting” step is not directed to the manual setup or calibration. Thus, the district court erred in reading this limitation into the claim.

With regard to the district court’s construction of “relaying,” the Federal Circuit held that the district court erred in limiting the claim to the method in the preferred embodiment. While

“Because this case seems to present an instance of after-arising technology (e.g., improvements on prior innovations), the district court may find it appropriate to consider infringement under the doctrine of equivalents.” Slip op. at 14.

the preferred embodiment uses pneumatic valves to relay the signal, there is no such limitation in the claim. Moreover, the disclosure of valves that “operate as relays” implies that other things could also operate to relay the signal. The Federal Circuit also considered extrinsic evidence to support the

breadth of the term “relaying,” quoting Pason’s expert and counsel in admitting that the term is not limited to pneumatic valves.

Because the district court’s construction was unduly narrow, the Federal Circuit vacated and remanded for further proceedings, and instructed the district court to further consider whether DOE applied, particularly in view of after-arising technology.

Evidence of Diligence in Interference Should Be Viewed as It Would Be by One Skilled in the Art

Steven R. Olsen

Judges: Newman (author), Rader, Prost

In *Brown v. Barbacid*, No. 05-1119 (Fed. Cir. Feb. 2, 2006), the Federal Circuit reversed the Board’s holding that reasonable diligence had not been shown by the senior party in the interference.

The interference proceeding (Interference No. 103,586) involved a method or assay for identifying compounds that inhibit the farnesyl transferase (“FT”) enzyme. Brown, the senior party, has an effective filing date of April 18, 1990, and Barbacid, the junior party, has a filing date of May 8, 1990. The Board accorded Barbacid an actual reduction-to-practice date of March 6, 1990.

In a previous appeal, *Brown v. Barbacid*, 276 F.3d 1327 (Fed. Cir. 2002) (“*Brown I*”), the Federal Circuit reversed the Board’s holding that the laboratory notebooks and autoradiographs of Brown’s inventor, Dr. Yuval Reiss, did not prove conception for want of adequate explanation. The Court explained that the Board must “weigh that

evidence from the vantage point of one of skill in the art,” *Brown I*, 276 F.3d at 1334, and Brown had presented adequate corroborated evidence of conception. Thus, Brown was held the first to conceive.

On remand, Brown provided Dr. Reiss’s testimony that he pursued experiments directed to the FT enzyme on a daily basis between Barbacid’s reduction-to-practice date and Brown’s filing date. As evidence of corroboration, Brown provided noninventor Debra Morgan’s declaration testimony on various FT inhibition studies, together with thirty-eight pages from Ms. Morgan’s laboratory notebook recording experiments designed by Dr. Reiss. The Board held that Brown failed to provide corroborative evidence of diligence because the content of Ms. Morgan’s notebooks was not explained, and awarded priority to Barbacid.

The parties presented three issues in the second appeal. First, the Federal Circuit held that the Board did not err in declining to permit Barbacid to raise the issue of the length of the period during which diligence should be shown on remand. The Board had previously granted Barbacid an actual reduction to practice date and no conception date. Barbacid’s silence on this issue throughout briefing, argument, and decision in *Brown I* resulted in waiver of the issue.

“The Board found that Ms. Morgan’s notebook records along with those of Dr. Reiss filled all but six days of the critical period, and that each of the six remaining days was a single-day gap; this was deemed sufficient to show substantially continuing activity.” Slip op. at 8.

Second, the Federal Circuit reversed the Board’s holding that Brown had not shown reasonable diligence. The Court explained that diligence and its corroboration may be shown by a variety of activities and that evidence must be viewed as it would be

viewed by persons experienced in the field of the invention, thereby rejecting the notion that such evidence must include an explanation of the “larger research purpose,” as the Board held. Because the Board agreed that Morgan’s activity, if accepted into evidence, established diligence, the Court concluded that Brown established diligence.

The Federal Circuit declined to address the remaining question of patentability. Although it would be in the interest of judicial economy, particularly given that the interference has been pending for over ten years, the Court cannot decide that question *ab initio* on appeal.

Inventors’ Priority Testimony Must Be Independently Corroborated

Jeffrey C. Totten

Judges: Schall, Gajarsa (author), Dyk

In *Medichem, S.A. v. Rolabo, S.L.*, Nos. 05-1179, -1248 (Fed. Cir. Feb. 3, 2006), the Federal Circuit affirmed the judgment of the district court on the proper establishment of interfering subject matter and on the finding of the existence of an interference-in-fact, but reversed the award of priority to Medichem, S.A. (“Medichem”) due to insufficient corroboratory evidence.

Medichem and Rolabo, S.L. (“Rolabo”) are assignees of patents claiming a process for making loratadine, the active ingredient in the allergy medication Claritin®, from two precursor chemicals by a chemical reaction known as the McMurry reaction. Medichem’s patent, U.S. Patent No. 6,084,100 (“the ’100 patent”), requires the claimed process to be carried out in the presence of a chemical known as a tertiary amine. Rolabo’s patent, U.S. Patent No. 6,093,827 (“the ’827 patent”),

on the other hand, permits, but does not require, a tertiary amine in the claimed process.

Medichem brought an action in the district court under 35 U.S.C. § 291, alleging an interference-in-fact between the ’100 and ’827 patents, claiming priority of invention, and seeking to invalidate Rolabo’s ’827 patent under 35 U.S.C. § 102(g). Following a bench trial, the district court found no interference-in-fact but nonetheless awarded priority to Medichem. In an earlier appeal, *Medichem, S.A. v. Rolabo, S.L.*, 353 F.3d 928 (Fed. Cir. 2003), the Federal Circuit vacated the award of priority and remanded the case to the district court to complete the determination of whether an interference-in-fact existed. The Federal Circuit instructed the district court that both prongs of the “two-way” test must be satisfied to create an interference-in-fact. Under this test, the two patents would interfere only if Medichem’s invention anticipates or renders obvious Rolabo’s invention, assuming for the purposes of the test that Medichem’s invention qualified as prior art to Rolabo’s process, and vice versa. The Federal Circuit noted that Medichem’s species claims anticipate the genus claims of the ’827 patent, but asked the district court to determine whether the patents meet the second prong of the two-way test. Only after finding an interference-in-fact may the district court consider priority.

“Even the most credible inventor testimony is *a fortiori* required to be corroborated by independent evidence, which may consist of documentary evidence as well as the testimony of non-inventors.” Slip op. at 24.

