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[Appealed from TTAB]	

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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Defining Words Appearing in Construction of a Claim Term, Not the Claim Term Itself, Also Requires Following the Intrinsic Evidence

Jason W. Melvin

Judges: Lourie (author), Dyk (dissenting-in-part), Prost

[Appealed from N.D.N.Y., Senior Judge Kahn]

In *Advanced Fiber Technologies (AFT) Trust v. J&L Fiber Services, Inc.*, No. 11-1243 (Fed. Cir. Apr. 3, 2012), the Federal Circuit revised the district court's construction of a term appearing only in the court's construction of a claim term, and therefore vacated SJ of noninfringement. The Court declined to address the district court's denial of SJ of no invalidity but affirmed SJ of no willful infringement.

The technology at issue relates to devices used to filter contaminants from paper pulp mixtures known as "stock" by passing the stock through screens with holes. The asserted U.S. Patent No. RE39,940 ("the '940 patent") resulted from a reissue of U.S. Patent No. 5,200,072 ("the '072 patent"). During prosecution of the reissue application, Advanced Fiber Technologies (AFT) Trust ("AFT") argued against a rejection in light of a prior art patent to Gillespie. Specifically, AFT argued that the '072 patent used terms of pulp treatment art and offered definitions from the *Handbook of Pulp and Paper Terminology* (the "*Handbook*"). According to the *Handbook*, "screen" and "screen plate" meant a perforated barrier. AFT further argued that Gillespie taught slots "over three times the size" compared with the size of the slots in the claimed invention. Slip op. at 7. In response, the PTO withdrew the rejection and reissued the patent as the '940 patent.

AFT sued J&L Fiber Services, Inc. ("J&L"), which asserted noninfringement and invalidity based on a number of prior art references. The district court construed "screening medium" and "screening plate" as "a perforated barrier through which stock is passed to remove oversized, troublesome, and unwanted particles from good fiber." *Id*. at 8 (quoting *Advanced Fiber Techs. Tr. v. J&L Fiber Servs., Inc.*, 751 F. Supp. 2d 348 361 (N.D.N.Y. 2010)). At AFT's request, the district court further construed "perforated," which appeared in the district court's construction but not the claims themselves. The district court looked to general and technical dictionary definitions to conclude that "perforated" means "pierced or punctured with holes." *Id*. (citation omitted). The district court observed that the patent specification contains a "one-sentence mention that 'a wedgewire screening plate may be used,'" but viewed the disclosure as insufficient to overcome the ordinary meaning of "perforated." *Id.* (citation omitted). Finally, the district court viewed AFT's statement regarding the sizes of holes in the prior art and the claimed invention as a disavowal of claim scope and therefore limited the claims to openings and slots no greater than 0.254 mm.

Based on its claim constructions, the district court granted SJ of noninfringement because J&L's accused product used wedgewire construction and therefore did not meet the court's construction for "perforated." It further denied SJ of no invalidity and dismissed AFT's claim of willful infringement. Regarding

willfulness, the district court reasoned that J&L presented "credible" and "compelling" arguments regarding noninfringement and invalidity. *Id*. at 10.

"The fact that an embodiment is disclosed in a single sentence is not a license to ignore that disclosure." Slip op. at 16-17.

On appeal, the Court reversed the district court's construction of perforated, holding that AFT had not restricted the term to structures pierced or punctured with holes. It agreed that sometimes the courts may have to further define words that appear only in the construction of a claim term, not the claim term itself. As the Court explained, such metaconstruction should follow the guiding principles of claim construction—specifically, focusing on intrinsic evidence. It held that the district court erred by elevating dictionary definitions above the specification and claims. Specifically, the Court looked to the claims generically reciting "screening medium" as "having a plurality of openings therethrough" and the specification including an embodiment of a perforated barrier made by assembling wires. *Id*. at 16. That the embodiment only appeared in a brief passage did not bother the Court, which explained that "[t]he fact that an embodiment is disclosed in a single sentence is not a license to ignore that disclosure." *Id*. at 16-17. Regarding the prosecution history, the Court held that AFT had limited the claims to "perforated" plates but had not defined "perforated" to require piercing or puncturing. Accordingly, the Court reversed SJ of noninfringement.

Turning next to the district court's construction of "slots" and "openings" as less than 0.254 mm, the Court agreed that AFT had disclaimed any larger opening when it argued that the prior art taught holes "over three times the size of the slot width of the present invention." *Id*. at 19.

Regarding invalidity, the Court explained that denial of SJ does not create an appealable issue. Specifically, because the denial of SJ of no invalidity was not "inextricably intertwined" with the grant of SJ of noninfringement and because review of the invalidity issue was not "necessary to ensure meaningful review" of the noninfringement issue, the Court declined to review the invalidity determination. *Id*. at 19-20.

Finally, the Court affirmed SJ of no willful infringement, reasoning that J&L had asserted objectively reasonable defenses to the suit. The fact that the Court had vacated SJ of noninfringement did not affect its analysis.

Judge Dyk dissented-in-part, explaining that in his view, the prosecution history showed that "perforated" required holes or openings made through an otherwise solid object. Because the patentee had distinguished prior art using a "wedgewire construction" as not within the scope of claims to a "screening medium" or "screening plate," Judge Dyk would have affirmed the district court's claim construction and SJ of noninfringement. As to the specification's disclosure of a wedgewire embodiment, Judge Dyk explained that a patent need not claim all embodiments, particularly when the applicant changes the claim scope during prosecution.

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Mark Denied Registration for Descriptiveness Because Mark Immediately Conveys Information About Designated Services

*Brian R. Westley**

Judges: Prost, Mayer, Reyna (author)

[Appealed from TTAB]

In *In re Chamber of Commerce of the United States of America*, No. 11-1330 (Fed. Cir. Apr. 3, 2012), the Federal Circuit affirmed the TTAB's refusal to register the U.S. Chamber of Commerce's ("COC") NATIONAL CHAMBER mark because it was merely descriptive.

COC filed two related intent-to-use applications for the NATIONAL CHAMBER service mark. The first application covered (1) providing online directory information services featuring information regarding local and state chambers of commerce; (2) providing information and news in the field of business; and (3) the administration of a discount program enabling participants to obtain discounts on goods and services (Class 35). The second application covered (1) analysis of governmental policy and regulatory activity relating to businesses to promote the interests of businessmen and businesswomen; and (2) business data analysis (Class 35).

The PTO refused registration of the NATIONAL CHAMBER mark after concluding that it was merely descriptive. The Examining Attorney found the mark unregisterable because it "immediately imparts information about an important feature, function or purpose of the identified services." Slip op. at 4 (citation omitted). COC then appealed to the TTAB. Before hearing the appeal, however, the TTAB twice remanded the case to the Examining Attorney for further prosecution and development of the record. On remand, the Examining Attorney further explained that descriptiveness refusal was proper because NATIONAL describes services nationwide in scope and CHAMBER is descriptive because it "illustrates the purposes of the services—promot[ing] the interests of businessmen and businesswomen," which "is a purpose common to chambers of commerce." *Id*. (alteration in original) (citation omitted). The TTAB affirmed the Examining Attorney's refusal, finding that a consumer encountering the NATIONAL CHAMBER mark would immediately understand the mark as conveying information about COC's services. The TTAB relied explicitly on dictionary definitions showing that (1) the word "national" means "of, relating to, or belonging to a nation as an organized whole"; (2) the word "chamber" can refer to "a chamber of commerce"; and (3) "chamber of commerce" is "an association of businesses and/or businesspersons for the promotion of commercial interests in a community." *Id*. at 4-5 (citation omitted). The TTAB also relied on printouts of COC's website showing its directory and search services for individuals seeking information about local and state chambers of commerce across the United States.

"[W]e need only find that NATIONAL CHAMBER immediately conveys information about one feature or characteristic of at least one of the

designated services within each of COC's applications. . . . Because we find that NATIONAL CHAMBER describes at least one designated service within each of COC's applications, we affirm the descriptiveness refusals." Slip op. at 8 (citation omitted).

On appeal, the Court held that substantial evidence supported the TTAB's finding of descriptiveness. The Court explained that to decide the case, "we need only find that NATIONAL CHAMBER immediately conveys information about one feature or characteristic of *at least one* of the designated services within each of COC's applications." *Id.* at 8 (emphasis added) (citation omitted). The Court declined, however, to adopt the government's argument that NATIONAL CHAMBER is merely descriptive of *any* nationwide service that is within a broad genus of "chamber of commerce services." In refusing to adopt such an expansive general rule, the Court explained that descriptiveness is determined based on the particular services recited in the application and must be supported by evidence of those particularly recited services.

With respect to the first application, the Federal Circuit noted that the TTAB cited printouts of COC's website showing its online directory services for individuals seeking information about chambers of commerce across the country. The Court concluded that NATIONAL CHAMBER was descriptive of such services since it provides information allowing individuals to identify chambers of commerce nationwide. Thus, the Court held that the TTAB's refusal of the application was proper.

