Last Month at the Federal Circuit

September 2006

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Spotlight Info

- The Federal Circuit decided two cases this month, finding state universities to be immune from patent infringement suits under the Eleventh Amendment to the Constitution. See the summaries in this issue for *Pennington Seed, Inc. v. Produce Exchange No. 299* and *Tegic Communications Corp. v. Board of Regents of the University of Texas System*.
- The Federal Circuit found one of two Lipitor® patents to be invalid this month based on the requirement in 35 U.S.C. § 112, ¶ 4, that a dependent claim must include at least one limitation not found in the claim from which it depends. See the summary of *Pfizer Inc. v. Ranbaxy Laboratories Ltd.* below.
- *Amgen, Inc. v. Hoechst Marion Roussel, Inc.* returned to the Federal Circuit for the second time. The Court reversed-in-part and remanded, disagreeing with the district court's interpretation of the meaning of a "therapeutically effective amount" of the genetically engineered hormone erythropoietin.

Patent Held Invalid for Improper Claim Dependency Under 35 U.S.C. § 112

Joyce Craig-Rient

Judges: Michel (author), Schall, Dyk

[Appealed from D. Del., Judge Farnan]

In *Pfizer, Inc. v. Ranbaxy Laboratories Ltd.*, No. 06-1179 (Fed. Cir. Aug. 2, 2006), the Federal Circuit affirmed a district court's finding of infringement of U.S. Patent No. 4,681,893 ("the '893 patent") and ruling that the '893 patent term extension was not invalid. The Federal Circuit reversed on the question of invalidity of U.S. Patent No. 5,273,995 ("the '995 patent") pursuant to 35 U.S.C. § 112, ¶ 4. In doing so, the Court reiterated that the fourth paragraph of § 112 is an invalidating provision.

Stereochemistry is the study of the three-dimensional structure of molecules. Stereoisomers have the same molecular formula or atomic composition, but different spatial arrangements. Enantiomers are a pair of stereoisomers that are nonsuperimposable mirror images of each other and often have distinct physical properties. A racemate (or racemic mixture) is an equal mixture of two enantiomers.

The two patents-in-suit concern the active ingredient in the prescription drug Lipitor®, which is used to reduce low-density lipoprotein (LDL) cholesterol levels. The active ingredient in Lipitor® is atorvastatin calcium. Claim 1 of the '893 patent recites a compound of structural formula I, drawn as having a particular configuration. The '995 patent covers the compound atorvastatin calcium. The '893 patent was to expire on May 20, 2006, but the PTO granted an extension pursuant to 35 U.S.C. § 156, extending the expiration date to September 24, 2009. The '995 patent expires on December 28, 2010. After a bench trial, the U.S. District Court for the District of Delaware found both patents infringed, not invalid, and not unenforceable.

On appeal, the parties agreed that, under the district court's claim construction, Ranbaxy Laboratories Ltd.'s ("Ranbaxy") ANDA product infringes claim 1 of the '893 patent. Ranbaxy argued that the district court erred in construing structural formula I recited in claim 1 to embrace all trans-form isomers instead of limiting it to racemates. The Federal Circuit disagreed, noting that the '893 patent consistently describes the invention as a class of "trans" compounds. Moreover, the Court concluded that there was no disavowal of claim scope in the specification that would limit the '893 patent to racemates. The Court especially noted that the terms "racemate" or "racemic mixture" do not appear in the '893 patent; nor is claim 1, unlike claim 5, limited by "trans-(±)," which designates a racemate. Moreover, the Court agreed with the district court's conclusion that the statements made during prosecution of foreign counterparts to the '893 patent were irrelevant to claim construction because they were made in response to patentability requirements unique to Danish and European law. Likewise, the Court held that statements made during prosecution of the later, unrelated '995 patent could not be used to interpret claims of the '893 patent. Having concluded that claim 1 was correctly construed, the Court affirmed the finding of infringement.

The Court also affirmed the district court's conclusion that the patent term extension was valid. Ranbaxy argued that because the '893 patent does not cover the active ingredient in Lipitor®, it was not eligible for a patent term extension. Based on its construction of claim 1, however, the Court found that the '893 patent

did cover the active ingredient in Lipitor® and, thus, was eligible for a patent term extension under 35 U.S.C. § 156. Further, the Court concluded that the district court's factual findings that there was no inequitable conduct were not clearly erroneous.

> "Although the district court was reluctant to find the fourth paragraph of § 112 to be an invalidating provision, doing so does not exalt form over substance. Rather, it is consistent with the overall statutory scheme that requires applicants to satisfy certain requirements before obtaining a patent, some of which are more procedural or technical than others." Slip op. at 13.

With regard to the '995 patent, Pfizer, Inc. ("Pfizer") asserted only dependent claim 6 against Ranbaxy's ANDA product. The claim reads: "The hemicalcium salt of the compound of claim 2." Claim 2 depends on claim 1, which recites atorvastatin acid, atorvastatin lactone, or pharmaceutically acceptable salts thereof. Claim 2, however, recites only atorvastatin acid; it does not include the pharmaceutically acceptable salts of atorvastatin acid.

The Court noted that, pursuant to 35 U.S.C. § 112, ¶ 4, "a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed." Ranbaxy argued that claim 6 fails to "specify a further limitation of the subject matter" of claim 2 because it is completely outside the scope of claim 2. The district court recognized the drafting problem in claim 6, but did not render the patent invalid under § 112, ¶ 4, because the court was unaware of any Federal Circuit precedent invalidating a patent under this paragraph.

The Federal Circuit reversed, noting that "[i]nvalidity of the patent or any claim in suit for failure to comply with *any* requirement of sections 112 or 251" is expressly included in the list of defenses to a claim of patent infringement provided for by 35 U.S.C. § 282(3). Further, the Court concluded that finding the fourth paragraph of § 112 to be invalidating is consistent with the overall statutory scheme requiring applicants to satisfy certain requirements before obtaining a patent.

Accordingly, the Court remanded the case to the district court for modification of the permanent injunction.

"Therapeutically Effective Amount" Need Not Heal or Cure

Lisa M. Matovcik

Judges: Michel (dissenting-in-part), Clevenger, Schall (author)

[Appealed from D. Mass., Judge Young]

In *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, No. 05-1157 (Fed. Cir. Aug. 3, 2006), the Federal Circuit ruled that Amgen, Inc.'s ("Amgen") claim term "therapeutically effective amount" is not limited to an amount that effectively heals or cures disease. The Federal Circuit vacated the district court's judgment of invalidity and remanded the case for a determination of whether a cited reference anticipated the claim. The Federal Circuit also reversed the district court's judgment that the defendant's accused product infringed under the DOE. Finally, it affirmed the district court's judgment that Amgen's method claims were not invalid and were literally infringed.

Amgen is the owner of U.S. Patent Nos. 5,618,698 ("the '698 patent"), 5,621,080 ("the '080 patent"), 5,756,349 ("the '349 patent"), and 5,955,422 ("the '422 patent"), all directed to a recombinant human erythropoietin, which is an engineered version of a naturally produced protein that stimulates red blood cell production and can be used to treat red blood cell disorders. Hoechst Marion Roussel, Inc. (now Aventis Pharmaceuticals, Inc.) ("HMR") and Transkaryotic Therapies, Inc. ("TKT") (collectively "HMR/TKT") collaborated to develop the recombinant erythropoietin HMR4396.

