IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

PFIZER INC., et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civ. No. 15-960-SLR
	)	
MYLAN INC., et al.,	)	
	)	
Defendants.	)	
	)	

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MEMORANDUM OPINION

Dated: August 12, 2016
Wilmington, Delaware

ROBINSON, District Judge

I. INTRODUCTION

On October 22, 2015, Pfizer Inc., Wyeth LLC, Pfizer Pharmaceuticals LLC, PF PRISM C.V., and Pfizer Manufacturing Holdings LLC, (collectively "plaintiffs") filed a complaint alleging infringement of three patents related to its injectable antibiotic product TYGACIL ® ("Tygacil") against defendants Mylan Inc., Mylan N.V., Mylan Laboratories Ltd. ("MLL"), and Mylan Pharmaceuticals ("MPI") (collectively "defendants"). (D.I. 1) Presently before the court is defendants' motion to dismiss for lack of personal jurisdiction and improper venue. (D.I. 6) Defendants Mylan Inc., Mylan N.V., and MPI have also filed a motion dismiss for failure to state a claim. (*Id.*) The court has jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331 and 1338(a).

II. BACKGROUND

A. The parties

Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware with a principal place of business in New York, New York. (D.I. 1 at ¶ 2) Plaintiff Wyeth LLC is a Delaware limited liability company with a principal place of business in New York, New York. (*Id.* at ¶ 3) Wyeth LLC's sole member is Pfizer Inc. (*Id.*) Plaintiff Pfizer Pharmaceuticals LLC is a Delaware limited liability company with a principal place of business in Vega Baja, Puerto Rico. (*Id.* at ¶ 4) Pfizer Pharmaceuticals LLC is a wholly-owned subsidiary of PF PRISM C.V. (*Id.*) Plaintiff PF PRISM C.V. is a Dutch limited partnership with a principal place of business in Rotterdam, Holland. (*Id.* at ¶ 5) Plaintiff Pfizer Manufacturing Holdings LLC is a Delaware limited liability company with a principal place of business in New York, New

York. (*Id.* at ¶ 6) Pfizer Manufacturing Holdings LLC is a general partner of PF PRISM C.V. (*Id.*)

MPI is a corporation organized and existing under the laws of the State of West Virginia with a principal place of business in Morgantown, West Virginia, and is a wholly-owned subsidiary of Mylan Inc. (D.I. 9 at ¶¶ 3, 4) MPI is registered to do business in Delaware. (D.I. 21 at 6) Mylan N.V. is a Dutch corporation, with a principal place of business in Hatfield, England. (D.I. 8 at ¶ 11) Mylan Inc. is a corporation organized and existing under the laws of the State of Pennsylvania with a principal place of business in Canonsburg, Pennsylvania. (*Id.* at ¶ 4) MLL is an Indian corporation with a principal place of business in Hyderabad, India and is a subsidiary of Mylan Inc. (D.I. 10 at ¶¶ 4, 6) Mylan N.V., Mylan Inc., and MLL are not registered to business in Delaware. (D.I. 8 at ¶¶ 6, 13; D.I. 10 at ¶ 10) MLL prepared and filed New Drug Application ("NDA") No. 208461. (*Id.* at ¶ 12)

B. Background

On September 11, 2015, MLL sent a notice letter pursuant to 21 U.S.C. § 355(b)(3) to plaintiffs in New York and Puerto Rico, notifying plaintiffs that MLL had submitted NDA No. 208461 to the Food and Drug Administration ("FDA"). (D.I. 1 at ¶¶ 1, 28) The notice letter advised plaintiffs that MLL sought to market a generic injectable tigecycline product in the United States and that one or more of plaintiffs' patents were invalid, unenforceable, and/or would not be infringed. Tigecycline products are used in the treatment of various bacterial infections such as staph and E. coli. (D.I. 7 at 3-4)

On October 22, 2015, plaintiffs filed the instant action for patent infringement arising out of defendants' submission of NDA No. 208461, seeking approval to

manufacture and sell a generic version of Pfizer's Tygacil, a tigecycline injectable IV infusion prior to the expiration of U.S. Patent Nos. 7,879,828; 8,372,995; and 8,975,242. On October 23, 2015, plaintiffs filed a protective suit in the Northern District of West Virginia (the "West Virginia Action"). (D.I. 21 at 3) Plaintiffs characterize the West Virginia Action as a "purely protective suit" filed "in order to protect the statutory right to a 30-month stay on [d]efendants' generic product." (*Id.*) Defendants describe the West Virginia Action as a "nearly identical suit" to the instant case. (D.I. 7 at 4) While plaintiffs did not serve the complaint in the West Virginia Action, defendants have answered the complaint and submitted counterclaims. (D.I. 21 at 3)

