IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SB PHARMCO PUERTO RICO, INC. d/b/a GLAXOSMITHKLINE, ET AL.	:	CIVIL ACTION
v.	:	NO. 08-CV-0549
MUTUAL PHARMACEUTICAL CO., INC., ET AL.	:	

SURRICK, J. **APRIL 28, 2008**

MEMORANDUM & ORDER

Presently before the Court are Plaintiffs' Motion for Judgment on the Pleadings, (Doc. No. 25), and Defendants-Counterclaimants' Cross-Motion for Leave to Amend Their Answer and Counterclaim, (Doc. No. 37). For the following reasons, Plaintiffs' Motion will be granted and Defendant's Motion will be denied.

I. BACKGROUND

A. Statutory Framework

The introduction of new prescription drugs to the marketplace is governed by the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* ("FDCA"). A company seeking to market a new drug must first receive the approval of the Food and Drug Administration ("FDA") by submitting a New Drug Application ("NDA"). *See id.* § 355(a) (Supp. 2007). The NDA is a thorough, time-consuming, and costly process in part because the application must include data from clinical studies that support the proposed drug's safety and effectiveness. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1063 (D.C. Cir. 1998). An NDA must contain a list of any patents "which claim[] the drug . . . or which claim[] 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." 21 U.S.C. § 355(b)(1). The FDA maintains a record of the patents that claim approved drugs in its publication entitled *Approved Drug Products with Therapeutic Equivalence*, commonly known as the Orange Book. *Id*.

Prior to 1984, both brand name and generic drug manufacturers who wished to bring a drug to market were required to file an NDA. Concerned that the NDA was a "cumbersome drug approval process [that] delayed the entry of relatively inexpensive generic drugs into the market place," *Mylan Pharm., Inc. v. Shalala*, 81 F. Supp. 2d 30, 32 (D.D.C. 2000), Congress enacted the Hatch-Waxman Act, which amended the FDCA. *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 90 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271(e) (1994)).

Under the Hatch-Waxman Act, a company seeking to market a generic version of a drug may file an Abbreviated New Drug Application ("ANDA"), by which a generic manufacturer can rely on the clinical studies performed by the pioneer drug manufacturer and is not required to prove the safety and effectiveness of its generic drug from scratch. *See* 21 U.S.C. § 355(j). The generic manufacturer must show principally that its drug is bioequivalent to the pioneer drug for which it will serve as a substitute. *See id.* § 355(j)(2)(A). The ANDA is not considered filed until the FDA acknowledges receipt following a preliminary review ensuring that the ANDA is sufficiently complete to permit substantive review. 21 C.F.R. § 314.101(b)(1).

Although Congress was interested in increasing the availability of generic drugs, it also wanted to protect the rights of those holding patents on pioneer drugs. *See Eli Lilly & Co. v.*

Medtronic, Inc., 496 U.S. 661, 676-77 (1990) ("These abbreviated drug-application provisions incorporated an important new mechanism designed to guard against infringement of patents relating to pioneer drugs."). An applicant filing an ANDA must certify whether its proposed generic drug will infringe any of the patents listed in connection with the pioneer drug in the Orange Book and, if not, why not. An applicant filing an ANDA has four certification options. It may certify (I) that the required patent information has not been filed, (II) that the patent has expired, (III) that the patent has not expired but will expire on a particular date, or (IV) that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV). The last of these options, and the one relevant here, is the so-called Paragraph IV certification.

Hatch-Waxman grants the first entity to file an ANDA with a Paragraph IV certification a 180-day exclusivity period in which to market its generic drug without competition from other ANDA applicants. *See* 21 U.S.C. § 355(j)(5)(B)(iv); *see also Mova Pharm.*, 140 F.3d at 1064-65 (describing exclusivity period).

An applicant who makes a Paragraph IV certification is required to give notice to the holder of the patent alleged to be invalid or not infringed, stating that an ANDA has been filed seeking approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent, and setting forth a detailed statement of the factual and legal basis for the applicant's opinion that the patent is not valid or will not be infringed. *See* 21 U.S.C. § 355(j)(2)(B)(iv). The applicant serves notice of a Paragraph IV certification to the patentee following confirmation from the FDA that the ANDA has been accepted as received. 21 U.S.C. § 355(j)(2)(B)(ii). Upon receiving the notice, the patent owner has forty-five days in which it

may initiate a patent infringement suit against the ANDA applicant, or else approval of the ANDA will be effective immediately. 21 U.S.C. § 355(j)(5)(B)(iii). If the patent owner brings such a suit, then approval of the ANDA may not be granted until the court rules that the patent is invalid or not infringed or until the expiration of thirty months, whichever occurs first. *Id*.

B. Statement of Facts

SB Pharmco Puerto Rico, Inc. and SmithKlineBeacham (collectively, "Plaintiffs"), both doing business as GlaxoSmithKline ("GSK"), bring this action for declaratory judgment on the grounds that the Paragraph IV notice sent by Mutual Pharmaceutical Company, Inc. ("Mutual") and United Research Laboratories, Inc. ("URL") (collectively, "Defendants") on December 21, 2007 was improper and premature.

