NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MERCK & CO., INC., Plaintiff, v. APOTEX, INC., et al., Defendants.	CIVIL ACTION NO. 06-5789 (MLC) **MEMORANDUM OPINION**

COOPER, District Judge

Defendants, Apotex, Inc., and Apotex Corporation (collectively, "Apotex"), asserted counterclaims against plaintiff, Merck & Co., Inc. ("Merck"), for, inter alia, a judgment declaring non-infringement and invalidity of United States Patent Nos. 6,248,735 ("'735 patent") and 6,316,443 ("'443 patent"). (Dkt. entry no. 17, Ans. & Countercl.) Merck moves to dismiss Counts IV, V, VI, and VII of Apotex's counterclaims, which concern the '735 and '443 patents, pursuant to Federal Rule of Civil Procedure ("Rule") 12(b)(1). (Dkt. entry no. 33.) Apotex cross-moves for summary judgment in its favor pursuant to Rule 56(c). (Dkt. entry no. 34.) The Court, for the reasons stated herein, will grant the motion to dismiss, and deny the cross motion for summary judgment as moot.

BACKGROUND

I. Statutory Background

A pharmaceutical company is required to submit a New Drug Application ("NDA") to the Federal Food and Drug Administration

("FDA") before introducing or delivering for introduction a new drug into interstate commerce. See 21 U.S.C. § 355(a). The NDA must, inter alia, identify any patents for "which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). When an NDA is approved by the FDA, this patent information is published in an official FDA publication entitled the Approved Drug Products with Therapeutic Equivalence Evaluations, known as the "Orange Book." Merck & Co., Inc. v. Hi-Tech Pharmacal, Inc., 482 F.3d 1317, 1319 (Fed. Cir. 2007).

Generic drug manufacturers may subsequently file an Abbreviated New Drug Application ("ANDA") for FDA approval of a generic version of a drug approved under an NDA. 21 U.S.C. § 355(j). An ANDA filer must submit, inter alia, one of four certifications with respect to each patent listed in the Orange Book by the NDA holder. 21 U.S.C. § 355(j)(2)(A)(vii). The type of certification at issue here is a "paragraph IV certification," where the ANDA filer, for each of the patents listed in the Orange Book by the NDA holder, certifies "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the ANDA is submitted." 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

The filing of an ANDA constitutes an act of infringement. 35 U.S.C. § 271(e)(2)(A); Teva Pharm. USA, Inc. v. Novartis Pharm. Corp., 482 F.3d 1330, 1342 (Fed. Cir. 2007). Therefore, an ANDA filer making a paragraph IV certification is required to give notice of this filing to the NDA holder and the patentee. 21 U.S.C. § 355(j)(2)(B). Then, the patentee may bring suit on any of the challenged patents within forty-five days of receiving notice of the ANDA filing. 21 U.S.C. § 355(j)(5)(B)(iii). If the patentee does bring such a suit, the ANDA cannot be approved until the earlier of a period of thirty months, or a court decision in that patent infringement case. Id.

The ANDA can be approved immediately if the patentee does not sue on the challenged patent within forty-five days of receiving notice of the paragraph IV ANDA filing. Id. The expiration of the forty-five day time period, however, does not preclude the patentee from pursuing future infringement suits under 35 U.S.C. § 271(e)(2)(A), as the patentee retains the right to sue on the patents listed in the Orange Book. See 35 U.S.C. § 271(e)(2)(A); see Teva Pharm. USA, Inc., 482 F.3d at 1341 (noting that expiration of forty-five day time period did not preclude patentee from bringing action for infringement). Thus, if the patentee does not bring an action for infringement within forty-five days, in order to obtain patent certainty, an ANDA filer may bring a civil action for a judgment declaring that the patent at issue is invalid or will not be infringed by the drug for which

the ANDA was submitted. 21 U.S.C. § 355(j)(5)(C)(i)(II).[1] Federal courts are to exercise jurisdiction over such actions "to the extent consistent with the Constitution." 35 U.S.C. § 271(e)(5).

The first ANDA filer making a paragraph IV certification is given a period of 180 days of marketing exclusivity before any subsequent ANDA filers making a paragraph IV certification can receive FDA approval. 21 U.S.C. § 355(j)(5)(B)(iv).

II. Factual Background

Merck received FDA approval on an NDA for the drug product COSOPT in April 1998. (Dkt. entry no. 33, Pl. Br., at 3.) Merck identified to the FDA the United States Patent No. 4,797,413 patent ("'413 patent"), the '735 patent, and the '443 patent for the COSOPT product. (Id. at 3-4.) The FDA listed these three patents in the Orange Book. (Id. at 4.)

