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[Appealed from D.N.M., Judge Browning]

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[Appealed from W.D. Wash., Judge Martinez]

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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In *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 10-1406 (Fed. Cir. July 29, 2011), the Federal Circuit held that composition claims to "isolated" DNA molecules are patentable subject matter, while method claims simply "comparing" or "analyzing" DNA sequences are not. After finding that one of the plaintiffs had standing, the Court looked to Supreme Court precedent for the framework for deciding the patent eligibility of isolated DNA molecules. The Federal Circuit found that the isolated *BRCA1* and *BRCA2* claimed were not the same molecules as DNA as it exists in the body, and were therefore patentable.

The Court also addressed a § 101 challenge to Myriad Genetics, Inc.'s ("Myriad") method claims. The Federal Circuit found that Myriad's claims involving methods of "comparing" or "analyzing" claimed only abstract mental processes and were not patentable subject matter under § 101. Regarding Myriad's method claim directed to a method for screening potential cancer therapeutics via changes in cell growth rates, the Federal Circuit found that this was patentable subject matter under § 101. Judge Moore concurred with the majority with respect to the patentability of isolated DNA sequences (other than cDNA sequences) and joined the majority opinion with respect to all other issues. Judge Bryson dissented from the Court's holding that isolated DNA was patentable, concurring with the rest of the Court's opinion.

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

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On July 7, 2011, the Federal Circuit heard oral argument in *FLFMC, LLC v. Wham-O, Inc.*, No. 11-1067, in which the parties and the U.S. government addressed the constitutionality and standing requirements of the False Marking statute, 35 U.S.C. § 292. Before the District Court of the Western District of Pennsylvania, defendant Wham-O, Inc. ("Wham-O") sought to dismiss FLFMC, LLC's complaint based on several grounds, including the lack of standing and alleged unconstitutionality of § 292(b) under the "Take Care" and "Appointments" Clauses of the U.S. Constitution. The current patent reform legislation pending before Congress amends § 292(b) and, in particular, the language upon which Wham-O's challenges are based. Thus, if Congress acts before the Federal Circuit issues a decision, this appeal would be rendered moot.

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Preliminary Injunction Upheld to Enforce Forum Selection Clause Where Continuations of Licensed Patents Are Impliedly Licensed

Kevin D. Rodkey

Judges: Linn (author), Schall, Dyk

[Appealed from D.N.M., Judge Browning]

In *General Protecht Group, Inc. v. Leviton Manufacturing Co.*, No. 11-1115 (Fed. Cir. July 8, 2011), the Federal Circuit affirmed the district court's decision to enforce a forum selection clause and found that the district court did not abuse its discretion in granting a preliminary injunction against Leviton Manufacturing Co., Inc.'s ("Leviton") infringement suits brought in other forums.

Leviton and General Protecht Group, Inc. ("GPG") are both manufacturers of ground fault circuit interrupters ("GFCIs"). In 2004 and 2005, Leviton sued GPG in the District of New Mexico, alleging infringement of U.S. Patent Nos. 6,246,558 ("the '558 patent") and 6,864,766 ("the '766 patent"). In 2007, the parties settled the dispute pursuant to a confidential settlement agreement ("Settlement Agreement"). In the Settlement Agreement, Leviton

> covenants not to sue (1) Defendants . . . for alleged infringement of the '558 and/or '766 patents based on the [Defendant's] products currently accused of infringement . . . and (2) Defendants . . . for alleged infringement of the '558 patent and/or the '766 patent with respect to an anticipated future new . . . product that Defendant . . . has indicated its intent to market in the U.S. in the future . . . .

Slip op. at 3. The Settlement Agreement also included a forum selection clause stating that "[a]ny dispute between the Parties relating to or arising out of this [Settlement Agreement] shall be prosecuted exclusively in the United States District Court for the District of New Mexico." *Id*. (second alteration in original).

In September 2010, Leviton filed complaints against GPG and its distributors in the ITC and the Northern District of California, alleging infringement of U.S. Patent Nos. 7,463,124 ("the '124 patent") and 7,764,151 ("the '151 patent"), which are continuations of the '558 and '766 patents, and issued after the Settlement Agreement was executed.

GPG informed Leviton that it believed it had a license to practice the asserted patents under the

Settlement Agreement. GPG then brought a DJ action in the District of New Mexico asserting noninfringement, invalidity, and breach of contract. GPG also sought a temporary restraining order and preliminary injunction against Leviton's continued litigation of the dispute outside of New Mexico. The district court, following the Federal Circuit's holding in *TransCore v. Electronic Transaction Consultants Corp.*, 563 F.3d 1271 (Fed. Cir. 2009), granted the preliminary injunction enforcing the forum selection clause of the Settlement Agreement. In the *TransCore* case, TransCore had previously settled a lawsuit that gave Electronic Transaction Consultants Corp. a license to practice the patents-in-suit. The settlement specifically stated that the covenant not to sue will not apply to any other patents issued as of the effective date of the agreement or to be issued in the future. When TransCore's continuation patent later issued, however, the Federal Circuit held that the new patent was also covered by an implied license and through legal estoppels. Leviton appealed the district court's grant of the preliminary injunction.

On appeal, Leviton made three arguments: (1) the forum selection clause does not apply because it does not extend to cases in which the only relationship the Settlement Agreement bears to the subsequent dispute is that it possibly gives rise to a defense; (2) even if the forum selection clause could apply in such cases, the Settlement Agreement does not give rise to an implied license defense in the present case as a matter of law; and (3) the district court erred in its application of the remaining three preliminary injunction factors.