Regarding the second application, the Federal Circuit noted that the record showed that chambers of commerce promote the interests of businesspersons generally. The record also included articles indicating that chambers of commerce often engage in activities to help their members network with other businesspeople, become informed about governments' business-related legal and policy decisions, and receive training and support to grow and retain business. The Court held that, on this record, "substantial evidence supports the TTAB's determination that the designated business and regulatory data analysis services are within the scope of traditional chambers of commerce activities." *Id.* at 9. The Court further explained that it did not need to decide the descriptiveness on that basis alone because NATIONAL CHAMBER also describes the expressly recited function of the first service listed in the application—that the service is performed for the purposes of promoting the interests of businesspersons. Here again, the Court held that the TTAB's refusal of the application was proper.

Finally, the Court addressed COC's argument that the TTAB's reasoning was not expressed with sufficient particularity to allow for meaningful appellate review. The Court noted that the TTAB specifically cited COC's online chambers of commerce directory and found that the promotion of business interests is the main function of a chamber of commerce. The Court explained that "[w]hile the TTAB's decision would have been more helpful to us had it more explicitly tied its particular evidentiary findings to the individually recited services within the two applications, its reasoning in this case is sufficiently clear to permit us to understand why it believed that NATIONAL CHAMBER was descriptive of at least the two services discussed above." *Id.* at 10. Thus, the Court upheld the TTAB's refusal to register the service mark.

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An Inventor's Lack of Credibility Can Lead to a Conclusion of Intent to Deceive and a Finding of Inequitable Conduct

Carlos M. Tellez

Judges: Linn, Dyk, Prost (author)

[Appealed from D. Del., Chief Judge Sleet]

In *Aventis Pharma S.A. v. Hospira, Inc.*, No. 11-1018 (Fed. Cir. Apr. 9, 2012), the Federal Circuit affirmed the district court's determinations that (1) the asserted claim from one of the two patents-in-suit was obvious and noninfringed; (2) the asserted claim from the other patent-in-suit was infringed but obvious; and (3) both of the patents-in-suit were unenforceable for inequitable conduct.

The two patents-in-suit, U.S. Patent Nos. 5,750,561 ("the '561 patent") and 5,714,512 ("the '512 patent"), relate to the administration of the chemotherapy cancer drug docetaxel, which is marketed as Taxotere. Docetaxel belongs to a class of compounds known as taxanes, which are administered intravenously by delivering the drug in a diluted aqueous solution called a "perfusion." Because taxanes have low solubility in water and tend to precipitate out of solution, they are mixed with additives like surfactants and ethanol to stabilize the solution and delay precipitation. The taxane and additives are mixed to form a stock solution, which is then mixed with an injectable solution to form the perfusion.

The surfactant Cremophor was used in the prior art to form taxane stock solutions, but was known to trigger allergic reactions, including anaphylactic shock. The '561 and '512 patents relate to using surfactants, other than Cremophor, with docetaxel and decreasing the amount of ethanol to reduce alcohol intoxication and anaphylactic effects.

Only claim 5 of the '561 patent and claim 7 of the '512 patent were at issue on appeal. Claim 5 of the '561 patent is directed to a perfusion comprising docetaxel and the surfactant polysorbate, and recites that the "perfusion is capable of being injected without anaphylactic or alcohol intoxication manifestations being associated therewith." Claim 7 of the '512 patent is directed to a composition comprising docetaxel and polysorbate, and recites that the composition is "essentially free or free of ethanol."

After Hospira, Inc. ("Hospira") and Apotex Inc. and Apotex Corp. (collectively "Apotex") applied to the FDA for approval to market generic versions of Taxotere, Aventis Pharma S.A. and Sanofi-Aventis U.S., L.L.C. (collectively "Sanofi") sued for infringement of the '561 and '512 patents. After a bench trial, the district court found claim 7 of the '512 patent obvious and not infringed, and claim 5 of the '561 patent infringed but obvious. The district court also determined that the '512 and '561 patents were unenforceable for inequitable conduct, finding that the *Vidal Dictionnaire* ("*Vidal*") and Guéritte-Voegelein ("GV") references were material to patentability and that inventor Jean-Louis Fabre intentionally withheld them with the intent to deceive the PTO.

With respect to claim 5 of the '561 patent, Sanofi argued that the district court erred in construing the term "perfusion" as "an injectable solution containing the active pharmaceutical ingredient and an aqueous infusion fluid." Slip op. at 6 (citation omitted). According to Sanofi, the construction should have also required that the perfusion be effective for treatment, safe, and stable for at least eight hours.

On appeal, the Court dismissed Sanofi's argument that the construction for "perfusion" should have required that it be effective for treatment, safe, and stable for at least eight hours. The Court explained that neither the claims, the specification, nor the prosecution history suggested that the claimed perfusion must satisfy certain safety or efficacy standards. With respect to the eight-hour stability limitation, the Court reiterated that narrowing a claim term beyond its plain and ordinary meaning was permissible only when a patentee acts as its own lexicographer, or when the patentee disavows the full scope of a claim term either in the specification or during prosecution. The Court explained that claim 5 contained no limitations with respect to the claimed perfusion's stability. Acknowledging that the specification did include embodiments in which the perfusions had stabilities of about eight hours or more, the Court explained that those general descriptions of the characteristics of the embodiments were not sufficient to limit the claims, even if all of the embodiments were to contain a particular limitation.

Finally, the Court noted that statements made by the patentee during prosecution neither indicated that "perfusion" had a special definition nor clearly and unmistakably manifested the patentee's intention to limit claim 5 to perfusions that were stable for at least eight hours.

"[A]lthough the district court did not have the benefit of our *Therasense* opinion . . . , the court nevertheless found that the withheld references were but-for material to patentability and made distinct intent and materiality findings . . . , [and] we conclude that the court's inequitable conduct determination withstands even the more rigorous standard adopted in *Therasense*." Slip op. at 15.

Regarding the finding that claim 5 was obvious in light of the prior art (the GV and *Vidal* references), the Federal Circuit affirmed the district court's determination because, during oral argument, Sanofi's counsel confirmed that under the district court's construction of "perfusion," Sanofi did not dispute the obviousness finding.

Claim 7 of the '512 patent claims a "composition," which can be either a stock solution or a perfusion. With respect to stock solutions, the parties had agreed that the phrase "essentially free or free of ethanol" in claim 7 means "no more than 5% ethanol by volume." Relying on that construction, the district court found that claim 7 was obvious in light of a prior art patent, which disclosed both ethanol-containing and essentially ethanol-free stock solutions. Because Sanofi did not address the district court's obviousness finding with respect to stock solutions in its opening brief, the Federal Circuit considered the issue waived, even if the issue was addressed in Sanofi's reply brief. Thus, because the district court's obviousness finding regarding stock solutions was unchallenged, the Federal Circuit affirmed the obviousness determination of claim 7 of the '512 patent.

Regarding inequitable conduct, the Court initially noted that "although the district court did not have the benefit of our *Therasense* opinion . . . , the court nevertheless found that the withheld references were but-for material to patentability and made distinct intent and materiality findings . . . , [and] we conclude that the court's inequitable conduct determination withstands even the more rigorous standard adopted in *Therasense*." *Id*. at 15.

With respect to the materiality prong, the Court indicated that a prior art reference "is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art." *Id.* at 16 (quoting *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1291 (Fed. Cir. 2011)). Here, the

Court affirmed the district court's finding that the '561 and '512 patents were invalid based on, inter alia, the withheld GV and *Vidal* references. Thus, the Court found that such references were necessarily material to patentability.

Citing the *Therasense* decision, the Federal Circuit indicated that, "[t]o satisfy the intent requirement, 'the accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it,'" and that "the specific intent to deceive must be 'the single most reasonable inference able to be drawn from the evidence.'" *Id*. at 16-17 (quoting *Therasense*, 649 F.3d at 1292).

During trial, Fabre testified that he did not cite the *Vidal* reference because the experiments disclosed in the reference resulted in perfusions that were not stable for eight hours and were considered failures. Regarding the intent prong, Sanofi argued that, based on that testimony, the district court erred in finding Fabre had the specific intent to deceive because that finding was not the single most reasonable inference that could be drawn. The Court, however, gave deference to the determinations made by the district court, which found that Fabre's testimony lacked credibility.

The Court also pointed out the district court's emphasis on Fabre having disclosed a reference to the PTO identifying the problem Fabre's invention was addressing, but then not citing the *Vidal* reference that contained the solution Fabre followed to solve the problem. Another inconsistency in Fabre's testimony highlighted by the Court was that, on direct examination at trial, he discussed only those experiments prompted by the *Vidal* reference that were alleged failures, but then admitted under cross-examination that some experiments displayed stabilities of over thirty hours.

The Court reached the same conclusion regarding intent to deceive with respect to Sanofi's GV reference. The GV reference disclosed a specific solution of docetaxel in a polysorbate 80/ethanol system. Fabre testified that he did not disclose the GV reference to the PTO because he only read an earlier draft that did not contain the reference to the polysorbate 80/docetaxel formulation. The Federal Circuit noted that the district court found that testimony not credible based on other evidence presented at trial.

