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

SB PHARMCO PUERTO RICO, INC. d/b/a GLAXOSMITHKLINE, and SMITHKLINE BEECHAM CORP., d/b/a GLAXOSMITHKLINE	)	
Plaintiffs,	)	
v.	)	**Civil Action No. _____**
MUTUAL PHARMACEUTICAL COMPANY, INC. and UNITED RESEARCH LABORATORIES, INC.	)	
Defendants.	)	

COMPLAINT

Plaintiffs SB Pharmco Puerto Rico, Inc. and SmithKlineBeecham Corporation, both doing business as GlaxoSmithKline (hereafter "GSK"), for their Complaint against Defendants Mutual Pharmaceutical Company, Inc. (hereafter "Mutual") and United Research Laboratories, Inc. (hereafter "URL"; collectively, "Defendants"), hereby allege as follows:

NATURE OF THE ACTION

1. In this action, GSK seeks to block Defendants' premature and improper triggering of the litigation process that Congress has carefully constructed for resolving patent disputes when a drug company seeks approval to market a generic version of a branded drug by filing an Abbreviated new Drug Application ("ANDA"), as described in more detail in paragraphs 13-21 below.

2. At least as of December 21, 2007, Defendants did not have an ANDA with respect to GSK's COREG CR™ heart medication that has been accepted by the United States

Food and Drug Administration ("FDA") as sufficiently complete to begin review. The acceptance for filing of an ANDA by the FDA is a prerequisite that must be satisfied before Defendants send GSK proper notification of the ANDA and a "Paragraph IV certification." Such a notice letter, if it were valid, would start a time period in which GSK must sue for patent infringement in order to obtain a 30-month statutory delay during which the FDA cannot approve Defendants' ANDA. However, since Defendants' ANDA has not been accepted for filing yet, Defendants could not send a valid notice letter to GSK, and therefore could not trigger GSK's statutory right to sue for infringement or commence the 30-month stay.

3. Nevertheless, on December 21, 2007, Defendants' sent a purported "Paragraph IV Notice" to GSK regarding an amendment to Defendants' not-yet-accepted ANDA submission to the FDA under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, and stating that Defendants have claimed to the FDA that GSK's patents related to COREG CR are either invalid, unenforceable, or will not be infringed by Defendants' generic products. Since Defendants' initial ANDA submission has not yet been accepted for filing by the FDA, by definition, their amendment also could not have been accepted for filing, and thus the service of this purported Paragraph IV Notice is not lawful and cannot trigger GSK 's right or obligation to sue Defendants or begin the 30-month stay of ANDA approval under 21 U.S.C. § 355(j)(5)(B)(iii) and 21 C.F.R. § 314.107(b)(3).

4. The FDA has sent GSK a letter, attached hereto as Exhibit A, indicating that Mutual's Paragraph IV Notice "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." On

information and belief, the FDA has sent a similar letter to Mutual. Nevertheless, Mutual has refused to withdraw its ineffective Paragraph IV Notice.

5. Since Defendants' premature attempt to trigger the ANDA patent litigation process is in violation of federal law, this Court should declare their Paragraph IV Notice and attempts to trigger the ANDA litigation process improper and without legal effect.

6. In addition, because Defendants' proposed generic products would infringe United States Patent No. 7,268,156 (the "'156 patent"), the filing of a proper ANDA which is accepted for filing by the FDA is an act of infringement under 35 U.S.C. 271(e)(2). Accordingly, in the alternative, if the purported Paragraph IV Notification received by GSK is deemed sufficient by the court to trigger the deadline for GSK to sue Defendants under 21 U.S.C. § 355(j)(5)(B)(iii) and 21 C.F.R. § 314.107(b)(3), GSK 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.

PARTIES

7. Plaintiff SB Pharmco Puerto Rico, Inc. is a Puerto Rico corporation, with its principal place of business at 105 Ponce de Leon Avenue, Hato Rey, Puerto Rico 00917. Plaintiff SB Pharmco Puerto Rico, Inc. is a wholly owned subsidiary of GlaxoSmithKline PLC and does business as GlaxoSmithKline.

8. Plaintiff SmithKlineBeecham Corporation is a Pennsylvania corporation, with its principal place of business at One Franklin Plaza, Philadelphia, Pennsylvania. Plaintiff SmithKlineBeecham Corporation is a wholly owned subsidiary of GlaxoSmithKline PLC and does business as GlaxoSmithKline.

9. Upon information and belief, Mutual is a Pennsylvania corporation with its principal place of business at 1100 Orthodox Street, Philadelphia, Pennsylvania 19124.

10. Upon information and belief, URL is a Pennsylvania corporation with its principal place of business at 1100 Orthodox Street, Philadelphia, Pennsylvania 19124.

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction over this case pursuant to 28 U.S.C. § 1331 and 1338(a) (patent infringement), and 28 U.S.C. §§ 2201 and 2202 (declaratory judgment).

12. Venue is proper in this District under 28 U.S.C. §§ 1391(c) and 1400(b) as Mutual and URL are Pennsylvania corporations with regular and established places of business in this District and have committed acts of infringement in this District.

FACTUAL BACKGROUND

The Drug Approval Process

13. A company seeking to market a new pharmaceutical drug in the United States must first obtain approval from the FDA, typically through the filing of a New Drug Application ("NDA"). *See* 21 U.S.C. § 355(a). The sponsor of the NDA is required to submit information on all patents claiming the drug that is the subject of the NDA, or a method of using that drug, to the FDA, and the FDA then lists such patent information in its publication, the *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book." *See* 21 U.S.C. § 355(b)(1) and (c)(2).

14. A company seeking to market a generic version of a previously approved drug is not required to submit a full NDA. Instead, it may file an ANDA. *See* 21 U.S.C. § 355(j). The generic drug approval process is considered "abbreviated" because the generic manufacturer may

piggyback on and take advantage of the innovator company's data and the FDA's prior finding of safety and efficacy by demonstrating, among other things, that the generic product is bioequivalent to the previously approved drug (the "listed drug" or "branded drug").

15. In conjunction with this "abbreviated" application process, Congress has put in place a process for resolving patent disputes relating to generic drugs, pursuant to which an ANDA filer must provide certifications addressing each of the patents listed in the Orange Book for the branded drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12). An ANDA filer may certify that it believes a patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug for which the ANDA is submitted. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12)(i)(A)(4). This certification is known as a so-called "Paragraph IV Certification."

16. When an applicant submits an ANDA to the FDA, the FDA has 60 days to preliminarily review the application to ensure that it is sufficiently complete to permit substantive review. 21 C.F.R. § 314.101. Only after FDA notifies the applicant that its ANDA is substantially complete is the ANDA deemed to have been "received" or filed by FDA. Id.

17. The sponsor of an ANDA which is accepted for review by the FDA that contains a Paragraph IV Certification must provide notice to both the owner of the listed patent and the holder of the NDA for the reference listed drug. This "Paragraph IV Notice" must include a detailed statement of the factual and legal bases for the applicant's belief that the challenged patent is invalid or not infringed by the proposed generic product. 21 U.S.C. § 355(j)(2)(B); 21 C.F.R. § 314.95. The federal regulations specifically govern the timing of such Paragraph IV Notifications, by directing that the sending of such notices should occur after FDA has officially

received the ANDA as "sufficiently complete" for review. 21 U.S.C. § 355(j)(2)(B)(ii), 21 C.F.R. § 314.95(b).

18. If the patentee or NDA holder files a patent infringement action within 45 days of receiving a Paragraph IV Notice from an ANDA filer, final approval of the ANDA is generally subject to a 30-month stay. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(b)(3). The 30-month stay is important to innovator companies, such as GSK, because it protects them from the severe financial harm that could otherwise ensue from the FDA granting approval to a potentially infringing product without first providing an opportunity for the infringement case to be resolved. The innovator company is thus assured of a 30-month period during which it may try to enforce its intellectual property rights and resolve any patent dispute before the generic product enters the market. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

19. There are powerful incentives for generic companies to obtain the earliest possible filing date by jumping the gun with incomplete ANDA filings. The earliest ANDA filer may be entitled to 180 days of market exclusivity, during which time no other ANDA filer may come to market with a competing generic product. 21 U.S.C. § 355(j)(5)(B)(iv). By filing prematurely or notifying the NDA- or patent-holder prematurely, the first ANDA filer may also be able to manipulate the rules surrounding the 30-month stay to its advantage and reach the market sooner than would otherwise be permitted.

20. Accordingly, one of the important protections built into the ANDA process is that a generic applicant may not even send a Paragraph IV Notice until it "receives from the 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).

21. This safeguard makes simple common sense. Incomplete ANDAs risk burdening the judicial system with premature, and perhaps entirely unnecessary, patent infringement litigation. If the incomplete ANDA is never completed, forcing the parties and the courts to conduct infringement litigation will be unnecessary and generate unnecessary litigation costs. Even if the incomplete ANDA is eventually completed, the premature filing would prejudice not only the innovator company but also other ANDA filers. Accordingly, the ANDA applicant may not trigger the litigation process by serving a Paragraph IV Notice unless and until it has an ANDA on file that the FDA has accepted for substantive review.

GSK's COREG CR Product and the '156 Patent

22. COREG CR is a delayed release commercial formulation of carvedilol phosphate developed, manufactured, and sold by GSK. On December 21, 2005, GSK filed an NDA seeking FDA approval to market carvedilol phosphate extended release capsules for hypertension, myocardial infarction/heart attack, and heart failure (NDA 22-012). On October 20, 2006, the FDA approved NDA 22-012.

23. On September 11, 2007, the '156 patent, titled "Carvedilol Phosphate Salts and/or Solvates Thereof, Corresponding Compositions and/or Methods of Treatment," was duly and legally issued to Christopher S. Brook, Wei Chen, and Paul G. Spoors, and assigned on its face to SB Pharmco Puerto Rico Inc. A true and correct copy of the '156 patent is attached hereto as Exhibit B. The '156 patent claims a solvate of carvedilol phosphate, including the crystalline carvedilol dihydrogen phosphate hemihydrate compound and pharmaceutical composition sold as COREG CR, and methods of using this compound and pharmaceutical composition to treat a variety of heart ailments, including hypertension and congestive heart failure. The claims of the '156 patent are valid and enforceable. The '156 patent expires in 2023.

Defendants' ANDA Filings and Notice Letter

24. On November 19, 2007, Defendants submitted ANDA 90-132 (the "Defendants' ANDA") seeking approval from the FDA to market Carvedilol Phosphate Extended Release 80 mg capsules, a generic version of GSK's COREG CR product.

25. As of December 21, 2007, the FDA had not notified Defendants that Defendants' ANDA was sufficiently complete to be accepted for review.

26. Nevertheless, on December 21, 2007, Defendants filed an "amendment" to their not-yet-accepted ANDA, seeking approval to market Carvedilol Phosphate Extended Release 40 mg capsules (together with the 80 mg capsules, "Defendants' Carvedilol Phosphate Capsules"). The amendment contains a Paragraph IV Certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), alleging that GSK's patents related to COREG CR, including the '156 patent, are invalid or not infringed.

