

No. 15-1456

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

ACORDA THERAPEUTICS INC.,
ALKERMES PHARMA IRELAND LIMITED,

Plaintiffs-Appellees,

v.

MYLAN PHARMACEUTICALS INC., MYLAN INC.,

Defendants-Appellants.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE IN
No. 1:14-cv-00935-LPS,
CHIEF JUDGE LEONARD P. STARK

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CERTIFICATE OF INTEREST

Counsel for Appellees certify the following:

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

Acorda Therapeutics, Inc. and Alkermes Pharma Ireland Limited.

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

Acorda Therapeutics, Inc. and Alkermes Pharma Ireland Limited.

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

Acorda Therapeutics, Inc. has no parent corporation and no publicly held company owns 10 percent or more of its stock. Alkermes Pharma Ireland Limited is a subsidiary of Alkermes plc, a publicly held corporation. FMR LLC; Wellington Management Company, LLP; and T. Rowe Price Associates, Inc. all own 10 percent or more of Alkermes plc's stock.

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TABLE OF CONTENTS

	<u>Page</u>
INTRODUCTION	1
STATEMENT OF THE CASE.....	4
SUMMARY OF ARGUMENT	11
STANDARD OF REVIEW	14
ARGUMENT	14
I. Mylan Knowingly And Voluntarily Consented To General Personal Jurisdiction In Delaware By Registering To Do Business In The State.....	14
A. The Requirement Of Personal Jurisdiction Is An Individual Right That May Be Waived By Consent.....	16
B. The Supreme Court’s Decision In <i>Daimler</i> Has No Bearing On Consent-Based General Personal Jurisdiction.....	26
C. Delaware’s Registration And Appointment Statutes Do Not Impose An Unconstitutional Condition On Foreign Corporations.....	33
II. Mylan Is Subject To Specific Personal Jurisdiction In Delaware.....	36
A. Mylan’s Request For FDA Approval To Distribute A Product That Will Give Rise To Future Infringing Sales In Delaware Is Sufficient To Establish Specific Personal Jurisdiction.....	36
B. Mylan’s Other Contacts With Delaware Reinforce That It Should Reasonably Have Expected To Be Haled Into Court In The State	40
C. Asserting Personal Jurisdiction Over Mylan Is Reasonable And Fair	47
CONCLUSION.....	51

TABLE OF AUTHORITIES

	<u>Page(s)</u>
Cases	
<i>Acorda Therapeutics Inc. v. Actavis Labs. FL Inc.</i> , No. 14-cv-882 (D. Del. filed July 7, 2014).....	42
<i>Adam v. Saenger</i> , 303 U.S. 59 (1938).....	23
<i>Allergan, Inc. v. Actavis, Inc.</i> , No. 2:14-cv-638, 2014 WL 7336692 (E.D. Tex. Dec. 23, 2014).....	46
<i>Allstate Ins. Co. v. Klein</i> , 422 S.E.2d 863 (Ga. 1992)	31
<i>Amoco Oil Co. v. United States</i> , 234 F.3d 1374 (Fed. Cir. 2000)	34
<i>Apotex, Inc. v. Daiichi Sankyo, Inc.</i> , 781 F.3d 1356 (Fed. Cir. 2015)	37, 46
<i>Asahi Metal Indus. Co. v. Superior Court</i> , 480 U.S. 102 (1987).....	47
<i>AstraZeneca AB v. Mylan Pharm., Inc.</i> , ___ F. Supp. 3d ___, No. 1:14-cv-696, 2014 WL 5778016 (D. Del. Nov. 5, 2014)	29
<i>Autogenomics, Inc. v. Oxford Gene Tech. Ltd.</i> , 566 F.3d 1012 (Fed. Cir. 2009)	36
<i>Avocent Huntsville Corp. v. Aten Int’l Co.</i> , 552 F.3d 1324 (Fed. Cir. 2008)	43
<i>Bagdon v. Pa. & Reading Coal & Iron Co.</i> , 111 N.E. 1075 (N.Y. 1916).....	20
<i>Bane v. Netlink, Inc.</i> , 925 F.2d 637 (3d Cir. 1991)	24
<i>Bauman v. DaimlerChrysler AG</i> , No. C-04-00194 RMW, 2005 WL 3157472 (N.D. Cal. Nov. 22, 2005)	27
<i>Beverly Hills Fan Co. v. Royal Sovereign Corp.</i> , 21 F.3d 1558 (Fed. Cir. 1994)	37, 38

Burger King Corp. v. Rudzewicz,
471 U.S. 462 (1985)..... 1, 4, 11, 12, 19, 29, 30, 33, 36, 38, 40, 43, 47, 48

Burgess v. Lowery,
201 F.3d 942 (7th Cir. 2000)34

Burnham v. Superior Court,
495 U.S. 604 (1990).....19

Calder v. Jones,
465 U.S. 783 (1984)..... 39, 41

Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S,
132 S. Ct. 1670 (2012)..... 4, 5, 6, 41

Chi. Life Ins. Co. v. Cherry,
244 U.S. 25 (1917).....23

Confederation of Can. Life Ins. Co. v. Vega y Arminan,
144 So. 2d 805 (Fla. 1962)31

Daimler AG v. Bauman,
134 S. Ct. 746 (2014)..... 2, 12, 15, 27, 28, 29, 33

Dolan v. City of Tigard,
512 U.S. 374 (1994).....34

Elecs. for Imaging, Inc. v. Coyle,
340 F.3d 1344 (Fed. Cir. 2003)14

Eli Lilly & Co. v. Medtronic, Inc.,
496 U.S. 661 (1990)..... 6, 13, 37

Eli Lilly & Co. v. Mylan Pharm., Inc.,
__ F. Supp. 3d __, No. 1:14-cv-389, 2015 WL 1125032
(S.D. Ind. Mar. 12, 2015).....49

Forest Labs, Inc. v. Amneal Pharm. LLC,
No. 14-cv-508, 2015 WL 880599 (D. Del. Feb. 26, 2015)29

Glaxo, Inc. v. Novopharm, Ltd.,
110 F.3d 1562 (Fed. Cir. 1997)37

Goodyear Dunlop Tires Ops., S.A. v. Brown,
131 S. Ct. 2846 (2011)..... 12, 15, 27, 28

Gucci Am., Inc. v. Weixing Li,
768 F.3d 122 (2d Cir. 2014)29

Hess v. Pawloski,
274 U.S. 352 (1927).....21

Holloway v. Wright & Morrissey, Inc.,
739 F.2d 695 (1st Cir. 1984).....48

Ins. Corp. of Ir., Ltd. v. Compagnie des Bauxites de Guinee,
456 U.S. 694 (1982)..... 3, 11, 15, 16, 23

Int’l Shoe Co. v. Washington,
326 U.S. 310 (1945)..... 15, 19, 21, 27

Janssen Pharmaceutica, N.V. v Apotex, Inc.,
540 F.3d 1353 (Fed. Cir. 2008)5, 6

Keeton v. Hustler Magazine, Inc.,
465 U.S. 770 (1984).....38

King v. Am. Family Mut. Ins. Co.,
632 F.3d 570 (9th Cir. 2011) 19, 25

Knowlton v. Allied Van Lines, Inc.,
900 F.2d 1196 (8th Cir. 1990) 2, 15, 24, 25

Merriman v. Crompton Corp.,
146 P.3d 162 (Kan. 2006).....31

Mittelstadt v. Rouzer,
328 N.W.2d 467 (Neb. 1982)31

N. Am. Philips Corp. v. Am. Vending Sales,
35 F.3d 1576 (Fed. Cir. 1994)37

Neirbo Co. v. Bethlehem Shipbuilding Corp.,
308 U.S. 165 (1939)..... 12, 18, 21, 22, 34, 35

Novartis Pharm. Corp. v. Mylan Inc.,
No. 1:14-cv-820, 2015 WL 1246285 (D. Del. Mar. 16, 2015)29

Olberding v. Ill. Cent. R.R.,
346 U.S. 338 (1953).....21

Otsuka Pharm. Co. v. Mylan Inc.,
__ F. Supp. 3d __, No. 14-cv-4508, 2015 WL 1305764
(D.N.J. Mar. 23, 2015).....29

Pa. Fire Ins. Co. v. Gold Issue Mining & Milling Co.,
243 U.S. 93 (1917)..... 17, 18, 35

Patent Rights Prot. Grp., LLC v. Video Gaming Techs., Inc.,
603 F.3d 1364 (Fed. Cir. 2010)14

Perkins v. Benguet Consol. Mining Co.,
342 U.S. 437 (1952)..... 19, 28

Perrigo Co. v. Merial Ltd.,
No. 8:14-cv-403, 2015 WL 1538088 (D. Neb. Apr. 7, 2015).....29

Ratliff v. Cooper Labs., Inc.,
444 F.2d 745 (4th Cir. 1971)26

Red Wing Shoe Co. v. Hockerson-Halberstadt, Inc.,
148 F.3d 1355 (Fed. Cir. 1998) 42, 43

Robert Mitchell Furniture Co. v. Selden Breck Constr. Co.,
257 U.S. 213 (1921)..... 18, 19, 25

Rykoff-Sexton, Inc. v. Am. Appraisal Assocs., Inc.,
469 N.W.2d 88 (Minn. 1991)31

Shaffer v. Heitner,
433 U.S. 186 (1977).....21

Siemer v. Learjet Acquisition Corp.,
966 F.2d 179 (5th Cir. 1992) 25, 26

Silent Drive, Inc. v. Strong Indus., Inc.,
326 F.3d 1194 (Fed. Cir. 2003) 42, 43

S. Pac. Co. v. Denton,
146 U.S. 202 (1892).....35

Sternberg v. O’Neil,
550 A.2d 1105 (Del. 1988)..... 2, 3, 11, 17, 20, 23, 26, 30, 31