III. PERSONAL JURISDICTION

A. Standard of review

Rule 12(b)(2) of the Federal Rules of Civil Procedure directs the court to dismiss a case when the court lacks personal jurisdiction over a defendant. Fed. R. Civ. P. 12(b)(2). When reviewing a motion to dismiss pursuant to Rule 12(b)(2), a court must accept as true all allegations of jurisdictional fact made by plaintiff and resolve all factual disputes in plaintiff's favor. *Traynor v. Liu*, 495 F. Supp. 2d 444, 448 (D. Del. 2007).

Once a jurisdictional defense has been raised, plaintiff bears the burden of establishing, with reasonable particularity, that sufficient minimum contacts have occurred between defendant and the forum to support jurisdiction. *See Provident Nat'l Bank v. Cal. Fed. Sav. & Loan Ass'n,* 819 F.2d 434, 437 (3d Cir. 1987). To meet this burden, plaintiff must produce "sworn affidavits or other competent evidence," since a Rule 12(b)(2) motion "requires resolution of factual issues outside the pleadings." *Time Share Vacation Club v. Atlantic Resorts, Ltd.,* 735 F.2d 61, 67 n. 9 (3d Cir. 1984).

Pursuant to the relevant portions of Delaware's long-arm statute, 10 Del. C. § 3104(c), a court may exercise personal jurisdiction over a defendant when a defendant or its agent:

> (1) Transacts any business or performs any character of work or service in the State;
>
> (2) Contracts to supply services or things in this State;
>
> (3) Causes tortious injury in the State by an act or omission in this State;
>
> (4) Causes tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State.

10 Del. C. § 3104(c)(1)-(4). With the exception of (c)(4), the long-arm statute requires a showing of specific jurisdiction. *See Shoemaker v. McConnell,* 556 F. Supp. 2d 351, 354-55 (D. Del. 2008). Subsection (4) confers general jurisdiction, which requires a greater number of contacts, but allows the exercise of personal jurisdiction even when the claim is unrelated to the forum contacts. *See Applied Biosystems, Inc. v. Cruachem, Ltd.,* 772 F. Supp. 1458, 1466 (D. Del. 1991). If a defendant is found to be within the reach of the long-arm statute, the court then must analyze whether the exercise of personal jurisdiction comports with due process, to wit, whether plaintiff has demonstrated that defendant "purposefully avail[ed] itself of the privilege of conducting activities within the forum state," so that it should "reasonably anticipate being haled into court there." *World–Wide Volkswagen Corp. v. Woodson,* 444 U.S. 286, 297 (1980) (citations omitted). For the court to exercise specific personal jurisdiction consistent with due process, plaintiff's cause of action must have arisen from defendant's activities in the forum State. *See Burger King Corp. v. Rudzewicz,* 471 U.S. 462, 472 (1985).

For the court to exercise general personal jurisdiction consistent with due process, plaintiff's cause of action can be unrelated to defendant's activities in the forum state, so long as defendant has "continuous and systematic contacts with the forum state." *Applied Biosystems, Inc.*, 772 F. Supp. at 1470. In *Daimler AG v. Bauman*, the Supreme Court stated that the "paradigm all-purpose forums for general jurisdiction are a corporation's place of incorporation and principal place of business." *Daimler AG v. Bauman*, —— U.S. ——, 134 S.Ct. 746, 749 (2014). The Supreme Court did not hold that a corporation may be subject to general jurisdiction only in one of these locations, but rejected the notion that "continuous and systematic" contacts alone could confer general jurisdiction, clarifying that the role of general jurisdiction is to "afford plaintiffs recourse to at least one clear and certain forum in which a corporate defendant may be sued on any and all claims." *Id.* at 760–62.