Plaintiffs hold the patent for the compound sold as COREG CR, and for methods of using this compound to treat hyptertension, myocardial infarcation, and heart failure. (Doc. No. 1, Ex. B (United States Patent No. 7,268,156 ("'156 patent"), "Carvedilol Phosphate Salts and/or Solvates Thereof, Corresponding Compositions and/or Methods of Treatment").) The FDA issued this patent on September 11, 2007, having approved Plaintiffs' NDA on October 20, 2006.

On November 19, 2007, Defendants submitted ANDA 90-132 for Carvedilol Phospate Extended Release 80 mg capsules, a generic version of COREG CR. (Doc. No. 1 ¶ 24; Doc. No. 8 ¶ 24.) On December 21, 2007, Defendants filed an amendment to ANDA 90-132 for 40 mg capsules. (Doc. No. 1 ¶ 26; Doc. No. 8 ¶ 26.) The amendment contained a Paragraph IV certification that the '156 patent was invalid, unenforceable, or not infringed. (*Id*.) Concurrently, Defendants sent Plaintiffs a Paragraph IV notice letter ("December 21 Paragraph IV Notice"). (Doc. No. 1 ¶ 27; Doc. No. 8 ¶ 27.) On December 21, 2007, ANDA 90-132 had

not yet been accepted by the FDA for filing. (Doc. No. 1 ¶¶ 25-26; Doc. No. 8 ¶ 25.)

On January 22, 2008, Plaintiffs emailed the FDA regarding the December 21 Paragraph IV Notice. (Doc. No. 1, Ex. A (Letter of G. Buehler to W. Zoffer).) On February 4, 2008, Gary J. Buehler, Director of the Office of Generic Drugs, Center for Drug Evaluation and Research, responded. (*Id*.) His response, in a two-page letter which discussed the agency's interpretation of the statutory and regulatory process for the approval of ANDAs, concluded as follows:

> FDA has advised Mutual that, because Mutual sent notice to SB Pharmco d.b.a. GlaxoSmithKline of its paragraph IV certification to the '562 and '156 patents before Mutual received acknowledgment from the FDA that ANDA No. 90-132 had been received for review, the notification is invalid and does not trigger either the 45-day period in which SB Pharmco d.b.a. GlaxoSmithKline may file suit against Mutual and obtain a 30-month stay under section 505(j)(5)(B)(iii) of the Act, or the beginning of any related 30-month stay. Mutual must renotify the NDA holder and patent owner(s) within 20 days after the FDA informs it that its application has been received for review."

(*Id*.) Plaintiffs subsequently requested that Defendants withdraw the December 21 Paragraph IV Notice. (Doc. No. 1 ¶¶ 29, 34; Doc. No. 8 ¶¶ 29, 34.) Defendants refused to do so. (*Id.*)

On February 4, 2008, forty-five days after receiving the December 21 Paragraph IV Notice, Plaintiffs filed a Complaint in this court. (Doc. No. 1 ¶ 30.) Count I of the Complaint seeks declaratory judgment that:

> (1) Defendants' Paragraph IV Notice is improper, null, void, and without legal effect and that Defendants were not entitled to trigger the ANDA patent litigation process; (2) this Court has no jurisdiction over Plaintiffs' alternative claims regarding the '156 patent because Defendants Paragraph IV Notice is null, void, and without legal effect; (3) the Paragraph IV Notice served by Defendants did not commence the 45 day period in which to file a patent infringement action pursuant to 21 U.S.C. § 355(j)(5)(B)(iii); (4) if and when the FDA accepts Defendants' ANDA, Defendants must serve new Paragraph IV Notices on GSK pursuant to 21 U.S.C. § 355(j)(2)(A)(vii); and (5) the 30-month stay will not begin until Defendants have sent a valid Paragraph IV Notice to GSK following FDA acceptance of Defendants' ANDA.

(*Id*. ¶ 38.) In the alternative, if the Court finds the December 21 Paragraph IV Notice to be valid, Count II of Plaintiffs' Complaint seeks "all available relief under the patent laws of the United States, 35 U.S.C. § 100 *et seq*. and other applicable laws for Defendants' infringement of its patent." (*Id.* ¶¶ 6, 42 ("Prayer for Relief").)

Defendants filed an Answer and Counterclaim on February 25, 2008 seeking a declaratory judgment that the '156 patent is invalid. (Doc. No. 8 ¶ 11.)

On March 17, 2008, following the FDA's acceptance of ANDA 90-132 for filing, Defendants sent Plaintiffs a Paragraph IV notice letter ("March 17 Paragraph IV Notice"). (Doc. No. 25 at 6 n.1; Doc. No. 36 at 4.) Plaintiffs agree that they received this notice on March 18, 2008. (Doc. No. 25 at 6 n.1.)

On March 19, 2008, Plaintiffs filed the instant Motion. (Doc. No. 25.) Plaintiffs argue that Defendants improperly triggered the ANDA litigation process with their invalid December 21 Paragraph IV Notice. (*Id*. at 11.) Plaintiffs request that the Court enter the declaratory relief sought in Count I of the Complaint and dismiss all remaining claims without prejudice as premature and unripe. (*Id*.)

