IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RECKITT BENCKISER PHARMACEUTICALS, INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC, Plaintiffs, v. PAR PHARMACEUTICAL, INC., and INTELGENX TECHNOLOGIES CORP., Defendants.	)	CA. No. 13-1461-RGA **Redacted Version D.I. 83**

DECLARATION OF DANA K. SEVERANCE IN SUPPORT OF PLAINTIFFS' MOTION TO DISMISS THE AMENDED COMPLAINT AND COUNTERCLAIMS

I, Dana K. Severance, do hereby declare:

1. I am an attorney at the law firm of Womble Carlyle Sandridge & Rice, LLP, counsel for Plaintiffs Reckitt Benckiser Pharmaceuticals, Inc., RB Pharmaceuticals Limited, and MonoSol RX, LLC, (collectively, "Plaintiffs") in the above-captioned matter.

2. I submit this Declaration in Support of Plaintiffs' Motion to Dismiss the Amended Complaint and Counterclaims.

3. Attached as Exhibit A is a true and correct copy of docket item 24 in *Otsuka Pharmaceutical Co. v. Par Pharmaceutical, Inc.*, No. 13-cv-1979 (D. Del. May 10, 2014).

4. Attached as Exhibit B is a true and correct copy of Defendant Par Pharmaceutical, Inc.'s Responses to Plaintiffs' First Set of Joint Interrogatories to Defendants, served March 31, 2014.

5. Attached as Exhibit C is a true and correct copy of docket item 23 in *Otsuka Pharmaceutical Co. v. Par Pharmaceutical, Inc.*, No. 13-cv-1979 (D. Del. May 7, 2014).

6. Attached as Exhibit D is a true and correct copy of docket item 15 in *Otsuka Pharmaceutical Co. v. Par Pharmaceutical, Inc.*, No. 13-cv-1979 (D. Del. Jan. 16, 2014)..

7. Attached as Exhibit E is a true and correct copy of the FDA's letter dated August 15, 2012, to Par Pharmaceuticals, Inc. located at, http://www.hpm.com/pdf/blog/Par%20Premature%20Notice%20Ltr.pdf.

I declare under penalty of perjury that the foregoing is true and correct to the best of my information and belief.

This Declaration is executed this 17th day of April 2014.

/s/ Dana K. Severance
Dana K. Severance (#4869)

CERTIFICATE OF SERVICE

I hereby certify that on April 17, 2014, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to all registered participants.

Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on April 17, 2014, upon the following individuals via electronic mail:

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EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OTSUKA PHARMACEUTICAL CO., LTD.,	)	
Plaintiff,	)	
v.	)	C.A. No. 13-1979 (RGA)
PAR PHARMACEUTICAL, INC.,	)	
Defendant.	)	

ORDER

AND NOW, this 10th day of March, 2014, upon consideration of the Motion of plaintiff Otsuka Pharmaceutical Co., Ltd. for Judgment on the Pleadings (D.I. 14) and any response thereto (D.I. 17), it is hereby ORDERED:

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

2. That Plaintiff's alternative counts (Counts II and III) are hereby DISMISSED WITHOUT PREJUDICE.

3. That defendant Par Pharmaceutical, Inc.'s counterclaims against Plaintiff are hereby DISMISSED WITHOUT PREJUDICE.

Richard G. Andrews
J.

EXHIBIT B

CONFIDENTIAL

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RECKITT BENCKISER PHARMACEUTICALS INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC,	)	
Plaintiffs,	)	C.A. No. 13-1461 RGA
v.	)	
PAR PHARMACEUTICAL, INC., and INTELGENX TECHNOLOGIES CORP.,	)	
Defendants.	)	

DEFENDANT PAR PHARMACEUTICAL, INC.'S RESPONSES TO PLAINTIFFS' FIRST SET OF JOINT INTERROGATORIES

Pursuant to Federal Rules of Civil Procedure 26 and 33, Defendant Par Pharmaceutical, Inc. ("Par") hereby provides the following responses and objections to Plaintiffs Reckitt Benckiser Pharmaceuticals Inc., RB Pharmaceuticals Limited, and Monosol RX, LLC's (collectively "Plaintiffs'") First Set of Joint Interrogatories to Defendants.

Par's responses and the objections and limitations contained herein are subject to and without waiver of: (a) the right to make additional or supplemental objections to these interrogatories; and (b) the right to revise, correct, amend, or modify these responses upon, among other things, the discovery and/or development of additional facts and materials, further investigation, expert testimony and discovery, and other developments in the case.

GENERAL OBJECTIONS

Par makes the following General Objections to Plaintiffs' First Set of Interrogatories, which General Objections are hereby incorporated by reference and made part of Par's response to each such interrogatory.

1. Par objects to Plaintiffs' definitions, instructions and interrogatories to the extent they seek information beyond the scope of discovery provided by the Federal Rules of Civil Procedure or the Local Civil Rules of the District of Delaware, and to the extent that they purport to impose any obligation on Par greater than or inconsistent with those rules.

