IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JUNO THERAPEUTICS, INC., MEMORIAL SLOAN KETTERING CANCER CENTER, and SLOAN KETTERING INSTITUTE FOR CANCER RESEARCH, Plaintiffs; v. KITE PHARMA, INC., Defendant.	Civil Action No. 16-1243-RGA

MEMORANDUM OPINION

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Attorneys for Defendant

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ANDREWS, U.S. DISTRICT JUDGE:

Presently before the Court is Defendant's Motion to Dismiss (D.I. 8) and related briefing (D.I. 9, 16, 19). For the reasons that follow, Defendant's motion is granted.

I. Background

Plaintiffs in this action are the assignee and exclusive licensee of U.S. Patent No. 7,446,190 ("the '190 patent"). (D.I. 16 at 7). Plaintiffs have not yet successfully developed an FDA approved therapy based on the invention disclosed in the '190 patent. (D.I. 9 at 10). Defendant, on the other hand, has initiated submission of a Biologics License Application ("BLA") to the FDA for a therapy Plaintiffs contend infringes or will infringe the '190 patent.[1] (D.I. 16 at 6). Defendant filed a petition for Inter Partes Review ("IPR") with the Patent & Trademark Office in 2015 seeking cancellation of all claims of the '190 patent. (D.I. 1, ¶19). The petition was granted, but on December 16, 2016, the Patent Trial and Appeal Board ("PTAB") issued a final decision finding Petitioner (Defendant in the instant action) had not proven that any of the claims were invalid. (D.I. 16 at 9). Plaintiffs brought this action on December 19, 2016, seeking a declaratory judgment that Defendant infringes or will infringe the '190 patent.

II. Legal Standard

The purpose of the Declaratory Judgment Act is "to prevent avoidable damages from being incurred by a person uncertain of his rights and threatened with damage by delayed adjudication." *Minnesota Min. & Mfg. Co. v. Norton Co.*, 929 F.2d 670, 673 (Fed. Cir. 1991).

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[1] Although the statute governing the BLA process includes provisions relating to infringement suits where the biological product at issue enjoys patent protection as well as an abbreviated FDA approval process for biosimilars of licensed biologics, this provision is not at issue in the instant case because there is no FDA approved biological product that is an embodiment of the '190 patent. *See* 42 U.S.C. § 262(k), (l). This is not a case, therefore, where Defendant's submission of its BLA is considered an act of infringement under 35 U.S.C. § 217(e)(2), which would otherwise provide the jurisdictional basis for Plaintiffs' suit. *See Sandoz Inc. v. Amgen Inc.*, 2017 WL 2507337, at *6 (U.S. June 12, 2017).

For a court properly to exercise declaratory judgment jurisdiction, there must exist "a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Maryland Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941). Determining whether immediacy and reality are present is fact specific and must be determined on a case-by-case basis by considering the totality of the circumstances. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007). "The burden is on the party claiming declaratory judgment jurisdiction to establish that such jurisdiction existed at the time the claim for declaratory relief was filed and that it has continued since." *Benitec Australia, Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1344 (Fed. Cir. 2007).

In order to meet the immediacy prong, "there must be a showing of 'meaningful preparation' for making or using that product." *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 881 (Fed. Cir. 2008) (quoting *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988)). Timing is important for a showing of immediacy. The longer the time between when suit is initiated and when potential infringement may occur, "the more likely the case lacks the requisite immediacy." *Sierra Applied Scis., Inc. v. Advanced Energy Indus., Inc.*, 363 F.3d 1361, 1379 (Fed. Cir. 2004). For example, immediacy was not found where an accused infringer's product "would not be finished until at least 9 months after the complaint was filed" and the accused infringer had not engaged in any marketing activities. *Lang v. Pac. Marine & Supply Co.*, 895 F.2d 761, 764 (Fed. Cir. 1990). The Federal Circuit also found immediacy lacking where a potentially infringing product was not "built and operational until about a year after the complaint was filed—a period longer than the nine months determined to be too long in *Lang*." *Sierra Applied Scis., Inc.*, 363 F.3d at 1379.

III. Discussion

Defendant seeks dismissal of this declaratory judgment action, arguing the Court lacks subject matter jurisdiction. (D.I. 9 at 11). Defendant contends its activities to date fall within the Safe Harbor Provision of the Patent Act and are, therefore, non-infringing activities. (*Id.*). Defendant further argues the alleged future infringement is speculative, as it is unclear when, or even whether, Defendant's BLA will be approved. (*Id.* at 18).

As an initial matter, I reject Plaintiffs' argument that Defendant's filing of a petition for IPR and its subsequent appeal of the PTAB's final decision means that Defendant "acknowledges its belief that Article III jurisdiction exists over the parties' dispute regarding the '190 Patent." (D.I. 16 at 12). Because the right to appeal an IPR decision is provided by statute, "certain requirements of standing—namely immediacy and redressability, as well as prudential aspects that are not part of Article III—may be relaxed." *Consumer Watchdog v. Wisconsin Alumni Research Found.*, 753 F.3d 1258, 1261 (Fed. Cir. 2014). In other words, Defendant's IPR appeal is not subject to the same requirement of immediacy as Plaintiffs' declaratory judgment action.

Plaintiffs argue that there is no "bright-line rule" that the § 271(e)(1) safe harbor protects an alleged infringer from a declaratory judgment action. (D.I. 15). The Safe Harbor Provision of the Patent Act provides protection for potentially infringing activities if those activities are "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." 35 U.S.C. § 271(e)(1). Defendant argues that all of its activities to date related to the accused product fall within this provision. (D.I. 9 at 12). Specifically, Defendant contends that it has only manufactured the accused product in connection with "clinical development studies,"

designed to generate the data necessary for its BLA submission, and it has only used the accused product in clinical trials, also designed to generate supporting data for the BLA submission. (*Id.*).

Plaintiffs have not alleged Defendant currently infringes, nor do they dispute that all of Defendant's activities to date are related to seeking FDA approval. Rather, Plaintiffs argue that "[t]he Federal Circuit has already rejected the bright-line rule" that the safe harbor provision protects an accused infringer from suit prior to FDA approval. (D.I. 16 at 15). Plaintiffs cite to *Glaxo*, a case in which the Defendant had submitted an Abbreviated New Drug Application ("ANDA") seeking to make and sell a generic version of an FDA approved drug. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1564 (Fed. Cir. 1997). I fail to see the relevance of *Glaxo* to the instant case. In *Glaxo*, the Federal Circuit upheld the District Court's discretionary decision to hear the declaratory judgment action because the plaintiff had alleged sufficient facts "to create an actual case or controversy." *Id.* at 1571. According to the court, those facts included "imminent FDA approval and actual threats of future infringement." *Id.* In the instant case, Defendant has not filed an ANDA because there is no FDA approved embodiment of the '190 patent. There is a significant difference, both in terms of timing and certainty, between the ANDA approval process and the process of obtaining approval of a BLA.

Plaintiffs have not alleged sufficient facts from which I could conclude that FDA approval of Defendant's BLA is imminent or even certain. Plaintiffs filed this suit on December 19, 2016, approximately six months ago. (D.I. 1). Plaintiffs have not alleged that Defendant's BLA will receive FDA approval at any time in the near future. Plaintiffs suggest that Defendant's recent BLA filings, coupled with Defendant's own statements of its intent to market the product once FDA approval is obtained, constitutes sufficient evidence to meet the

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