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**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

| | |
|---|---|
| AMARIN PHARMA, INC. and AMARIN PHARMACEUTICALS IRELAND LIMITED,<br><br>Plaintiffs,<br><br>v.<br><br>APOTEX, INC., *et al.*<br><br>Defendants. | Civil Action No. 3:14-CV-02550-MLC-TJB (Consolidated) |

**MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION**

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## INTRODUCTION

Acceptance of an Abbreviated New Drug Application ("ANDA") by the U.S. Food and Drug Administration ("FDA") triggers the statutory act of patent infringement under 35 U.S.C. § 271(e). *Allergan, Inc. v. Actavis, Inc. et al.,* Nos. 14-CV-638 and 14-CV-188, 2014 WL 7336692 at *2 (E.D. Tex. Dec. 23, 2014). It is this act of infringement that creates the case or controversy necessary for the district court to exercise subject matter jurisdiction over Hatch-Waxman patent infringement cases.

Here, the statutory act of infringement no longer exists due to recent Court and FDA action. FDA revoked its acceptance of the ANDAs at issue, which renders this dispute no longer justiciable.

Specifically, a recent decision by the United States District Court for the District of Columbia vacated a determination that FDA made regarding Plaintiffs Amarin Pharma, Inc.'s and Amarin Pharmaceuticals Ireland Ltd.'s (collectively, "Amarin" or "Plaintiffs") reference listed drug, Vascepa®. *See Amarin Pharm. Ireland Ltd. v. FDA et al.*, No. 14-CV-00324 (RDM), 2015 WL 3407061 (D.D.C. May 28, 2015). As a result of that decision, the agency determined that it could not accept Defendants' ANDAs, and accordingly informed the ANDA applicants that acceptance of the ANDAs had been revoked and agency review suspended. The effect of the agency's action is to vitiate the justiciable controversy.

Accordingly, pursuant to Fed. R. Civ. P. 12(b)(1) and Fed. R. Civ. P. 41(a)(2), Amarin respectfully requests that this Court grant Plaintiffs' Motion to Dismiss,

without prejudice, all claims in this action[1] against Defendants Apotex, Inc., Apotex Corp., Roxane Laboratories, Inc., Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories, Ltd., Watson Laboratories, Inc., Teva Pharmaceuticals USA, Inc., Andrx Labs, LLC, and Andrx Corp. (collectively, "Defendants"), as well as all of Defendants' counterclaims against Plaintiffs.

## BACKGROUND

### I. Relevant Hatch-Waxman Act Provisions

This litigation arises under the Hatch-Waxman Act,[2] the federal law governing the approval of new and generic drugs. To balance the incentives for pioneer drug manufacturers to research and invest in new drugs and generic drug companies to file ANDAs, Congress provided a five-year market exclusivity for approved new drugs, defined as containing "no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application." 21 U.S.C. §§ 355(c)(3)(E)(ii), 355(j)(5)(F)(ii). Congress also provided a more limited three-year period of exclusivity for new drugs that contain "an active ingredient (including any ester or salt of the active ingredient) that has been

[1] The cases captioned *Amarin Pharma, Inc. et al. v. Apotex, Inc. et al.*, No. 3:14-CV-02550; *Amarin Pharma, Inc. et al. v. Roxane Labs, Inc.*, No. 3:14-CV-02551; *Amarin Pharma, Inc. et al. v. DRL Labs, Inc. and DRL Labs, Ltd.*, No. 3:14-CV-02760; *Amarin Pharma, Inc. et al. v. Watson Labs, Inc.*, No. 3:14-CV-03259; *Amarin Pharma, Inc. et al. v. Teva Pharma USA, Inc.*, No. 3:14-CV-03558; and *Amarin Pharma, Inc. et al. v. Andrx Labs, LLC et al.*, No. 3:14-CV-03924 have been consolidated under No. 3:14-CV-02550 for pretrial purposes.