2. Par objects to Plaintiffs' interrogatories to the extent that they request information or documents protected by any privilege, including the attorney-client privilege or work product immunity, joint defense privilege, or any other applicable privilege or immunity. Nothing contained in these responses is intended as, or shall in any way be deemed, a waiver of any relevant privilege.

3. Par objects to Plaintiffs' "Definitions" and "Instructions" to the extent that they seek to impose requirements or obligations on Par in addition to or different from those imposed by the Federal Rules of Civil Procedure or the Local Civil Rules of the District of Delaware.

4. Par objects to Plaintiffs' interrogatories to the extent they are vague, overly broad, unduly burdensome, and/or not reasonably calculated to lead to the discovery of admissible evidence.

5. Par objects to Plaintiffs' interrogatories to the extent that they purport to require Par to provide "any" or "all" facts or documents as overly broad and unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. Subject to its General

Objections and any specific objections, Par will conduct a reasonable investigation and provide responsive, non-privileged information resulting from that investigation.

6. Par objects to Plaintiffs' interrogatories to the extent that they seek information, documents or things that are not within Par's possession, custody or control.

7. Par objects to Plaintiffs' interrogatories to the extent that they seek information, documents or things that are confidential information of non-parties.

8. Par objects to Plaintiffs' interrogatories to the extent that they contain discrete subparts, which should be counted as separate interrogatories pursuant to Federal Rule of Civil Procedure 33.

9. By identifying a document in response to an interrogatory, Par does not admit that the document is relevant, admissible, or free of information that is privileged or immune from discovery, nor does it waive its right to withhold any portion of the document that is privileged or immune from discovery.

10. Par objects to Plaintiffs' interrogatories to the extent that they call for a legal conclusion.

11. Par objects to Plaintiffs' interrogatories to the extent that they seek identification of documents equally available or already in the possession, custody or control of Plaintiffs or that are as accessible to Plaintiffs as they are Par, or that can be obtained more conveniently from a source other than Par.

12. Par makes these objections without prejudice to and without waiver of its right to object on any other grounds to any of Plaintiffs' interrogatories. Par specifically incorporates each of the foregoing objections into its specific responses to Plaintiffs' interrogatories, whether or not specifically referred to.

RESPONSES

INTERROGATORY NO. 1:

For each dosage of Defendants' Proposed Generic Products, state whether Defendants have received from the FDA an AFF Letter; state the date of any such AFF Letter; state the date that the sufficiently complete ANDA was received by FDA, as indicated in the AFF Letter; and identify all related documents, including but not limited to any correspondence with FDA relating to whether or when an AFF letter may be provided by FDA as to each such dosage.

RESPONSE:

Par incorporates its General Objections by reference. Par further objects to this Interrogatory to the extent that it seeks information protected by the attorney-client privilege or work product immunity. Par further objects to this Interrogatory on the grounds that it contains multiple subparts, which should be counted as separate interrogatories pursuant to Federal Rule of Civil Procedure 33. Par further objects to this Interrogatory to the extent that it purports to require Par to provide "all related documents" as overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence

Subject to and without waiving the foregoing objections, Par states it received an AFF Letter from the FDA on REDACTED, indicating that ANDA No. 205854 was received and acceptable for filing on REDACTED

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EXHIBIT C

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OTSUKA PHARMACEUTICAL CO., LTD.,	)	
Plaintiff/Counterclaim-Defendant,	)	
v.	)	C.A. No. 13-1979 (RGA)
PAR PHARMACEUTICAL, INC.,	)	REDACTED - PUBLIC VERSION
Defendant/Counterclaim-Plaintiff.	)	

REPLY BRIEF IN SUPPORT OF OTSUKA PHARMACEUTICAL CO., LTD.'S MOTION FOR JUDGMENT ON THE PLEADINGS

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INTRODUCTION

There are no material facts at issue here: Par admits that it sent purported Paragraph IV notice letters to Otsuka in October 2013, [redacted] after submitting its ANDA for generic tolvaptan tablets to FDA. Par admits that its ANDA had not yet been accepted for review by the FDA when it sent the notice letters, in violation of FDA regulations.[1] The notice letters themselves are deficient for failing to meet FDA regulations.[2]

Par further admits that it jumped the gun solely to be awarded potential first-filer status. Until Par's ANDA has been accepted for review by FDA, however, Par's status as a potential first-filer cannot be ascertained. Par's only argument—that the amendment provision of the Hatch-Waxman Act, 21 U.S.C. § 355(j)(2)(B)(ii)(II), mandates that an ANDA filer send a Paragraph IV notice, even where the underlying application has not been received for filing—defies common sense and logic, and has accordingly been rejected by the FDA and at least one court. Par's brazen attempt to game the system and accelerate the litigation process should not be allowed.