In 1997, Amgen filed suit for DJ in district court. The resulting proceedings included a *Markman* hearing, bench trial, Federal Circuit appeal, second *Markman* hearing, and second bench trial. In the second bench trial, the district court construed a "therapeutically effective amount" of erythropoietin as an amount that not only increased the percentage of blood occupied by red cells (hematocrit) but also healed or cured disease in the class of patients listed in the specification. According to the district court's construction, Amgen's claim to a composition comprising a therapeutically effective amount of human erythropoietin was not anticipated by a prior art reference describing the use of naturally produced erythropoietin in an amount too low to heal or cure a patient. The district court also found that HMR/TKT's HMR4396 comprising 165 amino acids infringed Amgen's claims to a 166 amino acid erythropoietin under the DOE. Finally, the district court ruled that Amgen's claims to a method of making recombinant erythropoietin were not invalid and were literally infringed.

On appeal, the Federal Circuit rejected the district court's narrow claim construction of "therapeutically effective amount," instead construing it to mean an amount that elicits *any* biological effect listed in the specification. It cited a statement in the specification that erythropoietin could lack *in vivo* activity and still possess therapeutic utility as evidence that the patentee did not intend the word "therapy" to limit the scope of its claim to an erythropoietin compound capable of curing a disease. Rather, the words "therapeutically effective" broadly claim a composition with a wide range of biological effects. According to the specification, Amgen's recombinant erythropoietin possessed all the properties attributed to the body's natural erythropoietin. Thus, a therapeutically effective amount of recombinant erythopoietin is an amount sufficient to elicit any of the listed effects of natural erythropoietin, including, but not limited to, the power to cure. Nor is it limited to require any one particular biological effect, such as an increase in hemoglobin. Accordingly, the district court was ordered to use this revised claim construction on remand. It was also ordered to evaluate a prior art reference report of naturally produced erythropoietin eliciting certain biological effects but failing to increase the hematocrits or heal the recipient patients, to determine whether it anticipated claim 1 of the '422 patent under the new claim construction.

"Based on a reading of the claims in light of the specification, it appears that the patentee used the words 'therapeutically effective' in order to broadly claim a pharmaceutical composition with a wide range of effects. Those effects do not *necessarily* include curing disease in humans." Slip op. at 16 (emphasis in original).

The Federal Circuit next reversed the district court's holding that Amgen infringed the '080 patent under the DOE, concluding that prosecution history estoppel prevented Amgen from asserting that its claims to an erythropoietin having 166 amino acids encompassed an erythropoietin of 165 amino acids. Amgen amended claims broadly encompassing an isolated human erythropoietin to read only on an erythropoietin having 166 amino acids. The Federal Circuit did not consider the requirement for 166 amino acids to be tangential to a 165 amino acid equivalent. Rather, it considered the amendment vital to avoiding a double patenting rejection. Amgen's argument that the sole reason for the amendment was to limit the claim to human erythropoietin was rejected because the amendment discontinued using the term "human" in favor of making reference to a particular sequence of 166 amino acids.

Lastly, the Federal Circuit affirmed the holding of the district court that Amgen's method claims to producing erythropoietin were not invalidated by a prior art reference because the reference was not enabled. The reference disclosed a method of making erythropoietin by fusing human erythropoietin-producing cells with a human cell line. Basing its conclusion on the testimony of several scientists experienced in the field, the court found that the reference did not disclose the cells necessary to perform the method, teach the selection of the fusion products, nor teach the purification of erythropoietin from the fused cells.

Judge Michel wrote in dissent that Amgen's claim to a "therapeutically effective amount" of erythropoietin should not be invalidated by a reference to a prior art compound capable of eliciting biological activity but incapable of healing or curing. Reasoning that merely eliciting a biological effect is not the same as demonstrating therapeutic effectiveness, he complemented the district court's reasoning that a "therapeutically effective amount" means a quantity that produces a result that in and of itself helps to heal or cure. He also cited the convention in the pharmaceutical arts to use the term to mean that a compound is useful in treating disease. He contended that the part of the specification cited by the majority for the proposition that a product can be therapeutically useful without having *in vivo* activity referred only to erythropoietin analogs, not to the claimed erythropoietin.

Use of Falsified Information in Financial Statements by Damages Expert Does Not Entitle Defendant to Relief from Judgment

Cortney S. Alexander

Judges: Linn, Dyk (author), Prost

[Appealed from E.D. Mich., Judge Cohn]

In *Venture Industries Corp. v. Autoliv ASP, Inc.*, No. 05-1537 (Fed. Cir. Aug. 7, 2006), the Federal Circuit affirmed-in-part and vacated-in-part the district court's denial of Autoliv ASP, Inc.'s ("Autoliv") motion for new trial under Fed. R. Civ. P. 60(b)(2) and (3).

In 1995, Venture Industries Corporation ("Venture") and Autoliv settled a patent dispute. As part of the settlement, they executed a supply agreement under which Autoliv was obligated to purchase airbag covers from Venture so long as Venture's bids were "reasonably competitive" with the bids of other suppliers. In 1999,

Venture sued Autoliv for breach of the supply agreement, alleging that Autoliv did not allow Venture to bid on certain projects or rejected its reasonably competitive bids. Venture also made several patent law claims in its complaint.

During discovery, Autoliv requested financial information from Venture, including internal and external financial statements and depositions of various representatives. Venture objected to these requests, and Autoliv filed several motions to compel. Ultimately, the district court ordered production of Venture's monthly, quarterly, and annual financial statements, but the SM and district court denied the remaining requests. Autoliv did not challenge or seek reconsideration of these rulings, nor did it submit further requests for the information or alert the district court to any further problems with discovery of Venture's financial information.

Trial on Venture's action for breach of the supply agreement began in November 2003, during which Venture's expert, Aron Levko, offered testimony on damages. Levko relied on financial information from a manufacturing facility in Grand Blanc, Michigan, operated by a Venture subsidiary ("the Grand Blanc facility"), which would have produced the airbag covers had Autoliv awarded Venture the projects at issue. In his damages calculation, Levko also relied on actual bids, third-party bids, and two independent studies previously commissioned by Venture. In December 2003, the trial concluded with the jury's return of a verdict finding that Autoliv breached the supply agreement and award of $27,576,001 in damages to Venture. A month later, the district court entered final judgment against Autoliv in the amount of the jury's verdict.

During discovery, Venture filed for reorganization under the Bankruptcy Code, and a forensic accounting firm, Doeren Mayhew & Company, P.C. ("Doeren"), was appointed by the bankruptcy court to investigate Venture's finances. After entry of final judgment in the breach of supply agreement litigation, Doeren issued a pair of reports stating that its preliminary investigation called into question representations in Venture's firm-wide financial statements and plant-wide statements from Grand Blanc, including accounting irregularities. The books and records of the Grand Blanc facility were among the materials used by Venture's expert in calculating damages. In April 2004, Venture filed a SEC form disclosing that its financial information previously publicly reported dating back at least to 1998 was unreliable.

Neither party immediately called Doeren's reports to the district court's attention. Several months after the Court entered judgment, however, Autoliv filed a motion for new trial pursuant to Fed. R. Civ. P. 60(b) based on the Doeren reports. The district court conducted an evidentiary hearing on Autoliv's motion, at which Levko testified that Doeren's conclusions had no effect on his trial testimony. The district court denied Autoliv's motion under Rule 60(b)(2), concluding that Autoliv failed to prove that the newly discovered financial information would have had an effect on the jury's damages award. The district court also denied the motion with regard to Rule 60(b)(3), holding that Venture did not commit discovery misconduct by failing to produce financial information that Autoliv contended would have disclosed the misrepresentations later found by Doeren. Because Autoliv never challenged the discovery rulings regarding this information or make additional requests, the district court concluded there was no discovery misconduct. The district court did not address Autoliv's argument that Levko's testimony entitled it to a new trial under Rule 60(b)(3).