[2] The formal name for the Hatch-Waxman Act is the Drug Price Competition and Patent Term Restoration Act of 1984, Pub.L. No. 98-417, 98 Stat. 1585 (1984), as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. No. 108-173, 117 Stat. 2066 (2003).

approved in another application" where the drug's sponsor was required to conduct new research to gain approval. 21 U.S.C. §§ 355(c)(3)(E)(iii), 355(j)(5)(F)(iii).[3]

When an ANDA may be submitted to FDA depends on whether the reference listed drug is granted five-year or three-year exclusivity. *See* 21 U.S.C. §§ 355(c)(3)(E)(ii), 355(c)(3)(E)(iii), 355(j)(5)(F)(ii) and 355(j)(5)(F)(iii). If a drug is granted five-year exclusivity, an ANDA for a generic version of the drug cannot be approved by FDA during the five-year period. FDA is not permitted to accept an ANDA that is submitted within the first four years of exclusivity, and will only accept an ANDA in the fifth year if it is accompanied by a Paragraph IV Certification of patent invalidity or noninfringement. *See* 21 U.S.C. §§ 355(c)(3)(E)(ii), 355(j)(5)(F)(ii); 21 C.F.R. § 314.101(e)(2). On the other hand, if a drug is granted three-year exclusivity, FDA may *accept* an ANDA anytime within the three-year exclusivity period but may not *approve* the ANDA until expiration of the three years. 21 U.S.C. §§ 355(c)(3)(e)(iii), 355(j)(5)(F)(iii). Due to the considerable amount of time it takes for FDA to approve an application once it is accepted, the difference between the three- and five-year exclusivity is significant. In addition, FDA cannot accept an ANDA while a decision regarding whether to grant a reference listed drug three- or five-year exclusivity is pending before FDA.

[3] For a fuller discussion of these exclusivities, *see Amarin Pharm. Ireland Ltd. v. FDA*, No. 14-CV-00324 (RDM), 2015 WL 3407061 (D.D.C. May 28, 2015).

*See* 21 C.F.R. § 314.101(e)(2)(ii); *See* "Clarification of Suspension of Review" FDA Letter Template Attachment and corresponding e-mail chain, Ex. A.[4]

Once an ANDA filer "receives from FDA an acknowledgement letter stating that its [ANDA] is sufficiently complete to permit a substantive review" the ANDA filer may send a Paragraph IV Notice to the reference listed drug holder. 21 C.F.R. § 314.95(b); *SB Pharmco Puerto Rico, Inc. v. Mutual Pharmaceutical Co., Inc., et al,* 552 F. Supp. 2d. 500, 511 (E.D. Pa. 2008) ("the term 'submit' in § 271(e)(2) clearly means that an ANDA has been received, not merely delivered").

Upon receiving a timely Paragraph IV Notice from an ANDA filer, the patentee or NDA holder has a 45 day period in which to determine whether and where to file a suit for patent infringement. *See* 21 U.S.C. § 355(j)(5)(B). If the patentee or NDA holder brings an infringement suit within this 45 day period, final approval of the ANDA is subject to a 30-month stay. *See* 21 U.S.C. § 355(j)(5)(B); 21 C.F.R. §314.107(b)(3).

## II. Factual Background

### A. FDA's Denial of Amarin's Request for Five-Year Exclusivity Was Recently Vacated.

This is a Hatch-Waxman case arising in connection with Plaintiffs' Vascepa® product. The FDA approved Amarin's new drug application for Vascepa® on July 26, 2012. During the approval process, Amarin requested that FDA grant

[4] "Ex. [_]" refers to exhibits attached to the Declaration of Megan P. Keane in Support of Plaintiffs' Motion to Dismiss for Lack of Subject Matter Jurisdiction.

Vascepa® five-year exclusivity as opposed to three-year exclusivity. *Amarin*, 2015 WL 3407061 at 5.

On February 21, 2014, FDA decided that Vascepa® is entitled to only three-year exclusivity. FDA rejected Amarin's request for five-year exclusivity because it believed that both Vascepa® and a prior approved product, Lovaza®, contain the same active moiety. *See Amarin*, 2015 WL 3407061 at 6-7.

