UNITEDD STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MERCK SHARP & DOHME CORP. *Plaintiff*, v. ACTAVIS LABORATORIES FL, INC., et al. *Defendants*.	)	Civil Action No: 15-cv-6075 (PGS)(DEA) **MEMORANDUM** **&** **ORDER**

SHERIDAN, U.S.D.J.

This matter comes before the Court on defendant Actavis, Inc. n/k/a Allergan Finance LLC's ("Allergan Finance") motion to dismiss plaintiff Merck Sharp & Dohme Corp.'s ("Merck") complaint for lack of subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1) ("Rule 12(b)(1)"). Defendants Actavis Laboratories FL, Inc., Andrx Corporation, & Actavis Pharma, Inc. (collectively, "Teva Defendants"), consent to this motion. (*See* Defs.' Br. at 1; Dkt. No. 114-1).

Allergan Finance argues that Merck's complaint lacks subject matter jurisdiction against Allergan Finance because it divested its interests in an Abbreviated New Drug Application ("ANDA") upon acquiring of its business by Teva Pharmaceuticals USA. The ANDA application is directed to posaconazole drug, which is protected by U.S. Pat. 5,661,151 (the "'151 patent"). Because of its divestiture of the ANDA application, Allergan Finance argues that it lacks the involvement in the marketing, distribution, or sale of Teva Defendants' ANDA products. As a result, extinguishing this Court's jurisdiction conferred by 35 U.S.C. § 271(e)(2).

In opposition, Merck argues that the subject matter jurisdiction under Rule 12(b)(1) was satisfied at the time of filing of the complaint. In the complaint, Merck alleged that Allergan

Finance submitted the ANDA application for purposes of engaging in commercial manufacture, use, or sale of the posaconazole (i.e., the ANDA product) prior to the expiration of the '151 patent. As such, Merck purports that this Court does have subject matter jurisdiction over Allergan Finance.

Based on the arguments made in the briefs, arguments presented on the record on March 20, 2016, and for the reasons set forth below, this Court denies Allergan Finance's motion to dismiss Merck's complaint for lack of subject matter jurisdiction under Rules 12(b)(1).

I.

On June 25, 2015, Merck received a letter from Actavis Laboratories FL, Inc. ("Actavis Florida"), which indicated that Actavis Florida had submitted the ANDA application 207355 to the Food and Drug Administration ("FDA"). The ANDA application sought approval to engage in the manufacture, use or sale of a generic version of the tablet formulation of Merck's drug NOXAFIL®. This letter is on Actavis Florida's letter head, signed by Janet Vaugh, Director of Regulatory Affairs of Actavis Florida. (*See* Pl.'s Opp. Br., Dkt. No. 119 ("Pl.'s Opp. Br.") at 5, *citing* Declaration of Charles H. Chevalier, Dkt. No. 119-1 ("Decl. of Chevalier") at Ex. 1).

On August 6, 2015 Merck initiated this suit alleging infringement of the '151 Patent against Actavis Florida, Actavis, Inc., and two other Actavis entities, which Merck believed were also actively involved in the preparation or submission of the ANDA application. (*See* Defs.' Br., Dkt. No. 114-1 ("Defs.' Br.") at 6; *citing* Complaint ("Compl.") at Dkt. No. 1). In its complaint, Merck alleged that—(i) Actavis, Inc. ultimately controlled Actavis Florida and other Actavis entities (Compl. at ¶ 12); (ii) defendants filed or caused the ANDA application to be filed, with the intent to seek to market and sell the ANDA product prior to the expiration of the '151 patent (*Id.* at ¶ 19); and (iii) thereby committing the tort of infringement under 35 U.S.C. § 271(e)(2) (*Id.* at ¶ 26).

On October 16, 2015, defendants filed their answer in which they admitted that—(i) they did file the ANDA application; (ii) they did send the letter on or about June 25, 2015 to Merck; and (iii) that "Actavis" (a term defined to include all defendants) sought approval to market the Actavis ANDA product. (Pl.'s Opp. Br. at 7, *citing* Defendants' Answer, Defenses, and Counterclaims (Dkt. No. 16)). Further, defendants' stipulated that filing of the ANDA application would constitute infringement under 35 U.S.C. § 271(e)(2) if the asserted claims the '151 patent are found valid and enforceable. (*See* Decl. of Chevalier, Ex. 4 at ¶ 1).

During the initiation of this suit, Actavis, Inc. was a parent company of Teva Defendants, which includes Actavis Florida; and was a subsidiary of Allergan plc (f/k/a Actavis plc). At that time Actavis Florida submitted the ANDA application. (*See* Declaration of Brian Anderson, Dkt. No. 114-2 ("Decl. of Anderson") at ¶ 3).

About a year after this lawsuit was filed, Allergan plc divested its generic pharmaceutical business to Teva Pharmaceutical USA ("Teva"), and as such Teva acquired Actavis Florida. At the oral argument, Merck did not contest this point. Thereafter, Actavis, Inc. changed its name to Allergan Finance, and remains a wholly owned subsidiary of Allergan plc. (Decl. of Chevalier, Ex. 3). Accordingly, the documents submitted indicate that Allergan Finance does not retain any interest in the ANDA application, and it submits that it has no plans to market, distribute, or sell the posaconazole drug described in the ANDA application. (Decl. of Anderson at ¶¶ 5-6).

