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September 2014

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Abbreviations

ALJ	Administrative Law Judge
ANDA	Abbreviated New Drug Application
APA	Administrative Procedures Act
APJ	Administrative Patent Judge
Board	Patent Trial and Appeal Board (formerly the 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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References to Documentary Evidence in Lieu of Source Code Are Sufficient to Create Genuine Issue of Material Fact

Kevin D. Rodkey

Judges: Newman (concurring-in-part and dissenting-in-part), Clevenger, Reyna (author)

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

In *Amdocs (Israel) Ltd. v. Openet Telecom, Inc.*, No. 13-1212 (Fed. Cir. Aug. 1, 2014), the Federal Circuit affirmed-in-part and vacated-in-part the district court's claim construction findings and vacated the district court's grant of SJ of noninfringement.

Amdocs (Israel) Limited ("Amdocs") owns U.S. Patent Nos. 7,631,065 ("the '065 patent"); 7,412,510 ("the '510 patent"); 6,947,984 ("the '984 patent"); and 6,836,797 ("the '797 patent") (collectively "the asserted patents"). The asserted patents are directed to data mediation software, which helps Internet service providers track customer usage and generate bills. Openet Telecom, Inc. and Openet Telecom Ltd. (collectively "Openet") make and sell Openet's FusionWorks Framework ("Framework"), which Openet refers to as its "mediation operating system." Slip op. at 14.

Amdocs filed suit against Openet, alleging infringement of the asserted patents by the Framework. The district court construed the claim terms "enhance," "enhancement," "completing," and "single record represent[ing] each of [the] plurality of services." *Id*. at 15-16 (first alteration in original). Openet moved for SJ of noninfringement and invalidity, and Amdocs moved for SJ that it had not committed inequitable conduct. The district court granted Openet's motion for noninfringement and granted Amdoc's motion regarding inequitable conduct. Amdocs appealed.

"Simply because a product will not 'operate' in a certain condition does not mean that it does not infringe in that condition. Here, the Framework may not operate without DSD scripts (or, indeed, without a computer or electricity) but making, using, or selling the installation CD may still, as a factual matter, infringe the asserted claims." Slip op. at 25 (footnote omitted).

On appeal, the Federal Circuit first addressed the claim constructions of the term "enhance" in the '065 patent and the term "completing" in the '510 and '984 patents. For the term "enhance," the Court affirmed the district court's construction that "enhance" means "to apply a number of field enhancements in a distributed fashion." *Id.* at 17-18 (citation omitted). The Court also considered the district court's clarification that "'distributed' means that the network usage records are processed close to their sources before being transmitted to a centralized manager." *Id.* at 18 (citation omitted). The Court rejected Amdocs's argument that the "enhance" term should be given its plain and ordinary meaning, instead

finding that there was no suggestion in the specification of centralized enhancement, as opposed to distributed enhancement in the district court's construction. To support this conclusion, the Court examined several portions of the '065 patent's specification, finding that it described distributed data gatherers and repeatedly recited advantages of the distributed enhancement. The Court therefore held that the district court did not err in reading "in a distributed fashion" and "close to the source" requirements into the term "enhance." *Id.* at 21.

Next, the Court affirmed the district court's construction of "completing" in the '510 and '984 patents, rejecting Amdocs's argument that the district court erred to the extent the construction included "in a distributed fashion" from its construction of "enhance." *Id*. Because the Court affirmed the district court's construction of "enhance," it also affirmed the construction of "completing." *Id*.

The Court then considered the construction of "single record represent[ing] each of the plurality of services" in the '797 patent and found that the district court erred in its construction. *Id*. at 21-23 (alteration in original). The Court explained that the district court's construction included "one record that includes customer usage data for each of the plurality of services used by the customer on the network," but did not include a record that aggregates usage data. *Id.* at 21 (citation omitted). The Court noted that the parties' dispute was over the meaning of the term "represent," and explained that although the specification of the '797 patent did not discuss representing a plurality of services, it did teach representing a plurality of records. Because the specification showed that separate records could represent a plurality of records by aggregation, the Court concluded that the person of ordinary skill would have also understood that separate records could also represent a plurality of services by aggregation. The Court therefore vacated the district court's construction and substituted the plain meaning.

