

No. \_\_\_\_\_

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In the  
**Supreme Court of the United States**

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MYLAN PHARMACEUTICALS INC. &  
MYLAN INC., *Petitioners*,

v.

ACORDA THERAPEUTICS INC. & ALKERMES PHARMA  
IRELAND LIMITED, *Respondents*.

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MYLAN PHARMACEUTICALS INC., *Petitioner*,

v.

ASTRAZENECA AB, *Respondent*.

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**On Petition for Writ of Certiorari to the  
United States Court of Appeals for the  
Federal Circuit**

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**PETITION FOR A WRIT OF CERTIORARI**

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## QUESTION PRESENTED

Under the Hatch-Waxman Act, before a generic pharmaceutical manufacturer can market a generic version of a brand-name drug, it must file an abbreviated new drug application (ANDA) with the Food and Drug Administration in Maryland. That filing generally constitutes an act of patent infringement, giving the brand-name manufacturer an immediate right to sue the generic manufacturer for patent infringement. Mylan prepared the ANDAs here in West Virginia and filed them in Maryland. Mylan was then sued for patent infringement in Delaware, despite the absence of any affirmative steps towards marketing the generic drugs there or any other suit-related contacts between Mylan and Delaware. Such Delaware ANDA-prompted suits were common, under a general jurisdiction theory, before this Court's decision in *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014). In the decision below, however, the Federal Circuit authorized such suits to be filed in Delaware (or virtually anywhere else) on a theory of specific personal jurisdiction because the ANDA "reliably indicate[s] plans to engage in marketing of the proposed generic drugs," including in Delaware. Thus, the decision below resurrects the pre-*Daimler* regime under a rubric of nationwide specific personal jurisdiction.

The question presented is:

Whether the mere filing of an abbreviated new drug application by a generic pharmaceutical manufacturer is sufficient to subject the manufacturer to specific personal jurisdiction in any state where it might someday market the drug.

### **PARTIES TO THE PROCEEDING**

This proceeding involves a court of appeals opinion that decided two separate proceedings.

In the first proceeding, petitioners Mylan Pharmaceuticals Inc. and Mylan Inc. were defendants in the District Court and defendants-appellants in the Court of Appeals. Respondents Acorda Therapeutics Inc. and Alkermes Pharma Ireland Limited were plaintiffs in the District Court and plaintiffs-appellees in the Court of Appeals.

In the second proceeding, petitioner Mylan Pharmaceuticals Inc. was the defendant in the District Court and the defendant-appellant in the Court of Appeals. Respondent AstraZeneca AB was the plaintiff in the District Court and plaintiff-appellee in the Court of Appeals.

## **CORPORATE DISCLOSURE STATEMENT**

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.

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## PETITION FOR WRIT OF CERTIORARI

Before this Court's landmark decision in *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014), patent infringement cases following the filing of an abbreviated new drug application (ANDA) under the Hatch-Waxman Act were concentrated in a handful of jurisdictions based on theories of general personal jurisdiction. Plaintiffs relied on general, not specific, personal jurisdiction because the only suit-related actions performed by defendants occurred where the generic manufacturers prepared and filed their ANDAs. Thus, this Court's watershed decision in *Daimler* should have dramatically altered and limited where infringement suits following ANDA filings could be filed. But old habits die hard.

The Federal Circuit managed to restore the status quo ante and deprive *Daimler* of practical effect by broadening traditional notions of specific personal jurisdiction to effectively cancel out *Daimler*'s narrowing of general jurisdiction. The net effect is a concept of specific personal jurisdiction that is fundamentally incompatible with this Court's precedents and even more "unacceptably grasping" than the general jurisdiction regime rejected in *Daimler*. *Id.* at 761.

In particular, the Federal Circuit held that the mere act of filing an ANDA is sufficient to subject the filer to specific jurisdiction anywhere it might someday market the proposed generic drugs, because the filing "reliably indicate[s] plans to engage in" such marketing. By relying on such potential "future activities," the court was able to hold that respondents could assert specific jurisdiction over petitioner Mylan

in federal court in Delaware even though Mylan’s only actions giving rise to respondents’ suits—the preparation and filing of ANDAs—took place in West Virginia and Maryland, respectively.

There is no basis in this Court’s precedents or the Hatch-Waxman Act for the Federal Circuit’s novel rule that merely filing an ANDA can subject a company to specific personal jurisdiction wherever it might someday market or sell the drug in question. This Court has repeatedly emphasized that for specific jurisdiction to comport with due process, “the defendant’s suit-related conduct must create a substantial connection with the forum State.” *Walden v. Fiore*, 134 S. Ct. 1115, 1121 (2014). The “defendant’s suit-related conduct” in a suit following an ANDA filing occurs solely where the ANDA was prepared or filed—here, West Virginia and Maryland. Premising specific jurisdiction on wherever the company might someday do business following an ANDA filing is not “suit-related conduct” and has the counterintuitive and erroneous consequence of permitting specific personal jurisdiction *everywhere*.

As a doctrinal matter, the decision below is incompatible with this Court’s precedents and decisions from other courts of appeals that make clear that the defendant’s actual suit-related conduct at the time of the suit, not speculation about the future, is what matters for due process purposes. *See, e.g., id.* at 1125. As a practical matter, the decision below robs *Daimler* of any real-world impact in suits under the Hatch-Waxman Act. Before *Daimler*, defendants could be sued anywhere they did any substantial business under a general jurisdiction theory. As a

result, Hatch-Waxman suits tended to be concentrated in jurisdictions like Delaware that were convenient to plaintiffs without regard to either the defendant's suit-related conduct or where the defendant was at home. After *Daimler*, by virtue of the Federal Circuit's decision, nothing but the label has changed. The same suits are concentrated in the same courts with equal disregard for the defendant's suit-related conduct or where the defendant is at home. The mere future possibility that the defendant will engage in substantial business activity in the forum is sufficient under the Federal Circuit's novel and erroneous concept of "specific" personal jurisdiction.

The stakes are high, not only for fidelity to this Court's precedents, but also for the Nation's generic pharmaceutical industry. Under the Hatch-Waxman Act, patent infringement suits are common; indeed, they are integral to the Act's purpose of speeding low-cost generic pharmaceuticals to market. Providing generic manufacturers with some modicum of predictability regarding where they can be haled into court by brand-name competitors attempting to protect their higher-priced products is thus paramount. Yet the decision below has created effectively national jurisdiction over any ANDA filer, eliminating the certainty and fairness that *Daimler* promised.

The bottom line is clear. Mylan prepared an ANDA in West Virginia and filed it Maryland, but was sued in Delaware. That result cannot be squared with *Daimler* or this Court's specific jurisdiction precedents. The Federal Circuit's contrary decision is

not only profoundly wrong; it will be the final word absent this Court's review. The need for this Court's review is plain.

### **OPINIONS BELOW**

The Federal Circuit's opinion is reported at 817 F.3d 755. App.1-38. The district court's opinion in the *AstraZeneca* case is reported at 72 F. Supp. 3d 549. App.42-62. The district court's opinion in the *Acorda* case is reported at 78 F. Supp. 3d 572. App.67-116.

### **JURISDICTION**

The Federal Circuit issued its opinion on March 18, 2016, and denied Mylan's petition for rehearing on June 20, 2016. App. 39-41. This Court has jurisdiction under 28 U.S.C. §1254(1).

### **CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED**

The Fourteenth Amendment to the United States Constitution provides in pertinent part that:

No State shall . . . deprive any person of life, liberty, or property, without due process of law.

The relevant portions of the Food, Drug, and Cosmetic Act, as modified by the Drug Price Competition and Patent Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, are reproduced at App.121-26.

## STATEMENT OF THE CASE

### A. Statutory Background

When a brand-name drug manufacturer wishes to market a new drug, it must first obtain approval from the FDA by filing a new drug application (NDA) 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). These procedures are 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.

The Hatch-Waxman Act “is designed to speed the introduction of low-cost generic drugs to market.” *Caraco Pharm. Labs., Ltd., v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012). It achieves this important goal through several mechanisms relevant here. First, instead of a lengthy NDA, the generic manufacturer need only file an abbreviated new drug application (ANDA) with the FDA certifying that its generic drug has the same active ingredients and is biologically equivalent to the brand-name version. *Actavis*, 133 S. Ct. at 2228.

Second, the Act provides a vehicle for weeding out weak patents covering brand-name pharmaceuticals. Each ANDA filer 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 what is known as a “paragraph IV” certification, which states that one or more patents listed by the brand-name manufacturer (covering the brand-name product for which the generic is an equivalent) 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 Act allows generic manufacturers to “make, use, offer to sell, or sell ... a patented invention” without facing an infringement action if they do so “solely for uses reasonably related to” their ANDA applications. 35 U.S.C. §271(e)(1); *see also Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 671 (1990) (observing that, “prior to the expiration of a patent” covering a brand-name product, a generic pharmaceutical company may “engage in otherwise infringing activities necessary to obtain regulatory approval”). Once the ANDA is filed with a paragraph IV certification, however, “[t]he patent statute treats such a filing as itself an act of infringement, which gives the brand an immediate right to sue.” *Caraco*, 132 S. Ct. at 1677; *see also* 35 U.S.C. §271(e)(2); *Eli Lilly*, 496 U.S. at 678 (noting that patent statute creates “a highly artificial act of infringement that consists of submitting an ANDA ... containing the fourth type of certification”). To encourage the patent owner to exercise that right, the Hatch-Waxman Act provides that 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.” *Caraco*, 132 S. Ct. at 1677 (citing 21 U.S.C. §355(j)(5)(B)(iii)).<sup>1</sup>

### **B. District Court Proceedings**

Mylan is a West Virginia corporation with its principal place of business in West Virginia. App.4. It develops and manufactures generic versions of brand-name pharmaceutical products for the United States market.

In 2013, Mylan filed two ANDAs with the FDA seeking approval to market generic versions of two of respondent AstraZeneca AB’s brand-name drugs before the expiration of certain patents. App.42-43. Similarly, in 2014, Mylan filed an ANDA seeking approval to market a generic version of one of respondent Acorda Therapeutics Inc.’s brand-name drugs before the expiration of several patents. App.72-73.<sup>2</sup> Mylan’s ANDA filings included

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<sup>1</sup> Not all ANDAs contain a paragraph IV certification. For example, if the brand-name pharmaceutical’s patents have expired, the ANDA need only certify to that effect. *See Caraco Pharms.*, 132 S. Ct. at 1676; 21 U.S.C. §§355(j)(2)(A)(vii)(I)-(III). Or the ANDA might contain only a “section vii statement,” which “asserts that the generic manufacturer will market the drug for one or more methods of use not covered by the brand’s patents.” *Caraco Pharms.*, 132 S. Ct. at 1676; 21 U.S.C. §355(j)(2)(A)(viii). The overwhelming majority of ANDA filings that result in litigation, however, contain paragraph IV certifications. For brevity, therefore, this petition uses the term “ANDA filing” to mean an ANDA filing with a paragraph IV certification.

<sup>2</sup> Acorda is the exclusive U.S. licensee of one of the relevant patents, which is assigned to respondent Alkermes Pharma Ireland Limited, and it holds all rights, titles, and interests in the

paragraph IV certifications stating that the relevant patents were invalid or would not be infringed by Mylan's generic versions. Mylan prepared the ANDAs in West Virginia and filed them with the FDA in Maryland. App.5.

Respondents separately sued Mylan for patent infringement in the District of Delaware, where Acorda is incorporated and AstraZeneca's U.S. subsidiary has its principal place of business. App.5. Mylan moved to dismiss both cases for lack of personal jurisdiction. App.4. Mylan noted, *inter alia*, that it has no offices, plants, facilities, or other real property of any kind in Delaware; it has no telephone listing and no mailing address in Delaware; and it had not marketed or sold any of the generic products referenced in the ANDAs (and, indeed, was prohibited from doing so absent FDA approval). App.72.

Both district courts denied Mylan's motions, but on different grounds. The *AstraZeneca* court rejected AstraZeneca's claim that Mylan was subject to general personal jurisdiction in Delaware by virtue of having registered to do business there in compliance with Delaware's mandatory business-registration statute. App.47-55; see Del. Code Ann. tit. 8, §371(b) (West 2010). The court considered that argument foreclosed by *Daimler*, because Mylan neither is incorporated nor has its principal place of business in Delaware. App.48 (citing 134 S. Ct. at 760). The court also held that Mylan's compliance with Delaware's mandatory

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other relevant patents. This petition refers to both Acorda and Alkermes as "Acorda" except when necessary to differentiate them.

registration statute did not constitute consent to jurisdiction. App.51-55.

Nevertheless, declaring that it was “necessary ... to look closely” at specific jurisdiction “now that the standard for general jurisdiction ... has changed” following *Daimler*, App.55, the *AstraZeneca* court held that Mylan was subject to specific personal jurisdiction in Delaware because the “consequences” of its ANDA filing “are suffered in Delaware” by AstraZeneca. App.58. In particular, it determined that Mylan had sufficient contacts with Delaware because Mylan, upon filing its ANDA, had mailed the statutorily-required notice letter to AstraZeneca’s subsidiary in Delaware and the suit “arose out of” that contact. App.59.

The *Acorda* court, by contrast, held that Mylan was subject to both general and specific jurisdiction in Delaware. In the court’s view, Mylan’s compliance with Delaware’s mandatory business-registration statute constituted consent to jurisdiction under Delaware state law (and, thus, to jurisdiction in federal courts in Delaware, *see* Fed. R. Civ. P. 4(k)(1)(A)). The court also held that Mylan was subject to specific jurisdiction in Delaware based on Mylan’s ANDA filing in Maryland and its sending the statutorily-required notice letters to Acorda in New York and Alkermes in Ireland. App.104. The court concluded that these actions were sufficiently related to Delaware because Acorda was a Delaware corporation, Acorda would suffer any injury in Delaware, and Acorda had already filed suit in Delaware against other defendants over the same patents. App.106-07, 110.

Recognizing that there were substantial grounds for differences with their opinions, both district courts certified their decisions for interlocutory review under 28 U.S.C. §1292(b). App.65, 120. The Federal Circuit granted permission to appeal. App.6.

### **C. Federal Circuit Proceedings**

The Federal Circuit affirmed, but on a different theory than was embraced by either district court. The panel majority held that Mylan was subject to specific personal jurisdiction in Delaware simply by virtue of having filed its ANDAs with the FDA in Maryland. In the majority's view, "[i]f Mylan had already begun its deliberate marketing of these drugs in Delaware, there is no doubt that it could be sued for infringement in Delaware." App.7. Although Mylan had concededly not engaged in any such marketing, the majority reasoned that merely filing the ANDAs was nevertheless sufficient to establish specific jurisdiction because the ANDA filings were undertaken "to engage in future activities ... that will be purposefully directed at Delaware." *Id.* Noting the "magnitude and costs of the work required before [an] ANDA is filed," App.12, the majority stated that ANDA filings "reliably confirm[] a plan to engage in real-world marketing," for by filing an ANDA, a company has "confirmed its plan to commit real-world acts that would make it liable for infringement," App.10. Thus, the majority concluded, "Mylan's ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs." App.21.

The majority then added that "Delaware is undisputedly a State where Mylan will engage in that

marketing if the ANDAs are approved.” App.8. The majority based this belief on other, non-suit-related contacts between Mylan and Delaware. The majority noted that Mylan “seeks approval to sell its generic drugs throughout the United States,” “does some business in every State,” is “registered to do business in Delaware,” “is registered with the Delaware Board of Pharmacy,” and has a network of distributors that sell its products in Delaware. App.15-16. Because “Mylan’s ANDA filings and its distribution channels establish that Mylan plans to market its proposed drugs in Delaware,” the majority concluded, Mylan was subject to specific personal jurisdiction in Delaware. App.14. The majority took no position on whether Mylan could be subject to general personal jurisdiction in Delaware. App.3.

Judge O’Malley concurred in the judgment. Acknowledging that the specific jurisdiction question is “complex[]” and “difficult,” she disagreed with the majority’s “predicat[ing] the exercise of” specific personal jurisdiction on “Mylan’s expressions of *future* intent” to market a drug. App.19, 33. Instead, Judge O’Malley believed that an ANDA filing causes “*immediate* harm” to patent holders “regardless of whether such marketing ever occurs.” App.37. Relying heavily on *Calder v. Jones*, 465 U.S. 783 (1984), Judge O’Malley believed that specific jurisdiction over Mylan was proper in Delaware “based on the ‘effects’ of the conduct [Mylan] aimed at Delaware.” App.35. Noting that Acorda and AstraZeneca are Delaware corporations, she stated that “[t]hese companies clearly experienced legally cognizable injuries in Delaware upon the filing of the ANDA applications by Mylan.” App.36. Judge

O'Malley also would have held that Mylan had consented to general personal jurisdiction by registering to do business in Delaware. App.21-31.<sup>3</sup>

Mylan petitioned the Federal Circuit for rehearing en banc. The Federal Circuit called for responses from Acorda and AstraZeneca, but ultimately declined to rehear the case en banc. App.40.

