UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MERCK & CO., INC. Plaintiff, v. APOTEX INC. and APOTEX CORPORATION, Defendants.	Civil Action No. 06-5789(MLP) Hearing Date: May 21, 2007 Time: 10:00 AM

APOTEX INC.'S BRIEF IN OPPOSITION TO PLAINTIFF'S MOTION TO DISMISS COUNTS IV-VII OF APOTEX INC.'S COUNTERCLAIMS FOR LACK OF SUBJECT MATTER JURISDICTION

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Defendant Apotex Inc. ("Apotex") respectfully submits this brief in opposition to Plaintiff Merck & Co., Inc.'s ("Merck") Motion to Dismiss Counts IV-VII of Apotex Inc.'s Counterclaims for Lack of Subject Matter Jurisdiction ("Plaintiff's motion to dismiss").

INTRODUCTION

The purported "disclaimer" of U.S. Patent Nos. 6,248,735 ("the '735 patent") and 6,316,443 ("the '443 patent"), as discussed in Merck's motion, does not divest this Court of subject matter jurisdiction or otherwise render this case moot. On the contrary, the underlying dispute between Apotex and Merck—Merck's listing with the FDA of the '735 and '443 patents and its subsequent gaming of the legislative and regulatory scheme governing approval of generic drugs to delay generic competition from Apotex and others—remains very much a live controversy of critical importance to Apotex. The Court, therefore, should deny the motion to dismiss.

This action arises out of Apotex's abbreviated new drug application ("ANDA") for a generic version of Merck's COSOPT®, known generically as dorzolamide hydrochloride/timolol maleate ophthalmic solution. To protect its brand monopoly, Merck listed the '735 and '443 patents in the United States Food and Drug Administration's ("FDA") "Orange Book" in connection with Merck's COSOPT ® New Drug Application ("NDA"). By doing so, Merck affirmatively declared that "a claim of patent infringement could reasonably be asserted" against any company attempting to market a generic dorzolamide/timolol product before these patents expire. Merck then sued Apotex. Merck had previously brought suit against another company, Hi-Tech Pharmacal Co., Inc., seeking to market a generic dorzolamide/timolol product.

The '735 and '443 patents pose two very significant obstacles for Apotex and its proposed generic product. The first, of course, is potential infringement liability, both for

Apotex *and* its prospective customers. The second and more important one here, however, is that Apotex cannot even obtain FDA approval to market a competing generic product in the first place without obtaining a declaratory of non-infringement and/or invalidity in its favor. This is because other generic applicants are entitled to so-called "180-day exclusivity" that blocks Apotex's approval indefinitely. As Congress intended and authorized, the only way to alleviate this delay is through a declaratory judgment claim.

Apotex therefore brought its counterclaims to alleviate the enormous harm that it was suffering, and continues to suffer, by virtue of Merck's conduct and refusal to resolve a legitimate patent dispute. Apotex's harm includes not only potential infringement liability, but its inability to obtain approval of its non-infringing generic product and to compete in the market in the first place. Merck now seeks to moot this case by pointing to its purported disclaimer of the '735 and '443 patents, despite the fact that the '735 and '443 patents remain listed in the FDA's Orange Book and continue to block Apotex's approval. While Apotex requested a consent judgment of non-infringement, Merck refused, knowing full well that such a judgment would clear the way for Apotex's approval. Merck clearly hopes that it can preclude Apotex from ever obtaining a judgment on the '735 and '443 patents, ***thus delaying the approval of Apotex's product indefinitely***. The Court should reject Merck's transparent attempt to manipulate this Court's jurisdiction and continue delaying Apotex's approval.

Apotex retains a legally cognizable interest in the outcome of this case notwithstanding Merck's strategically-timed purported disclaimer. The purported disclaimer does nothing to alleviate the harm caused by Apotex's inability to obtain the approval needed to enter the market in the first instance with a competing generic product, as it is entitled to do. For

these reasons alone, none of which Merck bothers to address, Apotex satisfies the Article III requirement for subject matter jurisdiction.

Moreover, the U.S. Supreme Court's recent decision in *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. ___, 127 S. Ct. 764 (2007), makes clear that all Apotex needs to do here is satisfy Article III, which merely requires (1) an actual or imminent injury-in-fact, (2) that is fairly traceable to the defendant, and (3) is redressible by a favorable decision. Apotex satisfies this standard. Under *MedImmune* and the Supreme Court's other Article III precedent, subject matter jurisdiction is proper; this is further supported by recent Federal Circuit decisions applying *MedImmume*.

STATUTORY FRAMEWORK

The approval of new and generic drugs is governed by the applicable provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (commonly known as the "Hatch-Waxman Amendments" or "Hatch-Waxman Act"), and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (the "MMA").

I. New Drugs.

Before marketing a new or previously unapproved drug, the law requires that an applicant submit, and that FDA approve, an NDA under 21 U.S.C. § 355(b). The NDA must include, *inter alia*, technical data on the composition of the drug, the means for manufacturing it, clinical trial results to establish the safety and efficacy of the drug, and labeling relating to the use of the drug for which approval is requested. Additionally, an applicant is required to submit information (*e.g.*, the patent number and expiration date) for each patent that claims the drug or method of using the drug that is the subject of the NDA and for which "a claim of patent

infringement could reasonably be asserted if a person not licensed by the patent owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1); *see also Id.* § 355(c)(2).