On remand, the district court held that, pursuant to the two-way test, an interference-in-fact exists because the claims of the ’827 patent would anticipate and render obvious the claims of the ’100 patent. The district court

thus awarded priority to Medichem after finding that Medichem reduced the invention to practice prior to Rolabo's constructive reduction to practice date. Rolabo appealed.

On appeal, the Federal Circuit affirmed the district court's finding that an interference-in-fact exists. The Federal Circuit agreed that the prior art, combined with the teachings of the '100 patent, would render the '827 patent obvious. The prior art disclosed potential advantages and disadvantages to using a tertiary amine in a McMurry reaction. Despite this conflict, when viewed as a whole, the art taught that adding a tertiary amine *sometimes* improves the yield of McMurry reactions. Thus, the art provides the requisite motivation to combine references and the reasonable expectation of success to render the '827 patent obvious.

The Federal Circuit also held that the district court did not err in failing to formally define a count corresponding to the interfering subject matter. The district court clearly identified the interfering subject matter by identifying the interfering claims, and need not refer to the subject matter as a "count."

Finally, the Federal Circuit reversed the award of priority of invention to Medichem. To establish priority, Medichem argued that its inventors reduced the claimed process to practice prior to Rolabo's effective filing date. Showing actual reduction to practice requires, *inter alia*, evidence sufficient to corroborate the purported reduction to practice. Credibility concerns underlie the corroboration requirement, which requires knowledge independent of the inventors.

The Federal Circuit considered three pieces of potentially corroborative evidence. The first piece of evidence, spectral data, showed the presence of loratadine, but failed to establish the process by which the inventors created the compound. As the disputed invention covered the process of making loratadine, the Court held that this evidence failed to establish

reduction to practice. The second piece of evidence, the inventors' laboratory notebooks, were not witnessed and do not provide independent authority. Therefore, the Court held that they have minimal corroborative value.

Finally, the Federal Circuit found the third piece of evidence, a noninventor's laboratory notebook, insufficient to corroborate reduction to practice as well. The inventor and the noninventor frequently made notes in each other's notebooks, and the noninventor did not testify at trial. Instead, the district court relied on the inventor's testimony to authenticate pertinent passages in the notebook. Because the district court lacked noninventor testimony regarding the notebook's contents and the notebook was unsigned and undated, the Federal Circuit held that the notebook was of minimal corroborative value. The Court noted that Medichem's fraudulent backdating of other documents relating to the case further diminished the value of the evidence. Absent corroboration, the district court erred in awarding priority to Medichem.

PTO May Limit Recognition of Aliens Practicing Before It

Timothy P. McAnulty

Judges: Newman, Mayer (author), Gajarsa

In *Lacavera v. Dudas*, No. 05-1204 (Fed. Cir. Feb. 6, 2006), the Federal Circuit affirmed the district court's grant of SJ in favor of the PTO and denial of SJ for Lacavera regarding the PTO's decision to grant Lacavera limited recognition to practice before the PTO.

Lacavera is a Canadian citizen and nonimmigrant alien who began working in the United States as an attorney in September 2001 pursuant to a one-year visa permitting

her to prepare and prosecute applications for a law firm. Lacavera passed the patent examination in April 2002 and was granted limited recognition by the PTO because of the legal restrictions imposed by her visa. Lacavera timely extended her visa and changed employers. Her visa listed preparation and prosecution of patent applications for a single company as her sole employable activity. After the PTO denied Lacavera's challenge to its grant of only limited recognition, she filed suit, asserting that (1) the PTO's decision was inconsistent with its regulations governing recognition; (2) the PTO's regulations exceeded the authority of its enabling statute; and (3) the PTO's decision denied her equal protection. The district court denied Lacavera's motion for SJ and granted SJ in favor of the PTO.

“Lacavera offered no evidence that she was treated unequally as compared to other aliens with visa restrictions, and therefore she suffered no individual equal protection violation.” Slip op. at 6.

On appeal, the Federal Circuit held that the PTO's grant of limited recognition was not an abuse of discretion because granting full recognition would have given Lacavera approval to do work that she could

not lawfully engage in under the conditions of her visa. The Court noted that the scope of review for claims of abuse of discretion is narrow and that the Court is not to substitute its judgment for that of an agency. In this case, the Court held that the PTO correctly applied 37 C.F.R. §§ 10.6(a) and 10.9(b) and the General Requirements Bulletin.

With regard to Lacavera's claim that the PTO exceeded its statutory authority in considering visa restrictions when determining whether to grant full recognition, the Federal Circuit noted that the PTO has broad authority to govern the recognition of attorneys pursuant to its enabling statute and the statute is silent regarding the consideration of visa restrictions and determining grants of recognition. The

statute does authorize the PTO to require applicants to show that they possess the necessary qualifications to render applicants valuable service. Thus, the Federal Circuit held that it was reasonable for the PTO to consider legal authority, e.g., visa restrictions limiting an alien's lawful employment, when determining if applicants have shown that they possess the necessary qualifications to render applicants valuable service.

With regard to Lacavera's equal protection claim, the Federal Circuit applied the rational review standard and noted that Lacavera presented no evidence that she was unequally treated as compared to other aliens with visa restrictions. Additionally, because the regulations are rationally related to a legitimate government interest, minimizing public harm associated with unauthorized practice before the PTO, the Federal Circuit concluded that the regulations do not violate the equal protection clause and are, therefore, valid.

Accordingly, the Federal Circuit affirmed the judgment of the district court.

Rule 56 Is Not the Exclusive Test for “Materiality”

John M. Mulcahy

Judges: Michel, Clevenger (author), Schall

In *Digital Control, Inc. v. Charles Machine Works*, No. 05-1128 (Fed. Cir. Feb. 8, 2006), the Federal Circuit affirmed the district court's partial grant of SJ based on the materiality of misstatements in a Rule 131 declaration, reversed the grant of partial SJ based on the materiality of an uncited patent, and vacated the district court's determination that the patents-in-suit were unenforceable due to inequitable conduct.

Digital Control, Inc. and Merlin Technology, Inc. (collectively “DCI”) asserted patents directed to methods for monitoring the orientation of a drilling apparatus underground. During prosecution, the inventor submitted a declaration under Rule 131 to establish that he had reduced his invention to practice by demonstrating it to a colleague prior to the effective date of the reference used in a rejection. The inventor’s statements were corroborated in a separate declaration by his colleague. Based on these declarations, the examiner allowed the claims. However, litigation revealed that the inventor had not demonstrated the complete system underground before the critical date. In light of the inventor’s material misstatements in his declaration and because DCI also failed to cite a prior art reference known to the inventor, The Charles Machine Works (“CMW”) alleged that the patents were unenforceable.

