No. 2015-1460

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

ASTRAZENECA AB,

Plaintiff-Appellee,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant-Appellant.

On Appeal from the United States District Court
for the District of Delaware,
(No. 1:14-cv-00664-GMS)
(No. 1:14-cv-00696-GMS)

BRIEF FOR APPELLANT

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May 18, 2015

CERTIFICATE OF INTEREST

Counsel for Appellant, Mylan Pharmaceuticals Inc., certifies the following:

1. The full name of every party represented by us is:

Mylan Pharmaceuticals Inc.

2. The name of the real party in interest represented by us is:

Mylan Pharmaceuticals Inc. The party named in the caption is the real party of interest.

3. All parent corporations and any other publicly held companies that own 10 percent or more of the stock of the party represented by us are:

Mylan Pharmaceuticals Inc. is wholly owned by Mylan Inc., which is indirectly wholly owned by Mylan N.V., a publicly held company. Abbott Laboratories, a publicly held company, owns more than 10% of Mylan N.V.'s stock through wholly-owned subsidiaries.

4. The names of all law firms and the partners or associates that appeared for Mylan Pharmaceuticals Inc. in trial court or are expected to appear in this court are:

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STATEMENT OF RELATED CASES

Pursuant to Federal Circuit Rule 47.5, appellant states:

(a) There have been no previous appeals in this case.

(b) Other cases that may directly affect or be directly affected by this Court's decision include *Acorda Therapeutics Inc. v. Mylan Pharmaceuticals Inc.*, No. 15-1456 (Fed. Cir. appeal docketed Mar. 17, 2015), and numerous pending district court cases raising issues of personal jurisdiction in ANDA litigation.

INTRODUCTION

Personal jurisdiction in abbreviated new drug application ("ANDA") cases has long been rooted in general personal jurisdiction doctrine. The Supreme Court's recent decision in *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014), however, changed the doctrinal landscape, forcing courts to reexamine their prior notions about where the exercise of personal jurisdiction over an ANDA filer is appropriate.

The district court appropriately acknowledged the sea change effected by *Daimler*, and held that Mylan Pharmaceuticals Inc. ("Mylan") was not subject to general personal jurisdiction in Delaware. But it was unable to resist the urge to expand specific personal jurisdiction doctrine in a manner that effectively recreates the pre-*Daimler* status quo. The court adopted a plaintiff-centric view of specific personal jurisdiction and wrongly treated the locus of the future harm alleged by the plaintiff as dispositive. That reasoning is irreconcilable with the Supreme Court's decision in *Walden v. Fiore*, 134 S. Ct. 1115 (2014), which made clear that it is the defendant's suit-related contacts with a forum—not the plaintiff's—that control for jurisdiction purposes. It is also in direct conflict with this Court's unbroken line of cases establishing that "the sending of letters threatening infringement litigation is not sufficient to confer personal jurisdiction." *Silent Drive, Inc. v. Strong Indus., Inc.*, 326 F.3d 1194, 1202 (Fed. Cir. 2003). If sending voluntary letters threatening infringement litigation does not give rise to specific personal jurisdiction in the

forum where the letter is received, neither can sending into the forum copies of statutorily required ANDA-related notice letters.

JURISDICTIONAL STATEMENT

This case involves claims under the patent laws of the United States, 35 U.S.C. §100 *et seq*. The district court has subject matter jurisdiction under 28 U.S.C. §1331 and §1338(a). On December 17, 2014, the district court certified the questions presented here for interlocutory review under 28 U.S.C. §1292(b). This Court granted permission to appeal on March 17, 2015, and has jurisdiction under 28 U.S.C. §1292(b) and (c)(1).

STATEMENT OF THE ISSUES

The district court certified its decision for interlocutory appeal, and this Court accepted the appeal, without limiting the issues presented. Mylan respectfully submits that the issues presented in this case are:

1) Whether Mylan is subject to general personal jurisdiction in Delaware based on its contacts with that state.

2) Whether Mylan "consented" to general personal jurisdiction in Delaware by registering to do business in that state.

3) Whether Mylan is subject to specific personal jurisdiction in Delaware in this ANDA suit because it mailed a copy of its statutorily-required notice letters to an AstraZeneca AB ("AstraZeneca") subsidiary in Delaware.

STATEMENT OF THE CASE

A. Statutory Background

"The FDA regulates the manufacture, sale, and labeling of prescription drugs under a complex statutory scheme." *Caraco Pharm. Labs. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1675 (2012). When a brand manufacturer wishes to market a new drug, it must first obtain approval from the FDA by demonstrating that the drug is safe and effective. *See* 21 U.S.C. §355(a), (b)(1). "[O]nce the FDA has approved a brand-name drug for marketing, a manufacturer of a generic drug can obtain similar marketing approval through use of abbreviated procedures." *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2228 (2013). Instead of a full new drug application (NDA), the generic manufacturer files an abbreviated new drug application (ANDA) certifying that its generic has the same active ingredients and is biologically equivalent to the brand-name version. *Id.* "[T]his process is designed to speed the introduction of low-cost generic drugs to market." *Caraco*, 132 S. Ct. at 1676.

The ANDA process is governed by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (as amended), better known as the Hatch-Waxman Act. Under that Act, a generic drug manufacturer filing an ANDA must assure the FDA that its proposed generic version will not infringe any valid patent that the NDA holder has listed with the FDA as covering the brand-name drug. *Caraco*, 132 S. Ct. at 1676. The generic

manufacturer can meet that requirement by filing a "paragraph IV" certification, which states that one or more listed patents claimed over the brand-name drug are invalid or will not be infringed by the manufacture, use, or sale of the generic version. 21 U.S.C. §355(j)(2)(A)(vii)(IV). The statute requires an ANDA applicant who files a paragraph IV certification to send notice of that certification to the owner or owners of the relevant patents and the NDA holder or their designees. 21 U.S.C. §355(j)(2)(B)(iii).

The patent statute treats the filing of an ANDA with a paragraph IV certification as a "highly artificial" act of patent infringement, which gives the patent owner an immediate right to sue. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990); *see Caraco*, 132 S. Ct. at 1677 (citing 35 U.S.C. §271(e)(2)(A)). If the patent owner does bring suit within 45 days of receiving the notice letter, "the FDA generally may not approve the ANDA until 30 months pass or the court finds the patent invalid or not infringed." *Id.* (citing 21 U.S.C. §355(j)(5)(B)(iii)).

B. Factual and Procedural Background

Mylan is a West Virginia corporation with its principal place of business in Morgantown, West Virginia. JA3. It develops and manufactures generic versions of branded pharmaceutical products for the United States market. Directly or indirectly, Mylan does some business in every state.

Mylan has no property, no employees, no mailing address, and essentially no direct sales in Delaware.[1] JA3. Because Mylan sporadically conducts business in the state, however, it has complied with Delaware law by registering to do business there. JA3. As part of that registration process, Mylan was required to name an agent to accept service of process in Delaware. JA3; *see* Del. Code tit. 8, §371(b).

In 2013, Mylan filed ANDA Nos. 205980 and 205981 with the FDA seeking its approval to market generic saxagliptin hydrochloride tablets and generic saxagliptin hydrochloride and metformin hydrochloride extended-release tablets for use in improving glycemic control for adults with type II diabetes. JA2. Mylan prepared the ANDAs in West Virginia, and filed them with the FDA in Maryland. JA3. Mylan sought permission to market its tablets—generic versions of AstraZeneca's brand-name drugs ONGLYZA® and KOMBIGLYZE™—before the expiration of U.S. Patent Nos. 7,951,400; RE44,186; and 8,628,799. JA2. Mylan's ANDA filings therefore included paragraph IV certifications stating that the relevant patents were invalid or would not be infringed by Mylan's generic versions.

AstraZeneca, a Swedish company with its principal place of business in Södertälje, Sweden, is the owner of the relevant patents. JA2. It does business in the United States through its marketing subsidiary AstraZeneca Pharmaceuticals LP,

[1] Mylan does sell pharmaceutical products to third parties who resell them in Delaware. *See* JA6.

a Delaware limited partnership with its principal place of business in Delaware. JA2-3. Thus, as required by statute, Mylan sent notice of its paragraph IV filing with the agency to AstraZeneca in Sweden, and sent copies to AstraZeneca Pharmaceuticals in Delaware.

AstraZeneca responded by suing Mylan for patent infringement in the United States District Court for the District of Delaware.[2] JA2. Mylan promptly moved to dismiss the case for lack of personal jurisdiction. JA2.