FDA publishes patent information submitted by an NDA-holder in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book"). By filing an NDA and submitting a patent for listing in the Orange Book, the NDA-holder/patent owner necessarily represents under penalty of perjury that the listed patent claims the approved NDA drug or an approved method of using such drug, and that an infringement suit could reasonably be asserted against anyone who engages in the manufacture, use, or sale of the drug, and in particular against any company that is seeking to make a generic version of the NDA drug. Thus, the NDA-holder/patent owner puts all prospective generic ANDA applicants on notice that a suit for infringement can and will be asserted against any ANDA applicant that attempts to seek approval for and market a competing generic version of the NDA drug.

II. Generic Drugs.

Before 1984, a company seeking to market a generic version of an FDA-approved drug had to complete expensive and time-consuming safety and efficacy studies on the drug, even though the NDA-holder already had established the drug's safety and efficacy. *See SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011, 1018 (N.D. Ill. 2003). In 1984, Congress simplified the procedure for obtaining approval of generic drugs with the Hatch-Waxman Amendments to the FFDCA. Under Hatch-Waxman, "an abbreviated new drug application ["ANDA"] process allows applicants . . . to proceed more quickly to the marketplace." *Teva Pharms., USA, Inc. v. FDA*, 182 F.3d 1003, 1004 (D.C. Cir. 1999).

An ANDA applicant must establish that its generic drug product is bioequivalent to the NDA drug. *See* 21 U.S.C. § 355(j)(2)(A). The ANDA also must include a "certification" to any properly-listed Orange Book patents. *See* 21 U.S.C. § 355(j)(2)(A)(vii). The statute

provides four certification options, only one of which is relevant here: the so-called "paragraph IV" certification, where the applicant seeks immediate approval because the listed patent is invalid and/or not infringed by the proposed ANDA product. *Id.* The timing of ANDA approval is tied to the type of certification contained in the ANDA. For paragraph IV ANDAs, the timing of approval depends upon two things.

First, the timing of approval depends upon whether the brand company brings an infringement action within 45 days of learning of the paragraph IV ANDA filing. More specifically, when an ANDA applicant submits a paragraph IV certification, it must notify the patentee and NDA-holder of the factual and legal bases for that certification. *See* 21 U.S.C. § 355(j)(2)(B). If the patentee or NDA-holder does not bring suit against the ANDA applicant within 45-days of receiving the notice letter, the statute mandates that FDA "shall" approve the ANDA immediately, once FDA's approval requirements have been satisfied. *See* 21 U.S.C. § 355(j)(5)(B)(iii). If, however, the brand company brings suit within 45-days, FDA "shall" approve the ANDA immediately upon expiration of the 30-month stay referenced in the statute. *See Id.* The 30-month statutory stay period is, however, immediately terminated if the court finds the patent-in-suit to be invalid or not infringed prior to expiration of that automatic stay period. 21 U.S.C. § 355(j)(5)(B)(iii)(I) (2004).

Second, the timing of approval for paragraph IV ANDAs also depends upon whether the company seeking approval filed the first paragraph IV ANDA. The first company to file an ANDA containing a paragraph IV certification to a listed patent obtains 180-days of generic marketing exclusivity. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(I) and (II) (2002). Congress created the 180-day generic marketing exclusivity period by preventing FDA from approving competing generic products until 180-days after the first-filer begins commercial marketing. *See*

id. Absent commercial marketing, however, the exclusivity will indefinitely delay subsequent filers, unless they can obtain a judgment of non-infringement and/or invalidity. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb). If the first-filer fails to market its product within 75-days after such a judgment, it can forfeit the exclusivity, thus allowing subsequent-filers to receive approval and go to market. Consequently, as Congress intended, obtaining such a court decision is critical to a subsequent-filer's ability to market a competing generic product.

Significantly, while Congress created the 180-day exclusivity period to encourage challenges to brand-name drug patents, it never intended first-filers to unduly delay all subsequent generic entrants indefinitely. *See Minn. Mining & Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775, 780 (Fed. Cir. 2002) ("*3M*"); *Granutec, Inc. v. Shalala*, 139 F.3d 889, 1998 WL 153410, at *5 (4th Cir. Apr. 3, 1998) (finding exclusivity triggered by a court decision involving a subsequent applicant). Quite the contrary, Congress expressly provided the means for later-filers, who successfully designed around a patent, to prevent the first-filer from "parking" its exclusivity and creating a "bottleneck" that indefinitely delays approval of all other generic products. *See* 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42,873, 42,876 (Aug. 6, 1999) (to be codified at 21 C.F.R. pt. 314) ("[I]f the agency permitted exclusivity for an applicant that lost its litigation and therefore could not market its product, the innovator might avoid generic competition for the life of its patent merely by refusing to sue any subsequent ANDA applicant. This outcome would not be justified by the first applicant's unsuccessful challenge to the patent.") (Alul Decl. Tab A[1]). Indeed, "it would be contrary to the very purpose of the Act to allow the first filer to block market entry of other generic manufacturers because the first filer is involved in protracted litigation." *3M*, 289 F.3d at

[1] References to "Alul Decl." are to the Declaration of Andrew M. Alul, submitted concurrently herewith.

780 (citation omitted); *accord Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1073 (D.C. Cir. 1998).

III. Congress Enacts The MMA To Curb Abuses Of The Hatch-Waxman Act, Which Unduly Delayed Generic Competition.

Congress enacted the Hatch-Waxman Act to get affordable generic drugs to the public through expedited generic market entry. Despite Congress' intent, brand companies found ways to manipulate Hatch-Waxman and unduly delay generic competition. One tactic relevant here involves listing patents, while delaying suit against later-filers. This tactic delays generic competition because most companies do not commercially market before obtaining patent certainty on all Orange Book-listed patents. But even more pertinent here, the brand company can also "bottleneck" the market using the first-filer's 180-day generic exclusivity period. The brand can delay later-filers indefinitely by not suing, thus ensuring there will be no court decision that would allow subsequent applicants to receive approval. This "parks" the exclusivity and creates a generic "bottleneck" that can be relieved only through a declaratory judgment action.