The district court found that there was no genuine issue of fact with respect to the materiality of the false declaration or to the materiality of the uncited reference. Because two acts of material misstatement or omission regarding the same three patents were presented, the district court concluded that the applicant had acted with the requisite intent to deceive the PTO, and therefore held the patents unenforceable on SJ.

On appeal, the Federal Circuit first addressed the proper standard for determining whether a statement or omission is “material to patentability.” The district court had applied the “reasonable examiner” standard set forth in the original version of Rule 56. However, in 1992, the PTO amended Rule 56 to define an arguably more narrow standard for materiality. The Court clarified that, just as the original version of Rule 56 did not supplant then-existing case law, new Rule 56 does not define the exclusive test for materiality. The Court noted that there is no reason to be bound by any single standard. In

determining whether a misstatement or omission renders a patent unenforceable, the district court must balance the defendant’s showings on the issues of materiality and intent to deceive, “to the extent that one standard requires a higher showing of materiality than another standard, the requisite finding of intent may be lower.” Slip op. at 12.

Applying the “reasonable examiner” standard, as adopted by the district court, the Federal Circuit agreed that the misstatements in the declaration “unquestionably” met the threshold requirement for materiality. However, the Court noted that a reference that is merely cumulative of references cited during prosecution is not material. Because “the scope and content of prior art and what the prior art teaches are questions of fact,” *id.* at 17, the Court held that the materiality of the uncited reference was not properly decided on SJ. Thus, even though it found the false declaration material, the Federal Circuit vacated the district court’s grant of SJ of unenforceability because the district court’s holding that the applicant had acted with intent to deceive the PTO was based, in part, on its erroneous determination that the uncited reference was material.

Defendant’s Bankruptcy Discharge Does Not Enjoin Plaintiff from Suit on Subsequent Infringing Acts

Courtney B. Meeker

Judges: Lourie, Clevenger (author), Bryson

In *Hazelquist v. Guchi Moochie Tackle Co.*, No. 05-1446 (Fed. Cir. Feb. 9, 2006), the Federal Circuit reversed the district court’s dismissal of Hazelquist’s claims.

Hazelquist sued Yamaguchi and Guchi Moochie Tackle Company (“Guchi Moochie”), of which Yamaguchi was the operator and sole owner, for infringement of his design patent. After Yamaguchi dismissed his attorneys and new counsel for Guchi Moochie failed to appear, the district court granted Hazelquist’s motion for default against Guchi Moochie and dismissed with prejudice Guchi Moochie’s counterclaims.

“[A discharge in bankruptcy] does not act as an injunction against a plaintiff asserting a claim for a debt incurred, or a cause of action that arose, after the date of bankruptcy discharge.” Slip op. at 5.

Yamaguchi then filed for bankruptcy and the infringement suit was stayed. Meanwhile, the court denied Hazelquist’s motion for default judgment against Guchi Moochie despite its earlier entry of default because judgment against Guchi Moochie would “in substance” be judgment against Yamaguchi and the court was barred from entering judgment on Yamaguchi until resolution of the bankruptcy petition.

Once Yamaguchi obtained discharge of his debts, the district court lifted the stay and ordered Hazelquist to show cause why the case should not be dismissed, as it appeared that the case was included in Yamaguchi’s discharged debts and liabilities. In response, Hazelquist alleged that Yamaguchi continued to infringe after the bankruptcy discharge. The district court, however, dismissed the claims, relying on 11 U.S.C. § 524(a), which states that “the discharge of a debtor’s liabilities in bankruptcy ‘operates . . . against the commencement or continuation of an action, . . . to collect, recover, or offset any such debt as a personal liability of the debtor.’” Slip op. at 3. The district court noted that, although Hazelquist argued that his case should continue because Yamaguchi admitted to the continued sale of allegedly infringing fishing lures, Hazelquist had not

cited any supporting legal authority. Thus, the court also denied Hazelquist’s motion for reconsideration.

On appeal, the Federal Circuit reversed the dismissal because the district court erred in treating a discharge in bankruptcy as an injunction against a plaintiff asserting a claim for a cause of action that arose after the date of bankruptcy. Section 524 only applies to debts that arose before the date of discharge, and the Court’s case law “clearly states that each act of patent infringement gives rise to a separate cause of action.” *Id.* at 5. Thus, the Court held that Hazelquist has a cause of action arising after the bankruptcy discharge and is not enjoined by § 524.

Claim Differentiation Improperly Used to Construe a Claim Term Too Broadly Inconsistent with the Specification and Context of the Invention

Maryann T. Puglielli

Judges: Rader (author), Friedman, Dyk

In *Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, No. 05-1373 (Fed. Cir. Feb. 15, 2006), the Federal Circuit vacated the district court’s grant of a preliminary injunction in favor of Curtiss-Wright Flow Control Corporation (“Curtiss-Wright”) and remanded the case back to the district court.

The relevant patent, U.S. Patent No. 6,565,714 (“the ’714 patent”), describes a coking drum with a de-heading system. In a process called delayed coking, refineries use coking drums to extract valuable products from heavy residual oil that remains after the refining process. After filling the coke drum with hot residual

oil, workers perform the dangerous task of de-heading the drums, which involves manually removing large metal plates known as “heads” that seal the drum’s openings in order to remove the solid coke from the drum. The ’714 patent claims a system and method that de-heads the coke drum without manually removing the heads. The system uses a “de-header valve” with an adjustment mechanism that adjusts the valve during operation of the de-header system.

Curtiss-Wright sought a preliminary injunction against Velan, Inc. (“Velan”) to prevent the launch of a valve that Curtiss-Wright believed infringed claims 14, 33, and 36 of the ’714 patent. Velan’s valves do not include adjustment mechanisms like those disclosed in the ’714 patent. Instead, Velan’s valves contain internal biasing springs that an operator must replace in order to perform a similar type of adjustment. Such replacement requires removing the valve from the coke drum.

