IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WARNER CHILCOTT COMPANY, LLC and HOFFMANN-LA ROCHE INC., *Plaintiffs,* v. TEVA PHARMACEUTICALS USA, INC., *Defendant.*	C.A. No.1: 08-cv-0627-LPS C.A. No. 1:11-cv-00081-LPS
WARNER CHILCOTT COMPANY, LLC and HOFFMANN-LA ROCHE INC., *Plaintiffs,* v. APOTEX, INC. and APOTEX CORP., *Defendants.*	C.A. No. 09-143-LPS (consolidated with C.A. No. 08-627-LPS)
WARNER CHILCOTT COMPANY, LLC and HOFFMANN-LA ROCHE INC., Plaintiffs, v. MYLAN PHARMACEUTICALS, INC., Defendant.	C.A. No. 10-285-LPS (consolidated with C.A. No. 08-627-LPS)
THE PROCTER & GAMBLE COMPANY and HOFFMANN-LA ROCHE INC., Plaintiffs, v. SUN PHARMA GLOBAL, INC., Defendant.	C.A. No. 09-61-LPS (consolidated with C.A. No. 08-627-LPS) **PUBLIC VERSION**

APOTEX'S BRIEF IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT OF NONINFRINGMENT OF U.S. PATENT NO. 6,165,513

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Defendants Apotex Corp. and Apotex, Inc. (collectively "Apotex") respectfully submit this Brief in Support of Their Motion for Summary Judgment of Noninfringement of US Patent No. 6,165,513 ("the '513 patent"). In support of this motion Apotex relies on the materials included in the Appendix, filed herewith. Although there is no genuine issue of material fact as to infringement, the parties disagree over the legal question of whether this court has subject matter jurisdiction to decide the issue of non-infringement of the '513 patent. This brief addresses both infringement and the court's jurisdiction.

NATURE AND STAGE OF PROCEEDINGS

Plaintiffs Warner Chilcott Company, LLC ("Warner Chilcott") and Hoffmann-La Roche Inc. ("Roche") allege that of Apotex's abbreviated new drug application that includes a generic version of Risedronate Sodium 150 mg tablets would infringes the methods of US Patents Nos. 7,192,938 ("the '938 patent") and 7,718,634 ("the '634 patent") under 35 U.S.C. § 271(e). (D.I. 42, D-APP-INF000001–9.) Apotex's answer included a counterclaim for a **civil action to obtain patent certainty** ("CAPC"), *see* 21 U.S.C. § 355(j)(5)(C); *Caraco Pharmaceutical Laboratories, Ltd. v. Forest Laboratories, Inc.*, 527 F.3d 1278, 1285 (Fed. Cir. 2008) ("The CAPC is designed to prevent NDA holders from 'gaming' the Hatch-Waxman Act by forestalling the resolution of patent disputes with ANDA filers."), as a declaratory judgment action on on US Patent No. 6,165,513 ("the '513 patent"). (D.I. 44, D-APP-INF000019–51.) A proposed Final Pretrial Order is due in this matter on June 18, 2012, the Court has scheduled a Final Pretrial Conference on July 2, 2012, and a one-week bench trial is scheduled to commence on July 23, 2012. (D.I. 125 ¶¶ 11, 13, D-APP-INF000060–68.)

SUMMARY OF THE ARGUMENT

Apotex's proposed product would not infringe. The parties agreed in the joint claim construction statement that the '513 patent claims are limited to an oval-shaped tablet, which is

different from a REDACTED. Apotex's proposed tablets are REDAC not oval-shaped. Apotex's abbreviated new drug application therefore does not infringe any claims of the '513 patent.

A covenant not to sue does not deprive the court of jurisdiction over a Hatch-Waxman CAPC claim. In the particular context of a Hatch-Waxman CAPC, a covenant not to sue does not divest the court of subject matter jurisdiction. In other circumstances, a covenant not to sue may remove all barriers to an accused infringer's commercialization of its product. In the Hatch-Waxman context, however, a covenant not to sue by the patentee does not necessarily eliminate all barriers to entry. A judgment of non-infringement may be necessary to remove some such barriers. This is a sufficient injury-in-fact for constitutional purposes, is traceable to the patentee, can be remedied by entry of judgment, and is not rendered moot by a covenant not to sue which does not remove all the patentee's barriers to Apotex's commercialization of its non-infringing product. Accordingly, this Court has subject matter jurisdiction to enter summary judgment of non-infringement.