Merck received notice from Hi-Tech Pharmacal, Co., Inc. ("Hi-Tech") in December 2005 that Hi-Tech had submitted an ANDA to market a generic version of COSOPT, challenging the validity

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[1] An ANDA filer may only seek a declaratory judgment if (1) the forty-five day time period has expired, (2) neither the patentee nor the NDA holder has brought an action for infringement during the forty-five day time period, and (3) the ANDA filer challenging the Orange Book patents has provided an offer of confidential access to the ANDA to the NDA holder and patentee for the purpose of determining whether an action for infringement under 21 U.S.C. § 355(j)(5)(B)(iii) should be brought. 21 U.S.C. §§ 355(j)(5)(C)(i)(I)(aa-cc), (III). Apotex has apparently satisfied these requirements here. (Dkt. entry no. 46, Def. Br., at 9.)

of the three listed Orange Book patents under a paragraph IV certification. (Id.) Hi-Tech was the first ANDA filer to make a paragraph IV certification as to these patents. (Dkt. entry no. 51, Pl. Reply Br., at 3.) Merck brought an action in this Court in January 2006 alleging infringement of the '413 patent only ("Hi-Tech litigation"). (Pl. Br., at 4.) This Court entered judgment in favor of Merck and against Hi-Tech on April 25, 2006. (No. 06-266 (MLC), dkt. entry no. 23.)

Merck filed statutory disclaimers in the United States Patent and Trademark Office in April 2006, disclaiming all claims of the '735 and '443 patents. (Pl. Br., at 4.) Merck also wrote to the FDA and requested that the agency remove, or "de-list" the disclaimed '735 and '443 patents from the Orange Book in April 2006. (Id.) The FDA apparently did not de-list the patents. (See Def. Br., at 11.)

Apotex submitted an ANDA to the FDA, seeking approval to market a generic version of COSOPT and challenging the three listed Orange Book patents under a paragraph IV certification in March 2006. (Dkt. entry no. 35, Decl. of Andrew M. Alul, Ex. I, ANDA Application, Ex. J, Paragraph IV Certification.) Apotex notified Merck of this ANDA filing in October 2006. (Dkt. entry no. 37, Decl. of Andrew M. Alul, Ex. M, Notice Letter; Pl. Br., at 4.) Merck responded to Apotex's notice letter, noting that it could not and did not intend to sue on the '735 and '443 patents as Merck disclaimed these patents. (Pl. Br., at 5.) Merck also

sent a second letter to the FDA in December 2006, repeating the request to de-list the '735 and '443 patents from the Orange Book. (Id.) The FDA apparently did not de-list the patents. (See Def. Br., at 11.)

Merck then filed a complaint in December 2006, alleging Apotex infringed the '413 patent due to Apotex filing an ANDA to market a generic version of COSOPT. (No. 06-5791 (MLC), dkt. entry no. 1, Compl.)[2] In March 2007, Apotex answered the complaint filed under No. 06-5791, and counterclaimed against Merck, requesting a judicial declaration of the (1) unenforceability of the '413 patent, (2) invalidity of the extended term of the '413 patent, (3) invalidity of the '413 patent, (4) non-infringement of the '735 patent, (5) invalidity of the '735 patent, (6) non-infringement of the '443 patent, and (7) invalidity of the '443 patent. (Ans. & Countercl.)

This Court stayed the proceedings of this action on March 8, 2007, pursuant to a stipulation by the parties as to the '413

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[2] Merck also filed a complaint in December 2006 alleging infringement of the '413 patent due to Apotex filing an ANDA to market a generic version of Merck's drug product TRUSOPT. (Dkt. entry no. 1, Compl.) This Court consolidated No. 06-5791 (MLC) into No. 06-5789 (MLC) pursuant to Rule 42(a). As discussed infra, this Court granted final judgment in favor of Merck and against Apotex as to the '413 patent. (Dkt. entry no. 39, Final J.) Because Merck's NDA for the TRUSOPT product only identified the '413 patent, any claims related to the TRUSOPT product were fully disposed of by the Court's final judgment. (See Pl. Br., at 3; Final J.)

patent only, agreeing that if this Court's decision in the Hi-Tech litigation was affirmed by the United States Court of Appeals for the Federal Circuit ("Federal Circuit"), judgment would be entered in favor of Merck and against Apotex with regard to the '413 patent. (Dkt. entry no. 22, Stip. & Order.) This Court's judgment in the Hi-Tech litigation was subsequently affirmed by the Federal Circuit on April 2, 2007. (No. 06-266 (MLC), dkt. entry no. 30.) This Court then granted final judgment in favor of Merck and against Apotex as to all claims concerning the '413 patent only on April 12, 2007. (Final J.) Because all claims as to the '413 claim were fully disposed of in this Court's final judgment, only Counts IV through VII of Apotex's counterclaims as to the '735 and '443 patents remain. (Id.)

