

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PFIZER INC., WYETH LLC, PFIZER)
PHARMACEUTICALS LLC, PF PRISM)
C.V. and PFIZER MANUFACTURING)
HOLDINGS LLC,)

Plaintiffs,)

v.)

Civil Action No. 15-26-SLR-SRF

MYLAN INC., AGILA SPECIALTIES)
PRIVATE LTD. and MYLAN)
PHARMACEUTICALS INC.,)

Defendant.)

REPORT AND RECOMMENDATION

I. INTRODUCTION

Presently before the court in this patent infringement action is a motion to dismiss for lack of personal jurisdiction and failure to state a claim upon which relief can be granted pursuant to Federal Rules of Civil Procedure 12(b)(2) and 12(b)(6), filed by defendants Agila Specialties Private Ltd. (“Agila”), Mylan Inc. (“Mylan”), and Mylan Pharmaceuticals Inc. (“MPI”) (collectively, “defendants”). (D.I. 16) For the following reasons, I recommend that the court deny the Rule 12(b)(2) motion to dismiss as it pertains to Agila and MPI, grant the Rule 12(b)(2) motion to dismiss as it pertains to Mylan but permit limited jurisdictional discovery, and deny the Rule 12(b)(6) motion as it pertains to MPI.

II. BACKGROUND

This action arises out of defendants’ submission of Abbreviated New Drug Application (“ANDA”) No. 203309 to the United States Food and Drug Administration. (D.I. 1 at ¶ 32) Plaintiffs Pfizer Inc., Wyeth LLC, Pfizer Pharmaceuticals LLC, PF Prism C.V. and Pfizer

Manufacturing Holdings LLC (collectively, “plaintiffs”) assert that defendants’ ANDA filing constitutes infringement of United States Patent Nos. 7,879,828 (“the ‘828 patent”) and 8,372,995 (“the ‘995 patent”), both of which relate to plaintiffs’ TYGACIL® brand tigecycline injectable IV infusion. (*Id.* at ¶ 1) TYGACIL® is an antibacterial for the treatment of complicated skin and intra-abdominal infections, and community-acquired bacterial pneumonia. (*Id.* at ¶ 27)

The ‘828 patent, entitled “Tigecycline Compositions and Methods of Preparation,” was issued on February 1, 2011 to Wyeth LLC, as assignee. (*Id.* at ¶ 28) In 2011, PF PRISM C.V. took an exclusive license to the ‘828 patent and the patent application which later issued as the ‘995 patent. (*Id.* at ¶ 29) PF PRISM C.V. subsequently contributed its rights under the exclusive license to Pfizer Pharmaceuticals LLC. (*Id.*) The ‘995 patent, entitled “Crystalline Solid Forms of Tigecycline and Methods of Preparing Same,” was issued on February 12, 2013 to Wyeth LLC, as assignee, and subject to an exclusive license. (*Id.* at ¶ 30) Pfizer has all right, title, and interest in the ‘828 patent and the ‘995 patent. (*Id.* at ¶ 31)

Defendant Agila is an Indian corporation with a place of business in West Virginia. (*Id.* at ¶ 8) Defendant MPI is a West Virginia corporation with its principal place of business in West Virginia. (*Id.* at ¶ 9) MPI is registered to do business in Delaware, has an agent for service of process in Delaware, and is licensed by the Delaware Board of Pharmacy to sell and distribute pharmaceuticals. (*Id.* at ¶ 22) Defendant Mylan is a Pennsylvania corporation with its principal place of business in Pennsylvania. (*Id.* at ¶ 7) Mylan wholly owns and controls both Agila and MPI. (*Id.* at ¶¶ 8-9) Mylan’s annual reports include financial information from Agila and MPI, and all three companies have overlapping officers, directors, and management. (*Id.* at ¶¶ 17-18)

Defendants notified plaintiffs Wyeth LLC, Pfizer Inc., and PF Prism C.V. in a letter dated November 26, 2014 (the “Notice Letter”) that they had submitted an ANDA to the Food and Drug Administration (“FDA”) seeking approval for tigecycline injectable IV infusion, a generic version of plaintiffs’ TYGACIL® product. (*Id.* at ¶ 32; D.I. 25, Ex. A) The Notice Letter was drafted in Atlanta, Georgia, and was sent to Wyeth LLC in New Jersey, Pfizer Inc. in New York, and PF Prism C.V. in the Netherlands. (D.I. 25, Ex. A) Defendants’ ANDA contained a certification that the ‘828 patent and the ‘995 patent would not be infringed by the manufacture, use, offer for sale, sale, or importation of defendants’ ANDA product or, alternatively, that those patents are invalid and/or unenforceable. (D.I. 1 at ¶ 34)

Plaintiffs filed the instant case on January 8, 2015, alleging that defendants infringed the patents-in-suit by filing the ANDA application with the FDA. (D.I. 1) The following day, plaintiffs filed a nearly identical suit against defendants in the Northern District of West Virginia (“the West Virginia Action”). *Pfizer Inc. et al. v. Mylan Inc. et al.*, N.D. W. Va. C.A. No. 15-04. On February 13, 2015, defendants answered plaintiffs’ complaint in the West Virginia Action and consented to jurisdiction. (*Id.*, D.I. 16) Defendants filed their answer and counterclaims in the case at bar on March 2, 2015, asserting that this court lacks personal jurisdiction over each of the defendants and that MPI is not a proper party to this action. (D.I. 9) Plaintiffs answered defendants’ counterclaims in the present action on March 5, 2015, and answered the counterclaims in the West Virginia Action on March 6, 2015. (D.I. 13) Plaintiffs also filed a motion to stay in the West Virginia Action, which was granted on April 24, 2015. (N.D. W. Va. C.A. No. 15-04, D.I. 22) On March 30, 2015, defendants filed the instant motion to dismiss for lack of personal jurisdiction and failure to state a claim. (D.I. 16)

