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Last Month at the Federal Circuit

October 2012

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No. 11-1392 (Fed. Cir. Sept. 4, 2012)

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

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[Appealed from Board]

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Nos. 11-1584, -1585, -1586

(Fed. Cir. Sept. 28, 2012)

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

Abbreviations

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

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To Prove Induced Infringement, a Patentee Must Show That All Steps of the Claimed Method Are Actually Performed, Not Just That the Accused Device Could Perform the Steps

Kevin D. Rodkey

Judges: Newman, Lourie (author), Prost (dissenting-in-part)
[Appealed from E.D. Tex., Judge Davis]

In *Mirror Worlds, LLC v. Apple Inc.*, No. 11-1392 (Fed. Cir. Sept. 4, 2012), the Federal Circuit affirmed the district court's grant of JMOL because Mirror Worlds, LLC ("Mirror Worlds") failed to provide substantial evidence to show that Apple Inc. ("Apple") itself directly infringed or induced its customers to infringe the asserted patents.

Mirror Worlds sued Apple, alleging infringement of U.S. Patent Nos. 6,006,227 ("the '227 patent"); 6,638,313 ("the '313 patent"); and 6,725,427 ("the '427 patent"), all generally directed to searching, displaying, and archiving computer files. Mirror Worlds accused certain versions of Apple's Mac OS X operating system and Apple's mobile devices running the iOS operating system of infringement. Specifically, Mirror Worlds alleged infringement based on Apple's Spotlight, Cover Flow, and Time Machine applications. Spotlight is a search and indexing application that continuously tracks all files generated in or received by the computer and allows a user to organize these indexed results based on various criteria. Cover Flow is a graphical interface that allows a user to flip through a stack of documents by manipulating a horizontal scroll bar at the bottom of the application screen. Time Machine is a backup and archiving application that allows a user to automatically archive or backup the user's files using an external hard drive.

At trial, the jury returned a verdict of direct infringement in favor of Mirror Worlds and awarded \$208.5 million in damages. In separate rulings—one at the end of Mirror Worlds' case-in-chief and another after the jury verdict—the district court entered JMOL in Apple's favor, finding that Apple was not liable as a matter of law for infringement of any of the asserted patent claims because Mirror Worlds did not provide any evidence of actual performance of the patented methods by third parties.

On appeal, the Federal Circuit considered three main issues. First, the Court discussed the asserted claims of the '313 and '427 patents against Apple's Cover Flow interface, for which Mirror Worlds relied solely on DOE. Noting that these asserted claims required two components (a cursor and a system that responds to the sliding of the cursor), the Court held that Mirror Worlds failed to show equivalence of the first component in Cover Flow. Specifically, the Court examined the testimony of Mirror Worlds' expert, who opined that although Cover Flow did not display a literal cursor, it had the equivalent, because "the user always is looking at the center [of the display] . . . , and that is where the cursor or pointer is by default." Slip op. at 11 (citation omitted). The Court determined that the testimony was inadequate because it amounted "to an argument that the absence of a feature is equivalent to its presence, which is

a negation of the doctrine of equivalents.” *Id.* Thus, the Court agreed with the district court that the evidence was insufficient to support the jury’s finding of infringement for all of the asserted claims of the ’313 and ’427 patents.

“Dr. Levy’s testimony was focused on capability, not actual use, with no discussion of inducement of infringement. It is not disputed that the Apple products *could* infringe. However, such testimony alone is not sufficient to find inducement of infringement of a method patent. Evidence of actual use of each limitation is required.” Slip op. at 17-18.

The Court next turned to asserted method claims 13 and 22 of the ’227 patent and whether they were infringed by the Spotlight application. The Court observed that infringement of the ’227 patent requires, at a minimum, searching in Spotlight, receiving data units from other computer systems (such as receiving e-mail), generating data units (sending an e-mail or creating a document), and generating a substream (“time-ordered” search results). First, the Court declined to rule on claim 22 because it was mentioned only in a footnote and had therefore not been preserved for appeal.

Next, turning to the direct infringement theory of claim 13, the Federal Circuit held that Mirror Worlds had not offered substantial evidence that Apple directly infringed the ’227 patent. Although a patentee may establish infringement by circumstantial evidence, the Court stated that Mirror Worlds must still show that Apple performed all of the steps of the claimed method. The Court rejected all of Mirror Worlds’ proffered evidence of Apple’s performance. For example, despite evidence that Apple performed the claimed method during a demonstration of Spotlight in 2005, the evidence conflicted about whether that version of the software was infringing. The Court also rejected the testimony of an Apple executive, because the circumstantial evidence did not establish that anybody at Apple had used an infringing version of the accused products to search e-mails. Finally, the Court rejected a demonstration of Spotlight during the trial because a demonstration to a jury during trial does not constitute evidence on which a claim of infringement can be based. Thus, the Federal Circuit affirmed the district court’s determination that Mirror Worlds failed to provide substantial evidence to the jury to support a verdict of direct infringement by Apple.

Finally, the Federal Circuit turned to whether Apple had induced its customers to infringe claim 13 of the ’227 patent. The Court rejected Mirror Worlds’ reliance on user manuals, software reviews, and Apple’s surveys regarding Spotlight, stating that Mirror Worlds cited no trial testimony of customers actually using each step of the method claims or tying together the various manuals, reviews, and surveys. Specifically, the Court noted that when manuals only teach each of the claimed method steps in isolation but not all of the steps together, the manuals alone cannot support induced infringement. The Court stated that the operating system can be used in a noninfringing manner and that the cited entries do not directly instruct a user how to infringe because the instructions for each of the method steps are found separately and in isolation from the other steps, and thus do not suffice for showing inducement. The Court noted that it was not disputed that Apple’s products could infringe, but such testimony alone is not sufficient to find inducement, because evidence of actual use of each limitation is required. Thus, the Federal Circuit then held that there was a lack of substantial evidence on which a jury could render a verdict of induced infringement and affirmed the district court’s grant of JMOL that Apple did not induce infringement of the ’227 patent.

Accordingly, noting that the necessary evidence was not put before the jury to support the verdict of infringement or damages, the Court affirmed the district court’s decisions in entering judgment of noninfringement.

Judge Prost dissented-in-part from the majority opinion. According to Judge Prost, under a correct reading of claim 13 of the ’227 patent, Mirror Worlds adduced sufficient evidence to allow a reasonable

jury to conclude that Apple's customers infringed the claim. In her view, the required steps are mostly performed automatically and without any need for user interaction. Judge Prost reasoned that claim 13 simply requires that a search query be run in Spotlight on a computer that contains at least one file and has received an e-mail or other type of file from another computer, and that Spotlight filters its organized database based on an inputted query. Judge Prost specifically noted that Apple's brochures and manuals encourage users to use Spotlight to search through their files, including e-mails, and that Apple taught its customers to use Spotlight to search through data that were both generated in and received by the computer. Thus, Judge Prost concluded that Mirror Worlds introduced sufficient evidence to allow a reasonable jury to find that Apple's customers used Spotlight to infringe claim 13, and dissented-in-part from the majority's opinion.