On April 1, 2008, Defendants filed a response in opposition to the Motion, (Doc. No. 36),[1] as well as a Cross-Motion for Leave to Amend Their Answer and Counterclaim to reflect the FDA's March 17 filing acceptance, (Doc. No. 37). Defendants argue that Plaintiffs' motion

[1] On April 3, 2008, Defendants filed an Unopposed Motion to File Exhibit Under Seal. (Doc. No. 38.) Defendants advised the Court that exhibits attached to their response and cross-motion memorandum, (Doc. No. 36), which contained confidential and proprietary information were filed inadvertently on the Court's electronic filing system ("ECF"), rather than being filed under seal. On April 4, 2008, the Clerk's office withdrew the documents from ECF and placed them under seal.

should be denied because the December 21 Paragraph IV Notice was timely and valid under 21 U.S.C. § 355(j)(2)(B)(ii)(II), and that, in any event, the Court has subject matter jurisdiction over this dispute irrespective of the validity of the notice. (*Id.* at 4-5.)

Plaintiffs filed a reply memorandum on April 8, 2008. (Doc. No. 42.)

II. LEGAL STANDARD

A. Motion for Judgment on the Pleadings

In reviewing a motion pursuant to Federal Rule of Civil Procedure 12(c), we apply the same standard used to review a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). *Constitution Bank v. DiMarco*, 815 F. Supp. 154, 157 (E.D. Pa. 1993). We may not grant a judgment on the pleadings under Rule 12(c) "'unless the movant clearly establishes that no material issue of fact remains to be resolved and that he is entitled to judgment as a matter of law.'" *CoreStates Bank, N.A. v. Huls Am., Inc.*, 176 F.3d 187, 193 (3d Cir. 1999) (quoting *Kruzits v. Okuma Mach. Tool, Inc.*, 40 F.3d 52, 54 (3d Cir. 1994)). We must "'view the facts presented in the pleadings and the inferences to be drawn therefrom in the light most favorable to the nonmoving party.'" *Jablonski v. Pan Am. World Airways, Inc.*, 863 F.2d 289, 290-91 (3d Cir. 1988) (quoting *Soc'y Hill Civic Ass'n v. Harris*, 632 F.2d 1045, 1054 (3d Cir. 1980)). Of course, to survive a motion for judgment on the pleadings, the non-moving party "must set forth facts, and not mere conclusions, that state a claim as a matter of law." *Allstate Transp. Co., Inc. v. SEPTA*, Civ. A. No. 97-1482, 1998 U.S. Dist. LEXIS 1740, at *4 (E.D. Pa. Feb. 13, 1998).

"As a general matter, a district court ruling on a motion to dismiss may not consider matters extraneous to the pleadings." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997). However, the Third Circuit has recognized an exception to this general

rule: when a document is "integral to or explicitly relied upon in the complaint," it may be considered "without converting the motion to dismiss into one for summary judgment." *Id.* (internal citations and quotation marks omitted); *see also Mele v. Fed. Reserve Bank of N.Y.*, 359 F.3d 251, 256 n.5 (3d Cir. 2004) (applying same to motion to dismiss on the pleadings under Rule 12(c)).

B. Motion for Leave to Amend

Federal Rule of Civil Procedure 15(a) provides that after the first amended pleading, a party may amend its complaint "only by leave of court or by written consent of the adverse party; and leave shall be freely given when justice so requires." Fed. R. Civ. P. 15(a). A court may deny a motion for leave to amend when certain factors are present. These include: "'undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of the amendment, etc.'" *Dole v. Arco Chem. Co.*, 921 F.2d 484, 487 (3d Cir. 1990) (quoting *Foman v. Davis*, 371 U.S. 178, 182 (1962)).

III. LEGAL ANALYSIS

A. Motion for Judgment on the Pleadings

1. Defendants' December 21 Paragraph IV Notice

In their Motion for Judgment on the Pleadings, Plaintiffs assert that there is no dispute as to a material fact in this case. (Doc. No. 25 at 5.) Arguing that Defendants improperly attempted to trigger the patent litigation process by sending the December 21 Paragraph IV Notice before ANDA 90-132 was accepted by the FDA for filing, Plaintiffs request that we grant the declaratory relief sought in Count I of the Complaint. (*Id*. at 1-2, 11.)

The procedure for submitting an ANDA is described in 21 C.F.R. § 314.101(b)(1) as follows:

> An abbreviated new drug application will be reviewed after it is submitted to determine whether the abbreviated application may be received. Receipt of an abbreviated new drug application means that FDA has made a threshold determination that the abbreviated application is sufficiently complete to permit a substantive review.

Id. Under this formulation, the ANDA applicant delivers the ANDA to the FDA. For some undefined period of time, the ANDA is in a kind of limbo. It is physically in the hands of the FDA, but it is not officially considered received or filed. As with the FDA procedure for receiving NDAs,[2] the application is not considered received or filed until it has undergone a review to ensure that the it is "sufficiently complete to permit a substantive review" on the merits. This framework was explained by the FDA when responding to comments on proposed C.F.R. sections published in the Federal Register. One comment suggested that "proposed § 314.101(b) should not authorize FDA to determine whether an abbreviated application may be received." 57 FR 17950, 17965 (April 28, 1992). The FDA responded: "FDA rejects this comment. By determining whether an application is 'received,' FDA encourages applicants to submit ANDA's that comply with statutory and regulatory requirements and are sufficiently complete for substantive review to begin. This conserves FDA resources by permitting FDA reviewers to devote their time to examining reviewable applications." *Id.* Clearly, the FDA has determined that there is an important distinction between physically- received ANDAs, which are

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[2] Subparagraph (a)(1) of 21 C.F.R. § 314.101 provides: "Within 60 days after FDA receives an application [NDA], the agency will determine whether the application may be filed. The filing of an application means that FDA has made a threshold determination that the application is sufficiently complete to permit a substantive review." 21 C.F.R. § 314.101(a)(1).

potentially incomplete, and officially-received ANDAs, which have been determined to be sufficiently complete to permit review.

