IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, and WARNER-LAMBERT COMPANY LLC,	)	Case No. 08 C 7231
Plaintiffs,	)	Consolidated for all purposes with Case No. 09-cv-6053
v.	)	
APOTEX INC., and APOTEX CORP.,	)	Judge Robert M. Dow, Jr.
Defendants.	)	

PLAINTIFF PFIZER'S BRIEF IN SUPPORT OF ITS MOTION TO DISMISS COUNTS III, IV, VII, AND VIII OF DEFENDANT APOTEX'S COUNTERCLAIMS PURSUANT TO FED. R. CIV. P. 12(b)(1)

John S. Mortimer
Jeffrey M. Drake
WOOD PHILLIPS
500 West Madison Street
Suite 3800
Chicago, IL 60661-2562
(312) 876-1800

OF COUNSEL:
Rudolf E. Hutz
Jeffrey B. Bove
Mary W. Bourke
Daniel C. Mulveny
CONNOLLY BOVE LODGE & HUTZ LLP
1007 North Orange Street
Wilmington, DE 19899
(302) 658-9141

William E. McShane
CONNOLLY BOVE LODGE & HUTZ LLP
1875 Eye Street, NW
Suite 1100
Washington, DC 20006
(202) 572-0335

Attorneys for Plaintiffs
Dated: July 21, 2010

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I. INTRODUCTION

The Pfizer plaintiffs (collectively "Pfizer") move, under Fed. R. Civ. P. 12(b)(1), to dismiss Counts III, IV, VII, and VIII of the Apotex defendants' (collectively "Apotex") counterclaims for lack of subject matter jurisdiction under the facts and circumstances that now exist in this case. For the reasons set forth below, this Court lacks subject matter jurisdiction over Apotex's counterclaims directed to Pfizer's U.S. Patents Nos. 6,686,104 ("the '104 patent") and 6,126,971 ("the '971 patent") (collectively "the Formulation Patents").

Pfizer previously moved to dismiss Apotex's counterclaims on the Formulation Patents. (D.I. 113). On June 30, 2010, the Court denied the motion based on the circumstances as they then existed. In response to the Court's decision, Pfizer has granted a covenant not to sue and it has sued Apotex on U.S. Patent No. 5,969,156 ("the '156 patent"). First, in light of the Court's decision Pfizer has now given Apotex a covenant not to sue on the Formulation Patents and thus there is no possibility of a future lawsuit on these patents related to Apotex's ANDA and its ANDA product described therein. Second, also in light of the Court's decision, Pfizer has brought a counter-counterclaim against Apotex on the '156 patent, which expires, including pediatric exclusivity, in January 2017, after the expiration of the Formulation Patents and after the November 30, 2011 date that Ranbaxy may enter the market under its settlement with Pfizer. Therefore, the earlier-expiring Formulation Patents and the Ranbaxy settlement with its November 30, 2011 license date cannot prevent Apotex from overcoming Ranbaxy's 180-day exclusivity rights unless and until Apotex prevails on the '156 patent. Third, another source of possible injury to Apotex is Ranbaxy's own inability to gain FDA approval due to regulatory issues. In light of these facts which result, in part, from the Court's June 30th decision, the Court lacks subject matter jurisdiction over Apotex's Formulation Patent counterclaims.

II. NATURE AND STATE OF THE PROCEEDINGS

On December 17, 2008, Pfizer sued Apotex for infringement of U.S. Patent No. 5,273,995 ("the '995 patent") after Apotex filed Abbreviated New Drug Application ("ANDA") No. 90-548, which sought approval from the Food and Drug Administration ("FDA") to market a generic copy of Pfizer's blockbuster drug Lipitor®. (D.I. 1). On March 17, 2009, the United States Patent and Trademark Office ("USPTO") reissued claim 6 of the '995 patent in U.S. Reissue Patent No. 40,667 ("the RE'667 patent"). Pfizer then amended its Complaint to include a count for infringement of the RE'667 patent. (D.I. 25 in No. 09-cv-6053[1], hereinafter "Complaint").

Apotex answered Pfizer's Complaint in Illinois and asserted counterclaims alleging non-infringement and invalidity of three additional Pfizer patents: the '156 patent, which is directed to certain crystalline forms of atorvastatin calcium, and the two Formulation Patents. Pfizer moved to dismiss Apotex's counterclaims against all three patents for, *inter alia*, lack of subject matter jurisdiction. (D.I. 113). This Court denied Pfizer's motion on June 30, 2010. (D.I. 144).