STATEMENT OF FACTS

Plaintiffs caused the FDA to list the '513 patent in the publication "Approved Drug Products with Therapeutic Equivalence Evaluations," which is commonly called the "Orange Book," in connection with new Drug Application No. 02-835 for ACTONEL®. (D.I. 44 ¶ 57 [D-APP-INF000040]; D.I. 45 ¶ 57 [D-APP-INF000053].) Plaintiffs admit that they thereby maintained that the '513 patent "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" with which the patents are listed in the Orange Book." (D.I. 44 ¶ 58 [D-APP-INF000040]; D.I. 45 ¶ 58 [D-APP-INF000053]) *See also,* 21 U.S.C. § 355(b)(1)(G). Plaintiffs admit that by maintaining the Orange Book listing of the '513 patent in connection with the Actonel® NDA, Warner Chilcott continues to represent that the '513 patent could reasonably be asserted against anyone making, using or selling a

generic risedronate sodium 150 mg tablet without a license from P&G and Roche. (D.I. 44 ¶ 62 [D-APP-INF000041]; D.I. 45 ¶ 62 [D-APP-INF000054].) Plaintiffs admit that they have not stipulated to or otherwise consented to the invalidity, noninfringement, or unenforceability of the claims of the '513 patent. (D.I. 44 ¶ 65 [D-APP-INF000042]; D.I. 45 ¶ 65 [D-APP-INF000054].) Plaintiffs admit that when Apotex brought its CAPC claim the '513 patent could be asserted against Apotex even after it prevailed in this litigation on the '938 and '634 patents. (D.I. 44¶ 65 [D-APP-INF000042]; D.I. 45 ¶ 67 [D-APP-INF000054].)

Discovery in this action included the '513 patent. Plaintiffs served document production requests on Apotex directed towards the '513 patent. [D-APP-INF000072–83, Requests Nos. 8–15, 23, 25.] Plaintiffs also served interrogatories on Apotex directed to the '513 patent. [D-APP-INF000084–92, Interrogatories Nos. 6–10.]

Apotex in an interrogatory asked plaintiffs, "Specifically identify each patent claim that Plaintiffs will assert in this action against Apotex . . . ." [D-APP-INF000100.] Plaintiffs responded, "Apotex's filing of ANDA No. 90-877 constitutes infringement of the '513 and '938 patents under 35 USC § 271(e)(2)(A)." [D-APP-INF000101.] Plaintiffs further responded, "Apotex literally infringes . . . at least claims 1,2, 5, 6, 7, 8, 9, and 10 of the '513 patent" [D-APP-INF000101.]

After the close of fact discovery, Warner Chilcott served on Apotex a document styled *Covenant Not To Sue*, which purported to be made effective November 16, 2011. [D-APP-INF000262–65] Apotex did not join, acquiesce, stipulate, or otherwise participate in that covenant not to sue. Instead, plaintiff Warner Chilcott generated that document unilaterally.

There is no genuine issue as to the fact that the tablet Apotex proposes to make will be round, not oval-shaped.

ARGUMENT

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 n.10 (1986). An assertion that a fact cannot be — or, alternatively, is — genuinely disputed must be supported either by citing to "particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for the purposes of the motion only), admissions, interrogatory answers, or other materials," or by "showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." FED. R. CIV. P. 56(c)(1)(A) & (B). If the moving party has carried its burden, the nonmovant must then "come forward with specific facts showing that there is a genuine issue for trial." *Matsushita*, 475 U.S. at 587 (internal quotation marks omitted).

I. There Is No Genuine Issue That Apotex's Proposed Product That Is A Round Tablet Would Not Infringe The '513 Patent Because Its Claims Are Limited To An Oval Shaped Tablet.

"An infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (*en banc*) (citations omitted), *aff'd*, 517 U.S. 370 (1996). Although comparison of the claims to the accused products poses a question of fact, an infringement claim is nonetheless amenable to summary judgment where the facts are not genuinely disputed.