Subsequent filers, like Apotex here, often tried to eliminate the bottleneck caused by generic exclusivity by bringing declaratory judgment claims in an attempt to obtain a triggering court decision that would clear the way for approval. But time after time, the district courts dismissed such declaratory judgment actions for failure to satisfy the Federal Circuit's "reasonable apprehension" test. Even though Congress clearly contemplated that generic manufacturers would be permitted to resolve patent claims through a declaratory judgment suit against the patentee, the precedent of the Federal Circuit, which has exclusive jurisdiction over patent appeals, held that a declaratory judgment suit was impermissible unless the declaratory

plaintiff itself faced a reasonable apprehension of suit from the patentee. *See, e.g.*, *BP Chems., Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978-80 (Fed. Cir. 1993).

Recognizing the enormous problem caused by repeated dismissals of declaratory judgment actions, Congress stepped in and enacted the MMA's declaratory judgment provision. Congress enacted these provisions to ensure that "courts . . . find jurisdiction . . . to prevent . . . improper effort[s] to delay infringement litigation between generic drug manufacturers and pioneer drug companies." H.R. CONF. REP. NO. 108-391, at 836 (2003), *reprinted in* 2004 U.S.C.C.A.N. 1808, 2187 (Alul Decl. Tab B). *Indeed, Congress enacted the MMA to address and rectify the exact problem created by Merck here, namely, to "ensure that the 180-day exclusivity period . . . cannot be used as a bottleneck to prevent additional generic competition."* 149 CONG. REC. S15,746 (daily ed. Nov. 24, 2003) (statement of Sen. Schumer) (Alul Decl. Tab C); *see also* 149 CONG. REC. S15,885 (daily ed. Nov. 25, 2003) (stating that Congress was concerned that "when generic applicants are blocked by a first generic applicant's 180-day exclusivity, the brand drug company could choose not to sue those other generic applicants so as to delay a final court decision that could trigger the 'failure to market' provision and force the first generic to market") (statement of Sen. Kennedy) (Alul Decl. Tab D).

To achieve its goal, Congress explicitly authorized "a civil action" under 28 U.S.C. § 2201 "for a declaratory judgment that the [listed] patent is invalid or will not be infringed by the drug for which the applicant seeks approval . . . ." 21 U.S.C. § 355(j)(5)(C)(i)(II). Congress also directed federal courts to exercise jurisdiction over such actions "to the extent consistent with the Constitution." 35 U.S.C. § 271(e)(5).[2]

[2] Under the MMA's declaratory judgment provisions, an ANDA applicant who has filed a paragraph IV certification may file and maintain an action for declaratory judgment against an NDA-holder/patent owner if: (a) the 45-day period has passed since notice of the paragraph IV

FACTUAL BACKGROUND

Merck does not—and indeed cannot—dispute the material facts that establish an actual controversy and require denial of Merck's motion to dismiss.

I. Merck's COSOPT® (Dorzolamide Hydrochloride/Timolol Maleate).

Merck currently holds approved NDA No. 20-869 for dorzolamide hydrochloride/timolol maleate ophthalmic solution, which is sold under the brand-name COSOPT® for the treatment of intraocular pressure in patients with ocular hypertension or open-angle glaucoma who are insufficiently responsive to beta-blockers. (Pl.'s Mem. at 3; April 5, 2007 Alul Decl. at Ex. D and E).[3] Merck also purports and claims to own the '735 and '443 patents, the term of which expires on or about February 12, 2018, according to FDA's Orange Book. (April 5, 2007 Alul Decl. at Ex. H). To protect its COSOPT® monopoly from generic competition, Merck listed three patents in FDA's Orange Book: the U.S. Patent No. 4,797,413, and the '735 and '443 patents, thus affirmatively representing to the world that a suit for infringement of any of these patents could reasonably be asserted against any generic ANDA-filer, including Apotex, who attempts to market a generic version of COSOPT® (dorzolamide/timolol). (*Id.*); *see also* 21 U.S.C. § 355(b)(1).

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certification was received; (b) neither the patent owner nor the NDA-holder brought an action for infringement of the patent within the 45-day period; and (c) if the ANDA applicant has a non-infringement claim, the NDA-holder/patent owner has been granted an Offer of Confidential Access to the ANDA. 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa-cc). The ANDA applicant can bring such an action regardless of whether the brand company accepts the Offer of Confidential Access to the ANDA. Apotex admittedly satisfied all of these requirements here.

[3] All references to "Pl.'s Mem." are to Plaintiff's memorandum of law in support of its motion to dismiss. All references to "April 5, 2007 Alul Decl." are to the April 5, 2007 Declaration of Andrew M. Alul, Esq. in Support of Apotex Inc.'s Motion for Summary Judgment of Non-Infringement of U.S. Patent Nos. 6,248,775 and 6,316,443.

II. Apotex's ANDA For Generic Dorzolamide/Timolol Ophthalmic Solution.

Apotex has submitted an ANDA seeking FDA approval to market dorzolamide hydrochloride/Timolol Maleate Ophthalmic Solution 2% (20 mg/mL)/0.5% (5 mg/mL), a generic version of COSOPT® (April 5, 2007 Alul Decl. at Ex. I). Apotex intends to market its generic product before expiration of the '413, '735 and '443 patents; to that end, after Merck listed those patents, Apotex filed its ANDA and included a Paragraph IV Certification to the '413, '735 and '443 patents, stating that these patents are invalid, unenforceable, and/or not infringed by Apotex's proposed generic dorzolamide/timolol ophthalmic solution. (April 5, 2007 Alul Decl. at Ex. J). As required by statute and regulation, Apotex duly notified Merck of its Paragraph IV ANDA, together with the factual and legal basis for its certification, and also provided Merck with an offer of confidential access to its ANDA. (April 5, 2007 Alul Decl. at Ex. M).