Claim 14 of the ’714 patent recites a de-header valve comprising an *adjustable* dynamic seat. The district court concluded that “adjustable” means that the bias force can be changed in a manner that is “not limited by any time, place, manner, or means of adjustment.” In reaching this construction, the district court relied on the term’s ordinary meaning and the doctrine of claim differentiation. Specifically, the court determined that a narrower construction of “adjustable” would be inconsistent with other claims in the ’714 patent, which recite an adjustment mechanism that allows adjustment while the device is in use or operation. Given this broad interpretation of “adjustable,” the district court concluded that Velan can “adjust” the bias force by replacing the springs in its de-header valve and thus granted the preliminary injunction.

The Federal Circuit vacated the preliminary injunction, concluding that the district court’s reasoning placed too much emphasis on the

ordinary meaning of “adjustable” without adequate grounding of that term within the context of the specification of the ’714 patent. The Court noted that the ’714 patent associates the adjustability with a critical aspect of the invention: the ability to de-head the coke drum without having to remove the head unit. Moreover, the patent consistently, and without exception, describes adjustment that occurs during operation of the de-header system and without removal of the head unit. The Court thus concluded that the district court’s construction of “adjustable,” which includes a structure that

requires dismantling of the valve to perform the adjustment, found no support in the overall context of the ’714 patent specification. The Federal Circuit also explained that the district court’s reliance on the doctrine of claim differentiation

was misplaced. The Court noted two considerations that generally govern the use of claim differentiation when applied to two independent claims: “(1) claim differentiation takes on relevance in the context of a claim construction that would render additional, or different, language in another independent claim superfluous; and (2) claim differentiation ‘can not broaden claims beyond their correct scope.’” Slip op. at 12. The Court concluded that both considerations weighed against the district court’s construction of “adjustable.”

According to the Court, construing “adjustable” to mean adjustable “on the fly” during de-heading did not render the recitation of an adjustment mechanism in other claims

“[T]wo considerations generally govern [the use of claim differentiation as a] claim construction tool when applied to two independent claims: (1) claim differentiation takes on relevance in the context of a claim construction that would render additional, or different, language in another independent claim superfluous; and (2) claim differentiation ‘can not broaden claims beyond their correct scope.’” Slip op. at 12.

superfluous. Moreover, the Court noted that in-use adjustability did not necessarily mean the same thing as the presence of an adjustment mechanism. The Court also pointed out that the district court's broad definition of "adjustable" provided no meaningful limit on claim 14 because any mechanical device would be adjustable under that definition. Lastly, the Court reiterated that the district court's definition of "adjustable," based on its claim differentiation analysis, contradicted the context of the invention as described in the specification, which stresses that the invention is "adjustable" during de-heading.

Failure to Disclose Relationship Between Declarants and Applicant Affirmed to Be Inequitable Conduct

Scott J. Popma

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

In *Ferring B.V. v. Barr Laboratories, Inc.*, No. 05-1284 (Fed. Cir. Feb. 15, 2006), the Federal Circuit upheld the district court's grant of SJ that Ferring B.V.'s ("Ferring") patent was unenforceable due to inequitable conduct, affirming that Ferring's failure to inform the PTO that key declarations were drafted by scientists who had significant ties to Ferring was both material and intentional.

Ferring submitted a patent application for a pharmaceutical compound and a method of administering it orally, whereby it is absorbed in the gastrointestinal tract. Ferring had a preliminary interview with the PTO to discuss a prior art reference, U.S. Patent No.

3,497,491 ("the '491 patent"), which disclosed administering the same pharmaceutical compound by "peroral" application. Ferring argued that "peroral" meant that the drug was absorbed in the mouth rather than in the gastrointestinal tract. The PTO requested that Ferring submit declarations from "non-inventors" to support its interpretation of "peroral." Ferring submitted four declarations in support of its position, including one declaration from a scientist who had recently received research funding from Ferring. However, Ferring did not disclose this relationship.

The application was nonetheless rejected over the '491 patent, and Ferring appealed to the Board. The Board generally agreed with Ferring's interpretation of "peroral" but found that when the '491 patent was combined with a previously undisclosed prior art reference ("Vavra"), the claims would still be obvious. The Board allowed Ferring to continue prosecution in response to this new matter rejection.

Ferring submitted five new declarations to support its argument that in light of the '491 patent and Vavra reference, it would not have been obvious that the drug would be absorbed in the gastrointestinal tract. Three of these declarations were submitted by scientists, who had either received funding from Ferring or were former employees. Again, Ferring did not disclose these relationships. Further, Ferring submitted a CV for one of these scientists that did not mention that he received research funding from Ferring and did not submit a CV for the other two scientists. After reviewing the declarations, the examiner allowed the claims and issued the patent as U.S. Patent No. 5,047,398 ("the '398 patent").

Ferring brought a patent infringement lawsuit against Barr Laboratories, Inc. ("Barr"), alleging that Barr infringed claims of the '398 patent. Barr moved for SJ, alleging that the

'398 patent was not infringed and unenforceable due to inequitable conduct during the prosecution of the patent. The district court granted SJ in favor of Barr on both issues. Ferring appealed.

The CAFC first examined whether Ferring's failure to disclose the past relationships with the declarants was material by examining whether "(1) the declarant's views on the underlying issue are material and (2) the past relationship to the applicant was a significant one." Slip op. at 12. The Court found that the declarations were "absolutely critical in overcoming the Board's obviousness rejection" and that the three undisclosed relationships were significant and ongoing during the prosecution of the application. *Id.* at 13. Ferring argued that the examiner would not have placed any significance on the identity of the declarants. The Court found that Ferring was placed on notice about the materiality of the relationship between Ferring and the declarants when the examiner informed applicants that it wanted "non-inventor" affidavits and stated that it was concerned about the objectivity of the declarants.

The CAFC then affirmed that the district court had appropriately granted SJ on the issue of intent by determining that "(1) the applicant knew of the information; (2) the applicant knew or should have known of the materiality of the information; and (3) the applicant has not provided a credible explanation for the withholding." *Id.* at 17-18.

The Court then held that the district court did not abuse its discretion when determining that the materiality and intent were raised to a sufficient level to render the failure to disclose inequitable. The Court placed significance on the fact that there were multiple failures to disclose the relationship, that the relationships, including past employment by Ferring, were significant, and that four of the five

declarations were submitted by scientists with significant ties to the applicant. The Court affirmed the inequitable conduct decision of the district court, concluding that "where the objectivity of the declarant is an issue in the prosecution, the inventor must disclose the known relationships and affiliations of the declarants so that those interests can be considered in weighing the declarations." *Id.* at 24. The Court did not reach the infringement issue.