The Court next turned to infringement of the '065, '510, and '984 patents, and reversed the district court's grant of SJ of noninfringement. The Court found that the district court first erred in determining that Openet's marketing materials presented to foreign entities were irrelevant to the infringement analysis. Acknowledging that solely extraterritorial activities do not infringe a U.S. patent, the Court noted that Openet had admitted that the Framework described in the foreign materials was the same product that it made and sold in the United States. The Court therefore concluded that the foreign materials were relevant to the infringement analysis. The Court next found that the district court erred by discounting Amdocs's citations to source code of the FusionWorks installation CD, based on Openet's assertion that the Framework was "inoperable without DSD [DataStream Decoder] scripts" that were not contained on the CD. *Id.* at 25. The Court explained that simply because a product will not "operate" without a certain condition does not mean that the product does not infringe. *Id.* Noting that the parties disputed whether the allegedly infringing code was located on the installation CD or whether some of the code was contained in the DSD scripts, the Court determined that the district court had improperly decided a disputed factual question in Openet's favor by discounting Amdocs's citation to the code present on the CD and by requiring expert evidence related to the DSD scripts. The Court also explained that Amdocs was entitled to establish genuine factual issues by relying on documentary evidence, without necessarily identifying the precise location of the allegedly infringing code. After reviewing the evidence, the Court concluded that the documents created a genuine issue of material fact regarding the location and operation of certain components of the FusionWorks system. For these reasons, the Court reversed the district court's grant of SJ of the '065, '510, and '984 patents.

Lastly, the Court vacated the grant of SJ of the '797 patent, which was based on the district court's erroneous construction of "single record represent[ing] each of the plurality of services," and remanded for a determination of infringement.

For the above reasons, the Court affirmed the constructions of "enhance" and "completing"; vacated the construction of "single record represent[ing] each of the plurality of services"; reversed the grant of SJ of noninfringement of the '065, '510, and '984 patents; and vacated and remanded the grant of SJ of noninfringement of the '797 patent.

Judge Newman concurred-in-part and dissented-in-part. Judge Newman concurred with the majority

regarding the ’065, ’510, and ’984 patents, but would have affirmed SJ of noninfringement of the ’797 patent for the same reasons as the district court.

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Claims That Omit a Feature Described in the Specification Do Not Lack Written Description Support

Mandy J. Song

Judges: Taranto (author), Bryson, Hughes

[Appealed from D. Kan., Judge Murguia]

In *ScriptPro, LLC v. Innovation Associates, Inc.*, No. 13-1561 (Fed. Cir. Aug. 6, 2014), the Federal Circuit reversed the district court's SJ decision that the asserted claims of U.S. Patent No. 6,910,601 ("the '601 patent") were invalid under 35 U.S.C. § 112, ¶ 1 (now 35 U.S.C. § 112(a)).

ScriptPro, LLC and ScriptPro USA, Inc. (collectively "ScriptPro") sued Innovation Associates, Inc. ("Innovation Associates") for infringement of the '601 patent. The '601 patent describes "a 'collating unit,' which works with an 'automatic dispensing system' that automatically fills and labels pill bottles or other prescription containers." Slip op. at 2. According to the specification, the collating unit "broadly comprises" several components, including "a plurality of sensors" operable to determine the presence of a container within the collating unit. *Id.* at 4 (citation omitted). The specification also describes the "control system" of the collating unit, which determines in which holding area to store a container based on the presence of previous containers in that holding area, a process that may be accomplished by the sensors. *Id.* at 4-5. Each of the asserted claims recites a collating unit comprising several elements, but none requires sensors. Innovation Associates moved for SJ of invalidity under 35 U.S.C. § 112, ¶ 1, which the district court granted, concluding that the '601 patent's specification did not describe the subject matter of the asserted claims because they did not require sensors.

"A specification can adequately communicate to a skilled artisan that the patentee invented not just the combination of all identified features but combinations of only some of those features (subcombinations)—which may achieve stated purposes even without omitted features." Slip op. at 8.

On appeal, the Federal Circuit reversed. The Court first recognized that, although the specification describes embodiments having sensors, "[i]t is common, and often permissible, for particular claims to pick out a subset of the full range of described features, omitting others." *Id*. at 7-8. And, according to the Court, "[t]here is no sufficiently clear language in the specification that limits the invention to a collating unit with the . . . sensors," and, thus, the asserted claims do not "have a scope incommensurate with what is described as the invention." *Id*. at 8. The Court then pointed to language in the specification that suggested that the control system itself may use a memory that keeps track of containers without the confirming check of the sensors. Accordingly, the Court held that "the specification itself creates a genuine issue of material fact on . . . [whether] a trier of fact could find that a skilled artisan would understand the specification to disclose" alternative embodiments that do not require sensors. *Id*. at 11.

Finally, the Court noted that some originally filed claims omitted the sensor requirement, which "fits the bases in the specification for deeming sensors to be merely optional." *Id.* at 11-12.

The Court thus reversed the district court's SJ decision that the asserted claims of the '601 patent were invalid under § 112, ¶ 1, for lack of an adequate written description.

