IN THE 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 for pretrial purposes)

DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION

TABLE OF CONTENTS

PRELIMINARY STATEMENT 1

BACKGROUND 3

I. The Hatch-Waxman Act 3

II. Procedural History 3

ARGUMENT 5

I. The Court Has Subject Matter Jurisdiction Over The Allegations In Plaintiffs' Complaint. 6

II. A Final Decision by the FDA on NCE Exclusivity Will Likely Render the Present Motion Moot. 10

III. The Court Has Jurisdiction Over Defendants' Declaratory Judgment Counterclaims 12

CONCLUSION 13

TABLE OF AUTHORITIES

Cases **Page(s)**

Abbott Labs. v. Roxane Labs., Inc.,
No. CIV.A. 12-457-RGA, 2013 WL 2322770 (D. Del. May 28, 2013) 5

Allergan, Inc. v. Actavis, Inc.,
14-cv-638, 2014 WL 7336692 (E.D. Tex. Dec. 23, 2014) 7

Amarin Pharmaceuticals Ireland Ltd. v. FDA et al.,
14-cv-00324 (RDM), 2015 WL 3407061 (D.D.C. May 28, 2015).....3, 4

AstraZeneca Pharmaceuticals LP v. Apotex Corp.,
669 F.3d 1370 (Fed. Cir. 2012).....6

Ben Venue Labs., Inc. v. Novartis Pharm. Corp.,
146 F. Supp. 2d 572 (D.N.J. 2001) 8

Bayer Healthcare LLC v. Norbrook Labs., Ltd.,
No. 08-C-0953, 2009 WL 6337911 (E.D. Wis. Sept. 24, 2009).....5

SB Pharmco Puerto Rico, Inc. v. Mutual Pharmaceutical Co. Inc.,
552 F.Supp.2d 500 (E.D. Pa. 2008) 6, 7, 9

Sunovion Pharm., Inc. v. Sandoz, Inc.,
No. 4:08-CV-89-H(3), 2011 WL 3875397 (E.D.N.C. Sept. 1, 2011).....8

Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.,
482 F.3d 1330 (Fed. Cir. 2007).....10

Statutes

Fed. R. Civ. P. 12(b)(1).....5

28 U.S.C. § 2201(a) 10

35 U.S.C. § 271(e)(5).....10

21 C.F.R. 314.101(b)(1).....7

21 C.F.R. 314.101(e)(2)(ii) 2

21 C.F.R. 314.108(b)(2).....2

21 U.S.C. § 355(c)(3)(E)(iii).....3

21 U.S.C. § 355(j)(5)(F)(ii).....3

Other Authorities

The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).....3

Defendants Roxane Laboratories, Inc., Watson Laboratories, Inc., Teva Pharmaceuticals USA, Inc., Andrx Labs, LLC and Andrx Corp. (collectively "Defendants"), respectfully submit this memorandum of law in opposition to the motion to dismiss (the "Motion") (D.I.100) of Plaintiffs Amarin Pharma, Inc., and Amarin Pharmaceuticals Ireland Ltd. ("Amarin" or "Plaintiffs").

PRELIMINARY STATEMENT

Plaintiffs attempt to take advantage of a novel and unprecedented procedural posture to dismiss this stayed patent infringement action before there is legal basis to do so—before the U.S. Food and Drug Administration ("FDA") has a chance to resolve the status of Plaintiffs' request for New Chemical Entity ("NCE") exclusivity and the status of Defendants' Abbreviated New Drug Applications ("ANDAs"). The Defendants are manufacturers of generic drugs and have filed ANDAs seeking permission to market versions of Plaintiffs' drug, Vascepa, which is derived from fish oil and used to treat adults with severe hypertriglyceridemia (*i.e.*, having high levels of triglycerides in the blood).

After the FDA approved Plaintiffs' new drug application ("NDA") for Vascepa in 2012, the Defendants followed the proper statutory procedure and submitted ANDAs with Paragraph IV certifications for generic versions of Vascepa. The FDA lawfully received the Defendants' ANDAs and the Defendants, in turn, complied with the regulatory requirements and sent Notice Letters to the Plaintiffs. Plaintiffs responded and filed this action for patent infringement.