The district court denied the motion. *AstraZeneca AB v. Mylan Pharm. Inc.*, No. 14-696, 2014 WL 5778016 (D. Del. Nov. 5, 2014). It began by correctly concluding that under the Supreme Court's recent decision in *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014), Mylan was not "at home" in Delaware and so was not subject to general personal jurisdiction on that basis. JA8. It found that neither of the two "paradigmatic" bases of general jurisdiction were available, because Mylan is not a Delaware corporation and has no principal place of business in Delaware. JA7-8. And it rejected AstraZeneca's argument that Mylan's registration to do business in Delaware and its "network of third-party contacts within the state"

[2] AstraZeneca also filed an identical suit against Mylan in the United States District Court for the Northern District of West Virginia, where Mylan is incorporated and has its principal place of business (and where it prepared its ANDA filing). *See AstraZeneca AB v. Mylan Pharm. Inc.*, No. 14-94 (N.D. W. Va. filed June 3, 2014). Personal jurisdiction is not at issue in that case.

were sufficient contacts to create general jurisdiction, explaining that "[u]pholding jurisdiction on these allegations alone would permit the 'exercise of general jurisdiction in every [s]tate,' a result specifically precluded by the Supreme Court." JA7. (second alteration in original) (quoting *Daimler*, 134 S. Ct. at 761). It also rejected AstraZeneca's "creativ[e]" argument that Mylan should face general jurisdiction in Delaware because it had often litigated there before, finding those contacts "fail[ed] to rise to th[e] level" necessary for general jurisdiction. JA7-8. The district court therefore correctly concluded that this was not an "exceptional case" in which general jurisdiction could rest on contacts between Mylan and Delaware. JA8. (quoting *Daimler*, 134 S. Ct. at 761 n.19).

The district court also rejected AstraZeneca's argument that Mylan had "consented" to general jurisdiction in Delaware by registering to do business there and appointing an agent for service of process in the state. JA8-12. It correctly recognized that "[i]n light of the holding in *Daimler*," mere "compliance with Delaware's registration statutes—mandatory for *doing business* within the state—cannot constitute consent to jurisdiction." JA11. "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*." JA11. To the extent that the Delaware Supreme Court had interpreted its business registration statutes as creating "consent" to general

jurisdiction, that interpretation "can no longer be said to comport with federal due process." JA11.

The district court nevertheless denied the motion to dismiss on the ground that Mylan was subject to specific jurisdiction in Delaware. JA12-17. It recognized that "specific jurisdiction has historically been disfavored by courts as a basis to exercise jurisdiction over generic drug company defendants in ANDA cases," but considered it "necessary … to look closely" at specific jurisdiction "now that the standard for general jurisdiction … has changed." JA12. "With this background in mind," the district court determined that Mylan was subject to specific jurisdiction in Delaware because the "consequences [of its ANDA filing] are suffered in Delaware." JA14. The district court explained that under Federal Circuit precedent, filing an ANDA with the FDA in Maryland does not create specific jurisdiction in Maryland. JA14. (citing *Zeneca Ltd. v. Mylan Pharm., Inc.*, 173 F.3d 829 (Fed. Cir. 1999)). It concluded that "the only possible alternative forum is the state of residence for the patent holder." JA15

The district court recognized that, as the Supreme Court has recently reaffirmed, "a plaintiff's contacts with the forum state should not be imputed to the defendant for the purposes of establishing minimum contacts." JA15 (citing *Walden v. Fiore*, 134 S. Ct. 1115 (2014)). It nevertheless held that Mylan had sufficient contacts with Delaware because Mylan had mailed a copy of its notice letters to

AstraZeneca's subsidiary in Delaware and (in the district court's view) the suit "arose out of" that contact. JA15. The district court declared itself "convinced" that these acts were sufficient contacts to support specific jurisdiction, and that the exercise of jurisdiction in Delaware would comport with "[c]onsiderations of fair play and substantial justice." JA16-17.

Recognizing that there were substantial grounds for difference with its opinion, the district court certified its decision for interlocutory review under 28 U.S.C. §1292(b). This Court granted permission to appeal.

SUMMARY OF ARGUMENT

While the district court's conclusion that it could not exercise general personal jurisdiction over Mylan in this case was manifestly correct, the court's ruling on specific personal jurisdiction was reversible error. Most fundamentally, in response to its felt need to compensate for *Daimler*'s elimination of any colorable basis for exercising general jurisdiction, the court overreached to exercise specific personal jurisdiction over a company with no relevant suit-related contacts to Delaware, merely because a Swedish corporation alleged that it will suffer an inchoate and intangible harm in Delaware. That analysis is irreconcilable with *Walden* and a host of personal jurisdiction precedents from both the Supreme Court and this Court. The minimum contacts inquiry asks "not where the plaintiff experienced a particular injury or effect but whether the defendant's conduct connects him to the forum in a

meaningful way." 134 S. Ct. at 1125. That rule forecloses exercising specific jurisdiction over Mylan in Delaware just because AstraZeneca allegedly will "suffer" there.

The district court was equally wrong to conclude that Mylan was subject to specific personal jurisdiction in Delaware just because it mailed a copy of the statutorily-required ANDA notice letters to AstraZeneca's subsidiary in Delaware. If anything caused AstraZeneca any suit-related injury, it was Mylan's ANDA filing with the FDA in Maryland. But this Court has already held that such an ANDA filing does not suffice to create personal jurisdiction. It would get matters backwards to find that merely providing notice of that Maryland filing somehow sufficed. The statutorily-required act of providing notice of that Maryland filing via a letter mailed to Delaware did not cause AstraZeneca's injury, let alone constitute purposeful availment of Delaware. Mylan did not purposely avail itself of Delaware in a manner related to this suit; it complied with a mandatory federal-law notice provision. This Court has repeatedly held that even voluntary letters threatening infringement are insufficient to sustain specific personal jurisdiction in other forms of infringement litigation. This case follows *a fortiori* from that controlling precedent.

ARGUMENT

Due process requires a court to have personal jurisdiction over a defendant before a lawsuit against the defendant may proceed. *See, e.g.*, *Walden*, 134 S. Ct. at

1121; *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 315-16 (1945). This Court decides issues of personal jurisdiction *de novo*, reviewing the district court's decision "without deference." *Merial Ltd. v. Cipla Ltd*, 681 F.3d 1283, 1292 (Fed. Cir. 2012). The burden of establishing personal jurisdiction rests squarely on the plaintiffs. *Avocent Huntsville Corp. v. Aten Int'l Co.*, 552 F.3d 1324, 1330 (Fed. Cir. 2008).[3]

Personal jurisdiction over a defendant can be either general or specific. General personal jurisdiction is the broader form; a court with general personal jurisdiction can hear "any and all claims against [the defendant], wherever in the world the claims may arise." *Daimler*, 134 S. Ct. at 751. A court normally cannot assert general jurisdiction over a corporation unless it is incorporated in the forum, uses the forum as its principal place of business, or its affiliations with the forum are "so continuous and systematic as to render it essentially at home in the forum State." *Id.* (quotation marks and brackets omitted) (quoting *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 131 S. Ct. 2846, 2851 (2011)). Specific personal jurisdiction, on the other hand, is confined to claims "related to or 'aris[ing] out' of a defendant's contacts with the forum." *Helicopteros Nacionales de Colombia, S.A.*

[3] This Court applies its own precedent (rather than regional circuit precedent) to resolve personal jurisdiction issues. *Merial*, 681 F.3d at 1292. An assertion of personal jurisdiction must comply with both the forum state's long-arm statute and with federal due process. *Grober v. Mako Prods.*, 686 F.3d 1335, 1345 (Fed. Cir. 2012). Even assuming the Delaware long-arm statute is satisfied here, the requirements of due process are not.

v. Hall, 466 U.S. 408, 414 (1984). That more limited jurisdiction is available whenever the defendant has "certain minimum contacts with [the forum] such that the maintenance of the suit does not offend 'traditional notions of fair play and substantial justice.'" *Int'l Shoe*, 326 U.S. at 316 (quoting *Milliken v. Meyer*, 311 U.S. 457, 463 (1940)).

I. The District Court Correctly Held That Mylan Is Not Subject To General Personal Jurisdiction In Delaware.

Before *Daimler*, courts normally relied on general jurisdiction to adjudicate ANDA claims against generic drug manufacturers, basing that jurisdiction on "continuous and systematic" business contacts between those manufacturers and the forum. *See, e.g.*, *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 693 F. Supp. 2d 409, 421 (D. Del. 2010) (finding general jurisdiction because the defendant derived "substantial revenue" from sales in the forum); *Eli Lilly & Co. v. Mayne Pharma (USA) Inc.*, 504 F. Supp. 2d 387, 394-95 (S.D. Ind. 2007); *see also* JA6.

That theory, however, is no longer viable. *Daimler* sent a clear message: A court cannot claim general jurisdiction over every corporation that does business in the forum. 134 S. Ct. at 760-61. Such an "exorbitant" view of personal jurisdiction, the Supreme Court held, is "barred by due process constraints on the assertion of adjudicatory authority." *Id.* at 751. Instead, general jurisdiction is only appropriate when the defendant is "essentially at home" in the forum. That holding forecloses

any attempt to subject Mylan to general jurisdiction based on its limited activities in Delaware.

A. Mylan Is Not "At Home" in Delaware.

As the district court recognized, *Daimler* clearly establishes that Mylan cannot be considered "at home" in Delaware. In *Daimler*, twenty-two Argentinian plaintiffs brought claims against the German corporation Daimler AG based on alleged human rights violations committed in Argentina. The plaintiffs filed their suit in federal court in California, asserting that Daimler was subject to general jurisdiction in California because its subsidiary Mercedes-Benz USA, LLC ("MBUSA") did substantial business there. *Id.* at 750-51. In particular, MBUSA had "multiple California-based facilities," was "the largest supplier of luxury vehicles to the California market," and its California sales "account[ed] for 2.4% of Daimler's worldwide sales." *Id.* at 752.