The Paragraph IV notice provisions reflect this same ANDA submission procedure. The timing for providing notice of an ANDA's Paragraph IV certification is governed by 21 U.S.C. § 355(j)(2)(B)(ii)(I), which provides that "[a]n applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph – (I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed." 21 U.S.C. § 355(j)(2)(B)(ii)(I). The federal regulation construing this section states: "The applicant shall send the notice required by paragraph (a) of this section when it receives from FDA an acknowledgment letter stating that its abbreviated new drug application is sufficiently complete to permit a substantive review." 21 C.F.R. § 314.95(b).

Defendants argue that "[s]ub-section (I) [of 21 U.S.C. § 355(j)(2)(B)(ii)] says nothing that prohibits giving voluntary notice *before* the FDA has issued filing acceptance." (Doc. No. 36 at 9.) Defendants seem to suggest that an ANDA applicant may send a Paragraph IV notice letter, and thus trigger patent litigation, at any time it chooses. Under the statute and regulations, the sending of notice of a Paragraph IV certification is expressly predicated upon the ANDA applicant receiving its own notice and acknowledgment from the FDA that the submitted ANDA has been received.

The timing of Paragraph IV notice is particularly significant because it is inextricably intertwined with the statutory framework for patent litigation. The notice of Paragraph IV certification sent by the ANDA applicant triggers a forty-five day period in which the patentee

may file an action for patent infringement. 21 U.S.C. § 355(j)(5)(B)(iii). If the patentee opts not to file such an action, the approval of the ANDA will be made immediately. *Id*. If the patentee opts to seek judicial relief, approval of the ANDA is suspended for thirty months or until judicial resolution of the patent infringement case, whichever occurs first. *Id*. The thirty-month stay serves "to create an adequate window of time during which to litigate the question of whether a generic will infringe the patented product . . . ." *Ben Venue Labs., Inc. v. Novartis Pharmaceutical Corp.*, 146 F. Supp. 2d 572, 579 (D.N.J. 2001) (citing, generally, 130 Cong. Rec. H9118 (daily ed. Sept. 6, 1984) (statement of Rep. Waxman); 130 Cong. Rec. S10504 (daily ed. Aug. 10, 1984) (statement of Sen. Hatch)).

Under traditional analysis, the fact that an ANDA applicant sent notice that it intended to manufacture or use a potentially-infringing drug compound, if the ANDA was approved by the FDA, would not ordinarily satisfy the "case and controversy" requirement for federal court jurisdiction. Hatch-Waxman, however, created a legitimate litigation process by making the filing of an ANDA with a Paragraph IV certification a statutory act of infringement sufficient to create federal subject matter jurisdiction. 35 U.S.C. § 271(e)(2). *See Ben Venue*, 146 F. Supp. 2d at 578 ("Since a United States District Court has exclusive jurisdiction to hear suits for patent infringement pursuant to 28 U.S.C. § 1338, the notional act of infringement created by 35 U.S.C. § 271(e)(2) creates a controversy over which the Court has subject matter jurisdiction."). The Supreme Court has described § 271(e)(2) as creating "a highly artificial act of infringement that consists of submitting an ANDA . . . containing the fourth type of certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent." *Medtronic*, 496 U.S. at 678. *See also Ben*

Venue, 146 F. Supp. 2d at 578 ("In effect, the submission of a Paragraph IV Certification to the FDA is itself an artificial, purely notional act of patent infringement."). Therefore, although ANDA applicants were not yet making, using, or selling the patented product, which are the traditionally statutorily-defined acts of infringement, "§ 271(e)(2) provided patentees with a defined act of infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity." *Glaxo Inc. v. Novopharm Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997).

The Paragraph IV notice sequence ensures that the statutory litigation triggers do not result in unnecessary patent infringement litigation initiated by incomplete ANDAs. As the legislative history makes clear, Congress was concerned with the submission of incomplete ANDAs: "Congress did 'not intend that applicants be permitted to circumvent this notice requirement [proposed 21 C.F.R. § 314.95(b)] by filing sham ANDA's or ANDA's which are substantially incomplete.'" 59 FR 50338, 50349 (Oct. 3, 1994) (quoting H. Rept. 857, 98th Cong. 2d Sess. 24 (1984)). This concern was shared by the FDA as reflected in its comments:

> As written, § 314.95(b) is consistent with the legislative history because it requires the ANDA applicant to provide notice once FDA has determined that the ANDA is substantially complete to permit a substantive review. To permit an ANDA applicant to provide notice before FDA has determined whether the ANDA is sufficiently complete would be contrary to the legislative history because it would only encourage ANDA applicants to file incomplete or 'sham' ANDA's and to supplement them later to secure a place in the review queue in an attempt to secure the first ANDA approval.