Theunissen v. Matthews,
935 F.2d 1454 (6th Cir. 1991)34

Walden v. Fiore,
134 S. Ct. 1115 (2014)..... 38, 39, 40

Wellness Int’l Network Ltd. v. Sharif,
135 S. Ct. 1932 (2015)..... 16, 23, 24

Werner v. Wal-Mart Stores, Inc.,
861 P.2d 270 (N.M. 1993)31

Wilson v. Humphries (Cayman) Ltd.,
916 F.2d 1239 (7th Cir. 1990)26

World-Wide Volkswagen Corp. v. Woodson,
444 U.S. 286 (1980)..... 11, 30, 48

Zeneca Ltd. v. Mylan Pharm., Inc.,
173 F.3d 829 (Fed. Cir. 1999) 44, 45, 49

Statutes

21 U.S.C. § 355(a)4
 21 U.S.C. § 355(b)(1).....5
 21 U.S.C. § 355(j)(2)(A)(ii).....5
 21 U.S.C. § 355(j)(2)(A)(iv)5
 21 U.S.C. § 355(j)(2)(A)(vii)(IV)6
 21 U.S.C. § 355(j)(2)(B)6
 21 U.S.C. § 355(j)(5)(B)(iii) 6, 44
 35 U.S.C. § 271(a)41
 35 U.S.C. § 271(e)(2)(A)6
 42 Pa. Cons. Stat. § 530131
 Ark. Code Ann. § 4-20-115 31, 32
 Del. Code tit. 8, § 371 2, 7, 9, 17, 22, 45
 Del. Code tit. 8, § 371(b)(2).....8
 Del. Code tit. 8, § 376 2, 9, 17
 Del. Code tit. 8, § 376(a).....8
 Del. Code tit. 8, § 38122
 Del. Code tit. 24, § 254046
 Del. Code tit. 24, § 2540(a).....46
 Miss. Code Ann. § 79-35-1532

Rules

Fed. R. Civ. P. 12(h)16

Other Authorities

Model Registered Agents Act (2011)32

Nat'l Conference of Comm'rs on Uniform State Laws, <i>Registered Agents Act, Model</i> , http://www.uniformlawcommission.com/Act.aspx?title=Registered%20Agents%20Act,%20Model%20(2006)%20(Last%20Amended%202011)	32
Restatement (Second) of Conflicts of Laws (1971)	22
Charles Alan Wright & Arthur R. Miller, <i>Federal Practice & Procedure</i> (4th ed. 2015)	25

STATEMENT OF RELATED CASES

Pursuant to Federal Circuit Rule 47.5, appellees state:

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

(b) Other cases that may directly affect or be directly affected by this Court's decision include *AstraZeneca AB v. Mylan Pharmaceuticals Inc.*, No. 15-1460 (Fed. Cir. appeal docketed Mar. 17, 2015).

INTRODUCTION

“[F]air warning” and “predictability” are the touchstones of the Due Process Clause’s personal-jurisdiction requirement. *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472 (1985) (internal quotation marks omitted). In this appeal, Mylan Pharmaceuticals Inc. (“Mylan”) claims that it would violate due process to permit Plaintiffs’ suit against Mylan to proceed in Delaware, even though (1) Mylan registered to do business in the State and appointed an agent for service of process pursuant to a statutory procedure that has long been interpreted by the Delaware Supreme Court as constituting consent to general personal jurisdiction; (2) Mylan declared its intent to produce a pharmaceutical product that would be distributed for future infringing sales across the country, including in Delaware, where Mylan is licensed to manufacture and distribute drugs; (3) Mylan committed an act of infringement with respect to the patents of a Delaware pharmaceutical company; and (4) by the time Mylan provided notice to Plaintiffs of its infringing conduct, Plaintiffs had already commenced litigation in Delaware relating to the same patents. Under the circumstances, Mylan’s objections to being sued in Delaware ring hollow and ignore the undisputed facts and settled law that establish the existence of both general and specific jurisdiction in this case.

The district court found general personal jurisdiction over Mylan based on “[o]ne of the most solidly established ways” of obtaining consent-based

jurisdiction over a corporate defendant: a state law that provides that registering to do business in a State and appointing an agent for service of process constitute consent to general personal jurisdiction. *Knowlton v. Allied Van Lines, Inc.*, 900 F.2d 1196, 1199 (8th Cir. 1990). In 1988, the Supreme Court of Delaware explicitly and authoritatively held that a foreign corporation that registers to do business in the State and appoints an agent for service of process “[e]xpress[ly] consents” to the “exercise of general jurisdiction by the Courts of Delaware.” *Sternberg v. O’Neil*, 550 A.2d 1105, 1116 (Del. 1988) (construing Del. Code tit. 8, §§ 371, 376). More than twenty years later, Mylan voluntarily chose to register to do business in Delaware and appoint an agent for service of process in the State. As a matter of long-standing Delaware law, this registration and appointment constituted knowing and voluntary consent by Mylan to general personal jurisdiction in the courts of Delaware.

Mylan nevertheless objects on due-process grounds to this well-established basis for exercising general personal jurisdiction, dismissing the registration-and-appointment process as “fictional” consent and contending that the Supreme Court in *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014), *sub silentio* rejected this basis for general personal jurisdiction. Mylan Br. 30. There is nothing “fictional,” however, about Mylan’s consent to general personal jurisdiction in this case: Mylan’s decision to register to do business in Delaware and to appoint an agent for

service of process represented actual, fully informed consent because, as Mylan itself concedes, Delaware law was “absolutely clear” that these voluntary steps constitute consent to general personal jurisdiction in the State. JA22 n.14; *see also Sternberg*, 550 A.2d at 1116.

Nor is there anything in *Daimler*—where the issue of consent-based jurisdiction was not addressed by the parties or the Court—that undercuts the “uncontroversial proposition,” with which even Mylan agrees, that “personal jurisdiction is ‘an individual right’ that ‘can, like other such rights, be waived.’” Mylan Br. 17 (quoting *Ins. Corp. of Ir., Ltd. v. Compagnie des Bauxites de Guinee*, 456 U.S. 694, 703 (1982)). Mylan knowingly and voluntarily waived its “individual right” not to be sued in Delaware on causes of action unrelated to its Delaware activities when it registered to do business in the State and appointed an agent for service. Mylan has never exercised its right to withdraw that registration and its accompanying consent to general personal jurisdiction in Delaware.

In addition, the district court correctly found that Mylan’s suit-related activities are sufficient to establish specific jurisdiction over Mylan in Delaware. Litigation regarding an abbreviated new drug application (“ANDA”) is focused, by statutory definition, on acts of infringement that will occur *in the future* based on the applicant’s stated intention to manufacture and distribute a generic version of the plaintiff’s brand-name pharmaceutical product before the patents on the brand-

name product have expired. Mylan's ANDA seeks approval to market and distribute a generic drug for sale nationwide, including in Delaware, where Mylan is registered to do business and licensed to manufacture and distribute its pharmaceutical products. JA82–86. Future sales of Mylan's generic drug in Delaware would be infringing acts in Delaware. Moreover, Mylan's ANDA had immediate effects in Delaware because it constituted a statutorily defined act of infringement with respect to the patents held by Plaintiffs, one of which is a Delaware corporation. In addition, when Mylan provided notice of its ANDA to Plaintiffs, they had already initiated litigation in Delaware against another generic manufacturer that had filed an ANDA regarding the same drug. For each of those reasons, Mylan should have “reasonably anticipate[d] being haled into court” in Delaware. *Burger King*, 471 U.S. at 474 (internal quotation marks omitted).

STATEMENT OF THE CASE

A. STATUTORY BACKGROUND

Under the Hatch-Waxman Act, the U.S. Food and Drug Administration (“FDA”) regulates the process by which new and generic drugs are approved, manufactured, and sold. *See* 21 U.S.C. § 355(a). The Act requires a brand-name drug company that “wishes to market a novel drug” to “submit a new drug application” (“NDA”) to the FDA for approval. *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012). The NDA must include, among

other items, a statement of the drug's components, a description of the drug's manufacturing process, proposed labeling describing the uses of the drug, and scientific data demonstrating that the drug is safe and effective. 21 U.S.C. § 355(b)(1). The applicant must also identify all patents that "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." *Janssen Pharmaceutica, N.V. v Apotex, Inc.*, 540 F.3d 1353, 1355 (Fed. Cir. 2008) (internal quotation marks omitted). The FDA publishes a list of those patents in the "Orange Book." *Id.*

Once an innovator has obtained FDA approval for a drug, another company may seek permission, after a specified time period, to market a generic version of the drug by "piggy-backing on the brand's NDA." *Caraco Pharm.*, 132 S. Ct. at 1676. "Generic drug companies are not required to conduct their own independent clinical trials to prove safety and efficacy, but can instead rely on the research of the pioneer pharmaceutical companies." *Janssen Pharmaceutica*, 540 F.3d at 1356. To do so, the generic manufacturer must file an ANDA in which it demonstrates the "bioequivalence of its generic drug to the NDA drug." *Id.*; see also 21 U.S.C. § 355(j)(2)(A)(ii), (iv). "The ANDA applicant must also include a certification to each patent listed in the Orange Book" with respect to the branded drug. *Janssen Pharmaceutica*, 540 F.3d at 1356. If the ANDA applicant is seeking FDA approval to market its generic product prior to the expiration of any

of those Orange Book-listed patents, it must file what is known as a “Paragraph IV certification” stating that the “patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.” 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

The Hatch-Waxman Act defines a Paragraph IV certification “as itself an act of infringement,” which gives the brand-name drug company “an immediate right to sue.” *Caraco Pharm.*, 132 S. Ct. at 1677; *see also* 35 U.S.C. § 271(e)(2)(A). Because no infringing sales have actually been made, the Act establishes “a highly artificial act of infringement,” *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990), that is intended to facilitate the early resolution of patent disputes between generic companies and innovators. To that end, “[t]he ANDA filer must provide notice to the patentee and NDA holder of the factual and legal bases for the Paragraph IV Certification.” *Janssen Pharmaceutica*, 540 F.3d at 1356; *see also* 21 U.S.C. § 355(j)(2)(B). The patent holder and NDA holder then have the option of suing on any or all of the patents included in the Paragraph IV certification. If the patent holder or NDA holder files suit within 45 days of receiving notice, “the FDA generally may not approve the ANDA until 30 months pass or the court finds the patent invalid or not infringed.” *Caraco Pharm.*, 132 S. Ct. at 1677 (citing 21 U.S.C. § 355(j)(5)(B)(iii)).

