NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

FERRING B.V., FERRING INTERNATIONAL CENTER S.A. and FERRING PHARMACEUTICALS INC., Plaintiffs, v. ACTAVIS, INC., WATSON LABORATORIES, INC., ANDRX CORP., WATSON LABORATORIES, INC. – FLORIDA and WATSON PHARMA, INC., Defendants.	**Civil Action No. 15-4222 (SRC)(CLW)** **OPINION**

CHESLER, District Judge

This matter comes before the Court upon the motion filed by Defendants Actavis, Inc., Watson Laboratories, Inc., Andrx Corporation, Watson Laboratories, Inc. – Florida, and Watson Pharma, Inc. (collectively, "Defendants") to dismiss Plaintiffs Ferring B.V., Ferring International Center S.A., and Ferring Pharmaceuticals Inc.'s (collectively, "Plaintiffs") patent infringement claim under 35 U.S.C. § 271(e)(2)(A), pursuant to Federal Rules of Civil Procedure 12(b)(1) or 12(b)(6) [Docket Entry 9]. Plaintiffs have opposed the motion. The Court has considered the papers filed by the parties and proceeds to rule on the motion without oral argument, pursuant to Federal Rule of Civil Procedure 78. For the reasons discussed below, the Court will grant Defendants' motion to dismiss Plaintiffs' § 271(e)(2)(A) claim, pursuant to Federal Rule of Civil Procedure 12(b)(6).

I. BACKGROUND

Plaintiff Ferring is the holder of United States Patent Number 9,060,939 ("the '939 patent"), issued June 23, 2015, which claims tranexamic acid formulations. (Compl. ¶ 19.) On November 13, 2009, the FDA approved Plaintiff Ferring Pharmaceuticals AS's New Drug Application ("NDA") No. 02-2430 for tranexamic acid tablets. (Compl. ¶ 20.) Plaintiffs currently sell a 650 mg dosage strength tablet of tranexamic acid under the trademark Lysteda®. (Compl. ¶ 21.)

Defendant Watson Laboratories, Inc. – Florida ("Watson Labs.") filed Abbreviated New Drug Application ("ANDA") No. 202093 on July 23, 2010, seeking FDA approval to market generic tablets containing 650 mg of tranexamic acid that are, allegedly, the same or substantially the same as Lysteda®. (Compl. ¶¶ 10, 19.) The FDA approved this ANDA application on December 27, 2012, after which time Defendants sold generic tranexamic acid tablets to consumers. (Compl. ¶¶ 30-31.)

In the Complaint, Plaintiffs raise two causes of action related to the '939 patent. First, Plaintiffs allege that, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed the '939 patent through the filing of Defendant Watson Labs.' ANDA for generic tranexamic acid tablets. (Compl. ¶¶ 10, 19, 23-25.) Second, Plaintiffs seek damages under 35 U.S.C. § 271(a), based on Defendants' alleged infringement of the '939 patent through Watson's sale of generic tranexamic acid tablets. (Compl. ¶¶ 11, 30.)

II. LEGAL STANDARDS

a. MOTION TO DISMISS UNDER RULE 12(B)(1)

Federal Rule of Civil Procedure 12(b)(1) permits the dismissal of a complaint for lack of

subject matter jurisdiction at any point during the case. *Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977). Rule 12(b)(1) challenges may be either facial or factual attacks on the Court's subject matter jurisdiction. *Id.*

"A motion to dismiss on the basis of Fed. R. Civ. P. 12(b)(1) for lack of subject matter jurisdiction made prior to the filing of the defendant's answer is a facial challenge to the complaint." *Bennett v. City of Atl. City*, 288 F. Supp. 2d 675, 678 (D.N.J. 2003) (citing *Mortensen*, 549 F.2d at 891). A facial challenge asserts that the Complaint does not allege sufficient grounds to establish subject matter jurisdiction or that there is a legal bar to the court hearing the case, such as sovereign immunity. *Id.* at 679-80. When reviewing a facial challenge under Rule 12(b)(1), Rule 12(b)(6)'s standards apply—requiring that the Court must accept all factual allegations in the Complaint as true, and that the Court may only consider the Complaint and documents referenced in or attached to the Complaint. *Gould Elecs., Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000).