On appeal, the Federal Circuit first addressed the timeliness of Autoliv's motion. The Court explained that the rule provides that a Rule 60(b) motion "shall be made within a reasonable time," not more than one year after judgment. Applying Sixth Circuit law, the Court observed that Venture made no colorable claim that it was prejudiced by Autoliv's nine-month delay in filing its motion. Therefore, the Court dismissed Autoliv's untimeliness argument.

Turning to the merits of Autoliv's motion under Rule 60(b)(2), the Federal Circuit affirmed the district court's denial. The Court found no error in the district court's finding that Levko's opinion was grounded in data that antedated December 2001, and there is no evidence that accounting irregularities at Grand Blanc affected such data. The Court also found no error in the district court's conclusion that any changes in the financial statements that Levko did rely on did not affect his opinions. The Court also noted that the district court properly reviewed the factual record in the light of the newly discovered evidence and made findings as to the weight of that evidence to determine the likely effect on the jury, which was that the jury's decision would not be altered.

With regard to Autoliv's motion under Rule 60(b)(3) alleging discovery misconduct, the Federal Circuit affirmed the district court's ruling that Autoliv was not entitled to a new trial based on Venture's failure to produce the corrected financial statements. The Court observed that Autoliv did not allege that Venture had not complied with the discovery requests as limited by the magistrate judge, and that Autoliv had ample opportunity to seek relief if it felt that its discovery requests were not being met. Thus, the district court did not abuse its discretion in holding that Venture had not committed discovery misconduct.

Finally, the Federal Circuit addressed Autoliv's claim under Rule 60(b)(3) that Levko's testimony, which was based on the incorrect financial statements, was fraud, misrepresentation, or misconduct entitling it to a new trial. The Court noted that, while the district court did not expressly address this argument, it did hold that Autoliv failed to establish that it was prejudiced according to the Rule 60(b)(2) standard. Thus, the Court deduced that even if Autoliv could establish that Levko's testimony was fraud, misrepresentation, or misconduct, it would not be entitled to a new trial unless the prejudice required under Rule 60(b)(3) is different than that of Rule 60(b)(2). The Court observed that while in some circuits the standard for prejudice under Rule 60(b)(3) is similar to the Rule 60(b)(2) standard, requiring the movant to show that fraud or misconduct prevented the movant from fully presenting its case, the Sixth Circuit differs. In the Sixth Circuit, prejudice is presumed if fraud, misconduct, or misrepresentation is shown, at which point the burden shifts to the nonmoving party to show by clear and convincing evidence that the misbehavior had no prejudicial effect. Accordingly, the Court remanded the case for the district court to determine whether fraud, misrepresentation, or misconduct occurred and, if so, whether Venture had shown by clear and convincing evidence that no prejudice occurred.

State's Patent Infringement Is Not Actionable in Federal Court Even When No State Forum Is Available for Suit, Provided Other State Remedies Are Available

Christopher T. Blackford

Judges: Rader, Schall (concurring), Gajarsa (author)

[Appealed from W.D. Mo., Judge Wright]

In *Pennington Seed, Inc. v. Produce Exchange No. 299*, No. 05-1440 (Fed. Cir. Aug. 9, 2006), the Federal Circuit affirmed the district court's dismissal of the Original Complaint filed against the University of Arkansas ("the University") and the First Amended Complaint filed against four University officials due to Eleventh Amendment immunity and lack of personal jurisdiction.

U.S. Patent No. 6,111,170 ("the '170 patent"), the patent-in-suit, which issued to AgResearch Limited and is licensed to Pennington Seed, Inc. (collectively "Pennington"), is directed to a type of nontoxic fescue grass that does not adversely affect livestock that grazes upon it. In its Original Complaint, Pennington sued the University for infringement and conversion of the '170 patent. The district court dismissed the Original Complaint for failure to state a claim upon which relief can be granted because the Eleventh Amendment bars the action against the University in federal court. However, the district court granted Pennington's motion to file the First Amended Complaint, in which Pennington sued four University officials for infringement of the '170 patent, deprivation of federal rights, and conversion. The district court subsequently dismissed the First Amended Complaint based on Eleventh Amendment immunity again and for lack of personal jurisdiction.

> "Allegations that a state official directs a University's patent policy are insufficient to causally connect that state official to a violation of federal patent law—i.e., patent infringement." Slip op. at 11.

First, the Federal Circuit affirmed the district court's finding that Pennington's claims were barred by the Eleventh Amendment because, although the district court found that no state forum exists in Arkansas in which to contest patent infringement, the district court did not find that other available state remedies were so insufficient that they violated the Fourteenth Amendment. The Court explained that the Eleventh Amendment prevents citizens from bringing suit against a state in federal court without the state's consent, and in the case of infringement by a state, the claim may be actionable in federal courts only where the state provides no remedy or only inadequate remedies to the patent owner. While Pennington alleged that the Arkansas Claims Commission is the only available forum and it could not issue injunctions, conduct discovery, or issue a monetary award over $10,000, the Court held that Pennington failed to allege how such procedures were so inadequate as to abrogate state sovereign immunity. Moreover, the Court reiterated that only Congress can abrogate Eleventh Amendment sovereign immunity for patent infringement if there is a showing that state remedies are insufficient and violate due process, and Pennington failed to allege or explain how Congress made the specific finding in this case.

Furthermore, the Court recognized that other remedies are available in Arkansas, including legislative consideration of claims and monetary awards greater

than $10,000, and a potential state judicial remedy for conversion, which although they may be uncertain or less convenient, or may undermine the uniformity of patent law, are insufficient to show that the patentee's due process rights have been violated.

Turning to Pennington's allegations against the University officials, the Federal Circuit acknowledged that under the *Ex parte Young* doctrine, the continuing prospective violations of a federal patent right by state officials may be enjoined by a federal court. However, the Court noted that this procedure cannot be applied to an action against any random state official and that there must be a connection between the state officer and the enforcement of the act. Specifically, the Court stated that the doctrine requires an actual violation of federal law by the state official.

In this case, the Federal Circuit affirmed the district court's finding that Pennington failed to allege any causal connection between the University officials and the alleged patent infringement. Instead, Pennington alleged that the University officials were liable because they supervised intellectual property activity and, therefore, had the ability to stop an ongoing violation of federal law. According to the district court and the Federal Circuit, these allegations were insufficient to causally connect the officials to a violation of federal patent law. Distinguishing this case from one where a state official's refusal to perform a duty is itself a violation of federal law, the Federal Circuit interpreted Pennington's allegations as improperly seeking the court to enjoin the University officials from neglecting their job duties under state law.

Additionally, regardless of the *Ex parte Young* claims, the Federal Circuit affirmed the district court's dismissal of Pennington's First Amended Complaint for lack of personal jurisdiction in Missouri over the University officials. Although Pennington only needed to make a prima facie case of personal jurisdiction in the absence of an evidentiary hearing on the issue, the Court found no allegation that the University officials had minimum contacts with the State of Missouri. In particular, the Court emphasized that the only place the word "Missouri" was used in the First Amended Complaint was in conjunction with the organization of a corporation no longer a party to the action, and the First Amended Complaint alleged residence in Arkansas, not Missouri.

