

No. 2015-1456

**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

ACORDA THERAPEUTICS INC. and
ALKERMES PHARMA IRELAND LIMITED,

Plaintiffs-Appellees,

v.

MYLAN PHARMACEUTICALS INC. and MYLAN INC.,

Defendants-Appellants.

On Appeal from the United States District Court
for the District of Delaware,
(No. 1:14-cv-00935-LPS)

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CERTIFICATE OF INTEREST

Counsel for Appellants, Mylan Pharmaceuticals Inc. and Mylan Inc., certifies the following:

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

Mylan Pharmaceuticals Inc. and Mylan Inc.

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

Mylan Pharmaceuticals Inc. and Mylan Inc. The parties named in the caption are the real parties 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 Inc. 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.

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 Inc. and 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, appellants state:

- (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 *AstraZeneca AB v. Mylan Pharmaceuticals Inc.*, No. 15-1460 (Fed. Cir. appeal docketed Mar. 17, 2015), and numerous pending district court cases raising issues of personal jurisdiction in ANDA litigation.

INTRODUCTION

Before the Supreme Court's decisions in *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014), and *Walden v. Fiore*, 134 S. Ct. 1115 (2014), personal jurisdiction in abbreviated new drug application ("ANDA") infringement cases was typically rooted in general personal jurisdiction doctrine, and many ANDA cases were brought in Delaware on that theory. The Supreme Court's recent *Daimler* decision, however, substantially cut back on the exercise of general jurisdiction over corporate defendants and limited it to the one or two jurisdictions where a defendant is truly "at home," typically the defendant's state of incorporation and principal place of business. *Daimler* should have spelled the end of the use of general jurisdiction in ANDA cases where the ANDA filer is not at home and lessened the artificial concentration of ANDA litigation in Delaware. But old habits die hard.

The district court's decision to exercise both general and specific personal jurisdiction over Mylan Pharmaceuticals Inc. ("Mylan") in this ANDA infringement case is a prime example. The district court recognized that Mylan was not "at home" in Delaware for general jurisdiction purposes, but nonetheless held that it could still exercise general personal jurisdiction over Mylan because the company had complied with Delaware's mandatory business registration statutes. While it is doubtful that such compliance ever sufficed under the Supreme Court's modern personal jurisdiction jurisprudence, any doubt should have been eliminated by

Daimler. *Daimler* made absolutely clear that not even “a substantial, continuous, and systematic course of business” supports the exercise of general personal jurisdiction. 134 S. Ct. at 761. More is required. But if a substantial course of business is insufficient, engaging in sufficient business to trigger a state’s mandatory registration requirement cannot possibly suffice. Indeed, given the ubiquity of business registration requirements, the district court’s analysis would reinstate the pre-*Daimler* reality that essentially every large corporate defendant could be subject to general jurisdiction in every state in the Union. Such an “unacceptably grasping” view of general personal jurisdiction is squarely foreclosed by *Daimler*. *Id.*

The district court’s specific personal jurisdiction analysis fares no better. The thrust of the district court’s opinion is that the exercise of specific personal jurisdiction over Mylan by a Delaware court is appropriate in this case because the company sent a notice letter, which is required by federal law, to the New York office of a company incorporated in Delaware. That reasoning is irreconcilable with the Supreme Court’s decision in *Walden*, 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 sending a letter “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 into the forum does not give rise to specific personal jurisdiction there, neither can sending copies of statutorily-required notice letters to a state distinct from the forum state.

JURISDICTIONAL STATEMENT

This case involves claims and counterclaims 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 January 30, 2015, 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 and this Court accepted the following questions:

- 1) Does Mylan Pharmaceuticals' compliance with Delaware's business registration statutes, 8 Del. C. §§ 371 and 376, constitute consent to general personal jurisdiction in Delaware?
- 2) Does the U.S. Constitution permit Delaware to exercise specific personal jurisdiction over Mylan Pharmaceuticals in this ANDA suit?

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-name drug 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 drug 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 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 holder of the NDA 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 brings 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. JA4. It formulates, develops, manufactures, packages, markets, and sells generic versions of branded pharmaceutical products for the United States market. JA4. Directly or indirectly, Mylan does some business in every state.

Mylan has no manufacturing plants, offices, facilities, or other real property of any kind in Delaware. It also has no telephone listing and no mailing address in that state. JA5. Mylan likewise had no direct sales in Delaware in 2013.¹ JA5.

¹ Mylan does sell pharmaceutical products to third parties who resell them in Delaware.

Nonetheless, because Mylan does sporadic business in Delaware, Mylan complied with Delaware law by registering to do business there. As part of that registration process, Mylan was required to name an agent to accept service of process in Delaware. JA4-5; *see* Del. Code tit. 8, §371(b).

In January 2014, Mylan filed ANDA No. 20-6858 with the FDA seeking its approval to market 10mg doses of dalfampridine extended-release tablets, which can be used to improve walking in individuals with multiple sclerosis. JA6. Mylan prepared its ANDA paperwork in West Virginia, and filed it with the FDA in Maryland. JA6. Mylan sought permission to market its dalfampridine tablets—a generic version of Acorda Therapeutics Inc.’s (“Acorda”) brand-name drug Ampyra®—before the expiration of U.S. Patent Nos. 5,540,938 (“the ’938 patent”); 8,007,826; 8,354,437; 8,440,703; and 8,663,685 (collectively, “the Ampyra® patents”).² JA4, JA6. Mylan’s ANDA filing therefore included a paragraph IV certification stating that the Ampyra® patents were invalid or would not be infringed by Mylan’s generic drug. JA6.

Acorda is the exclusive U.S. licensee of the ’938 patent—which is assigned to Alkermes Pharma Limited (“Alkermes”)—and holds all rights, title, and interest in the other four Ampyra® patents. JA4. Thus, as required by statute, Mylan sent

² The Ampyra® patents are scheduled to expire between 2018 and 2027. JA4.

notice of its paragraph IV filing with the agency to Acorda at its principal place of business in Ardsley, New York, and to Alkermes at its principal place of business in Ireland. JA7.

Acorda and Alkermes responded by suing Mylan for patent infringement in the United States District Court for the District of Delaware.³ JA7. Mylan promptly moved to dismiss the case for lack of personal jurisdiction. JA8.

The district court denied Mylan's motion to dismiss. *Acorda Therapeutics, Inc. v. Mylan Pharm. Inc.*, No. 14-935, 2015 WL 186833 (D. Del. Jan. 14, 2015). It began its analysis by correctly concluding that under the Supreme Court's recent pathmarking 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. JA14-15. It explained that this case presented "neither of the two paradigmatic scenarios" for general personal jurisdiction; Mylan was not a Delaware corporation and had no principal place of business in Delaware. JA15. It recognized that Mylan was "registered to do business in Delaware," and had "litigated frequently in the District of Delaware" (usually as a defendant), but it correctly held

³ Acorda and Alkermes also sued Mylan's parent corporation, Mylan Inc., but they have since voluntarily dismissed their claims against Mylan Inc. without prejudice. Acorda and Alkermes additionally 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 JA36 n.26. Personal jurisdiction is not at issue in that case.

that “these contacts are inadequate for purposes of general jurisdiction” under *Daimler*. JA15.

After reaching that conclusion, however, the district court held that Mylan was nevertheless subject to general personal jurisdiction in Delaware because it “register[ed] to do business in Delaware” and “appoint[ed] an agent here to accept service of process.” JA16. In the district court’s view, those actions were sufficient to show Mylan had consented to general personal jurisdiction in Delaware—that is, personal jurisdiction on any cause of action arising anywhere in the world. JA16-29. The court recognized that this holding was “in tension with the holding in *Daimler*,” and created the “odd result” that while a corporation is not subject to general personal jurisdiction in every state where it does business, it can nonetheless be subject to general jurisdiction in every state where it *registers* to do business. JA28. The district court also recognized that this holding squarely conflicted with a different decision two months earlier from the same court, which held that after *Daimler* mere compliance with the Delaware business registration statutes could not constitute consent to general personal jurisdiction. JA27-28 (citing *AstraZeneca AB v. Mylan Pharm.*, No. 14-696, 2014 WL 5778016 (D. Del. Nov. 5, 2014)).

In the alternative, the district court held that it could exercise specific personal jurisdiction over Mylan based on the statutorily-required notice of Mylan’s paragraph IV certification. JA32. It recognized that Mylan actually mailed the

notice letter to Acorda's principal place of business in New York, not Delaware. JA36. Nevertheless, the court concluded that specific jurisdiction was proper in Delaware because Acorda was a Delaware corporation, would suffer any "injury" in Delaware, and had already filed suit in Delaware against other defendants over the same patents. JA32, JA37. The district court also cited a number of other connections between Mylan and Delaware that, in its view, meant specific jurisdiction over Mylan would comport with "traditional notions of fair play and substantial justice." JA33. Those connections included that Mylan had registered to do business in Delaware and registered with the state pharmacy board, and that it had previously litigated a number of cases in Delaware. JA32-33.

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

SUMMARY OF ARGUMENT

The district court wrongly held that Mylan's required compliance with Delaware's business registration statutes amounted to consent to general personal jurisdiction in Delaware. The Supreme Court's recent decision in *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014), made crystal clear that in a case such as this one general personal jurisdiction is only appropriate where a corporation is "at home"—normally "where it is incorporated or has its principal place of business." *Id.* at 760.

Even “a substantial, continuous, and systematic course of business” does not justify general personal jurisdiction. *Id.* at 761. Mylan is not incorporated in Delaware; its principal place of business is not in Delaware; and its activities in Delaware come nowhere close to being “substantial, continuous, and systematic.” Nothing about Mylan’s compliance with Delaware’s business registration statutes changes these critical jurisdictional facts, and a straightforward application of *Daimler* requires a finding for Mylan on general personal jurisdiction. Were it otherwise, courts in all fifty states could exercise general personal jurisdiction over companies such as Mylan, which would render *Daimler* a dead letter.

The district court’s analysis of specific personal jurisdiction is equally irreconcilable with controlling Supreme Court precedent. The Court’s recent decision in *Walden v. Fiore*, 134 S. Ct. 1115 (2014), reaffirmed that it is the defendant’s suit-related contacts with the forum—not the defendant’s contact with a plaintiff or the plaintiff’s contacts with the forum—that are jurisdictionally relevant. The district court’s conclusion that sending a letter to Acorda in New York can give rise to specific jurisdiction in Delaware is thus as unsupported as it is unsupported. And even if the statutorily-required notice letter had been sent to Delaware, that act would not support the exercise of specific personal jurisdiction. Providing statutorily-required notice to a party hardly amounts to a voluntary decision to purposefully avail oneself of a forum or provides any other basis for specific

jurisdiction in that forum. Finally, the other contacts between Mylan and Delaware that the district court cited are plainly insufficient to justify the exercise of specific personal jurisdiction in this case.

ARGUMENT

The standard of review on issues of personal jurisdiction is *de novo*, and this Court reviews 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).⁴

Due process requires a court to have personal jurisdiction over a defendant before a lawsuit against the defendant may proceed. *See, e.g., Walden v. Fiore*, 134 S. Ct. 1115, 1121 (2014); *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 315-16 (1945). Personal jurisdiction over a defendant can be either general or specific. 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

⁴ 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.

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. 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 Co. v. Washington*, 326 U.S. 310, 316 (1945) (quoting *Milliken v. Meyer*, 311 U.S. 457, 463 (1940)).

The district court believed it could assert both general and specific personal jurisdiction over Mylan. It found general jurisdiction based on “consent,” holding that by registering to do business in Delaware, Mylan had implicitly agreed to face suit in Delaware on any cause of action arising anywhere in the world. And it found specific jurisdiction based on “minimum contacts,” largely based on Acorda’s—not Mylan’s—contacts with Delaware. Those holdings cannot be reconciled with the Supreme Court’s recent personal jurisdiction decisions in *Daimler* and *Walden*. This Court should reverse on both issues presented, and should instruct the district court to dismiss the case for lack of personal jurisdiction.

I. Mylan Did Not Consent To General Personal Jurisdiction In Delaware Merely By Registering To Do Business There.

Under Delaware law, with certain exceptions, non-Delaware corporations doing business in the state must 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.” *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, §378.⁵

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

⁵ 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).

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 authority of that agent, a corporation that registers under Delaware law implicitly gives “[e]xpress consent” to general jurisdiction in Delaware. *Id.* at 1116.⁶

The district court here relied on the Delaware registration statutes and *Sternberg* to hold that by complying with Delaware’s registration requirement, Mylan “consented to the jurisdiction of the District of Delaware” and so the “exercise of general jurisdiction over [Mylan] does not offend [its] right to due process.” JA23. It acknowledged that its theory of “consent” was in considerable tension with *Daimler*, but nevertheless found it constitutionally “permissible” to assert general jurisdiction over Mylan on that questionable basis. JA28-29.

⁶ 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).

The district court's holding cannot be squared with either *Daimler* or fundamental principles of due process. It converts mandatory registration into voluntary consent and resurrects the exorbitant reach of general jurisdiction that existed before *Daimler*, exposing nationwide corporations to suit on any cause of action not only "at home" but in every other state where they must register to do business. Such an "unacceptably grasping" approach cannot be sustained. *Daimler*, 134 S. Ct. at 761.

A. *Daimler* Establishes That a Corporation Cannot Be Subjected to General Personal Jurisdiction Everywhere It Does Business.

The Supreme Court sent a clear message in *Daimler*: A court cannot claim general jurisdiction over every corporation that does business in the forum. 134 S. Ct. at 761. Such an "exorbitant" view of personal jurisdiction, it held, is "barred by due process constraints on the assertion of adjudicatory authority." *Id.* at 751.

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 762 (quoting *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472 (1985)).

B. Treating Business Registration as Consent to General Jurisdiction Would Eviscerate *Daimler*.

In ANDA litigation before *Daimler*, “general jurisdiction traditionally provided the basis to assert jurisdiction over generic drug company defendants” where those defendants derived substantial revenue from the forum. *AstraZeneca*, 2014 WL 5778016, at *3. But as the district court here correctly recognized, that theory is no longer viable. After *Daimler*, a company like Mylan—incorporated and headquartered in West Virginia, with no property or direct sales in Delaware—cannot be considered “at home” in Delaware. JA14-15. That should have been the end of the district court’s general jurisdiction discussion. But it went further and held that Mylan remains subject to general jurisdiction in Delaware, and so could be forced to litigate these ANDA cases (and any other case arising anywhere in the world) there, because (in its view) Mylan “consented” to that jurisdiction by registering to do business and appointing an agent for service of process as required by Delaware law. JA16.

The district court began its “consent” analysis with the uncontroversial proposition that personal jurisdiction is “an individual right” that “can, like other such rights, be waived.” JA16. (quoting *Ins. Corp. of Ir. v. Compagnie des Bauxites de Guinee*, 456 U.S. 694, 704 (1982)). 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.⁷ 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 only relevant voluntary conduct here was Mylan's decision to conduct sufficient business in Delaware to trigger the registration requirement, but that just underscores why the decision below cannot be squared with *Daimler*, which held that even "a substantial, continuous, and systematic course of business" does not justify general personal jurisdiction. *Daimler*, 134 S. Ct. at 761. Indeed, 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). The logic of the decision below does not require a business to engage in "a substantial, continuous, and systematic course of business." As long as a corporation engages in a sufficient course of business to trigger the state's mandatory registration requirement, the court below would assert general jurisdiction pursuant to its mandatory-registration-equals-voluntary-consent theory of jurisdiction.

⁷ 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.

The decision below is incompatible with *Daimler* at a more fundamental level as well. The assertion of general personal jurisdiction in *Daimler* depended on California's long-arm statute, and the Court found that assertion of general jurisdiction incompatible with the Due Process Clause. But nothing in the Court's analysis turned on the nature of the state statute under which jurisdiction was asserted. Thus, the due process problems of asserting general personal jurisdiction over Mylan are no different if the assertion were based directly on the state long-arm statute (as in most pre-*Daimler* Hatch-Waxman litigation) or is based on the state registration statute (as here). In either case, the Due Process Clause does not permit a state to compel a defendant who does some business there to be open to all litigation there.

