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The Federal Circuit Upholds Eli Lilly and Company's Evista® Franchise to 2014

Eli Lilly & Co. v. Teva Pharmaceuticals USA, Inc.
Nos. 10-1005, -1033 (Fed. Cir. Sept. 1, 2010)
[Appealed from S.D. Ind., Judge Barker]

Korean Law Does Not Govern Successor Liability of Two U.S. Corporations

Funai Electric Co. v. Daewoo Electronics Corp.
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[Appealed from S.D. Cal., Judge Sabraw]

Abbreviations

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

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Spotlight Info

In *Fujitsu Ltd. v. Netgear Inc.*, No. 10-1045 (Fed. Cir. Sept. 20, 2010), the Federal Circuit declined to establish a rule precluding the use of industry standards in assessing infringement. Instead, the Federal Circuit held that if claims are construed such that the reach of the claims includes any device that practices a standard, this can be sufficient for a finding of infringement. Further, the Federal Circuit directed that, if an accused product operates in accordance with a standard, then comparing the claims to that standard is the same as comparing the claims to the accused products for the purposes of infringement analysis. But, only in the situation where the patent covers every possible implementation of a standard will it be enough to prove infringement by showing standard compliance. See the full summary in this issue.

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Looking Ahead

On October 12, 2010, the Supreme Court granted certiorari in *Global-Tech Appliances Inc. v. SEB S.A.*, No. 10-6, *opinion below*, *SEB S.A. v. Montgomery Ward & Co.*, 594 F.3d 1360 (Fed. Cir. 2010). Petitioner Global-Tech Appliances Inc. challenged the Federal Circuit ruling that inducement to infringe may be established without actual knowledge of the patent through a showing of a "deliberate indifference" to a risk that the patent exists. The particular question presented is "[w]hether the legal standard for the state of mind element of a claim for actively inducing infringement under 35 U.S.C. § 271(b) is 'deliberate indifference of a known risk' that an infringement may occur, . . . or 'purposeful, culpable expression and conduct' to encourage an infringement." The case will be briefed and argued in the coming months. A decision is expected before the end of June 2011.

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The Federal Circuit Upholds Eli Lilly and Company's Evista® Franchise to 2014

J. Derek McCorquindale

Judges: Rader (author), Linn, Prost

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

In *Eli Lilly & Co. v. Teva Pharmaceuticals USA, Inc.*, Nos. 10-1005, -1033 (Fed. Cir. Sept. 1, 2010), the Federal Circuit affirmed the district court's findings that the principal patents underlying Eli Lilly and Company's ("Lilly") blockbuster osteoporosis drug, Evista®, were valid and infringed. Specifically, U.S. Patent Nos. 6,906,086; RE39,049; RE38,968 (collectively "the Bone Loss Patents"); and RE39,050 ("the Low Dose Patent") were held nonobvious and enabled. The Court therefore affirmed the district court's permanent injunction preventing any manufacture or distribution of a generic version of Evista® until these patents expire in 2014. The Federal Circuit also affirmed the district court's ruling that certain claims of other patents directed to particle size, U.S. Patent Nos. 6,458,811 and 6,894,064 ("the Particle Size Patents") were invalid for lack of written description. Teva Pharmaceuticals USA, Inc. ("Teva") filed an ANDA with the FDA for raloxifene hydrochloride for the prevention of postmenopausal osteoporosis and included a Paragraph IV certification to Lilly's patents for Evista®. Lilly timely filed its infringement suit on the Bone Loss Patents, the Low Dose Patent, and the Particle Size Patents. After trial, the district court held that Lilly's Bone Loss Patents and its Low Dose Patent were not invalid for obviousness under 35 U.S.C. § 103. The district court held that the Bone Loss Patents and Low Dose Patent are not invalid for failure to satisfy the enablement requirement of 35 U.S.C. § 112. The district court, however, held that the Particle Size Patents lacked an adequate written description to satisfy 35 U.S.C. § 112.

"Teva points to no evidence from before the time of invention that would teach, suggest, or motivate or supply any common sense reason for a person of ordinary skill in the art to reject the bioavailability concerns and routinely, simply, or easily arrive at the inventive result." Slip op. at 12.

The Federal Circuit affirmed the district court on all counts. The Court held that raloxifene's long history of bioavailability problems, specifically the rapid metabolism and excretion of the compound, foreclosed a reasonable expectation of successfully treating postmenopausal osteoporosis with raloxifene. Because of this widely known deficiency, the Court noted that Teva pointed to no evidence that "would teach,

suggest, or motivate or supply any common sense reason for a person of ordinary skill in the art to reject the bioavailability concerns and routinely, simply, or easily arrive" at Lilly's invention in the Bone Loss Patents and Low Dose Patent. Slip op. at 12, 21-22. Moreover, the Court rejected Teva's argument that the Low Dose Patent claims were invalid for nonstatutory double patenting over the Bone Loss Patents. Teva acknowledged that it did not raise the issue before the district court, and the Court concluded that the record was insufficiently clear for it to conclude that the proper resolution was beyond any doubt. The Court therefore "decline[d] to excuse Teva for failing to raise the nonstatutory double patenting issue at trial." *Id*. at 23.

Teva further argued that if the Bone Loss Patents and the Low Dose Patent were nonobvious due to concerns about raloxifene's bioavailability, then the patents could not be enabled under § 112, first paragraph, because of the prevailing view that raloxifene would not work in humans. But the Federal Circuit affirmed that those skilled in the art could make and use the claimed invention, and that the specification disclosed the results of previously unpublished Lilly experiments. The Court also cited the PTO's policy that FDA approval of a clinical trial, the blueprint of which was described in the Bone Loss Patents and which was ongoing at the time the application was filed, presumptively establishes "that the subject matter of that trial is reasonably predictive of having the asserted therapeutic utility." *Id*. at 26 (emphasis omitted) (quoting MPEP § 2107.03(IV) (8th ed., rev. 6, Sept. 2007)).

Lastly, the Federal Circuit upheld the district court's invalidation of the Particle Size Patents under written description. The Court noted that the proper test for written description was "whether the disclosure of the application . . . reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Id*. at 29 (alteration in original) (quoting *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc)). While the Federal Circuit agreed that the district court may have improperly focused on "whether the patent includes a description of the steps that may be used to prove infringement," the result nevertheless could be affirmed. *Id*. at 29, 30. Because the specification only disclosed measurements of bulk raloxifene, and because the record was conflicting as to whether persons of ordinary skill would determine that the inventor possessed the invention of formulated raloxifene falling within the claimed size range, the Court could not hold that the district court made a clearly erroneous factual finding as to the Particle Size Patents. *Id*. at 30.

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Korean Law Does Not Govern Successor Liability of Two U.S. Corporations

Will Chen

Judges: Newman (author), Lourie, Linn (concurring)

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

In *Funai Electric Co. v. Daewoo Electronics Corp.*, Nos. 09-1225, -1244 (Fed. Cir. Sept. 1, 2010), the Federal Circuit affirmed the district court's grant of SJ of infringement of U.S. Patent No. 6,021,018 ("the '018 patent"), U.S. Patent No. 6,421,210 ("the '210 patent"), and U.S. Patent No. 6,064,538 ("the '538 patent") and the damages award, and reversed the district court's determination of no successor liability.

Funai Electric Company, Ltd. ("Funai") owns six patents directed to various electrical and mechanical components of video cassette players and recorders ("VCRs"). After receiving a default judgment for infringement by Daewoo Electronics Company Ltd. ("DECL") and Daewoo Electronics Company of America ("DECA"), which DECL and DECA did not pay, Funai amended its complaint to assert that U.S. successor companies (collectively "Daewoo") are liable for payment. The district court held on SJ that three of the six patents were not infringed. The district court then granted SJ that the '018 and '210 patents are not literally infringed but denied SJ as to infringement under the DOE. The district court denied SJ as to infringement of the '538 patent and held that the claims of the '538 patent are not invalid for indefiniteness. A jury found that Daewoo willfully infringed the '018 and '210 patents under the DOE and willfully infringed the '538 patent. The district court applied the law of South Korea as to successor liability and ruled that Daewoo is not liable for the judgment entered against predecessors DECL and DECA. Daewoo appealed issues of infringement, claim indefiniteness, and damages. Funai cross-appealed the district court's refusal to enhance damages and the ruling as to successor liability.

With regard to infringement of the '018 patent, Funai argued that claims 1-4 of the '018 patent were not literally infringed based on the construction of "holder drive gear." Daewoo appealed the district court's grant of SJ that the "opened" limitation was literally met. The Court held that the claims were predicated on the presence of a cassette tape, for all claims recite "loading," "receiving," "holding," and "moving" a video cassette, and affirmed the district court's ruling that the "holder drive gear" limitation could not be literally met. The Court also agreed that the "opened" limitation was literally met by the accused products and affirmed the jury's verdict of infringement under the DOE as supported by substantial evidence.

