IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, IPR PHARMACEUTICALS, INC., ASTRAZENECA AB, and THE BRIGHAM AND WOMEN'S HOSPITAL, INC.	)	C.A. No. 10-338 (RBK-KW)
Plaintiffs,	)	**PUBLIC VERSION**
v.	)	
APOTEX CORP.,	)	
Defendant.	)	

BRIEF IN SUPPORT OF APOTEX CORP.'S MOTION TO DISMISS UNDER FED. R. CIV. P. 12(b)(1) AND FED. R. CIV. P. 12(b)(6)

Richard L. Horwitz (#2246)
David E. Moore (#3983)
POTTER ANDERSON & CORROON LLP
Hercules Plaza 6th Floor
1313 N. Market Street
Wilmington, DE 19899
Tel: (302) 984-6000
rhorwitz@potteranderson.com
dmoore@potteranderson.com

Attorneys for Defendant Apotex Corp.

OF COUNSEL:

Robert B. Briesblatt
Craig M. Kuchii
Jeremy C. Daniel
Katten Muchin Rosenman LLP
525 W. Monroe Street
Chicago, IL 60661
Tel: (312) 902-5200

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I. NATURE AND STAGE OF THE PROCEEDINGS

On April 30, 2010, the Plaintiffs filed an amended complaint ("Complaint") alleging infringement of U.S. Patent Numbers 6,858,618 and 7,030,152 under 35 U.S.C. § 271(e)(2). (D.I. 5). On July 7, 2010, the Court entered an order extending the time to answer, move, or otherwise plead in response to the Complaint to July 23, 2010. (D.I. 8.) Apotex Corp. now moves to dismiss the Complaint for lack of subject matter jurisdiction, and for failure to state a claim upon which relief can be granted.

II. SUMMARY OF THE ARGUMENT

1. This Court should dismiss the Plaintiffs' patent infringement claims for lack of subject matter jurisdiction because the Complaint fails to set forth allegations sufficient to establish subject matter jurisdiction. The Complaint alleges that subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a). (D.I. 5, ¶ 14.) To establish subject matter jurisdiction under either of these sections, however, the Complaint must set forth a claim for patent infringement. It does not. Patent infringement under 35 U.S.C. § 271(e)(2) requires the submission of an abbreviated new drug application ("ANDA") with a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification"). The Complaint only alleges that Apotex Corp. submitted ANDA No. 79-145.[1] The Complaint does not allege that ANDA No. 79-145 contains a Paragraph IV certification concerning either the '618 patent or the '152 patent. Absent allegations concerning Paragraph IV certifications as to the asserted patents, the Complaint fails to present a justiciable Article III case or controversy. The Complaint further fails to present a justiciable Article III case or controversy in that it relies on contingent future events that have not occurred, thereby rendering the patent infringement claims not ripe.

[1] Apotex Corp. denies that it submitted ANDA No. 79-145. Apotex Corp. is the authorized agent for ANDA No. 79-145.

2. Additionally, there is no factual basis for the exercise of subject matter jurisdiction over the Plaintiffs' patent infringement claims under 35 U.S.C. § 271(e)(2). [redacted]

3. Should this Court exercise subject matter jurisdiction over this action, then it should dismiss the Complaint for failure to state a claim upon which relief can be granted. The Complaint does not allege that Apotex Corp. submitted a Paragraph IV certification for either the '618 patent or the '152 patent, which is necessary to state a claim for infringement under 35 U.S.C. § 271(e)(2). Further, the Plaintiffs' right to relief is speculative at best in view of allegations that refer to contingent future events that have not occurred. Therefore, even taking the Complaint's allegations as true, the Complaint fails to state a claim upon which relief may be granted.

III. STATEMENT OF FACTS

The Complaint alleges that Apotex Inc. and/or Apotex Corp. filed ANDA No. 79-145 with the U.S. Food and Drug Administration. (D.I. 5, ¶ 11.) The Complaint further alleges that Apotex Corp. infringed the '618 and '152 patents by submitting ANDA No. 79-145 to the FDA. (D.I. 5, ¶¶ 30, 44.) The Complaint also alleges that ANDA No. 79-145 seeks approval to market rosuvastatin calcium prior to expiration of the '618 and '152 patents. (D.I. 5, ¶¶ 21, 35.) Neither of the asserted patents claim the chemical compound rosuvastatin calcium. (*See* D.I. 5-1 *and* D.I. 5-3.)