The Federal Circuit first considered whether GPG was likely to succeed on the merits of applying the forum selection clause. The Court determined that the likelihood of success turned on whether GPG's implied license defense crossed the threshold required to trigger the "relating to or arising out of" provision of the clause. Applying its holding in *Texas Instruments Inc. v. Tessera Inc.*, 231 F.3d 1325, 1328 (Fed. Cir. 2000), the Court determined that, because the outcome of the dispute regarding the scope of the patent license would determine whether Leviton can sustain a patent infringement action, there is no question that the case "relates to or arises out of" the Settlement Agreement and that the forum selection clause applies.

"From our holding in *TransCore*, it reasonably follows that where, as here, continuations issue from parent patents that previously have been licensed as to certain products, it may be presumed that, absent a clear indication of mutual intent to the contrary, those products are impliedly licensed under the continuations as well." Slip op. at 11.

Next, the Federal Circuit turned to GPG's likelihood of success on its implied license defense. The Court compared the current case to its previous decision in *TransCore* and reaffirmed that "legal estoppel refers to a narrow[] category of conduct encompassing scenarios where a patentee has licensed or assigned a right, received consideration, and then sought to derogate from the right granted." Slip op. at 9 (alteration in original) (citing *TransCore*, 563 F.3d at 1279).

Leviton argued that *TransCore* does not control because (1) *TransCore* is limited to cases where the claims of the continuation are broader than and therefore necessary to practice the claims of the expressly licensed patents; (2) the manifest mutual intent of the parties in the present case was to convey narrower rights than were conveyed in *TransCore* such that no license can be implied here; and (3) such a result conflicts with this Court's holding in the earlier decided case of *Jacobs v. Nintendo of America*, 370 F.3d 1097 (Fed. Cir. 2004). The Federal Circuit addressed each argument in turn.

The Court first rejected Leviton's argument that *TransCore* did not apply because the newly asserted patents by Leviton were narrower in scope than the patents under the Settlement Agreement. The Court noted that the continuation '124 and '151 patents relied on the same disclosure as the original '558 and '766 patents, and that the same products were accused of infringement in the new suit as in the previous suit. The Court stated that *TransCore* prohibits a patent licensor from derogating rights granted under a license and that if Leviton did not intend to license the products to extend to claims presented in the continuation patents, then Leviton had an obligation to make that clear. The Court further determined that, based on its holding in *TransCore*, it reasonably follows that where continuations issue from parent patents that have been previously licensed as to certain products, it may be presumed that, absent a clear indication of mutual intent to the contrary, the products are impliedly licensed under the continuations as well. The Court concluded that the parties are free to contract around an interpretive presumption that does not reflect their intentions, but that it is the parties' burden to make such intent clear in the license.

Next, the Federal Circuit rejected Leviton's argument that the parties intended the Settlement Agreement to be a "walk away" agreement that preserved Leviton's rights to sue on other patents and to which *TransCore* does not apply. The Court determined that the language of the Settlement Agreement manifests a mutual understanding that future litigation between the parties concerning related patents is a distinct possibility, but that the language does not address whether the parties intended that continuation patents could be asserted against the same products, and, therefore, *TransCore* still applies.

The Court then rejected Leviton's argument that *TransCore* does not apply because *Jacobs* conflicts with *TransCore* and should control as the first-decided case. The Court observed that Leviton admitted at oral arguments that *Jacobs* did not hold that a covenant not to sue does not give rise to an implied license. For this reason, the Court rejected Leviton's final argument and concluded that *TransCore* does control.

Finally, the Federal Circuit analyzed the remaining factors in determining a preliminary injunction: irreparable harm to the moving party, balance of the hardships, and public interest. The Court agreed with GPG that the district court did not abuse its discretion in finding that GPG would likely be irreparably harmed in the absence of a preliminary injunction because it would be deprived of its bargained-for forum and would likely be forced to litigate the same issues on multiple fronts at the same time. The Court also concluded that the district court did not abuse its discretion in finding that the balance of hardships favored the injunction.

Finally, the Federal Circuit determined that public policy favors enforcing the forum selection clause, rejecting Leviton's argument that the injunction contravenes public interest by hindering an ITC investigation. The Court concluded that the preliminary injunction will not and cannot enjoin the ITC action, and there is no public interest served by excusing a party's violation of its previously negotiated contractual undertaking to litigate in a particular forum. Accordingly, the Court affirmed the district court's issuance of a preliminary injunction.

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Claim Differentiation Does Not Trump Written Description in Claim Construction

Justin E. Loffredo

Judges: Rader (dissenting-in-part), Plager (concurring), Lourie (author)
[Appealed from E.D. Tex., Chief Judge Folsom]

In *Retractable Technologies, Inc. v. Becton, Dickinson & Co.*, No. 10-1402 (Fed. Cir. July 8, 2011), the Federal Circuit affirmed-in-part and reversed-in-part. The Court affirmed the district court's construction of "retainer member" and "cutting" in the asserted claims, but reversed the district court's construction of "body" in the same claims. The Court reversed the district court's noninfringement decision with respect to one of Becton, Dickinson and Company's ("BD") devices, but affirmed with respect to another of BD's devices. Additionally, the Court affirmed the district court's exclusion of evidence of plaintiffs Retractable Technologies, Inc. and Thomas J. Shaw's (collectively "RTI") discovery responses and affirmed the district court's decision that claim 25 of U.S. Patent No. 6,090,077 ("the '077 patent") was not invalid as anticipated or obvious.