Turning to the '210 patent, the Federal Circuit first reviewed the claim construction of "insulating

material." Daewoo argued that the district court's definition of insulating material as a material having "poor electrical conduction" rendered the claim construction fatally flawed because it improperly used comparative language, and that the district court's further description of "insulating material" as a material that "acts to suppress switching noise generated by a pulse width modulation control of the direct driving motor" was functional and therefore circular and improper. The Court found no error in using comparative and functional explanations in construing claims.

"This is not a question of conflict with foreign law, or [a] choice between domestic and foreign law, for no foreign law is involved in this question of successor liability for a default judgment for violation of United States law." Slip op. at 41.

The Federal Circuit, however, found that the district court erred in finding that Funai failed to produce any evidence that one of ordinary skill in the art would consider Daewoo's bearing holders to be made of material with poor electrical conduction, and in granting SJ of no literal infringement. Nevertheless, the Federal Circuit found that even if SJ were granted on this question, the issue of infringement was decided by the DOE. For that reason, a trial on literal infringement was unwarranted. Daewoo contended that infringement by equivalents was precluded by prosecution history estoppel, but the Court found that the nature of the insulating material was not a factor in the allowance of claim 4. Thus, the Federal Circuit concluded that the district court correctly held that the cancellation of claims 1 and 2 did not surrender to equivalency with respect to the insulating material.

Next, considering the '538 patent, the Federal Circuit affirmed the district court's claim construction of "a series circuit connecting in series through a series junction point said entire-width erasing head and said linear record erasing head" in claim 5 of the '538 patent. Daewoo argued that claims 1, 3, and 4 were invalid for failure to meet the claim-definiteness requirement of 35 U.S.C. § 112, second paragraph, because the claim clause "a series junction point at least between said linear record erasing head and one of said entire-width erasing head and an inductance element" was fatally indefinite. The Federal Circuit concluded that "[a]n ungainly claim is not thereby indefinite, when its meaning can be understood by a person experienced in the field of the invention, on review of the patent documents." Slip op. at 25. Accordingly, the Court affirmed the district court's ruling of validity.

The Court turned next to the question of damages. Daewoo argued that Funai's letter notice of infringement was inadequate and that Funai's marking of its products was incomplete, such that damages could not accrue for infringement before the filing of suit. Daewoo also argued that Funai's notice letter was legally insufficient to provide actual notice as to Daewoo VCR models not mentioned in the letter, thus limiting the period of damages at least as to those models. The Federal Circuit, in affirming the jury's verdict, noted that "when the threshold specificity is met, the ensuing discovery of other models and related products may bring those products within the scope of the notice." *Id*. at 28.

With respect to constructive notice, Daewoo argued that Funai did not completely mark all products with the '018 patent and marked no products with the '538 patent, and that these lapses eliminated any benefit of constructive notice. Funai responded that 88-91% of its products sold at retail were properly marked and that marking need not be perfect, provided that it is sufficiently complete so that the interested public is reasonably apprised of the patented status of the product. The Court affirmed the district court's finding that substantial evidence supported the jury's application of a rule of reason to the

question of constructive notice and the calculations applying constructive notice to the '018 patent.

Daewoo also challenged the amount of the damages award on the basis that Funai failed to establish that, but for the infringement, Funai would have made 30% of these VCR sales. Daewoo also argued that Funai's patented technology was not the basis for demand for the Daewoo products, and therefore that damages should not have been based on the entire lost-sales value. The Court found that Daewoo's arguments did not undermine the sufficiency of the evidence supporting the verdict, and affirmed the award. The Court also did not disturb the district court's conclusions regarding willful infringement.

The Federal Circuit also found that the district court erred in ruling that Korean law applies to the successor-liability relationship of the two U.S. successor corporations. The Court summarized the question before it as "whether a domestic corporation incurring a judgment of a United States court is insulated from that judgment if the judgment would not be enforceable under the laws of its foreign parent." *Id*. at 40. Because "[t]his is not a question of conflict with foreign law, or [a] choice between domestic and foreign law, for no foreign law is involved in this question of successor liability for a default judgment for violation of United States law," the Court reversed. *Id*. at 41.

In choosing which U.S. state law applies, the Federal Circuit analyzed the situation in accordance with California's "governmental interest" choice-of-law test. Because both successor companies have principal places of business in New Jersey, the Court chose New Jersey law in accordance with the Supreme Court's ruling in *Hertz Corp. v. Friend*, 130 S. Ct. 1181, 1192 (2010), wherein it held that, for diversity jurisdiction, the "principal place of business" is "the place where a corporation's officers direct, control, and coordinate the corporation's activities," from which it follows that the laws of the principal place of business should normally apply to transactions flowing from the corporation's "nerve center."

Under New Jersey law, the transferee of corporate assets ordinarily is not liable for the debts of the transferor company, subject to several exceptions. The exceptions include instances where (1) there is an express or implied assumption of the liabilities, (2) the transaction amounts to an actual or de facto consolidation or merger of the two corporations, (3) the purchasing corporation is a mere continuation of the seller, or (4) the transaction is for the fraudulent purpose of escaping the seller's liabilities. The Court found that the transfer between DECA and one of the successor companies was simply a "new hat" for DECA, and ruled that the successor should be liable for the earlier default judgment entered against DECA.

Judge Linn joined the opinion of the Court with the exception of the constructive-notice issue. Judge Linn noted that the record was not fully developed as to the constructive notice of products made by a patentee for an Original Equipment Manufacturer ("OEM") customer. Judge Linn also observed that the jury might award damages for the '018 patent only for those time periods in which Funai carried its burden of showing that Daewoo had actual notice. For these reasons, Judge Linn would not decide the question of constructive notice and would simply affirm on the substantial evidence that fully supports the jury's verdict apart from the OEM sales, leaving the constructive-notice question as it relates to OEM sales for another day on a record that more comprehensively presents the question and requires an answer.

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Claimed Subject Matter That Can Be "Envisioned" from the Specification Fails to Meet the Written Description Requirement

Aaron J. Capron

Judges: Newman (author), Lourie, Bryson

[Appealed from Board]

In *Goeddel v. Sugano*, Nos. 09-1156, -1157 (Fed. Cir. Sept. 7, 2010), the Federal Circuit reversed the Board's decisions that, as to the counts of two interferences, party Haruo Sugano, Masami Muramatsu, and Tadatsugu Taniguchi (collectively "Sugano") had priority over party David V. Goeddel and Roberto Crea (collectively "Goeddel"). The Court determined that Sugano's initial Japanese Application did not constitute a constructive reduction to practice of the subject matter of the counts and that Sugano was not entitled to the benefit of the filing date of that application. The Court therefore remanded the cases back to the Board for further proceedings.

The involved patents and patent applications disclosed and claimed a recombinant DNA process for directly producing mature human fibroblast interferon ("hFIF"). Mature hFIF is created when the first 21 amino acids are cleaved from the precursor protein expressed from the naturally occurring hFIF gene. The recombinant DNA process modifies the naturally occurring hFIF gene such that, when inserted into a bacterium, the bacterium produces the desired mature hFIF having 166 amino acids without the 21 amino acid presequence of the precursor hFIF. Both counts are directed to this 166 amino acid mature hFIF without the 21 amino acid presequence. The question of priority for both interferences turned on whether Sugano's initial Japanese Application constituted a constructive reduction to practice of the counts' subject matter, as only that application predated Goeddel's priority date.

Before the Board were two interferences between the parties. The first interference, referred to as the "DNA Interference," involved Goeddel's U.S. Patent Application No. 07/374,311 and two Sugano patents, U.S. Patent Nos. 5,326,859 and 5,514,567. The second interference, referred to as the "Protein Interference," involved Sugano's U.S. Application No. 08/463,757 and Goeddel's U.S. Patent No. 5,460,811. Sugano's patents and application claim priority to the Japanese Application filed on March 19, 1980, which predates Goeddel's earliest claim for priority by six months. The Board held that Sugano's Japanese Application constituted constructive reduction to practice of the subject matter of both interferences and awarded priority to Sugano. Goeddel appealed.

"Section 112, in the context of interference priority, requires that the subject matter of the counts be described sufficiently to show that the applicant was in possession of the invention. That a modified gene encoding the 166 amino acid protein could have been 'envisioned' does not establish constructive reduction to practice of the modified gene." Slip op. at 12-13.

Sugano's Japanese Application described the invention as "a novel recombinant plasmid," having a gene that encompassed at least the entire coding region of the hFIF messenger RNA. Slip op. at 7. The application stated that the entire coding region was the part specifying the whole amino acid sequence of the protein of the hFIF in the hFIF messenger RNA sequence. The Japanese Application provided Table 5, listing the entire 187 amino acid sequence—without indication of either the presequence or the mature hFIF sequence. The Japanese Application also identified a scientific article by Knight, which disclosed a partial sequence of the first 13 amino acids of mature hFIF. Addressing this Knight article, the experts for both parties agreed that a skilled person "could" identify the boundary between the presequence and the mature hFIF.

