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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MERCK & CO., INC. Plaintiff, v. APOTEX INC. and APOTEX CORPORATION Defendants.	**DOCUMENT ELECTRONICALLY FILED** **Civil Action Nos.** **06-5789 & 06-5791 (MLC)** (Consolidated) Hearing Date: May 7, 2007 Time: 10:00 AM

PLAINTIFF'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO DISMISS COUNTS IV-VII OF APOTEX'S COUNTERCLAIMS FOR LACK OF SUBJECT MATTER JURISDICTION

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I. INTRODUCTION

Plaintiff Merck & Co., Inc. ("Merck") submits this memorandum in support of its motion under Fed. R. Civ. P. 12(b)(1) to dismiss Counts IV-VII of the counterclaims pled by defendants Apotex Inc. and Apotex Corp. ("Apotex").

Federal jurisdiction is a limited jurisdiction, limited to cases in which there is an actual controversy between two litigants that have adverse legal interests. *MedImmune, Inc. v. Genentech, Inc.*, 594 U.S. __, 127 S. Ct. 764, 771 (2007) (citing and quoting *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937)).

Apotex's Counterclaims IV-VII epitomize the absence of any actual controversy. Those counterclaims ask this Court to adjudicate the validity and infringement of claims of two patents that no longer exist.

Merck disclaimed all claims of those patents almost a year ago, and eight months prior to the initiation of this suit. Because those patents were disclaimed, Merck cannot enforce them, and there is no controversy between Merck and Apotex concerning them. Without an actual controversy between the only two parties before it, this Court lacks subject matter jurisdiction and should dismiss the counterclaims. Because, pursuant to the Stipulation entered March 8, 2007, judgment will be entered for Merck and against Apotex on the only live patent involved in these consolidated actions, dismissal of the counterclaims directed to the disclaimed patents will be case-dispositive.

II. BACKGROUND

A. The Hatch-Waxman Structure

This action arises under the Hatch-Waxman Act.[1] Under the provisions of that statute, when an innovator pharmaceutical company, such as Merck, files a New Drug Application ("NDA") in the United States Food & Drug Administration ("FDA"), it must, in addition to providing extensive clinical proof of the drug's safety and efficacy, also identify all patents that cover the drug or the use of the drug. 21 U.S.C. § 355(b)(1). Any patents so identified are then listed in an official FDA publication called the "Orange Book".

After the innovator drug is approved, generic companies are permitted to file Abbreviated New Drug Applications ("ANDA") in which they are relieved of the obligation of proving safety and efficacy, are permitted to rely instead on the studies performed by the innovator, and merely have to show that their copy of the drug is "bioequivalent", *i.e.*, produces the same blood levels when administered to a small group of patients. 21 U.S.C. § 355(j).

In addition, if there are patents listed in the Orange book for the copied drug, the ANDA filer must make one of three "certifications" with respect to each such patent. 21 U.S.C. § 355(j)(2)(vii). Those are:

1. The patent has expired (a "paragraph II certification").
2. The ANDA filer does not seek approval before the patent expires (a "paragraph III certification").
3. The patent is invalid or will not be infringed by the manufacture, use or sale of the ANDA filer's product (a "paragraph IV certification").

ANDA filers who make a paragraph IV certification are required to give notice of their filing to the NDA holder and the patentee. 21 U.S.C. § 355(j)(5)(B). If the patent owner

[1] The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

brings suit on the challenged patent, the ANDA cannot be approved until the earlier of a period of thirty months or a decision on the merits that the patent is either invalid or not infringed. 21 U.S.C. § 355(j)(5)(B)(iii)(I). If the patent owner does not sue on the challenged patent, the ANDA can be approved immediately, subject only to any exclusivity held by a prior paragraph IV challenger. 21 U.S.C. §§ 355(j)(5)(B)(iii) and (j)(5)(B)(iv)(I).

