IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA AB, Plaintiff, v. MYLAN PHARMACEUTICALS, INC., Defendant.	)	Civil Action No. 14-696-GMS

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OPINION

November 5, 2014
Wilmington, Delaware

SLEET, U.S. District Judge

I. INTRODUCTION

AstraZeneca AB ("AstraZeneca") filed a complaint against defendant Mylan Pharmaceuticals, Inc. ("Mylan") on June 2, 2014, alleging patent infringement of U.S. Patent Nos. 7,951,400 ("the '400 Patent"), RE44,186 ("the '186 Patent"), and 8,628,799 ("the '799 Patent"). (D.I. 1.) The cause of action was triggered when Mylan filed two Abbreviated New Drug Applications ("ANDA") Nos. 205980 and 205981 with the U.S. Food and Drug Administration ("FDA") for approval to market saxaglitptin hydrochloride tablets—generic versions of AstraZeneca's ONGLYZA® drug product—and saxaglitptin hydrochloride and metformin hydrochloride extended-release tablets—generic versions of AstraZeneca's KOMBIGLYZE™ XR drug product—prior to expiration of the '400 Patent, the '186 Patent, and the '799 Patent. (*Id.* ¶¶ 1–3.)

Currently before the court is Mylan's motion to dismiss this suit for lack of personal jurisdiction pursuant to Federal Rule of Civil Procedure 12(b)(2), filed on June 25, 2014. (D.I. 8.) For the reasons that follow, Mylan's motion to dismiss is denied.

II. BACKGROUND

AstraZeneca is a company operating and existing under the laws of Sweden, with its principal place of business in Södertälje, Sweden. (D.I. 1, ¶ 4.) AstraZeneca's U.S. subsidiary, AstraZeneca Pharmaceuticals LP ("AstraZeneca U.S.") is a limited partnership operating and existing under the laws of Delaware, with its principal place of business in Wilmington,

Delaware. (*Id.* ¶ 5.) Mylan is incorporated in West Virginia and has its principal place of business in Morgantown, West Virginia. (*Id.* ¶ 7.)

AstraZeneca filed this lawsuit in the U.S. District Court for the District of Delaware. In its complaint, AstraZeneca alleges:

> 10. This Court has jurisdiction over Mylan because, *inter alia*, this action arises from actions of Mylan directed toward Delaware and because Mylan has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Mylan regularly and continuously transacts business within the State of Delaware, including by selling pharmaceutical products in Delaware, either on its own or through its affiliates. Upon information and belief, Mylan derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.
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> 11. Mylan has previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction and has availed itself of Delaware courts through the assertion of counterclaims and by filing suits in Delaware.

(*Id.* ¶¶ 10, 11.)

In its motion to dismiss, Mylan challenges AstraZeneca's characterization of Mylan's Delaware contacts. The two ANDAs at issue in this case were prepared in West Virginia and filed in Maryland with the FDA. (D.I. 10, ¶ 10.) Mylan has no property or employees in Delaware, and Mylan conducts essentially no direct sales in Delaware. (*Id.* ¶¶ 6–8.) Mylan is, however, registered to do business in Delaware and has appointed a registered agent to accept service of process in Delaware, pursuant to 8 Del. C. §§ 371, 376. (D.I. 15, Ex. A.) Mylan has also litigated in the District of Delaware numerous times, mostly as a defendant, but also as a plaintiff in a handful of cases. (*Id.* Ex. E.)

III. STANDARD OF REVIEW

The 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 establishing that the defendants are properly subject to the court's jurisdiction. *See ICT Pharm., Inc. v. Boehringer Ingelheim Pharm., Inc.*, 147 F. Supp. 2d 268, 270–71 (D. Del. 2001).