59 FR 50338, 50350 (Oct. 3, 1994). (*See also* Doc. No. 1, Ex. A (Letter of G. Buehler to W. Zoffer) ("The requirement that the ANDA applicant wait to send notice until it receives confirmation from the FDA that the application meets the requirements for review (i.e., may be

'received') ensure that the NDA holder and patent owner do not needlessly expend resources to initiate litigation with respect to an ANDA that is incomplete and therefore may not be reviewed by agency.").) Thus, the FDA's role in accepting an ANDA for review, so that it is *received* and not merely *delivered*, acts as a safeguard to prevent a potentially incomplete ANDA from triggering the litigation process.

We are satisfied that the December 21 Paragraph IV Notice was premature and improper under 21 U.S.C. § 355(j)(2)(B)(ii)(I) and 21 C.F.R. § 314.95(b). Since ANDA 90-132 had not been accepted as received when the notice was sent, the litigation process was prematurely sparked at a time when the danger existed that the ANDA was in fact incomplete.[3]

2. 21 U.S.C. § 355(j)(2)(B)(ii)(II)

Defendants argue that the December 21 Paragraph IV Notice was not premature because the "express terms" of 21 U.S.C. § 355(j)(2)(B)(ii)(II) required that Defendants' send this notice. (Doc. No. 36 at 6.)

The statutory language on which Defendants' rely is the second paragraph of 21 U.S.C. § 355(j)(2)(B)(ii), which states that an ANDA applicant shall provide notice of Paragraph IV certification, "if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant

[3] Defendants incorrectly argue that the fact that ANDA 90-132 has now been accepted as filed nullifies any pre-March 17, 2008 concerns regarding the ANDA's completeness: "Part of GSK's motion is devoted to a parade-of-horribles argument premised on the possibility that FDA filing acceptance might never be granted. . . . Whatever merit these arguments might have had in the absence of FDA filing acceptance, they have been rendered moot now that the FDA has issued filing acceptance." (Doc. No. 36 at 21.) We disagree. The fact that the FDA has now officially received the ANDA does not alter the fact that at the time that Plaintiffs' filed this Complaint, the ANDA had not been accepted for filing and certainly could have been incomplete.

has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application." 21 U.S.C. § 355(j)(2)(B)(ii)(II).

Plaintiffs argue that Defendants' are employing a "hyper-literal reading of one particular subsection of 21 U.S.C. § 355(j)(2)(B)(ii) that makes no sense when read in the context of the statute as a whole, or even the context of the entire sentence in which it appears." (Doc. No. 42 at 2.) We agree.

When interpreting a statutory provision, the rules of statutory construction direct that courts look first to the plain language of the statute. *See United States v. Ron Pair Enters.*, 489 U.S. 235, 241 (1989). If the text is open to different interpretations,[4] courts must apply "'the cardinal rule that a statute is to be read as a whole, . . . since the meaning of statutory language,

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[4] Defendants argue that the statutory language of 21 U.S.C. § 355(j)(2)(B)(ii)(II) is "express and unambiguous," (Doc. No. 36 at 10), and requires the service of Paragraph IV notice "without regard to whether there has been FDA filing acceptance," (*id*. at 9). However, when one reads this subparagraph along with the rest of 21 U.S.C. § 355(j)(2)(B)(ii), it seems clear that subparagraph (II) refers to an amendment to an ANDA for which the FDA has already acknowledged receipt.

In its entirety, 21 U.S.C. § 355(j)(2)(B)(ii) provides:

> (ii) Timing of notice. An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph--
>
> (I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or
>
> (II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

Id.

plain or not, depends on context.'" *Tavarez v. Klingensmith*, 372 F.3d 188, 190 (3d Cir. 2004) (quoting *King v. St. Vincent's Hosp.*, 502 U.S. 215, 221 (1991). Moreover, agency interpretations of a statute may be considered:

> [A]gencies charged with applying a statute necessarily make all sorts of interpretive choices, and while not all of those choices bind judges to follow them, they certainly may influence courts facing questions the agencies have already answered. "The well-reasoned views of the agencies implementing a statute 'constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance.'"

United States v. Mead Corp., 533 U.S. 218, 227 (2001) (quoting *Bragdon v. Abbott*, 524 U.S. 624, 642 (1998) (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134, 139-40 (1944))).

In this case, we have the agency interpretation of 21 U.S.C. § 355(j)(2)(B)(ii)(II) in the February 4, 2008 letter response of the FDA to Plaintiffs' inquiry:

> Notice of paragraph IV certification submitted in an amendment or supplement to an ANDA is to be sent "at the time" the amendment or supplement is submitted to the agency. Section 505(j)(2)(B)(ii)(II). Notice in this context does not raise the same concerns about premature notice because the agency will have already determined under 21 CFR 314.101 that the application being amended or supplemented is sufficiently complete to permit review.

(Doc. No. 1, Ex. A n.1 (Letter of G. Buehler to W. Zoffer).) When we consider Defendants' argument in the context of the statute as a whole, the sequential ANDA submission framework, which distinguishes between ANDAs physically and officially received, the FDA's reasoning for this framework, including the concern that submitted ANDAs might be incomplete and could create unnecessary work for the FDA or trigger unnecessary litigation, the sequential timing provisions for sending notice of Paragraph IV certification, and Congress's interest in preventing the filing of "sham" ANDAs, it is clear that Defendants' reading of 21 U.S.C. § 355(j)(2)(B)(ii)(II) leads to a result that undermines the entire statutory framework. If an ANDA

applicant could send Paragraph IV notice when amending an ANDA that has not yet been accepted as received, the applicant could accelerate the timing provisions and litigation process well beyond the framework that Congress intended.

