UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

VALEANT INTERNATIONAL BERMUDA and
A.P. PHARMA, INC.,

Plaintiffs,

vs. Case No. 2:12-cv-43-FtM-29SPC

SPEAR PHARMACEUTICALS, INC.,

Defendant.

OPINION AND ORDER

This matter comes before the Court on Defendant's Motion to Dismiss Count II of Plaintiffs' Complaint for Lack of Subject Matter Jurisdiction (Doc. #18) filed on February 29, 2012. Plaintiffs filed a response in Opposition to Defendant's Motion to Dismiss (Doc. #23) on March 14, 2012. Defendant filed a reply in support (Doc. #29) on April 4, 2012. For the reasons set forth below, the motion is granted.

I.

Plaintiff A.P. Pharma, Inc. (A.P. Pharma) is the owner of U.S. Patent No. 6,670,335 (the '335 patent), issued on December 30, 2003, and plaintiff Valeant International Bermuda[1] (Valeant) is the exclusive license holder of the '335 patent. (Doc. #1, ¶¶ 9-10.) Valeant is also the current holder of New Drug Application (NDA)

[1]After filing its Complaint, Valeant International (Barbados) SRL changed its name to Valeant International Bermuda and the Court previously allowed the name to be amended in this action. (Doc. #33.)

No. 20985 for Carac® (fluorouracil 0.5% cream), a topical treatment of multiple actinic or solar keratoses of the face and anterior scalp. (Id., ¶ 11.) The '335 patent is listed in the U.S. Food and Drug Administration's (FDA) Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the "Orange Book"), certifying that Carac® is covered by the '335 patent. (Id., ¶ 14.)

On July 29, 2011, defendant Spear Pharmaceuticals, Inc. (Spear or defendant) submitted an Abbreviated New Drug Application (ANDA) with the FDA pursuant to 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, or sale of a generic version of Carac® before the expiration of the '335 patent. (Doc. #1, ¶ 15; Doc. #18, p. 4.) The ANDA contains a Paragraph IV certification alleging that the '335 patent will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted. (Doc. #1, ¶ 16.) A.P. Pharma was notified on December 12, 2011, that Spear had filed a certification under 21 C.F.R. § 314.95 in conjunction with ANDA No. 203122 for approval to manufacture a generic version of Carac®. (Id. at ¶ 17.) Plaintiffs initiated this action on January 26, 2012.

Plaintiffs' Complaint (Doc. #1) sets forth two claims. Count I alleges patent infringement of the '335 patent under 35 U.S.C. § 271(e)(2). Count II requests a declaratory judgment that the

future commercial conduct by Spear before expiration of the '335 patent will infringe the '335 patent.

II.

A brief review of the statutes which govern new and generic drug approvals and the enforcement of patents related to such drugs is set forth in Andrx Pharm., Inc. v. Biovail Corp., 276 F.3d 1368 (Fed. Cir. 2002):

> Under the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), codified at 21 U.S.C. §§ 355, 360cc, and 35 U.S.C. §§ 156, 271, (the "Hatch-Waxman Amendments" to the Federal Food, Drug and Cosmetic Act ("FFDCA")), Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market. Under the Hatch-Waxman Amendments, a manufacturer that seeks to market a generic drug may submit an ANDA for approval by the FDA, rather than submitting a full New Drug Application ("NDA") concerning the safety and efficacy of the generic drug, and it may rely on safety and efficacy studies previously submitted by the pioneer manufacturer by submitting information showing the generic drug's bioequivalence with the previously approved drug product. See 21 U.S.C. § 355(j)(2)(A).
>
> Also under the Hatch-Waxman Amendments, a pioneer drug manufacturer that holds an approved NDA is required to notify the FDA of all patents that "claim[ ] the drug for which the [NDA] applicant submitted the application. . . ." 21 U.S.C. § 355(b)(1), (c)(2). The FDA lists such patents in its Approved Drug Products With Therapeutic Equivalence Evaluations (otherwise known as the "Orange Book"). Under 35 U.S.C. section 71(e)(1), it is not patent infringement to conduct otherwise infringing acts necessary to prepare an ANDA. Under section 271(e)(2), however, a generic drug manufacturer infringes a patent by filing an ANDA to obtain approval for a generic drug product claimed by a valid and unexpired patent.