The Supreme Court ordered the case dismissed for lack of personal jurisdiction. Even assuming that Daimler was bound by the contacts between MBUSA and California, the Court held those "slim contacts" provided "no basis to subject Daimler to general jurisdiction in California." *Id.* at 760. It explained that general personal jurisdiction over a corporation is appropriate only where the defendant is "at home"—normally "a forum where it is incorporated or has its principal place of business." *Id.* at 760. The Court emphasized that the state of

incorporation and principal place of business "have the virtue of being unique—that is, each ordinarily indicates only one place—as well as easily ascertainable." *Id.* By basing general jurisdiction almost exclusively on those affiliations, the Court narrowed general jurisdiction and made it more predictable for defendants, while also ensuring plaintiffs "recourse to at least one clear and certain forum in which a corporate defendant may be sued on any and all claims." *Id.* The Court "d[id] not foreclose the possibility" that a corporation might be subject to general jurisdiction elsewhere "in an exceptional case." *Id.* at 761 n.19. But it held that even a "substantial, continuous, and systematic course of business" in the forum was not enough to subject a defendant to personal jurisdiction there on any and all claims. *Id.* at 761. "Such exorbitant exercises of all-purpose jurisdiction 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.* at 761-62 (quoting *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472 (1985)).

Given *Daimler*, the district court was clearly correct to hold that Mylan could not be held to general jurisdiction in Delaware based on its contacts with that state. JA6-8. Mylan is neither incorporated in Delaware nor headquartered there, and so satisfies neither of the paradigmatic bases for general jurisdiction. And its other contacts with Delaware are substantially less than the contacts between Daimler and

California; it owns no property, has no employees, and makes essentially no direct sales in the state. *Cf. Daimler*, 134 S. Ct. at 752. The few contacts that do exist between Mylan and Delaware—its registration to do business there, its network of third-party distributors, and its history of litigation in the state—are plainly insufficient to make Mylan "at home" in Delaware.

B. Mylan Has Not Consented to General Jurisdiction in Delaware.

The district court was also correct to hold that Mylan has not consented to general jurisdiction in Delaware. After *Daimler*, merely registering to do business in a state cannot subject a foreign corporation to general jurisdiction—whether the state chooses to call that registration "consent" or not.

Delaware law requires every non-Delaware corporation doing business in the state (with certain exceptions) to register with the Delaware Secretary of State. Del. Code tit. 8, §§371(b), 373. To complete the registration process, the corporation must give "the name and address of its registered agent in th[e] State." *Id.* §371(b)(2)(i). The registration statutes then provide that "[a]ll process issued out of any [Delaware] court … may be served on the registered agent of the corporation designated." *Id.* §376(a). A non-Delaware corporation that does business in

Delaware without registering faces statutory fines for violating the mandatory registration requirement. Del. Code tit. 8, §378.[4]

The Delaware registration statutes are silent on the issue of jurisdiction, and thus do not themselves assert the rather strange proposition that mandatory registration constitutes voluntary consent to general personal jurisdiction in Delaware courts. In *Sternberg v. O'Neil*, 550 A.2d 1105 (Del. 1988), however, the Delaware Supreme Court construed those statutes to mean just that: compliance with the mandatory registration requirement did, in fact, amount to consent to general personal jurisdiction. In reaching that counterintuitive conclusion, the court relied on two Supreme Court cases from the early twentieth century—before *International Shoe* and the advent of modern personal jurisdiction doctrine—holding that a corporation could consent to suit in a given forum by appointing an agent for service of process there. *Id.* at 1109 (citing *Neirbo Co. v. Bethlehem Shipbuilding Corp.*, 308 U.S. 165 (1939); *Pa. Fire Ins. Co. v. Gold Issue Mining & Milling Co.*, 243 U.S. 93 (1917)). It held that because the Delaware registration statutes require appointment of an agent for service in Delaware, and do not expressly limit the

[4] In addition, a foreign corporation that fails to register "shall be deemed" to have appointed the Delaware Secretary of State as its agent for service of process, but only for suits "arising or growing out of any business transacted … within th[e] State." Del. Code tit. 8, §382(a).

authority of that agent, a corporation that registers under Delaware law implicitly gives "[e]xpress consent" to general jurisdiction in Delaware. *Id.* at 1116.[5]

As the district court correctly recognized, that holding "can no longer be said to comport with federal due process." JA11. If even "a substantial, continuous, and systematic course of business" does not justify general personal jurisdiction, *Daimler*, 134 S. Ct. at 761, then surely mere *registration* to do business cannot suffice. Affirming the decision below "would sweep beyond even the 'sprawling view of general jurisdiction'" rejected in *Daimler*, *id.* at 760 (quoting *Goodyear*, 131 S. Ct. at 2856); it would force even a corporation that does *no* business in Delaware to face general jurisdiction there, merely because that corporation complied with the Delaware registration statutes. Such an "unacceptably grasping" approach to general jurisdiction cannot be sustained. *Daimler*, 134 S. Ct. at 761.

Indeed, allowing states to treat business registration as consent to general jurisdiction would render *Daimler* a practical nullity. All fifty states require foreign corporations doing business in the state to register and appoint a local agent for service of process. *See Sternberg*, 550 A.2d at 1109 n.5. "Finding mere compliance

[5] It bears noting that *Sternberg* is not even consistent with the full range of pre-*International Shoe* Supreme Court precedents. The Court long ago explicitly held that where a statute requiring a corporation to appoint an agent is ambiguous as to its scope, a court "should not construe it to extend to suits in respect of business transacted by the foreign corporation elsewhere." *Robert Mitchell Furniture Co. v. Selden Breck Constr. Co.*, 257 U.S. 213, 216 (1921).

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*." JA11. Of course, not all fifty states currently interpret their registration statutes as requiring consent to general jurisdiction. But if Delaware can adopt that interpretation, then every state can—creating a jurisdictional free-for-all, in which a corporation could be sued on any claim in any state where it operates. That interpretation would eviscerate the limitations on state judicial power due process demands. *See J. McIntyre Mach. v. Nicastro*, 131 S. Ct. 2780, 2786-91 (2011) (plurality opinion); *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 292 (1980) (due process ensures that states "do not reach out beyond the limits imposed on them by their status as coequal sovereigns"). And it would allow dozens of states to simultaneously claim general jurisdiction over the same corporation, encouraging forum shopping and making it impossible for corporate defendants to know in advance where their conduct "will and will not render them liable to suit." *Daimler*, 134 S. Ct. at 762 (quoting *Burger King*, 471 U.S. at 472); *see id.* at 760, 761 n.19 (limiting general jurisdiction to the "unique" and "easily ascertainable" states of incorporation and principal place of business, in all but "exceptional case[s]"); *see also* JA11.

Even before *Daimler*, courts were divided over whether business registration could be viewed as sufficient to create general jurisdiction. *Compare, e.g.*, *Wilson*

v. Humphreys (Cayman) Ltd., 916 F.2d 1239, 1245 (7th Cir. 1990) (allowing business registration to confer general jurisdiction would be "constitutionally suspect"); *Ratliff v. Cooper Labs.*, 444 F.2d 745, 748 (4th Cir. 1971) ("The principles of due process require [more than] mere compliance with state [registration] statutes."); *and Freeman v. Second Jud. Dist. Ct.*, 1 P.3d 963, 968 (Nev. 2000) (after *International Shoe*, the "mere act of appointing an agent to receive service of process … does not subject a non-resident corporation to general jurisdiction"), *with Bane v. Netlink, Inc.*, 925 F.2d 637, 640-41 (3d Cir. 1991) (taking the opposite view), *Knowlton v. Allied Van Lines, Inc.*, 900 F.2d 1196, 1199-1200 (8th Cir. 1990) (same), *and Sternberg*, 550 A.2d at 1115-16. *Daimler* should have eliminated any remaining doubts on the issue. "Administrative statutes like Delaware's … merely outline procedures for doing business in the state; compliance does not amount to consent to jurisdiction or waiver of due process." JA12. If a foreign corporation cannot be subjected to general jurisdiction even when it does "substantial, continuous, and systematic" business in the forum, it surely cannot be subjected to general jurisdiction just because it has undertaken sufficient business to be required to register and appoint a service agent. *Daimler*, 134 S. Ct. at 761.

The district court therefore correctly rejected AstraZeneca's argument that *Daimler* "plays no role in the consent analysis." JA10. "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." JA11. (citing *Daimler*, 134 S. Ct. at 761-62). That due process holding "sets the outer boundaries of a [state's] authority to proceed against a defendant," *Goodyear*, 131 S. Ct. at 2853—under either a contacts theory or a consent theory. *See* JA10-11 ("Both consent and minimum contacts (and all questions regarding personal jurisdiction) are rooted in due process.") A state could hardly escape *Daimler* by enacting a law that any "substantial, continuous, and systematic" business in the state would constitute "consent" to general jurisdiction. It likewise cannot escape *Daimler* by enacting that same law in two steps—first requiring all corporations that do business in the state to register, and then declaring that registration is "consent" to general jurisdiction. In short, the word "consent" is not a talisman that states can invoke to escape the limits imposed by due process.