With the instant motion, Pfizer is concurrently replying to Apotex's counterclaims, and, with this reply, Pfizer now asserts a counter-counterclaim against Apotex alleging that Apotex's ANDA infringes the '156 patent. Following the Court's denial (D.I. 144) of Pfizer's motion to dismiss Apotex's counterclaims (D.I. 113), Pfizer was to reply to Apotex's counterclaims on July 14, 2010. However, on July 9, 2010, the parties jointly moved to extend Pfizer's reply date to July 21, 2010. (D.I. 150). The parties' joint motion was granted on July 12, 2010 (D.I. 152) and the Court set Pfizer's counterclaim reply date for July 21, 2010.

Subsequent to the Court's ruling on Pfizer's initial motion to dismiss (D.I. 144), Pfizer has also granted Apotex a covenant not to sue on the Formulation Patents. The covenant

[1] *See* D.I. 109 (Minute Order deeming D.I. 25 in No. 09-cv-6053 to be the operative complaint).

addressed both Apotex's ANDA filing and any subsequent actions involving the ANDA product described in the ANDA. (Ex. A).

In view of these events, Pfizer now moves to dismiss Apotex's counterclaims against the Formulation Patents.

III. SUMMARY OF ARGUMENT

1. There is no case or controversy here with respect to the Formulation Patents. Pfizer has granted Apotex a covenant not to sue on these patents. Apotex is no longer subject to the threat of future patent infringement litigation over its ANDA, or its ANDA product as described therein, regarding those patents.

2. Pfizer has now sued Apotex on the Orange Book listed patent with the longest remaining term: the '156 patent. Unless Apotex can show either (a) that its ANDA product does not infringe the '156 patent or (b) that the '156 patent is invalid despite having been reexamined by the USPTO in full view of all the known prior art, the FDA will not be permitted to approve Apotex's ANDA until January 2017, regardless of any judicial determinations on the Formulation Patents, which expire before that time. Accordingly, any future injury alleged by Apotex as attributable to the Formulation Patents is purely speculative. Similarly, any future injury based on the Ranbaxy settlement is equally speculative.

3. Ranbaxy has not gained FDA approval to market its ANDA product. Its regulatory delay issues are not attributable to Pfizer. And the impact of the '156 patent on Ranbaxy's 180-day exclusivity period derives from the Hatch-Waxman Act, not Pfizer. Because any alleged injury to Apotex from the Formulation Patents and the Ranbaxy settlement is subservient to these two factors, the marketing delay, if any, to Apotex by reason of Ranbaxy's 180-day exclusivity period is not fairly traceable to Pfizer.

IV. STATEMENT OF FACTS

A. The Hatch-Waxman Act awards the first ANDA filer 180 days of marketing exclusivity

Generic drug companies like Apotex typically obtain market approval to copy an innovator's drug through Abbreviated New Drug Applications ("ANDAs") under the Hatch-Waxman Act.[2] To encourage generic drug manufacturers to challenge listed patents, the Hatch-Waxman Act provides that the first generic manufacturer to file an ANDA with a Paragraph IV certification will have 180 days of generic marketing exclusivity, during which the FDA may not approve later-filed ANDAs based on the innovator's NDA. *See* 21 U.S.C. § 355(j)(5)(B)(iv). Under the version of Hatch-Waxman applicable to this case,[3] the first-filer's 180-day exclusivity period can be triggered to begin by either the first Paragraph IV ANDA filer's commercial marketing of its generic drug product, or by a final Court decision of non-infringement or invalidity of the listed patent. *Id*. Only the first-filer can begin the 180-day exclusivity period via the commercial-marketing trigger, but a final Court judgment of noninfringement or invalidity obtained by a subsequent filer in an action in which all jurisdictional requirements are satisfied, could also trigger the first-filer's 180-day exclusivity period. *See Minn. Mining & Mfg. Co. v. Barr Labs, Inc.*, 289 F.3d 775, 780 (Fed. Cir. 2002). In such a case, the first filer's 180-day

[2] More formally known as The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984). Pfizer previously discussed the Hatch-Waxman Act in D.I. 56, which is incorporated herein by reference. Additional details regarding the Hatch-Waxman Act can be found in this Court's June 30, 2010 memorandum opinion (D.I. 144 at 2-5).

