IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MILLENNIUM PHARMACEUTICALS, INC., Plaintiff, v. PHARMASCIENCE INC. and PHARMASCIENCE LABORATORIES INC., Defendants.	)	C.A. No. 15-702-GMS

MEMORANDUM

I. INTRODUCTION

On August 13, 2015, the plaintiff, Millennium Pharmaceutical Inc. ("Millennium"), filed this lawsuit against defendant Pharmascience Laboratories Inc., ("PSL") and defendant Pharmascience Inc. ("PSI") (collectively "the Pharmascience Defendants"). (D.I. 1.) The Complaint alleges that the Pharmascience Defendants collaborated on filing and notifying Millennium of an Abbreviated New Drug Application ("ANDA") for a generic version of the drug VELCADE® (bortezomib). (*Id.*) The Complaint further alleges infringement of two of Millennium's drug patents: U.S. Patent Nos. 6,713,446 (the "'446 patent") and 6,958,319 (the "'319 patent"). (*Id.*) Presently before the court is PSI's motion to dismiss the complaint for lack of personal jurisdiction under 12(b)(2) of the Federal Rules of Civil Procedure (D.I. 6) and PSL's motion to dismiss the complaint for lack of personal jurisdiction and for failure to state a claim

under 12(b)(6) of the Federal Rules of Civil Procedure. (D.I. 9.) For the reasons below, the court will deny the motions in part.[1]

II. BACKGROUND

PSI filed ANDA No. 208392 with the U.S. Food and Drug Administration ("FDA"). (D.I. 1 at ¶ 1.) PSI's ANDA seeks "approval to manufacture and sell a generic version of VELCADE® for Injection before the expiration of U.S. Patent Nos. 6,713,446 and 6,958,319." (*Id.*) Millennium asserts that it is the exclusive licensee of the '446 and '319 patents, which are listed in the FDA's "Orange Book" as encompassing VELCADE®. (*Id.* at ¶¶ 22, 25.) On June 29, 2015, PSI sent its ANDA Notice Letter to Millennium, which included a "paragraph IV certification" that the '446 and '319 patents were invalid, unenforceable or would not be infringed by PSI's proposed bortezomib product. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); (D.I. 1 at ¶¶ 26-27.) On August 13, 2015, Millennium brought suit alleging that the Pharmascience Defendants collaborated on filing and notifying Millennium of an ANDA for a generic version of the drug VELCADE® (bortezomib).

On September 3, 2015, PSI moved to dismiss the complaint for lack of personal jurisdiction. (D.I. 6.) That same day, PSL moved to dismiss the complaint for lack of personal jurisdiction and for failure to state a claim. (D.I. 10.) Millennium opposed dismissal. (D.I. 13.) Millennium relied upon this court's decision in *AstraZeneca AB v. Mylan Pharm., Inc.*, which held that the act of filing an ANDA application that potentially infringes the patent of a Delaware entity provides sufficient minimum contacts with the state of Delaware under a specific

[1] The court will dismiss PSL for lack of personal jurisdiction. Therefore, the court need not address the arguments that PSL raises regarding lack of subject matter jurisdiction, which in any event are without merit with regard to PSI. *See AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1377 (Fed. Cir. 2012) (once a patentee alleges infringement there is subject matter). *See also* 28 U.S.C. § 1338 (providing exclusive federal jurisdiction over patent cases).

jurisdiction analysis, but also held that the court lacked general jurisdiction in that case. 72 F. Supp. 3d 549, 559–60 (D. Del. 2014). Subsequently, that case was consolidated for appeal with *Acorda Therapeutics, Inc. v. Mylan Pharm. Inc.* and affirmed. *Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755 (Fed. Cir. 2016). *See also Acorda Therapeutics, Inc. v. Mylan Pharm. Inc.,* 78 F. Supp. 3d 572 (D. Del. 2015) (holding that the court had specific jurisdiction and general jurisdiction over Mylan.)