Of course, it remains true that there are *some* valid ways in which a defendant can consent to personal jurisdiction. *See Ins. Corp. of Ir. v. Compagnie des Bauxites de Guinee*, 456 U.S. 694, 703 (1982) (personal jurisdiction is "an individual right" that "can, like other such rights, be waived"). For instance, a defendant may voluntarily consent to jurisdiction in a forum or expressly waive a personal jurisdiction objection. But like other individual rights, such consent or voluntary

relinquishment stems from voluntary conduct.[6] Thus, compliance with a *mandatory* registration requirement with an equally *mandatory* obligation to appoint an agent for service of process is not a promising basis for finding consent.

The district court likewise correctly concluded that the archaic Supreme Court cases on which AstraZeneca relied below are no longer "a viable path to finding jurisdiction." JA9 (citing *Neirbo Co.*, 308 U.S. 165; *Pa. Fire Ins. Co.*, 243 U.S. 93). Those cases were decided in the long-dead era of *Pennoyer v. Neff*, 95 U.S. 714 (1878), when personal jurisdiction could only be based on the "presence" or "consent" of the defendant. *Id.* at 733; *see Burnham v. Superior Court*, 495 U.S. 604, 616-17 (1990) (plurality opinion). Under that regime, state registration statutes were used to acquire jurisdiction over foreign corporations on the "purely fictional" theory that such registration provided the necessary "consent and presence." *Burnham*, 495 U.S. at 617-18 (plurality opinion). But in *International Shoe Co. v. Washington*, decided seventy years ago, the Supreme Court "cast those fictions aside," 495 U.S. at 618, and "abandoned 'consent' … and 'presence' as the standard for measuring the extent of state judicial power over [foreign] corporations." *McGee v. Int'l Life Ins. Co.*, 355 U.S. 220, 222 (1957). *International Shoe* established that

[6] A personal jurisdiction objection may also be forfeited by, for example, filing a responsive substantive pleading. *Cf. Ins. Corp. of Ir.*, 456 U.S. at 704. But there too the forfeiture stems from voluntary conduct by the defendant.

personal jurisdiction turns instead on whether the defendant has sufficient contacts with the forum such that exercising jurisdiction does not offend "traditional notions of fair play and substantial justice." *Int'l Shoe*, 326 U.S. at 316 (quoting *Milliken*, 311 U.S. at 463). "To the extent that prior decisions are inconsistent with this standard, they are overruled." *Shaffer v. Heitner*, 433 U.S. 186, 212 n.39 (1977). Cases like *Neirbo Co.* and *Pennsylvania Fire*—"decided in the era dominated by *Pennoyer*'s territorial thinking"—therefore "should not attract heavy reliance today." *Daimler*, 134 S. Ct. at 761 n.18.

II. Mylan Is Not Subject To Specific Personal Jurisdiction In Delaware.

After correctly recognizing that *Daimler* precluded general jurisdiction over Mylan in Delaware, the district court then turned to specific jurisdiction. For a state to exercise specific personal jurisdiction over a defendant consistent with due process, "the defendant's suit-related conduct must create a substantial connection with the forum State." *Walden*, 134 S. Ct. at 1121. Specific jurisdiction will be appropriate only if "(1) the defendant purposefully directed its activities at … the forum state, (2) the claim arises out of or relates to the defendant's activities with the forum state, and (3) assertion of personal jurisdiction is reasonable and fair." *Grober v. Mako Prods.*, 686 F.3d 1335, 1346 (Fed. Cir. 2012) (quoting *Elecs. for Imaging,*

Inc. v. Coyle, 340 F.3d 1344, 1350 (Fed. Cir. 2003)).[7] The first two parts together demonstrate the "minimum contacts" that are constitutionally required for specific jurisdiction under *International Shoe*. *Id.*

The district court recognized that specific jurisdiction "has historically been disfavored" in ANDA cases, but thought it should "look closely at AstraZeneca's argument [for specific jurisdiction] now that the standard for general jurisdiction—the typical avenue for bringing ANDA cases—has changed." JA12; *see also* JA14 (finding the "challenge [of choosing a forum for ANDA cases] is compounded by *Daimler*'s narrowing of the doctrine of general jurisdiction"). It ultimately held that Mylan was subject to specific jurisdiction in Delaware because AstraZeneca "suffered" the "consequences" of Mylan's paragraph IV filing, which was made at FDA headquarters in Maryland, in Delaware and because Mylan mailed a copy of that statutorily-required notice to AstraZeneca's subsidiary there. JA14-15.

The district court erred both in its approach and in its result. First, the court was wrong to believe that it needed to compensate for *Daimler* with a "closer look" at specific jurisdiction. *Daimler* indisputably narrowed the reach of general

[7] While *Grober* actually refers to activities "directed … at residents of the forum state," 686 F.3d at 1346, the Supreme Court made it entirely clear in *Walden* that the "'minimum contacts' analysis looks to the defendant's contacts with the forum State itself, not the defendant's contacts with persons who reside there." *Walden*, 134 S. Ct. at 1122.

jurisdiction, but that is no reason to extend the reach of specific jurisdiction. *Contra* JA12. General and specific jurisdiction are analytically distinct concepts, with different constitutional limits on when they can properly be exercised. *See Daimler*, 134 S. Ct. at 757 (noting that "general and specific jurisdiction have followed markedly different trajectories"); *Goodyear*, 131 S. Ct. at 2851 (rebuking the courts below for "[c]onfusing or blending general and specific jurisdictional inquiries"). One does not necessarily expand as the other contracts.

Second, the district court was equally wrong in its ultimate holding. As the Supreme Court has repeatedly explained, specific jurisdiction covers only claims based on "some act by which the defendant purposefully avails itself of the privilege of conducting activities within the forum State, thus invoking the benefits and protections of its laws." *Hanson v. Denckla*, 357 U.S. 235, 253 (1958). A "random, fortuitous, or attenuated" contact will not do; instead, "the defendant's suit-related conduct must create a substantial connection with the forum State." *Walden*, 134 S. Ct. at 1121, 1123. That "substantial connection" is lacking here. Under *Walden*, the mere fact that the plaintiff was allegedly injured in the forum does not suffice. *Id.* at 1122-26. Nor does the act of mailing a copy of a statutorily-required ANDA notice letter to a forum resident. *See id.* at 1122; *Avocent*, 552 F.3d at 1333; *Zeneca*, 173 F.3d 829.

Affirming the decision below would effectively declare that all Hatch-Waxman plaintiffs can assert specific personal jurisdiction in their own home states over all ANDA defendants. Furthermore, because the statute permits the patentee and NDA holder to designate representatives to receive the notice, 21 U.S.C. §355(j)(2)(B)(iii), patentees and NDA holders could choose to create specific personal jurisdiction over ANDA filers in any state in the Union. That rule is antithetical to the doctrine of limited personal jurisdiction created by *Daimler* and *Walden*, and would deprive ANDA defendants of the protection that the personal jurisdiction requirement is intended to provide against "the burdens of litigating in a distant or inconvenient forum." *World-Wide Volkswagen*, 444 U.S. at 292. Due process does not permit that result.

A. Even Assuming AstraZeneca Was Injured in Delaware, That Fact Cannot Create Specific Jurisdiction Over Mylan There.

The district court began its specific jurisdiction analysis by finding that the "consequences" of Mylan's ANDA filings were "suffered in Delaware." JA14. The only plaintiff in this case, however, and the only entity whose patents the ANDA filings allegedly infringed and who holds the underlying NDAs, is AstraZeneca—a Swedish company with its principal place of business in Sweden. JA2. AstraZeneca does have a Delaware subsidiary that markets the relevant branded drugs, but that subsidiary is not a plaintiff here because it does not own any of the patents in suit and does not hold either NDA. So to the extent that the ANDA filings caused any

consequences in the "state of residence of the patent holder," JA15, those consequences occurred in Sweden.

In all events, focusing on where AstraZeneca "suffered" the alleged "consequences" of Mylan's ANDA filings is irreconcilable with controlling precedent. Even if the ANDA filings submitted to the FDA in Maryland somehow caused AstraZeneca or its subsidiary some unspecified consequences in Delaware, that fact still could not create the necessary jurisdictional contacts. As the Supreme Court recently explained in *Walden*, the minimum contacts inquiry asks "not where the plaintiff experienced a particular injury or effect but whether the defendant's conduct connects him to the forum in a meaningful way." 134 S. Ct. at 1125. That should have squarely precluded the district court from holding Mylan to specific jurisdiction in Delaware just because AstraZeneca allegedly "suffered" there.

In *Walden*, two professional gamblers were traveling from Puerto Rico to Nevada carrying almost $97,000 in cash. 134 S. Ct. at 1119. During a layover in Georgia, they were stopped by an airport police officer who seized the money, suspecting that it was drug-related and thus subject to forfeiture. The officer then drafted an allegedly false affidavit about the encounter and submitted it to the United States Attorney's Office in Georgia to show probable cause for forfeiture of the funds. *Id.* at 1119-20. The government eventually decided not to file a forfeiture complaint, and returned the money several months later. *Id.* at 1120.

The gamblers brought suit against the police officer in federal court in Nevada. The district court dismissed the suit for lack of personal jurisdiction, but the Ninth Circuit reversed in part. It held that the Nevada court could take specific personal jurisdiction over the Georgia police officer on the ground that the officer had "expressly aimed" his allegedly tortious conduct at persons that he knew had a "significant connection" to Nevada. *Id.* at 1120, 1124 & n.8.