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Hatch-Waxman Infringement Claims and FDA Citizen Petition May Violate Antitrust Laws

Adam M. Breier

Judges: Newman (dissenting), Bryson (author), Moore

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

In *Tyco Healthcare Group LP v. Mutual Pharmaceutical Co.*, No. 13-1386 (Fed. Cir. Aug. 6, 2014), the Federal Circuit affirmed-in-part and vacated-in-part the district court's SJ decision that Hatch-Waxman infringement claims and a citizen petition filed with the FDA did not violate the antitrust laws.

Tyco Healthcare Group LP and Mallinckrodt, Inc. (collectively "Tyco") own several patents directed to temazepam (brand name Restoril), a drug used to treat insomnia. The patents all claim 7.5 mg formulations of temazepam having a specific surface area between 0.65 and 1.1 square meters per gram (m^2/g). Although the claims do not recite any measurement technique, the patent specifications state that surface-area measurements are made essentially in accordance with a known gas-adsorption technique, B.E.T. testing, which involves an outgassing step generally performed at an elevated temperature. Tyco used an outgassing temperature of 105°C in its B.E.T. testing.

Mutual Pharmaceutical Company, Inc. and United Research Laboratories, Inc. (collectively "Mutual") filed an ANDA seeking FDA approval of a generic 7.5 mg version of temazepam. Mutual's ANDA represented that the specific surface area of its proposed ANDA product would be not less than 2.2 m^2/g and thus made a Paragraph IV certification of noninfringement. Mutual used an outgassing temperature of 40°C in its B.E.T. testing.

Tyco sued Mutual, alleging infringement under 35 U.S.C. § 271(e)(2)(A). Mutual raised antitrust counterclaims, which the district court stayed pending resolution of Tyco's infringement claim. The district court first entered judgment of noninfringement. The next day—one week before the end of the statutory thirty-month stay of Mutual's ANDA approval—Tyco filed a citizen petition with the FDA. The citizen petition urged the FDA to change the parameters of evaluating the bioequivalence of generic temazepam. The FDA nevertheless approved Mutual's ANDA and, five months later, denied the citizen petition, finding "no basis" for adopting Tyco's proposed bioequivalence criteria. Slip op. at 5. The district court later granted SJ to Mutual on invalidity, which the Federal Circuit affirmed. Afterwards, the district court granted SJ to Tyco on all of Mutual's antitrust counterclaims, including that Tyco's infringement claim constituted sham litigation, that Tyco's citizen petition was a sham, and that Tyco's action was the product of fraud within the meaning of *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965). Mutual appealed.

"[I]t is not unreasonable for a patent owner to allege infringement under section 271(e)(2)(A) if the patent owner has evidence that the as-marketed commercial ANDA product will infringe, even though the hypothetical product

specified in the ANDA could not infringe." Slip op. at 10.

On appeal, the Federal Circuit rejected Mutual's first argument that a genuine dispute existed as to whether Tyco's infringement suit was objectively baseless and, thus, fell within the sham-litigation exception to *Noerr-Pennington* antitrust immunity. Mutual argued that because its ANDA recited a specific surface area falling outside the claimed range, its proposed generic could not infringe. The Court disagreed, explaining that the infringement inquiry in an ANDA case focuses on what is likely to be sold following FDA approval and is not limited to the ANDA itself.

Nonetheless, the Court vacated the district court's SJ decision regarding sham litigation and remanded. According to the Court, under Tyco's infringement theory, Mutual's use of 40°C as the outgassing temperature was inappropriate and that 105°C—the temperature at which Tyco tested Restoril—should have been used instead. While the parties did not dispute that Mutual's generic temazepam fell within the infringing range at an outgassing temperature of 105°C, the Court noted that there was also evidence that using 105°C physically altered the temazepam, inappropriately decreasing the specific surface area, and that, barring physical alterations, higher outgassing temperatures would potentially increase, not decrease, the surface area. The Court therefore concluded that, because Tyco's infringement theory would make it more likely that Mutual's commercial product would measure outside of the infringement range, further inquiry was required as to whether Tyco's factual theory of infringement was objectively baseless.

In contrast, the Federal Circuit affirmed SJ for Tyco on the invalidity portion of Mutual's sham-litigation counterclaim. According to Mutual, Tyco lacked a reasonable prospect of success in defending the nonobviousness of its patents because the only novel claim element was the 7.5 mg dose, which fell within a range disclosed in the prior art. The Court explained that although this scenario shifted the burden of production to the patent holder, it did not remove the burden of proof from the patent challenger. And, according to the Court, not only did Tyco offer evidence to meet its burden of production, which Mutual ignored, but also Tyco's "teaching away" argument was not objectively baseless.