While Plaintiffs' NDA was under review, Plaintiffs requested that the FDA grant Vascepa five-year NCE exclusivity. In February 2014, the FDA decided that Vascepa was entitled to only three-year exclusivity. Plaintiffs challenged the FDA's denial of NCE exclusivity in the District Court for the District of Columbia. On May 28, 2015, the D.C. District

Court vacated and remanded the FDA's decision on NCE exclusivity. Defendant Watson Laboratories Inc. ("Defendant Watson") moved to intervene and appeal that decision in July 2015. In light of the procedural posture, in June 2015 the parties agreed to stay the instant action for 90 days while the FDA's decision on remand is pending. Ignoring the stay, the Plaintiffs' filed this motion to dismiss.

This Court maintains subject matter jurisdiction over the Plaintiffs' patent infringement claims and the Defendants' declaratory judgment claims for patent invalidity and/or non-infringement. The Defendants' ANDAs were validly submitted and received by the FDA in 2013. While the FDA has temporarily suspended its review of Defendants' ANDAs and purported to treat these ANDAs as "submitted, but not yet received" after the D.C. District Court's decision remanding the question of Vascepa's NCE status, the FDA's action was premature and improper because the FDA has never made a final determination that Vascepa "is entitled" to NCE exclusivity and has never determined that Vascepa contains "a new chemical entity." *See* 21 C.F.R. 314.101(e)(2)(ii), 314.108(b)(2).

Defendants have spent significant time and resources attempting to bring their generic versions of Vascepa to market and will be unable to do so unless this Court resolves the pending litigation. It would lead to unnecessary litigation and a waste of judicial resources if the Court were to dismiss the case now, while the action is stayed, and before the FDA has an opportunity to rule on Vascepa's NCE status. Accordingly, the Court should deny Plaintiffs' Motion, or at minimum, stay the action and defer its decision until after a final determination on Vascepa's NCE status and a resolution of the appeal in *Amarin v. FDA et al.* (15-5214 (D.C. Cir.)).

BACKGROUND

I. The Hatch-Waxman Act

The purpose of the Hatch-Waxman Act[1] is to "balance two competing policy goals": (1) to encourage generic drug development, and (2) maintain incentives for companies to create new drugs. *See Amarin Pharm. Ireland Ltd. v. FDA*, 14-cv-00324 (RDM), 2015 WL 3407061, at *1 (D.D.C. May 28, 2015). To incentivize drug companies to develop new drugs, Congress created two categories of marketing exclusivity for manufacturers of new drugs: (1) three-year exclusivity for drugs that contain "an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application," *see* 21 U.S.C. §§ 355(c)(3)(E)(iii), 355(j)(5)(F)(iii), or (2) five-year exclusivity where there is "no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application," *see* 21 U.S.C. §§ 355(c)(3)(E)(ii), 355(j)(5)(F)(ii). *See also Amarin*, 2015 WL 3407061, at *1-2. To encourage the development of affordable, generic drugs, the Hatch-Waxman Act allows the FDA to receive an ANDA from generic manufacturers anytime within the three-year exclusivity period for drugs with previously-approved active ingredients. *See* 21 U.S.C. §§ 355(c)(3)(E)(iii), 355(j)(5)(F)(iii). In contrast, the FDA may not accept an ANDA application for the first four years of the five-year exclusivity period for drugs with no previously-approved active ingredient. *See* 21 U.S.C. §§ 355(c)(3)(E)(ii), 355(j)(5)(F)(ii).

II. Procedural History

On July 26, 2012, the FDA approved Plaintiffs' new drug application for Vascepa, a fish oil-derived treatment for severe hypertriglyceridemia. Subsequently, the Defendants submitted

[1] The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

ANDAs to the FDA with Paragraph IV certifications to obtain approval for the sale of generic versions of Vascepa.

On February 21, 2014, the FDA determined that Vascepa was not entitled to five years of exclusivity, but rather awarded only a three-year exclusivity because Vascepa's single molecule, icosapent ethyl, the ethyl ester of the fish oil commonly known as EPA, was also an active moiety in a previously-approved drug product, Lovaza. *See Amarin*, 2015 WL 3407061, at *5-6. On February 27, 2014, Plaintiffs filed a complaint in the D.C. District Court challenging the FDA's decision and arguing that Vascepa was entitled to a five-year exclusivity. *See Amarin Pharm. Ireland Ltd. v. FDA et al.*, 14-cv-00324-RDM (D.D.C.), at D.I. 1.