In other words, Delaware cannot accomplish in two steps what the Supreme Court held that California could not accomplish in one. If a state sought to declare by statute that any foreign corporation doing "substantial, continuous, and systematic" business in the state was subject to general jurisdiction because that voluntary business constituted "consent," it would be plainly inconsistent with *Daimler*. See *Daimler*, 134 S. Ct. at 760-61. The district court's approach, however, would let a state reach the same result in two steps—by (1) requiring corporations that engage in "substantial, continuous and systematic" business to register, and then (2) declaring that registration is consent to general jurisdiction. That cannot be the

law. After *Daimler*, “compliance with Delaware’s registration statutes ... 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.” *AstraZeneca*, 2014 WL 5778016, at *5.

The decision below not only conflicts with *Daimler*’s reasoning, but would render that recent and significant Supreme Court precedent 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; see also *AstraZeneca*, 2014 WL 5778016, at *5 (“Mylan itself is registered in over a dozen different states”). “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*.” *AstraZeneca*, 2014 WL 5778016, at *5. If merely complying with such a mandatory registration requirement constitutes “consent,” then law-abiding corporations can potentially be subjected to general jurisdiction everywhere they do business, just as if *Daimler* had never been decided. In fact, *Daimler* itself might even be subject to general jurisdiction in California on that theory. See *id.* at *5 n.5 (noting that the *Daimler* subsidiary MBUSA had registered and appointed an agent for service of process in California). *But cf.* JA30 (holding that consent by registration does not reach parent entities).

Of course, not all fifty states currently interpret their registration statutes such that compliance with state registration requirements is tantamount to consent to general personal jurisdiction. *See* JA26-27. But if the decision below is correct, then due process would allow every state to adopt that expansive approach—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 power that due process demands. *See J. McIntyre Mach. v. Nicastro*, 131 S. Ct. 2780, 2786-87 (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”). *Daimler* forecloses that result, making it clear that “[a] corporation that operates in many places can scarcely be deemed at home in all of them.” 134 S. Ct. at 762 n.20.

The holding below makes it impossible for corporate defendants to know in advance where their conduct “will and will not render them liable to suit,” in direct contravention of *Daimler*. 134 S. Ct. at 762 (quoting *Burger King*, 471 U.S. at 472). Instead of limiting general jurisdiction to the “unique” and “easily ascertainable” states of incorporation and principal place of business, *id.* at 760, the decision below allows dozens of states to simultaneously claim general jurisdiction over a corporation, making it impossible for a corporation to know in advance where it will be sued. *See AstraZeneca*, 2014 WL 5778016, at *5.

The district court believed its holding would create no “uncertainty,” because “when courts have clearly held that compliance with a state’s registration statute confers general jurisdiction,” corporations will know where they are subject to suit. JA28. There are several problems with that assurance of predictability. First, many states have not yet addressed the consequences of registration for consent to general jurisdiction. Second, even states like Delaware that have addressed the issue have not revisited the issue after *Daimler*, which obviously casts doubt on the constitutionality of such extravagant assertions of jurisdiction. Third, clarity about whether a state asserts a theory of jurisdiction does not answer the critical question of whether the assertion complies with due process. California was clear enough that it would assert jurisdiction under its long-arm statute, but the Supreme Court was just as clear that the Due Process Clause forbade that assertion of jurisdiction because defendants must have “some minimum assurance” of where they may be held liable, *Daimler*, 134 S. Ct. at 761-62.⁸

⁸ In addition, treating registration as consent to general jurisdiction would have the perverse result of encouraging foreign corporations to disregard registration requirements. Whatever penalties such a corporation would pay for ignoring the registration requirement, it would still only be subject to specific jurisdiction. Del. Code tit. 8, §382(a); see *Old Wayne Mut. Life Ass’n v. McDonough*, 204 U.S. 8, 22 (1906); *AstraZeneca*, 2014 WL 5778016, at *5.

C. The Outdated Precedent on Which the District Court Relied Does Not Justify Treating Business Registration as Consent to General Jurisdiction.

In holding that compliance with a state business registration statute can constitute consent to general personal jurisdiction, the district court relied on a handful of archaic Supreme Court cases from before the dawn of modern personal jurisdiction jurisprudence. To the extent those cases remain good law, however, they do not support the district court's sweeping theory of consent.

In *Pennoyer v. Neff*, 95 U.S. 714 (1878), the Supreme Court held that a court could not take personal jurisdiction over persons outside the geographic bounds of the forum. *See id.* at 720. Under that strict rule, a court could only hear claims against a defendant who was served with process in the forum or who agreed to appear there. *Id.* at 733; *see Burnham v. Superior Court*, 495 U.S. 604, 616-17 (1990) (plurality opinion).

But with “changes in the technology of transportation and communication” and the “tremendous growth of interstate business activity,” states sought broader jurisdiction over persons (especially corporations) outside their boundaries. *Burnham*, 495 U.S. at 617 (plurality opinion); *see McGee v. Int'l Life Ins. Co.*, 355 U.S. 220, 222-23 (1957). One mechanism for obtaining that jurisdiction was to “require[] ... that nonresident corporations appoint an in-state agent upon whom process could be served,” thereby satisfying *Pennoyer* by making the corporation

“present” within the state and establishing jurisdiction through in-state service. *Burnham*, 495 U.S. at 617; *see also Pennoyer*, 95 U.S. at 735-36. States also declared that doing business without a registered agent would constitute implied “consent” to service on an agent appointed by statute, generally a state official. *See, e.g., Old Wayne Mut. Life Ass’n v. McDonough*, 204 U.S. 8, 21-22 (1907). Such implied “consent” was limited to cases arising from business the corporation did in the forum state. *Id.* at 22-23. At the same time, the appointment of an in-state agent chosen by the corporation came to be seen as express consent to suit on any claim for which the agent was authorized to accept service. *See, e.g., Bagdon v. Phila. & Reading Coal & Iron Co.*, 111 N.E. 1075 (N.Y. 1916).⁹

“As many observed, however, the consent and presence [on which these theories rested] were purely fictional.” *Burnham*, 495 U.S. at 617-18 (plurality opinion); *see Shaffer v. Heitner*, 433 U.S. 186, 201-03 (1977). In *International Shoe*, decided in 1945, the Supreme Court “cast those fictions aside.” *Burnham*, 495 U.S. at 618 (plurality opinion). That opinion and its progeny “abandoned ‘consent’ ...

⁹ The artificial distinction these cases drew between corporations that comply with state registration statutes by appointing an agent, and corporations that do not—exposing the former to general jurisdiction, but the latter only to specific jurisdiction—was one of the considerable problems of the *Pennoyer* framework. *See Smolik v. Phila. & Reading Coal & Iron Co.*, 222 F. 148, 150-51 (S.D.N.Y. 1915) (Hand, J.); 4 Wright & Miller, *Federal Practice & Procedure* §1066 (West 3d ed. 2015) (calling this point “a particular source of objection to the use of the consent theory”).

and ‘presence’ as the standard for measuring the extent of state judicial power over [foreign] corporations.” *McGee*, 355 U.S. at 222. Instead of relying on personal service in the forum, the new approach focused on whether the defendant had “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*, 311 U.S. at 463). Since then, the Court has consistently reaffirmed that “the central concern of the inquiry into personal jurisdiction” is now “the relationship among the defendant, the forum, and the litigation,” rather than a narrow focus on the appointment of an agent for service in the forum or some purely fictional theory of consent. *Daimler*, 134 S. Ct. at 754 (quoting *Shaffer*, 433 U.S. at 204); see *Walden*, 134 S. Ct. at 1121; *World-Wide Volkswagen*, 444 U.S. at 292; cf. *Burnham*, 495 U.S. at 618 (plurality opinion) (“Subsequent cases have derived from the *International Shoe* standard the general rule that a State may dispense with in-forum personal service on nonresident defendants in suits arising out of their activities in the State.”). Today, every assertion of jurisdiction over an absent and nonresident defendant “must be evaluated according to the standards set forth in *International Shoe* and its progeny.” *Shaffer*, 433 U.S. at 212; see *Burnham*, 495 U.S. at 621 (opinion of Scalia, J.).¹⁰

¹⁰ The Delaware Supreme Court in *Sternberg* reached the opposite conclusion by relying on dicta in *Bendix Autolite Corp. v. Midwesco Enters.*, 486 U.S. 888 (1988), to the effect that that appointment of a registered agent in Ohio would subject an out-

The district court ignored that doctrinal evolution. In holding that “a corporation may be deemed to have consented” to general jurisdiction in a state by “complying with the requirements imposed by that state for registering or qualifying to do business there,” the district court relied first and foremost on precedent from the long-dead world of *Pennoyer*. JA17-18. That fatally flawed approach is well demonstrated by the court’s reliance on *Pennsylvania Fire Insurance Co. v. Gold Issue Mining Co.*, a four-page Justice Holmes opinion from 1917 in which the Court held that a state could treat in-state service on an appointed agent as a sufficient basis for general personal jurisdiction. 243 U.S. at 95-96. Adhering to the *Pennoyer* framework, the *Pennsylvania Fire* Court focused on whether the agent was properly authorized to accept service in the forum on a cause of action unrelated to the forum; if so, serving that agent in the forum would be the same as serving the corporation itself in the forum. *See id.* at 95 (“The defendant had executed a power of attorney that made service on [its agent] the equivalent of personal service. If by a corporate vote it had accepted service in this specific case, there would be no doubt of the jurisdiction of the state court”).

of-state corporation to general jurisdiction there. *Sternberg*, 550 A.2d at 1112-13. But *Bendix* did not consider whether that assertion of general jurisdiction would comply with due process. *See Bendix*, 486 U.S at 892-93.

The other early Supreme Court cases cited by the district court all follow similar reasoning and are thus similarly inapposite. *See Neirbo Co.*, 308 U.S. at 169, 173 (holding that appointing an agent for service of process constituted “effective consent” to venue in federal as well as state courts); *Robert Mitchell Furniture Co. v. Selden Breck Constr. Co.*, 257 U.S. 213, 215-16 (holding that ambiguous registration statutes should be construed as consent to specific rather than general jurisdiction); *Ex parte Schollenberger*, 96 U.S. 369, 376-77 (1877) (holding that a federal court could take jurisdiction over a defendant who “consent[s] to be ‘found’” in the forum by appointing an agent).

These cases, all “decided in the era dominated by *Pennoyer*’s territorial thinking ... should not attract heavy reliance today.” *Daimler*, 134 S. Ct. at 761 n.18. Today, “all assertions of state-court jurisdiction must be evaluated according to the standards set forth in *International Shoe* and its progeny.” *Shaffer*, 433 U.S. at 212. And “[t]o the extent that prior decisions are inconsistent with this standard,” they have long since been “overruled.” *Id.* at 212 n.39; *see also McGee*, 355 U.S. at 222 (explaining that the Court has “abandoned” its previous theories of consent and presence); *Freeman v. Second Jud. Dist. Ct.*, 1 P.3d 963, 968 (Nev. 2000) (same). Modern due process doctrine “places all suits against absent nonresidents on the same constitutional footing.” *Burnham*, 495 U.S. at 621 (opinion of Scalia, J.) Given the radical shift in personal jurisdiction jurisprudence between *Pennoyer* and

the present day, treating mere registration or appointment of an agent for service as sufficient to create general jurisdiction through some fiction of consent or presence would only “perpetuat[e] ... ancient forms” that cannot be squared with fair play and substantial justice. *Shaffer*, 433 U.S. at 212; see *Burnham*, 495 U.S. at 630 (Brennan, J., joined by Marshall, Blackmun, and O’Connor, JJ., concurring in the judgment).

Even before *Daimler*, courts were divided over whether business registration could be viewed as sufficient to create general personal 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*, 1 P.3d at 968 (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 1115-16.¹¹

¹¹ The district court cited *Holloway v. Wright & Morrissey, Inc.*, 739 F.2d 695, 697 (1st Cir. 1984), as holding that business registration can be construed as consent to jurisdiction. JA19. That case, however, holds only that business registration can represent consent to *specific* jurisdiction, in cases “causally connected to the defendant’s acts in [the forum].” *Id.* at 699. The district court also cited *King v. Am. Family Mut. Ins. Co.*, 632 F.3d 570 (9th Cir. 2011), and *Siemer v. Learjet Acquisition Corp.*, 966 F.2d 179 (5th Cir. 1992), as envisioning that registration might constitute

Daimler should have eliminated any remaining doubts on the issue. 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 *Pennoyer*-era fiction of consent through appointment of an agent cannot provide an end-run around *Daimler*.¹²

The district court believed that rejecting business registration as consent to jurisdiction would “eliminate consent as a basis for jurisdiction” and “threaten to fundamentally alter the personal jurisdiction defense from a waivable to a non-waivable right.” JA29. But true consent—as well as forfeiture through voluntary litigation conduct—will be alive and well no matter how this Court decides this

consent to general jurisdiction. Those citations are surprising, since both *King* and *Siemer* strongly indicated that mere registration should *not* be construed as consent to general jurisdiction. *See King*, 632 F.3d at 572 (“Mere appointment of an agent for service of process cannot serve as a talismanic coupon to bypass [minimum contacts analysis].”); *Siemer*, 966 F.2d at 183 (“To assert, as plaintiffs do, that mere service on a corporate agent automatically confers *general jurisdiction* displays a fundamental misconception of corporate jurisdictional principles.”).

¹² The district court cited two recent Second Circuit cases as “consistent with [its] view” that registering to do business could be consent to general jurisdiction even after *Daimler*. JA27 n.18. (citing *Gucci America v. Li*, 768 F.3d 122, 136 n.15 (2d Cir. 2014); *Tiffany (NJ) LLC v. China Merchants Bank*, 589 F. App’x 550, 553 (2d Cir. 2014) (summary order)). Those cases, however, expressed no view on whether registration could create general jurisdiction; they only remanded for the district court to consider the issue in the first instance.

appeal. The question here is only whether—consistent with due process—mere compliance with a state’s mandatory business registration statutes can be held to substitute for voluntary consent. The Court’s modern personal jurisdiction cases make clear that such purely fictional implied consent is no substitute for due process analysis. And after *Daimler*, it is crystal clear that the requirements of due process are not satisfied when a state requires corporations, as a condition of doing business, to appoint a local agent for service of process—and then treats the appointment of that agent as consent to *general personal jurisdiction* over any claim, by any plaintiff, arising anywhere in the world.¹³

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

In likely recognition that reasonable minds could disagree (and already had) with its general personal jurisdiction analysis, the district court held in the alternative that Delaware can permissibly assert specific personal jurisdiction over this ANDA

¹³ Although the district court saw no “meaningful difference” between jurisdiction based on consent in a private contractual agreement and jurisdiction based on compliance with a registration statute, JA29 n.19, the two differ markedly in their scope. Consent by contract is generally limited to jurisdiction over claims brought by the parties on matters related to the contract—effectively specific jurisdiction over the transaction. It does not open the consenting party to suit by unrelated plaintiffs. *See, e.g., Astra USA, Inc. v. Santa Clara Cnty.*, 131 S. Ct. 1342, 1347 (2011) (noting that a nonparty can enforce a contractual provision “only if the contracting parties so intend”). Treating registration as consent to general jurisdiction, by contrast, opens the defendant corporation to suit in the forum by any plaintiff on any claim arising anywhere in the world—a significant burden for a nonresident corporation. *Bendix*, 486 U.S. at 893.

suit against Mylan because Mylan provided the statutorily-required notice of Mylan's paragraph IV filing at FDA headquarters in Maryland to the New York headquarters of a Delaware corporation. That holding is equally unsustainable. For specific jurisdiction to exist, the suit must be 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). The provision of statutorily-required notice of a filing with a federal agency in Maryland hardly constitutes purposeful availment of a Delaware forum.