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A Negative Claim Limitation Has Adequate Written Description If the Specification Provides a Reason to Exclude the Limitation

*Xiaoxiao Xue**

Judges: Rader, Newman (concurring-in-part and dissenting-in-part), Moore (per curiam)
[Appealed from D. Del., Chief Judge Sleet]

In *Santarus, Inc. v. Par Pharmaceutical, Inc.*, Nos. 10-1360, -1380 (Fed. Cir. Sept. 4, 2012), the Federal Circuit reversed the district court's findings of inadequate written description and obviousness as to certain claims, and affirmed the district court's findings of obviousness as to certain other claims and no inequitable conduct.

Santarus, Inc. ("Santarus") is the exclusive licensee of patents directed to specified formulations of benzimidazole proton pump inhibitors ("PPI"), assigned to the University of Missouri ("the University"). Santarus markets the PPI product omeprazole under the brand name Zegerid® and sued Par Pharmaceutical, Inc. ("Par") based on Par's filing of an ANDA with the FDA to sell a generic counterpart of the Zegerid® products.

The district court found that Par's ANDA products would infringe the patents, but concluded that all of the asserted claims were invalid for obviousness and that some of the claims were invalid for inadequate written description. On the defense of unenforceability, the district court found no inequitable conduct by the inventor, the University, or their counsel in procuring the patents. Santarus and Par cross-appealed.

On appeal, the Federal Circuit affirmed the district court's ruling that inequitable conduct was not established, noting that it was in accord with the Court's decision in *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (en banc).

"Negative claim limitations are adequately supported when the specification describes a reason to exclude the relevant limitation. Such written description support need not rise to the level of disclaimer. In fact, it is possible for the patentee to support both the inclusion and exclusion of the same material." Slip op. at 12.

The Federal Circuit reversed the district court's determination that certain claims of U.S. Patent No. 7,399,772 ("the '772 patent") were invalid for lack of written description. The district court found that because the claims included the clause "wherein the [pharmaceutical] composition contains no sucralfate," it was necessary for the patent specification to include evidence demonstrating that sucralfate is "contraindicated." Slip op. at 12. The Federal Circuit disagreed, noting that claims may be restricted to

a preferred use by excluding alternatives. The Court held that “[n]egative claim limitations are adequately supported when the specification describes a reason to exclude the relevant limitation,” and that “[s]uch written description support need not rise to the level of disclaimer.” *Id.* “In fact, it is possible for the patentee to support both the inclusion and exclusion of the same material.” *Id.* The Court concluded that the negative claim limitation was adequately supported by statements in the specification expressly listing the disadvantages of using sucralfate.

The Federal Circuit also reversed the district court’s decision that certain asserted claims could not claim priority to an earlier patent, because the district court’s only reason for its finding was that there was no written description for the “no sucralfate” limitation. The Court noted that Santarus did not appeal the district court’s priority determination as to some of the claims, and thus considered the claims as two groups: those where the earlier patent was prior art, and those where the earlier patent was not prior art.

The Federal Circuit held that the district court correctly found that the earlier patent would have rendered obvious all claims to which it was prior art. The Court rejected Santarus’s argument that the earlier patent did not disclose nonenteric coated PPIs and buffer within the claimed ratios, noting that the earlier patent’s disclosed ranges overlapped with the claimed ranges. The Court also rejected Santarus’s argument that the claims reciting specific blood serum concentrations of PPI would have been nonobvious. The Court found that the initial blood serum concentration resulting from administering a PPI dosage is an inherent property of the formulation, and that “an obvious formulation cannot become nonobvious simply by administering it to a patient and claiming the resulting serum concentrations.” *Id.* at 18. “To hold otherwise would allow any formulation—no matter how obvious—to become patentable merely by testing and claiming an inherent property.” *Id.*

Regarding the claims to which the earlier patent was not prior art, the Federal Circuit affirmed the district court’s obviousness decision with regard to some claims and reversed it with regard to others. The Court first found that Santarus was partly correct in arguing that the prior art taught away from the claimed invention. The Court reversed the obviousness finding of certain claims since the prior art’s explicit “ruling out” of the claimed nonenteric coated forms would discourage a person of ordinary skill in the art from pursuing such forms. But the Court affirmed other claims as obvious since the prior art would not teach away from all nonenteric coated forms. The Court pointed out that “[d]escribing [the powder formulations] as ‘second best’ is not a ‘clear discouragement,’ as is required by our precedent.” *Id.* at 22. The Court also found that Santarus’s objective evidence was insufficient to overcome the obviousness of those claims.

Judge Newman dissented, stating that “[t]he court’s new rulings are contrary to statute, precedent, and common sense.” Newman Dissent at 2. In Judge Newman’s view, the majority creates a new written description requirement for limitations in claims, holds that the disclosure in a parent patent is a reference against the common disclosure in a CIP patent, and holds that most of the claims-in-suit are invalid for obviousness over references that explicitly teach away from the claimed inventions.

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Grant of SJ That Prior Art References Are Not “Analogous Art” Affirmed

Kevin D. Rodkey

Judges: Newman, Lourie (author), Prost
[Appealed from D. Utah, Judge Campbell]

In *K-TEC, Inc. v. Vita-Mix Corp.*, Nos. 11-1244, -1484, -1512 (Fed. Cir. Sept. 6, 2012), the Federal Circuit affirmed the district court’s SJ determinations that Vita-Mix Corporation (“Vita-Mix”) infringed the asserted patents, that two prior art references were not analogous art for purposes of obviousness, that substantial evidence supported the jury’s findings that the asserted claims were not invalid, that Vita-Mix’s infringement was willful, and that K-TEC, Inc. (“K-TEC”) was entitled to damages.

K-TEC owns U.S. Patent Nos. 6,979,117 (“the ’117 patent”) and 7,281,842 (“the ’842 patent”), which are directed to blending systems having a specific geometry. The claimed geometry includes a four-walled container also having a fifth truncated wall to reduce cavitation during blending. The fifth truncated wall is positioned between two of the side walls, in essence “truncating” one of the corners, to create a five-sided container. The shared specification of the ’117 and ’842 patents discloses that the truncated wall may be planar or curved. After K-TEC began selling blenders with this geometry, Vita-Mix introduced its “MP” containers in 2003, which Vita-Mix personnel admitted were copies of K-TEC’s five-sided container. K-TEC notified Vita-Mix in March 2005 that the MP containers infringed the parent of the ’117 and ’842 patents. Vita-Mix attempted to design around the ’117 patent and, after considering over a dozen noninfringing designs, Vita-Mix decided on the “XP” container design in which the fifth wall was curved instead of flat. After altering the design, Vita-Mix maintained the same part numbers for the XP containers as it had for the MP containers, and concluded that most customers would “never even notice the change.” Slip op. at 7 (citation omitted).