B. FACTUAL BACKGROUND

This case involves Ampyra®, the first and only drug approved by the FDA for improving walking in patients with multiple sclerosis (“MS”) and the first MS drug approved for oral administration. JA54. MS is a complex neurological disease that involves both the central nervous system and the immune system, and thus drug development and treatment are particularly challenging. After years of research on the active ingredient, 4-aminopyridine, Plaintiff Acorda Therapeutics, Inc. (“Acorda”)—a Delaware corporation with its principal place of business in Ardsley, New York—filed an NDA that received priority review and approval by the FDA. JA53–54. Acorda manufactures and sells Ampyra, and holds all right, title, and interest in four Ampyra patents, U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685. JA54. Acorda is also the exclusive licensee of U.S. Patent No. 5,540,938, which is assigned to Plaintiff Alkermes Pharma Ireland Limited (“Alkermes”). *Id.* The five patents (collectively, the “Ampyra Patents”) have expiration dates between 2018 and 2027. JA60.

Mylan is a West Virginia corporation with its principal place of business in Morgantown, West Virginia. JA4. In order to secure the benefits of doing business in Delaware, Mylan has qualified to do business in the State pursuant to the procedures set forth in Del. Code tit. 8, § 371. JA79. As specified in that statute, Mylan filed on April 7, 2010, a Foreign Corporation Certificate with the

Delaware Secretary of State and appointed the Corporation Service Company as its registered agent for service of process. *Id.*; *see also* Del. Code tit. 8, §§ 371(b)(2), 376(a).

On January 22, 2014, Mylan filed ANDA No. 20-6858, seeking the FDA's approval to manufacture and sell generic versions of Ampyra prior to the expiration of the Ampyra Patents. JA6. In connection with that application, Mylan submitted a Paragraph IV certification asserting that the Ampyra Patents are "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale" of Mylan's generic drug. *Id.* Mylan notified Plaintiffs of its ANDA filing on July 9, 2014, by sending letters to Acorda at its principal place of business in New York and to Alkermes at its principal place of business in Ireland. JA7.

Mylan was not the first company to notify Plaintiffs of an ANDA filing related to the Ampyra Patents. In addition to this suit, Plaintiffs have filed seven other lawsuits in the United States District Court for the District of Delaware alleging that other companies' ANDA filings infringed their rights in the Ampyra Patents. JA6–7. Plaintiffs filed the first of those lawsuits on July 7, 2014—two days before Mylan mailed the notice letters to Plaintiffs regarding its ANDA. JA7.

C. PROCEDURAL BACKGROUND

On July 16, 2014, Plaintiffs filed this ANDA infringement action in the District of Delaware against Mylan and its parent company, Mylan Inc. JA53. The defendants moved to dismiss for lack of personal jurisdiction.¹

The district court denied the motion to dismiss, holding that Mylan was subject to both general and specific personal jurisdiction in Delaware. Although the district court determined that Mylan was not “at home” in Delaware because it neither was incorporated nor had its principal place of business in the State, JA14–15, the court held that Mylan had consented to general personal jurisdiction in Delaware. Mylan gave this consent, the district court concluded, when it registered to do business in the State and appointed an agent to accept service of process pursuant to Del. Code tit. 8, §§ 371 and 376. JA21. As the district court explained, the Delaware Supreme Court has “long and unambiguously” interpreted a foreign corporation’s registration and appointment under those provisions as “constituting consent to general jurisdiction.” JA28.

The district court determined that the constitutionality of Delaware’s registration-and-appointment procedure was supported by “[n]early a century” of Supreme Court precedent on consent-based personal jurisdiction. JA17. A

¹ Pursuant to the parties’ stipulation, the district court dismissed Mylan Inc. without prejudice on February 10, 2015. JA120–22.

contrary conclusion, the court reasoned, “would threaten to fundamentally alter the personal jurisdiction defense from a waivable to a non-waivable right, a characteristic of the defense that was not before the *Daimler* Court and is not explicitly addressed in its opinion.” JA29. Where, as here, “courts have clearly held that compliance with a state’s registration statute confers general jurisdiction,” the court concluded, “corporations have the requisite notice to enable them to structure their conduct so as to be assured where they will, and will not, be subject to suit,” and therefore have no basis for raising a due-process objection to jurisdiction. JA28.

The district court also determined that Mylan was subject to specific jurisdiction in Delaware based on its suit-related contacts with the State, which included: (1) Mylan’s ANDA filing, which, if approved by the FDA, would enable Mylan to sell its generic version of Ampyra throughout the United States, including in Delaware, JA32; (2) Mylan’s transmission of the required notice of its ANDA filing to Acorda, a Delaware corporation, and to Alkermes after they had already initiated litigation in Delaware to enforce the Ampyra Patents, *id.*; and (3) Mylan’s registration to do business in Delaware, its license from the Delaware Board of Pharmacy to manufacture and distribute drugs, and its frequent litigation in the District of Delaware, particularly in ANDA cases, JA32–33. Based on these contacts with Delaware, the district court concluded that there was a “high

degree of predictability” that Mylan would be sued by Plaintiffs in Delaware regarding its ANDA filing and that exercising specific personal jurisdiction over Mylan was “reasonable and fair” under the circumstances of this case. JA34–35 (quoting *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 295 (1980); *Burger King*, 471 U.S. at 477).

The district court certified its jurisdictional ruling for interlocutory review under 28 U.S.C. § 1292(b). This Court granted Mylan permission to appeal in this case as well as in *AstraZeneca AB v. Mylan Pharmaceuticals Inc.*, No. 15-1460, which has been designated a companion case.

SUMMARY OF ARGUMENT

The district court correctly concluded that Mylan is subject to both general and specific personal jurisdiction in this case.

I. Personal jurisdiction is “an individual right” that “can, like other such rights, be waived” through knowing and voluntary consent. *Ins. Corp. of Ir., Ltd. v. Compagnie des Bauxites de Guinee*, 456 U.S. 694, 703 (1982). Mylan knowingly and voluntarily consented to general personal jurisdiction in Delaware when it registered to do business in the State and appointed an agent for service of process pursuant to a statutory procedure that the Delaware Supreme Court has long construed as constituting “[e]xpress consent” to general jurisdiction in the State. *Sternberg v. O’Neil*, 550 A.2d 1105, 1116 (Del. 1988). The U.S. Supreme

Court has repeatedly upheld the exercise of general jurisdiction based on similar registration-and-appointment procedures because nothing in the Due Process Clause prevents a State from making consent to general personal jurisdiction “part of the bargain by which [the corporation] enjoys the business freedom of the State.” *Neirbo Co. v. Bethlehem Shipbuilding Corp.*, 308 U.S. 165, 175 (1939).

The Supreme Court’s recent personal jurisdiction jurisprudence supports this conclusion. In fact, the Court’s decision in *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014), and its other leading opinions on general personal jurisdiction all expressly distinguish between general jurisdiction based on a corporation’s contacts with the forum State and general jurisdiction based on consent. *See id.* at 755–56; *see also Goodyear Dunlop Tires Ops., S.A. v. Brown*, 131 S. Ct. 2846, 2856 (2011). Although a corporation is subject to general personal jurisdiction based on its contacts only in those States where it is “essentially at home,” *Daimler*, 134 S. Ct. at 751 (internal quotation marks omitted), corporations remain free to consent to general personal jurisdiction in other States. Mylan knowingly and voluntarily gave such consent in Delaware when it registered to do business and appointed an agent for service in the State.

II. Mylan is also subject to specific personal jurisdiction in this case because it has significant suit-related contacts with Delaware that should have led it to “reasonably anticipate being haled into court” in the State. *Burger King Corp.*

v. Rudzewicz, 471 U.S. 462, 474 (1985) (internal quotation marks omitted). This ANDA case arises from a “highly artificial act of infringement”: Mylan’s submission of an ANDA in which it declared its intention to secure FDA approval to manufacture and sell its generic version of Ampyra throughout the United States, including in Delaware, where it is registered and licensed to do business. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). The Hatch-Waxman Act permitted Plaintiffs to bring suit prior to FDA approval in order to prevent those infringing sales. Because Mylan’s ANDA filing was purposefully directed at obtaining approval to make future infringing sales in Delaware, Mylan has sufficient contacts with the State to establish specific jurisdiction in this suit relating to those future infringing acts.

Moreover, Mylan’s statutorily defined act of patent infringement had immediate effects in Delaware because its ANDA infringed the intellectual-property rights of Acorda, a Delaware corporation. In addition, Mylan sent notice of its ANDA filing to Plaintiffs *after* they had already initiated litigation in Delaware regarding the same Ampyra Patents at issue in this case and thus should reasonably have foreseen that its notice would result in litigation with Plaintiffs in Delaware. Indeed, Mylan is a frequent patent litigant in Delaware (as both a plaintiff and a defendant) and is licensed in Delaware to operate as a wholesale pharmacy and as a manufacturer and distributor of controlled substances.

Exercising specific personal jurisdiction over Mylan in this case is therefore consistent with Mylan's reasonable expectations at the time it filed its ANDA and is entirely fair and reasonable.