Personal jurisdiction is technically derived from two separate sources: state statutory law and U.S. constitutional due process. *Inamed Corp. v. Kuzmak*, 249 F.3d 1356, 1359–60 (Fed. Cir. 2001). The Delaware long-arm statute, however, has been construed "broadly to confer jurisdiction to the maximum extent possible under the Due Process Clause," so the focus of the inquiry traditionally rests on the constitutional component. 10 Del. C. § 3104; *see Merck & Co., Inc. v. Barr Labs., Inc.*, 179 F. Supp. 2d 368, 372 (D. Del. 2002) (citing *Hercules Inc. v. Leu Trust & Banking Ltd.*, 611 A.2d 476, 480–81 (Del. 1992)).[1]

"[D]ue process requires only that in order to subject a defendant to a judgment in personam, if he be not present within the territory of the forum, he have certain minimum contacts with it such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice." *Int'l Shoe Co. v. State of Wash., Office of Unemployment Compensation & Placement*, 326 U.S. 310, 316 (1945) (internal quotation marks omitted). Since the Supreme Court initially announced this rule in *International Shoe*, the doctrine has split into two categories: specific and general jurisdiction. Specific jurisdiction exists where "the

[1] The court recognizes that "Delaware law is . . . unclear as to whether or not the long arm statute is coextensive with the due process clause," and whether separate analyses are required. *See Commissariat A L'Energie Atomique v. Chi Mei Optoelecs. Corp.*, 395 F.3d 1315, 1322 (Fed. Cir. 2005); *see also ICT Pharm.*, 147 F. Supp. 2d at 271 n.4 ("[T]he Delaware Supreme Court has not collapsed the analysis under the Delaware long-arm statute into the constitutional due process analysis, as some courts have done.") The parties have not challenged jurisdiction under Delaware's long-arm statute, however, so the court directs its attention to the constitutional analysis.

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) (internal citations omitted) (quoting *Keeton v. Hustler Magazine, Inc.*, 465 U.S. 770, 774 (1984); *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 414 (1984)). In contrast, general jurisdiction does not require that the cause of action arise out of contacts with the forum state. *Helicopteros*, 466 U.S. 408 at 421. Rather, general jurisdiction exists where the defendant's contacts with the forum "are so continuous and systematic as to render it essentially at home in the forum State." *Daimler AG v. Bauman*, 134 S. Ct. 746, 761 (2014) (quoting *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 131 S. Ct. 2846, 2851 (2011)). Recent Supreme Court opinions confirm that "specific jurisdiction has become the centerpiece of modern jurisdiction theory," whereas general jurisdiction—often referred to as "all-purpose" jurisdiction—"[has played] a reduced role." *Id.* at 755 (alteration in original) (quoting *Goodyear*, 131 S. Ct. at 2854).

IV. DISCUSSION

Faced with Mylan's challenge to personal jurisdiction, AstraZeneca "bears the burden of showing the basis for this Court's jurisdiction." *See Power Integrations, Inc. v. BCD Semiconductor Corp.*, 547 F. Supp. 2d 365, 369 (D. Del. 2008). AstraZeneca maintains that (1) Mylan has consented to general jurisdiction in Delaware, (2) Mylan is subject to specific jurisdiction in Delaware, and (3) Mylan is subject to general jurisdiction in Delaware. (D.I. 15.) The court addresses each of these arguments.[2]

[2] For the sake of convenience and clarity, the court analyzes AstraZeneca's arguments in a different order from that of the briefing.

A. General Jurisdiction

AstraZeneca argues that Mylan's contacts with Delaware are sufficient to render it "essentially at home" here. AstraZeneca points to the fact that Mylan is registered to do business in Delaware and allegedly derives substantial revenue from the sales of its products in Delaware, via an "extensive network of physicians, hospitals, long-term care facilities, group purchasing organizations, retailers, and wholesalers." (*Id.* at 10–11.) AstraZeneca also alleges that Mylan is "at home in Delaware district court" because of its involvement in numerous patent- and ANDA-related lawsuits over the past two decades. (*Id.* at 11; Ex. E.)

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. 746. The court finds that AstraZeneca has failed to allege contacts sufficient to render Mylan at home in Delaware, in light of *Daimler*.