On February 27, 2014, Amarin challenged FDA's determination that Vascepa® is not entitled to five-year exclusivity under the Federal Food, Drug, and Cosmetic Act ("FDCA"). On May 28, 2015, the U.S. District Court for the District of Columbia ("D.D.C.") agreed with Amarin and vacated and remanded FDA's decision denying five-year exclusivity for Vascepa®. *See Amarin*, 2015 WL 3407061. This decision expressly overturns FDA's February 21, 2014 decision denying NCE exclusivity to Vascepa®. *Id.* Accordingly, there is no current FDA determination regarding Vascepa®'s exclusivity status. *See* "Clarification of Suspension of Review" FDA Letter Template Attachment and corresponding e-mail chain, Ex. A.

### B. At Least Six ANDA Applicants Seek to Market a Generic Version of Vascepa®

Six generic companies submitted ANDAs with Paragraph IV Certifications to FDA requesting approval to market generic versions of Vascepa®. FDA's decision to give Vascepa® only three-year exclusivity in February 2014 resulted in the acceptance of numerous ANDAs with Paragraph IV certifications. Beginning in March 2014, each Defendant sent Amarin notice of a Paragraph IV Certification

and ANDA filed with FDA ("Paragraph IV Notice"). *See e.g.* Answer at ¶¶ 30 and 32, D.I. 33.[5]

In April through June of 2014, Plaintiffs sued each ANDA filer for infringement of sixteen U.S. Patents (the "Asserted Patents").[6] *See e.g.* Compl., D.I. 1.[7] Each Defendant asserted counterclaims of noninfringement and invalidity of each of the Asserted Patents.[8] *See e.g.*, Answer at pgs. 64-104, D.I. 33.[9] The Court consolidated the suits for pretrial purposes on October 2, 2014 under the caption *Amarin Pharma, Inc. et al. v. Apotex, Inc. et al.*, No. 3:14-CV-02550-MLC-TJB (Consolidated). Order, D.I. 42.

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[5] The docket entries referenced in this brief refer to *Apotex*, No. 3:14-CV-02550. *See also Roxane Labs,* No. 3:14-CV-02551, Answer at ¶¶ 25 and 27, D.I. 34; *DRL Labs,* No. 3:14-CV-02760, Answer at ¶¶ 31 and 33, D.I. 27; *Watson Labs,* No. 3:14-CV-03259, Answer at ¶¶ 30 and 32, D.I. 31; *Teva Pharma USA,* No. 3:14-CV-03558, Answer at ¶¶ 25 and 27, D.I. 25; *Andrx Labs*, No. 3:14-CV-03924, Answer ¶¶ 32 and 34, D.I. 27.

[6] The 16 Asserted Patents are Nos. 8,293,728; 8,318,715; 8,357,677; 8,367,652; 8,377,920; 8,399,446; 8,415,335; 8,426,399; 8,431,560; 8,440,650; 8,501,225; 8,518,929; 8,524,698; 8,546,372; 8,551,521; and 8,617,594.

[7] *See also Roxane Labs, Inc.*, No. 3:14-CV-02551, Compl., D.I. 1; *DRL Labs,* No. 3:14-CV-02760, Compl., D.I. 1; *Watson Labs,* No. 3:14-CV-03259, Compl., D.I. 1; *Teva Pharma USA,* No. 3:14-CV-03558, Compl., D.I. 1; *Andrx Labs*, No. 3:14-CV-03924, Compl., D.I. 1.

[8] One Defendant, Apotex, also asserted counterclaims of noninfringement and invalidity with respect to patents listed in the Orange Book for Vascepa® that have not been asserted in this litigation. These counterclaims were later dismissed. *See* Stipulation and Order of Dismissal, D.I. 86.

[9] *See also Roxane Labs, Inc.*, No. 3:14-CV-02551, Answer at pgs. 36-45, D.I. 34; *DRL Labs*, No. 3:14-CV-02760, Answer at pgs. 34-44, D.I. 27; *Watson Labs,* No. 3:14-CV-03259, Answer at pgs. 81-111, D.I. 31; *Teva Pharma USA,* No. 3:14-CV-03558, Answer at pgs. 20-53, D.I. 25; *Andrx Labs*, No. 3:14-CV-03924, Answer at pgs. 83-111, D.I. 27.