STANDARD OF REVIEW

“Where the facts upon which the jurisdictional inquiry turns are undisputed,” this Court “review[s] *de novo* whether a district court has personal jurisdiction over a defendant.” *Elecs. for Imaging, Inc. v. Coyle*, 340 F.3d 1344, 1348–49 (Fed. Cir. 2003). If the district court's ruling on personal jurisdiction is “based on affidavits and other written materials in the absence of an evidentiary hearing, a plaintiff need only to make a *prima facie* showing that defendants are subject to personal jurisdiction.” *Id.* at 1349. On an appeal from a motion to dismiss, the Court must “accept the uncontroverted allegations in the plaintiff's complaint as true.” *Id.*

ARGUMENT

I. Mylan Knowingly And Voluntarily Consented To General Personal Jurisdiction In Delaware By Registering To Do Business In The State.

The Due Process Clause permits a court to exercise personal jurisdiction “over a non-consenting out-of-state defendant” where the defendant has established “minimum contacts” with the forum State. *Patent Rights Prot. Grp., LLC v. Video Gaming Techs., Inc.*, 603 F.3d 1364, 1368 (Fed. Cir. 2010) (internal quotation marks omitted). Under the doctrine of “general jurisdiction,” a court has jurisdiction to hear “any and all claims against” a corporation when the

corporation's "affiliations with the State are so constant and pervasive 'as to render [it] essentially at home in the forum State.'" *Daimler AG v. Bauman*, 134 S. Ct. 746, 751 (2014) (alteration in original) (quoting *Goodyear Dunlop Tires Ops., S.A. v. Brown*, 131 S. Ct. 2846, 2851 (2011)). If general jurisdiction is lacking, a corporate defendant's "'single or occasional acts' in a State may be sufficient to render a corporation answerable in that State with respect to those acts" under the doctrine of "specific jurisdiction." *Goodyear*, 131 S. Ct. at 2853 (quoting *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 318 (1945)).

When a defendant consents to jurisdiction, however, "resort to minimum-contacts or due-process analysis to justify the jurisdiction is unnecessary." *Knowlton v. Allied Van Lines, Inc.*, 900 F.2d 1196, 1200 (8th Cir. 1990). Because personal jurisdiction "represents . . . an individual right" that "can, like other such rights, be waived," *Ins. Corp. of Ir., Ltd. v. Compagnie des Bauxites de Guinee*, 456 U.S. 694, 703 (1982), due process does not impose limits on personal jurisdiction where a defendant has knowingly and voluntarily consented to jurisdiction in a State with which it lacks minimum contacts.

The district court correctly held that Mylan consented to general personal jurisdiction in Delaware by registering to do business in the State and appointing an agent for service of process pursuant to a statutory procedure that has long been interpreted by the Delaware Supreme Court as constituting consent to jurisdiction.

In light of this knowing and voluntary consent, Mylan cannot evade jurisdiction in this case on due-process grounds.

A. The Requirement Of Personal Jurisdiction Is An Individual Right That May Be Waived By Consent.

The requirement that a court have personal jurisdiction over the defendant “represents a restriction on judicial power not as a matter of sovereignty, but as a matter of individual liberty” flowing from the Due Process Clause. *Ins. Corp. of Ir.*, 456 U.S. at 702. As Mylan itself acknowledges, personal jurisdiction “can, like other [individual] rights, be waived.” Mylan Br. 17 (quoting *Ins. Corp. of Ir.*, 456 U.S. at 703); cf. *Wellness Int’l Network Ltd. v. Sharif*, 135 S. Ct. 1932, 1944 (2015) (“personal right[s]” granted by the Constitution are “ordinarily subject to waiver”) (internal quotation marks omitted).

Parties may waive a personal jurisdiction defense in several ways. See *Ins. Corp. of Ir.*, 456 U.S. at 703–04. They may contract in advance to submit to the jurisdiction of a specified court. See *id.* They may also waive the defense by failing to timely assert it in a particular case. See Fed. R. Civ. P. 12(h). And parties may consent to personal jurisdiction through “the voluntary use of certain state procedures.” *Ins. Corp. of Ir.*, 456 U.S. at 704.

Mylan concedes that a federal court may exercise general personal jurisdiction over a foreign corporation that has “voluntarily consent[ed] to jurisdiction in a forum.” Mylan Br. 17–18. Mylan likewise does not dispute that,

when it registered to do business in Delaware and appointed an agent for service of process, it knew that it was consenting under Delaware law to general personal jurisdiction in the State. Indeed, more than twenty years before Mylan registered to do business and appointed an agent for service in Delaware, the state supreme court authoritatively held that compliance with those statutorily prescribed procedures constitutes “[e]xpress consent” to general personal jurisdiction in the State. *Sternberg v. O’Neil*, 550 A.2d 1105, 1116 (Del. 1988) (construing Del. Code tit. 8, §§ 371 and 376). Thus, “[b]y the time Mylan . . . chose to register in Delaware in 2010, it was well established . . . that such compliance constitutes consent to the general jurisdiction of the state and federal courts located in Delaware.” JA23; *see also* JA22 n.14 (“Mylan does not dispute that in *Sternberg* the Delaware Supreme Court was absolutely clear as to how it interprets the Delaware registration statute.”); Dec. 15, 2014 Hr’g Tr. at 18 (same).

Mylan nevertheless asks this Court to nullify its knowing and voluntary consent as a violation of due process. The U.S. Supreme Court, however, has repeatedly rejected constitutional challenges to state statutes that provide that registering to do business in the State and appointing an agent for service of process constitute consent to general personal jurisdiction. In *Pennsylvania Fire Insurance Co. v. Gold Issue Mining & Milling Co.*, 243 U.S. 93 (1917), for example, the Court rejected a due-process challenge to a Missouri statutory

procedure that required out-of-state corporations to appoint an agent for service, which the state supreme court had interpreted as constituting consent to general personal jurisdiction in the State. *Id.* at 95; *see also id.* (“The [statutory] language has been held to go to that length, and the construction did not deprive the defendant of due process of law . . .”). Similarly, in *Neirbo Co. v. Bethlehem Shipbuilding Corp.*, 308 U.S. 165 (1939), the Supreme Court confirmed the constitutionality of a New York statute that treated a corporation’s appointment of an agent for service as consent to general personal jurisdiction because “the designation of the agent [is] a voluntary act” that constitutes “actual consent” and is “part of the bargain by which [the corporation] enjoys the business freedom of the State of New York.” *Id.* at 175 (internal quotation marks omitted). In addition, the Court has made clear that whether compliance with a State’s registration statute constitutes consent to general personal jurisdiction is a matter of *state* law that should be resolved by *state* courts. *See Robert Mitchell Furniture Co. v. Selden Breck Constr. Co.*, 257 U.S. 213, 216 (1921).²

² Mylan twice misstates the holding of *Robert Mitchell*. Mylan Br. 14 n.6, 27. The Court did not hold, as Mylan suggests, that “where a statute requiring a corporation to appoint an agent is ambiguous as to its scope,” it “should not [be] construe[d]” to constitute consent to general personal jurisdiction. *Id.* at 14 n.6 (internal quotation marks omitted). Rather, the Court held that federal courts should not interpret an ambiguous statutory procedure as constituting consent to general jurisdiction “[u]nless the state law . . . by local construction gives” the procedure that effect. *Robert Mitchell*, 257 U.S. at 216 (emphasis added); *see also* (*Cont’d on next page*)

These authorities are consistent with the Court’s more recent personal-jurisdiction jurisprudence, which has repeatedly made clear that satisfying the “minimum contacts” standard adopted in *International Shoe* is only a constitutional prerequisite to the exercise of personal jurisdiction over a *nonconsenting* defendant. See *Perkins v. Benguet Consol. Mining Co.*, 342 U.S. 437, 443 n.4 (1952) (“[T]he doing of business in a state by a foreign corporation, which has *not* appointed a statutory agent upon whom service of process against the corporation can be made in that state *or otherwise consented to service*,” will not subject the corporation to a suit “in no way related to [that] business”) (emphases added); *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472 (1985) (same in the specific-jurisdiction setting). In this respect, personal jurisdiction over a consenting corporation is no different from personal jurisdiction over an individual served in the forum State; in neither case does the Due Process Clause require a minimum-contacts analysis. See *Burnham v. Superior Court*, 495 U.S. 604, 619 (1990) (plurality opinion of Scalia, J.) (concluding that minimum-

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King v. Am. Family Mut. Ins. Co., 632 F.3d 570, 575 (9th Cir. 2011) (“*Robert Mitchell* thus confirms that federal courts should look first and foremost to a state’s construction of its own statute to determine whether appointment of an agent for service of process is a sufficient basis for the exercise of personal jurisdiction over a foreign corporation.”). Unlike here, in *Robert Mitchell*, no state court had held that compliance with the State’s registration-and-appointment procedure constituted consent to general personal jurisdiction. 257 U.S. at 216.

contacts analysis is unnecessary where an individual is personally served in the forum State because “jurisdiction based on physical presence alone . . . is one of the continuing traditions of our legal system that define the due process standard”). Indeed, Mylan does not point to a single case in which the U.S. Supreme Court has undertaken a minimum-contacts inquiry with respect to a defendant who consented to jurisdiction in the forum.

Despite these settled authorities, Mylan asserts that its knowing and voluntary consent to general personal jurisdiction in Delaware was “purely fictional” and therefore cannot be reconciled with the requirements of due process. Mylan Br. 30. But there is nothing “fictional” about Mylan’s decision to register to do business in Delaware and appoint an agent for service of process in accordance with a statutory procedure that has been authoritatively construed to constitute consent to general personal jurisdiction. *See Sternberg*, 550 A.2d at 1116. In fact, courts have consistently distinguished between state statutes that require “*actual* consent” to jurisdiction through registration and appointment requirements, on the one hand, and forms of fictional consent, on the other. *Neirbo*, 308 U.S. at 175 (emphasis added); *see also Bagdon v. Pa. & Reading Coal & Iron Co.*, 111 N.E. 1075, 1076 (N.Y. 1916) (Cardozo, J.) (holding that a corporation’s appointment of an agent pursuant to a registration statute is “true consent”).