The Act provides incentives for early challenge of patents by awarding to the first ANDA filer who makes a paragraph IV certification a period of 180 days of marketing exclusivity before any subsequent paragraph IV certifiers can receive FDA approval. 21 U.S.C. § 355(j)(5)(B)(iv).

B. The Facts of This Case

Merck holds FDA approval for the drug products TRUSOPT® (which has a single active ingredient, dorzolamide hydrochloride) and COSOPT® (which has a combination of two active ingredients, dorzolamide hydrochloride and timolol maleate). (Hughes Exhs. 1, 3, Complaints ¶ 10; Hughes Exhs. 2, 4, Answers ¶ 10)[2] Both TRUSOPT® and COSOPT® are drugs that treat ocular hypertension and open-angle glaucoma, a disorder characterized by elevated intraocular pressure (pressure within the eyeball), which can lead to damage to the optic nerve and loss of vision, and is one of the leading causes of irreversible blindness in the United States. (Hughes Exhs. 1, 3, Complaints ¶ 10; Hughes Exhs. 2, 4, Answers ¶ 10)

Merck's TRUSOPT® and COSOPT® NDA's were approved by the FDA in April 1998. As required by the Act, Merck identified to the FDA one patent for the TRUSOPT® product – U.S. Patent 4,797,413 ("the '413 patent") and three patents for the COSOPT® product

[2] "Hughes Exh. __" refers to the Exhibits to the Declaration of Heather M. Hughes, filed herewith in support of Merck's motion to dismiss.

– the '413 patent and U.S. Patents 6,248,735 ("the '735 patent") and 6,316,443 ("the '443 patent"). (Hughes Exhs. 5-7) The FDA listed in its Orange Book the '413 patent for the TRUSOPT® product and all three patents for the COSOPT® product.

On December 5, 2005, Merck received a notice from the company Hi-Tech Pharmacal Co., Inc. ("Hi-Tech") stating that Hi-Tech had filed ANDA's for generic versions of both the TRUSOPT® and COSOPT® products and that it was challenging the validity of all three listed patents. Merck sued Hi-Tech on January 18, 2006, in this Court, alleging infringement of the '413 patent.[3] Merck did not sue Hi-Tech for infringement of either the '735 or the '443 patent. (Hughes Exhs. 8, 9)

On April 18, 2006, Merck filed, in the United States Patent and Trademark Office ("USPTO"), disclaimers by which it disclaimed all claims of the '735 and '443 patents. (Hughes Exh. 10, 11)

On April 26, 2006, Merck wrote to the FDA and requested that the agency remove from the Orange Book ("de-list") the disclaimed '735 and '443 patents. (Hughes Exh. 12)

On October 23, 2006, Apotex's counsel sent to Merck two notice letters informing Merck that Apotex had submitted ANDA's to the FDA seeking approval to market generic versions of the TRUSOPT® and COSOPT® products. (Hughes Exhs. 13, 14) Apotex's letters further informed Merck that: (i) in its ANDA for the generic version of the TRUSOPT®

[3] Hi-Tech's sole defense with respect to the '413 patent was the contention that a patent that had been terminally disclaimed could not be extended under 35 U.S.C. § 156, to compensate for regulatory delays in marketing. This Court decided that issue in favor of Merck and entered judgment against Hi-Tech. *Merck & Co., Inc. v. Hi-Tech Pharmacal Co., Inc.*, Nos. 06-266 and 06-268 (consolidated) (D.N.J. April 25, 2006). That decision was appealed by Hi-Tech and was affirmed by the Court of Appeals for the Federal Circuit on March 29, 2007. *Merck & Co., Inc. v. Hi-Tech Pharmacal Co., Inc.*, 2007 WL 926284 (Fed. Cir. March 29, 2007).

product, Apotex challenged the effectiveness of the term extension of the '413 patent (Hughes Exh. 13) and; (ii) in its ANDA for the generic version of the COSOPT® product, Apotex repeated that challenge to the '413 patent and also alleged invalidity and non-infringement of the '735 and '443 patents, specifically noting that all claims of the latter two patents had been disclaimed as, in fact, they had been, six months earlier. (Hughes Exhs. 14, Factual and Legal Basis, pp. 1-2, 5-6, 17 & 22)