In *Daimler*, elaborating on its previous decision in *Goodyear*, 131 S. Ct. 2846, 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 principal place of business are paradig[m] . . . bases for general jurisdiction." *Daimler*, 134 S. Ct. at 760 (alteration in original) (internal quotations marks omitted). The Court was careful to emphasize that the "place of incorporation" and the "principal place of business"

exemplars were not exhaustive. *Id.* at 760–61. But at the same time, the Court rejected the idea that "continuous and systematic" contacts, alone, are sufficient to confer jurisdiction. *Id.* at 761–62 (finding such a test for general jurisdiction would be "unacceptably grasping" and "exorbitant"). The role of general jurisdiction is a limited one: "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.[3]

The court finds that AstraZeneca has failed to allege sufficient facts to demonstrate that Mylan is "essentially at home" in Delaware. First, concerning Mylan's business contacts, AstraZeneca notes only that Mylan is registered to do business in Delaware and has a broad network of third-party contacts within the state. (D.I. 15 at 10–11.) Such allegations fail to show activity "comparable to domestic enterprise in [Delaware]." *See Daimler*, 134 S. Ct. at 758 n.11. Indeed, AstraZeneca does not identify any Mylan business activity in Delaware that sets it apart from other states. As AstraZeneca acknowledges, Mylan is "one of the largest generic pharmaceutical companies in the world." (D.I. 15 at 10.) Upholding jurisdiction on these allegations alone would permit the "exercise of general jurisdiction in every [s]tate," a result specifically precluded by the Supreme Court. *See Daimler*, 134 S. Ct. at 761.

Second, AstraZeneca argues that Mylan is at home in Delaware because of Mylan's extensive litigation history in this district. The court acknowledges the creativity of this argument but ultimately finds that familiarity with the court system of Delaware is insufficient to render a defendant at home here, as envisioned by *Daimler*. Although it left open the possibility that forum activity involving something other than the paradigmatic examples (place of

[3] The court recognizes that *Daimler* dealt with a very different set of facts than those in the present case, but the Supreme Court's analysis and discussion of general jurisdiction did not place any limits on the application of the rule announced.

incorporation or principal place of business) could satisfy general jurisdiction, the Supreme Court highlighted that such a fact pattern would be an "exceptional case." *Id.* at 761 n.19. The court finds that Mylan's litigation history in Delaware fails to rise to this level. Mylan has only initiated six lawsuits in the District of Delaware over the past two decades. (D.I. 15, Ex. E.) It is true that Mylan has defended against many more lawsuits in Delaware during this time, but such activity is not "so 'continuous and systematic' as to render them essentially at home." *See Daimler*, 134 S. Ct. at 754 (quoting *Goodyear*, 131 S. Ct. 2851); *see also In re Rosuvastatin Calcium Patent Litig.*, MDL No. 08-1949, 2009 WL 4800702, at *6 (D. Del. Dec. 11, 2009) ("Filing a counterclaim and defending a lawsuit, and consensually participating in other cases, is not enough to serve as a basis for a finding of a general presence in Delaware for all cases . . . .").

Mylan's place of incorporation and principal place of business are in West Virginia. There is no dispute that Mylan is subject to general jurisdiction in West Virginia. Moreover, the court does not rule out the possibility that Mylan may be subject to general jurisdiction in another forum, in the event that its contacts are sufficient to render it at home there. But AstraZeneca has not established that Mylan is properly subject to general jurisdiction in Delaware. The court rejects AstraZeneca's general jurisdiction justification.[4]

B. Consent to General Jurisdiction

AstraZeneca also argues that Mylan has consented to be subject to Delaware's general jurisdiction by registering to do business in the state and by appointing a registered agent to accept service of process. (D.I. 15 at 4–7; Ex. A.) AstraZeneca contends: "When there is

[4] The court is not convinced that AstraZeneca's request for jurisdictional discovery would add anything to the court's calculus. (D.I. 15 at 11.) Even if AstraZeneca were able to obtain more exact figures concerning Mylan's business dealing with Delaware, there is nothing to suggest that such dealings would be "exceptional" as compared to other states. *See Daimler*, 134 S. Ct. at 761 n.19.

consent, that ends the jurisdictional inquiry. . . . Consent to personal jurisdiction obviates the need to consider due proess and minimum contacts." (*Id.* at 5.)