III. The "Generic Bottleneck" Created By Merck.

On December 4, 2006, Merck filed Civil Action No. 06-5791 in this Court alleging that Apotex's ANDA infringed the '413 patent; Merck did not sue for infringement of the '735 or '443 patents.[4] (06-5791 Compl.). Apotex answered Merck's 06-5791 Complaint on February 1, 2007 and counterclaimed against Merck, asserting unenforceability of the '413 patent, invalidity of the '413 patent and its extended term, and invalidity and non-infringement of the '735 and '443 patents. (06-5791 Answer). On March 8, 2007, pursuant to a stipulation entered into by the parties, this Court entered an order staying all proceedings involving the '413

[4] Merck also filed a separate action against Apotex in this Court, No. 06-5781, alleging infringement of the '413 patent for Apotex's filing with the FDA of ANDA No. 78-395 seeking approval to market a generic version of Merck's TRUSOPT® (2% dorzolamide hydrochloride ophthalmic solution). (06-5781 Compl.) TRUSOPT® and COSOPT® are related in that they share a common active ingredient, dorzolamide hydrochloride. However, only the '413 patent is listed in the FDA's Orange Book for TRUSOPT®. Subsequent to the filing of the complaints in Nos. 06-5781 and 06-5791, the Court consolidated both actions under the 06-5781 docket. (Dec. 18, 2006 Order (06-5781 Dkt. No. 5)).

patent pending resolution of *Merck & Co., Inc. v. Hi-Tech Pharmacal Co., Inc.*, Appeal No. 2006-1401, by the U.S. Court of Appeals for the Federal Circuit. (March 8, 2007 Stipulation and Order (06-5781 Dkt. No. 22)). On March 29, 2007, the Federal Circuit rendered its decision in the *Merck v. Hi-Tech* appeal and thereafter, pursuant to the terms of the stipulation entered into by Merck and Apotex, this Court entered final judgment against Apotex on the '413 patent. (April 11, 2007 Judgment (06-5781 Dkt. No. 39)).

However, the '735 and '443 patents continue to remain listed in the FDA's Orange Book (April 5, 2007 Alul Decl. at Ex. H) and to pose a bottleneck to entry generic into the dorzolamide hydrochloride/timolol maleate ophthalmic solution market for Apotex and other generics. This is so because Apotex is not the first generic drug company to file an ANDA for COSOPT® with paragraph IV certifications for the '735 and '443 patents. (April 5, 2007 Alul Decl. at Ex. N; Pl.'s Mem. At 4). As such, another generic drug company besides Apotex has secured generic exclusivity with respect to the '735 and '443 patents pursuant to 21 U.S.C. § 355(j)(5)(B)(iv). Apotex can obtain approval of its ANDA and compete in the dorzolamide hydrochloride/timolol maleate ophthalmic solution market only by obtaining a judgment of non-infringement on the '735 and '443 patents.

Accordingly, Apotex thus had no option but to file its declaratory judgment counterclaims regarding the '735 and '443 patents in order to obtain patent certainty and the earliest possible approval date for its ANDA product. In response, Merck blatantly attempts to manipulate this Court's jurisdiction and prevent Apotex from obtaining a court judgment by claiming that its acts of purportedly disclaiming the '735 and '443 patents somehow divest this Court of jurisdiction—*even though such patents remain listed in the Orange Book and Merck continues to maintain the generic "bottleneck" that is indefinitely delaying Apotex's approval*

and the marketing of a competing generic product. To resolve this matter amicably, Apotex requested a consent judgment of non-infringement in order to clear the way for approval. (Alul Decl. Tab G). But Merck refused and revealed its true intent here: to continue using its '735 and '443 patents to block Apotex's approval indefinitely.

ARGUMENT

For this Court to have jurisdiction over Apotex's declaratory judgment claims, Apotex need only satisfy Article III, which, as discussed below, clearly it has done. Merck moves to dismiss Apotex's claims based solely upon acts of purportedly disclaiming the '735 and '443 patents and attempting to de-list these patents from the FDA Orange Book. (Pl.'s Mem. at 13). Despite Merck's complaints, so long as Apotex satisfies Article III's case or controversy requirement, jurisdiction exists, and here jurisdiction over Apotex's Counterclaims is entirely appropriate.

IV. The Supreme Court Affirms The Case Or Controversy Requirement Of Article III, And The Federal Circuit Follows.

Prior to the Supreme Court's decision in *MedImmune*, Federal subject matter jurisdiction in declaratory judgment actions for patent non-infringement or invalidity was governed by the Federal Circuit's "reasonable apprehension of suit" test. *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1332-1333 (Fed. Cir. 2005). In a detailed footnote in *MedImmune*, however, the Supreme Court made clear that the Federal Circuit's "reasonable apprehension of suit" test "conflicts" with and would "contradict" several Supreme Court decisions which had found that a declaratory judgment plaintiff had a justiciable controversy. *MedImmune*, 127 S. Ct. at 774, fn. 11.

