NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PADDOCK LABORATORIES, INC., Plaintiff, v. ETHYPHARM S.A., LUPIN LIMITED, and LUPIN PHARMACEUTICALS, INC. Defendants.	)	Civil Action No. 09-3779 (GEB) **MEMORANDUM OPINION**

BROWN, Chief Judge

This matter comes before the Court upon the motion to dismiss based on lack of a justiciable controversy filed by Defendants Ethypharm S.A., Lupin Limited, and Lupin Pharmaceuticals, Inc. (Doc. No. 98; Doc. No. 99 (brief).) Plaintiff filed an opposition brief on October 20, 2010, (Doc. No. 104), and Defendants filed their reply brief on October 27, 2010. (Doc. No. 112.) In addition to the normal briefing, the Court permitted Plaintiff to file a sur-reply to address new matter contained in Defendant's reply brief. (Doc. Nos. 119, 120.) The motion was returnable November 15, 2010.

However, after the briefing was completed, Plaintiff sent an update to the Court stating that the FDA has required it to file a new Paragraph IV Certification based on its amended formulation. (Letter from Arnold Rady (Dec. 20, 2010)). Defendants then renewed their motion to dismiss, arguing that they now are entitled to bring suit within the 45 day period after

service of the Paragraph IV Certification and that Paddock is unable to maintain suit during that 45 day period. (Letter from Karen Confoy (December 20, 2010)).

As explained in detail below, the Court exercises its discretion to decline jurisdiction under the Declaratory Judgment Act because such action reflects the Hatch-Waxman Act's intent to allow the branded drug company the first chance to sue under a Paragraph IV Certification. The Act did not intend for the branded pharmaceutical manufacturer to have to defend a declaratory judgment until after the expiration of the 45 day period.

I. BACKGROUND

Resolution of Ethypharm's motion requires an understanding of the complicated statutory scheme for the approval of new and generic drugs under the Hatch-Waxman Act.[1] The Hatch-Waxman Act aims to "balance two competing interests in the pharmaceutical industry: '(1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market.'" *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1355 (Fed. Cir. 2008) (quoting *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002)).

The Hatch-Waxman Act requires that before a drug manufacturer can market a new drug, it must submit a New Drug Application ("NDA") to the Food and Drug Administration ("FDA") for approval. 21 U.S.C. § 355(a). This process requires extensive safety testing and review. The manufacturer must also submit the patent number and expiration date of any patent that

[1] The Hatch-Waxman Act is the title commonly used to refer to 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, 360(c) (2000), 35 U.S.C. §§ 156, 271, 282 (2000)), as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

claims the drug or a method of using the drug for which the owner could reasonably assert a claim of patent infringement. 21 U.S.C. § 355(b)(1). The FDA lists this patent information with the approved drug in its Approved Drug Products with Therapeutic Equivalence Evaluations publication, commonly known as the "Orange Book." *See* 21 U.S.C. §§ 355(b)(1), 355(j)(2)(A)(II)(iii). This is designed to put potential generic manufacturers on notice of any patents that protect the drug.

The Hatch-Waxman Act makes the approval process easier for subsequent generic drug manufacturers. Generic drug manufacturers may obtain FDA approval for generic versions of previously-approved drugs by filing an Abbreviated New Drug Application ("ANDA"), without having to repeat the extensive safety testing required for a New Drug Application. *See* 21 U.S.C. § 355(j). Generic manufacturers are only required to show that the proposed generic is bioequivalent to the drug already tested in the NDA.

However, when submitting an ANDA for a drug to the FDA, the Hatch-Waxman Act requires a generic manufacturer to make one of the following four certifications for each of the patents listed in the Orange Book:

> (1) that the branded manufacturer filed no patents that cover the drug (a "Paragraph I Certification");
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> (2) that the patent has expired (a "Paragraph II Certification");
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> (3) that the patent will expire on a specific date (a "Paragraph III Certification"); or
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> (4) that the patent "is invalid or will not be infringed by the manufacture, use, or sale of the drug for which the application is submitted" (a "Paragraph IV Certification").