For the reasons set forth below, Otsuka respectfully requests that the Court enter judgment on the pleadings as to Otsuka's count for declaratory judgment, dismiss Otsuka's alternative counts of patent infringement without prejudice, and dismiss Par's declaratory judgment counterclaims without prejudice.

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1 Par's ANDA still has not been accepted for review by FDA, nearly five months after Par sent its purported Paragraph IV notice letters. 21 C.F.R. § 314.95(b)states that "[t]he applicant shall send the [Paragraph IV notice] *when it receives from FDA an acknowledgment letter stating that its abbreviated new drug application is sufficiently complete to permit a substantive review.*" (emphasis added).

2 21 C.F.R. § 314.95(c)(1) mandates that Paragraph IV notice letters "shall include . . . [a] statement that FDA *has received* an abbreviated new drug application submitted by the applicant." (emphasis added).

ARGUMENT

I. § 355(J)(2)(B)(ii)(II) Only Applies Where the Underlying ANDA Has Been Accepted by the FDA for Review

The crux of Par's argument is that the amendment provision, § 355(j)(2)(B)(ii)(II),[3] requires that an ANDA filer send a Paragraph IV notice to the patent owner and NDA holder, regardless of whether the original ANDA has been received by FDA for filing. *See* Par Pharm., Inc.'s Opp'n to Otsuka Pharm. Co., Ltd's Mot. for Judgment on the Pleadings (D.I. 17) (hereafter "Par's Opp'n Br.") at 3-4. As the court in *SB Pharmco Puerto Rico, Inc. d/b/a/ GlaxoSmithKline v. Mutual Pharm. Co.*, 552 F. Supp. 2d 500, 509 (E.D. Pa. 2008) noted, this interpretation of the amendment provision "makes no sense." The court explained that "when one reads [§ 355(j)(2)(B)(ii)(II)] 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." *Id.* at 510 n.4.

Par challenges *SB Pharmco*'s holding for its reliance on FDA's interpretation of the Hatch-Waxman Act and associated regulations. The court, however, engaged in proper statutory interpretation by evaluating § 355(j)(2)(B)(ii)(II) in the context of the entire Hatch-Waxman Act. "[T]he cardinal rule [is] that a statute is to be read as a whole, . . . since the meaning of statutory language, plain or not, depends on context." *King v. St. Vincent's Hosp.*, 502 U.S. 215, 221

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[3] "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)(I)-(II).

(1991). Moreover, *SB Pharmco* gave appropriate deference to the FDA's understanding of the Hatch-Waxman Act. As the Supreme Court has stated:

> We have long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer, and the principle of deference to administrative interpretations has been consistently followed by this Court whenever decision as to the meaning or reach of a statute has involved reconciling conflicting policies, and a full understanding of the force of the statutory policy in the given situation has depended upon more than ordinary knowledge respecting the matters subjected to agency regulations.

Chevron, U.S.A. v. NRDC, Inc., 467 U.S. 837, 843-44 (1984) (internal citations omitted); *see also United States v. Mead Corp.*, 533 U.S. 218, 227 (2001) ("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.") (internal citation omitted).

Using the proper framework to analyze § 355(j)(2)(B)(ii)(II), *SB Pharmco* concluded that the amendment provision 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."[4] 552 F. Supp. 2d at 510.

In addition, the FDA has consistently rejected Par's specious interpretation of § 355(j)(2)(B)(ii)(II). For example, in August 2012, the FDA responded to another premature Paragraph IV notice *sent by Par* under the auspices of the amendment provision. The FDA stated:

> FDA has not interpreted [the amendment provision] to require or permit applicants who amend their applications before receipt of an acknowledgement letter to provide notice before learning whether their application has been

[4] *SB Pharmco*'s interpretation of § 355(j)(2)(B)(ii) is consistent with FDA regulations governing the notice letters themselves. 21 C.F.R. §314.95(c)(1) requires each notice letter—including a notice letter sent as a result of an amendment—to contain a statement "that [the] FDA has received" the underlying ANDA. A notice letter sent pursuant to § 355(j)(2)(B)(ii)(II) prior to the ANDA being received is thus, by definition, deficient.

> determined to be sufficiently complete to be received. Rather, *this provision applies only to amendments made after an ANDA has been received*.

Krumplitsch Decl., Ex. 1 (August 15, 2012 letter from FDA, http://www.hpm.com /pdf/blog/Par%20Premature%20Notice%20Ltr.pdf (last visited March 4, 2014)) (emphasis added). FDA explained its rejection of Par's reliance on the amendment provision as follows:

> Patent certifications and related notice are part of a complex system . . . for resolution of patent disputes related to generic drug applications. . . . 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") ensures 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 the agency. . . . The agency believes Congress did not intend that incomplete application submissions would trigger legal action by a patent owner or NDA holder and therefore we implemented this interpretation of the notice requirement.