Judge Newman "urgently" dissented, arguing that this decision ignored the requirement set forth in *Kingsdown Medical Consultants Ltd. v. Hollister, Inc.*, 863 F.2d 867 (Fed. Cir. 1988) (en banc), for "clear and convincing evidence of a misrepresentation or omission material to patentability, made intentionally and for the purpose of deception" and instead set a "'should have known' standard of materiality."

Knorr-Bremse Does Not Prohibit Patentee from Challenging Competency of Opinions Produced to Rebut a Charge of Willfulness

Joseph E. Palys

Judges: Michel, Lourie, Linn (author)

In *Golden Blount, Inc. v. Robert H. Peterson Co.*, Nos. 04-1609, 05-1141, -1202 (Fed. Cir. Feb. 15, 2006), the Federal Circuit affirmed a district court's decision that U.S. Patent No. 5,988,159 ("the '159 patent") was willfully infringed by the Robert H. Peterson Company ("Peterson"). However, the Court vacated the damages award and remanded for the district court to determine whether certain units were actually returned to Peterson before being assembled into an infringing configuration.

Golden Blount, Inc. (“Golden Blount”) filed suit against Peterson for infringement of the ’159 patent. After a bench trial, the district court found willful infringement and awarded damages and attorney fees. On appeal, the Federal Circuit construed certain claims of the ’159 patent and affirmed the validity determination, but vacated the judgment as to infringement and remanded for specific factual findings. See *Golden Blount, Inc. v. Robert G. Peterson Co.*, 365 F.3d 1054 (Fed. Cir. 2004) (“*Golden Blount I*”). On remand, the district court initially adopted Peterson’s proposed findings of fact of noninfringement, but later vacated those same findings in response to oral arguments heard from Golden Blount on its motion to amend the judgment under Fed. R. Civ. P. (“Rule”) 52(b). In response to a request from the district court, Golden Blount submitted new findings of fact that were subsequently adopted. As a result, the district court found that Peterson willfully infringed the ’159 patent and awarded damages and attorney fees.

“[I]f the [attorney-client] privilege is not asserted, the patentee in making its threshold showing of culpable conduct is free to introduce as evidence whatever opinions were obtained and to challenge the competence of those opinions in satisfaction of the patentee’s burden on willfulness. Nothing in *Knorr-Bremse* precludes a patentee from attempting to make such a showing.” Slip op. at 24.

On appeal, the Federal Circuit first dismissed Peterson’s argument that the district court had erred in vacating *all* of its findings when Golden Blount’s Rule 52(b) motion only sought to amend *some* of the findings. The Court held that the district court did not abuse its discretion in amending all of its findings because a district court may reverse any or all of its findings in acting on a Rule 52(b) motion, and because a Rule 52(b) motion provides the district court discretion to amend any of its own findings.

The Court next turned to infringement. The ’159 patent is directed to a fireplace assembly that includes a combination of primary and secondary gas burner tubes. In *Golden Blount I*, the Federal Circuit concluded that claims 1 and 17 of the ’159 patent require that the top of the primary burner tube be above the top of the secondary burner tube. Although Peterson sells its secondary burner (also called an “ember burner” or “EMB”) to distributors packaged separately from the primary burner, the district court found that Peterson directly infringed by assembling the entire apparatus itself on a number of occasions, and indirectly infringed by selling the EMB with instructions leading end-users to assemble the device in the claimed configuration.

Upon examination of the instructions provided by Peterson and the testimony of various witnesses, the Federal Circuit concluded that the district court did not clearly err in finding that the instructions taught assembly of an infringing configuration with the top of the primary tube above the top of the EMB. Furthermore, noting that “[c]ircumstantial evidence can support a finding of infringement,” slip op. at 12, the Federal Circuit found that the district court did not clearly err in concluding that (1) direct infringement by Peterson could be inferred from Peterson’s assembly of eleven units in light of the instructions; and (2) direct infringement by the customers could be inferred from Peterson’s sales of the EMB packaged with the instructions. Moreover, nothing in the record suggested that Peterson or any end-users ignored the instructions or assembled the burners in a noninfringing way.

The Federal Circuit also held that the district court did not clearly err in finding that there were no substantial noninfringing uses of the EMB and thus that Peterson acted as a contributory infringer each time it sold an EMB that was ultimately assembled into an infringing device. The Court noted that the

instructions taught only the infringing configuration, and Peterson did not present any evidence that EMB end-users assembled the burners in a noninfringing way. Further, the Court agreed that because Peterson packaged the instructions with the EMB, it intended to have customers assemble the device in accordance with the instructions and thus was liable for inducing infringement.

Regarding the issue of willfulness, the Federal Circuit dismissed Peterson's arguments that (1) the district court improperly drew an adverse inference of the type prohibited by *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GMBH v. Dana Corp.*, 383 F.3d 1337 (Fed. Cir. 2004) (en banc), by considering the competency of the oral opinions of counsel obtained by Peterson; and (2) Peterson did not act in reckless disregard of the '159 patent because it had a good-faith belief that it did not infringe the '159 patent. As to the first argument, the Court explained that when an alleged infringer fails to obtain or produce an exculpatory opinion of counsel, *Knorr-Bremse* prohibits drawing an adverse inference that an opinion was or would have been unfavorable. But the Court elaborated that "if the privilege is not asserted, the patentee in making its threshold showing of culpable conduct is free to introduce as evidence whatever opinions were obtained and to challenge the competence of those opinions in satisfaction of the patentee's burden on willfulness." Slip op. at 24. Thus, the Court held that because Peterson did not assert attorney-client privilege with respect to the oral opinions it obtained from counsel, the competence of those opinions and the facts surrounding Peterson's obtaining those opinions were properly considered by the district court.

Regarding the second argument, the Court concluded that the district court did not clearly err in dismissing Peterson's asserted good-faith belief in noninfringement and thus in finding willfulness. The Court highlighted that (1) Peterson made little or no effort to assess whether it infringed or whether the

patent was invalid after receiving notice of the patent, (2) Peterson's outside counsel did not have the prosecution history or the accused device when he gave his oral opinions, and (3) Peterson did not respond substantively to Golden Blount's notice letters and only sought a thorough opinion of counsel after suit was filed, and then only out of a concern to avoid a willfulness finding and possible judgment for attorney fees.