The Supreme Court reversed and held that valid personal jurisdiction was lacking. It explained that result was compelled by two "[w]ell-established principles of personal jurisdiction." *Id.* at 1126. First, specific jurisdiction can only arise from "contacts that the 'defendant *himself*' creates with the forum." *Id.* at 1122 (quoting *Burger King*, 471 U.S. at 475). The Court had thus "consistently rejected attempts to satisfy the defendant-focused 'minimum contacts' inquiry by demonstrating contacts between the plaintiff (or third parties) and the forum State." *Id.* (citing *Helicopteros*, 466 U.S. at 417; *Hanson*, 357 U.S. at 253-54; *World-Wide Volkswagen*, 444 U.S. at 298). "Put simply, however significant the plaintiff's contacts with the forum may be, those contacts cannot be 'decisive in determining whether the defendant's due process rights are violated.'" *Id.* (quoting *Rush v. Savchuk*, 444 U.S. 320, 332 (1980)).

Second, the minimum contacts analysis "looks to the defendant's contacts with the forum State itself, not the defendant's contacts with persons who reside

there." *Id.* For that reason, "the plaintiff cannot be the only link between the defendant and the forum. Rather, it is the defendant's conduct that must form the necessary connection with the forum State that is the basis for its jurisdiction over him." *Id.* (citing *Burger King*, 471 U.S. at 478; *Kulko v. Superior Court*, 436 U.S. 84, 93 (1978)). "[A] defendant's relationship with a plaintiff or third party, standing alone, is an insufficient basis for jurisdiction." *Id.* at 1123.

Applying those principles, the Court held that the contacts between the Georgia police officer and the state of Nevada were not sufficient to sustain specific jurisdiction. *Id.* at 1124. It criticized the Ninth Circuit for "shifting the analytical focus from [the defendant's] contacts with the forum to his contacts with [the plaintiffs]," and "impermissibly allow[ing] a plaintiff's contacts with the defendant and forum to drive the jurisdictional analysis." *Id.* at 1124-25. Even if the defendant "allegedly directed his conduct at plaintiffs whom he knew had Nevada connections," that could not create jurisdiction where "none of [the defendant's] challenged conduct had anything to do with Nevada itself." *Id.* at 1125. The Court squarely and emphatically rejected the idea that "mere injury to a forum resident" could create a sufficient connection to the forum. *Id.* "Regardless of where a plaintiff lives or works, an injury is jurisdictionally relevant only insofar as it shows that the defendant has formed a contact with the forum State." *Id.*

Walden thus squarely forecloses basing specific jurisdiction over Mylan on the place where AstraZeneca "suffered" the "consequences" of the ANDA filings. Even if the ANDA filings did injure AstraZeneca in Delaware, and even if Mylan *knew* they would injure AstraZeneca in Delaware (a fact not alleged in the complaint), that still would not suffice to create specific jurisdiction there when "none of [Mylan's] challenged conduct had anything to do with [Delaware] itself." *Id.* at 1125. Relying on the place where AstraZeneca (or its subsidiary) felt the effects of the ANDA filings is exactly the kind of plaintiff-focused analysis that the Court has "consistently rejected." *Id.* at 1122.

The district court recognized that under *Walden*, "a plaintiff's contacts with the forum state should not be imputed to the defendant for the purposes of establishing minimum contacts." JA15 (citing *Walden*, 134 S. Ct. at 1122). That should have been the end of the matter. Whatever "consequences" AstraZeneca or its non-party subsidiary may have happened to "suffer" in Delaware, they cannot create a constitutionally sufficient connection between Mylan and that state. *Walden*, 134 S. Ct. at 1122-26. To decide otherwise would be to enable the exercise of specific personal jurisdiction over a defendant based on the whim of the plaintiff's corporate structure.

B. Mailing a Copy of the Statutorily-Required ANDA Notice Letters to AstraZeneca's Subsidiary in Delaware Cannot Create Specific Jurisdiction Over Mylan There.

The district court was equally wrong to find that the fact that Mylan mailed a copy of the statutorily-required ANDA notice letters to AstraZeneca's subsidiary in Delaware supported the exercise of specific personal jurisdiction. The letter and AstraZeneca's infringement claims are not related in any legally relevant way, and—even if they were—the mere mailing of a letter is insufficient to establish specific personal jurisdiction on the facts of this case.

1. The patent infringement claims asserted here do not arise from or relate to the notice letters.

Specific jurisdiction can only be asserted over claims that "arise out of or relate to" activities that the defendant has purposefully directed at the forum. *Burger King*, 471 U.S. at 472; *see Helicopteros*, 466 U.S. at 414 n.8; *Grober*, 686 F.3d at 1348. That connection simply does not exist between AstraZeneca's patent infringement claims and the act of mailing a copy of the notice letters to AstraZeneca's non-party marketing subsidiary.

AstraZeneca claims that Mylan infringed its patents by filing its ANDAs with the FDA, not by mailing notice letters. *See* JA56-58. That is not merely a pleading defect; it is the direct result of the statutory scheme, which creates a "highly artificial act of infringement" out of *submitting an ANDA to the FDA*, not mailing a notice letter to the patent owner. *Eli Lilly*, 496 U.S. at 678; *see* 35 U.S.C. §271(e)(2)(A).

The notice letter itself does not infringe; it only ensures that the patentholder is informed of the act of infringement. *See* 35 U.S.C. §271(e)(2)(A). And mailing a *copy* of the notice letter to a subsidiary of the patent-holder/NDA-holder—an act that is not even technically required by the statute—is even less close to the substance of the underlying infringement claim.[8] Basing specific jurisdiction on the notice letters here would be like basing specific jurisdiction over a breach of contract case on a phone call by which the plaintiff's son learned about the breach. Under this Court's view of the "arises out of or relates to" requirement, the notice letters have no sufficiently substantial connection with plaintiffs' claims to create specific jurisdiction. *Avocent*, 552 F.3d at 1336-37 (holding that commercial use of a patent does not "relate to" a claim that the patent is invalid).[9]

[8] The district court wrongly stated that mailing a copy of the notice letters to AstraZeneca's subsidiary "trigger[ed] the forty-five-day countdown for AstraZeneca to file a lawsuit" and so had "actual consequences" for the infringement claim. JA15. In fact, mailing a copy of the letters to AstraZeneca's subsidiary had no effect whatsoever on the 45-day clock. That clock began to run only when AstraZeneca, the patent-holder and NDA-holder, itself received the actual letters. *See* 21 U.S.C. §355(j)(5)(B)(iii).

[9] The federal circuits are currently divided over what a plaintiff must show to demonstrate that a claim "arises out of or is related to" a particular contact. *See Myers v. Casino Queen, Inc.*, 689 F.3d 904, 912 (8th Cir. 2012); *see also Helicopteros*, 466 U.S. at 415 n.10 (reserving the issue). Some circuits require a showing that the contact proximately caused the claim, *see, e.g.*, *Harlow v. Children's Hosp.*, 432 F.3d 50, 61 (1st Cir. 2005); others require only that the contact be a but-for cause of the claim, *see, e.g.*, *Shute v. Carnival Cruise Lines*, 897 F.2d 377, 385-86 (9th Cir. 1988), *rev'd on other grounds*, 499 U.S. 585 (1991); and still others require only a substantial connection between the contact and the claim, *see*

2. Mailing a copy of the notice letters is not a jurisdictional contact.

Second, even if the suit were related to the mailing of the notice letters, those letters did nothing more than inform AstraZeneca's marketing subsidiary of the ANDA filings. Under this Court's precedents, simply mailing such letters cannot qualify as a "contact" with any state. In *Zeneca Ltd. v. Mylan Pharmaceuticals, Inc.*, for instance, this Court held that filing an ANDA with the FDA at its offices in Maryland would not create specific personal jurisdiction in that state. 173 F.3d 829. *Zeneca* produced two separate opinions to explain its holding, with Judge Gajarsa and Judge Rader each writing individually to explain their different views. Under both opinions, however, mailing a copy of an ANDA notice letter cannot be considered a jurisdictional contact.

Judge Gajarsa saw *Zeneca* as based on the "government contacts" exception, under which "petitioning the national government does not 'count' as a jurisdictional contact in the personal jurisdiction analysis." *Id.* at 831 (opinion of Gajarsa, J.). He explained that finding specific jurisdiction over ANDA filers in Maryland would pose "serious constitutional issues" by conditioning their right to file an ANDA—a petition protected by the First Amendment—on their willingness to litigate in that

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Chew v. Dietrich, 143 F.3d 24, 29-30 (2d Cir. 1998). *See generally O'Connor v. Sandy Lane Hotel Co.*, 496 F.3d 312, 319-20 (3d Cir. 2007) (describing the various positions). This Court has taken the "far more permissive" third approach, although it has questioned the "soundness" of that rule. *Avocent*, 552 F.3d at 1337.

state. *Id.* at 832. He also pointed out that the Hatch-Waxman Act was intended to encourage the manufacture and approval of generic drugs through the ANDA process; treating an ANDA as the basis for specific jurisdiction in Maryland, by contrast, "results in an unnecessary and unintended punishment for filing a petition with the FDA, which undermines the purpose of the Hatch-Waxman Act." *Id.* at 833.[10]

Judge Rader reached the same result by a different route. In his view, filing an ANDA in Maryland could not support personal jurisdiction there because that "contact" was "not actually with the state of Maryland at all," but rather with "the federal government whose office for receipt of ANDAs happens to be within that state." *Id.* at 835 (opinion of Rader, J.). Because filing an ANDA "neither takes advantage of Maryland's commercial laws and legal structures nor targets Maryland's markets and residents"—and indeed, "does not at that point even cause a tangible injury to the patent holder"—Judge Rader concluded it was not a sufficient contact with the state to justify specific jurisdiction. *Id.* at 836.