III. LEGAL STANDARDS

A. Personal Jurisdiction

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 the 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 the plaintiff and resolve all factual disputes in the plaintiff's favor. *Miller Yacht Sales, Inc. v. Smith*, 384 F.3d 93, 97 (3d Cir. 2004); *Traynor v. Liu*, 495 F. Supp. 2d 444, 448 (D. Del. 2007). Once a jurisdictional defense has been raised, the plaintiff bears the burden of establishing, with reasonable particularity, that sufficient minimum contacts have occurred between the 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, the 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). A plaintiff "need only establish a *prima facie* case of personal jurisdiction" when the court has not held an evidentiary hearing. *O'Connor v. Sandy Lane Hotel Co.*, 496 F.3d 312, 316 (3d Cir. 2007).

To establish personal jurisdiction, a plaintiff must produce facts sufficient to satisfy two requirements by a preponderance of the evidence, one statutory and one constitutional. See *Time Share*, 735 F.2d at 66; *Reach & Assocs. v. Dencer*, 269 F. Supp. 2d 497, 502 (D. Del. 2003).

With respect to the statutory requirement, the court must determine whether there is a statutory basis for jurisdiction under the forum state's long-arm statute. See *IMO Indus., Inc. v. Kiekert AG*, 155 F.3d 254, 259 (3d Cir. 1998); *Reach & Assocs.*, 269 F. Supp. 2d at 502. The constitutional basis requires the court to determine whether the exercise of jurisdiction comports

with the defendant's right to due process. *See id.*; *see also Autogenomics, Inc. v. Oxford Gene Tech. Ltd.*, 566 F.3d 1012, 1016 (Fed. Cir. 2009) (noting that the court must apply the law of the Federal Circuit to the constitutional inquiry in patent cases); *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945).

Pursuant to the relevant portions of Delaware's long-arm statute, 10 *Del. C.* § 3104(c)(1)-(4), a court may exercise personal jurisdiction over a defendant when the 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 (c)(4) confers general jurisdiction, which requires a great 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 by determining whether the plaintiff has demonstrated that the 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). The court may exercise specific personal jurisdiction consistent with

due process when the plaintiff's cause of action arises from the defendant's activities in the forum state. *See Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472 (1985). The court may exercise general personal jurisdiction consistent with due process when the plaintiff's cause of action is unrelated to the defendant's activities in the forum state, so long as the defendant has "continuous and systematic contacts with the forum state." *Applied Biosystems, Inc.*, 772 F. Supp. at 1458.

In *Daimler AG v. Bauman*, 134 S. Ct. 746, 749 (2014), 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." 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. As a result of the Supreme Court's decision in *Daimler*, the traditional grounds for exercising jurisdiction over drug company defendants in Hatch-Waxman litigation have been narrowed. *See Acorda Therapeutics, Inc. v. Mylan Pharm. Inc.*, 78 F. Supp. 3d 572, 583, 597 (D. Del. 2015) (noting that specific jurisdiction has been traditionally disfavored as a basis for finding personal jurisdiction in ANDA cases, and the Supreme Court's decision in *Daimler* circumscribed the application of general jurisdiction).

B. Failure to State a Claim

Rule 12(b)(6) permits a party to move to dismiss a complaint for failure to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). When considering a Rule 12(b)(6) motion to dismiss, the court must accept as true all factual allegations in the complaint and view

them in the light most favorable to the plaintiff. *Umland v. Planco Fin. Servs.*, 542 F.3d 59, 64 (3d Cir. 2008).

To state a claim upon which relief can be granted pursuant to Rule 12(b)(6), a complaint must contain a “short and plain statement of the claim showing that the pleader is entitled to relief.” Fed. R. Civ. P. 8(a)(2). Although detailed factual allegations are not required, the complaint must set forth sufficient factual matter, accepted as true, to “state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009). A claim is facially plausible when the factual allegations allow the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. *Iqbal*, 556 U.S. at 663; *Twombly*, 550 U.S. at 555-56.

When determining whether dismissal is appropriate, the court must take three steps.¹ *See Santiago v. Warminster Twp.*, 629 F.3d 121, 130 (3d Cir. 2010). First, the court must identify the elements of the claim. *Iqbal*, 556 U.S. at 675. Second, the court must identify and reject conclusory allegations. *Id.* at 678. Third, the court should assume the veracity of the well-pleaded factual allegations identified under the first prong of the analysis, and determine whether they are sufficiently alleged to state a claim for relief. *Id.*; *see also Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011). The third prong presents a context-specific inquiry that “draw[s] on [the court’s] experience and common sense.” *Id.* at 663-64; *see also Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). As the Supreme Court instructed in *Iqbal*, “where the well-pleaded facts do not permit the court to infer more than the mere possibility of

¹Although *Iqbal* describes the analysis as a “two-pronged approach,” the Supreme Court observed that it is often necessary to “begin by taking note of the elements a plaintiff must plead to state a claim.” 556 U.S. at 675, 679. For this reason, the Third Circuit has adopted a three-pronged approach. *See Santiago v. Warminster Twp.*, 629 F.3d 121, 130 n.7 (3d Cir. 2010); *Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011).

misconduct, the complaint has alleged - but it has not ‘show[n]’ - ‘that the pleader is entitled to relief.’” *Iqbal*, 556 U.S. at 679 (quoting Fed. R. Civ. P. 8(a)(2)).