In his concurrence, Judge Schall explained that he was in full agreement with the Court's opinion regarding the University's Eleventh Amendment immunity from suit and the lack of jurisdiction over the four University officials, but he was of the opinion that the Court should not have reached the question of whether the *Ex parte Young* doctrine applies to the University officials.

Failure to Object to Jury Instructions Resulted in a Deferential Standard of Review for Claim Construction

Aaron J. Capron

Judges: Lourie, Rader (author), Linn

[Appealed from D. Md., Judge Quarles]

In *Serio-US Industries, Inc. v. Plastic Recovery Technologies Corp.*, Nos. 05-1106, -1143, -1306 (Fed. Cir. Aug. 10, 2006), the Federal Circuit affirmed a district court's entry of judgment of noninfringement following a jury trial. In doing so, the Federal Circuit upheld the district court's claim construction and affirmed the dismissal of Plastic Recovery Technologies Corporation's ("PRT") counterclaims.

Serio-US Industries, Inc. ("Serio-US") filed suit against PRT alleging that PRT's dumpster lock infringed certain claims of U.S. Patent Nos. 5,094,358 ("the '358 patent") and 5,662,364 ("the '364 patent"). The '358 and '364 patents are directed to a gravity-actuated dumpster lock that prevents a dumpster from opening until inverted for emptying. A jury rendered a verdict of noninfringement on both patents.

On appeal, Serio-US argued that the district court's jury instructions contained claim construction errors. The Federal Circuit noted that even though Serio-US submitted proposed jury instructions on the second day of trial, the record did not show that Serio-US objected to the district court's jury instructions, as required by Fed. R. Civ. P. 51(c). Thus, the Court held that Serio-US could only appeal "plain error" under Rule 51(d), which in the Fourth Circuit requires a showing of a "miscarriage of justice."

The Court perceived no miscarriage of justice in the trial court's jury instruction. In particular, the district court held that the claim limitation "front side" meant "a location on a front side surface of a dumpster," whereas Serio-US argued that it meant a portion of the container "toward the front." The Federal Circuit held that the district court's interpretation was supported by the claim language and the specification, and thus did not amount to a miscarriage of justice. Further, the Federal Circuit denied Serio-US's request to remand the case for a new trial on the issue of infringement because Serio-US did not file either a motion for JMOL or a new trial and because there was no prejudicial legal error in the trial court's claim construction. Finally, the Federal Circuit held that the district court did not abuse its discretion in

relying on expert testimony to arrive at its claim construction because it was not at odds with the intrinsic evidence.

Regarding PRT's cross appeal, the Federal Circuit affirmed the dismissal of PRT's counterclaims because it failed to find any proof that Serio-US had filed a "bad faith" action. The Court reasoned that Serio-US relied on the opinion of patent counsel before bringing the suit and found that Serio-US believed that they had a likelihood of success based on the district court's preliminary injunction. Accordingly, the Federal Circuit affirmed the dismissal of PRT's counterclaims and the refusal to award attorney fees.

State University's Filing of a Patent Infringement Suit Did Not Waive Immunity from a Declaratory Judgment Suit on the Same Patent in a Different District

John M. Williamson

Judges: Newman (author), Archer, Gajarsa

[Appealed from W.D. Wash., Judge Lasnik]

In *Tegic Communications Corp. v. Board of Regents of the University of Texas System*, No. 05-1553 (Fed. Cir. Aug. 10, 2006), the Federal Circuit affirmed the district court's grant of patentee's motion to dismiss a DJ action on the ground that patentee, as an arm of the state of Texas, was immune from suit under the Eleventh Amendment and had not waived its immunity.

The Board of Regents of the University of Texas System ("the University") owns U.S. Patent No. 4,674,112 ("the '112 patent") directed toward an apparatus and method for "inputting text into a device keyboard, wherein the device software recognizes the text and predicts the word the user intends to type." Slip op. at 2. The University sued forty-eight cellular-telephone companies in the Western District of Texas, alleging infringement of the '112 patent ("the Texas actions"). Tegic Communications Corporation ("Tegic") sells and licenses its "T9 Text Input" software to thirty-nine of the forty-eight defendants in the Texas actions.

Tegic is not a party to the Texas actions, but contended that those actions against Tegic's customers are really directed against Tegic, as the manufacturer and licensor of the software accused of infringing the '112 patent. Tegic reacted to the Texas actions by filing a DJ suit against the University in the Western District of Washington alleging invalidity, unenforceability, and noninfringement. The district court granted the University's motion to dismiss the DJ action on the ground that, as an arm of the State of Texas, the University is immune from suit under the Eleventh Amendment. Tegic appealed.

> "Although here the University obviously 'made itself a party to the litigation to the full extent required for its complete determination,' it did not thereby voluntarily submit itself to a new action brought by a different party in a different state and a different district court." Slip op. at 11 (citation omitted).

On appeal, the Federal Circuit first noted that it was undisputed that the University is properly accorded Eleventh Amendment immunity because it is deemed to be an arm of the State of Texas. The Court stated, however, that by voluntarily invoking federal jurisdiction in Texas, the University waived any immunity it may have had regarding its claims and counterclaims in the Texas actions. But the Federal Circuit determined that this waiver did not extend to Tegic's DJ action in the Western District of Washington because the University's filing of the Texas actions did not effect a "clear waiver" as to "a new action brought by a different party in a different state and a different district court." *Id.* at 11. The Court explained that a "[s]tate's constitutional interest in immunity encompasses not merely *whether* it may be sued, but *where* it may be sued." *Id.* at 10, *quoting Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 99 (1984) (emphases in original).

The Federal Circuit rejected Tegic's argument that the "customer suit exception" requires that the Eleventh Amendment waiver effected by the Texas actions extends to Tegic's DJ action in the Western District of Washington. The Court explained that the "customer suit exception" is an exception to the rule that favors the forum of the first-filed action. Where a patentee sues a manufacturer's customers, the "customer suit exception" affords preferential treatment to a manufacturer's later-filed action seeking to resolve the patent infringement charges leveled against the manufacturer's customers.

The Federal Circuit determined that the "customer suit exception" did not effect a waiver as to Tegic in Washington because the exception is grounded on principles of efficiency and judicial economy, and that Tegic failed to show that it would be more efficient to stay the Texas actions in favor of Tegic's DJ action in Washington. In reaching this conclusion, the Court noted that the defendants in the Texas actions are not "mere resellers" of Tegic's products, that the defendants in the Texas actions have not agreed to be bound by a

decision in favor of Tegic, and that other suppliers in addition to Tegic, including Motorola and Zi Corporation, provide software used in phones accused of infringing in the Texas actions. Without deciding whether the "customer suit exception" could justify a waiver of Eleventh Amendment immunity under different facts, the Federal Circuit determined that the exception does not effect a waiver under the facts of this case.

Finally, the Federal Circuit dismissed Tegic's argument that the University's immunity afforded it an unfair litigation advantage. Tegic suggested that the defendants in the Texas actions would not have the technical information necessary for their defenses and also would not be able to assert a laches defense that was personal to Tegic. But the Federal Circuit noted that Tegic was free to assist its customers in the Texas actions and that Tegic was also free to seek to formally intervene in the Texas actions.

Patentee May Regulate Use of Subsequent Generations of Patented Self-Generating Biotechnology

Jin Zhang

Judges: Mayer (author), Bryson, Dyk (concurring-in-part and dissenting-in-part)

[Appealed from N.D. Miss., Judge Pepper]

In *Monsanto Co. v. Scruggs*, Nos. 04-1532, 05-1120, -1121 (Fed. Cir. Aug. 16, 2006), the Federal Circuit affirmed the district court's grant of Monsanto Company's ("Monsanto") motions for SJ of patent invalidity and infringement, antitrust violations, patent misuse, and common law counterclaims, and vacated the district court's grant of permanent injunction.