Next, the Federal Circuit vacated the district court's SJ decision that Tyco's citizen petition was not a sham. First, following the precedent from other circuits, the Court held that the sham exception to *Noerr-Pennington* immunity was not limited to litigation, but also applied to administrative petitions, including FDA citizen petitions. Second, the Court held that disputed factual issues precluded SJ regarding whether the citizen petition was objectively baseless. The Court noted that particularly probative of whether the citizen petition was reasonable was the FDA's denial, which indicated that the FDA viewed the petition as wholly without merit. The Court also noted that Mutual's expert concluded that Tyco lacked a scientific basis to conclude that Mutual's product would not be bioequivalent. Third, regarding the subjective element of the test, the Court held that the timing of Tyco's citizen petition and an internal e-mail indicating that a bioequivalent temazepam formulation could be made with a different specific surface area together could support a finding that the petition was an attempt to interfere directly with a competitor's business relationships. The Court noted, however, that it remained an open question whether the filing of the citizen petition caused any antitrust injury to Mutual via a delay in its ANDA approval and that SJ for Tyco may still be appropriate on this basis.

Finally, the Court affirmed SJ on Mutual's claim that Tyco's predecessor in interest had fraudulently obtained the asserted patents from the PTO by omitting material information during prosecution and that Tyco had at least constructive knowledge of the fraud. The Court held that there was insufficient evidence that Tyco knew of any fraud, concluding instead that Mutual's evidence, at most, supported the inference that Tyco knew of prior art that could impact the validity or enforceability of the patents.

Accordingly, the Court affirmed SJ for Tyco on Mutual's antitrust counterclaims predicated on sham litigation regarding validity and on fraud, and vacated and remanded those predicated on sham litigation regarding Tyco's infringement claim and the citizen petition.

Dissenting, Judge Newman stated that the panel majority had created several new grounds of antitrust liability. In her view, litigation to enforce a presumptively valid patent following a Paragraph IV certification—a technical act of infringement under 35 U.S.C. § 271(e)—cannot be objectively baseless because the certification constitutes probable cause to initiate suit. In addition, she stated that Tyco had the constitutional right to communicate with the FDA concerning public information on matters within the agency's authority and responsibility without incurring antitrust liability. Thus, according to Judge Newman, "[t]he panel majority improperly inserts antitrust issues into the issues of infringement, validity, and communication to the government, contravening precedent and the Constitution." Newman Dissent at 3-4.

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Where Patentee Made Affirmative and Knowing Misrepresentations Regarding the Prior Art, Materiality Element of Inequitable-Conduct Analysis Was Met

Hojung Cho

Judges: Reyna (author), Wallach, Hughes

[Appealed from S.D. Fla., Judge Middlebrooks]

In *Apotex Inc. v. UCB, Inc.*, No. 13-1674 (Fed. Cir. Aug. 15, 2014), the Federal Circuit affirmed the district court's finding that Apotex Inc. and Apotex Corp.'s (collectively "Apotex") U.S. Patent No. 6,767,556 ("the '556 patent") was unenforceable due to inequitable conduct.

Dr. Bernard Charles Sherman, founder and chairman of Apotex, leads the development of Apotex's drug formulations and manufacturing processes, and has himself written approximately one hundred patent applications, including the patent-at-issue, the '556 patent. The '556 patent is directed to a process for manufacturing moexipril tablets. Moexipril is an angiotensin-converting enzyme ("ACE") inhibitor used to treat hypertension. The '556 patent covers a process of making moexipril tablets consisting mostly of moexipril magnesium obtained by reacting moexipril or its acid addition salts with an alkaline magnesium compound. The Background section of the '556 patent discusses U.S. Patent No. 4,743,450 ("the '450 patent") and Univasc, one of the accused products in the present action, both of which are prior art to the '556 patent.

During prosecution, three times the examiner rejected the pending claims as obvious in view of a combination of prior art, including the '450 patent, which teaches stabilizing ACE inhibitor drugs with an alkaline magnesium compound. At the direction of Dr. Sherman, Apotex's counsel repeatedly sought to overcome the rejections by arguing that the prior art merely combined moexipril hydrochloride with an alkaline stabilizing agent, but did not teach a reaction between them. Also at the direction of Dr. Sherman, Apotex submitted the declaration of a third-party expert reinforcing Apotex's representations that the prior art did not involve a reaction and amended the independent claim to require "greater than 80%" conversion to moexipril magnesium, after which the examiner allowed the '556 patent claims. Slip op. at 8.