Between April and May 2014, the Defendants provided Notice Letters to the Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B). In response, Plaintiffs' filed complaints against the Defendants on May 21, 2014 and June 18, 2014, requesting a declaration that the Defendants' proposed generic products would infringe on certain patents related to Vascepa. On July 28, 2014, Defendant Watson filed an answer and counterclaimed for declaratory judgment that the patents are invalid and/or will not be infringed by Watson's generic drug. (14-cv-03259-MLC-DEA (D.N.J.), at D.I. 31). The other Defendants have filed similar counterclaims.

On May 28, 2015, while this patent litigation was pending, the D.C. District Court granted summary judgment for Plaintiffs in *Amarin Pharmaceuticals Ireland Ltd. v. FDA et al.* and vacated the FDA's decision that denied five-year NCE exclusivity for Vascepa. *See Amarin*, 2015 WL 3407061, at *18. The D.C. District Court found that the FDA's interpretation of a mixture's "active ingredient" was contrary to the meaning of the Hatch-Waxman Act, and therefore, remanded the matter to the FDA to make a determination of whether or not Plaintiffs were entitled to NCE exclusivity for Vascepa. *See id.*

On June 26, 2015, the parties in the instant action agreed to stay this matter for 90 days in order to "assess the developments in the FDA proceedings." (D.I. 99). The 90-day stay will expire on September 24, 2015.

On July 22, 2015, Defendant Watson, moved to intervene in the FDA proceeding in order to appeal the District Court's decision. (14-cv-00324-RDM (D.D.C.), at D.I. 33). The Court of Appeals for the District of Columbia docketed the notice of appeal on July 30, 2015 and ordered the parties to submit initial documents by August 31, 2015. (15-5214 (D.C. Cir.), at Doc. #1565424). On August 10, 2015, in separate filings, both Amarin and the FDA opposed Watson's motion, arguing that the decision is not yet final and therefore not appealable. (14-cv-00324-RDM (D.D.C.), at D.I. 40, 41) (Defs.' Exs. A & B).

On July 24, 2015, while this action was stayed, Plaintiffs filed the instant motion to dismiss for lack of subject matter jurisdiction.

ARGUMENT

A court may dismiss a complaint for lack of subject matter jurisdiction. *See* Fed. R. Civ. P. 12(b)(1). A challenge to subject matter jurisdiction may be either facial or factual. *See Abbott Labs. v. Roxane Labs., Inc.*, No. CIV.A. 12-457-RGA-CJB, 2013 WL 2322770, at *3 (D. Del. May 28, 2013). When deciding a factual challenge to subject matter jurisdiction, the court does not attach a "presumption of truthfulness" to the allegations in the complaint and may consider evidence outside the pleadings to resolve factual issues. *See id.* The party seeking jurisdiction bears the burden to establish that subject matter jurisdiction exists. *See Bayer Healthcare LLC v. Norbrook Labs., Ltd.*, No. 08-CV-0953, 2009 WL 6337911, at *12-14 (E.D. Wis. Sept. 24, 2009).

I. The Court Has Subject Matter Jurisdiction Over The Allegations In Plaintiffs' Complaint.

This Court has jurisdiction over the Plaintiffs' patent infringement claims pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c), and (e). The Complaint seeks, among other relief, a judgment that the Defendants infringe on Plaintiffs' patents under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDAs with Paragraph IV certifications and a judgment declaring that the making, using, selling, offering to sell, or importing the products would infringe on Plaintiffs' patents pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c). (Compl. ¶¶ A, D.).

At the outset of this action, this Court undoubtedly had subject matter jurisdiction because the Defendants submitted, and the FDA received, ANDAs with Paragraph IV certifications. Section 271(e)(2) creates an act of patent infringement "triggered upon submission of an ANDA containing an erroneous Paragraph IV certification." *AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370, 1377 (Fed. Cir. 2012) (citing *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990)). An ANDA is deemed "submitted" when the FDA "receives" it. *See SB Pharmco Puerto Rico, Inc. v. Mutual Pharm. Co.*, 552 F. Supp. 2d 500, 511 (E.D. Pa. 2008). "Receipt of an abbreviated new drug application means that FDA has made a threshold determination that the abbreviated application is sufficiently complete to permit a substantive review." *Id.* at 506 (quoting 21 C.F.R. § 314.101(b)(1).). "[T]he 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 Pharm. LP*, 669 F.3d at 1377.

