**No. 2015-1460**

# In the United States Court of Appeals for the Federal Circuit

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ASTRAZENECA AB,
PLAINTIFF-APPELLEE

*v.*

MYLAN PHARMACEUTICALS, INC.,
DEFENDANT-APPELLANT

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*ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE*
*(CIV. NOS. 14-664 & 14-696)*
*(THE HONORABLE GREGORY M. SLEET, J.)*

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## BRIEF OF APPELLEE ASTRAZENECA AB

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## CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rule 47.4, undersigned counsel for appellee certifies the following:

1. The full name of the party represented by me is AstraZeneca AB.

2. The name of the real party in interest represented by me is the same.

3. The parent corporation and publicly held company that own 10 percent or more of the stock of the party represented by me is AstraZeneca PLC.

4. The following attorneys appeared for appellee in proceedings in the district court or are expected to appear in this Court:

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JULY 16, 2015

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## STATEMENT OF RELATED CASES

Pursuant to Federal Circuit Rule 47.5, appellee states the following:

1. The Court has ordered that *Acorda Therapeutics Inc.* v. *Mylan Pharmaceuticals, Inc.*, No. 15-1456, be treated as a companion case and be assigned to the same panel for oral argument.

2. In addition to this case and its companion case, appellant has filed motions to dismiss for lack of personal jurisdiction in the following cases: *Bayer Healthcare LLC* v. *Mylan Pharmaceuticals, Inc.*, Civ. No. 15-114 (D. Del.); *Eli Lilly & Co.* v. *Mylan Pharmaceuticals, Inc.*, Civ. No. 14-389 (S.D. Ind.); *Forest Laboratories, Inc.* v. *Amneal Pharmaceuticals LLC*, Civ. No. 14-508 (D. Del.); *Novartis Pharmaceuticals Corp.* v. *Mylan Inc.*, Civ. Nos. 14-777 & 14-820 (D. Del.); *Otsuka Pharmaceuticals Co.* v. *Mylan Inc.*, Civ. No. 14-508 (D.N.J.); *Pfizer Inc.* v. *Mylan Inc.*, Civ. No. 15-26 (D. Del.); and *Teva Pharmaceuticals USA Inc.* v. *Mylan Pharmaceuticals, Inc.*, Civ. No. 14-1278 (D. Del.).

## STATEMENT OF THE ISSUES

1. Whether appellant is subject to specific personal jurisdiction in Delaware in this patent-infringement suit where (a) it intended to injure appellee in Delaware by submitting abbreviated new drug applications targeting appellee's patents and products and seeking to market competing products and (b) it targeted appellee's corporate interests in Delaware.

2. Whether appellant consented to general personal jurisdiction in Delaware when it registered as a foreign corporation in Delaware while on notice that such registration constitutes consent to general personal jurisdiction under Delaware law.

## STATEMENT OF THE FACTS

Appellant Mylan Pharmaceuticals, Inc., and other generic drug manufacturers filed abbreviated new drug applications seeking approval from the Food and Drug Administration to manufacture and sell generic versions of two diabetes drugs before the expiration of patents held by appellee AstraZeneca AB. Pursuant to the Hatch-Waxman Act, the generic manufacturers included paragraph IV certifications asserting that the patents were invalid, unenforceable, and/or would not be infringed. AstraZeneca subsequently filed suit against the generic manufacturers in the United States District Court for the District of Delaware, asserting that they had infringed and would infringe various claims in the patents. Alone among the generic manufacturers, Mylan asserted, as it has in numerous other cases around the country, that it was not subject to the district court's jurisdiction. Like every other court to have considered the issue, the district court rejected Mylan's position, holding that Mylan was subject to personal jurisdiction in Delaware. The district court's holding was correct, and its order denying Mylan's motion to dismiss should therefore be affirmed.

### A. Statutory Background

Originally enacted in 1984, the Hatch-Waxman Act sought to balance "two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Allergan, Inc.* v. *Alcon Laboratories, Inc.*, 324 F.3d 1322, 1325 (Fed. Cir. 2003) (per curiam) (citation omitted).

In order to achieve that balance, the Hatch-Waxman Act established the now-familiar mechanism for a generic drug manufacturer to obtain approval by the Food and Drug Administration (FDA) to manufacture and sell generic prescription drugs. To obtain approval for a new prescription drug, a brand-name drug manufacturer such as AstraZeneca typically must submit a new drug application (NDA) and "undergo a long, comprehensive, and costly testing process." *FTC* v. *Actavis, Inc.*, 133 S. Ct. 2223, 2228 (2013); *see also* 21 U.S.C. § 355(b)(1). Once the brand-name manufacturer has obtained approval for a prescription drug, a generic drug manufacturer may submit an abbreviated new drug application (ANDA) that "piggy-back[s] on the brand's NDA." *Caraco Pharmaceutical Laboratories, Ltd.* v. *Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012). "Rather than providing independent evidence of safety and efficacy, the typical ANDA shows that the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug." *Id.*

To ensure that a generic drug manufacturer can engage in the activity required to obtain FDA approval of an ANDA without exposing itself to liability, the Hatch-Waxman Act exempts such activity from the definition of infringement under the patent laws. *See* 35 U.S.C. § 271(e)(1). "This allows competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval." *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 671 (1990).

On the other hand, the Hatch-Waxman Act "incorporate[s] an important new mechanism designed to guard against infringement of patents relating to pioneer drugs." *Eli Lilly*, 496 U.S. at 676-677. When a generic drug manufacturer submits an ANDA, it must make one of four certifications to satisfy FDA that the manufacture and sale of the generic product will not infringe patents protecting the drug. *Id.* at 677; *see also* 21 U.S.C. § 355(j)(2)(A)(vii). As is relevant here, the fourth certification—a so-called "paragraph IV certification"—is 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." 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

Critically for present purposes, the Hatch-Waxman Act treats the submission of an ANDA with a paragraph IV certification as an act of patent infringement. 35 U.S.C. § 271(e)(2)(A); *Actavis*, 133 S. Ct. at 2228. As a practical matter, "[f]iling a paragraph IV certification means provoking liti-

gation." *Caraco*, 132 S. Ct. at 1677. The Act requires an ANDA applicant to send the patentee and NDA holder a written notification of its submission of an ANDA with a paragraph IV certification. 21 U.S.C. § 355(j)(2)(B)(ii)-(iii). The notification must 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." 21 U.S.C. § 355(j)(2)(B)(iv). "The Hatch-Waxman Act added this artificial infringement provision to protect NDA patent holders, so that the infringement dispute could be resolved before the generic drug hits the market." Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 Food & Drug L.J. 417, 424 (2011).

Upon receipt of such a notification, the patentee must file a patent-infringement action against the ANDA applicant within 45 days in order to stay automatically FDA's approval of the generic drug. 21 U.S.C. § 355(j)(5)(B)(iii). The stay remains in effect for 30 months (unless the patent litigation concludes sooner or the court otherwise terminates the stay). 21 U.S.C. § 355(j)(5)(B)(iii)(I).

A patentee's remedies in an ANDA case are limited. *See Eli Lilly*, 496 U.S. at 678. If the court concludes that the patent is valid and will be infringed by the generic drug, it will order that approval of the ANDA cannot take effect until the patent expires. 35 U.S.C. § 271(e)(4)(A). It may also

award injunctive relief. 35 U.S.C. § 271(e)(4)(B). Damages are not available to the patentee unless "there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug." 35 U.S.C. § 271(e)(4)(C). The Hatch-Waxman Act thus provides a mechanism for resolving patent disputes without exposing prospective generic manufacturers to "ruinous liability for infringement." *Actavis*, 133 S. Ct. at 2247 (Roberts, C.J., dissenting).

The litigation that arises from a paragraph IV certification is a critical component of the Hatch-Waxman Act. As the Supreme Court has recognized, treating the submission of an ANDA with a paragraph IV certification for a drug claimed in a patent as an act of patent infringement is necessary to "enable the judicial adjudication upon which the ANDA . . . scheme[] depend[s]." *Eli Lilly*, 496 U.S. at 678. As a result, ANDA litigation is "an integral part of a generic drug company's business." JA15.

**B. Factual Background**

1. The AstraZeneca group of companies is engaged in the pharmaceutical business. Appellee AstraZeneca AB, referred to here as AstraZeneca, is based in Sweden. JA52. AstraZeneca is a subsidiary of AstraZeneca PLC, a United Kingdom company. AstraZeneca has substantial operations in the United States; it conducts business here through AstraZeneca Pharmaceuticals LP, a Delaware limited partnership that is headquartered in

Wilmington, Delaware. *Id.* AstraZeneca is the sole general partner of AstraZeneca Pharmaceuticals LP and controls its operations.

Two of AstraZeneca's prescription-drug products are Onglyza and Kombiglyze XR, both of which treat adults with Type 2 diabetes. JA52. Onglyza and Kombiglyze XR are the result of substantial investments of AstraZeneca's resources. Both products are protected by patents, including U.S. Reissue Patent No. RE44,186 ("the '186 patent"), owned by AstraZeneca. JA53. The '186 patent protects AstraZeneca's exclusive right to manufacture and sell Onglyza and Kombiglyze XR. JA53-JA54. FDA has approved both products, and those products and the relevant patents are listed in the Orange Book. *Id.*

2. Appellant Mylan Pharmaceuticals, Inc., referred to here as Mylan, is a subsidiary of Mylan N.V., a Dutch corporation. Mylan "develops and manufactures generic versions of branded pharmaceutical products for the United States market." Mylan Br. 4. According to public filings, Mylan and its affiliates rank as the largest generic drug manufacturer by sales in the United States. *See* Mylan Inc. Form 10-K, Mar. 2, 2015, at 5. One out of every 13 prescriptions dispensed in this country is a Mylan product. *See* Mylan, Mylan Fact Sheet (June 2015) <www.mylan.com/-/media/mylancom/files/company/mylanfactsheetjune2015.pdf>.

Mylan is a West Virginia corporation with its principal place of business in that State. JA3. Mylan's business operations, however, are not confined to West Virginia; Mylan does business, directly or indirectly, in every State in the Nation, including Delaware. Mylan Br. 4; JA53 (Compl. ¶ 10); *see, e.g.*, *Eli Lilly & Co.* v. *Accord Healthcare, Inc.*, Civ. No. 14-389, Dkt. No. 277, at 13 (S.D. Ind. Nov. 7, 2014) (quoting deposition testimony in which Mylan stated that it does not "carve out individual states" from its nationwide distribution network). In 2010, Mylan registered as an out-of-state corporation with the Delaware Secretary of State and appointed an agent to receive service of process in Delaware. JA3, JA65. In its certificate of registration, Mylan indicated that it intended to engage in "[p]harmaceutical manufacturing, distribution and sales" in Delaware. JA65. In addition, Mylan holds "pharmacy-wholesale" and "distributor/manufacturer" licenses from the Delaware Board of Pharmacy. JA68-JA70.