Based on these facts, the Board found that the gene described in the Japanese Application encoded the 187 amino acid precursor hFIF. The Board also found that the sequences of mature hFIF DNA or polypeptide were not explicitly disclosed. In awarding priority to Sugano, however, the Board found that mature hFIF would be "readily apparent" to a person skilled in this field, in view of the Japanese Application's description of the precursor hFIF and the Knight article. *Id*. at 8. The Board held that Knight's disclosure would allow a person skilled in the field of the invention to determine where in the 187 amino acid precursor the presequence ends and the mature sequence begins.

The Federal Circuit disagreed. While acknowledging that experts for both sides agreed that a skilled person "could" identify the boundary between the presequence and the mature hFIF based on the Knight article, the Court held that the Japanese Application did not describe the counts' subject matter. That is, the Japanese Application did not describe mature hFIF and did not describe the DNA coding for mature hFIF unaccompanied by the presequence.

The Court reasoned that Sugano described its invention, in the initial Japanese Application, as the recombinant production of the 187 amino acid precursor, using a gene that encompasses "at least the entire coding region." It noted that 35 U.S.C. § 112, in the context of interference priority, requires that the subject matter of the counts be described sufficiently to show that the applicant was in possession of the invention. And that a modified gene encoding the 166 amino acid protein could have been "envisioned" from the Japanese Application does not establish constructive reduction to practice of the modified gene. The Court stated, "The question is not whether one skilled in this field of science might have been able to produce mature hFIF by building upon the teachings of the Japanese Application, but rather whether that application 'convey[ed] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.'" *Id*. at 13 (alteration in original) (quoting *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc)). Accordingly, the Court held that the Japanese Application did not describe a bacterial expression vector that directly produces the mature hFIF, nor did it suggest producing a modified gene to directly encode the 166 amino acid mature hFIF.

The Court also disagreed with Sugano's argument that its precedent holds that priority is established if a person of skill in the art could "envision" the invention of the counts. Addressing Sugano's argument, the

Court explained that "[p]recedent in evolving science is attuned to the state of the science, but remains bound by the requirement of showing 'that the inventor actually invented the invention claimed.'" *Id*. at 14 (quoting *Bradford Co. v. Conteyor N. Am., Inc.*, 603 F.3d 1262, 1269 (Fed. Cir. 2010)).

Accordingly, the Federal Circuit concluded that the Board's decision that the Japanese Application constitutes constructive reduction to practice of the subject matter of the interferences was not in accordance with law, for the Japanese Application did not meet the criteria of § 112, first paragraph, as to this subject matter. The Court thus reversed the award of priority to Sugano and remanded the cases for appropriate further proceedings.

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Misidentifying Best Mode Did Not Warrant SJ and Trademark Counterclaims Met Case or Controversy Standard

Katherine L. Staba

Judges: Rader, Lourie (author), Bryson

[Appealed from E.D. Mo., Magistrate Judge Adelman]

In *Green Edge Enterprises, LLC v. Rubber Mulch Etc., LLC*, Nos. 09-1455, -1479 (Fed. Cir. Sept. 7, 2010), the Federal Circuit held that the district court erred in invalidating U.S. Patent No. 5,910,514 ("the '514 patent") for failure to describe the best mode and dismissing Rubber Mulch Etc., LLC's ("Rubber Mulch") counterclaims for trademark noninfringement and invalidity. The Court also held that the district court abused its discretion by excluding Rubber Resources, Ltd., LLP's ("Rubber Resources") evidence of damages for its unfair competition claim. The Court concluded, however, that the district court did not err in dismissing Rubber Resources' counterclaims for trademark invalidity and noninfringement.

Green Edge Enterprises, LLC ("Green Edge") owns the '514 patent, which claims a synthetic mulch that is colored with a "water based acrylic colorant" to imitate natural mulch. The '514 patent specification states that the colorant can be selected from a variety of different coloring systems as long as the colorant is available in earth-tone colors, adheres to rubber, and does not wash off when in contact with water. The specification indicates that preferred colorants are water-based acrylic systems such as the colorant systems sold under the name "Visichrome" by Futura Coatings, Inc. ("Futura"). Green Edge sued Rubber Mulch and Rubber Resources for patent infringement of the '514 patent.

Green Edge also owns the trademark RUBBERIFIC MULCH, which had been assigned to International Mulch Company ("International Mulch"). Green Edge claimed that Rubber Mulch had infringed its mark based on Rubber Mulch's use of the word "Rubber Mulch," which was printed on its products. Rubber Mulch and Rubber Resources both counterclaimed for noninfringement and invalidity of the RUBBERIFIC MULCH mark. Rubber Resources further asserted a counterclaim under the Lanham Act for unfair trade practices against Green Edge and International Mulch based on their assertion of the '514 patent in bad faith.

The district court held that the '514 patent failed to disclose the best mode of the invention because the specification referred to the use of the Visichrome colorant system by Futura, a product that the parties agreed did not exist. Instead, Green Edge had used a Futura product sold under the produce code

24009. Green Edge unsuccessfully argued that it believed the colorant system used to be called Visichrome based on a 1997 letter it received from Futura's vice president referencing the name. Nonetheless, the district court held that Green Edge did not disclose the best mode when it disclosed a nonexistent product, and furthermore had concealed the best mode by such disclosure of a product unavailable on the market.

The district court also granted SJ for International Mulch regarding Rubber Mulch and Rubber Resources' trademark counterclaims of noninfringement and invalidity, finding no case or controversy. After granting SJ for International Mulch, the district court ordered each party to submit a status report, to which Rubber Mulch did not reply. As a result, all of Rubber Mulch's counterclaims were dismissed.

Finally, the district court dismissed Rubber Resources' Lanham Act unfair competition counterclaim, holding that Rubber Resources was unable to show any damages, and thus was unable to establish a prima facie case of unfair competition.

In reversing the district court's grant of SJ for invalidity of the '514 patent, the Court evaluated whether Green Edge complied with the best mode requirement under a two-pronged inquiry: (1) whether, at the time the patent application was filed, the inventor possessed a best mode of practicing the claimed invention; and (2) whether the inventor disclosed the best mode and whether such disclosure adequately enabled one of ordinary skill in the art to practice the best mode of the invention. The first inquiry was not disputed. At the time the application was filed, the inventors possessed a best mode of using Futura's 24009 product as the claimed colorant. As to the second inquiry, the Court analyzed the objective question of whether Green Edge adequately disclosed its best mode by disclosing a material by a name that did not exist ("Visichrome") and not identifying the material it actually used (Product No. 24009). The Court relied on a letter of Jeffrey Jarboe, Futura's vice president, written months before the '514 patent was filed, referencing the Visichrome colorant system. Based on this letter, the Federal Circuit held that one skilled in the art could contact Futura to obtain the Visichrome colorant system and subsequently be directed by Futura to its 24009 product. Thus, there was a genuine issue of material fact relating to whether the best mode was disclosed, warranting reversal of SJ.

"Indeed, Green Edge and International Mulch have both accused Rubber Mulch of infringing a valid trademark, which is the hallmark of an actual controversy." Slip op. at 25.

The Court also held that the district court did not err in denying SJ of invalidity on the alternative grounds of anticipation, obviousness, indefiniteness, and nonenablement. The record before the Court was insufficient to determine whether SJ was warranted.

The Court held that the district court erred by dismissing Rubber Mulch's counterclaims of noninfringement and invalidity of Green Edge's RUBBERIFIC MULCH mark for a lack of case or controversy, but did not err in dismissing Rubber Resources' trademark counterclaims.

Rubber Mulch's counterclaims satisfied the justiciable case or controversy requirement of the Declaratory Judgment Act because they were pleaded in response to Green Edge's trademark infringement claims. Having been sued by Green Edge, Rubber Mulch had more than an apprehension of suit and thus established DJ jurisdiction. Similarly, Rubber Mulch also established DJ jurisdiction over its trademark

counterclaims against International Mulch, the assignee of the RUBBERIFIC MULCH mark, because International Mulch had threatened suit in the form of a cease and desist letter sent to Rubber Mulch. Not only had International Mulch threatened suit in its cease and desist letter, it was also a party to the action and could, if necessary, be substituted for Green Edge as the real party in interest in the trademark infringement claim.

The Court disagreed with International Mulch and Green Edge's argument that Rubber Mulch had no standing to appeal because it had been dismissed by the district court for failure to respond to the district court's order requesting a status report. The Court held that, at the time Rubber Mulch's claims were dismissed for failure to prosecute, its trademark claims were no longer in the case, having previously been dismissed for lack of case or controversy. Rubber Mulch could not be punished for failure to pursue trademark claims that were no longer in the case. Accordingly, Rubber Mulch had standing to appeal the district court's dismissal of its trademark counterclaims.