K-TEC sued Vita-Mix for infringement of the ’117 patent by Vita-Mix’s MP containers and of the ’842 patent by the XP containers. The district court construed the “fifth truncated wall” limitation to mean “a wall (planar or non-planar) that truncates, in essence, the typical corner that would otherwise be formed between two side walls.” *Id.* (citation omitted). The district court also granted K-TEC’s motion for SJ that the XP containers infringed the asserted claims. The district court partially granted K-TEC’s motion that the asserted claims are not invalid because two prior art references, referred to as “Hobbs” and “Grimes,” are not analogous art. The district court subsequently clarified its construction of the fifth truncated wall to explain that “the term ‘typical corner’ refers to a corner that, but for the addition of the truncated wall, would otherwise be typical—or in other words identical—to the other corners of the blending jar.” *Id.* at 8 (citation omitted). A jury found in favor of K-TEC on all issues of invalidity, willfulness, and damages, and the district court denied Vita-Mix’s post-trial motions. Vita-Mix appealed.

On appeal, the Federal Circuit first addressed the district court’s grant of SJ that the XP containers infringed the asserted claims. The Court rejected Vita-Mix’s argument that its expert testimony showed

that, under the court's construction, the XP container had only three walls, not four side walls and a fifth truncated wall, as recited in the asserted claims. The Federal Circuit concluded that there was no genuine dispute that the XP container has four side walls and a fifth truncated wall, and, therefore, there was no genuine dispute that the XP container's geometry falls within the asserted claims.

“To qualify as prior art for an obviousness analysis, a reference must qualify as ‘analogous art,’ i.e., it must satisfy one of the following conditions: (1) the reference must be from the same field of endeavor; or (2) the reference must be reasonably pertinent to the particular problem with which the inventor is involved.” Slip op. at 15.

Next, the Federal Circuit turned to the district court's SJ determination that Grimes and Hobbs are not analogous art for purposes of invalidity. The Court rejected Vita-Mix's arguments because Vita-Mix did not dispute that Hobbs and Grimes are not the same field of endeavor as the asserted patents, and because Vita-Mix failed to raise a genuine issue of material fact that the references would have been reasonably pertinent to the inventor in considering the problem to be solved. The Court concluded that it was Vita-Mix's burden to proffer evidence that a reasonable juror could find the asserted patents invalid and that Vita-Mix failed to meet that burden.

The Federal Circuit then concluded that the district court did not deny Vita-Mix a fair trial on four grounds set forth by Vita-Mix: (1) the district court instructed the jury that the PTO considered an “Ash” reference, when the PTO did not consider it during prosecution, only during an ongoing reexamination; (2) the district court changed its construction of the claim term “truncated wall” prior to trial; (3) the district court allowed K-TEC to cross-examine Vita-Mix's witness using the prosecution history from one of the witness's related patents; and (4) the district court erred in instructing the jury regarding a “Miller” reference.

Next, the Federal Circuit considered whether the district court erred in denying Vita-Mix's motion that the Ash reference invalidated the asserted claims as a matter of law. The Court agreed that Vita-Mix was not entitled to JMOL because K-TEC presented substantial evidence from which the jury could find that Ash did not disclose the “fifth truncated wall.” The Court identified, as examples, testimony from K-TEC's expert that the walls in Ash did not truncate an otherwise typical corner, and that even if there were truncated walls, the Ash reference would then fail to disclose corners formed by the four sidewalls because the reference would contain only truncated corners. The Court therefore reasoned that Ash did not anticipate the claims of the asserted patents. The Court also rejected Vita-Mix's argument that Ash rendered the asserted claims obvious because it would have been obvious to modify the Ash reference to add a handle. Thus, the Court upheld the district court's denial of Vita-Mix's motion for JMOL that the asserted claims are invalid.

The Court next rejected Vita-Mix's argument that the district court erred in denying JMOL that Vita-Mix did not willfully infringe the asserted patents. Specifically, the Court observed that K-TEC had presented evidence that Vita-Mix's original MP container was a direct copy of K-TEC's five-sided jar and that the XP container contained only a trivial change. The Court also noted that K-TEC proffered evidence that Vita-Mix did not opt for one of its numerous noninfringing designs, instead adopting a design that functioned in the same way as the MP containers, and was a design that its customers would not be able to distinguish from the MP container. The Court further observed that K-TEC presented evidence that Vita-Mix knew of the objectively high risk of infringing K-TEC's patents. The Federal Circuit therefore upheld the district court's determination of willful infringement.

Finally, the Federal Circuit held that the district court did not err in denying Vita-Mix's motion for JMOL that K-TEC failed to adequately prove damages dating back to December 2005. The Court stated that K-TEC provided notice that the MP containers infringed the parent of the '117 patent in March 2005, that

K-TEC provided evidence that the MP container infringed the '117 patent in October 2005, that Vita-Mix had actual notice of infringement of the '117 patent when the patent issued in December 2005, and that Vita-Mix treated the MP and XP products as related. Based on this evidence, the Court determined that the district court did not err in denying Vita-Mix's motion for JMOL on damages.

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After *Therasense*, Knowledge of a Reference's Materiality Does Not Prove an Intent to Deceive the PTO

Justin E. Loffredo

Judges: Rader, Linn (author), Wallach
[Appealed from D. Nev., Judge Mahan]

In *1st Media, LLC v. Electronic Arts, Inc.*, No. 10-1435 (Fed. Cir. Sept. 13, 2012), the Federal Circuit reversed the district court's grant of DJ of inequitable conduct and the district court's finding that U.S. Patent No. 5,464,946 ("the '946 patent") is unenforceable.

1st Media, LLC ("1st Media") owns the '946 patent, which is directed to an entertainment system used in purchasing and storing multimedia karaoke information. The '946 patent names Dr. Scott Lewis as the inventor. Lewis's lawyer, Joseph Sawyer, filed and prosecuted the application that led to the '946 patent. While the '946 patent was pending, Sawyer prosecuted the following three patent applications for related inventions made by Lewis: International Patent Application No. PCT/US93/10930 ("the PCT application"); the application that became U.S. Patent No. 5,325,423 ("the '423 patent"); and the application that became U.S. Patent No. 5,564,001 ("the '001 patent"). During examination of the PCT application, a European patent examiner rejected it, citing as the closest prior art International Publication WO 90/01243 ("Bush"). While examining the application that led to the '423 patent, a U.S. examiner rejected several claims as anticipated by U.S. Patent No. 5,027,400 ("Baji"). During examination of the application that led to the '001 patent, a U.S. examiner rejected claim 1 as obvious in view of U.S. Patent No. 5,220,420 ("Hoarty"). During prosecution of the '946 patent, neither Lewis nor Sawyer ever disclosed the Bush, Baji, or Hoarty references (collectively "the three references") to the PTO, and the PTO did not consider the three references.