27. On December 21, 2007, Defendants sent GSK a Paragraph IV Notice, advising GSK of their assertion that GSK's patents, including the '156 patent, are invalid, unenforceable, or not infringed.

28. The FDA has sent GSK a letter, attached hereto as Exhibit A, indicating that Mutual's Paragraph IV Notice "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." On information and belief, the FDA has sent a similar letter to Mutual.

29. Plaintiff GSK has requested that Defendants withdraw their ineffective Paragraph IV Notice, but Defendants have refused.

30. This suit is being filed within 45 days of GSK's receipt of the Paragraph IV Notice.

COUNT I: DECLARATORY JUDGMENT

31. Plaintiffs incorporate each of the preceding paragraphs as if set forth fully herein.

32. At the time of its Paragraph IV Notification Letter, Defendants did not have an ANDA for COREG CR that had been accepted by the FDA as sufficiently complete for substantive review. Absent an ANDA that has been accepted by the FDA as sufficiently complete to permit substantive review, Defendants have no legitimate basis to trigger the ANDA patent litigation process.

33. As a consequence, Defendants' Paragraph IV Notice to GSK was improper, null, void, and without legal effect.

34. Plaintiff GSK has asked Defendants to withdraw the improper Paragraph IV Notice, but Defendants have refused.

35. An actual, substantial and justiciable controversy exists between Defendants, on the one hand, and GSK on the other hand regarding whether Defendants' Paragraph IV Notice was null, void, and without legal effect and, as a consequence, whether Defendants improperly triggered the ANDA litigation process.

36. The controversy concerning the validity and effectiveness of Defendants' Paragraph IV Notice will cause GSK to suffer substantial prejudice and unnecessary legal fees and costs unless the controversy and the surrounding cloud of uncertainty is resolved by the Court.

37. Accordingly, GSK is entitled to a declaration 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.

COUNT II: INFRINGEMENT OF '156 PATENT

38. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

39. Defendants' submission of Defendants' ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of Defendants' Carvedilol Phosphate Capsules prior to the expiration of the '156 patent constitutes infringement of one or more of the valid claims of the '156 patent under 35 U.S.C. § 271(e)(2)(A).

40. Defendants' commercial manufacture, use, offer to sell, sale, or importation of Defendants' Carvedilol Phosphate Capsules prior to the expiration of the '156 patent, or their inducement of or contribution to such conduct, would further infringe the '156 patent under 35 U.S.C. §§ 271(a), (b) and/or (c). Defendants' filing of Defendants' ANDA and their intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of Defendants' Carvedilol Phosphate Capsules upon receiving FDA approval, create an actual case or controversy with respect to infringement of the '156 patent.

41. Upon FDA approval of Defendants' ANDA, Defendants will infringe the '156 patent by making, using, offering to sell, selling, or importing Defendants' Carvedilol Phosphate

Capsules in the United States, and by actively inducing and contributing to infringement by others, unless enjoined by this Court.

42. GSK will be irreparably harmed if Defendants' infringement is not enjoined. GSK does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, GSK requests that the Court:

A. Preliminarily and permanently enjoin Defendants (1) to withdraw their improper and ineffective Notice Letter, and (2) to refrain from sending any new Notice Letters to GSK unless and until the FDA has notified Defendants that their ANDA is sufficiently complete to be deemed received for review;

B. Enter a declaratory judgment that: (1) Defendants' Paragraph IV Notices are 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 Notices 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 a new Paragraph IV Notice 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.

C. Enter a declaratory judgment that the '156 patent is valid and enforceable;

D. Enter a declaratory judgment that a claim or claims of the '156 patent are infringed by the manufacture, use, sale, offer for sale or importation of the Defendants' Carvedilol Phosphate Capsules, that Defendants' submission of Defendants' ANDA is an act of

infringement of the '156 patent, that Defendants' making, using, offering to sell, selling, or importing Defendants' Carvedilol Phosphate Capsules, and its inducement of such conduct by others, will infringe the '156 patent;

E. Order that the effective date of any approval of the Defendants' ANDA shall be a date which is not earlier than the expiration of the '156 patent and any additional period of exclusivity to which Plaintiffs are or become entitled;

F. An Order permanently enjoining Defendants and their affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from making, using, offering to sell, selling, or importing Defendants' Carvedilol Phosphate Capsules and from inducing such conduct by others, until after expiration of the '156 patent and any additional period of exclusivity to which Plaintiffs are or may become entitled;

G. Damages or other monetary relief to GSK if Defendants engage in the commercial manufacture, use, offer to sell, sale, or importation of Defendants' Carvedilol Phosphate Capsules, or in inducing such conduct by others, prior to the expiration of the '156 patent, and any additional period of exclusivity to which Plaintiffs are or become entitled, and that any such damages or monetary relief be trebled and awarded to GSK with prejudgment interest;

H. Reasonable attorneys fees, filing fees, and reasonable costs of suit incurred by GSK in this action; and

I. Such further and other relief as this Court deems proper and just.

Respectfully submitted,

SB Pharmco Puerto Rico, Inc, d/b/a GlaxoSmithKline and

SmithKlineBeecham Corporation, d/b/a GlaxoSmithKline

By their attorneys,

Date: February 4, 2008

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CERTIFICATE OF SERVICE

I, hereby, certify that today I caused the foregoing Complaint to be served via hand-delivery on the following counsel of record for the defendants.

Jacques Semmelman, Esq.
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Date: February 4, 2008

Joseph R. Heffern

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

SB PHARMCO PUERTO RICO, INC. d/b/a GLAXOSMITHKLINE, and SMITHKLINE BEECHAM CORP., d/b/a GLAXOSMITHKLINE Plaintiffs/Counterclaim-Defendants, v. MUTUAL PHARMACEUTICAL COMPANY, INC. and UNITED RESEARCH LABORATORIES, INC. Defendants/Counterclaim-Plaintiffs.	Civil Action No. 2:08-cv-549-RBS

ANSWER AND COUNTERCLAIMS OF DEFENDANTS MUTUAL PHARMACEUTICAL COMPANY, INC. AND UNITED RESEARCH LABORATORIES, INC. TO THE COMPLAINT OF SB PHARMCO PUERTO RICO, INC. AND SMITHKLINE BEECHAM CORP.

Defendants Mutual Pharmaceutical Company, Inc. ("Mutual") and United Research Laboratories, Inc. ("URL") (collectively, "Defendants"), by their undersigned attorneys, hereby answer the Complaint as follows:

1. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 1 of the Complaint, except deny having prematurely or improperly triggered any litigation process, and admit having filed an Abbreviated New Drug Application ("ANDA"). To the extent the allegations of paragraph 1 of the Complaint constitute conclusions of law, no response is required.

2. Defendants deny the allegations in paragraph 2 of the Complaint, except admit that as of December 21, 2007, their ANDA had not yet been accepted for filing by the

United States Food and Drug Administration ("FDA"). To the extent the allegations of paragraph 2 of the Complaint constitute conclusions of law, no response is required.

3. Defendants deny the allegations in paragraph 3 of the Complaint, except admit that on December 21, 2007, Defendants sent a letter to Plaintiffs providing notice pursuant to 21 U.S.C. §355(j)(2)(B)(ii)(II) ("Paragraph IV Notification"), which speaks for itself. To the extent the allegations of paragraph 3 of the Complaint constitute conclusions of law, no response is required.

4. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 4 of the Complaint, except admit that Defendants have declined to withdraw their Paragraph IV Notification, and that on or about February 8, 2008, Mutual received a letter from the FDA. To the extent the allegations of paragraph 4 of the Complaint constitute conclusions of law, no response is required.

5. Defendants deny the allegations in paragraph 5 of the Complaint. To the extent the allegations of paragraph 5 of the Complaint constitute conclusions of law, no response is required.

6. Defendants deny the allegations in paragraph 6 of the Complaint. To the extent the allegations of paragraph 6 of the Complaint constitute conclusions of law, no response is required.

7. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 7 of the Complaint.

8. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 8 of the Complaint.

9. Defendants admit the allegations in paragraph 9 of the Complaint.

10. Defendants admit the allegations in paragraph 10 of the Complaint.

11. Defendants admit the allegations in paragraph 11 of the Complaint, except as provided in paragraph 37 below.

12. Defendants deny the allegations in paragraph 12 of the Complaint, except admit that venue is proper in this district and that Mutual and URL are Pennsylvania corporations with places of business in this district.

13. Defendants deny the allegations in paragraph 13 of the Complaint as stated, except admit that certain statutes and regulations are in effect. To the extent the allegations of paragraph 13 of the Complaint constitute conclusions of law, no response is required.

14. Defendants deny the allegations in paragraph 14 of the Complaint as stated, except admit that certain statutes and regulations are in effect. To the extent the allegations of paragraph 14 of the Complaint constitute conclusions of law, no response is required.

15. Defendants deny the allegations in paragraph 15 of the Complaint as stated, except admit that certain statutes and regulations are in effect. To the extent the allegations of paragraph 15 of the Complaint constitute conclusions of law, no response is required.

16. Defendants deny the allegations in paragraph 16 of the Complaint as stated, except admit that certain statutes and regulations are in effect. To the extent the

allegations of paragraph 16 of the Complaint constitute conclusions of law, no response is required.

17. Defendants deny the allegations in paragraph 17 of the Complaint as stated, except admit that certain statutes and regulations are in effect. To the extent the allegations of paragraph 17 of the Complaint constitute conclusions of law, no response is required.

18. Defendants deny the allegations in paragraph 18 of the Complaint as stated, except admit that certain statutes and regulations are in effect. To the extent the allegations of paragraph 18 of the Complaint constitute conclusions of law, no response is required.

19. Defendants deny the allegations in paragraph 19 of the Complaint as stated, except admit that certain statutes and regulations are in effect. To the extent the allegations of paragraph 19 of the Complaint constitute conclusions of law, no response is required.

20. Defendants deny the allegations in paragraph 20 of the Complaint as stated, except admit that certain statutes and regulations are in effect. To the extent the allegations of paragraph 20 of the Complaint constitute conclusions of law, no response is required.

21. Defendants deny the allegations in paragraph 21 of the Complaint as stated, except admit that certain statutes and regulations are in effect. To the extent the allegations of paragraph 21 of the Complaint constitute conclusions of law, no response is required.

22. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 22 of the Complaint.

23. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 23 of the Complaint, except deny that the '156 patent was duly and legally issued, and deny that the claims of the '156 patent are valid and enforceable. To the extent the allegations of paragraph 23 of the Complaint constitute conclusions of law, no response is required.

24. Defendants deny the allegations in paragraph 24 of the Complaint as stated, except admit that on November 19, 2007, Defendants filed ANDA No. 90-132, which speaks for itself.

25. Defendants admit the allegations in paragraph 25 of the Complaint.

26. Defendants deny the allegations in paragraph 26 of the Complaint as stated, except admit that on December 21, 2007, Defendants filed an amendment to ANDA 90-132, which speaks for itself.

27. Defendants deny the allegations in paragraph 27 as stated, except admit that on December 21, 2007, Defendants sent Plaintiffs a Paragraph IV Notification, which speaks for itself.

28. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 23 of the Complaint, except admit that on or about February 8, 2008, Mutual received a letter from the FDA.