As part of the divestment of its generic pharmaceuticals business, Teva Pharmaceutical Industries, Ltd. assumed all the liabilities of Allergan plc's generic pharmaceuticals business, including liabilities for infringement. (*Id.* at ¶ 9; *citing* Exhibit A: Master Purchase Agreement between Allergan plc and Teva Pharmaceutical Industries, Ltd., dated July 26, 2015).

II.

Pursuant to the Federal Rules of Civil Procedure, Rule 12(b)(1), a claim can be dismissed for "lack of jurisdiction over the subject matter." This motion to dismiss may be asserted at any time in a case. *In re Kaiser Group Int"l, Inc.*, 399 F.3d 558, 565 (3d Cir.2005). The court, when faced with a Rule 12(b)(1) motion to dismiss, usually determines jurisdiction based on the date the complaint is filed. 28 U.S.C.A. § 1338 ("The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents […]").

"The well-pleaded-complaint rule has long governed whether a case 'arises under' federal law for purposes of § 1331." *Holmes Group, Inc. v. Vornado Air Circulation Systems, Inc.*, 535 U.S. 826, 831 (2002) (*citing Phillips Petroleum Co. v. Texaco Inc.*, 415 U.S. 125, 127-128 (1974)). "As 'appropriately adapted to § 1338(a),' the well-pleaded-complaint rule provides that whether a case 'arises under' patent law 'must be determined from what necessarily appears in the plaintiff's statement of his own claim in the bill or declaration ... .'" *Id.* (internal citations omitted). "Section 1338(a) uses the same operative language as 28 U.S.C. § 1331, the statute conferring general federal-question jurisdiction, which gives the district courts 'original jurisdiction of all civil actions *arising* under the Constitution, laws, or treatise of the United States." *Id.* at 829-830.

III.

Here, the facts set forth in the complaint are clearly different from the facts presented in the current motion to dismiss under Rule 12(b)(1). The divesture of Allergan Finance's interest in the ANDA application, upon acquiring of its business by Teva, is a fact that is not alleged in the current complaint. As such, the Court notes that the fact of divesture is not alleged in the complaint.

"Section 271(e)(2) is not a jurisdictional statute in the strict sense of the word." *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1330 (Fed. Cir. 2003). It establishes a "defined act of

infringement [based on the filing of an ANDA] sufficient to create case or controversy [over which this court has jurisdiction]." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997) (*citing* 35 U.S.C. § 271(e)(2)). As the Supreme Court noted in *Eli Lilly Co. v. Medtronic, Inc.*, section 271(e)(2) creates an "act of infringement" based upon the filing of an ANDA. *Allergan Inc.*, 324 F.3d at 1330 (*citing Eli Lilly*, 496 U.S. 661, 678 (1990)). Further, the Federal Circuit has held that "the requirements for jurisdiction in the district courts are met once a patent owner alleges that another's filing of an ANDA infringes its patent under § 271(e)(2), and this threshold jurisdictional determination does not depend on the ultimate merits of the claims." *AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1377 (Fed. Cir. 2012).

Defendant Allergan Finance argues that Merck's complaint lacks subject matter jurisdiction against Allergan Finance because it assigned its interests in the ANDA application when it divested its generic business to Teva. Because of the divesture, Allergan Finance argues that it lacks the involvement in the marketing, distribution, or sale of Teva Defendants' ANDA products. As a result, this act extinguishes this Court's jurisdiction under 35 U.S.C. § 271(e)(2). (*See* Defs.' Br. at 6-8).

Additionally, defendant Allergan Finance argues that Merck's only injury is money damages that stem from a possible at-risk launch by Teva Defendants, which they assert as purely conjectural and hypothetical at this stage of the litigation. (*Id.* at 8). Allergan Finance notes that monetary damages are available against an infringer under § 271(e)(4)(c); however, such monetary damages are available "*only if* there has been commercial manufacture, use, offer to sell, or sale within the United States." (*Id.* at 9; *citing* 35 U.S.C. § 271(e)(4)(c)). That is, damages under § 271(e) are only available against a party which commercializes an ANDA product. And because

Allergan Finance does not have any connection to Teva Defendants, it asserts that it would not be liable for monetary damages to Merck stemming under § 271(e)(4)(c). (*Id.* at 10).

In a nutshell, Allergan Finance argues that Merck could only have a legitimate interest against Allergan Finance under § 271(e) if—"(1) Teva Defendants do in fact launch at-risk [at the end of the 30-month stay in December 2017]; (2) the patent-in-suit is held not invalid; and (3) Teva Defendants […] cannot alone satisfy any judgment" obtained by Merck; and therefore Merck may have some action against Allergan Finance to satisfy its loss. (*Id.* at 11). As such, because of the speculative nature of these claims, Allergan Finance asserts any claim against it is not ripe for determination.