This case presents the unique situation where the Defendants' ANDAs *were received* and then the FDA subsequently suspended its review pending the agency's resolution of Vascepa's NCE status on remand and appeal. Plaintiffs acknowledge that the FDA's actions with respect to

Defendants' ANDAs is a "novel issue" and they cite no law to support their proposition that the suspension of review of an ANDA also withdraws subject matter jurisdiction in a pending action. (Motion at 10.) The cases Plaintiffs cite in support of the proposition that courts will not entertain patent cases without FDA "receipt" of an ANDA are inapposite because in those cases the filings of the ANDAs were premature and had never been received in the first place. *See Allergan, Inc. v. Actavis, Inc.*, 14-cv-638, 2014 WL 7336692, at *2-3 (E.D. Tex. Dec. 23, 2014) (Defendants' Paragraph IV notice alleged that the FDA had received the ANDA even though the FDA told Defendants' that it was "refusing to receive" the ANDA); *SB Pharmco*, 552 F. Supp. 2d at 503-04, 508 (Defendants sent Paragraph IV notice at the same time they filed the ANDA with the FDA). Unlike in *Allergan*, the FDA did not refuse to receive Defendants' ANDAs at the outset. Nor did Defendants here prematurely send Paragraph IV notices in an attempt to improperly jumpstart the litigation process. *Cf. SB Pharmco*, 552 F. Supp. 2d at 503-05.

Amarin itself has recognized as much. In its Annual Report (Form 10-K) to the U.S. Securities and Exchange Commission, Amarin described the NCE litigation in the D.C. District Court and recognized that the FDA had "denied a grant of [five-year] NCE marketing exclusivity to Vascepa and granted three-year marketing exclusivity." Amarin Corp. plc, Annual Report (Form 10-K) at 31 (Feb. 27, 2014) (Defs.' Ex. C). Amarin also noted that it had received a premature paragraph IV notice from a generic company regarding an ANDA to Vascepa *before* the FDA had accepted any ANDA for review, and that Amarin did not "plan to initiate patent litigation against the generic company" because it "did not believe the purported paragraph IV notice is an effective notice." *Id.* In contrast, Amarin recognized that after a decision had been made about the three-year exclusivity, the FDA was free to receive ANDAs for Vascepa, including the ANDAs that are the subject of the present lawsuit. *Id.* Thus, Amarin itself has

publicly and accurately recognized the important distinction between the facts of this case and the premature notice cases to which it now improperly attempts to draw an analogy.

Here, the FDA determined that Defendants' ANDAs were "received" and ready for substantive review prior to the Defendants' Notice Letters to Plaintiffs. After obtaining a remand to the FDA from the D.C. District Court, Amarin requested *ex parte* that the FDA "rescind ANDA acceptance immediately," and the FDA now purports to consider the ANDAs "submitted, but not yet received." (Motion at Ex. A.) Defendants contend that the FDA has unlawfully suspended its review of the ANDAs and such a decision does not change the threshold determination that the ANDAs are "sufficiently complete to permit a substantive review." *See* 21 C.F.R. 314.101(b)(1). Here, the Court had subject matter jurisdiction pursuant to § 271(e)(2) when Plaintiffs filed the complaints and retains it pending the final determination of Vascepa's NCE status and resolution of the appeal in *Amarin v. FDA et al*.

While we have found no cases that discuss the rare situation where an ANDA is received and then the FDA purports to revoke that receipt, a case involving a subsequent amendment to an ANDA is instructive. In *Sunovion Pharm., Inc. v. Sandoz, Inc.*, the court denied a generic manufacturer's motion to dismiss for lack of subject matter jurisdiction where the claim arose after the manufacturer submitted an ANDA with a Paragraph IV certification. *See Sunovion Pharm., Inc. v. Sandoz, Inc.*, No. 4:08-CV-89-H(3), 2011 WL 3875397, at *2 (E.D.N.C. Sept. 1, 2011). Sandoz, the generic manufacturer, argued that its subsequent amendment to the ANDA "carved out the patented use, thereby divesting this court of subject matter jurisdiction." *Id.* Sandoz argued that "without a Paragraph IV certification, there is no § 271(e)(2) infringement and, therefore, no jurisdiction over plaintiff's infringement claim." *Id.* While not addressing the

merits of Sandoz's argument as to jurisdiction based on § 271(e)(2), the court denied Sandoz's motion to dismiss because:

> Sandoz fails to recognize that plaintiffs' infringement claim is not premised solely upon § 271(e)(2)—it also asserts alternative theories of recovery under 35 U.S.C. § 271(a), (b), (c), and (f). Each of these alternative theories also arises under federal patent law. Consequently, subject matter jurisdiction exists over plaintiffs' infringement claim notwithstanding any dispute as to the viability of plaintiffs' theory that Sandoz violated § 271(e)(2).

Id. *See also Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 146 F. Supp. 2d 572, 580 (D.N.J. 2001) ("[T]he Court concludes that once a Paragraph IV Certification has been filed, notice given, and suit commenced, it may examine any materials which aid in its analysis of whether the final product to be marketed . . . will infringe. By necessity, this includes any post-certification amendments to an ANDA."). Here, the FDA's suspension of its review of Defendants' ANDAs and purported revocation of receipt is more analogous to a post-certification amendment than the scenario described in any case law Plaintiffs have cited. It does not change the fact that the FDA received the Defendants' ANDAs and determined they were sufficiently complete to permit a substantive review at the time that Plaintiffs filed the instant patent infringement action requesting a declaration that the Defendants' products infringed on certain patents related to Vascepa pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c), and (e). Until a final determination on Vascepa's NCE status is made and the appeal in *Amarin v. FDA et al.* is resolved, the FDA's original acceptance is valid and this court maintains jurisdiction over Plaintiffs' other infringement claims and Defendants' counterclaims.

The policy considerations behind section 271(e)(2) jurisdiction also support the denial of Plaintiffs' motion to dismiss. Congress intended courts to have jurisdiction over legitimate ANDA applications and to prevent the circumvention of the Paragraph IV notice requirement in the case of "sham ANDAs or ANDAs which are substantially incomplete." *SB Pharmco*, 552 F.

Supp. 2d at 508 (quoting 59 FR 50338, 50349 (Oct. 3, 1994)). The goal was to prevent unnecessary patent infringement litigation. *Id.* Here, the Defendants' ANDAs were received and ready for substantive review when Plaintiffs filed the complaint. Defendants did not file "sham" or "incomplete" ANDAs. The parties have litigated the matter for over a year and agreed to stay the matter for 90 days pending resolution of Vascepa's NCE status. Rather than preventing unnecessary patent infringement litigation, it would lead to unnecessary litigation if the Court dismissed the case now and the parties had to re-start the litigation from the beginning, after Vascepa's exclusivity is resolved.

II. A Final Decision by the FDA on NCE Exclusivity Will Likely Render the Present Motion Moot.

This Court should defer its decision on the Motion until the FDA makes a final determination on Vascepa's NCE status and the D.C. courts rule on the appeal in *Amarin v. FDA et al.*, 15-5214 (D.C. Cir.). Here, there will be no harm to the Plaintiffs if the court defers its decision, and in fact, Plaintiffs have consented to a 90-day stay which is in effect until September 24, 2015 to "assess the developments in the FDA proceedings." (D.I. 99). Defendants would also be willing to agree to a further stay of the case until the FDA decides the NCE exclusivity issue. In contrast, Defendants will suffer irreparable harm if the Court prematurely dismisses the action because they will be forced to re-tread ground that has already been covered in a new, and potentially the same, litigation after a final determination of Vascepa's NCE status.