Both opinions in *Zeneca* indicate that an ANDA notice letter cannot create specific jurisdiction. The notice letter is simply a statutorily-required adjunct to an

[10] Judge Gajarsa also noted that allowing specific jurisdiction in Maryland would would turn the District of Maryland into a "supercourt" for ANDA cases. *Zeneca*, 173 F.3d at 832 (opinion of Gajarsa, J.).

ANDA filing with a paragraph IV certification. 21 U.S.C. §355(j)(2)(B)(iii). Specific jurisdiction based on the notice letter would create an "unnecessary and unintended punishment" for filing an ANDA just like specific jurisdiction based on the filing itself, burdening the First Amendment right to petition and undercutting the Hatch-Waxman Act in exactly the same way. *See Zeneca*, 173 F.3d at 832-33 (opinion of Gajarsa, J.); *see also id.* at 833 (an ANDA filing "was not called an act of infringement in order to dissuade generic drug manufacturing"). And just as filing an ANDA does not "take advantage" of the laws of Maryland or "cause a tangible injury to the patent holder" there, mailing the statutorily-required notice letter does not "take advantage" of any forum or cause any injury to anyone. *Id.* at 836 (opinion of Rader, J.). Indeed, the notice letter causes even *less* injury than the ANDA filing, since the notice letter itself is not even an act of infringement. Under both opinions in *Zeneca*, then, the notice letter "does not 'count' as a jurisdictional contact in the personal jurisdiction analysis." *Id.* at 831 (opinion of Gajarsa, J.).[11]

Moreover, the sending of a statutorily-required notice of a filing made in Maryland does not constitute purposeful availment of the laws and benefits of the state in which the recipient resides or is incorporated. While it could perhaps be

[11] Here as in *Zeneca*, this holding "would not deprive [the plaintiff] of a forum in which to seek relief," since personal jurisdiction over Mylan has already been established in West Virginia. 173 F.3d at 832 (opinion of Gajarsa, J.).

argued that an ANDA applicant purposefully avails itself of Maryland because the ANDA filing is voluntary, *but see Zeneca*, 173 F.3d at 836 (opinion of Rader, J.), the same surely cannot be said of the notice letter. That letter results not from any voluntary decision of the ANDA applicant, but directly from the statutory requirement that notice of the federal filing be provided to certain interested parties. That mandatory notice cannot be understood as the kind of purposeful availment that satisfies due process. Complying with that government-mandated service requirement is no different from mailing a service copy of a legal filing to the opposing party, and no one would view compliance with the service rules as purposeful availment of the forum to which the service copy is mailed.

It should make no difference that the Hatch-Waxman Act did not technically require Mylan to send a copy of the notice letters to AstraZeneca's subsidiary. *See* 21 U.S.C. §355(j)(2)(B)(iii)(I) (requiring notice to "each owner of the patent" and "the holder of the approved [NDA]"). If an ANDA filer cannot be subjected to personal jurisdiction in a distant forum for petitioning the government, it surely cannot be subjected to personal jurisdiction for merely notifying a third party about that petition. Like the ANDA petition itself, the courtesy notifications that Mylan sent were an exercise of its First Amendment rights, and furthered the purposes of the Hatch-Waxman Act by ensuring that all interested parties would be aware of the relevant ANDA filings. *See Zeneca*, 173 F.3d at 832-33 (opinion of Gajarsa, J.).

And like the ANDA filings themselves, Mylan's courtesy letters neither took advantage of nor caused harm in the state to which they were sent. *See id.* at 836 (opinion of Rader, J.). Treating that common politeness as a jurisdictional contact would only discourage ANDA filers from informing all interested parties about their filings, by exposing them to specific jurisdiction any time they sent a notification not specifically required by the statute. Neither law nor common sense favors that approach.

In fact, this Court has already rejected the idea that a letter like the ones Mylan sent here can suffice to sustain specific jurisdiction. This Court has repeatedly held that "the sending of letters threatening infringement litigation is not sufficient to confer personal jurisdiction" in declaratory judgment actions against the patentholder. *Silent Drive*, 326 F.3d at 1202; *see also, e.g.*, *Radio Sys. Corp. v. Accession, Inc.*, 638 F.3d 785, 789 (Fed. Cir. 2011); *Autogenomics, Inc. v. Oxford Gene Tech.*, 566 F.3d 1012, 1019-20 (Fed. Cir. 2009); *Avocent*, 552 F.3d at 1333 (Fed. Cir. 2008); *Inamed Corp. v. Kuzmak*, 249 F.3d 1356, 1361 (Fed. Cir. 2001); *Red Wing Shoe Co. v. Hockerson-Halberstadt, Inc.*, 148 F.3d 1355, 1360-61 (Fed. Cir. 1998). The same considerations that cut against treating infringement letters as a sufficient jurisdictional contact also cut against treating ANDA notice letters as a jurisdictional contact. *See Avocent*, 552 F.3d at 1333. Just as a patentee must have "sufficient latitude to inform others of its patent rights without subjecting itself to

jurisdiction in a foreign forum," *id.* (quoting *Red Wing Shoe*, 148 F.3d at 1360-61), an ANDA filer must have sufficient latitude to notify interested parties of its ANDA filings without subjecting itself to specific jurisdiction. *See also Red Wing Shoe*, 148 F.3d at 1361 ("Standards of fairness demand that [a defendant] be insulated from personal jurisdiction in a distant foreign forum when its only contacts with that forum were efforts to give proper notice of its patent rights."). Any other result would needlessly undermine the Hatch-Waxman Act, harming both ANDA filers and the interested parties they would otherwise have notified.

Indeed, the notification letters at issue here create even less of a "relationship among the defendant, the forum, and the litigation," *Shaffer*, 433 U.S. at 204, than an infringement letter creates in a declaratory judgment patent action. In a declaratory judgment action, the plaintiff (usually an accused infringer) sues the patentholder and seeks a declaration that the patents in suit are invalid or not infringed. In such cases, "the central purpose" of the action is normally "to clear the air of infringement charges." *Red Wing Shoe*, 148 F.3d at 1360. The very injury of which the plaintiff complains is often "the threat of an infringement suit, as communicated in a cease-and-desist letter." *Id.*; *see Avocent*, 552 F.3d at 1332-33. Infringement letters therefore "might be expected to support an assertion of specific jurisdiction" in a declaratory judgment action, because they actually cause the harm that gives rise to the suit. *Avocent*, 552 F.3d at 1333. Here, by contrast, the "injury"

of which AstraZeneca complains is not that its subsidiary received a copy of the notice letter in Delaware; it is the "highly artificial act of infringement" that occurred when Mylan filed its ANDA in Maryland. *Eli Lilly*, 496 U.S. at 678. The letter mailed to Delaware neither caused nor contributed to that injury. If specific jurisdiction cannot rest on an infringement letter without "'other activities' directed at the forum *and related to the cause of action*," *Avocent*, 552 F.3d at 1333 (quoting *Silent Drive*, 326 F.3d at 1202), then *a fortiori* it cannot rest on a copy of an ANDA notice letter.[12]

The district court believed that because *Zeneca* ruled out the possibility of holding an ANDA defendant to specific jurisdiction in Maryland for filing an ANDA there, "the only possible alternative forum is the state of residence for the patent holder." JA15. If that were true, of course, it would make Sweden (not Delaware) the "only possible" forum here. *See* JA2 (explaining that AstraZeneca is incorporated and headquartered in Sweden). Fortunately for Sweden, however, that

[12] Other circuits have likewise concluded that merely sending a letter into the forum is not enough to create specific jurisdiction. *See, e.g.*, *Fastpath, Inc. v. Arbela Techs. Corp.*, 760 F.3d 816, 824 (8th Cir. 2014) ("Although letters and faxes may be used to support … personal jurisdiction, they do not themselves establish jurisdiction."); *Rockwood Select Asset Fund XI (6)-1 v. Devine, Millimet & Branch*, 750 F.3d 1178, 1180 (10th Cir. 2014) (holding that "sending [an] opinion letter to a Utah address" is "insufficient for personal jurisdiction in Utah"); *Vetrotex Certainteed Corp. v. Consolidated Fiber Glass Prods. Co.*, 75 F.3d 147, 152 (3d Cir. 1996) ("some telephone calls and letters" constituting "informational communications in furtherance of [a contract]" do not create specific jurisdiction).

is not the case.[13] A corporate defendant will always be subject to general jurisdiction—including on ANDA claims—in its state of incorporation and principal place of business. "These bases afford plaintiffs recourse to at least one clear and certain forum in which a corporate defendant may be sued on any and all claims," *Daimler*, 134 S. Ct. at 760, and so ensure that at least one forum will be available for ANDA litigation against any defendant.