Hi-Tech may begin to market a generic version of COSOPT on October 28, 2008 as a result of the Hi-Tech litigation. (Pl. Reply Br., at 5.) This date reflects the expiration of the '413 patent on April 28, 2008, plus six months of additional exclusivity due to Merck's performance of pediatric clinical studies requested by the FDA. (Id.) As the first challenger to Merck's listed Orange Book patents, Hi-Tech is entitled to 180 days of exclusivity to market a generic version of COSOPT over any subsequent ANDA challenger. (Id. at 3, 5.) Hi-Tech's 180-day period of marketing exclusivity exists despite the fact that

Hi-Tech's challenge to the validity of the '413 patent was unsuccessful. (Id.; see No. 06-266 (MLC), dkt. entry no. 30.) Hi-Tech is not a party to this action, which is between Merck, as the patent holder, and Apotex, as a subsequent ANDA challenger.

Merck now moves to dismiss Counts IV, V, VI, and VII of Apotex's counterclaims pursuant to Rule 12(b)(1), arguing that there is no actual case or controversy as to the '735 and '443 patents to support entry of a declaratory judgment of invalidity or non-infringement of those two patents. (Pl. Br., at 10-13.)

DISCUSSION

I. Standard of Review for a 12(b)(1) Motion to Dismiss

A party may move under Rule 12(b)(1) to dismiss a claim for lack of subject matter jurisdiction at any time. Fed.R.Civ.P. 12(b)(1); Iwanowa v. Ford Motor Co., 67 F.Supp.2d 424, 437-38 (D.N.J. 1999). The nonmovant bears the burden of persuasion to show subject matter jurisdiction exists when it is challenged under Rule 12(b)(1). Kehr Packages, Inc. v. Fidelcor, Inc., 926 F.2d 1406, 1409 (3d Cir. 1991). Moreover, a court should consider a Rule 12(b)(1) motion first, because if such a motion is granted, the claim at issue must be dismissed for lack of subject matter jurisdiction. Pashun v. Modero, No. 92-3620, 1993 WL 185323, at *2 (D.N.J. May 26, 1993). The accompanying defenses, therefore, become moot and need not be addressed. Id.

A movant may challenge subject matter jurisdiction facially. Iwanowa, 67 F.Supp.2d at 438. In doing so, the movant asserts that the claim, on its face, does not allege sufficient grounds to establish subject matter jurisdiction. Id. Under this standard, the Court assumes that the allegations in the claim are true, and may dismiss the claim only if it appears to a certainty that the nonmovant will not be able to assert a colorable claim of subject matter jurisdiction. Cardio-Med. Assocs., Ltd. v. Crozer-Chester Med. Ctr., 721 F.2d 68, 75 (3d Cir. 1983); Iwanowa, 67 F.Supp.2d at 438.

A movant also may attack subject matter jurisdiction by factually attacking the nonmovant's jurisdictional allegations as set forth in the claim at issue. Iwanowa, 67 F.Supp.2d at 438. Under this standard, no presumptive truthfulness attaches to the nonmovant's allegations, and the existence of disputed material facts will not preclude the Court from evaluating the merits of jurisdictional claims. Robinson v. Dalton, 107 F.3d 1018, 1021 (3d Cir. 1997). The Court may consider affidavits, depositions, and testimony outside of the claim to resolve factual issues, and is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case. Id.; Iwanowa, 67 F.Supp.2d at 438.

A movant need not have yet answered the claim to factually attack subject matter jurisdiction. Berardi v. Swanson Mem'l

Lodge No. 48, 920 F.2d 198, 200 (3d Cir. 1990). A district court may consider evidence beyond the allegations of the claim at issue when a movant moves to dismiss. Id. Although an answer to the claim has not yet been served, a movant may submit an affidavit disputing a nonmovant's factual basis for jurisdictional allegations. Id. at 199. This is a sufficient method of factually attacking a claim. Id. at 200; see Iwanowa, 67 F.Supp.2d at 438 (treating Rule 12(b)(1) motion as a factual attack because both parties attached declarations to their briefs).

Merck disputes Apotex's factual basis for its jurisdictional allegations as set forth in Apotex's counterclaims. (See Pl. Br.) Therefore, the Court will evaluate the 12(b)(1) motion as a factual challenge to subject matter jurisdiction, and consider the declarations submitted by both parties.

II. Jurisdiction under the Declaratory Judgment Act

A. General Standard

The Declaratory Judgment Act ("DJA"), 28 U.S.C. §§ 2201, 2202, provides 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. The burden of proving jurisdiction is on the party claiming such jurisdiction. Benitec

Austl., Ltd. v. Nucleonics, Inc., 495 F.3d 1340, 1344 (Fed. Cir. 2007). That party must establish that such jurisdiction existed at the time the claim for declaratory relief was filed and that it has continued since. Id.