[3] Congress amended the Hatch-Waxman provisions governing the commencement of the 180-day exclusivity period as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (the "MMA"). However, grandfather provisions within the MMA make the amended triggering provisions inapplicable to this case. *See* MMA § 1102(b); *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1357 n.2 (Fed. Cir. 2008) (explaining the grandfather provisions).

exclusivity period will begin to run even if the first filer is not able to market its product at that time.

B. Lipitor®

Lipitor® is Pfizer's brand name for a medication containing atorvastatin calcium as its active ingredient. Lipitor® is used to treat cardiovascular disease and prevent hyper-cholesterolemia thereby preventing heart attacks and stroke. Pfizer's Lipitor® was approved by the FDA in 1996 and sales began in the U.S. in 1997. Pfizer owns a number of patents that protect Lipitor®. Six of these patents are listed in the Orange Book: U.S. Patent Nos. 4,681,893 ("the '893 patent", now expired), the '995 patent, the RE'667 patent, the '156 patent, and the two Formulation Patents.

C. Ranbaxy, Teva, Cobalt, and Apotex seek approval to market generic atorvastatin products

Apotex is not the first, or the last, generic company to attempt to copy Lipitor® before Pfizer's relevant patents expire. Indeed, Apotex is the fourth ANDA filer behind Ranbaxy, Cobalt, and Teva and has been followed by at least four others who were all sued by Pfizer.[4]

1. Ranbaxy was the first to file an ANDA for generic atorvastatin calcium and has been awarded 180 days of marketing exclusivity under the Hatch-Waxman Act

Ranbaxy filed the first ANDA seeking to market a generic atorvastatin product, on or around August 19, 2002. Ranbaxy's ANDA included Paragraph IV certifications as to all five

[4] Currently, the following active litigations are pending involving Pfizer patents claiming atorvastatin calcium, its use in medicine and/or methods of making it: *Pfizer v. Mylan* (Lipitor®), C.A. No. 09-441 (D. Del.), *Pfizer v. Mylan* (Caduet®), C.A. No. 10-85 (D. Del.), *Pfizer v. Sandoz*, CA No. 09-742 (D. Del.), *Pfizer v. Sandoz*, C.A. No. 10-103 (D. Del.), *Sandoz v. Pfizer*, C.A. No. 10-104 (D. Del.), *Pfizer v Dr. Reddy's Laboratories*, C.A. No. 09-943 (D.Del.), *Pfizer v. Kremers*, C.A. No. 09-924 (D. Del.)

then listed Orange Book patents.[5] Pfizer sued Ranbaxy in the United States District Court for the District of Delaware alleging infringement of only the '893 patent and one claim of the '995 patent. The district court found both patents to be valid and infringed, but the Federal Circuit reversed based on a technical defect in the asserted claim of the '995 patent. *See Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 405 F. Supp. 2d 495 (D. Del. 2005), *affirmed in part*, 457 F.3d 1284 (Fed. Cir. 2006).[6] Because it was the first to file an ANDA with a Paragraph IV challenge, Ranbaxy was awarded 180 days of Congressionally-mandated generic marketing exclusivity. Further, because Ranbaxy prevailed against Pfizer's '995 patent, the FDA was free to approve Ranbaxy's ANDA when the '893 patent expired on March 24, 2010. The FDA, however, has not yet approved Ranbaxy's ANDA for reasons discussed below in section IV.C.3.

2. Ranbaxy settled with Pfizer to give Ranbaxy freedom to market its generic atorvastatin calcium product on November 30, 2011

While Ranbaxy obtained its 180-day marketing exclusivity when it filed its atorvastatin calcium ANDA and could obtain FDA approval to market its ANDA after the '893 patent expired (assuming it otherwise satisfied all regulatory requirements, which it has not), there was still substantial uncertainty for Ranbaxy to market a generic product without infringing Pfizer's other Lipitor® patents that were not part of the prior *Ranbaxy* litigation. These patents include the '156 patent as well as other patents, such as U.S. Patent Nos. 6,087,511 and 6,274,740. Additionally, a second suit between Pfizer and Ranbaxy was filed due to a Ranbaxy ANDA for Pfizer's drug Caduet®, based on U.S. Patent No. 6,455,574.[7]

[5] The RE'667 patent, which is a reissue of the '995 patent after the *Ranbaxy* litigation, did not exist at the time Ranbaxy filed its ANDA.
[6] This technical defect has been corrected, and this claim of the '995 patent was reissued by the USPTO on March 17, 2009 in Reissue Patent No. RE'667.
[7] Attached as Exhibits, B, C, and D are consent decrees entered in separate *Pfizer v. Ranbaxy* litigations which identify these patents.