### REASONS FOR GRANTING THE PETITION

The Federal Circuit's novel rule that the mere filing of an ANDA under the Hatch-Waxman Act subjects a generic pharmaceutical manufacturer to specific personal jurisdiction anywhere it might someday market the drug fundamentally conflicts with this Court's precedents in two critical respects. *First*, it is well-settled that specific personal jurisdiction is permissible only where the defendant's present suit-related conduct creates a substantial connection with the forum state. In a patent infringement case following an ANDA filing, the defendant's only suit-related conduct is the preparation and filing of the ANDA. Therefore, at

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<sup>3</sup> Like the *Acorda* district court, Judge O'Malley based her general jurisdiction holding on *Sternberg v. O'Neil*, 550 A.2d 1105 (Del. 1988), in which the Delaware Supreme Court held that compliance with Delaware's registration statute constitutes consent to general personal jurisdiction. After the Federal Circuit issued its decision in this case, however, the Delaware Supreme Court overruled *Sternberg*, holding that, in light of *Daimler*, Delaware's registration statute cannot be read "as a broad consent to personal jurisdiction in any cause of action," *Genuine Parts Co. v. Cepec*, 137 A.3d 123, 127 (Del. 2016). Accordingly, the question of whether Mylan can be subject to general personal jurisdiction in Delaware is no longer at issue.

most, specific jurisdiction may be exercised over the ANDA filer only in the states where those activities were undertaken—here, West Virginia and Maryland. There is no basis for exercising specific jurisdiction now based on hypothetical “future activities” that may or may not occur in Delaware or any place else. This Court’s jurisdictional decisions look to extant, not future, conduct, and other courts of appeals have rightly rejected relying on future conduct when assessing jurisdiction.

*Second*, the Federal Circuit’s rule sanctions a massive end-run around this Court’s *Daimler* decision. Before *Daimler*, infringement suits against generic manufacturers were typically asserted in a handful of plaintiff-convenient jurisdictions under general jurisdiction principles that permitted suit wherever the defendant ANDA filer did substantial business. *Daimler*, however, largely limited general jurisdiction to where a company is incorporated or has its principal place of business, which should have spelled the end of essentially nationwide jurisdiction against generic pharmaceutical manufacturers following ANDA filings. But the Federal Circuit’s new rule simply re-creates the pre-*Daimler* status quo, this time under the specific jurisdiction rubric. A plaintiff now need only point to an ANDA filing, because, according to the Federal Circuit, that filing “reliably indicate[s] plans to engage in marketing” of the proposed drug. App.8. That is a recipe for subjecting generic manufacturers to the very sort of nationwide jurisdiction that *Daimler* intended to foreclose, and on the even more analytically suspect grounds of specific, rather than general, jurisdiction. Indeed, the fact that pre-*Daimler* courts never thought to employ the

Federal Circuit's novel specific jurisdiction theory underscores its infirmity.

The Federal Circuit's holding also evinces a fundamental misunderstanding of the Hatch-Waxman Act and the ANDA-based litigation that the Act facilitates as a means of fostering low-cost generic pharmaceuticals. The immediate statutory right to sue in Hatch-Waxman patent infringement actions following an ANDA filing is triggered by the ANDA filing itself, not future marketing. There would have been no need for Congress to provide that trigger if an ANDA filing necessarily leads to the marketing of the product, as the Federal Circuit wrongly presumed, since such marketing would constitute an independent basis for an infringement suit. Furthermore, the central premise of the majority's decision is that filing an ANDA necessarily results in marketing the product in question. But that assumption is demonstrably wrong: numerous obstacles and off-ramps exist in between the filing of an ANDA and the marketing of a drug. The Federal Circuit's rule will also require courts to resolve complex factual disputes regarding the nature and extent of a generic manufacturer's plans to market the proposed drug in the forum in which it has been haled, a cumbersome approach to the threshold question of personal jurisdiction that has little to recommend it.

The Federal Circuit's new specific-jurisdiction-everywhere methodology for patent infringement cases amounts to an ANDA-specific exemption from the normal rules of specific personal jurisdiction and due process. By eliminating the predictability promised by *Daimler* and the Court's specific

jurisdiction precedents, the Federal Circuit’s novel rule will frustrate Congress’ objectives of facilitating the production of life-saving, low-cost generic drugs, as ANDA filers face new uncertainty of being sued anywhere in the nation under jurisdictional rules even more grasping than under the pre-*Daimler* regime. And this uncertainty is not limited to ANDA filers, as the Federal Circuit’s anomalous reasoning can apply to any patent case and has already been cited to support jurisdiction in non-ANDA infringement cases.

The Federal Circuit acknowledged the importance of this issue when it accepted these cases on interlocutory review. And absent this Court’s review now, the Federal Circuit’s anomalous rule will be the final word. It is imperative that the Court address this nationally significant question, reject the notion of an “ANDA exception” to core jurisdictional principles, and restore elemental protections of due process.

**I. The Federal Circuit’s Novel Rule Squarely Conflicts With This Court’s Precedents And The Hatch-Waxman Act.**

**A. Mylan’s Only “Suit-Related Conduct” Occurred in West Virginia and Maryland, Limiting Specific Jurisdiction to Those States.**

The Due Process Clause of the Fourteenth Amendment prohibits a state from authorizing its courts to exercise personal jurisdiction over an out-of-state defendant unless 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.” *Daimler*,

134 S. Ct. at 754 (quoting *Int’l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945)) (brackets omitted); *see also* Fed. R. Civ. P. 4(k)(1)(A) (permitting district court jurisdiction over defendant subject to jurisdiction in court of forum state).

“[T]wo categories of personal jurisdiction” have developed in this Court’s decisions. *Daimler*, 134 S. Ct. at 754. Under the doctrine of general personal jurisdiction, a court can hear “any and all claims against [the defendant].” *Id.* at 751. For general jurisdiction to be appropriate, however, the defendant’s “affiliations with the State in which suit is brought” must be “so constant and pervasive ‘as to render [it] essentially at home in the forum State.’” *Id.* (quoting *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915, 924 (2011)). Absent “exceptional” circumstances, a corporation is “at home,” and thus subject to general jurisdiction, only in the states in which it is incorporated and where it has its principal place of business. *Id.* at 760-61 & n.19; *see also Goodyear*, 564 U.S. at 924.

Specific personal jurisdiction, by contrast, is appropriate when the suit “arises out of or relates to the defendant’s contacts with the forum.” *Goodyear*, 564 U.S. 923-24 (quoting *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 414 n.8 (1984)) (brackets omitted). For a state to exercise specific jurisdiction consistent with due process, “the defendant’s suit-related conduct must create a substantial connection with the forum State.” *Walden v. Fiore*, 134 S. Ct. 1115, 1121 (2014). Because the specific jurisdiction inquiry “focuses on the relationship among the defendant, the forum, and the

litigation,” neither contacts “between the plaintiff (or third parties) and the forum State” nor “the defendant’s contacts with persons who reside” in the forum State affect the analysis. *Id.* at 1121-22. Instead, specific jurisdiction is established when the defendant has “purposefully directed” its activities at the forum state, and the claims in a suit “‘arise out of or relate to’ those activities.” *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472-73 (1985); *see also Walden*, 134 S. Ct. at 1122 (“[I]t is the defendant’s conduct that must form the necessary connection with the forum State[.]”); *id.* at 1125 (“proper question” is “whether the defendant’s conduct connects him to the forum in a meaningful way”).

Under these black-letter constitutional principles, this should be a straightforward case. As even the Federal Circuit recognized, Mylan’s only “suit-related” conduct here took place in West Virginia, where the ANDAs were prepared, and Maryland, where the ANDAs were filed. App.4-5. To be sure, the filing of each ANDA constituted an “act of infringement” of respondents’ patents, albeit an “artificial” one. *Eli Lilly*, 496 U.S. at 678. But there is no connection whatsoever—much less a “substantial connection,” *Walden*, 134 S. Ct. at 1121—between those ANDA-triggered “acts of infringement” and Delaware, or any other State save West Virginia and Maryland. The “acts of infringement” upon which respondents’ suits are based did not “arise[] out of an act done or transaction consummated in” Delaware, *Hanson v. Denckla*, 357 U.S. 235, 251 (1958); the only acts giving rise to them took place in West Virginia and Maryland.

While Mylan may have other, more general contacts with Delaware—*e.g.*, registering to do business there, occasionally litigating there, and so forth—none of those contacts gives rise to or relates to the specific patent infringement claims brought by respondents here, as required to establish specific jurisdiction. *See Goodyear*, 564 U.S. at 923 (specific jurisdiction turns on activity that “gave rise to the episode-in-suit”). Respondents did not sue Mylan for previously participating in ANDA litigation there. Without suit-related contacts that the litigation “arise[s] out of or relate[s] to,” there cannot be specific jurisdiction. *Burger King*, 471 U.S. at 472-73; *Walden*, 134 S. Ct. at 1121. 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. But if, as here, a plaintiff cannot first show a suit-related contact by the defendant that creates the “substantial connection” between the defendant and the forum state, then no amount of other contacts can create specific jurisdiction. *Walden*, 134 S. Ct. at 1121; *see also Hanson*, 357 U.S. at 254 (noting that court “does not acquire ... jurisdiction by being the ‘center of ‘gravity’ of the controversy, or the most convenient location for litigation”).

**B. The Federal Circuit’s Novel Rule Disregards This Court’s Specific Jurisdiction Precedents, Conflicts With Other Circuits’ Decisions, and Improperly Restores the Pre-*Daimler* Status Quo.**

Even though Mylan’s only suit-related contacts are with West Virginia and Maryland, the Federal Circuit majority nevertheless permitted specific personal jurisdiction over Mylan in Delaware by crafting a novel rule that permits specific jurisdiction to be exercised over an ANDA filer *anywhere in the country*, on the basis that an ANDA filing “reliably confirm[s] a plan to engage in real-world marketing.” App.10. In two critical respects, however, this unprecedented holding departed sharply from this Court’s personal jurisdiction precedents.

First, nothing in this Court’s cases supports the court’s reliance on an ANDA filer’s potential “future activities” to establish specific jurisdiction. App.7. The prospect of future distribution or sales—which may never occur—does not create specific jurisdiction over an ANDA filer now. *Walden* is only the latest in a long line of precedent making plain that the only “jurisdictionally relevant” suit-related contacts for purposes of specific personal jurisdiction analysis are those that “show[] that the defendant *has formed* a contact with the forum State.” 134 S. Ct. at 1125 (emphasis added); *see also Burger King*, 471 U.S. at 474 (“[T]he constitutional touchstone remains whether the defendant purposefully *established* ‘minimum contacts’ in the forum State.” (emphasis added)); *Hanson*, 357 U.S. at 251 (court may not

exercise jurisdiction unless defendant “*has had* the ‘minimal contacts’ with that State that are a prerequisite to its exercise of power over him” (emphasis added)). After all, to determine whether a claim “arise[s] out of” a contact with the forum state, one must necessarily look *back*, not forward. *Goodyear*, 564 U.S. 923-24; *Burger King*, 471 U.S. at 472-73; *Int’l Shoe*, 326 U.S. at 319. An ANDA filer might one day form “a contact with the forum state” based on actual distribution or sales of the drugs referenced in the ANDA, *Walden*, 134 S. Ct. at 1125, but until those potential future activities come to pass, they are plainly insufficient to support jurisdiction now.

In contrast to the Federal Circuit, other courts of appeals have correctly recognized that “future” activities are “not relevant in” personal jurisdiction analysis. *Fastpath, Inc. v. Arbela Techs. Corp.*, 760 F.3d 816, 822 (8th Cir. 2014); *see also Roche v. Pebble Beach Co.*, 541 F. App’x 208, 212 (3d Cir. 2013) (“Generally, ‘the proper focus in the specific jurisdiction analysis is on those contacts leading up to and surrounding the accrual of the cause of action. Later events are not considered.’” (quoting 16 Moore’s Federal Practice—Civil §108.42 (3d ed. 2010))); *Cossaboon v. Maine Med. Ctr.*, 600 F.3d 25, 37 (1st Cir. 2010) (in jurisdictional analysis, “[p]reparations to do business at an indeterminate future date ... cannot be confused with actually doing business”); *Moncrief Oil Int’l Inc. v. OAO Gazprom*, 481 F.3d 309, 312 (5th Cir. 2007) (rejecting specific jurisdiction based on nonresident defendant’s “purposeful and affirmative action, the effect of which is to cause business activity (foreseeable by the defendant) in the forum state”);

*Hyatt Int’l Corp. v. Coco*, 302 F.3d 707, 716 (7th Cir. 2002) (“[W]hen conducting business with a forum in one context, potential defendants should not have to wonder whether some aggregation of other past and future contacts will render them liable to suit there.”). Indeed, it is well-established that “personal jurisdiction depends on the defendant’s contacts with the forum state at the time the lawsuit was filed,” not later-developed contacts. *Klinghoffer v. S.N.C. Achille Lauro*, 937 F.2d 44, 52 (2d Cir. 1991); *see also, e.g., Pohlmann v. Bil-Jax, Inc.*, 176 F.3d 1110, 1112 (8th Cir. 1999); *McFarlane v. Esquire Magazine*, 74 F.3d 1296, 1300-01 (D.C. Cir. 1996); *Asarco, Inc. v. Glenara, Ltd.*, 912 F.2d 784, 787 n.1 (5th Cir. 1990); *Farmers Ins. Exch. v. Portage La Prairie Mut. Ins. Co.*, 907 F.2d 911, 913 (9th Cir. 1990); *Rossman v. State Farm Mut. Auto. Ins. Co.*, 832 F.2d 282, 287 n.2 (4th Cir. 1987).

This unwillingness to exercise jurisdiction now based on potential future activities makes perfect sense. To establish specific personal jurisdiction, not only must “the defendant’s suit-related conduct ... create a substantial connection with the forum State,” *Walden*, 134 S. Ct. at 1121; the exercise of jurisdiction must independently comport with “fair play and substantial justice,” *Burger King*, 471 U.S. at 476-77; *Int’l Shoe*, 326 U.S. at 316; App.16. No conception of “fair play and substantial justice” allows a state to exercise jurisdiction over a defendant based on potential actions that might never be undertaken.

The majority held that the “fair play and substantial justice” requirement was satisfied because the case “involve[s] the pricing and sale of products in Delaware and harms to firms doing business in

Delaware.” App.17. But, at this stage, the case involves none of those things. It involves the preparation of an ANDA and its filing in West Virginia and Maryland, respectively. Whether any generic product will ever be marketed in Delaware is entirely speculative, and exercising jurisdiction over Mylan in Delaware now based on such speculation about the future does not comport with fair play or substantial justice.

The majority also held that upholding specific jurisdiction based on an ANDA filing was not unfair because it “will serve the interest of the plaintiffs and the judicial system in efficient resolution of litigation,” by permitting plaintiffs to file “multiple lawsuits” in a single jurisdiction. App.17. That plaintiff-focused, ends-driven argument disregards the fundamental principle that “[d]ue process limits on the State’s adjudicative authority principally protect the liberty of the nonresident defendant—not the convenience of plaintiffs.” *Walden*, 134 S. Ct. at 1122; *see also Fuentes v. Shevin*, 407 U.S. 67, 90 n.22 (1972) (noting that “due process is not intended to promote efficiency,” because “the Constitution recognizes higher values than speed and efficiency”); *Hanson*, 357 U.S. at 254.

Second, the Federal Circuit’s novel rule also conflicts with—and creates a massive end-run around—this Court’s *Daimler* decision. Before *Daimler*, “general jurisdiction traditionally provided the basis to assert jurisdiction over generic drug company defendants.” *Otsuka Pharm. Co. v. Mylan Inc.*, 106 F. Supp. 3d 456, 463 (D.N.J. 2015). Parties whose patents were named in an ANDA filing could

sue in almost any state where the ANDA filer did substantial business. *E.g.*, *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 693 F. Supp. 2d 409, 421 (D. Del. 2010) (exercising general jurisdiction based on defendant's "substantial revenue" from Delaware drug sales). Specific jurisdiction was "disfavored by courts as a basis to exercise jurisdiction over generic drug company defendants in ANDA cases," App.55, precisely because the actions required to file an ANDA generally were considered insufficient to establish specific jurisdiction except perhaps in the state where the ANDA was prepared. *See Zeneca Ltd. v. Mylan Pharm.*, 173 F.3d 829 (Fed. Cir. 1999) (holding that filing 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 ANDA was prepared).