IV. DISCUSSION

A. Personal Jurisdiction

1. Agila

a. Specific jurisdiction

Defendants allege that the exercise of personal jurisdiction over Agila in Delaware would not comport with the minimum contacts requirement of the due process analysis because Agila is an Indian corporation with its principal place of business in India, it has not registered under Delaware’s business registration statute, it does not have any employees or facilities in Delaware, and the preparation and filing of the ANDA were not performed in Delaware. (D.I. 17 at 7) In response, plaintiffs allege that Agila is subject to specific jurisdiction in this district because it filed an ANDA related to the TYGACIL® patents and sent the Notice Letter to Pfizer, a Delaware corporation. (D.I. 25 at 9-10) Plaintiffs argue that Agila’s litigation history in Delaware also supports a finding that Agila reasonably anticipated being haled into court in Delaware. (*Id.* at 11)

“Specific jurisdiction refers to the situation in which the cause of action arises out of or relates to the defendant’s contacts with the forum It contrasts with general jurisdiction, in which the defendant’s contacts have no necessary relationship to the cause of action.” *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1562 n.10 (Fed. Cir. 1994) (internal citations and quotation marks omitted); *see also Boone v. Oy Partek Ab*, 724 A.2d 1150, 1155 (Del. Super. Ct. 1997). Determining the existence of specific jurisdiction requires an inquiry into “whether there was some act by which the defendant purposefully avail[ed] itself of the privilege

of conducting activities within the forum State, thus invoking the benefits and protections of its laws.” *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 131 S. Ct. 2846, 2854 (2011) (internal quotation marks omitted). A defendant may be constitutionally haled into court under a theory of specific jurisdiction, consistent with the defendant’s right to due process, if: “(1) . . . the defendant purposefully directed activities at residents of the forum; (2) . . . the claim arises out of or relates to those activities; and (3) . . . assertion of personal jurisdiction is reasonable and fair.” *Nuance Commc’ns, Inc. v. Abby Software House*, 626 F.3d 1222, 1231 (Fed. Cir. 2010).

The jurisdictional analysis in ANDA cases presents unique challenges because infringement under § 271(e)(2) is “a highly artificial act.” *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990). As a statutory creation, “infringement under § 271(e)(2) has no readily apparent situs of injury for the purpose of finding specific jurisdiction,” and patent litigation is built into the approval process of the Food and Drug Administration (“FDA”). *AstraZeneca AB v. Mylan Pharm., Inc.*, 72 F. Supp. 3d 549, 558 (D. Del. 2014), *aff’d*, *Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, --- F.3d ----, 2016 WL 1077048 (Fed. Cir. Mar. 18, 2016). The Federal Circuit recently clarified the issue, holding that the filing of an ANDA, combined with distribution channels reaching Delaware, satisfies the minimum contacts standard because it “confirms [the defendant’s] plan to commit real-world acts that would make it liable for infringement if it commits them without the patentees’ permission and it is wrong in its challenges to patent scope or validity.” *Acorda*, 2016 WL 1077048, at *4 (“[I]t 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 and the lawsuit is about patent constraints on such in-State marketing.”).

This court has specific jurisdiction² over Agila because Agila filed the ANDA and plans to market and sell its generic product throughout the United States, including in Delaware. *See Acorda*, 2016 WL 1077048, at *3. As the Federal Circuit recently explained, the “costly, significant step” of filing an ANDA to engage in future activities, including the marketing of a generic drug, constitutes an activity purposefully directed at Delaware. *Id.* (“In our view, 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.”). Agila’s conduct in filing the ANDA indicates its plan to market the proposed generic drug in Delaware and elsewhere, and its marketing activity is suit-related because this action regarding patent validity and scope will affect the ANDA approval process. *Id.* Therefore, pursuant to the Federal Circuit’s decision in *Acorda*, Agila’s conduct in filing the ANDA is sufficiently “suit-related” and has a “substantial connection” with Delaware. *Id.* (quoting *Walden v. Fiore*, 134 S. Ct. 1115, 1121 (2014)).

Although the ANDA filing and distribution channels are all that is required to establish minimum contacts with Delaware pursuant to the Federal Circuit’s decision in *Acorda*, Agila’s sending of the Notice Letter to a Delaware corporation provides further support for the minimum contacts analysis pursuant to recent case law from this district. *See Acorda Therapeutics, Inc. v. Mylan Pharm. Inc.*, 78 F. Supp. 3d 572 (D. Del. 2015); *AstraZeneca*, 72 F. Supp. 3d 549 (D. Del. 2014). Even though the Notice Letter was not sent to Delaware,³ the exercise of specific

² Plaintiffs do not argue that general jurisdiction exists over Agila in Delaware.