B. Analysis

1. General jurisdiction

As noted, the Supreme Court held in *Daimler* that "[w]ith respect to a corporation, the place of incorporation and principal place of business are "paradig[m] . . . bases for general jurisdiction." *Daimler AG*, 134 S. Ct. at 760. While the Court did reject the idea that these "exemplar bases" are the only places where general jurisdiction could be found, it held that using a "substantial, continuous, and systematic course of business" to confer general jurisdiction is "unacceptably grasping." *Id.* at 761. While defendants may have "regularly and routinely litigated NDA and abbreviated new drug application ("ANDA") cases without contesting jurisdiction in this judicial district" and "engaged in a persistent course of conduct within Delaware by continuously and systematically placing

goods into the stream of commerce for distribution throughout the United States, including Delaware," defendants are not Delaware corporations and do not have a principal places of business in Delaware. (D.I. 1 at ¶¶ 15-16; D.I. 7 at 6) Accordingly, the court finds that it does not have general jurisdiction over defendants.[1]

2. Specific jurisdiction

Plaintiffs allege that this court has specific jurisdiction over MLL. In order to determine if the court has specific personal jurisdiction over a defendant, courts use a two-step inquiry. *Elecs. For Imaging, Inc. v. Coyle*, 340 F.3d 1344, 1349 (Fed. Cir. 2003). First, the court considers "whether a forum state's long-arm statute permits service of process." *Id.* Second, the court considers "whether the assertion of jurisdiction would be inconsistent with due process." *Id.* In *Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755 (Fed. Cir. 2016), plaintiffs sued defendants (MPI and Mylan, Inc.) for patent infringement. MPI prepared and filed an ANDA outside of Delaware and "intend[ed] to direct sales of its drugs into Delaware, among other places, once it ha[d] the requested FDA approval to market them." *Id.* at 758. The Federal Circuit stated that "there is no dispute that [MPI] would be subject to Delaware courts' jurisdiction under Delaware's long-arm statute, [10 Del. C. § 3104,] as long as Delaware's exercise of personal jurisdiction over [MPI] would be consistent with the Fourteenth Amendment's Due Process Clause." *Id.* at 759. "ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic

[1] In light of the Delaware Supreme Court's decision in *Genuine Parts Co. v. Cepec*, 2016 WL 1569077 (Del. 2016), plaintiffs have conceded that consent can no longer be a basis for personal jurisdiction when premised solely on Delaware's registration statute. (D.I. 30 at 12) Accordingly, plaintiffs have withdrawn the argument that MPI is subject to this court's general jurisdiction by registering to do business in Delaware.

drugs" based on the plain text of the Hatch-Waxman Act which, "recognizes the close connection between an ANDA filing and the real-world acts that approval of the ANDA will allow and that will harm patent-owning brand-name manufacturers." *Id.* at 760. The "infringement inquiry called for by § 271(e)(2) is 'whether, if a particular drug **were** put on the market, it **would** infringe the relevant patent' in the usual, non-artificial sense." *Acorda*, 817 F.3d at 760 (quoting *Bristol–Myers Squibb Co. v. Royce Labs., Inc.,* 69 F.3d 1130, 1135 (Fed. Cir. 1995)) (emphasis in original). By filing the NDA, MPI caused "an 'artificial act of infringement' allowing the brand-name manufacturer to . . . litigate patent validity and coverage." *Id.* (quoting *Eli Lilly & Co. v. Medtronic, Inc.,* 496 U.S. 661, 678 (1990)). Moreover, "[t]he magnitude and costs of the work required before the ANDA is filed soundly link the ANDA filing to the filer's entry into the market to compete with the brand-name manufacturer if approval is obtained." *Id.* at 761. The Federal Circuit concluded that MPI's NDA "filings, including its certifications regarding the patents at issue here, are thus suit-related, and they have a substantial connection with Delaware because they reliably, non-speculatively predict Delaware activities by Mylan." *Id.* at 762.

In the case at bar, MLL sought "approval to market an injectable tigecycline product in the United States." As in *Acorda*, MLL's "ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs." Although MLL has not yet taken any activity in Delaware in this regard, it is undisputable that Delaware is a "State where [MLL and/or defendants] will engage in that marketing if the [NDA is] approved."[2] *Id.* at 760.

[2] For the same reasons, Delaware's long-arm statute reaches MLL.