RTI sued BD for infringement of the '077 patent, U.S. Patent No. 5,632,733 ("the '733 patent"), and U.S. Patent No. 7,351,224 ("the '224 patent"). RTI and BD both design and sell retractable syringes, which are medical syringes having a needle that is retractable into the syringe body. Both parties agreed that retractable syringes have existed since at least the early 1990s, as evidenced by U.S. Patent Nos. 5,053,010 ("the '010 patent") and 5,211,629 ("the '629 patent"). BD produces both 3 mL and 1 mL Integra™ syringes. Excluding a plunger, which includes a cutter to allow a spring to expand in order to retract the needle into the body, BD's 3 mL Integra™ syringe contains two pieces: a syringe body and a needle assembly that screws into the body. BD's 1 mL Integra™ syringe, on the other hand, is a one-piece syringe that includes the needle assembly.

The district court construed the claim terms "retainer member" and "needle holder" need not be two separate parts and that the claimed "body" was not limited to a one-piece structure. The district court also concluded that the patents did not disclaim the use of "cutting." The jury found that BD infringed multiple claims of the asserted patents, and that BD failed to prove that any of the asserted claims were invalid. BD then moved for JMOL of noninfringement and invalidity, or, in the alternative, for a new trial. The district court denied the motions and entered judgment against BD.

On appeal, the Federal Circuit affirmed the district court's claim construction of "retainer member," but reversed as to the claimed "body." Regarding the "retainer member," BD argued that the "retainer

member" must be separate from the "needle holder" because the asserted claims list them as separate claim limitations and because the specifications only describe a retainer member that is separate from the needle holder. The Federal Circuit, however, disagreed because the claims and the specification indicate that the "retainer member" need not be separately molded from the "needle holder" and that they can be integrally formed.

Regarding the claimed "body," BD argued that "body" is limited to a one-piece structure, and the panel agreed. The Court noted that claim construction requires more than viewing the claim language in isolation, that claim language must always be read in view of the written description, and that any presumption created by the doctrine of claim differentiation will be overcome by a contrary construction dictated by the written description or prosecution history. Here, the specifications of the patents expressly state that each syringe embodiment contains a one-piece body and lacks any disclosure of a body having multiple pieces. Each figure also depicts a one-piece syringe body. Furthermore, the specifications note that the prior art fails to recognize a retractable syringe that can be molded as a one-piece outer body. The Court focused on the need to "capture the scope of the actual invention," and reasoned that, in this case, while the claims leave open the possibility that the recited "body" may encompass a syringe body composed of multiple pieces, "the specification tells us otherwise." Accordingly, the Federal Circuit reversed the district court and construed the claimed term "body" as comprising a one-piece body.

"In reviewing the intrinsic record to construe the claims, we strive to capture the scope of the actual invention, rather than strictly limit the scope of claims to disclosed embodiments or allow the claim language to become divorced from what the specification conveys is the invention." Slip op. at 17 (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1323-24 (Fed. Cir. 2005) (en banc)).

The Court also agreed with the district court that the patents do not disclaim the use of "cutting." BD argued that the specifications expressly criticize and distinguish prior art devices that operate by methods other than friction, thereby disclaiming devices that operate by cutting. Citing *Epistar Corp. v. International Trade Commission*, 566 F.3d 1321, 1335 (Fed. Cir. 2009), the Court disagreed that the claims should be construed to disclaim cutting, because in order to disavow claim scope, the specification must contain "expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." Slip op. at 18. Here, nothing in the claim language or the written description clearly excludes "cutting" from the scope of the claims.

Additionally, the Court reversed the district court's decision of infringement of BD's 3 mL Integra™ syringe, but affirmed the decision of infringement of BD's 1 mL Integra™ syringe. Regarding the 3 mL syringe, which contains two pieces, BD argued that because the specifications of the patents criticize prior art syringes having multiple bodies, RTI cannot assert infringement under the DOE. Having construed the claimed "body" as a one-piece body, the Court agreed. When a specification excludes certain prior art alternatives from the literal scope of the claims and criticizes those alternatives, the patentee cannot then use the DOE to capture those alternatives. Regarding the 1 mL syringe, BD argued for noninfringement based on their construction of the claimed "retainer member" and because the patents exclude "cutting" from the scope of the claims. As discussed above, however, the Court disagreed with BD's construction of the claimed "retainer member" and "cutting," and therefore affirmed the district court's determination of infringement of BD's 1 mL Integra™ syringe.

Finally, the Court affirmed the district court's decision that the patents were not invalid for anticipation or obviousness. BD argued that each of the '010 and the '629 patents disclose each limitation of claim 25, including the limitation for "lodging the thumb cap in the open back barrel." RTI, however, provided expert testimony that neither the '010 nor the '629 patent discloses this "lodging" limitation. The jury agreed with RTI's expert testimony and the Court held that substantial evidence supported the jury's verdict. The Court disagreed, however, as to the holding of nonobviousness. RTI presented expert testimony that artisans of ordinary skill would not have been motivated to replace a "locking" mechanism disclosed by the '010 and the '629 patents with the "lodging" mechanism disclosed by UK Patent Application GB 2197792A. Thus, the Court held that substantial evidence supported the jury's verdict of nonobviousness.