Rather, each asserted patent claims methods of using rosuvastatin calcium. (*See id.*) The independent claims of the '618 patent disclose a method for treating heterozygous familial

hypercholesterolemia in a patient suffering heterozygous familial hypercholesterolemia and a method for reducing LDL-C, raising HDL-C, reducing Apo B, and raising Apo A-I in a patient suffering heterozygous familial hypercholesterolemia. (*See* D.I. 5-1, at col. 9, line 45 – col. 10, line 44.) The sole independent claim of the '152 patent discloses a method for treating a nonhypercholesterolemic human in need thereof to reduce the risk of a cardiovascular disorder. (*See* D.I. 5-3, at col. 32, lines 8-27.)

The Complaint does not allege that Apotex Corp. certified that the uses claimed in either the '618 patent or the '152 patent are invalid or not infringed. (*See* D.I. 5.) The Complaint also does not allege that Apotex Corp. sent notice letters concerning either the '618 patent or the '152 patent to the Plaintiffs. (*See id.*) Further, the Complaint does not allege that the label contained in ANDA No. 79-145 presently has an indication for any use covered by the '618 and '152 patents. (*See id.*)

[redacted]

IV. ARGUMENT

A. Subject matter jurisdiction is lacking.

This Court lacks subject matter jurisdiction because the Complaint does not set forth allegations sufficient to establish an Article III case or controversy. Under 35 U.S.C. § 271(e)(2), it is an act of infringement to submit an ANDA seeking approval to engage in the

commercial manufacture, use, or sale of a drug 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). The U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have described 35 U.S.C. § 271(e)(2) as an artificial act of infringement that consists of submitting an ANDA containing a Paragraph IV certification. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) ("[35 U.S.C. § 271(e)(2) created a] highly artificial act of infringement that consists of submitting an ANDA or a paper NDA containing the fourth type of certification . . .") *and Novo Nordisk A/S v. Caraco Pharmaceutical Laboratories, Ltd.*, 601 F.3d 1359, 1362 (Fed. Cir. 2010) ("[The Hatch-Waxman Act] makes a Paragraph IV certification into an act of patent infringement.").[2] By submitting a Paragraph IV certification, an ANDA applicant certifies that the patent identified in the certification is invalid or will not be infringed by the drug or use described in the ANDA. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358 (Fed. Cir. 2003). This certification is essential to a civil action under 35 U.S.C. § 271(e)(2), *see Novo Nordisk A/S*, 601 at 1363, ("[The Hatch-Waxman Act] makes a Paragraph IV certification into an act of patent infringement."), as it evinces the applicant's intention to seek approval for a claimed drug or use prior to patent expiry.

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[2] *See also Caraco Pharm. Labs., Ltd. v. Forest Labs., Ltd.*, 527 F.3d 1278, 1283 (Fed. Cir. 2008) ("[T]he . . . act of filing a *Paragraph IV* ANDA constitutes an act of patent infringement.") (emphasis added); *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1356 (Fed. Cir. 2008) (citing *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990)) ("[The Hatch-Waxman] Act provides that the filing of a *Paragraph IV Certification* is an act of patent infringement.") (emphasis added); *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358 (Fed. Cir. 2003) (". . . [Section] 271(e)(2)(A) . . create[s] an artificial act of infringement that consists of submitting an ANDA *containing a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV)* . . . . ") (emphasis added); *Bristol-Myers Squibb Co. v. Royce Labs., Inc.*, 69 F.3d 1130, 1131 (Fed. Cir. 1995) ("Inclusion of a *paragraph IV certification* in an ANDA . . . is deemed an act of infringement.") (emphasis added); *id.* at 1135 (". . . [T]he Hatch-Waxman Act gives a drug patent owner the right to bring an action for infringement upon *the filing of a paragraph IV certification.*") (emphasis added).

1. On its face, the Complaint does not present a justiciable case or controversy.

A district court may dismiss an action for lack of subject matter jurisdiction for legal insufficiency where the claims are wholly insubstantial and frivolous. *Kehr Packages, Inc. v. Fidelcor, Inc.*, 926 F.2d 1406, 1408-409 (3d Cir. 1991). In reviewing a facial challenge to subject matter jurisdiction, "the court must only consider the allegations of the complaint and the documents referenced therein and attached thereto, in the light most favorable to the plaintiff." *Gould Elecs. Inc. v. U.S.*, 220 F.3d 169, 176 (3d Cir. 2000). Here, the Complaint does not allege that Apotex Corp. submitted an ANDA with a Paragraph IV certification related to either the '618 patent or the '152 patent. As a result, the Complaint does not set forth claims sufficient to establish subject matter jurisdiction.

a) The Plaintiffs' patent infringement claims are insubstantial and frivolous absent allegations concerning Paragraph IV certifications related to the asserted patents.