A. The '513 Patent Claims As Properly Construed Are Limited To An Oval-Shaped Tablet, Which Differs From A Round Tablet.

The broadest claim of the '513 patent is Claim 1, which reads as follows:

> 1. An oral dosage form comprising a safe and effective amount of a bisphosphonate **wherein said oral dosage form is oval shaped,** about 0.23 to about 0.85 inches in length, about 0.11 to about 0.4 inches in width, and about 0.75 to about 0.3 inches in thickness and said oral dosage form is film coated to facilitate rapid esophageal transit and avoid irritation in the mouth, buccal cavity, pharynx, and esophagus wherein said film coating allows for delivery of said bisphosphonate to the stomach.

[D-APP-INF000017, the '513 patent, Claim 1, emphasis added.] The remaining claims 2–10 all depend from claim 1 and therefore incorporate each of its limitations including the "oval shaped" dosage form. As stated in the Joint Claim Construction Chart, Ex. B, n.1, filed with the Court, the parties agree as a matter of claim construction that the term "oval" in the '513 patent does not include a tablet with a REDACTED. (D.I. 159, Ex. B n.1, D-APP-INF000118.)

Materials cited in the prosecution of the '513 patent further explain this distinction between "oval" and "round" as terms of art in the field of pharmaceutical dosage forms. In response to a rejection for indefiniteness, applicants amended their claims to read "oval shaped." [D-APP-INF00013.] In support of the definiteness of that terminology, applicants submitted materials including the Tableting Specification Manual 4th ed. (1995). [D-APP-INF000137.] That reference differentiates between "Round Tablets" [D-APP-INF000149] and "Shaped Tablets" [D-APP-INF000150] such as "Oval" shaped [D-APP-INF000154, box 17]. The '513 patent is limited to "oval shaped" tablets.

B. Apotex's Proposed Product Will Be Round — Not Oval, As Required By The Claims Of The '513 Patent.

Apotex's ANDA product at issue in this case is a REDACTED

REDACTED. Apotex's ANDA unequivocally describes

Apotex's ANDA product as REDACTED. (*see* D-APP-INF000194–259 at D-APP-INF000236.) In light of the foregoing, the fact that Apotex's proposed tablet would be REDACTED not oval is not genuinely disputed.

C. Apotex's Round Tablet Would Not Infringe Because It Does Not Fit The '513 Patent's Oval-Shaped Claim.

In view of the foregoing, there is no question that the alleged invention claimed in '513 patent is limited to oval shaped tablets and cannot include round tablets. Furthermore, Dr. Dansereau, who is named as an inventor on the '513 patent, testified as follows REDACTED

REDACTED

(D-APP-INF000261 at 57:21–22.) Apotex's REDACTED is not oval-shape, and therefore cannot literally infringe. *Elkay Mfg. v. Ebco Mfg.*, 192 F.3d 973, 980 (Fed. Cir. 1999) ("If even one limitation is missing or not met as claimed, there is no literal infringement.").

Moreover, there can be no infringement here under the doctrine of equivalents because (i) such a finding would vitiate the limitation "oval shaped" contrary to the all-elements rule, *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997) ("[T]he doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole."), and (ii) the doctrine of equivalents cannot be used to "recapture subject matter surrendered during prosecution." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 493 F.3d 1368, 1377 (Fed. Cir. 2007) (quoting *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1579 (Fed. Cir. 1995)). Accordingly, Apotex is entitled to summary judgment of noninfringement.

II. This Court Has Subject Matter Jurisdiction On Apotex's Civil Action To Obtain Patent Certainty.

Although plaintiffs listed the '513 patent in the Orange Book and maintained that Apotex could have been sued on that patent for its proposed generic risedronate sodium tablets, Apotex believes plaintiffs will contend that the Court now lacks subject matter jurisdiction to enter summary judgment of non-infringement because plaintiffs have purported to grant Apotex a covenant not to sue. If a unilateral covenant not to sue removed jurisdiction from the Court, plaintiffs might be able to limit generic competition for a period of time due to its Orange Book listing of the '513 patent, which it is undisputed Apotex does not infringe. In the context of ANDA litigation, where a ***judgment*** of non-infringement can be required in order for a party to enter the market, a mere unilateral covenant not to sue does not render the controversy moot. *Caraco Pharmaceutical Laboratories, Ltd. v. Forest Laboratories, Inc.*, 527 F.3d 1278, 1297 (Fed. Cir. 2008) ("Under these circumstances, **even after a covenant not to sue has been granted,** the dispute as to infringement or invalidity of the relevant Orange-Book-listed patents constitutes "a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.") (emphasis added).