Consistent with the FDA's interpretation of 21 U.S.C. § 355(j)(2)(B)(ii)(II), we conclude that this provision only makes sense if read with the implicit condition that the notice be sent concurrently with the amendment *only* if the amendment is submitted for an ANDA that has already been accepted for filing. Accordingly, Defendants' December 21 Paragraph IV Notice was not valid or timely under 21 U.S.C. § 355(j)(2)(B)(ii)(II).

3. Subject Matter Jurisdiction

Defendants argue that regardless of the validity of the December 21 Paragraph IV Notice, this Court has subject matter jurisdiction over Plaintiffs' patent infringement claim and Defendants' patent invalidity counterclaim because there is a justiciable Article III case or controversy. (Doc. No. 36 at 7, 11 (citing 35 U.S.C. § 271; 28 U.S.C. § 1338(a)).) Plaintiffs respond that we should dismiss the remaining claims without prejudice because Plaintiffs' filed their patent claim only as an alternative to their claim for declaratory judgment. (Doc. No. 42 at 11-12.)

Federal courts have subject matter jurisdiction over patent actions pursuant to 28 U.S.C. § 1338(a): "The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents . . . ." *Id.* (2006).

a. Plaintiffs' Patent Infringement Claim (Count II)

Plaintiffs filed the patent infringement claim in Count II of their Complaint pursuant to 35

U.S.C. § 271(e)(2) and 35 U.S.C. §§ 271(a)-(c).[5] (Doc. No. 1 ¶¶ 39, 40.)

As hereinabove discussed, 35 U.S.C. § 271(e)(2) provides subject matter jurisdiction for patent infringement claims by making the submission of an ANDA an "artificial" act of infringement that satisfies the traditional case and controversy requirement. *See Medtronic*, 496 U.S. at 678. Defendants assert that "[n]othing in those statutes [35 U.S.C. §§ 271(e)(2), (a)-(c)] requires, as a *jurisdictional* prerequisite, that the FDA have issued filing acceptance, or that a valid Paragraph IV notice have been served." (Doc. No. 36 at 11.) We disagree. Considering the statutory framework and legislative history that we have addressed above, the term "submit" in § 271(e)(2) clearly means that an ANDA has been received, not merely delivered. It would be illogical for the statutory provisions and federal regulations to carefully construct a safeguard against incomplete ANDAs, only to allow those same potentially insufficient applications to constitute the act of infringement that triggers litigation. This view is supported by the

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[5] 35 U.S.C. §§ 271(a)-(c) provides:

> (a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.
>
> (b) Whoever actively induces infringement of a patent shall be liable as an infringer.
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> (c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

Id.

congressional record: "[T]he Hatch-Waxman Act has always provided that patent owners and brand drug companies can bring patent infringement suits against a generic applicant immediately upon receiving notice that the generic applicant is challenging a patent." 149 Cong. Rec. S 15882, 15885 (Nov. 25, 2003) (remarks of Sen. Kennedy). The "notice" referred to is the notice provided to the patentee by the ANDA applicant under 21 U.S.C. § 355(j)(2)(B)(ii)(I) and 21 C.F.R. § 314.95(b), after FDA acknowledgment that an ANDA has been received.

In this case, at the time that Plaintiffs' filed their Complaint, Defendants' actions had not satisfied the statutorily-defined act of infringement that an ANDA be submitted to the FDA because ANDA 90-132 had not yet been received. Therefore, the subject matter jurisdiction afforded by 35 U.S.C. § 271(e)(2) was not available when this case was filed. There was no artificial case or controversy to support federal court jurisdiction.

Defendants' also contend that this Court has jurisdiction over Plaintiffs' patent infringement claim pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201 (2006). (Doc. No. 36 at 15.) The Declaratory Judgment Act provides: "In a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a). In *MedImmune, Inc. v. Genentech, Inc.*, 127 S.Ct. 764 (2007), the Supreme Court articulated the test for jurisdiction in declaratory judgment actions: "[W]hether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient

immediacy and reality to warrant the issuance of a declaratory judgment."[6] *Id*. at 771. The Court stated that the correct standard for declaratory judgment is "that the dispute be definite and concrete, touching the legal relations having adverse legal interests and that it be real and substantial and admit of specific relief through a decree of conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." *Id*. (internal citations and quotation marks omitted). The Federal Circuit has explained that, after *MedImmune*, the Declaratory Judgment Act requires an Article III controversy, which "is found where a plaintiff has demonstrated an injury-in-fact caused by the defendant that can be redressed by the court. *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1340 (Fed. Cir. 2007). Moreover, "[a] justiciable controversy can arise from either an actual or imminent injury." *Id*. at 1341.