Although Mylan represented in the district court that its net sales in Delaware essentially amount to zero, that representation is misleading. As Mylan has averred in public filings, it primarily sells its drugs through a "network of independent distributors and wholesalers," which are the entities that bring the drugs into Delaware, *see Reed* v. *Mylan, Inc.*, Civ. No. 10-404, Dkt. No. 20-3, at 2 (S.D. W. Va. Aug. 24, 2010); in calculating its net sales in Delaware, Mylan obviously did not include those sales. In some cases,

Mylan negotiates prices directly with managed-care organizations or hospitals, but it still instructs those customers to buy the product through a wholesaler at the agreed-upon price. *See* Mylan Inc. Form 10-K, *supra*, at 72. All in all, Mylan derives a "significant portion" of its sales from a "relatively small number of drug wholesalers and retail drug chains." *Id.* at 38.

3. Mylan and other generic manufacturers filed ANDAs seeking approval from FDA to manufacture and sell generic versions of Onglyza and/or Kombiglyze XR before the expiration of AstraZeneca's patents. JA2, JA17. In April 2014, Mylan sent the paragraph IV notification letters required by the Hatch-Waxman Act. JA55-JA57, JA72-JA74, JA76-JA78. Mylan sent those letters both to AstraZeneca in Sweden and to AstraZeneca Pharmaceuticals LP at its headquarters in Wilmington, Delaware. JA72, JA76.

### C. Procedural History

1. In May and June 2014, AstraZeneca filed an initial ten lawsuits against Mylan and other generic manufacturers in the United States District Court for the District of Delaware, asserting that they had infringed and would infringe various claims in the patent protecting Onglyza and Kombiglyze XR. As is customary in ANDA cases, the district court consolidated the cases for trial. JA23, JA41.[1]

[1] After filing suit against Mylan in Delaware, AstraZeneca also filed a protective suit against Mylan in West Virginia. That case has been stayed pend-

2. Alone among the eighteen defendants named in the lawsuits, Mylan moved to dismiss AstraZeneca's complaint for lack of personal jurisdiction, as it has recently done in numerous other ANDA cases nationwide. Like every other court to have considered the issue, the district court rejected Mylan's position, holding that Mylan is subject to personal jurisdiction in Delaware. JA12-JA17.

a. Informed by its understanding of the "balance" struck in the Hatch-Waxman Act, the district court first determined that Mylan is subject to specific jurisdiction in Delaware. JA12-JA17. The peculiarity of the Hatch-Waxman Act, the court noted, is that it contemplates that patent litigation will follow from an ANDA filing even before the generic product has been marketed or sold. JA14-JA15.

The district court reasoned that Mylan's submission of its ANDAs was "a real act with actual consequences," and it determined that those consequences were suffered by AstraZeneca in Delaware, where AstraZeneca Pharmaceuticals LP is organized. JA14-JA15 (quoting *Zeneca Ltd.* v. *Mylan Pharmaceuticals, Inc.*, 173 F.3d 829, 833-834 (Fed. Cir. 1999)). The court explained that Mylan had purposefully directed its activities at AstraZeneca in Delaware by submitting the ANDAs and directing the notification letters

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ing the resolution of Mylan's interlocutory appeal; the district court has indicated that it intends to dismiss that later-filed suit unless Mylan's appeal is successful. *See* Order, Civ. No. 14-94, Dkt. 31 (N.D. W. Va. Nov. 13, 2014).

to AstraZeneca in Delaware. JA15-JA16. And it observed that "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." JA15 (quoting *Burger King Corp.* v. *Rudzewicz*, 471 U.S. 462, 474 (1985)).

The district court added that the exercise of specific jurisdiction comported with "traditional notions of fair play and substantial justice." JA16 (quoting *International Shoe Co.* v. *Washington*, 326 U.S. 310, 316, 324-326 (1945)). On the one hand, the court noted, Mylan would not be meaningfully burdened if it had to defend this lawsuit in Delaware. *Id.* On the other hand, the court observed, AstraZeneca would be "substantially burdened" if it had to bring separate ANDA lawsuits in each generic company's home State. JA16-JA17. The court deemed Mylan's position "inconsistent" with the balance that Congress struck in the Hatch-Waxman Act, JA16, and it explained that "[r]esolution of these cases in a single district would promote judicial economy and avoid the possibility of inconsistent outcomes," JA17.

b. Although it determined that Mylan is subject to specific jurisdiction in Delaware, the district court proceeded to reject AstraZeneca's alternative argument that Mylan had consented to the exercise of general jurisdiction in Delaware when it registered as an out-of-state corporation under Delaware law and appointed a registered agent to receive service of process

in Delaware. JA8-JA12. The district court acknowledged that the Supreme Court had not expressly overruled cases holding that compliance with a state business registration statute may constitute consent to the exercise of general jurisdiction in that State. JA9-JA10 (citing, *inter alia*, *Pennsylvania Fire Insurance Co.* v. *Gold Issue Mining & Milling Co.*, 243 U.S. 93 (1917)). And the district court observed that the Delaware Supreme Court had ruled in *Sternberg* v. *O'Neil*, 550 A.2d 1105 (1988) (en banc), that an out-of-state corporation's decision to register in Delaware constitutes express consent to the exercise of general jurisdiction by Delaware courts. JA10.

The district court nevertheless asserted that the Supreme Court had implicitly abrogated *Sternberg* (and, by extension, the earlier Supreme Court cases on which it relied) in *Daimler AG* v. *Bauman*, 134 S. Ct. 746 (2014). JA10-JA11. *Daimler* held that, under the minimum-contacts test adopted in *International Shoe*, a defendant is subject to general jurisdiction only in those states where it is "fairly regarded as at home." 134 S. Ct. at 760 (quoting *Goodyear Dunlop Tires Operations, S.A.* v. *Brown*, 131 S. Ct. 2846, 2854 (2011)). Under that test, merely doing business in a State does not give rise to sufficient minimum contacts to support the exercise of general jurisdiction. *See Daimler*, 134 at 760-761. According to the district court, because *Daimler* held that "doing business" in a State cannot support the exercise of general jurisdiction on a minimum-contacts analysis, a defendant cannot val-

idly "consent" to the exercise of general jurisdiction in a forum by complying with state-law requirements for doing business in that forum. JA11.[2]

3. Mylan moved for certification for interlocutory appeal pursuant to 28 U.S.C. § 1292(b), proposing certification of the following question:

> 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)?

JA104 n.1. Although the district court granted Mylan's motion for certification for interlocutory appeal, it declined to certify "the narrow question put forth by Mylan in its briefing," which the court considered "an oversimplification of its holding." *Id.*

4. This Court then granted Mylan's petition for permission to appeal. JA105-JA107. This appeal follows.

## SUMMARY OF ARGUMENT

The district court in this case correctly held that Mylan is subject to personal jurisdiction in Delaware.

I. The district court correctly determined that Mylan is subject to specific jurisdiction in Delaware. All relevant conduct points to the exercise

[2] The district court also rejected AstraZeneca's argument that Mylan's contacts with Delaware render it "essentially at home" in Delaware, thus justifying the exercise of general jurisdiction even in the absence of consent. JA6-JA8. AstraZeneca is not renewing that argument in this Court.

of jurisdiction in that State. In filing its paragraph IV certification, Mylan attacked the validity of AstraZeneca's nationwide patent rights and sought nationwide approval from FDA to market competing drugs. Under the effects test set forth by the Supreme Court in *Calder* v. *Jones*, 465 U.S. 783 (1984), that intentional act of infringement created minimum contacts with every State, including Delaware. In addition, in filing its paragraph IV certification, Mylan specifically targeted AstraZeneca's corporate interests in Delaware, the State from which AstraZeneca, through AstraZeneca Pharmaceuticals LP, manages and organizes its patent-related activity in the United States. And Mylan further targeted Delaware by mailing notice letters to AstraZeneca Pharmaceuticals LP in that State.

The exercise of personal jurisdiction in Delaware, moreover, is both fair and reasonable. Mylan would face no significant burden litigating this dispute in Delaware—not only because it is geographically close to Mylan's home base in West Virginia, but also because it is where Mylan has initiated a number of actions as a plaintiff. Conversely, AstraZeneca's interests and those of the judicial system as a whole both favor the exercise of jurisdiction in Delaware. As is true here, a patentee will often file suit against multiple generics that have filed ANDAs concerning the same patented drug. AstraZeneca's rule would allow consolidation of multiple cases in a single forum, while Mylan's rule would force AstraZeneca to litigate those cases separately

in each generic's home State, wasting the resources of the parties and burdening the federal courts with duplicative litigation.

II. The district court's order denying Mylan's motion to dismiss can also be affirmed on the alternative ground that Mylan consented to general jurisdiction in Delaware when it elected to register there. Under Delaware case law that preceded Mylan's registration, an out-of-state corporation's registration in Delaware constitutes consent to the exercise of general jurisdiction by courts in that State. As the Supreme Court held nearly a century ago, it does not violate due process to hold Mylan to its end of the bargain it struck with the State of Delaware when it decided to do business there.

The district court rejected this basis for personal jurisdiction because it concluded that *Daimler* had implicitly overruled earlier Supreme Court decisions affirming the exercise of general jurisdiction in circumstances identical to those presented here. But neither the district court nor this Court has the authority to deem Supreme Court precedent overruled. For that reason alone, the district court erred.

In any event, even if this Court had the authority to consider Supreme Court precedent overruled, there is no basis for reaching that conclusion. Neither *Daimler* nor the Supreme Court's earlier decision in *International Shoe* implicitly discarded the principle that a State may treat an out-of-state corporation's registration as consent to general jurisdiction. In cases such as

this one, where the defendant had notice of the consequences of its decision to enter a State's market, it does not violate the Due Process Clause to hold that the defendant has consented to the exercise of general jurisdiction.