1st Media sued Electronic Arts, Inc. ("Electronic Arts") for infringement of the '946 patent. Electronic Arts asserted an inequitable conduct defense, based in part on 1st Media's failure to cite the three references, and counterclaimed for DJ of inequitable conduct.

At trial, Lewis and Sawyer both testified that they did not appreciate the materiality of the three references. Specifically, Lewis testified that "nondisclosure of the Bush reference was 'an oversight that got lost in the cracks at that time and wasn't a conscious decision not to report [it].'" Slip op. at 6 (alteration in original) (citation omitted). Sawyer testified that while he was prosecuting the '946 patent, he had newly set up a solo office out of his home, and his practice at that time was very active. Both Lewis and Sawyer further testified that the technology in the applications that led to the '423 and '001 patents was so distinct from the '946 patent that it did not occur to them to disclose Baji or Hoarty during prosecution of the '946 patent. The district court concluded that these explanations were not credible and that Lewis and Sawyer knew that the references were material. The district court then inferred intent to deceive the PTO during prosecution of the '946 patent and held the '946 patent

unenforceable for inequitable conduct.

“Knowledge of the reference and knowledge of materiality alone are insufficient after *Therasense* to show an intent to deceive.” Slip op. at 12.

On appeal, the Federal Circuit reversed the district court based on the standard set forth in *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011) (en banc). The Court noted that under *Therasense*, to find inequitable conduct “absent affirmative egregious misconduct, a defendant must prove by clear and convincing evidence both of the ‘separate requirements’ that: (1) ‘the patentee acted with the specific intent to deceive the PTO’; and (2) the non-disclosed reference was but-for material.” Slip op. at 8 (citing *Therasense*, 649 F.3d at 1290-91). For requirement (1), a defendant must prove the following three elements: that the applicant knew of the reference, knew that it was material, and “*made a deliberate decision to withhold it.*” *Id.* (quoting *Therasense*, 649 F.3d at 1290). The Court noted that post-*Therasense*, a court can no longer infer intent to deceive from nondisclosure of a reference solely because that reference was known and material. Moreover, a patentee does not need to provide any good-faith explanation for his or her conduct unless and until an accused infringer has met his or her burden to prove an intent to deceive by clear and convincing evidence.

Because the district court issued its opinion before the Federal Circuit’s *Therasense* opinion, the Federal Circuit applied the *Therasense* standard in reversing the district court’s finding that Lewis and Sawyer committed inequitable conduct. Although Electronic Arts admitted that it had no direct evidence that Lewis or Sawyer intended to deceive the PTO, it argued that the way in which Lewis and Sawyer became aware of the references, coupled with statements they made during prosecution of the ’946 patent, demonstrated the necessary mens rea to infer a deliberate decision to withhold the references. Rejecting Electronic Arts’ arguments, the Court reiterated that knowledge of the reference and knowledge of materiality alone are insufficient after *Therasense* to show an intent to deceive. Nor is it enough to argue carelessness, lack of attention, poor docketing, or anything else that might be considered negligent or even grossly negligent. The Court distinguished *Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324 (Fed. Cir. 2012), in which there was affirmative conduct by the applicants showing not only specific awareness of materiality, but “careful and selective manipulation of where, when, and how much of the most material information to disclose.” Slip op. at 13-14. Evidence of such selective disclosure was not present in the instant case.

Regarding the Bush reference, although Lewis testified that he now thinks that Bush is relevant, the record did not support the inference that Lewis and Sawyer deliberately chose to withhold Bush. Similarly, the Court explained that there was “simply no evidence” in the record that either Lewis or Sawyer deliberately withheld the Baji or Hoarty references from the PTO during the prosecution of the application that led to the ’946 patent, and there can be no inference that Lewis or Sawyer intended to deceive the PTO. *Id.* at 15-16.

Accordingly, the Court reversed both the district court’s grant of DJ of inequitable conduct and the district court’s finding that the ’946 patent was unenforceable.

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DJ Plaintiff Licensee Bears Burden of Proving Noninfringement Where DJ Defendant Licensor Cannot File DJ Counterclaim Under the License

Victoria S. Lee

Judges: Lourie, Linn (author), Prost
[Appealed from D. Del., Judge Robinson]

In *Medtronic Inc. v. Boston Scientific Corp.*, Nos. 11-1313, -1372 (Fed. Cir. Sept. 18, 2012), the Federal Circuit vacated the district court's judgment of noninfringement and determination that Mirowski Family Ventures, LLC's ("MFV") U.S. Reissue Patent Nos. RE38,119 ("the RE'119 patent") and RE39,897 ("the RE'897 patent") (collectively "the patents-in-suit") were valid because the district court relied on a legally incorrect allocation of the burden of proof in its findings and incorrectly construed the claim terms in question.

The patents-in-suit cover a cardiac resynchronization therapy ("CRT") device used for treating heart conditions, such as congestive heart failure. Medtronic, Inc. ("Medtronic") entered into a sublicense agreement covering the RE'119 patent. The sublicense provided Medtronic the right to challenge the RE'119 patent's validity, enforceability, and scope via a DJ action. A Litigation Tolling Agreement ("LTA") was subsequently executed that obligated MFV to inform Medtronic of which Medtronic products MFV believed to be covered by the RE'119 patent (or patents claiming priority from the RE'119 patent (e.g., the RE'897 patent)), and were subject to royalty payments. Under the LTA, if Medtronic disagreed, Medtronic maintained the right to retain its license but was obligated to seek a DJ of noninfringement. MFV identified several Medtronic products that MFV thought practiced its patents. Pursuant to the LTA, Medtronic then filed the complaint for the instant DJ action.

At the trial court, the parties disagreed over whether MFV, the patentee, bore the burden of proving infringement, or whether Medtronic, the DJ plaintiff, bore the burden of proving noninfringement. The district court concluded that the burden is always on the patentee to show infringement, and, thus, MFV bore the burden of proof by a preponderance of the evidence. The district court found that MFV failed to prove infringement (both literal and under the DOE) based on deficiencies in MFV's expert report. The district court also construed certain preamble terms in the patents-in-suit as being limited specifically to the treatment of congestive heart failure, relying on portions of the specification.

"A contrary result would allow licensees to use *MedImmune's* shield as a sword—haling licensors into court and forcing them to assert and prove what had already been resolved by license. Because the declaratory judgment plaintiff is the only party seeking the aid of the court in the circumstances presented here, that party must bear the burden of persuasion." Slip op. at 12.