Unlike Rubber Mulch, Rubber Resources' counterclaims of trademark invalidity and noninfringement were properly dismissed for a lack of case or controversy. Rubber Resources had neither been sued nor threatened with suit relating to its trademarks. Rubber Resources' sole argument in support of its satisfaction of the case or controversy requirement was that it, like Rubber Mulch, was using the term "Rubber Mulch." This attempt to establish a pattern of litigation for DJ jurisdiction, however, was unavailing. This single suit did not create the necessary pattern of litigation sufficient to confer jurisdiction. Moreover, had Green Edge intended to sue Rubber Resources for trademark infringement, it could have asserted a claim against Rubber Resources in this case. For these reasons, the Court affirmed the district court's dismissal of Rubber Resources' counterclaims.

Reviewing the district court's decision to exclude all of Rubber Resources' evidence of damages for abuse of discretion, the Court held that Rubber Resources had enumerated categories of damages under the Lanham Act in its amended counterclaim. Specifically, Rubber Resources sought relief in the form of its damages, Green Edge and International Mulch's profits, and "exemplary damages." Despite seeking three theories of damages, Rubber Resources did not argue that it presented evidence of its damages and "exemplary damages." Thus, the Court only addressed whether Rubber Resources presented evidence of damages sufficient to entitle it to recover Green Edge's profits. Under the Lanham Act, Rubber Resources need only prove Green Edge's sales to recover Green Edge's profits. Because Rubber Resources and Green Edge had stipulated to a calculation of Green Edge's sales, Rubber Resources satisfied this requirement. Accordingly, the district court erred in excluding all evidence of damages and subsequently dismissing Rubber Resources' Lanham Act claim for inability to prove damages.

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DJ Action Based on Claim of Invalidity Not Barred by Settlement Agreement

Jin Zhang

Judges: Lourie, Linn, Dyk (author)
[Appealed from D.D.C., Judge Friedman]

In *Baseload Energy, Inc. v. Roberts*, No. 10-1053 (Fed. Cir. Sept. 9, 2010), the Federal Circuit reversed the district court's SJ holding that the terms of a 2008 settlement agreement barred all claims between the parties. The Federal Circuit reversed the district court's SJ after concluding that the language of the settlement agreement did not release either claims of infringement or the accompanying defenses of invalidity or unenforceability.

After a breach of contract action between the founder and CEO of Baseload Energy, Inc. ("Baseload"), David Resnick, and Bryan W. Roberts, the parties entered into a settlement agreement that contained a release of claims by Baseload that could have been brought against Roberts. Baseload subsequently sought DJ that U.S. Patent No. 6,781,254 ("the '254 patent") owned by Roberts was invalid and unenforceable. Roberts moved for SJ on the ground that Baseload's claims were barred by the settlement agreement and the district court granted the motion.

"Once an accused infringer has challenged patent validity, has had an opportunity to conduct discovery on validity issues, and has elected to voluntarily dismiss the litigation with prejudice under a settlement agreement containing a clear and unambiguous undertaking not to challenge validity and/or enforceability of the patent in suit, the accused infringer is contractually estopped from raising any such challenge in any subsequent proceeding." Slip op. at 11 (quoting *Flex Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1370 (Fed. Cir. 2001)).

On appeal, the Federal Circuit first addressed the issue of whether consent decrees and settlement agreements may at the same time provide for a patent license while barring challenges to patent invalidity and unenforceability. Baseload argued that the district court erred in granting SJ because the settlement agreement failed to meet the standard for a valid release of patent invalidity claims. The

Federal Circuit reaffirmed that release language must be clear and unambiguous to release patent invalidity claims, and reminded that "[o]nce an accused infringer has challenged patent validity, has had an opportunity to conduct discovery on validity issues, and has elected to voluntarily dismiss the litigation with prejudice under a settlement agreement containing a clear and unambiguous undertaking not to challenge validity and/or enforceability of the patent in suit, the accused infringer is contractually estopped from raising any such challenge in any subsequent proceeding." Slip op. at 11 (quoting *Flex Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1370 (Fed. Cir. 2001)).

Baseload argued that the settlement agreement was inadequate to release its patent invalidity claims because the prior litigation between the parties did not involve patent invalidity issues or actual litigation on those issues. The Court disagreed. Although the absence of a prior dispute and litigation on invalidity is pertinent, the Court rejected the argument that a settlement agreement is ineffective to release invalidity claims unless the exact circumstances described in *Flex Foot* are present. The Court held that each case must be examined on its own facts in light of the agreement between the parties. Clear and unambiguous language barring the right to challenge patent validity in future infringement action is sufficient, even if invalidity claims had not been previously at issue and had not been actually litigated.

The Federal Circuit found, however, no such clear language and thus no release of either patent claims or defenses. There was no specific language in the settlement agreement making reference to invalidity issues. There was also reason to question whether the general language of the agreement was intended to cover such disputes. This is so because there was no issue in the breach-of-contract litigation concerning patent infringement or patent invalidity and unenforceability, and no prior dispute between the parties on such issues. Most importantly, the parties could not possibly have intended to release all patent infringement claims, because the settlement agreement granted Baseload an option to acquire a nonexclusive license to use the technology claimed by the '254 patent. The license provision would be unnecessary if all infringement claims under the '254 patent were released. Thus, the Court concluded that the parties must have intended to exclude infringement from the scope of the settlement agreement. Because the Court found nothing in the text of the settlement agreement to suggest that somehow infringement claims were preserved while patent invalidity defenses were released, the Court held that the clear and unambiguous language necessary to effect a release of patent invalidity defenses was not present.

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Selection of and Motivation to Modify a Lead Compound Follows from the Possession of Useful Properties, Not Mere Structural Similarity

David Albagli

Judges: Lourie (author), Friedman, Linn

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

In *Daiichi Sankyo Co. v. Matrix Laboratories, Ltd.*, No. 09-1511 (Fed. Cir. Sept. 9, 2010), the Federal Circuit affirmed the district court's ruling that the patent at issue was not invalid as obvious under 35 U.S.C. § 103. Defendants Matrix Laboratories, Ltd., Mylan Inc., Mylan Laboratories, Inc., and Mylan Pharmaceuticals, Inc. (collectively "Mylan") failed to establish a prima facie case for the selection of a lead compound and, even if selected, failed to establish a motivation to modify the lead compound to obtain the claimed compound.

Daiichi Sankyo Company, Ltd. and Daiichi Sankyo, Inc. (collectively "Daiichi") own U.S. Patent No. 5,616,599 ("the '599 patent"), which claims compounds and their use as angiotensin receptor blockers ("ARBs") for treating high blood pressure. Claim 13 covers the compound olmesartan medoxomil, an FDA-approved drug and the active ingredient in Benicar®, Benicar HCT®, and Azor®.

The invention of olmesartan medoxomil follows from the development of small-molecule ARBs beginning in the late 1970s. Years later, scientists at E.I. du Pont de Nemours and Company ("DuPont") invented the first orally active ARB, losartan. Like the earlier compounds, losartan contained an imidazole ring core, but DuPont modified the 1- and 5-position substituents found in a lead compound. In its patent covering losartan, DuPont disclosed more than 400 related compounds as well as binding affinity data for more than half of the compounds. The data were used by chemists to correlate chemical structure with activity ("structural-activity relationships," or SARs), which could be used to develop improved compounds.

More than twenty pharmaceutical companies launched research programs for ARBs; Daiichi's program resulted in the synthesis of olmesartan medoxomil. Olmesartan shares the imidazole ring, 1-position biphenyltetrazole substituent, and 2-position alkyl group of losartan. Olmesartan differs from losartan, however, at both the 4- and 5-positions.

At the 4-position, olmesartan replaces losartan's lipophilic chlorine atom with a hydrophilic

hydroxyisopropyl group. The vast majority of compounds disclosed in DuPont's patent contained lipophilic groups at the 4-position. One compound disclosed in the DuPont patent with a hydrophilic group at the 4-position is a regioisomer of losartan, in which the 4- and 5-position substituents were exchanged.

At the 5-position, olmesartan replaced losartan's hydroxymethyl group with a masked carboxy group, carboxy medoxomil. In the body, the medoxomil group is removed to yield the carboxylic acid group. Losartan's hydroxymethyl group is also metabolized to a carboxylic acid in the body.

Some second-generation ARBs, which are prior art to olmesartan, replaced losartan's 4-position chlorine atom with other lipophilic groups, such as alkyl or perfluoroalkyl groups. The court determined that ARBs disclosed in another patent to DuPont, U.S. Patent No. 5,137,902 ("the '902 patent"), are the closest structurally to olmesartan. Example 6 of the '902 patent differs only by the replacement of a hydroxy group with hydrogen. Other second-generation ARBs vary more significantly by using, for example, a different core ring than imidazole.

Mylan filed several ANDAs and served Paragraph IV certifications challenging the validity of the '599 patent. Daiichi filed suit for patent infringement. The parties stipulated to infringement of claim 13, but the case proceeded on Mylan's counterclaim of invalidity for obviousness. The district court ruled after a bench trial that the '599 patent was not invalid as obvious, and Mylan appealed.