As the district court noted, "specific jurisdiction has traditionally been disfavored as a basis for finding personal jurisdiction in an ANDA case." JA38. (citing *AstraZeneca*, 2014 WL 5778016, at *6). For good reason: the actions required to file an ANDA generally are not enough to establish specific jurisdiction anywhere except perhaps the state where the ANDA was prepared. *See Zeneca Ltd. v. Mylan Pharm.*, 173 F.3d 829 (Fed. Cir. 1999) (holding that the filing of an ANDA application in Maryland does not create specific jurisdiction there); *Pfizer Inc. v. Apotex, Inc.*, No. 08-948, 2009 WL 2843288, at *3 n.5 (D. Del. Aug. 13, 2009) ("[T]he location of the injury ... is the location of the preparation and submission of the ANDA."); *Pfizer Inc. v. Synthom Holding, B.V.*, 386 F. Supp. 2d 666, 675-76 (M.D.N.C. 2005) (finding specific jurisdiction where the ANDA is prepared). This

case illustrates the point: it involves no contact between Mylan and Delaware at all, let alone a purposeful contact that could conceivably give rise to specific personal jurisdiction. The suit arises from the “highly artificial” act of patent infringement that Mylan committed by filing its ANDA application with the FDA in Maryland. Neither that action, nor the subsequent provision of the statutorily-required notice of that Maryland filing via a letter to Acorda in New York, can create jurisdiction in a state where the letter was neither sent nor received. The mere fact that the plaintiff who received the letter was a Delaware corporation does not (and cannot) show that Mylan “purposefully avail[ed] itself” of the laws of Delaware, *Hanson*, 357 U.S. at 253, or “submit[ted] to the judicial power” of Delaware through “contact with and activity directed at” that state, *Nicastro*, 131 S. Ct. at 2788 (plurality opinion).

Moreover, sending a statutorily-required notice letter is not a voluntary “activity” that could create specific jurisdiction in any state. *See Zeneca*, 173 F.3d 829. And the other contacts between Mylan and Delaware that the district court cited come nowhere close to justifying the exercise of specific personal jurisdiction in this case. *See Burger King*, 471 U.S. at 472-73 (specific jurisdiction requires the litigation to “arise out of or relate to” activities “purposefully directed” at the forum).

Affirming the decision below would effectively declare that all ANDA plaintiffs can claim personal jurisdiction in their own home states over all ANDA defendants. That rule 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 simply does not permit that result.

A. This Suit Does Not Arise From Any Activity Mylan Has Purposefully Directed at Delaware.

As the Supreme Court recently underscored in *Walden*, 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.” 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)).¹⁴ The first two parts together demonstrate the “minimum contacts” that are constitutionally required for specific jurisdiction under *International Shoe. Id.*

¹⁴ While *Grober* actually refers to activities “directed at residents of the forum state,” 686 F.3d at 1346, the Supreme Court made abundantly 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.

Although purporting to apply this framework, *see* JA31-32, the district court failed to identify any activities that Mylan purposely directed at Delaware and that also give rise to plaintiffs' claims.

1. Mailing an ANDA notice letter to New York is not suit-related activity purposefully directed at Delaware.

The primary suit-related activity on which the district court relied was the fact that after making its ANDA filing with the FDA in Maryland, Mylan provided the statutorily-required notice of that Maryland filing to Acorda at its headquarters in New York. For at least three reasons, that "activity" cannot provide the "minimum contacts" necessary to hale Mylan into court in Delaware.

a. The notice letter is not a contact with Delaware.

First, mailing a letter from West Virginia to New York providing notice of a Maryland filing does not create jurisdictional contacts with Delaware. The only connection between the notice letter and Delaware is the fact that it was received by a Delaware corporation. But under the Supreme Court's decision last year in *Walden v. Fiore*, it is clear beyond all doubt that such a connection is irrelevant. *Walden* clearly underscores 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. That squarely forecloses the assertion of specific jurisdiction over Mylan in Delaware.

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 exercise 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 noted it had "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 (2014)).

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 explained that “no part” of the officer’s conduct occurred in Nevada—he never “traveled to, conducted activities within, contacted anyone in, or sent anything or anyone” to that state. *Id.* And 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 specific jurisdiction could be based merely on doing injury to a resident of the forum:

[M]ere injury to a forum resident is not a sufficient connection to the forum. 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. The proper question is 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.

Id.

The same principles compel the conclusion that the notice letter is not a constitutionally sufficient minimum contact between Mylan and Delaware. As the district court recognized, Mylan mailed the letter to Acorda at its headquarters in New York, not Delaware. JA36. In other words, Mylan did not purposefully direct the notice letter toward Delaware at all. The district court acknowledged that fact, but held that “the absence of a mailing into Delaware” did not “eliminate[] the possibility of exercise of specific jurisdiction.” JA36. Instead, it relied on the fact that Acorda is a Delaware corporation, and so was allegedly “injured” in Delaware. JA37. But *Walden* makes clear that only the defendant’s own actions can create the

minimum contacts necessary for specific jurisdiction. *Walden*, 134 S. Ct. at 1122. Relying on the place where the plaintiff is incorporated and the place where the plaintiff is injured is exactly the kind of plaintiff-focused analysis that the Court has “consistently rejected.” *Id.*

What is more, the minimum contacts analysis looks to whether Mylan had any suit-related contacts *with Delaware*, not whether it had any suit-related contacts with “persons who reside there.” *Id.* Communicating with a Delaware corporation in New York may be a contact with a Delaware resident, but it is certainly not a contact with the state of Delaware—just as harassing a Nevada resident in Georgia is a contact with a Nevada resident but not the state of Nevada. *See id.* at 1122-23. Even assuming that Mylan “knew or should have known” that Acorda was a Delaware corporation, JA32, that cannot transform Mylan’s contacts with Acorda into contacts with Delaware. As *Walden* states, and as at least three federal courts of appeals have since confirmed, a defendant cannot create jurisdictional contacts with a forum just by interacting with a person it knows is a resident of that forum. *Walden*, 134 S. Ct. at 1125; *see Fastpath, Inc. v. Arbela Techs. Corp.*, 760 F.3d 816, 822-23 (8th Cir. 2014) (finding no specific jurisdiction in Iowa over a defendant that “aggressively pursu[ed]” business with a plaintiff it knew was an Iowa corporation); *Advanced Tactical Ordnance Sys., LLC v. Real Action Paintball, Inc.*, 751 F.3d 796, 802 (7th Cir. 2014) (“The district court also thought personal jurisdiction proper because

[defendant] knew that [plaintiff] was an Indiana company and could foresee that its misleading emails and sales would harm [plaintiff] in Indiana. *Walden*, however, shows the error of this approach.”); *Rockwood Select Asset Fund XI (6)-1, LLC v. Devine, Millimet & Branch*, 750 F.3d 1178, 1180 (10th Cir. 2014) (finding no jurisdiction over a defendant who merely “interacted with the plaintiff after learning of its strong connections to the forum state”). Basing specific jurisdiction on the fact that a defendant knows the plaintiff is a foreign resident “improperly attributes a plaintiff’s forum connections to the defendant and makes those connections ‘decisive’ in the jurisdictional analysis.” *Walden*, 134 S. Ct. at 1125. The Court squarely rejected that theory of specific jurisdiction in *Walden*, and the district court was wrong to apply it here.

The district court attempted to bolster its holding by pointing to other connections between *Acorda* and Delaware that Mylan “knew or should have known” existed before sending the notice letter. Specifically, it noted that “Acorda had already begun litigating the Ampyra® patents in the District of Delaware”; that “Acorda would file suit against [Mylan] within 45 days of receiving the [notice letter]; and that “to obtain the efficiencies of coordinated litigation in a single district, Plaintiffs would almost certainly sue [Mylan] in Delaware.” JA32. These additional facts about *Acorda*’s Delaware contacts (even well-known ones) simply double down on the mistaken focus on the plaintiff’s forum contacts, when it is the

defendant's forum contacts that are relevant. *Walden*, 134 S. Ct. at 1125; *see Fastpath*, 760 F.3d at 822-23; *Advanced Tactical*, 751 F.3d at 802; *Rockwood*, 750 F.3d at 1180.

Under *Walden*, activity directed outside the forum simply is not enough to create specific jurisdiction in the forum, even if it intentionally injures a forum resident. 134 S. Ct. at 1122-26. “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). The district court’s analysis ignored that critical principle, treating the interaction between Mylan and Acorda in New York as sufficient to create a relationship between Mylan and Delaware. That logic cannot be squared with *Walden*.

The district court’s attempts to distinguish *Walden* are unavailing. The court pointed out that the plaintiffs in *Walden* were “natural persons experiencing a real injury, not corporations experiencing an artificial injury.” JA38. But nothing in *Walden* turned on the corporeality of the plaintiffs, and the district court gave no reason why that would make any legal difference. The district court also noted that the defendant in *Walden* apparently had no other contacts with Nevada, while Mylan has some limited contacts with Delaware that are unrelated to the present suit. JA38.

But unrelated contacts with the forum insufficient for general jurisdiction cannot create *suit-related* contacts between Mylan and Delaware sufficient to generate specific jurisdiction. *Walden* makes plain that sending the notice letter to Acorda in New York cannot serve as a suit-related contact between Mylan and Delaware. *See Walden*, 134 S. Ct. at 1122-23. On that issue, *Walden* is indistinguishable from this case, regardless of any unrelated contacts between Mylan and Delaware.

b. The claims in suit do not arise from or relate to the notice letter.

Second, the patent infringement claims asserted by Acorda and Alkermes do not “arise out of or relate to” the provision of notice of the filing in Maryland. *Burger King*, 471 U.S. at 472; *see Helicopteros*, 466 U.S. at 414 n.8; *Grober*, 686 F.3d at 1348. Acorda and Alkermes claim that Mylan infringed their patents by filing its ANDA with the FDA, not by mailing the required notice letters describing that filing. *See* JA61-66. 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 providing notice of that filing. *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 patentee is informed of the act of infringement. *See* 35 U.S.C. §271(e)(2)(A). Basing specific jurisdiction on the notice letter would be like basing specific jurisdiction over a breach of contract case on a phone call by which the plaintiff learned about the breach. Under this Court’s view of the “arises out of or

relates to” requirement, the notice letter is not sufficiently connected to the substance of plaintiffs’ claims to create specific jurisdiction. *See 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).

c. The notice letter cannot be a jurisdictional contact.

Third, even if the suit were related to the notice letter as opposed to the FDA filing, that letter is a statutorily-required part of a petition to the federal government that cannot qualify as a “contact” with any state. That conclusion follows from *Zeneca Ltd. v. Mylan Pharmaceuticals, Inc.*, in which 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.

Judge Gajarsa and Judge Rader wrote separately in *Zeneca* to explain their different reasons for their decision. For Judge Gajarsa, the case turned 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 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 833.¹⁵

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 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

¹⁵ Judge Gajarsa also noted that allowing specific jurisdiction in Maryland would turn the District of Maryland into a “supercourt” for ANDA cases. *Zeneca*, 173 F.3d at 832 (opinion of Gajarsa, J.).

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.). 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.).¹⁶

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

¹⁶ 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.).

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 avilment 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 avilment of the forum to which the service copy is mailed.

Indeed, this Court has repeatedly held that the sending of wholly voluntary “letters threatening infringement litigation is not sufficient to confer personal jurisdiction.” *Silent Drive*, 326 F.3d at 1202; *see Avocent*, 552 F.3d at 1333; *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.* at 1333 (quoting *Red Wing Shoe*, 148 F.3d at 1360-61), an ANDA filer must have sufficient latitude to notify the brand-name patentholder of its intentions—as required by statute—without subjecting itself to specific jurisdiction. *See also Red Wing*, 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.”).¹⁷

2. The other contacts between Mylan and Delaware do not give rise to the suit.

Along with the notice letter, the district court identified a number of other contacts between Mylan and Delaware that it saw as contributing to specific jurisdiction. It noted again that Mylan had registered to do business and appointed an agent for service of process in Delaware, and that Mylan had registered with the Delaware state board of pharmacy. JA32. It also pointed out that Mylan has “been a frequent litigant in the District of Delaware” in ANDA cases—typically as a defendant—and such litigation was a normal part of its “business model” as a generic drug manufacturer. JA33 n.23.

None of those contacts can create specific jurisdiction here, however, because none of them gives rise to or relates 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”). *Acorda* and *Alkermes* are not suing Mylan for

¹⁷ Other circuits have likewise concluded that merely sending a letter into the forum is not enough to create specific jurisdiction. *See, e.g., Fastpath*, 760 F.3d at 824 (“Although letters and faxes may be used to support ... personal jurisdiction, they do not themselves establish jurisdiction.”); *Rockwood*, 750 F.3d at 1180 (holding that “sending [an] opinion letter to a Utah address” is “insufficient for personal jurisdiction in Utah”).

registering to do business in Delaware, appointing an agent there, or previously participating in ANDA litigation there. Without suit-related contacts 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.”). Once some minimum suit-related contacts have been established, then other unrelated contacts “may be considered ... to determine whether the assertion of personal jurisdiction would comport with ‘fair play and substantial justice.’” *Burger King*, 471 U.S. at 476-77; *see Grober*, 686 F.3d at 1346. But if the plaintiff cannot show a suit-related contact first, then no amount of unrelated contacts can create specific jurisdiction.

The district court believed specific jurisdiction was appropriate because of the “high degree of predictability that Acorda, a Delaware corporation, would sue [Mylan] in Delaware.” JA34. It took judicial notice of a published report stating that “nearly 41% of all ANDA cases filed over the last five years have been filed in the District of Delaware,” JA34 n.24, and concluded that Mylan should have known that developing generic drugs would “regularly render [it] liable to suit in the District of Delaware.” JA34-35. And it emphasized again that Acorda had already filed suit on the same patents in Delaware against another defendant. JA34. Those facts, however, do nothing to show that Mylan has “purposefully directed” any relevant activity at Delaware. *Burger King*, 471 U.S. 472 (quoting *Keeton v. Hustler*

Magazine, Inc., 465 U.S. 770, 774 (1984)). The fact that Acorda would likely bring suit in Delaware, or that many other ANDA plaintiffs have previously brought suit in Delaware, simply cannot create a jurisdictional contact between Mylan and that state. *See Walden*, 134 S. Ct. at 1122; *Helicopteros*, 466 U.S. at 417 (“[The] unilateral activity of another party or a third person is not an appropriate consideration when determining whether a defendant has sufficient contacts with a forum State to justify an assertion of jurisdiction.”).

3. The allegations of future indirect sales in Delaware are not sufficient to show conduct by Mylan purposefully directed at Delaware.

Although Mylan had no direct sales in Delaware as of 2013, JA5, plaintiffs’ complaint alleges that if Mylan’s ANDA is approved, its generic dalfampridine tablets “will be distributed and sold in the United States, including in Delaware.” JA58. To the extent the district court relied on that allegation to find specific jurisdiction, it again erred.

First, plaintiffs’ claim that Mylan infringed its patents by its ANDA filing does not arise from or relate to any future sales by Mylan in Delaware. That artificial act of alleged infringement was complete the moment that Mylan filed an ANDA with a paragraph IV certification in Maryland; plaintiffs will have an equally valid (or invalid) claim of infringement under 35 U.S.C. §271(e)(2)(A) whether or not Mylan ever makes any future sales. *See Caraco*, 132 S. Ct. at 1677 (ANDA filing is “itself

an act of infringement, which gives the brand an immediate right to sue”). 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).