³ Defendants cite a string of cases from the Federal Circuit holding that the sending of an infringement notice letter is insufficient to satisfy the due process requirement when exercising jurisdiction over a defendant. *See Silent Drive, Inc. v. Strong Indus., Inc.*, 326 F.3d 1194, 1202 (Fed. Cir. 2003) (holding that “the sending of letters threatening infringement litigation is not sufficient to confer personal jurisdiction.”); *Inamed Corp. v. Kuzmak*, 249 F.3d 1356, 1361 (Fed.

jurisdiction over a defendant is appropriate when the ANDA notice letter is directed to a Delaware corporation and sent to a location outside of Delaware. *See Acorda*, 78 F. Supp. 3d at 593 (“It does not follow, however, that the absence of a mailing into Delaware eliminates the possibility of exercise of specific jurisdiction.”). The sending of a notice letter to a Delaware corporation outside of Delaware cannot be “the *sole* basis for finding jurisdiction” over the defendants, but as previously discussed, the filing of the ANDA and the distribution channels for marketing the generic drug are sufficient to meet the minimum contacts requirement of the due process analysis.⁴ *Acorda*, 2016 WL 1077048, at *6. In contrast to Judge Andrews’ reasoning in

Cir. 2001) (“We have . . . repeatedly held that the sending of an infringement letter, without more, is insufficient to satisfy the requirements of due process when exercising jurisdiction over an out-of-state patentee.”); *Red Wing Shoe Co. v. Hockerson-Halberstadt, Inc.*, 148 F.3d 1355, 1361 (Fed. Cir. 1998) (same). These cases do not specifically address the significance of notice letters in the ANDA context, which is unique due to the forward-looking nature of the injury as compared to standard infringement. *See Acorda*, 2016 WL 1077048, at *4. Defendants also rely on *Glaxo Inc. v. Genpharm Pharm., Inc.*, 796 F. Supp. 872 (E.D.N.C. 1992), which took place in the ANDA context, but is factually distinct from the matter presently before the court because the notice letter was sent to the plaintiff’s state of incorporation. For these reasons, the court has largely focused its analysis on the Federal Circuit’s recent decision in *Acorda Therapeutics Inc. v. Mylan Pharm. Inc.* and other recent ANDA cases from this district addressing the impact of ANDA notice letters on the jurisdictional analysis.

⁴ The record reflects that Agila has participated in litigation within this district as a defendant on six occasions, and four of those cases were dismissed at the pleadings stage. (D.I. 25, Ex. D; *see also* C.A. No. 12-520-GMS, C.A. No. 13-851-SLR, C.A. No. 13-1679-GMS, C.A. No. 14-1438-RGA, C.A. No. 14-1499-LPS, C.A. No. 13-2080-GMS) Although the *Acorda* court considered the defendant’s litigation history in Delaware in connection with the personal jurisdiction due process analysis, the court noted that the defendant in that matter had litigated over fifty cases in Delaware. Likewise, the *AstraZeneca* court concluded that the exercise of personal jurisdiction over the defendant would not offend traditional notions of fair play and substantial justice because the defendant initiated six lawsuits in Delaware and defended against many more lawsuits in this forum. *AstraZeneca*, 72 F. Supp. 3d at 555, 560 (“Mylan is no stranger to ANDA litigation in Delaware, and the court is not convinced that it would be ‘unfair’ to subject Mylan to suit here.”). Agila’s litigation history in Delaware does not reach the same scale as that of the defendants in *Acorda* and *Astra Zeneca* and, as such, its litigation history does not weigh as heavily in the analysis. More importantly, Agila’s litigation history in Delaware, by itself, is insufficient to establish personal jurisdiction. *See Acorda*, 78 F. Supp. 3d at 597; *Novartis*, 2015 WL 4720578, at *5.

Novartis Pharm. Corp. v. Zydus Noveltech Inc., C.A. No. 14-1104-RGA, 2015 WL 4720578 (D. Del. Aug. 7, 2015), that future sales of the product in Delaware are too speculative, the Federal Circuit concluded that the ANDA filings and distribution channels sufficiently affirm plans to market the proposed drug in Delaware, *Acorda*, 2016 WL 1077048, at *6.⁵

Exercising personal jurisdiction over Agila under the circumstances presently before the court is also consistent with traditional notions of fair play and substantial justice. Three other TYGACIL® ANDA cases are currently underway in this court, and exercising jurisdiction would advance judicial efficiency as a result. *See Acorda*, 78 F. Supp. 3d at 593-96 (“The lack of unfairness to [the defendant] . . . is particularly evident from the chronology of events relevant to this litigation . . . including particularly that when [the defendant] sent the Mylan Notice Letter, [the plaintiff] and already initiated Ampyra® related litigation in Delaware.”). Unlike the circumstances before Chief Judge Stark in *Acorda*, Agila has not registered to do business, appointed a registered agent, registered with the Board of Pharmacy, or frequently participated in ANDA litigation in Delaware. *See Acorda*, 78 F. Supp. 3d at 593. However, Chief Judge Stark placed particular emphasis on the fact that litigation relating to the generic drug was ongoing in Delaware when the notice letter was sent. *Id.* at 594 (“The lack of unfairness to Mylan Pharma from having to litigate its efforts to obtain FDA approval of [the generic product] in the District of Delaware is particularly evident from the chronology of events relevant to this litigation . . .

⁵ In *Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 2016 WL 1077048, at *14-16 (Fed. Cir. Mar. 18, 2016), Judge O’Malley issued a concurring opinion analyzing specific jurisdiction under the Supreme Court’s decision in *Calder v. Jones*, 465 U.S. 783 (1984). Pursuant to Judge O’Malley’s reasoning, the harm in Delaware is immediate, not future, because the targeted nature of an ANDA filing which challenges a particular patent owned by a known party at a known location causes immediate harm to the intellectual property rights of that known party, calling into question the value of its business even before a single sale of product is made. *Acorda*, 2016 WL 1077048, at *15.

including particularly that when Mylan Pharma sent the Mylan Notice Letter, Acorda had already initiated Ampyra® related litigation in Delaware.”).