On March 18, 2016, the Federal Circuit held in *Acorda* that the act of filing an ANDA with the FDA for a generic drug product subjected Mylan to specific personal jurisdiction in Delaware because Mylan would engage in marketing and selling its intended product in Delaware. 817 F.3d at 757. The *Acorda* court reasoned that in filing its ANDAs, Mylan indicated an intention to sell that product in every state, including Delaware. *Id.* at 763-64. The court concluded that "the minimum-contacts standard is satisfied by the particular actions Mylan has already taken—its ANDA filings—for the purpose of engaging in that injury-causing and allegedly wrongful marketing conduct in Delaware." *Id.* at 760.

III. STANDARD OF REVIEW

Under Federal Rule of Civil Procedure 12(b)(2), a court must dismiss a case when it lacks personal jurisdiction over the defendant. Fed. R. Civ. P. 12(b)(2); *Freres v. SPI Pharma, Inc.,* 629 F. Supp. 2d 374, 382 (D. Del. 2009). The plaintiff bears the burden of proving that personal jurisdiction is proper. *ICT Pharms., Inc. v. Boehringer Ingelheim Pharms., Inc.,* 147 F. Supp. 2d 268, 270-71 (D. Del. 2001). Likewise, the plaintiff "must sustain its burden of proof in establishing jurisdictional facts through sworn affidavits or other competent evidence." *Time Share Vacation Club v. Atlantic Resorts*, Ltd., 735 F.2d 61, 66 n.9 (3d Cir. 1984); *see also Autogenomics, Inc. v. Oxford Gene Tech. Ltd.*, 566 F.3d 1012, 1023 (Fed. Cir. 2009).

To determine whether there is personal jurisdiction, the court must first determine whether it has jurisdiction over the defendant under the Delaware long-arm statute. 10 Del. C. § 3104. *See Bell Helicopter Textron, Inc. v. C & C Helicopter Sales, Inc.,* 295 F.Supp.2d 400, 402-03 (D. Del. 2002). Specific jurisdiction exists where "the defendant has 'purposefully directed' his activities at residents of the forum, and the litigation results from alleged injuries that 'arise out of or relate to' those activities." *Burger King Corp. v. Rudzewicz,* 471 U.S. 462, 472–73 (1985); *see also Nuance Commc'ns, Inc. v. Abbyy Software House,* 626 F.3d 1222, 1231 (Fed. Cir. 2010) (citing *Akro Corp. v. Luker,* 45 F.3d 1541, 1545–46 (Fed. Cir. 1995)). A defendant is subject to jurisdiction under Delaware's long-arm statute, Del. Code Ann. tit. 10, § 3104, as long as Delaware's exercise of personal jurisdiction over the defendant would be consistent with the Fourteenth Amendment's Due Process Clause. *Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 759 (Fed. Cir. 2016). Thus, the court must determine whether an exercise of jurisdiction violates the defendant's Constitutional right to due process. *Id.*

A court may exercise specific personal jurisdiction without violating the Due Process Clause when the defendant "ha[s] certain minimum contacts with [the forum] such that the maintenance of the suit does not offend 'traditional notions of fair play and substantial justice.'" *Int'l Shoe Co. v. Washington,* 326 U.S. 310, 316 (1945) (citing *Milliken v. Meyer*, 311 U.S. 457, 463 (1940)). The minimum-contacts requirement focuses on whether "the defendant's suit-related conduct ... create[s] a substantial connection with the forum State." *Walden v. Fiore,* 134 S. Ct. 1115, 1121 (2014). Whether the conduct at issue is suit-related depends on "the relationship among the defendant, the forum, and the litigation," *Keeton v. Hustler Magazine, Inc.,* 465 U.S. 770, 775 (1984), including the nature of the claim asserted. *See Calder v. Jones,* 465 U.S. 783, 789–90 (1984).

Finally, even if a defendant has minimum suit-related contacts with a state, the defendant may defeat specific personal jurisdiction by sufficiently demonstrating that other considerations render jurisdiction unreasonable. *See Burger King,* 471 U.S. at 477. The Supreme Court has identified a number of factors for courts to consider, including "the burden on the defendant," "the forum State's interest in adjudicating the dispute," "the plaintiff's interest in obtaining convenient and effective relief," and "the interstate judicial system's interest in obtaining the most efficient resolution of controversies." *World–Wide Volkswagen Corporation v. Woodson,* 444 U.S. 286, 292 (1980).