Id. at 1-2. The FDA concluded that Par's premature notification was invalid and did not trigger the 45-day litigation window or 30-month stay. *Id*. at 2. *See also* February 1, 2008 letter from FDA to GSK Legal (Gencarelli Decl. In Support Of Par's Opp'n Br. (D.I. 18), Ex. 1) ("Notice in [context of the amendment provision] does not raise the same concerns about premature notice because the agency will have already determined under 21 C.F.R. § 314.101 that the application being amended or supplemented is sufficiently complete to permit review.").

Par relies on *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 888 (D.C.C. 2004) for the proposition that an ANDA applicant must provide notice to the NDA holder and patent owner when an amendment or supplement is filed or risk losing first-filer rights. *Purepac*, however, is inapposite. It involved two ANDAs *that had already been received for review* when the applicants submitted new Paragraph IV certifications and sent notices under the amendment provision. *Purepac* does not address notice pursuant to § 355(j)(2)(B)(ii)(II) where the underlying ANDA has not yet been accepted for review.

Moreover, *Purepac* does not even support Par's point. In *Purepac*, the FDA concluded that a generic company was entitled to first-filer status *despite* its delay in providing notice of the amendment to its ANDA, rejecting the contention that the statute requires notice of the amendment simultaneous with its filing, lest the new Paragraph IV certification be rendered invalid. *Purepac*, 354 F.3d at 888. It held that the penalty for an applicant that fails to provide notice at the same time that it files an amendment to an already-accepted ANDA is that the certification simply becomes effective when the applicant does provide proper notice. *Id*. Both the district court and appellate court upheld this decision.

Par is unable to cite to a single court opinion or agency decision to support its interpretation of § 355(j)(2)(B)(ii). Its hyper-literal reading of the amendment provision has been rejected by both the FDA and the *SB Pharmco* court. Par's nonsensical reliance on a single subparagraph to directly controvert the timing provisions and litigation process set forth in the Hatch-Waxman Act is without support and cannot stand.

II. Par's Concerns for Judicial and Party Economy Are Derisible

Par weakly contends that granting judgment on the pleadings at this stage would cause an "unnecessary expenditure of resources by both this Court and the parties because the case would simply be re-filed by Otsuka once Par receives notification from FDA that its tolvaptan ANDA has been accepted for filing." Par Opp'n Br. at 7. There is no telling when or even if the FDA will accept Par's ANDA for review. Indeed, although Par purports to expect that [redacted] *id.*, Par's ANDA *still* has not been accepted for review as of the date of this brief.

Par's improper conduct has already caused Otsuka to expend significant resources, and any future harm befalling Par as a result of that conduct would be entirely of its own making.

Par admits that it submitted its ANDA to FDA "[redacted]" before February 17, 2014. *See id.* Par's ANDA was thus submitted to FDA [redacted] Par's purported Paragraph IV notice letters to Otsuka are dated October 10, 2014, [redacted] after Par submitted its ANDA to FDA. Rather than wait for the FDA's acknowledgement letter,[5] Par admits that it jumped the gun in order to "preserve its potential status as first ANDA filer." Par Opp'n Br. at 1.

Par cannot claim surprise at this outcome. The 2008 FDA letter cited by Par in its opposition brief plainly states the FDA's position: a Paragraph IV notice sent before receipt of FDA's acknowledgment that the underlying ANDA has been received for review is invalid. February 1, 2008 letter from FDA to GSK Legal (Gencarelli Decl. In Support Of Par's Opp'n Br., Ex. 1) at 2. Similarly, in 2012, when Par itself attempted to use the amendment provision to jumpstart the litigation process, the FDA again concluded that such notification was invalid. (Krumplitsch decl., Ex. 1).

Par took a calculated gamble and once again attempted to improperly jumpstart the litigation process to obtain potential first-filer exclusivity rights. Any complaint by Par that it might be forced to unnecessarily expend resources as a result of its improper behavior is unjustified.

---

[5] Par admits that "actual review times are much longer" than the sixty-day statutorily mandated time frame for FDA to make an initial determination whether to accept an ANDA for filing. Par's Opp'n Br. at 7; *see also* 21 C.F.R. § 314.101(a)(1) ("Within 60 days after FDA receives an application, 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.") Despite this understanding, Par waited [redacted] before sending an invalid Paragraph IV notice to Otsuka.

CONCLUSION

For the foregoing reasons, Otsuka respectfully requests that the Court enter judgment on the pleadings as to Count I of the Complaint and dismiss the remaining claims without prejudice.

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March 6, 2014 - Original Filing Date
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EXHIBIT D

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OTSUKA PHARMACEUTICAL CO., LTD.,	)	
Plaintiff,	)	
v.	)	C.A. No. 13-1979 (RGA)
PAR PHARMACEUTICAL, INC.,	)	
Defendant.	)	

OPENING BRIEF IN SUPPORT OF OTSUKA PHARMACEUTICAL CO., LTD.'S MOTION FOR JUDGMENT ON THE PLEADINGS

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Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Otsuka") submits this memorandum in support of its motion for judgment on the pleadings against defendant Par Pharmaceutical, Inc. ("Par").