On June 18, 2008, Pfizer and Ranbaxy announced a worldwide settlement of their various patent disputes, including those involving Lipitor® and Caduet®, the terms of which are confidential. Ranbaxy was granted a license to sell generic versions of Lipitor® and Caduet® under all relevant Pfizer United States patents effective November 30, 2011. (*See* Ex. E).

3. Regulatory issues have prevented approval of Ranbaxy's ANDA

Due to various FDA problems, Ranbaxy has been and remains unable to receive tentative approval from the FDA for its generic atorvastatin calcium ANDA (Ex. F). The approval of Ranbaxy's ANDA, for reasons wholly unrelated to Pfizer, remains uncertain at this time.

D. Pfizer has granted Apotex an irrevocable covenant not to sue on the Formulation Patents

Subsequent to this Court's June 30, 2010 ruling, Pfizer provided Defendants with a covenant not to sue on the Formulation Patents. The covenant expressly provides that Pfizer will not sue Apotex for infringement of the Formulation Patents by reason of the ANDA and/or for the manufacture, use, distribution, sale, offer for sale, or importation by, for or to Apotex of the ANDA product described in that ANDA. (Ex. A, Pfizer-Apotex Covenant Not to Sue (July 21, 2010), Paragraph 1.b.)

V. ARGUMENT

In its June 30th opinion, this Court ruled that it had subject matter jurisdiction over Apotex's counterclaims based on the '156 patent and the Formulation Patents (D.I. 144). The central question before this Court today is whether, based on the current facts and circumstances, Pfizer's settlement with Ranbaxy sufficiently implicates either the court decision trigger or the commercial marketing trigger relating to Ranbaxy's 180-day exclusivity rights under applicable rules pertaining to subject matter jurisdiction as applied to the Formulation patents. As we demonstrate below, it does not.

Article III of the Constitution limits the judicial power of the United States to the resolution of "cases" and "controversies". U.S. CONST. art. III, § 2, cl. 1; *Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 471 (1982). The Declaratory Judgment Act permits a court to declare the rights and other legal relations of an party seeking such declaration only in "a case of actual controversy." 28 U.S.C. § 2201.

Apotex counterclaims for a declaratory judgment against Pfizer over the Formulation Patents. A party seeking the declaratory relief of patent invalidity or non-infringement must prove that "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." *Medimmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 126 (2007) (quotation omitted) (emphasis added). For jurisdiction, the dispute must be "definite and concrete," and redressable through "a decree of conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." *Janssen*, 540 F.3d at 1359 (quotation omitted). It must be "based on a real and immediate injury…an objective standard that cannot be met by a purely subjective or speculative fear of future harm." *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1339 (Fed. Cir. 2008). Without sufficient immediacy and reality, a declaratory judgment action fails to meet the actual controversy requirement of the Declaratory Judgment Act. *Id.*

The Federal Circuit views the "immediacy and reality" requirement "through the lens of standing." *Id.* at 1338. Thus, the party seeking a declaratory judgment must allege: "(1) an injury-in-fact, *i.e.*, a harm that is '"concrete" and actual or imminent, not "conjectural" and "hypothetical,"' (2) that is "fairly traceable" to the defendant's conduct, and (3) redressable by a favorable decision. *Id.* (quoting *Caraco Pharm. Labs, Ltd. v. Forest Labs, Inc.*, 527 F.3d 1278,

1291 (Fed. Cir. 2008)). In practical terms, the Supreme Court requires that any action satisfy three requirements: standing, ripeness, and lack of mootness. *Caraco Pharm. Labs.*, 527 F.3d at 1291. It is Apotex's burden to meet these requirements. *United Phosphorus, Ltd. v. Angus Chem. Co.*, 322 F.3d 942, 946 (7th Cir. 2003).