On appeal, the Court first considered which party bore the burden of proving infringement. MFV argued that because Medtronic was the DJ plaintiff, Medtronic bore the burden of proving noninfringement. MFV further argued that the terms of the LTA precluded it from counterclaiming for infringement and the district court erred because MFV did not technically assert infringement. In agreeing with MFV, the Court recognized that, under *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 134 (2007), a licensee making royalty payments pursuant to a license should not be forced to cease payments and risk infringement liability before the licensee can challenge the extent of coverage of the license. Thus, *MedImmune* shielded licensees from economic consequences “while enabling those licensees to file declaratory judgment suits to clarify the rights and obligations of the parties under their license agreements.” Slip op. at 8. The Court recognized that in customary DJ actions, a DJ defendant must assert a counterclaim for infringement, as such a counterclaim is compulsory, and that the burden is on the counterclaiming defendant to show infringement.

Here, however, the Court found that the continued existence of the license, as sanctioned by *MedImmune*, precluded MFV from asserting an infringement counterclaim, distinguishing from customary DJ actions. The Court noted that Medtronic sought relief relating directly to its contractual obligations under the license, while MFV sought nothing more than to be permitted to continue the quiet enjoyment of its contract. The Court found that because Medtronic was the party seeking disturbance of “the status quo ante” in seeking relief from liability under the license and the only party seeking aid from the courts, Medtronic had the burden to present evidence that it was entitled to such relief. *Id.* at 11. Accordingly, the Court reversed the district court’s decision, holding that in “the limited circumstance when an infringement counterclaim by a patentee is foreclosed by the continued existence of a license, a licensee seeking a declaratory judgment of noninfringement and of no consequent liability under the license bears the burden of persuasion.” *Id.* at 12. Thus, the Court held that MFV did not have the burden of proof and the district court’s holding that the defendants failed to prove infringement could not stand.

The Court then addressed the district court’s claim construction. The Court agreed with Medtronic and found that the district court erred by restricting the claimed invention to the treatment of congestive heart failure. The Court noted that the specification discloses the use of the invention to treat other diseases besides congestive heart failure, and the district court’s claim construction was improper. The Court therefore vacated the district court’s determination of no invalidity predicated on the improper claim construction.

Accordingly, the Court remanded the case for additional proceedings consistent with the Court’s opinion.

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Obviousness by Combination of References Is Not Undermined by Inventor's Declarations to the Contrary

*Steven C. Rushing**

Judges: Newman, Moore (author), O'Malley
[Appealed from Board]

In *In re Droge*, No. 11-1600 (Fed. Cir. Sept. 21, 2012), the Federal Circuit affirmed the Board's decision rejecting an independent claim of U.S. Patent Application No. 10/082,772 ("the '772 application") as obvious over the prior art.

Assigned to Peter Droge, Nicole Christ, and Elke Lorbach (collectively "Droge"), the '772 application is directed to recombining DNA in eukaryotic cells through various methods and combinations. This is accomplished by using a special virus containing a protein that facilitates the sequence-specific recombination of DNA at a predetermined location on the target cell's DNA. The '772 application teaches this method by use of modified integrases Int-h and Int-h/218 instead of naturally occurring (wild-type) integrases, as previously used.

During examination, the PTO rejected the independent claim as obvious over two prior art references. Specifically, the examiner cited a prior patent that taught the use of wild-type integrases and an article written by two of the inventors of the '772 application. Droge appealed to the Board, arguing that the claim was not obvious because a person of ordinary skill in the art would not have had a reasonable expectation of success in using the wild form of the virus to induce recombination in eukaryotic cells. Applying the teaching of the prior art to the claim, the Board found that it would have been obvious over the combination of the references.

"Obviousness does not require absolute predictability of success . . . all that is required is a reasonable expectation of success." Slip op. at 8 (alteration in original) (quoting *In re Kubin*, 561 F.3d 1351, 1360 (Fed. Cir. 2009)).

On appeal, the Federal Circuit faced the issue of whether there was a reasonable expectation of success sufficient to combine the teachings in the two references. According to Droge, although the use of modified integrases had been shown to facilitate recombination in prokaryotic cells, a person reasonably skilled in the art would not expect the same result in eukaryotic cells. Droge also argued that the article reference taught away from the claimed invention and the Board erred in holding otherwise. Additionally, Droge relied on a declaration from one of the inventors, concluding that a person skilled in the art would not expect success from the combination of the references because it was unclear at the time of invention whether that combination would work.

In response to Droge's argument, the Court first noted that the patent reference revealed that wild-type Int can induce DNA recombination in both eukaryotic and prokaryotic cells. The Court then agreed that the patent reference did not teach the use of the modified integrases Int-h and Int-h/218 as claimed in the '772 application. However, the Court found that the article written by two of the inventors did teach this element and provided the motivation for doing so in the manner prescribed in the rejected claim. Specifically, the Court held that "[t]he article *directly* contradicts the assertion in the Droge Declaration that a skilled artisan would not expect the modified integrases Int-h and Int-h/218 to work in eukaryotic cells based on the three-dimensional structure of DNA in those cells." Slip op. at 7.

Therefore, the Court found that the method in the rejected claim would have been obvious to a person skilled in the art. The Court affirmed the Board's decision that the '772 application was obvious over the prior art and found no merit in all remaining arguments.

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Even If Statement Associated with Small Entity Fee Payment Is Per Se Material, Court Finds No Evidence of Intent to Deceive the PTO

*Alice Wang**

Judges: Newman (concurring-in-part and dissenting-in-part), Prost, O'Malley (per curiam)
[Appealed from N.D. Ga., Senior Judge Evans]

In *Outside the Box Innovations, LLC v. Travel Caddy, Inc.*, No. 09-1171 (Fed. Cir. Sept. 21, 2012), the Federal Circuit reversed the district court's judgment of unenforceability based on inequitable conduct, affirmed judgments related to infringement, vacated and remanded for redetermination of obviousness, and remanded for determination of a remedy for infringement.

Outside the Box Innovations, LLC, doing business as Union Rich USA ("Union Rich"), brought a DJ patent suit against Travel Caddy, Inc. ("Travel Caddy") and its distributor/sales agent Rooster Products ("Rooster") regarding cases for carrying tools. The district court held that Travel Caddy's U.S. Patent No. 6,823,992 ("the '992 patent") and its continuation, U.S. Patent No. 6,991,104 ("the '104 patent"), are unenforceable due to inequitable conduct. The district court also held some claims of the '104 patent and all the claims of the '992 patent invalid on the ground of obviousness. The district court further held on SJ that the version of the Union Rich tool carry case called the Electricians Carryalls ("Electricians Bag I") infringes various patent claims, but that a modified version, called the Electricians Bag II, and the tool carry case, called the Heavy-Duty ProTool Bag, do not infringe. The district court also dismissed Union Rich's unfair competition claims against Travel Caddy.