Turning to the factors discussed in *Burger King* regarding whether the exercise of personal jurisdiction would be reasonable and fair in the present case, the court reaches the same conclusion. *See Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472 (1985) (evaluating “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 social policies.”). First, Agila has not articulated a specific burden associated with litigating in Delaware, and has a history of previous litigation in Delaware. (D.I. 25, Ex. D; *see also* C.A. No. 12-520-GMS, C.A. No. 13-851-SLR, C.A. No. 13-1679-GMS, C.A. No. 14-1438-RGA, C.A. No. 14-1499-LPS, C.A. No. 13-2080-GMS) Second, Delaware’s interest in litigating the present dispute is significant because the filing of the ANDA caused injury to a Delaware corporation, and because there is ongoing related ANDA litigation regarding the patents-in-suit in Delaware. *See Acorda*, 78 F. Supp. 3d at 595; *AstraZeneca*, 72 F. Supp. 3d at 560 (observing that resolution of the plaintiff’s ten ANDA suits in a single district “would promote judicial economy and avoid the possibility of inconsistent outcomes.”). With respect to the third and fourth *Burger King* factors, plaintiffs’ interest in obtaining convenient and effective relief and the judicial system’s interest in obtaining the most efficient result favor litigating in Delaware because there is co-pending litigation in Delaware regarding the same patents-in-suit. *Acorda*, 78 F. Supp. 3d at 595; *AstraZeneca*, 72 F. Supp. 3d at 560. Consequently, “there is no substantial argument that considerations of unfairness override the

minimum-contacts basis for Delaware’s exercise of specific personal jurisdiction over” Agila. *Acorda*, 2016 WL 1077048, at *7.

b. Rule 4(k)

Defendants contend that personal jurisdiction over Agila exists in West Virginia, where Agila maintains substantial contacts and has consented to jurisdiction, precluding application of the federal long arm statute pursuant to Rule 4(k)(2). (D.I. 17 at 7-8) Plaintiffs contend that Rule 4(k)(2) is not the exclusive avenue by which a federal court may exercise jurisdiction over foreign corporations, in light of the alternative grounds for personal jurisdiction available in Rule 4(k)(1)(A). (D.I. 25 at 11-12)

Under Federal Rule of Civil Procedure 4(k), a district court usually exercises personal jurisdiction according to the law of the state in which it sits. Fed. R. Civ. P. 4(k)(1)(A) (“Serving a summons or filing a waiver of service establishes personal jurisdiction over a defendant . . . who is subject to the jurisdiction of a court of general jurisdiction in the state where the district court is located . . .”). The court previously determined that plaintiffs satisfied the due process analysis in accordance with Rule 4(k)(1)(A). *See* § IV.A.1.a, *supra*. Therefore, the court need not apply the federal long-arm statute set forth at Rule 4(k)(2).

c. Imputation of Agila’s contacts to MPI and Mylan

Plaintiffs allege that Agila’s jurisdictional contacts should be imputed to Mylan and MPI because Agila acted under the control of Mylan and MPI in preparing and filing the ANDA and sending the Notice Letter to Pfizer. (D.I. 25 at 12) In response, defendants contend that plaintiffs have failed to establish an agency relationship between either Mylan and Agila or MPI and Agila. (D.I. 28 at 7-9) Moreover, defendants allege that Mylan’s signing of a patent amendment in West Virginia and receipt of a copy of the Notice Letter do not establish any

contact with Delaware. (*Id.* at 7-8) Defendants refute plaintiffs' assertion that "discovery will reveal evidence of" Mylan and MPI's involvement in Agila's ANDA because the ANDA itself reflects no such involvement. (*Id.* at 8-9)

"Agency relationships . . . may be relevant to the existence of specific jurisdiction," *Daimler*, 134 S. Ct. at 759 n.13, and courts within this district have imputed jurisdictional contacts between parent corporations and their subsidiaries, as well as between subsidiaries of the same corporation, *see 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 discretion." *Intellectual Ventures I LLC v. Nikon Corp.*, 935 F. Supp. 2d 787, 793 (D. Del. 2013) (quoting *C.R. Bard, Inc. v. Guidant Corp.*, 997 F. Supp. 556, 560 (D. Del. 1998)). In conducting this inquiry, the court should focus 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*, 997 F. Supp. at 560; *see also Applied Biosystems*, 772 F. Supp. at 1464 ("[O]nly the precise conduct shown to be instigated by the parent is attributed to the parent"); *Freres v. SPI Pharma, Inc.*, 629 F. Supp. 2d 374, 384-85 (D. Del. 2009) (same). When the agency theory is applied not only to parents and subsidiaries, but also to two subsidiary companies, the court analyzes whether the subsidiaries 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." *Intellectual Ventures*, 935 F. Supp. 2d at 793 (quoting *Cephalon*, 629 F. Supp. 2d at 348; *Wesley-Jessen Corp. v. Pilkington Visioncare, Inc.*, 863 F. Supp. 186, 188-89 (D. Del. 1993)). The agency theory does not treat the parent and subsidiary as one entity, but rather attributes specific acts to the parent because of the parent's authorization of those acts.

Cephalon, 629 F. Supp. 2d at 348 (citing *C.R. Bard*, 997 F. Supp. at 560; *Applied Biosystems*, 772 F. Supp. at 1464).