*Daimler*, however, vastly reduced the scope of general personal jurisdiction, largely limiting it to where a defendant company is "at home," meaning where it is incorporated or has its personal place of business. *See* 134 S. Ct. at 751, 760-61 & n.19. That should have spelled the end of essentially nationwide jurisdiction against generic pharmaceutical companies.

The Federal Circuit's new rule simply recreates the pre-*Daimler* status quo by broadening specific personal jurisdiction to counteract this Court's

narrowing of general jurisdiction in *Daimler*. Because, according to the majority, the mere filing of an ANDA “reliably confirm[s] a plan to engage in real-world marketing” of the drug in question, App.10, an ANDA filer is thus subject to specific personal jurisdiction in all fifty states, based wholly on non-suit-related contacts in those other states, such as nationwide distribution networks. Accordingly, even though *Daimler* made clear that not even a defendant’s “continuous and systematic” contacts with a state render it subject to specific jurisdiction unless they “also give rise to the liabilities sued on,” 134 S. Ct. at 761, under the majority’s decision, ANDA filers can be forced to litigate in states wherever they may one day do business. That is a jurisdictional rule even more “exorbitant” and “grasping” than the one *Daimler* rejected. *Id.*

If the Federal Circuit were correct that future activities “reliably confirmed” by the mere filing of an ANDA were sufficient to create specific jurisdiction in every forum across the country, then courts have been missing the obvious for decades. Specific jurisdiction should have been the rule, not the exception, in patent infringement cases following ANDA filings. There would have been no need to ground jurisdiction in general jurisdiction because specific personal jurisdiction could have been exercised over an ANDA filer in any state where that filer could be presumed to engage in future sales. But specific jurisdiction was “disfavored,” App.55, 112, specifically because courts understood that merely filing an ANDA does not establish the necessary constitutional predicates for specific jurisdiction except perhaps in the state where the ANDA was prepared. *See* pp.22-23, *supra*; *see also*

*Rush v. Savchuk*, 444 U.S. 320, 330 (1980) (“It is apparent that ... a ‘contact’” connecting defendant to “all 50 States and the District of Columbia ... simultaneously ... can have no jurisdictional significance.”).<sup>4</sup>

This Court has repeatedly reminded the Federal Circuit that traditional rules of litigation remain equally binding in patent litigation. See *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 836-37 (2015); *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 394 (2006). This principle applies with even greater force in the context of fundamental due process protections. Like the district courts in this case, which believed it “necessary” to reconsider specific jurisdiction “now that the standard for general jurisdiction ... has changed” following *Daimler*, App.55, the Federal Circuit engaged in a felt need to compensate for *Daimler*’s narrowing of general jurisdiction by broadening specific jurisdiction beyond all known bounds.

### **C. The Federal Circuit’s Rule Misconstrues the Hatch-Waxman Act.**

The Federal Circuit’s new rule also evinces a fundamental misunderstanding of the Hatch-Waxman Act and the nature of ANDA litigation facilitated—indeed, encouraged—by the Act. To begin

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<sup>4</sup> Indeed, Acorda and Alkermes filed an identical suit against Mylan in the United States District Court for the Northern District of West Virginia, where Mylan prepared its ANDA filing, is incorporated, and has its principal place of business. See *Acorda Therapeutics, Inc. v. Mylan Pharm. Inc.*, No. 1:14-cv-00139 (N.D. W. Va. filed Aug. 22, 2014). Personal jurisdiction is not at issue in that case.

with, the “artificial act of infringement” giving rise to a suit against generic pharmaceutical manufacturers under the Hatch-Waxman Act is complete the moment the filing manufacturer files an ANDA with a paragraph IV certification. *Eli Lilly*, 496 U.S. at 678; *Caraco*, 132 S. Ct. at 1677 (ANDA filing is “itself an act of infringement, which gives the brand an immediate right to sue”). Plaintiffs have an equally valid (or invalid) claim of infringement under 35 U.S.C. §271(e)(2)(A) whether or not an ANDA filer ever engages in any future marketing or sales. Specific jurisdiction over that claim therefore cannot turn on such future activities.

Furthermore, if the prospect of future distribution, future sales, or other “future activities” were sufficient to create jurisdiction, there would have been no need for Congress to make an ANDA filing into an artificial act of infringement by enacting 35 U.S.C. §271(e)(2)(A). Plaintiffs could simply have brought suit under §271(a)-(c) on the theory that the ANDA would lead to future distribution and sales. *See, e.g.*, 35 U.S.C. §271(a) (“[W]hoever ... makes, uses, offers to sell, or sells any patented invention ... infringes the patent.”). But Congress enacted §271(e)(2)(A) “to enable the judicial adjudication” of the challenged patents’ validity upon an ANDA filing, precisely because such a filing *lacks* the requisite connection to the actual sale of products, let alone to the sale of those products in specific jurisdictions. *Eli Lilly*, 496 U.S. at 678.

The Federal Circuit’s new rule also turns on a fundamental misunderstanding of the connection between an ANDA filing and future marketing. The

central premise of the majority's decision was that the mere filing of an ANDA will result in a generic manufacturer marketing the product in question in a manner that interferes with the patent holder's rights. *See* App.10-13. But that assumption is demonstrably false. Numerous obstacles and off-ramps exist between the filing of an ANDA and the marketing of a drug in any state, much less all fifty states. Among other things, the FDA could reject the ANDA filing; the generic manufacturer could lose in ANDA litigation; or, by the time the ANDA is approved, the generic could determine that the overall market (or the market in a certain state) does not justify the costs of production and marketing. *See, e.g.,* Tracy Staton, *Teva Says No Thank You to Generic Lipitor*, FiercePharma (May 29, 2012), <http://bit.ly/2d37KQH> (reporting company's decision not to market approved generic drug due to economic considerations); Sumeet Chatterjee, *Ranbaxy Unable to Launch New Generic, Shares Fall*, Reuters (Mar. 3, 2010), <http://reut.rs/2cyFOl0> (reporting company's failure to receive expected FDA approval).

Similarly, the Federal Circuit's belief that an ANDA filing necessarily presages "injury-causing and allegedly wrongful marketing," App.8, is simply incorrect and ignores how ANDA litigation works under the Hatch-Waxman Act. In the paragraph IV certification accompanying an ANDA filing, the generic manufacturer declares its view that the brand-name manufacturer's "patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." 21 U.S.C. §355(j)(2)(A)(vii)(IV). The brand-name manufacturer then brings a complaint that the generic

product infringes its valid patent. If the brand-name manufacturer prevails, then there will be no future sales of the generic, because they would infringe the patent. If the generic manufacturer prevails (because, for example, the patent is found invalid or the generic is found not to infringe the patent), then any sales will be non-infringing. In short, either there will be no marketing at all (under the first scenario), or there will be non-wrongful marketing (under the second scenario). The majority's notion of "injury-causing" marketing that occurs by virtue of the ANDA filing is untenable.

Moreover, as Judge O'Malley recognized, by premising personal jurisdiction on potential "future activities," App.7, the Federal Circuit's new rule will require courts to wade into a "fact-intensive morass," App.21, as parties "dispute a host of factual questions" as to the extent and likelihood of those "future activities," App.19. Such complex inquiries "complicate a case, eating up time and money as the parties litigate, not the merits of their claims, but which court is the right court to decide those claims." *Hertz Corp. v. Friend*, 559 U.S. 77, 94 (2010). Indeed, in this case, while the majority declared that "Delaware is undisputedly a State where Mylan will engage in ... marketing if the ANDAs are approved," App.8, Judge O'Malley correctly noted that this point was, at the very least, disputed, App.19 ("The parties dispute ... whether and to what extent Mylan ultimately may be authorized to—or decide to—market generic drugs in Delaware."). If anything, the parties recognized that predicting "future activities" was an imprecise science: Acorda conceded that an ANDA filing "doesn't say 'we intend to do this and we'll

do it no matter what,” Oral Arg. At 23:29-33, *Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755 (Fed. Cir. 2016) (No. 15-1456), and AstraZeneca conceded that Mylan “may never sell in certain ... jurisdictions.” Oral Arg. at 44:12-18, *AstraZeneca AB v. Mylan Pharm. Inc.*, 817 F.3d 755 (Fed. Cir. 2016) (No. 15-1460).

Though Judge O’Malley correctly rejected the majority’s strained attempt to establish specific personal jurisdiction based on uncertain “future activities,” her approach to specific personal jurisdiction was likewise at odds with this Court’s precedent. She would have held that Mylan could be haled into Delaware because *respondents* “experienced legally cognizable injuries” there “upon the filing of the ANDA applications.” App.36. Judge O’Malley argued that this case was “just like” *Calder v. Jones* because the ANDA was “targeted only to these Delaware companies.” App.37.

This Court, however, has “consistently rejected attempts to satisfy the defendant-focused ‘minimum contacts’ inquiry by demonstrating contacts between *the plaintiff* ... and the forum State,” *Walden*, 134 S. Ct. at 1122 (emphasis added), as Judge O’Malley’s approach advocates. Furthermore, as *Walden* explained, the connection between the tort and the “effects” in *Calder* “was largely a function of the nature of the libel tort,” which requires a third-party reaction. *Id.* at 1124. “The crux of *Calder* was that the reputation-based ‘effects’ of the alleged libel connected the defendants to California, not just to the plaintiff.” *Id.* at 1123-24. This is because libelous literature “can lead to a loss of reputation only if

communicated to (and read and understood by) third persons.” *Id.* at 1124; *see also Stroman Realty, Inc. v. Wercinski*, 513 F.3d 476, 486 (5th Cir. 2008) (describing “effects” jurisdiction under *Calder* as “rare”).

The “effects” of Mylan’s ANDA filings lack any comparable relation to Delaware. By operation of the Hatch-Waxman Act, respondents’ harm, if any, was immediately suffered when Mylan filed its ANDA. The “artificial” act of infringement occasioned by that filing, *Eli Lilly*, 496 U.S. at 678, is not contingent on third-party conduct in Delaware. Respondents would have suffered the effects of that infringement “in California, Mississippi, or wherever else [it] might have [located its business].” *Walden*, 134 S. Ct. at 1125. Thus, like the majority, Judge O’Malley compensated for the narrowing of general jurisdiction in *Daimler* by establishing a specific-jurisdiction-everywhere rule unmoored from this Court’s precedents.

## **II. This Issue Is Exceptionally Important And Should Be Addressed In This Case.**

The Federal Circuit’s specific-jurisdiction-everywhere rule, premised on future suit-related contacts that an ANDA filer might develop with a forum state, permits brand-name manufacturers to bring a patent infringement suit against a generic manufacturer *anywhere in the country*. The profound implications of the majority’s decision were not lost on those who follow the pharmaceutical industry. Commentators noted that the “sweeping scope” of the decision has created “effectively national jurisdiction over any ANDA filer.” Paul A. Ainsworth & Joshua I.

Miller, *Acorda Therapeutics v. Mylan Pharmaceuticals: A New Kind of Jurisdiction for ANDA Cases*, Bloomberg BNA Pharm. Law & Indus. Report (Apr. 8, 2016), <http://bit.ly/23vjZtF>. Because the majority’s analysis “is dedicated not to the facts of the case but to generally applicable ANDA filing requirements,” generic manufacturers “are now at risk of being haled into federal court in virtually every jurisdiction in the country.” *Id.*; see also Brenda Sandburg, *Have Patent, Will Travel: Brand Firms Can File Infringement Suits Anywhere*, Pink Sheet Daily, Mar. 18, 2016 (“Brand-name drug makers will be able to file patent infringement suits against generic manufacturers in whatever jurisdiction they wish[.]”). Acorda’s own counsel described the decision as “very broadly” holding that brand manufacturers “could essentially sue [ANDA filers] anywhere.” Ryan Davis, *Fed. Circ. Sets Wide Jurisdiction Rule in ANDA Patent Cases*, Law360 (Mar. 18, 2016), <http://bit.ly/1oYpNsv>.

These predictions have already been borne out. In one recent case, a Canadian generic manufacturer, PSI, was sued in Delaware after filing an ANDA. *Millennium Pharm., Inc. v. Pharmascience Inc.*, No. 15-702-GMS, 2016 WL 3382131, at \*3 (D. Del. June 10, 2016). The defendant, which had never sold a single drug in Delaware, argued that it should not be subject to personal jurisdiction because, “unlike Mylan, ... it does not have additional contacts with Delaware besides the filing of its ANDA.” *Id.* The district court was unmoved. Based on the Federal Circuit’s opinion in this case, the court held that “Delaware is a state where PSI will engage in marketing if the ANDA is approved and that

marketing is directly related to this suit.” *Id.* (citing *Acorda*, 817 F.3d at 760). Other ANDA filers—from established U.S.-based manufacturers to foreign startups that have yet to make a single sale—can expect the same result anywhere they are sued.

The high volume and high stakes of ANDA litigation magnify the importance of this case. Each year, hundreds of ANDA cases are filed, and in each case, millions of dollars are at stake. ANDA cases comprise a substantial (ten percent) and growing percentage of all patent cases filed in the federal courts. *See* Lex Machina, 2015 Hatch-Waxman/ANDA Report (Apr. 26, 2016), <http://bit.ly/2chtoPS>. The volume, importance, and high stakes of ANDA litigation may explain why jurisdictions that grew used to these cases in the pre-*Daimler* world are reluctant to give them up. But it also underscores why this Court should intervene now—before hundreds of cases are filed in the wrong courts in disregard of defendants’ due process rights.

The Federal Circuit’s decision dramatically expands the limits of specific jurisdiction not just for generic pharmaceutical manufacturers, but for any company that may find itself on the receiving end of a patent infringement suit. For while the majority focused on why ANDA filings in particular could “non-speculatively predict Delaware activities,” App.13, that language is broad enough to encompass many other now-jurisdictionally-relevant contacts. At least one district court has already relied on the Federal Circuit’s novel reasoning to support jurisdiction in a standard patent infringement case. *See Segway Inc. v. Inventist, Inc.*, No. 15-808-SLR, 2016 WL 1650468,

at \*4 n.6 (D. Del. Apr. 25, 2016) (noting that “a defendant’s planned, non-speculative harmful conduct’ as evidenced, e.g., through the filing of an [ANDA], passed constitutional muster” (quoting App.13)). Indeed, even before the Federal Circuit’s decision in this case, the *Acorda* district court’s decision had been cited as evidence that “courts may take a more liberal view of ‘related contacts’” to counteract *Daimler*, a phenomenon that risks “regenerating general jurisdiction under a different name.” Linda J. Silberman, *The End of Another Era: Reflections on Daimler and Its Implications for Judicial Jurisdiction in the United States*, 19 Lewis & Clark L. Rev. 675, 685 & n.58 (2015). Yet the district court’s flawed but comparably modest effort to expand specific jurisdiction based on sending notice letters pales in comparison to the Federal Circuit’s even more “unacceptably grasping” holding that the mere act of filing an ANDA subjects the filer to specific personal jurisdiction anywhere in the country. *Daimler*, 134 S. Ct. at 761.

The majority’s decision also undercuts one of the primary aims of the Hatch-Waxman Act: to “make available more low cost generic drugs.” *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997); *see also Caraco*, 132 S. Ct. at 1676 (ANDA “process is designed to speed the introduction of low-cost generic drugs to market”). The decision denies ANDA filers “a degree of predictability ... that allows [them] to structure their primary conduct with some minimum assurance as to where that conduct will and will not render them liable to suit.” *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 297 (1980). Indeed, before *Daimler*, generic

manufacturers could at least safely assume they would not be haled into court in a state where they had never done any business. But after the majority's decision, even a tiny startup or foreign manufacturer that has never sold a drug in the United States can be subject to nationwide jurisdiction based on where it might *one day* conduct business. See, e.g., *Millennium Pharm.*, 2016 WL 3382131, at \*3. The decision thus will have a substantial chilling effect on generic activity, as ANDA filers will face the prospect of litigation anywhere in the country based on actions they might never take.

The Federal Circuit recognized the significance of the personal jurisdiction issue here when it accepted these cases on interlocutory review. That court's subsequent radical departure from personal jurisdiction precedents in favor of a novel rule that imposes nationwide specific jurisdiction on ANDA filers has only heightened the importance of these cases. The Court thus should take this opportunity to bring "specific jurisdiction ... into sharper relief," *Daimler*, 134 S. Ct. at 755, by rejecting the Federal Circuit's break from settled constitutional doctrine.

There are no vehicle issues preventing the Court's review of this case. The case is on a motion-to-dismiss posture, and the relevant underlying facts are undisputed: Mylan prepared ANDAs in West Virginia and filed them in Maryland, and there are no other suit-related activities by Mylan in Delaware. Moreover, the dispute turns entirely on the constitutional question, as "Mylan ma[d]e[] no argument against jurisdiction other than one based on due-process standards." App.6.

