United States Court of Appeals for the Federal Circuit

01-1257

MYLAN PHARMACEUTICALS, INC.,

Plaintiff-Appellee,

v.

TOMMY G. THOMPSON, Secretary of Health and Human Services,
BERNARD A. SCHWETZ, D.V.M., Ph.D, Acting Principal Deputy Commisssioner,
U.S. Food and Drug Administration, and U.S. FOOD AND DRUG ADMINISTRATION,

Defendants-Appellees,

and

BRISTOL-MYERS SQUIBB COMPANY,

Defendant-Appellant.

E. Anthony Figg, Rothwell, Figg, Ernst & Manbeck, P.C. of Washington, DC, argued for plaintiff-appellee. With him on the brief were Steven M. Lieberman and Elizabeth A. Leff.

Howard S. Scher, Attorney, Appellate Staff, Civil Division, Department of Justice, of Washington, DC, argued for defendants-appellees. With him on the brief were Stuart E. Schiffer, Acting Assistant Attorney General; and Douglas N. Letter, Attorney. Of counsel on the brief were Michael M. Landa, Acting Chief Counsel; and Kevin M. Fain, Associate Chief Counsel, Office of the Chief Counsel, U.S. Food and Drug Administration, of Rockville, Maryland.

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Appealed from: United States District Court for the District of Columbia

Judge Ricardo M. Urbina

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TOMMY G. THOMPSON, Secretary of Health and Human Services, BERNARD A. SCHWETZ, D.V.M., Ph.D., Acting Principal Deputy Commissioner, U.S. Food and Drug Administration, and U.S. FOOD AND DRUG ADMINISTRATION,

Defendants-Appellees,

v.

BRISTOL-MYERS SQUIBB COMPANY,

Defendant-Appellant.

DECIDED: October 12, 2001

Before MAYER, Chief Judge, NEWMAN and MICHEL, Circuit Judges.

MAYER, Chief Judge.

Bristol-Myers Squibb Co. ("Bristol") appeals the order of the United States District Court for the District of Columbia granting the motion for a preliminary injunction brought by Mylan Pharmaceuticals, Inc. ("Mylan"). See Mylan Pharms., Inc. v. Thompson, No. 00-2876 (D.D.C. Mar. 14, 2001). The injunction directed Bristol to take measures to delist United States Patent No. 6,150,365 from the U.S. Food and Drug Administration's "Orange Book," and directed the FDA to grant final approval of Mylan's abbreviated new drug application for a generic version of buspirone. Id. Because we find that such a declaratory relief action against Bristol was not available to Mylan under the patent laws and was not created by the Hatch-Waxman

Amendments to the Federal Food, Drug, and Cosmetic Act ("FFDCA") and to Title 35 of the United States Code, we reverse.

Regulatory Background

This case turns on the statutory framework governing new and generic drug approvals and its mechanisms for patent enforcement. Under the FFDCA, a pharmaceutical company seeking to manufacture a new drug is required to file a New Drug Application ("NDA") for consideration by the FDA. 21 U.S.C. § 355(a) (1994). Preparing an NDA is frequently a time-intensive and costly process, because among other things, it must contain detailed clinical studies of the drug's safety and efficacy. See id. § 355(b)(1) (Supp. V 1999). The NDA must also include a list of patents which claim the drug:

> The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. . . . Upon approval of the application, the Secretary shall publish information submitted under [this section].

Id.

If the FDA approves the NDA, it publishes a listing of the drug and patents on the drug's approved aspects in Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book." Id. § 355(j)(7)(A)(iii) (1994); id. § 355(b)(1); see also 21 C.F.R. § 314.53(c)(2) (2001). Because an applicant may not receive original approval for all aspects of the drug as described in the original NDA submission, once the NDA is approved, the applicant must amend the patent submission to list only the patents that meet the listing criteria for the approved drug product. 21 C.F.R. § 314.53(c)(2)(ii) (2001).