29. Defendants deny the allegations in paragraph 29, except admit that Plaintiffs have requested that Defendants withdraw their Paragraph IV Notification, and that Defendants have declined to do so.

30. Defendants admit the allegations in paragraph 30.

31. Defendants incorporate by reference their answers to paragraphs 1-30 of the Complaint.

32. Defendants deny the allegations in paragraph 32 of the Complaint, except admit that at the time Defendants delivered their Paragraph IV Notification to Plaintiffs, the Defendants' ANDA for Carvedilol Phosphate Extended Release 80 mg Capsules had not yet been accepted for filing by the FDA. To the extent the allegations of paragraph 32 of the Complaint constitute conclusions of law, no response is required.

33. Defendants deny the allegations in paragraph 33 of the Complaint.

34. Defendants deny the allegations in paragraph 34 of the Complaint, except admit that Plaintiffs have requested that Defendants withdraw their Paragraph IV Notification, and that Defendants have declined to do so.

35. Defendants deny the allegations in paragraph 35 of the Complaint, except admit that an actual, justiciable controversy exists between Defendants on the one hand and Plaintiffs on the other hand. To the extent the allegations of paragraph 35 of the Complaint constitute conclusions of law, no response is required.

36. Defendants deny the allegations in paragraph 36 of the Complaint. To the extent the allegations of paragraph 36 of the Complaint constitute conclusions of law, no response is required.

37. Defendants deny the allegations in paragraph 37 of the Complaint, and further deny that the Court has jurisdiction to issue the relief requested in subparagraphs (4) and (5). To the extent the allegations of paragraph 37 of the Complaint constitute conclusions of law, no response is required.

38. Defendants incorporate by reference their answers to paragraphs 1-37 of the Complaint.

39. Defendants deny the allegations in paragraph 39 of the Complaint.

40. Defendants deny the allegations in paragraph 40 of the Complaint, except admit that there is an actual, justiciable controversy. To the extent the allegations of paragraph 40 of the Complaint constitute conclusions of law, no response is required.

41. Defendants deny the allegations in paragraph 41 of the Complaint.

42. Defendants deny the allegations in paragraph 42 of the Complaint.

FIRST AFFIRMATIVE DEFENSE

The '156 patent is invalid for failing to meet one or more of the requisite Conditions of Patentability specified in 35 U.S.C. §§ 102, 103, 112, and/or the judicial doctrine of double-patenting.

COUNTERCLAIMS

Jurisdiction

1. This is an action for Declaratory Relief, over which this court has jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338, and 2201.

2. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400.

Parties

3. Counterclaim Plaintiffs Mutual Pharmaceutical Co., Inc. ("Mutual") and United Research Laboratories, Inc. ("URL") are corporations incorporated under the laws of the state of Pennsylvania, having places of business at 1100 Orthodox Street, Philadelphia, Pennsylvania 19124.

4. Upon information and belief, Counterclaim Defendant SmithKlineBeecham Corporation is a Pennsylvania corporation, with its principal place of business at One Franklin Plaza, Philadelphia, Pennsylvania.

5. Upon information and belief, Counterclaim Defendant SB Pharmco Puerto Rico, Inc. is a Puerto Rico corporation, with its principal place of business at 105 Ponce de Leon Avenue, Hato Rey, Puerto Rico.

6. SmithKlineBeecham Corporation and SB Pharmco Puerto Rico, Inc. are collectively referred to herein as "GSK," "Plaintiffs," or "Counterclaim Defendants."

First Counterclaim
(Declaratory Judgment of Invalidity)

7. Counterclaim Plaintiffs incorporate by reference their allegations in paragraphs 1-6 above.

8. GSK has asserted that Counterclaim Plaintiffs have infringed and are infringing the '156 patent.

9. There is an actual, justiciable controversy between the parties concerning the validity of the '156 patent.

10. The '156 patent is invalid for failure to meet the Conditions of Patentability specified in 35 U.S.C. §§ 102, 103, 112, and/or the judicial doctrine of double-patenting.

11. Accordingly, Counterclaim Plaintiffs are entitled to a judgment declaring the '156 patent invalid.

PRAYER FOR RELIEF

WHEREFORE, Defendants-Counterclaim Plaintiffs respectfully request that this Court enter judgment in their favor and against Plaintiffs-Counterclaim Defendants, as follows:

(a) Dismissing the Complaint with prejudice and denying each request for relief made by Plaintiffs;

(b) Declaring the '156 patent invalid;

(c) Awarding Defendants-Counterclaimants' reasonable attorneys' fees under 35 U.S.C. § 285;

(d) Awarding costs to Defendants-Counterclaimants; and

(e) Awarding such other and further relief as the Court deems just and proper.

Dated: Philadelphia, Pennsylvania
February 25, 2008

/s/ James J. Rodgers- JR797
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Attorneys for Defendants Mutual Pharmaceutical Company, Inc. and United Research Laboratories, Inc.

CERTIFICATE OF SERVICE

I hereby certify that I caused the foregoing pleading to be served upon counsel for Plaintiff through the court's ECF system, as well as by first class mail addressed to:

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JR 797
James D. Rodgers

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

SB PHARMCO PUERTO RICO, INC. d/b/a GLAXOSMITHKLINE, and SMITHKLINE BEECHAM CORP., d/b/a GLAXOSMITHKLINE	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 08-cv-549**
MUTUAL PHARMACEUTICAL COMPANY, INC. and UNITED RESEARCH LABORATORIES, INC.	)	
Defendants.	)	

GLAXOSMITHKLINE'S REPLY TO MUTUAL PHARMACEUTICAL COMPANY, INC. AND UNITED RESEARCH LABORATORIES, INC.'S ANSWER AND COUNTERCLAIM

Plaintiffs SB Pharmco Puerto Rico, Inc. and SmithKlineBeecham Corporation, both doing business as GlaxoSmithKline (hereafter "GSK"), respond to the Answer and Counterclaim by Defendants Mutual Pharmaceutical Company, Inc. (hereafter "Mutual") and United Research Laboratories, Inc. (hereafter "URL"; collectively, "Defendants"), as follows:

COUNTERCLAIMS

Jurisdiction

1. Counterclaim Paragraph 1 does not contain allegations of fact requiring an answer from GSK. To the extent that an answer is deemed required, GSK denies that this Court has jurisdiction to grant the Declaratory Relief sought in the Counterclaim.

2. Counterclaim Paragraph 2 does not contain allegations of fact requiring an answer from GSK. To the extent that an answer is deemed required, GSK admits that venue would be

proper in this Court pursuant to 28 U.S.C. § 1391 for proper claims of the kind alleged by Defendants if the Court had jurisdiction. Except as expressly admitted, GSK denies the allegations set forth in Counterclaim Paragraph 2.

Parties

3. Admitted.

4. Admitted.

5. Admitted.

6. Counterclaim Paragraph 6 does not contain allegations of fact requiring an answer from GSK. To the extent that an answer is deemed required, GSK admits the allegations set forth in Counterclaim Paragraph 6.

First Counterclaim
(Declaratory Judgment of Invalidity)

7. GSK repeats and reasserts all responses to Counterclaim Paragraphs 1-6 as if they were stated in full herein.

8. GSK denies the allegations in Counterclaim Paragraph 8, except to admit that GSK has filed an action seeking a declaration that Defendants have not sent a valid Paragraph IV Notice, and said action includes an alternative claim for patent infringement against Defendants.

9. GSK denies the allegations set forth in Counterclaim Paragraph 9.

10. GSK denies the allegations set forth in Counterclaim Paragraph 10.

11. GSK denies the allegations set forth in Counterclaim Paragraph 11.

PRAYER FOR RELIEF

GSK denies that Defendants are entitled to any relief whatsoever, either as contained in Defendants' Answer and Counterclaim or otherwise.

FIRST AFFIRMATIVE DEFENSE

This Court lacks jurisdiction to consider Defendants' Counterclaim.

Respectfully submitted,

SB Pharmco Puerto Rico, Inc, d/b/a GlaxoSmithKline and

SmithKlineBeecham Corporation, d/b/a GlaxoSmithKline

By their attorneys,

/s/ Joseph R. Heffern

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Dated: March 17, 2008

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

SB PHARMCO PUERTO RICO, INC. d/b/a GLAXOSMITHKLINE, and SMITHKLINE BEECHAM CORP., d/b/a GLAXOSMITHKLINE	)	
Plaintiffs,	)	
v.	)	**Civ. A. No. 08-549-RBS**
MUTUAL PHARMACEUTICAL COMPANY, INC. and UNITED RESEARCH LABORATORIES, INC.	)	
Defendants.	)	

CERTIFICATE OF SERVICE

I, hereby, certify that today I caused the foregoing to be served via ECF, first class mail and e-mail on the following counsel for the defendants.

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/s/ Joseph R. Heffern
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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SB PHARMCO PUERTO RICO, INC. d/b/a GLAXOSMITHKLINE, and SMITHKLINE BEECHAM CORP., d/b/a GLAXOSMITHKLINE **Plaintiffs** **v.** **MUTUAL PHARMACEUTICAL COMPANY, INC. and UNITED RESEARCH LABORATORIES, INC.** **Defendants**	**Civil Action No. 08-cv-00549**

ORDER

AND NOW, this ____ day of _____, 2008, upon consideration of the Motion of plaintiffs SB Pharmco Puerto Rico, Inc. and SmithKlineBeecham Corporation's ("Plaintiffs") for Judgment on the Pleadings and any response thereto, it is hereby ORDERED:

1. That the Motion is GRANTED with regard to Count I.

2. That Plaintiffs' alternative count (Count II) is hereby be DISMISSED WITHOUT PREJUDICE.

3. That the counterclaim by defendants Mutual Pharmaceutical Company and United Research Laboratories, Inc. against plaintiffs is hereby DISMISSED WITHOUT PREJUDICE.

Surrick, J.

UNITED STATES DISTRICT JUDGE

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

SB PHARMCO PUERTO RICO, INC. d/b/a GLAXOSMITHKLINE, and SMITHKLINE BEECHAM CORP., d/b/a GLAXOSMITHKLINE **Plaintiffs** **v.** **MUTUAL PHARMACEUTICAL COMPANY, INC. and UNITED RESEARCH LABORATORIES, INC.** **Defendants**	**Civil Action No. 08-cv-00549**

MOTION FOR JUDGMENT ON THE PLEADINGS

Pursuant to Fed. R. Civ. P. 12(c), plaintiffs SB Pharmco Puerto Rico, Inc. and SmithKlineBeecham Corporation, both doing business as GlaxoSmithKline (hereafter "GSK"), hereby move for judgment on the pleadings on Count I against defendants Mutual Pharmaceutical Company and United Research Laboratories, Inc. ("Defendants") because defendants' Paragraph IV notice was improper, null, void, and without legal effect.

Because plaintiffs are entitled to judgment on Count I, Plaintiff's alternative count should be dismissed without prejudice and the Defendants' declaratory counterclaim should be dismissed for lack of subject matter jurisdiction or in the exercise of the Court's discretion. Plaintiffs' Motion is supported by the attached Memorandum of Law.