The issue of general personal jurisdiction, discussed in the district court opinions and Judge O'Malley's concurring opinion, does not create a vehicle problem. The Delaware Supreme Court's decision in *Genuine Parts Co. v. Cepec*, 137 A.3d 123 (Del. 2016), postdating the Federal Circuit's decision, removed that issue from the case when it held that, in light of *Daimler*, Delaware's registration statutes cannot be read "as a broad consent to personal jurisdiction in any cause of action, however unrelated to the foreign corporation's activities in Delaware." *Id.* at 127; *see also* n.3, *supra*. If anything, the fact that Mylan cannot be subject to general personal jurisdiction in Delaware even on a consent theory only highlights the need for this Court's review of the specific jurisdiction question.

Finally, the time to review the Federal Circuit's anomalous and far-reaching rule of specific jurisdiction everywhere is now. Because the post-*Daimler* rule was unsettled, the district courts here certified this jurisdictional question for interlocutory review. But now that the Federal Circuit has announced a nationwide rule, such an interlocutory appeal is unlikely to arise again. Absent this Court's review of this petition, district courts will find jurisdiction over all ANDA filers going forward, which will send these cases to trial, usually in improper fora. To challenge the Federal Circuit's holding here, a defendant would have to endure trial, lose, and appeal to the Federal Circuit on an issue that is now settled circuit law. And there is no benefit to further percolation; the decision below already departs from other circuits' application of general due process principles, *see* pp. 20-21, *supra*, and the ANDA-specific

issue will not arise in any other court of appeals because the Federal Circuit has exclusive jurisdiction over patent cases. *See* 28 U.S.C. §1295(a)(1). If the Court does not intervene, the Federal Circuit's profoundly incorrect and consequential decision will be the final word. Accordingly, the Court should act now to affirm that there is no "ANDA exception" to fundamental due process protections and to reject the Federal Circuit's novel rule eviscerating *Daimler* and endorsing national specific jurisdiction.

### CONCLUSION

This Court should grant the petition.

Respectfully submitted,

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September 19, 2016

## **APPENDIX**

# APPENDIX

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*Appendix A*

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

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No. 2015-1456

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ACORDA THERAPEUTICS INC.,  
ALKERMES PHARMA IRELAND LIMITED,  
*Plaintiffs-Appellees,*

v.

MYLAN PHARMACEUTICALS INC., MYLAN INC.,  
*Defendants-Appellants.*

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Appeal from the United States District Court for the  
District of Delaware in No. 1:14-cv-00935-LPS,  
Chief Judge Leonard P. Stark.

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No. 2015-1460

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ASTRAZENECA AB,  
*Plaintiff-Appellee,*

v.

MYLAN PHARMACEUTICALS INC.,  
*Defendant-Appellant.*

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Appeal from the United States District Court for the  
District of Delaware in Nos. 1:14-cv-00664-GMS,  
1:14-cv-00696-GMS, Judge Gregory M. Sleet.

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Decided: March 18, 2016

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Before NEWMAN, O'MALLEY, and TARANTO,  
*Circuit Judges.*

Opinion for the court filed by *Circuit Judge* TARANTO.

Opinion concurring in the judgment filed by  
*Circuit Judge* O'MALLEY.

TARANTO, *Circuit Judge.*

These appeals involve two actions brought in the District of Delaware against generic drug manufacturer Mylan Pharmaceuticals Inc. One, assigned to Chief Judge Stark, was brought by brand-name drug manufacturers Acorda Therapeutics Inc. and Alkermes Pharma Ireland Ltd.; the other, assigned to Judge Sleet, was brought by brand-name drug manufacturer AstraZeneca AB. The plaintiffs brought the actions under 35 U.S.C. § 271(e)(2), alleging that their patents cover drugs that Mylan has sought permission from the Food and Drug Administration to manufacture and market. Mylan moved to dismiss on the ground that Delaware could not (and so the federal court may not) exercise personal jurisdiction—either general or specific personal jurisdiction—over Mylan in these cases. Chief Judge Stark and Judge Sleet denied the motions. Although they reached different conclusions about whether Delaware could exercise general personal jurisdiction over Mylan based on consent given in registering to do business in the State, they both concluded that Delaware could exercise specific personal jurisdiction, based on Mylan's suit-related

contacts with Delaware. On interlocutory appeal, we affirm, holding that Mylan is subject to specific personal jurisdiction in these cases. We do not address the issue of general personal jurisdiction.

#### BACKGROUND

Under the authority of the FDA’s approval of its New Drug Application (NDA), 21 U.S.C. § 355(a), (c), Acorda markets Ampyra® to help individuals with multiple sclerosis walk. In seeking approval for Ampyra®, Acorda identified five patents for listing in the FDA’s *Approved Drug Products with Therapeutic Equivalence Evaluations* publication—the “Orange Book.” See 21 U.S.C. § 355(b)(1); 21 C.F.R. §§ 314.3, 314.53. Acorda owns four of the patents and is the exclusive licensee of the fifth, owned by Alkermes. In January 2014, Mylan filed an Abbreviated New Drug Application (ANDA) with the FDA under 21 U.S.C. § 355(j), seeking approval to market generic versions of Ampyra®. Under paragraph IV of § 355(j)(2)(A)(vii), Mylan certified that Acorda’s Orange Book patents for Ampyra® are invalid or would not be infringed by Mylan’s marketing of its proposed drug. Acorda and Alkermes then sued Mylan in the District of Delaware for patent infringement, invoking the declaration of 35 U.S.C. § 271(e)(2)(A) that the submission of a paragraph IV certification constitutes an act of infringement.<sup>1</sup>

AstraZeneca markets FDA-approved Onglyza® and Kombiglyze™ to help individuals with type II

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<sup>1</sup> Acorda and Alkermes also sued Mylan’s parent corporation, Mylan Inc., but the parties voluntarily dismissed Mylan Inc. without prejudice.

diabetes. AstraZeneca owns three patents listed in the Orange Book for those drugs. Mylan filed two ANDAs seeking approval to market generic versions of the two drugs and certified that AstraZeneca's three patents are invalid or would not be infringed by Mylan's marketing of its proposed drugs. AstraZeneca sued Mylan for infringement under 35 U.S.C. § 271(e)(2)(A) in the District of Delaware.

Mylan filed motions to dismiss under Federal Rule of Civil Procedure 12(b)(2) on the ground that the State of Delaware could not—and therefore, derivatively, the federal district court in Delaware may not—exercise personal jurisdiction over Mylan in these matters under the Due Process Clause of the Fourteenth Amendment. The parties do not dispute that the standards of the Due Process Clause control whether there is personal jurisdiction in these matters. Nor do they dispute that the Due Process Clause standards permit a State to exercise either specific personal jurisdiction over a defendant in a case (based on the connection of the State to the subject matter of the particular case) or general personal jurisdiction over the defendant (based on certain facts even where the case involves subject matter not itself sufficiently connected to the State). The parties have debated both specific and general personal jurisdiction in this case. The debate over the latter issue focuses on Mylan's registration to do business in Delaware as giving consent to the exercise of general personal jurisdiction.

The motions were decided on facts that are not in material dispute. Mylan is incorporated in West Virginia and has its principal place of business there.

Mylan submitted its ANDAs to the FDA in Maryland, and it did much if not all of its preparation of its ANDA filings in West Virginia. Regarding the notices of its ANDA filings required by 21 U.S.C. § 355(j)(2)(B)(iii), Mylan sent notices to Acorda in New York and Alkermes in Ireland (for the *Acorda* matter), and it sent notices to AstraZeneca's subsidiary in Delaware and AstraZeneca in Sweden (for the *AstraZeneca* matter). Mylan has registered to do business and appointed an agent to accept service in Delaware. And, of particular importance, Mylan intends to direct sales of its drugs into Delaware, among other places, once it has the requested FDA approval to market them. The plaintiffs, for their part, also have connections with Delaware: Acorda is incorporated in Delaware, AstraZeneca's U.S. subsidiary has its principal place of business in Delaware, and both Acorda and AstraZeneca have sued other generic manufacturers for infringement of the same patents in Delaware.

Chief Judge Stark (in the *Acorda* case) and Judge Sleet (in the *AstraZeneca* case) denied the motions to dismiss. Both judges concluded that Delaware had sufficient contacts related to the subject of these cases that it could exercise specific personal jurisdiction over Mylan. *See Acorda Therapeutics, Inc. v. Mylan Pharm. Inc.*, 78 F. Supp. 3d 572, 593-95 (D. Del. 2015); *AstraZeneca AB v. Mylan Pharm., Inc.*, 72 F. Supp. 3d 549, 558-60 (D. Del. 2014). The two judges disagreed about whether Delaware could exercise general personal jurisdiction (independent of suit-related contacts) on the ground that Mylan consented to such jurisdiction in registering to do business: they took different views of the status of Supreme Court decisions supporting such jurisdiction, e.g., *Pa. Fire*

*Ins. Co. v. Gold Issue Mining & Milling Co.*, 243 U.S. 93 (1917), in light of later decisions such as *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014). *See Acorda*, 78 F. Supp. 3d at 587-90; *AstraZeneca*, 72 F. Supp. 3d at 556-57. But the latter disagreement did not alter the finding of personal jurisdiction in these cases.

In each case the district court certified its decision for interlocutory review, and we granted permission to appeal. We have jurisdiction under 28 U.S.C. § 1292(b) and (c)(1).

#### DISCUSSION

Under Fed. R. Civ. P. 4(k)(1)(A), the district court has personal jurisdiction over Mylan in these cases if Mylan would be “subject to the jurisdiction of a court of general jurisdiction in the state where the district court is located,” here Delaware. And there is no dispute that Mylan would be subject to Delaware courts’ jurisdiction under Delaware’s long-arm statute, Del. Code Ann. Tit. 10, § 3104, as long as Delaware’s exercise of personal jurisdiction over Mylan would be consistent with the Fourteenth Amendment’s Due Process Clause. The jurisdictional dispute therefore turns on the constitutional question, and Mylan makes no argument against jurisdiction other than one based on due-process standards. We decide the question de novo, applying our own (not regional-circuit) law. *Merial Ltd. v. Cipla Ltd.*, 681 F.3d 1283, 1292 (Fed. Cir. 2012); *Akro Corp. v. Luker*, 45 F.3d 1541, 1543 (Fed. Cir. 1995).

A court may exercise specific personal jurisdiction without violating the Due Process Clause when the defendant “ha[s] 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). The minimum-contacts requirement focuses on whether “the defendant’s suit-related conduct . . . create[s] a substantial connection with the forum State.” *Walden v. Fiore*, 134 S. Ct. 1115, 1121 (2014). What conduct is suit-related depends on “the relationship among the defendant, the forum, and the litigation,” *Keeton v. Hustler Magazine, Inc.*, 465 U.S. 770, 775 (1984), including specifically the nature of the claim asserted. See *Calder v. Jones*, 465 U.S. 783, 789-90 (1984); *Walden*, 134 S. Ct. at 1124 (“The strength of [the defendant’s] connection [to California in *Calder*] was largely a function of the nature of the libel tort.”). In a formulation worded to address suits for retrospective relief based on past acts, the Supreme Court has said that the minimum-contacts requirement is met when the defendant “purposefully directed” activities at the forum, “and the litigation results from alleged injuries that ‘arise out of or relate to’ those activities.” *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472-73 (1985) (citations omitted); see *Grober v. Mako Prods., Inc.*, 686 F.3d 1335, 1346 (Fed. Cir. 2012).

Here, Mylan has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at Delaware (and, it is undisputed, elsewhere). If Mylan had already begun its deliberate marketing of these drugs in Delaware, there is no doubt that it could be sued for infringement in Delaware. Its Delaware sales would be acts committed in the State that are wrongful—if the plaintiffs here are right about infringement and

validity—and would concretely injure Acorda and AstraZeneca in the State by displacing some of their Delaware sales and likely lowering the price they could charge there. *See World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 297 (1980); *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1565-66 (Fed. Cir. 1994). In our view, the minimum-contacts standard is satisfied by the particular actions Mylan has already taken—its ANDA filings—for the purpose of engaging in that injury-causing and allegedly wrongful marketing conduct in Delaware.

Mylan’s ANDA conduct is “suit-related” and has a “substantial connection” with Delaware, *Walden*, 134 S. Ct. at 1121, because the ANDA filings are tightly tied, in purpose and planned effect, to the deliberate making of sales in Delaware (at least) and the suit is about whether that in-State activity will infringe valid patents. Thus, Mylan’s ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs. Delaware is undisputedly a State where Mylan will engage in that marketing if the ANDAs are approved. And the marketing in Delaware that Mylan plans is suit-related: the suits over patent validity and coverage will directly affect when the ANDA can be approved to allow Mylan’s Delaware marketing and when such marketing can lawfully take place. *See* 21 U.S.C. § 355(j)(5)(B).

The Hatch-Waxman Act recognizes the close connection between an ANDA filing and the real-world acts that approval of the ANDA will allow and that will harm patent-owning brand-name manufacturers. In 35 U.S.C. § 271(e)(2), Congress

declared the ANDA filing to be what has been called an “artificial act of infringement,” allowing the brand-name manufacturer to sue the ANDA filer to litigate patent validity and coverage. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). In so doing, Congress stressed the ANDA filer’s “purpose . . . to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent,” 35 U.S.C. § 271(e)(2)(A)—concrete, non-artificial acts of infringement. The relief available in such a suit, moreover, is focused on preventing or remedying the distinctly non-artificial infringing activities that threaten commercial harm: an order to delay the ANDA approval that is a precondition to marketing; an injunction to prevent commercial manufacture, sale, importation, etc.; and monetary relief for such commercial activities in the past. *Id.* § 271(e)(4).

Likewise, an ANDA filer’s paragraph IV certification regarding patents addresses the real-world actions for which approval is sought—specifically, whether those actions would infringe. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (certification states that patent will not be infringed “by the manufacture, use, or sale of the new drug for which the application is submitted”); 21 C.F.R. § 314.94(a)(12)(i)(A)(4) (same). This court has long recognized that the infringement inquiry called for by § 271(e)(2) is “whether, if a particular drug *were* put on the market, it *would* infringe the relevant patent” in the usual, non-artificial sense. *Bristol-Myers Squibb Co. v. Royce Labs., Inc.*, 69 F.3d 1130, 1135 (Fed. Cir. 1995); see *Sunovion Pharm., Inc. v. Teva Pharm. USA, Inc.*, 731

F.3d 1271, 1278-79 (Fed. Cir. 2013) (question is whether the conduct for which filer seeks approval would infringe); *see also Eli Lilly & Co.*, 496 U.S. at 678 (§ 271(e)(2)’s “act of infringement . . . consists of submitting an ANDA . . . containing . . . [a] certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent.”).

Notably, Congress did not authorize a patent-owning brand-name manufacturer to bring a suit over patent validity or coverage just because someone, no matter who, has called the manufacturer’s patent into question by declaring in some forum—to the FDA, to investors, to the public—that the patent is invalid or of limited scope. Congress added § 271(e)(2) as a special means of litigating patent scope and validity only when such a declaration has been made by an ANDA filer—which has, by its filing, confirmed its plan to commit real-world acts that would make it liable for infringement if it commits them without the patentees’ permission and it is wrong in its challenges to patent scope or validity. Congress also added a provision that confers on the ANDA filer alone a special right to seek a declaratory judgment regarding patent scope and validity if the NDA holder or patent owner does not file suit first. 35 U.S.C. § 271(e)(5). Those statutory provisions treat the ANDA filer as distinctive, and what distinguishes it is that it has, by its filing, reliably confirmed a plan to engage in real-world marketing.

All of the parties acknowledged as much at oral argument. *Acorda* Oral Arg. At 48:32-48:48, 49:18-

49:27 (Mylan), 22:59-23:47 (Acorda); *AstraZeneca* Oral Arg. At 21:57-22:32 (AstraZeneca). And the economic realities of preparing an ANDA confirm that filing realistically establishes a plan to market. The current fee for filing the ANDA itself is \$76,030. Generic Drug User Fee—Abbreviated New Drug Application, Prior Approval Supplement, Drug Master File, Final Dosage Form Facility, and Active Pharmaceutical Ingredient Facility Fee Rates for Fiscal Year 2016, 80 Fed. Reg. 46,015-01, 46,016 (Aug. 3, 2015). The applicant must show bioequivalence of its proposed drug to the drug listed in the NDA, 21 U.S.C. § 355(j)(2)(A)(iv), and that showing, along with other requirements for approval of an ANDA, commonly requires costly research, *see, e.g.*, Fiona M. Scott Morton, *Entry Decisions in the Generic Pharmaceutical Industry*, 30 RAND J. Econ. 421, 423 (1999) (“Interviews with FDA officials and several generic pharmaceutical managers generated estimated costs of filing an ANDA of \$250,000 to \$20 million.”); Jeremy A. Greene, *Generic: The Unbranding of Modern Medicine* 124 (2014) (estimating the cost for measuring bioequivalence of Valium tablets, which requires nearly two thousand blood assays on human subjects over sixteen days, at \$75,000-\$125,000). The applicant must also identify “the facilities and controls used for[] the manufacture, processing, and packing of [its proposed] drug,” 21 U.S.C. § 355(b)(1)(D); 21 C.F.R. § 314.50(d)(1)(ii)(a), and certify that its facilities comply with the extensive good-manufacturing practices detailed in 21 C.F.R. pts. 210, 211, *see* FDA Form 356h. The FDA will inspect each facility to “evaluate whether the site is able to reliably perform intended operation(s) at a

commercial scale.” Guidance for Industry: ANDA Submissions—Content and Format of Abbreviated New Drug Applications 4 n.11. The magnitude and costs of the work required before the ANDA is filed soundly link the ANDA filing to the filer’s entry into the market to compete with the brand-name manufacturer if approval is obtained.