The phrase "case of actual controversy" in 28 U.S.C. § 2201 refers to the type of "Cases" and "Controversies" that are justiciable under Article III of the United States Constitution. MedImmune, Inc. v. Genentech, Inc., 127 S.Ct. 764, 771 (2007). A declaratory judgment action is justiciable if 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 relief. Id. The party asserting jurisdiction, however, need not assert that it was in "reasonable apprehension of suit" by the other party in order to establish jurisdiction in an action seeking a declaratory judgment. See MedImmune, 127 S. Ct. at 774 n.11; SanDisk Corp. v. STMicroelectronics, Inc., 480 F.3d 1372, 1380 (Fed. Cir. 2007) (noting that MedImmune opinion rejected Federal Circuit's requirement that party seeking declaratory judgment show reasonable apprehension of suit by other party in order to establish jurisdiction).

B. Standard Applied Here

There is no actual case or controversy under all the circumstances here to support jurisdiction. The '735 and '443

patents have been statutorily disclaimed by Merck. (Pl. Br., at 4.) "A statutory disclaimer under 35 U.S.C. § 253 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). As a result of a disclaimer, the patentee has no further right to enforce the claims that have been disclaimed, or to obtain a reissue of any of these claims. W.L. Gore & Assocs., Inc. v. Oak Materials Group, Inc., 424 F.Supp. 700, 702 (D. Del. 1976); see also Altoona Publix Theatres, Inc. v. Am. Tri-Ergon Corp., 294 U.S. 477, 492 (1935) (noting that when patentee filed disclaimer, "the original claims were withdrawn from the protection of the patent laws, and the public was entitled to manufacture and use the device originally claimed as freely as though it had been abandoned.") Thus, because Merck has formally disclaimed the '735 and '443 patents, and can no longer enforce any claims as to these patents, there is no justiciable case or controversy to support jurisdiction in an action for a declaratory judgment here. See W.L. Gore & Assocs, Inc., 424 F.Supp. at 702 (finding no jurisdiction with respect to validity or invalidity of patent because plaintiff disclaimed all claims of patent).

The Federal Circuit recently held that there was a justiciable controversy in a factually similar dispute between an NDA holder and an ANDA filer asserting jurisdiction in an action for a declaratory judgment. See Teva, 482 F.3d at 1340-46. That

case, however, is distinguishable here. Novartis, the NDA holder, sued Teva, the ANDA filer, for infringement on only one of the five Orange Book patents listed for the drug at issue that were challenged by Teva's paragraph IV certification. Id. at 1334-35. Novartis did not, however, disclaim the four other Orange Book patents. See id. at 1345. Novartis thus retained the right to sue Teva for infringement of those patents based on Teva's ANDA that challenged all five of the Orange Book patents for the drug at issue. Id. As a result, Teva's legal rights under its ANDA were uncertain, and it faced possible future litigation on the four other Orange Book patents, thus creating legal injuries sufficient to establish a justiciable controversy. Id. Merck, by contrast, cannot further enforce any claims as to the '735 and '443 patents because it statutorily disclaimed these patents. See W.L. Gore & Assocs., 424 F.Supp. at 702. Therefore, the legal status of Apotex's ANDA is not uncertain, nor does Apotex face possible future litigation, as a result of Merck not bringing an action for infringement on the '735 and '443 patents. See id.

The legislative history of the applicable statutory provisions also indicates that jurisdiction does not exist here. See Teva, 482 F.3d at 1343. In particular, the Teva court cited to legislative history noting 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." Id. (quotation and citation omitted). This circumstance is present here, as Merck has formally acknowledged by statutory disclaimer that Apotex's generic version of COSOPT will not infringe on the '735 and '443 patents. (Pl. Br., at 10.)

III. Apotex's Cross Motion for Summary Judgment

Apotex cross-moves for summary judgment, asserting that it is entitled to summary judgment as a matter of law because the generic version of COSOPT it seeks approval for under its ANDA will not infringe on the '735 and '443 patents, as Merck has disclaimed those patents. (Dkt. entry no. 35, Def. Br., at 11.) As discussed supra, this Court does not have jurisdiction with respect to infringement of the '735 and '443 patents. Therefore, Apotex's cross motion is moot.

CONCLUSION

The Court, for the reasons stated supra, will (1) grant the motion to dismiss, and (2) deny the cross motion as moot. The Court will issue an appropriate order and judgment.

s/ Mary L. Cooper
MARY L. COOPER
United States District Judge

Dated: November 15, 2007