Under the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417,

98 Stat. 1585 (1984), codified at 21 U.S.C. §§ 355, 360cc, and 35 U.S.C. §§ 156, 271, 282 (the "Hatch-Waxman Amendments" to the FFDCA and to Title 35 of the U.S. Code relating to patents), a pharmaceutical manufacturer seeking approval to market a generic version of a previously approved drug may submit an abbreviated new drug application ("ANDA") to the FDA. 21 U.S.C. § 355(j) (1994). An ANDA offers an expedited approval process for generic drug manufacturers. Instead of filing a full NDA with new safety and efficacy studies, in an ANDA a generic manufacturer may rely in part on the pioneer manufacturer's work by submitting data demonstrating the generic product's bioequivalence with the previously approved drug. See id. § 355 (j)(2)(A) (Supp. V 1999). These provisions of the Hatch-Waxman Amendments "emerged from Congress' efforts to balance two conflicting policy objectives: to induce name brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market." Abbott Labs. v. Young , 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting on other grounds). Thus, Title I of the Act was intended to "make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962." H.R. Rep. No. 98-857, pt. 1 at 14 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647. Title II, on the other side of the scale, was intended to benefit pioneer drug manufacturers by "restor[ing] . . . some of the time lost on patent life while the product is awaiting pre-market approval." H.R. Rep. No. 98-857, pt. 1 at 15, 1984 U.S.C.C.A.N. at 2648.

The Hatch-Waxman provisions concerning patent infringement are part of this balance. Under 35 U.S.C. § 271(e)(1), it is not infringement to conduct otherwise infringing acts necessary to prepare an ANDA. 35 U.S.C. § 271(e)(1) (Supp. V 1999) ("It shall not be an act of infringement to make, use, offer to sell, or sell . . . a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs."). Under section 271(e)(2), however, a generic drug manufacturer infringes by filing an ANDA to obtain FDA approval for the purpose of marketing a

generic drug product claimed in a patent before the patent expires. 35 U.S.C. § 271(e)(2) (1994) ("It shall be an act of infringement to submit . . . [an ANDA] . . . if the purpose of such submission is to obtain [FDA] approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent before the expiration of such patent.") (emphasis added). Despite this provision, not all ANDA applicants can be sued immediately for infringement; moreover, they cannot sue immediately for declaratory judgment with respect to the patent, as further discussed below.

As part of the ANDA process, an applicant seeking to market a generic version of a listed drug must make a certification as to each patent listed in the Orange Book which "claims the listed drug . . . or which claims a use for such listed drug for which the applicant is seeking approval." 21 U.S.C. § 355(j)(2)(A)(vii) (1994). Further, according to regulations enacted by the FDA, an applicant whose ANDA is pending when a pioneer drug manufacturer lists additional patents in the Orange Book must make certifications as to the new patents, unless the additional patents are submitted more than thirty days after they were issued. 21 C.F.R. § 314.94(a)(12)(vi) (2001).

In either case, the applicant must certify either that: (I) no such patent information has been submitted to the FDA; (II) the patent has expired; (III) the patent is set to expire on a certain date; or (IV) such patent is invalid or will not be infringed by the manufacture, use, or sale of the new generic drug for which the ANDA is submitted. 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV) (1994). These are commonly referred to as Paragraph I, II, III, and IV certifications. Further, if one of the listed patents is a method-of-use patent which does not claim a use for which the applicant is seeking approval, the applicant must make a statement to that effect (a "Section viii Statement"). Id. § 355(j)(2)(A)(viii).

An ANDA containing a Paragraph I or II certification may be approved without additional delay. See 21 U.S.C. § 355(j)(5)(B)(i) (Supp. V 1999). An ANDA containing a Paragraph III certification indicates that the applicant does not intend to market the drug until after the expiration of the

patent, and the approval of the ANDA cannot be made final until the patent expires. Id. § 355(j)(5)(B)(ii).

When an ANDA contains a Paragraph IV certification, the ANDA applicant must give notice to the patentee and must provide detailed bases for its belief that the patent is invalid, unenforceable, or not infringed. Id. § 355(j)(2)(B)(i); 21 C.F.R. § 314.95(c)(6) (2001). The patentee is then given forty-five days to sue the ANDA applicant for infringement. 21 U.S.C. § 355(j)(5)(B)(iii) (Supp. V 1999). If the patentee does not file suit, the application may be approved. If the patentee files suit within that period, the FDA may not approve the ANDA until the expiration of the patent, judicial resolution of the infringement suit, a judicial determination that the patent is invalid or unenforceable, or thirty months from the patentee's receipt of notice, whichever is earliest. Id.; 21 C.F.R. § 314.107(b)(1)(iv) (2001). The court in which the suit is pending may order a shorter or longer stay on the approval time if "either party to the action fail[s] to reasonably cooperate in expediting the action." 21 U.S.C. § 355(j)(5)(B)(iii) (Supp. V 1999). Moreover, the availability of declaratory judgment actions is limited: "Until the expiration of forty-five days from the date the notice made under paragraph (2)(B)(i) is received, no action may be brought under section 2201 of Title 28, for a declaratory judgment with respect to the patent." Id. These provisions give the pioneer manufacturer the first opportunity to file suit against the ANDA applicant for infringement, and may substantially delay the ANDA approval during the pendency of the litigation.