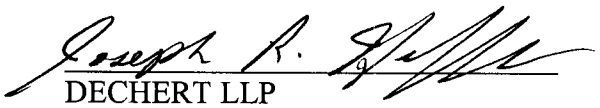
Respectfully submitted,

SB Pharmco Puerto Rico, Inc, d/b/a GlaxoSmithKline and

SmithKlineBeecham Corporation, d/b/a GlaxoSmithKline

By their attorneys,

Date: March 19, 2008



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IN THE UNITED STATES DISTRICT COURT
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SB PHARMCO PUERTO RICO, INC. d/b/a GLAXOSMITHKLINE, and SMITHKLINE BEECHAM CORP., d/b/a GLAXOSMITHKLINE **Plaintiffs** **v.** **MUTUAL PHARMACEUTICAL COMPANY, INC. and UNITED RESEARCH LABORATORIES, INC.** **Defendants**	**Civil Action No. 08-cv-00549**

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION FOR JUDGMENT ON THE PLEADINGS

Plaintiffs SB Pharmco Puerto Rico, Inc. and SmithKlineBeecham Corporation, both doing business as GlaxoSmithKline (hereafter "GSK"), submit this memorandum in support of their motion for judgment on the pleadings against defendants Mutual Pharmaceutical Company and United Research Laboratories, Inc. ("Defendants").

GSK seeks to prevent Defendants' improper and unlawful attempt to trigger the litigation process that Congress has carefully constructed for resolving patent disputes between branded and generic drug manufacturers. Federal law prohibits a generic drug manufacturer from triggering that litigation process unless and until the United States Food and Drug Administration ("FDA") informs that company that its Abbreviated New Drug Application ("ANDA") has been accepted for filing. Here, Defendants' Answer admits that their ANDA had not been accepted for filing when they triggered this litigation process. Accordingly, for the reasons set forth below, GSK respectfully requests judgment on the pleadings as to Count I of

the Complaint, that its alternative count of patent infringement be dismissed without prejudice and that the Defendants' declaratory judgment counterclaim likewise be dismissed without prejudice.

BACKGROUND

I. The ANDA Litigation Process

A company seeking to market a new pharmaceutical drug in the United States must first obtain approval from the FDA, typically through the filing of a New Drug Application ("NDA"). *See* 21 U.S.C. § 355(a); Complaint at ¶ 13. The sponsor of the NDA is required to submit information on all patents claiming the drug that is the subject of the NDA, or a method of using that drug, to the FDA, and the FDA then lists such patent information in its publication, the *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book." *See* 21 U.S.C. § 355(b)(1) and (c)(2); Complaint at ¶ 13.

A company seeking to market a generic version of a previously approved drug is not required to submit a full NDA. Instead, it may file an ANDA. *See* 21 U.S.C. § 355(j); Complaint at ¶ 14. The generic drug approval process is considered "abbreviated" because the generic manufacturer may take advantage of the innovator company's data and the FDA's prior finding of safety and efficacy by demonstrating, among other things, that the generic product is bioequivalent to the branded drug. Complaint at ¶ 14.

In conjunction with this "abbreviated" application process, Congress has put in place a process for resolving patent disputes relating to generic drugs, pursuant to which an ANDA filer must provide certifications addressing each of the patents listed in the Orange Book for the branded drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12); Complaint at ¶ 15. An ANDA filer may certify that it believes a patent is invalid or will not be infringed by the

manufacture, use, or sale of the generic drug for which the ANDA is submitted. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12)(i)(A)(4); Complaint at ¶ 15. This certification is known as a "Paragraph IV Certification."

When an applicant submits an ANDA to the FDA, the FDA has 60 days to preliminarily review the application to ensure that it is sufficiently complete to permit substantive review. 21 C.F.R. § 314.101; Complaint at ¶ 16. Only after FDA notifies the applicant that its ANDA is sufficiently complete is the ANDA deemed to have been filed. 21 C.F.R. § 314.101; Complaint at ¶ 16.

The sponsor of an ANDA that is accepted for review by the FDA and contains a Paragraph IV Certification must provide notice to both the owner of the listed patent and the holder of the NDA for the reference listed drug. This "Paragraph IV Notice" must include a detailed statement of the factual and legal bases for the applicant's belief that the challenged patent is invalid or not infringed by the proposed generic product. 21 U.S.C. § 355(j)(2)(B); 21 C.F.R. § 314.95; Complaint at ¶ 17. The federal regulations specifically govern the timing of such Paragraph IV Notices by directing that the sending of such notices should occur after FDA has officially received the ANDA as "sufficiently complete" for review. 21 U.S.C. § 355(j)(2)(B)(ii), 21 C.F.R. § 314.95(b); Complaint at ¶ 17.

If the patentee or NDA holder files a patent infringement action within 45 days of receiving a Paragraph IV Notice from an ANDA filer, final approval of the ANDA is generally subject to a 30-month stay. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(b)(3); Complaint at ¶ 18. The 30-month stay is important to innovator companies, such as GSK, because it protects them from the severe financial harm that could otherwise ensue from the FDA granting approval to a potentially infringing product without first providing an opportunity for

the infringement case to be resolved. The innovator company is thus assured of a 30-month period during which it may litigate to enforce its intellectual property rights and resolve any patent dispute before the generic product enters the market. *See* 21 U.S.C. § 355(j)(5)(B)(iii); Complaint at ¶ 18.

There are powerful incentives for generic companies to obtain the earliest possible filing date by jumping the gun with incomplete ANDA filings. Complaint at ¶ 19. The earliest ANDA filer may be entitled to 180 days of market exclusivity, during which time no other ANDA filer may come to market with a competing generic product. 21 U.S.C. § 355(j)(5)(B)(iv); Complaint at ¶ 19. By filing prematurely or notifying the NDA- or patent-holder prematurely, the first ANDA filer may also seek to manipulate the rules surrounding the 30-month stay to its advantage and reach the market sooner than would otherwise be permitted. Complaint at ¶ 19. Likewise, improper notification would unnecessarily force the NDA- or patent-holder to incur the significant costs associated with a patent infringement litigation that may never be necessary, because the FDA may not ever accept the ANDA for filing. *Id.*

Accordingly, one of the important protections built into the ANDA process is that a generic applicant may not send a Paragraph IV Notice until it "receives from the 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); Complaint at ¶ 20. This safeguard makes sense. Serving a Paragraph IV Notice based on an incomplete ANDA burdens the judicial system with premature—and perhaps entirely unnecessary—patent infringement litigation. If the incomplete ANDA is never completed, forcing the parties and the courts to conduct infringement litigation will be unnecessary and generate unnecessary litigation costs. Even if the incomplete ANDA is eventually completed, the premature filing would prejudice not only the innovator

company but also other ANDA filers (whose rights to exclusivity may be compromised). Accordingly, the ANDA applicant may not trigger the litigation process by serving a Paragraph IV Notice unless and until it has an ANDA on file that the FDA has accepted for substantive review. Complaint at ¶ 21.

II. MUTUAL'S UNFILED ANDA AND PREMATURE PARAGRAPH IV NOTICE

There is no dispute over the material facts surrounding Defendants' unfiled ANDA and premature notice. On November 19, 2007, Defendants submitted ANDA 90-132, seeking approval from the FDA to market Carvedilol Phosphate Extended Release 80 mg capsules, a generic version of GSK's COREG CR product. Complaint at ¶ 24, Answer at ¶ 24. Subsequently, on December 21, 2007, Defendants submitted an "amendment" to their ANDA, seeking approval to market generic COREG CR. Complaint at ¶ 26, Answer at ¶ 26. The amendment contained a Paragraph IV Certification and alleged that GSK's patents related to COREG CR are invalid or not infringed. Complaint at ¶ 26, Answer at ¶ 26. Also on December 21, 2007, Defendants sent a purported "Paragraph IV Notice" to GSK regarding the amendment. Complaint at ¶ 27, Answer at ¶ 27. At the time Defendants sent their Paragraph IV Notice in connection with the "amendment," their ANDA had not been accepted for filing by the FDA. Complaint at ¶¶ 2, 25, 32, Answer at ¶¶ 2, 25, 32.

The FDA has sent GSK a letter indicating stating that:

> 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 acknowledgement 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 5-505(j)(5)(B)(iii) of the Act, ***or the beginning of the 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.***

Letter of Gary J. Buehler, Director, Office of Generic Drugs, Center for Drug Evaluation and Research, FDA to William Zoffer of GSK, February 4, 2008 (attached as Exhibit A to Complaint) (emphasis supplied). Mutual has nevertheless refused to withdraw its ineffective Paragraph IV Notice. Complaint at ¶¶ 4, 29, 34, Answer at ¶¶ 4, 29, 34.[1]

LEGAL STANDARD

Judgment on the pleadings should be granted where, as here, all pleadings are closed, and "no material issue of fact remains to be resolved and that [the moving party] is entitled to judgment as a matter of law." *Jablonski v. Pan American World Airways, Inc.*, 863 F.2d 289, 290-291 (3d Cir. 1988) (citing *Society Hill Civic Association v. Harris*, 632 F.2d 1045, 1054 (3d Cir. 1980) (citation omitted)). In resolving such a motion, all factual assertions are taken as true, and all reasonable inferences are drawn in favor of the non-moving party. *See* Fed. R. Civ. P. 12(c); *Jablonski*, 863 F.2d at 290-291; *DeFiore v. Vignola*, 823 F. Supp. 315, 316 (E.D. Pa. 1993).

ARGUMENT

I. THE COURT SHOULD ENTER JUDGMENT ON THE PLEADINGS THAT DEFENDANTS IMPROPERLY TRIGGERED THE ANDA LITIGATION PROCESS.

This case arises from Defendants' premature and improper attempt to trigger the ANDA litigation process by sending GSK a Paragraph IV Notice ***before*** Defendants' ANDA was accepted for filing by the FDA. In the face of federal law requiring that such notices cannot be sent until ***after*** the FDA has accepted the ANDA for filing, Defendants nevertheless sent their

[1] On March 17, Defendants provided GSK with a notice from the FDA indicating that the FDA has accepted Defendants' ANDA for filing. On March 18, GSK received a new Paragraph IV Notice from the Defendants. Defendants thus appear to concede that their first notice was not compliant with the rules of the statute. With the receipt of the second notice, GSK now has 45 days to consider whether to bring a Hatch Waxman action and on what patents.

Paragraph IV Notice. Upon being directly told by the FDA that this notice was invalid and ineffective and that a new notice would need to be filed if and when its ANDA is accepted for filing by the FDA, Defendants still refused to withdraw their improper notice. Accordingly, GSK filed this suit to obtain a judicial declaration that Defendants' notice is improper, and that the ANDA litigation process, including GSK's 45 day window to sue, should not begin, until proper notice has been provided. Complaint, Count I (¶¶ 31-37).[2]

There is only one material fact needed to establish that this relief is proper— Defendants' ANDA had not been accepted for filing at the time Defendants served the Paragraph IV Notice at issue. Indeed, Defendants have admitted in their Answer that, at the time they sent the Paragraph IV Notice, the ANDA "had not yet been accepted for filing by the FDA." Answer at ¶32.