### C. Due to a Recent Decision from D.D.C., the ANDAs Are Not Received by FDA.

As a result of the *Amarin* decision, it is Amarin's understanding that FDA sent two letters to each Defendant. The first set of letters informed each Defendant that FDA has suspended review of Defendants' ANDAs, and, if FDA determines Vascepa® qualifies for five-year exclusivity, the exclusivity will bar submission of an ANDA that references Vascepa® until at least July 26, 2016. *See* "Suspension of Review" FDA Letter Template Attachment and corresponding e-mail chain, Ex. B. The second set of letters clarifies FDA's first letter, stating that FDA considers each ANDA "to have been submitted, but not yet received, notwithstanding our previous communications on this ANDA." *See* "Clarification of Suspension of Review" FDA Letter Template Attachment and corresponding e-mail chain, Ex. A. FDA explained:

> [B]ecause the Court has vacated FDA's previous exclusivity determination for Vascepa, FDA currently has no exclusivity determination in effect for Vascepa. We generally cannot receive an ANDA until we have determined whether the reference listed drug is eligible for NCE exclusivity. See 21 C.F.R. 314.101(e)(2)(ii).

*Id.*

After the *Amarin* decision issued, the parties in this case conferred and agreed to stay the litigation for ninety days in order to assess the developments in the FDA proceedings. Consent Order, D.I. 99. In light of FDA's recent correspondence with each of the Defendants clarifying that their ANDAs have not been received, Amarin requests that the Court dismiss this action in its entirety. Before filing this motion, Amarin asked Defendants if they agree that this case is no

longer justiciable. Defendants Watson, Andrx, Roxane, and Teva do not agree that this case is no longer justiciable. Defendants DRL and Apotex have not stated their positions.

**LEGAL STANDARD**

When a court determines that it lacks subject matter jurisdiction, it must dismiss the complaint in its entirety. *Lursardi v. Xerox Corp.*, 975 F.2d 964, 974 (3d Cir. 1992) ("Article III requires that a plaintiff's claim be live not just when he first brings the suit but throughout the entire litigation, and once the controversy ceases to exist the court must dismiss the case for lack of jurisdiction"); *see also* Fed. R. Civ. P. 12(b)(1). In a factual challenge to subject matter jurisdiction, such as in this case, the court may consider matters outside the pleadings such as affidavits and other material properly before the court to determine whether the court has power to hear the case. *Hoffman-La Roche Inc. et al. v. Genpharm Inc.*, 50 F. Supp. 2d 367, 371 (D.N.J. 1999) (*citing Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977)).

Rule 41(a)(2) provides, in pertinent part, that "an action may be dismissed at the plaintiff's request only by court order, on terms that the court considers proper." Rule 41(a)(2) also provides that "[u]nless the order states otherwise, a dismissal under this paragraph (2) is without prejudice." *See, e.g.*, *Hoffman-La Roche Inc.,* 50 F. Supp. 2d at 372 (citations omitted). Courts have found that Rule 41(a)(2) is an appropriate vehicle to voluntarily dismiss plaintiffs' complaint in similar circumstances. *See, e.g., Allergan*, 2014 WL 7336692 (dismissing plaintiffs'

complaint under Fed. R. Civ. P. 41(a)(2) where a premature Paragraph IV Notice was sent).

## ARGUMENT

### I. These Actions Are Not Justiciable.

Without an ANDA that has been received by FDA, there is no "case or controversy" that establishes jurisdiction. The Hatch-Waxman Act creates a statutory act of patent infringement under 35 U.S.C. § 271(e) to allow for the resolution of patent disputes. The statutory act of infringement consists of submitting an ANDA to FDA seeking approval to market a generic version of an approved drug prior to expiration of patents listed in the Orange Book. *AstraZeneca Pharm. LP v. Apotex Corp.,* 669 F.3d 1370, 1378 (Fed. Cir. 2012) ("section 271(e)(2) makes it possible for the district court to exercise its section 1338(a) jurisdiction in the situation in which an ANDA has been filed" (quoting *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1330 (Fed. Cir. 2003)).