Second, even if plaintiffs’ claims did arise from the possibility of future sales in Delaware, plaintiffs do 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 in Delaware.” JA32. A four-Justice plurality of the Supreme Court has twice concluded that such activity is insufficient to give rise to specific personal jurisdiction. *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, the allegations of future sales in the complaint—which give no indication that Mylan has purposefully directed its product toward Delaware rather than toward the United States market as a whole—are not enough. *See Nicastro*, 131 S. Ct. at 2790 (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.” Eric. H. Weisblatt & Claire Frezza, *Who to Sue and Where in ANDA Litigation: Personal Jurisdiction Post-Daimler*, 69 Food & Drug L.J. 351, 352-53 (2014); *see Intendis, Inc. v. River’s Edge Pharm.*, No. 11-2838, 2011 WL 5513195, at *3-5 (D.N.J. Nov. 10, 2011) (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.

B. The District Court Erred by Finding Specific Jurisdiction Even Though Mylan Did Not Purposefully Direct Any Suit-Related Conduct at Delaware.

Specific jurisdiction requires not only that the suit arise from activity purposefully 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 (explaining that the reasonableness inquiry only applies “[o]nce it has been decided that a defendant purposefully established minimum contacts”). The district court erred by conflating these two distinct issues. Its analysis simply recited all the alleged contacts between Mylan and Delaware, including contacts obviously unrelated to the suit, and then concluded that holding Mylan to specific jurisdiction would comply with “fair play and substantial justice.” JA32-33. But that reasoning misses the point: if the defendant has not purposefully directed his conduct at the forum, or the suit does not arise from that conduct, that is the end of the analysis. *Nicastro*, 131 S. Ct. at 2790-91 (plurality opinion) (“expediency” cannot create jurisdiction absent minimum contacts).

The district court spent pages explaining why, in its view, suit in Delaware was “predictab[le]” and the so-called *Burger King* factors supported jurisdiction. JA34-36. But as the district court itself recognized, those factors are only “pertinent

to determining ‘whether assertion of personal jurisdiction is reasonable and fair in a particular case.’” JA35. Even if the district court were correct that those factors favor the fairness of exercising any jurisdiction that exists, they cannot *create* jurisdiction over a defendant who has not purposefully directed any suit-related activity at the forum. *See Walden*, 134 S. Ct. at 1122 (explaining that the rules of personal jurisdiction “principally protect the liberty of the nonresident defendant—not the convenience of plaintiffs or third parties”).

In all events, the district court was wrong to conclude that specific jurisdiction over Mylan would be fair and reasonable. This Court has repeatedly held that exercising specific jurisdiction over a defendant who merely sends a letter threatening infringement litigation is *per se* unreasonable and unfair, 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. 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). 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 on a

statutorily-required ANDA notice letter—regardless of the “predictability” of suit in the forum or the *Burger King* factors. See *Avocent*, 552 F.3d at 1333; *Silent Drive*, 326 F.3d at 1202; *Red Wing Shoe*, 148 F.3d at 1360-61.

CONCLUSION

The district court’s general jurisdiction analysis would nullify *Daimler*, and its specific jurisdiction analysis cannot be reconciled with *Walden*. For the reasons set forth above, this Court should reverse on both questions presented and order the case dismissed for lack of personal jurisdiction.

Respectfully submitted,

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May 22, 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 13,045 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 tpestyle 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 22, 2015

s/Paul D. Clement
Paul D. Clement

Addendum

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

ACORDA THERAPEUTICS, INC. and)
ALKERMES PHARMA IRELAND)
LIMITED,)

Plaintiffs,)

v.)

Civil Action No. 14-935-LPS

MYLAN PHARMACEUTICALS INC.)
and MYLAN INC.)

Defendants.)

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OPINION

January 14, 2015
Wilmington, Delaware



STARK, U.S. District Judge:

Defendants Mylan Pharmaceuticals Inc. (“Mylan Pharma”) and Mylan Inc. (“Mylan Inc.” and, together with Mylan Pharmaceuticals, “Mylan” or “Defendants”) have moved to dismiss the complaint filed against them by Plaintiffs Acorda Therapeutics, Inc. (“Acorda”) and Alkermes Pharma Ireland Limited (“Alkermes” and, together with Acorda, “Plaintiffs”). (D.I. 10) Defendants bring their motion pursuant to Federal Rule of Civil Procedure 12(b)(2), asserting a lack of personal jurisdiction. Specifically, Mylan contends that the Supreme Court’s recent decision in *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014), has resulted in the District of Delaware lacking general jurisdiction over Mylan in this (and likely all)¹ Abbreviated New Drug Application (“ANDA”) lawsuits. Mylan further contends that its relationship with Delaware and with this litigation does not support the exercise of specific jurisdiction.

After reviewing thorough briefing and hearing oral argument, the Court has concluded that it does have personal jurisdiction over Mylan Pharma in this action. While *Daimler* altered the analysis with respect to general jurisdiction – and the Court agrees with Mylan that this Court cannot exercise general personal jurisdiction over either of the Mylan Defendants on the basis that they are “at home” in Delaware – *Daimler* does not change the fact that Mylan Pharma consented to this Court’s exercise of personal jurisdiction when it registered to do business and appointed an agent for service of process in the State of Delaware. In addition, Plaintiffs have met their burden to establish that this Court has personal jurisdiction over Mylan Pharma based

¹At oral argument on the motion to dismiss, Mylan’s attorney stated, “The *Daimler* court changed the game. Because of that, we don’t expect to be sued here any more.” (See Transcript of Dec. 15, 2014 Hearing (D.I. 29) (“Tr.”) at 9)

on specific jurisdiction, which provides an independent reason for denying the motion as it relates to Mylan Pharma.

With respect to Mylan Inc., which is the parent of Mylan Pharma, the Court lacks general jurisdiction, as Mylan Inc. is neither “at home” nor registered to do business in Delaware. However, Plaintiffs allege but have not proven a non-frivolous claim that Mylan Inc. used Mylan Pharma as its agent in connection with the ANDA filing giving rise to this litigation. Therefore, the Court will permit Plaintiffs to take jurisdictional discovery of Mylan Inc.’s relationship with Mylan Pharma and with the ANDA filing at issue in this case.

BACKGROUND

I. Plaintiffs: Acorda and Alkermes

Plaintiff Acorda is a corporation organized under the laws of the State of Delaware, having a principal place of business in Ardsley, New York. (D.I. 1 at ¶ 3) Acorda researches, develops, and sells biotech and pharmaceutical products, including therapies to restore neurological functioning in people with multiple sclerosis (“MS”). (*Id.*) Plaintiff Alkermes is a corporation organized under the laws of Ireland, having a principal place of business in Dublin, Ireland. (*Id.* at ¶ 4)

Acorda’s “flagship drug product” is Ampyra®, which has been shown to improve walking in people with MS. (*Id.* at ¶¶ 2, 30) Acorda holds New Drug Application (“NDA”) No. 022250, approved by the U.S. Food and Drug Administration (“FDA”), for the use of 10 mg dalfampridine extended release tablets. (*Id.* at ¶ 30) It is this product which Acorda sells under the registered name Ampyra®. (*Id.*)

There are five patents-in-suit: U.S. Patent Nos. 5,540,938 (the “’938 patent”), 8,007,826 (the “’826 patent”), 8,354,437 (the “’437 patent”), 8,440,703 (the “’703 patent”), and 8,663,685 (the “’685 patent”) (collectively, “the Ampyra® patents”). All of the Ampyra® patents are listed in the FDA’s “Orange Book”² and have expiration dates of between 2018 and 2027. (*Id.* at ¶¶ 32-33) Acorda is the exclusive U.S. licensee of the ’938 patent – which is assigned to co-Plaintiff Alkermes – and has all right, title, and interest in the other four Ampyra® patents. (*Id.* at ¶¶ 5-6, 25)

II. Defendants: Mylan Pharma and Mylan Inc.

Mylan Pharma is a corporation organized under the laws of the State of West Virginia, having a principal place of business in Morgantown, West Virginia. (*Id.* at ¶ 7; D.I. 12 at 2) It “formulat[es], develop[s], manufactur[es], packag[es], market[s], and sell[s] generic copies of branded pharmaceutical products for the United States market, including in Delaware.” (D.I. 1 at ¶ 8)

On April 7, 2010, pursuant to sections 371 and 376 of title 8 of the Delaware Code, Mylan Pharma qualified to do business in Delaware, by filing with the Secretary of State (1) a certificate of incorporation, representing its business as “[p]harmaceutical manufacturing, distribution and sales,” and (2) a statement naming Corporation Services Company, in Wilmington, Delaware, as its registered agent to accept service of process in the State of

²As the Supreme Court has explained, “To facilitate the approval of generic drugs as soon as patents allow, the Hatch-Waxman Amendments and FDA regulations direct brand manufacturers to file information about their patents. . . . [T]he FDA . . . [then] publishes the . . . patent numbers and expiration dates, in a fat, brightly hued volume called the Orange Book (less colorfully but more officially denominated Approved Drug Products with Therapeutic Equivalence Evaluations).” *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012) (internal citations omitted).

Delaware. (D.I. 1 at ¶ 7; D.I. 15 at 5; D.I. 16, Exs. A & B) Mylan Pharma is also registered with the Delaware Board of Pharmacy as a licensed “Pharmacy-Wholesale” and a “Distributor/Manufacturer CSR.” (D.I. 1 at ¶ 9; D.I. 16, Exs. C & D) Additionally, Mylan Pharma has “litigat[ed], as a defendant, over 50 other civil actions initiated in this jurisdiction in the last 19 years and affirmatively invoked this Court’s jurisdiction by asserting counterclaims in at least 46 of those cases.” (D.I. 1 at ¶ 17)

Mylan Inc. is a corporation organized under the laws of the Commonwealth of Pennsylvania, having a principal place of business in Canonsburg, Pennsylvania. (*Id.* at ¶ 10) Mylan Inc. is “a pharmaceutical company which develops, licenses, manufacturers, markets and distributes generic pharmaceuticals in the U.S.” (*Id.* at ¶ 11) In fact, Mylan Inc. reports that “it is one of the largest generic pharmaceutical companies in the world today in terms of revenue as a result of, *inter alia*, its ‘ability to efficiently obtain [ANDA] approvals.” (*Id.* at ¶ 19; D.I. 16, Ex. E at 5) More particularly, Mylan Inc. “holds the number one ranking in the U.S. generics prescription market in terms of sales and the number two ranking in terms of prescriptions dispensed.” (D.I. 1 at ¶ 19)

Although 20 Mylan Inc. subsidiaries have incorporated in Delaware (*see* D.I. 16, Ex. E at 37-40), Mylan Inc. is not registered to do business in Delaware (*see* Tr. at 43). Mylan Inc. has “litigat[ed] as a defendant and assert[ed] counterclaims in at least 15 cases initiated in this jurisdiction over the past ten years.” (D.I. 1 at ¶ 20)

Neither of the Defendants has any manufacturing plants, offices, facilities, other real property, a telephone listing, or a mailing address in the State of Delaware. (D.I. 12 at ¶ 5) In 2013, Mylan Pharma had no sales in Delaware, and that same year Mylan Inc.’s sales in

Delaware produced just \$429 in revenue. (*Id.* at ¶ 5) These figures do not include any revenue the Mylan Defendants derive from distribution of generic drug products in Delaware through out-of-state distributors. (*See* Tr. at 57)

Mylan Pharma is a wholly-owned subsidiary of Mylan Inc. (*Id.* at ¶ 7) Plaintiffs allege that Mylan Pharma and Mylan Inc. “are agents of each other and/or work in concert with each other with respect to the development, regulatory approval, marketing, sale, and distribution of pharmaceutical products throughout the United States, including into Delaware.” (*Id.* at ¶ 21) It is undisputed, however, that Defendants are separate corporate entities. (D.I. 17 at 8)

III. Mylan’s ANDA Filing and ANDA Notice Letter

On January 22, 2014, Mylan Pharma filed ANDA No. 20-6858 (“Mylan’s ANDA Filing”)³ seeking FDA approval to market generic 10 mg doses of dalfampridine extended-release tablets (“Mylan’s Generic Product”) in the United States before the expiration of the Ampyra® patents. (D.I. 12 at ¶ 7; *see also* D.I. 1 at ¶ 36) Mylan’s ANDA Filing included a “paragraph IV certification,” pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), contending that the Ampyra® patents are “invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale” of Mylan’s Generic Product. (D.I. 1 at ¶ 35) Mylan Pharma prepared Mylan’s ANDA Filing in West Virginia and filed it with the FDA in Maryland. (D.I. 12 at 2-3) Plaintiffs allege that “Defendants collaborated and acted in concert in the decision to file and the filing of ANDA No. . . . 20-6858 identified in the Mylan Notice Letter.” (D.I. 1 at

³Mylan’s notice letter to Plaintiffs mistakenly identified Mylan’s ANDA Filing as having been given No. 20-6268. (*See* D.I. 1 at ¶ 34; D.I. 12 at 2 n.2)

¶ 37) If Mylan's Generic Product is approved by the FDA, it will be marketed and distributed, prescribed by physicians, and dispensed by pharmacies, throughout the United States, including in Delaware. (*Id.* at ¶¶ 22-23)

On July 9, 2014, Mylan Pharma gave Plaintiffs notice of Mylan's ANDA Filing (the "Mylan Notice Letter"). (*Id.* at ¶ 34) Specifically, Mylan Pharma mailed the Mylan Notice Letter to Acorda at its principal place of business in New York and also to Alkermes at its principal place of business in Ireland. (*See* Tr. at 24, 50)

IV. Plaintiffs' ANDA Suits

On July 16, 2014, Plaintiffs commenced this action, alleging that Defendants directly and indirectly infringed claims of all of the Ampyra® patents by submitting or causing submission of the Mylan ANDA Filing. (D.I. 1 at 9-16) Because Plaintiffs filed suit within 45 days of receiving the Mylan Notice Letter, the FDA is automatically stayed from giving final approval to Mylan's Generic Product for 30 months. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

In their complaint, Plaintiffs assert five counts of infringement – one for each of the Ampyra® patents – against both Defendants, as well as a sixth count alleging that Mylan Inc. induced infringement by its role in bringing about Mylan's ANDA Filing. (D.I. 1 at ¶¶ 39-86)

Numerous other generic pharmaceutical companies besides Mylan have filed ANDAs seeking FDA approval to market generic versions of Ampyra®. Consequently, Plaintiffs filed seven other related ANDA suits in the District of Delaware in July 2014, all of which are assigned to the same undersigned Judge.⁴ Notably, the first of the Ampyra® patent ANDA suits

⁴*See Acorda Therapeutics Inc. v. Actavis Labs. FL Inc.*, C.A. No. 14-882-LPS (filed July 7, 2014); *Acorda Therapeutics Inc. v. Aurobindo Pharma Ltd.*, C.A. No. 14-909-LPS (filed July 10, 2014); *Acorda Therapeutics Inc. v. Alkem Labs. Ltd.*, C.A. No. 14-917-LPS (filed July 11,

was filed in this Court two days before Mylan Pharma sent Plaintiffs the Mylan Notice Letter.

See Acorda Therapeutics Inc. v. Actavis Labs. FL Inc., C.A. No. 14-882-LPS (filed July 7, 2014), D.I. 1.

V. Mylan's Motion to Dismiss

On August 20, 2014, Defendants filed their motion to dismiss the complaint, pursuant to Federal Rule of Civil Procedure 12(b)(2), contending that this Court lacks personal jurisdiction over both of them. (D.I. 10) Briefing on the motion was completed on September 26, 2014 (D.I. 21), although the parties thereafter submitted letter briefs addressing the subsequent decision by the Honorable Gregory M. Sleet in *AstraZeneca v. Mylan*, 2014 WL 5778016 (D. Del. Nov. 5, 2014) (hereinafter "*AstraZeneca*"). The Court heard oral argument on December 15, 2014.