A. The Brand Manufacturer's Decision To List The '513 Patent In The Orange Book As Covering Generic Versions Of Its Actonel Product Creates An Actual Controversy Impeding Apotex's Market Entry, Over Which This Court Has Subject Matter Jurisdiction.

The Hatch-Waxman Act "facilitates the early resolution of patent disputes between generic and pioneering drug companies by providing that the mere act of filing a Paragraph IV ANDA constitutes an act of patent infringement" under 35 U.S.C. § 271(e). *Caraco*, 527 F.3d at 1283; *see also, Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). The act also

provides incentives to challenge patents, including a 180-day period of exclusivity for the first filer during which the FDA cannot approve the applications of subsequent filers. The court in *Caraco* explained:

> Fourth, to incentivize ANDA filers to challenge the validity of listed patents or design around those patents as early as possible, the Hatch-Waxman Act provides that the first ANDA applicant to file a Paragraph IV certification ("first Paragraph IV ANDA filer") shall enjoy a 180-day period of generic marketing exclusivity. *See* 21 U.S.C. § 355(j)(5)(B)(iv). Until the first Paragraph IV ANDA filer's exclusivity period expires, the FDA may not approve a later-filed Paragraph IV ANDA based on the same NDA (hereinafter a "subsequent Paragraph IV ANDA"). *Id.* Importantly, the first Paragraph IV ANDA filer is entitled to the 180-day exclusivity period **whether or not it establishes that the NDA holder's Orange-Book-listed patents are invalid or not infringed by the drug described in its ANDA**; all that is required is that the first Paragraph IV ANDA filer submit a substantially complete ANDA that contains a Paragraph IV certification. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb).

Caraco, 527 F.3d at 1283.

The act also defines various events that can trigger the running of this 180 day period. Among those triggering events, the 180 day exclusivity period for the first filer can begin when the first filer begins to market commercially ***or*** on the date of a final court decision as to the Orange-Book-listed patents. *Caraco*, 527 F.3d at 1283 ("The Hatch-Waxman Act provides that the 180-day period of exclusivity begins either on the date that the first Paragraph IV ANDA filer begins marketing its generic drug, or on the date of a final court decision finding the relevant Orange-Book-listed patents invalid or not infringed, whichever comes first."). That 180 day period during which subsequent filers cannot be approved can also begin ***before*** the first filer is able to begin selling. For example, here the '122 patent on the risedronate compound was upheld as valid and infringed. A final judgment as to the remaining patents (the '513 patent, the '938 patent, and the '634 patent) would therefore trigger the start of a party's 180 day period, which can begin before the '122 patent expires in 2014. Also, the Hatch-Waxman act provides

that various events will result in forfeiture of the 180 exclusivity period, 21 U.S.C. § 355(j)(5)(D), but the FDA does not determine whether a party is entitled to 180 day exclusivity unless circumstances make that determination necessary.

Here, for example, Teva Pharmaceuticals Inc. ("Teva") may have been the first to file an ANDA on the product in suit. Teva made a paragraph IV certification that the '513 patent is invalid or not infringed by its patent. However, Teva has since reached an agreement with plaintiffs regarding that claim resulting in dismissal of the claims against Teva on that patent. Accordingly, even if the defendants prevail as to the '938 patent and '634 patent, if plaintiffs can prevent there being a judgment on the '513 patent they may be able to keep the generic manufacturers other than Teva out of the market for an additional six months, based on the listing in the Orange Book of the '513 patent.