Otsuka seeks to prevent Par's premature and improper attempt to initiate the litigation process carefully designed by Congress for resolving patent disputes between branded and generic pharmaceutical companies. Federal law prohibits a generic drug company from triggering that litigation process unless and until the United States Food and Drug Administration ("FDA") informs the generic drug company that its Abbreviated New Drug Application ("ANDA") has been accepted for filing. Par admits that its ANDA had not been accepted for filing by the FDA when it started the litigation process. In fact, Par's ANDA has still not been accepted for filing as of the date of this motion. Therefore, for the reasons set forth below, Otsuka respectfully requests (1) judgment on the pleadings as to Count I of the Complaint; (2) that its alternative counts of patent infringement be dismissed without prejudice; and (3) that Par's declaratory judgment counterclaims also be dismissed without prejudice.

BACKGROUND

I. THE ANDA LITIGATION PROCESS

In order to market a new pharmaceutical drug in the United States, a pharmaceutical company must first obtain approval from the FDA, normally through the filing of a New Drug Application ("NDA"). *See* 21 U.S.C. § 355(a); Complaint (D.I. 1) at ¶12. The innovator company 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. 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)(l) and (c)(2); Complaint at ¶12.

In order to market a generic version of a previously approved pharmaceutical drug, a generic drug manufacturer may file an ANDA instead of an NDA. *See* 21 U.S.C. § 355(j); Complaint at ¶13. The generic drug approval pathway is "abbreviated" because the generic drug manufacturer may rely on 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. *Id*.

Along with this "abbreviated" generic drug application process, Congress has crafted a process for resolving patent disputes between innovator companies and generic drug manufacturers. Under this statutory framework, the ANDA filer must provide certifications for 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 ¶14. More specifically, the 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 ¶14. This certification is known as a "Paragraph IV Certification."

When a generic drug company submits an ANDA to the FDA, the FDA first conducts an initial, preliminary review of the abbreviated application to determine whether it may be "received." 21 C.F.R. § 314.101(b)(1); Complaint at ¶15. The ANDA is deemed received only after the FDA has made a threshold determination that the abbreviated application is sufficiently complete to permit further substantive review. *Id*. If the FDA determines that the application may be received, the applicant is notified in writing. 21 C.F.R. § 314.101(b)(2).

If the FDA formally receives the ANDA for further substantive review and the ANDA contains a Paragraph IV Certification, the generic company must provide notice to both the owner of the listed patent and the holder of the NDA for the reference listed drug. *See* 21 U.S.C. § 355(j)(2)(B); 21 C.F.R.§ 314.95; Complaint at ¶ 16. This "Paragraph IV Notice" must include a detailed statement of the factual and legal bases for the generic company's belief that the challenged patent is invalid and/or not infringed by the manufacture, use, or sale of the proposed generic product. *Id*.

Federal regulations specifically govern the timing of such Paragraph IV Notices. Such notices are to be sent only *after* the 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) ("The applicant shall send the notice [of certification] when it receives from FDA an acknowledgment letter stating that its abbreviated new drug application is sufficiently complete to permit a substantive review."); Complaint at ¶ 16.

After receiving a proper, timely Paragraph IV Notice from an ANDA filer, the patentee or NDA holder has 45 days in which to file a patent infringement suit to invoke a statutorily-mandated 30-month stay delaying FDA approval of the ANDA. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(b)(3); Complaint at ¶ 17. The 30-month stay is vital to innovator companies, such as Otsuka, because it protects them from the severe financial harm and uncertainty 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. Under this statutory framework, the innovator company is 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 ¶ 17.

There are powerful economic incentives for generic companies to obtain the earliest possible filing date by "jumping the gun" with incomplete ANDA filings. Complaint at ¶ 18. The first ANDA filer may be entitled to 180 days of generic market exclusivity, during which time no other ANDA filer may come to market with a competing generic product. *See* 21 U.S.C. § 355(j)(5)(B)(iv); Complaint at ¶ 18. By filing prematurely or notifying the NDA holder or patent owner 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. *Id*. Improper, premature notification would force the NDA holder or patent owner to incur significant costs associated with a patent infringement suit that may never be necessary because the FDA may not ever accept the ANDA for filing. Complaint at ¶ 20.

Accordingly, as discussed above, one of the important protections built into the ANDA framework is that a generic applicant may not even send a Paragraph IV Notice until it "receives from FDA an acknowledgment letter stating that its abbreviated new drug application is sufficiently complete to permit a substantive review." *See* 21 C.F.R. § 314.95(b); Complaint at ¶ 19. This safeguard conserves judicial and party resources by avoiding premature, and perhaps entirely unnecessary, patent litigation. If the incomplete ANDA is never completed, the innovator company and the courts would have conducted unnecessary, costly infringement litigation. Even if the incomplete ANDA is eventually completed, the premature initiation of litigation prejudices not only the innovator company, but also other ANDA filers. Complaint at ¶ 20. Therefore, the ANDA applicant may not trigger the litigation process by serving a

Paragraph IV Notice unless and until its ANDA has been formally received by the FDA for substantive review. *Id*.