The consequences of this admission are clear, unavoidable, and dispositive of this entire case. An ANDA is not deemed "filed" simply when an applicant labels a document as an ANDA and delivers it to the FDA. Rather, under federal regulation, "[w]ithin 60 days after FDA receives an application, ***the agency will determine whether the application may be filed.***" 21 C.F.R. § 314.101 (emphasis added). A Paragraph IV Notice may only be sent ***after*** the FDA provides "an acknowledgment letter stating that [the ANDA] is sufficiently complete to permit a substantive review." 21 C.F.R. § 314.95(b); *see also* 21 U.S.C. § 355(j)(2)(B)(ii)(I) (Paragraph

---

[2] Count I of GSK's Complaint seeks a 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.

Complaint, ¶ 37. GSK also pled in the alternative a claim of patent infringement (Count II).

IV Notice to be sent "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"). Because no ANDA had yet been accepted as filed by the FDA, Defendants' purported Paragraph IV Notice was improper and invalid.

Defendants attempt to avoid this conclusion by referring only to the part of the statute concerning Paragraph IV Notices that accompany amendments. *See* Answer ¶ 3 (citing 21 U.S.C. §355(j)(2)(B)(ii)(II)). By citing only to subsection (II), Defendants apparently suggest that the statute permits them to amend an ANDA that has not yet been accepted for filing, and then send out a Paragraph IV Notice based on the amendment, even though the law expressly forbids such a notice based on the underlying (and not yet filed) ANDA. Such a reading of the statute is directly contrary to Congress's clearly expressed intent that a notice is not to be sent until after the ANDA has been accepted as filed. *See* 21 U.S.C. § 355(j)(2)(B)(ii)(I); 21 C.F.R. § 314.95(b).[3] Indeed, as the FDA recognized in the preamble to the final regulations, "[t]o permit an ANDA applicant to provide notice before FDA has determined that the ANDA is substantially complete would be contrary to the legislative history because it would only encourage ANDA applicants to file incomplete or 'sham' ANDAs and to supplement them later to secure a place in the review queue in an attempt to secure the first ANDA approval." 59 Fed. Reg. 50338, 50350 (Oct. 3, 1994), citing H. Rep. 857, 98th Cong. 2d. Sess. 24 (1984) (Congress

[3] The entire relevant section of the statute makes clear that Congress intended notices to be sent after the FDA had deemed the application filed:

> (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.

21 U.S.C. § 355(j)(2)(B)(ii); *see also* FDA Letter of Feb. 4 at 2, n.1 (Ex. A to Complaint) (noting that amendment provision applies to ANDAs that have already been accepted as filed under 21 C.F.R. 314.101.).

did "not intend that applicants be permitted to circumvent this notice requirement by filing sham ANDA's or ANDA's which are substantially incomplete.").

In this case, the FDA did not notify the Defendants that the ANDA had been accepted for filing before Defendants sent a Paragraph IV Notification. Rather, the FDA notified them that their Paragraph IV Notice was invalid and ineffective:

> 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 acknowledgement 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 5-505(j)(5)(B)(iii) of the Act, ***or the beginning of the 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.***

Letter of Gary J. Buehler, Director, Office of Generic Drugs, Center for Drug Evaluation and Research, FDA to William Zoffer of GSK, February 4, 2008 (attached as Exhibit A to Complaint) (emphasis supplied). Further, the FDA stated that "Congress did not intend that incomplete application submissions would trigger legal action by a patent owner or NDA holder." *Id.*

The absence of a filed ANDA before the sending of a Paragraph IV Notification also mandates dismissal of GSK's alternative patent infringement claim and Defendants' counterclaim. GSK's alternative count is unnecessary and should be dismissed because there was no filed ANDA and no proper Paragraph IV Notification. Likewise, because 45 days have not elapsed since a valid Paragraph IV notice, the Defendants have no right to commence a declaratory judgment action. 35 U.S.C. §271(e)(5). Even if Defendants had such a right, the Court should exercise is discretion and decline to entertain a declaratory judgment claim in light of Defendants' transparent attempt to circumvent the statutory scheme.

Defendants' assertion in their Answer at ¶ 37 that the Court lacks jurisdiction to grant certain of the relief requested in Count I is without merit. First, Defendants appear to concede, as they must, that the Court has jurisdiction to grant the relief in parts (1) through (3) of Count I. These issues go directly to whether this Court has jurisdiction over the ANDA litigation Defendants have improperly attempted to trigger. A federal court has jurisdiction to determine facts necessary to decide its own jurisdiction. *See, e.g., Chicot County Drainage Dist. v. Baxter State Bank* 308 U.S. 371, 376 (1940).

In any event, cases in which courts have determined that they lack jurisdiction to enforce certain provisions of the Hatch-Waxman Act are distinguishable from the facts here. For example, in *Minnesota Mining and Mfg. Co. v. Barr Lab.*, 289 F.3d 775, 784 (Fed. Cir. 2002) ("*3M*"), the United States Court of Appeals for the Federal Circuit held that certain claims about the contents of a Paragraph IV Notice should be directed against the FDA in a suit under the Administrative Procedure Act ("APA"). Unlike in this case, however, *3M* involved a situation in which the FDA had not yet addressed the alleged deficiencies of the Paragraph IV Notice. In fact, the *3M* opinion expressly distinguishes circumstances such as this case, in which the FDA has already determined that the Paragraph IV Notice is deficient. *See id.* ("[W]e do not decide whether, if the FDA had determined that Barr did not satisfy the paragraph IV notice requirement, this would have entitled 3M to a dismissal without prejudice in the infringement suit").[4] Here, the FDA has expressly determined that the Paragraph IV Notice is deficient, but the Defendants simply refuse to withdraw it. As such, this Court is the proper forum for GSK to

[4] Here, unlike in *3M*, an APA action against the FDA would not be a feasible alternative for GSK. The FDA has already rendered a decision that is ***consistent*** with the outcome GSK seeks – i.e., a finding that the Paragraph IV Notice is deficient.

obtain the remedy it seeks. For the reasons described above GSK respectfully requests that the Court enter the declaratory relief sought in Count I of the Complaint.

II. ALL REMAINING CLAIMS SHOULD BE DISMISSED WITHOUT PREJUDICE AS PREMATURE AND UNRIPE.

For the reasons set forth above, if and when this Court enters judgment on the pleadings as to Count I, all remaining claims in this case should be dismissed without prejudice. Even though Defendants' ANDA is now approved for filing and Defendants have sent a new Paragraph IV Notice, the prior Notice cannot be used to initiate the ANDA litigation process. Under these circumstances, this Court lacks jurisdiction to consider infringement and validity.

CONCLUSION

For the reasons set forth above, GSK respectfully requests that the Court enter judgment on the pleadings as to Count I and dismiss the other claims without prejudice.

Respectfully submitted,

SB Pharmco Puerto Rico, Inc, d/b/a GlaxoSmithKline and

SmithKlineBeecham Corporation, d/b/a GlaxoSmithKline

By their attorneys,

Date: March 19, 2008

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Plaintiffs,	)	
v.	)	**Civ. A. No. 08-549-RBS**
MUTUAL PHARMACEUTICAL COMPANY, INC. and UNITED RESEARCH LABORATORIES, INC.	)	
Defendants.	)	

CERTIFICATE OF SERVICE

I, hereby, certify that today I caused the foregoing to be served via ECF, first class mail and e-mail on the following counsel for the defendants.

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Date: March 19, 2008

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

SB PHARMCO PUERTO RICO, INC. d/b/a GLAXOSMITHKLINE, and SMITHKLINE BEECHAM CORP. d/b/a GLAXOSMITHKLINE, Plaintiffs/Counterclaim-Defendants, v. MUTUAL PHARMACEUTICAL COMPANY, INC. and UNITED RESEARCH LABORATORIES, INC., Defendants/Counterclaim-Plaintiffs.	Civil Action No. 2:08-cv-549-RBS

DEFENDANTS-COUNTERCLAIMAINTS' MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION FOR JUDGMENT ON THE PLEADINGS AND IN SUPPORT OF THEIR CROSS-MOTION FOR LEAVE TO AMEND THEIR ANSWER AND COUNTERCLAIM TO REFLECT FDA FILING ACCEPTANCE

Defendants-Counterclaimants Mutual Pharmaceutical Company, Inc. and United Research Laboratories, Inc. (collectively "URL Mutual") respectfully submit this Memorandum of Law in opposition to the motion for judgment on the pleadings filed pursuant to Fed. R. Civ. P. 12(c) by SB Pharmco Puerto Rico, Inc., d/b/a GlaxoSmithKline, and SmithKline Beecham Corp., d/b/a GlaxoSmithKline (collectively "GSK"), and in support of URL Mutual's cross-motion, pursuant to Fed. R. Civ. P. 15(a), for leave to amend their answer and counterclaim to reflect FDA filing acceptance received March 17, 2008.

Introduction

GSK's motion for judgment on the pleadings (which is in essence a motion to dismiss without prejudice GSK's own claim for patent infringement, as well as URL Mutual's

counterclaim for patent invalidity) confuses two separate and distinct issues: (a) whether this Court has subject matter jurisdiction over the patent infringement claim and the patent invalidity counterclaim; and (b) the *timing* of the expiration of the statutory stay of (up to) 30 months, to which GSK is entitled by virtue of filing this lawsuit.

These two issues should be analyzed and decided separately. As shown below, this Court has subject matter jurisdiction over the patent infringement claim and the patent invalidity counterclaim. This is so *irrespective* of whether the statutory stay began on February 4, 2008, when GSK filed its complaint, 45 days after URL Mutual served GSK with a Paragraph IV notice, or whether the statutory stay will only begin on May 1, 2008, 45 days after the FDA issued filing acceptance.

GSK's motion for judgment on the pleadings should be denied, and URL Mutual's cross-motion for leave to amend its answer and counterclaim should be granted.

Statement Of Facts

On November 19, 2007, URL Mutual filed Abbreviated New Drug Application No. 90-132 (the "ANDA") for Carvedilol Phosphate Extended Release 80 mg Capsules with the U.S. Food and Drug Administration ("FDA"). (Complaint ¶ 24) The ANDA contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV"), that, inter alia, one of GSK's patents related to COREG CR, United States Patent No. 7,268,156 (the "'156 Patent"), is invalid, unenforceable, and/or not infringed by the manufacture, use, or sale of the generic drug for which the ANDA is submitted. (Complaint ¶ 24)

On December 21, 2007, while awaiting FDA filing acceptance of the ANDA, URL Mutual filed an amendment to ANDA 90-132 for Carvedilol Phosphate Extended Release 40 mg Capsules. The amendment contains a Paragraph IV certification, inter alia, that the '156

Patent is invalid, unenforceable, and/or not infringed by the manufacture, use, or sale of the generic drug for which the amendment is submitted. (Complaint ¶ 26)

Concurrently with the filing of the amendment, URL Mutual sent a Paragraph IV notice letter to GSK (the "December 21 Paragraph IV Notice") pursuant to 21 U.S.C. § 355(j)(2)(B)(ii)(II). That statute requires an ANDA applicant to provide Paragraph IV notice to the patentee if the ANDA applicant has filed an amendment. By its terms, the statute applies irrespective of whether the ANDA has been accepted by the FDA for filing.