In this case, there was no actual or substantial controversy at the time that Plaintiffs' filed their Complaint. Plaintiffs' claim of patent infringement was based upon service of an invalid Paragraph IV notice for an amendment to an ANDA that had not yet been received by the FDA. During the preliminary review stage, ANDA 90-132 could not have been approved by the FDA. Under the circumstances, Defendants' ANDA could not cause an injury-in-fact to Plaintiffs. It was potentially incomplete and could not constitute an act of infringement. Under the statute and

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[6] Prior to *MedImmune*, courts dealing with declaratory judgment actions in patent cases used a two-prong test articulated by the Federal Circuit: "There must be both (1) an explicit threat or other action by the patentee which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit; and (2) present activity by the declaratory judgment plaintiff which could constitute infringement, or concrete steps taken with the intent to conduct such activity." *Teva Pharm. USA, Inc. v. Pfizer Inc.*, 395 F.3d 1324, 1332 (Fed. Cir. 2005). *MedImmune* found that the reasonable apprehension test conflicted with Supreme Court precedent. *MedImmune*, 127 S.Ct. at 774 n.11.

the case law, we conclude that Defendants' delivery of the ANDA to the FDA did not create the actual or imminent controversy necessary to satisfy the Declaratory Judgment Act.

In addition, Plaintiffs specifically pled their patent infringement claim in the alternative. The primary claim in Plaintiffs' Complaint is the claim in Count I that Defendants' December 21 Paragraph IV Notice is invalid. Plaintiffs filed Count II only because they were required to do so if the Paragraph IV notice was valid. We have determined that the notice was invalid. Count II of Plaintiffs' Complaint will be dismissed without prejudice.

b. Defendants' Counterclaim

Defendants argue that even if the Court dismisses Plaintiffs' patent infringement claim without prejudice, we retain subject matter jurisdiction over Defendants' counterclaim. (Doc. No. 36 at 18-19.) Plaintiffs respond that dismissal of Defendants' counterclaim without prejudice is appropriate because "Mutual's new notices guarantee that Mutual will have an opportunity to litigate its claim for invalidity either as a counterclaim in Hatch-Waxman litigation, or as a declaratory judgment count in an action for patent certainty under § 271(e)(5)." (Doc. No. 42 at 11.)

ANDA applicants are authorized to bring counterclaims to Hatch-Waxman Act patent infringement actions pursuant to 21 U.S.C. § 355(j)(5)(C)(ii), which provides that if a patent holder "brings a patent infringement action against the applicant, the applicant may assert a counterclaim . . . ." 21 U.S.C. § 355(j)(5)(C)(ii)(I). This provision does not, however, authorize an independent cause of action by the ANDA applicant. *Id.* § 355(j)(5)(C)(ii)(II).

In addition, where no patent infringement claim is filed under 35 U.S.C. § 271(e)(2), 35 U.S.C. § 271(e)(5) (Supp. 2007) provides jurisdiction for a declaratory judgment action:

> Where a person has filed an application described in paragraph (2) that includes a certification under subsection . . . (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act **(21 U.S.C. 355), and** neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection . . . (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

Id. *See also* 21 U.S.C. § 355(j)(5)(C) ("Civil action to obtain patent certainty."); 149 Cong. Rec. S 15882, 15885 (Nov. 25, 2003) (remarks of Sen. Kennedy) ("These provisions authorize a generic applicant to bring a declaratory judgment action to obtain a judicial determination that a listed patent is invalid or is not infringed if the applicant is not sued within 45 days of having given notice to the patent owner and brand-name drug company that it is challenging the patent.") Here, forty-five days have not elapsed since the service of a valid Paragraph IV notice. Therefore, Defendants cannot assert jurisdiction for their counterclaim pursuant to 35 U.S.C. § 271(e)(5).

As discussed above, under *MedImmune* and *Novartis*, a justiciable Article III controversy exists if there is either an actual or imminent injury. *MedImmune,* 127 S.Ct. at 771; *Novartis,* 482 F.3d at 1340-41. *Novartis* is instructive here. **In *Novartis*, a patentee filed a patent infringement action against an ANDA applicant as to only one of five patents implicated by the ANDA applicant's Paragraph IV certification. 482 F.3d at 1334-35. The ANDA applicant subsequently filed a declaratory judgment action on the four remaining patents to establish "patent certainty." *Id*. at 1335. The court found that there was a justiciable controversy because (1) the patentee listed its patents in the Orange Book, (2) the ANDA applicant submitted an**

ANDA with Paragraph IV certifications and the act of submitting an ANDA is an act of infringement, (3) the combination of 21 U.S.C. § 355(j)(5)(C) ("'civil action to obtain patent certainty'"), 35 U.S.C. § 271(e)(5) ("the ANDA declaratory judgment provision"), and the purpose of the Hatch-Waxman Act to prevent patentees from "'gaming'" the system, (4) the patentee's pending patent infringement action, and (5) the possibility of future litigation by the patentee as to the four remaining patents. *Id.* at 1341-45. The court interpreted the patentee's filing of a patent infringement action as to only one of its actions to be an attempt "to simultaneously leverage the benefits provided to a patentee under the Hatch-Waxman Act and avoid the patentee's accompanying responsibilities." *Id.* at 1343. The court found:

> A justiciable declaratory judgment controversy arises for an ANDA filer when a patentee lists patents in the Orange Book, the ANDA applicant files its ANDA certifying the listed patents under paragraph IV, and the patentee brings an action against the submitted ANDA on one or more of the patents. The combination of these three circumstances is dispositive in establishing an actual declaratory judgment controversy as to all the paragraph IV certified patents.