II. PAR'S PURPORTED NOTICE OF PARAGRAPH IV CERTIFICATION

There is no dispute over the material facts regarding Par's premature and improper Paragraph IV notice to Otsuka. Par has submitted ANDA No. 206119 to the FDA, seeking approval to market tolvaptan tablets, a generic version of Otsuka's SAMSCA® product. Complaint at ¶ 24, Answer (D.I. 7) at ¶ 24. On October 10, 2013, Par sent purported "Notice of Paragraph IV Certification" letters (the "Purported Notice Letters") to Otsuka, the patent owner, and Otsuka America Pharmaceutical, Inc., the NDA holder. Complaint at ¶ 26, Answer at ¶ 26. The Purported Notice Letters state that Otsuka's patents related to SAMCSA® (tolvaptan) are either invalid or will not be infringed by Par's generic tolvaptan product.[1] Complaint at ¶ 3, Answer at ¶ 3. Par sent the Purported Notice Letters concurrently with filing an amendment to ANDA No. 206119. Answer at ¶ 26.

As of October 10, 2013, the date Par sent the Purported Notice Letters to Otsuka, Par's ANDA had not been accepted for review by the FDA. Complaint at ¶ 25, Answer at ¶ 25. Otsuka contacted the FDA and confirmed that more than one month later, as of November 14, 2013, the FDA had still not yet accepted Par's ANDA for review. Complaint at ¶ 27. Otsuka contacted Par and requested that Par withdraw its improper Purported Notice Letters, but Par refused. Complaint at ¶ 28, Answer at ¶ 28.

LEGAL STANDARD

Pursuant to Fed. R. Civ. P. 12(c), judgment on the pleadings should be granted where, as here, all pleadings are closed, "no material issue of fact remains to be resolved and that [the

[1] The patents-in-suit are U.S. Patent Nos. 5,753,677 and 8,501,730 B2.

moving party] is entitled to judgment as a matter of law." *Rosenau v. Unifund Corp.*, 539 F.3d 218, 221 (3d Cir. 2008). In deciding a Rule 12(c) motion, all factual allegations are taken as true and are viewed in the light most favorable to the non-moving party. *Id.* "The purpose of judgment on the pleadings is to dispose of claims where the material facts are undisputed and judgment can be entered on competing pleadings and exhibits thereto, and documents incorporated by reference." *BuySAFE, Inc. v. Google Inc.*, No. 11-1282-LPS, 2013 U.S. Dist. LEXIS 105601, at *3-5 (D. Del. July 29, 2013) (citing *Venetec Int'l, Inc. v. Nexus Med., LLC*, 541 F. Supp. 2d 612, 617 (D. Del. 2008)).

ARGUMENT

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

This case arises from Par's premature and improper attempt to trigger the ANDA litigation process by sending Purported Notice Letters to Otsuka ***before*** Par's ANDA was accepted for filing by the FDA. Par ignored federal law governing the timing of Paragraph IV notice letters, which requires that such notices cannot be sent until after the FDA has accepted the ANDA for filing. Given the improper, unlawful, and premature nature of the Purported Notice Letters, Otsuka immediately requested that Par withdraw its improper notice. Par refused. Accordingly, Otsuka filed this lawsuit to obtain a judicial declaration that Par's notice is improper. Further, the ANDA litigation process—including Otsuka's 45-day period to sue and the 30-month stay—cannot begin until Par's ANDA has been accepted by the FDA and Otsuka has received a timely, proper notice of Paragraph IV certification. Complaint, Count I (¶¶30-36).[2]

[2] Count I of Otsuka's Complaint seeks a declaratory judgment that:

There are no material facts in dispute here. Par admitted that its ANDA had not been accepted for filing by the FDA at the time Par sent its Purported Notice Letters to Otsuka. Answer at ¶ 25. The FDA confirmed that more than a month after Par sent the Purported Notice Letters, its ANDA had not been accepted for filing by the FDA. Complaint at ¶ 27. Indeed, it appears that Par's ANDA has still not been accepted for filing as of the date of this motion. *See* http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedanddApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM293268.pdf (No entry for tolvaptan on FDA's list of received Paragraph IV certifications dated January 6, 2014.)

21 U.S.C. § 355(j)(2)(B)(ii)(I) governs the timing for providing notice of an ANDA's Paragraph IV certification.

> 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.

21 U.S.C. § 355(j)(2)(B)(ii)(I). The corresponding federal regulation construing this provision provides:

> (1) Par's Purported Notice Letters are improper, null, void, and without legal effect, and that Par was not entitled to trigger the ANDA patent litigation process; (2) this Court has no subject matter jurisdiction over Otsuka's alternative claims regarding infringement of the '677 and '730 patents because Par's Purported Notice Letters are null, void, and without legal effect; (3) the Purported Notice Letters served by Par 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 Par's ANDA, Par must serve new and valid Paragraph IV Notices on Otsuka pursuant to 21 U.S.C. § 355(j)(2)(A)(vii); and (5) the 30-month stay and 45-day period in which to file a patent infringement action pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) will not begin until Par has sent valid Paragraph IV Notices to Otsuka following FDA acceptance of Par's ANDA. Complaint ¶ 36. Otsuka also pled in the alternative claims of patent infringement (Counts II and III).