LEGAL STANDARDS

Pursuant to Federal Rule of Civil Procedure 12(b)(2), a party may move to dismiss a case based on the court's lack of personal jurisdiction over that party. When a defendant moves to dismiss a lawsuit for lack of personal jurisdiction, the plaintiff bears the burden of showing the basis for jurisdiction. *See Power Integrations, Inc. v. BCD Semiconductor*, 547 F. Supp. 2d 365, 369 (D. Del. 2008). If no evidentiary hearing has been held, a plaintiff "need only establish a *prima facie* case of personal jurisdiction." *O'Connor v. Sandy Lane Hotel Co.*, 496 F.3d 312, 316 (3d Cir. 2007). A plaintiff "presents a *prima facie* case for the exercise of personal

2014); *Acorda Therapeutics Inc. v. Roxane Labs. Inc.*, C.A. No. 14-922-LPS (filed July 14, 2014); *Acorda Therapeutics Inc. v. Accord Healthcare Inc.*, C.A. No. 14-932-LPS (filed July 15, 2014); *Acorda Therapeutics Inc. v. Teva Pharm. USA Inc.*, C.A. No. 14-941-LPS (filed July 17, 2014); *Acorda Therapeutics Inc. et al. v. Apotex Corp.*, C.A. No. 14-955-LPS (filed July 18, 2014). Other than the first of these suits, C.A. No. 14-882, in which only Acorda is a plaintiff and the '938 patent is not asserted, all of these suits were brought by both Acorda and Alkermes and assert infringement of all five of the Ampyra® patents.

jurisdiction by establishing with reasonable particularity sufficient contacts between the defendant and the forum state.” *Mellon Bank (E) PSFS, Nat’l Ass’n v. Farino*, 960 F.2d 1217, 1223 (3d Cir. 1992). On a motion to dismiss for lack of personal jurisdiction, “the Plaintiff is entitled to have its allegations taken as true and all factual disputes drawn in its favor.” *Miller Yacht Sales, Inc. v. Smith*, 384 F.3d 93, 97 (3d Cir. 2004). A court is always free to revisit the issue of personal jurisdiction if it later is revealed that the facts alleged in support of jurisdiction are in dispute. *See Metcalfe v. Renaissance Marine, Inc.*, 566 F.3d 324, 331 (3d Cir. 2009).

Determining the existence of personal jurisdiction generally requires a two-part analysis – one statutory and one constitutional.⁵ With respect to the statutory analysis, typically the court analyzes the long-arm statute of the state in which the court is located. *See IMO Indus., Inc. v. Kiekert AG*, 155 F.3d 254, 259 (3d Cir. 1998). Next, the court must determine whether exercising jurisdiction over the moving defendant in this state comports with the Due Process Clause of the U.S. Constitution. *See id.* Due process is satisfied if the court finds the existence of “minimum contacts” between the non-resident defendant and the forum state, “such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice.” *Int’l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945) (internal quotation marks omitted). As explained below, due process may also be satisfied by consent of the party asserting a lack of personal jurisdiction.

⁵With regard to the statutory inquiry, the court applies the law of the state in which the district court is located; as to the constitutional inquiry, in a patent case such as this one the court applies the law of the Federal Circuit. *See Autogenomics, Inc. v. Oxford Gene Tech. Ltd.*, 566 F.3d 1012, 1016 (Fed. Cir. 2009).

DISCUSSION

In opposing Defendants' motion, Plaintiffs assert three bases for this Court's exercise of personal jurisdiction over both Mylan Defendants: (1) general jurisdiction, notwithstanding *Daimler*; (2) general jurisdiction based on consent; and (3) specific jurisdiction. In the Discussion below, the Court first describes the *Daimler* decision, and then turns to each of Plaintiffs' grounds for finding personal jurisdiction.

I. The Supreme Court's Decision in *Daimler*

Daimler involved a dispute over whether the United States District Court for the Northern District of California could exercise general jurisdiction over a German manufacturer of luxury vehicles, DaimlerChrysler Aktiengesellschaft ("Daimler"). The plaintiffs in *Daimler* were 22 Argentinian residents, who alleged that a subsidiary of Daimler, Mercedes-Benz Argentina, violated the Alien Tort Statute, 28 U.S.C. § 1350, and the Torture Victim Protection Act of 1991, 106 Stat. 73, note following 28 U.S.C. § 1350, by collaborating with Argentinian security forces to commit human rights violations during Argentina's "Dirty War." *Daimler*, 134 S. Ct. at 750-51. Daimler's subsidiary allegedly committed the violations in Argentina between 1976 and 1983; the plaintiffs filed suit against Daimler in California in 2004. *See id.* at 751. The plaintiffs asserted that the California court could exercise general jurisdiction; that is, they contended that California "is a place where Daimler may be sued on any and all claims against it, wherever in the world the claims may arise." *Id.*

As the basis for the California court to exercise jurisdiction over Daimler, plaintiffs alleged that an agency relationship existed between Daimler and another of its subsidiaries, Mercedes-Benz USA, LLC ("MBUSA"). *See id.* at 752. MBUSA, which was an "indirect"

subsidiary of Daimler wholly-owned by another Daimler subsidiary, served as Daimler's exclusive importer and distributor in the United States. *See id.* at 752 & n.3. MBUSA was incorporated in Delaware and had its principal place of business in New Jersey. *See id.* at 751-52. MBUSA's U.S. distribution included California, where MBUSA had several corporate facilities. *See id.* at 751-52, 758. MBUSA's annual sales of Daimler vehicles in California generated approximately \$4.6 billion in revenues, accounting for 2.4% of Daimler's global sales. *See id.* at 766-67 (Sotomayor, J., concurring).

Daimler's own contacts with California were sporadic, but the plaintiffs argued that MBUSA's contacts with California could be attributed to Daimler for jurisdictional purposes. *See id.* at 751-52. The district court disagreed, finding that MBUSA was not Daimler's agent, and, further, that Daimler's own contacts with California were insufficient to support a finding of general jurisdiction in California over Daimler. *See id.* at 752. The district court dismissed the case.

On appeal, the Court of Appeals for the Ninth Circuit initially affirmed the dismissal. *See id.* at 753. Later, however, the appellate court granted the plaintiffs' petition for rehearing and reversed the district court, finding general jurisdiction based on an agency relationship between Daimler and MBUSA. *See id.* at 753. Thereafter, the Supreme Court "granted certiorari to decide whether, consistent with the Due Process Clause of the Fourteenth Amendment, Daimler is amenable to suit in California courts for claims involving only foreign plaintiffs and conduct occurring entirely abroad." *Id.* at 753.

In a unanimous holding,⁶ the Supreme Court reversed the Ninth Circuit, agreeing instead with the district court's dismissal. In doing so, the Supreme Court first rejected the Ninth Circuit's view that a subsidiary could be considered an agent for jurisdictional purposes if the subsidiary's services to the parent were important enough that the parent stood ready to perform the services itself. *See id.* at 758-59. The Court then proceeded to explain that, even assuming that MBUSA's contacts with California could be attributed to Daimler, Daimler itself still could not be subjected to the general jurisdiction of California courts. *See id.* at 760.

In reaching its conclusion, the *Daimler* Court emphasized that although "continuous and systematic contacts" are sufficient to support an exercise of specific jurisdiction when those contacts give rise to the cause of action, an exercise of general jurisdiction requires much more. *See id.* at 761. To assess whether general jurisdiction was available, the Supreme Court undertook an analysis of whether Daimler was "essentially at home" in California, a concept the Court had described in *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 131 S. Ct. 2846, 2851 (2011). "[T]he inquiry under *Goodyear* is not whether a foreign corporation's in-forum contacts can be said to be in some sense 'continuous and systematic,' it is whether that corporation's 'affiliations with the State are so 'continuous and systematic' as to render [it] essentially at home in the forum state.'" *Daimler*, 134 S. Ct. at 761 (quoting *Goodyear*, 131 S. Ct. at 2851).

Daimler went on to explain that in all but the most exceptional circumstances, a corporation is "at home" only in the two "paradig[m] . . . bases for general jurisdiction": its place of incorporation and its principal place of business. *Id.* at 760-61 & n.19. These "affiliations

⁶Justice Sotomayor wrote a concurring opinion. *See* 134 S. Ct. at 763-73 (Sotomayor, J., concurring).

have the virtue of being unique – that is, each ordinarily indicates only one place – as well as easily ascertainable.” *Id.* at 760. Accordingly, limiting general jurisdiction to only those forums in which a corporation is “at home” allows corporations “to structure their primary conduct with some minimum assurance as to where that conduct will and will not render them liable to suit,” while “afford[ing] plaintiffs recourse to at least one clear and certain forum in which a corporate defendant may be sued on any and all claims.” *Id.* at 760-62. By contrast, “exorbitant” theories of general jurisdiction, which would render a corporation potentially liable to suit for all claims in many if not all states, lead to unpredictability for the corporation and are thus “unacceptably grasping.” *Id.* at 761-62.

The factual and legal contexts in which *Daimler* arose could hardly be more different than those in which the instant case arises. Most fundamentally, in the 1970s and 1980s, when *Daimler*’s subsidiary was allegedly engaged in the activities ultimately giving rise to the 2004 lawsuit against *Daimler*, *Daimler could not have foreseen* that, more than *two decades later*, it would be sued for *human rights violations* that had occurred in Argentina, and that the suit would be brought in *California*. See, e.g., 134 S. Ct. at 761-62 (describing *Daimler* as “Argentina-rooted case,” involving “claims by foreign plaintiffs having nothing to do with anything that occurred or had its principal impact in California”).⁷ Here, by contrast, when Mylan Pharma sent the Mylan Notice Letter to Plaintiffs on July 9, 2014, it knew to a *near certainty* that, *within 45 days*, it would be sued for *patent infringement*, and that the suit would

⁷The *Daimler* majority opinion concludes by emphasizing “the risks to international comity” that the Ninth Circuit’s “expansive view of general jurisdiction posed.” 134 S. Ct. at 762-63. No one contends that any similar risk is posed in the ANDA context now before this Court.

be brought in *the District of Delaware*. (See Tr. at 9-11) This last, crucial, piece of knowledge was due to the facts that Plaintiff Acorda is a Delaware corporation, which is “at home” in Delaware; and at the time Mylan sent Plaintiffs the Mylan Notice Letter, Acorda had already filed related Ampyra® ANDA litigation in the District of Delaware.

II. Mylan Is Not “At Home” in Delaware

The first basis on which Plaintiffs oppose Mylan’s motion is that, according to Plaintiffs, this Court may exercise general jurisdiction over both Mylan Defendants based on Defendants’ continuous and systematic contacts with Delaware. Plaintiffs maintain that general jurisdiction is present here in Delaware notwithstanding the Supreme Court’s decision in *Daimler*. The Court disagrees.

As an initial matter, the Court agrees with both sides that the general jurisdiction analysis required in this case involves consideration solely of the due process issue, as Defendants have not challenged Plaintiffs’ contention that Delaware’s long-arm statute is satisfied. (See Tr. at 4)

In order for this Court to have general jurisdiction over Mylan based on minimum contacts, the Court must find that Mylan’s “affiliations with the State are so ‘continuous and systematic’ as to render them essentially at home in the forum State.” *Daimler*, 134 S. Ct. at 754 (quoting *Goodyear*, 131 S. Ct. at 2846). *Daimler* explains:

General jurisdiction . . . calls for an appraisal of a corporation’s activities in their entirety, nationwide and worldwide. A corporation that operates in many places can scarcely be deemed at home in all of them. Otherwise, “at home” would be synonymous with “doing business” tests framed before specific jurisdiction evolved in the United States.” Nothing in *International Shoe* and its progeny suggests that “a particular quantum of local activity” should give a state authority over a “far larger quantum of . . . activity” having no connection to any in-state activity.

Id. at 762 n.20.

Here, neither of the two paradigmatic scenarios in which a corporation is “at home” are present, as neither Mylan Pharma nor Mylan Inc. are Delaware corporations or have their principal place of business in Delaware. The Supreme Court has not “foreclose[d] the possibility that in an exceptional case, a corporation’s operations in a forum other than its formal place of incorporation or principal place of business may be so substantial and of such a nature as to render the corporation at home in that State.” *Id.* at 761 n.19. But Plaintiffs do not articulate any persuasive basis for finding either Mylan Pharma or Mylan Inc. to have *operations* in Delaware of such a type and extent as to render either corporation “at home” in Delaware. While both Mylan entities have litigated frequently in the District of Delaware, Mylan Pharma is registered to do business in Delaware, and numerous Mylan Inc. subsidiaries are incorporated in Delaware, these contacts are inadequate for purposes of general jurisdiction. In short, this is not an “exceptional case” in which Mylan should be deemed to be “at home” in Delaware.

For these reasons, this Court cannot exercise general personal jurisdiction over either of the Mylan Defendants on the basis that these corporations are “at home” in Delaware.⁸

⁸Judge Sleet reached the same conclusion in *AstraZeneca*, 2014 WL 5778016, at *3 (“The court finds that AstraZeneca has failed to allege contacts sufficient to render Mylan at home in Delaware, in light of *Daimler*.”).

III. Mylan Pharma Has Consented to the Jurisdiction of Delaware Courts

Plaintiffs next argue that this Court may exercise general jurisdiction over at least Mylan Pharma as a result of that entity's compliance with Delaware's registration statute. That is, Mylan Pharma's decision to register to do business in Delaware and, as Delaware requires, appoint an agent here to accept service of process, has the consequence that Mylan Pharma has consented to the jurisdiction of the courts in Delaware. Mylan Pharma disagrees, arguing that registration to do business in a state "is of no jurisdictional consequence," for reasons including that Mylan Pharma has registered to do business in 22 states (including Delaware), and it cannot be "at home" in all 22 states. (D.I. 12 at 2, 8-9 (citing *Daimler*, 134 S. Ct. at 762 n.20 ("A corporation that operates in many places can scarcely be deemed at home in all of them.))) On this dispute, the undersigned Judge sides with Plaintiffs.

"Because the requirement of personal jurisdiction represents first of all an individual right, it can, like other such rights, be waived." *Ins. Corp. of Ir., Ltd. v. Compagnie des Bauxites de Guinee*, 456 U.S. 694, 704 (1982). As the Supreme Court has explained:

In sum, the requirement of personal jurisdiction may be intentionally waived, or for various reasons a defendant may be estopped from raising the issue. These characteristics portray it for what it is – a legal right protecting the individual. The plaintiff's demonstration of certain historical facts may make clear to the court that it has personal jurisdiction over the defendant as a matter of law – *i.e.*, certain factual showings will have legal consequences – but this is not the only way in which the personal jurisdiction of the court may arise. ***The actions of the defendant may amount to a legal submission to the jurisdiction of the court, whether voluntary or not.***

Id. at 704-05 (emphasis added); see also *Capriotti's Sandwich Shop, Inc. v. Taylor Family Holdings, Inc.*, 857 F. Supp. 2d 489, 499 (D. Del. 2012) ("It is well settled that the requirement

of personal jurisdiction is intended to protect a defendant's liberty interests. Because the defense is a personal right, it may be obviated by consent or otherwise waived.") (internal citation and quotation marks omitted).