Monsanto owns U.S. Patent No. 5,352,605 ("the '605 patent"), which is directed to insertion of a synthetic gene consisting of a 35S cauliflower mosaic virus ("CaMV") promoter, a protein sequence of interest, and a stop signal, into plant DNA to create herbicide resistance. Monsanto also owns three other patents (collectively "the McPherson patents"), which are directed to insect-resistant traits and expanded upon the '605 patent. Monsanto used these patents to develop Roundup Ready (R) soybeans and cotton and stacked trait cotton, sold as Bollgard/Roundup Ready (R) cotton, which is resistant to glyphosate herbicide and certain insects. Monsanto licensed its technology to seed companies ("seed sellers"), allowing the licensees to incorporate the Monsanto biotechnology into their germplasm to produce Roundup Ready (R) and Bollgard/Roundup Ready (R) seeds. The licenses also restrict seed sellers from selling seed containing Monsanto's technology to growers unless the growers sign a license agreement and agree to grow only a single commercial crop.

Scruggs purchased both types of seeds but never signed a licensing agreement. Scruggs planted the purchased seeds and retained the new generation of seeds after harvesting. It planted subsequent crops with those seeds, as well as with seeds obtained from subsequent generations of crops.

> "Applying the first sale doctrine to subsequent generations of self-replicating technology would eviscerate the rights of the patent holder." Slip op. at 9.

Monsanto filed suit against Scruggs for infringement of the '605 and McPherson patents. The district court issued a preliminary injunction, prohibiting Scruggs from sale and use of seeds containing the patented biotechnology. Scruggs answered the complaint with federal and state antitrust claims and patent misuse defenses. Additionally, Scruggs asserted common law counterclaims of invasion of privacy, trespass, tortious interference with contract and/or business relations, abuse of process, conversion, nuisance, strict liability in tort, negligence, and unfair competition. Scruggs also denied infringement and sought a declaration of invalidity of the '605 and McPherson patents. Monsanto moved for SJ on infringement, the antitrust and patent misuse defenses, and the common law counterclaims. The district court granted Monsanto's motions and denied Scruggs's motion to vacate the preliminary injunction. The district court then issued a permanent injunction and a final judgment.

On appeal, the Federal Circuit affirmed the district court's grant of SJ of infringement in view of Scruggs's admission that it purchased the Roundup Ready (R) and Bollgard/Roundup Ready (R) seeds, it did not obtain a license, and it saved seeds for further use, in conjunction with Monsanto's scientific tests showing Scruggs's crops contained the patented technology. Rejecting Scruggs's argument that the Roundup Ready (R) seeds are not covered by the '605 patent, the Court explained that the specification in the '605 patent states that different strains of CaMV may be used in the invention, and Scruggs did not appeal the district court's claim construction of the '605 patent as covering "a promoter element selected from the group consisting of either a 35S cauliflower mosaic virus promoter or a 19S cauliflower mosaic promoter . . . ." Thus, the district court's finding that the '605 patent employs the

promoter from CaMV generally stands, as does the conclusion that the Roundup Ready (R) seeds are covered by the '605 patent. Furthermore, the Court concluded that Scruggs failed to present any evidence contradicting Monsanto's testing results showing infringement.

The Federal Circuit also rejected Scruggs's argument that it purchased the Monsanto seeds in an unrestricted sale and, therefore, it was entitled to use those seeds in an unencumbered manner under the doctrine of patent exhaustion. The Court concluded that the doctrine of patent exhaustion was inapplicable because there was no unrestricted sale. The use of seeds by seed growers was conditioned on obtaining a license from Monsanto. The Court further noted that the "'first sale' doctrine of exhaustion of the patent right is not implicated, as the new seeds grown from the original batch had never been sold." Slip op. at 8. "The fact that a patented technology can replicate itself does not give a purchaser the right to use replicated copies of the technology." *Id*. at 9.

The Federal Circuit also held that Scruggs did not have an implied license to use Monsanto's technology, as indicated by the circumstances of the sale. Furthermore, the seed distributors had no authority to confer a right to use Monsanto's biotechnology and, therefore, could not have conferred a license to use the seeds.

The Federal Circuit affirmed the district court's holding that the '605 and McPherson patents were not invalid for lack of written description and enablement. The district court found, and the Federal Circuit agreed, that Monsanto was not required to disclose a specific gene sequence because the patents do not claim one particular sequence. The Court explained that the written description requirement was satisfied because the '605 patent incorporates by reference deposits that are publicly available, and given the knowledge in the art, it was unnecessary to include specific gene sequences. The Court also held that the McPherson patents satisfy the written description requirement for the same reason.

The Federal Circuit held that Scruggs failed to present sufficient evidence to demonstrate that the '605 patent was invalid for lack of enablement as well. While the Court acknowledged that in some cases specific DNA sequences may be required to satisfy the enablement requirement, in this case, the specific sequences are not required because CaMV is well known and well documented. "The fact that *some* experimentation may be necessary to produce the invention does not render the '605 patent invalid for lack of enablement." *Id*. at 13 (emphasis in original).

The Federal Circuit further held that Monsanto's licensing agreements, which contained an exclusivity provision, no replant policy, and technology fee payments, were not illegal anticompetitive practices. The no replant policy is a valid exercise of patent rights by preventing purchasers of the seeds from using the patented biotechnology when that biotechnology makes a copy of itself. Likewise, Monsanto's uniform technology fee is also within the scope of the patent right. Finally, the Court explained that the no research policy is a field of use restriction within the protection of the patent laws.

The Federal Circuit also held that Scruggs did not provide sufficient evidence to prove that Monsanto's practices constituted unlawful tying of the Roundup Ready trait to the Bollgard trait. The Court explained that the grower incentive program was optional, and Monsanto's seed partners were not forced to buy Roundup under the seed partner agreements. Additionally, Monsanto sells cotton without the Bollgard trait.

The Federal Circuit also held that Scruggs did not present evidence of activity constituting patent misuse because Monsanto's activities were within the patent grant. The Court agreed with Monsanto's argument that its contract provisions lacked any anticompetitive effect because the Environmental Protection Agency's regulations prohibited growers from using competing glyphosate herbicides for over-the-top application, and therefore, even if growers elected to use such herbicides for over-the-top application, they would not be legally free to use competing brands. Because Scruggs did not show that the challenged contracts had an actual adverse effect on competition, it cannot use the challenged contract provisions as a defense against patent infringement.

With respect to the tortious interference, unfair competition, and invasion of privacy claims, the Court held that Scruggs's arguments were not adequately developed for the Court to reach the merits. Scruggs's attempts to make arguments by incorporation in its brief violated Fed. R. App. P. 28(a) and were deemed waived.

With respect to the permanent injunction, the Court vacated the district court's decision in view of *eBay Inc. v. MercExchange, L.L.C.*, 126 S. Ct. 1837 (2006), and remanded for consideration of the standard four-part test for permanent injunctions in patent cases.

Judge Dyk joined the majority opinion on the issue of unlawful tying. Judge Dyk stated that he would vacate the judgment as to the alleged tie in the 1996-1998 grower agreements, and remand for the district court to determine whether the relevant contract provision in fact constituted patent misuse and, if misuse occurred, whether it was purged.