We have emphasized the link in several cases where we have discussed why the litigation authorized by § 271(e)(2) and (5) meets Article III’s requirement of a case or controversy. We have pointed to the future real-world market acts as sufficiently connected to the ANDA that triggers the litigation. *See Apotex, Inc. v. Daiichi Sankyo, Inc.*, 781 F.3d 1356, 1365 (Fed. Cir. 2015) (“When a generic manufacturer seeks to enter the market, the concrete stakes are the market sales upon entry.”); *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1292 (Fed. Cir. 2008) (explaining that “exclude[ing] non-infringing generic drugs from the market” is the factual injury that gives rise to a case or controversy). We have noted that Congress deemed the ANDA filing to have a non-speculative causal connection to the ANDA filer’s future infliction of real-world market injury on the patent holder and that Congress may “articulate chains of causation that will give rise to a case or controversy where none existed before.” *Massachusetts v. EPA*, 549 U.S. 497, 516 (2007); *see Apotex*, 781 F.3d at 1365; *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1281 (Fed. Cir. 2014) (Congress may “effectively creat[e] justiciability that attenuation concerns would otherwise preclude”); *Consumer Watchdog v. Wis. Alumni Research Found.*, 753 F.3d 1258, 1261 (Fed. Cir. 2014). The Article III analysis

thus confirms the closeness of the connection between Mylan's ANDA filings and the marketing activities for which Mylan, by those filings, seeks approval.

Those activities will unquestionably take place in Delaware (at least). The subject of the cases before us is whether those activities will infringe valid patents and should be stopped under the remedial provisions of the Hatch-Waxman Act. Mylan's ANDA filings, including its certifications regarding the patents at issue here, are thus suit-related, and they have a substantial connection with Delaware because they reliably, non-speculatively predict Delaware activities by Mylan.

In arguing against this application of due-process standards, Mylan does not meaningfully develop an argument that a rigid past/future dividing line governs the minimum-contacts standard. Specifically, Mylan does not show that a State is forbidden to exercise its judicial power to prevent a defendant's planned future conduct in the State, but must wait until the conduct occurs. Such a rule would run counter to the legal tradition of injunctive actions to prevent a defendant's planned, non-speculative harmful conduct before it occurs. *See United States v. W. T. Grant Co.*, 345 U.S. 629, 633 (1953) ("The purpose of an injunction is to prevent future violations, . . . and, of course, it can be utilized even without a showing of past wrongs."); 43A C.J.S. *Injunctions* § 49 (2015); 11A Charles Alan Wright, Arthur R. Miller, Mary Kay Kane, Richard L. Marcus, & Adam N. Steinman, *Federal Practice & Procedure* § 2948.1 (3d ed. 2015). As long as the connection to the planned acts is close enough, the subject of such

actions readily fits the terms of the minimum-contacts standard—conduct purposefully directed at the State that gives rise and is related to the suit. A State’s exercise of jurisdiction over a defendant planning such conduct can hardly come as a surprise to the defendant and does nothing to “offend ‘traditional notions of fair play and substantial justice.’” *Int’l Shoe*, 326 U.S. at 316 (citation omitted); *see also Burger King*, 471 U.S. at 479 (explaining that personal jurisdiction should realistically consider the object of the dispute and noting that “contemplated future consequences” can play a role in the inquiry); *Roth v. Garcia Marquez*, 942 F.2d 617, 622 (9th Cir. 1991) (finding purposeful availment to support specific personal jurisdiction over defendant in a contract dispute because “the contract [at issue] concerned a film, most of the work for which would have been performed in [the forum]”).

For those reasons, it suffices for Delaware to meet the minimum-contacts requirement in the present cases that Mylan’s ANDA filings and its distribution channels establish that Mylan plans to market its proposed drugs in Delaware and the lawsuit is about patent constraints on such in-State marketing. And we are not barred from adopting that common-sense conclusion by this court’s decision in *Zeneca Ltd. v. Mylan Pharmaceuticals, Inc.*, 173 F.3d 829 (Fed. Cir. 1999). That case was decided without any majority opinion, and neither of the two single-judge opinions (Judge Rich dissented without opinion) addresses whether the location of the ANDA filer’s future sales could support specific personal jurisdiction over the filer in the § 271(e)(2) suit, so *Zeneca* is not precedent on that issue. *See Automated Merchandising Sys., Inc.*

*v. Lee*, 782 F.3d 1376, 1381 (Fed. Cir. 2015); *Lumbermens Mut. Cas. Co. v. United States*, 654 F.3d 1305, 1317 n.10 (Fed. Cir. 2011). The issue was not presented to the court in *Zeneca*. The parties consistently stated in their briefs that the only contact with the forum at issue was the act of making the ANDA filing (at the FDA's office in Maryland). Brief for Defendant-Appellant Mylan Pharmaceuticals, Inc. at 2, *Zeneca* (No. 97-1477), 1997 WL 33545105; Brief for Plaintiff-Appellee Zeneca Limited at 11, *Zeneca* (No. 97-1477), 1997 WL 33545104. That limit on the issue before this court was reflected in the question certified for interlocutory appeal. *See Zeneca*, 173 F.3d at 830-31 (Gajarsa, J., concurring in the judgment of reversal). In deciding only that issue, this court in *Zeneca* simply did not examine whether planned marketing in Maryland would have supported personal jurisdiction there.

Here, to reiterate, Mylan seeks approval to sell its generic drugs throughout the United States, including in Delaware, and it is undisputed that Mylan plans to direct sales of its generic drugs into Delaware. The complaints in these cases allege that Mylan's generic drugs would be distributed and sold in Delaware and that Mylan intends to commercially manufacture, use, and sell the generics upon receiving FDA approval. As Mylan admits, it develops drugs for the entire U.S. market and does some business in every State, either directly or indirectly. Pursuant to Del. Code Ann. Tit. 8, §§ 371(b)(2), 376(a), Mylan has registered to do business in Delaware and appointed an agent to accept service of process there. Mylan indicated in its certificate of registration that it intends to engage in "[p]harmaceutical manufacturing, distribution and

sales” in Delaware, *Acorda* J.A. 79; *AstraZeneca* J.A. 65, and Mylan registered with the Delaware Board of Pharmacy as a licensed “Pharmacy Wholesale” and a “Distributor/Manufacturer CSR.” And even if Mylan does not sell its drugs directly into Delaware, it has a network of independent wholesalers and distributors with which it contracts to market the drugs in Delaware. Such directing of sales into Delaware is sufficient for minimum contacts. *See Beverly Hills Fan*, 21 F.3d at 1565 (finding purposeful contacts where “the accused [infringing device] arrived in Virginia through defendants’ purposeful shipment . . . through an established distribution channel”).

One point remains. A finding of minimum contacts does not end the due-process inquiry—let alone any non-constitutional venue inquiries—into whether a case properly remains in a forum. Even if a defendant has minimum suit-related contacts with a State, the defendant may defeat specific personal jurisdiction by sufficiently demonstrating that other considerations render jurisdiction unreasonable. *See Burger King*, 471 U.S. at 477. The Supreme Court has identified a number of factors to consider, including “the burden on the defendant,” “the forum State’s interest in adjudicating the dispute,” “the plaintiff’s interest in obtaining convenient and effective relief,” and “the interstate judicial system’s interest in obtaining the most efficient resolution of controversies.” *World-Wide Volkswagen*, 444 U.S. at 292. But Mylan cannot show that those due-process factors weigh against litigating the present cases in Delaware.

The burden on Mylan will be at most modest, as Mylan, a large generic manufacturer, has litigated many ANDA lawsuits in Delaware, including some that it initiated. Delaware has an interest in providing a forum to resolve the disputes before us because they involve the pricing and sale of products in Delaware and harms to firms doing business in Delaware, some of them incorporated or with principal places of business in Delaware. And upholding personal jurisdiction will serve the interests of the plaintiffs and the judicial system in efficient resolution of litigation, because multiple lawsuits against other generic manufacturers on the same patents are pending in Delaware. Indeed, Mylan sent its required notice to Acorda after those actions had already begun. In these cases, there is no substantial argument that considerations of unfairness override the minimum-contacts basis for Delaware's exercise of specific personal jurisdiction over Mylan.

#### CONCLUSION

The decisions of the district court that Mylan is subject to specific personal jurisdiction in the district court for Delaware are affirmed.

AFFIRMED

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

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No. 2015-1456

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ACORDA THERAPEUTICS INC.,  
ALKERMES PHARMA IRELAND LIMITED,  
*Plaintiffs-Appellees,*

v.

MYLAN PHARMACEUTICALS INC., MYLAN INC.,  
*Defendants-Appellants.*

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Appeal from the United States District Court for the  
District of Delaware in No. 1:14-cv-00935-LPS,  
Chief Judge Leonard P. Stark.

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No. 2015-1460

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ASTRAZENECA AB,  
*Plaintiff-Appellee,*

v.

MYLAN PHARMACEUTICALS INC.,  
*Defendant-Appellant.*

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Appeal from the United States District Court for the  
District of Delaware in Nos. 1:14-cv-00664-GMS,  
1:14-cv-00696-GMS, Judge Gregory M. Sleet.

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O'MALLEY, *Circuit Judge*, concurring.

I agree that the district judges in these appeals have jurisdiction to hear the cases before them. I write separately because I believe we should reach the question of general jurisdiction, which the parties raise and the district judges decided. The specific jurisdiction issue, which the majority exclusively decides, is a more difficult question to resolve than the question of the continuing precedential effect of the line of Supreme Court authority articulated most clearly in *Pennsylvania Fire Insurance Co. of Philadelphia v. Gold Issue Mining & Milling Co.*, 243 U.S. 93 (1917). The parties dispute a host of factual questions regarding the specific jurisdiction issue, including whether and to what extent Mylan ultimately may be authorized to—or decide to—market generic drugs in Delaware. And, as I explain below, I would find specific jurisdiction over Mylan in these cases under a different legal theory than employed by the majority, evidencing the complexity of the question posed in the circumstances created by operation of the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly known as the Hatch-Waxman Act.

While there is no requirement that a court consider general jurisdiction before, or in addition to, its consideration of specific jurisdiction, the Supreme Court has given some guidance about the sequencing of jurisdictional decisions. In *Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83 (1998) and *Ruhrgas AG v. Marathon Oil Co.*, 526 U.S. 574 (1999), the Court reiterated the longstanding principle that,

“[w]ithout jurisdiction the court cannot proceed at all in any cause. Jurisdiction is power to declare the law, and when it ceases to exist, the only function remaining to the court is that of announcing the fact and dismissing the cause.” 523 U.S. at 94 (quoting *Ex parte McCardle*, 74 U.S. (7 Wall.) 506, 514 (1868)) (internal quotation marks omitted). Without jurisdiction, a court may not proceed to dispose of a case on the merits.

*Ruhrgas* addressed the particular question of whether, “[i]f, as *Steel Co.* held, jurisdiction generally must precede merits in dispositional order, must subject-matter jurisdiction precede personal jurisdiction on the decisional line? Or, do federal district courts have discretion to avoid a difficult question of subject-matter jurisdiction when the absence of personal jurisdiction is the surer ground?” 526 U.S. at 577-78. Rather than dictate a required order, the Court found “no unyielding jurisdictional hierarchy” between personal jurisdiction and subject-matter jurisdiction. *Id.* at 578. Yet it did endorse addressing more straightforward jurisdictional questions first. The Court found that, when “a district court has before it a straightforward personal jurisdiction issue presenting no complex question of state law, and the alleged defect in subject-matter jurisdiction raises a difficult and novel question, the court does not abuse its discretion by turning directly to personal jurisdiction.” *Id.* at 588. So too here, when a case may be decided on the grounds of either general or specific personal jurisdiction, I believe we should begin with the more straightforward of the two.

As Ockham’s Razor advises, the simpler path is usually best. *See, e.g., Awkal v. Mitchell*, 613 F.3d 629, 655 (6th Cir. 2010) (Boyce, J., dissenting) (“At some point, Ockham’s Razor must apply—the simplest answer is usually the correct one.”); *Commodity Futures Trading Comm’n v. Zelener*, 373 F.3d 861, 868 (7th Cir. 2004) (Easterbrook, J.) (“Best to take Occam’s Razor and slice off needless complexity.”). The majority finds specific personal jurisdiction because “Mylan’s ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs” in Delaware, Maj. Op. at 9, while expressly declining to discuss general personal jurisdiction, *id.* at 4. In this case, however, because I believe that the question of general jurisdiction is more straightforward—as it merely requires acknowledging a century-old line of Supreme Court precedent—I believe it should be addressed first. And, to the extent this court finds it necessary to venture into the more fact-intensive morass of specific jurisdiction, I believe the effects-based test of *Calder v. Jones*, 465 U.S. 783 (1984), provides a simpler underpinning for resolution, one that does not require reliance on a defendant’s “planned future conduct in the State.” Maj. Op. at 13.

## DISCUSSION

### A. General Jurisdiction

The requirement that a court have personal jurisdiction over a defendant before it may act “represents a restriction on judicial power not as a matter of sovereignty, but as a matter of individual liberty.” *Ins. Corp. of Ir. v. Compagnie des Bauxites de Guinee*, 456 U.S. 694, 702 (1982). As such, personal

jurisdiction is a “personal privilege respecting the venue, or place of suit, which [a defendant] may assert, or may waive, at his election.’ Being a privilege it may be lost.” *Neirbo Co. v. Bethlehem Shipbuilding Corp.*, 308 U.S. 165, 168 (1939) (quoting *Commercial Cas. Ins. Co. v. Consol. Stone Co.*, 278 U.S. 177, 179 (1929)).

A defendant may, thus, consent to personal jurisdiction and thereby waive its right to contest it. “[B]ecause the personal jurisdiction requirement is a waivable right, there are a ‘variety of legal arrangements’ by which a litigant may give ‘express or implied consent to the personal jurisdiction of the court.’” *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472 n.14 (1985) (citing *Ins. Corp. of Ir.*, 456 U.S. at 703). A defendant may consent to personal jurisdiction explicitly, by stipulating in advance to litigate its claims in a particular jurisdiction through a forum selection clause or some other agreement. *See Nat’l Equip. Rental, Ltd. v. Szukhent*, 375 U.S. 311, 315-16 (1964) (“[I]t is settled . . . that parties to a contract may agree in advance to submit to the jurisdiction of a given court . . .”). A party may also signal consent to personal jurisdiction through its actions, for example, by appearing in court and arguing the merits of the case. *See Ins. Corp. of Ir.*, 456 U.S. at 703 (“[A]n individual may submit to the jurisdiction of the court by appearance.”). At issue in these appeals is, among other things, whether compliance with a state statute that requires registration and the appointment of an in-state agent for service of process in order to conduct business in that state remains a valid form of express consent to general personal jurisdiction after the Supreme Court’s decision in *Daimler AG v. Bauman*,

134 S. Ct. 746 (2014). Delaware employs just such a scheme.

In particular, Delaware requires foreign corporations to register to do business in Delaware and to appoint an agent for service of process. Del. Code Ann. Tit. 8, § 371(b)(2)(i) (prohibiting a foreign corporation from doing business in Delaware until it registers with the Secretary of State and files “[a] statement . . . setting forth (i) the name and address of its registered agent” in Delaware). According to the Delaware Code, “[a]ll process issued out of any [Delaware] court . . . may be served on the registered agent of the corporation designated in accordance with § 371.” *Id.* § 376(a). Foreign corporations that do business in Delaware without registering face statutory fines for violating the mandatory registration requirement. *Id.* § 378.