Mylan first challenged the lower court's finding that one of skill in the art would not have chosen the ARBs in DuPont's '902 patent as lead compounds. The Federal Circuit, however, affirmed the ruling that Mylan failed to show that one of ordinary skill in the art would have selected the '902 patent's ARBs as lead compounds. The Court accepted as true that the '902 compounds represented a continuation of the disclosure and the data found in the earlier DuPont patent, and recognized that the compounds exhibited about 2- to 4-fold higher activity than the most active compounds in DuPont's previous disclosure. However, other second-generation ARBs exhibited even greater activity and had been more thoroughly studied than the DuPont ARBs. Thus, the Court found that a skilled artisan would have selected the other secondary ARBs, which exhibited 7-, 100-, and 180-fold higher activity to be a lead compound, not the '902 compounds.

"[P]roving a reason to select a compound as a lead compound depends on more than just structural similarity, but also knowledge in the art of the functional properties and limitations of the prior art compounds." Slip op. at 14.

The Court did not accept Mylan's argument that because the '902 compounds have the closest structure in the prior art, that should be dispositive for finding them to be lead compounds. Instead, the Court emphasized that "it is the possession of promising useful properties in a lead compound that motivates a chemist to make structurally similar compounds." Slip op. at 14. To choose the '902 compounds as lead compounds would suffer from hindsight bias. The state of the art at the time of the invention must be the basis for finding motivation to select and then modify a lead compound. The Court stated that "[p]otent and promising activity in the prior art trumps mere structural relationships." *Id.* at 15. The oral activity, binding activity, and selectivity data, for example, among the other second-generation compounds would motivate their selection as lead compounds over the '902 compounds. A court is not required to find a

single, best lead compound. Here, several compounds were selected as leads, and the '902 compounds were not included in that set. The lower court did not commit clear error in reaching this finding.

Mylan next challenged the finding that one would not be motivated to modify the '902 patent's compounds at the 4- and 5-positions where the first DuPont patent specifically taught a hydroxyalkyl group at the 4-position, and the art taught medoxomil as a prodrug providing improved oral activity. The Federal Circuit, however, again affirmed the lower court's finding that even if the '902 compounds were selected as lead compounds, one of skill in the art would not be motivated to modify them to obtain olmesartan medoxomil.

The Federal Circuit first explained that the prior art as a whole taught away from the use of a hydrophilic substituent at the 4-position of the imidazole ring. The SAR data and the use of lipophilic groups at this position in the other second-generation compounds would teach away from modifying the '902 compounds' lipophilic alkyl groups to the hydrophilic hydroxyisopropyl group of olmesartan. The DuPont data revealed a clear preference for lipophilic groups at the 4-position. Three subseries analyzing the binding affinity as a function of the 4-position substituent confirmed the preference for having a lipophilic group. "Thus, the compounds in the prior art, including [Mylan's] proposed lead compounds, favor lipophilic 4-substituents rather than the 4-hydrophilic group of olmesartan medoxomil." *Id.* at 17.

Regioisomers that transpose the 4- and 5-position substituents and DuPont's second-generation ARBs all demonstrated the preference for lipophilicity at the 4-position. No other second-generation ARB besides olmesartan had a hydrophilic group at this position. Mylan argued that the motivation to modify was nonetheless found in one of the DuPont example compounds having a hydrophilic group at the 4-position. The Court found, however, that the SAR data contradicted this, and that Mylan's argument relied on selecting the '902 compounds, which improved on losartan by using even more lipophilic groups at the 4-position, only to reject that very feature to obtain olmesartan medoxomil.

Finally, Mylan challenged the finding that one of skill in the art would not have had a reasonable expectation of success in modifying the '902 patent's ARBs to arrive at olmesartan as a similarly effective ARB. The Court declined to address this alternative ground for the ruling because it had affirmed the district court's findings that Mylan failed to establish the selection of prior art ARBs as a lead compound, or the motivation to modify the prior art compounds to obtain olmesartan medoxomil.

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Lost Profits Not Awarded Where the Patentee Corporation Did Not Sell Any Patented Products and Patentee's Parent and Sister Companies Were Not Owners or Exclusive Licensees of the Patent

Mukta Jhalani

Judges: Dyk, Friedman, Moore (author)

[Appealed from W.D. Tenn., Judge McCalla]

In *Spine Solutions, Inc. v. Medtronic Sofamor Danek USA, Inc.*, No. 09-1538 (Fed. Cir. Sept. 9, 2010), the Federal Circuit affirmed the district court's denial of Medtronic Sofamor Danek USA, Inc. and Medtronic Sofamor Danek, Inc.'s (collectively "Medtronic") motion for JMOL on obviousness, its denial of Medtronic's motion for SJ of invalidity for failure to satisfy the written description requirement, and its grant of Spine Solutions, Inc.'s ("SSI") motion for partial SJ dismissing Medtronic's 35 U.S.C. § 112 defenses. The Federal Circuit affirmed the district court's construction of the term "operative engagement" as used in the asserted claims. Reversing the district court's grant of SJ of infringement with respect to Medtronic's O-Maverick product, the Federal Circuit remanded to the district court to enter judgment of noninfringement with respect to O-Maverick. The Court also reversed denial of Medtronic's motion for JMOL of no lost profits and of no willfulness, vacating the enhanced damages and attorney fee awards. Finally, the Court remanded to allow modification in the terms of the permanent injunction by deleting the extraterritorial portion.

SSI is the assignee of U.S. Patent No. 6,936,071 ("the '071 patent"), which relates to artificial intervertebral implants that are used to replace degenerated or diseased discs between vertebrae in the spinal column. The '071 patent discloses an implant having an upper part and a lower part, each with a single anchor, that is centrally positioned on a support face for an adjacent vertebra. The anchors affix the upper and lower parts into the adjacent vertebrae. In a preferred embodiment, a pivot insert is placed between the upper and lower parts to allow certain pivotability of the two parts relative to one another, attaining a pivotability of the adjacent vertebra.

SSI sued Medtronic, alleging that Medtronic's Maverick, A-Maverick, and O-Maverick implants infringed certain claims of the '071 patent. Medtronic raised several defenses, including noninfringement and invalidity for obviousness and failure to comply with the written description requirement. After claim construction, Medtronic filed a motion for SJ of noninfringement with respect to the O-Maverick. The district court denied Medtronic's SJ motion, granted SSI's motion for partial SJ that O-Maverick infringed

the ’071 patent, and granted SSI’s cross-motion to dismiss all of Medtronic’s 35 U.S.C. § 112 defenses.

Before trial, Medtronic filed a motion in limine precluding SSI from offering evidence relating to lost profits because SSI, although the assignee of the ’071 patent, did not make or sell any device covered by the product. The district court allowed SSI to amend its complaint to add its sister company Synthes Spine Co., L.P. (“Synthes Spine”), which made and sold a commercial embodiment of the ’071 patent, and SSI’s parent company, Synthes, Inc., as coplaintiffs.

At trial, the jury considered Medtronic’s obviousness defense, SSI’s willful infringement claim, and damages award. The jury found that Medtronic did not prove that the ’071 patent was invalid for obviousness and also found that Medtronic’s infringement was willful, awarding SSI lost profits for the 2005-2007 timeframe and an 18% reasonable royalty on the remaining $9.1 million in revenue from infringing sales of the accused products. The district court denied Medtronic’s motions for JMOL of obviousness, no willfulness, and no entitlement to lost profits. After doubling the damages award and awarding attorney fees, the district court entered a permanent injunction forbidding Medtronic from using or selling any accused devices that were already outside the United States.

On appeal, Medtronic first argued that the district court erred in denying its JMOL of obviousness. It was undisputed that U.S. Patent No. 5,314,477 (“the ’477 patent”) disclosed every element of claim 1 of the ’071 patent except for the “single anchor” limitation. Although the ’477 patent utilized a dual-anchor design, the inventor of the ’071 patent testified that he knew the possibility of using a single anchor as early as ten years before the priority of the ’071 patent. The Court agreed with Medtronic that the prior art reference disclosed the “single anchor” design. However, the Court found substantial evidence in the record to support the jury’s finding that it would not have been obvious to use the single anchor design in the implant claimed in the ’071 patent. First, a person of ordinary skill in the art would not have viewed a single anchor as being stable enough for a disc replacement device. Second, the inventor performed extensive testing of the single anchor design prior to filing the ’071 patent. And finally, Medtronic’s own engineers were unsure whether a single anchor would provide sufficient fixation.

“Given that SSI fails to point to any evidence other than its current ‘organization’ to show that Synthes Spine is an exclusive licensee, we conclude that SSI failed to meet its burden of establishing that Synthes Spine has standing to bring suit.” Slip op. at 23.