The forms of “fictional consent” that the Supreme Court has disapproved are far different from Mylan’s “actual consent” to general personal jurisdiction. For example, in the pre-*International Shoe* era, some States provided that an out-of-state motorist using the State’s highways “had by using those highways appointed a designated state official as his agent to accept process.” *Shaffer v. Heitner*, 433 U.S. 186, 202 (1977) (citing *Hess v. Pawloski*, 274 U.S. 352 (1927)). Those States *deemed* the motorist to have appointed an agent for service of process and thereby to have consented to jurisdiction in the absence of any *actual* appointment. *Id.* After *International Shoe*, the Supreme Court rejected this artificial justification for personal jurisdiction because, in fact, it did “not rest on consent at all.” *Olberding v. Ill. Cent. R.R.*, 346 U.S. 338, 341 (1953).

In so doing, however, the Court expressly distinguished *Neirbo*—which recognized the constitutionality of New York’s registration statute—and similar “situations where a state may validly require the designation of an agent for service of process as a condition of carrying on activities within its borders, and such designation has in fact been made.” *Olberding*, 346 U.S. at 342. As *Olberding* makes clear, the Supreme Court’s rejection of “purely fictional” theories of consent in *International Shoe* and later cases did not undermine the principle that corporations may give *actual* consent to jurisdiction by qualifying to do business under a state law that provides that registration and appointment of an agent

constitute consent. *See* Restatement (Second) of Conflicts of Laws § 43 cmts. a, b (1971) (identifying compliance with a registration statute as one of the “[m]ost common[]” ways a foreign corporation may give “actual assent” to jurisdiction).

Mylan also seeks to obscure the voluntary nature of its consent to general personal jurisdiction by casting Delaware’s registration-and-appointment procedure as “mandatory.” Mylan Br. 18 (emphasis omitted). But registration and appointment of an agent are only mandatory under Delaware law for those foreign corporations that make the *voluntary* decision to do business in the State. Del. Code tit. 8, § 371. Corporations are not *required* to do business in Delaware, and those corporations that are unwilling to consent to general personal jurisdiction in the State are free to take their business elsewhere without submitting to jurisdiction in Delaware. *See Neirbo*, 308 U.S. at 175 (“the designation of [an] agent” pursuant to a statute requiring foreign corporations to appoint an agent to accept service in the State is “a voluntary act”) (internal quotation marks omitted). In fact, Mylan asserts that it does only “sporadic business in Delaware,” Mylan Br. 6, but concedes that it has never exercised its right to withdraw its registration and attendant consent to suit in the State. *See* Del. Code tit. 8, § 381.

Nor can Mylan escape the jurisdictional implications of its consent by characterizing its consent as “implied” rather than “express.” The Delaware Supreme Court has definitively determined that a foreign corporation gives

“[e]xpress consent” to general personal jurisdiction when it “appoint[s] . . . a statutory agent to receive service of process” in accordance with Delaware law. *Sternberg*, 550 A.2d at 1116 (emphasis added).

In any event, even if Mylan’s consent is implied from its actions in registering to do business and appointing an agent, there is no requirement that a constitutional right be waived expressly. In fact, the Supreme Court has repeatedly “upheld state procedures which find *constructive* consent to the personal jurisdiction of the state court in the voluntary use of certain state procedures.” *Ins. Corp. of Ir.*, 456 U.S. at 704 (emphasis added) (citing *Adam v. Saenger*, 303 U.S. 59, 67–68 (1938); *Chi. Life Ins. Co. v. Cherry*, 244 U.S. 25, 29–30 (1917)). The same holds true with respect to other constitutional rights, which may be waived either expressly or impliedly. *See, e.g., Wellness Int’l Network*, 135 S. Ct. at 1943, 1948 (holding that litigants may consent—through “actions rather than words”—to adjudication by a bankruptcy or magistrate judge and thereby waive their “personal constitutional right[]” to “an impartial and independent federal adjudication” by an Article III judge) (citations omitted).

Whether described as express or implied, Mylan’s consent was knowing and voluntary because, given the Delaware Supreme Court’s settled jurisprudence, Mylan plainly understood when it made the choice to register to do business in the State and to appoint an agent for service that it was consenting to general personal

jurisdiction in Delaware. *See* JA22 n.14; *see also* Dec. 15, 2014 Hr’g Tr. at 18 (The Court: “Nonetheless, the Delaware Supreme Court was absolutely clear as to how they interpret the Delaware registration statute; right?” Mylan’s counsel: “Yes.”). The knowing and voluntary nature of the consent is all that matters for constitutional purposes. *See, e.g., Wellness Int’l Network*, 135 S. Ct. at 1948 n.13.

This conclusion is consistent with every federal appellate court decision that has addressed the constitutionality of state statutes that provide that a foreign corporation’s registration or appointment of an agent constitutes consent to general personal jurisdiction. In *Bane v. Netlink, Inc.*, 925 F.2d 637 (3d Cir. 1991), for example, the Third Circuit upheld a Pennsylvania statute that stated that general personal jurisdiction over corporations could be established by “qualification as a foreign corporation under the laws of” Pennsylvania. *Id.* at 640. The court reasoned that, in light of the statute’s language, the defendant had “notice that [it] was subject to personal jurisdiction in Pennsylvania” when it qualified to do business in the State. *Id.* at 641. Similarly, in *Knowlton v. Allied Van Lines, Inc.*, the Eighth Circuit upheld general personal jurisdiction under Minnesota’s registration statute, which, like the Delaware statute, did not expressly reference personal jurisdiction on its face but had been “interpreted . . . in just this way” by the state supreme court. 900 F.2d at 1200. The court concluded that the defendant’s registration pursuant to the statute was “a valid basis of personal

jurisdiction, and resort to minimum-contacts or due-process analysis to justify the jurisdiction [was] unnecessary.” *Id.*; see also 4B Charles Alan Wright & Arthur R. Miller, *Federal Practice & Procedure* § 1116 (4th ed. 2015) (“[A] company’s registration under a state appointment statute can also constitute consent to be sued in the courts of that state and a waiver of objections to the assertion of personal jurisdiction over the corporation.”).

Mylan fails in its effort to manufacture a division of appellate authority on this issue. Mylan Br. 28–29. The federal appellate decisions that have deemed corporate registration to be an insufficient ground for exercising general personal jurisdiction reached that result because the underlying state statute did not provide—either on its face or through state judicial construction—for jurisdiction over suits arising from out-of-state conduct. These cases merely reaffirm the “default rule that, *in the absence of broader statutory language or state court interpretations*, the appointment of an agent for the service of process is, by itself, insufficient to subject foreign corporations to suits for business transacted elsewhere,” and that federal courts must “look to state statutes and case law in order to determine whether a foreign corporation is subject to personal jurisdiction in a given case.” *King*, 632 F.3d at 575, 576 (emphasis added) (citing *Robert Mitchell*, 257 U.S. 213); see also *Siemer v. Learjet Acquisition Corp.*, 966 F.2d 179, 183 (5th Cir. 1992) (declining to find consent where “[n]o Texas state court

decision ha[d] held that” the State’s business registration statute gave rise to general personal jurisdiction over foreign corporations); *Wilson v. Humphries (Cayman) Ltd.*, 916 F.2d 1239, 1245 (7th Cir. 1990) (applying the canon of constitutional avoidance to conclude that corporate registration pursuant to a state statute did not constitute consent in the absence of a state court interpretation to the contrary); *Ratliff v. Cooper Labs., Inc.*, 444 F.2d 745, 748 (4th Cir. 1971) (holding that “mere compliance with state domestication statutes” did not create personal jurisdiction, without considering whether state law treated registration as consent).

Here, the Delaware Supreme Court has expressly and unambiguously held that a foreign corporation’s registration to do business in the State and appointment of an agent for service constitute consent to general personal jurisdiction. *Sternberg*, 550 A.2d at 1116. Due process therefore poses no barrier to exercising general personal jurisdiction over Mylan in this case.

B. The Supreme Court’s Decision In *Daimler* Has No Bearing On Consent-Based General Personal Jurisdiction.

Nothing in *Daimler* alters the availability of consent as a basis for general personal jurisdiction. The issue of consent was not briefed by the parties or addressed by the Court in *Daimler*, and the reasoning of the decision is fully consistent with the settled principle that foreign corporations consent to general personal jurisdiction when they register to do business and appoint an agent for service under a state law that provides that these actions constitute consent.

In *Daimler*, twenty-two Argentine residents filed a complaint in the Central District of California against a German company, alleging that its Argentine subsidiary had committed human-rights violations in Argentina. 134 S. Ct. at 750–51. The plaintiffs’ argument that the German company was subject to general personal jurisdiction in California was not based on consent—indeed, the defendant was not registered to do business in California and had no agent to accept service in the State, *see Bauman v. DaimlerChrysler AG*, No. C-04-00194 RMW, 2005 WL 3157472, at *1, *6 (N.D. Cal. Nov. 22, 2005)—but rather on the substantial volume of business that the company’s U.S. subsidiary transacted in California. *Daimler*, 134 S. Ct. at 752. The Supreme Court rejected the plaintiffs’ “grasping” approach to general personal jurisdiction, holding that a corporation may only be compelled to answer claims unrelated to its activities in the forum when its “affiliations with the State in which suit is brought are so constant and pervasive ‘as to render [it] essentially at home in the forum State.’” *Id.* at 751, 761 (alteration in original) (quoting *Goodyear*, 131 S. Ct. at 2851). The Court explained that the “paradigm all-purpose forums” are where the corporation “is incorporated or has its principal place of business.” *Id.* at 760.

In reaching that conclusion, the Court drew heavily upon, and reaffirmed the holdings of, the two other leading general jurisdiction cases that it has decided after *International Shoe*: *Goodyear* and *Perkins*. *See Goodyear*, 131 S. Ct. at

2851 (setting forth the “at home” standard for general personal jurisdiction); *Perkins*, 342 U.S. at 448 (holding that a company incorporated in the Philippines was subject to general personal jurisdiction in Ohio because the State was its principal place of business during World War II). In all three of those cases, the Court was careful to distinguish between general jurisdiction based on a corporation’s contacts with the forum State and general jurisdiction based on consent. See *Daimler*, 134 S. Ct. at 755–56; *Goodyear*, 131 S. Ct. at 2856; *Perkins*, 342 U.S. at 443 n.4. In fact, in both *Daimler* and *Goodyear*, the Court explicitly described *Perkins* 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 755–56 (emphasis added) (quoting *Goodyear*, 131 S. Ct. at 2856).