The December 21 Paragraph IV Notice explicitly informed GSK that "Mutual has filed *(but FDA has not yet accepted)* Abbreviated New Drug Application . . . No. 90-132 . . ." (Emphasis added). (Complaint ¶ 27)

The service of the December 21 Paragraph IV Notice triggered a 45-day statutory period during which GSK had the right – but not the obligation – to file a complaint against URL Mutual for patent infringement, and, by so doing, obtain certain statutory benefits, notably a stay of FDA approval of the ANDA for up to 30 months. *See* 21 U.S.C. § 355(i)(5)(B)(iii).

GSK waited until February 4, 2008 – exactly 45 days from the December 21 Paragraph IV Notice – to file a complaint for patent infringement. GSK's complaint seeks a declaratory judgment that the '156 Patent is valid and enforceable, and that URL Mutual has infringed the '156 Patent, as well as an injunction prohibiting URL Mutual from further infringing the '156 Patent. (Complaint ¶¶ 38-42)

Prior to filing its complaint, GSK made no effort to secure a judicial determination as to the timeliness and validity of the December 21 Paragraph IV Notice. GSK had ample opportunity to seek such a determination, but chose not to do so.

GSK's lawsuit for patent infringement should now be proceeding on the merits. However, GSK has taken the position that its own claim for patent infringement is jurisdictionally defective and should be dismissed without prejudice. GSK contends that the December 21 Paragraph IV Notice was a nullity, because it was served at a time when URL Mutual had yet to receive FDA filing acceptance. Ignoring the express language of 21 U.S.C. § 355(j)(2)(B)(ii)(II), GSK's complaint seeks a declaratory judgment that the December 21 Paragraph IV Notice was premature and therefore invalid, and that GSK was entitled to wait until 45 days after URL Mutual receives FDA filing acceptance (and provides notice thereof) before filing a lawsuit for patent infringement. (Complaint at ¶¶ 31-37)

On February 25, 2008, URL Mutual filed its answer, denying that its December 21 Paragraph IV Notice was premature. (Answer ¶¶ 1-6, 13-37) URL Mutual also filed a counterclaim against GSK, seeking a declaratory judgment that the '156 Patent is invalid and unenforceable. (Counterclaim ¶¶ 7-11) On March 17, 2008, GSK filed a reply to URL Mutual's counterclaim. Issue is now fully joined.

On March 17, 2008, URL Mutual received FDA filing acceptance for its ANDA. (Ex. 1)[1] That same day, URL Mutual sent GSK a Paragraph IV notice letter (the "March 17 Paragraph IV Notice").[2]

GSK's motion should be denied for the following reasons:

(1) The December 21 Paragraph IV Notice was timely and valid under 21 U.S.C. § 355(j)(2)(B)(ii)(II).

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[1] Citations in the form "Ex. __" refer to exhibits to the affidavit of Jacques Semmelman, counsel for URL Mutual, sworn to April 1, 2008.

[2] The March 17 Paragraph IV Notice was required by statute, as was the December 21 Paragraph IV Notice. There is no merit to GSK's footnoted remark that the service of the March 17 Paragraph IV Notice is an admission that the December 21 Paragraph Notice was invalid. (GSK Mem. p. 6, n. 1) It is not.

(2) This Court has subject matter jurisdiction over GSK's patent infringement claim, and URL Mutual's counterclaim, pursuant to 35 U.S.C. § 271 and 28 U.S.C. § 1338(a), irrespective of whether or not the December 21 Paragraph IV Notice was timely and valid.

To ensure that GSK's motion for judgment on the pleadings is determined on the basis of pleadings that properly reflect URL Mutual's receipt of FDA filing acceptance, URL Mutual hereby cross-moves, pursuant to Fed. R. Civ. P. 15(a), for leave to amend its answer and counterclaim to reflect the FDA filing acceptance.

The Court should issue an order: (1) granting URL Mutual's cross-motion for leave to amend its answer and counterclaim to reflect FDA filing acceptance; and (2) denying GSK's motion for judgment on the pleadings.

Argument

POINT ONE

THE COURT SHOULD GRANT URL MUTUAL LEAVE TO AMEND ITS ANSWER AND COUNTERCLAIM TO REFLECT FDA FILING ACCEPTANCE

On March 17, 2008, after URL Mutual had filed its answer and counterclaim in this action, the FDA notified URL Mutual that it had accepted URL Mutual's ANDA 90-132 for filing. (Ex. 1) To ensure that this fact is properly taken into account by the Court for purposes of deciding GSK's motion for judgment on the pleadings, URL Mutual hereby moves, pursuant to Fed. R. Civ. P. 15(a), for leave to amend its answer and counterclaim to reflect the FDA filing acceptance. URL Mutual submits a proposed Amended Answer and Counterclaim (Ex. 3), along with a redline showing the changes from the prior pleading (Ex. 4).

Pursuant to Fed. R. Civ. P. 15(a), "[l]eave to amend must generally be granted unless equitable considerations render it otherwise unjust." Arthus v. Maersk, Inc., 434 F.3d 196, 204 (3d Cir. 2006), *citing* Foman v. Davis, 371 U.S. 179, 182 (1962). Absent factors such

as undue delay, bad faith, or prejudice to the non-moving party, leave to amend should be "freely given." *Id.*; *see also* Venetec Int'l, Inc. v. Nexus Med., LLC., C.A. No. 07-57-MPT, 2008 U.S. Dist. LEXIS 24499, at *9 (D. Del. March 28, 2008).

URL Mutual seeks to amend its answer and counterclaim to reflect a material new fact – the March 17, 2008 FDA filing acceptance – that should be considered by this Court in deciding GSK's motion for judgment on the pleadings. It would be unfairly prejudicial to URL Mutual if the Court were unable to take this important development into account. GSK will not be prejudiced by the requested amendment, and there is no factual dispute that the FDA has issued filing acceptance. (GSK Mem. p. 11) ("Defendants' ANDA is now approved for filing").

Under these circumstances, URL Mutual's motion for leave to amend should be granted.

POINT TWO

THE COURT SHOULD DENY GSK'S MOTION FOR JUDGMENT ON THE PLEADINGS

GSK chose to institute this action for patent infringement on February 4, 2008 – exactly 45 days after URL Mutual served the December 21 Paragraph IV Notice, as URL Mutual was obligated to do under the express terms of 21 U.S.C. § 355(j)(2)(B)(ii)(II). The December 21 Paragraph IV Notice was timely and valid.

URL Mutual has been informed that, notwithstanding the express language of 21 U.S.C. § 355(j)(2)(B)(ii)(II), the FDA reads the statute differently, to include a condition – FDA filing acceptance – nowhere set forth in the text of the statute. URL Mutual disagrees with the FDA's reading of the statute, which is in derogation of its plain meaning. URL Mutual respectfully submits that it has read and has properly followed the statute in accordance with its express terms, and that the Court should so find.

As shown below, regardless of whether URL Mutual's reading of the statute is correct, this Court has subject matter jurisdiction over GSK's patent infringement claim and URL Mutual's counterclaim, pursuant to 35 U.S.C. § 271 and 28 U.S.C. § 1338(a), as there is a justiciable Article III case or controversy regardless of the validity of the December 21 Paragraph IV Notice.

GSK confuses two separate and distinct issues: (i) the *timing* of the expiration of GSK's statutory stay of (up to) 30 months; and (ii) whether this Court has subject matter jurisdiction over the patent infringement claim and the patent invalidity counterclaim. The second issue is independent of the first.

A. The Timing of the Expiration of the Statutory Stay Has No Bearing On This Court's Jurisdiction

Under 21 U.S.C. § 355(j)(5)(B)(iii), the filing of a complaint for patent infringement following receipt of Paragraph IV notice triggers a statutory stay of up to 30 months (less if the litigation concludes earlier), during which the FDA withholds approval of the ANDA. Now that the FDA has issued filing acceptance of URL Mutual's ANDA (Ex. 1), either party may seek a determination as to when the 30-month statutory stay terminates.

URL Mutual's position is that the 30-month stay began to run on February 4, 2008, when GSK chose to file this lawsuit. Accordingly, in the event this litigation is still ongoing on August 4, 2010 (30 months from February 4, 2008), the 30-month period will end at that time. GSK's position, apparently, is that the 30-month period will begin to run 45 days from the March 17 Paragraph IV Notice, i.e., on May 1, 2008. If GSK is correct, the 30-month period will end on November 1, 2010.

The only issue, then, is whether the 30-month stay will still be in effect during the period between August 4, 2010, and November 1, 2010. That issue will be mooted if this

litigation is resolved prior to August 4, 2010. If not, as August 4, 2010 draws near, the Court can schedule briefing and argument on the issue of precisely when the 30-month stay expires.[3] That issue need not draw upon the Court's time and resources just yet, as it is likely to become moot in due course. More importantly, it has no effect on the immediate litigation of the patent dispute, and certainly does not impair this Court's subject matter jurisdiction.

B. The December 21 Paragraph IV Notice Was Timely and Valid

GSK seeks to dismiss its own patent infringement claim on the ground that URL Mutual's December 21 Paragraph IV Notice was premature and therefore invalid, and, as a result, failed to start the 45-day period in which GSK was allowed to file a patent infringement suit and thereby obtain the benefit of the 30-month statutory stay. The Court should deny GSK's motion, as URL Mutual's December 21 Paragraph IV Notice was timely and valid under the plain meaning of the governing statute.

21 U.S.C. § 355(j)(2)(B)(ii), titled "Timing of notice," addresses two distinct circumstances, *either of which* triggers a duty on the part of the ANDA applicant to serve a Paragraph IV notice on the patentee:

> 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

[3] It might be necessary at that time to bring the FDA into the case as a party. In light of the more than two years that remain before this issue could start warranting attention, and the strong likelihood that this litigation will have been concluded by then, URL Mutual sees no need to bring the FDA into the case at this time, but respectfully reserves its rights.

> contained in the application or in an amendment or supplement to the application.

(Emphasis added).

Sub-section (I) makes explicit reference to the FDA's notification of filing acceptance, and requires that Paragraph IV notice be given "not later than 20 days" following the postmark date of the FDA's filing acceptance letter. Sub-section (I) says nothing that prohibits giving voluntary notice *before* the FDA has issued filing acceptance.

Sub-section (II), which is preceded by the disjunctive "or," contains no reference whatsoever to FDA filing acceptance. On its face, it requires the ANDA applicant to serve Paragraph IV notice at the time the ANDA applicant submits an amendment, without regard to whether there has been FDA filing acceptance. The introductory phrase "shall give notice," affords the ANDA applicant no discretion. If the ANDA applicant ignores the statutory mandate, it risks losing the protection of the statute.

GSK baldly and incorrectly declares that "the law expressly forbids" an ANDA applicant from serving Paragraph IV notice before receipt of FDA filing acceptance. (GSK Mem. p. 8) In support of that assertion, GSK cites no statute, regulation, or judicial decision that forbids such voluntary provision of notice, let alone that overrides the express obligation under 21 U.S.C. § 355(j)(2)(B)(ii)(II) to provide Paragraph IV notice upon filing an amendment. GSK cites 21 U.S.C. § 355(j)(2)(B)(ii)(I), which (as discussed above) does not address the issue of when the ANDA applicant *may* (as opposed to *must*) serve Paragraph IV notice.