Apotex filed suit, accusing the defendants of infringing claims 8-12 of the '556 patent by manufacturing and selling Univasc and Uniretic. Prior to a jury trial on the issues of infringement and invalidity, the district court conducted a three-day bench trial on the issues of claim construction and UCB, Inc.'s equitable defenses. The district court concluded that the '556 patent was unenforceable due to Dr. Sherman's inequitable conduct before the PTO. Specifically, the district court found that Dr. Sherman's combined misrepresentations and withholding of prior art were material to the prosecution of the '556 patent application, and that Dr. Sherman engaged in egregious misconduct during prosecution with intention to deceive the PTO. Apotex appealed.

"To be clear, we agree with Apotex that Dr. Sherman had no duty to disclose

his own suspicions or beliefs regarding the prior art. There is nothing wrong with advocating, in good faith, a reasonable interpretation of the teachings of the prior art. The misconduct at issue, however, goes beyond failing to disclose a personal belief or alternative interpretations of the prior art; here, Dr. Sherman affirmatively and knowingly misrepresented material facts regarding the prior art." Slip op. at 14-15 (footnotes omitted).

On appeal, the Federal Circuit held that the district court's findings regarding materiality and intent were not clearly erroneous. Regarding materiality, the Court found that Dr. Sherman engaged in material misconduct for at least three reasons. First, the Court found that Dr. Sherman was responsible for the alleged misconduct. Particularly, the Court stated that Dr. Sherman directly instructed his counsel to continue pressing the arguments made in response, including the representation that the prior art did not involve a reaction, and to bolster them through an expert declaration. Second, the Court found that Dr. Sherman made affirmative misrepresentations of material facts. Specifically, the Court determined that despite Apotex's internal testing data showing the contrary, Dr. Sherman repeatedly asserted to the PTO that the process of the '450 patent used to manufacture Univasc did not involve a reaction that would produce moexipril magnesium. Third, the Court held that Dr. Sherman's misconduct was "but-for material" to the issuance of the '556 patent. *Id*. at 14. The Court observed that the examiner's rejections were based on the very same prior art that was the subject of Dr. Sherman's misrepresentations. The Court also found that "[t]he Examiner's erroneous belief regarding the prior art corresponds precisely with Dr. Sherman's repeated misrepresentations made through his counsel and the hired expert." *Id*. While the Court agreed with Apotex's contention that "Dr. Sherman had no duty to disclose his own suspicions or beliefs regarding the prior art," the Court explained that "[t]he misconduct at issue, however, goes beyond failing to disclose a personal belief or alternative interpretations of the prior art; here, Dr. Sherman affirmatively and knowingly misrepresented material facts regarding the prior art." *Id.* at 14-15.

While stating that it need not decide whether Dr. Sherman's conduct rose to the level of egregious misconduct or the materiality of Dr. Sherman to disclose certain prior art and his falsification of examples in the '556 patent, the Court further noted that Dr. Sherman's actions, at a minimum, came close to the type of affirmative misconduct that in *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011) (en banc), the Court held could justify finding inequitable conduct without showing but-for materiality. The Court found "particularly significant and inexcusable the fact that Dr. Sherman arranged for the preparation and submission of an expert declaration containing false statements instrumental to issuance of the patent." Slip op. at 15.

Regarding intent, the Court also affirmed the district court's finding of Dr. Sherman's intent to deceive the PTO. The Court explained that "Dr. Sherman was aware that some of the assertions he made in the specification regarding the prior art were at least misleadingly incomplete, if not plainly inaccurate." *Id.* at 15-16. The Court noted Dr. Sherman's admission that he did not actually perform the experiments in the '556 patent's specification even though he drafted the examples in the past tense. The Court further noted that Dr. Sherman directed his counsel to bolster those misrepresentations by submitting a declaration on behalf of an expert who was never informed of the truth. Based on the above findings, the Court agreed with the district court's finding that "deceptive intent is the single most reasonable inference that can be drawn from the evidence." *Id.* at 16.

Accordingly, the Court held that the district court did not abuse its discretion by finding that the '556 patent was unenforceable due to Dr. Sherman's inequitable conduct. Thus, the Court did not need to address the district court's findings pertaining to claim construction, indefiniteness, laches, or judicial estoppel.

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Species Are Unpatentable When Prior Art Disclosures Describe the Genus Such That a Person of Ordinary Skill in the Art Would Be Able to Envision Every Member of the Class

Corinne Miller LaGosh

Judges: Dyk (author), Wallach, Chen

[Appealed from S.D.N.Y., Judge Crotty]

In *AbbVie Inc. v. Mathilda & Terence Kennedy Institute of Rheumatology Trust*, No. 13-1545 (Fed. Cir. Aug. 21, 2014), the Federal Circuit affirmed the district court's finding of obviousness-type double patenting.