Daimler thus makes clear that the mere fact that a foreign corporation regularly conducts business in the forum is not sufficient to establish general personal jurisdiction over the corporation. 134 S. Ct. at 761. The decision says nothing, however, about the availability of general personal jurisdiction based on a corporation’s consent. See *id.* at 760 (“*Goodyear* did not hold that a corporation may be subject to general jurisdiction *only* in a forum where it is incorporated or has its principal place of business . . .”). Even if a corporation is not “at home in the forum State” within the meaning of *Daimler*, it still may be subject to general

personal jurisdiction there based on its consent. *See Gucci Am., Inc. v. Weixing Li*, 768 F.3d 122, 135–36 n.15 (2d Cir. 2014) (holding that a foreign bank was not “at home” in New York but remanding, after *Daimler*, for the district court to determine whether the bank “consented to personal jurisdiction in New York by applying for authorization to conduct business in New York and designating the New York Secretary of State as its agent for service of process”).³

Nor will the district court’s decision “make[] it impossible for corporate defendants to know in advance where their conduct ‘will and will not render them liable to suit’” in supposed “contravention of *Daimler*.” Mylan Br. 21 (quoting *Burger King*, 471 U.S. at 472). Absent consent, corporate defendants are subject to general personal jurisdiction only where they can be said to be “at home.” *Daimler*, 134 S. Ct. at 751. And where a state statute—either through explicit language or judicial construction—provides that registration to do business and appointment of an agent constitute consent, a corporation will “know in advance”

³ *See also, e.g., Perrigo Co. v. Merial Ltd.*, No. 8:14-cv-403, 2015 WL 1538088, at *7 (D. Neb. Apr. 7, 2015) (concluding that *Daimler* “does nothing to affect the long-standing principle that a defendant may consent to personal jurisdiction” by registering to do business in Nebraska); *Otsuka Pharm. Co. v. Mylan Inc.*, ___ F. Supp. 3d ___, No. 14-cv-4508, 2015 WL 1305764, at *1 (D.N.J. Mar. 23, 2015) (same); *Novartis Pharm. Corp. v. Mylan Inc.*, No. 1:14-cv-820, 2015 WL 1246285, at *3 (D. Del. Mar. 16, 2015) (same); *Forest Labs, Inc. v. Amneal Pharm. LLC*, No. 14-cv-508, 2015 WL 880599, at *10 (D. Del. Feb. 26, 2015) (magistrate judge). *But see AstraZeneca AB v. Mylan Pharm., Inc.*, ___ F. Supp. 3d ___, No. 1:14-cv-696, 2014 WL 5778016 (D. Del. Nov. 5, 2014).

that, if it chooses to avail itself of those procedures, it will become subject to general personal jurisdiction in the State upon registering to do business and appointing an agent. That is precisely the type of “predictability . . . that allows potential defendants to structure their primary conduct with some minimum assurance as to where that conduct will and will not render them liable to suit.” *Burger King*, 471 U.S. at 472 (quoting *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 297 (1980)).

Mylan can hardly complain that it was surprised by the district court’s ruling that it is subject to general personal jurisdiction in Delaware. Mylan registered to do business and appointed an agent for service of process in Delaware more than twenty years after the Delaware Supreme Court had unambiguously held that those actions constitute consent to general personal jurisdiction. JA79; *see also Sternberg*, 550 A.2d at 1116. Upon taking those steps, Mylan was in a position to predict with absolute certainty that Delaware was among the States in which it is subject to general personal jurisdiction. At no point has Mylan exercised its right to withdraw its registration and appointment and the consent that accompanied those actions.⁴

⁴ The fact that “many states have not yet addressed the consequences of registration for consent to general jurisdiction” therefore has no bearing on this case, where it has been established for more than two decades that registration and appointment constitute consent in Delaware and Mylan knowingly and voluntarily
(*Cont’d on next page*)

Mylan has equally little basis for contending that a decision upholding general personal jurisdiction here would lead to a “jurisdictional free-for-all, in which a corporation could be sued on any claim in any state where it operates.” Mylan Br. 21. Although every State has a foreign corporation registration statute, no more than a dozen States have expressly and unambiguously provided, through statutory language or state judicial decision, that foreign corporations consent to general personal jurisdiction in the State when they register to do business there.⁵ In fact, several States have expressly limited the scope of an agent’s authorization to accept service on behalf of a foreign corporation when that agent is appointed pursuant to the State’s business-registration statute. *See, e.g.*, Ark. Code Ann. § 4-20-115 (“The appointment or maintenance in this state of a registered agent does

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decided to invoke those procedures. Mylan Br. 22. Moreover, while the Delaware Supreme Court “ha[s] not revisited the issue after *Daimler*,” *id.*, there is no reason to think that the court would abandon its settled interpretation of state law on the basis of a U.S. Supreme Court decision that addressed neither consent-based jurisdiction nor Delaware law.

⁵ *See, e.g.*, *Sternberg*, 550 A.2d at 1113 (Delaware); *Confederation of Can. Life Ins. Co. v. Vega y Arminan*, 144 So. 2d 805, 810 (Fla. 1962); *Allstate Ins. Co. v. Klein*, 422 S.E.2d 863, 864–65 (Ga. 1992); *Merriman v. Crompton Corp.*, 146 P.3d 162, 170 (Kan. 2006); *Rykoff-Sexton, Inc. v. Am. Appraisal Assocs., Inc.*, 469 N.W.2d 88, 90–91 (Minn. 1991); *Mittelstadt v. Rouzer*, 328 N.W.2d 467, 469 (Neb. 1982); *Werner v. Wal-Mart Stores, Inc.*, 861 P.2d 270, 272–73 (N.M. 1993); 42 Pa. Cons. Stat. § 5301 (Pennsylvania).

not by itself create the basis for personal jurisdiction over the represented entity in this state.”); Miss. Code Ann. § 79-35-15.⁶

States have therefore reached different conclusions as to whether it is good policy to pass laws providing that foreign corporations that register to do business in the State and appoint an agent for service of process thereby consent to general personal jurisdiction. While nothing in the Due Process Clause constrains States’ ability to enact such laws, that does not mean that corporations are left helpless in the face of these enactments. If corporations are reluctant to submit to general personal jurisdiction in States where they are not “at home,” they can choose to forgo doing business in States where registration and appointment of an agent constitute consent to general personal jurisdiction. That step would shield corporations from general personal jurisdiction in States where they are not “at home” and may ultimately prompt the legislatures of some States to amend their registration-and-appointment statutes to limit the scope of corporations’ consent in order to make their States more attractive to foreign corporations. In either event,

⁶ Many of these provisions are based on the Model Registered Agents Act § 15 (2011), which was drafted by the National Conference of Commissioners on Uniform State Laws. Ten States and the District of Columbia have adopted this model act. See Nat’l Conference of Comm’rs on Uniform State Laws, *Registered Agents Act, Model*, [http://www.uniformlawcommission.com/Act.aspx?title=Registered%20Agents%20Act,%20Model%20\(2006\)%20\(Last%20Amended%202011\)](http://www.uniformlawcommission.com/Act.aspx?title=Registered%20Agents%20Act,%20Model%20(2006)%20(Last%20Amended%202011)) (last visited July 15, 2015).

it is within corporations' ability "to structure their primary conduct" based on where they are, and are not, amenable to general jurisdiction. *Burger King*, 471 U.S. at 472 (internal quotation marks omitted). The Due Process Clause does not demand anything more in this setting.⁷

C. Delaware's Registration And Appointment Statutes Do Not Impose An Unconstitutional Condition On Foreign Corporations.

Amicus U.S. Chamber of Commerce—but not Mylan itself—argues that States impose unconstitutional conditions on the ability of foreign corporations to do business in the State when they enact measures that provide that registering to do business and appointing an agent for service constitute consent to general personal jurisdiction in the State. *See* Chamber Br. 18–21. *Amicus'* argument is not properly before this Court because it was not raised in Mylan's opening brief.

⁷ Mylan contends that the district court's decision would permit Delaware to "accomplish in two steps what the Supreme Court held [in *Daimler*] that California could not accomplish in one" by "(1) requiring corporations that engage in 'substantial, continuous and systematic' business to register, and then (2) declaring that registration is consent to general jurisdiction." Mylan Br. 19. But the voluntary and knowing act of registering to do business in a State—and accepting the consequence that, in Delaware at least, registration and appointment have already been determined by the courts to constitute consent—provides precisely the "ascertainab[ility]" and "predictability" that were lacking in *Daimler*, 134 S. Ct. at 760 (internal quotation marks omitted), where companies doing business in California had no ready means of determining when their in-state conduct had become sufficiently "continuous and systematic" to render them subject to general personal jurisdiction in the State.

See Amoco Oil Co. v. United States, 234 F.3d 1374, 1377–78 (Fed. Cir. 2000). In any event, the argument is flawed in multiple respects.

Under “the law of ‘unconstitutional conditions,’ . . . conditions can lawfully be imposed on the receipt of a benefit—conditions that may include the surrender of a constitutional right . . . —provided the conditions are reasonable.” *Burgess v. Lowery*, 201 F.3d 942, 947 (7th Cir. 2000) (Posner, J.); *see also Dolan v. City of Tigard*, 512 U.S. 374, 385 (1994) (“[T]he 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 has little or no relationship to the [right].”). State registration and appointment statutes that require consent to general personal jurisdiction readily meet this “reasonable[ness]” threshold because States possess a clear interest in ensuring that their courts have jurisdiction to adjudicate claims against foreign corporations that transact business in the State. *See Theunissen v. Matthews*, 935 F.2d 1454, 1462 (6th Cir. 1991) (holding that a State has an interest “in regulating the conduct of foreign businesses trading in” the State). In particular, these statutes ensure that state residents have a local forum in which to seek relief against foreign corporations that do business in the State. The requirement that a foreign corporation consent to general personal jurisdiction when registering to do business is simply “part of the bargain by which [the corporation] enjoys the business freedom of the State.” *Neirbo*, 308 U.S. at 175.