In a letter solicited by GSK for purposes of this litigation (Ex. A to the Complaint),[4] the FDA takes the position that 21 C.F.R. 314.95(b) prohibits an ANDA applicant

[4] The FDA's letter, signed electronically February 1, 2008, indicates that it is being written in response to a January 22, 2008 email from a William M. Zoffer at "GSK Legal." The contents of GSK Legal's soliciting email have not been disclosed.

from serving Paragraph IV notice prior to receipt of FDA filing acceptance. (*Id.* at p. 1) But 21 C.F.R. 314.95(b) does not say that. It merely *directs* the ANDA applicant to serve notice on the patentee upon receipt of a filing acceptance letter: "The applicant shall send the notice . . . when it receives from FDA an acknowledgement letter stating that its abbreviated new drug application is sufficiently complete to permit a substantive review." (Emphasis added).

The regulation is silent with respect to (i) whether the applicant *may* serve notice voluntarily before receipt of the filing acceptance letter; and (ii) the mandate of 21 U.S.C. § 355(j)(2)(B)(ii)(II), which *requires* the ANDA applicant to serve Paragraph IV notice upon filing any amendment. The word "only" (or a synonym such as "solely") does not appear anywhere in 21 C.F.R. 314.95(b), as it would have if the regulation prohibited service of the notice before receipt of the filing acceptance letter.

The only support GSK can muster for its position is a "preamble" to final regulations, published in the Federal Register, in which the FDA presents a rationale as to *why* an ANDA applicant *should* not be permitted to serve Paragraph IV notice before receipt of FDA filing acceptance. (GSK Mem. p. 8) (quoting 59 Fed. Reg. 50338, 50350 (Oct. 3, 1994). But that reasoning on the part of the FDA never made its way into the regulations themselves. In light of the express and unambiguous statutory language of 21 U.S.C. § 355(j)(2)(B)(ii)(II), which requires the ANDA applicant to serve Paragraph IV notice in conjunction with any amendment, the FDA's aspirational logic set forth in the Federal Register must yield to the language of the statute. *See* Chevron U.S.A., Inc. v. Natural Res. Defense Council, 467 U.S. 837, 842-43 (1984) (in reviewing an agency's construction of a statute which it administers, "the Court, as well as the agency, must give effect to the unambiguously expressed intent of Congress").

In sum, as expressly mandated by 21 U.S.C. § 355(j)(2)(B)(ii)(II), URL Mutual properly served its December 21 Paragraph IV Notice on GSK. The Court should so find.

C. This Court Has Subject Matter Jurisdiction, Pursuant to 35 U.S.C. § 271 and 28 U.S.C. § 1338(a), Irrespective of Whether or Not the December 21 Paragraph IV Notice Was Valid

In its motion, GSK argues that 21 U.S.C. § 355(j)(2)(B)(ii)(II) should not be read literally but should, in effect, be rewritten by the Court to render it more consistent with other statutory provisions.

While URL Mutual disagrees, it is important to recognize that this Court has subject matter jurisdiction over the patent infringement claim and counterclaim *irrespective* of whether the December 21 Paragraph IV Notice was valid at the time it was served.

GSK's statutory authority to bring its infringement claims is based upon 35 U.S.C. §§ 271(e)(2) and 271(a)-(c). The claims are brought under 35 U.S.C. § 271(e)(2)(A) (patent infringement with respect to the submission of ANDA applications) and 35 U.S.C. §§ 271(a)-(c) (infringement with respect to the manufacture, use, offer to sell, sale or importation of patented products, as well as the inducement of or contribution to same). (Complaint ¶¶ 39-40)

This Court has subject matter jurisdiction over these patent infringement claims pursuant to 28 U.S.C. § 1338(a), which provides that "[t]he district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents."

On February 4, 2008, GSK elected to file its complaint under 35 U.S.C. §§ 271(e)(2) and 271(a)-(c). Nothing in those statutes requires, as a *jurisdictional* prerequisite, that the FDA have issued filing acceptance, or that a valid Paragraph IV notice have been served. Accordingly, even if GSK were correct that the December 21 Paragraph IV Notice was

premature (which URL Mutual disputes), the Court would still have subject matter jurisdiction over the patent infringement claim and counterclaim.

GSK elected to bring this lawsuit, seeking relief under 35 U.S.C. § 271. Whether or not GSK could have waited past February 4, 2008 to sue, and still have obtained the statutory benefits available under 21 U.S.C. § 355, is perhaps relevant to the issue of when the 30-month stay expires, but has no bearing on whether the Court has subject matter jurisdiction over the pending patent infringement claim that GSK elected to bring under 35 U.S.C. § 271.

1. This Court Has Jurisdiction Over GSK's § 271(e)(2) Claim

In its Complaint, GSK pleads a claim for patent infringement against URL Mutual, premised upon 35 U.S.C. § 271(e)(2). (Complaint ¶ 39) That statute provides:

> It shall be an act of infringement to submit –
>
> (A) an application under section 505(j) of the Food, Drug, and Cosmetic Act [i.e., an ANDA] … for a drug claimed in a patent or the use of which is claimed in a patent …
>
> if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug … claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

Section 271(e)(2) provides 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); *see also* Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 676 (1990) (§ 271(e)(2) creates an "artificial" act of infringement for jurisdictional purposes). District courts have subject matter jurisdiction over claims arising under § 271(e)(2) pursuant to 28 U.S.C. § 1338(a), which provides for original jurisdiction for any civil action "arising under any Act of

Congress relating to patents." *See* Allergan, Inc. v. Alcon Labs, Inc., 324 F.3d 1322, 1330 (Fed. Cir. 2003).

GSK's complaint alleges that URL Mutual committed an act of infringement under § 271(e)(2). Specifically, GSK alleges:

> *Defendants' submission of Defendants' ANDA* to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of Defendants' Carvedilol Phosphate Capsules prior to the expiration of the '156 patent *constitutes infringement* of one or more of the valid claims of the '156 patent under 35 U.S.C. § 271(e)(2)(A).

(Complaint ¶ 39) (emphasis added).

Thus, GSK pleads that URL Mutual's submission of the ANDA, in and of itself, constitutes infringement of the '156 Patent. While URL Mutual disputes the validity and enforceability of the '156 Patent, URL Mutual admits that it has submitted an ANDA which implicates the '156 Patent. (Answer ¶ 24) More specifically, URL Mutual had notified GSK that it was taking active steps, including the submission of an ANDA, to meet the applicable regulatory requirements for approval of its Carvedilol Phosphate Capsules, and that upon receiving such approval from the FDA, Mutual will manufacture and sell those drugs prior to the expiration of GSK's '156 Patent. (Ex. 2) Mutual further provided GSK with an in-depth legal and factual analysis demonstrating that the '156 Patent is invalid, unenforceable, and/or will not be infringed by Mutual's bringing its Carvedilol Phosphate Capsules to market upon receiving FDA approval. (Ex. 2)

Under Novopharm, these circumstances give rise to an Article III case or controversy. The requirements for a case or controversy arising under § 271(e)(2) are therefore met, and this Court has jurisdiction over GSK's patent infringement claim pursuant to 28 U.S.C. § 1338(a).

Nothing in § 271(e)(2) confines jurisdiction to circumstances under which the FDA has issued filing acceptance. Nevertheless, GSK asserts, in conclusory fashion, that the fact that the FDA had not accepted URL Mutual's ANDA submission for filing prior to GSK's filing suit against URL Mutual "mandates dismissal of GSK's alternative patent infringement claim." (GSK Mem. at p. 9) GSK cites no legal support for this proposition, nor does GSK explain why lack of notice of filing acceptance from the FDA would deprive this Court of the jurisdiction conferred upon it by virtue of 35 U.S.C. § 271(e)(2) and 28 U.S.C. § 1338(a).

In sum, there is an Article III case or controversy, and nothing in 35 U.S.C. § 271(e)(2) conditions subject matter jurisdiction on FDA filing acceptance. While FDA filing acceptance followed by Paragraph IV notice is unquestionably a *means* of creating an Article III case or controversy, it is not the only means by which an Article III case or controversy can arise. Here, there was an Article III case or controversy as soon as the December 21, 2007 Paragraph IV Notice was served on GSK. GSK may or may not have *had* to do so by February 4, 2008, but on that date it filed this lawsuit for patent infringement.

The requirements of a § 271(e)(2) claim have been pleaded, and this Court therefore has subject matter jurisdiction over GSK's § 271(e)(2) claim pursuant to 28 U.S.C. § 1338(a). To the extent GSK's motion seeks dismissal of its own § 271(e)(2) claim for purported lack of jurisdiction, the motion should be denied.

2. This Court Has Jurisdiction Over GSK's §§ 271(a)-(c) Claims

GSK's Complaint also pleads claims arising under 35 U.S.C. §§ 271(a)-(c), which prohibit as acts of infringement the unauthorized manufacture, use, sale, or offer to sell of a patented product, and further prohibit the inducement of or contribution to such conduct. (Complaint at ¶ 40) As with GSK's claims arising under § 271(e)(2), this Court has subject

matter jurisdiction over these claims pursuant to 28 U.S.C. § 1338(a). *See* ProBatter Sports, LLC v. Joyner Techs., Inc., 463 F. Supp. 2d 949, 953 (N.D. Iowa 2006) (district courts have subject matter jurisdiction over § 271(a)-(c) claims pursuant to 28 U.S.C. § 1338(a)).

URL Mutual has not yet received approval from the FDA to commercially manufacture and sell its Carvedilol Phosphate Capsules. Nevertheless, GSK has sued under §§ 271(a)-(c) seeking, inter alia, declaratory judgments with respect to the manufacture and sale of Carvedilol Phosphate Capsules that will occur following URL Mutual's receipt of FDA approval. Pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201, a district court may exercise jurisdiction over precisely this type of claim – i.e., where the patentee seeks a declaration that a company will be infringing its patent if it manufactures and sells a proposed generic product following receipt of FDA approval. *See* Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1570-72 (Fed. Cir. 1997) (upholding exercise of jurisdiction over patentee's claim for declaratory judgment that ANDA applicant will infringe the patent once FDA approves ANDA).

In order for a district court to have jurisdiction over a declaratory judgment claim, there must be a "substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." MedImmune, Inc. v. Genentech, Inc., __ U.S. __, 127 S.Ct. 764, 771 (2007) (internal citation omitted).

In Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562 (Fed. Cir. 1997), the Federal Circuit determined that this standard had been met, and upheld the district court's exercise of jurisdiction over the plaintiff's declaratory judgment claim because, as here: (i) the complaint was based on notice to the plaintiff-patent holder that the defendant intended to begin marketing its pharmaceutical product following approval by the FDA but before the expiration of the

plaintiff's patent; and (ii) the defendant indicated that it had submitted an ANDA accompanied by data sufficient to make FDA approval imminent. Id. at 1571. Under these circumstances, the Federal Circuit held that there was a sufficient case or controversy for the district court to exercise jurisdiction over the claim. 110 F.3d at 1570-72.