In a separate opinion, Judge Plager concurred with the majority. He wrote to reinforce a fundamental point made by the majority: that "the specification is the heart of the patent" and that the claims must be interpreted in light of the specification. Plager Concurrence at 2. Judge Plager noted that judges should not be persuaded by "the siren song of litigation counsel to give the jury wide scope regarding what is claimed," because the primary obligation of patentees is to make full disclosure of what is actually invented, and to claim that and nothing more. *Id.* "However much desired by the claim drafters, who want claims that serve as business weapons and litigation threats . . . , the claims cannot go beyond the actual invention that entitles the inventor to a patent. For that we look to the written description." *Id.* (citations omitted).

Chief Judge Rader dissented-in-part because he would affirm the district court's judgment that the 3 mL Integra™ syringe infringed the asserted claims. Rader Dissent at 5. Chief Judge Rader would adhere to the '"bedrock principle of patent law' that the claims themselves, not the written description portion of the specification, define the patented invention." *Id.* at 1-2 (quoting *Phillips*, 415 F.3d at 1312). In his view, the claimed term "body" has no special, technical meaning, and is not inherently a one-piece body. *Id.* at 2. Chief Judge Rader noted that under the doctrine of claim differentiation, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim. *Id.* Applying this doctrine, the term "body" as recited in the independent claims of the patents cannot be interpreted as a one-piece body because of dependent claims, such as claim 14, which claim "[t]he syringe of claim 1 comprising a one-piece barrel." *Id.* (alteration in original) (citation omitted). Chief Judge Rader further noted that there is no exclusion of a body having multiple pieces in the specification and that the continued use of the phrase "one-piece body" implies that the term "body," standing alone, does not inherently contain a one-piece structural limitation. *Id.* at 4.

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Disclosure of a Less-Than-Ideal Use of a Prior Art Compound Is Sufficient to Render It Foreseeable for Purposes of Prosecution History Estoppel

*Derrick L. Wang**

Judges: Lourie (author), Gajarsa, Dyk

[Appealed from S.D.N.Y., Senior Judge Sand]

In *Duramed Pharmaceuticals, Inc. v. Paddock Laboratories, Inc.*, No. 10-1419 (Fed. Cir. July 21, 2011), the Federal Circuit affirmed the district court's grant of SJ of noninfringement, finding that prosecution history estoppel barred Duramed Pharmaceuticals, Inc.'s ("Duramed") allegations of infringement under the DOE.

Duramed owns U.S. Patent No. 5,908,638 ("the '638 patent"), which claims conjugated estrogen pharmaceutical compositions for use in hormone replacement therapies. The conjugated estrogens are extremely water sensitive and highly susceptible to moisture degradation during storage. To counteract those limitations, Duramed developed a formulation that included a moisture barrier coating ("MBC").

Claim 1 of the original '638 patent application recited a conjugated estrogen pharmaceutical composition "coated with a moisture barrier coating." Claim 7 limited the coating to one that "comprises ethylcellulose." During prosecution, the examiner rejected the claims as obvious, but advised that the application would be allowed if Duramed amended claim 1 to include, inter alia, the ethylcellulose limitation of claim 7. Duramed complied, and amended claim 1 thus recited, "A pharmaceutical composition in a solid, unit dosage form . . . comprising: conjugated estrogens . . . wherein said solid unit dosage form is coated with a moisture barrier coating comprising ethylcellulose."

Duramed sued Paddock Laboratories, Inc. ("Paddock") for infringement of the '638 patent based on Paddock's ANDA for a generic version of Duramed's hormone replacement therapy product, Cenestin®. Duramed alleged infringement under the DOE because Paddock's proposed generic product used a polyvinyl alcohol ("PVA") MBC marketed as Opadry AMB, and not an ethylcellulose MBC.

Paddock moved for SJ of noninfringement, arguing that Duramed was barred by amendment-based prosecution history estoppel from alleging that PVA was equivalent to ethylcellulose in the MBC limitation of the asserted patent claims. The district court granted Paddock's motion, finding that (1) Duramed's amendment was substantially related to patentability and, because it narrowed the scope of the asserted claims, it triggered the presumption under *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*,

344 F.3d 1359, 1366-67 (Fed. Cir. 2003) (en banc), that Duramed surrendered all territory between the original and amended claim scope; and (2) Duramed's argument—that the use of PVA as an MBC in a pharmaceutical formulation was unforeseeable at the time of the amendment—did not rebut the *Festo* presumption.

On appeal, Duramed argued that the district court applied the wrong legal test for foreseeability because the district court held that any mention of an alleged equivalent in the prior art makes that equivalent foreseeable as a matter of law. Instead, Duramed asserted that an equivalent is not foreseeable if it was not understood by one of ordinary skill in the art to be suitable for use in the invention as originally claimed. As applied here, Duramed alleged that the relevant art did not disclose either PVA or Opadry AMB as suitable MBCs for moisture-sensitive pharmaceutical compounds similar to conjugated estrogens.

"[F]oreseeability does not require such precise evidence of suitability." Slip op. at 9.

The Federal Circuit agreed with the district court that Duramed failed to rebut the presumption of prosecution history estoppel on the basis of unforeseeability. First, the Court found that Duramed's narrowing amendment in response to a prior art rejection triggered the *Festo* presumption. Second, the Court rejected Duramed's attempt to unduly narrow the field of invention and consequently limit the prior art that could lead to a conclusion of foreseeability. The Court noted that "an alternative is foreseeable if it is known in the field of invention as reflected in the claim scope before amendment." Slip op. at 6 (quoting *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 493 F.3d 1368, 1379 (Fed. Cir. 2007)).

