Last Month at the Federal Circuit

May 2014

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[Appealed from Board]

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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To Establish That the Prior Art Is "Basically the Same" as a Design Patent, the District Court Only Needs to Describe the Relevant Design Characteristics of the Claimed Design in Comparison with the Prior Art

Ming W. Choy

Judges: Rader, Prost (author), Chen

[Appealed from N.D. Ohio, Judge Gaughan]

In *MRC Innovations, Inc. v. Hunter Manufacturing, LLP*, No. 13-1433 (Fed. Cir. Apr. 2, 2014), the Federal Circuit affirmed the district court's SJ of invalidity with respect to U.S. Design Patent Nos. D634,488 S ("the '488 patent") and D634,487 S ("the '487 patent").

Plaintiff MRC Innovations, Inc. ("MRC"), the assignee of both patents-in-suit, sued Defendants Hunter Manufacturing, LLP and CDI International, Inc. (collectively "Hunter") for willful infringement of the '487 and '488 patents. The '487 patent claims an ornamental design for a baseball jersey for a dog, and the '488 patent claims an ornamental design for a football jersey for a dog. The district court granted SJ on the ground that both patents are obvious in view of several prior art pet jerseys. The district court specifically found that the '488 patent was obvious in view of a green pet jersey bearing a Philadelphia Eagles logo ("the Eagles Jersey"), as a primary reference, together with a "V2" football jersey ("the V2 Jersey") and a "Sporty K9" jersey ("the Sporty K9 Jersey"), as secondary references. The district court also found that the '487 patent was obvious over the baseball version of the Sporty K9 Jersey ("the Sporty K9 Baseball Jersey"), as a primary reference, together with the V2 Jersey and the Eagles Jersey, as secondary references. MRC appealed.

The pictures of the claimed design of the '488 patent, the Eagles Jersey, and the V2 Jersey are presented below:

'488 patent	Eagles Jersey	V2 Jersey
		
		

On appeal, the Federal Circuit noted the obviousness inquiry, in the context of design patents, is whether a designer of ordinary skill "would have combined teachings of the prior art to create the same overall visual appearance as the claimed design." Slip op. at 6 (quoting *Durling v. Spectrum Furniture Co.*, 101 F.3d 100, 103 (Fed. Cir. 1996)). Such an inquiry involves a two-step process. First, a single primary reference must be identified that creates "basically the same" visual impression created by the patented design as a whole, and the reasoning behind choosing such a primary reference must be provided.

Second, secondary references may be identified, which must be "so related [to the primary reference] that the appearance of certain ornamental features in one would suggest the application of those features to the other." *Id.* at 7 (alteration in original) (quoting *Durling*, 101 F.3d at 103).

"As an initial matter, it is true that the district court did not expressly undertake to translate the claimed design into a verbal description. However, *High Point* makes clear that the purpose of requiring district courts to describe the claimed design in words is so that the parties and appellate courts can discern the trial court's reasoning in identifying a primary reference. It is entirely clear from the district court's opinion what it considered to be the relevant design characteristics of the '488 patented design." Slip op. at 7-8 (citing *High Point Design LLC v. Buyers Direct, Inc.*, 730 F.3d 1301, 1314 (Fed. Cir. 2013)).

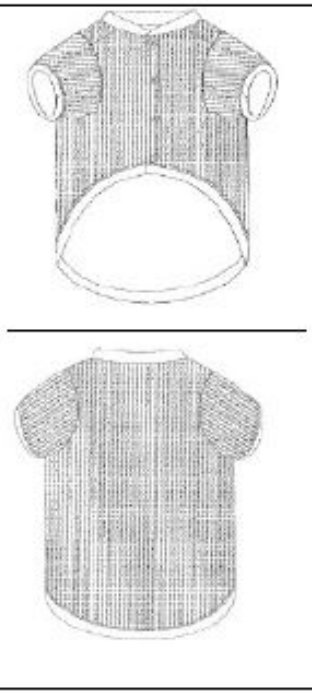
In finding the '488 patent invalid as being obvious, the Court agreed with the district court's determination that the Eagles Jersey served as a primary reference to the claimed design of the '488 patent. While the Court acknowledged that the district court did not expressly undertake to translate the claimed design into a verbal description, the Court explained that "the purpose of requiring district courts to describe the claimed design in words is so that the parties and appellate courts can discern the trial court's reasoning in identifying a primary reference." *Id.* at 7-8 (citing *High Point Design LLC v. Buyers Direct, Inc.*, 730 F.3d 1301, 1314 (Fed. Cir. 2013)). Thus, the Court held that the district court had fully provided its

reasoning by describing the claimed design in the context of comparing it to the prior art. The Court determined that the district court's analysis of the Eagles Jersey, in which the district court cited five design similarities and three differences between the claimed design and the Eagles Jersey, was sufficient to support its reasoning behind using the Eagles Jersey as the primary reference. In particular, the Court held that the district court had thoroughly considered the distinctive visual appearances of the reference and the claimed design. The Court also agreed with the district court that the design characteristics of the '488 patent design created "basically the same" overall visual impression as the Eagles Jersey because both designs contain the same overall shape, similar fabric, and ornamental surge stitching. The Court regarded the design differences as slight differences in the precise placement of the interlock fabric and the ornamental stitching, which did not defeat the claim of obviousness.

After concluding that the Eagles Jersey could be a "primary reference," the Court turned to the district court's determination that the V2 Jersey and the Sporty K9 Jersey were "so related to the primary reference" that they could serve as "secondary references." *Id.* at 11 (quoting *MRC Innovations, Inc. v. Hunter Mfg., LLP*, 921 F. Supp. 2d 800, 809 (N.D. Ohio 2013)). The Court clarified that while there must be some suggestion in the prior art to modify the basic design with the secondary reference, mere similarity in appearance can provide the suggestion that one should apply certain features to another design. The Court also noted that the V2 Jersey and the Sporty K9 Jersey were "so related" to the Eagles Jersey—each being a football jersey designed to be worn by dogs—"that the striking similarity in appearance across all three jerseys would have motivated a skilled designer to combine features from one with features of another." *Id.* at 13. The Court also held that the third design difference, the surge stitching on the rear of the jersey, was a "*de minimis* change[]" well within the skill of an ordinary designer in the art. *Id.* (alteration in original) (quoting *MRC*, 921 F. Supp. 2d at 809). The Court disagreed with MRC that adding any ornamental feature not suggested by prior art to a primary reference is by definition more than de minimis. The Court agreed with the district court that it would be an insubstantial change obvious to a skilled designer to add ornamental surge stitching on top of an already existing seam.

Addressing MRC's evidence of secondary considerations, the Court held that MRC failed to satisfy its burden of production to demonstrate a nexus between the claimed design and the secondary considerations, and found that the evidence of record before the district court did not create a genuine issue of material fact. Accordingly, the Court held that the evidence provided by MRC for secondary considerations was insufficient to overcome the other evidence of obviousness as to the '488 patent. In affirming the district court's finding of invalidity, the Court did not need to address Hunter's alternative argument that the '488 patent was invalid under 35 U.S.C. § 112.

The Court also affirmed the district court's finding that the '487 patent was invalid as being obvious over the Sporty K9 Baseball Jersey in view of the V2 Jersey and the Eagles Jersey. The pictures of the claimed design of the '487 patent and the Sporty K9 Baseball Jersey are presented below:

'487 patent	Sporty K9 Baseball Jersey
	

The Court held that the district court's analysis of the Sporty K9 Baseball Jersey, in which the district court cited common and different design characteristics between the claimed design in the '487 patent and the Sporty K9 Baseball Jersey, was sufficient to support its reasoning behind using the Sporty K9 Baseball Jersey as the primary reference for the '487 patent. The Court also agreed with the district court that the Sporty K9 Baseball Jersey created "basically the same" overall visual impression as the claimed design in the '487 patent. The Court noted that although the less tubular shape of the '487 patent design may affect its overall visual impression, such a difference is minimized when the jersey is actually worn by a pet. The Court also agreed with the district court's reliance on the V2 Jersey and the Eagles Jersey as secondary references, as these jerseys are so related to the Sporty K9 Baseball Jersey that the mere similarity in visual appearance would suggest the combination of these jerseys.

Accordingly, the Court affirmed the district court's SJ of invalidity with respect to the '487 and the '488 patents.

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Patentee May Not Challenge the Result of an Ex Parte Reexamination in District Court

Robert A. Hall

Judges: Dyk (author), Moore, Wallach

[Appealed from Board]

In *In re Teles AG Informationstechnologien*, No. 12-1297 (Fed. Cir. Apr. 4, 2014), the Federal Circuit held that the United States District Court for the District of Columbia ("D.D.C.") lacked subject matter jurisdiction over a patent owner's appeal of a Board decision in an ex parte reexamination, but erred in dismissing rather than transferring the case to the Court. Treating the case as properly transferred, the Court affirmed the Board's rejection of claim 35 of U.S. Patent No. 6,954,453 ("the '453 patent") as obvious.