AstraZeneca maintains that Supreme Court cases holding that personal jurisdiction is satisfied merely by complying with state business registration statutes remain a viable path to finding jurisdiction even after *International Shoe* and its progeny. *See Neirbo Co. v. Bethlehem Shipbuilding Corp.*, 308 U.S. 165 (1939); *Penn. Fire Ins. Co. of Phila. v. Gold Issue Min. & Mill. Co.*, 243 U.S. 93 (1917). Evidently there is a circuit split as to whether this type of "statutory consent" is an adequate basis on which to ground a finding of personal jurisdiction. Several courts have held that a minimum-contacts analysis that meets the dictates of *International Shoe* is required. *See, e.g., Ratliff v. Cooper Labs., Inc.*, 444 F.2d 745, 748 (4th Cir. 1971) ("The principles of due process require a firmer foundation than mere compliance with state domestication statutes."); *Wenche Siemer v. Learjet Acquisition Corp.*, 966 F.2d 179, 183 (5th Cir. 1992) ("Not only does the mere act of registering an agent not create Learjet's general business presence in Texas, it also does not act as consent to be hauled into Texas courts on any dispute with any party anywhere concerning any matter."). Nonetheless, others, including the Third Circuit, have upheld a finding of general jurisdiction on statutory registration grounds alone. *See, e.g., Bane v. Netlink, Inc.*, 925 F.2d 637, 640 (3d Cir. 1991) ("We need not decide whether authorization to do business in Pennsylvania is a 'continuous and systematic' contact with the Commonwealth . . . because such registration by a foreign corporation carries with it consent to be sued in Pennsylvania courts."); *Knowlton v. Allied Van Lines, Inc.*, 900 F.2d 1196 (8th Cir. 1990) ("We conclude that appointment of an agent for service of process under [the Minnesota statute] gives consent to the jurisdiction of Minnesota courts for any cause

of action, whether or not arising out of activities within the state. Such consent is a valid basis of personal jurisdiction, and resort to minimum-contacts or due-process analysis to justify . . . jurisdiction is unnecessary.") The Supreme Court has never expressly addressed the continuing vitality of cases like *Neirbo* and *Gold Issue* in the wake of *International Shoe*. *But see Shaffer v. Heitner*, 433 U.S. 186, 212 (1977) ("[A]ll assertions of state-court jurisdiction must be evaluated according to the standards set forth in *International Shoe* and its progeny). Unsurprisingly, there is also little guidance as to *Daimler*'s impact, if any, on this question.

The Delaware statutes at issue in this case are sections 371 and 376. 8 Del. C. §§ 371, 376. Section 371 provides mandatory registration requirements for all foreign (*i.e.*, non-Delaware) corporations seeking to "do business" in Delaware. Section 376 provides that process may be served on foreign corporations in compliance with section 371 via a designated registered agent. AstraZeneca argues that the Delaware Supreme Court has already established that compliance with these statutes suffices to create express consent "to the exercise of general jurisdiction by the Courts of Delaware." *See Sternberg v. O'Neil*, 550 A.2d 1105, 1116 (Del. 1988). AstraZeneca asserts that *Daimler* plays no role in the consent analysis because that case dealt with the minimum-contacts aspect of *International Shoe*, which is distinct from the question of consent. *See id.* at 1111 ("[E]xpress consent is a valid basis for the exercise of general jurisdiction in the absence of any other basis for the exercise of jurisdiction, i.e. 'minimum contacts.'").

The court finds, however, that *Daimler* does weigh on this issue. Both consent and minimum contacts (and all questions regarding personal jurisdiction) are rooted in due process. Just as minimum contacts must be present so as not to offend "traditional notions of fair play and

substantial justice," the defendant's alleged "consent" to jurisdiction must do the same. *See Int'l Shoe*, 326 U.S. at 316. The Supreme Court's discussion of due process in *Daimler*, therefore, informs the court's analysis here. In holding that "continuous and systematic contacts" alone are insufficient to establish general jurisdiction, the Supreme Court rejected the idea that a company could be haled into court merely for "doing business" in a state. *Daimler*, 134 S. Ct. at 761–62. Such a theory, the Court held, "would scarcely permit out-of-state defendants 'to structure their primary conduct with some minimum assurance as to where that conduct will and will not render them liable to suit.'" *Id.*

In light of the holding in *Daimler*, the court finds that Mylan's compliance with Delaware's registration statutes—mandatory for *doing business* within the state—cannot constitute consent to jurisdiction, and the Delaware Supreme Court's decision in *Sternberg* can no longer be said to comport with federal due process. A large number of states have enacted foreign corporation registration statutes similar to Delaware; Mylan itself is registered in over a dozen different states.[5] (D.I.. 18, Exs. C–P.) Finding mere compliance with such statutes sufficient to satisfy jurisdiction would expose companies with a national presence (such as Mylan) to suit all over the country, a result specifically at odds with *Daimler*. *Daimler*, 134 S. Ct. at 761–62. Moreover, a contrary holding would lead to perverse incentives: foreign companies that comply with the statute in order to conduct business lawfully are disadvantaged, whereas those who do not register and do business in Delaware illegally are immune.