Beyond that, specific jurisdiction over ANDA defendants may often be appropriate in the forum where the ANDA was prepared—which is, after all, the forum where the defendant actually engaged in the conduct from which the infringement claim arises. *See, e,g.*, *Pfizer Inc. v. Synthon Holding, B.V.*, 386 F. Supp. 2d 666, 675-76 (M.D.N.C. 2005); *see also Intendis, Inc. v. River's Edge Pharm.*, No. 11-2838, 2011 WL 5513195, at *4 (D.N.J. Nov. 10, 2011) (ANDA claim arises where the ANDA is prepared); *Pfizer Inc. v. Apotex, Inc.*, No. 08-948, 2009 WL 2843288, at *3 n.5 (D. Del. Aug. 13, 2009) (same); *Bristol-Myers Squibb Co. v. Andrx Pharm.*, No. 03-2503, 2003 WL 22888804, at *3 (S.D.N.Y. Dec. 5, 2003) (same); Eric. H. Weisblatt & Claire Frezza, *Who to Sue and Where in ANDA Litigation: Personal Jurisdiction Post-Daimler*, 69 Food & Drug L.J. 351, 353, 355 (2014) ("Patent holders have successfully asserted specific jurisdiction over ANDA

[13] In fact, under *Walden*, it can never be the case. *See Walden*, 134 S. Ct. at 1122 ("[T]he plaintiff cannot be the only link between the defendant and the forum.").

filers based on where the ANDA was prepared."); *cf. Walden*, 134 S. Ct. at 1122 ("[I]t is the defendant's conduct that must form the necessary connection with the forum State ….").[14] Applying those principles here, the correct "alternative forum" for this suit is not Delaware but West Virginia, where Mylan is incorporated and headquartered and where it prepared the ANDAs. That forum can provide AstraZeneca all the opportunity it needs to litigate its claims—as it has already recognized by filing an identical suit there. *See AstraZeneca AB v. Mylan Pharm. Inc.*, No. 14-94 (N.D. W. Va. filed June 3, 2014).

3. Mailing the copy of the notice letters was at best a contact with a Delaware resident, not with the state of Delaware.

Basing jurisdiction on the copies of the ANDA notice letters must also fail because those letters were at best a contact with a Delaware resident—AstraZeneca's marketing subsidiary—rather than with the state of Delaware itself. As *Walden* made

[14] The district court recognized these precedents, but thought they were wrong to focus on where the ANDA was prepared because (1) the statute "explicitly exempts drug development activity" from infringement liability and (2) "merely *preparing* the ANDA," unlike "*filing* the ANDA," does not constitute infringement. JA16 n.13. Neither rationale is persuasive. First, the statute exempts drug development from the definition of infringement in order to "allow[] competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval." *Eli Lilly*, 496 U.S. at 671. It says nothing about where drug developers should or should not be subject to personal jurisdiction. Second, while preparing an ANDA is not an act of infringement, it is both a proximate and a but-for cause of the infringement (filing the ANDA). That means it is clearly a minimum contact that could support specific jurisdiction. *See Avocent*, 552 F.3d at 1336-37. By contrast, mailing a copy of the notice letter—which the district court thought *would* support jurisdiction—is neither infringement itself *nor* causally related to the infringement.

clear, the minimum contacts analysis "looks to the defendant's contacts with the forum State itself, not the defendant's contacts with persons who reside there." 134 S. Ct. at 1122. "Due process requires that a defendant be haled into court in a forum State based on his own affiliation with the State, not based on the 'random, fortuitous, or attenuated contacts' he makes by interacting with other persons affiliated with the State." *Id.* at 1123 (quoting *Burger King*, 471 U.S. at 475). While a defendant's "physical entry into the State [by] mail … is certainly a relevant contact," that entry alone does not create a "substantial connection with the forum State," *id.* at 1121-22; *see Maynard v. Phila. Cervical Collar Co.*, 18 F. App'x 814, 817 (Fed. Cir. 2001) (an "isolated act of sending a letter" into the forum "is insufficient to invoke personal jurisdiction"). And that is especially true when (as here) the letter neither derives any benefit from the forum state nor causes any harm there. *Cf. Zeneca*, 173 F.3d at 836 (opinion of Rader, J.). The fact that AstraZeneca's subsidiary happens to be located in Delaware rather than another state should hardly change the analysis.

As *Walden* indicates, and as at least three federal courts of appeals have since repeated, a defendant cannot create jurisdictional contacts with a forum by doing no more than sporadically exchanging information with a person in that forum. *See Fastpath, Inc. v. Arbela Techs. Corp.*, 760 F.3d 816, 823-24 (8th Cir. 2014) (no jurisdiction in Iowa based on "some emails and phone calls" to Iowa); *Advanced*

Tactical Ordnance Sys., LLC v. Real Action Paintball, Inc., 751 F.3d 796, 802 (7th Cir. 2014) (no jurisdiction in Indiana based on "the sending of two allegedly misleading emails to a list … that included Indiana residents"); *Rockwood Select Asset Fund XI (6)-1 v. Devine, Millimet & Branch*, 750 F.3d 1178, 1180 (10th Cir. 2014) (no jurisdiction in Utah based on "sending [an] opinion letter to a Utah address"). Those cases confirm that Mylan made no jurisdictionally significant contact with Delaware by merely sending a courtesy copy of its ANDA filings to a Delaware resident.

C. The Other Contacts Cited by AstraZeneca in Opposing Review Cannot Create Specific Jurisdiction Over Mylan.

In unsuccessfully opposing review of the district court's decision, AstraZeneca cited a number of other contacts between Mylan and Delaware that (in its view) might contribute to specific jurisdiction. The district court correctly refused to rely on any of these additional connections to satisfy the minimum contacts requirement.

First, AstraZeneca cited the same facts that it relied on in seeking to show general jurisdiction: that Mylan had registered to do business in Delaware, registered with the state board of pharmacy, derived revenue from a network of third-party distributors in the state, and had previously litigated a number of cases in Delaware. None of those contacts can create specific jurisdiction here, however, because none of them give rise to or relate to the patent infringement claims brought

in this suit. *See Goodyear*, 131 S. Ct. at 2853 (specific jurisdiction requires activity that "*gave rise to the episode-in-suit*," making the defendant "answerable in that State with respect to those acts"). AstraZeneca is not suing Mylan for registering to do business in Delaware, having distributors in the state, or participating in previous ANDA litigation there. And without some significant suit-related contact that the litigation "arises out of or relates to," there cannot be specific jurisdiction. *Grober*, 686 F.3d at 1346; *see Walden*, 134 S. Ct. at 1121 ("[T]he defendant's suit-related conduct must create a substantial connection with the forum State.").[15]

Second, AstraZeneca claimed that Mylan would promote sales of its generic drug products throughout the United States, including in Delaware, if its ANDAs were approved. According to AstraZeneca, those sales would infringe its patents. Of course, AstraZeneca does not assert that Mylan itself will sell the allegedly infringing products in Delaware; as the district court explained, Mylan "conducts essentially no direct sales in Delaware." JA3; *cf. Walden*, 134 S. Ct. at 1126 ("[I]t is the defendant, not the plaintiff or third parties, who must create contacts with the forum State."). But even if those alleged future sales could be attributed to Mylan,

[15] The district court thought it relevant that "patent litigation is an integral part of a generic drug company's business," and so Mylan could "reasonably anticipate being haled into court" upon making its ANDA filings. JA15 (quoting *Burger King*, 471 U.S. at 474); *see Actavis*, 133 S. Ct. at 2228 (filing a paragraph IV certification "often 'means provoking litigation'"). But those facts hardly show that Mylan should have anticipated suit *in Delaware*.

they still could not sustain specific jurisdiction over AstraZeneca's claim of infringement based on Mylan's ANDA filings. That claim does not arise from or relate to any future sales; instead, the highly artificial act of infringement it alleges was complete the moment that Mylan filed an ANDA with a paragraph IV certification. 35 U.S.C. §271(e)(2)(A); *see Caraco*, 132 S. Ct. at 1677 (ANDA filing is "itself an act of infringement, which gives the brand an immediate right to sue"). AstraZeneca will have an equally valid (or invalid) claim of infringement on that basis whether or not Mylan ever makes the unspecified future sales that AstraZeneca alleges. Specific jurisdiction over that claim therefore cannot be based on the alleged future sales. *See Seiferth v. Helicopteros Atuneros, Inc.*, 472 F.3d 266, 274-75 (5th Cir. 2006) (plaintiff must establish specific jurisdiction as to each claim); *Remick v. Manfredy*, 238 F.3d 248, 255 (3d Cir. 2001) (same); *Phillips Exeter Acad. v. Howard Phillips Fund*, 196 F.3d 284, 289 (1st Cir. 1999) (same).[16]