In 2003, Congress amended the Hatch-Waxman Act and the patent statute to provide later-filed ANDA applicants that file Paragraph IV certifications with a means to seek a declaratory judgment with respect to Orange Book-listed patents not asserted by the pioneer drug company. 21 U.S.C. § 355(j)(5)(C); 35 U.S.C. § 271(e)(5). Under these provisions, declaratory judgment jurisdiction in ANDA cases may only be exercised "to the extent [it is] consistent with the Constitution." 35 U.S.C. § 271(e)(5), *Janssen*, 540 F.3d at 1359.

A. There is no subject matter jurisdiction because Pfizer's covenant not to sue eliminates any case or controversy regarding Apotex's infringement of the Formulation Patents

An Article III Case or Controversy requires a dispute touching the legal relations of parties having adverse interests. *MedImmune, Inc.*, 549 U.S. at 126; *see also Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937). The Federal Circuit has explained that, when determining whether a dispute meets this requirement, "a useful question to ask in determining whether an actual controversy exists is what, if any, cause of action the declaratory judgment defendant may have against the declaratory judgment plaintiff." *Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1344 (Fed. Cir. 2007).

In its June 30th opinion, the Court first noted Apotex's claim of injury due to uncertainty about future lawsuits on the Formulation Patents. The Court observed: "First, Apotex contends that, by not suing Apotex on the Unasserted Patents while reserving the right to do so in the future, Pfizer has created uncertainty as to Apotex's legal rights under its ANDA. According to Apotex, that uncertainty, as well as the threat of future litigation based on the Unasserted Patents,

are injuries-in-fact." (D.I. 144 at 12). This alleged uncertainty has now been eliminated by reason of Pfizer's covenant not to sue. As stated in the Congressional Record concerning the 2003 amendments to the Hatch-Waxman Act that are part of the MMA:

> We believe that the only circumstance in which a case or controversy might not exist would arise in the rare circumstance in which the patent owner and brand drug company have given the generic applicant a covenant not to sue, or otherwise formally acknowledge that the generic applicant's drug does not infringe.

149 CONG. REC. S15885 (2003).

B. Because Pfizer has now sued Apotex on the last-to-expire '156 patent, any alleged future injury-in-fact attributable to the earlier expiring non-asserted Formulation Patents is purely speculative and not fairly traceable to Pfizer.

In its June 30th opinion, the Court also noted Apotex's claimed injury based on Pfizer's refusal to litigate the Formulation Patents and its settlement agreement with Ranbaxy. (D.I. 144 at 12). However, as explained, Pfizer has not only removed any patent uncertainty related to the Formulation Patents but it has also now sued Apotex on the last-to-expire '156 patent. Whether viewed through the lens of standing or ripeness, (*see* D.I. 144 at 11-12), the result is the same—there is no present justiciable controversy concerning the Formulation Patents. Application of the *Teva v. Novartis* analysis to these facts further establishes that there is no case or controversy with respect to the Formulation Patents.

The Federal Circuit applied the Supreme Court's *MedImmune* "all the circumstances" test in the ANDA context in *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330 (Fed. Cir. 2007). In *Teva*, Novartis chose to sue only on the Orange Book-listed patent that was to expire first, leaving open for later litigation listed patents that could prevent the ANDA applicant from marketing its generic product four to five years after the asserted patent would expire. *Id.* at 1334-35, 1340 n.5. Thus, win or lose on the asserted patent, Novartis still held patents that could be asserted years into the future. Moreover, Novartis' four non-asserted patents claimed methods

of using the active ingredient in accordance with the approved FDA label. (Exs. G - K). In other words, the mere use of the generic drug in accordance with the approved FDA labeling would almost certainly infringe the later-expiring method patents. As the drug was almost certain to be used in accordance with its proposed labeling, infringement of the non-asserted method patents, expiring after the patent Novartis asserted, was a sure bet.

Under these facts, Teva filed counterclaims with respect to the four non-asserted, but later-expiring method patents, and Novartis moved to dismiss the counterclaims for lack of subject matter jurisdiction. *Teva*, 482 F.3d at 1335. The Federal Circuit found a case or controversy based on the presence of the patents in the Orange Book, Teva's Paragraph IV certifications, Novartis's suit on the patent covering the active compound, and suspicion that Novartis was holding the (later-to-expire) method patents in reserve for later assertion. *Id.* at 1341-45.