## STANDARD OF REVIEW

Because personal jurisdiction is a question of law, this Court reviews a district court's decision on a motion to dismiss for lack of personal jurisdiction de novo. *See, e.g.*, *Patent Rights Protection Group, LLC* v. *Video Gaming Technologies, Inc.*, 603 F.3d 1364, 1368 (Fed. Cir. 2010). In a patent-infringement case, this Court applies its own law in determining the existence of personal jurisdiction. *See, e.g.*, *id.*

## ARGUMENT

This case involves both categories of personal jurisdiction: specific and general. A State may acquire specific jurisdiction over a defendant where the defendant's contacts with that State caused an injury on which the plaintiff's suit is based. *See, e.g.*, *Daimler AG* v. *Bauman*, 134 S. Ct. 746, 754 (2014). A State may assert general jurisdiction, by contrast, where the defendant has contacts with the State that are so "continuous and systematic" that the defendant may be sued on any claim there. *Id.*

Mylan makes the startling assertion that it is subject to neither specific nor general jurisdiction in Delaware. Consistent with its position in numerous cases nationwide—a position that has been rejected by every court to

have considered it—Mylan asks this Court to hold that it is subject to personal jurisdiction in ANDA cases only in its home State of West Virginia. It is irrelevant, according to Mylan, that it intentionally committed an act of patent infringement intended to injure AstraZeneca in Delaware, where AstraZeneca's American operations are headquartered and organized. It is irrelevant, according to Mylan, that it sought approval to distribute generic versions of AstraZeneca's drugs in Delaware. It is also irrelevant, in Mylan's view, that it has registered to do business in Delaware and appointed an agent to receive service of process in that State in the face of longstanding Delaware precedent holding that such registration constituted consent to general jurisdiction in Delaware.

Of course those facts are relevant. And under longstanding precedent from the Supreme Court and this Court, those facts give rise to both specific and general jurisdiction in Delaware. Mylan argues that the Supreme Court's recent decision in *Daimler* silently overruled the long line of cases that gave Delaware general jurisdiction over Mylan, and further argues that *Daimler* rendered it improper for district courts to consider whether specific jurisdiction provides an alternative basis for exercising jurisdiction over ANDA defendants. But *Daimler* is not the be-all and end-all of personal jurisdiction: it does not occupy the field or obliterate preexisting bases for personal jurisdiction, as Mylan overreachingly suggests. *Daimler* neither ad-

dressed, nor purported to address, the bases for jurisdiction at issue here. The district court correctly determined that it could exercise personal jurisdiction over Mylan, and its order denying Mylan's motion to dismiss should therefore be affirmed.

## I. THE DISTRICT COURT CORRECTLY DETERMINED THAT MYLAN IS SUBJECT TO SPECIFIC PERSONAL JURISDICTION IN DELAWARE

To maintain suit over a nonresident defendant under the doctrine of specific jurisdiction, a plaintiff must establish that jurisdiction is proper under both the applicable state long-arm statute and the Due Process Clause of the federal Constitution. *See Commissariat à l'Energie Atomique* v. *Chi Mei Optoelectronics Corp.*, 395 F.3d 1315, 1319 (Fed. Cir. 2005). In this case, Mylan does not contest that Delaware's long-arm statute is satisfied. Accordingly, the only issue is whether the assertion of jurisdiction by a Delaware court comports with due process.

For a defendant to be subject to specific jurisdiction in a State consistent with due process, the defendant must have "minimum contacts" with the State "such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice." *Walden* v. *Fiore*, 134 S. Ct. 1115, 1121-1122 (2014). In conducting the minimum-contacts inquiry, a court asks both whether the defendant has "purposefully directed" his activities at the forum and whether "the litigation results from alleged injuries that arise out

of or relate to those activities." *Inamed Corp.* v. *Kuzmak*, 249 F.3d 1356, 1360 (Fed. Cir. 2001). If the plaintiff can establish the requisite minimum contacts, the court will also consider whether the assertion of personal jurisdiction over the defendant is fair and reasonable. *See Asahi Metal Industry Co.* v. *Superior Court of California*, 480 U.S. 102, 113-114 (1987); *id.* at 116 (Brennan, J., concurring). Both steps of the analysis are satisfied here.

### A. Mylan Established Minimum Contacts With Delaware

In this case, the district court correctly determined that Mylan established sufficient contacts with Delaware to be subject to specific jurisdiction there. In filing a paragraph IV certification, Mylan challenged AstraZeneca's exclusive right to market drugs in that State and sought approval from FDA to market a competing product in that State. In addition, Mylan caused intentional injury to AstraZeneca's corporate interests in Delaware, and AstraZeneca suffered resulting injury there. Either of those justifications provides a sufficient basis for specific jurisdiction—and thus for affirming the district court's order.

#### *1. Mylan Intended To Injure AstraZeneca In Delaware*

a. A Delaware court may exercise specific jurisdiction over Mylan because Mylan engaged in an intentional act of patent infringement that satisfies the effects test set forth by the Supreme Court in *Calder* v. *Jones*, 465 U.S. 783 (1984). There, the Court held that, when a defendant engages in in-

tentional action directed at the forum State and the plaintiff suffers effects of that action in the forum State, the defendant may be called before the courts of that State consistent with due process. *Id.* at 788-790; *accord Silent Drive, Inc.* v. *Strong Industries, Inc.*, 326 F.3d 1194, 1204 (Fed. Cir. 2003).

The question in *Calder* was whether a California court could exercise personal jurisdiction over two nonresident journalists who had been sued for libel by a California plaintiff. Although the journalists wrote and edited their allegedly libelous article in Florida, the Court held that their conduct was "expressly aimed" at California because their article "concerned the California activities of a California resident." 465 U.S. at 788-789. Because the journalists knew their story "would have a potentially devastating impact" on the plaintiff in California, they could "reasonably anticipate being haled into court there." *Id.* at 789-790. In those circumstances, the Court concluded, due process did not require the plaintiff to sue in a distant forum in order to obtain redress from out-of-state defendants who knowingly caused her injury at home. *Id.* at 790.

*Calder* prescribed the jurisdictional rule for intentional torts, and ANDA cases involving paragraph IV certifications are properly evaluated under that rule. The Hatch-Waxman Act defines the filing of such a certification as an intentional act of patent infringement. *See* 35 U.S.C. § 271(e)(2)(A). A generic files a paragraph IV certification only when a

brand-name drug manufacturer has listed a patent in the Orange Book and thus announced to the world that, in its view, it holds exclusive patent rights that protect the drug. Instead of waiting for those rights to expire, the generic manufacturer filing the ANDA has chosen to trigger litigation over the brand-name manufacturer's patent. The purpose of that litigation, from the generic manufacturer's perspective, is to extinguish the manufacturer's exclusive nationwide right to its patent and obtain approval from FDA to market a competing generic version before the patent has expired. Unsurprisingly, this Court has described the filing of a paragraph IV certification as a "real act with serious consequences." *Zeneca Ltd.* v. *Mylan Pharmaceuticals, Inc.*, 173 F.3d 829, 834 (Fed. Cir. 1999) (opinion of Gajarsa, J.).

Under the effects test of *Calder*, personal jurisdiction may lie in every State to which the defendant's actions are directed and in which their effects are felt. In filing a paragraph IV certification, the generic manufacturer attacks the patentee's nationwide right to exclude and seeks nationwide permission to compete with the brand manufacturer or its licensees. Under *Calder*, then, the filing of a paragraph IV certification gives rise to minimum contacts in every State, subject to the important condition that the exercise of personal jurisdiction in that State be fair and reasonable. *Cf. Keeton* v. *Hustler Magazine, Inc.*, 465 U.S. 770, 772-777, 781 (1984) (concluding that specific jurisdiction over "a national publication aimed at a nationwide audi-

ence" lies in any State where the libel defendant targeted its conduct and plaintiff suffered reputational harm).[3]

This Court has already embraced the foregoing reasoning. In *Beverly Hills Fan Co.* v. *Royal Sovereign Corp.*, 21 F.3d 1558 (1994), the Court considered the location of a patentee's injury in an ordinary infringement action. It recognized that "[a] patent is a federally created property right, valid throughout the United States," and concluded that the situs of the patentee's injury is therefore "anywhere" the patent "is called into play." *Id.* at 1570. In the typical Hatch-Waxman case, the generic manufacturer seeks to invalidate the patent at issue; at a minimum, the generic manufacturer certifies that its new drug is not covered by the patent. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Either way, it is no exaggeration to say that the generic manufacturer deliberately seeks to eliminate the value of the brand's "federally created property right" and to enter the nationwide market for the brand-name drug before that property right expires. *Beverly Hills Fan*, 21 F.3d at 1570. Thus, upon the filing of a paragraph IV certification, the patentee has suffered a "tortious injury" to its "right to exclude others." *Id.* And the test

[3] Even if Mylan would effectively be subject to personal jurisdiction nationwide, that outcome would be consistent with the outcome in non-Hatch-Waxman Act patent-infringement actions, where infringers "are frequently subject to personal jurisdiction in practically any federal court in the country." Megan M. La Belle, *Patent Litigation, Personal Jurisdiction, and the Public Good*, 18 Geo. Mason L. Rev. 43, 70 (2010).

for where that injury has occurred is "the location, or locations, at which the infringing activity directly impacts on the interests of the patentee." *Id.* at 1571.[4] As noted above, those locations include every State where the patent is valid and where the generic has sought permission to market and sell its competing product—including Delaware.

Mylan protests that it is improper to premise jurisdiction on its request for approval to distribute competing drugs in Delaware because it has committed only a "highly artificial act of infringement" that "was complete the moment that Mylan filed an ANDA." Mylan Br. 43-44. Not only does Mylan's position overlook the required inquiry into the effects of that act, as discussed above, but it misses the point of the Hatch-Waxman Act. The Hatch-Waxman Act requires a hypothetical and prospective inquiry into "whether, if a particular drug *were* put on the market, it *would* infringe the patent." *Bristol-Myers Squibb Co.* v. *Royce Laboratories, Inc.*, 69 F.3d 1130, 1135 (Fed. Cir. 1995); *see generally Burger King* v. *Rudzewicz*, 471 U.S. 462,

[4] This Court's decision in *Beverly Hills Fan* is consistent with a long line of cases in other circuits holding that deliberate interference with property rights or business relationships creates personal jurisdiction in the State where the tortfeasor's actions are directed and in which the effects of those actions will be felt. *See, e.g.*, *Tamburo* v. *Dworkin*, 601 F.3d 693, 702-710 (7th Cir. 2010) (tortious interference); *Dudnikov* v. *Chalk & Vermilion Fine Arts, Inc.*, 514 F.3d 1063, 1073-1078 (10th Cir. 2008) (copyright infringement); *Bancroft & Masters, Inc.* v. *Augusta Nat'l Inc.*, 223 F.3d 1082, 1087-1088 (9th Cir. 2000) (trademark infringement).