> 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). The directive is plain—before sending a Paragraph IV notice to the patent owner and NDA holder, the ANDA filer must receive acknowledgement from the FDA that its ANDA has been filed (i.e., is sufficiently complete to permit substantive review). Because Par's ANDA had not yet been accepted as filed by the FDA, Par's Purported Notice Letters were improper, invalid, and without legal effect.

This timing requirement for Paragraph IV notices is "particularly significant because it is inextricably intertwined with the statutory framework for patent litigation." *SB Pharmco Puerto Rico, Inc. d/b/a GlaxoSmithKline v. Mutual Pharm. Co.*, 552 F. Supp. 2d 500, 507 (E.D. Pa. 2008). Receipt of Paragraph IV certifications by the patent owner and NDA holder start the clock on the 45-day period in which the patentee may file an infringement suit. 21 U.S.C. § 355(j)(5)(B)(iii). If the patentee chooses to sue the ANDA filer for patent infringement, approval of the ANDA is suspended for thirty months or until judicial resolution of the infringement suit, whichever comes first. *Id.*

The legislative history of the Hatch-Waxman Act reveals important policy considerations articulated by both Congress and the FDA regarding the timing of Paragraph IV notices. "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." *SB Pharmco*, 552 F. Supp. 2d at 507 (citing 59 FR 50338, 50349 (Oct. 3, 1994) (quoting H. Rept. 857, 98th Cong. 2d Sess. 24 (1984))) (internal quotations omitted). The FDA expressed similar concerns:

> To permit an ANDA applicant to provide notice [to the patentee] 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.

SB Pharmco, 552 F. Supp. 2d at 508 (citing 59 FR 50338, 50350 (Oct. 3, 1994)).

Par's apparent reliance on the amendment provision, 21 U.S.C. § 355(j)(2)(B)(ii)(II), is a red herring. *See* Answer at ¶ 26. Par refers to the part of the statute that governs Paragraph IV notices accompanying amendments or supplements to an already-filed ANDA. This provision directs an ANDA applicant to provide Paragraph IV certification "if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant 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).

Par appears to be taking a literal reading of the statute to an absurd extreme by suggesting that an ANDA applicant can amend an application that has not yet been received for filing, send a Paragraph IV notice to the patent holder based on the amendment, and start the clock running on the 45-day litigation window and 30-month stay—even though the applicant may not send such a notice on the original (and not yet received) ANDA. Such a result would allow an ANDA applicant to game the system by accelerating the timing provisions and litigation process. This outcome is directly contrary to the policy considerations articulated by Congress and the FDA and results in wasted judicial resources and economic injury to innovator companies and other potential ANDA filers.

SB Pharmco, a case with facts very similar to the instant matter, is squarely on point. In *SB Pharmco*, the generic ANDA filer sent out Paragraph IV notices based on the same amendment provision, before its underlying ANDA was accepted by the FDA for filing. The court cited correspondence from the FDA interpreting 21 U.S.C. § 355(j)(2)(B)(ii)(II):

> 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.

SB Pharmco, 552 F. Supp. 2d at 510 (citation omitted). The court also noted that reading the entire provision in its entirety,[3] "it seems clear that subparagraph (II) refers to an amendment to an ANDA for which the FDA has already acknowledged receipt." *Id*. at 509 n.4. The court interpreted 21 U.S.C. § 355(j)(2)(B)(ii)(II) to mean that notice be sent simultaneously with the amendment or supplement "*only* if the amendment is submitted for an ANDA that has already been accepted for filing." *Id.* at 510. The court concluded that the ANDA filer's Paragraph IV notice was not valid or timely under 21 U.S.C. § 355(j)(2)(B)(ii)(II). As a result of the invalid, untimely Paragraph IV notice, the court dismissed without prejudice the patentee's alternative counts of infringement and the defendant's counterclaims. *Id*. at 511.

The same relief is warranted here. Par's Purported Notice Letters are invalid, untimely, and without legal effect. As a result, and for the reasons described above, Otsuka 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 FOR LACK OF SUBJECT MATTER JURISDICTION

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[3] 21 U.S.C. § 355(j)(2)(B)(ii) states:

> (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.