In this case, unlike *Teva*, Pfizer has itself placed at issue the Orange Book-listed patent with the latest expiration date by suing Apotex on the '156 patent. Success by Pfizer on the '156 patent alone will prevent the FDA from approving Apotex's ANDA until January 2017—well after the Formulation Patents have expired.[8] Unless Apotex can show that the '156 patent is not infringed or is invalid,[9] while at the same time proving to the FDA that its proposed ANDA products are bioequivalent to Pfizer's Lipitor®, the issues of infringement and validity of the non-asserted Formulation Patents, which will both expire before 2017, are irrelevant to whether

[8] The Formulation Patents as listed in the Orange Book expire, including pediatric exclusivity, in July 2013 (the '971 patent) and May 2015 (the '104 patent).

[9] Invalidity will be a difficult road for Apotex. In addition to the presumption of validity attached to all patents, the '156 patent has been reexamined by the USPTO office and even with that additional examination of the prior art, the patent emerged valid. *See Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 961 (Fed. Cir. 1986) (results of PTO's reexamination of a patent must be considered).

the FDA can approve Apotex's ANDA. Any allegation that the Orange Book listing of the non-asserted patents is causing an injury-in-fact to Apotex is therefore based solely on the possibility that the '156 patent is not infringed or is invalid. Such a speculative injury is "'conjectural' and 'hypothetical'," and does not rise to the level of "concrete and actual or imminent." *See Prasco*, 537 F.3d at 1338 (quotation omitted).

Moreover, in *Teva*, the method of use of the approved ANDA product in accordance with its labeling would almost certainly have infringed the non-asserted method patents in that case. The *Teva* court identified five circumstances that together warranted finding a case or controversy: (1) Novartis listed the non-asserted patents in the Orange Book, *Teva*, 482 F.3d at 1341-42; (2) Teva filed a Paragraph IV certification with respect thereto, *id.* at 1342; (3) the combination of 21 U.S.C. § 355(j)(5)(C), 35 U.S.C. § 271(e)(5), and the purpose of the Hatch-Waxman Act promoted timely resolution of patent disputes, *id.* at 1342-43; (4) "Novartis [was]...selectively suing on the patent with the earliest expiration date," *id.* at 1340 n.5; and (5) Novartis held open the possibility of future suits by not asserting the later-to-expire method patents, *id.* at 1343-45. Where the non-asserted patents in *Teva* were directed to methods of using the drug in accordance with its approved labeling (Exs. G - K), these factors weighed in favor of finding a justiciable controversy. In sharp contrast, the non-asserted Formulation Patents in this case are directed to specific, stable chemical formulations that have little relevance to the crystal forms of the '156 patent at issue here. Moreover, there is no possibility of future suits on the Formulation Patents because the covenant not to sue removes any such threat.

In the present case, there is no non-speculative imminent or concrete controversy. The circumstances examined in *Teva* do not apply to the situation here because the filing of Pfizer's suit on the '156 patent does not suggest that any later suit will, or even could, be brought on the

Formulation Patents, which are subjects of the covenant not to sue. While a purpose of the Hatch-Waxman Act is to timely resolve patent disputes, it does not create justiciable controversies where none exist. Instead, a comprehensive review of "all the circumstances," as instructed by *MedImmune* and *Teva*, shows a lack of any "definite and concrete" dispute.

Because: (1) at the time Apotex filed its counterclaims there was no immediate injury-in-fact to due to Apotex's Paragraph III certification on the '893 patent, (2) unlike *Teva*, there is no possibility of future harm that rises above the level of mere speculation because infringement of the non-asserted Formulation Patents is irrelevant unless the later expiring '156 patent is proven invalid or not infringed, and (3) Pfizer's covenant not to sue on the Formulation Patents is directed to formulations and not FDA-approved methods of use (as in *Teva*), this Court lacks subject matter jurisdiction over the Formulation Patents, and Apotex's counterclaims against the Formulation Patents should be denied for lack of subject matter jurisdiction.