Regarding the determination of lost-profit damages, the Court rejected Peterson's argument that the district court clearly erred in finding that the parties did not compete for sales of two-burner assemblies. The Court noted that a properly configured assembly infringes regardless of whether the two burners were bought separately. Further, the Court pointed to testimony that the standard practice in the industry is to sell the primary burner as part of the entire burner assembly—evidence that Peterson did not rebut. However, the Court vacated the damages award and remanded for the purpose of determining whether 802 EMBs were returned to Peterson from distributors before being sold to retailers and before being assembled into an infringing configuration, and therefore should not have been included in the damages award.

Appellee's Conditional Cross-Appeal on Claim Construction Dismissed as Improper

Aaron L. Parker

Judges: Michel, Newman (dissenting), Bryson (per curiam)

In Nautilus Group, Inc. v. ICON Health & Fitness, Inc., Nos. 05-1577, -1603 (Fed. Cir. Feb. 15, 2006), the Federal Circuit granted appellant The Nautilus Group, Inc.'s ("Nautilus") motion to dismiss appellee ICON

Health and Fitness, Inc.’s (“ICON”) cross-appeal from the district court’s claim construction order “in the event that Nautilus prevails on appeal.”

Nautilus filed a patent infringement suit in the U.S. District Court for the Western District of Washington, asserting that ICON infringed two patents. ICON filed a counterclaim for DJ of noninfringement of both patents. The district court dismissed with prejudice Nautilus’s claims for infringement of both patents and entered judgment in favor of ICON. Nautilus appealed and ICON filed a conditional cross-appeal. Nautilus then moved to dismiss ICON’s cross-appeal.

In dismissing ICON’s cross-appeal, the Court likened this case to *Bailey v. Dart Container Corp.*, 292 F.3d 1360 (Fed. Cir. 2002), in which a similar cross-appeal was dismissed. Dart Container Corporation (“Dart”), like ICON, sought review of certain claim construction rulings in the event the Federal Circuit reversed on the issue of noninfringement. The Court noted that an appellee like Dart, and ICON, can “make appropriate arguments regarding claim construction [on appeal] that would result in affirmance of the judgment of noninfringement.” Slip op. at 2. The Court noted, however, that a conditional cross-appeal “unnecessarily expands the amount of briefing that is otherwise allowed, as well as giving the appellee an unfair opportunity to file the final brief and have the final oral argument, contrary to established rules.” *Id.* at 3. The Court held that the principles of *Bailey* apply squarely to the facts of this case. The Court also cited language from the panel’s decision in *Phillips v. AWH Corp.*, 363 F.3d 1207, 1216 (Fed. Cir. 2004), in which the panel dismissed a similar cross-appeal. The panel stated that a “party has no right of cross-appeal from a decision in its favor. Similarly, a party who prevails on noninfringement has no right to file a ‘conditional’ cross-appeal to introduce new arguments or challenge a claim construction, but may simply assert alternative

grounds in the record for affirming the judgment.” *Id.* The en banc court in *Phillips* specifically adopted the panel’s disposition of the cross-appeal and underlying reasoning. *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). Accordingly, the Court dismissed ICON’s conditional cross-appeal.

Judge Newman dissented, pointing out that ICON’s conditional cross-appeal is not requested as an alternative ground for SJ of noninfringement, but as a basis for further proceedings should the Court order further proceedings. Judge Newman noted that dismissal of ICON’s cross-appeal is problematic because, if the Court reverses or vacates the district court’s judgment on appeal and remands for trial, the district court’s claim construction that was not relied on in the judgment on appeal will be the law of the case, despite lack of review by the Federal Circuit. Accordingly, such a remand for trial on potentially incorrect law will simply lead to additional appeals, remands, and retrials. Because conditional cross-appeals of claim construction-based judgments in patent cases present a significant chance of requiring further proceedings, Judge Newman concluded that when such a cross-appeal can significantly advance those further proceedings, the procedure should not be discouraged.

Combination of Old Elements Does Not Satisfy the “Point of Novelty” Test in Determining Infringement of a Design Patent

Meredith H. Schoenfeld

Judges: Michel, Friedman (author), Dyk

In *Lawman Armor Corp. v. Winner International, LLC*, No. 05-1253 (Fed. Cir.

Feb. 22, 2006), the Federal Circuit upheld a SJ of noninfringement of Lawman Armor Corporation's ("Lawman") patent for the ornamental design for a portion of a vehicle steering wheel lock assembly.

Lawman was the exclusive licensee of U.S. Design Patent No. Des. 357,621 ("the '621 patent"). The '621 patent claims "[t]he ornamental design for a sliding hook portion of a vehicle steering wheel lock assembly, as shown and described." Lawman sued Winner International, LLC and Winner Holding LLC (collectively "Winner") in the Eastern District of Pennsylvania for infringement of the '621 patent. Winner moved for SJ of noninfringement. In opposition, Lawman specified eight "points of novelty" in the patented design. In response, Winner simply listed Lawman's "points of novelty" and cited to automobile wheel lock patents that depicted the alleged "points of novelty." The district court held that Lawman's "points of novelty" were found in the prior art and that no material issue of fact exists regarding the "point of novelty" test. Therefore, the district court granted Winner SJ of noninfringement.

The Federal Circuit affirmed, explaining that to show infringement, a design patent holder must satisfy two separate tests: (a) the "ordinary observer" test, and (b) the "point of novelty" test. The "ordinary observer" test requires comparison of the two designs from the viewpoint of the ordinary observer to "determine whether the patented design as a whole is substantially the same as the accused design." Slip op. at 3. Under the "point of novelty" test, a court must determine whether "the accused device . . . appropriate[s] the novelty in the patented device which distinguishes it from the prior art." *Id.*

Lawman did not challenge the district court's finding that each of the points of novelty was present in the prior art. Instead, Lawman argued that the district court failed to make sufficient findings as to the scope and content

of the prior art and also failed to determine the "points of novelty" of the patent. The Federal Circuit rejected these arguments, concluding that each of the eight points of novelty specified by Lawman was present in the prior art and the district court was not required to make more detailed findings.

Lawman further argued that there was no suggestion to combine the prior art references and that the combination in a single design of the eight points of novelty is itself a point of novelty. The Court rejected these arguments, concluding that "[w]hether there is any suggestion to combine prior art references may be relevant in a validity inquiry to determine obviousness. . . . It has no place in the infringement issue in this case." *Id.* at 5. The purpose of the points of novelty approach is to focus on the aspects of a design that renders it different from prior designs. The Court noted that "[i]f the combination of old elements shown in the prior art is itself sufficient to constitute a 'point of novelty' of a new design, it would be the rare design that would not have a point of novelty." *Id.* at 5-6. Thus, because all of the points of novelty of the '621 patent were present in the prior art, the Court affirmed the SJ of noninfringement.