As applied here, the Federal Circuit reiterated that when the language of both the original and issued claims "begins with the words '[a] pharmaceutical composition,' that language defines the field of the invention for purposes of determining foreseeability." *Id.* at 7-8 (alteration in original) (citing *Schwarz Pharma, Inc. v. Paddock Labs., Inc.*, 504 F.3d 1371, 1377 (Fed. Cir. 2007)). Further, the prior art established that PVA MBCs were known in the field of pharmaceutical compositions at the time of Duramed's amendment. The Court rejected Duramed's arguments that the prior art failed to establish that PVA-based Opadry AMB was suitable as an MBC because the prior art reference provided only conclusory statements and lacked any data on the stability of the pharmaceutical compounds coated with Opadry AMB, finding instead that "foreseeability does not require such precise evidence of suitability." *Id.* at 9.

The Court noted that even if PVA was disclosed as less than ideal in some pharmaceutical uses as an MBC, "it is still disclosed to be useful as such, and that renders it foreseeable for purposes of prosecution history estoppel. Foreseeability does not require flawless perfection to create an estoppel." *Id.* Thus, Duramed failed to overcome the *Festo* presumption on the basis of unforeseeability because the prior art disclosed the use of PVA as an MBC in the field of pharmaceutical compounds prior to Duramed's amendment.

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Merely Pointing Out Differences in What the Claims Cover Is Not a Substantive Argument as to Separate Patentability of the Claims

Ruby J. Natnithithadha

Judges: Bryson, Mayer, Dyk (author)

[Appealed from Board]

In *In re Lovin*, No. 10-1499 (Fed. Cir. July 22, 2011), the Federal Circuit affirmed the Board's decision that claims 1-15, 17-24, and 30-34 in Jeff Lovin, Robert Adams, Dan Kuruzar, and Dietmar Spindler's (collectively "applicants") U.S. Patent Application No. 10/924,633 ("the '633 application") would have been obvious, and found that the Board reasonably interpreted 37 C.F.R. § 41.37(c)(1)(vii) ("Rule 41.37") in refusing to separately address claims 2-15, 17-24, and 31-34 in its obviousness determination.

The '633 application is directed to "a method and system of friction welding." In friction welding, a first part is brought into contact with a second part and rotated so that the heat generated fuses the two parts together. The invention is designed to decrease the variation in "upset" (displacement of material from the parts) between parts from repeated use of welding machinery. The '633 application has thirty-four claims, of which claims 1, 8, 17, 23, 30, and 34 are independent. Before the examiner, applicants presented arguments with respect to the independent claims, but did not provide separate arguments for the dependent claims. Even with respect to the independent claims, applicants merely repeated the claim language and stated that the prior art did not contain those features. The examiner rejected claims 1-24 and 30-34 as obvious.

In applicants' appeal brief to the Board, applicants attempted to address the patentability of the dependent claims by listing each claim under a separate subheading with separate arguments. For the dependent claims, applicants adopted the arguments from the corresponding independent claims, but with respect to the additional elements of the dependent claims, applicants simply asserted that these elements were not present in the prior art and were thus nonobvious over the combined teachings of the prior art. The Board affirmed the examiner's obviousness rejection and invoked Rule 41.37 to find that "claims 2-15 and 17-24 stand or fall with claim 1, and claims 31-34 stand or fall with claim 30." Slip op. at 6 (citation omitted). The Board also denied applicants' request for rehearing.

On appeal to the Federal Circuit, applicants did not challenge the Board's decision finding claims 1 and 30 obvious; rather, applicants challenged whether the Board correctly interpreted Rule 41.37 in refusing to separately address the obviousness of claims 2-15, 17-24, and 31-34. Applicants argued that their

appeal brief before the Board satisfied Rule 41.37 because it contained separate headings and substantive arguments for each dependent claim and that the only requirement for substantive argumentation for dependent claims was that the applicant "point out the essential elements as compared with prior claims and the inapplicability of the cited references, which ha[d] previously been discussed in the [applicant's] brief." *Id.* at 7 (alterations in original) (citation omitted). In response, the PTO argued that the Court should defer to the Board's interpretation of Rule 41.37 as requiring more than the truncated arguments appearing in applicants' appeal brief.

"Although [applicants] properly included separate subheadings for each claim in [their] appeal brief as required by the rule, [their] arguments under those subheadings merely 'point[ed] out what the claims recite[d] and then assert[ed] that there [was] no corresponding combination of steps taught or suggested in the applied references.'" Slip op. at 15 (citation omitted).

The Federal Circuit acknowledged that Congress delegated to the PTO the rulemaking power to "establish regulations, not inconsistent with the law, which . . . shall govern the conduct of proceedings in the Office." *Id.* at 8 (alteration in original) (quoting 35 U.S.C. § 2(b)(2)). Further, the PTO's interpretation of its own regulations is entitled to "'substantial deference' unless the interpretation is 'plainly erroneous or inconsistent with the regulation.'" *Id.* (citations omitted). The Court noted, however, that *In re Garner*, 508 F.3d 1376, 1378-79 (Fed. Cir. 2007), and *Dethmers Manufacturing, Inc. v. Automatic Equipment Manufacturing Co.*, 272 F.3d 1365, 1370 (Fed. Cir. 2001), held that the PTO must follow the Court's judicial interpretations of the PTO's regulations. That obligation, however, is not absolute unless "the judicial precedent 'unambiguously forclose[d] the agency's interpretation, and therefore contain[ed] no gap for the agency to fill.'" Slip op. at 9 (alterations in original) (citation omitted).