On appeal, the Federal Circuit first addressed the issue of enforceability of the '992 and the '104 patents. The district court found inequitable conduct on two grounds: Travel Caddy's failure to disclose to the PTO the '992 patent litigation during the prosecution of the '104 patent, and its allegedly incorrect claim of "small entity" status in the PTO. The Court rejected both grounds and reversed the judgment of unenforceability.

"Where there is no evidence that small entity status was deliberately falsely claimed, a finding of unenforceability is inappropriate. Importantly, the regulations do not contemplate that an incorrect claim of small entity status, with no evidence of bad faith, is punishable by loss of the patent." Slip op. at 13.

With regard to Travel Caddy's failure to disclose to the PTO the '992 patent litigation, the Federal Circuit found neither but-for materiality nor specific intent to deceive the examiner into granting the '104 patent application. Specifically, the Federal Circuit concluded that no information relevant to patentability of the

'104 patent application had been provided in the '992 patent litigation while the '104 patent application was pending. The Court further concluded that no ground of invalidity was included in the complaint against the '992 patent or communicated informally despite Travel Caddy's inquiries. Indeed, Travel Caddy's patent attorney testified that he did not file a notice of the '992 patent litigation in the prosecution of the '104 patent application because "[t]here was nothing in there that was what I understood to be material under Rule 56. There was nothing that related to patentability, enforceability or validity." Slip op. at 6 (alteration in original) (citation omitted).

The Federal Circuit turned next to Travel Caddy's allegedly incorrect claim of small entity status. The district court held that small entity status was not available to Travel Caddy, although it met the small entity definition of having fewer than 500 employees, because of Travel Caddy's commercial arrangement with Rooster, which had more than 500 employees, including its Mexican affiliates. The issue was whether a certain provision of a sales agreement between Travel Caddy and Rooster amounted to a patent license for purposes of evaluating small entity status under 37 C.F.R. § 1.27(a)(2), or merely offered protection to Rooster to obtain an alternative supply if Travel Caddy failed to provide the product. The Court declined to characterize the agreement provision. Instead, the Court concluded that, even if a false assertion of small entity status were per se material, here, there was no clear and convincing evidence that anyone involved in the patent prosecution knew that a patent license had been granted to a large entity and deliberately withheld that information in order to pay small entity fees. For these reasons, the Court reversed the district court's ruling of unenforceability due to inequitable conduct.

Next, the Federal Circuit addressed the validity of the '992 and the '104 patents. Union Rich offered attorney argument that combinations of five references rendered both patents obvious. Travel Caddy sought to rebut this argument through the testimony of an expert witness with experience in the relevant technical field. The district court, however, prevented the expert witness from testifying because he was not a lawyer. The district court then ruled that Travel Caddy's structure "was an obvious solution to simple problems inherent in the prior art patents." *Id.* at 15 (citation omitted). Applying Eleventh Circuit law, the Federal Circuit found that the district court had abused its discretion in excluding the testimony of the expert. Specifically, the Court stated that "the exclusion of a technical expert for the reason that he is not a lawyer is contrary to Federal Rule of Evidence 702 and the benefits of technological assistance in resolution of technological issues." *Id.* at 17. Accordingly, the Court vacated the district court's invalidity decision and remanded for redetermination of the issue of obviousness on the entirety of the evidence, including expert testimony.

The Federal Circuit next considered issues of infringement. The district court construed thirteen claim terms, and the Federal Circuit had previously reviewed the construction of these terms in an interlocutory appeal from the denial of Travel Caddy's request for a preliminary injunction. Travel Caddy argued that the district court's previous claim construction was not final and that claim constructions rendered on appeal from a preliminary injunction ruling are not binding on the Federal Circuit. The Court agreed that, generally, the tentative claim construction for preliminary injunction purposes does not remove the issue from later review after the facts are elaborated, but found some merit in Union Rich's argument that, because the district court's claim construction decision was issued after a full *Markman* hearing and the parties had not identified any new factual findings, the Federal Circuit's prior decision affirming the district court's claim construction constituted law of the case. The Court declined to decide this issue, affirming the constructions on other grounds. In so doing, the Court held that Figure 4 of the '104 patent is the only figure depicting the binding used in the claimed invention. The Court affirmed (1) the unchallenged judgment of infringement by Union Rich's Electricians Bag I; and (2) the judgment of noninfringement by the Heavy-Duty ProTool Bag and the Electricians Bag II. The Court remanded for determination of remedy with respect to infringement by the Electricians Bag I.

Judge Newman concurred-in-part and dissented-in-part with the majority's decision. Judge Newman first disagreed that a misstatement of small entity status was per se material to patentability, and thus could render the patent permanently unenforceable for inequitable conduct. Judge Newman explained that the

immateriality of an affidavit that is not the basis of the patent grant was long ago established by precedent. Second, in Judge Newman's view, the panel majority was incorrect in suggesting that pretrial claim construction on interlocutory appeal of a preliminary injunction was "law of the case" and could not be reviewed on final appeal. Finally, Judge Newman disagreed that the accused Heavy-Duty ProTool Bag does not infringe the '104 patent. According to Judge Newman, "The panel majority construes the claims of the patents to exclude the bag in Figure 10, and thus to exclude infringement by the bag that Union Rich copied from Travel Caddy's embodiment of Figure 10" Newman op. at 7-8.

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Jurisdiction for a DJ Patent Action Requires Sufficient Immediacy and Reality

Jeffrey D. Smyth

Judges: Radar, Mayer (author), Schall
[Appealed from W.D. Pa., Judge Fischer]

In *Matthews International Corp. v. Biosafe Engineering, LLC*, No. 12-1044 (Fed. Cir. Sept. 25, 2012), the Federal Circuit affirmed the district court's determination that the dispute lacked sufficient immediacy and reality to support the exercise of DJ jurisdiction.

Matthews International Corporation ("Matthews") manufactures and sells cremation equipment, caskets, and bronze memorials, including a Bio Cremation™ product that uses an "environmentally friendly" alkaline-hydrolysis process rather than incineration for cremation. Biosafe Engineering, LLC and Digester, LLC (collectively "Biosafe") hold several patents related to the application of alkaline hydrolysis to the disposal of various types of waste, including five method patents ("the Method Patents") and one system patent ("the System Patent").

Matthews filed suit against Biosafe, seeking a DJ of noninfringement, invalidity, and unenforceability of the Method Patents. Matthews later amended its complaint to include the System Patent. At the time of the amended complaint, Matthews had sold three Bio Cremation™ units, but none of them had been installed by its customers. Matthews's suit also included state-law claims of trade libel, defamation, and tortious interference with contractual relations. The district court granted Biosafe's motion to dismiss for lack of DJ jurisdiction and for failure to adequately plead the state-law claims. Matthews appealed.

"Until some specific and concrete evidence regarding how Matthews' customers plan to use the cremation units is available, any judicial determination regarding whether such use would infringe the Method Patents would be premature." Slip op. at 9-10.