In its December 21 Paragraph IV Notice, URL Mutual notified GSK of its intent to market its Carvedilol Phosphate Capsules upon FDA approval and prior to the expiration of GSK's patent, and that URL Mutual had submitted an ANDA accompanied by data sufficient to obtain FDA approval. (Ex. 2) URL Mutual further notified GSK that GSK's '156 Patent "is invalid, unenforceable, and/or will not be infringed" by the manufacture, use or sale of URL Mutual's Carvedilol Phosphate Capsules, and provided a detailed factual and legal analysis to support that conclusion – a conclusion which GSK disputes. Id. On these facts, there is an Article III case or controversy, and therefore subject matter jurisdiction.

GSK confuses two distinct issues: the existence of subject matter jurisdiction over the patent infringement claim and counterclaim; and the *timing* of the expiration of the statutory stay of (up to) 30 months. Whether or not GSK had the right, if it so chose, to wait until 45 days after FDA filing acceptance (and notice thereof) to commence this lawsuit, the fact is that GSK elected not to wait, but went ahead and filed its complaint on February 4, 2008, the 45th day after the December 21 Paragraph IV Notice. Having made that choice, and with issue now fully joined, GSK cannot claim that the Court should simply relieve GSK of its decision, and dismiss this lawsuit with leave to refile on May 1, 2008. GSK cannot just walk away from the lawsuit it chose to file – especially not with URL Mutual's counterclaim pending.

If GSK had any uncertainty as to whether the December 21 Paragraph IV Notice was valid, GSK had ample opportunity between December 21, 2007 and February 4, 2008 – 45

days, to be exact – to initiate a declaratory judgment action and seek an expedited determination as to the validity of the December 21 Paragraph IV Notice. Indeed, GSK admits that, before filing this lawsuit, it reached out to URL Mutual and requested that URL Mutual withdraw its December 21 Paragraph IV Notice, and that URL Mutual *declined to do so*. (Complaint ¶ 29) Thus, before February 4, 2008, there was an Article III case or controversy between GSK and URL Mutual regarding the propriety of the December 21 Paragraph IV Notice. Yet, GSK waited until the very last day of the 45-day period, filed its lawsuit for patent infringement, and included a count for a declaratory judgment that the December 21 Paragraph IV Notice was premature. That issue has been mooted by GSK's decision to file this lawsuit for patent infringement.

GSK's motion does not address the legal standards with respect to jurisdiction. Instead, GSK asserts in conclusory fashion that its claim is "unnecessary" because of a purported deficiency in the notice sent to GSK – i.e., that the ANDA had not yet been accepted for filing. (GSK Mem. p. 9) Even if GSK's assertion with respect to the purported deficiency were correct – and for the reasons discussed above, it is not – GSK fails to establish that such a deficiency would impair the Court's jurisdiction. In MedImmune, the Supreme Court established that there are no technical impediments for a court to exercise jurisdiction over declaratory judgment actions, but rather, jurisdiction exists where there is a controversy "of sufficient immediacy and reality" – i.e., whenever there is a definite, concrete and not hypothetical dispute between the parties. 127 S.Ct. at 771. Pursuant to the Federal Circuit's holding in Novopharm, this standard is met here. Nothing about the complained-of deficiency makes the case or controversy currently before the Court any less immediate or real.

In light of the foregoing, this Court has jurisdiction over GSK's claims arising under §§ 271(a)-(c). To the extent GSK's motion seeks dismissal of these claims without prejudice, it should be denied.

3. This Court Has Jurisdiction Over URL Mutual's Counterclaim

In response to the complaint filed by GSK, URL Mutual filed a counterclaim seeking a declaratory judgment that GSK's '156 Patent is invalid. (Counterclaim ¶¶ 7-11) *See* Akzona Inc. v. E.I. du Pont de Nemours & Co., 662 F. Supp. 603, 620 (D. Del. 1987) (a defendant in a patent infringement suit must counterclaim for a judgment of noninfringement or patent invalidity "[i]n order to preserve its rights"). This Court has subject matter jurisdiction over URL Mutual's counterclaim.

As an initial matter, URL Mutual's counterclaim presents a case or controversy within the meaning of the Declaratory Judgment Act sufficient to confer subject matter jurisdiction over the counterclaim.

URL Mutual has communicated to GSK its position that the '156 Patent is invalid, that URL Mutual is actively taking steps to obtain FDA approval of its ANDA, and that, upon receiving approval from the FDA, URL Mutual will begin the manufacture and sale of its Carvedilol Phosphate Capsules prior to the expiration of the '156 Patent. In response, GSK has filed this lawsuit, alleging patent infringement. There is therefore a "substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." MedImmune, 127 S.Ct. at 771 (internal citation omitted); *see also* Sandisk Corp. v. Stmicroelectronics, Inc., 480 F.3d 1372, 1381 (Fed. Cir. 2007) ("where a patentee asserts rights under a patent based on certain identified ongoing or

planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license, an Article III case or controversy will arise").

In its motion, GSK erroneously argues that jurisdiction over URL Mutual's counterclaim is lacking because "45 days have not elapsed since a valid Paragraph IV notice" was served, and therefore URL Mutual had "no right to commence a declaratory judgment action." (GSK Mem. p. 9) In support of its position, GSK cites only to 35 U.S.C. § 271(e)(5), which provides that an ANDA applicant may *initiate* a declaratory judgment action against the patent holder only if the 45-day waiting period that follows the issuance of a paragraph IV notice has expired. GSK's argument ignores the critical fact that URL Mutual's declaratory judgment claim is a *counterclaim* filed in response to the complaint that GSK elected to file against URL Mutual. URL Mutual did not initiate this lawsuit. Once GSK initiated it, URL Mutual had the right, *see* Fed. R. Civ. P. 13(b) – if not the obligation, *see* Fed. R. Civ. P. 13(a) – to file its counterclaim. And nothing in 21 U.S.C. § 355 (or in any other statute or regulation) prohibits an ANDA applicant from filing a counterclaim *after* the patentee has filed suit. *See* 21 U.S.C. § 355(j)(5)(C)(ii) (if patentee "brings a patent infringement action against the applicant, the applicant may assert a counterclaim . . .").

Even if this Court dismisses GSK's infringement claims, such dismissal would not impair the Court's jurisdiction over URL Mutual's counterclaim. Dismissal of a patentee's infringement claims does not deprive the court of subject matter jurisdiction over a counterclaim challenging the validity of the patent. *See* Altvater v. Freeman, 319 U.S. 359, 363-364 (1943) (dismissal of patent holder's infringement claim "does not dispose of the counterclaim which raises the question of validity" because the counterclaim is still a justiciable controversy pursuant to the Declaratory Judgment Act), *cited in* MedImmune, 127 S.Ct. at 773; *see also* Shelcore, Inc.

v. Durham Industries, Inc., 745 F.2d 621, 624 (Fed. Cir. 1984) (patent holder "could not unilaterally remove the validity issue" by voluntarily withdrawing its infringement claims); Biacore v. Thermo Bioanalysis Corp., 79 F. Supp. 2d 422, 453-54 (D. Del. 1999) ("a court is not automatically denied jurisdiction over counterclaims upon the withdrawal of an allegation of infringement"); Akzona Inc. v. E.I. du Pont de Nemours & Co., 662 F. Supp. 603, 619 (D. Del. 1987) (same) (collecting authority).

GSK then argues that "[e]ven if Defendants had such a right [to file a counterclaim], the Court should exercise is [sic] discretion and decline to entertain a declaratory judgment claim in light of Defendants' transparent attempt to circumvent the statutory scheme." (GSK Mem. p. 9)

There is no reason for the Court to indulge GSK. As noted above, prior to February 4, 2008, GSK had ample opportunity to seek an expedited judicial determination regarding the validity of the December 21 Paragraph IV Notice. GSK elected not to seek such a ruling, but to wait until Day 45, file this lawsuit for patent infringement, wait until a counterclaim was filed, and then ask the Court for permission to walk away and start over. GSK's behavior presents no justification whatsoever for the Court to exercise its discretion for GSK's benefit.

In sum, URL Mutual had the right to file its counterclaim in response to GSK's complaint, and this Court has jurisdiction over the counterclaim pursuant to the Declaratory Judgment Act and 28 U.S.C. § 1338(a). To the extent GSK's motion seeks dismissal of URL Mutual's counterclaim, it should be denied.

D. The FDA's Issuance of Filing Acceptance Further Moots Any Jurisdictional Challenge

That the Court has subject matter jurisdiction is further reinforced by the fact that on March 17, 2008, the FDA issued filing acceptance.

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. For example, GSK argues that "improper notification would unnecessarily force the NDA- or patent holder to incur the significant costs associated with a patent infringement litigation that may never be necessary, because the FDA may not ever accept the ANDA for filing." (GSK Mem. p. 4) In a similar vein, GSK argues that "[s]erving a Paragraph IV Notice based on an incomplete ANDA burdens the judicial system with premature – and perhaps entirely unnecessary – patent infringement litigation." (GSK Mem. p. 4) 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.

In sum, there is Article III jurisdiction over GSK's patent infringement claim and URL Mutual's counterclaim. There is no basis for granting GSK's motion for judgment on the pleadings. The motion should be denied.

CONCLUSION

The Court should deny GSK's motion for judgment on the pleadings, and should grant URL Mutual's cross-motion for leave to amend its answer and counterclaim to reflect FDA filing acceptance.

Dated: Philadelphia, Pennsylvania
April 1, 2008

Respectfully submitted,

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

SB PHARMCO PUERTO RICO, INC. d/b/a GLAXOSMITHKLINE, and SMITHKLINE BEECHAM CORP., d/b/a GLAXOSMITHKLINE Plaintiffs/Counterclaim-Defendants, v. MUTUAL PHARMACEUTICAL COMPANY, INC. and UNITED RESEARCH LABORATORIES, INC. Defendants/Counterclaim-Plaintiffs.	Civil Action No. 2:08-cv-549-RBS

ORDER

AND NOW, this ___ day of _____, 2008, upon consideration of the Motion of Defendants-Counterclaimants Mutual Pharmaceutical Company, Inc. and United Research Laboratories, Inc. ("Defendants") for Leave To Amend Its Answer And Counterclaim, it is HEREBY ORDERED:

1. That Defendants' Motion for Leave to File Amended Answer and Counterclaim is GRANTED.

2. Plaintiffs' motion for judgment on the pleadings is DENIED.

SO ORDERED this ___ day of _____, 2008.

_____
UNITED STATES DISTRICT JUDGE
EASTERN DISTRICT OF PENNSYLVANIA

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

[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.

the FDA's March 17 filing acceptance, (Doc. No. 37). Defendants argue that Plaintiffs' motion 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

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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).

determined that there is an important distinction between physically- received ANDAs, which are 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

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[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.

applicant 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

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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.

cardinal rule that a statute is to be read as a whole, . . . since the meaning of statutory language, 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 congressional record: "[T]he Hatch-Waxman Act has always provided that patent owners and

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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.
>
> (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.

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.

[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

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 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.

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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 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