[5] Mercedes Benz USA, the subsidiary at issue in *Daimler*, was a foreign corporation registered to do business in California, with an appointed agent for service of process. (D.I. 18, Ex. A.) The Supreme Court did not address the question of whether this amounted to consent.

Administrative statutes like Delaware's sections 371 and 376 merely outline procedures for doing business in the state; compliance does not amount to consent to jurisdiction or waiver of due process.[6] Mylan did not consent to general jurisdiction in this case.

C. Specific Jurisdiction

Finally, AstraZeneca argues that Mylan is subject to specific jurisdiction in Delaware. The court notes that specific jurisdiction has historically been disfavored by courts as a basis to exercise jurisdiction over generic drug company defendants in ANDA cases. *See, e.g., Zeneca Ltd. v. Mylan Pharm., Inc.*, 173 F.3d 829 (Fed. Cir. 1999); *In re Cyclobenzaprine*, 693 F. Supp. 2d at 420–21; *Glaxo Inc. v. Genpharm Pharm. Inc.*, 796 F. Supp. 872, 875–76 (E.D.N.C. 1992). The court finds it necessary, however, to look closely at AstraZeneca's argument now that the standard for general jurisdiction—the typical avenue for bringing ANDA cases—has changed. Before discussing the particulars of specific jurisdiction, the court believes some background on ANDA litigation is helpful.

ANDA litigation is a product of the Drug Price Competition and Patent Term Restoration Act of 1984—otherwise known as the "Hatch-Waxman Act." Pub. L. No. 98-417, 98 Stat. 1585 (1984). The Hatch-Waxman Act created the ANDA process to increase the availability of generic versions of drugs and reduce delays in FDA approval. 21 U.S.C. §355(j); H.R. Rep. No. 98-856, pt. 1, at 14 (1984). Along with the ANDA mechanism, Congress also amended the

[6] The court limits its holding to Delaware's statutes specifically. The court does not address the more difficult question raised when state statutes expressly indicate that foreign corporations consent to general jurisdiction by complying with the statutes. *See, e.g., Bane*, 925 F.2d at 640 ("The existence of any of the following relationships between a person and this Commonwealth shall constitute a sufficient basis of jurisdiction to enable the tribunals of this Commonwealth to exercise general personal jurisdiction over such person: . . . (i) Incorporation under or qualification as a foreign corporation under the laws of this Commonwealth." (quoting 42 Pa. Cons. Stat. Ann. § 5301)).

patent laws. Pre-ANDA testing and development activity was exempted,[7] whereas the actual filing of an ANDA for a drug with patent protection triggered a statutory cause of action for patent holders.[8] Thus, the Hatch-Waxman Act attempted to strike a balance: generic drug companies were given greater protection in developing their drugs, but the brand or pioneer drug companies were given the right to initiate an infringement lawsuit before the generic companies could go to market.[9]

This history helps to inform the court's approach to its analysis of AstraZeneca's specific jurisdiction argument. As stated above, 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*, 471 U.S. at 472–73; *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)). The difficulty in ANDA cases is that infringement under § 271(e)(2) is "a highly artificial act," precisely because of the goals of the Hatch-Waxman Act. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990). As a statutory creation, distinct from making, using, or selling a patented technology, infringement under § 271(e)(2) has no readily apparent situs of injury for the purpose of finding

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[7] 35 U.S.C. § 271(e)(1). Previously, generic drug companies faced significant barriers because drug development and experimentation qualified as infringement. *See Roche Prods., Inc. v. Bolar Pharm. Co., Inc.*, 733 F.2d 858 (Fed. Cir. 1984).

[8] Section 271(e)(2) states, in relevant part:

> It shall be an act of infringement to submit—
>
> (A) an application under [21 U.S.C. § 355(j)] for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2).