The Mathilda and Terence Kennedy Institute of Rheumatology Trust ("Kennedy") is the owner of U.S. Patent Nos. 6,270,766 ("the '766 patent") and 7,846,442 ("the '442 patent"), directed to methods of treating rheumatoid arthritis by co-administering a disease-modifying antirheumatic drug and an antibody. The '766 patent claims a method of co-administering the Tumor Necrosis Factor Alpha ("TNFα") antibody and methotrexate. After the '766 patent issued, Kennedy obtained the '442 patent, which contains "method of treatment" claims. While Kennedy admits that the claims of the '442 patent are encompassed by the '766 patent, the claims of the '442 patent are directed towards a more specific patient group. The '766 patent previously expired on October 8, 2012, and the '442 patent, which claimed a later priority date than the '766 patent, expires on August 21, 2018.

In 2002, AbbVie Inc. and AbbVie Biotechnology Limited (collectively "AbbVie") licensed the '766 patent and obtained FDA approval to sell Humira, an anti-TNFα antibody, for use either alone or in combination with methotrexate, for the treatment of rheumatoid arthritis. After the '442 patent issued in 2010, Kennedy demanded that AbbVie pay royalties under the '442 patent in order to continue sales of Humira. In response, AbbVie sued Kennedy for DJ that the claims of the '442 patent were invalid over the '766 patent under the doctrine of obviousness-type double patenting. After conducting a bench trial, the district court found that the '442 patent covered the same invention as the '766 patent and was invalid over the claims of the '766 patent for obviousness-type double patenting. The district court entered a partial final judgment, under Fed. R. Civ. P. 54(b), in favor of AbbVie, and Kennedy appealed.

"Thus, species are unpatentable when prior art disclosures describe the genus containing those species such that a person of ordinary skill in the art would be able to envision every member of the class." Slip op. at 24.

The Federal Circuit first turned to Kennedy's argument that the statutory and policy rationales for the doctrine of obviousness-type double patenting no longer exist and, thus, the doctrine should be discarded. Specifically, "[n]ow that the patent term is measured from the earliest claimed priority date, as

opposed to the date of issuance, Kennedy contends that the submarine patent problem no longer exists and that the [Uruguay Round Agreements Act] amendment vitiated the policy basis for the doctrine of obviousness-type double patenting." Slip op. at 11. The Court, however, disagreed, explaining that Kennedy ignored that the doctrine is also designed to prevent inventors from obtaining a second, later expiring patent on the same invention, which is another "crucial purpose of the doctrine." *Id.* Noting its recent decision in *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208 (Fed. Cir. 2014), the Court stated, "We now make explicit what was implicit in *Gilead*: the doctrine of obviousness-type double patenting continues to apply where two patents that claim the same invention have different expiration dates." Slip op. at 13. Indeed, the Court explained, "Kennedy is not entitled to an extra six years of monopoly solely because it filed a separate application unless the two inventions are patentably distinct." *Id.*

The Court next addressed whether the doctrine of obviousness-type double patenting applied in the instant case. Noting that obviousness-type double patenting is a two-step inquiry, the Court first turned to the claim construction of the terms "co-administration" and "active disease" as used in both the '766 and '442 patents.

As to the term "co-administration," the Court found that, by way of claim construction, Kennedy was attempting to enlarge the scope of the '766 patent while simultaneously narrowing the scope of the '442 patent. Kennedy took the position that the district court's claim construction of the term "co-administration" erroneously excluded a fourth form of co-administration. The Court, noting that the specification confirmed the correctness of the district court, found that "[t]he specification never uses the term 'co-administering' to refer to patients who only received the antibody after discontinuing treatment with methotrexate." *Id.* at 14. Indeed, the Court explained, the '766 patent's specification "makes clear that the invention described in the claims is limited to concomitant and adjunctive use." *Id.* Kennedy also argued that the principle of claim differentiation favored its interpretation that claim 8 encompassed embodiments where "*single* doses of either the antibody *or* methotrexate are delivered to patients," whereas claim 9 demonstrated that "the only additional limitation is that the anti-TNFα antibody must be administered in a series of doses separated by intervals of days or weeks." *Id.* at 18 (citation and internal quotation marks omitted). The Court did not find Kennedy's argument persuasive because it found that claim 9 does not disclose discontinuation of methotrexate and that the administration of methotrexate is assumed to be ongoing with the single or multiple antibody doses. Thus, the Federal Circuit found that the specification and claims of the '766 patent supported the district court's correct interpretation of the term "co-administration."