Teles AG Informationstechnologien and Sigram Schindler Beteiligungsgesellschaft MBH (collectively "Teles") own all substantial rights in the '453 patent, which is directed to a method and apparatus for transmitting data in a telecommunications network. Following a third-party request, the PTO conducted an ex parte reexamination of the '453 patent and rejected certain claims as obvious over U.S. Patent No. 6,069,890 ("White") combined with either U.S. Patent No. 6,137,792 ("Jonas") or U.S. Patent No. 4,996,685 ("Farese"). Teles appealed, and the Board affirmed. Teles then sought review of the Board's decision in the D.D.C. pursuant to 35 U.S.C. § 145. The D.D.C. dismissed the case for lack of subject matter jurisdiction, concluding that after the 1999 amendments to the Patent Act, § 145 proceedings could not be maintained by patent owners. The D.D.C. then attempted to transfer the case to the Federal Circuit pursuant to 28 U.S.C. § 1631.

The Federal Circuit first held that the D.D.C. erred in dismissing the case since a transfer is not proper when combined with a dismissal, but held that it would review the case as though properly transferred. According to the Court, because the statutory deadline for filing an appeal to the Court had passed and there was no evidence suggesting bad faith in Teles's filing with the district court, it was in the interest of justice to transfer the case.

"Amendments intended to clarify statutory language do not indicate that the original language should be construed to mean the opposite of the clarifying language. The 2011 amendments do not manifest Congress' intent to preserve the availability of § 145 in the earlier version of the section."
Slip op. at 13-14 (citation omitted).

The Federal Circuit then held that the district court lacked jurisdiction over a patent owner's appeal under § 145 following the 1999 American Inventors Protection Act. The Court explained that when Congress

amended the Patent Act in 1999 to create a system of inter partes reexamination, it changed the text of existing statutory provisions, amending (1) § 141 to limit patent owner appeals in any reexamination proceeding "only" to the Federal Circuit; (2) § 134 to list appeals to the Board individually by (a) patent applicants, (b) patent owners, and (c) third-party requestors; and (3) § 145 to refer only to § 134(a), governing applicants. The Court rejected Teles's argument that a § 145 civil action was not an "appeal," and, thus, § 141 limits patent owner appeals to the Federal Circuit as opposed to other circuit courts, concluding that such a reading would render the provision superfluous since the Court already had exclusive jurisdiction over Board decisions.

The Court also rejected Teles's argument that concluding that the 1999 amendments restricted § 145 to patent applicants was inconsistent with 35 U.S.C. § 306, which expressly states a patent owner in a reexamination may seek court review under § 145. The Court concluded that "this inconsistency in retaining a reference to § 145 in § 306 does not undermine the clear intention of the 1999 amendments to eliminate § 145 as to patent owners." Slip op. at 9. The Court also dismissed Teles's reliance on the legislative history, including Congress's failure to adopt bills that would have amended § 306 to remove the reference to § 145, concluding that "reliance on failed legislative proposals is disfavored as a means of inferring legislative intent." *Id.* at 11.

Finally, the Court rejected Teles's argument that nonretroactive amendments made in 2011 to § 306 to remove the reference to § 145 showed that prior to 2011, patent owners could appeal under § 145. The Court observed that Teles's theory "contradicts the legislative history, which recognized that the amendments corrected a drafting error in the 1999 legislation . . . ." *Id.* at 13. The Court therefore held "that the 1999 amendments eliminated the right of patent owners to secure review under § 145" and affirmed that the district court lacked jurisdiction over the § 145 action. *Id.* at 14.

Finally, the Federal Circuit turned to the Board's obviousness rejection of claim 35 of the '453 patent. Regarding claim construction, the Court held that the Board did not err by not construing the function of claim 35 under 35 U.S.C. § 112, ¶ 6 in terms of an alternative possibility in the specification. According to the Court, "[w]hen construing functional claims under § 112 ¶ 6, '[t]he statute does not permit limitation of a means-plus-function claim by adopting a function different from that explicitly recited in the claim.'" *Id.* at 17-18 (second alteration in original) (quoting *Micro Chem., Inc. v. Great Plains Chem. Co.*, 194 F.3d 1250, 1258 (Fed. Cir. 1999)). The Court also rejected Teles's argument that the Board's claim construction was erroneous because *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, 1294 (2012), "requires that the 'inventive concepts' embodied by the claimed invention be identified as part of construing claims." Slip op. at 18. The Court concluded that *Mayo* referred to an "inventive concept" only in the context of § 101 patent eligibility analysis, which had no bearing on claim construction.

Regarding obviousness, the Court affirmed the Board's decision that White combined with either Jonas or Farese taught all the limitations of claim 35. The Court rejected Teles's argument that Jonas failed to disclose monitoring an individual communication rather than the entire network, concluding that this argument "assumes an overly limiting construction of the prior art reference and the language of claim 35." *Id.* at 20. Finally, the Court rejected Teles's assertion that a person of ordinary skill in the art would not have found it obvious, or even possible, to combine White with Jonas, because doing so would be an extremely complicated process. Rather, the Court concluded that White presumes that redesigned equipment would be required, and Jonas would "clearly be envisioned in this network redesigned by White." *Id.* at 21 (citation omitted). Accordingly, the Court affirmed the Board's obviousness rejection of claim 35 of the '453 patent.

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Describing Algorithms in Understandable Terms That Provide Structure to a Person of Ordinary Skill in the Art Renders Definite Computerized Means-Plus-Function Claims

James A. Cooke

Judges: Rader, Reyna (author), Wallach

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

In *Chicago Board Options Exchange, Inc. v. International Securities Exchange, LLC*, No. 13-1326 (Fed. Cir. Apr. 7, 2014), the Federal Circuit affirmed the district court's judgment of noninfringement of U.S. Patent No. 6,618,707 ("the '707 patent") by the Chicago Board Options Exchange, Inc. ("CBOE"), and reversed the district court's finding that claim 2 of the '707 patent was indefinite.

International Securities Exchange, LLC ("ISE") is the owner of the '707 patent, which is directed to an "automated exchange" for trading financial instruments, and which distinguishes the "automated" exchange from the traditional, floor-based "open-outcry" system for trading options contracts. ISE brought suit against CBOE for patent infringement based on CBOE's Hybrid Trading System, and CBOE subsequently brought suit against ISE seeking a DJ of noninfringement.

CBOE moved for SJ of noninfringement, and the district court denied the motion. On appeal, the Federal Circuit construed the phrase "automated exchange" to require a fully computerized system for executing financial trades that does not include matching or allocating orders through the use of open outcry, and remanded on the issue of infringement. On remand, the district court made certain evidentiary and other pretrial rulings, including rulings that established a jury instruction for the claimed "automated exchange," and assigned to the jury the question of whether CBOE's accused products represented stand-alone automated exchanges or systems that included matching or allocating through open outcry. The district court also found that claim 2 of the '707 patent, a computer-implemented means-plus-function claim, was indefinite because the specification of the '707 patent failed to disclose a step-by-step algorithm for performing the revised function.

In view of the district court's pretrial rulings, ISE concluded that it could not prove that CBOE's accused products met the "automated exchange" claim limitation, and as such, ISE stipulated to noninfringement. The district court entered final judgment for CBOE based on ISE's stipulation, and ISE appealed.

"We hold that, because this factual issue was unresolved in the previous appeal, the trial court did not violate the mandate rule by allowing this unresolved issue to go to the jury." Slip op. at 11.

In the present appeal, the Federal Circuit first addressed the district court's pretrial rulings, and in particular, ISE's assertions that the district court's pretrial rulings precluded it from accusing certain CBOE products of infringement. Upon review of the record, the Court found no evidence that the district court precluded ISE from accusing certain CBOE products of infringing the claims of the '707 patent. Rather, the Court found that the district court expressly invited ISE to demonstrate the independence of CBOE's products from open-outcry systems, as required by the Court's construction of "automated exchange."

The Court next turned to ISE's assertion that the district court's jury instructions violated the mandate rule by imposing additional limitations to the Court's prior claim construction. The Court again rejected ISE's assertion, noting that the district court correctly framed the factual issue remaining for the jury by requiring ISE to show that CBOE's accused product did not include open outcry. Indeed, the Court held that "because this factual issue was unresolved in the previous appeal, the trial court did not violate the mandate rule by allowing this unresolved issue to go to the jury." Slip op. at 11.

Finally, the Court turned to the district court's finding of indefiniteness regarding claim 2 of the '707 patent. As an initial point, the Court noted that claim 2 represents a computerized means-plus-function claim, and that both CBOE and ISE agreed that the function of claim 2 included "matching" a remaining portion of professional orders or quotations in a book memory means on a "pro rata basis." The Court further observed that the district court's test of indefiniteness of a computerized means-plus-function claim (i.e., the disclosure in the specification of a "step-by-step" algorithm for performing the claimed function) was too restrictive, and noted that such an "algorithm" may be expressed "in any understandable terms including as a mathematical formula, in prose, or as a flow chart, or in any other manner that provides sufficient structure" to a person of ordinary skill in the art. *Id.* at 12-13 (quoting *Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1340 (Fed. Cir. 2008)). Thus, because the specification of the '707 patent described an algorithm for matching the remaining orders on a pro rata basis, which would provide sufficient structure to a person of ordinary skill in the art, the Court found claim 2 of the '707 patent definite and reversed the district court on this issue.