Moreover, "[a] variety of legal arrangements have been taken to represent express or implied consent to the personal jurisdiction of [a] court." *Ins. Corp. of Ir.*, 456 U.S. at 703. In particular, the Supreme Court "has upheld state procedures which find constructive consent to the personal jurisdiction of the state court in the voluntary use of certain state procedures." *Id.* at 704 (citing *Adam v. Saenger*, 303 U.S. 59, 67-68 (1938); *Chicago Life Ins. Co. v. Cherry*, 244 U.S. 25, 29-30 (1917)). Importantly, "[w]hat acts of the defendant shall be deemed a submission to [a court's] power is a matter upon which States may differ." *Ins. Corp. of Ir.*, 456 U.S. at 704 (emphasis added) (quoting *Chicago Life Ins.*, 244 U.S. at 29-30). Even after *International Shoe*, assessing whether a corporation may be held to have consented to the personal jurisdiction of the courts of a particular state is a matter to be determined by examination of the law of that state.¹²

One manner in which a corporation may be deemed to have consented to the jurisdiction of the courts in a particular state is by complying with the requirements imposed by that state for registering or qualifying to do business there. Nearly a century ago, in *Pennsylvania Fire Insurance Co. v. Gold Issue Mining & Milling Co.*, 243 U.S. 93, 94 (1917), the Supreme Court stated that "there would be . . . little doubt" as to the existence of personal jurisdiction by a

¹²Thus, Mylan's suggestion that Plaintiffs' position on consent to general jurisdiction cannot be correct, since adoption of this position would undermine uniformity in the administration of patent laws (*see, e.g.*, Tr. at 15-16), is unpersuasive. After *Daimler*, as before, states are free to vary in their laws relating to jurisdiction. *See generally Daimler*, 134 S. Ct. at 753 ("Federal courts ordinarily follow state law in determining the bounds of their jurisdiction over persons.").

state's courts over a corporation that appointed an agent to accept service of process in that state when the state's supreme court had interpreted the statute requiring such an appointment to constitute such consent, and the statute itself might "rationally be held to go to that length." See also *Neirbo Co. v. Bethlehem Shipbuilding Corp.*, 308 U.S. 165, 175 (1939) ("[S]tate legislation and consent of parties may bring about a state of facts which will authorize the courts of the United States to take cognizance of a case.") (quoting *Ex parte Schollenberger*, 96 U.S. 369, 377 (1877)).

In *Robert Mitchell Furniture Co. v. Selden Breck Construction Co.*, 257 U.S. 213 (1921), the Supreme Court clarified the rationale and scope of *Pennsylvania Fire*.

The purpose in requiring the appointment of such an agent is primarily to secure local jurisdiction in respect of business transacted within the State. Of course when a foreign corporation appoints one as required by statute it takes the risk of the construction that will be put upon the statute and the scope of the agency by the State Court. . . . ***Unless the state law either expressly or by local construction gives to the appointment a larger scope, we should not construe it to extend to suits in respect of business transacted by the foreign corporation elsewhere***

Id. at 215-16 (internal citation omitted).

Consistent with *Pennsylvania Fire* and its progeny, the Third Circuit upheld the constitutionality of Pennsylvania's registration statute, which expressly treated registration to do business in Pennsylvania as consent to the jurisdiction of Pennsylvania's courts over suits against the registering corporation. See *Bane v. Netlink, Inc.*, 925 F.2d 637, 641 (3d Cir. 1991). The corporate registration statute at issue in *Bane*, 15 Pa. Stat. Ann. 2004(6) (Purdon 1967) (repealed 1988), required the "designation of the Secretary of the Commonwealth . . . as the true and lawful attorney of the corporation upon whom all lawful process in any action against it may be served

... [with] the same legal force and validity as if served on the corporation” *Bane*, 925 F.2d at 640. The Pennsylvania legislature had explicitly established that the scope of consent under this provision extended to general jurisdiction. *See id.* (quoting 42 Pa. Cons. Stat. Ann. § 5301(a)(2)(i) (1990)). In finding Pennsylvania’s statutory scheme to be constitutional, the Third Circuit observed that “[c]onsent is a traditional basis for assertion of jurisdiction long upheld as constitutional.” *Bane*, 925 F.2d at 641; *see also Davis v. Smith*, 253 F.2d 286, 288-89 (3d Cir. 1958) (finding that appointment of agent in Pennsylvania constituted waiver of venue privilege, because “[e]ven though a statute may require the designation of an agent to receive process, such designation is still deemed a voluntary act evidencing consent to the suit”).

The Federal Circuit, whose interpretation on this point will be governing in patent cases like this one, has not addressed the constitutionality of treating registration to do business in a state as consent to the jurisdiction of courts in that state. (*See Tr.* at 20) Two other courts of appeals that have addressed the issue have upheld the constitutionality of such constructions. *See Knowlton v. Allied Van Lines, Inc.*, 900 F.2d 1196, 1199-1200 (8th Cir. 1990) (upholding general jurisdiction based on statutory interpretation of Minnesota Supreme Court and noting that “[t]he whole purpose of requiring designation of an agent for service is to make a nonresident suable in the local courts”); *Holloway v. Wright & Morrissey, Inc.*, 739 F.2d 695, 697 (1st Cir. 1984) (upholding statutory consent to personal jurisdiction based on “natural reading” of relevant New Hampshire statute and explaining that “[i]t is well-settled that a corporation that authorizes an agent to receive service of process in compliance with the requirements of a state statute, consents to the exercise of personal jurisdiction in any action that is within the scope of the agent’s authority”). Two additional circuits appear to agree with the principle that a state may

condition doing business in that state on an agreement to submit to the general jurisdiction of the courts of that state – although the statutes these circuits were analyzing did not, the courts found, amount to such consent. *See King v. Am. Family Mut. Ins. Co.*, 632 F.3d 570, 576, 578 (9th Cir. 2011) (“[F]ederal courts must, subject to federal constitutional restraints, look to state statutes and case law in order to determine whether a foreign corporation is subject to personal jurisdiction in a given case because the corporation has appointed an agent for service of process. . . . [T]he Montana law regarding appointment of an agent for service of process does not, standing alone, subject foreign corporations to jurisdiction in Montana for acts performed outside of Montana, at least when the corporations transact no business in the state.”); *Wenche Siemer v. Learjet Acquisition Corp.*, 966 F.2d 179, 183 (5th Cir. 1992) (“No Texas state court decision has held that this provision acts as a consent to jurisdiction over a corporation in a case such as ours – that is where Plaintiffs are non-residents and the defendant is not conducting substantial activity within the state.”).

As far as the Court is aware, only two circuits appear to have held that a state registration requirement cannot be the basis for finding consent to general jurisdiction (and one did so years before the Supreme Court’s decision in *Insurance Corp. of Ireland*). *See Wilson v. Humphreys (Cayman) Ltd.*, 916 F.2d 1239, 1245 (7th Cir. 1990) (“Registering to do business is a necessary precursor to engaging in business activities in the forum state. However, it cannot satisfy . . . standing alone . . . the demands of due process. Such an interpretation of the Indiana registration statute would render it constitutionally suspect. . . .”); *Ratliffe v. Cooper Laboratories, Inc.*, 444 F.2d 745, 748 (4th Cir. 1971) (“Applying for the privilege of doing business is one thing, but the actual exercise of that privilege is quite another. The principles of due process require a firmer

foundation than mere compliance with state domestication statutes.”).

Plaintiffs’ consent argument rests on Delaware’s registration statute, which provides:

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

8 Del. C. § 376 (emphasis added). In turn, Section 371 provides, in pertinent part, that:

[n]o foreign corporation shall do any business in this State . . . until it . . . shall have filed . . . [a] statement executed by an authorized officer of each corporation setting forth . . . the name and address of its registered agent in this State¹³

While neither section 371 nor section 376 expressly addresses whether registration to do business in Delaware constitutes consent to the general jurisdiction of courts in Delaware, this has long been the definitive judicial interpretation of these statutes. In 1988, the Delaware Supreme Court decided *Sternberg v. O’Neil*, in which it unambiguously held:

Section 376 does not in [its] terms limit the amenability of service of a qualified corporation to one which does business in Delaware or with respect to a cause of action arising in Delaware. By the generality of its terms, a foreign corporation qualified in Delaware is subject to service of process in Delaware **on any transitory cause of action**. Express consent to jurisdiction by a foreign corporation takes the form of an appointment of a statutory agent to receive service of process in compliance with the statutory requirements of the state in which the corporation desires to do business. **A corporation that authorizes an agent to receive service of process in compliance with the requirements of a state statute, consents to the exercise of personal jurisdiction in any action that is within the scope of the agent’s authority.**

¹³Delaware law further provides that the Secretary of State will serve as the designated agent to accept service of process for a non-qualified foreign corporation that transacts business in Delaware. See 8 Del. C. §§ 376, 382.

550 A.2d 1105, 1115-16 (Del. 1988) (emphasis added; internal quotation marks omitted). In this way, *Sternberg* held that a corporation qualified to do business in Delaware, which requires appointment of an agent to accept service of process, has consented to the general jurisdiction of the courts in the State of Delaware.¹⁴

Prior to *Daimler*, the District of Delaware had adhered to *Sternberg* and the Delaware Supreme Court's interpretation of Delaware's registration statute. In *Continental Casualty Co. v. American Home Assurance Co.*, 61 F. Supp. 2d 128 (D. Del. 1999), now-retired Judge Farnan wrote:

Both the United States Supreme Court and the Supreme Court of Delaware have held that a foreign corporation which authorizes an agent to receive service of process in compliance with the requirements of a state registration statute has consented to the exercise of personal jurisdiction in that state, even with regard to causes of action that do not arise from events or transactions occurring within that state.

Id. at 129-30 & n.3 (citing *Penn. Fire*, 243 U.S. at 95; *Sternberg*, 550 A.2d at 1108-12). The parties have not cited, nor has the Court through its own research discovered, any decision prior to *Daimler* which rejected or even questioned the constitutionality of *Sternberg*.

Given the analysis above, the undersigned Judge concludes that this Court may exercise general jurisdiction over Mylan Pharma based on Mylan Pharma's consent, consent which Mylan Pharma gave when it complied with the Delaware business registration statute by appointing a registered agent in Delaware to accept service of process. It is undisputed that Mylan Pharma is and has been qualified to do business in Delaware since 2010. (*See* D.I. 15 at 5; Tr. at 55) As

¹⁴Mylan does not dispute that in *Sternberg* the Delaware Supreme Court was absolutely clear as to how it interprets the Delaware registration statute. (*See* Tr. at 18)

required by Delaware law, Mylan Pharma has appointed a registered agent in Delaware who is authorized to accept service of process on behalf of the company. (See D.I. 1 at ¶ 7; D.I. 16, Ex. B) By the time Mylan Pharma chose to register in Delaware in 2010, it was well established – by *Sternberg* and its progeny, including this Court’s *Continental Casualty* decision – that such compliance constitutes consent to the general jurisdiction of the state and federal courts located in Delaware. Cf. *Rockefeller University v. Ligand Pharms. Inc.*, 581 F. Supp. 2d 461, 466 (S.D.N.Y. 2008) (“In maintaining an active authorization to do business and not taking steps to surrender it as it has a right to do, defendant was on constructive notice that New York deems an authorization to do business as consent to jurisdiction.”). Delaware’s statute can, at minimum, be “rationally” held to treat compliance as consent. Hence, Mylan Pharma has consented to the jurisdiction of the District of Delaware, exercise of general jurisdiction over Mylan Pharma does not offend Mylan Pharma’s right to due process, and the motion to dismiss must be denied as to Mylan Pharma.¹⁵

¹⁵Because Mylan Pharma has consented to this Court’s jurisdiction, it is unnecessary to consider whether Mylan Pharma has sufficient “minimum contacts” with Delaware. See, e.g., *Bancorp Bank v. Blackburn*, 2014 WL 4100895, at *3 (D. Del. Aug. 20, 2014) (“Consent to personal jurisdiction renders unnecessary a traditional jurisdictional analysis.”); *Capriotti’s Sandwich Shop*, 857 F. Supp. 2d at 500-01 (same); *Cont’l Cas. Co.*, 61 F. Supp. 2d at 130 n.3 (“In *Sternberg* [550 A.2d at 1113], the Delaware Supreme Court held that where a foreign corporation has expressly consented to the jurisdiction of a state by registration, due process is satisfied and an examination of ‘minimum contacts’ to find implied consent is unnecessary.”).

Mylan points out that the *Sternberg* Court itself undertook a due process analysis, despite stating that this inquiry was unnecessary, and ultimately found sufficient minimum contacts on which to base the exercise of jurisdiction there. See 550 A.2d at 1117 (“[D]espite our conclusion that a minimum contact analysis is not required, in view of the broad language in *Shaffer*, we will examine [plaintiff’s] claim according to the standards enunciated in *International Shoe*.”). The defendant in *Sternberg*, of course, did not have the benefit of the Delaware Supreme Court’s analysis in *Sternberg* at the time it was deciding to register to do business in Delaware. The same potential prejudice, due to arguable lack of notice, is not present here, given the 22-year gap between the *Sternberg* decision and Mylan Pharma’s decision to register in Delaware.

Mylan Pharma challenges this conclusion based on *Daimler*. In Mylan Pharma's view, *Daimler* narrowed the due process analysis for general jurisdiction, rendering *Sternberg* unconstitutional. (See Tr. at 58 (Mylan arguing that pre-*Daimler* cases "were decided when the assumption was that there was this breadth of general jurisdiction that does not occur anymore")) Mylan Pharma reads *Daimler* as broadly standing for the proposition that due process requires *all* exercises of general jurisdiction, including those based on consent, to be limited to a "corporation's place of incorporation and principal place of business" or, in exceptional circumstances, equivalent locales where the corporation is "at home." Under this reasoning, merely registering to do business in a state and appointing an agent for service of process cannot be held to confer general jurisdiction.

It is the view of the undersigned Judge that, to the contrary, *Daimler* does not eliminate consent as a basis for a state to establish general jurisdiction over a corporation which has appointed an agent for service of process in that state, as is required as part of registering to do business in that state. (See Tr. at 39 (Plaintiffs arguing: "*Daimler* doesn't address what happens if somebody says, well, I'm prepared to forego that defense, to give up my right not to be sued here and to register to do business.")) Mylan Pharma concedes, as it must, that *Daimler* does not expressly address consent. (See Tr. at 17) Indeed, in the entire opinion in *Daimler*, there is but a single, passing reference to the concept of consent: "[The Court's] 1952 decision in *Perkins v. Benguet Consol. Mining Co.*[, 342 U.S. 437 (1952),] remains the textbook case of general jurisdiction appropriately exercised over a foreign corporation that has *not consented* to suit in the forum." 134 S. Ct. at 755-56 (emphasis added). In this way, *Daimler* distinguishes between consensual and non-consensual bases for jurisdiction. It preserves what has long been the case:

that these are two distinct manners of obtaining jurisdiction over a corporation. Consistent with *Daimler*, it remains the law that general jurisdiction may be established by showing that a corporation is “at home” in the sense described in detail in *Daimler*, or separately general jurisdiction may be established by a corporation’s consent to such jurisdiction. *Daimler* is directed to the former situation and has nothing to say about the latter scenario.