Product-by-Process Claims Not Limited by Claimed Process Steps for Purposes of Anticipation

Beth Z. Shaw

Judges: Newman (dissenting), Schall, Dyk (author)

In *SmithKline Beecham Corp. v. Apotex Corp.*, No. 04-1522 (Fed. Cir. Feb. 24, 2006), the Federal Circuit affirmed a district court's SJ holding that product-by-process claims were anticipated by a previously disclosed product.

In 1992, SmithKline Beecham Corporation and SmithKline Beecham, P.L.C. (collectively “SmithKline”) obtained FDA approval to market a pharmaceutical composition (“paroxetine”) sold under the trade name Paxil®. SmithKline applied for and was granted U.S. Patent No. 6,113,944 (“the ’944 patent”). Claims 1 and 2 of the ’944 patent are product-by-process claims reciting paroxetine tablets made by certain processes.

In March 1998, generic drug manufacturer Apotex Corporation, Apotex, Inc., and Torpharm, Inc. (collectively “Apotex”) filed

“[O]nce a product is fully disclosed in the art, future claims to that same product are precluded, even if that product is claimed as made by a new process.” Slip op. at 5.

an ANDA to the FDA seeking to market a generic version of Paxil®. Apotex also filed a “paragraph IV certification” in connection with its ANDA, stating, among other things, that the ’944 patent was invalid. Pursuant to 35 U.S.C.

§ 271(e)(2), which makes submitting an ANDA an act of infringement, SmithKline sued Apotex for infringement of the ’944 patent in the Eastern District of Pennsylvania. Apotex counterclaimed that the ’944 patent was invalid and moved for SJ of invalidity. Apotex argued that an earlier SmithKline patent, U.S. Patent No. 4,721,723 (“the ’723 patent”), anticipated the ’944 patent. The ’723 patent disclosed tablets containing a crystalline form of paroxetine, paroxetine hydrochloride hemihydrate.

The district court held that it was bound to follow the Federal Circuit’s decision in *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991), which required the district court to evaluate the validity of the ’944 patent claims

without reference to any process limitations in the product-by-process claims. Because the ’723 patent disclosed tablets containing paroxetine, the district court held that the product disclosed in the ’723 patent anticipated the product-by-process claims of the ’944 patent. In so holding, the district court did not consider any differences in the products because any such differences were caused by the process limitations, which the court held it could not consider.

On appeal, SmithKline argued that if the district court had treated the process steps recited in claims of the ’944 patent as claim limitations, the district court would have held that the ’723 patent did not anticipate the ’944 patent, or that there was a genuine issue of fact over whether the ’723 patent disclosed those process limitations. The Federal Circuit rejected SmithKline’s arguments, holding that “once a product is fully disclosed in the art, future claims to that same product are precluded, even if that product is claimed as made by a new process.” Slip op. at 5.

The Federal Circuit noted a potential conflict between *Scripps*, where the court construed product-by-process claims without reference to process steps, and *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992), where the court read process steps in a product-by-process claim as claim limitations. Although the Federal Circuit declined to directly address the conflict between the two cases, it nevertheless stated that a product-by-process claim is “always to a product, not a process.” The Court stated that while the process set forth in a product-by-process claim may be new, that novelty can only be captured by obtaining a process claim. Accordingly, the Federal Circuit affirmed the district court’s finding of anticipation.

The Federal Circuit also held that SmithKline waived any argument regarding the differences between the products claimed in the '723 patent and the '944 patent by not including the argument in its opening brief.

Judge Newman dissented, arguing that Federal Circuit precedent requires that all claim limitations limit a claim, and therefore, process limitations cannot be ignored. In Judge Newman's view, process limitations may distinguish an invention as a whole from prior art. Accordingly, a mere product disclosure could not anticipate the product-by-process claims at issue. Additionally, Judge Newman argued that the issues not briefed in SmithKline's appeal should not be deemed waived, because the appeal related solely to the question mentioned in the SJ, i.e., whether the process limitations in the product-by-process claims should be read as limiting the claim. She added that "when the appellant sticks to the issues on appeal he risks a waiver of the non-issues; and when he argues non-issues he risks a scolding."

Lack of Explanation for Nondisclosure of Prior Art Device Does Not Establish Intent to Deceive

Jennifer H. Roscetti

Judges: Lourie (author), Rader, Bryson

In *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co.*, Nos. 05-1224, -1228 (Fed. Cir. Feb. 27, 2006), the Federal Circuit reversed the district court's grant of SJ of inequitable conduct and vacated related findings that were premised on the erroneous inequitable conduct determination.

Fisher Tooling Company, Inc., doing business as Astro Pneumatic Tool Company ("Astro"), owns U.S. Patent No. 5,259,914 ("the '914 patent"), which is directed to a combination of a pneumatic driver with an eraser wheel to remove decals from a motor vehicle. Irving Fisher, Astro's founder and former president, filed the '914 patent application and submitted a declaration stating that at the time of the filing, he was unaware of any relevant prior art and had not performed a novelty search. Six months later, Irving Fisher died and Stephen Fisher took over the prosecution. Subsequently, the examiner issued an Office Action specifically stating that claims 1-3 were allowable "because none of the art of record shows all of the detailed internal workings of the instant claims."

Astro sent letters alleging infringement of the '914 patent to M. Eagles Tool Warehouse, Inc., doing business as S&G Tool Aid Corporation ("S&G"), and to its distributors and suppliers. S&G responded by filing suit in the District of New Jersey seeking, among other things, a judgment that it did not infringe the '914 patent.

Later, the district court denied S&G's motion for SJ of invalidity but granted its motion for unenforceability due to inequitable conduct during prosecution of the '914 patent before the PTO. The district court found the Model 220, a model die grinder that Astro had been selling for twenty years, was material prior art that Astro did not submit to the PTO. The district court used Astro's nondisclosure of the Model 220 and lack of a good-faith explanation for its omission to infer that Astro intended to deceive the PTO. According to the district court, Astro must have known of the Model 220's relevance when Astro was given notice by the examiner's statement that he could not find some of the limitations in the prior art, given that the Model 220 contained a

number of these very limitations. The district court also granted SJ in favor of S&G on claims of Lanham Act violations, state unfair competition, and tortious interference, and awarded attorney fees and damages.