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A Direct Competitor in a Tight Niche Market May Receive a Preliminary Injunction Despite Not Practicing the Patent

Jia W. Lu

Judges: Rader (author), Lourie, Prost

[Appealed from D. Mont., Judge Haddon]

In *Trebro Manufacturing, Inc. v. FireFly Equipment, LLC*, No. 13-1437 (Fed. Cir. Apr. 9, 2014), the Federal Circuit vacated and remanded the district court's denial of a motion for a preliminary injunction by Trebro Manufacturing, Inc. ("Trebro") against FireFly Equipment, LLC ("FireFly"). The Court held that the district court abused its discretion in denying Trebro's motion based on a record that strongly suggested both a likelihood of success on the merits and irreparable harm, but remanded for the district court to determine the balance of equities and the public interest in the first instance.

U.S. Patent No. 8,336,638 ("the '638 patent") is directed to sod harvesters that cut sod pieces from the ground and transport the pieces by conveyor belts for stacking on pallets. Claim 1 of the '638 patent recites "wherein said horizontal conveyor is moveable in a vertical direction toward said sod carrier." After acquiring the '638 patent, Trebro sued FireFly for infringement and moved for a preliminary injunction, which the district court denied. The district court found that Trebro had no substantial likelihood of success on the merits because FireFly's accused product, the ProSlab 150, failed to meet the limitation that the horizontal conveyor is moveable in a vertical direction since the ProSlab 150's conveyer does not raise the horizontal bed frame, but rather has a belt that changes shape to lift the sod. The district court also found a substantial question as to the validity of the '638 patent, finding that the same limitation was known in the sod harvesting industry, including by the inventors and assignee, so that claim 1 was not novel or nonobvious. Finally, the district court found no irreparable harm to Trebro, dismissing Trebro's evidence as speculative and concluding that Trebo could be compensated through an award of lost profits or a reasonable royalty. The case was certified for interlocutory appeal.

On appeal, the Federal Circuit held that the district court abused its discretion in denying Trebro's preliminary injunction motion. The Court first held that Trebro had shown that the FireFly's ProSlab 150 sod harvester "more likely than not" infringed the '638 patent. Slip op. at 10 (quoting *Revision Military, Inc. v. Balboa Mfg. Co.*, 700 F.3d 524, 525-26 (Fed. Cir. 2012)). According to the Court, the district court erred in construing claim 1 to require "rais[ing] the horizontal bed frame" because (1) the language of claim 1 does not mention or imply that a "bed frame" must be part of, or otherwise attached to, the claimed "horizontal conveyor"; (2) imposing the use of a bed frame improperly imported into claim 1 a limitation from a preferred embodiment; and (3) claim 10, which depends from claim 1, recites a "bed frame," and, thus, reading the "bed frame" limitation from claim 10 into claim 1 rendered the term redundant and offended principles of claim differentiation. *Id*. at 10-11 (alteration in original). The Court then held that the district court also clearly erred in finding that the ProSlab 150's horizontal conveyer was not moveable in a vertical direction since the horizontal conveyor belt changed shape only because it was a part of the horizontal conveyor moving vertically toward the sod carrier. According to the Court, "[t]hat certain components of the ProSlab 150 involved in raising the sod may not move vertically does not defeat the likelihood of infringement." *Id*. at 14.

"In multiple instances, this court has held that a party that does not practice the asserted patent may still receive an injunction when it sells a competing product." Slip op. at 18.

The Federal Circuit next held that the district court clearly erred in finding a substantial question as to the '638 patent's validity. First, the Court assumed that the district court's statement that "[c]laim 1 is not novel or non-obvious" was a misstatement, as it was not adequately supported by the district court's analysis. *Id*. at 15. Second, the Court held that the district court's conclusion that the vertically moveable horizontal conveyor was "not a novel or non-obvious feature" was clearly erroneous because it was based solely on testimony about other sod harvesters that had been on the market in 2006 or later without regard for the '638 patent's undisputedly earlier priority date. *Id*. (citation omitted). Finally, the Court noted that the parties had initially heavily disputed the scope and content of two earlier-filed patents by the '638 patent inventors, but, as the PTO recognized after initially granting ex parte reexamination, neither reference qualifies as prior art, and, thus, the record did not contain a single prior art reference to raise a substantial question as to the '638 patent's validity.

Finally, the Federal Circuit held that the district court abused its discretion in determining that Trebro did not show a likelihood of irreparable harm. Specifically, the Court held that the district court clearly erred in finding as speculative the harm Trebro was likely to suffer from a direct competitor selling an infringing product in the small niche sod harvester market. The Court concluded that the uncontroverted testimony established that Trebro sold only about eight sod harvesters a year in a tight market, making every sale to FireFly, a new market entrant, a lost sale. The Court continued that, because of a harvester's lifespan, each lost sale was also a lost customer for Trebro. According to the Court, Trebro was likely to lose significant market share as well as customers, evidence the district court incorrectly categorically dismissed, and, thus, money damages for lost profits were not automatically adequate. Finally, the Court explained that the fact that Trebro did not presently practice the '638 patent did not detract from its likely irreparable harm because Trebro and FireFly were direct competitors in the sod harvester market.

The Court then made several observations regarding the final two factors in determining a motion for preliminary injunction to guide the district court's analysis on remand. The Court observed that, with respect to the balance of equities, the evidence suggested that (1) Trebro was losing business to a new market entrant selling a likely infringing product; and (2) the '638 patent, which Trebro only recently acquired from a market player having difficulties meeting financial obligations to Trebro, "will have significantly less value if Trebro cannot use it to exclude an infringing product from the market." *Id*. at 20. With respect to public interest, the Court observed that "there is scant evidence on this record showing that an injunction would harm the public." *Id*.

Accordingly, the Federal Circuit vacated the district court's decision denying Trebro's motion for a preliminary injunction and remanded for further proceedings consistent with the Court's opinion.

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SJ of Obviousness of Once Monthly Administration of Pharmaceutical Compound Affirmed

Kara A. Specht

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

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

In *Hoffmann-La Roche Inc. v. Apotex Inc.*, Nos. 13-1128, -1161, -1162, -1163, -1164 (Fed. Cir. Apr. 11, 2014), the Federal Circuit affirmed the district court's grant of SJ that claims 1-8 of U.S. Patent No. 7,718,634 ("the '634 patent") and claims 1-10 of U.S. Patent No. 7,410,957 ("the '957 patent") are invalid as obvious.

Hoffmann-La Roche Inc. ("Roche") owns the '634 and '957 patents, which are directed to methods of treating osteoporosis through the once monthly administration of about 150 mg of a salt of ibandronic acid. Roche markets ibandronate, a salt of ibandronic acid, in a 150 mg dose as once monthly Boniva® for the treatment of osteoporosis. Apotex Inc. and the other defendants (collectively "the defendants") submitted ANDAs with the FDA, seeking approval to engage in the manufacture and sale of generic versions of Boniva® prior to the expiration of Roche's patents, and Roche sued for patent infringement.

The defendants moved for SJ of invalidity of claims 1-8 of the '634 patent, and the district court raised on its motion the issue of SJ of invalidity of claims 1-10 of the '957 patent. The district court concluded that all of the claims-at-issue were invalid as obvious. Roche appealed.

"The evidence of superior efficacy does nothing to undercut the showing that there was a reasonable expectation of success with the 150 mg monthly dose, even if the level of success may have turned out to be somewhat greater than would have been expected." Slip op. at 17.

On appeal, the Federal Circuit stated the issue as "whether it would have been obvious at the time of invention to select a once monthly oral dosing regimen of ibandronate to treat osteoporosis and to set that dose at 150 mg." Slip op. at 8. The Court first determined that the prior art established at least a reasonable expectation that once monthly dosing of ibandronate could successfully treat osteoporosis and reduce fracture risk. The Court noted that "[a] relatively infrequent dosing schedule has long been viewed as a potential solution to the problem of patient compliance stemming from the inconvenience of oral bisphosphonate regimens," pointing to a prior art bisphosphonate product and several prior art references. *Id.*

The Court rejected Roche's argument that the art taught away from once monthly dosing, which Roche primarily based on its alleged failure in its intravenous ibandronate study and a prior art article describing

it. The Court reasoned that the study was a "failure" only in the sense that the reduction in fractures was statistically insignificant given the large number of patients that would have been required to reach a statistically significant conclusion about the relative rates of fractures in the control and subject groups. The Court stated that "[the study's] failure to generate statistically significant results points to a fault in the study; it does not teach that infrequent ibandronate dosing is ineffective in treating osteoporosis." *Id.* at 10.

The Court next found that the prior art pointed to a monthly treatment of 150 mg of ibandronate, stating that, "[a]t the very least, the 150 mg dose was obvious to try." *Id.* at 13. The Court reasoned that a person skilled in the art looking to scale the known-effective daily dose to a monthly dose was faced with a very limited set of possibilities, and would have expected that a 150 mg monthly dose would have equivalent success to the 5 mg daily dose taught in the prior art.

The Court rejected Roche's argument that findings by the FDA taught away from further development of the 5 mg daily dose (and its total-dose equivalents). The Court reasoned that even though the FDA approved a 2.5 mg daily dose of ibandronate instead of a 5 mg daily dose, the FDA never made any findings contrary to the 5 mg daily dose and was never asked to approve that dose. The Court also rejected Roche's argument that the district court misinterpreted and misapplied the total-dose concept from the prior art. The Court explained that the evidence before the district court showed that the total-dose concept could be used as an effective rule of thumb by a person skilled in the art deciding how to scale an efficacious intermittent dose of ibandronate.