In support of its interpretation of *Daimler*, Mylan Pharma contends that “*International Shoe* changed the focus of the jurisdictional inquiry from one based on a defendant’s ‘physical presence’ in the forum State to one based on ‘substantial contacts,’ ‘fair play and substantial justice,’ and ‘fundamental fairness.’” (D.I. 11 at 10) However, the undersigned Judge finds that the conclusion reached in this opinion is in fact consistent with *International Shoe*, which did not consider the traditional route to personal jurisdiction of consent, as there the defendant “had no agent within the state upon whom service could be made.” 326 U.S. at 312. Rather, *International Shoe* described how a corporation may have sufficient “presence” in a forum to give rise to personal jurisdiction over it “even though *no consent* to be sued or authorization to an agent to accept service of process has been given.” *Id.* at 318 (emphasis added). Hence, in *Insurance Corp. of Ireland*, the Supreme Court described *International Shoe* (and related cases) as establishing “minimum contacts” that are “a constitutional prerequisite to the exercise of *in personam* jurisdiction over an *unconsenting* defendant.” 456 U.S. at 712 (emphasis added) (citing *Int’l Shoe*, 326 U.S. at 310).¹⁶

¹⁶Other decisions are consistent with the long-standing distinction between consent and non-consent as separate bases for personal jurisdiction. See *Perkins*, 342 U.S. at 443 (“[T]he doing of business in a state by a foreign corporation, *which has not appointed a statutory agent upon whom service of process against the corporation can be made in that state or otherwise consented* to service of summons upon it in actions brought in that state, will not make the corporation subject to service of summons in an action in personam brought in the courts of that

Aside from *International Shoe*, none of the cases which the Court has cited in reaching its holding that Mylan Pharma has consented to this Court's jurisdiction is cited in *Daimler*. The Supreme Court in *Daimler* did not reference *Insurance Corp. of Ireland, Adam, Chicago Life Insurance, Pennsylvania Fire, Neirbo, Ex parte Schollenberger*, or *Robert Mitchell Furniture*. It follows that *Daimler* did not overrule or even criticize these precedents.¹⁷

Moreover, *Daimler* does not address whether personal jurisdiction is an individual right, whether it may therefore be waived, whether waiver may occur by consent, or whether consent is assessed as a matter of state law. *Daimler* does not indicate whether MBUSA had appointed an agent to accept service of process in California. This may be due to California courts having found that such registration does not suffice to establish personal jurisdiction. *See, e.g., World Lebanese Cultural Union, Inc. v. World Lebanese Cultural Union of N.Y., Inc.*, 2011 WL 5118525, at *4 (N.D. Cal. Oct. 28, 2011) ("California courts, however, have declined to find that a party has consented to a state's jurisdiction merely by appointing an in-state agent for service of

state to enforce a cause of action in no way related to the business or activities of the corporation in that state.") (emphasis added). Similarly, in *Shaffer v. Heitner*, 433 U.S. 186, 212 (1977), the Court distinguished between "consent to jurisdiction in the State" – in the form of acceptance of a board directorship pursuant to a state statute providing that such acceptance constitutes consent – and the situation in which a party "had no reason to expect to be haled before a Delaware court." Given the fundamental distinction between consent and non-consent as bases for exercising jurisdiction, a distinction found even in *Shaffer*, the undersigned Judge does not read the Supreme Court's seemingly broad statement in *Shaffer*, 433 U.S. at 212 – that "all assertions of state-court jurisdiction must be evaluated according to the standards set forth in *International Shoe* and its progeny" – to apply to situations in which a defendant has consented to jurisdiction, or has otherwise waived the requirement of personal jurisdiction.

¹⁷Importantly, these are largely the same cases on which the Delaware Supreme Court relied in *Sternberg* – and that decision has not been revisited, by the Delaware Supreme Court or the Delaware General Assembly, in the time since *Daimler* or even in the decades since *Sternberg* was handed down. It is also noteworthy that the Third Circuit's decision in *Bane* remains precedent, even after *Daimler*.

process.”) (citing *DVI, Inc. v. Super. Ct.*, 104 Cal. App. 4th 1080, 1095 (2002); *Gray Line Tours v. Reynolds Elec. & Eng'g Co.*, 193 Cal. App. 3d 190, 193-95 (1987)). Regardless of the reason for the lack of discussion of these points, that absence further demonstrates that *Daimler* has nothing to do with consent as a basis for personal jurisdiction.¹⁸

The undersigned Judge is aware, of course, that a fellow member of this Court has reached a contrary conclusion on this point. In *AstraZeneca*, Judge Sleet, addressing the same issue presented here, concluded that, after *Daimler*, exercising general jurisdiction over Mylan Pharma based on consent is untenable, because, “[i]n light of the holding in *Daimler* . . . the Delaware Supreme Court’s decision in *Sternberg* can no longer be said to comport with federal due process.” 2014 WL 5778016, at *5. Judge Sleet stated that in *Daimler*, “the Supreme Court rejected the idea that a company could be haled into court merely for doing business in a state,” because “[s]uch a theory . . . 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.* (quoting *Daimler AG*, 134 S. Ct. at 761-62) (internal quotation marks omitted).

¹⁸Consistent with this view that jurisdiction by consent has continuing vitality is the recent action of the Second Circuit, in remanding two cases to the Southern District of New York, to consider whether a party which post-*Daimler* was not “at home” in New York might, nonetheless, be found to have consented to jurisdiction by virtue of registering to do business in New York. *See Gucci America Inc. v. Li*, 2014 WL 4629049 (2d Cir. Sept. 17, 2014); *see also Tiffany (NJ) LLC v. China Merchants Bank*, 2014 WL 4627662, at *3 (2d Cir. Sept. 17, 2014), *as amended* Sept. 23, 2014 (“[A]s in *Gucci*, the district court’s exercise of jurisdiction here rested on the only recently abrogated principle that the presence of the Banks’ branches in New York subjected them to general jurisdiction. Accordingly, the district court had no reason to consider, or to develop the record as to, whether it could properly assert specific jurisdiction over the Banks, or whether the Banks consented to jurisdiction by applying for authorization to conduct business in New York and designating the New York Secretary of State as their agent for service of process.”).

However, in the view of the undersigned Judge, when courts have clearly held that compliance with a state's registration statute confers general jurisdiction, corporations have the requisite notice to enable them to structure their conduct so as to be assured where they will, and will not, be subject to suit. The problem identified in *Daimler* only arises when continuous and systematic contacts are used to assess whether a corporation is "at home" in a forum state, which requires a corporation to predict what level of contacts a court will find sufficient. When, instead, the basis for jurisdiction is the voluntary compliance with a state's registration statute, which has long and unambiguously been interpreted as constituting consent to general jurisdiction in that state's courts, the corporation can have no uncertainty as to the jurisdictional consequences of its actions.

Judge Sleet further concluded in *AstraZeneca* that "[f]inding 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*." 2014 WL 5778016, at *5. Plainly, today's holding is at one level in tension with the holding in *Daimler* that it would be "unacceptably grasping" to find general jurisdiction over a corporation "in every State in which a corporation engages in a substantial, continuous, and systematic course of business." See *Daimler*, 134 S. Ct. at 761 (internal quotation marks omitted). It seems an odd result that while there is not general jurisdiction over a corporation in every state in which the corporation does business, there may be general jurisdiction over a corporation in every state in which that corporation appoints an agent to accept service of process as part of meeting the requirements to register to do business in that state. But if consent remains a valid basis on

which personal jurisdiction may arise – and the undersigned Judge concludes that *Daimler* did not change the law on this point – then this result, though odd, is entirely permissible.

In short, the undersigned Judge does not believe that *Daimler* meant, *sub silentio*, to eliminate consent as a basis for jurisdiction. Such a holding would threaten to fundamentally alter the personal jurisdiction defense from a waivable to a non-waivable right, a characteristic of the defense that was not before the *Daimler* Court and is not explicitly addressed in its opinion. The scope of a corporation’s right to consent to jurisdiction in the courts of a particular state has never been thought to be limited to any certain number of states. It may well be that a corporation will voluntarily consent – whether by compliance with state registration statutes, by contract,¹⁹ or by some other means – to the jurisdiction of courts in many more states than the number of states in which that corporation might be found to be “at home” for purposes of general jurisdiction.

Judge Sleet’s rejection of consent as a basis for general jurisdiction over Mylan Pharma is well-reasoned and may well be the correct view. Nevertheless, for the reasons explained in this Opinion, the undersigned Judge has reached a different conclusion. Accordingly, Mylan Pharma’s motion to dismiss will be denied.²⁰

¹⁹Mylan Pharma attempts to distinguish consent by compliance with Delaware’s registration statute from consent by contract, insisting, “voluntary, contractual consent is significantly different than conferring jurisdiction based on a registration statute that is silent with respect to jurisdiction.” (D.I. 17 at 5 n.5; *see also* Tr. at 63-65 (“[T]he contract analysis. If we put a provision in there, it’s consent to specific jurisdiction.”) The Court is not persuaded there is a meaningful difference between the voluntary nature of consent found in a private contract and consent based on compliance with a statute that has long and clearly been interpreted to constitute consent.

²⁰The Court takes judicial notice of the fact that, on December 17, 2014, Judge Sleet certified an interlocutory appeal of his order in *AstraZeneca* to the Federal Circuit. (*See AstraZeneca AB v. Aurobindo Pharma Ltd.*, C.A. No. 14-664-GMS D.I. 103) As far as this

IV. Mylan Inc. Has Not Consented to the General Jurisdiction of this Court

Mylan Inc. has not registered to do business in Delaware or appointed a registered agent to accept service of process on its behalf. Yet Plaintiffs assert that if personal jurisdiction exists over Mylan Pharma on a consent theory, personal jurisdiction must also exist over Mylan Inc. by virtue of it having allegedly caused Mylan Pharma, its wholly-owned subsidiary, to register in Delaware and to appoint an agent to accept service of process here. This takes consent too far; it would effectively manufacture consent out of a lack of consent.

As the Delaware Supreme Court stated in *Sternberg*, “[j]urisdiction over a wholly owned Delaware subsidiary does not automatically establish jurisdiction over the parent corporation in any forum . . . both the parent and the subsidiary corporation’s contacts with the forum state must be assessed individually.” 550 A.2d at 1119-20 (emphasis omitted). Even assuming Plaintiffs could prove that Mylan Inc. directed Mylan Pharma to register to do business in Delaware, this contact with Delaware (in addition to the others discussed previously in connection with the general jurisdiction analysis above) would neither render Mylan Inc. “at home” in Delaware nor constitute Mylan Inc.’s consent to general jurisdiction here. Thus, it is insufficient to give rise to general jurisdiction over Mylan Inc. in Delaware.²¹

Court is aware, Mylan’s request to pursue its interlocutory appeal is pending before the Federal Circuit. The undersigned Judge wholeheartedly agrees with Judge Sleet that the existence of personal jurisdiction in an ANDA case in a post-*Daimler* world is an important question of first impression that will be (and has been) raised in many pending ANDA cases. (*See id.* at 1 n.1)

²¹As the Supreme Court noted in *Daimler*, 134 S. Ct. at 758-59 & n.13, it is not clear whether agency theory is available in the context of general jurisdiction at all (as opposed to specific jurisdiction). There is, however, authority within the Third Circuit that would support this as a basis for general jurisdiction. *See generally Kehm Oil Co. v. Texaco, Inc.*, 537 F.3d 290, 300 (3d Cir. 2008) (“To obtain general jurisdiction over Chevron in Pennsylvania based on Texaco’s contacts, Kehm would need to show that Chevron controls Texaco.”); *Applied Biosystems, Inc. v. Chruachem, Ltd.*, 772 F. Supp. 1458, 1469 (D. Del. 1991) (stating that general

V. This Court Has Specific Jurisdiction over Mylan Pharma

As a final and independent basis for this Court to exercise personal jurisdiction over Mylan Pharma and Mylan Inc., Plaintiffs assert specific jurisdiction. The Court agrees that Plaintiffs have met their burden to establish that this Court may exercise specific jurisdiction as to Mylan Pharma.²²

“Specific jurisdiction refers to the situation in which the cause of action arises out of or relates to the defendant’s contacts with the forum. . . . It contrasts with general jurisdiction, in which the defendant’s contacts have no necessary relationship to the cause of action.” *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1562 n.10 (Fed. Cir. 1994) (internal citations and quotation marks omitted); *see also Boone v. Oy Partek Ab*, 724 A.2d 1150, 1155 (Del. Super. Ct. 1997). Assessing whether specific jurisdiction is present requires an inquiry into “whether there was some act by which the defendant purposefully avail[ed] itself of the privilege of conducting activities within the forum State, thus invoking the benefits and protections of its laws.” *Goodyear*, 131 S. Ct. at 2854 (internal quotation marks omitted). That is, the inquiry is “trained on the relationship among the defendant, the forum, and the litigation.” *Daimler*, 134 S. Ct. at 758 (internal quotation marks omitted). Thus, a defendant may be constitutionally haled into court under a theory of specific jurisdiction, consistent with the defendant’s right to due process, if: “(1) . . . the defendant purposefully directed activities at residents of the forum; (2) . . . the claim arises out of or relates to those activities; and (3) . . . assertion of personal jurisdiction

jurisdiction under section 3104(c)(4) of Delaware long-arm statute may apply to defendant or its agent).

²²As with the general jurisdiction analysis, the Court need not analyze the specifics of Delaware’s long-arm statute, as Mylan is not arguing the statutory prerequisites are unmet. (*See* Tr. at 4)

is reasonable and fair.” *Nuance Commc’ns, Inc. v. Abby Software House*, 626 F.3d 1222, 1231 (Fed. Circ. 2010).

Having undertaken the requisite analysis here, the Court finds that it may, consistent with Mylan Pharma’s due process rights, exercise specific jurisdiction over Mylan Pharma in this case. Plaintiffs’ claims in this litigation arise out of and relate to Mylan Pharma’s activities that are, and will be, directed to Delaware. This suit arises from Mylan’s ANDA Filing, which is a prerequisite to obtaining FDA approval, which is necessary in order to sell Mylan’s Generic Product in the United States, including in Delaware. More directly, this lawsuit arises from Mylan Pharma’s sending the Mylan Notice Letter to Plaintiffs, including to Acorda, a Delaware corporation. At the time Mylan Pharma sent the Mylan Notice Letter to Acorda, Acorda had already initiated litigation in Delaware to enforce the Ampyra® patents against efforts to introduce generic Ampyra® to the U.S. market. Therefore, when it sent the Mylan Notice Letter to Acorda, Mylan Pharma knew or should have known that: (i) Acorda is a Delaware corporation; (ii) Acorda had already begun litigating the Ampyra® patents in the District of Delaware by filing suit against another ANDA filer (Actavis) here; (iii) Acorda would file suit against Mylan Pharma within 45 days of receiving the Mylan Notice Letter; and (iv) to obtain the efficiencies of coordinated litigation in a single district, Plaintiffs would almost certainly sue Mylan Pharma in Delaware.

Mylan Pharma has directed other activities at Delaware, including registering to do the business of “[p]harmaceutical manufacturing, distribution and sales” here, appointing a registered agent to accept service of process here, and registering with the Delaware Board of Pharmacy as a “Pharmacy/Wholesale” and “Distributor/Manufacturer CSR.” (*See* D.I. 1 at ¶¶ 7,

9; D.I. 15 at 20; D.I. 16, Exs. A & B) Mylan Pharma has also been a frequent litigant in the District of Delaware, in precisely the type of case now before the Court – ANDA litigation – and its business model is expressly dependent on the certainty of its participation in such litigation. (See D.I. 1 at ¶ 11) Indeed, Mylan Pharma has litigated over 50 cases in Delaware. (*Id.* at ¶ 17)²³

Exercising personal jurisdiction over Mylan Pharma is entirely consistent with the principles underlying specific jurisdiction, as emphasized by the Supreme Court over decades, from *International Shoe* up through and including in *Daimler*. For instance, as reiterated in *Daimler*:

The canonical opinion in this area remains *International Shoe*, in which we held that a State may authorize its courts to exercise personal jurisdiction over an out-of-state defendant if the defendant has certain minimum contacts with [the State] such that the maintenance of the suit does not offend ***traditional notions of fair play and substantial justice***.

134 S. Ct. at 754 (emphasis added; internal citation and quotation marks omitted).

Fundamentally, for all of the reasons explained above, no traditional notions of fair play and substantial justice are offended by exercising specific jurisdiction over Mylan Pharma. The lack of unfairness to Mylan Pharma from having to litigate its efforts to obtain FDA approval of

²³The record in *AstraZeneca* established that Mylan Pharma had initiated at least six suits in the District of Delaware over the past two decades and had defended here against many more suits. See 2014 WL 5778016, at *4. The Court understands that “prior appearance [does] ***not necessarily*** waive the personal jurisdiction requirement in future actions, nor constitute related business conduct within the jurisdiction.” *Rozenblat v. Sandia Corp.*, 2006 WL 678923, at *3 (Fed. Cir. Mar. 17, 2006) (emphasis added); see also *In re Rosuvastatin Calcium Patent Litigation*, 2010 WL 661599, at *2 (D. Del. Feb. 19, 2010) (“[T]he Court is not persuaded that Apotex’s participation, primarily as a defendant, in litigation in this District is ***sufficient*** to support the exercise of general jurisdiction,” although not stating such experience is entirely irrelevant) (emphasis added). With respect to specific jurisdiction, the Court does not view Mylan Pharma as having waived its personal jurisdiction defense; the Court simply finds that Mylan Pharma has not prevailed on that defense.

