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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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

PLAINTIFFS' REPLY IN FURTHER SUPPORT OF THEIR MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION

All parties agree that, at the very least, this consolidated action should be stayed until FDA makes a determination regarding Vascepa's exclusivity status. D.I. 107 at 1 (Dr. Reddy's); D.I. 108 at 10, 13 (Watson, Andrx, Teva, and Roxane joint response, hereinafter "Opposition"); D.I. 109 at 2 (Apotex). In addition, Amarin and at least the Watson, Andrx, Teva, and Roxane defendants agree that if FDA determines Vascepa is entitled to five-year exclusivity, this action should then be dismissed in its entirety for lack of subject-matter jurisdiction.[1] Opposition at 11. The parties disagree only over whether the Court *currently* has subject matter jurisdiction over this action.

As the Court is aware, "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." *Lursardi v. Xerox Corp.*, 975 F.2d 964, 974 (3d Cir. 1992). Here, no Defendant's ANDA is "received" by FDA. Without an ANDA that has been received by FDA there is no justiciable controversy. (D.I. 100-1, "Mot.", at 9-11.) Defendants nonetheless contend that litigation should continue because the Court had jurisdiction in the past and might have jurisdiction again in the future. But even if so, the Court does not have jurisdiction now. Thus, for the reasons discussed herein and in Amarin's opening brief, this action should be dismissed.

[1] DRL and Apotex did not address this issue in their responses. D.I. 107, 109.

ADDITIONAL FACTUAL BACKGROUND

Since Amarin submitted its Motion to Dismiss, there have been some additional developments in *Amarin Pharm. Ireland Ltd. v. FDA et al.*, No. 14-CV-00324-RDM (D.D.C.). In particular, FDA's deadline to file a notice of appeal lapsed on July 26, 2015, and FDA did not appeal. By not appealing, FDA has acquiesced in the district court's decision, which is now binding and final as to FDA. As of this writing, FDA has not made a determination regarding the exclusivity status of Vascepa pursuant to the mandate issued in *Amarin v. FDA*, 2015 WL 3407061 (D.D.C. May 28, 2015), a determination which is a necessary predicate to acceptance of any ANDAs. As FDA itself has acknowledged, the Agency cannot accept an ANDA for review until after it resolves Vascepa's exclusivity status.[2]

ARGUMENT

The facts relevant to this motion are not in dispute. After FDA made the initial determination that Vascepa was entitled to only three years of exclusivity in February 2014, FDA received defendants' ANDAs. Amarin sued the six ANDA filers. Then, FDA's exclusivity determination was vacated by the district court in *Amarin v. FDA*. Because FDA's decision was vacated, there is no determination by

[2] Before the deadline to appeal, Watson filed a motion to intervene and filed a purported notice of appeal. No. 14-CV-00324-RDM (D.D.C.), D.I. 33. Both FDA and Amarin have opposed Watson's motion to intervene on various grounds, including that Watson lacks standing to appeal the decision. *Id.*, D.I. 40, 41 Regardless of the propriety of Watson's attempted appeal, FDA itself has vacated its prior exclusivity decision for Vascepa and rescinded acceptance of Watson's ANDA, rendering the patent litigation presently non-justiciable, regardless of how Watson's appeal is ultimately resolved.

FDA regarding Vascepa's exclusivity status. As a result, FDA notified Defendants that receipt of their ANDAs was revoked and the status of the ANDAs was changed to "submitted, but not yet received." D.I. 100-2 (Keane Declaration), Ex. A.

Because no ANDA is currently "received" by FDA, there is no basis for jurisdiction under § 271(e).[3] In light of the current status of Defendants' ANDAs, the ANDAs cannot be approved by FDA. Therefore, "[u]nder the circumstances, Defendants' ANDA[s] could not cause an injury-in-fact to [Amarin]." *SB Pharmco Puerto Rico., Inv. v. Mutual Pharma.*, 552 F.Supp.2d 500, 512 (E.D. Pa. 2008). Without a justiciable controversy, the Court cannot retain jurisdiction.

Defendants cite no case in which a Hatch-Waxman patent infringement case was found to be justiciable when an ANDA is not received by FDA. Defendants' comparison of the current situation to situations concerning amended ANDAs is inapposite, because in those cases the ANDAs remained continuously on file and subject to review and approval by FDA. *Sunovion Pharma., Inc. v. Sandoz, Inc.*, 2011 WL 3875387, at *2 (E.D.N.C. Sept. 1, 2011); *Ben Venue Labs. v. Novartis Pharma. Corp.*, 146 F.Supp.2d 572, 578 (D.N.J. 2001). Thus, in both *Sunovion* and *Ben Venue Labs.*, the ANDAs were at all times "received" by FDA and subject to FDA review. The circumstances presented here, by contrast, are akin to that where Paragraph IV Notices are sent prematurely—before FDA has determined whether

[3] Defendants seem to suggest that the claims in this case survive under § 271 (a), (b), and/or (c). Opposition at 8-9. Not so. Receipt of an ANDA is necessary for patent infringement claims arising from filing of an ANDA. *SB Pharmco*, 552 F.Supp.2d at 512. Claims under § 271 (a), (b), and/or (c) in Hatch-Waxman patent cases are directed to the infringing conduct that would occur once an ANDA product is marketed. They do not create separate bases for jurisdiction.

the ANDA can be received—in which circumstance the Courts have uniformly held the patent case to be non-justiciable. Mot. at 9-10 (citing cases). These cases make clear that an ANDA applicant's unilateral action of submitting an ANDA to FDA is not enough to render subsequent patent litigation justiciable. Instead, to maintain that litigation, FDA must determine that the ANDA can be received; a determination now lacking here.