On appeal, the Federal Circuit held that the trial court correctly concluded that Matthews's dispute with Biosafe lacked the requisite immediacy and reality to support the exercise of DJ jurisdiction. The Court stated that "in determining whether a justiciable controversy is present, the analysis must be calibrated to the particular facts of each case, with the fundamental inquiry being 'whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" Slip op. at 7-8 (quoting *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007)).

Regarding "immediacy," the Federal Circuit found that there was no evidence as to when, if ever, the

Bio Cremation™ equipment would be used in a manner that could potentially infringe the Method Patents. The Court noted that none of the three units sold by Matthews had been installed, and that there were noninfringing uses of the equipment. “Until some specific and concrete evidence regarding how Matthews’ customers plan to use the cremation units is available, any judicial determination regarding whether such use would infringe the Method Patents would be premature.” *Id.* at 9-10.

The Federal Circuit likewise found that the dispute failed to meet the reality requirement for DJ jurisdiction. The Court reasoned that the Bio Cremation™ equipment could be operated using noninfringing processes, and that there was no indication that Matthews’s customers had settled upon a fixed protocol for using it. “Because Matthews’ technology is ‘fluid and indeterminate’ rather than ‘substantially fixed,’ its dispute with Biosafe lacks the requisite reality to support the exercise of declaratory judgment jurisdiction.” *Id.* at 12 (citing *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 882 (Fed. Cir. 2008)).

The Federal Circuit also held that the district court properly determined it had no jurisdiction over the System Patent. The Court explained that “because the trial court had no jurisdiction over the Method Patents at issue in Matthews’ original complaint, it was without authority to consider the System Patent which issued after that complaint was filed.” *Id.* at 13-14. “It has long been the case that the jurisdiction of the court depends upon the state of things at the time of the action brought.” *Id.* at 14 (quoting *Grupo Dataflux v. Atlas Global Grp., L.P.*, 541 U.S. 567, 570-71 (2004)).

Regarding the state-law claims, the Federal Circuit held that Matthews failed to plead the bad-faith element necessary to support its claims. “Even assuming *arguendo* that Biosafe made infringement allegations, . . . there is no evidence that such allegations were objectively baseless.” *Id.* at 14-15. The Court noted that the state-law claims would not have been ripe for review even if the required bad-faith element had been pleaded properly, because there was no specific evidence regarding the operating parameters for the Bio Cremation™ units.

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A “Clear Disavowal” in a Patent Specification Is Not Required to Disclaim Claim Scope

Pier D. DeRoo

Judges: Lourie, Prost (author), Wallach
[Appealed from Board]

In *In re Abbott Diabetes Care Inc.*, Nos. 11-1516, -1517 (Fed. Cir. Sept. 28, 2012), the Federal Circuit vacated-in-part the Board’s final rejection of numerous claims in the ex parte reexamination of U.S. Patent Nos. 6,175,752 (“the ’752 patent”) and 6,565,509 (“the ’509 patent”) due to the Board’s unreasonably broad claim construction. The Court also vacated the Board’s official notice rejections based on the PTO’s concession that they should be withdrawn.

The ’752 and ’509 patents describe methods and devices for monitoring glucose levels in the blood stream for diabetics. Both claim inventions comprising, in addition to other features, an “electrochemical sensor.” The ’752 and ’509 patents share a common specification, which disparages electrochemical sensors in the prior art because they employ external cables and wires that hinder the convenient use of these devices for everyday applications. The ’509 patent claims also recite the additional limitation that the electrochemical sensor in the claims must be in a “substantially fixed” position.

During reexamination, the examiner finally rejected all of the claims under reexamination as indefinite, anticipated, or obvious over various references, and Abbott Diabetes Care, Inc. (“Abbott”) appealed to the Board. In construing the “electrochemical sensor” claim element, the Board noted that the specification criticizes external cables and wires, and that none of the embodiments in the ’752 and ’509 patents include external cables or wires. But the Board determined that the absence of any explicit disclaimer meant that the broadest reasonable interpretation in light of the specification included the external cables and wires present in the prior art. The Board also determined that the “substantially fixed” limitation in the ’509 patent would be understood to “allow some movement of the sensor.” Slip op. at 7 (citation omitted). Applying these claim constructions, the Board found that the lead wires of the prior art are part of the electrochemical sensor and that the wires are “somewhat restrained in movement, and are therefore ‘substantially fixed.’” *Id.* at 9 (citation omitted). Thus, the Board affirmed all of the examiner’s rejections and rejected Abbott’s arguments in its requests for rehearing.

“[T]his is not an instance where the specification would necessarily have to disavow an embodiment that would otherwise be covered by the plain language of the claims We have held that ‘[e]ven when guidance is not provided in explicit definitional format, the specification may define claim terms by implication such that the meaning may be found in or ascertained by a reading of the patent documents.’” Slip op. at 14 (quoting *Iredeto Access*,

On appeal, the Federal Circuit held that the Board's claim constructions were unreasonable in light of the specifications of the '752 and '509 patents. The PTO argued that, while the specification disparages external cables or wires, Abbott was still required to make a "clear disavowal" or "express disclaimer" of external cables and wires in order to disclaim those features. *Id.* at 11-12. But the Court recognized that "the specification contains only disparaging remarks with respect to the external cables and wires of the prior-art sensors," and that none of the disclosed embodiments contain external cables or wires. *Id.* at 13. Furthermore, other limitations in the claims (e.g., "coupled" and "receiving") were consistent with electrochemical sensors having no external cables or wires. *Id.* at 14. Thus, the Court stated that "this is not an instance where the specification would necessarily have to disavow an embodiment that would otherwise be covered by the plain language of the claims," distinguishing from Federal Circuit case law requiring an explicit disclaimer. *Id.* Concluding that the Board's claim construction went beyond the broadest reasonable interpretation in light of the '752 and '509 patents' specifications, the Court vacated and remanded to the Board to apply the correct claim construction of an electrochemical sensor devoid of external connection cables or wires.

Regarding the "substantially fixed" limitation in the '509 patent claims, the parties disputed whether "some movement" of the Board's original construction includes the "somewhat restrained" movement of the prior art. The Court concluded that the Board's modified construction requiring only a "somewhat restrained" sensor resulted in a degree of movement significantly greater than that described in the specification, and was therefore unreasonable. Thus, the Court remanded to the Board with instructions to apply the original claim construction.

Finally, the Court addressed the Board's rejection of certain claims based on the examiner's invoking of the doctrine of official notice in combination with other primary references. Because the PTO agreed that the rejection should be remanded and withdrawn, the Court vacated the rejection and remanded to the Board.