[16] As well as claiming that Mylan has already infringed its patents under §271(e)(2)(A) by its ANDA filings, AstraZeneca also claims that Mylan will someday manufacture its proposed generic drugs if its ANDA filings are approved, and will then be liable under §271(a)-(c) for direct, induced, and contributory infringement. That speculative possibility, however, is not enough to create a claim under §271(a)-(c) against Mylan now. *Cf. Matthews Int'l Corp. v. Biosafe Eng'g*, 695 F.3d 1322, 1328-30 (Fed. Cir. 2012) (declaratory judgment jurisdiction based on "potential future infringement" is not available unless the controversy has sufficient "immediacy and reality"); *Eisai Co. v. Mutual Pharm. Co.*, No. 06-3613, 2007 WL 4556958, at *17-18 (D.N.J. Dec. 20, 2007). If it were, there would have been no need for Congress to make an ANDA filing into an artificial act of infringement by enacting §271(e)(2)(A). Plaintiffs could simply have brought suit under §271(a)-(c) on the theory that the ANDA would lead to future drug sales. *But*

Third, even if AstraZeneca's claims did arise from the possibility of future sales in Delaware, AstraZeneca does not allege that Mylan has purposefully targeted or will target the Delaware market with those sales—only that the generic drug will be sold across the United States (including Delaware). A four-Justice plurality of the Supreme Court has twice concluded that is not enough to satisfy due process. *Nicastro*, 131 S. Ct. at 2788-91 (plurality opinion); *Asahi Metal Indus. Co. v. Superior Court*, 480 U.S. 102, 111-13 (1987) (plurality opinion); *see also AFTG-TG, LLC v. Nuvoton Tech. Corp.*, 689 F.3d 1358, 1362-65 (Fed. Cir. 2012). Under those plurality opinions, due process does not allow specific jurisdiction where a defendant merely places goods into the stream of commerce with the knowledge that they may eventually be sold in the forum State. Selling a product that eventually winds up in the forum is not enough to show that the defendant *purposefully* availed itself of that forum; there must be some indication that the defendant intentionally directed its sales toward that market, such as by specifically designing its product for that market. *Asahi*, 480 U.S. at 112-13 (plurality opinion). On that analysis, AstraZeneca's allegations of future sales—which provide no facts to indicate that Mylan will purposefully direct its product toward Delaware rather than toward the United States market as a whole—are insufficient. *See Nicastro*, 131 S. Ct. at 2790

see Eli Lilly, 496 U.S. at 678 (explaining that §271(e)(2)(A) was necessary "to enable the judicial adjudication" of the challenged patents' validity).

(plurality opinion) (finding no specific jurisdiction in New Jersey where the defendant intended to serve the United States market rather than specifically the New Jersey market).

Finally, the mere fact that third parties may someday distribute the generic Mylan drug in Delaware—if that drug is ever approved—cannot serve as a suit-related contact between Mylan and Delaware today. *See Walden*, 134 S. Ct. at 1122 (contacts between third parties and the forum are irrelevant). Indeed, courts faced with allegations that an ANDA filer "inten[ded] to sell drugs within the state after [FDA] approval" have "largely dismissed this argument as being insufficient to exercise specific jurisdiction." Weisblatt & Frezza, *supra*, at 352-53; *see Intendis*, 2011 WL 5513195, at *3-5 (transferring case despite alleged future sales in the forum). Such an attenuated contact, depending on the speculative possibility of future sales by a third party at some unspecified date, cannot provide the "substantial connection" required for personal jurisdiction. *Walden*, 134 S. Ct. at 1121-23; *see Burger King*, 471 U.S. at 475-76.

D. Holding Mylan to Specific Jurisdiction in Delaware Would Not Be Fair and Reasonable.

Specific jurisdiction requires not only that the suit arise from some activity directed at the forum, but also that the exercise of jurisdiction be fair and reasonable. *See Grober*, 686 F.3d at 1346; *Burger King*, 471 U.S. at 476. Even if the former

requirement were met—and as described above, it is not—exercising jurisdiction over Mylan in Delaware still would not qualify as fair and reasonable.

Once again, that conclusion flows immediately from this Court's precedents regarding infringement letters. In *Avocent*, *Silent Drive*, *Red Wing Shoe*, and numerous other cases in the same vein, this Court has unmistakably held that specific jurisdiction over a defendant who merely sends a letter threatening infringement litigation is not fair and reasonable unless the plaintiff can show the defendant engaged in "'other activities' directed at the forum *and related to the cause of action*." *Avocent*, 552 F.3d at 1333 (quoting *Silent Drive*, 326 F.3d at 1202). The same reasoning applies *a fortiori* here. Like an infringement letter, a courtesy copy of an ANDA notice letter does nothing but provide information to the recipient. An ANDA filer "should not subject itself to personal jurisdiction in a forum solely by informing a party who happens to be located there of [its filing]. Grounding personal jurisdiction on such contacts alone would not comport with principles of fairness." *Id.* (quoting *Red Wing Shoe*, 148 F.3d at 1360-61).[17] Just as "[p]rinciples of fair play and substantial justice" bar specific jurisdiction based on an infringement letter, *Red Wing Shoe*, 148 F.3d at 1360, they must also bar specific jurisdiction based

[17] As explained above, a courtesy copy like the one Mylan mailed to AstraZeneca's subsidiary in Delaware does not start the 45-day suit clock. *See supra* note 8. *Contra* JA15.

on a courtesy copy of an ANDA notice letter. *See Avocent*, 552 F.3d at 1333; *Silent Drive*, 326 F.3d at 1202; *Red Wing Shoe*, 148 F.3d at 1360-61.

In opposing review, AstraZeneca argued that specific jurisdiction here could comport with *Avocent* and similar cases because although the notice letters alone were not enough to support specific jurisdiction, the other unrelated contacts between Mylan and Delaware—such as its registration to do business there, its registration with the state pharmacy board, its history of litigation there, etc.—made exercising specific jurisdiction fair and reasonable. But that argument ignores the primary teaching of *Avocent*: that specific jurisdiction based on an infringement letter is only reasonable if there are other contacts between the defendant and the forum "*related to the cause of action*." *Avocent*, 552 F.3d at 1333 (quoting *Silent Drive*, 326 F.3d at 1202). Relying on that principle, *Avocent* held that when a plaintiff brings a declaratory judgment action of invalidity or noninfringement, specific jurisdiction over the defendant patentholder will only be appropriate if that defendant has engaged in "'other activities' that relate to the *enforcement* or the *defense of the validity* of the relevant patents." *Id.* at 1334. But unrelated activities, like "the defendant patentee's own commercialization activity," cannot turn an infringement letter into a reasonable basis for specific jurisdiction. *Id.* at 1335; *see Radio Sys. Corp.*, 638 F.3d at 789-90 (applying *Avocent*); *Autogenomics*, 566 F.3d at 1019-21 (same). In this case, as described in detail above, there are simply no

suit-related contacts between Mylan and Delaware that could help prop up the notice letter. *Avocent* and its allies therefore preclude specific jurisdiction.

Instead of applying *Avocent*, the district court balanced and counterbalanced a number of different factors to determine whether jurisdiction would be reasonable, including its assessment of the burdens on each party and the needs of judicial efficiency. JA15-16; *see Burger King*, 471 U.S. at 476-77 (listing factors relevant to the reasonableness test). But *Avocent* makes clear that those factors are no substitute for adequate suit-related contacts between the defendant and the forum. *Avocent*, 552 F.3d at 1333-36; *see Walden*, 134 S. Ct. at 1122 (explaining that due process "principally protect[s] the liberty of the nonresident defendant—not the convenience of plaintiffs or third parties"). That is why neither *Avocent*, nor *Silent Drive*, nor *Red Wing Shoe*, nor any other case in this line has gone on to consider the *Burger King* factors after finding that an infringement letter was the only suit-related contact between the defendant and the forum. Where (as here) the defendant has no more substantial suit-related contact with the forum, personal jurisdiction is *per se* unfair and unreasonable. *Radio Sys. Corp.*, 638 F.3d at 790-91; *Avocent*, 552 F.3d at 1333; *Red Wing Shoe*, 148 F.3d 1360-61.

CONCLUSION

For the reasons set forth above, this Court should reverse the decision below and order the case dismissed for lack of personal jurisdiction.

Respectfully submitted,

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May 18, 2015

CERTIFICATE OF COMPLIANCE

1. This Brief complies with the type-volume limitation of Rule 32(a)(7)(B) of the Federal Rules of Appellate Procedure because, according to the "word count" function of Microsoft Word 2013, the Brief contains 12,150 words, excluding the parts of the Brief exempted from the word count by Rule 32(a)(7)(B)(iii) of the Federal Rules of Appellate Procedure and Fed. Cir. R. 32(b).

2. This Brief complies with the typeface requirements of Rule 32(a)(5) and the typestyle requirements of Rule 32(a)(6) of the Federal Rules of Appellate Procedure because the Brief has been prepared in a proportionally spaced typeface using Microsoft Word 2013 in 14-point Times New Roman font.

Dated: May 18, 2015

s/Paul D. Clement
Paul D. Clement

Addendum

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.
>
> 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)).

[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.)

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

ORDER

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

The defendant's Motion to Dismiss for Lack of Personal Jurisdiction (D.I. 8) is DENIED.

Dated: November 5, 2014

UNITED STATES DISTRICT JUDGE

CERTIFICATE OF SERVICE

I hereby certify that on May 18, 2015, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

s/Paul D. Clement
Paul D. Clement