Numerical Ranges of a Preferred Embodiment Do Not Limit Claim Language

Arthur A. Smith

Judges: Bryson, Archer, Gajarsa (author)

[Appealed from S.D. Tex., Judge Rainey]

In *Conoco, Inc. v. Energy & Environmental International, L.C.*, Nos. 05-1363, -1461 (Fed. Cir. Aug. 17, 2006), the Federal Circuit affirmed the district court's findings of infringement.

Conoco, Inc.'s ("Conoco") U.S. Patent No. 5,244,937 ("the '937 patent") claims a process for making suspension-based drag reducing agents ("DRAs"), which are high molecular weight polymers suspended within a carrier system, such as a gel. When injected into, for example, an oil pipeline, a DRA is capable of reducing friction caused by the pumping operation and, thus, is capable of improving overall efficiency. The '937 patent discloses a process of coating the polymers with a stearate partitioning agent to prevent agglomeration of the polymers, as well as replacing the gel as a carrier system with water or a water-alcohol liquid medium. Conoco's U.S. Patent No. 6,172,151 ("the '151 patent") improves the process by disclosing the use of a fatty acid wax as the partitioning agent, instead of a stearate, in a nonaqueous suspension.

> "Indeed, an inventor may use the specification to intentionally disclaim or disavow the broad scope of a claim. However, this intention must be clear, . . . and cannot draw limitations into the claim from a preferred embodiment." Slip op. at 12 (citations omitted).

Conoco sued Energy & Environmental International, L.C. ("EEI"), alleging that EEI had infringed the '937 and '151 patents. EEI stipulated to the validity and enforceability of the patents. The district court held that EEI literally infringed claim 1 of the '937 patent. The court further held that EEI infringed claims 1-3 of the '151 patent under the DOE and enjoined EEI from further activities that would infringe the patent. Subsequently, after a contempt hearing, the district court clarified its order and expanded the injunction, prohibiting EEI from manufacturing its reformulated product using polyethylene wax ("PE wax").

On appeal, the Federal Circuit held that the district court correctly construed the claim term "water-alcohol mixture" to mean "more than negligible amounts of water and alcohol." The Court noted that a disclosure of a preferred embodiment by itself is not enough to demonstrate a clear disclaimer of an ordinary meaning of a claim term. In particular, the Court concluded that the statements in the specification that the amount of alcohol in the suspending material "may vary widely" and that it "usually forms between about 0 and 70 weight percent of the suspending material" demonstrated that there was no clear intention to limit the ordinary meaning of the claim language.

Regarding the construction of the terms "consisting of" and "stable nonagglomerating suspension," the Federal Circuit held that, although EEI did not raise the construction of these terms at the district court level, the doctrine of waiver on appeal did not apply. Specifically, the Court held that "consisting of" is a term of art in patent law with its own construction. And, although EEI did waive its rights regarding the construction of the term "stable nonagglomerating suspension," because the district court explicitly construed the term *sua sponte* in its Findings of Facts and Conclusions of Law, the construction must also be reviewed.

The Federal Circuit explained that, while the term "consisting of" excludes nonrecited components and steps, it does not exclude components and steps that are unrelated to the invention or impurities that are normally found in any of the listed components. Therefore, the Court agreed with the district court's finding that any nonalcohol and nonwater components in EEI's product were impurities and the district court did not err in finding that the product met the limitations of the claim.

Further, relying on the intrinsic and extrinsic evidence, the Federal Circuit held that the district court properly construed the term "stable nonagglomerating suspension" to mean stable "at the time the DRA is introduced into the pipeline." The Court explained that the district court's construction recognized that the suspension could be assessed at the time of introduction and did not have to be transported over long distances. Moreover, the Court held that the district court did not err in its application of the facts to the construction, as there was sufficient evidence to support the finding that EEI's product was stable when injected.

The Federal Circuit also agreed with the district court's finding of infringement under the DOE, rejecting EEI's argument that Conoco was estopped from claiming a fatty acid wax equivalent in view of the prosecution history of the '151 patent. During prosecution of the application, an Examiner's Amendment was made to

add the term "fatty acid wax" to the one claim that lacked the limitation, but the record did not contain an explicit explanation for the amendment. The Court explained, however, that the absence of an explanation for the amendment is not an absolute bar and can be rebutted. The Court went on to note that throughout the prosecution history, the Examiner and Applicants focused their arguments around this limitation as if it were present in the claims. Therefore, the Court concluded the amendment was not made for reasons related to patentability, but instead made to correct an obvious omission.

Moreover, the Court noted that a clear and unmistakable surrender of subject matter must be evident for argument-based estoppel to be applied. In the prosecution of the '151 patent, Applicants argued that "fatty acid wax," a stearamide derivative, was not equivalent to another stearamide derivative, "metal stearates," as disclosed in cited prior art. The Court explained that this argument demonstrates a clear surrender of "metal stearates" as an equivalent, but does preclude Applicants from other possible fatty acid wax equivalents.

The Court also affirmed the district court's extension of the injunction to encompass PE wax, stating that the district court heard sufficient evidence to conclude that PE wax and "fatty acid wax" are functionality equivalent and, therefore, the extension of the injunction was proper.

No Infringement Under the Doctrine of Equivalents Where Claim Specifically Excluded Accused Product

Krista E. Bianco

Judges: Newman, Lourie, Prost (author)

In *Cook Biotech Inc. v. ACell, Inc.*, Nos. 05-1458, -1558, -1559 (Fed. Cir. Aug. 18, 2006), the Federal Circuit reversed the district court's claim construction and found that under the correct construction, ACell, Inc.'s ("ACell") commercial product did not infringe Purdue Research Foundation's ("PRF") U.S. Patent No. 5,554,389 ("the '389 patent"), either literally or under the DOE. The Federal Circuit also affirmed the district court's grant of SJ that Dr. Badylak was not an inventor of ACell's U.S. Patent No. 6,576,265 ("the '265 patent").

The '389 patent generally relates to tissue compositions known as extracellular matrices that can be implanted to repair or support damaged or diseased tissue. The '389 patent resulted from work Dr. Badylak and three other inventors completed while employed by Purdue University. Pursuant to his employment contract, Dr. Badylak assigned the '389 patent rights to PRF, and on February 9, 2003, PRF granted Cook Biotech Inc. ("Cook") an exclusive license.

> "A claim that specifically excludes an element cannot through a theory of equivalence be used to capture a composition that contains that expressly excluded element without violating the 'all limitations rule.'" Slip op. at 23.

After Dr. Badylak developed his urinary bladder submucosa-derived tissue graft composition, Dr. Spievack, a Harvard University professor and surgeon, also began testing techniques for removing various tissue layers of the bladder wall. When Dr. Spievack could not obtain a license from PRF, he formed ACell in 1999 to research and develop extracellular matrix technology. On December 1999, Dr. Spievack filed a provisional application relating to a matrix of urinary bladder tissues, an application which led to the issuance of the '265 patent and lists Dr. Spievack as the sole inventor. While the '265 patent was pending, PRF had asked the PTO to declare an interference, asserting four other individuals, including Dr. Badylak, were coinventors of the '265 patent, since Dr. Spievack had visited Dr. Badylak at Purdue University and discussed his work on graft compositions during the time period of 1996 through the end of 1999.

Cook and PRF then sued ACell for patent infringement of claims 1, 7, and 8 of the '389 patent, correction of inventorship for a number of issued patents, including the '265 patent, and common law unjust enrichment for the research and inventions disclosed in the disputed patents. After construing the claims, the district court granted PRF and Cook's motion for partial SJ that the only infringement issue left for the jury was whether ACell's product contains any urinary bladder submucosa. The jury found ACell infringed claims 1, 7, and 8 of the '389 patent, but that its infringement was not willful.