"A generic manufacturer that files a Paragraph IV certification must give notice to the patentee and the NDA holder and provide a detailed basis for its belief that the patent is invalid or not infringed." *Novo Nordisk A/S*, 601 F.3d at 1362 (citing 21 U.S.C. § 355(j)(2)(B)(i)). It is the Paragraph IV certification that gives rise to a claim for patent infringement under 35 U.S.C. § 271(e)(2), and the notice letter that triggers the period during which the patentee may sue for patent infringement under 35 U.S.C. § 271(e)(2). *Id.* Without a Paragraph IV certification or related notice letter, there is no factual or legal basis for the Plaintiffs' patent infringement claims.

Here, the Complaint alleges that Apotex Corp. filed ANDA No. 79-145 with the FDA, (D.I. 5, ¶ 11), and notified the Plaintiffs of the filing of ANDA No. 79-145 by letters dated November 5 and December 4, 2007. (D.I. 5, ¶ 12.) Neither notice letter referenced in the

Complaint, however, concerned a Paragraph IV certification related to either of the patents asserted in this case. (Exhibits C and D, hereto.) Rather, the November 5, 2007, letter notified the Plaintiffs of a Paragraph IV certification regarding U.S. Patent No. 6,316,460, (Exhibit C); the December 4, 2007, letter notified the Plaintiffs of a Paragraph IV certification regarding U.S. Patent No. RE37,314. (Exhibit D.) Neither of these patents is at issue in this case. Moreover, each notice letter sent to the Plaintiffs indicated that Apotex was not certifying under Paragraph IV with respect to the '618 patent. (Exhibit C, at 2; Exhibit D, at 2.)

The patents that are at issue here—the '618 and '152 patents—were not the subject of notice letters sent to the Plaintiffs. Coincidentally, the Complaint fails to allege that ANDA No. 79-145 contains Paragraph IV certifications as to the '618 and '152 patents. The Complaint also fails to allege that Plaintiffs' received notice letters concerning Paragraph IV certifications for the '618 and '152 patents. The absence of allegations concerning Paragraph IV certifications and accompanying notice letters related to the '618 and '152 patents reveal the insubstantial and frivolous nature of the Complaint. In short, the Plaintiffs had no basis to file this Complaint for patent infringement. The inclusion of allegations concerning notice letters related to the '460 and '314 patents serve only to obfuscate the issues, and further highlights the Complaint's frivolity.

Absent allegations that Apotex Corp. made a Paragraph IV certification concerning either the '618 patent or the '152 patent, the Complaint cannot set forth a legally sufficient claim with respect to either patent. Therefore, the Complaint does not present an Article III case or controversy, and warrants dismissal under Fed. R. Civ. P. 12(b)(1).

b) The Plaintiffs' patent infringement claims are not ripe.

Despite the Complaint's attempts to bolster its legally insufficient allegations with conjecture, the patent infringement allegations contained in the Complaint are not ripe. "A claim

is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *Texas v. United States*, 523 U.S. 296, 300 (1998) (internal quotation marks omitted). An action must be ripe to present a justiciable Article III controversy. *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1291 (Fed. Cir. 2008).

Here, the Complaint alleges, "[o]n information and belief, the FDA will require the label for the Apotex Rosuvastatin Calcium Tablets to include information relating to the use to treat pediatric patients 10 to 17 years of age having HeFH." (D.I. 5, ¶ 25; *see also* ¶ 39, which is a similar allegation with respect to the '152 patent.) This is mere speculation. The Complaint does not allege that the label contained in ANDA No. 79-145 includes an indication for a use claimed in either the '618 patent or the '152 patent. The Complaint does not allege that the FDA has required an amendment to the label contained in ANDA No. 79-145. The Complaint does not allege that the label contained in ANDA No. 79-145 has been amended.

Nonetheless, the Complaint presumes a label amendment has occurred as it alleges "[o]n information and belief, *in view of the label amendment*, Apotex Inc. and/or Apotex Corp. will need to satisfy, *inter alia*, 21 U.S.C. § 355(j)(2)(A), and the regulations promulgated thereunder, to obtain FDA approval for ANDA No. 79-145." (D.I. 5, ¶ 26, (emphasis added) *see also* ¶ 40, which is a similar allegation with respect to the '152 patent.) The antecedent bases for the "in view of the label amendment" allegations, which include allegations that the "FDA will require" label amendments, do not exist.