Medtronic then asserted that the district court erred in granting SJ that the ’071 patent contains adequate written description to support the limitation “single anchor . . . *adapted to enter a groove*.” Slip op. at 11 (emphasis added). Finding adequate written description support, the Federal Circuit found the failure to mention the word “groove” in the specification insufficient to create a genuine dispute of material fact. Rather, the Court concluded that the disclosure of the shape of the anchor in combination with its placement adequately described an anchor adapted to enter a groove.

Medtronic also appealed the district court’s construction of the term “operative engagement” as used in claim 1 of the ’071 patent, which recites “a lower part having a lower surface for engaging a vertebrae and an upper surface portion in *operative engagement* with the rounded portion of the upper part.” *Id*. at 14. Medtronic proposed construing “operative engagement” to mean “the interaction between the pivot insert and the rounded portion of the upper part.” *Id.* The district court, however, adopted SSI’s

proposed construction, construing "operative engagement" as "permitting movement (for example pivotability)." *Id.* Medtronic asserted that the district court erred in construing "operative engagement" as not incorporating a pivot insert. Agreeing with SSI, the Federal Circuit found that the language of the limitation made it clear that the lower part of the implant engages "operatively" with the rounded portion of the upper part, allowing the upper and lower parts of the implant to move relative to each other, whether or not a pivot insert is used.

With respect to infringement, Medtronic appealed from the district court's grant of SJ that the O-Maverick implant infringed the '071 patent. Finding that O-Maverick did not literally infringe the '071 patent, the Federal Circuit noted that O-Maverick had two anchors on each of the upper and lower pieces, whereas the claim recites a single anchor. The Court also found no infringement under the DOE on the basis that the applicants made a clear surrender of any design containing more than one anchor during prosecution of the '071 patent. In light of the disclaimer of claim scope contained in the prosecution history, the Federal Circuit barred SSI from arguing that a two-anchor device was equivalent to the claimed implant.

Medtronic also challenged the district court's discretion in allowing SSI to amend its complaint to add Synthes Spine and Synthes, Inc. as coplaintiffs. The sole owner of the '071 patent is SSI. SSI did not show that Synthes, Inc., SSI's parent company, had standing to bring suit because the record did not indicate that Synthes, Inc. was an owner or exclusive licensee of the '071 patent. As for SSI's sister corporation, Synthes Spine, the Court found no evidence of an exclusive license between Synthes Spine and SSI, even though Synthes Spine was the only entity to make and sell products practicing the '701 patent. Because SSI itself did not sell any products and neither Synthes Spine nor Synthes, Inc. had standing to sue on the '071 patent, SSI could not recover for any lost profits. The Federal Circuit remanded to determine the proper reasonable royalty based on infringing sales of Medtronic's Maverick and A-Maverick products.

Regarding Medtronic's motion for JMOL of no willfulness, the Court found Medtronic was not objectively reckless in relying on its obviousness defense, which the district court noted was "reasonable." *Id*. at 26. Accordingly, the Court found substantial evidence did not support the jury's finding that Medtronic willfully infringed and reversed the district court's denial of JMOL of no willfulness. The Court therefore vacated the award of enhanced damages and attorney fees.

Lastly, the Federal Circuit remanded to allow the district court to remove the extraterritorial portion of the permanent injunction for Medtronic devices that were already outside of the United States because overseas sales of Maverick products would not have infringed any U.S. patent, especially when there was no risk that the infringing devices would be imported into the United States.

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Patent Assignment Properly Transferred Ownership to Successor Corporations

Michael R. Justus

Judges: Newman (author), Bryson, Dyk

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

In *Tri-Star Electronics International, Inc. v. Preci-Dip Durtal SA*, No. 09-1337 (Fed. Cir. Sept. 9, 2010), the Federal Circuit affirmed the district court's denial of defendant's motion to dismiss a patent infringement suit for lack of standing. The Court held that the inventor properly assigned the patent to his former employer and its successors, and so the plaintiff, one of the succeeding companies, may bring an infringement suit.

On June 16, 1998, Leslie Kerek, an inventor employed by Tri-Star Electronics International, Inc. ("Tri-Star Ohio"), executed an assignment of his invention set forth in a patent application entitled "Socket Contact." In accordance with Kerek's employment contract, he assigned the invention to "Tri-Star Electronics International, Inc., its successors, legal representatives, and assigns." Tri-Star was identified in the assignment document as an Ohio corporation. The patent application was filed in the PTO and the assignment recorded on June 25, 1998. Kerek executed an assignment for a CIP application on September 7, 1999, which also assigned the invention to "Tri-Star Electronics International, Inc., its successors, legal representatives, and assigns," and identified Tri-Star as an Ohio corporation. This application issued as U.S. Patent No. 6,250,974 ("the '974 patent").

Tri-Star Ohio merged with a California corporation of the same name ("Tri-Star California") on June 24, 1998. In August 2005, the Tri-Star California corporation merged into a newly created Delaware corporation ("Tri-Star Delaware"). Tri-Star Delaware sued Preci-Dip Durtal SA ("Preci-Dip") for infringement of the '974 patent in June 2008. Preci-Dip moved to dismiss the suit, arguing that Kerek had assigned his invention to a nonexistent entity, the Tri-Star Ohio corporation, and, therefore, the chain of ownership never came into effect. Kerek executed a "Confirmatory Assignment" in response, reciting the status of each succeeding Tri-Star corporate entity and stating that he confirmed his assignment to the appropriate Tri-Star corporations.

The district court denied Preci-Dip's motion to dismiss, holding that Kerek's September 7, 1999, assignment conveyed ownership of the invention to the Tri-Star California corporation, because it transferred Kerek's ownership rights to Tri-Star Ohio and its "successors, legal representatives, and

assigns." The district court held that Tri-Star California existed as the successor of Tri-Star Ohio at the time of the assignment, and, therefore, Tri-Star California validly acquired Kerek's patent rights. Ohio law provides that whenever an assignment is necessary to vest property or rights in a new entity, the merged corporation continues to exist for these purposes. *Id*. at 3-4 (citing Ohio Rev. Code § 1701.82(A)(1) (2010)). Accordingly, the district court held that Tri-Star Ohio continued to exist for the purpose of vesting property rights in its successor Tri-Star California, including the patent application at issue. Preci-Dip appealed.

"The district court held that Tri-Star of California, as the existing successor to Tri-Star of Ohio, received the assignment of the patent at the time of the assignment. This interpretation maintains the validity of every contract provision, and gives effect to the contract's purpose of assigning the invention to Mr. Kerek's employer." Slip op. at 5 (citations omitted).

On appeal, the Federal Circuit addressed Preci-Dip's argument that Tri-Star California did not come into the patent application's chain of ownership through Kerek's assignment, and, thus, Tri-Star Delaware did not have standing to sue. Preci-Dip also argued that the "successor, legal representatives, and assigns" language in the assignment document was "merely boilerplate" and could not be viewed as conveying ownership to an unnamed successor. The Court examined the patent assignment under Ohio law, which strives to give effect to every contract provision and favors interpreting a doubtful condition in a construction that would give it "meaning and purpose." The district court held that Tri-Star California, as the existing successor to Tri-State Ohio, received the assignment of the patent at the time of assignment. The Court agreed with this interpretation, stating: "The district court held that Tri-Star of California, as the existing successor to Tri-Star of Ohio, received the assignment of the patent at the time of the assignment. This interpretation maintains the validity of every contract provision, and gives effect to the contract's purpose of assigning the invention to Mr. Kerek's employer." *Id*. at 5 (citations omitted). The district court also looked to the contracting parties' mutual intent, since all contracts must be construed in this direction. It was not disputed that Kerek intended to assign his patent rights to Tri-Star Ohio as required by his employment contract, and Preci-Dip did not offer any reason to disregard this contractual intent as evidenced in the assignment. The parties to the assignment agreed that Tri-Star California, as Tri-Star Ohio's successor, was the intended recipient of the ownership rights at the time of the assignment's execution. The term "successor" in the assignment language gave further effect to this intention, and, therefore, the Court affirmed the district court's ruling that the assignment transferred ownership to Tri-Star California. Since Preci-Dip did not challenge the ensuing transfer to Tri-Star Delaware, Tri-Star Delaware had standing to bring its patent infringement suit.

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Preamble Term That Is Not an Essential Component of the the Invention Should Not Be Construed as a Claim Limitation

Eric K. Chiu

Judges: Bryson (author), Dyk (dissenting), Prost

[Appealed from D. Mass., Judge Ponsor]

In *American Medical Systems, Inc. v. Biolitec, Inc.*, No. 09-1323 (Fed. Cir. Sept. 13, 2010), the Federal Circuit reversed the district court's grant of SJ of noninfringement, holding that the district court erred when it construed the preamble phrase "photoselective vaporization" as a claim limitation rather than merely a label for the invention as a whole.