Southern Pacific Co. v. Denton, 146 U.S. 202 (1892)—on which the U.S. Chamber primarily relies—is not to the contrary. There, the Supreme Court held that Texas could not condition the right to transact business within the State on a corporation’s waiver of the right to remove a case filed against it to federal court. *Id.* at 207. Because the State lacked a legitimate interest in denying a corporation an otherwise-available federal forum, the Court held that “requiring the corporation, as a condition precedent to obtaining a permit to do business within the State, to surrender a right and privilege secured to it by the Constitution and laws of the United States, was unconstitutional and void.” *Id.*

The Supreme Court has made clear, however, that *Denton* “involved an entirely different situation” from the one in which state law requires a foreign corporation to appoint an agent for service and provides that the appointment constitutes consent to general personal jurisdiction. *Neirbo*, 308 U.S. at 173. “A statute calling for such a designation is constitutional, and the designation of the agent ‘a voluntary act.’” *Id.* at 175 (quoting *Pa. Fire Ins. Co.*, 243 U.S. at 96). Those words remain as true today as when they were written, and are dispositive here.

II. Mylan Is Subject To Specific Personal Jurisdiction In Delaware.

In addition to having consented to general personal jurisdiction in Delaware, Mylan is subject to specific personal jurisdiction in this case based on its suit-related contacts with Delaware. The district court correctly concluded that Mylan's ANDA filing, the notice letters it sent to Plaintiffs, and its other contacts with Delaware were a constitutionally sufficient basis for exercising specific personal jurisdiction because, in light of those contacts with the State, Mylan "should [have] reasonably anticipate[d] being haled into court" in Delaware. *Burger King*, 471 U.S. at 474 (internal quotation marks omitted).

A. Mylan's Request For FDA Approval To Distribute A Product That Will Give Rise To Future Infringing Sales In Delaware Is Sufficient To Establish Specific Personal Jurisdiction.

Specific personal jurisdiction is based on a defendant's suit-related contacts with the forum, and is consistent with due process where a defendant has "fair warning that a particular activity may subject [it] to the jurisdiction of" the forum State. *Burger King*, 471 U.S. at 472 (internal quotation marks omitted). This "fair warning" requirement is met if "(1) the defendant purposefully directed its activities at . . . the forum, (2) the claim arises out of or relates to those activities, and (3) assertion of personal jurisdiction is reasonable and fair." *Autogenomics, Inc. v. Oxford Gene Tech. Ltd.*, 566 F.3d 1012, 1018 (Fed. Cir. 2009).

In a traditional patent infringement action—where the defendant is accused of infringement based on the actual sale of an infringing product—“patent infringement occurs where allegedly infringing sales are made.” *N. Am. Philips Corp. v. Am. Vending Sales*, 35 F.3d 1576, 1578–79 (Fed. Cir. 1994). In such a case, it is therefore consistent with due process to subject the alleged infringer to specific personal jurisdiction in any State in which an infringing sale occurred. *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1571 (Fed. Cir. 1994).

In ANDA cases, however, the alleged tortious conduct is not the actual sale of an infringing product but “a highly artificial act of infringement”: the submission of an ANDA in which the generic pharmaceutical company declares its intention to manufacture and distribute a generic drug upon receiving FDA approval and certifies that its generic product will not infringe valid patents covering the branded drug. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). Unlike in a traditional patent infringement action focused on actual sales that have already taken place, “the question of infringement” in an ANDA case therefore “focus[es] on what the ANDA applicant will likely market if its application is approved, an act that has not yet occurred.” *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997); *see also Apotex, Inc. v. Daiichi Sankyo, Inc.*, 781 F.3d 1356, 1365 (Fed. Cir. 2015) (“When a generic

manufacturer seeks to enter the market, the concrete stakes are the market sales upon entry.”).

Mylan filed its ANDA with the intention of securing FDA approval to sell its generic version of Ampyra across the United States, including in Delaware, where it is registered to do business and is licensed as a wholesale pharmacy and as a manufacturer and distributor of controlled substances. *See* JA84–86; *see also* JA79 (Mylan’s registration certificate listing “the business which it proposes to do in the State of Delaware” as “[p]harmaceutical manufacturing, distribution and sales”). If Mylan obtains FDA approval, Delaware would be a “place of the infringing sales.” *Beverly Hills Fan Co.*, 21 F.3d at 1571. Mylan therefore had “fair warning” that Plaintiffs may file suit against it in Delaware when Mylan filed an ANDA declaring its intention to manufacture and distribute a product that, if approved by the FDA, will give rise to infringing acts in the State. *Burger King*, 471 U.S. at 472 (internal quotation marks omitted); *see also Keeton v. Hustler Magazine, Inc.*, 465 U.S. 770, 781 (1984) (where a defendant “produce[d] a national publication aimed at a nationwide audience,” there was “no unfairness in calling it to answer for the contents of that publication wherever a substantial number of copies are regularly sold and distributed”).

The Supreme Court’s decision in *Walden v. Fiore*, 134 S. Ct. 1115 (2014), does not compel a different result. There, the Court held that Nevada lacked

specific personal jurisdiction over a Georgia police officer who seized cash from two Nevada residents at the Atlanta airport. *Id.* at 1119–20. The plaintiffs alleged that they were injured in Nevada because they could not access their funds while residing in that State. *Id.* at 1125. The Court deemed that allegation to be a constitutionally insufficient basis for asserting specific jurisdiction, and restated the basic principle that the specific-jurisdiction inquiry focuses on the “defendant’s contacts with the forum State itself, not the defendant’s contacts with persons who reside there.” *Id.* at 1122. “The proper question,” the Court explained, “is not where the plaintiff experienced a particular injury or effect but whether the defendant’s conduct connects him to the forum in a meaningful way.” *Id.* at 1125. The Court concluded that Nevada’s assertion of specific jurisdiction over the Georgia defendant violated due process because the defendant’s only connection with the State was his interaction with the Nevada-resident plaintiffs in Georgia. *Id.* at 1124.

In reaching that conclusion, however, the Court reaffirmed its prior decision in *Calder v. Jones*, 465 U.S. 783 (1984), which upheld specific personal jurisdiction in California over defendants who had authored in Florida an allegedly libelous story about a California resident for national publication. *Id.* at 789. The Court in *Walden* explained that the *Calder* defendants had “expressly aimed” their tortious conduct at California because they knew that it “would have a potentially

devastating impact there” and that, in light of the “nature of the libel tort,” which required publication to third parties as a necessary element, the “intentional tort actually occurred *in* California.” 134 S. Ct. at 1124 & n.7 (internal quotation marks omitted).

The same reasoning applies here. Mylan’s ANDA filing is a sufficient contact with Delaware to establish specific personal jurisdiction because the filing was purposefully directed toward making future infringing sales in Delaware and Plaintiffs’ suit relates to those future infringing sales.

B. Mylan’s Other Contacts With Delaware Reinforce That It Should Reasonably Have Expected To Be Haled Into Court In The State.

Mylan has further contacts with Delaware that provided it with “fair warning” that it would be sued by Plaintiffs in a Delaware forum. *Burger King*, 471 U.S. at 472 (internal quotation marks omitted). In particular, Mylan filed an ANDA that infringed the intellectual-property rights of a Delaware corporation, transmitted its ANDA notice letter to Plaintiffs after they had already initiated litigation in Delaware regarding the same Ampyra Patents, and registered to do business in the State and obtained a license from the Delaware Board of Pharmacy as a wholesale pharmacy and distributor/manufacturer of controlled substances. These suit-related contacts with Delaware are sufficient to establish specific jurisdiction over Mylan in this case.

The Hatch-Waxman Act treats an ANDA “filing as itself an act of infringement.” *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1677 (2012). Mylan’s ANDA therefore had immediate effects on Plaintiffs’ intellectual-property rights in the Ampyra Patents because it sought to extinguish the exclusive rights granted to Plaintiffs by those patents, including their exclusive rights to make, use, and sell Ampyra. *See* 35 U.S.C. § 271(a). Those effects were felt in every State—including in Delaware—because the property rights that the Ampyra Patents granted to Plaintiffs, and that Mylan infringed when it filed its ANDA, apply nationwide. *See id.* The effects of Mylan’s ANDA were particularly acute in Delaware because Acorda is a Delaware corporation. Thus, wherever else Plaintiffs felt the effects of Mylan’s infringing activity, there can be no doubt that Mylan’s tortious conduct was “expressly aimed” at, and had an immediate impact on, Acorda in Delaware. *Calder*, 465 U.S. at 789.

For that reason, among several others, Mylan—a generic manufacturer intimately familiar with ANDA litigation—should have known that it was likely to be sued in Delaware after it filed its ANDA. Indeed, it is universally understood in the pharmaceutical industry that “[f]iling a paragraph IV certification means provoking litigation.” *Caraco Pharm.*, 132 S. Ct. at 1677. When Mylan provided notice of its Paragraph IV certification to Plaintiffs on July 9, 2014, Plaintiffs had already initiated infringement litigation in the District of Delaware against another

ANDA filer with respect to the same Ampyra Patents. JA7–8, 32; *see also Acorda Therapeutics Inc. v. Actavis Labs. FL Inc.*, No. 14-cv-882 (D. Del. filed July 7, 2014). Mylan should have known that Plaintiffs would likely file future suits regarding the Ampyra Patents in Delaware—both for reasons of efficiency and because Delaware is Acorda’s home State.