MLL may still "defeat specific personal jurisdiction by sufficiently demonstrating that other considerations render jurisdiction unreasonable." *Id.* at 763. To assist in determining when jurisdiction is unreasonable, the Supreme Court has set out a series of factors for consideration, which include "the burden on the defendant," "the forum State's interest in adjudicating the dispute," "the plaintiff's interest in obtaining convenient and effective relief," "the interstate judicial system's interest in obtaining the most efficient resolution of controversies," and "the shared interest of the several States in furthering fundamental substantive social policies." *World-Wide Volkswagen Corp.*, 444 U.S. at 292.

Defendants have litigated (and initiated) disputes in Delaware. Delaware has an interest in adjudicating this dispute, as plaintiffs are Delaware corporations. *See McGee v. Int'l Life Ins. Co.*, 355 U.S. 220, 223 (1957) (noting that a forum state has a "manifest interest in providing effective means of redress for its residents."). Plaintiffs' "interest in obtaining convenient and effective relief" is met here. Plaintiffs may obtain relief either in Delaware or in West Virginia. This factor is neutral. *World-Wide Volkswagen Corp.*, 444 U.S. at 292. Litigating this case in Delaware would, as plaintiffs note, "advance judicial efficiency," as other cases regarding tigecycline products are currently before this court. (D.I. 21 at 16); *AstraZeneca AB v. Mylan Pharm., Inc.*, 72 F. Supp. 3d 549, 560 (D. Del. 2014).

4. Agency theory

Plaintiffs request that the court impute MLL's jurisdictional contacts to Mylan Inc., Mylan N.V., and MPI under an agency theory, as MLL acted under the control of Mylan Inc., Mylan N.V., and MPI in preparing and filing the NDA, as well as in sending the

notice letter to Pfizer. (D.I. 21 at 12) To "establish jurisdiction under an agency theory," plaintiffs must "show that the defendant exercises control over the activities of the third-party." *Celgard, LLC v. SK Innovation Co.*, 792 F.3d 1373, 1379 (Fed. Cir. 2015); *see Daimler AG,* 134 S.Ct. at 759 n. 13 ("[A] corporation can purposefully avail itself of a forum by directing its agents or distributors to take action there."); *Cephalon, Inc. v. Watson Pharm., Inc.*, 629 F. Supp. 2d 338, 348 (D. Del. 2009) ("Under the agency theory, the court may attribute the actions of a subsidiary company to its parent where the subsidiary acts on the parent's behalf or at the parent's direction."). If the court finds that an agency relationship exists, the court "will not ignore the separate corporate identities of parent and subsidiary, but will consider the parent corporation responsible for specific jurisdictional acts of the subsidiary." *Applied Biosystems, Inc. v. Cruachem, Ltd.*, 772 F. Supp. 1458, 1463 (D. Del. 1991). This theory applies "not only to parents and subsidiaries, but also to companies that are 'two arms of the same business group,' operate in concert with each other, and enter into agreements with each other that are nearer than arm's length." *Cephalon, Inc.*, 629 F. Supp. 2d at 348. To decide if an agency relationship exists, "a court should focus its inquiry on the arrangement between the parent and the subsidiary, the authority given in that arrangement, and the relevance of that arrangement to the plaintiff's claim." *C.R. Bard, Inc. v. Guidant Corp.*, 997 F. Supp. 556, 560 (D. Del. 1998); *see Wesley-Jessen Corp. v. Pilkington Visioncare, Inc.*, 863 F. Supp. 186, 188 (D. Del. 1993) (finding an agency relationship when "the business strategies and financial statements of the defendant companies are analyzed as a unit, and these companies present themselves as a unified entity to their employees and to the marketplace"). Other factors have been described as "the extent

of overlap of officers and directors, methods of financing, the division of responsibility for day-to-day management, and the process by which each corporation obtains its business." *Applied Biosystems, Inc.*, 772 F. Supp. at 1463. No specific factor is "either necessary or determinative," and instead "it is the specific combination of elements which is significant." *Id.* However, "only acts by the agent which were directed by the principal may provide the basis for jurisdiction." *Id.* at 1467.