The Hatch-Waxman Amendments, however, do not include any explicit provisions either enabling or prohibiting an action to challenge a patentee's listing of a patent in the Orange Book. By regulation, the FDA has provided a limited process for disputing the accuracy or relevance of patent information submitted to the FDA and listed in the Orange Book. 21 C.F.R. § 314.53(f) (2001). One who questions the accuracy of the patent information may write to the FDA, and the FDA will request that the applicant confirm the information. Id. According to the FDA's regulations, however, "[u]nless the application holder withdraws or amends its patent information

in response to FDA's request, the agency will not change the patent information in the list" and an ANDA applicant must still make certifications for each patent despite its disagreement. Id.

Factual Background

Bristol owns U.S Patent No. 4,182,763 ("'763 patent") directed to the treatment of anxiety through the administration of buspirone hydrochloride. The '763 patent is listed in the Orange Book as covering Bristol's FDA-approved drug "BuSpar." Bristol's patent was set to expire at the end of the day on November 21, 2000. In anticipation of its expiration, Mylan, a generic manufacturer, had filed and received tentative approval of an ANDA for its buspirone product under a Paragraph III certification. Mylan manufactured and was ready to ship its product at 12:00 a.m. on November 22, 2000, the moment the '763 patent was to have expired.

Approximately eleven hours before the '763 patent's expiration, Bristol hand-delivered to the FDA copies of U.S. Patent No. 6,150,365 (the "'365 patent") which issued earlier that day. The '365 patent contains only one claim, directed towards:

> A process for ameliorating an undesirable anxiety state in a mammal comprising systemic administration to the mammal of an effective but non-toxic anxiolytic dose of . . . [BMY 28674 (the active metabolite of buspirone)] or a pharmaceutically acceptable acid addition salt or hydrate thereof.

'365 patent, col. 16, ll. 27-32. Bristol sought to have the '365 patent listed in the Orange Book as covering buspirone.

Upon receiving the '365 patent from Bristol, the FDA suspended approval of Mylan's ANDA and the ANDAs filed by other prospective generic manufacturers of buspirone. Mylan and other ANDA applicants wrote to the FDA to challenge the listing of the '365 patent on the grounds that it only covered a metabolite of buspirone and therefore should not be listed because it did not claim the drug, citing our ruling in Hoechst-Roussel Pharmaceuticals, Inc. v. Lehman, 109 F.3d 756, 42

USPQ2d 1220 (Fed. Cir. 1997). Mylan also filed a Section viii Statement that the '365 patent did not claim a use for which it was seeking approval.

The FDA responded on November 30, 2000, by asking Bristol to provide a clarification as to whether the '365 patent claimed only a metabolite of buspirone. The FDA also requested additional information from the ANDA applicants concerning the effect of our Hoechst ruling on the '365 patent claim. Bristol responded that the '365 patent did not simply claim a method of using the metabolite, but also a method of using buspirone itself. The FDA informed Bristol that its response was adequate and that the '365 patent would be deemed listed in the Orange Book.

Instead of filing a Paragraph IV certification with respect to the ANDA at issue here, Mylan commenced the present action against Bristol and the FDA on the same day, November 30, 2000. It sought a declaratory judgment that Bristol improperly listed the '365 patent, and a preliminary injunction requiring Bristol to take steps to delist the '365 patent and directing the FDA to approve Mylan's ANDA. Mylan also filed an action in the United States District Court for the District of West Virginia for a declaration of noninfringement and invalidity, and Bristol sued Mylan for infringement in the Southern District of New York.