American Medical Systems, Inc. and Laserscope brought suit against Biolitec, Inc. ("Biolitec") for infringement of U.S. Patent No. 6,986,764 ("the '764 patent"). The '764 patent relates to treatments for Benign Prostatic Hyperplasia ("BPH"), a condition in which growth of the prostate gland restricts the passage of urine through the urethra and out of the bladder. As described in the '764 patent, vaporization of some of the prostate tissue reduces the size of the prostate and can relieve bladder outlet obstructions. This type of BPH treatment generally involves the insertion of a cytoscope into the urethra, the provision of an irrigant such as sterile water, and the application of high-intensity laser radiation to the target tissue by means of an optical fiber.

The '764 patent discloses that the use of high "volumetric power density," i.e., a high amount of energy delivered to a given volume of tissue, would result in increased vaporization efficiency while minimizing the side effect of "residual tissue coagulation." Accordingly, the '764 patent is directed to various methods and devices for achieving high volumetric power density for tissue vaporization by manipulating variables such as wavelength, output power, beam quality, irrigant composition, and distance between the optical fiber and the tissue. Those variables in turn affect the resulting irradiance level, spot size, and absorption depth.

Biolitec's Evolve^{TM} laser system is a laser-powered tissue ablation system that uses radiation having a wavelength of 980 nm. It includes an optical fiber for administering the radiation by direct contact with the target tissue.

Before the district court, the parties disputed the proper construction of the preamble term "photoselective

vaporization." Finding that the specification and claims indicated that "photoselective vaporization" is a "fundamental characteristic" of the invention, the district court construed the term to mean "using a wavelength that is highly absorptive in the tissue, while being absorbed only to a negligible degree by water or other irrigant." In light of this claim construction, the district court found that 980 nm laser light (as in the accused product), as compared with 532 nm laser light (the wavelength of the '764 patent's preferred and commercial embodiment), is more than negligibly absorbed by the water irrigant, and thus did not satisfy the "photoselective vaporization" limitation.

On appeal, the Federal Circuit determined that the preamble phrase "photoselective vaporization of tissue," and particularly the descriptor "photoselective," does not limit the claims of the '764 patent. The Court reasoned that the prosecution history of the '764 patent does not suggest that the inventors added the phrase "photoselective vaporization" in order to distinguish their invention from the prior art. Rather, the examiner's primary reason for approval was the claims' use of high-power densities to vaporize tissue without causing significant residual tissue damage.

"Third, and most importantly, the descriptor 'photoseslective' does not embody an essential component of the invention. Instead, the term 'photoselective vaporization' is simply a descriptive name for the invention that is fully set forth in the bodies of the claims." Slip op. at 10.

In addition, the Court rejected Biolitec's argument that the preamble term "photoselective vaporization of tissue" provides a necessary antecedent basis for the term "the tissue" in the bodies of each of the independent claims. The Court found that the preamble's reference to "vaporization of tissue" does not specify a particular type or location of tissue and does not provide any "context essential to understand[ing]" the meaning of "the tissue" in the body of each claim. That is, the claim drafters did not rely on the preamble language to define or refine the scope of the asserted claims.

Furthermore, the Court concluded that, "most importantly," the phrase "photoselective" does not embody an essential component of the invention and is simply a descriptive name for the invention that is fully set forth in the body of the claims. The Court observed that the bodies of the asserted apparatus claims describe a structurally complete device and that those claims identify the covered wavelengths by function ("sufficient to cause vaporization"), without suggesting that the term "photoselective" further limits those wavelengths. Additionally, the Court noted that each of the asserted method claims also recites the invention in functional terms. Thus, as long as the stated objective is achieved through various recited combinations of wavelength, irradiance, output power, spot size, irrigant type, and distance between the optical fiber and the tissue, it is irrelevant whether a particular wavelength is used that would satisfy an independent requirement of being "photoselective."

The Court further found that the specification of the '764 patent confirms that "photoselective vaporization" is not a limitation on the claims because the phrase is consistently used in reference to the entire invention's emphasis on improved vaporization efficiency through high-power densities, and is not limited to describing radiation with wavelengths that are absorbed to a substantially greater degree by tissue than by water. The Court explained that specification passages delineating particular wavelength ranges merely suggest but do not require the use of certain wavelengths as a means of increasing the invention's overall effectiveness in conjunction with other variables. Thus, the Court concluded that while the specification as a whole indicates that wavelength is one of the variables employed in the invention,

the claims are not limited to particular wavelengths exhibiting particular levels of differential absorption in tissue and water. Accordingly, the Court reversed the judgment of the district court.

Judge Dyk dissented from the majority opinion, finding that the preamble term "photoselective vaporization" should have been construed as a claim limitation. Judge Dyk observed that the parent of the '764 patent never used the term "photoselective vaporization" in its claims or in its specification, and found that the addition of the term in the preamble of the claims of the '764 patent was significant. In particular, Judge Dyk noted that the '764 patent applicant took considerable care to add new matter to the specification describing and defining photoselective vaporization and to reduce the claimed wavelength ranges. Furthermore, Judge Dyk found that minimal absorption by the irrigant and strong absorption by the tissue are mandatory aspects of the invention because the specification stated that "[t]he wavelength used *according to the present invention* for BPH treatment should be strongly absorbed in the prostate tissue to help initiate and maintain tissue vaporization . . . [and] . . . [t]he wavelength also *must be minimally absorbed* by the irrigant." Dyk Dissent at 7-8. As a result, Judge Dyk concluded that, by adding the term "photoselective vaporization" during prosecution, the patentee conceded that the term gave life, meaning, and vitality to the claims.

Judge Dyk further proposed that the Federal Circuit adopt a uniform rule that all preambles are limiting, and suggested that the Court should sit en banc to "eliminate this vague and confusing rule" as to when a preamble should be construed as limiting. *Id*. at 4.

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October 2010

Federal Circuit Permits Use of Industry Standards to Establish Direct Infringement

Charles D. Cathey

Judges: Lourie, Friedman, Moore (author)
[Appealed from W.D. Wis., Chief Judge Crabb]

In *Fujitsu Ltd. v. Netgear Inc*., No. 10-1045 (Fed. Cir. Sept. 20, 2010), the Federal Circuit affirmed the district court's grant of SJ of noninfringement of U.S. Patent No. 4,974,952 ("the '952 patent") for all but four models of the accused products for which evidence of direct infringement was presented. For these four models, the Court reversed the district court's SJ of no contributory and no induced infringement. The Court also affirmed the district court's grant of SJ of noninfringement of U.S. Patent No. 6,018,642 ("the '642 patent") and of U.S. Patent No. 6,469,993 ("the '993 patent").

U.S. Philips Corporation ("Philips"), Fujitsu Limited ("Fujitsu"), and LG Electronics, Inc. ("LG") own by assignment the '952 patent, the '642 patent, and the '993 patent, respectively. Each patent relates to a different aspect of wireless communication technologies. Philips's '952 patent is directed to a method for transmitting data messages in a communications network. The sole independent claim describes a method for segmenting and transmitting messages. Fujitsu's '642 patent is directed to a system for reducing power consumption in mobile devices that access wireless networks. A mobile station's wireless communication subsystem is configured to only power up in time to receive one type of beacon signal. After this signal, the mobile station is capable of receiving data for a fixed period of time called the data receive-ready ("DRR") period. If a beacon signal indicates there is no data to send to the mobile station, then the mobile station immediately powers off. LG's '993 patent is directed to a method for ensuring quality of service in a communications network. The '993 patent describes a plurality of mobile terminals each having a priority value. The base station, considering the overall traffic load, groups the priority values into batches.

The '952, '642, and '993 patents implicate two industry standards: the Institute of Electrical and Electronics Engineers 802.11 2007 Standard ("802.11") and the Wi-Fi Alliance Wireless Multi-Media Specification, Version 1.1 ("WMM").

The three plaintiffs were part of a licensing pool ("Via Licensing") that purported to include patents that any manufacturer of 802.11- and WMM-compliant products must license. Via Licensing sent a letter to Netgear Inc. ("Netgear"), offering to license a set of patents allegedly essential to the practice of the

standard. Of the patents-in-suit, this letter mentioned only the '952 patent and expressly stated that it was not alleging infringement.

After Netgear refused to take a license, Philips, Fujitsu, and LG sued Netgear, accusing it of infringement by implementing wireless networking protocols for sending and receiving messages between a base station, such as a wireless router, and a mobile station, such as a laptop. The plaintiffs moved for SJ of infringement, arguing that, by simply complying with the standards, Netgear necessarily infringed the asserted claims. The district court denied the motion, holding that the plaintiffs must show evidence of infringement for each accused product.

Philips also alleged contributory and induced infringement for two classes of products: those that only fragment messages and those that only defragment messages. The district court held that any product that complied with certain sections of the IEEE 802.11 Standard infringed the asserted claims. The district court, however, also noted that the fragmentation option is disabled by default in the accused products and required Philips to show evidence of direct infringement by users turning on the fragmentation function. Moreover, the district court held that the notice letters sent by Philips prior to the instant suit were insufficient to establish the knowledge and intent elements of contributory and induced infringement, respectively. Accordingly, the district court denied the plaintiffs' motions for SJ of infringement and granted Netgear's cross motion for SJ of noninfringement. Fujitsu, LG, and Philips appealed the construction of certain claim terms, its denial of SJ of infringement, and its grant of SJ of noninfringement.