The Federal Circuit concluded that the district court's inequitable conduct determination was not an abuse of discretion because the district court's thorough discussion of its factual findings and its well-reasoned analysis were consistent with *Therasense*. Accordingly, the Federal Circuit affirmed.

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Litigation Settlement Negotiations Related to Reasonable Royalties and Damage Calculations Are Not Protected by a Settlement Negotiation Privilege

James A. Cooke

Judges: Rader, Dyk (author), Moore

[Appealed from N.D. Ill., Judge Chang]

In *In re MSTG, Inc.*, No. 11-M996 (Fed. Cir. Apr. 9, 2012), the Federal Circuit denied MSTG, Inc.'s ("MSTG") petition for a writ of mandamus directing the district court to vacate its order compelling MSTG to produce documents related to license negotiation discussions between MSTG and other companies. In so doing, the Court determined that such license negotiation discussions are not protected from discovery based on a settlement negotiation privilege and that the district court did not clearly abuse its discretion by ordering the production of such documents.

MSTG filed suit against AT&T Mobility, LLC ("AT&T") and other cell phone service providers and mobile device manufacturers, claiming infringement of patents covering third-generation ("3G") mobile telecommunications technologies. MSTG eventually settled with all defendants other than AT&T. As part of the settlement agreements, most defendants were granted licenses under the patents-in-suit, and one defendant entered into an agreement giving it an option to license the patents-in-suit at a predetermined rate.

MSTG produced six license agreements and an option agreement (collectively the "settlement agreements") to AT&T. AT&T then sought further discovery into the negotiations of the settlement agreements on the theory that those negotiations could be pertinent to an amount of any reasonable royalty. After MSTG objected on relevancy, AT&T moved to compel production of the documents. A magistrate judge denied AT&T's motion to compel under Fed. R. Civ. P. 26.

Later, MSTG's expert opined on a reasonable royalty, relying on deposition testimony of an MSTG executive to determine that the settlement agreements reflected "litigation-related compromises" and, as such, the royalty rates in the settlement agreements were not reflective of hypothetical negotiations between MSTG and AT&T.

AT&T subsequently sought reconsideration of the magistrate judge's order, arguing that the discussion of the license agreements in the expert report constituted new evidence supporting discovery of the settlement negotiations. Granting the motion, the magistrate judge found that the negotiation documents could shed light on why the parties reached their royalty agreements, and could provide guidance on whether some or all of the licenses could be considered a basis for calculating a reasonable royalty between AT&T and MSTG. The district court adopted the magistrate judge's conclusions and issued a final discovery order that compelled MSTG to produce the negotiation documents leading up to the settlement agreements.

MSTG petitioned the Federal Circuit for a writ of mandamus to vacate the discovery order, asserting that the license negotiations between it and its other licensees are protected by a settlement negotiation privilege.

"Therefore, in light of reason and experience, we hold that settlement negotiations related to reasonable royalties and damage calculations are not protected by a settlement negotiation privilege." Slip op. at 19.

After noting that mandamus is extraordinary relief and usually an inappropriate remedy for review of discovery orders, the Court noted that review was appropriate here because this was a matter of first impression and the district courts are split. Slip op. at 7. In analyzing the privilege issue, the Court noted that Rule 501 of the Federal Rules of Evidence authorizes federal courts to recognize new testimonial privileges through a process of "evolutionary development." *Id*. at 9 (citing *Jaffee v. Redmond*, 518 U.S. 1, 8-9 (1996)). The Federal Circuit subsequently analyzed the factors outlined in *Jaffee* to conclude that settlement negotiations related to reasonable royalties and damage calculations are not protected by a settlement negotiation privilege.

With respect to the *Jaffee* factors, the Court first noted that no state consensus exists as to a statutory privilege for settlement negotiations conducted absent mediation. Due to the lack of such a consensus, the Court found that a failure to recognize a federal privilege for MSTG's settlement negotiations will not "frustrate the purposes" of any state legislation.

Second, in determining whether a new privilege should be adopted for settlement negotiations, the Court looked to whether Congress had considered that or related questions. The Court noted that Congress, in adopting Rule 408 of the Federal Rules of Evidence, directly addressed the admissibility of settlements and settlement negotiation, but in doing so did not take the additional step of protecting settlement negotiations from discovery. Thus, the Court found that "[a]dopting a settlement privilege would . . . go further than Congress thought necessary to promote the public good of settlement, or in other words, to strike the balance differently from the one Congress has already adopted." *Id*. at 12-13.

Third, the Court noted that in determining whether new privileges should be recognized, the Supreme Court has been influenced by the list of evidentiary privileges recommended by the Advisory Committee of the Judicial Conference in its proposed Federal Rules of Evidence. Here, the Court found that the absence of a settlement negotiation privilege from the nine specific privileges recommended by the Advisory Committee cuts against MSTG's arguments.

Fourth, the Court noted that "[t]he Supreme Court requires that a party seeking judicial recognition of a new evidentiary privilege under Rule 501 demonstrate . . . that the proposed privilege will effectively advance a public good." *Id.* at 14 (alterations in original) (quoting *In re Sealed Case*, 148 F.3d 1073, 1076 (D.C. Cir. 1998)). In analyzing MSTG's assertion that settlement negotiations are rooted in an "imperative need for confidence and trust" and thus serve a public good, the Court noted that the need for confidence and trust alone is an insufficient reason to create a new privilege, and in other circumstances, the Supreme Court has rejected new privileges under Rule 501, even though recognition of a privilege would foster a relationship based on trust and confidence. *Id*. Further, while there is clearly an important public interest in favoring the compromise and settlement of disputes, the Court observed that disputes are routinely settled without the benefit of a settlement privilege. Thus, the Court found that "an across-the-board recognition of a broad settlement negotiation privilege is not necessary to achieve settlement." *Id*. at 15.

Finally, the Court noted that a privilege for settlement negotiations would necessarily be subject to numerous exceptions, and the existence of such exceptions would distract from the effectiveness, clarity, and certainty of such privilege. After examining the authority of the federal courts to impose heightened

standards for discovery to protect confidential settlement discussions, the Court found that the public policy goals asserted by MSTG in support of a privilege can more appropriately and effectively be achieved by limiting the scope of discovery.

Accordingly, the Federal Circuit denied MSTG's petition for writ of mandamus and held that settlement negotiations related to reasonable royalties and damage calculations are not protected by a settlement negotiation privilege.

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Software-Related Means-Plus-Function Claims Found Indefinite for Lack of Algorithmic Structure Corresponding to One of Multiple Identified Functions

John S. Sieman

Judges: Rader, O'Malley (author), Reyna

[Appealed from W.D. Pa., Judge Schwab]

In *Noah Systems, Inc. v. Intuit Inc.*, No. 11-1390 (Fed. Cir. Apr. 9, 2012), the Federal Circuit affirmed the district court's holding of invalidity on the ground of indefiniteness, where the specification of a patent with claims directed to an "access means" limitation did not disclose an algorithm to perform that function.

Noah Systems, Inc. ("Noah") brought suit against Intuit Inc. ("Intuit"), alleging infringement of U.S. Patent No. 5,875,435 ("the '435 patent"), directed to an automated financial accounting system. All of the asserted claims of the '435 patent contain an "access means" limitation, which the parties agreed was a means-plus-function limitation performing the function of "providing access to said file of said financial accounting computer for said first entity and/or agents of said first entity so that said first entity and/or said agent can perform one or more activities selected from the group consisting of entering, deleting, reviewing, adjusting and processing said data inputs." Slip op. at 5-6 (emphasis and citation omitted). In Noah's view, its specification adequately disclosed an algorithm corresponding to this function because it disclosed a financial access computer programmed to allow access upon entry of a passcode. In Intuit's view, on the other hand, the specification did not disclose any sufficient algorithm corresponding to the function.

The district court, adopting the recommendation of a special master, found the "access means" limitation indefinite during claim construction. In a motion for reconsideration, Noah asserted that expert evidence was necessary to explain how one of ordinary skill in the art would have understood the specification. The district court denied the motion, determining that expert evidence was inappropriate because no algorithm was disclosed.

Based on the claim construction order finding the "access means" limitation indefinite, Intuit sought an SJ motion of invalidity. In opposition, Noah renewed its position that an indefiniteness determination should not have been made without expert opinion, and submitted two expert declarations in support of its position. Again adopting the special master's recommendation, the district court granted SJ, finding that the specification lacked the necessary structure because it disclosed no algorithm at all, and, therefore, the district court need not consider the expert testimony proffered by Noah. Noah appealed.

"When the specification discloses an algorithm that only accomplishes one of multiple identifiable functions performed by a means-plus-function limitation, the specification is treated as if it disclosed no algorithm." Slip op. at 29.