On December 4, 2006, Merck responded to Apotex's notice letter for COSOPT®, and stated:

> In your letter, you make reference to U.S. Patents 6,248,735 B1 and 6,316,443 B1. As you correctly note, all claims of both of those patents were voluntarily disclaimed by Merck in April, 2006. Because of the disclaimers, there are no exclusionary rights remaining under either of those patents. Accordingly, Merck cannot, and does not intend to, sue any entity, including Apotex, Inc. for infringement of either of those patents. (Hughes Exh. 15)

On December 18, 2006, Merck sent a second letter to the FDA, repeating its request that the '735 and '443 patents be removed from the Orange Book because they had been disclaimed. (Hughes Exh. 16)

On December 4, 2006, Merck filed two complaints against Apotex. The complaint relating to Apotex's generic version of the TRUSOPT® product alleged only infringement of the '413 patent (Civil Action no. 06-5789). (Hughes Exh. 1, ¶¶ 17, 18, 23) The complaint relating to Apotex's generic version of the COSOPT® product also alleged infringement of only the '413 patent (Civil Action no. 06-5791). (Hughes Exh. 3, ¶¶ 17, 18, 23) Both actions were consolidated under the 06-5789 docket number. Merck did not allege infringement of the '735 or '443 patents.

With regard to the '413 patent, Apotex agreed that its defense to both complaints was the same one already adjudicated in the Hi-Tech case, and would stand or fall with the

appellate decision in that case. The parties stipulated to that outcome and to a stay of all proceedings relating to that patent. (Hughes Exh. 17) The Federal Circuit affirmed this Court's Hi-Tech decision and, therefore, final, non-appealable judgment against Apotex on the '413 patent will be entered here that fully disposes of the "TRUSOPT®" action and leaves, in the "COSOPT®" action, only the counterclaims for which this motion seeks dismissal. As a result of the stipulation and the Hi-Tech decision, Apotex will be precluded from selling either product until the '413 patent expires on April 28, 2008 and any subsequent "pediatric exclusivity" to which Merck is entitled based on that patent.

Although the Complaint relating to Apotex's proposed version of the COSOPT® product did not allege any claims based on the disclaimed '735 or '443 patent, and Merck had specifically told Apotex that Merck could not and would not sue any entity on them, when Apotex answered the complaint, it pleaded counterclaims IV-VII seeking an adjudication of invalidity and non-infringement of the claims of those disclaimed patents. (Hughes Exh. 4)

III. ARGUMENT

A. An Actual Case or Controversy Between the Litigants Is Essential for Jurisdiction Under Article III of the Constitution

An actual case or controversy must exist in order for this Court to have jurisdiction under Article III of the Constitution. *See Preiser v. Newkirk*, 422 U.S. 395, 401 (1975). This requirement is "no less strict in a declaratory judgment proceeding than in any other type of suit." *Alabama State Fed'n of Labor v. McAdory*, 325 U.S. 450, 461 (1945) (citations omitted); 28 U.S.C. § 2201(a).

As the Supreme Court recently reiterated, "Our decisions have required that the dispute be 'definite and concrete, touching 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 conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.'" *MedImmune*, 127 S. Ct. at 771 (citing and quoting *Aetna Life Ins.*, 300 U.S. at 240-41) (emphasis added). "'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.'" *Id.* (quoting *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941)) (emphasis added).

Similarly, the Federal Circuit held, in *Spectronics Corp. v. H.B. Fuller Co., Inc.*, 940 F.2d 631 (Fed. Cir. 1991), if no actual controversy exists between the parties regarding the subject matter on which a declaratory judgment is sought, the court must dismiss the action for lack of subject matter jurisdiction. *Id.* at 634 & n.1. Furthermore, the declaratory judgment plaintiff carries the burden of proving the existence of the jurisdictional facts. *See Indium Corp. of Am. v. Semi-Alloys, Inc.*, 781 F.2d 879, 883 (Fed. Cir. 1985).