In *Sternberg v. O’Neil*, 550 A.2d 1105 (Del. 1988), the Delaware Supreme Court held that compliance with Delaware’s registration statute constitutes consent to general personal jurisdiction. That court held that, “when [a corporation] qualified as a foreign corporation, pursuant to 8 Del.C. § 371, and appointed a registered agent for the service of process, pursuant to 8 Del.C. § 376, [that corporation] consented to the exercise of general jurisdiction by the Courts of Delaware.” *Sternberg*, 550 A.2d at 1116. In support of its holding, the Delaware Supreme Court cited to *Pennsylvania Fire Insurance Co. v. Gold Issue Mining & Milling Co.*, 243 U.S. 93, 96 (1917): “[W]hen a power actually is conferred by a document, the party executing it takes the risk of the interpretation that may be put upon it by the courts.” *Sternberg*, 550 A.2d

at 1116 n.19; *see also id.* at 1113-15 (finding that the foreign corporation’s “consent to the general personal jurisdiction of Delaware courts by qualifying as a foreign corporation satisfies due process” and does not constitute an undue burden on interstate commerce).

Chief Judge Stark (in the *Acorda* case) and Judge Sleet (in the *AstraZeneca* case) came to different conclusions on whether compliance with a state’s registration statute that requires appointment of a registered agent for service of process continues to constitute a valid form of consent to general personal jurisdiction after *Daimler*. Compare *Acorda Therapeutics, Inc. v. Mylan Pharm. Inc.*, 78 F. Supp. 3d 572, 583-92 (D. Del. 2015) (holding that, “*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”), with *AstraZeneca AB v. Mylan Pharm., Inc.*, 72 F. Supp. 3d 549, 555-58 (D. Del. 2014) (holding that, “[i]n light of the holding in *Daimler*, the court finds that Mylan’s compliance with Delaware’s registration statutes—mandatory for *doing business* within the state—cannot constitute consent to jurisdiction, and the Delaware Supreme Court’s decision in *Sternberg* can no longer be said to comport with federal due process”). I agree with Chief Judge Stark that *Daimler* did not overrule the line of Supreme Court authority establishing that a corporation may consent to jurisdiction over its person by choosing to comply with a state’s registration statute.

That line began with *Ex parte Schollenberger*, 96 U.S. (6 Otto) 369 (1877). In *Schollenberger*, the Supreme Court first held that a state legislature may require a foreign corporation to consent to general personal jurisdiction as a condition of being granted the right to do business in that state:

[I]f the legislature of a State requires a foreign corporation to consent to be “found” within its territory, for the purpose of the service of process in a suit, as a condition to doing business in the State, and the corporation does so consent, the fact that it is found gives the jurisdiction, notwithstanding the finding was procured by consent.

*Id.* at 377. In *St. Clair v. Cox*, 106 U.S. (16 Otto) 350 (1882), the Court discussed the problems with the “doctrine of exemption of a corporation from suit in a state other than that of its creation.” *Id.* at 355. Given “[t]he great increase in the number of corporations of late years, and the immense extent of their business,” the Court found that such jurisdictional exemptions led to “inconvenience and injustice.” *Id.* In response to those issues, “the legislatures of several states interposed and provided for service of process on officers and agents of foreign corporations doing business therein.” *Id.* The Court found “no sound reason why, to the extent of their agency, [officers and agents of foreign corporations] should not be equally deemed to represent [the foreign corporation] in the states for which they are respectively appointed when it is called to legal responsibility for their transactions.” *Id.* As such:

[a] corporation of one state cannot do business in another state without the latter's consent, express or implied, and that consent may be accompanied with such conditions as it may think proper to impose . . . . The state may, therefore, impose as a condition upon which a foreign corporation shall be permitted to do business within her limits, that it shall stipulate that in any litigation arising out of its transactions in the state, it will accept as sufficient the service of process on its agents or persons specially designated, and the condition would be eminently fit and just.

*Id.* at 356. This line of reasoning continued in *Pennsylvania Fire*, the key, though not final, case addressing the question.

In *Pennsylvania Fire*, the Court affirmed that it had "little doubt" that the appointment of an agent by a foreign corporation for service of process could subject it to general personal jurisdiction. 243 U.S. at 95. In that case, the defendant was a foreign insurance company who had obtained a license to do business in Missouri, and, in accordance with the law of Missouri, "filed with the superintendent of the insurance department a power of attorney consenting that service of process upon the superintendent should be deemed personal service upon the company so long as it should have any liabilities outstanding in the state." *Id.* at 94. The defendant argued that "such service was insufficient except in suits upon Missouri contracts, and that if the statute were construed to govern the present case, it encountered the 14th Amendment by denying to the defendant due process of law." *Id.* at 94-

95. A unanimous Court disagreed with the defendant, holding that, “when a power is actually conferred by a document, the party executing it takes the risk of the interpretation that may be put upon it by the courts. The execution was the defendant’s voluntary act.” *Id.* at 96.

In the almost 100 years since the Supreme Court decided *Pennsylvania Fire*, it has had ample opportunity to reconsider its holding. Yet each time the issue arose, the Supreme Court reaffirmed that registration statutes, mandatory for doing business, could confer jurisdiction through consent depending on the interpretation given to those state statutes by state courts. See *Robert Mitchell Furniture Co. v. Selden Breck Constr. Co.*, 257 U.S. 213, 216 (1921) (finding no jurisdiction over a foreign corporation when the compliance statute was limited to “liability incurred within the State,” but noting that “the state law [could] either expressly or by local construction give[] to the appointment a larger scope”); *Louisville & N.R. Co. v. Chatters*, 279 U.S. 320, 329 (1929) (holding “that, in the absence of an authoritative state decision giving a narrower scope to the power of attorney filed under the state statute, it operates as a consent to suit” (citing *Pa. Fire*, 243 U.S. 93)); *Neirbo*, 308 U.S. at 175 (holding that, “[a] statute calling for [designation of an agent for service of process in the forum state] is constitutional, and the designation of the agent ‘a voluntary act’” (citing *Pa. Fire*, 243 U.S. 93)).

The Supreme Court’s subsequent decisions in *International Shoe* and *Daimler* did not overrule this historic and oft-affirmed line of binding precedent.

Indeed, both cases are expressly limited to scenarios that do not involve *consent* to jurisdiction. In *International Shoe*, the Court restricted its discussion to cases where “*no consent* to be sued or authorization to an agent to accept service of process has been given.” 326 U.S. at 317 (emphasis added). Based on the limitation placed on the reach of *International Shoe* by the Supreme Court itself, after *International Shoe*, numerous circuit courts continued to uphold the exercise of general jurisdiction over defendants registered to do business in the states at issue, relying on the continuing vitality of *Pennsylvania Fire*. See, e.g., *King v. Am. Family Mut. Ins. Co.*, 632 F.3d 570, 576, 578 (9th Cir. 2011) (“*Pennsylvania Fire, Chipman[, Ltd., v. Thomas B. Jeffrey Co.*, 251 U.S. 373 (1920)], and *Robert Mitchell* thus collectively stand for the proposition that federal 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.”); *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.”); *Bane v. Netlink, Inc.*, 925 F.2d 637, 641 (3d Cir. 1991) (observing that “[c]onsent is a traditional basis for assertion of jurisdiction long upheld as constitutional”); *Knowlton v. Allied Van Lines, Inc.*, 900 F.2d 1196, 1199-1200 (8th Cir. 1990) (noting that, as interpreted by the Supreme Court of Minnesota,

“[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) (“It 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.”). And, the Second Restatement adopted that same view in 1971. Restatement (Second) of Conflict of Laws § 44 (1971) (“A state has power to exercise judicial jurisdiction over a foreign corporation which has authorized an agent or a public official to accept service of process in actions brought against the corporation in the state as to all causes of action to which the authority of the agent or official to accept service extends.”). *Daimler* did not change the law on this point, either.

There is no discussion of registration statutes in *Daimler* and no citation to *Schollenberger*, *Pennsylvania Fire*, or the cases post-dating those two. Indeed, *Daimler* confirms that consent to jurisdiction is an alternative to the minimum contacts analysis discussed in that case, citing to *Perkins v. Benguet Consolidated Mining Co.*, 342 U.S. 437 (1952), as “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). Thus, *Daimler* did not impliedly eradicate the distinction between cases involving an express consent to general jurisdiction and those analyzing general jurisdiction in the absence of consent; it actually maintains it. Notably, the Court had no occasion to consider the rule it laid down in

*Pennsylvania Fire* because California—the state where the action at issue was pending—had interpreted its registration statute as one that did not, by compliance with it, give rise to consent to personal jurisdiction. The only question the Court considered was whether the foreign defendant was subject to jurisdiction solely by virtue of its contacts with the state, which were unrelated to the cause of action.

Any argument that Mylan’s express consent to general personal jurisdiction was involuntary, moreover, is not well-taken. In *Insurance Corporation of Ireland*, the Supreme Court noted that it “has upheld state procedures which find constructive consent to the personal jurisdiction of the state court in the voluntary use of *certain state procedures*.” 456 U.S. at 704 (citing, among other cases, *Chicago Life Ins. Co. v. Cherry*, 244 U.S. 25, 29-30 (1917) (“[W]hat acts of the defendant shall be deemed a submission to [a court’s] power is a matter upon which States may differ.”)). The relevant inquiry is not whether Mylan voluntarily consented to jurisdiction in Delaware, but whether it voluntarily elected to do business in Delaware and to register and elect an agent for service of process in that state. It undoubtedly did.

Notably, *Pennsylvania Fire* was decided almost 100 years before Mylan chose to register to do business in Delaware. And *Sternberg’s* interpretation of the registration statute had been on the books for almost twenty of those years. In the face of that legal authority, Mylan knowingly chose to register to do business in Delaware, thereby accepting the implication of having done so.

By virtue of the Delaware Supreme Court's decision in *Sternberg*, the Delaware registration statute falls squarely within the rule of *Pennsylvania Fire* and its progeny. Unless the Supreme Court or Congress overrules this line of Supreme Court authority, we are bound to follow it. *Rodriguez de Quijas v. Shearson/Am. Exp., Inc.*, 490 U.S. 477, 484 (1989) ("If a precedent of this Court has direct application in a case, yet appears to rest on reasons rejected in some other line of decisions, the Court of Appeals should follow the case which directly controls, leaving to this Court the prerogative of overruling its own decisions."); *see also State Oil Co. v. Khan*, 522 U.S. 3, 20 (1997) (Even if a Supreme Court precedent contains many "infirmities" and rests upon "wobbly, moth-eaten foundations," it remains the "Court's prerogative alone to overrule one of its precedents."). While there may well be reasons why the Supreme Court would choose to overrule *Pennsylvania Fire*—similar to those discussed in *Daimler* or others—that is the Court's prerogative, not ours. Accordingly, I would conclude that Mylan is subject to general personal jurisdiction in Delaware by virtue of its voluntary, express consent to such jurisdiction and end our jurisdictional discussion there.<sup>1</sup>

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<sup>1</sup> One amicus argues that a finding of general personal jurisdiction by virtue of Delaware's consent-by-registration statute would violate the unconstitutional conditions doctrine. *See* Br. of Amicus Curiae Chamber of Commerce 18-21. Because neither party has raised the question, however, it is not before us. Even if it were, moreover, the Supreme Court has upheld the validity of consent-by-registration statutes numerous times since the development of the unconstitutional conditions doctrine. In *Neirbo*, the Supreme Court commented that, the decision to

## B. Specific Jurisdiction

A finding that Mylan has consented to general personal jurisdiction obviates the need to consider whether the district courts here had the authority to exercise specific jurisdiction over Mylan in these circumstances. If general jurisdiction exists, a court may “hear any and all claims against” the parties, whereas specific jurisdiction “depends on an ‘affiliatio[n] between the forum and the underlying controversy.’” See *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 131 S. Ct. 2846, 2851 (2011) (citing von Mehren & Trautman, *Jurisdiction to Adjudicate: A Suggested Analysis*, 79 HARV. L. REV. 1121, 1136 (1966) (hereinafter von Mehren & Trautman)). “In contrast to general, all-purpose jurisdiction, specific jurisdiction is confined to adjudication of ‘issues deriving from, or connected with, the very controversy that establishes jurisdiction.’” *Id.* (citing von Mehren & Trautman).

The majority addresses only specific jurisdiction, and finds that it properly can be exercised here. I concur with the majority’s judgment, but not entirely with its reasoning. I agree that Mylan is subject to specific jurisdiction in Delaware, but I would find specific jurisdiction under the Supreme Court’s precedent in *Calder v. Jones*, 465 U.S. 783 (1984), and

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strike down the Texas statute at issue, “which not merely regulated procedure for suit but sought to deny foreign corporations access to the federal courts” was “wholly consistent” with the decision in *Schollenberger*, which allowed state legislatures to require foreign corporations to consent to general personal jurisdiction as a condition of being granted the right to do business in that state. *Neirbo*, 308 U.S. at 173-74.

not predicate the exercise of jurisdiction primarily on Mylan's expressions of *future* intent.

In *Calder*, the Court held that, when a defendant engages in intentional acts expressly aimed at the forum state, knowing that those acts will harm a potential plaintiff residing in that state, the courts in that state do not violate due process in exercising jurisdiction over that defendant. *Id.* at 788-90. The defendants in *Calder*, two nonresident journalists, argued that a California court could not exercise personal jurisdiction over them for the distribution of an "allegedly libelous story concern[ing] the California activities of a California resident." *Id.* at 788. The Court analyzed "the relationship among the defendant, the forum, and the litigation" to find that minimum contacts existed, justifying the exercise of jurisdiction over the defendants. *Id.* (quoting *Shaffer v. Heitner*, 433 U.S. 186, 204 (1977)) (internal quotation marks omitted). Specifically, the Court relied upon the following facts:

The allegedly libelous story concerned the California activities of a California resident. It impugned the professionalism of an entertainer whose television career was centered in California. The article was drawn from California sources, and the brunt of the harm, in terms both of respondent's emotional distress and the injury to her professional reputation, was suffered in California.

*Id.* at 788-89. Because "California [was] the focal point both of the story and of the harm suffered," it was appropriate to exercise jurisdiction over the

defendants “in California based on the ‘effects’ of their Florida conduct in California.” *Id.* at 789.

The Supreme Court discussed the reach of *Calder* in *Walden v. Fiore*, 134 S. Ct. 1115, 1123-26 (2014). There, the Court noted:

The crux of *Calder* was that the reputation-based “effects” of the alleged libel connected the defendants to California, not just to the plaintiff. The strength of that connection was largely a function of the nature of the libel tort. However scandalous a newspaper article might be, it can lead to a loss of reputation only if communicated to (and read and understood by) third persons.

*Id.* at 1123-24. *Walden* serves to clarify *Calder*, but does not overrule it or limit its holding exclusively to libel cases. Rather, it makes clear that due process is not satisfied by a showing of “mere injury to a forum resident”; a court must examine “whether the defendant’s conduct connects him to the forum in a meaningful way.” *Id.* at 1125. In *Calder*, the defendants “‘expressly aimed’ ‘their intentional, and allegedly tortious, actions’ at California because they knew the National Enquirer ‘ha[d] its largest circulation’ in California, and that the article would ‘have a potentially devastating impact’ there.” *Id.* at 1124 n.7 (quoting *Calder*, 465 U.S. at 789-90). The nature of ANDA litigation is such that, as in *Calder*, “the focal point both of the [filing of the ANDA] and of the harm suffered” is Delaware. *Id.* at 1123 (quoting *Calder*, 465 U.S. at 789) (internal quotation marks omitted). Jurisdiction over Mylan is proper in

Delaware based on the “effects” of the conduct it aimed at Delaware. *Id.*

A generic drug manufacturer, like Mylan, files an Abbreviated New Drug Application (“ANDA”) with the FDA, seeking approval to market generic versions of drugs produced by brand-name drug manufacturers, like Acorda and AstraZeneca. *See* Maj. Op. at 4-5. Mylan’s filing under paragraph IV of 21 U.S.C. § 355(j)(2)(A)(vii) certifies its belief that Acorda’s and AstraZeneca’s Orange Book patents are invalid or would not be infringed by Mylan’s proposed drug. *Id.* In this way, the filing of the paragraph IV certifications in ANDA applications at issue here were not random acts that happen to harm someone living in a particular state. As in *Calder*, the acts were calculated and directed to cause harm to the intellectual property rights of a known party with a known location. It is an act which—even before a single sale of product in the State of Delaware—called into question the validity and value of property rights protecting the marketing of profitable products by Acorda and AstraZeneca. In so doing, it called into question the very value of their respective businesses. By virtue of the provisions of the Hatch-Waxman Act requiring that they do so, the paragraph IV certification filing also triggered an obligation to quickly file an expensive “infringement” action in an effort to lift the cloud placed on the Appellees’ business interests. *See Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1677 (2012) (“Filing a paragraph IV certification means provoking litigation.”).