In the present action, the United States District Court for the District of Columbia held that Mylan was entitled to declaratory relief that the '365 patent was improperly listed in the Orange Book under the patent laws and the Declaratory Judgment Act, as a defense to the infringement suit Bristol could have brought against Mylan under 35 U.S.C. § 271(e)(2). Mylan, slip op. at 18-27. It held that it possessed subject matter jurisdiction over the case under the patent laws, and that Mylan was not attempting to enforce the FFDCA against Bristol. Id. at 17-18. The court proceeded to review the '365 patent's claim, specification, and prosecution history, and found that the '365 patent did not claim the drug for which the applicant submitted the application or claim a method of using such drug upon which a claim of patent infringement could reasonably be asserted. Id. at 29-44 (applying 21 U.S.C. § 355(b)(1)(F) (1994)). It therefore held that Mylan was

likely to succeed on the merits of its claim. See Mylan, slip op. at 45. Although the court said that Mylan made no showing of irreparable harm, it granted the injunction. Id. at 48, 50-51.

Bristol appeals the district court's order. Although the FDA opposed Mylan's motion in the district court, stating that its role in listing patents was solely ministerial and that Mylan's remedy was to seek modification of the presumptive thirty-month stay in the infringement litigation, id. at 16, the FDA does not appeal the portion of the order directing it to approve Mylan's ANDA. Instead, the FDA argued to this court that this portion of the order was harmless error, and that Mylan has a cognizable cause of action against Bristol for declaratory judgment under the patent laws that was not prohibited by the FFDCA. We therefore do not address any cause of action that Mylan has or may assert against the FDA.

Discussion

The grant or denial of a preliminary injunction under 35 U.S.C. § 283 is within the sound discretion of the district court. Purdue Pharma L.P. v. Boehringer Ingelheim Gmbh, 237 F.3d 1359, 1363, 57 USPQ2d 1647, 1649 (Fed. Cir. 2001) (citations omitted).[1] An abuse of discretion may be established by showing that the court made a clear error of judgment in weighing relevant factors or exercised its discretion based upon an error of law or clearly erroneous factual findings. Id.; Amazon.com, Inc. v. barnesandnoble.com, Inc., 239 F.3d 1343, 1350, 57 USPQ2d 1747, 1751 (Fed. Cir. 2001) (citing Novo Nordisk of N. Am., Inc. v. Genentech, Inc., 77 F.3d 1364, 1367, 37 USPQ2d 1773, 1775 (Fed. Cir. 1996)). To the extent that a district court's decision to grant a preliminary injunction hinges on questions of law, our review is de novo. See Globetrotter Software, Inc. v. Elan Computer Group, Inc., 236 F.3d 1363, 1367, 57 USPQ2d 1542, 1545 (Fed. Cir. 2001).

As the moving party, Mylan was required to establish its right to a preliminary injunction in light of four factors: "(1) a reasonable likelihood of success on the merits; (2) irreparable harm if the

injunction were not granted; (3) the balance of the hardships and (4) the impact of the injunction on the public interest." Purdue, 237 F.3d at 1363, 57 USPQ2d at 1649 (citing Polymer Techs. v. Bridwell, 103 F.3d 970, 973, 41 USPQ2d 1185, 1188 (Fed. Cir. 1996)). If we find that Mylan was not likely to succeed on the merits, we may reverse the injunction. Reebok Int'l Ltd. v. J. Baker, Inc., 32 F.3d 1552, 1556, 32 USPQ2d 1781, 1785 (Fed. Cir. 1994).

With respect to the first factor, Bristol argues that the district court erred because Mylan did not assert a cognizable cause of action. According to Bristol, Mylan's claim seeks to delist a patent from the Orange Book, which is an impermissible attempt by a private party to enforce the FFDCA. See 21 U.S.C. § 337(a) (1994) ("Except as provided in subsection (b) of this section [regarding suits by states in their own names], all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."); see also Buckman Co. v. Plaintiffs' Legal Comm., 121 S.Ct. 1012, 1017, 1018 n.4, 1019 (2001); In re: Orthopedic Bone Screw Prods. Liab. Litig., 193 F.3d 781, 788 (3d Cir. 1999) ("It is well settled . . . that the FDCA creates no private right of action."). Therefore, Bristol argues that granting declaratory relief is improper because, under the well-pleaded complaint rule, Bristol would have no cause of action against Mylan to "list" the '365 patent.

Mylan and the FDA concede that there is no cause of action to delist a patent from the Orange Book. They also concede that such an action would be a private right of action barred by the FFDCA. They submit, however, that Mylan's cause of action, and the basis for our jurisdiction and declaratory relief, arises under the patent laws as a defense to patent infringement.