The Federal Circuit rejected applicants' argument—that *In re Nielson*, 816 F.2d 1567 (Fed. Cir. 1987), and *In re Beaver*, 893 F.2d 329 (Fed. Cir. 1989), represented binding authority that should control the PTO's construction of Rule 41.37—because neither of those decisions directly confronted Rule 41.37 or its predecessor regulation, 37 C.F.R. § 1.192. Thus, the Board was not foreclosed from interpreting Rule 41.37.

The Court found that the Board reasonably interpreted Rule 41.37 to require applicants to articulate more substantive arguments if applicants want individual claims treated separately. "Although [applicants] properly included separate subheadings for each claim in [their] appeal brief as required by the rule, [their] arguments under those subheadings merely 'point[ed] out what the claims recite[d] and then assert[ed] that there [was] no corresponding combination of steps taught or suggested in the applied references.'" Slip op. at 15 (citation omitted). Thus, the Board's conclusion—that applicants waived any argument for separate patentability of claims 2-15, 17-24, and 31-34—was not manifestly unreasonable.

Further, the Court noted that the Board's interpretation of Rule 41.37 was not new to this case. Rather, it reflected the Board's consistent interpretation of the rule since it was promulgated in 2004 and was thus the governing interpretation before applicants filed their appeal brief to the Board.

Accordingly, the Federal Circuit held that the Board reasonably interpreted Rule 41.27 and did not err in refusing to separately address claims 2-15, 17-24, and 31-34 in its obviousness determination.

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Isolated DNA Is Patent-Eligible Subject Matter Under 35 U.S.C. § 101

Troy A. Petersen

Judges: Lourie (author), Bryson (concurring-in-part and dissenting-in-part), Moore (concurring-in-part)

[Appealed from S.D.N.Y., Senior Judge Sweet]

In *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 10-1406 (Fed. Cir. July 29, 2011), the Federal Circuit held that composition claims to "isolated" DNA molecules are patentable subject matter, while method claims simply "comparing" or "analyzing" DNA sequences are not.

The plaintiffs, who include an assortment of medical organizations, researchers, genetic counselors, and patients (collectively "Association"), brought a DJ action against Myriad Genetics, Inc. ("Myriad"), challenging the patentability under 35 U.S.C. § 101 of certain composition and method claims in seven different patents directed to human genetics. The challenged composition claims cover two "isolated" human genes or DNA molecules, *BRCA1* and *BRCA2* (collectively "*BRCA1/2*"), and certain alterations in these genes associated with a predisposition to breast and ovarian cancers. Isolated DNA has been cleaved (i.e., had covalent bonds in its backbone chemically severed) or synthesized to consist of just a fraction of the naturally occurring DNA molecule. All but one of the challenged method claims cover methods of "analyzing" or "comparing" a patient's *BRCA* sequence with the normal sequence to identify the presence of cancer-predisposing alterations. The final method claim challenged is directed to a method of screening potential cancer therapeutics.

After the Association filed suit, Myriad moved to have the case dismissed, alleging that the Association did not have standing. The district court disagreed, finding that the plaintiffs had established Article III standing under the "all the circumstances" test. The parties moved for SJ on the merits of the § 101 challenge. The district court found that all the challenged claims were drawn to nonpatentable subject matter, and Myriad appealed.

The Federal Circuit first addressed the issue of whether the Association had standing. The Federal Circuit found that one plaintiff, researcher Dr. Harry Ostrer, had standing. Ostrer's standing was based on two findings. First, Ostrer alleged an injury traceable to Myriad. This injury stemmed from Myriad's demand for royalties under its patents from Ostrer at the same time Myriad was suing other, similarly situated parties for patent infringement. Second, Ostrer alleged a controversy of sufficient reality and immediacy. This was based on Ostrer's intention and resources to undertake breast cancer diagnostic

testing (that Myriad claimed required a license under its patents) if the patents are found invalid. While Myriad argued that its demand for licensing from Ostrer in 1998 was too far in the past to provide a controversy of sufficient reality and immediacy, the Federal Circuit found that the relevant circumstances had not changed despite the passage of time. Thus, although the Federal Circuit disagreed with the district court's holding that all the plaintiffs had standing, having found one plaintiff with standing, the Court addressed the merits of the appeal, specifically, the validity of the claims under 35 U.S.C. § 101.

"The distinction, therefore, between a product of nature and a human-made invention for purposes of § 101 turns on a change in the claimed composition's identity compared with what exists in nature. Specifically, the Supreme Court has drawn a line between compositions that, even if combined or altered in a manner not found in nature, have similar characteristics as in nature, and compositions that human intervention has given 'markedly different,' or 'distinctive,' characteristics." Slip op. at 41.