> As part of the approval process, an ANDA applicant must make a certification addressing each patent listed in the Orange Book that claims the drug. 21 U.S.C. § 355(j)(2)(A)(vii). . . . In either case, the ANDA applicant must certify that (I) no such patent information has been submitted to the FDA; (II) the patent has expired; (III) the patent is set to expire on a certain date; or (IV) the patent is invalid or will not be infringed by the manufacture, use, or sale of the new generic drug for which the ANDA is submitted. 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV). These are commonly referred to as paragraph I, II, III, and IV certifications.
>
> When an ANDA contains a paragraph IV certification, the ANDA applicant must give notice to the patentee and the NDA holder and provide a detailed basis for its belief that the patent is not infringed, invalid, or unenforceable. 21 U.S.C. § 355(j)(2)(B)(i); 21 C.F.R. § 314.95(c)(6). The patentee then has forty-five days to sue the ANDA applicant for patent infringement, and the ANDA applicant may not file a declaratory judgment during this time (based on the filing of the ANDA application). 21 U.S.C. § 355(j)(5)(B)(iii). If the patentee does not sue, the ANDA will be approved. If the patentee does file suit, the FDA may not approve the ANDA until expiration of the patent, resolution of the suit, or thirty months after the patentee's receipt of notice, whichever is earlier. Id. The court in which the suit is pending may order a shorter or longer stay if "either party to the action fail[s] to reasonably cooperate in expediting the action. . . ." Id.

Andrx Pharm., 276 F.3d at 1370-71. See also Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1059 n.2 (11th Cir. 2005).

> The exemption to infringement under section 271(e)(1) allows a generic drug manufacturer to take the steps needed to bring a generic drug to market without waiting until the patent expires. At the same time, by deeming the filing of an ANDA to be an act of infringement under section 271(e)(2), the Hatch-Waxman Act allows a brand name drug manufacturer to challenge the ANDA application and a generic drug manufacturer to challenge the validity and infringement of an asserted patent before the patent expires.

Allergan, Inc. v. Alcon Labs., Inc., 324 F.3d 1322, 1326 (Fed. Cir. 2003)(citing Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1568-69 (Fed. Cir. 1997)). Thus, in 35 U.S.C. § 271(e)(2), Congress created a new cause of action for patent infringement which provides patentees a jurisdictional basis for bringing suit in a federal district court under 28 U.S.C. § 1338(a). Astrazeneca Pharm., LP v. Apotex Corp., 669 F.3d 1370, 1377 (Fed. Cir. 2012). The infringement is "artificial" because no specific infringing conduct has taken place, and the district court must engage in a hypothetical inquiry grounded in the ANDA application and the extensive materials typically submitted in its support to determine whether, if the drug was approved based upon the ANDA, the manufacture, use, or sale of that drug would infringe the patent in the conventional sense. Glaxo, Inc., 110 F.3d at 1569.

III.

By filing an ANDA with a Paragraph IV certification, Spear engaged in an "artificial" act of infringement sufficient to allow plaintiffs to maintain a claim in federal court under 35 U.S.C. § 271(e)(2). Defendant does not challenge the jurisdiction of the district court as to this count. See 28 U.S.C. § 1338(a)("The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents. . . ."). Plaintiffs also purport to state a claim under the Declaratory Judgment Act, 28 U.S.C. § 2201, and defendant does

challenge the subject matter jurisdiction of the district court as to that count.

The Court starts with the proposition that there is nothing inherently improper if a patent holder adds a claim under the Declaratory Judgment Act to its § 271(e)(2) substantive infringement claim. Lang v. Pacific Marine & Supply Co., Ltd., 895 F.2d 761, 763-64 (Fed. Cir. 1990); Glaxo, 110 F.3d at 1570-71. The issue is not whether declaratory relief can ever be pursued, but whether this declaratory judgment claim is sufficiently pled to state a valid cause of action.

The Declaratory Judgment Act provides that "[i]n a case of actual controversy within its jurisdiction . . . any court of the United States . . . may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a). "A party has standing to bring an action under the Declaratory Judgment Act if an 'actual controversy' exists, 28 U.S.C. § 2201(a), which is the same as an Article III case or controversy. [ ] The burden is on the party claiming declaratory judgment jurisdiction to establish that an Article III case or controversy existed at the time the claim for declaratory relief was filed." Arris Grp., Inc. v. British Telecomms. PLC, 639 F.3d 1368, 1373 (Fed. Cir. 2011)(internal citations and quotation marks omitted). "[I]f there is no actual controversy the district court is without

jurisdiction to hear a claim for declaratory relief." Glaxo, 110 F.3d at 1570. Whether an actual controversy exists is a question of law. Dey Pharma, LP v. Sunovion Pharm., Inc., 677 F.3d 1158, 1162 (Fed. Cir. 2012); Matthews Int'l Corp. v. Biosafe Eng'g LLC, No. 2012-1044, ____ F.3d ___, 2012 WL 4354663, *3 (Fed. Cir. Sept. 25, 2012).

Under the standard set forth in MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 127 (2007),

> [A]n Article III case or controversy exists when "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." MedImmune, 549 U.S. at 127 (internal quotation marks and citation omitted). The dispute must be "definite and concrete, touching the legal relations of parties having adverse legal interests," such that the dispute is "real and substantial" and "admi[ts] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." Id. (internal quotation marks and citation omitted).