The Court then assessed the district court's claim construction of the term "active disease." Kennedy contended that the '442 patent provided an explicit definition for the term "active disease." In support of this contention, Kennedy relied on the prosecution history and the examiner's indefiniteness rejection of the '442 patent for failing to define the term "active disease." Kennedy provided an explanation that after it pointed to a particular portion of the specification as providing a more specific definition of the term "active disease" during prosecution, the examiner allowed the '442 patent's claims. AbbVie argued that the particular quoted portion of the specification set forth two definitions and, thus, the inventors could not be viewed as having acted as their own lexicographers. The Court, however, assumed, without deciding, that Kennedy's proposed construction for "active disease" was correct. Accordingly, the Court stated that, in the second step of the obviousness-type double patenting inquiry, it "must decide whether a patent that claims to treat a subset of patients with more severe rheumatoid arthritis (the '442 patent) is an obvious variant of a patent that claims treatment of rheumatoid arthritis patients generally (the '766 patent)." *Id.* at 21.

Turning to the obviousness inquiry in the second step of its analysis, the Federal Circuit provided a discussion of the law of obviousness-type double patenting and found that "it is clear that a reader of the '766 patent could have easily envisioned a species limited to sicker patients. The district court was correct in concluding that the species of the '442 patent was not patentably distinct from the genus of the '766 patent." *Id.* at 24. The Court also addressed Kennedy's claim that the species had unexpected results, but found that such a claim was unsupported. The Court explained that to assess whether the '442 patent yielded unexpected results, the Court had to assess what results were expected at the time

the ’766 patent application was filed. The Court concluded that the ’442 patent merely claimed the known utility of the ’766 patent and did not claim a species with unexpected results. The Court also acknowledged Kennedy’s argument that the ’766 patent’s disclosures could not be used to determine whether the results of the ’442 patent were unexpected because doing so would be tantamount to treating the disclosures of the ’766 patent as prior art. The Court explained that while “a reference patent’s specification cannot be used as prior art in an obviousness-type double patenting analysis,” “it is also well settled that we may look to a reference patent’s disclosures of utility to determine the question of obviousness.” *Id.* at 26 (citations omitted). Because the Court determined that the ’442 patent did not claim a species manifesting unexpected results, the Court concluded that the ’442 patent would have been obvious over the ’766 patent.

Accordingly, the Federal Circuit affirmed the district court’s finding that the ’442 patent was invalid for obviousness-type double patenting in light of the ’766 patent and awarded costs to AbbVie.

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District Court Did Not Err by Clarifying Claim Construction in Postverdict JMOL Opinion

Justin N. Mullen

Judges: Prost (author), Schall, Hughes

[Appealed from N.D. Cal., Judge Chen]

In *Mformation Technologies, Inc. v. Research In Motion Ltd.*, Nos. 12-1679, 13-1123 (Fed. Cir. Aug. 22, 2014), the Federal Circuit affirmed the district court's grant of JMOL of noninfringement.

Mformation Technologies, Inc. ("MT") previously owned U.S. Patent No. 6,970,917 ("the '917 patent"), directed to wireless activation and management of electronic devices. Research In Motion Limited and Research In Motion Corporation (collectively "BlackBerry") market the Blackberry Enterprise Server ("BES") product to corporate customers to deliver e-mail and remotely manage employees' devices.

MT filed suit against BlackBerry, alleging infringement of the '917 patent based on BlackBerry's BES product. At trial, a jury found infringement of the '917 patent and returned a verdict in favor of MT. After the trial, the district court requested supplemental briefing, explaining that the claimed "establishing a connection" substep must be completed before the claimed "transmitting the contents of the mailbox" substep can commence in the '917 patent. After briefing, the district court granted BlackBerry's JMOL motion, overturning the jury verdict, and granted BlackBerry's conditional motion for a new trial. The district court denied MT's motion for a new trial. MT appealed.

During the appeal, MT assigned its rights in the '917 patent to mFormation Software Technologies, Inc. ("MST"), who filed a separate appeal. The Federal Circuit consolidated the two appeals and remanded to the district court to consider BlackBerry's motion that MST lacked standing and to consider whether MST could be substituted for MT as a party in the case. The district court joined MST as a party, and the appeals by MT and MST (collectively "Mformation") proceeded at the Federal Circuit.

"We agree with BlackBerry and, therefore, conclude that the district court did not change its claim construction post-verdict. Rather, the district court at most clarified its previous construction that was already present in the jury instructions." Slip op. at 11.

On appeal, the Federal Circuit first considered whether Mformation had waived its right to argue that the district court changed its claim construction after the jury verdict. After reviewing the record, the Court concluded that Mformation had not waived this challenge and proceeded to address the merits of Mformation's appeal.