In *Caraco*, the company Ivax had been the first filer, but could not commercially launch to trigger its 180-day exclusivity period because it lost on one of the two patents, Re. 34,712. *Caraco*, 527 F.3d at 1286–87. In just the same way, Teva is here blocked from launching until a later date because it did not prevail on its certification regarding the '122 patent. In these circumstances, the plaintiffs' actions in listing the '513 patent in the Orange Book then seeking to evade judgment on it can have the effect of delaying Apotex's entry into the market even though Apotex would not infringe that patent. The Federal Circuit concluded that in this scenario, a second filer (like Apotex) presents a judicially cognizable injury-in-fact. *Caraco*, 527 F.3d at 1291–92 ("If Caraco is correct that its generic drug does not infringe Forest's '941 patent, then it has a right to enter the generic drug market, and its exclusion from the generic drug market by Forest's actions is a sufficient Article III injury-in-fact."). It also concluded that the injury is traceable to the brand manufacturer:

> Here, Forest's listing of the '712 and '941 patents in the Orange-Book effectively denies Caraco an economic opportunity to enter the marketplace unless Caraco can obtain a judgment that both those patents are invalid or not infringed by its generic drug. Under these circumstances, Forest's listing of the '941 patent (the patent-in-suit) in the Orange-Book creates an independent barrier to the drug market that deprives Caraco of an economic opportunity to compete. It is well established that **the creation of such barriers to compete satisfies the causation requirement of Article III standing.**

Caraco, 527 F.3d at 1292–93 (emphasis added). The Federal Circuit also concluded that in such circumstances the injury to the second filer is redressible by a favorable judgment. *Caraco*, 527 F.3d at 1293 ("Caraco's injury-in-fact is redressible by a declaratory judgment that the '941 patent is not infringed."). Here, just as in Caraco, Apotex's claim for a Hatch-Waxman civil action seeking patent certainty satisfies the injury-in-fact, causation, and redressibility requirements. *Id.* at 1293 ("In sum, Caraco's declaratory judgment action satisfies the injury-in-fact, causation, and redressibility requirements of standing.").

B. The Absence Of A Genuinely Disputed Issue Of Material Fact Does Not Deprive This Court Of Jurisdiction.

Here, it is no longer disputed that although the patentees could assert the '513 patent against Apotex or any generic manufacturer seeking to sell a generic version of Actonel® (risedronate sodium) 150 mg tablets, the actual product that Apotex proposes to sell would not, in fact, infringe the claims of the '513 patent. That result does not deprive the court of jurisdiction. Whenever summary judgment is proper it is because the facts are no longer genuinely disputed. If parties agree to entry of a consent judgment, that, too, does not deprive the court of jurisdiction to enter such a judgment. *Caraco*, 527 F.3d at 1293 n.11 ("Although we do not so decide, it appears that if Forest would submit to a consent decree that the drug described in Caraco's ANDA does not infringe the '941 patent, such a decree would redress Caraco's alleged injury-in-fact just as well as any other court judgment. Thus, if Forest's

objective in granting the covenant not to sue on the '941 patent was to avoid costly litigation with Caraco, this might be the best approach to resolve the controversy between the parties."). The fact that it is now clear Apotex would not infringe this patent is what entitles Apotex to judgment. In the absence of judgment the indisputable fact of non-infringement does not itself eliminate the controversy, because in the absence of such judgment Apotex is still faced with barriers to entering the market due to the brand manufacturer listing this patent in the Orange Book.

C. A Covenant Not To Sue From The Patentee Does Not Eliminate Subject Matter Jurisdiction Over a Hatch-Waxman CAPC Claim.

In correspondence and discussions between counsel, plaintiffs have contended that a covenant not to sue on the '513 patent would deprive the court of subject matter jurisdiction. In the context of an ordinary infringement suit, or, for example, a suit brought by a supplier concerning infringement allegations against its customers, such a covenant not to sue can eliminate any apprehension of litigation and in some circumstances may eliminate any actual controversy. Such a covenant, however, does not render moot a Hatch-Waxman CAPC claim. *Caraco*, 527 F.3d at 1296–97 ("Under these circumstances, even after a covenant not to sue has been granted, the dispute as to infringement or invalidity of the relevant Orange-Book-listed patents constitutes 'a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.') (quoting *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007)).