When the 12(b)(1) motion is "factual," in that it challenges the facts underpinning the Court's jurisdiction, the Court may "consider and weigh evidence outside the pleading and properly place[] the burden of establishing jurisdiction" on the plaintiff. *U.S. ex rel. Atkinson v. PA. Shipbuilding Co.*, 473 F.3d 506, 514 (3d Cir. 2007). The Court may not place any "presumption of truthfulness" on a plaintiff's allegations in the Complaint when analyzing a factual attack under Rule 12(b)(1). *CNA v. United States*, 535 F.3d 132, 139 (3d Cir. 2008). The plaintiff bears the burden to prove that subject matter jurisdiction exists over a complaint once it has been challenged. *Mortensen*, 549 F.2d at 891. "Dismissal for lack of subject-matter jurisdiction because of the inadequacy of the federal claim is proper only when the claim is so

insubstantial, implausible, foreclosed by prior decisions of [the Supreme Court], or otherwise completely devoid of merit as not to involve a federal controversy." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 89 (1998) (internal quotation marks omitted).

b. MOTION TO DISMISS UNDER RULE 12(B)(6)

In deciding a motion to dismiss pursuant to Rule 12(b)(6), courts must "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008) (quoting *Pinker v. Roche Holdings, Ltd.*, 292 F.3d 361, 374 n.7 (3d Cir. 2002)). A Rule 12(b)(6) motion to dismiss should be granted only if the plaintiff is unable to articulate "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "The defendant bears the burden of showing that no claim has been presented." *Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005).

"Federal Rule of Civil Procedure 8(a)(2) requires only 'a short and plain statement of the claim showing that the pleader is entitled to relief,' in order to 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.'" *Twombly*, 550 U.S. at 555 (*quoting Conley v. Gibson*, 355 U.S. 41, 47 (1957)). "While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id.* (internal citations omitted); *see also* Fed. R. Civ. P. 8(a)(2). "Factual allegations must be enough to raise a right to

relief above the speculative level on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Id.* (internal citations omitted).

Factual allegations must be well-pleaded to give rise to an entitlement to relief:

> [A] court considering a motion to dismiss can choose to begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth. While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations. When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief.

Ashcroft v. Iqbal, 556 U.S. 662, 679 (2009).

In reviewing a motion to dismiss, pursuant to Rule 12(b)(6), a court may consider the allegations of the complaint, as well as documents attached to or specifically referenced in the complaint, and matters of public record. *Pittsburgh v. W. Penn Power Co.*, 147 F.3d 256, 259 (3d Cir. 1998); *see also* 5B Charles Alan Wright & Arthur R. Miller, Federal Practice & Procedure: Civil 3d § 1357 (3d ed. 2007). "Plaintiffs cannot prevent a court from looking at the texts of the documents on which its claim is based by failing to attach or explicitly cite them." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997)

III. DISCUSSION

a. MOTION TO DISMISS UNDER RULE 12(B)(1)

As noted above, Plaintiffs' Complaint recites a cause of action under § 271(e)(2)(A) of the Hatch-Waxman Act, based on Defendants' filing of an ANDA for a generic version of Lysteda®. Defendants challenge whether Plaintiffs have subject matter jurisdiction to bring this

claim, given that the patent Plaintiffs assert in this action was issued after Defendants' ANDA was filed with (and had been approved by) the FDA.

"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). Instead, § 271(e)(2) establishes a "defined act of infringement [based on the filing of an ANDA] sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997) (citing 35 U.S.C. § 271(e)(2)). Congress has determined that "[t]he district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents," including § 271(e)(2)(A). 28 U.S.C. § 1338(a). 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). 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.

b. MOTION TO DISMISS UNDER RULE 12(B)(6)

Defendants also move to dismiss Plaintiffs' § 271(e)(2)(A) claim under Rule 12(b)(6). Defendants assert that Plaintiffs have not alleged facts that could plausibly support an infringement claim under § 271(e)(2)(A), given that Plaintiffs' asserted patent issued after Defendants' ANDA was filed and approved. At the outset, Defendants do not dispute that

Plaintiffs have stated a claim upon which relief can be granted under § 271(a), since, allegedly, Defendants have sold a generic version of tranexamic acid since the '939 patent was issued. (Compl. ¶¶ 10, 19, 23-25.)

Section 271(e)(2) reads as follows:

> It shall be an act of infringement to submit—(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act [codified at 21 U.S.C. § 355(j)] for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2) (2012). In enacting § 271(e)(2), Congress created "a highly artificial act of infringement that consists of submitting an ANDA or a paper NDA containing [a Paragraph IV] certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent." *Eli Lilly & Co. v. Medtronic Inc.*, 496 U.S. 661, 678 (1990). Given that 35 U.S.C. § 271(e)(1) creates a "safe harbor" permitting generic companies to use a patented invention for the purpose of obtaining premarketing approval, an important purpose of § 271(e)(2) is to permit a pioneer drug patent holder to enforce their rights before the generic company's product has been approved by the FDA and brought to market. *Id.* at 677-78. "Thus, § 271(e)(2) provide[s] patentees with a defined act of infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity . . . when . . . the ANDA applicant was not making, using, or selling the patented product, the traditional statutorily-defined acts of infringement." *Glaxo*, 110 F.3d at 1569.