Because the patent litigation presently lacks a necessary requisite for this Court's jurisdiction it should be dismissed, even if subsequent events may support an action in the future (as may happen, for example, in the case of premature paragraph IV notices). Furthermore, Defendants' suggestion that all that is required for jurisdiction under § 271(e) is an initial receipt, Opposition at 8, 9, would lead to the absurd result that, when FDA receives an ANDA, but that ANDA is later withdrawn in its entirety, the Court retains jurisdiction over any pending Hatch-Waxman patent case.[4]

The suggestion that FDA's decision to revoke receipt of Defendants' ANDAs is "unlawful", and, therefore, this Court retains jurisdiction until the proceedings in *Amarin v. FDA* have concluded, is incorrect. Opposition at 8, 9. Defendants' apparent disagreement with FDA's action in revoking receipt does not create a basis

[4] The statements in Amarin's 10K, Opposition at 7-8, are entirely beside the point. Amarin is not disputing, and never has disputed, that jurisdiction existed when these cases were filed. Amarin disputes whether jurisdiction exists now. At the time Amarin filed the complaints against each defendant, each defendant's ANDA was received by FDA. The ANDA referenced in Amarin's 10K was never, to Amarin's knowledge, received by FDA. Now that FDA has revoked receipt of Defendants' ANDAs, the defendants in this case are in the same situation as the entity referenced in Amarin's 10K.

for this Court's subject-matter jurisdiction, just as Amarin's disagreement with the FDA's *prior* decision to recognize only three-year exclusivity, and the resulting receipt of Defendants' ANDAs, did not *prevent* this Court from exercising subject-matter jurisdiction at the inception of this action. Defendants cite no authority for the proposition that this Court can simply ignore FDA's decision to revoke receipt.

Defendants also assert that dismissal of this litigation now would prejudice defendants, in view of the resources they claim to have expended in this litigation to date. Opposition at 12. There is of course no protected interest in maintaining a federal court action rendered non-justiciable by events, and Defendants tellingly cite no authority establishing that such alleged prejudice is relevant to whether the Court has subject-matter jurisdiction. Indeed, Defendants have known all along that the issue of five-year exclusivity for Vascepa was a disputed issue, and they can hardly claim surprise or unfair prejudice from the outcome of that dispute.

To the contrary, it is Amarin that would be prejudiced by the continued maintenance of this patent litigation. As the *Amarin v. FDA* court found (a finding to which the Agency has acquiesced), the Agency's denial of five-year exclusivity to Vascepa in 2014 was unlawful. As a result, Amarin was forced to begin litigation with six generic defendants under the Hatch-Waxman Act before proper resolution of that exclusivity, in contravention of controlling law and regulation. Moreover, if FDA now determines on remand (as Amarin expects) that Vascepa is a new chemical entity protected by five-year exclusivity, Amarin will thus have been deprived of the full period of repose it had earned by obtaining FDA approval of a

new chemical entity. Amarin should not now be subject to the *continued* uncertainty and expense of pending patent litigation after the FDA has revoked the predicate event that permits this Court to exercise jurisdiction in the first place.

In any event, the parties agree that if FDA recognizes five-year exclusivity to Vascepa, then this case should be dismissed. Opposition at 11. The parties appear to disagree, however, about what should happen if FDA determines that Vascepa is not entitled to five-year exclusivity. Defendants assert that "if the FDA determines on remand that Vascepa is not entitled to five-year NCE exclusivity, then the *status quo ante* will be restored, the Plaintiffs would have no basis for the current motion, and these cases should continue toward trial." Opposition at 11. Defendants' position ignores FDA regulations. Paragraph IV Notice Letters are required to be sent by ANDA after FDA has received an ANDA, 21 C.F.R. § 314.95(b), as discussed above, paragraph IV notices sent before that receipt have uniformly been held to be inoperative and insufficient to support subsequent patent litigation. So too here. Because Defendants' ANDAs are not currently received, their prior notice letters will necessarily predate any legally effective FDA determination of exclusivity for Vascepa and subsequent receipt of Defendants' ANDAs. Hence, once the ANDAs are received by FDA (whether after expiration of the 5-year exclusivity period or before), Defendants will be required to send new notice letters, restarting the Hatch-Waxman process for litigating patents. Hence, regardless of how FDA ultimately resolves Vascepa's exclusivity, this litigation arises from premature

paragraph IV notices and lacks any ANDAs received by FDA; in such circumstances, the case is not justiciable and should be dismissed.

CONCLUSION

For the foregoing reasons, this consolidated action should be dismissed, in its entirety, without prejudice for lack of subject-matter jurisdiction. In the alternative—as Defendants agree—this consolidated action should be stayed pending FDA's decision regarding the exclusivity status of Amarin's Vascepa product.

Dated: September 1, 2015

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 1, 2015, I caused a copy of the foregoing Plaintiffs' Reply in Further Support of Their Motion to Dismiss for Lack of Subject Matter Jurisdiction to be served via CM/ECF on the following:

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