This is a matter of first impression for this court. The Declaratory Judgment Act, 28 U.S.C. § 2201, is remedial only. It "enlarged the range of remedies available in the federal courts but did not extend their jurisdiction." Skelly Oil v. Phillips Petroleum Co., 339 U.S. 667, 671 (1950). A party's legal interest under the Act must relate to an actual "claim arising under federal law which another asserts against him . . . ." Lowe v. Ingalls Shipbuilding, A Div. of Litton, 723 F.2d 1173,

1179 (5th Cir. 1984). Because it is "the underlying cause of action of the defendant against the plaintiff that is actually litigated in a declaratory judgment action, a party bringing a declaratory judgment action must have been a proper party had the defendant brought suit on the underlying cause of action." Collin County, Tex. v. Homeowners Ass'n for Values Essential to Neighborhoods (HAVEN), 915 F.2d 167, 171 (5th Cir. 1990). Therefore, we are required to identify the federal law under which Mylan is proceeding.

Applying the "well-pleaded complaint rule" for analyzing a purported declaratory judgment, we do not look to the plaintiff's complaint to determine which federal law is the basis of the declaratory plaintiff's cause of action, "but to the action that the declaratory defendant would have brought" to enforce its rights. Speedco, Inc. v. Estes, 853 F.2d 909, 912, 7 USPQ2d 1637, 1640 (Fed. Cir. 1988); see Fina Oil and Chem. Co. v. Ewen, 123 F.3d 1466, 1470, 43 USPQ2d 1935, 1938 (Fed. Cir. 1997) ("We apply [the well-pleaded complaint rule] not to the declaratory judgment complaint but to the hypothetical action the declaratory defendant would have brought.") Although in Speedco and Fina we used this rule to determine whether the district court had subject matter jurisdiction, the principles also are helpful for determining which federal law is the basis for the declaratory plaintiff's cause of action.

Mylan argues that the action Bristol, the declaratory judgment defendant, would have brought is an action for patent infringement under 35 U.S.C. § 271(e)(2). This section provides that an applicant infringes a patent if it submits an ANDA "for a drug claimed in a patent or the use of which is claimed in a patent . . . before the expiration of such patent." 35 U.S.C. § 271(e)(2) (1994). Mylan argues that had it filed an ANDA with a Paragraph IV certification, it would have been charged with infringing the '365 patent. One of the defenses, which Mylan argues would be available to it in Bristol's hypothetical patent infringement suit, is that Mylan should not have been required to file a Paragraph IV certification in the first instance because the '365 patent did not claim BuSpar or an approved method of using BuSpar, and accordingly, Bristol improperly

submitted the '365 patent for listing in the Orange Book.

This assertion, however, is not a recognized defense to patent infringement. Defenses to allegations of patent infringement fall into two broad groups: statutory and equitable. The statutory defenses are set forth in 35 U.S.C. § 282 and include non-infringement, absence of liability for infringement, unenforceability, and invalidity (for failure to meet the conditions of patentability or to comply with any requirement of sections 112 or 251). 35 U.S.C. § 282 (Supp. V 1999). The equitable defenses include unclean hands, unenforceability of the patent for fraud and inequitable conduct, misuse, and delay in filing suit resulting in laches or estoppel. See E.B. Lipscomb III, Lipscomb's Walker on Patents, § 261:1 (3d. ed. 1988); c.f. J.P. Stevens & Co. v. Lex Tex, Ltd., 747 F.2d 1553, 1561, 223 USPQ 1089, 1093 (Fed. Cir. 1984) (stating that 35 U.S.C. section 282 paragraph 1 incorporates equitable defenses).

Mylan does not tie its argument to any of these defenses. The issue that Mylan seeks to litigate under this declaratory judgment action is not infringement of the '365 patent, i.e., that Mylan did not infringe under 35 U.S.C. § 271(e)(2)(A) because its ANDA was not "for a drug claimed in the patent or the use of which is claimed in a patent." Instead, it seeks to litigate whether Bristol is barred from asserting the '365 patent against any ANDA applicant because Bristol did not properly comply with the listing requirements set forth in the FFDCA. Although this issue may be akin to an estoppel defense or an unenforceability defense for a patentee's inequitable conduct in prosecuting a patent in the Patent and Trademark Office, Mylan has not asserted any such link.