479 (1985) (noting that the "future contemplated consequences" of a defendant's actions are relevant to the minimum-contacts analysis). For that reason, it is no answer that Mylan has not yet begun to sell infringing products in Delaware (or that Mylan would not make sales in Delaware if approval were granted). *See Eli Lilly & Co.* v. *Mylan Pharmaceuticals, Inc.*, ___ F. Supp. 3d ___, Civ. No. 14-389, 2015 WL 1125032, at *6 n.11 (S.D. Ind. Mar. 12, 2015); *Allergan, Inc.* v. *Actavis, Inc.*, Civ. No. 14-188, 2014 WL 7336692, at *7 (E.D. Tex. Dec. 23, 2014).

The foregoing approach—under which the appropriate inquiry in Hatch-Waxman cases focuses on what Mylan has *sought approval* to do—finds support in this Court's decision in *Sunovion Pharmaceuticals, Inc.* v. *Teva Pharmaceuticals USA, Inc.*, 731 F.3d 1271 (2013). *Sunovion* involved a patentee that held the exclusive right to market a drug containing no more than 0.25% of a particular compound. A generic drug manufacturer filed an ANDA in which it sought permission to market a drug containing no more than 0.6% of that same compound. The generic manufacturer sought to avoid a finding of infringement by pledging to the Court that it would only market drugs containing 0.3% to 0.6% of the compound—even though its ANDA permitted it to do more. This Court rejected the generic manufacturer's position, holding that the inquiry in the Hatch-Waxman context focuses on what the generic manufacturer has sought approval to do in its ANDA, not how it

plans to put that approval into practice. *Id.* at 1278-1279. So too here, the personal-jurisdiction inquiry properly centers on what Mylan has asked FDA for permission to do—*viz.*, to market its competing drugs in Delaware and every other State.

In any event, at least in cases involving a generic manufacturer such as Mylan with a nationwide business, there is little reason to doubt that the generic will in fact distribute its product in every State, whether directly or through intermediaries. Although Mylan protests that it "conducts essentially no direct sales" in Delaware, Mylan Br. 43-44, that is beside the point. As AstraZeneca's complaint alleged, and as public records confirm, Mylan's products will be sold into Delaware through its established network of wholesalers and distributors. *See* pp. 8-9, *supra*.

This Court has recognized that, where a manufacturer specifically targets a State's market through an established distribution channel, that suffices to give rise to specific jurisdiction. *See Beverly Hills Fan*, 21 F.3d at 1565-1566 (finding purposeful contacts where the infringing product arrived in the forum State "through defendants' purposeful shipment . . . through an established distribution channel"); *see also Momenta Pharmaceuticals, Inc.* v. *Amphastar Pharmaceuticals, Inc.*, 841 F. Supp. 2d 514, 520-521 (D. Mass. 2012) (determining that drug manufacturers purposely targeted forum State even though they made sales through "middlemen," and observing that

drug manufacturers typically distribute their products in that manner). And in fact, there is good reason to believe here that Mylan will interact directly with customers in Delaware. As its public filings indicate, Mylan often negotiates prices directly with buyers, even if those buyers ultimately make their purchases through Mylan's designated wholesalers. *See* Mylan Inc. Form 10-K, Mar. 2, 2015, at 72.

Mylan responds that it is not sufficient that its products will somehow reach Delaware through the stream of commerce. *See* Mylan Br. 45. But Mylan does not simply hand off its products to third-party distributors to distribute wherever they see fit; instead, it targets the market in every State through its established network, excepting no State from its operation. *See, e.g.*, *Eli Lilly & Co.* v. *Accord Healthcare, Inc.*, Civ. No. 14-389, Dkt. No. 277, at 13 (S.D. Ind. Nov. 7, 2014) (quoting deposition testimony in which Mylan stated that it does not "carve out individual states" from its nationwide distribution network).[5]

Mylan's registration to do business in Delaware further confirms its intent to make future sales in that State. In its registration certificate, Mylan

[5] Under Mylan's cramped view of specific jurisdiction, by contrast, consumers purchasing products from Mylan's wholesalers could not bring suit against Mylan in their home States even though Mylan intends to target those States. But Mylan has previously moved to transfer consumer cases *from* West Virginia *to* consumers' home States. *See, e.g.*, *Arnett* v. *Mylan, Inc.*, Civ. No. 10-114, 2010 WL 3220341 (S.D. W. Va. Aug. 13, 2010).

indicated that its intention was to engage in "[p]harmaceutical manufacturing, distribution, and sales" in Delaware. JA65. In addition, Mylan holds "pharmacy-wholesale" and "distributor/manufacturer" licenses from the Delaware Board of Pharmacy. JA68-JA70. Mylan attempts to downplay the significance of its registration, contending that it cannot give rise to specific jurisdiction because "AstraZeneca is not suing Mylan for registering to do business in Delaware." Mylan Br. 42-43. Again, however, that simply misses the point. Mylan's registration to do business in Delaware constitutes a relevant suit-related contact because it demonstrates Mylan's intent to engage in sales in that State.

***2. Mylan Targeted AstraZeneca's Corporate Interests in Delaware***

a. Not only has Mylan sought approval to distribute its ANDA product nationwide, including in Delaware, during the term of AstraZeneca's patent; it also specifically targeted the interests of AstraZeneca as a corporation with strong ties to Delaware. AstraZeneca organizes and conducts its patent-related activity in the United States from AstraZeneca Pharmaceuticals LP's headquarters in that State. By triggering a dispute concerning AstraZeneca's patent rights, Mylan's certification was targeted specifically to AstraZeneca's Delaware activity; that State is the very "focal point" of Mylan's conduct. *Calder*, 465 U.S. at 789; *see also* Steven M. Reiss, *Applying the Effects Test Theory of Personal Jurisdiction in Patent Infringement Ac-*

*tions*, 23 AIPLA Q.J. 99, 100-101 (1995) (arguing that the *Calder* effects test "favors a corporate intentional infringer being subject to personal jurisdiction in the patentee's home forum").

For that reason, Mylan could "reasonably anticipate being haled into court" in Delaware. *Burger King*, 471 U.S. at 474; *accord Eli Lilly & Co.*, ___ F. Supp. 3d ___, 2015 WL 1125032, at *6. After all, the very purpose of filing a paragraph IV certification is to provoke litigation by which the parties will obtain a determination of a patent's validity and scope. *See Caraco*, 132 S. Ct. at 1677. As the district court noted, such litigation is "an integral part of a generic drug company's business," JA15, enabling a generic manufacturer to test the validity and scope of a brand-name manufacturer's patent without incurring the risk of damages liability. *See also* Mylan Inc. Form 10-K, Mar. 2, 2015, at 3 (crediting Mylan's "leadership position" in the generics market to its "ability to efficiently obtain [ANDA] approvals").

There can also be no question that AstraZeneca will suffer the effects of Mylan's purposeful conduct in Delaware. To begin with, Mylan's certification to FDA that AstraZeneca's patents are invalid or will not be infringed works an immediate harm in Delaware, chilling AstraZeneca's prospective business relationships by raising questions about whether the company will maintain its exclusive right to market the drugs at issue. *See* John C. O'Quinn, *There's No Place Like Home: Finding Personal Jurisdiction in*

*ANDA Patent Cases After* Zeneca *v.* Mylan Pharmaceuticals, 13 Harv. J.L. & Tech. 129, 138-139 (1999). If Mylan were to succeed in extinguishing that right, moreover, Mylan would not only harm AstraZeneca's corporate interests in Delaware, but also earn the right to begin competing with AstraZeneca in Delaware (and elsewhere).

b. Mylan complains that permitting personal jurisdiction against it in Delaware in this case would be tantamount to "declar[ing] that all Hatch-Waxman plaintiffs can assert specific jurisdiction in their own home states over all ANDA defendants." Mylan Br. 25. But AstraZeneca is not arguing that jurisdiction is proper in Delaware simply because it happens to be based there and no better forum is available. *Cf. Beverly Hills Fan*, 21 F.3d at 1570. Instead, AstraZeneca is arguing that jurisdiction is proper in Delaware because Mylan engaged in a purposeful act of infringement directed at AstraZeneca's corporate interests in that State. It is beyond dispute that, where a defendant expressly aims conduct at the plaintiff's home State and causes injury to the plaintiff there, it may be called to answer for its conduct in that State. *See Calder*, 465 U.S. at 788-790.

To the extent that Mylan complains about the breadth of AstraZeneca's proposed rule, *see* Mylan Br. 25, that rule is vastly preferable to Mylan's cramped alternative. According to Mylan, specific (as opposed to general) jurisdiction is available only in the State where the ANDA defendant pre-

pared its application to FDA. *See id.* at 39. But that rule makes little sense as a matter of statutory interpretation, because the Hatch-Waxman Act specifically exempts such preparatory work from its definition of patent infringement. *See* 35 U.S.C. § 271(e)(1), (2); JA16 n.13. In addition, a provision added to the statutory scheme in 2003 suggests that Congress did not envision that jurisdiction would lie in the forum where the ANDA was prepared. Under that provision, if a patentee fails to file suit within 45 days of receiving notice of a generic manufacturer's paragraph IV certification, the generic manufacturer may seek a declaration of non-infringement—but it must do so where the patentee has its principal place of business (or "a regular and established place of business"). *See* 21 U.S.C. § 355(j)(5)(C)(i)(II).

As a practical matter, Mylan's approach would mean that a patentee would ordinarily have no choice but to sue an ANDA defendant on the defendant's home turf. In the typical case, including this one, the ANDA defendant would be expected to prepare its application in the State where it has its principal place of business. Under Mylan's view, then, the specific jurisdiction inquiry effectively provides no alternative to what is already available under a general-jurisdiction analysis, and a patentee is limited to suing in the ANDA defendant's home forum.

c. Mylan also contends that, even if AstraZeneca suffered an injury in Delaware, the Supreme Court's recent decision in *Walden* v. *Fiore*, 134

S. Ct. 1115 (2014), forecloses the exercise of specific jurisdiction in that State. But *Walden* did not change the law: it merely applied the Supreme Court's "traditional" personal-jurisdiction analysis, *see Picot* v. *Weston*, 780 F.3d 1206, 1214 (9th Cir. 2015), to reverse an outlying court of appeals decision that permitted jurisdiction based on contacts with the forum State that were "random, fortuitous, [and] attenuated." *Walden*, 134 S. Ct. at 1123.