The Court affirmed, but based on different reasoning. After rejecting Intuit's argument that Noah presented a new claim construction argument on appeal and therefore waived it, the Court turned to the merits of Noah's argument and agreed—contrary to the views of the district court and Intuit—that the specification disclosed at least some algorithm related to the function of the "access means." In particular, the Court found Noah correctly identified an algorithm in its specification for the passcode function associated with the "access means." That algorithm was not enough, however, to provide the necessary structure for the "access means" because that really included two functions: (1) providing access to the file, and (2) once access is provided, enabling the performance of one or more delineated activities. Noah's passcode algorithm only supported the first function.

Analyzing the question of whether Noah's specification disclosed an algorithm corresponding to the second function, the Court held the specification deficient. The Court found that several disclosures identified by Noah, including disclosures related to unlocking a computer file, did not suffice because those disclosures did not correspond to the other acts recited in the "access means" limitation, such as "entering," "deleting," "reviewing," and "adjusting" financial transaction data. *Id*. at 21. These specialized functions, the Court explained, could not be accomplished absent specialized programming. And the Court noted Noah's failure to disclose this specialized programming.

Noah disclosed that some type of accounting software was required for the patented system to operate, such as "off-the-shelf accounting software" for a personal computer. *Id*. at 24. But the specification described the operation of such software using functional, not structural, language. For example, according to the specification, the software would allow users to "perform activities selected from the group consisting of entering, deleting, reviewing, adjusting and processing data inputs in the master ledger," or "change orders, recording instruction adjustments, manual transactions, and the like." *Id*. (citations omitted). This purely functional language, in the Court's view, simply restates the function associated with the means-plus-function limitation, and cannot provide the required corresponding structure.

Noah tried to fill this gap in its specification by attempting to import its reference to off-the-shelf software into the claims and asserting that those of ordinary skill would have understood how to accomplish the function described with the assistance of off-the-shelf software. The Court rejected these arguments, explaining that the disclosure itself must identify the method for performing the function, whether or not a skilled artisan might otherwise be able to glean such a method from other sources or from his own understanding. This rule requiring the disclosure of specific programming, the Court explained, safeguards against purely functional claiming when a patentee employs a special purpose computer-implemented means-plus-function limitation.

After concluding that the specification only disclosed a partial algorithm for the functional language associated with the "access means" limitation, the Court explained that its case law differentiates between cases where a patent specification discloses no algorithm and cases where the specification discloses an algorithm that a defendant challenges as inadequate. Where no algorithm is disclosed, expert testimony is irrelevant. On the other hand, when the parties dispute the adequacy of a disclosed algorithm, adequacy is judged from the viewpoint of a person of ordinary skill, making expert testimony potentially relevant.

For cases like this one, where the specification discloses an algorithm for less than all of multiple identifiable functions recited in a claim, the Court decided to analyze the disclosures as if no algorithm is disclosed. The Court explained, in support of this approach, that it could not allow disclosure as to one function to fill the gaps in a specification as to a different, albeit related, function, or else it would open the door to generic and unbounded functional claiming. Applying this rule, the Court concluded that the district court did not err when it refused to allow expert testimony or other evidence regarding what one skilled in the art would understand from the specification before it held the "access means" limitation as

indefinite, and granted SJ of invalidity.

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Federal Circuit Affirms TTAB Decision Finding Design of a Closure Cap for Blood Collection Tubes Functional and Not Entitled to Registration

Stephanie H. Bald

Judges: Bryson, Clevenger (author), Linn (dissenting)

[Appealed from TTAB]

In *In re Becton, Dickinson & Co.*, No. 11-1111 (Fed. Cir. Apr. 12, 2012), the Federal Circuit affirmed the TTAB's finding that Becton, Dickinson and Company's ("BD") design of a closure cap for blood collection tubes ("BD Mark") was functional and thus not entitled to registration. The Court did not reach the issue of acquired distinctiveness (which BD had also appealed) because, even if the BD Mark had acquired distinctiveness, it would still be barred registration on the ground that it was functional.

BD applied to register the BD Mark for "closures for medical collection tubes," shown below, claiming acquired distinctiveness under 15 U.S.C. § 1052(f).

The Examining Attorney refused registration on the ground that the cap design was functional and, even assuming it was not functional, the cap design was a nondistinctive configuration. Further, she found that BD's declaration was insufficient to establish acquired distinctiveness. Considering the four *Morton-Norwich* factors, the TTAB concluded that the cap design, considered in its entirety, was functional. In its analysis, the TTAB gave less weight to less prominent features of the BD Mark, such as the exact spacing or shape of the ribs, because it found them to be incidental to the overall adoption of those features and hardly discernible when viewing the mark. The TTAB relied on Federal Circuit precedent, finding that the presence of nonfunctional features in a mark would not affect the functionality decision where the evidence showed the overall design to be functional. The TTAB also concluded that even if the cap design was not functional, BD had not established acquired distinctiveness.

"[T]he Board committed no legal error by weighing the functional and non-functional features of BD's mark against each other. Our functionality precedent indeed mandates that the Board conduct such an assessment as part of its determination of whether a mark in its entirety is overall de jure functional." Slip op. at 10-11.

On appeal, the Court found that one objective of the *Morton-Norwich* inquiry was to weigh the elements of the mark against one another to develop an understanding of whether the mark as a whole is functional and thus nonregistrable. The Court explained that whenever a proposed mark includes both functional and nonfunctional features, the critical question is the degree of utility present in the overall design of the mark. The Court noted that the *Morton-Norwich* decision stated the importance of the "degree of utility" proposition and explained how the distinction between de facto and de jure functionality gives shape to the Court's inquiry into the mark's degree of utility. De facto functionality simply means that a design has a function, like the closure cap in this case. Such functionality is irrelevant to the question of whether the mark as a whole is functional as to be ineligible for trademark protection. De jure functionality, on the other hand, means that the product is in its particular shape because it works better that way. And where a mark is composed of functional and nonfunctional features, whether an overall design is functional should be based on the superiority of the design as a whole rather than on whether each design feature is useful or serves a utilitarian purpose. A mark with significant functional features should not qualify for trademark protection where insignificant elements of the design are nonfunctional. Thus, the Court held that the TTAB had not committed legal error by weighing the functional and nonfunctional features of the BD Mark against each other.

The Federal Circuit then turned to the TTAB's functionality assessment under the *Morton-Norwich* factors, namely, (1) the existence of a utility patent disclosing the utilitarian advantages of the design; (2) advertising materials in which the originator of the design touts the design's utilitarian advantages; (3) the availability to competitors of functionally equivalent designs; and (4) facts indicating that the design results in a comparatively simple or cheap method of manufacturing the product.

The Federal Circuit found that the TTAB did not err in finding that the first factor weighed in favor of a finding of functionality. The Court agreed that one of the claims in BD's utility patent showed the utilitarian nature of at least two prominent features of the BD Mark: (1) the two concentric circles at the top of the closure cap, which allow a needle to be inserted; and (2) the ribs, which serve as a gripping surface. BD argued that these features, while disclosed in the patent, were not themselves claimed in the patent. But the Federal Circuit held that there need not be a patent claim for the exact configuration for which trademark protection is sought to undermine an applicant's assertion that an applied-for mark is not functional. Rather, statements in a patent's specification illuminating the purpose served by a design may constitute equally strong evidence of functionality. Accordingly, the Court found that the TTAB correctly read the patent to indicate that at least two of the important elements of the proposed mark were functional.

Regarding the second *Morton-Norwich* factor, the Federal Circuit agreed that BD's advertisements touted the utilitarian features of the BD Mark. BD argued that the designs shown in the ads are not exactly the same type as the BD Mark, but the Court rejected this contention, finding that it was a distinction without a difference. The Court explained that although the spire-like tops of the ribs may not be shown in the ads, the arrangement of the ribs along the side of the top and the same of the opening were sufficiently like the features of the claimed mark to show an identity of functionality between the articles shown in the advertising and the BD Mark's prominent features. BD also argued that the ads were "look for" ads that were not intended to tout particular features, but rather to cause the viewer to look at one part of the design in particular. But the Federal Circuit found that nothing in the text of the advertisements supported this "look for" concept, and rejected BD's argument.

As to the third factor, the Federal Circuit noted that if functionality is found based on other considerations, there is "no need to consider the availability of alternative designs, because the feature cannot be given trade dress protection merely because there are alternative designs available." Slip op. at 15 (quoting *Valu Eng'g v. Rexnord Grp*., 278 F.3d 1268, 1276 (Fed. Cir. 2002)). Thus, since the patent and advertising evidence established functionality, the Board did not even need to analyze whether alternative designs existed. Nonetheless, the Board did conduct this analysis and found that one of the proposed designs was irrelevant and the other two could not be characterized as alterative designs because they shared the same utilitarian features of the BD Mark.