Because the Hatch-Waxman Amendments create the statutory act of infringement here, however, we should also examine them to determine whether they add an additional defense.[2] A review of the amendments shows no explicit provisions allowing an accused infringer to defend against infringement by challenging the propriety of the Orange Book listing of the patent. Section 271(e)(4) authorizes specific remedies available to the patentee for the act of infringement of submitting an ANDA, but does not contemplate any remedies to the accused applicant (except,

perhaps, for attorney fees under 35 U.S.C. § 285). 35 U.S.C. § 271(e)(4) (1994).

The only explicit statement in the amendments concerning an applicant's rights to seek judicial relief against the patentee is in 21 U.S.C. § 355(j)(5)(B)(iii)(III). This section provides that no one, including the ANDA holder, may commence "an action . . . for declaratory judgment with respect to the [listed] patent" before the expiration of forty-five days from the date the patent owner receives notice of the ANDA holder's Paragraph IV certification. 21 U.S.C. § 355(j)(5)(B)(iii) (Supp. V 1999). Mylan and the FDA argue that this rule does not apply to Mylan's declaratory judgment action. They argue that section 355(j)(5)(B)(iii)'s reference to an "action" must be read in a manner consistent with the prior references to "action," "an action," or "such an action" in the remainder of the section and the amendments. Therefore, the type of "action" referred to here is one for infringement under 35 U.S.C. § 271(e)(2)(A), responding to a Paragraph IV certification that the patent is invalid, unenforceable, or will not be infringed. See 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (1994); 21 C.F.R. § 314.107(b)(3) (2001). Because an allegation that a patent is improperly listed does not raise any of these issues, Mylan asserts that its claim here is not an "action" covered by this forty-five day exclusion rule.

Mylan's arguments further bolster our conclusion that its claim is not a recognized defense to patent infringement. There is no indication in 21 U.S.C. § 355(j)(5)(B)(iii)(III) that Congress intended to provide an additional defense. Instead it indicates that Congress only envisioned that recognized defenses could be raised in declaratory judgments in patent infringement actions. See 21 C.F.R. § 314.107(b)(3) (2001) (expanding Paragraph IV certification to include "unenforceability" defense in addition to the invalidity and noninfringement defenses stated in 21 U.S.C. § 355(j)(2)(A)(vii)(IV), because unenforceability is a recognized reason why a generic drug product would not violate a patent holder's rights); see also Merck v. Danbury Pharmacal, Inc., 873 F.2d 1418, 10 USPQ2d 1682 (Fed. Cir. 1989) (applying unenforceability as a defense in the section 355 context); 59 Fed. Reg. at 50339. Finally, the parties have shown nothing in the scant

legislative history of the amendments pointing to an intent to provide such a defense, or to create a private action for delisting a patent from the Orange Book for a patentee's failure to comply with section 355.

Therefore, we are forced to conclude that Mylan's action here against Bristol is in essence an attempt to assert a private right of action for "delisting" under the FFDCA. We see nothing in the Hatch-Waxman Amendments to alter the statement in section 337(a) of the FFDCA that "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C § 337(a) (1994). "In a case in which neither the statute nor the legislative history reveals a congressional intent to create a private right of action for the benefit of the plaintiff," the inquiry is at an end. Northwest Airlines, Inc. v. Transp. Workers, 451 U.S. 77, 94 n.31 (1981). Mylan is not merely using the standards enunciated by the FFDCA to support an independent cause of action (as in the district court cases Mylan cites). Instead, its entire cause of action rests on proving that Bristol improperly listed the '365 patent because it does not comply with the requirements of 21 U.S.C. § 355(b)(1). In substance, Mylan's claim is analogous to those barred in the long line of cases precluding private rights of action under the FFDCA. See In re Orthopedic Bone Screw Prods. Liab. Litig., 193 F.3d at 790 ("A claim of civil conspiracy cannot rest solely upon the violation of a federal statute for which there is no corresponding private right of action."); see also Mylan Labs., Inc. v. Matkari, 7 F.3d 1130, 1139 (4th Cir. 1993) ("We agree with the defendants that permitting Mylan to proceed on the theory that the defendants violated § 43(a) merely by placing their drugs on the market would, in effect, permit Mylan to use the Lanham Act as a vehicle by which to enforce the Food, Drug, and Cosmetic Act ("FDCA") and the regulations promulgated thereunder. An attempt, by ingenious pleading, to escape one principle of law by making it appear that another not truly appropriate rule is applicable appears to have been attempted.").[3]

Our cases do not suggest a different result. In Abbott Laboratories v. Novopharm Ltd., 104 F.3d