In *Walden*, a federal agent seized cash from the plaintiffs at the airport in Atlanta, where they were catching a connecting flight from Puerto Rico to their home State of Nevada. 134 S. Ct. at 1119. Although the plaintiffs eventually got their money back, they sued the agent for damages in Nevada, alleging Fourth Amendment violations. *Id.* at 1119-1120. The agent filed a motion to dismiss, asserting that the search and seizure conducted in Georgia did not establish a basis for the exercise of personal jurisdiction by a federal court in Nevada. *Id.* at 1120.

The Supreme Court agreed with the agent. The Court recited the familiar rule that specific jurisdiction "must arise out of contacts that the defendant himself creates with the forum," and not random or fortuitous contacts the defendant happens to have with residents of that forum. 134 S. Ct. at 1122 (emphasis and internal quotation marks omitted). Applying that rule, the Court concluded that the federal agent "formed no jurisdictionally relevant contacts with Nevada" because he "never traveled to, conducted activi-

ties within, contacted anyone in, or sent anything or anyone to Nevada." *Id.* at 1124. In fact, "none" of the agent's conduct "had anything to do with Nevada." *Id.* at 1125. The mere fact that the agent had contact with two Nevada residents *in Atlanta* was not enough to subject him to jurisdiction in the plaintiffs' home State, even if he knew that his conduct might affect the plaintiffs there. *Id.* at 1120. As the Court reasoned, "our minimum contacts analysis looks to the defendant's contacts with the forum State itself, not the defendant's contacts with persons who reside there." *Id.* at 1122 (internal quotation marks omitted).

Mylan seizes on that language to argue that "*Walden* thus squarely forecloses basing specific jurisdiction over Mylan on the place where AstraZeneca 'suffered' the 'consequences' of the ANDA filings." Mylan Br. 29. But *Walden* merely reiterated the familiar precept that a defendant's fortuitous contacts with a plaintiff *outside the plaintiff's home State* are insufficient to establish jurisdiction in that State, even where the plaintiff feels the effects there. This is what the Court meant when it said that "the plaintiff cannot be the *only* link between the defendant and the forum." 134 S. Ct. at 1122 (emphasis added).

*Walden* did nothing to disturb the long line of cases holding that conduct *purposely directed at a plaintiff in its home State* may subject the defendant to jurisdiction there. *See, e.g.*, *Calder*, 465 U.S. at 788-790; *cf. McGee*

v. *International Life Insurance Co.*, 355 U.S. 220, 223 (1957). In such a case, the defendant's contacts with the plaintiff and with the forum State are closely "intertwined," as *Walden* recognized. *See* 134 S. Ct. at 1123. Indeed, where a defendant's act causes injury in a plaintiff's home State, the plaintiff's residence in that State "may strengthen the case for the exercise of specific jurisdiction." *Goodyear Dunlop Tires Operations, S.A.* v. *Brown*, 131 S. Ct. 2846, 2857 n.5 (2011) (emphasis omitted); *accord Keeton*, 465 U.S. at 780.

In this case, AstraZeneca is not arguing that jurisdiction is proper in Delaware merely because some injury that Mylan caused outside that State is having ripple effects in Delaware. To the contrary, Mylan took express aim at AstraZeneca's interests in Delaware, and AstraZeneca suffered the effects of that conduct there. Nothing in *Walden* suggests that jurisdiction is improper under those circumstances.

d. In addition, as the district court correctly noted, Mylan created an additional suit-related contact with Delaware that supports the exercise of specific jurisdiction in this case: it sent letters notifying AstraZeneca Pharmaceuticals LP of the paragraph IV certifications. *See* JA15.

This Court's own decisions acknowledge that the mailing of a letter ranks as a jurisdictionally significant contact. The Court has confronted the issue in the context of declaratory-judgment actions in which the plaintiff, an

alleged infringer, seeks to establish jurisdiction over a patentee on the basis of a cease-and-desist letter that the patentee mailed into the forum State. In multiple cases, the Court has recognized that the mailing of such a letter suffices to create "minimum contacts" with the forum State, though it ultimately held in each case that principles of fairness and reasonableness precluded the exercise of personal jurisdiction. *See, e.g.*, *Avocent Huntsville Corp.* v. *Aten International Co.*, 552 F.3d 1324, 1333 (Fed. Cir. 2008); *Red Wing Shoe Co.* v. *Hockerson-Halberstadt, Inc.*, 148 F.3d 1355, 1360-1361 (Fed. Cir. 1998). Specifically, the Court reasoned that a patentee should be permitted to notify a potential infringer of its property rights without subjecting itself to litigation in a distant forum. *See Avocent*, 552 F.3d at 1333; *Red Wing Shoe*, 148 F.3d at 1360-1361. Those policy concerns are inapposite here for the simple reason that Mylan is the alleged infringer, not the patentee.

Mylan contends that the notice letters it sent to AstraZeneca Pharmaceuticals LP in Delaware cannot give rise to personal jurisdiction because it is the filing of an ANDA, and not the mailing of the notice letters, that constitutes the act of infringement under the Hatch-Waxman Act. *See* Mylan Br. 30-31. But the Supreme Court's precedents treat a defendant's contacts with the forum State as relevant even if they do not give rise to the claim at issue; it is sufficient that the contacts "relate to" the claim in some way. *See Burger King*, 471 U.S. at 472; *Helicopteros Nacionales de Colombia, S.A.* v. *Hall*,

466 U.S. 408, 414 (1984). Here, the letters relate to the claim because they are part and parcel of the broader statutory mechanism by which Mylan has triggered litigation concerning AstraZeneca's patent rights.

Next, Mylan contends that this Court's decision in *Zeneca*, *supra*, precludes treating the notice letters as jurisdictionally relevant contacts. *See* Mylan Br. 32-34. In that case, the Court held that the filing of an ANDA with FDA does not give rise to specific jurisdiction in Maryland, where FDA's offices are based. But the two judges who formed the majority in that case relied on grounds unique to the context of petitioning the federal government. *See* 173 F.3d at 832 (opinion of Gajarsa, J.); *id.* at 835 (opinion of Rader, J.). *Zeneca* thus does not stand for the broader proposition that the mailing of a document to a private party does not qualify as a contact with the forum State.

Finally on this point, Mylan contends that the mailing of the letters should not be considered as part of the jurisdictional analysis because it did not result from a "voluntary decision" on Mylan's part, but was instead required by the statutory scheme. *See* Mylan Br. 35. But the letters were "voluntary" in the sense that matters here, because they resulted from Mylan's purposeful decision to challenge a drug manufacturer's patent rights under the procedures established by the Hatch-Waxman Act. That action could hardly be considered an "involuntary" contact with the forum State.

Of course, as the preceding discussion makes clear, AstraZeneca takes the position that, even if Mylan had mailed the notice letters only to AstraZeneca's headquarters in Sweden, Mylan engaged in sufficient additional contacts with Delaware to support the exercise of specific jurisdiction there. At a minimum, however, the mailing of the letters, like any other purposeful conduct by Mylan, is "certainly a relevant contact" for purposes of the jurisdictional analysis here. *Walden*, 134 S. Ct. at 1122.

### B. Subjecting Mylan To Specific Personal Jurisdiction In Delaware Would Be Fair And Reasonable

After determining that a defendant has established minimum contacts with a forum State, a court must further determine whether "the assertion of personal jurisdiction would comport with fair play and substantial justice." *Burger King*, 471 U.S. at 476 (internal quotation marks omitted). As is relevant here, in making that determination, courts consider "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." *Id.* at 476-477 (internal quotation marks omitted). Where, as here, the defendant "purposefully has directed his activities at forum residents," the defendant "must present a compelling case that the presence of some other considerations would render jurisdiction unreasonable." *Id.* at 477.

Tellingly, Mylan does not even attempt to argue that the exercise of jurisdiction is unfair or unreasonable when those factors are taken into account; instead, it argues only that exercising jurisdiction would be unfair and unreasonable because the act of mailing a letter into a forum is an insufficient basis for jurisdiction. *See* Mylan Br. 46-49. As explained above, however, this Court has held that exercising jurisdiction based on the mailing of a letter is unfair and unreasonable only where it was the *patentee* that sent a letter into the forum threatening suit for patent infringement. *See* p. 34, *supra*. No comparable policy consideration exists in this case. If the Court concludes that Mylan has sufficient minimum contacts with Delaware, it should proceed to consider the familiar factors set out above. And as the district court correctly determined, each of those factors strongly weighs in favor of the exercise of jurisdiction here. *See* JA16.

### *1. Mylan Is Not Burdened By Litigating In Delaware*

Any burden to Mylan of litigating this case in Delaware—a scant 300 miles from its home in West Virginia—is slight indeed. As this Court has recognized, "'modern transportation and communications have made it much less burdensome for a party sued to defend [itself]' outside its home state." *Patent Rights Protection Group*, 603 F.3d at 1370 (alteration in original) (quoting *Burger King*, 471 U.S. at 474). Mylan cannot possibly show that litigation in Delaware would be "so gravely difficult and inconvenient" that it is

at a "severe disadvantage" in comparison to AstraZeneca. *Burger King*, 471 U.S. at 478.

That is particularly true because Mylan is no stranger to Delaware or the Delaware courts. As noted above, Mylan has registered to do business in Delaware and is licensed by the Delaware Board of Pharmacy—factors that undoubtedly bear not just on the existence of minimum contacts, but also on the fairness of exercising jurisdiction over Mylan in Delaware. *See* p. 27, *supra*. What is more, Mylan frequently appears in the Delaware courts. JA16. Not only does Mylan regularly defend patent-infringement actions in the district court in Delaware; since 2010, it has filed at least four actions in that court as a *plaintiff*. *See Mylan Inc.* v. *Boehringer Ingelheim Int'l GMBH*, Civ. No. 10-244; *Mylan Pharmaceuticals, Inc.* v. *Eurand Inc.*, Civ. No. 10-306; *Mylan Pharmaceuticals, Inc.* v. *Galderma Labs. Inc.*, Civ. No. 10-892; *Mylan Pharmaceuticals, Inc.* v. *Ethypharm SA*, Civ. No. 10-1064. It is therefore unsurprising that Mylan does not even assert that it would be substantially burdened by litigating in Delaware.

In considering the burden to Mylan of litigating in Delaware, moreover, the Court should take into account the valuable benefit the Hatch-Waxman Act confers on generic manufacturers by permitting them to challenge patent rights without actually launching a potentially infringing product that could subject them to ruinous damages. If, as Mylan asserts, a pa-

tentee were limited to suing a generic manufacturer on the latter's home turf, the generic manufacturer would reap all of the benefits of the Section 271(e) cause of action while obtaining the added benefit of litigating all disputes at home. Nothing in the Hatch-Waxman Act suggests that Congress intended to afford that added benefit to potential infringers.