Finally, regarding the fourth factor, there was little record evidence before the TTAB to determine whether the cap design resulted from a comparatively simple or inexpensive method of manufacture. The only evidence on this factor consisted of the declarations of two BD witnesses, who both averred that the design features did not lower the cost of manufacture. Because of this scarce evidence, the Court found that the TTAB did not err in refusing to weigh the fourth factor in its analysis. And the Court correctly found that the *Morton-Norwich* factors supported a finding of functionality.

In sum, because the Board committed no legal error in its assessment of the functionality of the BD Mark, and because substantial evidence supported the TTAB's findings of fact under the *Morton-Norwich* factors, the Federal Circuit affirmed the TTAB's decision.

In dissent, Judge Linn disagreed that substantial evidence supported the TTAB's conclusion of functionality under the *Morton-Norwich* factors. In his view, although certain features of the BD Mark were functional, the evidence fell short of supporting a finding that the BD Mark, as a whole, was functional. Judge Linn noted that de jure functionality is directed to the appearance of the design (not the thing itself) and is concerned with whether the appearance is dictated by function. While agreeing with the majority that the degree of design utility must be considered in determining de jure functionality, Judge Linn disagreed with the majority's approval of the TTAB's weighing the elements of a mark against one another to develop an understanding of whether the mark as a whole is functional. The proper inquiry, according to Judge Linn, is to examine the degree to which the mark as a whole is dictated by utilitarian considerations or is arbitrary. He found that in focusing on the functional attributes of the individual components, the TTAB and the majority overlooked the arbitrary nature of the overall design of the BD Mark.

Further, because the Board's analysis of distinctiveness was influenced in material respects by its legally erroneous finding of functionality, Judge Linn also indicated that he would vacate that portion of the TTAB's opinion and remand for reconsideration.

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No Liability for Induced Infringement Where Drug Label Does Not Instruct the Patented Method of Use

Marian T. Flattery

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

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

In *Bayer Schering Pharma AG v. Lupin, Ltd.*, Nos. 11-1143, -1228 (Fed. Cir. Apr. 16, 2012), the Federal Circuit affirmed the district court's dismissal of Bayer Schering Pharma AG and Bayer HealthCare Pharmaceuticals, Inc.'s (collectively "Bayer") claims for infringement of a method-of-use patent in two ANDA cases.

Bayer produces and markets Yasmin®, an oral contraceptive containing the active ingredient drospirenone. The FDA-approved label for Yasmin® states in the Indications and Usage section that "Yasmin is indicated for the prevention of pregnancy in women who elect to use an oral contraceptive." Slip op. at 12. The Pharmacodynamics subsection of the Clinical Pharmacology section of the label recites that drospirenone "is a spironolactone analogue with antimineralocorticoid activity. . . . Preclinical studies in animals have also shown that drospirenone has antiandrogenic activity." *Id*. at 13.

Bayer had listed three patents in the FDA's Orange Book in connection with Yasmin®, including U.S. Patent No. 5,569,652 ("the '652 patent"). The '652 patent claims a method of use for simultaneously achieving three effects: an antiandrogenic effect, an antialdosterone effect (also known as an antimineralocorticoid effect), and a contraceptive effect in a premenopausal or menopausal female patient. Defendants filed ANDAs with the FDA to market generic versions of Yasmin®. The ANDAs track the original NDA and seek FDA approval for the use of generic versions of Yasmin® for oral contraception. Bayer filed a complaint against defendants Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc. (collectively "Watson") and Sandoz, Inc. ("Sandoz") in 2008, and a complaint against Lupin, Ltd. and Lupin Pharmaceuticals, Inc. (collectively "Lupin") in 2010, alleging infringement of the '652 patent. The district court entered a judgment of noninfringement based on the pleadings in favor of Watson and Sandoz, holding that because the FDA had not approved the use of Yasmin® for the simultaneous treatment of the three conditions as claimed in the '652 patent, Bayer could not state a claim for patent infringement. Based on that ruling, Bayer and Lupin stipulated to, and the district court entered, final judgment of noninfringement in Bayer's suit against Lupin.

In a consolidated appeal, the Court addressed "whether the FDA has approved the use of Yasmin to achieve the combination of the three effects claimed in the '652 patent." *Id*. at 11. First, the Court rejected Bayer's argument that the label recognizes FDA approval of all three effects claimed in the '652 patent because of the recitation in the Clinical Pharmacology section that Yasmin® exhibits antimineralocorticoid activity and has potential for antiandrogenic activity. The Federal Circuit found that "[t]he reference in the Clinical Pharmacology section of the label to the antimineralocorticoid and

antiandrogenic activity of drospirenone is certainly not a direct indication of an appropriate use for Yasmin, and even if it could be considered an 'implied or suggested' indication of an appropriate use, the [FDA] regulation expressly states that such implied or suggested uses do not constitute approved ones." *Id.* at 14.

"My colleagues hold that the '652 patent cannot be infringed, as a matter of law, unless the label specifically authorizes physicians to prescribe Yasmin® to treat acne or as a diuretic. Maj. op. at 19. This criterion of infringement is as irrelevant as it is factually incorrect." Newman Dissent at 7.

The Court was unpersuaded by four pieces of evidence, including a declaration from a physician and a declaration from a former FDA official, that Bayer relied upon to support its argument that the references to antimineralocorticoid and antiandrogenic activity in the Clinical Pharmacology section indicated that the FDA had approved the use of Yasmin® to induce these effects. The Court found that this evidence demonstrates only that the FDA was aware that Yasmin® could cause the effects discussed in the '652 patent and does not go to the critical question of whether the FDA has found Yasmin® to be safe and effective for the purpose of inducing these effects in a patient with a specific need for those effects. "Absent that finding of safety and efficacy . . . on the Yasmin label, the Yasmin label cannot instruct (and the ANDA proposed label cannot induce infringement of) the method of use claimed in the '652 patent." *Id.* at 16-17.

Finally, the Federal Circuit indicated that the defendants' ANDAs seek approval to market the generic form of Yasmin® solely for contraceptive use, and there is no valid patent on the use of the drug for that purpose only. Applying *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003), and *Allergan, Inc. v. Alcon Laboratories, Inc.*, 324 F.3d 1322 (Fed. Cir. 2003), the Court concluded that it was clear that the defendants do not infringe Bayer's '652 patent under 35 U.S.C. § 271(e)(2)(A) and that their sale of the generic form of Yasmin® would not induce infringement of that patent. Accordingly, the Federal Circuit affirmed the district court's dismissal of the infringement claims.

In her dissent, Judge Newman stated that the Court erred in endorsing the dismissal of the complaint on the pleadings, thereby denying Bayer the opportunity to litigate infringement of the '652 patent before the marketing of generic counterparts of Yasmin®. According to Judge Newman, neither the district court nor the Federal Circuit conducted a standard infringement analysis into whether the sale or use of the generic equivalent of Yasmin®, in accordance with the representations in the ANDA, infringes the '652 patent. Judge Newman maintained that Bayer had sufficiently alleged that an "intended use" for Yasmin®, as approved by the FDA, is simultaneous treatment of all three effects, and that it was improper for the Court to make contrary findings in considering a motion to dismiss.

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DJ Jurisdiction Exists Even If the Action May Later Become Moot

Mindy L. Ehrenfried

Judges: Bryson, Dyk (author), Moore

[Appealed from D. Del., Judge Stark]

In *Dey Pharma, LP v. Sunovion Pharmaceuticals Inc.*, No. 11-1507 (Fed. Cir. Apr. 16, 2012), the Federal Circuit affirmed the district court's holding that Sunovion Pharmaceuticals Inc.'s ("Sunovion") proffered covenant not to sue Dey Pharma, LP ("Dey") did not divest the district court of subject matter jurisdiction over Dey's DJ action, despite the possibility that the action could later become moot.

Sunovion manufactures and sells Xopenex, an FDA-approved drug used to prevent or relieve breathing difficulties resulting from asthma and chronic obstructive pulmonary disease. Breath Ltd. ("Breath") filed the first ANDA, with Paragraph IV certifications for all of the nonexpired, Orange-Book-listed patents for Xopenex: U.S. Patent Nos. 5,362,755 ("the '755 patent"); 5,547,994 ("the '994 patent"); and 6,451,289 ("the '289 patent"). Sunovion sued Breath, asserting infringement of all three patents, but the parties settled, entitling Breath to enter the market with its generic on a certain date or the date of an earlier third-party commercial launch.

Subsequently, Dey filed a second ANDA, also with Paragraph IV certifications for the same three patents. Sunovion sued Dey, asserting infringement of only the '755 patent and the '994 patent, but not the '289 patent—the last to expire of the three patents. Dey filed a DJ action that the '289 patent is invalid or not infringed. The DJ action was "designed to trigger" Breath's exclusivity period, thereby hastening the FDA's approval of Dey's ANDA and, in turn, Dey's market entry. Sunovion responded by offering Dey a covenant not to sue and filing a motion to dismiss the DJ action for lack of subject matter jurisdiction. The district court denied Sunovion's motion to dismiss, holding that (1) covenants not to sue do not defeat DJ jurisdiction; and (2) even if the district court found the '755 patent and the '994 patent invalid or not infringed, the '289 patent would remain a legal barrier to FDA approval of Dey's ANDA, which is a cognizable injury properly addressed by a DJ action. The parties stipulated to a final judgment of noninfringement, and Sunovion appealed, disputing only the district court's holding on subject matter jurisdiction.