Contrary to the Plaintiffs allegations, (D.I. 5, ¶¶ 24 and 38), there is no requirement to amend the label contained in ANDA No. 79-145 to include the uses claimed in the asserted patents. *See Warner-Lambert Co.*, 316 F.3d at 1362 ("Congress contemplated the possibility that

there could be more than one approved indication for a given drug, and that an ANDA applicant can seek approval to label and market the drug for fewer than all of those indications."); *see also Bristol-Myers Squibb Co. v. Shalala*, 91 F.3d 1493, 1500 (D.C. Cir. 1996) ("the statute [21 U.S.C. § 355(j)] expresses the legislature's concern that the new generic be safe and effective for each indication that will appear on its label, whether the label for the new generic lists every indication approved for use of the pioneer [drug] is a matter of indifference."). Consequently, the Complaint's allegations concerning label amendments have no basis in law.

The Complaint also alleges: "on information and belief, (1) if the FDA approves ANDA No. 79-145, the sale of the Apotex Rosuvastatin Calcium Tablets with their associated labeling before the expiration of the '618 patent will cause infringement of one or more claims of the '618 patent," (D.I. 5, ¶ 28; *see also* ¶ 42, which is a similar allegation with respect to the '152 patent); (2) "the Apotex Rosuvastatin Calcium Tablets, if approved by the FDA, will be prescribed and administered to human patients to treat HeFH, which uses will constitute direct infringement of the '618 patent," (D.I. 5, ¶ 29; *see also* ¶ 43, which is a similar allegation with respect to the '152 patent); and (3) "Apotex Corp. will actively induce, encourage, aid and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of the '618 Patent Plaintiffs' rights under the '618 patent." (D.I. 5, ¶ 29; *see also* ¶ 43.) None of the events described in paragraphs 28, 29, 42, and 43 of the complaint have occurred. Further, none of the events described in paragraphs 28, 29, 42, and 43 of the complaint are relevant to a 35 U.S.C. § 271(e)(2)(A) claim, which considers only whether an ANDA applicant has submitted an ANDA with a Paragraph IV certification. These irrelevant and unfounded allegations serve only to confuse matters, and further reflect the insubstantial and frivolous nature of the Complaint.

Even with these allegations, the Complaint remains legally insufficient with respect to patent infringement claims concerning the '618 and '152 patents. The allegations concerning Paragraph IV certifications related to patents other than those asserted in this action are immaterial. Under 35 U.S.C. § 271(e)(2)(A), a Paragraph IV certification gives rise to a patent infringement action with respect to the patent that is the subject of the certification. *See, e.g., Novo Nordisk, Inc. v. Mylan Pharmaceuticals Inc.*, C.A. No. 09-2445 (FLW) 2010 WL 1372437, at *10 (D.N.J.) ("where no Paragraph IV certification has been filed in connection with the only claim at issue with regard to the [asserted patent], the Court fails to see how the filing of a Paragraph IV Certifications in connection with [the claims not asserted] are even relevant."). This failure to allege that Apotex Corp. submitted Paragraph IV certifications for the uses claimed in the '618 and '152 patents precludes patent infringement claims under 35 U.S.C. § 271(e)(2)(A). Moreover, the Complaint's reliance on events that have not occurred, many of which are not relevant to a patent infringement claim under 35 U.S.C. § 271(e)(2)(A), shows that the Plaintiffs' claims are not ripe. Accordingly, the Complaint does not present a justiciable Article III case or controversy over which this Court may exercise subject matter jurisdiction.

[redacted]

This Court should dismiss the Complaint for lack of subject matter jurisdiction because the facts do not satisfy jurisdictional prerequisites. *See United States v. Pa. Shipbuilding Co.*, 473 F.3d 506, 514, 531 (3d Cir. 2007) (dismissing the plaintiff's claim because it failed to comport with subject matter jurisdiction prerequisites). The Plaintiffs have the burden of proving that subject matter jurisdiction exists. *See Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005). Further, the Plaintiffs' allegations are not entitled to a presumption of truthfulness. *See Mortensen*, 549 F.2d at 891 (suggesting that plaintiffs enjoy no presumption of

truthfulness as to their allegations on a Rule 12(b)(1) motion to dismiss for lack of subject matter jurisdiction). When considering a factual attack on subject matter jurisdiction, courts may weigh evidence beyond the pleadings. *Petruska v. Gannon Univ.*, 462 F.3d 294, 302 n.3 (3d Cir. 2006) (citing *Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977)).