#### *2. The Interests Of The Plaintiff And Of The Judicial System Both Favor The Assertion of Jurisdiction In Delaware*

Mylan's proposed rule—that specific jurisdiction is available, if at all, only in the State where the defendant prepared the ANDA—would ordinarily consign patentees to litigating in the defendant's home forum. Such a rule would have particularly acute consequences in cases such as this one, where multiple generic manufacturers file ANDAs concerning the same patented drug. If, as Mylan proposes, the patentee may sue only in the State where the ANDA was prepared, the patentee would often have to prosecute its patent-infringement claim against each defendant in a different State—even though the claim, and the evidence, would be virtually identical across all of those cases.

Even if the cases could be consolidated for discovery purposes through the multidistrict litigation process, moreover, the delays inherent in that process would threaten to jeopardize completion of litigation within the 30-month period prescribed in the Hatch-Waxman Act—leading to the distinct

possibility that brand-name manufacturers would face generic competition even before a decision on the merits. In addition, patentees could well face inconsistent verdicts across various jurisdictions, raising the prospect that a district court's finding of invalidity could trigger approval of a generic manufacturer's ANDA before this Court is able to intervene. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(I). As this Court has held, such practical considerations are appropriately taken into account in assessing the propriety of a jurisdictional rule. *See Avocent*, 552 F.3d at 1333; *Red Wing Shoe*, 148 F.3d at 1360-1361.

As the district court recognized, AstraZeneca's interest in litigating related ANDA cases together in a single forum is a compelling one. *See* JA16. And that interest is shared by Delaware and the entire judicial system. Delaware has an interest in discouraging patent infringement that causes injury in Delaware. *Beverly Hills Fan*, 21 F.3d at 1568; *see generally McGee*, 355 U.S. at 223 (noting that a State "has a manifest interest in providing effective means of redress for its residents"). And the entire judicial system has an interest "in cooperating . . . to provide a forum for efficiently litigating plaintiff's cause of action." *Beverly Hills Fan*, 21 F.3d at 1568 (citing *Keeton*, 465 U.S. at 777). Those interests far outweigh the minimal burden to Mylan of litigating in Delaware. Because Mylan established minimum contacts with Delaware, and because it would not be unfair or unreasonable to subject Mylan to personal jurisdiction there, the district court correctly determined

that Mylan is subject to specific jurisdiction in Delaware, and its order denying Mylan's motion to dismiss should be affirmed.

## II. IN THE ALTERNATIVE, MYLAN IS SUBJECT TO GENERAL JURISDICTION IN DELAWARE

The district court's order denying Mylan's motion to dismiss can also be affirmed on the alternative ground that Mylan consented to general jurisdiction in Delaware when it elected to register there.

### A. Consent Is A Valid Basis For The Exercise Of General Jurisdiction

#### *1. The Supreme Court Has Long Recognized Consent As A Basis For General Jurisdiction*

a. It is well established that, because the requirement that a court have personal jurisdiction is an "individual right," a defendant can waive that requirement by consenting to the exercise of jurisdiction. *Insurance Corp. of Ireland* v. *Compagnie des Bauxites de Guinee*, 456 U.S. 694, 703 (1982). And a defendant need not provide that consent expressly; the Supreme Court has long held that defendants may consent to personal jurisdiction by voluntarily using "certain state procedures." *Id.* at 704.

b. Applying that principle, the Supreme Court has held for more than a century that States may validly condition an out-of-state corporation's registration to do business on its consent to be sued in that State's courts. In *Ex Parte Schollenberger*, 96 U.S. (6 Otto) 369 (1878), the Court first held that

a state legislature may require an out-of-state corporation to "consent" to be sued in state courts as a condition of being granted the privilege of doing business in the State. *See id.* at 377.

The Court expanded that rule in *Pennsylvania Fire Insurance Co.* v. *Gold Issue Mining & Milling Co.*, 243 U.S. 93 (1917). There, the defendant had obtained a license to do business in Missouri and appointed the state superintendent of insurance as its agent to receive service of process. *Id.* at 94. An out-of-state plaintiff brought suit against the defendant in Missouri based on a contract issued outside Missouri. *Id.* The defendant contested personal jurisdiction, arguing that its appointment of an agent conferred specific but not general jurisdiction. *See id.* at 94-95. The Missouri Supreme Court disagreed with the defendant's interpretation of the statute and held that it was subject to general jurisdiction. *See id.* at 95.

The Supreme Court affirmed the Missouri courts' exercise of general jurisdiction. The Court noted that, if the defendant had consented to service of process in that particular case, "there would be no doubt of the jurisdiction of the state court over a transitory action of contract." *Pennsylvania Fire Insurance*, 243 U.S. at 95. Similarly, if the defendant had authorized an agent to accept service in transitory cases in general, there would be "equally little doubt" of the court's jurisdiction. *Id.* Because the defendant did appoint an agent pursuant to a state law with language that "rationally might

be held to go to that length"—and that the Missouri Supreme Court had in fact construed to go to that length—the Court concluded that the exercise of jurisdiction "did not deprive the defendant of due process of law." *Id.*

The Court distinguished the case before it from cases involving out-of-state corporations doing business in a State "*without* authority." *Pennsylvania Fire Insurance*, 243 U.S. at 95 (emphasis added). In such cases, the Court recognized, the corporations were subject to specific jurisdiction on the "fiction" that they were "presumed to have assented," but they were not presumed to have consented to general jurisdiction. *Id.* at 96 (citing, *inter alia*, *Old Wayne Mutual Life Ass'n* v. *McDonough*, 204 U.S. 8 (1907), and *Lafayette Insurance Co.* v. *French*, 59 U.S. (18 How.) 404 (1856)). In contrast to those cases, the Court reasoned, the case before it involved actual rather than fictional consent: "[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. The execution was the defendant's voluntary act." *Id.*

The Court provided further clarification in *Robert Mitchell Furniture Co.* v. *Selden Breck Construction Co.*, 257 U.S. 213 (1921). There, as in *Pennsylvania Fire Insurance*, the plaintiff sought to obtain general jurisdiction over an out-of-state corporation that had appointed an in-state agent to receive service of process. *Id.* at 214-215. The Court remarked that "[t]he

purpose in requiring the appointment of such an agent is primarily to secure local jurisdiction in respect of business transacted within the State." *Id.* at 215. Citing *Pennsylvania Fire Insurance*, however, the Court additionally observed that a state court may construe a statute requiring out-of-state corporations to appoint in-state agents to "extend [jurisdiction] to suits in respect of business transacted by [a] foreign corporation elsewhere." *Id.* at 216.

Together, *Pennsylvania Fire Insurance* and *Robert Mitchell Furniture* permit States to condition the privilege of doing business within a State on an out-of-state corporation's consent to the State's exercise of general jurisdiction. *See Neirbo Co.* v. *Bethlehem Shipbuilding Corp.*, 308 U.S. 165, 175 (1939) (citing *Pennsylvania Fire Insurance* for the proposition that "[a] statute calling for such a designation is constitutional, and the designation of the agent a voluntary act" (internal quotation marks omitted)).

#### *2.* Pennsylvania Fire Insurance *Remains Valid Precedent That This Court Must Follow*

a. Mylan acknowledges *Pennsylvania Fire Insurance* and its progeny, but asserts that the Supreme Court implicitly overruled those cases in either *International Shoe Co.* v. *Washington*, 326 U.S. 310 (1945), or *Daimler AG* v. *Bauman*, 134 S. Ct. 746 (2014). *See* Mylan Br. 15-18, 21-22. Mylan is incorrect. As a preliminary matter, this Court does not have authority to deem Supreme Court cases implicitly overruled, because only the Supreme

Court has "the prerogative of overruling its own decisions." *De Quijas* v. *Shearson/American Express, Inc.*, 490 U.S. 477, 484 (1989).

b. In any event, neither *International Shoe* nor *Daimler* undermines *Pennsylvania Fire Insurance* or *Robert Mitchell Furniture* in any way. In *International Shoe*, the Supreme Court shifted the focus of the personal-jurisdiction analysis from a defendant's physical "presence" in a State to the defendant's "minimum contacts" with the State. 326 U.S. at 316. In so doing, the Court did away with the "legal fiction" that a company impliedly "consent[s]" to be sued in a State simply by doing business there. *See id.* at 318. At the same time, however, the Court reaffirmed that consent was an alternative basis for jurisdiction. *See id.* at 317 (noting that specific jurisdiction may exist "when the activities of the corporation there have not only been continuous and systematic, but also give rise to the liabilities sued on, *even though no consent to be sued or authorization to an agent to accept service of process has been given*" (emphasis added)).

Mylan's argument that *International Shoe* silently abrogated *Pennsylvania Fire Insurance* and *Robert Mitchell Furniture* rests on its mistaken assertion that those cases involved a theory of "fictional" consent. Mylan Br. 21. They did not. As noted above, in *Pennsylvania Fire Insurance*, the Court expressly distinguished *actual* consent (by means of compliance with a state registration statute) from *fictional* consent; indeed, the Court cited a

New York Court of Appeals decision by Justice Cardozo drawing precisely that distinction. *See* 243 U.S. at 95-96 (citing *Bagdon* v. *Philadelphia & Reading Coal & Iron Co.*, 217 N.Y. 432, 436-437 (1916)).

Likewise, none of the cases decided by the Court in the period between *International Shoe* and *Daimler* can be read to overrule *Pennsylvania Fire Insurance* and *Robert Mitchell Furniture*. To the contrary, even after *International Shoe*, the Court has cited pre-*International Shoe* cases for the proposition that States may properly construe "the voluntary use of certain state procedures" to constitute consent to jurisdiction. *Insurance Corp. of Ireland*, 456 U.S. at 704. The Court has specifically cited *Pennsylvania Fire Insurance* in a post-*International Shoe* general-jurisdiction case, *see Perkins* v. *Benguet Consolidated Mining Co.*, 342 U.S. 437, 446 n.6 (1952), and has reaffirmed the distinction between actual and fictional consent on which *Pennsylvania Fire Insurance* relied, *see Olberding* v. *Illinois Central Railroad Co.*, 346 U.S. 338, 340-342 (1953); *see also Burger King*, 471 U.S. at 472 (noting that the requirement of *International Shoe* that a defendant have fair warning that its activities will confer jurisdiction applies to an "out-of-state defendant *who has not consented to suit there*" (emphasis added)).