The Court next addressed Roche's argument that there were disputed issues of fact as to whether it would have been obvious to administer once monthly doses of 150 mg in light of alleged safety concerns about the adverse gastrointestinal effects of ibandronate and other bisphosphonates. The Court concluded that the prior art established that doses even higher than 150 mg were considered safe, and that Roche did not point to any references to the contrary. The Court also noted that Roche's expert was also not "aware of anything that taught that a once monthly, 150 mg dose of ibandronate would be unsafe." *Id.* at 16.

Turning to Roche's argument that the 150 mg monthly dose demonstrated unexpected results, the Court held that neither the effectiveness nor the nonlinear bioavailability of the dose rebutted the prima facie showing of obviousness. Regarding effectiveness, the Court stated that "[t]he evidence of superior efficacy does nothing to undercut the showing that there was a reasonable expectation of success with the 150 mg monthly dose, even if the level of success may have turned out to be somewhat greater than would have been expected." *Id.* at 17. The Court similarly stated that, regarding nonlinear bioavailability, "[t]he increased level of bioavailability has not been shown to be responsible for the improved osteoporosis treatment efficacy of the 150 mg dose." *Id.* Accordingly, the Court affirmed the judgment of the district court that claims 1-8 of the '634 patent and claims 1-10 of the '957 patent were invalid for obviousness.

Judge Newman dissented, stating that "[n]owhere amid the many studies of bisphosphonate osteoporosis treatments over a wide range of dosages and conditions, did any reference show or suggest the Boniva® combination of a single 150 mg dose and once-a-month administration." Newman Dissent at 4. According to Judge Newman, "[the majority's] primary reason, that 150 mg is thirty times the daily dose of 5 mg, does not mention that the FDA refused to approve the 5 mg dose due to its toxic side effects," and that "[s]urely this leads away from the obviousness of a single dose thirty times larger." *Id.*

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May 2014

Refusal to Approve Competitor's Resin for Use in 3D Printers Does Not Amount to Antitrust Violation

Timothy V. Fisher

Judges: Moore, Schall (author), Reyna

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

In *DSM Desotech Inc. v. 3D Systems Corp.*, No. 13-1298 (Fed. Cir. Apr. 18, 2014), the Federal Circuit affirmed the grant of SJ against three categories of claims brought by plaintiff-appellant DSM Desotech Inc. ("Desotech") against defendants-appellees 3D Systems Corp. and 3D Systems, Inc. (collectively "3DS"). The Federal Circuit held that Desotech failed to show genuine issues of material fact that (1) stereolithography ("SL") machines or resins form a distinct product market, an element necessary to its antitrust claims; (2) 3DS's refusal to approve Desotech's resin was done out of spite or ill will, an element necessary to Desotech's tortious interference claim; or (3) 3DS engaged in deceptive trade practice under the Illinois Uniform Deceptive Trade Practices Act by telling customers that Desotech's resin was not approved for use in 3DS machines.

Desotech makes resins for use in SL machines, a type of 3D printer used for rapid prototyping. 3DS makes SL machines as well as its own resins. Around 2005, 3DS began equipping some of its machines with radio frequency identification ("RFID") capability, which allowed the machines to recognize resin bottles and lock out the machine if an unapproved resin bottle is detected. 3DS approved two of Desotech's resins for use in 3DS machines. Desotech and 3DS entered into negotiations to approve additional Desotech resins. When those negotiations broke down, Desotech brought suit against 3DS, including various antitrust violations, state law claims, and a claim of patent infringement. At the close of fact discovery, the district court granted 3DS's motions for SJ regarding the antitrust claims and the state law claims. The district court entered final judgment after the parties stipulated dismissal of the remaining claims, including the patent infringement claim. Desotech appealed. The Federal Circuit retained jurisdiction over the appeal under 28 U.S.C. § 1295(a)(1) despite the dismissal with prejudice of the patent claim.

"Because we conclude that Desotech failed to prove an independent market for SL machines or resins—as it acknowledged it must do—we affirm the district court's grant of summary judgment on Desotech's antitrust claims." Slip op. at 23-24.

On appeal, the Federal Circuit affirmed the district court's grant of SJ on Desotech's antitrust claims, holding that Desotech failed to prove an independent product market for SL machines or resins. The Court applied the law of the Seventh Circuit, which requires economic evidence to prove the existence of a distinct market, and looked to the sufficiency of Desotech's data and analysis. The Court found,

however, that "[r]ather than analyze economic data, Desotech and its expert relied on four of the *Brown Shoe* practical indicia: (1) distinct prices; (2) the product's peculiar characteristics and uses; (3) industry or public recognition of the submarket as a separate economic entity; and (4) sensitivity to price changes." Slip op. at 14-15. The Court nevertheless weighed Desotech's proffered evidence regarding the four factors.

With regard to distinct prices, the Court noted that Desotech inflated the price distinction by "compar[ing] SL machines to some of the cheapest possible substitutes—3D printing machines," and "ignore[d] the evidence showing that 3DS offers a range of SL machines with a broad range of prices comparable to those of other rapid-prototyping technologies." *Id.* at 15. With regard to peculiar characteristics and uses, the Court found that Desotech's arguments that 3DS's machines are more accurate and can produce larger parts than other technologies "are tenuous at best." *Id.* at 16. But because the appeal came from grant of SJ, the Court viewed this evidence in the light most favorable to Desotech: "Accordingly, we consider this factor as evidence of a potential distinct market for SL machines." *Id.* With regard to "industry or public recognition of the [SL machine] submarket as a separate economic entity," the Court noted that the district court had dismissed customer testimony favorable to Desotech because, "although customers were asked about substitutes, none was asked about *reasonable* substitutes." *Id.* (alteration in original) (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962)). The Court nevertheless found the testimony "insufficient to establish that SL machines constitute a separate market." *Id.* at 17.

With regard to the final factor, "sensitivity to price changes," Desotech relied on the testimony of four customers, which it argued made up 12% of the market for SL resin. The Court found, however, that this evidence failed to address the more pertinent question of what percentage of the SL machine market the customers comprised. The Court further discounted this evidence because Desotech did not justify the conclusion that these purchasers were representative of purchasers at different price points. In sum, the Court found that only two out of the four *Brown Shoe* factors favored Desotech, and that "[g]iven the limited and tenuous nature of the evidence, . . . a reasonable jury could not find an independent market for SL machines." *Id.* at 19. The Court similarly held that SL resins also did not constitute an independent market.

The Court next addressed Desotech's state law claims. The Court found that 3DS implemented its RFID and unapproved resin lockout features for the legitimate purposes of increasing sales and maintaining quality control, and that Desotech did not provide evidence to demonstrate that 3DS "acted out of spite or ill will." *Id.* at 25. Finally, the Court found that "[t]he allegedly wrongful statements about Desotech's resins not being authorized, approved, licensed, qualified, or tested all relate to 3DS's licensing and approval policy." *Id.* at 28. As a result, the Court held that the alleged wrongful statements did not violate relevant state laws regarding deceptive trade practices, and Desotech failed to raise a genuine issue of material fact that the statements were false.

Accordingly, the Court affirmed the district court's grant of SJ on Desotech's seven claims.

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May 2014

Combination Is Not Obvious to Try Based on Later-Manifest Unexpected Benefits

Forrest A. Jones

Judges: Newman (author), Linn, Wallach
[Appealed from D.N.J., Judge Cavanaugh]

In *Sanofi-Aventis Deutschland GmbH v. Glenmark Pharmaceuticals Inc., USA*, No. 12-1489 (Fed. Cir. Apr. 21, 2014), the Federal Circuit, holding that it had appellate jurisdiction, affirmed the district court's rulings and judgment that the asserted patent was not invalid as obvious, that the jury instruction regarding evidence spoliation was not prejudicial, and that certain coplaintiff companies had standing. The Court then remanded for an accounting of any postverdict damages.

U.S. Patent No. 5,721,244 ("the '244 patent") is directed to antihypertension drugs that utilize a combination of two active ingredients in a single dosage product: an angiotensin converting enzyme ("ACE") inhibitor and a calcium channel blocker. Claim 3 of the '244 patent claims the ACE inhibitors trandolapril and quinapril, both of which are "double-ring" compounds, as opposed to the "single-ring" compounds combined with calcium channel blockers in the prior art.

Sanofi-Aventis Deutschland GmbH, Aventis Pharma S.A., Abbott GmbH, Abbott Laboratories, and Abbott Laboratories Inc. (collectively "Plaintiffs") own or exclusively license the '244 patent, which covers the antihypertension drug Tarka®. Tarka® is a combination of trandolapril and the calcium channel blocker verapamil hydrochloride, and is longer lasting than previously known treatments with significant advantages, including improved kidney function and blood vessel structure. Plaintiffs sued Glenmark Pharmaceuticals Inc. and Glenmark Pharmaceuticals Ltd. (collectively "Glenmark") after Glenmark filed an ANDA with the FDA, seeking to market a generic version of Tarka®. Glenmark admitted infringement, and after the thirty-month stay under 21 U.S.C. § 355(j)(5)(B)(iii) expired and Glenmark launched its generic version of Tarka® "at-risk," a jury found that the '244 patent had not been proved invalid and awarded damages. Slip op. at 3. The district court denied posttrial motions and entered judgment on the verdict, retaining authority to assess postverdict damages if the Federal Circuit sustained the judgment. Glenmark appealed.