By filing its motion to dismiss, Amarin asks the Court to resolve a set of difficult questions of first impression because the statute contemplates that FDA decisions about exclusivity will be made before ANDAs are received and litigation is commenced. What to do when the FDA purports to revoke receipt is a statutory conundrum fraught with competing policy

concerns. But once the FDA makes a decision about NCE exclusivity, the present motion will be easy to resolve. If the FDA determines on remand that Vascepa is entitled to five-year NCE exclusivity, then the FDA would not be allowed to accept Defendants' ANDAs until July 2016 at the earliest pursuant to 21 U.S.C. § 355(j)(5)(F)(ii) and 21 C.F.R. § 314.108(b)(2). If that happens, then it would be appropriate to dismiss the present cases. Conversely, 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. In short, once the FDA makes a final determination regarding exclusivity and the D.C. courts rule on the appeal in *Amarin v. FDA et al.*, the resolution of Amarin's motion to dismiss should be straightforward. Therefore, it makes eminent sense to defer a decision on the motion to dismiss until a final decision on NCE exclusivity has been made and all appeals are resolved.

In other contexts, when doing so suits its purposes, Amarin has warmly embraced the fact that the FDA has not yet made a final decision on NCE exclusivity. For example, in opposing Watson's motion to intervene in the D.C. District Court case for the purposes of appeal, both Amarin and the FDA argued that that court's decision remanding the exclusivity determination to the FDA is not a final, appealable order because the agency is still charged with conducting "significant further proceedings," not merely "ministerial" action. (14-cv-00324-RDM (D.D.C.), at D.I. 40, 41) (Defs.' Exs. A & B). Amarin added that the FDA's proceedings on remand could render any appeal "unnecessary" if the FDA decides not to grant NCE exclusivity. *Id.* at D.I. 41 (Defs.' Ex. B). Having made these arguments elsewhere, Amarin cannot seriously dispute here that the FDA could well deny NCE exclusivity, thus eliminating the basis for Amarin's present motion to dismiss. By filing its motion prematurely, Amarin is attempting to gain an unfair

regulatory advantage by obtaining dismissal of these suits before the FDA has resolved the underlying issue.

If the Court dismissed the present cases and the FDA subsequently denied NCE exclusivity to Vascepa, Amarin would reap an undeserved windfall by forcing the defendants to re-start the process to lead to re-filed suits that were properly filed in the first place and thereby delaying the onset of generic competition. Such a dismissal would unfairly prejudice Defendants, who have invested significant litigation resources defending against Amarin's assertion of hundreds of patent claims and who have been engaged for years in the Hatch-Waxman process so that Americans can benefit from affordable, generic versions of icosapent ethyl. Conversely, if the Court reserved judgment on the question of jurisdiction and the FDA ultimately decided to grant NCE exclusivity, Amarin would suffer no undue prejudice. The only potential prejudice Amarin points to is that it must continue to expend resources on patent litigation (Motion at Ex. A). But that concern can be obviated simply by staying the case so that no further resources need be expended until the question of NCE exclusivity has been decided.

III. The Court Has Jurisdiction Over Defendants' Declaratory Judgment Counterclaims

The Court has independent jurisdiction over Defendants' counterclaims pursuant to the Declaratory Judgment Act. *See* 28 U.S.C. § 2201(a). Congress specifically extended declaratory judgment jurisdiction to ANDA filers to bring a declaratory judgment action that a patent is invalid or not infringed. *See* 35 U.S.C. § 271(e)(5); *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1336 (Fed. Cir. 2007). To establish an "actual controversy" for the purpose of declaratory judgment, a party must show that "under 'all the circumstances' an actual or imminent injury caused by the defendant that can be redressed by judicial relief and that is of 'sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" *Teva*

Pharmaceuticals USA, Inc., 482 F.3d at 1338 (quoting *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 S.Ct. 764, 771 (2007)).

Here, the Court has jurisdiction over Defendants' declaratory judgment counterclaims because Defendants face actual and imminent injury as a result of the justiciable controversy created when they submitted their ANDAs. *See Teva Pharm. USA, Inc.*, 482 F.3d at 1344 ("A justiciable declaratory judgment controversy arises for an ANDA filer when a patentee lists patents in the Orange Book, the ANDA applicant files its ANDA certifying the listed patents under paragraph IV, and the patentee brings an action against the submitted ANDA on one or more of the patents."). Therefore, for the reasons discussed in Part I, this court also maintains jurisdiction over Defendants' counterclaims.

CONCLUSION

For the reasons set forth above, Defendants respectfully requests that the Court deny Plaintiffs' Motion to Dismiss. In the alternative, Defendants respectfully request that the Court stay the action and defer its decision on Plaintiffs' Motion until the underlying issues around Vascepa's NCE status are resolved.

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