Mylan relies on *Shaffer* v. *Heitner*, 433 U.S. 186 (1977), which stated that, "[t]o the extent that prior decisions are inconsistent with [the *International Shoe*] standard, they are overruled," *id.* at 212 n.39. But *Shaffer* did

not involve a question of consent, and the Court in *Shaffer* expressly recognized the possibility that compliance with a state statute would constitute consent to jurisdiction. *See id.* at 216. It seems unlikely that the Court would have mentioned that possibility if it thought it had overruled that basis for jurisdiction in the very same opinion.[6]

c. Mylan's principal argument, accepted by the district court below, is that the Supreme Court's recent decision in *Daimler* implicitly invalidated consent-by-registration as a basis for general jurisdiction. But *Daimler* merely concerns what contacts a defendant must have with a forum in order to confer general jurisdiction *absent consent*, and it therefore has no bearing on the issue this case presents.

In *Daimler*, Argentinian plaintiffs brought suit against Daimler, a German company, in California federal court based on events that had occurred in Argentina. 134 S. Ct. at 750-751. The Court held that Daimler was not subject to general jurisdiction in California. *Id.* at 751. In so doing, it re-

[6] Mylan also cites the plurality opinion in *Burnham* v. *Superior Court*, 495 U.S. 604 (1990), as having recognized that *International Shoe* abrogated a "consent" theory of jurisdiction. *See* Mylan Br. 21. As an example of that "consent" theory, however, the plurality cited *Hess* v. *Pawloski*, 274 U.S. 352 (1927), in which the Court held that a state could deem a natural person's use of a State's highways to create "implied consent" to jurisdiction in proceedings arising from that use. *Id.* at 356. *Hess* was a prototypical case of fictional consent. Notably, the *Burnham* plurality recognized the ongoing validity of *actual* consent as a basis for jurisdiction. *See* 495 U.S. at 617.

jected the argument that a defendant is subject to general jurisdiction wherever its in-state contacts are "continuous and systematic." *Id.* at 761. Instead, the Court held that, in order to justify the exercise of general jurisdiction, a defendant's in-state contacts must be "so continuous and systematic as to render it essentially at home in the forum State." *Id.* (internal quotation marks and alterations omitted). The Court explained that a defendant will satisfy that test in the States of its incorporation and its principal place of business, although the Court left open the possibility that a defendant's other contacts may suffice in "exceptional" cases. *Id.* at 761 n.19.

There was no argument in *Daimler*—nor could there have been—that the defendant had consented to general jurisdiction by registering to do business in California. The Court did not indicate that either Daimler or its American subsidiary was registered to do business as an out-of-state corporation in California. But even if they were, the California courts have long construed California's registration statutes not to require consent to general jurisdiction. *See, e.g.*, *Thomson* v. *Anderson*, 113 Cal. App. 4th 258, 268 (2003).

Directly contrary to Mylan's argument, moreover, *Daimler* actually *confirms* that consent is an alternative basis for a court to exercise general jurisdiction over an out-of-state defendant. In discussing its general-jurisdiction precedents, the Court described *Perkins*, *supra*, as "the textbook

case of general jurisdiction appropriately exercised over a foreign corporation *that has not consented to suit in the forum*." *Daimler*, 134 S. Ct. at 755-756 (emphasis added) (quoting *Goodyear*, 131 S. Ct. at 2856). The Court therefore affirmed that the minimum-contacts analysis conducted in *Perkins* (as refined in *Daimler* itself) does *not* apply when the defendant has consented to jurisdiction. In other words, *Daimler* expressly distinguishes between the exercise of general jurisdiction based on a defendant's contacts with a forum and the exercise of general jurisdiction based on a defendant's consent. *See id.*; *see also Goodyear*, 131 S. Ct. at 2856; *Perkins*, 342 U.S. at 443 n.4.

Because *Daimler*'s only reference to "consent" belies Mylan's argument, Mylan cannot colorably argue that the Court overruled *Pennsylvania Fire Insurance* in *Daimler*, even implicitly. Instead, Mylan's position amounts to an argument that this Court should itself overrule *Pennsylvania Fire Insurance* in order to avoid rendering *Daimler* a "practical nullity." Mylan Br. 17.

Needless to say, this Court lacks that power. *See, e.g.*, *De Quijas*, 490 U.S. at 484. But in any event, it would be wholly consistent with *Daimler* for this Court to reaffirm the longstanding principle that a State may require out-of-state corporations to consent to the exercise of general jurisdiction. The Court's rejection in *Daimler* of a more expansive test for contacts-based

general jurisdiction rested on the Court's view that such a test "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." 134 S. Ct. at 761-762 (internal quotation marks and citation omitted). But where, as here, "the state law either expressly or by local construction" has deemed registration to constitute consent to general jurisdiction, *Robert Mitchell Furniture*, 257 U.S. at 216, a registrant is on notice of the consequences of registration and can structure its conduct accordingly. *See Acorda Therapeutics, Inc.* v. *Mylan Pharmaceuticals, Inc.*, No. 14-935, 2015 WL 186833, at *14 (D. Del. Jan. 14, 2015); *Rykoff-Sexton, Inc.* v. *American Appraisal Associates, Inc.*, 469 N.W.2d 88, 90 (Minn. 1991) (en banc).

Mylan also argues that, if a State cannot circumvent *Daimler* by enacting a statute providing that a corporation doing continuous and systematic business in a State is subject to general jurisdiction, it cannot achieve that result in "two steps" by means of consent. Mylan Br. 20. The problem with a statute that imposes general jurisdiction on corporations doing continuous and systematic business in a State, however, is that the indefinite nature of that test would not allow corporations "to structure their primary conduct with some minimum assurance as to where that conduct will and will not render them liable to suit." *Daimler*, 134 S. Ct. at 762 (citation omitted). That

concern is absent when a corporation takes the affirmative step of registering to do business in a State that construes such registration as consent to general jurisdiction.

d. Courts around the country have recognized the enduring validity of *Pennsylvania Fire Insurance*, in the wake of both *International Shoe* and *Daimler*.

Since *International Shoe*, the Third and Eighth Circuits have recognized consent-by-registration as a valid basis for the exercise of general jurisdiction. *See Bane* v. *Netlink, Inc.*, 925 F.2d 637, 640 (3d Cir. 1991); *Knowlton* v. *Allied Van Lines, Inc.*, 900 F.2d 1196, 1200 (8th Cir. 1990). The American Law Institute agrees. *See* Restatement (Second) of Conflict of Laws § 44 & reporter's note (1971) (citing *Pennsylvania Fire Insurance* as support for the rule that "[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").

For its part, the Ninth Circuit has also recognized that *Pennsylvania Fire Insurance* and *Robert Mitchell Furniture* remain good law, though it ultimately concluded that the state law at issue did not require consent to jurisdiction. *See King* v. *American Family Mutual Insurance Co.*, 632 F.3d 570, 574-578 (9th Cir. 2011) (citing *Pennsylvania Fire Insurance* and *Robert Mitchell Furniture* for the principle that "federal courts must, subject to

federal constitutional restraints, look to state statutes and case law in order to determine" whether registration under state law confers jurisdiction); *see also Spiegel* v. *Schulmann*, 604 F.3d 72, 77 n.1 (2d Cir. 2010) (per curiam) (stating, in dicta, that registration to do business in New York "would have been sufficient to establish [general] personal jurisdiction").

More recently, courts have correctly construed *Daimler* as leaving consent untouched as a basis for the exercise of general jurisdiction. *See Gucci America, Inc.* v. *Bank of China*, 768 F.3d 122, 136 n.15 (2d Cir. 2014); *Perrigo Co.* v. *Merial Ltd.*, Civ. No. 14-403, 2015 WL 1538088, at *7 (D. Neb. Apr. 7, 2015); *Acorda Therapeutics*, 2015 WL 186833, at *12.

To create the illusion of a circuit conflict, Mylan cites three cases holding that compliance with a State's registration statute does not in and of itself confer general jurisdiction. *See* Mylan Br. 18-19 (citing *Wilson* v. *Humphreys (Cayman) Ltd.*, 916 F.2d 1239 (7th Cir. 1990); *Ratliff* v. *Cooper Laboratories, Inc.*, 444 F.2d 745 (4th Cir. 1971); and *Freeman* v. *Second Judicial District Court*, 1 P.3d 963 (Nev. 2000) (per curiam) (en banc)). *Wilson* and *Ratliff*, however, did not consider an argument that the relevant state courts had construed their States' registration statutes to require consent to general jurisdiction. Those cases therefore had no occasion to analyze the ongoing validity of *Pennsylvania Fire Insurance*, and they would have been

decided exactly the same way under *Robert Mitchell Furniture*'s clarification of *Pennsylvania Fire Insurance*.

*Freeman*, a Nevada state-court opinion, is the only appellate case cited by Mylan to have suggested that *Pennsylvania Fire Insurance* was abrogated by *International Shoe*, but that court failed to consider the distinction between actual and fictional consent and, in any event, was ultimately construing Nevada law. *See* 1 P.3d at 968. *Freeman* is also inconsistent with the weight of authority from state courts of last resort. *See, e.g.*, *Sternberg*, 550 A.2d at 1111; *Confederation of Canada Life Insurance Co.* v. *Vega y Arminan*, 144 So. 2d 805, 810 (Fla. 1962); *Merriman* v. *Crompton Corp.*, 146 P.3d 162, 174-177 (Kan. 2006); *Rykoff-Sexton*, 469 N.W.2d at 89-91.

### B. Mylan Knowingly Consented To General Jurisdiction When It Voluntarily Registered To Do Business In Delaware

Under the foregoing principles, Mylan consented to general jurisdiction in Delaware when it elected to register there.

1. Out-of-state corporations that wish to conduct intrastate business in Delaware must register with the Delaware Secretary of State. 8 Del. Code §§ 371(b), 373. The registration must identify the corporation's registered agent in Delaware, on whom "[a]ll process issued out of any court of this State . . . may be served." 8 Del. Code § 376(a); *see* 8 Del. Code § 371(b)(2). Failure to comply with the registration requirement subjects a corporation to minimal fines and prevents the corporation from initiating suit

in Delaware courts until it has complied with the law. 8 Del. Code §§ 378, 383(a).