B. The Supreme Court's *MedImmune* Decision and Subsequent Caselaw Does Not Eliminate the "Case or Controversy" Requirement

In its recent *MedImmune* decision, the Supreme Court held that there was an actual controversy between the licensor of a patent and its licensee, when the latter disputed whether a particular product fell within valid claims of the licensed patent and therefore required payment of a royalty. *MedImmune*, 127 S. Ct. at 777.

In so doing, the Court reversed the Federal Circuit's decision that Article III jurisdiction was lacking because, so long as the licensee paid royalties, it need not fear being sued. *Id.* The Supreme Court criticized prior decisions of the Federal Circuit that had made "reasonable apprehension of suit" a prerequisite for declaratory relief. *Id.* at 774, n. 11.

The Supreme Court reasoned that there was an actual controversy because MedImmune faced the choice between acceding to the patent owner's royalty demands or "bet the farm" by taking violative action and risk losing its license and facing infringement damages. *Id.* at 775. The linchpin was that the patents and their potential enforcement posed a coercive threat that created an actual controversy between the two parties to the suit – the patent owner and its licensee.

In *SanDisk Corp. v. STMicroelectronics, Inc.*, WL 881008 (Fed. Cir. March 26, 2007), the first Federal Circuit decision on declaratory jurisdiction after *MedImmune*, the Court acknowledged that the "reasonable apprehension of suit" requirement was dead. *Id.* at *7. It held that, where the patent owner, SanDisk, had made express statements that products of ST infringed its patents, and had requested that ST take a license under those patents, an actual controversy existed, even though SanDisk expressly disclaimed any intention of suing. As the Court explained,

> We only hold that where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license, an Article III case or controversy will arise and the party need not risk a suit for infringement by engaging in the identified activity before seeking a declaration of its legal rights. *Id.*
>
> We decline to hold that [ST's Vice President's] statement that ST would not sue SanDisk eliminates the justiciable controversy created by ST's actions, because ST has engaged in a course of conduct that shows a preparedness and willingness to enforce its patent rights despite [her] statement. Having approached SanDisk, having made a studied and considered determination of infringement by SanDisk, having communicated that determination to SanDisk, and then saying that it does not intend to sue, ST is engaging in the kinds of 'extra-judicial patent enforcement with scare-the-customer-and-run tactics' that the Declaratory Judgment Act was intended to obviate. *Id.* at *9.

The critical factor in *SanDisk* – and the one that is not present here – is that, despite any facial statement of having no intention to sue on the patents, the patent owner retained the right to enforce them. Merck has no right to enforce the '735 and '443 patents. It disclaimed every claim of those patents long before Apotex sent its notice letter. Therefore, there cannot be any actual controversy here.

The second post-*MedImmune* Federal Circuit decision is *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*, WL 942201 (Fed. Cir. March 30, 2007). There, the patent owner had listed five patents in the Orange Book, Teva certified against all five, and the patent owner sued on only one. *Id.* at *1. Teva then sought a declaration that the other four patents were invalid or not infringed. *Id.*

On the patent owner's motion, the trial court dismissed the declaratory claims, Teva appealed, and the Federal Circuit reversed and reinstated them.

While observing that the "reasonable apprehension of suit" test was no longer viable, the court acknowledged that a declaratory claim nevertheless had to satisfy the "actual case or controversy" requirement. *Id.* at *3 & *5. It noted that, while the patent owner had only sued on one of the five listed patents, it had "the right of an immediate action … on any or all of the remaining [ones]", and "[t]hese actions could be brought at any time until the patents expire." *Id.* at *6. It further commented that "Teva remains under the threat of an infringement suit" under the four patents. *Id.*

In contrast, Apotex is not subject to suit on the disclaimed '735 and '443 patents. Merck has neither an immediate nor a future right of action under those patents against Apotex or anyone else.