The Federal Circuit first addressed the § 101 challenge to Myriad's composition claims directed to "isolated" DNA molecules. The Federal Circuit looked to Supreme Court precedent for the framework for deciding the patent eligibility of isolated DNA molecules. Specifically, "the Supreme Court has drawn a line between compositions that, even if combined or altered in a manner not found in nature, have similar characteristics as in nature, and compositions that human intervention has given 'markedly different,' or 'distinctive,' characteristics." Slip op. at 41. The Supreme Court found that the former remains a product of nature and is not patentable subject matter under § 101. Applying this test, the Federal Circuit found that the isolated *BRCA1*/*2* claimed were "not the same molecules as DNA as it exists in the body; human intervention in cleaving or synthesizing a portion of a native chromosomal DNA imparts on that isolated DNA a distinctive chemical identity from that possessed by native DNA." *Id*. at 42. The Federal Circuit distinguished the chemical cleaving required to obtain these isolated compositions from purification, i.e., a situation where a material existing in nature is purified from a physical mixture. The chemical differences between the isolated compositions and naturally occurring DNA were enough to satisfy the "markedly different" or "distinctive characteristic" tests, regardless of whether the two might have the same genetic information content, according to the Federal Circuit. "The ability to visualize a DNA molecule . . . when it is bonded to other genetic material, is worlds apart from possessing an isolated DNA molecule that is in hand and usable." *Id*. at 45. Finally, the Federal Circuit noted that its decision that isolated DNA molecules are patentable comported with the long-standing practice of the PTO, and that any change to long-standing practice should come from Congress, not the courts.

Next, the Federal Circuit addressed the § 101 challenge to Myriad's method claims. Regarding Myriad's claims involving methods of "comparing" or "analyzing" sequences, the Federal Circuit found that these claimed only abstract mental processes and were not patentable subject matter under § 101. The claims in question recited, for example, a "method for screening a tumor sample" by "comparing" a first *BRCA1* sequence from a tumor sample with a second *BRCA1* sequence from a nontumor sample, wherein a difference in sequence indicates an alteration in the tumor sample. The Court found that this was nothing more than a recitation of "the abstract mental steps necessary to compare two different nucleotide sequences." *Id*. at 50. The Court noted that while "the *application* of a formula or abstract idea in a process may describe patentable subject matter, Myriad's claims do not apply the step of comparing two nucleotide sequences in a process. Rather, the step of comparing two DNA sequences is the entire process claimed." *Id*. at 50-51 (citation omitted). This was distinguishable from a method claim upheld under § 101 where a "determining" step was both (1) transformative because it could not be completed

by mere inspection, and (2) central to the purpose of the claims.

Regarding Myriad's method claim directed to a method for screening potential cancer therapeutics via changes in cell growth rates, the Federal Circuit found that this was patentable subject matter under § 101. Stating that the machine-or-transformation test was an "important clue" to determining patent-eligible processes under *Bilski*, the Federal Circuit noted that the claim recited steps of "growing" transformed host cells, which was inherently transformative, and "determining" the growth rate of the host cells, which necessarily involved physical manipulation of the cells beyond a mere "comparing" step. These "growing" and "determining" steps were also central to the purpose of the process: assessing a compound's potential as a cancer therapeutic. The Federal Circuit also emphasized that the claim was not so "manifestly abstract" that it would cover all cells, all compounds, or all methods of determining the therapeutic effect of a compound; "[r]ather, it is tied to specific host cells transformed with specific genes and grown in the presence or absence of a specific type of therapeutic. Moreover, the claim is tied to measuring a therapeutic effect on the cells solely by changes in the cells' growth rate." *Id*. at 54. Thus, the Federal Circuit found that this claim was patentable subject matter.

Judge Moore concurred with the majority with respect to the patentability of isolated DNA sequences (other than cDNA sequences) and joined the majority opinion with respect to all other issues. For her concurrence, Judge Moore relied heavily on the long-standing PTO precedent of allowing patents on isolated DNA sequences.

Judge Bryson dissented from the Court's holding that isolated DNA was patentable, concurring with the rest of the Court's opinion. Judge Bryson argued that the isolated DNA was not different from the native gene. Therefore, in Judge Bryson's view, similar to the purification of a mineral, isolation of a DNA molecule would not be patent-eligible subject matter under § 101.

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Federal Circuit Affirms Exceptional Case Finding and Rule 11 Sanctions Against a Patent-Holding Company and Its Counsel

Elizabeth A. Laughton

Judges: Lourie (author), Mayer, O'Malley

[Appealed from W.D. Wash., Judge Martinez]

In *Eon-Net LP v. Flagstar Bancorp*, No. 09-1308 (Fed. Cir. July 29, 2011), the Federal Circuit affirmed the district court's exceptional case finding under 35 U.S.C. § 285 and its imposition of Fed. R. Civ. P. 11 sanctions against plaintiff Eon-Net LP ("Eon-Net") and counsel for Eon-Net, Zimmerman & Levi, L.L.P., including its principal, Jean-Marc Zimmerman.

Eon-Net asserted U.S. Patent Nos. 6,683,697 ("the '697 patent"), 7,075,673 ("the '673 patent"), and 7,184,162 ("the '162 patent") against Flagstar Bancorp ("Flagstar"). These patents are part of a larger patent family ("the Patent Portfolio"), share a common specification, and relate to systems and methods for inputting information from a "hard copy" document by scanning, storing portions of the inputted document information in memory, and formatting the stored document information for use by a computer program, thus effectuating a paperless office. Eon-Net, a patent-holding company, and Zimmerman have filed over 1000 lawsuits, asserting infringement of the Patent Portfolio, most ending in quick and inexpensive settlements far below the cost of litigation.