"As illustrated in *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988), it would not be 'obvious to try' when 'the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful.'" Slip op. at 9.

On appeal, the Federal Circuit first held that the Court had appellate jurisdiction even though the district court retained authority to award postjudgment damages and did not issue a document entitled "final judgment." *Id.* at 4. Relying on 28 U.S.C. § 1292(c)(2), which assigns the Federal Circuit appellate

jurisdiction of patent infringement actions if the judgment is "final except for an accounting," the Court reiterated that "'an accounting' includes the determination of damages." *Id*. The Court also held that the wording of the Order closing the case did not negate the finality of the judgment, as "[n]o 'magic words' are needed to confer final judgment." *Id.* at 5.

The Court then considered the jury's verdict that claim 3 of the '244 patent was not invalid as obvious. The Court rejected Glenmark's argument that claim 3 was invalid as a matter of law because the prior art tested single-ring ACE inhibitors in combination with calcium channel blockers, and, thus, "it was 'obvious to try' every combination of effective ACE inhibitor and calcium channel blocker," including double-ring ACE inhibitors. *Id.* at 8. Citing *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007), the Court explained that "obvious to try" may apply when there are a finite number of identified, predictable solutions to a known problem, and that "the identified path must 'present a finite (and small in the context of the art) number of options easily traversed to show obviousness.'" Slip op. at 9 (quoting *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008)). The Court also rejected Glenmark's argument that later-discovered benefits cannot be considered in the obviousness analysis, holding that "patentability may consider all of the characteristics possessed by the claimed invention, whenever those characteristics become manifest." *Id.* at 10. Distinguishing the cases cited by Glenmark—*Merck & Co. v. Biocraft Laboratories, Inc.*, 874 F.2d 804 (Fed. Cir. 1989), and *Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476 (Fed. Cir. 1997)—the Court observed that, in both cases, the drug combinations were without unexpected results and deemed obvious to try in conformity with the Supreme Court's explication in *KSR*.

Turning to the facts of this case, the Court concluded that the jury could reasonably have relied on the testimony of the Plaintiffs' expert that persons skilled in the art at the time of the invention would not have predicted the longer-lasting hypertension control demonstrated by the double-ring ACE inhibitors quinapril and trandolapril because of the widespread belief that double-ring inhibitors would not fit into the pocket structure of ACE. The Court thus affirmed the judgment that claim 3 was invalid as obvious.

The Federal Circuit next held that Glenmark was not entitled to a new trial based on the district court's jury instruction that the jury may draw an adverse inference that electronic documents deleted by Glenmark would have been unfavorable to Glenmark. The Court noted that it was undisputed that Glenmark did not retain emails for longer than one month in 2005 and 2006, and that this policy continued as Glenmark prepared for litigation related to its generic product, as evidenced by work-product entries on its privilege log. Applying the Third Circuit's four-factor test for spoliation, the Court agreed that "[i]t was reasonable for the district court to infer that some destroyed emails related to issues for which litigation was expected by Glenmark," and that Glenmark did not negate this reasonable inference. Slip op. at 14. According to the Court, "[t]he courts are not required to tolerate acts in derogation of the integrity of judicial process," and, thus, the adverse jury instruction was well within the district court's discretion. *Id.* at 15.

Finally, the Federal Circuit held that Abbott Laboratories and Abbott Laboratories, Inc. ("ALI") had standing as coplaintiffs to recover damages due to infringement. The Court first noted that it was undisputed that Sanofi-Aventis, as the owner by assignment of the '244 patent, and Aventis Pharma, as exclusive licensee, had standing; that Aventis Pharma in turn granted an exclusive license to Abbott GmbH; that Abbott Laboratories had owned the FDA-approved NDA for Tarka® since 2001; and that ALI was the exclusive U.S. distributor for Abbott Laboratories. The Court then rejected Glenmark's assertions that since Abbott Laboratories acquired the NDA in 2001, before Abbott GmbH's exclusive license in 2004, the NDA could not support a finding of express or implied exclusive rights and that a 2010 "Confirmatory Agreement" was void for lack of consideration. Rather, the Court concluded that the evidence as a whole was sufficient to support a finding that "the Plaintiffs intended that the Abbott United States companies have exclusive rights in the United States under the '244 patent." *Id.* at 18.

Accordingly, the Court affirmed the rulings and judgment of the district court, and remanded for the reserved accounting for any postverdict damages.

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Claim Construction Analysis Begins and Remains Centered on the Language of the Claims Themselves

*Yieyie Yang**

Judges: Dyk (concurring-in-part, dissenting-in-part, and concurring in the result), Prost (author), Moore (dissenting)

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

In *Braintree Laboratories, Inc. v. Novel Laboratories, Inc.*, No. 13-1438 (Fed. Cir. Apr. 22, 2014), the Federal Circuit affirmed the district court's validity finding, reversed the district court's claim construction of the claim term "clinically significant electrolyte shifts," vacated the district court's SJ of infringement, and remanded for further factual findings on the issue of infringement.

Braintree Laboratories, Inc. ("Braintree") holds U.S. Patent No. 6,946,149 ("the '149 patent"), directed to a composition for inducing purgation of a patient's colon in preparation for a colonoscopy. The commercial embodiment of the '149 patent is Braintree's SUPREP® Bowel Prep Kit ("SUPREP"). Upon learning that Novel Laboratories, Inc. ("Novel") had filed an ANDA to market a proposed generic copy of SUPREP, Braintree filed an action for infringement of the '149 patent against Novel. In response, Novel asserted counterclaims of noninfringement and invalidity. After construing claim terms, the district court granted SJ of infringement in favor of Braintree and found that the '149 patent was valid.

On appeal, Novel challenged the district court's (1) construction of the claim terms "purgation" and "clinically significant electrolyte shifts"; (2) failure to find U.S. Patent No. 4,975,286 ("Hechter") anticipated the claims of the '149 patent; (3) failure to find the asserted claims of the '149 patent obvious in light of the prior art; and (4) failure to find the claim term "purgation" indefinite.

Considering the district court's construction of "purgation" as "an evacuation of a copious amount of stool from the bowels after oral administration of the solution" and Novel's argument relying on evidence from the specification that the claim term "purgation" should be interpreted instead as "cleansing," the Federal Circuit found Novel's arguments unpersuasive. Slip op. at 5 (citations omitted). The Court stressed that claim construction must be centered on the claims themselves, and that while cleansing was the goal specifically articulated in the specification, it was not a claim requirement. The Court also concluded that Novel's reliance on the claim term "effective amount" was also misplaced because "effective amount" only required purgation and not a full cleansing. Moreover, the Court concluded that Braintree's statement in its postissuance patent term extension request, in which it stated that SUPREP is a product for "cleansing *(i.e., purging)*," did not constitute a clear and unmistakable disavowal and did not redefine "purgation." *Id*. at 6 (citation omitted).

"In construing claims, the analytical focus must begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to 'particularly point[] out and distinctly claim[] the subject

matter which the patentee regards as his invention.'" Slip op. at 7 (alterations in original) (quoting *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001)).

In reversing the district court's construction of the term "clinically significant electrolyte shifts," the Court emphasized its precedent that "the patentee's lexicography must govern the claim construction analysis." *Id*. at 9 (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (en banc)). The Court disagreed with the district court's construction because it modified the specification's clear language. Accordingly, the Court reversed the district court's construction and construed "clinically significant electrolyte shifts" consistent with the inventor's clear definition of the term in the specification.

Because the district court correctly construed "purgation" as not requiring a full cleanse, the Court affirmed the district court's finding that one (half-dose) bottle of SUPREP practiced this claim limitation. The Court concluded, however, that the district court's finding that SUPREP practiced the "wherein the composition does not produce any clinically significant electrolyte shifts" limitation was based on its erroneous construction of the term "clinically significant electrolyte shifts," its importation of the preamble term "a patient" into the limitation, and its subsequent improper construction of the term as "one or more patients." *Id*. at 10 (citations omitted). The Court determined that "a patient" should mean a patient population because this definition is consistent with the specification's language. Since the record showed that at least some patients experienced alterations in blood chemistry outside the normal upper or lower limits of their normal range, the Court held that there remained a genuine issue as to whether SUPREP avoids producing any clinically significant electrolyte shifts in a patient population. Accordingly, the Court vacated the district court's SJ of noninfringement and remanded for further factual findings.

Turning to invalidity, the Court considered the prosecution history of the '149 patent and both parties' expert witnesses' statements, and found Novel's arguments that the asserted claims were anticipated by Hechter were flawed for three reasons. First, the Court found that Hechter did not actually disclose administration of the one-liter solution to the patient. Second, the Court found that while, theoretically, the initial one-liter solution taught in Hechter could be hypertonic in a patient, Novel had no evidence disclosing that the mixture had actually been tested in patients. Third, Hechter actually taught away from administering a hypertonic solution by stating that its solution needed to be isotonic. Novel also argued that the combination of sixteen prior art references, including Hechter, rendered the asserted claims of the '149 patent obvious. The Court concluded that Novel "failed to prove a 'plausible rational[e] as to why the prior art references would have worked together.'" *Id.* at 15-16 (alteration in original) (quoting *Power-One, Inc. v. Artesyn Techs., Inc.*, 599 F.3d 1343, 1352 (Fed. Cir. 2010)). Thus, the Court concluded that the district court did not err in finding nonobviousness.