C. Apotex's Declaratory Judgment Counterclaims Should Be Dismissed for Lack of Subject Matter Jurisdiction Because There Is No Actual Case or Controversy

In this case, Apotex cannot legitimately contend that there is an actual controversy between it and Merck concerning the two patents that have been disclaimed, and, therefore, Merck has no ability to enforce. *Vectra Fitness, Inc. v. TNWK Corp.*, 162 F.3d 1379, 1383-84 (Fed. Cir. 1998); *see also W.L. Gore & Assoc., Inc., v. Oak Materials Group, Inc.*, 424 F. Supp. 700, 702 (D. Del. 1976) ("The patentee has no further right either to enforce the claims which have been disclaimed, or to obtain a reissue of any of those claims."). Apotex's Counterclaims ask this Court to make substantive adjudications on the merits of non-infringement and invalidity of the two nonexistent patents.

When Merck disclaimed the '735 and '443 patents, almost a year ago, and six months before Apotex sent the notice letters that triggered this litigation, Merck relinquished any ability to enforce these patent. *See W.L. Gore*, 424 F. Supp. at 702. Merck cannot exclude others from manufacturing or using the subject matter of those patents' claims. *See Altoona Publix Theatres, Inc. v. American Tri-Ergon Corp.*, 294 U.S. 477, 492 (1935).

Apotex agrees. In its notice letter for COSOPT®, Apotex attached copies of those disclaimers and asserted, "Once a patent term has ended a patent is no longer enforceable and an ANDA applicant risks no liability to the patent holder." (Hughes Exh. 14, Factual and Legal Basis, p. 1) With regard to the '735 patent, Apotex stated, "On or about April 18, 2006, Merck submitted to the PTO a Statutory Disclaimer, disclaiming the entire interest in claims 1-27 of the '735 patent. … In view of the Statutory Disclaimer described above and because claims 1-27 of the '735 patent have been disclaimed, they cannot be infringed." (Hughes Exh. 14, Factual and Legal Basis, p. 17) Apotex stated the same with regard to the '443 patent. (Hughes Exh. 14, Factual and Legal Basis, p. 22)

Apotex further asserted,

> A patent cannot be infringed, directly or indirectly, past its term. Similarly, a patent term, or portion thereof, that has been disclaimed cannot be later enforced against an accused infringer. As noted above, a patent can be statutorily disclaimed by the assignee. By doing so, the assignee relinquishes legal rights to the patent, including the right to enforce said patent. Therefore, the effect of a statutory disclaimer is that the claims are dedicated to the public and are not enforceable by the assignee, nor can the claims be infringed. (Hughes Exh. 14, Factual and Legal Basis, p. 5)

Merck did not dispute Apotex's statements. Merck's counsel expressly stated in the responsive letter to Apotex:

> Because of the disclaimers, there are no exclusionary rights remaining under either of those patents. Accordingly, Merck cannot, and does not intend to, sue any entity, including Apotex, Inc. for infringement of either of those patents. (Hughes Exh. 15)

Therefore, Merck has no rights in the '735 and '443 patents that this Court can adjudicate. *See W.L. Gore*, 424 F. Supp. at 702 ("As plaintiff has formally disclaimed all claims of the patent, there is no longer a justiciable case or controversy before the Court…"). Apotex's Counterclaims should be dismissed because Article III's jurisdictional limit precludes a court from deciding "'questions *that cannot affect the rights of litigants in the case before them.*'" *Preiser*, 422 U.S. at 401 (quoting *North Carolina v. Rice*, 404 U.S. 244, 246 (1971)) (emphasis added).

Contrary to Apotex's allegations in paragraph 69 of its counterclaim (Hughes Exh. 4), the initial listing of the '735 and '443 patents does not create a present justiciable controversy. No court has held that merely listing patents with the FDA has that effect. Moreover, even if there had been an actual controversy in the past, the jurisdictional question presented here is whether there was one when Apotex asserted its counterclaims – and there clearly was not.