In *MedImmune*, the petitioner—which had licensed the patent-in-suit and was paying royalties—filed a declaratory judgment action seeking a judicial declaration that the

patent was invalid and not infringed. *See MedImmune*, 127 S. Ct. at 768. Applying the Federal Circuit's reasonable apprehension test, the district court dismissed the action for lack of subject matter jurisdiction because the court felt that the license eliminated any reasonable apprehension that the licensee will be sued for infringement. *See Id.* The Federal Circuit affirmed. *Id.* But the Supreme Court reversed, holding that there was indeed a justiciable case or controversy under Article III, and thus subject matter jurisdiction, regardless of the fact that no reasonable apprehension of suit existed. *See Id.* at 777.

In reaching this conclusion, the Court expressly considered and rejected the Federal Circuit's reasonable apprehension test. The Supreme Court began its analysis with the very language of the Federal Declaratory Judgment Act, which states that, "[i]n a case of actual controversy within its jurisdiction ... any court of the United States ... may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a). The Court then reaffirmed that the "actual controversy" language in the Act refers to the type of "Cases" and "Controversies" that are justiciable under Article III. *MedImmune*, 127 S. Ct. at 771 (*citing Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240 (1937)). The Court went on to state that while its cases "do not draw the brightest of lines between those declaratory-judgment actions that satisfy the case-or-controversy requirement and those that do not," its decisions have required that:

> the legal relations of parties having adverse legal interests"; and that it be "real and substantial" and "admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts."

Id. (quoting *Aetna*, 300 U.S. at 240-41). The Court then summarized the "actual controversy" requirement from its prior decision in *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941):

> Basically, the question in each case is whether 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, 127 S. Ct. at 771.

Thus, the Supreme Court expressly rejected the notion that a declaratory judgment plaintiff have a reasonable apprehension of suit before it can bring a patent infringement declaratory judgment suit, and further reaffirmed that the correct standard for determining a justiciable declaratory judgment action is the "Cases" and "Controversies" requirement of Article III as expounded in its decisions such as *Aetna* and the cases following it. *Id.*

Since *Medimmune*, the Federal Circuit has interpreted and applied *MedImmune* in two separate declaratory judgment cases. In both of these cases, the Federal Circuit acknowledged that under *MedImmune* the "reasonable apprehension of suit" test was dead.

In the first case, *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372 (Fed. Cir. 2007), the court, after acknowledging the Supreme Court's rejection of the "reasonable apprehension of suit test in *MedImmune*, held that where the patent owner, ST, asserted rights under the patent based on products sold or to be sold by the declaratory judgment plaintiff, SanDisk, and where SanDisk contended that it had the right to proceed on its conduct without payment of royalties as requested by ST, *an Article III case or controversy existed irrespective of statements made by ST expressly disclaiming any intention of suing*. *SanDisk*, 480 F.3d at 1380-81.

In *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, ---F.3d---, 2007 WL 942201 (Fed. Cir. March 30, 2007), the first post-*MedImmune* Federal Circuit subject matter jurisdiction case in the ANDA-declaratory judgment context, the Federal Circuit again acknowledged that its two-part "reasonable apprehension of suit" test was dead under *MedImmune*. *Teva v. Novartis*, 2007 WL 942201, *5. In *Teva v. Novartis*, the patent owner, Novartis, had listed 5 patents in the Orange Book. *Id.* at *1. The ANDA applicant, Teva, included in its ANDA paragraph IV certifications for all 5 patents. *Id.* Novartis only sued on one of the five listed patents. *Id.* Teva then brought a declaratory judgment action on the four remaining patents. *Id.* In response to a motion brought by Novartis, the trial court dismissed the declaratory judgment claims. *Id*. at *2.

The Federal Circuit, however, reversed the trial court's decision in light of *MedImmune*, and specifically ruled that, in light of the *MedImmune* decision, the "reasonable apprehension of suit" test was overruled. *Id.* at *5. The court then followed *MedImmune*'s teaching to look to *Aetna* and the cases following it to determine whether the "Cases" and "Controversies" requirement of Article III was met. *Id.* at *3. Under that jurisprudence, the court noted that "[a] justiciable Article III controversy requires the party instituting the action to have standing and the issue presented to the court to be ripe." *Id.* (*citing Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)). The court then noted that "Article III standing requires '[a] plaintiff [to] allege personal injury fairly traceable to the defendant's allegedly unlawful conduct and likely to be redressed by the requested relief.'" *Id.* (*quoting Allen v. Wright*, 468 U.S. 737, 751 (1984)). With respect to ripeness, the court stated that "[a] 'controversy' is 'ripe' if the question presented is 'fit for judicial review,' meaning it is entirely or substantially a question of law and postponing a decision would work a substantial hardship on the challenging party." *Id.* (*citing Abbott Labs. v. Gardner*, 387 U.S. 136, 149-50 (1967)).

In discussing the Declaratory Judgment Act and 35 U.S.C. § 271(e)(5), the ANDA declaratory judgment provision of the patent statute, the court went on to state that:

> under both provisions, a declaratory judgment plaintiff is only required to satisfy Article III, which includes standing and ripeness, by showing under "all the circumstances" an actual or imminent injury caused by the defendant that can be redressed by judicial relief and that is of "sufficient immediacy and reality to warrant the issuance of a declaratory judgment."

Id. (*citing MedImmune*, 127 S. Ct. at 771 (internal citations omitted)). The court went on to hold that an Article III controversy is found where a declaratory judgment plaintiff has, under "all the circumstances," "demonstrated an injury-in-fact caused by the defendant that can be redressed by the court." *Id.* at *6. (*citing Steel Co. v. Citizens For A Better Env't*, 523 U.S. 83, 102-03 (1998)).