In fact, what is actually the cause of Apotex's avowed concerns is Ranbaxy's own failure to gain approval of its ANDA due to the FDA. The record suggests that Ranbaxy is unable to gain approval because of its own actions, having nothing to do with any agreement with Pfizer. (Exs. F, L, M and N). Without Ranbaxy's FDA approval, Apotex cannot get to market. Ranbaxy's failure to get FDA approval is due to FDA rules and is the superseding and intervening cause of Apotex's delay in getting to market, not the speculation that Pfizer's Formulation Patents or the Ranbaxy settlement may create some sort of block to FDA approval while the '156 patent is still being litigated. There is no real or immediate injury as a result of the Formulation Patents or Pfizer's agreement with Ranbaxy.

Equally important, the situation here is not like *Dey, L.P. v. Sepracor, Inc.*, 595 F. Supp. 2d 355 (D. Del. 2009) because in *Dey,* Sepracor, the pioneer patentee, did not assert the latest

expiring patent. *Id.* at 359 (noting that the unasserted patent expired in 2021). Again, if Apotex cannot succeed on the '156 patent, the Ranbaxy settlement is irrelevant. Moreover, unlike *Dey*, Apotex may still be barred until some unknown time in the future because of Ranbaxy's problems with the FDA which also prevent FDA approval and similarly render any alleged harm from the Ranbaxy settlement speculative.

C. Under the circumstances, that Apotex is subject to Ranbaxy's 180-day exclusivity rights is not an injury fairly traceable to Pfizer.

Ranbaxy's regulatory issues are not attributable to Pfizer. Ranbaxy itself is responsible for complying with FDA's rules and Pfizer can do nothing to change that. Once Ranbaxy solves its issues with the FDA, the FDA will approve Ranbaxy's ANDA allowing Ranbaxy to market and Apotex will be free to go to market after the 180-day period of exclusivity authorized by Congress. The timing of the resolution of those issues is wholly dependent on the FDA and Ranbaxy. This is the only possible imminent harm Apotex is facing. It is a result of the FDA and Ranbaxy and the procedures the FDA must apply to ensure proper approval of drug applications. Further, the '156 patent's impact on Apotex's ANDA approval also only arises as a result of proper operation of the Hatch-Waxman Act. These two factors supersede any effect Pfizer's agreement with Ranbaxy might have. The resolution of Ranbaxy's troubles with the FDA and the impact of the '156 patent on Ranbaxy's exclusivity rights are not fairly traceable to Pfizer. They are the result of rules, regulations, and statutes and they preclude Apotex's standing to challenge the Formulation Patents. Under the *Janssen* case, Apotex's inability to promptly launch its generic product "is not a cognizable Article III controversy, but a result envisioned by the Hatch-Waxman Act." (D.I. 144 at 16 (*citing Janssen*)).

VI. CONCLUSION

For the above reasons, Pfizer respectfully moves this Court to dismiss, under Fed. R. Civ. P. 12(b)(1), Counts III, IV, VII, and VIII of Apotex's Counterclaim concerning the Formulation Patents for lack of subject matter jurisdiction.

RESPECTFULLY SUBMITTED,

_/s/Jeffrey M. Drake_____
John S. Mortimer
jsmortimer@woodphillips.com
Jeffrey M. Drake
jmdrake@woodphillips.com
WOOD PHILLIPS
500 West Madison Street
Suite 3800
Chicago, IL 60661-2562
(312) 876-1800

OF COUNSEL:
Rudolf E. Hutz
Jeffrey B. Bove
Mary W. Bourke
Daniel C. Mulveny
CONNOLLY BOVE LODGE & HUTZ LLP
1007 North Orange Street
Wilmington, DE 19899
(302) 658-9141

William E. McShane
CONNOLLY BOVE LODGE & HUTZ LLP
1875 Eye Street, NW
Suite 1100
Washington, DC 20006
(202) 572-0335
Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I, Jeffrey M. Drake, caused to be served a copy of the foregoing:

PLAINTIFF PFIZER'S BRIEF IN SUPPORT OF ITS MOTION TO DISMISS COUNTS III, IV, VII, AND VIII OF DEFENDANT APOTEX'S COUNTERCLAIMS PURSUANT TO FED. R. CIV. P. 12(b)(1)

by filing same with the Clerk of the Court using the CM/ECF system which will send electronic notification of such filing to the following counsel of record:

William A. Rakoczy
Andrew M. Alul
Rakoczy Molino Mazzochi Siwik, LLP
6 West Hubbard Street
Suite 500
Chicago Illinois 60654

Attorneys for Defendants Apotex Inc. and Apotex Corp.

/s/ Jeffrey M. Drake