On the merits, the Court first considered whether the district court improperly added an order-of-steps requirement to the claims in its JMOL opinion. The Court examined the jury instructions from the district court and determined that the district court had "at most clarified its previous construction that was already present in the jury instructions." Slip op. at 11. The Court noted that the jury instructions explained that the phrase "connection is established" in the claim's "wherein" clause means that the connection "must not only be initiated, but must be 'made by the server with the wireless device.'" *Id.* (citation omitted). The Court then determined that because the next section of the jury instructions discussed the transmitting substep, a "logical reading of these instructions would be that the sub-step discussed in the first section of the jury instructions must be completed before moving on to the next section discussing a separate sub-step." *Id.* The Court compared this case to its opinion in *Cordis Corp. v. Boston Scientific Corp.*, 658 F.3d 1347 (Fed. Cir. 2011), in which it determined that clarifying inherent features of a claim construction postverdict did not improperly alter the construction. Here, the Court concluded that it was "inherent in [the jury] instructions that, to complete the 'establishing a connection' sub-step, the connection must be 'established,' and that must happen before the transmitting sub-step begins." Slip op. at 12. Accordingly, the Federal Circuit held that the district court did not alter its claim construction.

The Court then considered whether claim 1 of the '917 patent requires the connection to be completely established before the transmitting step. Agreeing with BlackBerry's argument, the Court determined that the "establishing" substep "would become 'superfluous'" if the connection did not have to be established before transmission. *Id*. at 14. The Court also explained that the claim inherently requires an order of steps, stating that, "[a]s a matter of logic, a mailbox must be established before the contents of said mailbox can be transmitted." *Id*. Accordingly, the Federal Circuit held that the connection must be established prior to transmission in the claims.

Lastly, the Court considered whether the JMOL was proper. The Court rejected Mformation's argument that it had presented substantial evidence of infringement even if an order-of-steps requirement was read into the claims, because BlackBerry's BES software could use an existing communication channel rather than creating the communication channel itself. The Court disagreed, pointing out that Mformation's expert based his infringement opinion on his understanding that the claims did not require a connection to be established between the server and the wireless device before transmission. Based on this mistaken view, the Court observed Mformation's expert testified that the "establishing a connection" substep was performed by two actions that occurred entirely within the BES software installed on a company server, neither of which established a connection between the BES software and the BlackBerry device. Thus, the Court distinguished between selecting a path for a wireless communication and establishing a wireless connection. For this reason, the Court held that there was not substantial evidence to support a jury verdict of infringement.

Accordingly, the Court affirmed the district court's grant of JMOL of no infringement.

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Spotlight Info

In *AbbVie Inc. v. Mathilda & Terence Kennedy Institute of Rheumatology Trust*, No. 13-1545 (Fed. Cir. Aug. 21, 2014), the Federal Circuit affirmed the district court's finding of obviousness-type double patenting. The Mathilda and Terence Kennedy Institute of Rheumatology Trust ("Kennedy") argued, inter alia, that the statutory and policy rationales—specifically, the problem of "submarine" patents—for the doctrine of obviousness-type double patenting no longer exist; thus, the doctrine should be discarded. Slip op. at 11. The Federal Circuit, however, disagreed, explaining that Kennedy ignored that the doctrine is also designed to prevent inventors from obtaining a second, later expiring patent on the same invention, which is another "crucial purpose of the doctrine." *Id.* Noting its recent decision in *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208 (Fed. Cir. 2014), the Court stated, "We now make explicit what was implicit in *Gilead*: the doctrine of obviousness-type double patenting continues to apply where two patents that claim the same invention have different expiration dates." Slip op. at 13. Indeed, the Court explained, "Kennedy is not entitled to an extra six years of monopoly solely because it filed a separate application unless the two inventions are patentably distinct." *Id.* See this month's edition of *Last Month at the Federal Circuit* for a full summary of this decision.

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Looking Ahead

On September 3, 2014, in *buySAFE, Inc. v. Google, Inc.*, No. 13-1575 (Fed. Cir. Sept. 3, 2014), the Federal Circuit affirmed that claims directed to familiar commercial arrangements using computers and networks were invalid for covering subject matter not eligible for patent protection under 35 U.S.C. § 101. The asserted claims recite methods and machine-readable media encoding steps for guaranteeing a party's performance of its online transaction. Applying the approach to § 101 affirmed by the Supreme Court in *Alice Corp. v. CLS Bank International*, 134 S. Ct. 2347 (2014), the Federal Circuit held that the claims were squarely about a contractual relationship—a "transaction performance guaranty"—that was beyond question of ancient lineage and an abstract idea. Furthermore, according to the Court, the claims' invocation of computers added no inventive concept, rendering the claims invalid under § 101.

Read the full summary in the next edition of *Last Month at the Federal Circuit*.

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