"What Sunovion ignores is that there is a difference between finding that a controversy exists to initiate a suit and determining that the controversy has become moot. While Article III requires that 'an actual controversy must be extant at all stages of review, not merely at the time the complaint is filed,' the question of whether a controversy exists at a later stage of the proceeding is governed by mootness doctrine." Slip op. at 14 (citation omitted).

The Court first analyzed whether DJ jurisdiction existed at the time Dey filed its DJ action. Sunovion argued that DJ jurisdiction did not exist, because even if Dey secured success in the DJ action, Dey would still need to succeed in establishing invalidity or noninfringement of the other two Orange-Book-listed patents in order to trigger Breath's exclusivity period. Finding the facts "materially identical" to those in *Caraco Pharmaceutical Laboratories, Ltd. v. Forest Laboratories, Inc.*, 527 F.3d 1278 (Fed. Cir. 2008), the Court rejected Sunovion's argument and stated that "simply eliminating one barrier [to market entry] is sufficient for declaratory jurisdiction, so long as litigation is also pending that could eliminate the other barriers." Slip op. at 11.

The Court then turned to whether DJ jurisdiction continued to exist after Dey filed its DJ action. In arguing against continuing DJ jurisdiction, Sunovion reasoned that pursuant to their settlement agreement, Breath could launch its generic before the pending litigation between Sunovion and Dey over the '755 patent and the '994 patent reached final conclusion, thereby extinguishing the case or controversy. The Court rejected Sunovion's argument, explaining that although Breath *could* launch its generic on the agreed-upon date, no guarantee exists that Breath *will* launch its generic on that date. Thus, if Breath delays its launch (i.e., delays triggering its 180-day exclusivity period), Dey and other subsequent ANDA filers would be barred from the market, unless they obtain a court judgment of invalidity or noninfringement.

Finally, the Court noted that "[w]hat Sunovion ignores is that there is a difference between finding that a controversy exists to initiate a suit and determining that the controversy has become moot." *Id*. at 14. The Court found Sunovion failed to meet "the heavy burden" of coming forth with evidence of mootness, in light of Sunovion's admission that the case will not become moot until Breath actually launches its generic. Accordingly, the Court held that because DJ jurisdiction existed when Dey filed its action, "the case may proceed until rendered moot." *Id*. at 15.

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Federal Circuit Reaffirms Broad and Expansive Obviousness Inquiry, Rejecting a Formal Burden-Shifting Framework

Lillian M. Robinson

Judges: Newman, O'Malley (author), Reyna

[Appealed from D. Del., Judge Robinson]

In *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litigation*, Nos. 11-1399, -1409 (Fed. Cir. Apr. 16, 2012), the Federal Circuit reversed the district court's obviousness finding, holding that it failed to consider the lack of a known pharmokinetic/pharmodynamic ("PK/PD") relationship for the claimed drug formulation, thereby erring in assessing the importance of the teachings of the prior art. The Court also affirmed the rejection of the defendants' alternate argument that the asserted patents were invalid for failure to disclose the best mode, stating that the evidence supported a finding that the patents enable one of ordinary skill in the art to practice the inventor's preferred dew points.

The plaintiffs, Aptalis Pharmatech, Inc. (formerly Eurand, Inc.), Anesta AG, and Cephalon, Inc. (collectively "Cephalon"), are the owners and exclusive licensees, respectively, of U.S. Patent Nos. 7,387,793 ("the '793 patent") and 7,544,372 ("the '372 patent"). The '793 patent covers an extended-release dosage form of skeletal-muscle relaxants; the '372 patent covers a method of relieving muscle spasms with the formulation. Cephalon markets a drug covered by the '793 and '372 patents with cyclobenzaprine hydrochloride as the active pharmaceutical ingredient under the brand name Amrix. To formulate a therapeutically effective extended-release version of the drug, the inventors had to determine the correct PK/PD profile. The PK value indicates what a person's body does to the drug, and the PD value describes the effect the drug renders on a person's body.

The defendants, Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively "Mylan"), and Par Pharmaceutical, Inc. ("Par"), filed ANDAs for generic versions of extended-release cyclobenzaprine hydrochloride. The defendants filed Paragraph IV certifications in support of their ANDAs, alleging that their generic products would not infringe the '793 patent, or that the patent was invalid or unenforceable. Because Mylan was the first party to file a Paragraph IV certification, the FDA granted it a 180-day exclusive marketing period for its generic product.

Cephalon sued Mylan and Par for patent infringement based on their ANDA filings. The district court ruled that the defendants' products infringed the '793 and '372 patents, but that Cephalon's asserted patent claims were invalid as obvious, finding the claimed extended-release PK profile was bioequivalent to the immediate-release PK profile. Mylan launched its generic product the day after this order, and Cephalon moved to enjoin Mylan's launch pending appeal. The district court granted Cephalon's motion for injunctive relief, holding that the potential harm to Cephalon and lack of corresponding harm to Mylan weighed in favor of an injunction.

"[O]n the facts of this case—in which therapeutic effectiveness is a claimed limitation and the parties do not dispute that cyclobenzaprine lacked a known PK/PD relationship—[the defendants] cannot rely on bioequivalence as the sole basis for an obviousness finding, particularly given the heavy burden of proof imposed on them in this context." Slip op. at 38.

On appeal, the Court held that the district court should have gone beyond bioequivalence and also considered the asserted claims' limitation requiring therapeutic effectiveness. Further, the district court should have determined whether it would have been obvious to a skilled artisan at the time of the invention that a bioequivalent PK value would satisfy that limitation. Because cyclobenzaprine lacked a known PK/PD relationship at the time of the invention, skilled artisans could not predict whether any particular PK profile, including a bioequivalent one, would produce a therapeutically effective formulation. The Court determined that while the prior art references may teach the claimed physical drug delivery system or dissolution profile, they did not reveal anything about the therapeutically effective PK profile. Accordingly, the Court held that because therapeutic effectiveness is a claimed limitation and the parties did not dispute that cyclobenzaprine lacked a known PK/PD relationship, the defendants could not rely on bioequivalence as the only basis for an obviousness finding.

The Court further clarified the proper framework for making an obviousness determination generally. According to the Court, the district court erred by making its finding that the patents-in-suit were obvious before considering the objective (or "secondary") considerations and by shifting the burden of persuasion to Cephalon. The Court reiterated the "expansive and flexible" nature of the obviousness inquiry, affirming that the fact-finder must consider *all* objective evidence before reaching an obviousness conclusion. This approach, the Court noted, guards against the hindsight bias by requiring the fact-finder to withhold judgment on an obviousness challenge until it considers all relevant evidence. In doing so, the Court rejected the formal burden-shifting approach taken by the district court, where secondary considerations are only considered to rebut a "prima facie" case of obviousness. The Court found the secondary considerations of nonobviousness particularly helpful in this case, determining that a long-felt need for an extended-release formulation and the failure of others to formulate one strongly support a conclusion of nonobviousness.

The defendants also argued that the asserted claims were invalid for failure to meet the best mode requirement because the specification failed to disclose the best mode by omitting a particular range of dew points. The Court, however, rejected this argument, determining that the specification need not disclose the optimal dew points to enable skilled artisans to practice the best mode.

Finally, the Court considered Mylan's appeal of the district court's order enjoining their launch of a generic version of Amrix. Because Mylan was no longer a prevailing party and several issues had not yet been litigated between the parties, the Court declined to consider the arguments relating to when an injunction pending appeal may be imposed on a prevailing party in an ANDA action.

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Federal Circuit Considers Transferred Patent-Related State Law Malpractice Case, but Questions Balance Between Federal and State Judicial Responsibilities

Hojung Cho

Judges: Prost (concurring), Mayer, O'Malley (concurring) (per curiam)
[Appealed from W.D. Tex., Chief Judge Biery]

In *USPPS, Ltd. v. Avery Dennison Corp.*, No. 11-1525 (Fed. Cir. Apr. 17, 2012), the Federal Circuit affirmed the district court's decision to dismiss a claim for breach of fiduciary duty and fraud, holding that the Court had jurisdiction pursuant to 28 U.S.C. § 1338 and that USPPS, Ltd.'s ("USPPS") complaint was untimely.

In 1999, Joe Pat Beasley filed a patent application for personalized postage stamps. In 2001, the PTO issued a notice of allowance of U.S. Patent Application No. 09/326,712 ("the '712 application"). Beasley then entered into a licensing agreement with Avery Dennison Corporation ("Avery"). The agreement specified that Avery would assume responsibility for prosecution of the '712 application and would pay patent prosecution expenses. Beasley appointed Renner, Otto, Boisselle & Sklar, L.L.P. ("Renner") to prosecute the '712 application. A Renner attorney filed a supplemental IDS disclosing a prior art reference and also filed a continuation application. The PTO issued a second notice of allowance.