Under § 271(e) it is an act of infringement to "submit" an ANDA. "Submission" of an ANDA under § 271(e) means that FDA has received the ANDA, *i.e.*, confirmed that the ANDA is in a position for review by FDA. *Allergan*, 2014 WL 7336692 at *12; *SB Pharmco,* 552 F. Supp. 2d. at 508. This is distinct from mere transmission of the ANDA to FDA. *Allergan*, 2014 WL 7336692 at *12; *SB Pharmco,* 552 F. Supp. 2d. at 511 ("the term 'submit' in §271(e)(2) clearly means that an ANDA has been received, not merely delivered"). Recognizing this distinction, numerous courts have refused to entertain patent cases arising from Paragraph IV Notice sent without FDA acceptance ("receipt") of an ANDA. *See SB*

*Pharmco,* 552 F. Supp. 2d. at 510-512; *Allergan,* 2014 WL 7336692 at *10-12; *Merck & Cie v. Watson Pharms., Inc.*, No. 12-CV-161 (RGA) (D. Del. Sept. 25, 2012) (Order, D.I. 37), Ex. C; *Otsuka Pharm. Co. v. Par Pharm., Inc.*, No. 13-CV-1979 (RGA) (D. Del. Mar. 10, 2014) (Order, D.I. 24), Ex. D; and *Reckitt Benckiser Pharms., Inc. et al. v. Par Pharm., Inc. et al.*, No. 13-CV-1461 (RGA) (D. Del. May 27, 2014) (Order, D.I. 92), Ex. E; *see also* 21 C.F.R. § 314.95(b).

Here, the May *Amarin* decision vacated FDA's determination regarding the exclusivity status of Vascepa®. *See* "Clarification of Suspension of Review" FDA Letter Template Attachment and corresponding e-mail chain, Ex. A ("FDA considers [Defendants'] ANDA[s] to have been submitted but not yet received.") Because Defendants' ANDAs are not received by FDA, the ANDAs "cannot trigger infringement under 35 U.S.C. § 271(e)(2), as a matter of law." *Allergan*, 2014 WL 7336692 at *12.

While this case presents the novel issue of FDA *revocation* of ANDA receipt—as opposed to the more common situation of premature Paragraph IV Notice served prior to ANDA receipt by the FDA—the same principle applies. Revocation of ANDA receipt by the FDA has the same effect as non-acceptance of the ANDA in the first place, rendering the ANDAs unaccepted and nullifying the Paragraph IV Notice. FDA will not undertake review of an ANDA that is no longer received. And if there is no ANDA that has been received, there is no statutory act of infringement that forms the basis for jurisdiction.

In the absence of FDA acceptance of an ANDA that creates the statutory act of patent infringement, this Court lacks subject matter jurisdiction over the claims in this Hatch-Waxman litigation. Plaintiffs' infringement claims against Defendants should be dismissed without prejudice.

## II. Defendants' Counterclaims Should Also Be Dismissed.

The Hatch-Waxman Act only permits a declaratory judgment action by an ANDA applicant, where there is no § 271(e) suit, in limited circumstances. Specifically, when the ANDA applicant has provided a proper Paragraph IV Notice and the patent holder does not bring suit within 45 days. *See* 21 U.S.C. § 355(j)(5)(C). Here, Defendants have not served proper Paragraph IV Notices. Therefore, 45 days have not elapsed and Defendants are barred by statute from maintaining a declaratory judgment action. Thus, the Court does not have jurisdiction over Defendants' counterclaims. *See SB Pharmco,* 552 F. Supp. 2d. at 513 ("Here, forty-five days have not elapsed since the service of a valid Paragraph IV notice. Therefore, Defendants cannot assert jurisdiction for their counterclaim pursuant to 35 U.S.C. § 271(e)(5).").

Absent authorization under the Hatch-Waxman framework for their claims, Defendants cannot establish that a justiciable controversy has arisen here. *See MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007); *SB Pharmco,* 552 F. Supp. 2d. at 513-514. To the extent there is any delay in Defendants' entrance into the market with a generic product, that delay is due to the Hatch-Waxman statutory scheme and FDA, s*ee SB Pharmco,* 552 F. Supp. 2d. at 514, not Amarin.

## CONCLUSION

For the foregoing reasons, Plaintiffs' Motion to Dismiss should be granted, without prejudice, and all of Defendants' counterclaims against Plaintiffs should be dismissed.

Dated: July 24, 2015

Respectfully Submitted,

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