Finally, Novel argued that the claim term "purgation" was indefinite because the term "copious" lacked any clear definition in the district court's construction. Unpersuaded by Novel's argument, the Court emphasized that the word "copious" was only used in the district court's construction and not in the claim, and that such descriptive words are commonly used in patent claims. In addition, the Court explained that a descriptive word like "copious" would not be indefinite to one skilled in the art in this context. Thus, the Court dismissed Novel's indefiniteness challenge.

Accordingly, the Court affirmed the district court's claim construction of "purgation" and finding that the asserted claims of the '149 patent are valid, reversed the district court's claim construction of the term "clinically significant electrolyte shifts," vacated the district court's SJ of noninfringement, and remanded for further proceedings.

Judge Dyk agreed that the district court erred in its construction of "clinically significant electrolyte shifts." While Judge Dyk thought that Novel established noninfringement as a matter of law under the correct "clinically significant electrolyte shifts" construction, he nevertheless joined the remand decision on that issue. Judge Dyk further agreed that the asserted claims of the '149 patent were not invalid. However, Judge Dyk dissented from the majority's conclusion that Novel's ANDA met the volume limitation of the

asserted claims. Particularly, Judge Dyk cited the Court's precedent that an ANDA cannot infringe an asserted patent when the FDA-approved dose is not the dose claimed in the patent. Accordingly, he concluded that Novel's ANDA that sought approval for a two-bottle dose to induce purgation did not infringe the '149 patent, which claims a one-bottle dose regimen. Additionally, Judge Dyk found that even without the Hatch-Waxman issue, the specification of the '149 patent and Braintree's own expert made clear that the invention was directed at "small volume" solutions of 100-500 mL total, not large volume solutions that could be divided into 100-500 mL administrations. Therefore, Judge Dyk concluded that Novel's ANDA with the 946 mL regimen did not meet the volume limitation and could not infringe the '149 patent.

Judge Moore joined the majority opinion, but dissented from the majority's construction of the term "a patient" and concluded that the plain and ordinary meaning of the term, based on the Court's precedent on the meaning of "a," should be one or more patients. Judge Moore concluded that nothing in the specification of the '149 patent or its prosecution history defined "a patient" as a plural "patient population" contrary to the words of the claim. Judge Moore expressed her understanding of the majority's concern that construing "a patient" to be singular would result in finding noninfringement, even if 99 patients out of 100 experienced clinically significant electrolyte shifts, as long as one patient did not. However, according to Judge Moore, this is a question of damages, not infringement, and the majority should not rewrite the claim language to avoid this unwanted outcome.

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May 2014

A Later-Issued but Earlier-Expiring Patent Can Serve as an Obviousness-Type Double Patenting Reference to Invalidate an Earlier-Issued, Later-Expiring Patent

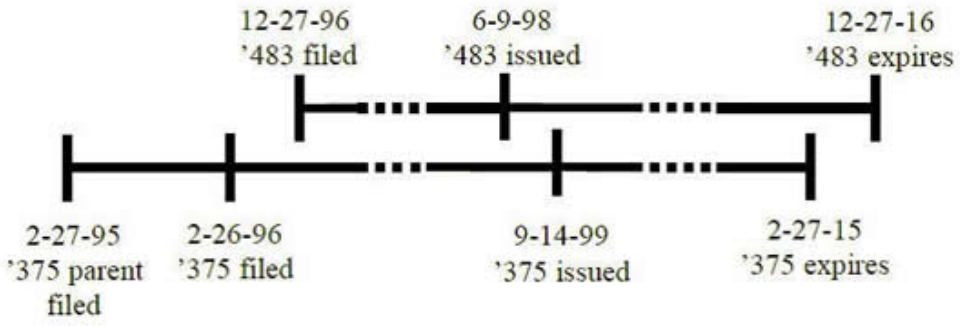
Sarah E. Craven

Judges: Rader (dissenting), Prost, Chen (author)

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

In *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, No. 13-1418 (Fed. Cir. Apr. 22, 2014), the Federal Circuit vacated and remanded the district court's SJ decision that Gilead Sciences, Inc.'s ("Gilead") asserted patent was not invalid, holding that a later-issued, earlier-expiring Gilead patent could serve as an obviousness-type double patenting reference against the asserted patent.

Gilead owns U.S. Patent Nos. 5,763,483 ("the '483 patent") and 5,952,375 ("the '375 patent"), both directed to antiviral compounds and methods for their use. The '483 and '375 patents list the same inventors, but they do not claim priority to a common patent application and they have different expiration dates as governed by the provisions of the Uruguay Round Agreements Act ("URAA"). As illustrated in the figure below, the '375 patent, which claims priority to an application filed on February 27, 1995, issued on September 14, 1999, and will expire on February 27, 2015. The '483 patent, which was filed on December 27, 1996, and claims priority to a provisional application filed on December 29, 1995, issued on June 9, 1998 (before the '375 patent), but will expire on December 27, 2016 (after the '375 patent). A terminal disclaimer was filed for the '375 patent based on the '483 patent, but no terminal disclaimer was filed for the '483 patent.



Slip op. at 4.

Gilead sued Natco Pharma Limited ("Natco") for infringement of the '483 patent after Natco filed an ANDA seeking FDA approval to market a generic version of one of Gilead's drugs allegedly covered by the '483 patent. As its only invalidity defense, Natco asserted that the '483 patent was invalid for obviousness-type double patenting over the '375 patent. The district court granted SJ in favor of Gilead, concluding that a later-issued but earlier-expiring patent cannot serve as a double patenting reference against an earlier-issued but later-expiring patent. After Natco conditionally stipulated to infringement, the district court certified its SJ ruling for appeal.

"In cases where such obviousness-type double patenting is present, a terminal disclaimer can preserve the validity of the later-expiring patent by aligning its expiration date with that of the earlier-expiring patent." Slip op. at 16.

On appeal, the Federal Circuit held that the district court erred in excluding the '375 patent as a potential double patenting reference against the '483 patent. The Court first reviewed the obviousness-type double patenting doctrine, explaining that this long-standing patent law doctrine "is based on the core principle that, in exchange for a patent, an inventor must fully disclose his invention and promise to permit free use of it at the end of his patent term." *Id*. at 6. The Court also explained that the scope of the bar against double patenting has been well established, with federal courts applying the doctrine's principles for over a century to preserve the public's right to use not only the exact invention claimed by an inventor but also obvious modifications of that invention that are not patentably distinct. The Court noted the addition of 35 U.S.C. § 253 in 1952, which in part permits a patentee to disclaim any terminal part of a patent term, as well as the Court's recognition in *In re Robeson*, 331 F.2d 610, 614 (CCPA 1964), that § 253's terminal disclaimer provision provided patent owners a remedy against a charge of obviousness-type double patenting.

The Federal Circuit then held that the principle protected by the obviousness-type double patenting doctrine "is violated when a patent expires and the public is nevertheless barred from practicing obvious modifications of the invention claimed in that patent because the inventor holds another later-expiring patent with claims for obvious modifications of the invention," as "is the case here." Slip op. at 11. Assuming for the appeal that the '483 patent covers obvious modifications of the invention claimed in the '375 patent, the Court explained that once the '375 patent expires on February 27, 2015, the public will not be free to use the invention claimed in that patent and all obvious variants of that invention for another twenty-two months, because the '483 patent will not expire until December 27, 2016. Rejecting Gilead's argument that the '375 patent in no way extends the term of the '483 patent, which issued first, the Court saw "little import here in the fact that the '483 patent issued first." *Id.* at 12. The Court distinguished cases directed to pre-URAA patents, explaining that for double patenting inquiries, looking to patent issue dates had in those cases served as a reliable stand-in for the date that mattered—patent expiration. Thus, according to the Court, "in light of the principles reflected in our prior case law as explained above, it is the comparison of Gilead's patent expiration dates that should control, not merely the issuance dates." *Id.* at 13.

The Court decided that relying only on issuance dates for post-URAA patents would have several shortcomings. First, "the terms of such patents could be subject to significant gamesmanship during prosecution." *Id.* Specifically, the Court contemplated that "inventors could routinely orchestrate patent term extensions by (1) filing serial applications on obvious modifications of an invention, (2) claiming priority to different applications in each, and then (3) arranging for the application claiming the latest filing date to issue first," thus allowing inventors to obtain additional patent term while also exploring the value of an earlier priority date. *Id.* Second, the Court noted the possibility for significant yet arbitrary differences in patent term based on mere days' difference in patent issuance. Using Gilead's patents as an example, the Court observed that if the '375 patent issued *the day before* the '483 patent, going strictly by issuance date would make the last twenty-two months of the '483 patent's term an improper patent term extension, but not if the '375 patent issued *the day after* the '483 patent. In contrast, the Court concluded, "[p]ermitting any earlier expiring patent to serve as a double patenting reference for a patent subject to the URAA guarantees a stable benchmark that preserves the public's right to use the invention (and its obvious variants) that are claimed in a patent when that patent expires" and preserves the ability of inventors to use a terminal disclaimer of later-expiring patents to create one expiration date for their term of exclusivity. *Id.* at 15. Finally, the Court noted that looking to the expiration date was consistent with the PTO's guidance in MPEP § 804(I)(B)(1), which instructs that a terminal disclaimer is required for the later-filed (and thus later-expiring) of two pending applications.