In response, Merck argues that subject matter jurisdiction under Rule 12(b)(1) against Allergan Finance was satisfied at the time of the filing of the complaint. The complaint alleged that Allergan Finance submitted the ANDA application for purposes of engaging in commercial manufacture, use, or sale of posaconazole prior to the expiration of the '151 patent. (*See* Pl.'s Br. at 10; *citing* Compl. at ¶¶ 26, 28). And, in its answer, Allergan Finance admitted that it filed the ANDA application with the purpose of engaging in the sale of posaconazole prior to the expiration of the '151 patent. (*Id.* at 11; *citing* Answer at ¶¶ 19, 21 (Dkt. No. 16)).

Relying on Federal Circuit case law, Merck argues that filing of an ANDA application constitutes an act of infringement, which is a tort that gives right to an actionable injury. (*Id.* at 11-12; *citing Acorda Therapeutics, Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755, 760 (Fed. Cir. 2016) ("[t]he Hatch-Waxman Act recognizes the close connection between an ANDA filing and the real-world acts that approval of the ANDA will allow and that will harm patent-owning brand-name manufacturers.")). Merck argues that because Allergan Finance filed the ANDA application, this in-effect resulted in injury-in-fact to Merck under § 271(e), irrespective of Allergan Finance

profiting from the sale of the infringing products (i.e., generic version of posaconazole). (*Id.* at 13).

Further, Merck argues that the injury-in-fact traces back to Allergan Finance because Allergan Finance filed the ANDA application, which caused the injury (*Id.* at 14-15); and such injury is redressable by injunction under § 271(e)(4)(A) or by money damages under § 271(e)(4)(C). With respect to the money damages under § 271(e)(4)(C), Merck argues that the language of this statute places no restriction on the entity "who" ultimately engage the final manufacture, use, offer to sell, or sale of the infringing products, because doing so would deprive victims of tort of § 271(e)(2) infringement from enjoying recovery from all joint tortfeasors. (*Id.* at 17-18).

Here, the Court does not find defendant Allergan Finance's arguments persuasive for at least the following reasons. First, the case law is clear that a district court does have subject matter jurisdiction over a defendant where plaintiff alleges in its complaint that the defendant's ANDA filings infringed its listed patents under § 271(e)(2). *Allergan Inc.*, 324 F.3d at 1330; *see also AstraZeneca Pharms.*, 669 F.3d at 1377 ("the requirements for jurisdiction in the district courts are met once a patent owner alleges that another's filing of an ANDA infringes its patent under § 271(e)(2), and this threshold jurisdictional determination does not depend on the ultimate merits of the claims.").

In *AstraZeneca*, for example, the Federal Circuit noted that the district court did have subject matter jurisdiction over AstraZenca's claims that Apotex's ANDA filings infringed its listed patents under § 271(e)(2), and further noted that nothing more was required to establish the district court's subject matter jurisdiction pursuant to § 1338(a). *AstraZeneca Pharms.*, 669 F.3d at 1377. Additionally, the Court cited *Warner-Lambert* case, where the Court held that a patented

method of using a drug can only be infringed under § 271(e)(2) by filing an ANDA that seeks approval market the drug for that use. *Id.* at 1379 (*citing Warner-Lambert v. Apotex Corp.*, 316 F.3d 1348, 1358-59 (Fed. Cir.2003). As such, this Court has subject matter jurisdiction over Allergan Finance based on the claims alleged in Merck's complaint. (*See B.V. v. Actavis, Inc.*, 2016 WL 3027446, at *3 (D.N.J. 2016) ("Since Plaintiffs have alleged that Defendants' ANDA infringes the '939 patent, this Court may not dismiss Plaintiffs' § 271(e)(2)(A) claim for lack of subject matter jurisdiction, no matter the merits of Plaintiffs' claim.")).

Moreover, the Court finds Allergan Finance's argument that it is no longer involved in the marketing, distribution or sale of the ANDA products meritless because the requirements for subject matter jurisdiction were satisfied at the time of the filing of the complaint. Here, Merck's complaint alleged that Allergan Finance submitted the ANDA application for purposes of engaging in commercial manufacture, use, or sale of the ANDA product prior to the expiration of the '151 patent. (*See* Compl. at ¶¶ 26, 28; Dkt. No. 1). And, in its answer, Allergan Finance admitted the same. As such, divestment of Allergan Finance's interest does not affect this Court's subject matter jurisdiction over Allergan Finance.

To the Court the present motion is more akin to one for summary judgment where the facts with the divesture could be analyzed after discovery is conducted. In addition, the Court notes that Allergan Finance could have sought that this action be administratively terminated against it, and be reopened if the case continues to one seeking damages. Neither motions were brought before the Court.

ORDER

IT IS on this 24TH day of March, 2017,

ORDERED that Defendants' motion to dismiss Plaintiff's complaint for lack of subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1) (*see* Dkt. No. 114) is DENIED.

s/Peter G. Sheridan
PETER G. SHERIDAN, U.S.D.J.