On appeal, the question of infringement of the '389 patent hinged on the district court's construction of the claim term "urinary bladder submucosa," as recited in claim 1. Relying on *Phillips*, the Federal Circuit found that the specification defined "urinary bladder submucosa" as "urinary bladder submucosa delaminated from abluminal muscle cell layers and at least the luminal portion of the tunica mucosa of the urinary bladder tissue." While the Federal Circuit noted the

composition may include tissues other than urinary bladder submucosa, it cannot include what was expressly excluded by the inventors in their definition, i.e., the "abluminal muscle cell layers and at least the luminal portion of the tunica mucosa."

The Federal Circuit next found that the '389 patent specification defined the claim term "the luminal portion of the tunica mucosa" as "epithelial layers." Since the term "epithelial layers" may arguably have two interpretations, the Federal Circuit chose the interpretation that was supported by a discussion of a procedure that was incorporated by reference into the '389 patent. Based on this discussion, the Federal Circuit concluded that the "the luminal portion of the tunica mucosa" should be construed to mean "the lamina epithelialis mucosa (or transitional epithelium layer), the basement membrane, and the lamina propria."

Having construed the claims, the Federal Circuit then reversed the judgment of literal infringement, holding that ACell's product did not infringe claims 1, 7, and 8 of the '389 patent. ACell's product retains part of "the luminal portion of the tunica mucosa" of a segment of a urinary bladder and therefore lacks the claim limitation that the claimed compositions be delaminated.

Alternatively, in its appeal, PRF and Cook had also requested a new trial, arguing that ACell's product infringes under the DOE since compositions that include lamina propria and submucosa are functionally equivalent to compositions that consist essentially of submucosa. Under a corollary to the "all limitations rule," the Federal Circuit held no infringement existed under the DOE since "the concept of equivalency cannot embrace a structure that is specifically excluded from the scope of the claims." Slip op. at 23. The ACell Vet product consists of basement membrane and tunica propria, two tissue layers specifically excluded from the claimed composition by delaminating "the luminal portion of the tunica mucosa."

Addressing PRF's cross appeal, the Federal Circuit affirmed the district court's grant of SJ that Dr. Badylak was not an inventor of the '265 patent, concluding that PRF failed to point to evidence sufficient to create a genuine issue of material fact that Dr. Badylak "contributed in some significant manner" to the conception of the invention claimed in the '265 patent. The Federal Circuit found that Dr. Spievack's testimony that he and Dr. Badylak had talked about "basement membrane stuff" in 1997 and 1998 was insufficient to overcome the presumption that named inventors are the actual inventors.

Statutory Scheme for Protesting Seizure Does Not Divest District Court of Jurisdiction to Consider an Injunction

Dominic P. Ciminello

Judges: Rader (author), Clevenger, Dyk

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

In *Fuji Photo Film Co. v. Benun*, No. 05-1445 (Fed. Cir. Aug. 23, 2006), the Federal Circuit affirmed the district court's imposition of a preliminary injunction enjoining the defendants from, among other things, importing certain lens fitted film packages ("LFFPs"), sometimes called "disposable" or "single use" cameras, into the United States.

In April 2005, Fuji sued Ribi Tech Products LLC and others (collectively "Ribi Tech"), alleging infringement of its patents covering aspects of LFFP technology and moved for an emergency order and a preliminary injunction. The dispute between the parties, however, dates back to 1998 at the ITC, when Fuji sought to bar the import of LFFPs that, according to Fuji, infringed one or more of its patents. As a result of the proceedings, the ITC issued a general exclusion order under which many of the LFFPs were seized.

> "28 U.S.C. § 1581(a) only provides the [ITC] exclusive jurisdiction for actions 'commenced to contest the denial of a protest.'" Slip op. at 7.

In its answer to Fuji's complaint, Ribi Tech argued that it intended to import only LFFPs "of a kind" that would not infringe Fuji's patents. In response, Fuji requested the district court to allow it to sample some of the LFFPs that Ribi Tech was trying to import. The district court granted Fuji's motions for an emergency order and preliminary injunction. In particular, the district court prohibited Ribi Tech from "transferring, removing or otherwise disposing of any LFFPs" from inventory, and enjoined Ribi Tech from "importing, manufacturing, selling, offering for sale or otherwise transferring in any manner" LFFPs that did not originate from shells of LFFPs first sold in the United States, or which were made according to a specific identified process.

The only issue on appeal was whether the district court had jurisdiction to enjoin any importation that is already the subject of the exclusion order issued by the ITC, and

the Federal Circuit affirmed the district court's decision, stating that the ITC's "final decision to issue a general exclusion order does not alter the district court's authority to proceed with remedies that may affect the same goods." Slip op. at 8.

The Federal Circuit began by noting that 28 U.S.C. § 1388(a) and 35 U.S.C. § 283 work together to supply the district court with the jurisdiction and the authority to issue an injunction. In fact, Ribi Tech did not contest that a patentee can bring actions in federal district court and the ITC, nor did Ribi Tech contest the authority of the district court to prohibit importation of infringing goods after the ITC has refused to issue a general exclusion order. Rather, Ribi Tech argued that a distinction should be made in situations, such as in this case, where the ITC has issued a general exclusion order, thereby allowing an importer to challenge the seizure of its goods. Under such circumstances, Ribi Tech argued, the district court should be prevented from considering importation issues involving those same goods.

The Federal Circuit, however, explained that nothing in the relevant statutes "even vaguely suggests" that the statutory scheme for protesting a seizure divests a district court of jurisdiction to consider an injunction on goods subject to a general exclusion order. *Id.* at 5-6. For example, while 28 U.S.C. § 1581(a) gives the ITC exclusive jurisdiction over denials of protests arising under 19 U.S.C. § 1515, the section is silent as to a district court's jurisdiction over patent infringement claims or injunctions. Likewise, as noted by the Court, although § 1515 states that a district court does not have the jurisdiction to consider a seizure protest, the statute does not mention, let alone limit, a district court's jurisdiction to enjoin importation.

Moreover, the Federal Circuit distinguished this case from Federal Circuit precedent because Fuji's complaint in the district court was not an action "commenced to contest the denial of a protest," thereby granting the ITC exclusive jurisdiction under § 1581(a). The Court noted that while such a result may open the door to duplicative litigation by the parties, such a dilemma is simply not relevant to the jurisdictional inquiry raised by the litigants. Furthermore, "[t]he parties and remedies associated with a general exclusion order differ markedly from a civil action seeking a preliminary injunction to remedy patent infringement." *Id.* at 6.

Accordingly, because the district court possessed jurisdiction under 28 U.S.C. § 1338(a), and because Ribi Tech has raised only a jurisdictional challenge, the Federal Circuit affirmed the district court's decision.

Providing Retainers in a Single Package with Instructions Did Not Render Patented System Nonobvious

Edward J. Naidich

Judges: Schall, Gajarsa, Dyk (author)

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

In *Ormco Corp. v. Align Technology, Inc.*, No. 05-1426 (Fed. Cir. Aug. 30, 2006), the Federal Circuit reversed the district court's grant of SJ that Align Technology, Inc.'s ("Align") U.S. Patent Nos. 6,554,611 ("the '611 patent") and 6,398,548 ("the '548 patent") were not invalid. The Federal Circuit held that the asserted claims of those patents would have been obvious in view of the prior art.