Where, as here, a patentee has disclaimed the claims of its patent, those claims are effectively dedicated to the public, and, therefore, are no longer enforceable, nor can they be infringed. *See Vectra Fitness*, 162 F.3d at 1383-84. A disclaimer is "considered as part of the original patent." *Id.* at 1382-84. It "has the effect of canceling the claims from the patent and the patent is viewed as though the disclaimed claims *had never existed in the patent*." *Guinn v. Kopf*, 96 F.3d 1419, 1422 (Fed. Cir. 1996) (emphasis added); *Altoona Publix Theatres*, 294 U.S. at 492 ("Upon the filing of the disclaimers, … the public was entitled to manufacture and use the device originally claimed as freely as though [the claim] had been abandoned.").

The consequence of Merck's disclaimers is that the patent claims are viewed as though they "never existed." *Guinn*, 96 F.3d at 1422. The disclaimers were not only made long prior to Apotex's assertion of counterclaims – they were made six months before Apotex sent its notice letters that triggered these litigations (the complaints in which were based on the only true controversy, the one involving the '413 patent, that has been resolved favorably for Merck). There was not and cannot be an actual controversy over the two patents that no longer exist.

Apotex's Counterclaims ask this Court to make an impermissible adjudication of the validity and infringement of nonexistent patent claims. Such an adjudication would be precisely the type of advisory opinion that the Supreme Court and Federal Circuit have prohibited. *Coffman v. Breeze Corp., Inc.*, 323 U.S. 316, 324 (1945) (holding that the declaratory judgment procedure "may not be made the medium for securing an advisory opinion in a controversy which has not arisen.") (citations omitted); *Teva Pharm. USA*, 2007 WL 942201, at *4 (quotations omitted). Accordingly, Apotex's Counterclaims for declaratory judgment should be dismissed. *See Indium Corp.*, 781 F.2d at 883.

D. Apotex's Dispute Is with the FDA, Not Merck

Finally, Apotex's allegation that Merck "has not removed the '735 and '443 patents from the Orange Book, nor taken any other action to alleviate the enormous harm that Apotex is suffering from the delay in approval caused by the '735 and '443 patents," (Hughes Exh. 4, Counterclaim ¶ 71), is untrue, and, in any case (as discussed above), cannot be the basis for allowing these counterclaims to stand.

If, as Apotex alleges, it is precluded from obtaining FDA approval of its ANDA for a generic version of the COSOPT® product because Hi-Tech made an earlier certification, that is the result of the statutory scheme constructed by Congress and the fact that Hi-Tech acted before Apotex. Moreover, Merck is no part of any alleged bottleneck that Apotex faces. In fact, Merck disclaimed the '735 and '443 patents long before Apotex sent its notice letters and has twice written letters to the FDA requesting that the those patents be de-listed from the Orange Book. (Hughes Exhs. 12, 16) If Apotex now contests the Orange Book's listing, its dispute is with the FDA, not Merck. Accordingly, if Apotex has a controversy with anyone, it is with the FDA, and Apotex has frequently sued the FDA when it was displeased with the Agency's position. *See, e.g.*, *Apotex Inc. v. FDA*, 2006 WL 1030151 (D.D.C. 2006); *Apotex Inc. v. FDA*, 414 F. Supp. 2d 61 (D.D.C. 2006).

IV. CONCLUSION

For the foregoing reasons, this Court does not have subject matter jurisdiction to entertain Counts IV-VII of Apotex's Counterclaims, which seek substantive adjudications of non-infringement and invalidity of two nonexistent patents and are asserted against an entity that has relinquished all of its substantive rights in them. Accordingly, Apotex's Counterclaims should be dismissed under Rule 12(b)(1) of the Federal Rules of Civil Procedure.

Dated: April 5, 2007

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