IV. DISCUSSION

PSI moves to dismiss for lack of personal jurisdiction, arguing that there is no basis for specific or general jurisdiction. (D.I. 7 at 1.) Millennium responds that the court has personal jurisdiction over Pharmascience Inc. because: (1) Pharmascience Inc. purposefully directed its activities to a Delaware resident by sending its Paragraph IV Letter to Millennium, a Delaware corporation (D.I. 13 at 4); (2) Pharmascience Inc. knew or should have known that Millennium would sue for infringement in Delaware if Pharmascience Inc. filed an ANDA seeking approval for a generic version of VELCADE® for Injection (*Id.* at 6); (3) judicial economy weighs in favor of exercising specific jurisdiction (*Id.* at 8); and (4) if Pharmascience, Inc. is not subject to personal jurisdiction based on its contacts with Delaware, it is subject to personal jurisdiction based on Federal Rule of Civil Procedure 4(k)(2), the federal long-arm statute. (*Id.*)

Subsequently, Millennium filed a Notice of Supplemental Authority (D.I. 18) in which it argued that the March 18, 2016 opinion of the Federal Circuit in *Acorda* establishes that there is jurisdiction in this case. *Acorda*, 817 F.3d 755. In *Acorda*, the Federal Circuit found that when a plaintiff files an ANDA the minimum-contacts standard is satisfied. *Id.* The *Acorda* court

reasoned that if proven, infringement would concretely injure Acorda and AstraZeneca in the State by displacing some of their Delaware sales. *Id.* at 759-60. Millennium argues that based upon this decision, PSI created personal jurisdiction by filing its ANDA and creating a future harm to a Delaware corporation sufficient for minimum contacts. (D.I. 18 at 2.)

The Pharmascience Defendants respond that though PSI did file an ANDA, unlike Mylan, the ANDA is PSI's sole contact with Delaware. (D.I. 19.) PSI points out that in its analysis, the Federal Circuit pointed to other contacts that Mylan had with Delaware. *See, e.g., Acorda*, 817 F.3d at 762 ("...it suffices for Delaware to meet the minimum-contacts requirement in the present cases that Mylan's ANDA filings and its distribution channels establish that Mylan plans to market its proposed drugs in Delaware..."); *id.* at 763 ("Mylan has registered to do business in Delaware and appointed an agent to accept service of process there."); *id.* (Mylan indicated in its certificate of registration that it intends to engage in "[p]harmaceutical manufacturing, distribution and sales" in Delaware, and Mylan registered with the Delaware Board of Pharmacy as a licensed "Pharmacy-Wholesale" and a "Distributor/Manufacturer CSR.").

PSI claims that it is a Canadian company with a principal place of business in Montreal. (D.I. 7 at 8.) According to PSI, it prepared the ANDA in Canada, the ANDA was submitted to the FDA in Maryland, and PSI sent its Paragraph IV Letter to Millennium in Massachusetts. (*Id.* at 4.) PSI asserts that it is not incorporated in Delaware, is not registered to do business in Delaware, and it has no employees or agents in Delaware, does not maintain a post office box, mail drop, telephone number, office, or any place of business in Delaware. (D.I. 19 at 2.) PSI does not have any bank accounts in Delaware, nor does it file taxes in Delaware. McDiarmid Decl. ¶¶ 3, 5. PSI claims that it does not have any distribution channels or an agent to accept

service of process in Delaware. (D.I. 19 at 2.) PSI asserts that it has only defended itself in one Delaware litigation, which was unrelated to this case. (*Id.* at 15.) *See In re Bendamustine*, 1:2013-cv-02046-GMS. Finally, unlike Mylan, PSI claims it does not have an approved and active ANDA, does not import any drug products into the United States, and has no sales of any drug products in the United States, including Delaware. (D.I. 19 at 2.)