21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV). A company seeking to market a generic version of a listed drug prior to the expiration of the Orange Book-listed patents must file a Paragraph IV

Certification. The Paragraph IV Certification puts the branded manufacturer on notice that the ANDA filer may potentially infringe its patent.

To protect the patent holders from potentially infringing generics who are seeking approval, the Hatch-Waxman Act provided a means by which the patent holder could sue to prevent the marketing of the generic drug prior to its distribution. The Act provides that the filing of a Paragraph IV Certification is a technical act of patent infringement. *Janssen,* 540 F.3d at 1356 (citing 35 U.S.C. § 271(e)(2)(A); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990)). Upon receiving notice from the ANDA filer of the Paragraph IV Certification and its factual and legal bases, the NDA holder may bring an infringement suit on all, some, or none of the patents included in the Certification. 21 U.S.C. § 355(j)(5)(B)(iii). If the NDA holder fails to sue on any of the patents subject to the Paragraph IV Certification within 45 days of notice, the FDA may approve the ANDA. If the NDA holder files suit, the FDA will delay its approval of the ANDA for 30 months. *Id.*

Congress amended the Hatch-Waxman Act in 2003 to allow generics to bring an action pursuant to 28 U.S.C. § 2201 seeking a declaratory judgment if the NDA holder does not sue within the 45 day period. *Janssen*, 540 F.3d at 1357 (citing 21 U.S.C. § 355(j)(5)(C)). The amendment was necessitated because NDA holders abused the prior system in order to avoid the prompt resolution of disputes. *See Janssen,* 540 F.3d at 1357. Specifically, "[b]efore the declaratory judgment provisions, competitors were victimized by patent owners who engaged in extrajudicial patent enforcement with scare-the-customer-and-run tactics that infect[ed] the competitive environment of the business community with uncertainty and insecurity and that rendered competitors helpless and immobile so long as the patent owner refused to . . . sue." *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1336 n.2 (Fed. Cir. 2007)

(internal quotations omitted). In the declaratory judgment action, the ANDA filer may litigate any questions of infringement and invalidity. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1570 (Fed. Cir. 1997).

II. FACTUAL BACKGROUND

This case involves the FDA Approval of and subsequent ANDA for the capsule form of a drug known as Antara. On November 30, 2004, the FDA approved New Drug Application No. 21-695 for Antara Capsules. (Compl. at 18; Doc. No. 27.) The FDA lists United States Patent Number 7,101,574 ("the '574 patent") in the Orange Book for Antara capsules. (Compl. at ¶¶24-25; Doc. No. 27.)

Along with other generic manufacturers, Paddock submitted its original ANDA to the FDA seeking approval of drug products that purport to be generic versions of Antara capsules. (*Id.* at ¶38.) Paddock's original ANDA contained a Paragraph IV Certification to the '574 patent, indicating that Paddock intended to market its proposed generic product prior to the expiration of the '574 patent. (*See id.* at ¶¶38-39.)

In connection with the original ANDA, Paddock sent Ethypharm a letter entitled "Notice of Paragraph IV Certification" dated May 15, 2009 ("the Notice Letter"), with an accompanying "Detailed Statement" of the factual and legal bases why, in Paddock's view, the '574 patent is invalid, unenforceable, and/or will not be infringed by Paddock's proposed generic product. (*Id.* at ¶39.) For reasons unknown, neither Ethypharm nor Lupin filed suit in response to this notice and lost their right to a thirty month stay. (*Id.* at ¶¶40-44.) Subsequently, Paddock filed a complaint for declaratory judgment of noninfringement on July 30, 2009. (Doc. Nos. 1, 27.)