[redacted] As discussed *supra*, the Complaint does not allege that ANDA No. 79-145 contains a Paragraph IV certification for either the '618 patent or the '152 patent. Furthermore, the Plaintiffs have not alleged that ANDA No. 79-145 should have contained a Paragraph IV certification for either patent.

[redacted]. This undermines the Complaint's allegations concerning future label amendments (D.I. 5, ¶¶ 25, 26, 39, 40), and demonstrates that there is no factual basis supporting these allegations. There is also no legal

basis for these allegations, as there is no requirement to amend the label contained in ANDA No. 79-145 to include the uses claimed in the asserted patents. *See Warner-Lambert Co.*, 316 F.3d at 1362.

[redacted], and the absence of Paragraph IV certifications concerning the asserted patents, the Complaint cannot raise a claim for patent infringement under 35 U.S.C. § 271(e)(2). Absent a valid claim for patent infringement, there is no basis for subject matter jurisdiction under either 28 U.S.C. §§ 1331 and 1338(a). Therefore, this Court should dismiss the Complaint for lack of subject matter jurisdiction.

B. The Complaint fails to state a claim upon which relief may be granted.

Should this Court exercise subject matter jurisdiction over the Plaintiffs' patent infringement claims, then this Court should dismiss the Plaintiffs' claims for failure to state a claim upon which relief can be granted. "To withstand a Rule 12(b)(6) motion, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Max v. Republican Comm. of Lancaster County*, 587 F.3d 198, 200 (3d Cir. 2009) (internal quotations omitted). This requires more than "a formulaic recitation of a cause of action's elements," and requires factual allegations that "raise a right to relief above the speculative level." *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citations omitted).

Here, a claim for relief under 35 U.S.C. § 271(e)(2) requires a Paragraph IV certification with respect to the asserted patents. Setting aside ¶¶ 30 and 44, which are formulaic recitations of the elements of a claim under § 271(e)(2), the Complaint lacks factual allegations sufficient to show that the Plaintiffs are entitled to relief. Specifically, as discussed *supra* with respect to Apotex Corp.'s facial challenge to subject matter jurisdiction, the Complaint does not allege that Apotex Corp. submitted a Paragraph IV certification related to either the '618 patent or the '152

patent. Similarly, the Complaint does not allege that Apotex Corp. should have submitted a Paragraph IV certification with respect to either of the asserted patents. Further, many of the allegations in the Complaint refer to events that have not occurred. (*See* D.I. 5, ¶¶ 25, 26, 28, 29, 39, 40, 42, 43.) As a result, the Complaint does not contain sufficient factual matter to state a claim to relief under 35 U.S.C. § 271(e)(2). Therefore, this Court should dismiss the Complaint.

V. CONCLUSION

For the reasons stated herein, this Court should dismiss the Complaint for lack of subject matter jurisdiction pursuant to Fed. R. Civ. P. 12(b)(1). Should this Court exercise subject matter jurisdiction in this case, then this Court should dismiss the Complaint for failure to state a claim upon which relief can be granted pursuant to Fed. R. Civ. P. 12(b)(6).

Respectfully submitted,

POTTER ANDERSON & CORROON LLP

By: */s/ Richard L. Horwitz*
Richard L. Horwitz (#2246)
David E. Moore (#3983)
Hercules Plaza 6th Floor
1313 N. Market Street
Wilmington, DE 19899
Tel: (302) 984-6000
rhorwitz@potteranderson.com
dmoore@potteranderson.com

Attorneys for Defendant Apotex Corp.

OF COUNSEL:

Robert B. Briesblatt
Craig M. Kuchii
Jeremy C. Daniel
Katten Muchin Rosenman LLP
525 W. Monroe Street
Chicago, IL 60661
Tel: (312) 902-5200

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CERTIFICATE OF SERVICE

I, David E. Moore, hereby certify that on July 30, 2010, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I hereby certify that on July 30, 2010, the attached document was electronically mailed to the following person(s)

Mary W. Bourke
Dana K. Severance
Connolly, Bove, Lodge & Hutz, LLP
The Nemours Building
1007 North Orange Street
P.O. Box 2207
Wilmington, DE 19899
mbourke@cblh.com
dseverance@cblh.com

William E. McShane
Connolly, Bove, Lodge & Hutz, LLP
1875 Eye Street, NW, Suite 1100
Washington, DC 20006
wmcshane@cblh.com

/s/ David E. Moore
Richard L. Horwitz
David E. Moore
POTTER ANDERSON & CORROON LLP
(302) 984-6000
rhorwitz@potteranderson.com
dmoore@potteranderson.com

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