On appeal, Astro argued that the district court improperly found an intent to deceive solely from the fact that Astro failed to disclose the Model 220 to the PTO, without relying on any evidence that the applicant or attorney deliberately withheld information concerning the Model 220. The Federal Circuit agreed, concluding that “a failure to disclose a prior art device to the PTO, where the only evidence of intent is a lack of a good faith explanation for the nondisclosure, cannot constitute clear and convincing evidence sufficient to support a determination of culpable intent.” Slip op. at 11-12.

S&G, however, argued that there was additional evidence for inferring intent to deceive. Specifically, S&G pointed to the district court’s finding that Astro was aware of the relevancy of the Model 220 due to the examiner’s statement concerning allowance of the claims being based on his inability to find all of the limitations in the prior art. The Federal Circuit disagreed, noting that important differences between the Model 220 and claim 1 of the ’914 patent could lead a reasonable fact-finder to conclude that Astro would not have appreciated the relevance of the Model 220 from the examiner’s statement alone. Accordingly, the Court reversed the district court’s grant of SJ of inequitable conduct due to a lack of sufficient evidence to infer an intent to deceive the PTO. Further, the Federal Circuit vacated the holdings on the Lanham Act, state law unfair competition, tortious interference, and award of attorney fees because they were based on the erroneous inequitable conduct determination.

Circumstantial Evidence Sufficiently Establishes First Sale Defense

Jeffrey C. Totten

Judges: Newman, Lourie (author), Schall

In *Jazz Photo Corp. v. Fuji Photo Film Co.*, Nos. 05-1096, -1109, -1175 (Fed. Cir. Feb. 28, 2006), the Federal Circuit affirmed the decision of the Court of International Trade (“CIT”) ordering the United States Bureau of Customs and Border Protection (“Customs”) to allow certain lens-fitted film packages (“LFFPs”) into the United States. The Federal Circuit found that the CIT did not err by finding that the affirmative defense of first sale and permissible repair applied to the subject LFFPs, by denying Fuji Photo Film Company, Ltd. (“Fuji”) leave to intervene and not joining Fuji as a necessary party, and by denying Fuji’s request for attendance at trial and access to the trial record.

“[T]here is no requirement that Jazz establish the defense of first sale to a certainty or that Jazz submit all commercially available evidence as to first sale to meet its burden. Because the trial court permissibly weighed the evidence . . . , there is no error in the court’s conclusion that Jazz met its burden of proof.” Slip op. at 13.

Customs excluded two shipments of LFFPs—commonly known as “single-use” or “disposable” cameras—that Jazz Photo Corporation (“Jazz”) attempted to import into the United States. The shipments consisted entirely of “reloaded” cameras that were initially manufactured by Fuji or one of its

licensees and used by consumers. Following film processing, the LFFPs were collected, processed by Polytech Enterprise Limited (“Polytech”) in China, and imported by Jazz for resale. Customs concluded that Jazz failed to prove that the LFFPs in the two shipments were beyond the scope of an existing exclusion order and denied entry, causing Jazz to file suit in the CIT under 28 U.S.C. § 1581(a).

Following a bench trial, the CIT ruled that Jazz had carried its burden of proving that a certain subset of the LFFPs were first sold in the United States and later repaired. In reaching this conclusion, the CIT relied on oral testimony regarding the collection and refurbishment of the spent LFFPs. Applying the “presumption of regularity,” the CIT concluded that, as Customs would have excluded any unlawfully imported LFFPs before their first sale, the LFFPs collected in the United States must have been sold by Fuji or one of its licensees and thus licensed under Fuji’s patents. The government and Fuji appealed.

The Federal Circuit did not find clear error in the decision. While Jazz did not provide direct evidence that each LFFP was first sold in the United States under license to Fuji, it offered circumstantial evidence to that end. The trial court heard testimony regarding the market for new LFFPs in the United States and the collection of the LFFPs at issue. The Federal Circuit noted that nothing required Jazz to prove its case by direct evidence and refused to find clear error in the CIT’s decision on the circumstantial evidence of record.

Turning to the “presumption of regularity,” the Federal Circuit found no error in the trial court’s limited application of the presumption.

At trial, Jazz proffered evidence that at least 85% of the reloaded LFFPs were purchased in the United States at the same location as where film processing occurred. Thus, the presumption applied only to the remaining minority of the LFFPs. As the government offered no evidence to counter the presumption, the trial court did not err in applying the presumption to this small group of LFFPs.

The Federal Circuit also did not find clear error in the trial court’s finding permissible repair, rather than impermissible reconstruction, without discussing “various minor operations” performed on the LFFPs. The Court discerned no error in the trial court’s conclusion that these minor operations were “incidental” to the repair of the LFFPs and thus did not result in reconstruction.

The Court also rejected Fuji’s argument that the trial court had erred in denying Fuji leave to intervene. The Court noted that the plain language of 28 U.S.C. § 2631 prohibits third-party intervention, and the Federal Circuit concluded that Fuji’s status as a patent owner did not give rise to an exception. Moreover, Fuji’s interest in protecting its patent rights did not make it a necessary party, as Congress chose to charge the government with the protection of a patentee’s rights under the Tariff Act of 1930.

Finally, the Federal Circuit noted that the trial court did not err by issuing a protective order sealing the proceeding and documents, thereby denying Fuji the ability to attend the entire trial and access the trial record. The documents included Jazz’s confidential information, which the court properly protected.

Abbreviated Forms | Acronyms

In *Last Month at the Federal Circuit*, certain terms, titles, and names that are frequently used are abbreviated as listed below.

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

Looking Ahead

- On February 21, 2006, the Supreme Court granted the petition for writ of certiorari in *MedImmune, Inc. v. Genentech, Inc.*, No. 05-608. In *MedImmune, Inc. v. Genentech, Inc.*, 427 F.3d 958 (Fed. Cir. 2005), the Federal Circuit affirmed the district court's decision that a licensee who continues to comply with the terms of a license, leaving no possibility for infringement or cancellation of the license by licensor, does not have standing to bring a DJ action challenging the validity of the licensed patent. The Federal Circuit stated that "there is no controversy of immediacy or reality because there is no reasonable apprehension of suit." *Id.* at 964-65. The Supreme Court will consider whether licensees in good standing may challenge the validity of the licensed patents. The Court is expected to hear the case in the fall of 2006.

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Last Month at the Federal Circuit



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