Par's failure to follow the relevant statutory scheme governing ANDA litigation also mandates dismissal of Otsuka's alternative patent infringement claims and Par's counterclaims. Otsuka's alternative counts are unnecessary and should be dismissed because there was no filed ANDA and no proper Paragraph IV notification. Further, as there was no proper Paragraph IV notification, 45 days could not have not elapsed since receipt of a valid Paragraph IV notice, and Par has no right to commence a declaratory judgment action. 35 U.S.C. §271(e)(5). Even if Par had such a right, the Court should exercise is discretion and decline to entertain a declaratory judgment claim in light of Par's blatant and improper attempt to circumvent the timing provisions set forth in the relevant statutes and regulations. 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 for lack of subject matter jurisdiction.

CONCLUSION

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

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January 16, 2014

CERTIFICATE OF SERVICE

I hereby certify that on January 16, 2014, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on January 16, 2014, upon the following in the manner indicated:

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/s/ Maryellen Noreika
Maryellen Noreika (#3208)

EXHIBIT E

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

Dear

This is in response to , regarding the notice that received from Par Pharmaceuticals, Inc. (Par) with respect to their claim of non-infringement of U.S. Patent Nos.
for an abbreviated new drug application (ANDA) No. that they submitted to the Food and Drug Administration (FDA) for

The Federal Food, Drug, and Cosmetic Act (the Act) provides that an ANDA applicant may challenge a listed patent for the reference drug as invalid or not infringed by submitting to FDA a certification pursuant to section 505(j)(2)(A)(vii)(IV)(a paragraph IV certification). Section 505(j)(2)(B)(ii)(I) of the Act governs the provision of notice to the NDA holder and patent owner of a paragraph IV certification submitted in an application. It provides that the applicant shall give notice "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."

There are two parameters governing the timing of notice to the NDA holder of a paragraph IV patent challenge: (1) the date before which notice may not be given, and (2) the date by which notice must be given. FDA's regulation at 21 CFR 314.95(b), which was promulgated pursuant to the 1984 Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Amendments), describes the agency's position regarding the date before which notice may not be given. The regulation provides that the ANDA applicant 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." Although the regulation further provides that if an ANDA is "amended to include [a paragraph IV certification] the applicant shall send the notice required . . . . at the same time the amendment to the abbreviated application is submitted to FDA," FDA has not interpreted this to require or permit applicants who amend their applications before receipt of an acknowledgement letter to provide notice before learning whether their application has been determined to be sufficiently complete to be received. Rather, this provision applies only to amendments made after an ANDA has been received.

Patent certifications and related notice are part of a complex system described in section 505(j) of the Act for resolution of patent disputes related to generic drug applications. Receipt of notice that an ANDA applicant has submitted a paragraph IV certification begins a 45-day period within which the NDA holder and patent owner must initiate patent infringement litigation against the ANDA applicant in order to obtain a 30-month stay of the approval of the ANDA. 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") ensures

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 the agency. 54 Fed. Reg. 28872, 28887 (July 10, 1989); 59 Fed. Reg. 50338, 50349-50 (Oct. 3, 1994). The agency believes that Congress did not intend that incomplete application submissions would trigger legal action by a patent owner or NDA holder and therefore we implemented this interpretation of the notice requirement.

The date by which notice of a paragraph IV certification must be given was changed by statute in 2003. FDA's regulation at 21 CFR 314.95(b), which was promulgated to implement the Hatch-Waxman Amendments, states that the ANDA applicant must give notice "when" it receives acknowledgement from FDA that the application is eligible for review. The term "when" was subject to multiple interpretations by industry, resulting in ANDA applicants providing notice to NDA holders and patent owners at times ranging from immediately upon receipt of an acknowledgement letter to months after such receipt.

The 2003 Medicare Prescription Drug Improvement and Modernization Act (MMA) revised the Act to identify a specific date by which notice of a paragraph IV certification contained in an application must be given, i.e., not later than 20 days after the date of the postmark on the notice informing the applicant that the ANDA has been accepted for review. This revision established a new, more clearly identified, date by which notice must be given; it did not revise the date before which notice may not be given. The new provision adopts – and thus ratifies – the agency's use of acknowledgement that the ANDA has been filed as a bench mark against which to measure the sending of notice of the patent challenge to the NDA holder. Therefore, an ANDA applicant may not send notice of a paragraph IV certification submitted in an application to the NDA holder or patent owner until the FDA informs the applicant that the ANDA is sufficiently complete to permit review.

You have informed FDA that Par sent notice to of its paragraph IV certifications to the patents before Par received acknowledgement from the FDA that ANDA had been received for review. FDA considers such a notification to be invalid and such notice does not trigger either the 45-day period in which may file suit against Par 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. Par will be required to renotify the NDA holder and patent owner(s) within 20 days after the FDA informs it that its application has been received for review.

If you have any questions concerning this letter, please contact Cecelia M. Parise, Regulatory Policy Advisor to the Director, Office of Generic Drugs, at 240-276-9310.

Sincerely,

{See appended electronic signature page}

Gregory P. Geba, M.D., M.P.H.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: Par Pharmaceuticals, Inc.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ROBERT L WEST
08/15/2012
Deputy Director, Office of Generic Drugs
for Gregory P. Geba, M.D., M.P.H.