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DOE Not Foreclosed Where Qualitative Claim Limitation Is Given a Quantitative Construction

*Benjamin A. Saidman**

Judges: Newman, Clevenger (dissenting-in-part), Wallach (author)

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

In *Pozen Inc. v. Par Pharmaceutical, Inc.*, Nos. 11-1584, -1585, -1586 (Fed. Cir. Sept. 28, 2012), the Federal Circuit affirmed the district court's decision that the patents-in-suit were not invalid for obviousness or inadequate written description, and that they were infringed under the DOE.

Pozen Inc. ("Pozen") markets Treximet®, a combination of sumatriptan, which is a 5-HT receptor agonist, and naproxen, a well-known nonsteroidal anti-inflammatory drug ("NSAID"). Pozen holds three related patents ("the patents-in-suit"): U.S. Patent Nos. 6,060,499 ("the '499 patent"), directed to a method of treating migraines comprising cotimely administration of 5-HT agonists and long-acting NSAIDs; 6,586,458 ("the '458 patent"), a continuation of the '499 patent directed to methods and compositions combining 5-HT agonists and long-acting NSAIDs; and 7,332,183 ("the '183 patent"), directed to a multilayer pharmaceutical tablet with a triptan, such as sumatriptan, and an NSAID in separate layers that dissolve independently.

Pozen sued Par Pharmaceutical, Inc., Alphapharm Pty Ltd., and Dr. Reddy's Laboratories, Inc. (collectively "Par") based on Par's filing of an ANDA to market a generic version of Treximet® before the expiration of the patents-in-suit. The district court determined that the asserted claims were not invalid for anticipation, obviousness, or inadequate written description, and that the ANDA products were infringing. The district court thus enjoined Par from making or selling the ANDA products. Par appealed.

On appeal, the Federal Circuit agreed with the district court that the prior art would not have provided one of ordinary skill in the art with motivation to combine sumatriptan and naproxen in order to benefit from longer lasting efficacy as compared to when either agent is taken alone. The Court held that Par failed to rebut the presumption of validity afforded issued patents by clear and convincing evidence, and that the patents-in-suit were thus not invalid for obviousness.

"[A]lthough the claim language itself is a qualitative measure, the claim construction pulls directly from the specification to give the term 'substantially all' a quantitative definition, specifically, 'at least 90%, and preferably greater than 95%,' and this court has previously concluded that the doctrine of equivalents is not foreclosed with respect to claimed ranges"
Slip op. at 31 (citations omitted).

Regarding written description, the Federal Circuit held that the district court did not clearly err in finding there was adequate written description to support the '499 patent. The Court reasoned that the specification met the requirement because it described the invention in such a way that it is understandable to a person of ordinary skill in the art. The Court agreed with the district court that the limitations "therapeutic package," "finished pharmaceutical container," and "said container further containing or comprising labeling directing the use of said package in the treatment of migraine" were supported, because "persons of skill in the art would know [that the disclosed] pharmaceutical dosages are administered to a patient in containers or packages with labeling and inserts with dosage instructions." Slip op. at 23-24 (quoting *Pozen Inc. v. Par Pharm., Inc.*, 800 F. Supp. 2d 789, 821 (E.D. Tex. 2011)).

Turning to infringement, the Federal Circuit held that the district court did not err in finding that the ANDA products infringed the '183 patent under the DOE. The Court rejected Par's argument that the products did not meet the "independent dissolution" and "substantially all" limitations. For the "independent dissolution" limitation, the Court explained that "[a]lthough there is no direct evidence comparing the rate of dissolution of the ANDA products to that of the agents individually, no such actual comparison was necessary." *Id.* at 28. "Under the doctrine of equivalents analysis[,] Pozen need only show that the ANDA products performed the same function in the same way to achieve the same result as the claimed elements of the '183 patent." *Id.*

For the "substantially all" limitation, the Court first held that the DOE could apply to the limitation. "[A]lthough the claim language itself is a qualitative measure, the claim construction pulls directly from the specification to give the term 'substantially all' a quantitative definition, specifically, 'at least 90%, and preferably greater than 95%'" *Id.* at 31 (citation omitted). "[T]his court has previously concluded that the doctrine of equivalents is not foreclosed with respect to claimed ranges." *Id.* (citing *Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, 616 F.3d 1283, 1291-92 (Fed. Cir. 2010)). The Court thus applied the DOE and held that a tablet layer with 85% of the agent can be fairly characterized as an insubstantial change from a tablet layer with 90% of the agent. The Court affirmed the district court's decision that the ANDA products infringed the "substantially all" limitation under the DOE.

Judge Clevenger dissented-in-part, stating that the Court erred in sustaining the district court's judgment that the "substantially all" limitation was infringed under the DOE. Judge Clevenger characterized the issue as a question of "whether 85% can be 'substantially all' given the District Court's construction of the limitation." Clevenger Dissent at 4. In Judge Clevenger's view, Pozen and the district court avoided answering the question by using the notion of an equivalent layer. Judge Clevenger stated that a layer cannot be equivalent if it is numerically nonequivalent, and that he disagreed with the majority's determination that "a reasonable person could determine that a tablet layer with 85% of the agent is within the scope of the doctrine of equivalents." *Id.* at 5.

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Looking Ahead

This month, in *In re Miracle Tuesday, LLC*, No. 11-1373 (Fed. Cir. Oct. 4, 2012), the Federal Circuit affirmed the TTAB's refusal to register the mark JPK PARIS 75 and design in connection with sunglasses, wallets, purses, suitcases, belts, and shoes. The Court held that the mark could not be registered, because it was "primarily geographically deceptively misdescriptive under Section 2(e)(3) of the Lanham Act." Slip op. at 2.

Read the full summary of the Court's decision in next month's edition of *Last Month at the Federal Circuit*.

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Spotlight Info

In *Outside the Box Innovations, LLC v. Travel Caddy, Inc.*, No. 09-1171 (Fed. Cir. Sept. 21, 2012), the Federal Circuit, inter alia, reversed and remanded the district court's judgment of unenforceability based on inequitable conduct. The district court held two related patents assigned to Travel Caddy, Inc. ("Travel Caddy") were unenforceable due to inequitable conduct, because Travel Caddy failed to disclose the patent litigation of the parent patent during the prosecution of the continuation patent and because Travel Caddy incorrectly claimed "small entity" status during prosecution. As to the first point, the Federal Circuit found neither but-for materiality nor specific intent to deceive the examiner, because no information relevant to the patentability of the continuation application had been provided in the litigation of the parent patent while the application was pending. Second, although Travel Caddy, with fewer than 500 employees, met the definition of small entity, it also had a sales agreement with a larger distributor, which had more than 500 employees. The Court concluded that even if a false assertion of small entity status were per se material, there was no clear and convincing evidence that anyone involved in the prosecution knew about the agreement and deliberately withheld that information in order to pay small entity fees. See this month's edition of *Last Month at the Federal Circuit* for a full summary of this decision.

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