Although the complaint establishes that Agila and MPI are subsidiaries of Mylan, plaintiffs have failed to establish the existence of an agency relationship among the defendants. (D.I. 1 at ¶¶ 7-8) The fact that Agila copied Mylan on the Notice Letter does not demonstrate direct involvement by Mylan in the ANDA process to the degree contemplated by the case law addressing the agency theory of specific jurisdiction. *See Applied Biosystems*, 772 F. Supp. at 1464 (“[O]nly the precise conduct shown to be instigated by the parent is attributed to the parent”). Mylan’s passive receipt of a copy of the Notice Letter is not indicative of a “nearer than arm’s length” relationship in which Mylan and Agila worked in concert to send the Notice Letter, which was prepared and mailed by Agila in Georgia. (D.I. 1 at ¶ 20) Plaintiffs stress that a Mylan employee also signed a patent amendment to Agila’s ANDA, further illustrating Mylan’s involvement in the ANDA process. (D.I. 18 at ¶ 12) However, these allegations again fall short of demonstrating that Mylan authorized or directed Agila’s actions with respect to the filing of the ANDA. Because more information on Mylan’s role in Agila’s submission of the ANDA could alter the analysis on this point, the court concludes that jurisdictional discovery⁶ limited to establishing the agency relationship between Mylan and Agila should be permitted.

⁶ Generally, “jurisdictional discovery should be allowed unless the plaintiffs’ claim [of personal jurisdiction] is clearly frivolous.” *Mass. Sch. of Law at Andover, Inc. v. Am. Bar Ass’n*, 107 F.3d 1026, 1042 (3d Cir. 1997) (internal quotation marks omitted); *see also Toys “R” Us, Inc. v. Step Two, S.A.*, 318 F.3d 446, 456 (3d Cir. 2003). However, a court should not permit discovery as a matter of course simply because a plaintiff has named a particular party as a defendant. *See Hansen v. Neumueller GmbH*, 163 F.R.D. 471, 474 (D. Del. 1995). Instead, before allowing jurisdictional discovery to proceed, “[t]he court must be satisfied that there is some indication that this particular defendant is amenable to suit in this forum.” *Id.* at 475.

With respect to the analysis of an agency relationship between MPI and Agila, the agency theory of specific jurisdiction is not determinative as to MPI because of the court's conclusion that MPI consented to personal jurisdiction by registering to do business in Delaware. *See* § IV.A.2.b, *infra*. Because the court has already concluded that MPI is subject to this court's general jurisdiction, jurisdictional discovery is not necessary with respect to MPI. *See Acorda*, 78 F. Supp. 3d at 598 (conducting a jurisdictional discovery analysis as to Mylan only after concluding that plaintiffs failed to meet their burden of establishing personal jurisdiction over Mylan).

2. MPI & Mylan

a. General jurisdiction

Defendants next argue that the court lacks personal jurisdiction over Mylan and MPI because neither defendant is incorporated or domiciled in Delaware, and neither has employees or facilities in Delaware, as typically required to establish general jurisdiction. (D.I. 17 at 9) Defendants allege that MPI's designation of a registered agent in Delaware has no bearing on the jurisdictional inquiry because MPI is registered to do business in a number of states, but cannot be considered "at home" in all of them for purposes of due process. (*Id.* at 12-13)

To have general jurisdiction over a defendant, the court must find that the defendant's "affiliations with the State are so 'continuous and systematic' as to render them essentially at home in the forum State." *Daimler*, 134 S. Ct. at 754 (quoting *Goodyear*, 131 S. Ct. at 2846).

General jurisdiction . . . calls for an appraisal of a corporation's activities in their entirety, nationwide and worldwide. A corporation that operates in many places can scarcely be deemed at home in all of them. Otherwise, "at home" would be synonymous with "doing business" tests framed before specific jurisdiction evolved in the United States. Nothing in *International Shoe* and its progeny suggests that "a particular quantum of local activity" should give a state authority

over a “far larger quantum of . . . activity” having no connection to any in-state activity.

Id. at 762 n.20. In ANDA litigation, general jurisdiction traditionally provided the basis to assert jurisdiction over generic drug company defendants. *See, e.g., In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 693 F. Supp. 2d 409, 421 (D. Del. 2010) (focusing on defendant’s “substantial revenue” from Delaware drug sales in upholding general jurisdiction). Since the Supreme Court’s recent decision in *Daimler*, however, the standard for exercising general jurisdiction has shifted. *See Daimler*, 134 S. Ct. at 746.

In *Daimler*, the Supreme Court explained that a corporation is “at home” for the purposes of general jurisdiction in only a narrow set of circumstances: “With respect to a corporation, the place of incorporation and the principal place of business are paradig[m] . . . bases for general jurisdiction.” *Daimler*, 134 S. Ct. at 760 (internal quotation marks omitted). The Supreme Court was careful to emphasize that the “place of incorporation” and the “principal place of business” bases were not exhaustive. *Id.* at 760-61. However, the Supreme Court rejected the idea that “continuous and systematic” contacts, without more, are sufficient to confer jurisdiction. *Id.* at 759, 761-62 (concluding that such a test for general jurisdiction would be “unacceptably grasping” and “exorbitant”). Pursuant to *Daimler*, general jurisdiction is limited to “afford[ing] 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. The Supreme Court further rejected the Ninth Circuit’s agency theory, which subjects a foreign corporation to jurisdiction “wherever they have an in-state subsidiary or affiliate.” *Id.* at 760.