Ormco Corporation ("Ormco") filed suit against Align, alleging infringement of its patents, and Align counterclaimed for infringement of its own patents. Align's '611 and '548 patents are directed to a series of retainers used for aligning teeth that may be switched in and out by a patient. The district court granted SJ of noninfringement and invalidity of Ormco's patents, but held that certain claims of Align's '611 and '548 patents were infringed and not invalid.

On appeal, Ormco contended that the asserted claims of Align's '611 and '548 patents were invalid because they would have been obvious in view of Dr Truax's orthodontic practice and an instruction sheet he distributed to orthodontists. Thus, Ormco relied on "knowledge or use by others" that is corroborated by documentary evidence. First, the Federal Circuit determined that Dr. Truax's system and instruction sheet were sufficiently publicly accessible to qualify as prior art. In reaching this decision, the Court noted that it was undisputed that Dr. Truax promoted his system to other orthodontists through seminars and clinics, and distributed his instruction sheet at those clinics.

Next, the Federal Circuit held that the asserted claims of the '611 and '548 patents were obvious in view of Dr. Truax's system and regulations of the FDA, which generally require the provision of instructions with medical devices. Claim 1 of the '611 patent essentially requires (a) three or more appliances with geometries selected to progressively reposition teeth; (b) instructions regarding order of use; and (c) provision of the appliances in a single package to the patient.

Dr. Truax's orthodontic system used several clear plastic appliances of different thicknesses that fit over the patient's teeth. In the district court's view, the different thicknesses of Dr. Truax's devices did not qualify as different "geometries," as required by claim 1. The Federal Circuit disagreed, noting that the specification did not define the term "geometry" and, therefore, it was appropriate to look to dictionary definitions. Based on such definitions, the Court concluded that "geometry" means "configuration" or "shape." Because objects of different thicknesses plainly have different configurations or shapes, the Court concluded that the Truax devices satisfied the "geometries" limitation of claim 1.

The Federal Circuit also disagreed with the district court's conclusion that the "single package" limitation of claim 1 of the '611 patent merely requires that devices be "capable of" being provided to the patient in a single package. The Court concluded that in similar contexts, its cases have rejected claim constructions that would merely require that infringing devices be capable of being modified to conform to a specified claim limitation.

Align further contended that Dr. Truax never provided his patients with several appliances in a single package, and that it would not have been obvious to vary Truax in this respect. Indeed, Align contended that Truax taught away from providing all appliances at one time, because Dr. Truax taught that the treatment was more effective if the orthodontist determined when to change the appliances, rather than providing several appliances to the patient and allowing the patient to change from one appliance to the next. The Federal Circuit rejected Align's arguments, noting that there was nothing in the claim language that requires the device be substitutable by the patient. Indeed, the specification made clear that the patient may periodically visit the dentist during treatment. Thus, the Court concluded that "[p]roviding the devices to the patient in one package, as opposed to two packages or three packages is not a novel or patentable feature in the light of the well-known practice of packaging items in the manner most convenient to the purchaser." Slip op. at 16.

The Court further concluded that the instructions limitation did not render claim 1 of the '611 patent nonobvious. The Court noted that Align conceded at oral argument that the general practice of providing instructions on how to use a medical device would have been obvious. Furthermore, FDA statutes and regulations generally require instructions for medical devices. Thus, the Court found ample evidence of a motivation to provide instructions as to how to use the devices.

With respect to a dependent claim that required that at least some of the appliances be marked to indicate their order of use, the Court found that the thicknesses of Truax's devices served as markings to indicate their order of use, thus rendering the dependent claim obvious in view of Truax.

The Court next turned to Ormco's argument that claim 17 of the '548 patent would have been obvious in view of Truax. Claim 17 adds the limitation "wherein the appliances are successively replaced at an interval in the range of 2 days to 20 days." The Court first rejected the district court's conclusion that this limitation requires that the devices be "capable of" being replaced within a two- to twenty-day interval. The Court stated that "[m]ethod claims are only infringed when the claimed process is performed, not by the sale of an apparatus that is capable of infringing use." *Id.* at 19. Thus, the Court held that the claim requires that the device actually be replaced within the specified period.

The Court then noted that Dr. Truax's instruction sheet clearly indicated that the appliances are to be replaced every fourteen to twenty-one days, which substantially overlapped the claimed two- to twenty-day interval, and thus there was a presumption of obviousness. Moreover, Align did not rebut that presumption by showing that Truax teaches away from the claimed range or that the claimed range produces new and unexpected results. Thus, the Court held that the claimed range was obvious in view of Truax.

Finally, the Court rejected Align's contention that secondary considerations supported the district court's finding of nonobviousness. Although it was undisputed that Align's Invisalign product was commercially successful, the Court found that the evidence clearly rebutted the presumption that the Invisalign's success was due to the claimed and novel features. The Court found that, in large part, Align's witnesses testified that the commercial success was due to unclaimed or non-novel features of the device. Although Align's witnesses also suggested that the commercial success was due to reduction in time spent in the dentist's chair, the Court held that "to the extent that such a time savings was the result of the use of multiple appliances (rather than a single device requiring individual adjustment), that feature was not new; Truax had already accomplished this." *Id.* at 23. And to the extent that the time savings resulted from the patient's substitution of a new device without visiting the dentist, that feature was not claimed. Thus, the Court concluded that the evidence did not show that the commercial success was the result of claimed and novel features. The Court thus held that the claims at issue in the '611 and '548 patents were invalid as obvious and, therefore, reversed the district court's finding that the claims were valid.

Abbreviations | Acronyms

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 & Drug Administration
IDS	Information Disclosure Statement
IP	Intellectual Property
ITC	International Trade Commission
JMOL	Judgment as a Matter of Law
MPEP	Manual of Patent Examining Procedure
PCT	Patent Cooperation Treaty
PTO	United States Patent and Trademark Office
SEC	Securities and Exchange Commission
SJ	Summary Judgment
SM	Special Master

Looking Ahead

- On September 13, 2006, the House Judiciary Committee approved a bill to institute a judiciary pilot program in certain districts that would assign more patent cases to those judges who have expressed an interest in hearing such cases. On September 21, 2006, a counterpart bill was introduced in the Senate.

- District courts are starting to address, with conflicting results, the question of whether a patentee is still entitled to a presumption of irreparable harm after the Supreme Court's decision in *eBay, Inc. v. MercExchange, L.L.C.* It seems likely that the issue will be squarely before the Federal Circuit very soon. *See Canon Inc. v. GCC Int'l Ltd.*, No. 06 Civ. 3324(PKC), 2006 WL 2516568 (S.D.N.Y. Aug. 29, 2006) (granting injunction, but holding that patentee had to prove irreparable harm); *Sanofi-Synthelabo v. Apotex Inc.*, No. 02 Civ. 2255(SHS), 2006 WL 2516486, at *22 (S.D.N.Y. Aug. 31, 2006) (holding that patentee was entitled to a presumption of irreparable harm); *Voda v. Cordis Corp.*, No. CIV-03-1512-L, 2006 WL 2570614, at *5-6 (W.D. Okla. Sept. 5, 2006) (denying request for permanent injunction while refusing to apply a presumption of irreparable harm).

- On October 4, 2006, the Supreme Court heard oral arguments in *MedImmune, Inc. v. Genentech, Inc.*, No. 05-608. The oral arguments included argument by the Solicitor General as amicus curiae. We await the Supreme Court's decision on whether licensees in good standing may challenge the validity of the licensed patents.

- Additionally, the Supreme Court is scheduled to hear oral arguments in *KSR International Co. v. Teleflex, Inc.*, No. 04-1350, on November 28, 2006. This case addresses the test for obviousness.

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