At bar, plaintiffs allege many of the factors from *Applied Biosystems* in the complaint.[3] Plaintiffs, through "sworn affidavits" and "other competent evidence," have shown that MPI and MLL have close connections and arrangements that are unusual for "truly independent companies." *Wesley-Jessen Corp.*, 863 F. Supp. at 189; *Purdue Pharma L.P. v. Collegium Pharma., Inc.*, 2015 WL 4653164 (D. Del. 2015). Specifically, plaintiffs include correspondence to the FDA transferring ownership of NDA No. 208461 from MPI to MLL, as well as substantive correspondence to the FDA from MPI regarding such NDA. (D.I. 474, ex. C, E) The court will impute MLL's contacts to MPI, as there is enough evidence to support an agency relationship. Plaintiffs have not produced information that Mylan Inc. and Mylan N.V. directed MLL's action. However, more information regarding Mylan Inc.'s and Mylan N.V.'s role could provide the necessary evidence, and plaintiffs have demonstrated that the allegations are not

[3] Including that defendants have overlapping officers and directors. (D.I. 1 at ¶ 20) Plaintiffs use statements from Mylan N.V.'s website which state that Mylan N.V. applies "one global quality standard," operates "a global vertically-integrated manufacturing platform," and that defendants conduct business through MLL. (*Id.* at ¶¶ 19, 21) Furthermore, plaintiffs allege Mylan N.V. issues press releases for Mylan N.V., MPI, and MLL, and Mylan N.V. receives FDA warning letters sent to MLL and MPI. (*Id.* at ¶¶ 21-22) According to plaintiffs, when Mylan Inc. and MLL were held jointly and severally liable for a judgment of $21.7 million by the European Commission, Mylan Inc. paid the full amount. (*Id.* at ¶ 23)

"clearly frivolous." *Acorda*, 78 F. Supp. 3d at 598; *see Toys "R" Us, Inc. v. Step Two, S.A.*, 318 F.3d 446, 456 (3d Cir. 2003) ("courts are to assist the plaintiff by allowing jurisdictional discovery unless the plaintiff's claim is 'clearly frivolous.'"). Accordingly, the court grants jurisdictional discovery to plaintiffs to determine whether an agency relationship exists between Mylan Inc. and Mylan N.V. and MLL.[4]

V. VENUE

A. Standard of Review

Rule 12(b)(3) of the Federal Rules of Civil Procedure provides that a motion to dismiss may be made on the basis of improper venue. Fed. R. Civ. P. 12(b)(3). The purpose of venue, in most instances, "is to protect the defendant against the risk that a plaintiff will select an unfair or inconvenient place of trial." *Cottman Transmission Sys., Inc. v. Martino,* 36 F.3d 291, 294 (3d Cir. 1994). Title 28 of U.S.C. § 1400(b) provides that a "civil action for patent infringement may be brought in the judicial district where the defendant resides, or where the defendant has committed acts of infringement and has a regular and established place of business." 28 U.S.C. § 1400(b) (2006). For the purposes of venue, a defendant "that is a corporation . . . reside[s] in any judicial district in which it is subject to personal jurisdiction at the time the action is commenced." *Id.* § 1391(c). Additionally, § 1391(d) states that an alien may be sued in any district.

B. Analysis

[4] Defendants' 12(b)(6) motion depends on the allegations that there is no agency relationship between defendants. As discussed above, plaintiffs' allegations support an agency relationship and are, therefore, sufficient for purposes of defeating a 12(b)(6) motion.

The parties do not dispute that venue for a patent suit is proper wherever the court has personal jurisdiction. (D.I. 21 at 17, D.I. 23 at 7) Furthermore, the Federal Circuit has held that "venue in a patent infringement case includes any district where there would be personal jurisdiction over the corporate defendant at the time the action is commenced." *VE Holding Corp. v. Johnson Gas Appliance Co.*, 917 F.2d 1574, 1583 (Fed. Cir. 1990). As discussed above, the court has personal jurisdiction over MLL and MPI. The court has permitted jurisdictional discovery for purposes of determining if an agency relationship exists between MLL, Mylan Inc., and Mylan N.V, thus conferring personal jurisdiction. Defendants' motion to dismiss for improper venue is dismissed without prejudice to renew. *See Belden Techs., Inc. v. LS Corp.*, 626 F. Supp. 2d 448, 460 (D. Del. 2009).

VII. CONCLUSION

For the foregoing reasons, the court denies defendants' motion to dismiss for lack of personal jurisdiction as to MPI and MLL. The court grants plaintiffs' request for jurisdictional discovery and denies without prejudice to renew defendants' motion to dismiss for lack of personal jurisdiction as to Mylan Inc. and Mylan N.V.; for improper venue; and for failure to state a claim. (D.I. 6) An appropriate order shall issue.