Id. at 1344.

When Defendants filed their Counterclaim on February 4, 2008, no justiciable controversy had arisen here. Although, as in *Novartis*, Plaintiffs had listed patents in the Orange Book, Defendants had not yet filed their ANDA. In addition, while Plaintiffs did bring an action against Defendants, they had no choice. The only way that they could protect their patent under Hatch-Waxman was to file this action. However, the patent infringement claim was based on Defendants' unfiled ANDA and was offered only as an alternative to Plaintiffs' primary contention that the December 21 Paragraph IV Notice could not trigger Hatch-Waxman patent litigation. Defendants cannot argue that the listing of the '156 patent or the filing of Plaintiffs'

patent infringement action have delayed approval of their ANDA and their entrance into the market, because, under the statutory and regulatory framework, the FDA had not even begun to review the ANDA on the merits. *Cf. Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 2008 U.S. LEXIS 6838, Docket No. 2007-1404, at *33 (Fed. Cir. April 1, 2008) (finding that Caraco's injury was traceable to the patentee because "[i]t is not the Hatch-Waxman Act or the FDA framework that prevents Caraco's ANDA from being approved by the FDA, but rather [the patentee's] actions in the context . . . of the Hatch-Waxman framework."). Therefore, at the time that Defendants' filed their Counterclaim, the FDA and the Hatch-Waxman framework, not Plaintiffs, had created the barrier depriving Defendants' of the immediate opportunity to compete. *Cf. Caraco*, 2008 U.S. LEXIS 6838, at *34 ("It is well established that the creation of . . . barriers to compete satisfies the causation requirement of Article III standing.").

A number of courts have concluded that "'[t]he purpose of the Declaratory Judgment Act . . . in patent cases is to provide the allegedly infringing party relief from uncertainty and delay regarding its legal rights.'" *Micron Technology, Inc. v. MOSAID Technologies, Inc.*, 518 F.3d 897, 2008 U.S. App. LEXIS 4387, at *10 (Fed. Cir. 2008) (quoting *Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953, 956 (Fed. Cir. 1987)). There was no uncertainty or delay here. Due to the unfiled status of the ANDA, Defendants were not alleged infringers at the time that this case was brought. Similarly, there was no delay regarding Defendants' legal rights, except those delays built into the statutory and regulatory framework. Under the circumstances, we are compelled to conclude that at the time of filing Defendants' counterclaim there was no Article III case and controversy.

Accordingly, having concluded that we do not have subject matter jurisdiction over

Plaintiffs' patent infringement claim or Defendants' patent invalidity counterclaim, we will dismiss these claims without prejudice.

B. Cross-Motion for Leave to Amend Answer and Counterclaim to Reflect FDA Filing Acceptance

Defendants seek leave to amend their Answer and Counterclaim to reflect the fact that, on March 17, 2008, after Defendants had filed their Answer and Counterclaim, the FDA notified Defendants that ANDA 90-132 had been accepted as filed. (Doc. No. 36 at 5.) Defendants argue (1) that it would be unfairly prejudicial to Defendants if the Court could not consider this fact, (2) that Plaintiffs will not be prejudiced by the proposed amendment, and (3) that there is not factual dispute that the FDA accepted the ANDA as received. (*Id*. at 6.)

Plaintiff responds that (1) the FDA's March 17, 2008 receipt of the ANDA does not change the fact that the December 21 Paragraph IV Notice was premature and improper, (2) that Defendants have no need to amend their answer and counterclaim if all claims, other than Count I of the Complaint, are dismissed without prejudice, and (3) that Defendants will have the opportunity to plead the updated facts in a new action. (Doc. No. 42 at 14.)

Since we are dismissing Defendants' counterclaim without prejudice, Defendants are free, subject to the time-frames laid out in Hatch-Waxman, to file a new action or counterclaim where the pleadings will reflect the fact of the FDA's filing acceptance on March 17, 2008. Defendants' will not be prejudiced by the denial of their motion for leave to amend since this matter will simply be returned to the track laid out by Congress and the FDA for patent litigation.

Accordingly, Defendants' motion for leave to amend their answer and counterclaim will be denied.

IV. CONCLUSION

An appropriate Order follows.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SB PHARMCO PUERTO RICO, INC. d/b/a GLAXOSMITHKLINE, ET AL.	:	CIVIL ACTION
v.	:	NO. 08-CV-0549
MUTUAL PHARMACEUTICAL CO., INC., ET AL.	:	

ORDER

AND NOW, this 28th day of April, 2008, upon consideration of Plaintiffs' Motion for Judgment on the Pleadings, (Doc. No. 25), and Defendants-Counterclaimants' Cross-Motion for Leave to Amend Their Answer and Counterclaim, (Doc. No. 37), and all papers submitted in support thereof and in opposition thereto, it is ORDERED as follows:

1. Plaintiffs' Motion for Judgment on the Pleadings is GRANTED.

2. Count II of Plaintiff's Complaint is DISMISSED WITHOUT PREJUDICE.

3. Defendants' Counterclaim is DISMISSED WITHOUT PREJUDICE.

4. Defendants' Cross-Motion for Leave to Amend is DENIED.

IT IS SO ORDERED.

BY THE COURT:

R. Barclay Surrick, Judge