[9] "[T]his procedure fairly balances the rights of a patent owner to prevent others from making, using, or selling its patented product and the rights of third parties to contest the validity of a patent or to market a product which they believe is not claimed by a patent." H.R. Rep. No. 98-856, pt. 1, at 28 (1984).

specific jurisdiction. Another peculiarity of the Hatch-Waxman Act is that it builds patent litigation into the FDA approval process. Patent holders have forty-five days after receiving a "paragraph IV" certification from the generic company to initiate an infringement lawsuit; the lawsuit, if filed, triggers an automatic thirty-month stay for the FDA's approval of the generic. Thus, ANDA litigation is unlike other patent infringement litigation: The injury is abstract, making it difficult to point to a location out of which the injury "arises" for jurisdictional purposes. At the same time, defending against an infringement lawsuit is an inherent and expected part of the ANDA filer's business. To put it simply: a lawsuit is often inevitable, but it is not clear where it should be held.[10] This challenge is compounded by *Daimler*'s narrowing of the doctrine of general jurisdiction.

With this background in mind, the court turns to the issue at hand and determines that Mylan is subject to specific jurisdiction in Delaware. "That the Supreme Court has viewed the tortious act [of submitting an ANDA] as 'highly artificial' . . . is not a proper reason . . . to conclude that the ANDA filing is not a 'real act' with 'actual consequences.'" *Zeneca*, 173 F.3d at 833–34 (quoting *Eli Lilly*, 496 U.S. at 663–64). The court finds that these consequences are suffered in Delaware. Mylan argues its activities are not purposefully directed at the state of Delaware, where AstraZeneca U.S. is organized. (D.I. 18 at 5–7.) Mylan's argument, however, creates the untenable position that its conduct is not directed to any jurisdiction. The Federal Circuit in *Zeneca* eliminated the possibility that Maryland (the location of the FDA and where ANDAs are filed) could exercise specific jurisdiction over ANDA filers, in order to avoid creating a "supercourt" with jurisdiction in all cases. *Zeneca*, 173 F.3d at 832.

[10] "While it is clear what Congress intended to accomplish in terms of substantive legal effects, it is unclear what effect, if any, Congress intended section 271(e)(2) would have on the personal jurisdiction of a defendant." *Zeneca Ltd. v. Mylan Pharm., Inc.*, 968 F. Supp. 268, 273 (W.D. Pa. 1997), *rev'd* 173 F.3d 829 (Fed. Cir. 1999).

Judge Rader's concurring opinion stated that "Mylan's contacts are not actually with the state of Maryland at all. Rather Mylan's contacts involve the federal government whose office for receipt of ANDAs happens to be within that state." *Id.* at 835 (Rader, J., concurring).[11] The court finds that the only possible alternative forum is the state of residence for the patent holder.[12]

The court is cognizant of the fact that a plaintiff's contacts with the forum state should not be imputed to the defendant for the purposes of establishing minimum contacts. *See Walden v. Fiore*, 134 S. Ct. 1115, 1122 (2014) ("We have consistently rejected attempts to satisfy the defendant-focused 'minimum contacts' inquiry by demonstrating contacts between the plaintiff (or third parties) and the forum State."). Mylan's contact with Delaware is not illusory, however. Mylan sent its paragraph IV certification to AstraZeneca U.S. in Delaware, thus triggering the forty-five-day countdown for AstraZeneca to file a lawsuit—a "real act with actual consequences." *See Zeneca*, 173 F.3d at 833–34 (internal quotation marks omitted). Thus, AstraZeneca's cause of action—albeit the "artificial" injury created by § 271(e)(2)—arose out of Mylan's contact with AstraZeneca in Delaware. Moreover, Mylan cannot plausibly argue that it could not "reasonably anticipate being haled into court" in Delaware when patent litigation is an integral part of a generic drug company's business. *See Burger King*, 471 U.S. at 474 (quoting *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 295 (1980)).

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[11] In his opinion for the court, Judge Gajarsa disagreed with Judge Rader's view on this matter; he, however, used the "government contacts exception" to find specific jurisdiction did not exist. *Zeneca*, 173 F.3d at 833–34. Under either Judge Gajarsa's or Judge Rader's opinions, Maryland was eliminated as a forum for specific jurisdiction in ANDA cases.