Beasley transferred the ownership of the '712 application to USPPS. USPPS and Avery entered into an agreement concerning the personalized postage stamps. Later, as part of its own independent quality review, the PTO vacated its notice of allowance and issued final rejections in the '712 application and the continuation application, based on a newly discovered prior art patent reference.

Beasley and USPPS alleged that Avery mismanaged the applications. In a prior action, Beasley brought suit against Avery and Renner, alleging negligence, among other things, but the district court dismissed Beasley's suit, concluding that Beasley lacked standing because he had transferred title to the '712 application to USPPS. Later, USPPS filed the instant action, alleging breach of fiduciary duty and fraud, based on Avery's alleged representation that Beasley was the client of Renner and failure to inform USPPS that Avery (not Beasley or USPPS) was the client. USPPS contended that Beasley and USPPS had no legal representation in the prosecution of the patent that caused injury and damages. The district court dismissed USPPS's complaint as barred by the statute of limitations, but the Court of Appeals for the Fifth Circuit reversed, determining that it could not definitively say that the discovery rule and fraudulent concealment exceptions to the running of the limitations period did not apply. On remand, following a limited discovery period, the district court granted Avery's motion for SJ, concluding that neither exception served to postpone the accrual of USPPS's claims. USPPS appealed for a second time to the Fifth Circuit.

"For this court to refuse to adjudicate the merits of USPPS'[s] appeal at this stage of the proceedings would subject the parties to precisely the sort of 'jurisdictional ping-pong' the Supreme Court has cautioned against." Slip op. at 10 (citing *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 818 (1988)).

This time, the Fifth Circuit transferred the appeal to the Federal Circuit, reasoning that the Federal Circuit has exclusive jurisdiction of an appeal where the district court's jurisdiction was based, in whole or in part, on 28 U.S.C. § 1338. The Fifth Circuit also found that the Federal Circuit has jurisdiction over state law malpractice claims where the alleged malpractice involves "a question of patentability [even] where no patent ha[s] actually issued." Slip op. at 7 (alterations in original) (quoting *USPPS, Ltd. v. Avery Dennison Corp.*, 647 F.3d 274, 280 (5th Cir. 2011) ("Transfer Order")). The Fifth Circuit acknowledged that the decision to transfer USPPS's state law tort claim raised an important "federalism inquiry," and noted that the transfer would be appropriate only if the patent issue presented in USPPS's state law claim rose "to the level of creating a substantial federal interest such that the Federal Circuit has exclusive appellate jurisdiction." *Id.* at 8 (quoting Transfer Order, 647 F.3d at 278). The Fifth Circuit then concluded that the patent issues raised in USPPS's appeal involved a sufficiently substantial federal interest to permit federal jurisdiction over a state law tort.

Following the transfer, the Federal Circuit affirmed that it has jurisdiction over the state law malpractice claims. Citing *Davis v. Brouse McDowell, L.P.A.*, 596 F.3d 1355, 1359-62 (Fed. Cir. 2010), the Court reasoned that unless USPPS could demonstrate that its invention was patentable over the prior art, it could not establish that the defendants' actions "caused [it] to suffer any damages." Slip op. at 9 (alteration in original). The Court concluded that it is bound by the *Davis* decision regarding the exercise of § 1338 jurisdiction, unless it is overruled en banc. The Court also noted that if the Court refused to adjudicate the merits of USPPS's appeal, it would subject the parties to precisely the sort of "jurisdictional ping-pong" the Supreme Court has cautioned against. *Id.*

Next, the Court held that the district court correctly determined that USPPS's complaint was untimely. In its analysis, the Court reviewed two exceptions to the Texas law that the statute of limitations begins to run when a legal injury occurs, i.e., the "discovery rule" and the "fraudulent concealment" doctrine. *Id.* at 11. Regarding the discovery rule, the Court observed that because USPPS knew, or should have known, by May 2003 that it had suffered an actionable injury as a result of the defendants' alleged wrongdoing, the discovery rule does not serve to defer the accrual of its claim. After considering USPPS's arguments, the Court found that regardless of whether USPPS believed that the defendants had acted negligently or with fraudulent intent, USPPS's cause of action accrued when it learned that it had suffered an actionable injury.

Regarding the fraudulent concealment doctrine exception, the Court rejected USPPS's assertions that, due to Avery's alleged misrepresentations and fraud, USPPS did not learn until 2004 that Renner was working for Avery and not for USPPS. The Court pointed out that the fraudulent concealment doctrine "only tolls the running of limitations until the fraud is discovered or could have been discovered with reasonable diligence." *Id*. at 14 (quoting *BP Am. Prod. Co. v. Marshall*, 342 S.W.3d 59, 67 (Tex. 2011)).

Given that Avery was paying Renner's fees and had acted to restrict communications between Renner and USPPS, the Court found that USPPS knew, or in the exercise of due diligence should have known, that Renner was acting as legal counsel to Avery in the prosecution of the '712 application. Further, the Court noted that, even assuming arguendo that the defendants failed to disclose the fact that Renner was working for Avery, the statute of limitations was tolled only until such time as USPPS, with exercise of reasonable diligence, should have discovered that fact. Thus, the Court affirmed the district court's dismissal, holding that it had jurisdiction and that USPPS's complaint was untimely.

In her concurring opinion, Judge Prost agreed that the Fifth Circuit's transfer to the Federal Circuit was

appropriate, but noted that the federalism question raised in Judge O'Malley's concurring opinion was not presented, briefed, or argued in this case. Referring to the concurrence in the denial of the petition for rehearing en banc in *Byrne v. Wood*, No. 11-1012, 2012 U.S. App. LEXIS 6021, at *2-8 (Fed. Cir. Mar. 22, 2012), Judge Prost also noted that the substantive patent law issues implicated in the patent-based malpractice cases in the Court necessarily make the issues "substantial" within the meaning of *Christianson v. Colt Industries Operating Corp.*, 486 U.S. 800, 809 (1988), and indicate a "serious federal interest" in federal adjudication within the meaning of *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing*, 545 U.S. 308, 313 (2005).

In her separate concurring opinion, Judge O'Malley reviewed the federalism concerns raised by the Court's exercise of jurisdiction over state law claims. According to her opinion, the Court's case law requiring the exercise of jurisdiction over state law claims such as those at issue conflicts with Supreme Court precedent, citing *Christianson*, 486 U.S. at 817-19. In Judge O'Malley's view, under the correct application of Supreme Court case law, this case did not invoke jurisdiction under 28 U.S.C. § 1338. She reasoned that USPPS asserted only state law claims for fraud and breach of fiduciary duty, for which federal law does not create a cause of action. Further, Judge O'Malley stated that even considering the Supreme Court's warning against "jurisdictional ping-pong," it is inefficient and unproductive for this Court to hear the same case upon which the Fifth Circuit has already ruled.

Judge O'Malley noted that the claims in this case fail at least two factors under the *Grable* analysis, i.e., "if a federal issue is substantial," and if "exercising federal jurisdiction will disturb the balance of federal and state." O'Malley Concurrence at 5-6 (citing *Grable*, 545 U.S. at 314). First, the purported "patent" issue in this case is not "substantial" under *Grable*, because determining whether USPPS likely could have obtained a patent in light of the specific prior art is a case-specific, factual inquiry and requires only application, not interpretation, of the federal patent laws. Second, exercising federal jurisdiction in this case would disturb the balance of federal and state judicial responsibilities. Judge O'Malley noted that state courts are the traditional arbiter of such misconduct, which is governed by long-standing common law principles of negligence, fraud, and breach of fiduciary duty. Judge O'Malley raised a concern about "the far-reaching nature of [the Court's] reasoning" in these patent-related malpractice cases. *Id*. at 8.

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May 2012

Federal Circuit Has Jurisdiction over State Law Fraud Claim Arising out of Patent Prosecution

Victoria S. Lee

Judges: Bryson, Clevenger (author), O'Malley (concurring)

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

In *Landmark Screens, LLC v. Morgan, Lewis & Bockius, LLP*, No. 11-1297 (Fed. Cir. Apr. 23, 2012), the Federal Circuit reversed the district court's SJ dismissal of Landmark Screens, LLC's ("Landmark") state law fraud claim against Morgan, Lewis & Bockius, LLP ("MLB") and Thomas D. Kohler under the California statute of limitations, vacated the district court's partial SJ damages order, and remanded the case for trial on the fraud claim.