Eon-Net sued Flagstar in 2005, alleging that the processing of information entered by customers on Flagstar's website infringed the '697 patent. Flagstar sought SJ of noninfringement because it used document-processing technology provided by a licensee of the '697 patent. Flagstar also moved for Rule 11 sanctions based on Eon-Net's failure to investigate or identify allegedly infringing products and because Eon-Net asserted baseless infringement claims. The district court granted both motions and assessed attorneys' fees and costs against Eon-Net and Zimmerman.

Eon-Net and Zimmerman appealed to the Federal Circuit, which in 2007 vacated and remanded both the SJ ruling and the imposition of sanctions "because the district court failed to afford Eon-Net notice and the opportunity to present its infringement and claim construction arguments during the briefing on the motions." Slip op. at 8. On remand, the district judge who initially handled the case recused herself, and Eon-Net added infringement allegations for the '673 and '162 patents as well. After a full claim construction process, the district court construed the disputed claim terms. In particular, the district court concluded that the claim terms "document," "file," "extract," and "template" (collectively "the disputed

claim terms") were limited to information originating from a hard copy document. Eon-Net accordingly stipulated to noninfringement. Flagstar subsequently moved for attorneys' fees under 35 U.S.C. § 285 and the district court, concluding that this was an exceptional case, granted the motion. Eon-Net, upon invitation from the district court, renewed its motion for Rule 11 sanctions, which the district court granted. The district court awarded attorneys' fees and costs under Rule 11 and under § 285. Eon-Net and Zimmerman appealed, contesting the district court's construction of the disputed claim terms, the imposition of Rule 11 sanctions, and the exceptional case finding.

On appeal, Eon-Net argued that the ordinary meanings of the disputed claim terms do not limit them to information derived from a hard copy document. The Federal Circuit disagreed, affirming the district court's claim constructions in all respects. Noting that "[t]he written description repeatedly and consistently defines the invention as a system that processes information derived from hard copy documents," *id*. at 11, and detailing the myriad ways in which the specification supports this reading, the Federal Circuit stated that this issue was not a "close call" and that "the specification unequivocally compels the constructions adopted by the district court," *id*. at 15-16. Accordingly, the Federal Circuit affirmed the judgment of noninfringement.

"Eon-Net argues that it is not improper for a patentee to vigorously enforce its patent rights or offer standard licensing terms, and Eon-Net is correct. But the appetite for licensing revenue cannot overpower a litigant's and its counsel's obligation to file cases reasonably based in law and fact and to litigate those cases in good faith." Slip op. at 24.

Next, the Federal Circuit reviewed the district court's finding that this case was "exceptional" under 35 U.S.C. § 285. (Eon-Net did not appeal the district court's determination of the amount of attorneys' fees and costs.) The district court based its determination that this case was exceptional on its findings that Eon-Net engaged in litigation misconduct and filed a baseless infringement action "in bad faith for an improper purpose." *Id*. at 17-18. The Federal Circuit detailed Eon-Net's numerous instances of litigation misconduct, including destruction of relevant documents, intentional failure to implement a document retention plan, "lack of regard for the judicial system," and improper litigation tactics, such as failing to offer a construction for any disputed claim terms, lodging incomplete and misleading extrinsic evidence with the court, and submitting declarations that contradicted earlier deposition testimony by the declarants. The Federal Circuit concluded that Eon-Net failed to show that the district court's findings as to litigation misconduct were clearly erroneous. Further, the Federal Circuit concluded that the district court did not clearly err in finding that Eon-Net pursued baseless infringement allegations, noting again that "the written description as a whole repeatedly and expressly defines [the information] as information originating from a hard copy document." *Id*. at 21-22. The Federal Circuit also upheld the district court's finding that Eon-Net filed the lawsuit in bad faith and for an improper purpose, recounting nonpracticing entity Eon-Net's extensive history of filing "[m]eritless cases like this one," *id*. at 23, and "exploiting the high cost to defend complex litigation to extract a nuisance value settlement," *id*. at 22. Though "it is not improper for a patentee to vigorously enforce its patent rights or offer standard licensing terms," the Federal Circuit opined that "the appetite for licensing revenue cannot overpower a litigant's and its counsel's obligation to file cases reasonably based in law and fact and to litigate those cases in good faith." *Id*. at 24. As such, the Federal Circuit affirmed the district court's exceptional case finding.

Regarding the district court's imposition of Rule 11 sanctions, the Federal Circuit noted that "all aspects of a district court's imposition of Rule 11 sanctions [are reviewed] under an abuse of discretion

standard." *Id*. at 25. Applying Ninth Circuit law, the Federal Circuit observed that in order to impose sanctions, the district court must determine that the complaint is legally or factually baseless from an objective perspective and that the attorney failed to conduct a reasonable and competent inquiry before filing the complaint. The Federal Circuit concluded that for the reasons explained above, the district court did not clearly err in concluding that Eon-Net's infringement was objectively baseless, and for the same reasons, the district court did not abuse its discretion in finding that Eon-Net's infringement contentions were legally baseless. The Federal Circuit opined that "[a] reasonable pre-suit investigation" requires more than comparing the potential defendant's website and publicly available source code to each claim limitation and generating a claim chart, as Zimmerman did here. *Id*. at 26. Rather, "counsel [must] perform an objective evaluation of the claim terms when reading those terms on the accused device." *Id*. For the reasons described above, the Federal Circuit concluded that "Eon-Net has failed to meet its high burden to show that the district court abused its discretion in imposing Rule 11 sanctions." *Id*. at 26-27.

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