The Court therefore held that Gilead's earlier-expiring '375 patent could qualify as an obviousness-type double patenting reference for Gilead's later-expiring '483 patent. Accordingly, the Court vacated the district court's SJ decision and remanded for further proceedings consistent with this opinion.

Judge Rader dissented. According to Judge Rader, none of the policy concerns behind obviousness-type double patenting justified in this case the "new rule" crafted by the Court—that in the case of competing patents, the earliest expiration date governs the inquiry irrespective of filing or issue dates. Rader Dissent at 3, 4-5. First, Judge Rader observed that this case did not raise the policy concern regarding subsequent extensions of patent term, since Gilead's subsequent '375 patent unquestionably did not extend the term of the earlier-issued '483 patent, noting that "if the '375 patent had never issued, Gilead would certainly be entitled to the '483 patent's 2016 expiration date." *Id.* at 4. Second, the case did not involve the potential for harassment by multiple assignees asserting essentially the same patented invention since the '375 patent was subject to a terminal disclaimer over the '483 patent and thus was only enforceable so long as both were commonly owned. Judge Rader found the Court's reasoning not only unpersuasive, since under 35 U.S.C. § 154(b) Gilead followed the precise approved course—obtaining a longer patent term by subjecting the '483 patent to roughly ten months of intervening prior art—but also based on a flawed assumption that, upon expiration of a patent, the public obtained an absolute right to use the previously claimed subject matter. Viewing the question through "the lens of judicial restraint," Judge Rader concluded that Gilead's conduct was not so manifestly unreasonable to warrant the Court's new judicially created exception to invalidate patents. *Id.* at 6.

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Decision to Not Institute an Inter Partes Review Is Not Appealable to the Federal Circuit

Robert A. Hall

Judges: Prost, O'Malley, Taranto (author)

[Appealed from Board]

In *St. Jude Medical, Cardiology Division, Inc. v. Volcano Corp.*, No. 14-1183 (Fed. Cir. Apr. 24, 2014), the Federal Circuit held that it did not have jurisdiction to hear an appeal of a decision to not institute an inter partes review.

In 2010, St. Jude Medical, Cardiology Division, Inc. ("St. Jude") filed an action for infringement against Volcano Corporation ("Volcano"), alleging infringement of five of St. Jude's patents. Subsequently, in September 2010, Volcano asserted a counterclaim of infringement of U.S. Patent No. 7,134,994 ("the '994 patent") against St. Jude. In October 2012, based on a stipulation of the parties, the district court dismissed all claims related to the '994 patent. Six months after the district court's dismissal, St. Jude petitioned the Director of the PTO to institute an inter partes review of the '994 patent owned by Volcano. The Director, through her delegee, denied the petition on the basis that the 2010 counterclaim against St. Jude constituted a complaint for patent infringement served more than one year before filing the petition within the meaning of 35 U.S.C. § 315(b). St. Jude appealed the noninstitution decision, contending that the Court had subject matter jurisdiction and that 35 U.S.C. § 314(d) did not bar immediate review. Volcano and the Director moved to dismiss the appeal.

"In fact, the statute goes beyond merely omitting, and underscoring through its structure the omission of, a right to appeal the non-institution decision. It contains a broadly worded bar on appeal. Under the title, 'No Appeal,' Section 314(d) declares that '[t]he determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable.' That declaration may well preclude all review by any route, which we need not decide. It certainly bars an appeal of the non-institution decision here." Slip op. at 5 (alteration in original) (quoting 35 U.S.C. § 314(d)).

On appeal, the Federal Circuit held that it did not have jurisdiction to hear St. Jude's appeal. The Court explained, "Chapter 31 authorizes appeals to this court only from 'the final written decision of the [Board] under section 318(a).' [35 U.S.C.] § 319. Likewise, section 141(c) in relevant part authorizes appeal only by 'a party to an *inter partes* review . . . who is dissatisfied with the final written decision of the [Board] under section 318(a).' *Id.* § 141(c)." Slip op. at 4 (first and third alterations in original). The Court stated that St. Jude challenged the Director's noninstitution decision under 38 U.S.C. § 314(a) and (b), which was not a "final written decision" of the Board under § 318(a). The Court further noted that the statutory

provisions addressing inter partes review contain no authorization to appeal a noninstitution decision to the Court, but rather provide for an appeal to the Court only of the Board's decision with respect to patentability. Indeed, the Court explained, the statute "declares that '[t]he determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable.'" *Id.* at 5 (alteration in original) (quoting 38 U.S.C. § 314(d)). Accordingly, taking into consideration the chapter 31 provisions and section 141(c), the Court determined that it lacked jurisdiction to hear the appeal.

The Court then turned to St. Jude's argument that 28 U.S.C. § 1295(a)(4)(A) provided the Court with jurisdiction over an appeal from a decision of the Board with respect to an inter partes review under title 35. The Court, however, found that provision was "most naturally read to refer precisely to the Board's decision under section 318(a) on the merits of the *inter partes* review, after it 'conducts' the proceeding that the Director has 'instituted.' Under that reading, the statutory grant of jurisdiction to this court matches the appeal right in chapter 31 and section 141(c), and St. Jude's appeal is outside both." *Id.* at 5-6.

Accordingly, the Court granted the motions to dismiss the appeal to not institute an inter partes review.

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Patent Assignors Do Not Retain a Right of Appeal Under 35 U.S.C. § 141

Richard Hanna

Judges: Rader (author), Linn, Taranto

[Appealed from Board]

In *Vaillancourt v. Becton Dickinson & Co.*, No. 13-1408 (Fed. Cir. Apr. 24, 2014), the Federal Circuit held that there is no cause of action for an appeal in a reexamination proceeding under 35 U.S.C. § 141 where the appellant has assigned the entire right, title, and interest to the appealed patent.

Michael Vaillancourt was the holder of U.S. Patent No. 6,699,221 ("the '221 patent"). On August 12, 2010, Becton Dickinson & Company requested an inter partes reexamination of the '221 patent. During reexamination, the patent examiner rejected all claims of the '221 patent. Vaillancourt appealed this decision to the Board on April 25, 2011. During the pendency of the appeal, on April 24, 2012, Vaillancourt assigned "the entire right, title, and interest in and to" the '221 patent to VLV Associates, Inc. ("VLV"), of which Vaillancourt is the sole owner. Slip op. at 3 (citation omitted). The Board affirmed the examiner's rejections on June 29, 2012, and subsequently denied Vaillancourt's request to alter this affirmance. Vaillancourt then appealed to the Federal Circuit, citing a cause of action under 35 U.S.C. § 141, and identifying himself in the notice of appeal as both the patent owner and appellant.

"Section 141 grants a procedural right to the patent owner to appeal decisions from the PTAB. This court sees no reason . . . to extend [the] procedural right beyond what is clearly set forth in § 141." Slip op. at 5.

On appeal, the Federal Circuit dismissed Vaillancourt's appeal, finding that, "[u]nder the unambiguous language of § 141, Vaillancourt, the sole appellant here, has no cause of action to bring this appeal." *Id.* at 5. The Court noted that "[t]he unambiguous language of § 141 provides that a patent owner alone can appeal a final decision in an inter partes reexamination to this court," and, therefore, the statute itself "requires the patent owner to initiate any appeal." *Id.* at 4.

Vaillancourt argued that despite his assignment of rights in the '221 patent, he was authorized to proceed with the appeal on behalf of VLV based in part on being the sole owner of VLV. The Court found that such an argument suggested that § 141 allows a patent owner to delegate to a third party its authority to bring an appeal, but the Court noted that Vaillancourt provided no support for this interpretation of the statute, and instead only argued that the language of § 141 does not explicitly bar such delegation. The Court dismissed Vaillancourt's argument, noting that the statute grants a procedural right to the patent owner, and the statute's failure to forbid unmentioned classes of appellants does not justify interpreting the statute to extend rights of appeal to such unmentioned classes.

Accordingly, the Federal Circuit dismissed Vaillancourt's appeal as lacking a cause of action to bring the appeal.

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No Per Se Rule Against Injunctions for Standard-Essential Patents

Jeff T. Watson

Judges: Rader (dissenting-in-part), Prost (concurring-in-part and dissenting-in-part), Reyna (author)

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

In *Apple Inc. v. Motorola, Inc.*, Nos. 12-1548, -1549 (Fed. Cir. Apr. 25, 2014), the Federal Circuit affirmed the district court's claim construction decisions, with the exception of its construction of certain "heuristic" claim limitations, reversed the district court's decision to exclude damages evidence (with a minor exception), and reversed the district court's grant of SJ of no damages for infringement of Apple Inc. and Next Software, Inc.'s (collectively "Apple") patents. Based on its reversal of the district court's construction of the "heuristic" limitations, the Court vacated the grant of SJ regarding Apple's request for an injunction. The Court also affirmed the district court's decision that Motorola, Inc. and Motorola Mobility, Inc. (collectively "Motorola") were not entitled to an injunction for infringement of its FRAND (fair, reasonable, and nondiscriminatory) committed patent.

Apple filed a complaint against Motorola, and Motorola counterclaimed. The district court, based on its claim construction decisions, granted SJ of noninfringement with respect to certain claims and excluded most of the parties' damages expert evidence for the remaining claims. With little expert evidence on damages deemed admissible, the district court granted SJ that neither party was entitled to damages or an injunction and dismissed all claims with prejudice before trial. On appeal, the parties contested the district court's claim construction, admissibility, damages, and injunction decisions for three Apple and three Motorola asserted patents.