As previously discussed, Defendant Watson Labs. filed an ANDA on July 23, 2010, and Plaintiffs allege that Defendants sold generic tranexamic acid tablets after the FDA approved Defendants' ANDA on December 27, 2012. (Compl. ¶¶ 30-31.) Plaintiffs did not hold the '939 patent at the time that Defendant Watson Labs. filed their ANDA; in fact, this patent did not issue until June 23, 2015.[1] Plaintiffs base their § 271(e)(2)(A) claim on the fact that Defendants filed an ANDA in 2010 that now allegedly infringes the '939 patent.

Section 271(e)(2)(A) makes clear that the artificial act of infringement claim is triggered by the filing of an ANDA. But Defendant Watson Labs. filed its ANDA (and the FDA approved Defendants' ANDA) several years before the '939 patent was issued. As an important purpose of § 271(e)(2)(A) is to provide patentees with a cause of action for infringement during the period of time in which the generic company has not actually infringed the patentee's patent, it is illogical to conclude that the facts of this case should give rise to a § 271(e)(2)(A) claim. *Eli Lilly*, 496 U.S. at 678. Based on the facts Plaintiffs have pled, they no longer need an artificial act of infringement claim under § 271(e)(2)(A) to enforce their patent rights. Instead, Plaintiffs can bring actual infringement claims against Defendants under § 271(a), based on Defendants' alleged marketing of a generic version of Lysteda®.

Nothing in the statutory language or legislative history of the Hatch-Waxman Act indicates that Congress intended for Plaintiffs to be permitted to raise a cause of action under § 271(e)(2)(A) on these facts. In fact, the statutory language of § 271(e)(2) supports the interpretation of this Court that a § 271(e)(2)(A) claim is not available to Plaintiffs, given that

[1] In 2014, the Federal Circuit determined that the district court had erred in finding that Defendants' generic product infringed several patent claims asserted by Plaintiffs. *Ferring B.V. v. Watson Labs., Inc.-Fl.*, 764 F.3d 1401, 1411 (Fed. Cir. 2014). These patents and claims are not at issue in this case.

submission of an ANDA "for a drug claimed in a patent or the use of which is claimed in a patent," for the purpose of obtaining FDA approval for commercial marketing, is an act of infringement. 35 U.S.C. § 271(e)(2)(A). Congress's inclusion of the phrase "claimed in a patent" in the statute indicates that a § 271(e)(2)(A) claim must be based upon a patent that has already been issued at the time the infringing ANDA is filed. *See Endo Pharms. Inc. v. Amneal Pharms., LLC*, No. 12-8115, 2016 WL 1732751, at *3 (S.D.N.Y. Apr. 29, 2016). It is undisputed that at the time that Defendants filed the ANDA, and indeed at the time that the FDA approved Defendants' ANDA, Plaintiffs' '939 patent had not issued.

Finally, permitting such a cause of action would conflict with several of the purposes underlying the Hatch-Waxman Act. Congress intended to "incentivize ANDA filers to challenge the validity of listed patents or design around those patents as early as possible" by creating a cause of action where litigation could commence before the generic company began marketing its product. *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1282 (Fed. Cir. 2008). Furthermore, in the Hatch-Waxman Act, Congress sought to provide ANDA filers with finality with respect to their potential litigation risk. *Id.* at 1285. Permitting Plaintiffs to use § 271(e)(2)(A) to bring a claim years after Defendants filed an ANDA directly contradicts these purposes.

The Court finds that Plaintiffs cannot bring a § 271(e)(2)(A) claim on the facts they have alleged. For these reasons, the Court will dismiss Plaintiffs' § 271(e)(2)(A) claim, for failure to state a claim upon which relief can be granted.

IV. CONCLUSION

For the foregoing reasons, the Court will grant Defendants' motion to dismiss the § 271(e)(2)(A) claim in Count 1 of Plaintiffs' Complaint, pursuant to Federal Rule of Civil Procedure 12(b)(6). An appropriate Order will be filed herewith.

s/Stanley R. Chesler
STANLEY R. CHESLER
United States District Judge

Dated: May 26, 2016