The *Teva v. Novartis* court then held that, under "all the circumstances," Teva had an injury-in-fact and therefore a justiciable controversy under Article III. *Id.* Specifically, the court found a justiciable controversy with Novartis based on, among other things: (1) Novartis' listing of the 5 patents in the Orange Book; (2) Teva's paragraph IV certifications on all 5 Orange Book patents; (3) the legislative intent underlying 21 U.S.C. § 355(j)(5)(C) ("civil action to obtain patent certainty"), 35 U.S.C. § 271(e)(5) (ANDA declaratory judgment provision of the patent statute), and the Hatch-Waxman Act; and (4) Novartis' suit against Teva on 1 of the 5 listed patents. *Id.* at *7-*10.

Given the framework established by *MedImmune* and the Federal Circuit cases interpreting and applying that precedent, Apotex easily satisfies Article III's case or controversy requirement.

V. Apotex's Claim For Declaratory Relief Presents A Justiciable Case Or Controversy Under Article III Of The Constitution.

Apotex brought its declaratory judgment counterclaims to alleviate two enormous harms that it was suffering by virtue of Merck's conduct and refusal to resolve a legitimate patent dispute. Apotex's harm includes both potential infringement liability and, more importantly, its inability to obtain prompt approval of its non-infringing generic dorzolamide/timolol ophthalmic solution and compete in the market. The '735 and '443 patents continue to be listed in the FDA's Orange Book to this day, posing a barrier to generic entry into the dorzolamide/timolol ophthalmic solution market. An Article III case or controversy continues to exist because Apotex retains a cognizable interest in the outcome of this case because there is (1) an actual or imminent injury-in-fact, (2) that is fairly traceable to the defendant, and (3) is redressible by a favorable decision. *See MedImmune*, 127 S. Ct. at 771; *see also Bennett v. Spear*, 520 U.S. 154, 167 (1997); *Allen*, 468 U.S. at 751; and *Aetna*, 300 U.S. at 240-41. The motion to dismiss must therefore be denied.

A. Apotex Plainly Satisfies Article III's Test For Subject Matter Jurisdiction.

A real and immediate controversy exists between adverse parties because Merck's conduct creates a bottleneck that delays Apotex from receiving FDA approval, just as assuredly as if Merck had successfully enforced the '735 and '443 patents against Apotex. This dispute is ripe because Merck's conduct causes immediate injury to Apotex. These actual and continuing injuries to Apotex are not mere speculation. Rather, these injuries present an actual controversy. *See NRA v. Magaw*, 132 F.3d 272, 279-80 (6th Cir. 1997) (finding that a declaratory judgment plaintiff may show "a significant possibility of future harm" to satisfy actual controversy standard). Indeed, courts have acknowledged that such delays and bottlenecks alone are sufficient to confer subject matter jurisdiction on this Court:

> It is possible that such a statutorily-created bottleneck, coupled with the statute's express reference to declaratory judgment actions as a means of relieving that bottleneck, might suffice to allow a plaintiff to show the existence of a 'case or controversy' without demonstrating an immediate risk of being sued.

Mova Pharm., 140 F.3d at 1073 n.18. Judge Gajarsa of the Federal Circuit likewise recognized that "the inability to market a product without a court decision may create sufficient case or controversy for purposes of a declaratory judgment action." *3M,* 289 F.3d at 791 (Gajarsa, J., concurring).

1. Apotex is suffering actual and continuing injury from the generic bottleneck that admittedly delays Apotex's approval.

First, the parties have clear and adverse legal interests regarding infringement of the patent-in-suit, and Apotex continues to suffer an actual and imminent injury-in-fact. Apotex filed an ANDA seeking approval to sell a generic dorzolamide/timolol ophthalmic solution before expiration of the '735 and '443 patents. By listing the '735 and '443 patents in the FDA Orange Book, Merck affirmatively declared that "a claim of patent infringement could reasonably be asserted" against Apotex. Those adversely-held patents remain listed in the Orange Book to this day. Merck's litigious conduct and assertion of other patents against Apotex and other generic drug manufacturers only amplifies these facts—as does Merck's suit against Apotex regarding the '413 patent.

While Merck will argue that its purported disclaimer of the '735 and '443 patents and its attempts to delist those patents from the Orange Book somehow eliminates this harm, these acts do absolutely nothing to eliminate the second—and more important—harm that Apotex is suffering: the inability to promptly launch its generic dorzolamide/timolol ophthalmic solution and to compete fairly in that market. As Merck well knows (and indeed counts on), Apotex's approval is currently blocked by the exclusivity of others. That exclusivity will not run

unless and until those first-filers commercially market their drugs – something that may never happen. Apotex then would be forced to sit on the sidelines, watching its substantial investment and ability to effectively compete in the market vanish—which is exactly what Merck intends. Indeed, Apotex has requested a consent judgment of non-infringement, which Merck has refused precisely so that it can continue to block Apotex's approval. The fact is that, if Merck truly had no intent to continue blocking Apotex's approval, it could easily have entered a consent judgment as Apotex requested. Merck's refusal speaks volumes here and confirms the existence of an actual controversy between the parties.