Arris Group, 639 F.3d at 1373-74. To demonstrate an Article III case or controversy, "plaintiff must allege facts from which it appears there is a substantial likelihood that he will suffer injury in the future. [ ] Injury in the past . . . does not support a finding of an Article III case or controversy when the only relief sought is a declaratory judgment." Walden v. CDC & Prevention, 669 F.3d 1277, 1284 (11th Cir. 2012)(internal citations omitted and quotation marks omitted).

> There is, however, no facile, all-purpose standard to police the line between declaratory judgment actions which satisfy the case or controversy requirement and those that do not. [ ] To the contrary, "[t]he difference between an abstract question and a 'controversy' contemplated by the Declaratory Judgment Act is necessarily one of degree, and it would be difficult, if it would be possible, to fashion a precise test for determining in every case whether there is such a controversy." [ ] Accordingly, the analysis must be calibrated to the particular facts of each case, with the fundamental inquiry being "'whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'"

Cat Tech LLC v. TubeMaster, Inc., 528 F.3d 871, 879 (Fed. Cir. 2008)(internal citations omitted).

Count II asserts that "[a]n actual, substantial and justiciable controversy exists . . ." (Doc. #1, ¶ 8), and the existence of a "concrete, real, and immediate dispute" between the parties which creates "an actual case or controversy" sufficient to satisfy Article III of the United States Constitution (Doc. #1, ¶ 23). These conclusory allegations are not entitled to a presumption of truth, as are factual allegations. See Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007). The specifics of the dispute between the parties are set forth as follows: Spears intends to begin manufacturing, marketing, offering to sell, or selling its Generic Product within the United States after FDA approval; Spear will make substantial preparation in the United States to do so before the expiration of the '335 patent; and such conduct will infringe the '335 patent. (Doc. #1, ¶¶ 24-28.)

Plaintiffs seek a declaration that such future commercial conduct after FDA approval, but before the expiration of the '335 patent, will infringe the '335 patent. (Doc. #1, ¶ 29.)

Plaintiffs must adequately plead both "immediacy" and "reality" for their complaint to state a claim for declaratory relief in a patent infringement case. The Court concludes that in this case the Complaint alleges neither with sufficiency. T h e factual allegations are largely generic assertions without specificity which do not support either the immediacy or reality requirement.

If a declaratory judgment defendant "has not taken significant, concrete steps to conduct infringing activity, the dispute is neither 'immediate' nor 'real' and the requirements for justiciability have not been met." Cat Tech, 528 F.3d at 880 (citation omitted). "[A]lthough a party need not have engaged in the actual manufacture or sale of a potentially infringing product to obtain a declaratory judgment of non-infringement, there must be a showing of 'meaningful preparation' for making or using that product." Id. at 881 (citations omitted). "In general, the greater the length of time before potentially infringing activity is expected to occur, 'the more likely the case lacks the requisite immediacy.'" Id. (quoting Sierra Applied Scis., Inc. v. Advanced Energy Indus., Inc., 363 F.3d 1361, 1379 (Fed. Cir. 2004)). The FDA may not approve the ANDA until the resolution of this action or

June 12, 2014 (30 months from the date the notice was received), and there are no specifically alleged facts which would allow a court to plausibly infer "meaningful preparation" in order to satisfy the immediacy prong.

As to the reality requirement, the Federal Circuit has stated:

> In the context of patent litigation, the reality requirement is often related to the extent to which the technology in question is "substantially fixed" as opposed to "fluid and indeterminate" at the time declaratory relief is sought. Accordingly, "[t]he greater the variability of the subject of a declaratory-judgment suit, particularly as to its potentially infringing features, the greater the chance that the court's judgment will be purely advisory, detached from the eventual, actual content of that subject-in short, detached from eventual reality."

Cat Tech, 528 F.3d at 882 (citations omitted). The factual allegations in Count II are simply too humble to show that the reality component has plausibly been satisfied. See Telectronics Pacing Sys., Inc. v. Ventritext, Inc., 982 F.2d 1520, 1527 (Fed. Cir. 1992)(upholding the dismissal of a declaratory judgment action where the product had just begun clinical trial because "[t]here was no certainty that the device when approved [by the FDA] would be the same device that began clinical trials"); see also Glaxo, 110 F.3d at 1569 ("The FDA's interest in fixing the exact nature of such a product to be sold, in discharging its own responsibility to ensure the purity, efficacy, and safety of the product, may cause the nature of the product originally applied for to differ somewhat

from that ultimately approved."). Therefore, the motion must be granted.

Accordingly, it is now

ORDERED:

Defendant's Motion to Dismiss Count II of Plaintiffs' Complaint (Doc. #18) is **GRANTED** to the extent that Count II is dismissed without prejudice.

DONE AND ORDERED at Fort Myers, Florida, this 30th day of September, 2012.

JOHN E. STEELE
United States District Judge

Copies:
Counsel of record