Based upon the *Acorda* decision, the court concludes that there is specific personal jurisdiction over PSI, even though PSI claims it does not have additional contacts with Delaware besides the filing of its ANDA. The *Acorda* court noted that Mylan was incorporated in West Virginia, prepared its ANDA primarily in West Virginia, and filed its ANDA in Maryland. *Acorda*, 817 F.3d at 758. The court also acknowledged that Mylan was registered to do business in Delaware and AstraZeneca and Acorda are incorporated in Delaware, however, the holding in the case was not based upon these facts. *Id.* at 763. Thus, the court must conclude that specific personal jurisdiction over PSI exists in this case based upon PSI's ANDA filing. Delaware is a state where PSI will engage in marketing if the ANDA is approved and that marketing is directly related to this suit. *See* 21 U.S.C. § 355(j)(5)(B). *Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 760 (Fed. Cir. 2016). *See also id.* at 761-62 (Fed. Cir. 2016) ("We have noted that Congress deemed the ANDA filing to have a non-speculative causal connection to the ANDA filer's future infliction of real-world market injury on the patent holder…").

Considerations of fairness do not override the minimum contacts that justify exercising personal jurisdiction over PSI, particularly given that there are already related ANDA litigations concerning VELCADE® taking place in this district. (D.I. 7 at 2.) Thus, requiring Millennium to pursue an infringement action against Pharmascience Inc. outside of Delaware unnecessarily

wastes judicial resources and could result in an outcome that is inconsistent with decisions issued in the other ANDA cases relating to VELCADE® and the patents at issue. In addition, Millennium would be substantially burdened if forced to bring a lawsuit against any ANDA filer challenging its patent in the location selected by the defendant. *See AstraZeneca AB*, 72 F. Supp. 3d 549 at 560.[2]

With regard to PSL, however, Millennium fails to demonstrate a basis for general or specific personal jurisdiction. Thus, PSL must be dismissed as a party to the lawsuit. When a motion to dismiss for lack of personal jurisdiction under Federal Rules of Civil Procedure 12(b)(2) is brought, the plaintiffs must establish with reasonable particularity "that sufficient minimum contacts have occurred between the defendant[s] and the forum state to support jurisdiction." *Reach & Associates, P.C. v. Dencer,* 269 F. Supp.2d 497, 502 (D. Del. 2003) (citing *Provident National Bank v. California Federal Savings & Loan Assoc.,* 819 F.2d 434, 437 (3d Cir. 1987)). Millennium does not allege that PSL filed an ANDA, but rather that it collaborated with PSI to do so, an assertion that Millennium fails to support with reasonable particularity. On the other hand, PSL declares that it has no ANDA, it did not participate in the accused ANDA, and it did not work on the accused ANDA product. *See* Declaration of Sophie Tanguay ("Tanguay Decl.") ¶¶ 5, 7-8. Additionally, Millennium fails to assert that PSL has any physical presence in Delaware or that PSL is incorporated or registered to do business in Delaware. (D.I. 10 at 1.) PSL has no systematic and continuous contacts by which it is "at home" in the state. In fact, PSL claims that it does not make or sell any products in the United States and does not import or distribute any products in this country, for PSI or anyone. (*Id.*)

[2] Having found there is a basis for personal jurisdiction over PSI, the court need not address the parties' arguments regarding general jurisdiction.

There is no personal jurisdiction over PSL because Millennium fails to establish a general or specific basis for finding such.

V. CONCLUSION

For the foregoing reasons, the court will deny PSI's motion to dismiss (D.I. 6) and grant PSL's motion to dismiss (D.I. 9) for lack of personal jurisdiction.

Dated: June 16, 2016

UNITED STATES DISTRICT COURT

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ORDER

For the reasons stated in the court's Memorandum of this same date, IT IS HEREBY ORDERED that:

1. The defendant Pharmascience Inc.'s motion to dismiss (D.I. 6) is DENIED.
2. The defendant Pharmascience Laboratories Inc.'s motion to dismiss (D.I. 9) is GRANTED.
3. The defendant Pharmascience Laboratories Inc. is DISMISSED.

Dated: June 10, 2016

UNITED STATES DISTRICT COURT