On appeal, the Federal Circuit first considered contributory infringement of Philips's '952 patent, which requires a showing of (1) direct infringement, (2) knowledge of the patent, (3) no substantial noninfringing uses, and (4) the accused component constituting a material part of the invention. With regard to direct infringement, the Federal Circuit agreed with the district court that Philips failed to establish a genuine issue of material fact for all but four product models for which Philips had produced customer service records showing that Netgear's support staff had advised customers to activate fragmentation. The Court reminded that it is not enough to simply show that a product is capable of infringement. The patent owner must show evidence of specific instances of direct infringement, unless the claim language only requires the capacity to perform a particular claim element.

"Only in the situation where a patent covers every possible implementation of a standard will it be enough to prove infringement by showing standard compliance." Slip op. at 9.

Netgear asked the Federal Circuit to establish a rule precluding the use of industry standards in assessing infringement because it is legally incorrect to compare claims to a standard rather than directly to accused products. The Court declined to do so, holding that, if claims are construed such that the reach of the claims includes any device that practices a standard, this can be sufficient for a finding of infringement. The Court directed that, if an accused product operates in accordance with a standard, then comparing the claims to that standard is the same as comparing the claims to the accused product for purposes of infringement analysis. In cases where the relevant section of the standard is optional, and standards compliance alone would not establish that the accused infringer chooses to implement the optional section, however, the patent owner must compare the claims to the accused products or, if appropriate, prove that the accused products implement any relevant optional sections of the standard.

The Court stated that only in the situation where a patent covers every possible implementation of a standard will it be enough to prove infringement by showing standard compliance.

Next, considering the other three prongs of contributory infringement analysis, the Federal Circuit held that there were genuine issues of material fact relating to Netgear's knowledge that preclude SJ of noninfringement. The Court disagreed with Netgear that, because a user can turn off the infringing features, there are substantial noninfringing uses. Finally, the Federal Circuit agreed with the district court that the asserted claims included no defragmentation steps and therefore held that models that only defragment messages cannot constitute a "material part" of the invention. Accordingly, the Federal Circuit reversed the district court's SJ of no contributory infringement for the four accused models for which Philips showed evidence of direct infringement and affirmed SJ of no contributory infringement for all other models.

The Court also held that there are genuine issues of material fact that preclude SJ of no induced infringement, such as whether the Via Licensing letters put Netgear on notice of the allegedly infringing acts by identifying the '952 patent and 802.11-compliant products, and whether Netgear had the requisite intent to induce infringement were disputed facts. Accordingly, the Court reversed the district court's SJ of no induced infringement for the four accused models for which Philips presented evidence of direct infringement and affirmed SJ of no induced infringement for all other models.

Considering any limitation on damages, the Federal Circuit reversed the district court's decision that Philips failed to mark its products under 35 U.S.C. § 287(a), that Philips did not provide notice to Netgear prior to filing suit, that the letters from Via Licensing did not constitute adequate notice under § 287, and that because the '952 patent expired before filing of the present action, there could be no damages. The Court reiterated that the notice provisions of § 287 do not apply where the patent is directed to a process or method.

Turning to the construction of claims in Fujitsu's '642 patent, the Federal Circuit held that the proper construction of "synchronously" is "just before or at the same time," because this is the only construction consistent with the specification. The Court found the district court's construction too narrow because it required the term "synchronous" to mean "simultaneous," and would directly contradict the disclosure of the '642 patent. The Court however concluded that the district court did not err in its construction of the term "data receive-ready period" as being "a fixed period of time during which an intermittent power-on type mobile station is in its power-on state and prepared to receive data, with the period beginning immediately after the intermittent power-on type mobile station receives the first beacon signal telling it there is data to be transmitted to it."

With regard to infringement of Fujitsu's '642 patent, the Federal Circuit agreed with the district court that there was no genuine issue of material fact and that the accused products did not satisfy the DRR period limitation. The Court found that the DRR period limitation must be fixed and that Fujitsu's expert's tests established that there is no fixed period of time that the mobile station is available to receive data. The Court therefore affirmed the district court's grant of SJ of noninfringement of the asserted claims of the '642 patent.

Finally, the Federal Circuit agreed with the district court that the accused products did not infringe LG's '993 patent as a matter of law. The Court noted that the WMM specification explicitly assigns priority levels to messages, not to terminals. The Court reasoned that because the undisputed facts

demonstrate that a lower priority message may transmit before a higher priority message, it showed that the terminals did not adopt the priority level of the highest priority message. Thus, the Court affirmed the district court's grant of SJ of noninfringement, as there was no genuine issue of material fact that the accused products did not set a priority level of each of a plurality of terminals.

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Summary Judgment Vacated After Erroneous Construction of Claim Term "Backplate"

Justin A. Hendrix

Judges: Rader, Lourie, Moore (author)

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

In *Laryngeal Mask Co. v. Ambu A/S*, Nos. 10-1028, -1062 (Fed. Cir. Sept. 21, 2010), the Federal Circuit vacated the district court's SJ of noninfringement because it was based on an erroneous claim construction, and vacated the SJ of invalidity for lack of written description because genuine issues of material fact existed.

The Laryngeal Mask Company Ltd. and LMA North America, Inc. (collectively "LMA") asserted U.S. Patent No. 7,156,100 ("the '100 patent") against Ambu A/S, Ambu Inc., and Ambu Ltd. (collectively "Ambu"). The '100 patent, which is directed to a laryngeal mask airway device, contains the claim term "backplate." The district court construed "backplate" as "the relatively rigid mask structure surrounded by the cuff and including a tube joint." Finding that the accused products were integrally molded and contained no tube joint, the district court granted Ambu's motion for SJ of noninfringement. Additionally, finding a portion of claim 1 unsupported by the specification, the district court granted Ambu's motion for SJ of invalidity for lack of written description.

In determining whether the district court properly granted SJ, the Federal Circuit began by interpreting the claim term "backplate." Claim 1 recites a laryngeal mask airway device comprising a cuff attached to a backplate. But it makes no mention of an airway tube or how the backplate or mask structure might attach itself to that tube. The specification, on the other hand, contained ample discussion of a tube joint but made only a single reference to it being part of the backplate in a preferred embodiment. The Court found this single reference insufficient to require every backplate to include a tube joint. As the Court explained, a claim is generally not limited to a preferred embodiment. And though a patentee may act as his own lexicographer, the specification did not clearly indicate any intent of the patentee to give the term a unique definition. While the specification described connecting or attaching the backplate to an airway tube, it did not require that connection be made with a tube joint.

"The failure to introduce a dictionary definition for the disputed claim term

does not preclude a conclusion that there exists a plain meaning to one of skill in the art." Slip op. at 11 n.3.

Following its consideration of the specification, the Federal Circuit turned to the prosecution history. Just prior to issuance, the applicant deleted language from the claims that required the backplate to have a tube joint. The examiner subsequently allowed the claims with no objection to the deletion. Though Ambu contended that LMA deleted the tube-joint limitation in order that the claims would read on Ambu's products, the Court was not persuaded. As the Court explained, regardless of why LMA amended the claims, it would be improper to read the limitation back into them.

Turning finally to the extrinsic evidence, the Federal Circuit first noted that neither party introduced a treatise or dictionary definition for the term "backplate." But this did not preclude a conclusion that a plain and ordinary meaning existed. And, the Court continued, it certainly did not mean that the patentee must have acted as his own lexicographer. Though no dictionary definition was available, the Court found guidance for construing the term in two related prior art patents. Both listed the same inventor as the patent at issue—Dr. Brain. While both prior art patents disclosed a backplate, the Court found that neither included a tube joint. In light of this and the intrinsic evidence, the Court concluded that one of ordinary skill in the art would understand "backplate" to mean "the relatively rigid mask structure surrounded by the cuff." Because the district court based its decision on an erroneous construction, the Federal Circuit vacated the SJ of noninfringement.

The Federal Circuit next considered whether the district court erred in finding all claims of the '100 patent invalid for failing to satisfy the written description requirement. Claim 1 requires that a portion of the cuff be "thicker and stiffer than other portions of the cuff." Upon construing the phrase, the district court concluded that this reinforced portion need not be connected to the backplate. And because the specification did not describe an embodiment where the reinforced portion of the cuff was not connected to the backplate, the district court found the claims invalid. But the Federal Circuit disagreed.

As the Federal Circuit noted, the Summary of the Invention described a reinforcement incorporated into the distal end of the cuff. It also described the reinforcement extending from the backplate in a preferred embodiment. LMA's experts testified that these passages combined with a Cuff Wall Thickening Passage provided support for the invention of claim 1. Based on this evidence, the Court concluded that a genuine issue of material fact existed as to written description. The Court therefore vacated the grant of SJ of invalidity for lack of written description and remanded.

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