This is not a situation where the generic manufacturer has, by its own actions, eliminated jurisdiction as to the very patent in dispute. *See Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1360 (Fed. Cir. 2008). There, the generic manufacturer had brought suit on several patents, but during the course of litigation had ***stipulated*** as to the validity and

infringement of one. *Id.* at 1358 ("Apotex stipulated to infringement, validity, and enforceability of the '663 patent . . . ."). In the absence of such a stipulation, jurisdiction would have been proper in that case just as it was in *Caraco*. *Janssen,* 540 F.3d at 1360 ("We agree with the parties that if Apotex had not stipulated to the validity of the '663 patent, then *Caraco* would have been controlling."). In the case at bar, Apotex has *never* stipulated to the validity, infringement, and enforceability of any of the patents in suit. Accordingly, this case is controlled by *Caraco*, not *Janssen*, and jurisdiction is proper. *Janssen,* 540 F.3d at 1360 ("Therefore, while the harm that created a justiciable Article III controversy in *Caraco* **was present when Apotex filed its counterclaims** on April 25, 2006, that harm ceased to exist **upon Apotex's stipulation**."). While the party alleging injury under a Hatch-Waxman CAPC claim can eliminate the controversy by stipulation, as in *Janssen*, the patentee cannot by unilateral covenant not to sue deprive the Court of jurisdiction, as was explained in *Caraco*. *See also, Impax Laboratories, Inc. v. Pfizer Inc.* No. 10–CV–06554 (DMC–JAD), 2011 WL 4594824, at *4 (D.N.J., Sep. 30, 2011) ("*Janssen* stands for the proposition that a **stipulation** to be bound will divest a federal court of declaratory judgment jurisdiction, as such stipulation is **not fairly traceable** to the [declaratory judgment] Defendant's actions and will prevent a judgment in Plaintiff's favor from redressing the injury alleged.").

Instead, this is a case in which a favorable judgment can eliminate a barrier to Apotex's entry into the market. *See Seattle Children's Hosp. v. Akorn, Inc.*, No. 10–CV–5118, 2011 WL 6378838, at *6 (N.D. Ill., Dec. 20, 2011) ("Here, as in *Caraco,* a favorable judgment "would eliminate the potential for the ['269 patent] to exclude [Akorn] from the drug market.") (quoting *Caraco*). The district court in *Seattle Children's Hosp.* also found persuasive the reasoning of

another Federal Circuit case, which was subsequently vacated on other grounds after being rendered moot. The district court in *Seattle Children's Hosp.* explained:

> Although vacated for other reasons, the Federal Circuit's language in *Teva Pharms. Usa, Inc. v. Eisa Co., Ltd.* also supports this result. 620 F.3d 1341, 1346–47 (Fed.Cir.2010) ("Because a company is not free to manufacture or market drugs until it receives FDA approval, under the Hatch–Waxman framework such an injury occurs when the holder of an approved NDA takes action that delays FDA approval of subsequent ANDAs") (reversing dismissal of lawsuit by district court). Although the *Teva* decision was recently vacated by the Supreme Court and remanded to the Federal Circuit with instructions to dismiss the case as moot, the case had become moot not because of a covenant not to sue but because non-party Ranbaxy, the first filer, began marketing its generic drug, thus triggering its 180 day exclusivity period. See *Teva Pharms. Usa, Inc. v. Eisa Co., Ltd.*, — U.S. —, 131 S.Ct. 2991, 180 L.Ed.2d 818 (June 13, 2011) (citing *United States v. Munsingwear, Inc.*, 340 U.S. 36, 71 S.Ct. 104, 95 L.Ed. 36 (1950)). In *Teva*, the Federal Circuit reiterated that, under the Hatch–Waxman framework, "a judicially cognizable injury-in-fact * * * occurs when the holder of an approved NDA takes action [i.e., 'listing particular patents in the Orange Book'] that delays FDA approval of subsequent ANDAs." *Teva*, 620 F.3d at 1346–47. The Federal Circuit's decision "turn[ed] on whether a subsequent Paragraph IV filer has a legally cognizable interest in when the first-filer's exclusivity period begins, such that delay in triggering [or forfeiting under the current regime] that period qualifies as 'injury-in-fact' for the purposes of Article III," which the court when on to state a subsequent filer does have pursuant to *Caraco*. See *Teva*, 620 F.3d at 1343 (citing *Caraco*, 527 F.3d 1278).

Seattle Children's Hosp., 2011 WL 6378838, at *6n.3. Accordingly, subject matter jurisdiction is proper here.

CONCLUSION

For the foregoing reasons, Apotex requests the Court enter summary judgment that Apotex's ANDA U.S. Patent No. 6,165,513 ("the '513 patent") is not infringed and enter judgment on Apotex's declaratory judgment counterclaim.

Respectfully submitted,

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FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, Richard L. Horwitz, hereby certify that on April 23, 2012, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

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