The Delaware Supreme Court has construed those statutes to provide that, when an out-of-state corporation submits a registration, it "express[ly]" consents to the exercise of general jurisdiction by Delaware courts. *Sternberg*, 550 A.2d at 1116. The Delaware Supreme Court reached that conclusion by contrasting the broad language of section 376(a) with the language of section 382(a), which appoints the Delaware Secretary of State as the agent of any out-of-state corporation that does business in Delaware *without* authorization, to accept process in any case "arising or growing out of any business transacted by [the corporation] within this State." 8 Del. Code § 382(a). Regardless of whether this Court would adopt that construction in the first instance, it is undoubtedly a "rational[]" one. *Pennsylvania Fire Insurance*, 243 U.S. at 95. And it has a rational purpose: *viz.*, to put in-state and out-of-state corporations on an equal footing and to provide a convenient forum for Delaware residents to sue out-of-state defendants that have registered to do business in Delaware and, in so doing, themselves gained access to the Delaware courts.

Notably, in *Sternberg*, the Delaware Supreme Court considered, and rejected, the argument that *International Shoe* rendered *Pennsylvania Fire Insurance* bad law. 550 A.2d at 1110-1113. The court concluded that the Su-

preme Court's post-*International Shoe* cases were entirely consistent with *Pennsylvania Fire Insurance*, stating as follows:

> If a foreign corporation has not expressly consented to a state's jurisdiction by registration, "minimum contacts" with that state can provide a due process basis for finding an implied consent to the state's jurisdiction. If 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.

*Id.* at 1113 (citations omitted).

2. When Mylan registered to do business in Delaware in 2010, *Sternberg* had been the law there for over two decades. Mylan thus knew—or should certainly be held to have known—that "state law . . . by local construction" construed registration to do business as consent to general jurisdiction in the Delaware courts. *Robert Mitchell Furniture*, 257 U.S. at 216. Under *Pennsylvania Fire Insurance* and *Robert Mitchell Furniture*, Mylan's voluntary decision to register to do business in Delaware constitutes consent to the general jurisdiction of the Delaware courts.[7]

[7] Mylan incorrectly suggests that *Sternberg* is inconsistent with *Robert Mitchell Furniture* because the latter decision stated that an *ambiguous* registration statute should not be construed to confer general jurisdiction. *See* Mylan Br. 17 n.5. In *Robert Mitchell Furniture*, however, the Court held only that an ambiguous registration statute should not be construed to confer general jurisdiction absent a definitive construction by the relevant state court. *See* 257 U.S. at 216. *Sternberg*, of course, provided just such a definitive state-court construction.

Mylan argues that it did not *voluntarily* consent to general jurisdiction because registration is *required* for corporations that wish to do business in Delaware. *See* Mylan Br. 20-21. But even assuming that is true in Mylan's case, Mylan's argument misunderstands the relevant inquiry. The Supreme Court has made clear that a defendant's *consent* need not be voluntary, as long as the defendant's underlying *actions* giving rise to the consent were voluntary. *See Insurance Corp. of Ireland*, 456 U.S. at 704. Mylan voluntarily elected to do business (and thus to register) in Delaware; that was Mylan's "voluntary act." *Pennsylvania Fire Insurance*, 243 U.S. at 96. If Mylan does not want to be subject to general jurisdiction in Delaware, it is free to withdraw its registration and to forgo doing business there. Under pre- and post-*International Shoe* case law, the voluntariness of Mylan's decision to accept both the privileges and burdens of doing business in Delaware satisfies the minimum requirements of due process. *See Insurance Corp. of Ireland*, 456 U.S. at 704; *Pennsylvania Fire Insurance*, 243 U.S. at 96.

3. As an amicus curiae in support of neither party, the Chamber of Commerce argues that Delaware's consent-by-registration statute violates the unconstitutional-conditions doctrine. *See* Chamber Br. 18-21. But Mylan itself did not make that argument in its opening brief, and it has therefore forfeited it. *See SmithKline Beecham Corp.* v. *Apotex Corp.*, 439 F.3d 1312, 1319 (Fed. Cir. 2006).

Unsurprisingly, the Chamber has not identified any case that supports its novel argument that a State may not condition registration to do business on a defendant's consent to the exercise of general jurisdiction. The Chamber principally relies on *Southern Pacific Co.* v. *Denton*, 146 U.S. 202 (1892), in which the Court invalidated a statute that required corporations to waive their right to remove cases to federal court in order to do business within the State. *Id.* at 207. In *Neirbo*, *supra*, the Court considered whether *Denton* conflicted with the rule announced in *Schollenberger* (which was later expanded in *Pennsylvania Fire Insurance*). The Court found no such conflict. The Court observed that, in *Denton*, the defendants had not validly consented to suit pursuant to the registration statute at issue because the statutory prohibition on removal to federal court rendered the statute invalid. *Neirbo*, 308 U.S. at 174. By contrast, the Court noted, "[a] statute calling for [consent to jurisdiction through appointment of an agent] is constitutional." *Id.* at 175 (citing *Pennsylvania Fire Insurance*, 243 U.S. 93). The Court thus effectively considered, and rejected, the very unconstitutional-conditions argument made by the Chamber here.[8]

[8] Notably, *Pennsylvania Fire Insurance* and *Robert Mitchell Furniture* were decided long *after* the Supreme Court developed the unconstitutional-conditions doctrine. In fact, *Pennsylvania Fire Insurance* cited earlier case law that invoked the doctrine in upholding specific jurisdiction on a theory of fictional consent. *See* 243 U.S. at 96 (citing *Lafayette Insurance*, *supra*).

The Chamber's view of the unconstitutional-conditions doctrine, moreover, ignores the doctrine's limits. The unconstitutional-conditions doctrine is not absolute; instead, it provides that "the government may not require a person to give up a constitutional right . . . in exchange for a discretionary benefit conferred by the government where the benefit sought has little or no relationship to the [right]." *Dolan* v. *City of Tigard*, 512 U.S. 374, 385 (1994). The Delaware statute, which provides its residents a convenient forum in which to sue companies that have entered Delaware to do business, easily satisfies that test, because it does not impose an "unreasonable" condition on the benefit being granted. *See Schollenberger*, 96 U.S. (6 Otto) at 376. The relationship between condition and benefit distinguishes this case from the extreme hypotheticals the Chamber posits (many of which also involve the unequal treatment of in-state and out-of-state corporations). *See* Chamber Br. 20-21.

### C. The Policy Arguments In Support Of A Contrary Rule Are Unpersuasive

Finally, to the extent that Mylan seeks to overcome the Supreme Court's black-letter law on general jurisdiction with policy arguments, those arguments are unavailing.

1. Mylan suggests that recognizing general jurisdiction by consent in this case would produce a rush to enact consent-by-registration statutes across the Nation. *See* Mylan Br. 17-18. But *Pennsylvania Fire Insurance*

has been on the books for nearly a century—and, as Mylan admits, "not all fifty states currently interpret their registration statutes as requiring consent to general jurisdiction." *Id.* at 18. In fact, ten States and the District of Columbia have adopted the Model Registered Agent Act, which expressly provides that a foreign corporation's appointment of an agent to receive service of process within a State "does not by itself create the basis for personal jurisdiction over the represented entity in this state." Uniform Law Commission, Model Registered Agents Act § 15 (2006) (amended 2011) <tinyurl.com/modelagentsact>; Uniform Law Commission, Model Registered Agents Act: Enactment Status Map <tinyurl.com/modelagentsactmap> (last generated July 16, 2015). And courts in other States have construed their registration statutes similarly. *See*, *e.g.*, *Thomson*, 113 Cal. App. 4th at 268; *Washington Equipment Manufacturing Co.* v. *Concrete Placing Co.*, 931 P.2d 170, 172-173 (Wash. Ct. App. 1997).

Moreover, the Supreme Court has recognized that "what acts of the defendant shall be deemed a submission to its power is a matter upon which states may differ." *Chicago Life Insurance Co.* v. *Cherry*, 244 U.S. 25, 29-30 (1917). Corporations may decide not to do business in States such as Delaware that require them to consent to general jurisdiction, and States that do not require consent may be viewed as being friendlier to business. It well may be that state legislatures decide it is bad policy to require out-of-state

corporations to consent to general jurisdiction. In the words of Justice Brandeis, however, "[i]t is one of the happy incidents of the federal system that a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country." *New State Ice Co.* v. *Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting). Mylan's prediction that all fifty States will quickly follow Delaware's lead, when they have not done so already, is pure fantasy.[9]

2. For its part, the Chamber of Commerce goes into full-fledged Chicken Little mode when it posits that recognizing general jurisdiction by consent in this case would subject foreign companies to claims arising "anywhere in the world," threatening international comity and impeding investment in the United States. Chamber Br. 10-13. That argument fails because there is simply no basis for concluding that foreign corporations themselves (as opposed to their American subsidiaries) are registering to do business in the United States. To use the Chamber's own hypothetical, although Toyota's American subsidiary, Toyota Motor Sales, U.S.A., Inc., is registered as a foreign corporation in Delaware, its Japanese parent is not. The Chamber provides no reason to believe that, if this Court simply adheres to the well-

[9] Moreover, Mylan's prediction of a jurisdictional "free-for-all" (Br. 18) overlooks the existence of potential Commerce Clause limitations on a State's ability to require out-of-state corporations to register in the first place. *See, e.g.*, *Allenberg Cotton Co.* v. *Pittman*, 419 U.S. 20, 33-34 (1974).

established rule that States may treat registration as consent to general jurisdiction, it will somehow trigger a flood of claims by foreign consumers against foreign companies.

In sum, the district court's holding that Mylan is subject to personal jurisdiction in Delaware is supported by well-established principles of both specific and general jurisdiction. On either or both of those grounds, the order under review should be affirmed.

## CONCLUSION

The order of the district court denying Mylan's motion to dismiss should be affirmed.

Respectfully submitted,

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JULY 16, 2015

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**CERTIFICATE OF COMPLIANCE**
**WITH TYPEFACE AND WORD-COUNT LIMITATIONS**

I, Kannon K. Shanmugam, counsel for appellee and a member of the Bar of this Court, certify, pursuant to Federal Rule of Appellate Procedure 32(a)(7)(B), that the attached Brief of Appellee is proportionately spaced, has a typeface of 14 points or more, and contains 13,975 words.

/s/ Kannon K. Shanmugam
KANNON K. SHANMUGAM

JULY 16, 2015

## CERTIFICATE OF SERVICE

I, Kannon K. Shanmugam, counsel for appellee and a member of the Bar of this Court, certify that, on July 16, 2015, a copy of the attached Brief of Appellee was filed with the Clerk and served on the parties through the Court's electronic filing system. I further certify that all parties required to be served have been served.

/s/ Kannon K. Shanmugam
KANNON K. SHANMUGAM