However, Paddock's ANDA and Paragraph IV Certification were unusual because the proposed drug did not seem to be identical to the Antara capsules to which it claimed bioequivalence. Paddock's "Detailed Statement" described its proposed drug product as having the active ingredient coated on the *exterior* surface of the capsule. As a result, the FDA issued a decision on August 31, 2009, that suspended the Division of Chemistry's review of Paddock's original ANDA because its proposed product was not a "capsule" as required for approval based on bioequivalence. (Lesciotto Dec., Exh. C at 1-2.) The FDA recommended that Paddock reformulate the drug. (*Id.*) In response to this decision, Paddock filed a "Major Amendment" to its ANDA and reformulated its product to comply with the definition of a capsule. (*Id.*) This involved placing the previous formulation inside an outer capsule. (Lesciotto Decl., Exh. E at PLI-0008551). After Paddock made this change, the FDA contacted Paddock again and required it to file a new Paragraph IV Certification for the new formulation. (Letter from Arnold Rady (Dec. 20, 2010)).

III. DISCUSSION

A. Standard of Review

In the 2003 amendment of the statute, "Congress extended federal court jurisdiction over [Hatch-Waxman] declaratory judgment actions 'to the extent consistent with the Constitution.'" *Janssen*, 540 F.3d at 1357 (quoting 35 U.S.C. § 271(e)(5)). Thus, a federal court's jurisdiction over such a declaratory judgment depends upon whether the action presents an Article III case or controversy. *Id.* (citing *Caraco*, 527 F.3d at 1285). That controversy "must be extant at all stages of review, not merely at the time the complaint [was] filed." *Benitec Australia, Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1345 (Fed. Cir. 2007) (citing *Steffel v. Thompson*, 415 U.S. 452,

459 n.10 (1974)). "The burden is on the party claiming declaratory judgment jurisdiction to establish that such jurisdiction existed at the time the claim for declaratory relief was filed and that it has continued since." *Id.* at 1344.

Further, under the Declaratory Judgment Act, a federal court has the discretion to decline jurisdiction over a case. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 136 (2007) (discretion to deny jurisdiction vested in the District Court in the first instance); s*ee also* 28 U.S.C. § 2201(a) (a district court "*may* declare the rights and other legal relations of any interested party.").

B. Analysis

This Court will not exercise its discretionary jurisdiction over this action because its continued jurisdiction is contrary to the intent of the Hatch-Waxman Act. In balancing its two competing purposes, the Hatch-Waxman Act set forth a specific sequence of events to allow name brand and generic companies reasonable process of law: The generic manufacturer files the Paragraph IV Certification, then the patent owner has 45 days in which to file suit – the generic company may file a declaratory judgment only after that period elapses. *See Janssen*, 540 F.3d at 1356-57.

Given this framework, it is improper to require Defendants to respond to a lawsuit when the 45 day period has not lapsed for the only active Paragraph IV Certification. The Hatch-Waxman Act clearly contemplated that owners of pharmaceutical patents would have the opportunity to file suit in response to a new Paragraph IV Certification. *See Janssen*, 540 F.3d at 1356; 21 U.S.C. § 355(j)(5)(B)(ii). Further, as discussed, the purpose of allowing a declaratory judgment in the Hatch-Waxman Act was to prevent NDA holders from putting off resolution of the suit and harassing ANDA filers with scare tactics, not to require NDA holders to suffer a

lawsuit when they still have the opportunity to bring their own suit. *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1336 n.2; *Janssen*, 540 F.3d at 1357. Thus, while the Act does not specifically prohibit a generic from *maintaining* a suit during the 45 day period, it clearly intended for the NDA holder to have the first opportunity to sue.

If this Court leaves this case open, it requires Defendants to defend a lawsuit before they have even had the opportunity to bring a suit of their own in response to the new Paragraph IV Certification and may ultimately require Defendants to participate in two cases when there is only one active Paragraph IV Certification. Thus, allowing this case to continue would undermine the balance struck in the Hatch-Waxman Act. As such, the Court exercises its discretion to decline jurisdiction over the suit.

IV. CONCLUSION

Because continuing this lawsuit is contrary to the intent of the Hatch-Waxman Act, this Court declines its discretionary jurisdiction over the suit. The case is dismissed without prejudice.

Dated: January 18, 2011

/s/ Garrett E. Brown, Jr.
GARRETT E. BROWN, JR., U.S.D.J.