Cases within this district have consistently held that the District of Delaware does not have general jurisdiction over Mylan or MPI. *See AstraZeneca*, 72 F. Supp. 3d at 554; *Acorda*,

78 F. Supp. 3d at 583. In reaching this conclusion, these cases noted that neither corporation is a Delaware corporation, neither maintains its headquarters in Delaware, and neither has operations in Delaware. Moreover, frequent litigation in Delaware and registration to do business in Delaware are inadequate for purposes of establishing general jurisdiction pursuant to the relevant case authorities. *Id.* The same reasoning applies to Mylan and MPI in the present matter.

b. Consent to jurisdiction

In *Acorda*, Chief Judge Stark determined that registration to do business in Delaware constitutes consent to the general jurisdiction of Delaware courts. *See Acorda*, 78 F. Supp. 3d at 584 (holding that, under Delaware law, “a corporation qualified to do business in Delaware, which requires appointment of an agent to accept service of process, has consented to the general jurisdiction of the courts in the State of Delaware.”). Chief Judge Stark reached this conclusion after examining Delaware’s business registration statute, which provides that:

[a]ll process issued out of any court of this State, all orders made by any court of this State, all rules and notices of any kind required to be served on any foreign corporation which has qualified to do business in this State may be served on the registered agent of the corporation designated in accordance with § 371 of this title, or, if there be no such agent, then on any officer, director or other agent of the corporation then in this State.

8 *Del. C.* § 376. Corresponding section 371 provides that “[n]o foreign corporation shall do any business in this State . . . until it . . . shall have filed . . . [a] statement executed by an authorized officer of each corporation setting forth . . . the name and address of its registered agent in this State” 8 *Del. C.* § 371. Chief Judge Stark viewed these statutory provisions in conjunction with the Delaware Supreme Court’s decision in *Sternberg v. O’Neil*, which expressly held that “[a] corporation that authorizes an agent to receive service of process in compliance with the

requirements of a state statute, consents to the exercise of personal jurisdiction in any action that is within the scope of the agent's authority." 550 A.2d 1105, 1115-16 (Del. 1988).

After conducting a thorough analysis, Chief Judge Stark specifically rejected MPI's argument that the Supreme Court's decision in *Daimler* eliminated consent as a basis for establishing general jurisdiction over a corporation that appointed an agent for service of process in the state. *Acorda*, 78 F. Supp. 3d at 588-89; *see also Acorda*, 2016 WL 1077048, at *10 (O'Malley, J., concurring) ("I agree with Chief Judge Stark that *Daimler* did not overrule the line of Supreme Court authority establishing that a corporation may consent to jurisdiction over its person by choosing to comply with a state's registration statute."). Chief Judge Stark observed that consensual and non-consensual bases for jurisdiction are two distinct manners of obtaining jurisdiction over a corporation, and the Supreme Court's decision in *Daimler* analyzed only the non-consensual bases for general jurisdiction.⁷ *Id.* at 589. In this regard, Chief Judge Stark's decision in *Acorda* is at odds with Judge Sleet's decision in *AstraZeneca*, which held that exercising general jurisdiction over MPI based on consent is untenable after *Daimler*, and *Sternberg* can no longer be said to comport with federal due process. *AstraZeneca*, 72 F. Supp. 3d at 556. If *Daimler* is construed to eliminate consent as a basis for jurisdiction, Chief Judge Stark cautioned that "[s]uch a holding would threaten to fundamentally alter the personal jurisdiction defense from a waivable to a non-waivable right, a characteristic of the defense that was not before the *Daimler* Court and is not explicitly addressed in its opinion." *Id.* at 591.

⁷ Chief Judge Stark acknowledges that the result is "odd" because general jurisdiction does not exist over a corporation in every state in which the corporation does business, but may exist in every state in which that corporation appoints an agent to accept service of process as part of meeting the requirements to register to do business in that state. However, Chief Judge Stark insisted that if consent remains a valid basis to establish personal jurisdiction, then "this result, though odd, is entirely permissible." *Acorda*, 78 F. Supp. 3d at 591.

The parties do not dispute that MPI is registered to do business in Delaware. (D.I. 1 at ¶ 22; D.I. 17 at 12) In accordance with Chief Judge Stark’s decision and Judge O’Malley’s concurrence in *Acorda*, and consistent with the Supreme Court’s decision in *Daimler*, the court recommends that MPI’s registration to do business in Delaware amounts to its consent to the personal jurisdiction of Delaware. *See Acorda*, 2016 WL 1077048, at *10 (O’Malley, J., concurring); *Acorda*, 78 F. Supp. 3d at 588-89; *Forest Labs., Inc. v. Amneal Pharm., LLC*, C.A. No. 14-508-LPS, 2015 WL 880599, at *13-14 (D. Del. Feb. 26, 2015) (“[E]ven if it is at home in only one State, surely Mylan can freely agree to be subject to personal jurisdiction in other states—so long as that consent is knowing and voluntary in the eyes of the law.”). In *Daimler*, the Supreme Court identified the distinction between consensual and non-consensual forms of personal jurisdiction, but proceeded to conduct its analysis of only the non-consensual criteria for general jurisdiction. *Daimler*, 134 S. Ct. at 755-56; *see also Forest Labs.*, 2015 WL 880599, at *13 (“In the one instance in which *Daimler* mentions consent to jurisdiction . . . it does so to distinguish the concept of consent from the circumstances relevant to its decision.”). The holding in *Daimler* was limited to the conclusion that continuous and systematic contacts, by themselves, were not enough to establish general personal jurisdiction. *Daimler*, 134 S. Ct. at 760-63. The Supreme Court’s holding contained no specific guidance on acceptable criteria for jurisdiction by consent.