Merck's repeated reliance on the purported disclaimer of the '735 and '443 patents misses the point here. As an initial matter, Merck cannot divest this Court of jurisdiction based on Apotex's patent defenses. *See Hernandez-Santiago v. Ecolab, Inc.*, 397 F.3d 30 (1st Cir. 2005); *Ventrassist Pty Ltd. v. Heartware Inc.*, 377 F. Supp. 2d 1278, 1284 (S.D. Fla. 2005) ("Defendant, however, has failed to cite any case in which a federal court had concluded that it lacked subject matter jurisdiction over a well-pleaded patent infringement claim, and the undersigned is unaware of any. The absence of such case law is not surprising; Defendant has confused this Court's authority to adjudicate a patent infringement claim (subject matter jurisdiction) with its defense that its activities are statutorily exempt from patent infringement."). In other words, whether the patents are unenforceable due to a disclaimer is a question to be decided on the merits as part of Apotex's pending motion for summary judgment of non-infringement of those patents---it is not a jurisdictional question. Under Merck's absurd theory, the Court's jurisdiction is somehow dependent upon, and directly proportional with, the strength of the patent case. Not so. Just because Merck's patent case may be weak has nothing to do with jurisdiction, which is an entirely separate inquiry. The Court should reject Merck's

invitation to decide the merits of Apotex's patent defense in the context of this jurisdictional motion to dismiss, but rather should address that question where it belongs, in connection with Apotex's summary judgment motion.

Second, despite Merck's repeated assertions that the patents no longer "exist," the '735 and '443 patents remain listed in the FDA's Orange Book for COSOPT® and therefore remain an obstacle to generic entry of Apotex's dorzolamide/timolol ophthalmic solution. Therefore, the patents still pose a barrier to generic entry of Apotex's dorzolamide/timolol ophthalmic solution. 21 U.S.C. § 355(j)(5)(B)(iv)(I). The only way that Apotex can obtain approval earlier is through a declaratory judgment of non-infringement from this Court. 21 U.S.C. § 355(j)(5)(D)(I)(bb). This is the exact bottleneck that Congress sought to end by enacting the MMA's declaratory judgment provisions. *See* H.R. CONF. REP. NO. 108-391, at 836 (2003), *reprinted in* 2004 U.S.C.C.A.N. 1808, 2187 (Congress enacted these provisions to ensure that "courts . . . find jurisdiction . . . to prevent . . . improper effort[s] to delay infringement litigation between generic drug manufacturers and pioneer drug companies.") (Alul Decl. Tab B); *see also* 149 CONG. REC. S15,746 (daily ed. Nov. 24, 2003) (stating that Congress enacted the MMA "ensure that the 180-day exclusivity period . . . cannot be used as a bottleneck to prevent additional generic competition") (statement of Sen. Schumer) (Alul Decl. Tab C); 149 CONG. REC. S15,885 (daily ed. Nov. 25, 2003) (stating that Congress was concerned that "when generic applicants are blocked by a first generic applicant's 180-day exclusivity, the brand drug company could choose not to sue those other generic applicants so as to delay a final court decision that could trigger the 'failure to market' provision and force the first generic to market") (statement of Sen. Kennedy) (Alul Decl. Tab D).

Thus, the only way to resolve this real, immediate, and substantial harm is with a court decision. This lost opportunity to compete constitutes an "injury" sufficient to satisfy the Article III standard for jurisdiction. *See, e.g.*, *Northeastern Fla. Chapter of the Associated Gen. Contractors of Am. v. City of Jacksonville, Fla.*, 508 U.S. 656, 664-68 (1993) (finding injury under Article III where plaintiff was precluded by law from competing); *Watt v. Energy Action Educ. Found.*, 454 U.S. 151, 160-61 (1981) (same); *NRA*, 132 F.3d at 279-80 (finding that a declaratory judgment plaintiff may show "a significant possibility of future harm" to satisfy the actual controversy standard).[5] Only a judgment of non-infringement or invalidity can alleviate this harm and risk. *See Minn. Mining & Mfg. Co. v. Norton Co.*, 929 F.2d 670, 673-74 and n.4 (Fed. Cir. 1991) (noting that Declaratory Judgment Act sought to alleviate problems caused by threat of infringement liability to 3M and its customers, and rejecting argument that threats to 3M's customers did not cause harm to 3M).

Thus, Apotex retains a legally cognizable interest in the outcome of this litigation regardless of the purported disclaimer.

2. Apotex's injuries are directly traceable to Merck.

Second, Merck, and Merck alone, is directly responsible for Apotex's injury. Apotex has suffered an injury directly traceable to conduct by Merck—Merck's listing of the '735 and '443 patents. Because Merck chose to list these two patents, which it purportedly disclaimed subsequent to listing (in the case of the '735 patent, less than five years after it was listed; in the case of the '443 patent, a little over two years after it was listed), but after Apotex

[5] The Federal Trade Commission likewise agrees that the delay and inability to compete caused by a generic bottleneck alone constitutes sufficient injury to confer subject matter jurisdiction under Article III. (*See* Br. of *Amicus Curiae* Federal Trade Comm'n supporting Appellant and Urging Reversal, at 8, filed on March 31, 2004, in *Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324 (Fed. Cir. 2005) (Alul Decl. Tab E).

filed its ANDA, all generic drug companies seeking to market bioequivalent (generic) versions of COSOPT® must address those two patents to the FDA in the form of a patent certification described in 21 U.S.C. § 355(j)(2)(A)(vii). Pursuant to the generic exclusivity provisions of the FFDCA, as amended by the Hatch-Waxman Act and the MMA, the first to seek FDA approval of a generic to COSOPT® prior to the expiration of the '735 and '443 patent (the first paragraph IV filer), is entitled to 180-days of generic exclusivity. As stated earlier, Apotex is not the first paragraph IV filer with respect to the '735 and '443 patents. As such, FDA approval of Apotex's ANDA will not be made effective until 180-days after the first commercial marketing of the first filer's generic COSOPT®, which will likely not occur until sometime after October 28, 2008 (the April 28, 2008 expiration date of the '413 patent plus 6 months of pediatric marketing exclusivity granted pursuant to 21 U.S.C. § 355a, if at all, as settlements between brand name drug companies and first filers that keep the first filer off the market in order to "park" a 180-day exclusivity period have been found by the Federal Trade Commission to be a real tactic used by brand name drug companies. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* at vii (July 2002) (Alul Decl. Tab F).