1305, 1309, 41 USPQ2d 1535, 1538 (Fed. Cir. 1997), we held that, as part of its inherent power to give effect to a judgment, a court may order the delisting of a patent in the context of a properly filed patent infringement suit. Abbott and its rationale, however, do not provide us the authority to hear an independent cause of action seeking delisting outside a properly filed patent case. In DuPont Merck Pharmaceutical Co. v. Bristol-Myers Squibb Co., 62 F.3d 1397, 35 USPQ2d 1718 (Fed. Cir. 1995), we held that an actual controversy was presented under the Declaratory Judgment Act where the declaratory judgment plaintiffs sought a declaration as to whether and how a specific statutory safe harbor relating to equitable remuneration in lieu of damages for infringement suits would apply to them. In Dupont, unlike here, there was no question that the statutory safe harbor and remuneration provisions were remedies responsive to would-be infringement claims.

Notably, Congress has considered legislation to amend the FFDCA to loosen the restrictions on generic ANDA applicants under 21 U.S.C. § 355(j)(5). See Greater Access to Affordable Pharmaceuticals Act of 2001, S. Res. 812, 107th Cong. (2001). The bill proposes, among other things, amending the forty-five day rule to allow a declaratory judgment with respect to the patent such that "if information on a patent for a listed drug has been published under subsection (c)(2) for at least 1 year after the date on which an abbreviated application for approval of a new drug was filed under this subsection in relation to the listed drug, the person that filed the abbreviated application or the holder of the approved application for the listed drug may immediately bring a civil action to determine the legal status of the patent for the listed drug." This provision appears to recognize Mylan's cause of action, subject to a one-year time delay from the publication of the patent information. It reinforces our conclusion that neither the general patent laws nor the Hatch-Waxman Amendments now permit Mylan's asserted action against Bristol in this case.[4]

Conclusion

Accordingly, the judgment of the United States District Court for the District of Columbia is

reversed.

REVERSED

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[1] We apply the law of the regional circuit to which the district court appeal normally lies unless "the issue pertains to or is unique to patent law," in which case we will apply our own law to both substantive and procedural issues "intimately involved in the substance of enforcement of the patent right." Amana Refrigeration, Inc. v. Quadlux, Inc., 172 F.3d 852, 856-57, 50 USPQ2d 1304, 1307 (Fed. Cir. 1999) (citations omitted) (affirming district court's analysis of personal jurisdiction on state law trade libel and defamation claims under Eighth Circuit law and analyzing mootness of declaratory judgment of patent invalidity and noninfringement under Federal Circuit law). Here, the questions of choice of law and the existence of declaratory relief are intertwined. Because the issues of law underlying the preliminary injunction are "intimately involved in the substance of enforcement of the patent right," namely, Bristol's ability to list and enforce its patent rights under the mechanisms provided under the Hatch-Waxman Amendments, we will apply Federal Circuit law. We note that the parties have cited cases from both the D.C. Circuit and the Federal Circuit, and have not pointed to any material difference between the circuits with respect to the substantive requirements for a preliminary injunction and its standards of review.

[2] The Hatch-Waxman Amendments were made both to the FFDCA and to Title 35 of the United States Code relating to patents. As such, a number of the Hatch-Waxman Amendments constitute part of the patent laws, and are essential to defining whether a defense to infringement is available under 35 U.S.C. § 271(e)(2)(A).

[3] Our conclusion that a declaratory relief action to "delist" is unavailable under the patent laws does not preclude jurisdiction. The determination of whether federal patent law creates such a remedy invokes our jurisdiction per Christianson v. Colt Industries Operating, Corp., 486 U.S. 800, 7 USPQ2d 1109 (1988). Jurisdiction under 28 U.S.C. § 1338 extends to those cases in which a well-pleaded complaint establishes "that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law." Id. at 809, 7 USPQ2d at 1113. Resolution favoring the plaintiff is not required for jurisdiction, because a case arises under the federal patent laws if the "'plaintiff set[s] up some right, title or interest under the patent laws, or at least make[s] it appear that some right or privilege will be defeated by one construction, or sustained by the opposite construction of these laws.'" Id. at 807-08, 7 USPQ2d at 1113 (quoting Pratt v. Paris Gas Light & Coke Co., 168 U.S. 255, 259 (1897)).

[4] Because our review of the above issues disposes of the case, we need not address the remainder of the arguments submitted by the parties.