Mylan's Generic Product in the District of Delaware is particularly evident from the chronology of events relevant to this litigation, recited above, including particularly that when Mylan Pharma sent the Mylan Notice Letter, Acorda had already initiated Ampyra® related litigation in Delaware.

In *World-Wide Volkswagen Corp. v. Woodson*, the Supreme Court explained:

The Due Process Clause, by ensuring the orderly administration of the laws, gives ***a degree of predictability*** to the legal system that ***allows potential defendants to structure their primary conduct with some minimum assurance as to where that conduct will and will not render them liable to suit.***

444 U.S. 286, 297 (1980) (emphasis added; internal citations and quotation marks omitted).

Even back in January 2014, when Mylan Pharma submitted Mylan's ANDA Filing, there was a high degree of predictability that Acorda, a Delaware corporation, would sue Mylan Pharma in Delaware to enforce the Ampyra® patents.²⁴ Mylan Pharma has long been able to structure its primary conduct – developing and marketing generic drug products, which almost always requires parallel patent litigation (*see* D.I. 16, Ex. E at 5 (“We [i.e., Mylan] expect to achieve growth in our U.S. business by launching new products for which we may attain . . . [FDA] first-

²⁴A published report recently found that nearly 41% of all ANDA cases filed over the last five years have been filed in the District of Delaware. *See* “Hatch-Waxman/ANDA Litigation Report,” *Lex Machina*, 1 (Nov. 6, 2014) (hereinafter, the “Lex Machina Report”), *available at* <https://lexmachina.com/2014/11/lex-machina-releases-hatch-waxman-anda-litigation-report/>. The Lex Machina Report found that between 2009 and September 2014, 1,671 new ANDA cases were filed nationwide, and 678 of these cases were filed in Delaware. Indeed, the Lex Machina Report further found that in the same five-year period nearly eighty percent of all ANDA cases were filed in just three Districts: Delaware (678), New Jersey (481), and the Southern District of New York (148). This data further illustrates the predictability of Mylan Pharma ending up litigating the instant case in Delaware.

to-file status with Paragraph IV certification.”)²⁵ – with substantial assurance that this conduct will regularly render Mylan Pharma liable to suit in the District of Delaware. At bottom, Mylan Pharma’s conduct has been “such that [it] should *reasonably anticipate being haled into court*” here in the District of Delaware. *World-Wide Volkswagen Corp.*, 444 U.S. at 297 (emphasis added); *see also AstraZeneca*, 2014 WL 5778016, at *7 (“Mylan [Pharma] 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.”).

The Court reaches the same conclusion by considering the factors described in *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 477 (1985), as being pertinent to determining “whether assertion of personal jurisdiction is ‘reasonable and fair’” in a particular case. Applying those factors here, the Court concludes that: (i) “the burden on the defendant” to litigate in the District of Delaware is minimal, as demonstrated by Mylan Pharma’s frequent presence in Delaware and its failure to articulate any prejudice (beyond purported injury to its constitutional rights) attendant to litigating here; (ii) the forum state’s interest in adjudicating the dispute, which is significant given that Acorda is a Delaware corporation seeking to enforce its patents and that this Plaintiff has ongoing related litigation pending in this Court; (iii) Plaintiffs’ interest in obtaining convenient and effective relief, which also favors Delaware, given that Acorda is a small company facing eight generic challenges to its principal product (*see Tr.* at 31); and

²⁵As Judge Sleet described in *AstraZeneca*, “Another peculiarity of the Hatch-Waxman Act is that it builds patent litigation into the FDA approval process.” 2014 WL 5778016, at *6.

(iv) “the interstate judicial system’s interest in obtaining the most efficient resolution of controversies,” which again strongly favors keeping the case against Mylan Pharma here,²⁶ rather than burdening another district court and another district judge with issues that are already before this Court (e.g., construction of disputed claim terms in the Ampyra® patents and validity of the Ampyra® patents).²⁷

In *AstraZeneca*, Judge Sleet found that this Court has specific jurisdiction over Mylan Pharma in another ANDA case. One factual distinction between *AstraZeneca* and the instant case is that in *AstraZeneca* Mylan Pharma had mailed its paragraph IV certification letter to the plaintiff, AstraZeneca Pharmaceuticals LP (“AstraZeneca”), in Delaware, where AstraZeneca is both incorporated and has its principal place of business. *See* 2014 WL 5778016, at *1, 7. Here, there was no mailing by Mylan Pharma into Delaware. Instead, the Mylan Notice Letter was sent to Acorda in New York and to Alkermes in Ireland. (*See* Tr. at 24, 50) The undersigned Judge agrees with Judge Sleet that mailing a paragraph IV certification letter *into* Delaware is an additional activity directed at Delaware that should be considered in assessing whether this Court can exercise specific jurisdiction. It does not follow, however, that the absence of a mailing into Delaware eliminates the possibility of exercise of specific jurisdiction.

²⁶None of the defendants in the other seven, related Ampyra® ANDA cases have challenged this Court’s jurisdiction. (Tr. at 31) Hence, all seven of those cases will proceed here, regardless of whether the Mylan case remains here or not. If the Court were to dismiss the case against Mylan, it would not reduce the amount of litigation in federal courts. Instead, the case against Mylan would proceed in the Northern District of West Virginia, where Plaintiffs have already filed a protective action against both Mylan Defendants. (*See* Tr. at 28, 31)

²⁷*Burger King*, 471 U.S. at 477, identifies a fifth factor – the “shared interest of the several States in furthering fundamental substantive social policies” – which seems to have no applicability here, but also does not disfavor the Court’s exercise of specific jurisdiction over this case.

Moreover, because Acorda is a Delaware corporation, it seems proper to conclude that Acorda suffers “injury” in Delaware as a result of Mylan’s ANDA Filing. Of course, identifying a physical place where Acorda is injured by an ANDA submission is difficult, as a corporation is not a natural person, *see Citizens United v. Fed. Election Comm’n*, 558 U.S. 310, 343 (2010), and as the infringement injury here is “highly artificial,” *see Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). Mylan argues this means that Acorda is not injured anywhere. (*See, e.g.*, Tr. at 60) But it is more logical to conclude that Acorda *is* injured, *somewhere*.²⁸ With the benefit of *Daimler*, and its explanation that a corporation is “at home” at least where it is incorporated, it seems logical to conclude that the state of incorporation is at least one place in which a corporation whose patents are artificially infringed by an ANDA filing is injured. For Acorda, that is Delaware.²⁹

The Court recognizes, as Mylan emphasizes (*see, e.g.*, Tr. at 60-61), that Plaintiffs’ contacts cannot be the *sole* basis for finding jurisdiction over Defendants. That does not, however, mean that an injury felt by a Delaware corporate citizen is entirely irrelevant to the specific jurisdiction inquiry. Such injury is felt in Delaware given that Delaware is one of the places at which a Delaware corporation is “at home.”

²⁸If the ANDA injury, artificial though it may be, were not felt somewhere, there would arguably not be a case or controversy, and there would then also not be subject matter jurisdiction. Mylan does not argue there is a lack of case or controversy among the parties here.

²⁹The Court recognizes that there is pre-*Daimler* authority supporting the contention that “injury in a patent infringement action occurs not where the patent holder resides but where ‘the infringing activity directly impacts on the interests of the patentee,’ like the place of an infringing sale.” *Pfizer Inc. v. Apotex, Inc.*, 2009 WL 2843288, at *3 n.5 (D. Del. Aug. 13, 2009) (quoting *Beverly Hills Fan*, 21 F.3d at 1571). In this ANDA case, there has not yet been an infringing sale, but if sales are eventually to be made they will be made nationwide, including in Delaware.

Walden v. Fiore, 134 S. Ct. 1115 (2014), which the Supreme Court decided shortly after *Daimler*, does not change this result. In *Walden*, the Court found a lack of specific jurisdiction over a law enforcement officer (in a *Bivens* tort action) who had no contacts with the forum state and whose conduct took place entirely outside of the forum state, even though the plaintiffs' alleged injury was felt entirely in the forum state. *Walden* dealt with natural persons experiencing a real injury, not corporations experiencing an artificial injury. Moreover, here Mylan Pharma has contacts with Delaware beyond its injuring a Delaware corporation – such as its registration to do business in Delaware, registration with the Delaware Board of Pharmacy, and its litigation history in Delaware. Hence, here, unlike in *Walden*, the “forum State’s exercise of jurisdiction over an out-of-state intentional tortfeasor [is] based on intentional conduct by the defendant that creates the necessary contacts with the forum.” *Id.* at 1123.

Finally, as noted by Judge Sleet in *AstraZeneca*, it appears that specific jurisdiction has traditionally been disfavored as a basis for finding personal jurisdiction in an ANDA case. *See AstraZeneca*, 2014 WL 5778016, at *6 (citing *Zeneca*, 173 F. 3d at 829 and *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 693 F. Supp. 2d at 420-21). Like Judge Sleet, the undersigned Judge does not view this as a bar to finding specific jurisdiction here. In a post-*Daimler* world, it may very well be that specific jurisdiction becomes a more prominent basis for exercising jurisdiction in ANDA cases.

Accordingly, the Court concludes that it may, consistent with the Due Process Clause, exercise specific jurisdiction over Mylan Pharma, which is a second basis for the Court to deny the motion to dismiss as to Mylan Pharma.

VI. The Court Will Permit Jurisdictional Discovery as to Whether There Is Specific Jurisdiction Over Mylan Inc.

Plaintiffs contend that this Court may exercise specific jurisdiction over Mylan Inc. as well. To the extent Plaintiffs' theory is that the direct contacts among Mylan Inc., Delaware, and this lawsuit are sufficient to justify the exercise of specific jurisdiction over Mylan Inc., the Court disagrees. Unlike Mylan Pharma, Mylan Inc. is not registered to do business in Delaware and there is no allegation that Mylan Inc. was directly involved in the preparation or submission of Mylan's ANDA Filing. The only potentially relevant contacts among Mylan Inc., Delaware, and the instant lawsuit are Mylan Inc.'s involvement in other ANDA litigation (*see* D.I. 1 at ¶ 20), the incorporation of 20 Mylan Inc. subsidiaries in Delaware (*see* D.I. 15 at 17; D.I. 16, Ex E at 37-40), and the vast extent of Mylan Inc.'s presence in United States (*see* D.I. 1 at ¶ 19; D.I. 16, Ex. E at 5). These contacts, on their own, are insufficient to show that Mylan Inc. purposefully directed activities at Delaware and that Plaintiffs' claims arise out of or relate to those activities.

Plaintiffs alternatively contend that this Court can exercise specific jurisdiction over Mylan Inc. on the basis of an agency relationship between Mylan Inc. and Mylan Pharma, its wholly-owned subsidiary. Plaintiffs allege: "Defendants are agents of each other and/or work in concert with each other with respect to the development, regulatory approval, marketing, sale, and distribution of pharmaceutical products throughout the United States, including into Delaware," including with respect to Mylan's ANDA Filing at issue here. (D.I. 1 at 6) While "the mere fact that a non-Delaware corporation owns a Delaware subsidiary is not sufficient in itself to justify Delaware's exercise of personal jurisdiction over the non-Delaware parent," *ACE & Co. v. Balfour Beatty PLC*, 148 F. Supp. 2d 418, 422-23 (D. Del. 2001), "[u]nder the agency theory, the court may attribute the actions of a subsidiary company to its parent where the

subsidiary acts on the parent's behalf or at the parent's direction," *Intellectual Ventures I LLC v. Nikon Corp.*, 935 F. Supp. 2d 787, 793 (D. Del. 2013) (quoting *C.R. Bard, Inc. v. Guidant Corp.*, 997 F. Supp. 556, 560 (D. Del. 1998)). "When applying the agency theory, a court should focus its inquiry on the arrangement between the parent and the subsidiary, the authority given in that arrangement, and the relevance of that arrangement to the plaintiff's claim." *C.R. Bard*, 997 F. Supp. at 560; *see also Applied Biosystems, Inc. v. Cruachem, Ltd.*, 772 F. Supp. 1458, 1464 (D. Del. 1991) ("[O]nly the precise conduct shown to be instigated by the parent is attributed to the parent . . .") (internal quotation marks omitted); *Freres v. SPI Pharma, Inc.*, 629 F. Supp. 2d 374, 384-85 (D. Del. 2009) (same).

Plaintiffs have alleged that Mylan Pharma's relevant contacts can be attributed to Mylan Inc. Plaintiffs request that, if the Court concludes they have failed to meet their burden of establishing personal jurisdiction over either of the Defendants, the Court allow Plaintiffs to undertake jurisdictional discovery instead of dismissing Plaintiffs' claims. (*See* D.I. 15 at 19)

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

Plaintiffs' allegation of an agency relationship between Mylan Inc. and Mylan Pharma is not clearly frivolous. In addition to the undisputed parent-subsidary relationship, Plaintiffs have specifically alleged that Mylan Pharma's appointment of a registered agent for service of process in Delaware can be attributed to Mylan Inc. (*See* D.I. 1 at 6) This, taken together with allegations about Mylan Inc's 20 Delaware subsidiaries and nationwide distribution of products (*see* D.I. 16, Ex. E), at least suggests, with reasonable particularity, the possible existence of requisite contacts among Mylan Inc., Delaware, and this litigation.

Therefore, the Court will permit Plaintiffs to take limited jurisdictional discovery into whether the Court may exercise specific personal jurisdiction over Mylan Inc. based on an agency theory.³⁰

CONCLUSION

For the reasons stated above, the Court will deny the motion to dismiss as to Mylan Pharma. This Court has general jurisdiction over Mylan Pharma due to Mylan Pharma's consent, and it has specific jurisdiction over Mylan Pharma based on Mylan Pharma's relationship with Delaware and the particular circumstances of this ANDA litigation. With respect to Mylan Inc., this Court may not exercise general jurisdiction, because Mylan Inc. is not "at home" here and has not consented to general jurisdiction here. However, the Court will permit Plaintiffs to take limited jurisdictional discovery in order to determine whether the Court may exercise specific jurisdiction over Mylan Inc.

An appropriate Order follows.

³⁰By separate Order the Court will solicit the parties' views as to the scope and timing of such jurisdictional discovery, as well as a procedure by which, following the completion of such discovery, Mylan Inc. may renew its motion to dismiss for lack of personal jurisdiction.

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

ACORDA THERAPEUTICS, INC. and)
ALKERMES PHARMA IRELAND)
LIMITED,)

Plaintiffs,)

v.)

C.A. No. 14-935-LPS

MYLAN PHARMACEUTICALS INC.)
and MYLAN INC.)

Defendants.)

ORDER

At Wilmington this **14th** day of **January, 2015**:

For the reasons stated in the Opinion issued this same date,

IT IS HEREBY ORDERED that:

1. Defendants' Motion to Dismiss for Lack of Jurisdiction Over the Person (D.I. 10) is **DENIED** with respect to Defendant Mylan Pharmaceuticals Inc. and **DENIED WITHOUT PREJUDICE** with respect to Defendant Mylan Inc. Defendant Mylan Inc. may again move to dismiss after the completion of jurisdictional discovery.

2. Plaintiffs' request for jurisdictional discovery (D.I. 15 at 19) is **GRANTED** with respect to the remaining issue of whether there is specific jurisdiction over Defendant Mylan Inc.

3. The parties shall meet and confer and shall submit, no later than January 28, 2015, a joint status report containing their proposal(s) as to how this matter should proceed in light of the Court's ruling. Among other things, the parties shall provide their view(s) as to the scope

and timing of jurisdictional discovery, as well as a procedure by which, following the completion of such discovery, Mylan Inc. may renew its motion to dismiss for lack of personal jurisdiction.


UNITED STATES DISTRICT JUDGE

CERTIFICATE OF SERVICE

I hereby certify that on May 22, 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