The harm to Apotex of indefinite delay in approval of is COSOPT® ANDA is a direct result of Merck obtaining the '735 and '443 patents, and then listing them in the FDA's Orange Book. Congress has specified a remedy for this injury by legislatively sanctioning subsequent paragraph IV filers to file declaratory judgment actions to "obtain patent certainty" (21 U.S.C. § 355(j)(5)(C)) and hasten the effective approval date of their ANDAs.

Moreover, it is Merck who now refuses to provide a consent judgment of non-infringement or to engage in litigation precisely because doing so will allow the company to delay generic competition and thus hold on to its monopoly longer than it should. This result

harms not only Apotex, but also the consumers and taxpayers that desperately need access to affordable medication. Merck's tactics, therefore, are the direct cause of Apotex's injuries.

3. A favorable decision from the district court can redress Apotex's injuries.

Third, this Court can redress Apotex's injury with a court decision that its ANDA product does not infringe the '735 and '443 patents and/or that these patents are invalid. 21 U.S.C. § 355(j)(5)(D)(I)(bb). Such a decision would not only give Apotex and, just as importantly, its customers, patent certainty, but would allow Apotex to launch its generic dorzolamide/timolol ophthalmic solution at the earliest possible time. Indeed, Apotex would not only be able to launch at the earliest possible time, but it would be able to launch with all other eligible applicants, without another company getting a head start.

B. The Facts Of This Case Are Very Similar To Those In *Teva v. Novartis*, Thus Warranting A Denial Of Merck's Motion.

The facts of the instant case are very similar to those in the *Teva v. Novartis* case; specifically, virtually all of the circumstances found by the Federal Circuit in that decision sufficient to establish an "actual controversy" and therefore a justiciable claim under Article III are present in this case. First, it is undisputed that Merck listed the '413, '735, and '443 patents in the Orange Book for COSOPT®. Second, Apotex has filed an ANDA seeking FDA approval to market a generic version of COSOPT®, which included paragraph IV certifications for all three listed patents.

Third, the very same statutory provisions at play in *Teva v. Novartis* also govern Apotex's counterclaims. As such, the Congressional intent underlying 21 U.S.C. § 355(j)(5)(C) ("civil action to obtain patent certainty"), 35 U.S.C. § 271(e)(5) (ANDA declaratory judgment provision of the patent statute), and the Hatch-Waxman Act "to enable generic competitors to bring cheaper, generic … drugs to the market as quickly as possible," *Teva v. Novartis*, 2007 WL

942201, *9 (citations and internal quotations omitted), also contributes to Apotex's justiciable controversy. As in *Teva v. Novartis*, Merck's actions "frustrate this purpose and create a basis for finding a justiciable controversy." *Id.*

Fourth, as in *Teva v. Novartis*, the patent owner, Merck, has sued the generic drug applicant, Apotex, on at least one of several Orange Book patents. As the court in *Teva v. Novartis* held:

> A justiciable declaratory judgment controversy arises for an ANDA filer when a patentee lists patents in the Orange Book, the ANDA applicant files its ANDA certifying the listed patents under paragraph IV, and the patentee brings an action against the submitted ANDA on one or more of the patents. The combination of these three circumstances is dispositive in establishing an actual declaratory judgment controversy as to all the paragraph IV certified patents, whether the patentee has sued on all or only some of the paragraph IV certified patents. Our conclusion supports what we have already established in non-ANDA cases-that related litigation involving the same technology and the same parties is relevant in determining whether a justiciable declaratory judgment controversy exists on other related patents.

Id.

In accordance with this very holding, Apotex has established a declaratory judgment controversy sufficient to confer subject matter jurisdiction on this Court to hear Apotex's counterclaims. Merck listed the '413, '735, and '443 patents in the Orange Book, Apotex has filed an ANDA with paragraph IV certifications for all three patents, and Merck has filed suit on one of the three patents.

CONCLUSION

In sum, Apotex's dilemma in this case is precisely the "sad and saddening" situation that Congress designed the Declaratory Judgment Act to remedy. *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 734-35 (Fed. Cir. 1988). The stakes here are real, and satisfy the case-or-controversy requirement as set forth by the Supreme Court:

> Although we have packaged the requirements of constitutional 'case' or 'controversy' somewhat differently in the past 25 years--an era rich in three-part tests--the point has always been the same: whether a plaintiff 'personally would benefit in a tangible way from the court's intervention.'

Steel Co., 523 U.S. at 104 n.5 (citation omitted). It can hardly be disputed that Apotex "personally would benefit in a tangible way from the court's intervention." It is difficult to conceive of a setting in which application of the Declaratory Judgment Act would be more appropriate.

This case admits of a real controversy for which this Court can and should exercise subject matter jurisdiction. As a direct result of Merck's patents, Orange Book-listing, and refusal to litigate or provide a consent judgment of non-infringement, Apotex is suffering enormous harm that can be alleviated only by a declaratory judgment from this Court. Otherwise, the approval of Apotex's competing generic product will be delayed indefinitely. Accordingly, Apotex has established an Article III case or controversy sufficient to vest this Court with subject matter jurisdiction over Apotex's declaratory judgment claims. Thus, under *MedImmune* and the Supreme Court's other Article III precedent, this Court should deny Merck's motion to dismiss.

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