"The framework laid out by the Supreme Court in *eBay*, as interpreted by subsequent decisions of this court, provides ample strength and flexibility for addressing the unique aspects of FRAND committed patents and industry standards in general." Slip op. at 71-72.

The Federal Circuit first analyzed the district court's claim construction decisions, beginning with certain "heuristic" claim limitations in Apple's U.S. Patent No. 7,479,949 ("the '949 patent"). The district court concluded that these limitations were means-plus-function limitations under 35 U.S.C. § 112, ¶ 6, despite not reciting the word "means." The Federal Circuit disagreed, holding that, when a claim limitation lacks the term "means," the determination of whether the claim limitation invokes means-plus-function claiming is based on "whether the limitation, read in light of the remaining claim language, specification, prosecution history, and relevant extrinsic evidence, has sufficiently definite structure to a person of ordinary skill in the art." Slip op. at 12-13. The Court explained that "the 'structure' of computer software is understood through, for example, an outline of an algorithm, a flowchart, or a specific set of instructions

or rules," and may be provided by "describing the claim limitation's operation, such as its input, output, or connections." *Id.* at 13-14. Applying this standard, the Court determined that the "heuristic" claim limitations had sufficiently definite structure, and thus did not invoke 35 U.S.C. § 112, ¶ 6. Based on its reversal of the district court's construction of the "heuristic" claim limitations, the Court vacated the district court's grant of SJ of noninfringement for the '949 patent. The Court affirmed the remainder of the district court's claim constructions and the related grants of SJ of noninfringement.

The Federal Circuit next considered the admissibility of the parties' damages expert evidence. With respect to Apple's '949 patent, the Court found that the district court improperly excluded Apple's proposed expert testimony on damages because the district court based its damages analysis on an incorrect claim construction and, further, because the district court did not consider the full scope of the asserted claims, questioned the conclusions of Apple's expert, and substituted its own opinion. The Court explained that, in determining whether to admit expert testimony, the court must ask, "with the entire scope of the asserted claims and the correct claim construction in mind, whether [the expert] employed reliable principles and methods, reliably applied them, and relied upon legally sufficient facts or data." *Id.* at 46.

With respect to Apple's U.S. Patent No. 6,343,263 ("the '263 patent"), the Federal Circuit held that it was improper for the district court to exclude proposed expert testimony for the sole reason that the expert relied on another expert hired by Apple to identify a replacement chip used in the damages calculations. The Court explained that "Rule 703 explicitly allows an expert to rely on information he has been made aware of 'if experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject.'" *Id.* at 52 (quoting Fed. R. Evid. 703). The Court stated that any concern regarding potential bias was to be addressed by the weight given to the expert's testimony, not its admissibility.

Turning to Motorola's U.S. Patent No. 6,359,898 ("the '898 patent"), the Federal Circuit affirmed the district court's exclusion of certain testimony that relied on testimony from Motorola's licensing expert, but found that the district court erred when it excluded the remainder of Motorola's proposed expert testimony on damages. The Court explained that proof of damages must be "carefully tied to the claimed invention itself." *Id.* at 58. Relying on a declaration of Motorola's licensing expert, Charles Donohoe, Motorola's damages expert, Carla Mulhern, testified that the first few patents from a given portfolio would typically command 40-50% of the entire portfolio rate. However, the Court noted that Donohoe's 40-50% theory corresponded to standards-essential telecommunications patents in general, and not to the specific portfolio at issue, and was therefore not tied to the facts of the case. Thus, the Court affirmed the district court's exclusion of expert testimony based on that theory. The Court, however, reversed the district court's exclusion of Mulhern's remaining proposed testimony.

The Federal Circuit next considered the district court's grant of SJ regarding damages. Based on its decisions regarding the admissibility of damages evidence, the Court vacated the district court's grant of SJ regarding damages for Apple's '949 and '263 patents, and for Motorola's '898 patent. The Court also reversed the district court's grant of SJ regarding Apple's U.S. Patent No. 5,946,647 ("the '647 patent"). The district court found that Apple was not entitled to any damages because Apple failed to show its measure of damages was correct. The Federal Circuit disagreed, holding that "a finding that a royalty estimate may suffer from factual flaws does not, by itself, support the legal conclusion that zero is a reasonable royalty." *Id.* at 63. The Court explained that "[i]f a patentee's evidence fails to support its specific royalty estimate, the fact finder is still required to determine what royalty is supported by the record." *Id.* at 64.

The Federal Circuit then addressed the district court's grant of SJ regarding injunctive relief. The district court granted Motorola's motion for SJ that Apple was not entitled to an injunction for infringement of the '949, '263, and '647 patents because Apple had failed to show a causal nexus between any alleged irreparable harm and Motorola's infringement. The Federal Circuit noted that its reversal of the district court's claim construction decision for the '949 patent altered the potential scope of infringement and thus vacated the district court's grant of SJ regarding Apple's request for an injunction.

The Federal Circuit affirmed the district court's grant of SJ that Motorola is not entitled to an injunction for infringement of the FRAND-committed '898 patent. The Court noted, however, that to the extent the district court applied a per se rule that injunctions are unavailable for standard-essential patents, it erred, explaining that it saw no reason to create a separate rule or analytical framework for addressing injunctions for FRAND-committed patents. Rather, the Court held that "[t]he framework laid out by the Supreme Court in *eBay*, as interpreted by subsequent decisions of this court, provides ample strength and flexibility for addressing the unique aspects of FRAND committed patents and industry standards in general." *Id.* at 71-72. Applying that framework, the Court found that Motorola's FRAND commitments strongly suggested that money damages were adequate to fully compensate Motorola for infringement, and that Motorola had not demonstrated that Apple's infringement caused it irreparable harm.

Judge Rader dissented as to the portion of the Court's opinion affirming the district court's denial of Motorola's request for an injunction. Judge Rader found that "the record contains sufficient evidence to create a genuine dispute of material fact on Apple's posture as an unwilling licensee whose continued infringement of the '898 patent caused irreparable harm." Rader Dissent at 1. According to Judge Rader, the district court did not develop the facts necessary to apply *eBay* as it should have and, thus, the case should be remanded.

Judge Prost dissented with respect to the proper construction of the "heuristic" claim limitations and with respect to the majority's decision to vacate the district court's grant of SJ regarding Apple's request for an injunction. According to Judge Prost, the majority misstated Federal Circuit law on means-plus-function claiming. As Judge Prost explained, "In effect, what the majority has done is imported the second step of the analysis (where you define the scope of a means-plus-function claim term based on the corresponding structure in the specification) into the first step (where you identify whether the term is drafted in means-plus-function format)." Prost Dissent at 3. Judge Prost found that the "heuristic" limitations are means-plus-function limitations. With respect to Apple's request for an injunction, Judge Prost found that Apple's evidence was insufficient to establish the requisite nexus between the accused features and the demand for the accused Motorola products as a whole. Accordingly, Judge Prost agreed with the district court that Apple could not show that Motorola's infringement caused it irreparable harm and, thus, would affirm the district court's grant of SJ of no injunctive relief.

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Looking Ahead

On April 29, 2014, the Supreme Court issued unanimous reversals of the Federal Circuit in *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, No. 12-1184 (Apr. 29, 2014), and *Highmark Inc. v. Allcare Health Management Systems, Inc.*, No. 12-1163 (Apr. 29, 2014). In *Octane Fitness*, the Supreme Court held that the Federal Circuit's framework in which "a case is 'exceptional' [under 35 U.S.C. § 285] only if a district court either finds litigation-related misconduct of an independently sanctionable magnitude or determines that the litigation was both 'brought in subjective bad faith' and 'objectively baseless' . . . superimposes an inflexible framework onto statutory text that is inherently flexible." No. 12-1184, slip op. at 8 (quoting *Brooks Furniture Mfg., Inc. v. Dutailier Int'l, Inc.*, 393 F.3d 1378, 1381 (Fed. Cir. 2005)). In *Highmark*, the Supreme Court held that "all aspects" of a district court's exceptional-case determination under § 285 should be reviewed for "abuse of discretion." No. 12-1163, slip op. at 1.

Stay tuned to *Last Month at the Federal Circuit* to see how these decisions by the Supreme Court affect future Federal Circuit decisions.

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Spotlight Info

In *St. Jude Medical, Cardiology Division, Inc. v. Volcano Corp.*, No. 14-1183 (Fed. Cir. Apr. 24, 2014), the Federal Circuit held that it did not have jurisdiction to hear an appeal of a decision to not institute an inter partes review. The Court explained that the statute "declares that '[t]he determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable.'" Slip op. at 5 (alteration in original) (quoting 38 U.S.C. § 314(d)). Addressing the argument that 28 U.S.C. § 1295(a)(4)(A) provided jurisdiction, the Court further held that that provision was "most naturally read to refer precisely to the Board's decision under section 318(a) on the merits of the *inter partes* review, after it 'conducts' the proceeding that the Director has 'instituted.' Under that reading, the statutory grant of jurisdiction to this court matches the appeal right in chapter 31 and section 141(c), and St. Jude's appeal is outside both." *Id.* at 5-6. See this month's edition of *Last Month at the Federal Circuit* for a full summary of this decision.

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