In *Acorda*, Chief Judge Stark acknowledged that application of the consent doctrine in the context of the business registration statute led to an “odd” result following *Daimler*, because it essentially permits a finding of personal jurisdiction in any state in which the company does business. *See Acorda*, 78 F. Supp. 3d at 591. However, an expansive reading of *Daimler* would be required to extend the Supreme Court’s holding to issues of consent to personal jurisdiction.

See Forest Labs., 2015 WL 880599, at *13-14. The court declines to recommend extending the holding of *Daimler* in this manner, and instead concludes that application of Delaware’s business registration statute and the Delaware Supreme Court’s decision in *Sternberg* require a finding that MPI has consented to jurisdiction in Delaware as a result of its compliance with Delaware’s business registration statute.

Mylan has not registered to do business in Delaware or appointed a registered agent to accept service of process on its behalf. *See Acorda*, 78 F. Supp. 3d at 592. Pursuant to the court’s holding in *Acorda*, Mylan cannot be found to have consented to personal jurisdiction simply because MPI registered to do business in Delaware and appointed an agent to accept service of process there. *Id.* (“[J]urisdiction over a wholly owned Delaware subsidiary does not automatically establish jurisdiction over the parent corporation in any forum . . . both the parent and the subsidiary corporation’s contacts with the forum state must be assessed individually.”). Even if Mylan instructed MPI to register to do business in Delaware, this contact with Delaware would not render Mylan “at home” in Delaware and would not constitute Mylan’s consent to general jurisdiction in Delaware. Mylan’s parent-subsidiary relationship with MPI is insufficient to give rise to general jurisdiction over Mylan in Delaware. *Id.* Consequently, Mylan is not subject to general jurisdiction in Delaware.

For the foregoing reasons, I recommend that the court deny the motion to dismiss for lack of personal jurisdiction with respect to MPI because MPI consented to jurisdiction in Delaware by complying with the Delaware business registration statute. However, there is no basis to exercise general jurisdiction over Mylan under the facts of this case. Having previously concluded that plaintiffs also failed to establish specific jurisdiction over Mylan based on the agency theory, I recommend that the court grant defendants’ motion to dismiss for lack of

personal jurisdiction with respect to Mylan and permit limited jurisdictional discovery regarding the existence of an agency relationship between Agila and Mylan regarding the filing of the ANDA.

B. Failure to State a Claim Against MPI

In support of their motion to dismiss for failure to state a claim against MPI, defendants contend that MPI was not involved in the submission of the ANDA and therefore should be dismissed from the litigation. (D.I. 17 at 8) In response, plaintiffs allege that disclaiming liability for, or involvement in, patent infringement that was alleged in a pleading is insufficient grounds for dismissal of a complaint. (D.I. 25 at 19-20)

As a preliminary matter, the court addresses important distinctions between the Rule 12(b)(2) and Rule 12(b)(6) analyses that guide the court's assessment in the present case. To establish personal jurisdiction pursuant to Rule 12(b)(2), the plaintiff must produce facts sufficient to satisfy the statutory and constitutional requirements of the inquiry by a preponderance of the evidence. *See Time Share*, 735 F.2d at 66. In contrast, the court may not generally consider matters outside the pleadings when considering a Rule 12(b)(6) motion to dismiss for failure to state a claim. *See Lum v. Bank of Am.*, 361 F.3d 217 n.3 (3d Cir. 2004) ("In deciding motions to dismiss pursuant to Rule 12(b)(6), courts generally consider only the allegations in the complaint, exhibits attached to the complaint, matters of public record, and documents that form the basis of a claim."); *see also In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997). The declaration of Frank Mullery, which was produced by defendants in support of their motion to dismiss, does not fall within one of the exceptions to this general rule. (D.I. 18)

The allegations in plaintiffs' complaint, taken as true, contain sufficient factual allegations to state a claim at this stage of the proceedings. Paragraph 10 of the complaint alleges that "Agila's preparation and submission of ANDA No. 203309 was done at the direction, under the control, and for the direct benefit of Mylan and/or Mylan Pharmaceuticals. Upon information and belief, Mylan and/or Mylan Pharmaceuticals directed Agila to submit ANDA No. 203309." (D.I. 1 at ¶ 10) The complaint further states that MPI participated in extensive litigation activity in this district, is the only Mylan entity registered to do business in Delaware, and operates as an integrated business with Mylan and Agila. (D.I. 1 at ¶¶ 17-18, 21-22, 25-26) Accepting the allegations in the complaint as true, as the court must at this stage of the proceedings, the court concludes that there is no sufficient basis to dismiss MPI as an improper party at this stage of the litigation. For these reasons, I recommend that the court deny defendants' Rule 12(b)(6) motion to dismiss MPI without prejudice.

V. CONCLUSION

For the foregoing reasons, I recommend that the court grant-in-part defendants' motion to dismiss pursuant to Rule 12(b)(2), and deny defendants' motion to dismiss pursuant to Rule 12(b)(6) without prejudice. (D.I. 16) Specifically, I recommend that the court grant the Rule 12(b)(2) motion as it pertains to Mylan, permitting limited jurisdictional discovery on the agency theory, deny the Rule 12(b)(2) motion as it pertains to Agila and MPI, and deny without prejudice the Rule 12(b)(6) motion as it pertains to MPI.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The objections and responses to the objections are limited to ten (10)

pages each. The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the District Court. *See Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

The parties are directed to the court's Standing Order For Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the court's website, <http://www.ded.uscourts.gov>.

Dated: April 4, 2016



Sherry R. Fallon
UNITED STATES MAGISTRATE JUDGE