Both Acorda and AstraZeneca are corporations organized under the laws of the State of Delaware. *See Acorda Therapeutics*, 78 F. Supp. 3d at 577 (“Plaintiff Acorda is a corporation organized under the laws of the State of Delaware . . . .”); *AstraZeneca AB*, 72 F. Supp. 3d at 552 (“AstraZeneca’s U.S. subsidiary, AstraZeneca Pharmaceuticals LP . . . is a limited partnership operating and existing under the laws of Delaware, with its principal place of business in Wilmington, Delaware.”). These companies clearly experienced legally cognizable injuries in Delaware upon the filing of the ANDA applications by Mylan.<sup>2</sup>

Of course, “[t]he 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.” *Walden*, 134 S. Ct. at 1125. The situs of plaintiff’s injury and the nature of it are factors in the analysis, but are not determinative standing alone. *Id.* In *Calder*, the Supreme Court found specific personal jurisdiction in California even though the allegedly libelous publication was published elsewhere and marketed nationwide.

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<sup>2</sup> The act of infringement, which the Supreme Court has called “highly artificial,” *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990), is nevertheless a defined and very real act of infringement that takes place wherever the ANDA filer seeks to market its product. On this point, I disagree with Judge Rader’s concurrence in *Zeneca Ltd. v. Mylan Pharm., Inc.*, 173 F.3d 829 (Fed. Cir. 1999), in which he found that filing an ANDA application merely “create[s] case or controversy jurisdiction” but does not, like “[m]anufacture, use, offers for sale, and sales,” constitute a “real act[] with actual consequences.” *Id.* at 836. I agree instead with Judge Gajarsa that the filing of an ANDA application “is a real act with serious consequences.” *Id.* at 834.

*Calder*, 465 U.S. at 785 (noting that the National Enquirer “publishes a national weekly newspaper with a total circulation of over 5 million”). Here, there is no physical, nationally distributed product causing harm to the plaintiffs. Despite that, the targeted nature of an ANDA filing—which is intended to challenge a particular patent owned by a known party with a known location—makes the case at hand just like that in *Calder*—the harm is targeted only to these Delaware companies, occurs only in Delaware, and is only triggered by the filing of the ANDA. While it is true, as the majority notes, that the filing of an ANDA application indicates Mylan’s desire to market its product on a nation-wide basis, including in Delaware, I find that expression of interest meaningful for different reasons. I believe it reinforces the *immediate* harm caused by the ANDA filing, regardless of whether such marketing ever occurs.

Finally, I agree with the majority and both district judges that the exercise of specific personal jurisdiction in these cases is reasonable under the Supreme Court’s precedent in *Burger King* and *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286 (1980). Maj. Op. at 15-16; *Acorda*, 78 F. Supp. 3d at 594-95; *AstraZeneca*, 72 F. Supp. 3d at 559-60.

For these reasons, I believe that Mylan’s activity falls squarely within the minimum contacts analysis described in *Calder* and clarified in *Walden*. Mylan’s paragraph IV certification in its ANDA filing connects it to Delaware—not just to these corporate residents—in a manner that supports a finding of specific personal jurisdiction in that forum.

CONCLUSION

Thus, I would find that Mylan is subject to general personal jurisdiction in Delaware by virtue of its registration to do business there. To the extent this court has chosen to address the question of specific personal jurisdiction, moreover, I concur in the result reached by the majority that Mylan also is subject to specific personal jurisdiction in Delaware.

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*Appendix B*

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

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No. 2015-1456

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ACORDA THERAPEUTICS INC.,  
ALKERMES PHARMA IRELAND LIMITED,  
*Plaintiffs-Appellees,*

v.

MYLAN PHARMACEUTICALS INC., MYLAN INC.,  
*Defendants-Appellants.*

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Appeal from the United States District Court for the  
District of Delaware in No. 1:14-cv-00935-LPS,  
Chief Judge Leonard P. Stark.

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No. 2015-1460

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ASTRAZENECA AB,  
*Plaintiff-Appellee,*

v.

MYLAN PHARMACEUTICALS INC.,  
*Defendant-Appellant.*

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Appeal from the United States District Court for the  
District of Delaware in Nos. 1:14-cv-00664-GMS,  
1:14-cv-00696-GMS, Judge Gregory M. Sleet.

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Filed: June 20, 2016

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ON PETITIONS FOR REHEARING EN BANC

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Before PROST, *Chief Judge*, NEWMAN, LOURIE, DYK,  
MOORE, O'MALLEY, REYNA, WALLACH, TARANTO,  
CHEN, and HUGHES, *Circuit Judges*.\*

PER CURIAM.

**ORDER**

Appellants Mylan Inc. and Mylan Pharmaceuticals Inc. filed petitions for rehearing en banc in 2015-1456 and 2015-1460. Responses to the petitions were invited by the court and filed by appellees in their respective cases. The petitions were first referred as petitions for rehearing to the panel that heard the appeals, and thereafter the petitions for rehearing en banc were referred to the circuit judges who are in regular active service.

Upon consideration thereof,

IT IS ORDERED THAT:

The petitions for panel rehearing were denied.

The petitions for rehearing en banc were denied.

The mandates of the court will issue on June 27, 2016.

FOR THE COURT

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\* Circuit Judge Stoll did not participate.

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June 20, 2016  
Date

/s/ Peter R. Marksteiner  
Peter R. Marksteiner  
Clerk of the Court

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*Appendix C*

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

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No. 14-696-GMS

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ASTRAZENECA AB,  
*Plaintiff,*

v.

MYLAN PHARMACEUTICALS INC.,  
*Defendant.*

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Filed: November 5, 2015  
Wilmington, Delaware

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s/[handwritten: signature]  
SLEET, U.S. District Judge

**OPINION**

**I. INTRODUCTION**

AstraZeneca AB (“AstraZeneca”) filed a complaint against defendant Mylan Pharmaceuticals, Inc. (“Mylan”) on June 2, 2014, alleging patent infringement of U.S. Patent Nos. 7,951,400 (“the ‘400 Patent”), RE44,186 (“the ‘186 Patent”), and 8,628,799 (“the ‘799 Patent”). (D.I. 1.) The cause of action was triggered when Mylan filed two Abbreviated New Drug Applications (“ANDA”) Nos. 205980 and 205981 with the U.S. Food and Drug Administration (“FDA”) for approval to market saxagliptin hydrochloride tablets—generic versions of AstraZeneca’s

ONGLYZA® drug product—and saxagliptin hydrochloride and metformin hydrochloride extended-release tablets—generic versions of AstraZeneca’s KOMBIGLYZE™ XR drug product—prior to expiration of the ‘400 Patent, the ‘186 Patent, and the ‘799 Patent. (*Id.* ¶¶ 1-3.)

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

## II. BACKGROUND

AstraZeneca is a company operating and existing under the laws of Sweden, with its principal place of business in Södertälje, Sweden. (D.I. 1, ¶ 4.) AstraZeneca’s U.S. subsidiary, AstraZeneca Pharmaceuticals LP (“AstraZeneca U.S.”) is a limited partnership operating and existing under the laws of Delaware, with its principal place of business in Wilmington, Delaware. (*Id.* ¶ 5.) Mylan is incorporated in West Virginia and has its principal place of business in Morgantown, West Virginia. (*Id.* ¶ 7.)

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

10. This Court has jurisdiction over Mylan because, *inter alia*, this action arises from actions of Mylan directed toward Delaware and because Mylan has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts

with Delaware. Mylan regularly and continuously transacts business within the State of Delaware, including by selling pharmaceutical products in Delaware, either on its own or through its affiliates. Upon information and belief, Mylan derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

11. Mylan has previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction and has availed itself of Delaware courts through the assertion of counterclaims and by filing suits in Delaware.

(*Id.* ¶¶ 10,11.)

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

## III. STANDARD OF REVIEW

The court must dismiss a case when it lacks personal jurisdiction over the defendant. Fed. R. Civ. P. 12(b)(2); *Freres v. SPI Pharma, Inc.*, 629 F. Supp. 2d 374, 382 (D. Del. 2009). The plaintiff bears the burden of establishing that the defendants are properly subject to the court's jurisdiction. *See ICT Pharm., Inc. v. Boehringer Ingelheim Pharm., Inc.*, 147 F. Supp. 2d 268, 270-71 (D. Del. 2001).

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

"[D]ue process requires only that in order to subject a defendant to a judgment in personam, if he

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

be not present within the territory of the forum, he have certain minimum contacts with it such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice.” *Int’l Shoe Co. v. State of Wash., Office of Unemployment Compensation & Placement*, 326 U.S. 310, 316 (1945) (internal quotation marks omitted). Since the Supreme Court initially announced this rule in *International Shoe*, the doctrine has split into two categories: specific and general jurisdiction. Specific jurisdiction exists where “the defendant has ‘purposefully directed’ his activities at residents of the forum, and the litigation results from alleged injuries that ‘arise out of or relate to’ those activities.” *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472-73 (1985) (internal citations omitted) (quoting *Keeton v. Hustler Magazine, Inc.*, 465 U.S. 770, 774 (1984); *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 414 (1984)). In contrast, general jurisdiction does not require that the cause of action arise out of contacts with the forum state. *Helicopteros*, 466 U.S. at 421. Rather, general jurisdiction exists where the defendant’s contacts with the forum “are so continuous and systematic as to render it essentially at home in the forum State.” *Daimler AG v. Bauman*, 134 S. Ct. 746, 761 (2014) (quoting *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 131 S. Ct. 2846, 2851 (2011)). Recent Supreme Court opinions confirm that “specific jurisdiction has become the centerpiece of modern jurisdiction theory,” whereas general jurisdiction—often referred to as “all-purpose” jurisdiction—“[has played] a reduced role.” *Id.* at 755 (alteration in original) (quoting *Goodyear*, 131 S. Ct. at 2854).

## IV. DISCUSSION

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

## A. General Jurisdiction

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

In ANDA litigation, general jurisdiction traditionally provided the basis to assert jurisdiction over generic drug company defendants. *See, e.g., In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 693 F. Supp. 2d 409, 421

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<sup>2</sup> For the sake of convenience and clarity, the court analyzes AstraZeneca's arguments in a different order from that of the briefing.

(D. Del. 2010) (focusing on defendant’s “substantial revenue” from Delaware drug sales in upholding general jurisdiction). Since the Supreme Court’s recent decision in *Daimler*, however, the standard for exercising general jurisdiction has shifted. See *Daimler*, 134 S. Ct. 746. The court finds that AstraZeneca has failed to allege contacts sufficient to render Mylan at home in Delaware, in light of *Daimler*.

In *Daimler*, elaborating on its previous decision in *Goodyear*, 131 S. Ct. 2846, the Supreme Court explained that a corporation is “at home” for the purposes of general jurisdiction in only a narrow set of circumstances: “With respect to a corporation, the place of incorporation and principal place of business are paradigm[m] ... bases for general jurisdiction.” *Daimler*, 134 S. Ct. at 760 (alteration in original) (internal quotations marks omitted). The Court was careful to emphasize that the “place of incorporation” and the “principal place of business” exemplars were not exhaustive. *Id.* at 760-61. But at the same time, the Court rejected the idea that “continuous and systematic” contacts, alone, are sufficient to confer jurisdiction. *Id.* at 761-62 (finding such a test for general jurisdiction would be “unacceptably grasping” and “exorbitant”). The role of general jurisdiction is a limited one: “afford plaintiffs recourse to at least one clear and certain forum in which a corporate defendant may be sued on any and all claims.” *Id.* at 760.<sup>3</sup>

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<sup>3</sup> The court recognizes that *Daimler* dealt with a very different set of facts than those in the present case, but the Supreme

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

Second, AstraZeneca argues that Mylan is at home in Delaware because of Mylan’s extensive litigation history in this district. The court acknowledges the creativity of this argument but ultimately finds that familiarity with the court system of Delaware is insufficient to render a defendant at home here, as envisioned by *Daimler*. Although it left open the possibility that forum activity involving something other than the paradigmatic examples (place of incorporation or principal place of business) could satisfy general jurisdiction, the Supreme Court highlighted that such a fact pattern would be an “exceptional case.” *Id.* at 761 n.19. The court finds that

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Court’s analysis and discussion of general jurisdiction did not place any limits on the application of the rule announced.

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

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

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<sup>4</sup> The court is not convinced that AstraZeneca's request for jurisdictional discovery would add anything to the court's calculus. (D.I. 15 at 11.) Even if AstraZeneca were able to obtain more exact figures concerning Mylan's business dealing with Delaware, there is nothing to suggest that such dealings would be 'exceptional' as compared to other states. *See Daimler*, 124 S. Ct. at 761 n.19.

## B. Consent to General Jurisdiction

AstraZeneca also argues that Mylan has consented to be subject to Delaware’s general jurisdiction by registering to do business in the state and by appointing a registered agent to accept service of process. (D.I. 15 at 4-7; Ex. A.) AstraZeneca contends: “When there is consent, that ends the jurisdictional inquiry . . . . Consent to personal jurisdiction obviates the need to consider due process and minimum contacts.” (*Id.* at 5.)

AstraZeneca maintains that Supreme Court cases holding that personal jurisdiction is satisfied merely by complying with state business registration statutes remain a viable path to finding jurisdiction even after *International Shoe* and its progeny. See *Neirbo Co. v. Bethlehem Shipbuilding Corp.*, 308 U.S. 165 (1939); *Penn. Fire Ins. Co. of Phila. v. Gold Issue Min. & Mill. Co.*, 243 U.S. 93 (1917). Evidently there is a circuit split as to whether this type of “statutory consent” is an adequate basis on which to ground a finding of personal jurisdiction. Several courts have held that a minimum-contacts analysis that meets the dictates of *International Shoe* is required. See, e.g., *Ratliff v. Cooper Labs., Inc.*, 444 F.2d 745, 748 (4th Cir. 1971) (“The principles of due process require a firmer foundation than mere compliance with state domestication statutes.”); *Wenche Siemer v. Learjet Acquisition Corp.*, 966 F.2d 179, 183 (5th Cir. 1992) (“Not only does the mere act of registering an agent not create Learjet’s general business presence in Texas, it also does not act as consent to be hauled into Texas courts on any dispute with any party anywhere concerning any matter.”). Nonetheless, others,

including the Third Circuit, have upheld a finding of general jurisdiction on statutory registration grounds alone. *See, e.g., Bane v. Netlink, Inc.*, 925 F.2d 637, 640 (3d Cir. 1991) (“We need not decide whether authorization to do business in Pennsylvania is a ‘continuous and systematic’ contact with the Commonwealth . . . because such registration by a foreign corporation carries with it consent to be sued in Pennsylvania courts.”); *Knowlton v. Allied Van Lines, Inc.*, 900 F.2d 1196 (8th Cir. 1990) (“We conclude that appointment of an agent for service of process under [the Minnesota statute] gives consent to the jurisdiction of Minnesota courts for any cause of action, whether or not arising out of activities within the state. Such consent is a valid basis of personal jurisdiction, and resort to minimum-contacts or due-process analysis to justify . . . jurisdiction is unnecessary.”) The Supreme Court has never expressly addressed the continuing vitality of cases like *Neirbo* and *Gold Issue* in the wake of *International Shoe*. *But see Shaffer v. Heitner*, 433 U.S. 186, 212 (1977) (“[A]ll assertions of state-court jurisdiction must be evaluated according to the standards set forth in *International Shoe* and its progeny”). Unsurprisingly, there is also little guidance as to *Daimler*’s impact, if any, on this question.

The Delaware statutes at issue in this case are sections 371 and 376. 8 Del. C. §§ 371, 376. Section 371 provides mandatory registration requirements for all foreign (*i.e.*, non-Delaware) corporations seeking to “do business” in Delaware. Section 376 provides that process may be served on foreign corporations in compliance with section 371 via a designated registered agent. AstraZeneca argues that the

Delaware Supreme Court has already established that compliance with these statutes suffices to create express consent “to the exercise of general jurisdiction by the Courts of Delaware.” *See Sternberg v. O’Neil*, 550 A.2d 1105, 1116 (Del. 1988). AstraZeneca asserts that *Daimler* plays no role in the consent analysis because that case dealt with the minimum-contacts aspect of *International Shoe*, which is distinct from the question of consent. *See id.* at 1111 (“[E]xpress consent is a valid basis for the exercise of general jurisdiction in the absence of any other basis for the exercise of jurisdiction, i.e. ‘minimum contacts.’”).