[12] Mylan's reliance on *Glaxo Inc. v. Genpharm Pharmaceuticals, Inc.* is unavailing. 796 F. Supp. 872 (E.D.N.C. 1992). The case predates *Zeneca*—in fact the North Carolina court ultimately transferred the case to the District of Maryland, the very result that *Zeneca* found impermissible. *Id.* at 876 & n.9. The court is not persuaded that *Glaxo* retains any meaningful viability.

The court is convinced that the act of filing an ANDA and the paragraph IV notification provide sufficient minimum contacts with the state of Delaware under a specific jurisdiction analysis.[13] Furthermore, as discussed above, the exercise of jurisdiction must comport with "traditional notions of fair play and substantial justice." *See Int'l Shoe*, 326 U.S. at 316, 324–26. This factor, the court finds, weighs strongly in favor of exercising specific jurisdiction. 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. (D.I. 15, Ex. E.) Conversely, AstraZeneca would be substantially burdened if forced to bring lawsuits against each ANDA filer in the defendants' home states. Such a result would be inconsistent with the "balance" that Congress sought to create in passing the Hatch-Waxman Act. The Supreme Court has stated:

> Implicit in this emphasis on reasonableness is the understanding that the burden on the defendant, while always a primary concern, will in an appropriate case be considered in light of other relevant factors, including the forum State's interest in adjudicating the dispute, the plaintiff's interest in obtaining convenient and effective relief, *at least when that interest is not adequately protected by the plaintiff's power to choose the forum*, 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, 444 U.S. at 292 (emphasis added) (internal citations omitted). Having found no meaningful burden on Mylan in defending in Delaware, the court considers these

[13] Several district courts have found that the state in which the ANDA is prepared or the state where the generic drug is tested or developed is the proper forum for the exercise of specific jurisdiction. *See, e.g.*, *Pfizer Inc. v. Apotex, Inc.*, No. 08-cv-00984-LDD, 2009 WL 2843288, at *3 n.5 (D. Del. Aug. 13, 2009); *Pfizer Inc. v. Synthon Holding, B.V.*, 386 F. Supp. 2d 666, 674–75 (M.D.N.C. 2005); *see also Intendis, Inc. v. River's Edge Pharm., LLC*, No. 11-2838 (FSH)(PS), 2011 WL 5513195, at *4 (D.N.J. Nov. 10, 2011). The court is not convinced that the focus should be on these factors. First, § 271(e)(1) explicitly exempts drug development activity as a basis for infringement. 35 U.S.C. § 271(e)(1). It strikes the court as odd to nonetheless treat such activity as an injury for the purposes of finding specific jurisdiction in ANDA cases. Second, because of the "artificial" nature of the injury under § 271(e)(2), the act of merely *preparing* an ANDA does not create a harm. Only the act of *filing* the ANDA, and thus triggering the patent holder's forty-five days to initiate a lawsuit, is recognized as an injury giving rise to potential infringement liability. § 271(e)(2).

additional factors and determines that they favor the exercise of specific jurisdiction. In particular, under Mylan's theory, AstraZeneca would only be able to bring suit in Mylan's home state of West Virginia. Again, the Hatch-Waxman Act was not intended to burden patent holders or reduce the patent protection afforded in ANDA cases; limiting AstraZeneca's choice of forum to West Virginia is not "adequ[ate] protection." *See id.* Additionally, judicial efficiency weighs in favor of exercising specific jurisdiction. In this case, which is by no means unique in the ANDA litigation sphere, AstraZeneca has filed suit against no fewer than ten generic defendant groups. Resolution of these cases in a single district would promote judicial economy and avoid the possibility of inconsistent outcomes.

In sum, it is the court's view that Mylan is appropriately subject to specific jurisdiction in Delaware. AstraZeneca's cause of action under § 271(e)(2) arises out of Mylan's activities, which were purposefully directed at AstraZeneca in the state of Delaware. Considerations of fair play and substantial justice also justify the exercise of jurisdiction. Mylan's motion to dismiss for lack of personal jurisdiction (D.I. 8) is denied.

V. CONCLUSION

For the foregoing reasons, Mylan's motion to dismiss for lack of personal jurisdiction is denied. (D.I. 8.)