Landmark invented a light-emitting diode electronic billboard and retained Kohler, who was at that time a partner at Pennie & Edmonds LLP ("Pennie"), to acquire a patent. In 2002, Kohler filed U.S. Patent Application No. 10/045,096 ("the '096 application"), which included seventy-two claims covering different aspects of Landmark's invention. The PTO issued a restriction requirement and Kohler chose one embodiment, electing to pursue the others through divisional applications. Ultimately, the PTO issued U.S. Patent No. 6,639,574 ("the '574 patent") that covered the elected claims. In addition, Kohler submitted Divisional Application No. 10/640,916 ("the '916 divisional application"), but he failed to include the required drawings and specifications, did not incorporate by reference materials filed in the '096 application, and did not use the PTO's "postcard receipt method" (and therefore did not receive prompt notification from the PTO). The PTO issued a notice about these missing parts, but neither Kohler nor MLB (Kohler's new firm) took action until more than one year after the publication of the application that led to the parent '574 patent. Therefore, that published application became prior art against the '916 divisional application under 35 U.S.C. § 102(b). "Unless the PTO could be convinced to give the '916 divisional application the benefit of an earlier filing date, all claims in the '916 divisional application would be lost." Slip op. at 4. Rather than notifying Landmark, Kohler filed an unsuccessful petition, which the PTO dismissed, to grant the '916 divisional application the original filing date. Kohler told Landmark, without explanation, that the claims in the '916 divisional application were "lost," but indicated that the firm was working to fix the claims. *Id.* at 5. Landmark alleged Kohler and MLB actively misled it at that point by falsely communicating a possibility to fix the claims. *Id.*

The following year, Landmark turned to new patent counsel to rectify the "lost" claims. The new counsel determined that Landmark could seek a broadening reissue of the '574 patent under 35 U.S.C. § 251. The PTO granted reissue patent RE40,953 ("the RE'953 patent"), which includes the claims in the '574 patent and new claims 24-66. *Id.* at 15-16.

Landmark filed suit against Kohler, Pennie, and MLB in the California state court, alleging legal malpractice, negligence, and breach of fiduciary duty. Landmark settled with Pennie and entered a

partial settlement with Kohler. On May 21, 2008, the California state court dismissed Landmark's remaining claims against MLB and Kohler as an MLB lawyer for lack of subject matter jurisdiction, stating that the federal courts had exclusive jurisdiction, as the case depended on a substantial question of patent law. *Id.* at 5-6.

That same day, Landmark filed a complaint in the federal district court that contained the same claims as in the state court action plus a claim for breach of contract. Landmark subsequently also added a claim for fraud. With the exception of the fraud claim, the district court dismissed all of the claims for being barred by California's one-year statute of limitations for legal malpractice—which Landmark did not appeal. *Id.* at 6. Regarding the fraud claim, the district court entered partial SJ to damages, limiting Landmark's recovery were it to succeed on the merits of its fraud claim, and the district court granted SJ to the defendants, ruling that Landmark had notice of its fraud claim more than three years before filing its federal lawsuit, and that the claim was barred by the three-year statute of limitations. *Id.* at 6-7.

"Because the underlying question here is whether Landmark would have been able to achieve patent protection for its invention absent the alleged malpractice, there is a substantial question of patent law presented that conferred jurisdiction to the district court under 28 U.S.C. § 1338(a) at the time of filing of the original complaint." Slip op. at 8-9.

On appeal, as an initial matter, the Court determined, based on a review of the original complaint, that it had proper jurisdiction over Landmark's claims because they were appealed from a final district court decision where the action arose "under any Act of Congress relating to patents." *See id.* at 7-9. As the underlying question of Landmark's original claims was whether it "would have been able to achieve patent protection for its invention" absent the alleged malpractice and fraud, *id.*, the Court's jurisdiction was proper, *id.* at 8-9 (citing California state law). The Court applied the Ninth Circuit's standard of review and statute of limitations laws, reviewing the district court's SJ order and decision whether to toll the statute of limitations de novo.

Under the California Code of Civil Procedure, a fraud claim has a three-year statute of limitations. *See id.* at 11 (citing Cal. Civ. Proc. Code § 338(d) (West 2011)). Landmark filed the district court suit on May 21, 2008. The district court found that Landmark had received notice of its fraud claim over three years earlier in late March 2005, when Kohler sent Landmark a letter stating that there had been an error with the '916 divisional application and that all of the claims were potentially lost, triggering the statute of limitations. Landmark sought relief from the statute of limitations via equitable estoppel and equitable tolling. The district court rejected Landmark's equitable estoppel theory and did not address the tolling issue. The Court concluded that the district court erred in not tolling the three-year statute of limitations for fraud claims during the time the case was pending in the state courts and, therefore, did not address equitable estoppel.

Under California state law, equitable tolling applies when a party with several legal remedies in good faith pursues one remedy designed to lessen the extent of his injuries or damage. The law tolls the limitation period of a second action during the pendency of a first action later found to be defective because "California law 'favors avoiding forfeitures and allowing good faith litigants their day in court.'" *Id.* at 12 (citation omitted). In determining whether equitable tolling should apply, courts consider (1) timely notice to the defendant in filing the first claim; (2) lack of prejudice to the defendant in gathering evidence to defend against the second claim (i.e., if the claims are based on essentially the same set of facts); and (3) good faith and reasonable conduct by the plaintiff in filing the second claim. Landmark gave timely notice to MLB and Kohler by filing the state court lawsuit less than one year after receiving notice of problems with the '916 divisional application, within the statute of limitations for malpractice. MLB and Kohler were on notice of all key facts from the state court action, so they did not suffer any prejudice. Lastly, because "Landmark reasonably and in good faith pursued a remedy in the state courts,

only to learn that the state courts lacked jurisdiction over its legal remedy[,] Landmark thus qualifies for equitable tolling under California law." *Id.* at 14-15. Accordingly, the Federal Circuit reversed the district court's judgment that the fraud claim was time barred.

Regarding the appeal from the damages order, the Federal Circuit found that the district court erred in holding Landmark could suffer no harm after the issuance of the RE'953 patent. *Id.* at 15-17. Under 35 U.S.C. § 251, patent protection cannot be extended to substantially identical claims that were not properly prosecuted in divisional applications, but rather where claims in a reissue application are not substantially identical to previously nonelected claims. When the reissue claims are broader than the corresponding issued claims, the patentee may assert that the issued claims are "wholly or partly inoperative or invalid . . . by reason of the patentee claiming . . . less than he had a right to claim in the patent." *Id.* at 16 (alterations in original) (citing *In re Doyle*, 293 F.3d 1355, 1360 (Fed. Cir. 2002)). The district court compared the claim language of independent reissue claims 43 and 58 (and their dependent claims) to corresponding claims in the '916 divisional application. It reasoned that the scope of the reissue claims were broader and that because the scope of the "lost" claims was recovered by the broader reissue claims, Landmark's right to any damages related to those reissue claims must be cut off from the date of the reissue patent. The Federal Circuit, however, found that the district court overlooked the fact that reissue claims 43 and 58 are—in *other* respects—actually more narrow than their corresponding divisional claims. *Id.* at 17-18. Because the district court did not reconcile these opposing scopes, its conclusion that the reissue claims necessarily encompass the divisional claims was incorrect. The Court therefore vacated the damages order.

In a concurring opinion, Judge O'Malley stated additional reasons why the damages order should be vacated, namely, that reasonable jurors could have predicted a damages award to Landmark and that the judge failed to address what a reasonable juror might or might not have concluded on the facts presented. The trial judge had treated the issue as a matter of law, as proper in a patent infringement action—not a matter of fact as it were in the state law fraud action at hand. Judge O'Malley additionally indicated that she believed the case law regarding the scope of the Federal Circuit's jurisdiction should be considered en banc, specifically in light of the fact that Landmark's malpractice claims, which were "far from frivolous," were "irretrievably lost" due to changes in the Federal Circuit's case law regarding jurisdiction. O'Malley Concurrence at 5.

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Looking Ahead

On May 4, 2012, in *Minkin v. Gibbons, P.C.*, No. 11-1178 (Fed. Cir. May 4, 2012), the Federal Circuit affirmed the district court's grant of SJ in favor of the law firm of Gibbons, P.C. ("Gibbons"), finding that Herman Minkin failed to raise a genuine dispute of material fact regarding causation, a necessary element in New Jersey legal malpractice cases. Minkin alleged that Gibbons committed malpractice in prosecuting a patent application for a hand tool where he was the sole inventor, when a Minkin customer developed a competing product by easily designing around his patent. Minkin alleged that his patent was so negligently drafted by Gibbons that it offered no meaningful protection against infringers.

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 *In re MSTG, Inc.*, No. 11-M996 (Fed. Cir. Apr. 9, 2012), the Federal Circuit denied MSTG, Inc.'s ("MSTG") petition for a writ of mandamus, finding that license negotiation discussions are not protected from discovery based on a settlement negotiation privilege, after MSTG's expert had relied upon the discussions in his determination of a reasonable royalty. Noting that this was an issue of first impression, the Court analyzed the recognition process for new testimonial privileges under the Federal Rules of Evidence and determined that the public policy goals asserted by MSTG in support of a privilege can more appropriately and effectively be achieved by limiting the scope of discovery.

See this month's edition of *Last Month at the Federal Circuit* for a full summary of this decision.

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