The court finds, however, that *Daimler* does weigh on this issue. Both consent and minimum contacts (and all questions regarding personal jurisdiction) are rooted in due process. Just as minimum contacts must be present so as not to offend “traditional notions of fair play and substantial justice,” the defendant’s alleged “consent” to jurisdiction must do the same. *See Int’l Shoe*, 326 U.S. at 316. The Supreme Court’s discussion of due process in *Daimler*, therefore, informs the court’s analysis here. In holding that “continuous and systematic contacts” alone are insufficient to establish general jurisdiction, the Supreme Court rejected the idea that a company could be haled into court merely for “doing business” in a state. *Daimler*, 134 S. Ct. at 761-62. Such a theory, the Court held, “would scarcely permit out-of-state defendants ‘to structure their primary conduct with some minimum assurance as to where that conduct will and will not render them liable to suit.’” *Id.*

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

Administrative statutes like Delaware’s sections 371 and 376 merely outline procedures for doing business in the state; compliance does not amount to consent to jurisdiction or waiver of due process.<sup>6</sup>

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

<sup>6</sup> The court limits its holding to Delaware’s statutes specifically. The court does not address the more difficult question raised when state statutes expressly indicate that foreign corporations consent to general jurisdiction by complying with the statutes. See, e.g., *Bane*, 925 F.2d at 640 (“The existence of any of the following relationships between a person and this

Mylan did not consent to general jurisdiction in this case.

### C. Specific Jurisdiction

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

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

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Commonwealth shall constitute a sufficient basis of jurisdiction to enable the tribunals of this Commonwealth to exercise general personal jurisdiction over such person: . . . (i) Incorporation under or qualification as a foreign corporation under the laws of this Commonwealth.” (quoting 42 Pa. Cons. Stat. Ann. § 5301).

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

This history helps to inform the court’s approach to its analysis of AstraZeneca’s specific jurisdiction argument. As stated above, specific jurisdiction exists where “the defendant has ‘purposefully directed’ his

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

<sup>8</sup> Section 271(e)(2) states, in relevant part:

It shall be an act of infringement to submit—

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

35 U.S.C. § 271(e)(2).

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

activities at residents of the forum, and the litigation results from alleged injuries that ‘arise out of or relate to’ those activities.” *Burger King*, 471 U.S. at 472-73; see also *Nuance Commc’ns, Inc. v. Abby Software House*, 626 F.3d 1222, 1231 (Fed. Cir. 2010) (citing *Akro Corp. v. Luker*, 45 F.3d 1541, 1545-46 (Fed. Cir. 1995)). The difficulty in ANDA cases is that infringement under § 271(e)(2) is “a highly artificial act,” precisely because of the goals of the Hatch-Waxman Act. See *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990). As a statutory creation, distinct from making, using, or selling a patented technology, infringement under § 271(e)(2) has no readily apparent situs of injury for the purpose of finding specific jurisdiction. Another peculiarity of the Hatch-Waxman Act is that it builds patent litigation into the FDA approval process. Patent holders have forty-five days after receiving a “paragraph IV” certification from the generic company to initiate an infringement lawsuit; the lawsuit, if filed, triggers an automatic thirty-month stay for the FDA’s approval of the generic. Thus, ANDA litigation is unlike other patent infringement litigation: The injury is abstract, making it difficult to point to a location out of which the injury “arises” for jurisdictional purposes. At the same time, defending against an infringement lawsuit is an inherent and expected part of the ANDA filer’s business. To put it simply: a lawsuit is often inevitable, but it is not clear where it should be held.<sup>10</sup>

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<sup>10</sup> “While it is clear what Congress intended to accomplish in terms of substantive legal effects, it is unclear what effect, if any, Congress intended section 271(e)(2) would have on the personal jurisdiction of a defendant.” *Zeneca Ltd. v. Mylan Pharm., Inc.*,

This challenge is compounded by *Daimler*'s narrowing of the doctrine of general jurisdiction.

With this background in mind, the court turns to the issue at hand and determines that Mylan is subject to specific jurisdiction in Delaware. "That the Supreme Court has viewed the tortious act [of submitting an ANDA] as 'highly artificial' . . . is not a proper reason . . . to conclude that the ANDA filing is not a 'real act' with 'actual consequences.'" *Zeneca*, 173 F.3d at 833-34 (quoting *Eli Lilly*, 496 U.S. at 663-64). The court finds that these consequences are suffered in Delaware. Mylan argues its activities are not purposefully directed at the state of Delaware, where AstraZeneca U.S. is organized. (D.I. 18 at 5-7.) Mylan's argument, however, creates the untenable position that its conduct is not directed to any jurisdiction. The Federal Circuit in *Zeneca* eliminated the possibility that Maryland (the location of the FDA and where ANDAs are filed) could exercise specific jurisdiction over ANDA filers, in order to avoid creating a "supercourt" with jurisdiction in all cases. *Zeneca*, 173 F.3d at 832. Judge Rader's concurring opinion stated that "Mylan's contacts are not actually with the state of Maryland at all. Rather Mylan's contacts involve the federal government whose office for receipt of ANDAs happens to be within that state." *Id.* at 835 (Rader, J., concurring).<sup>11</sup> The court finds

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968 F. Supp. 268, 273 (W.D.Pa.1997), *rev'd* 173 F.3d 829 (Fed. Cir. 1999).

<sup>11</sup> In his opinion for the court, Judge Gajarsa disagreed with Judge Rader's view on this matter; he, however, used the "government contacts exception" to find specific jurisdiction did not exist. *Zeneca*, 173 F.3d at 833-34. Under either Judge

that the only possible alternative forum is the state of residence for the patent holder.<sup>12</sup>

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

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Gajarsa's or Judge Rader's opinions, Maryland was eliminated as a forum for specific jurisdiction in ANDA cases.

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

471 U.S. at 474 (quoting *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 295 (1980)).

The court is convinced that the act of filing an ANDA and the paragraph IV notification provide sufficient minimum contacts with the state of Delaware under a specific jurisdiction analysis.<sup>13</sup> Furthermore, as discussed above, the exercise of jurisdiction must comport with “traditional notions of fair play and substantial justice.” *See Int’l Shoe*, 326 U.S. at 316, 324-26. This factor, the court finds, weighs strongly in favor of exercising specific jurisdiction. Mylan is no stranger to ANDA litigation in Delaware, and the court is not convinced that it would be “unfair” to subject Mylan to suit here. (D.I. 15, Ex. E.) Conversely, AstraZeneca would be substantially burdened if forced to bring lawsuits against each ANDA filer in the defendants’ home states. Such a

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

result would be inconsistent with the “balance” that Congress sought to create in passing the Hatch-Waxman Act. The Supreme Court has stated:

Implicit in this emphasis on reasonableness is the understanding that the burden on the defendant, while always a primary concern, will in an appropriate case be considered in light of other relevant factors, including the forum State’s interest in adjudicating the dispute, the plaintiff’s interest in obtaining convenient and effective relief, *at least when that interest is not adequately protected by the plaintiff’s power to choose the forum*, the interstate judicial system’s interest in obtaining the most efficient resolution of controversies; and the shared interest of the several States in furthering fundamental substantive social policies.

*World-Wide Volkswagen*, 444 U.S. at 292 (emphasis added) (internal citations omitted). Having found no meaningful burden on Mylan in defending in Delaware, the court considers these additional factors and determines that they favor the exercise of specific jurisdiction. In particular, under Mylan’s theory, AstraZeneca would only be able to bring suit in Mylan’s home state of West Virginia. Again, the Hatch-Waxman Act was not intended to burden patent holders or reduce the patent protection afforded in ANDA cases; limiting AstraZeneca’s choice of forum to West Virginia is not “adequ[ate] protection.” *See id.* Additionally, judicial efficiency weighs in favor of exercising specific jurisdiction. In this case, which is by no means unique in the ANDA

litigation sphere, AstraZeneca has filed suit against no fewer than ten generic defendant groups. Resolution of these cases in a single district would promote judicial economy and avoid the possibility of inconsistent outcomes.

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

#### V. CONCLUSION

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

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*Appendix D*

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

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No. 14-696-GMS

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ASTRAZENECA AB,  
*Plaintiff,*

v.

MYLAN PHARMACEUTICALS INC.,  
*Defendant.*

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Filed: November 5, 2014

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**ORDER**

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

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

Dated: November 5, 2014

s/[handwritten: signature]\_\_\_\_\_  
UNITED STATES DISTRICT JUDGE

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*Appendix E*

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

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No. 14-664-GMS  
CONSOLIDATED

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ASTRAZENECA AB,  
*Plaintiff,*

v.

AUROBINDO PHARMA LTD. and  
AUROBINDO PHARMA U.S.A., INS.,  
*Defendants.*

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Filed: November 5, 2014

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**ORDER**

WHEREAS, presently before the court is the Motion for Certification for Interlocutory Appeal (D.I. 63), filed on November 11, 2014, by defendant Mylan Pharmaceuticals Inc. ("Mylan").

WHEREAS, the court having considered the parties' briefing and the applicable law; IT IS HEREBY ORDERED THAT:

Mylan's Motion for Certification for Interlocutory Appeal (D.I. 63) is GRANTED.<sup>1</sup>

Dated: December 17, 2014

s/[handwritten: signature]  
UNITED STATES DISTRICT JUDGE

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<sup>1</sup> Mylan seeks interlocutory appellate review of the court's memorandum and order denying Mylan's motion to dismiss for lack of personal jurisdiction, issued on November 5, 2014. (C.A. No. 14-696-GMS, D.I. 26, 27.) Pursuant to 28 U.S.C. § 1292(b):

When a district judge, in making in a civil action an order not otherwise appealable under this section, shall be of the opinion that such order involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation, he shall so state in writing in such order.

§ 1292(b).

The court finds that the elements of § 1292(b) are met in this case and will certify Mylan's request for interlocutory appeal to the Court of Appeals for the Federal Circuit. The court is not familiar with any other judicial decision analyzing person jurisdiction in "Hatch-Waxman litigation," in the wake of the Supreme Court's ruling in *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014). The court agrees with Mylan that this is a controlling (and novel) question of law for which there is substantial ground for difference of opinion. The plaintiff AstraZeneca AB ("AstraZeneca") argues that interlocutory review will not "advance the ultimate termination of litigation" because the case is likely to proceed in this or some other forum, even if the court's jurisdiction ruling is reversed. But given the volume of Hatch-Waxman cases pending in this district, the court is of the view that interlocutory appellate review will provide necessary guidance as to whether these cases are properly before the court.

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Thus, immediate appeal may indeed advance the termination of this and other litigation.

The court declines, however, to certify the narrow question put forth by Mylan in its briefing:

Does the Due Process Clause of the Fourteenth Amendment to the United States Constitution permit specific personal jurisdiction over Mylan in Delaware based on Mylan's act of sending a paragraph IV certification letter to AstraZeneca in Delaware, as required under 21 U.S.C. § 355(j)(2)(B)(iii)?

(C.A. No. 14-664-GMS, D.I. 64 at 5.) The court considers this question to be an oversimplification of its holding, as AstraZeneca points out in its answering brief. (D.I. 94 at 6 & n.3.) The court will therefore certify Mylan's request for interlocutory appeal of the November 5, 2014, memorandum and order, but without further limitation.

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*Appendix F*

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

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No. 14-935-LPS

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ACORDA THERAPEUTICS, INC. and  
ALKERMES PHARMA IRELAND LIMITED,

*Plaintiffs,*

v.

MYLAN PHARMACEUTICALS INC.  
and MYLAN INC.,

*Defendants.*

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Filed: January 14, 2015  
Wilmington, Delaware

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s/[handwritten: signature]  
STARK, U.S. District Judge

**OPINION**

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)<sup>1</sup> 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 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

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<sup>1</sup> At 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)

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”<sup>2</sup> 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

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<sup>2</sup> As 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).

accept service of process in the State of 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”)<sup>3</sup> 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*

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<sup>3</sup> Mylan’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)

*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 ¶ 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.<sup>4</sup> Notably, the first of the Ampyra® patent ANDA suits 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.

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<sup>4</sup> *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, 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.

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*, 72 F. Supp. 3d 549, 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 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.<sup>5</sup> 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, 66 S. Ct. 154 (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.

## DISCUSSION

In opposing Defendants’ motion, Plaintiffs assert three bases for this Court’s exercise of personal

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<sup>5</sup> With 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)

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,<sup>6</sup> 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

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

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 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 761-762 (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”).<sup>7</sup> 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 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

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<sup>7</sup> The *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.

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.<sup>8</sup>

### 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

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<sup>8</sup> Judge 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*.”).

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, 102 S. Ct. 2099 (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, 102 S. Ct. 2099 (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.<sup>12</sup>

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<sup>12</sup> Thus, 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.”).

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 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. . . .”); *Ratliff 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 State . . . .<sup>[13]</sup>

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.

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<sup>13</sup> Delaware law further provides that the Secretary of State will serve as the designated agent to accept service of process for a nonqualified foreign corporation that transacts business in Delaware. *See* 8 Del. C. §§ 376, 382.

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.***

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.<sup>14</sup>

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<sup>14</sup> Mylan 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)

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, 37 S. Ct. 344; *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 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.<sup>15</sup>

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<sup>15</sup> Because 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 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

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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.

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, 66 S. Ct. 154. 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).<sup>16</sup>

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<sup>16</sup> Other 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 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

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.<sup>17</sup>

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

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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.

<sup>17</sup> Importantly, 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*.

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 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.<sup>18</sup>

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,

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<sup>18</sup> Consistent 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.”).

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).

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,<sup>19</sup> 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.<sup>20</sup>

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<sup>19</sup> Mylan 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.

<sup>20</sup> The 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 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)

#### 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.<sup>21</sup>

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<sup>21</sup> As 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

## 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.<sup>22</sup>

“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.”

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

<sup>22</sup> As 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)

*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 is reasonable and fair.” *Nuance Commc’ns, Inc. v. Abby Software House*, 626 F.3d 1222, 1231 (Fed. Cir. 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)<sup>23</sup>

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<sup>23</sup> The 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

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 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

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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.

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.<sup>24</sup> Mylan Pharma has long been able

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<sup>24</sup> A 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 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-to-file status with Paragraph IV certification.”)<sup>25</sup>—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, 100 S. Ct. 559 (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

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<sup>25</sup> As 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.

(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 (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,<sup>26</sup> 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).<sup>27</sup>

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<sup>26</sup> None 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)

<sup>27</sup> *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.

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.

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*.<sup>28</sup> 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.<sup>29</sup>

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.”

*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

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<sup>28</sup> If 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.

<sup>29</sup> The 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.

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.<sup>30</sup>

### 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.

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<sup>30</sup> By 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.

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*Appendix G*

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

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No. 14-935-LPS

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ACORDA THERAPEUTICS, INC. and  
ALKERMES PHARMA IRELAND LIMITED,

*Plaintiffs,*

v.

MYLAN PHARMACEUTICALS INC.  
and MYLAN INC.,

*Defendants.*

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Filed: January 14, 2015

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**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.

s/[handwritten: signature]  
UNITED STATES DISTRICT JUDGE

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*Appendix H*

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

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No. 14-935-LPS

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ACORDA THERAPEUTICS, INC. and  
ALKERMES PHARMA IRELAND LIMITED,

*Plaintiffs,*

v.

MYLAN PHARMACEUTICALS INC.  
and MYLAN INC.,

*Defendants.*

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Filed: January 30, 2015

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**ORDER**

At Wilmington this 30th day of January, 2015:

Upon consideration of Mylan Pharmaceuticals Inc. and Mylan Inc.'s Motion for Certification for Interlocutory Appeal, which is unopposed (D.I. 32) and good cause showing,

IT IS HEREBY ORDERED THAT:

Defendants Mylan Pharmaceuticals Inc. and Mylan Inc's Motion for Certification for Interlocutory Appeal is GRANTED. The Court hereby certifies the following questions of law from its Order (D.I. 31) dated January 14, 2015 for immediate appellate review:

- (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?

The Court finds certification is warranted because its order presents “controlling question[s] of law as to which there [are] substantial ground[s] for difference of opinion” and “an immediate appeal from the order may materially advance the ultimate termination of the litigation . . . .” 28 U.S.C. § 1292(b).

s/[handwritten: signature]  
UNITED STATES DISTRICT JUDGE

*Appendix I*

**21 U.S.C. §355**

(a) Necessity of effective approval of application

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.

\* \* \*

(j) Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2) (A) An abbreviated application for a new drug shall contain—

\* \* \*

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted

\* \* \*

(B) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

(i) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

(ii) TIMING OF NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph—

(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(iii) RECIPIENTS OF NOTICE.—An applicant required under this subparagraph to give notice shall give notice to—

(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(II) the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is

claimed by the patent (or a representative of the holder designated to receive such a notice).

(IV) CONTENTS OF NOTICE.—A notice required under this subparagraph shall—

(I) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsections for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

\* \* \*

(5)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

\* \* \*

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the

certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) of this section before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

(aa) the date on which the court enters judgment reflecting the decision; or

(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of such period the district court decides that the patent has been infringed—

(aa) if the judgment of the district court is appealed, the approval shall be made effective on—

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35:

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or

(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II).

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In such an action, each of the parties shall reasonably cooperate in expediting the action.