In response, Mylan attempts to equate an ANDA notice letter with a cease-and-desist letter threatening infringement litigation, which this Court has held is “not sufficient to confer personal jurisdiction” over the patent holder absent “‘other activities’ directed at the forum.” *Silent Drive, Inc. v. Strong Indus., Inc.*, 326 F.3d 1194, 1202 (Fed. Cir. 2003); *see also* Mylan Br. 45–46. But that analogy disregards the reason that cease-and-desist letters have been found insufficient to confer jurisdiction, which has nothing to do with whether the patent holder has minimum contacts with the forum. In fact, this Court has stated that “cease-and-desist letters alone are often substantially related to the cause of action (thus providing minimum contacts).” *Red Wing Shoe Co. v. Hockerson-Halberstadt, Inc.*, 148 F.3d 1355, 1360 (Fed. Cir. 1998); *see also Silent Drive*, 326 F.3d at 1202 (“[Cease-and-desist] letters are purposefully directed at the forum and the declaratory judgment action arises out of the letters”) (internal quotation marks omitted). Mylan’s analogy to cease-and-desist letters therefore *reinforces* the existence of minimum contacts in this case.

Rather than resting on the absence of minimum contacts, the Court’s jurisdictional approach to cease-and-desist letters is based on its determination that premising jurisdiction solely on the fact that a patentee sent a cease-and-desist letter to an alleged infringer in the forum State does not “comport with fair play and substantial justice,” which is a separate component of the specific-jurisdiction inquiry. *Red Wing Shoe*, 148 F.3d at 1360–61 (internal quotation marks omitted); *see also Silent Drive*, 326 F.3d at 1202. In other words, it is not reasonable, in this Court’s view, for a patent holder to “subject itself to personal jurisdiction in a forum solely by informing a party who happens to be located there of suspected infringement.” *Avocent Huntsville Corp. v. Aten Int’l Co.*, 552 F.3d 1324, 1333 (Fed. Cir. 2008).

While “[p]rinciples of fair play and substantial justice afford a patentee sufficient latitude to inform others of its patent rights without subjecting itself to jurisdiction in a foreign forum,” *Red Wing Shoe*, 148 F.3d at 1360–61, those same principles of fairness militate *in favor* of providing a forum for a patent holder to bring suit against a patent infringer who has provided formal notice of its intent to begin infringing sales upon receiving approval from the FDA—especially where the patent holder resides in the forum State. *See Burger King*, 471 U.S. at 473 (“A State generally has a ‘manifest interest’ in providing its residents with a convenient forum for redressing injuries inflicted by out-of-state actors.”) (citation omitted).

Moreover, applying the same *per se* rule of “unreasonableness” to both cease-and-desist letters and ANDA notices would ignore the significant differences between them. Under the Hatch-Waxman Act, Mylan’s notice was a significant act with important legal consequences specified by statute. The notice triggered the forty-five-day period for Plaintiffs to file an infringement action against Mylan and thereby obtain an automatic stay of FDA approval of Mylan’s ANDA application. *See* 21 U.S.C. § 355(j)(5)(B)(iii). In contrast, a cease-and-desist letter does not trigger any legally relevant timeline within which the patent holder must assert its rights.

Nor do any of the opinions in this Court’s fractured decision in *Zeneca Ltd. v. Mylan Pharmaceuticals, Inc.*, 173 F.3d 829 (Fed. Cir. 1999), support Mylan’s attempt to evade jurisdiction in this case. Mylan Br. 43–44. The conclusion reached by the Court in *Zeneca*—that a generic manufacturer’s transmission of an ANDA to the FDA’s headquarters in Maryland does not give rise to specific personal jurisdiction in Maryland—is inapposite here. While the plaintiff in *Zeneca* sought to premise jurisdiction on Mylan’s transmission of its ANDA to a particular State, Mylan’s notice letters are relevant to the jurisdictional inquiry in this case because they were sent to Plaintiffs, one of which is a Delaware corporation, *after* Plaintiffs had already initiated ANDA litigation in Delaware regarding the *same* patents that were the subject of Mylan’s notice letters. The

reasoning of the two judges who authored opinions concluding that jurisdiction was lacking in *Zeneca* does not call into question the district court's conclusion in this case that, given this "chronology of events," Mylan should have anticipated being sued by Plaintiffs in Delaware. JA33–34.

Judge Gajarsa's opinion in *Zeneca* applied the "government contacts exception" to conclude that Mylan's ANDA was a "petition [to] the government for the right to market its generic drug" and therefore did not "count" as a jurisdictional contact with Maryland. 173 F.3d at 832 (opinion of Gajarsa, J.). The "government contacts exception" is inapplicable here because Mylan's ANDA notices were directed to Acorda and Alkermes, not a government agency. Similarly, Judge Rader concluded in *Zeneca* that Mylan's ANDA filing was a contact with "the federal government whose office for receipt of ANDAs happens to be within" Maryland, which he deemed inconsequential for minimum-contacts purposes. *Id.* at 835 (opinion of Rader, J.). The same cannot be said of Mylan's ANDA notices; they were directed to two private companies (including a Delaware corporation) that had already initiated litigation in Delaware with respect to the same patents that Mylan gave notice of its intent to infringe.

Mylan also has significant additional contacts with Delaware relating to the manufacture and sale of pharmaceuticals. Mylan has registered to do business in the State with the Delaware Secretary of State, Del. Code tit. 8, § 371, and has

obtained a license from the Delaware Board of Pharmacy to operate in the State as a wholesale pharmacy and as a manufacturer and distributor of controlled substances. Del. Code tit. 24, § 2540; *see also* JA84, 86. That license permits Mylan to manufacture and distribute drugs within Delaware. Del. Code tit. 24, § 2540(a).

Mylan contends that its business registration and license are not suit-related because “Acorda and Alkermes are not suing Mylan for registering to do business in Delaware.” Mylan Br. 46–47. But Mylan’s argument again ignores the unique context of ANDA litigation, which is focused on the future sales that will take place in the event the FDA approves the ANDA. *Apotex, Inc.*, 781 F.3d at 1365. The fact that Mylan has qualified to do business in Delaware and obtained a license to manufacture and distribute drugs in the State is directly related to the future infringing sales that are the subject of this suit because Mylan’s business registration and license will enable it to undertake infringing conduct in Delaware once it receives FDA approval to produce its generic version of Ampyra. Mylan’s Delaware registration and license therefore confirm that it has sufficient contacts with the State to satisfy the requirements of due process. *See Allergan, Inc. v. Actavis, Inc.*, No. 2:14-cv-638, 2014 WL 7336692, at *6 (E.D. Tex. Dec. 23, 2014).

C. Asserting Personal Jurisdiction Over Mylan Is Reasonable And Fair.

Exercising specific personal jurisdiction over Mylan in this case would also be “reasonable[],” *Asahi Metal Indus. Co. v. Superior Court*, 480 U.S. 102, 113 (1987), and “comport with fair play and substantial justice.” *Burger King*, 471 U.S. at 476 (internal quotation marks omitted). Mylan’s cursory arguments to the contrary are not persuasive. Mylan Br. 51–53.

To assess whether an assertion of jurisdiction is reasonable, a court “may evaluate the burden on the defendant, the forum State’s interest in adjudicating the dispute, the plaintiff’s interest in obtaining convenient and effective relief, the interstate judicial system’s interest in obtaining the most efficient resolution of controversies, and the shared interest of the several States in furthering fundamental substantive social policies.” *Burger King*, 471 U.S. at 477 (internal quotation marks omitted). Mylan does not seriously dispute that the assertion of jurisdiction in this case is reasonable in light of these considerations, instead arguing that the district court conflated the issues of “minimum contacts” and “reasonableness.” Mylan Br. 51. But the district court separately discussed the two requirements and concluded both that Mylan had sufficient minimum contacts with Delaware and that exercising jurisdiction over Mylan would be “reasonable and fair” under the factors set forth in *Burger King*. JA35 (internal quotation marks omitted).

That conclusion was plainly correct because each of the *Burger King* factors weighs heavily in favor of the reasonableness of jurisdiction. With respect to any burden on the defendant, Mylan has never suggested that Delaware would be an inconvenient forum or asserted any other possible prejudice from litigating this case in Delaware. In fact, Mylan is a frequent litigant in Delaware, having litigated more than 50 cases in the State, including six suits as a plaintiff. JA33.

Delaware also has a strong interest in adjudicating this dispute because the State has an interest in providing Acorda, a Delaware corporation, with a forum in which to seek relief from Mylan's infringement of its Ampyra Patents, including through the sale of generic versions of the drug in Delaware. *See Burger King*, 471 U.S. at 473; *see also, e.g., Holloway v. Wright & Morrissey, Inc.*, 739 F.2d 695, 699 (1st Cir. 1984) (“[B]ecause Holloway is a New Hampshire resident, that state has an interest in insuring that he has a forum in which to seek relief.”). For similar reasons, Plaintiffs' interests in obtaining convenient and effective relief strongly favor a Delaware forum. Not only is Acorda a Delaware corporation, but both Acorda and Alkermes are plaintiffs in seven other ANDA suits regarding the Ampyra Patents that are currently pending in Delaware. JA7–8. Litigating this case in Delaware would therefore be most convenient for Plaintiffs and would promote “the interstate judicial system's interest in obtaining the most efficient resolution of controversies.” *World-Wide Volkswagen*, 444 U.S. at 292.

In *Zeneca*, Judge Gajarsa expressed concern that finding specific jurisdiction in Maryland based solely on the submission of an ANDA to the FDA's headquarters in the State would create a "supercourt" for handling all Hatch-Waxman claims. *Zeneca*, 173 F.3d at 832 (opinion of Gajarsa, J.). Mylan's position, however, creates the opposite problem because ANDA litigation often involves suits against multiple generic filers. *See Eli Lilly & Co. v. Mylan Pharm., Inc.*, ___ F. Supp. 3d ___, No. 1:14-cv-389, 2015 WL 1125032, at *7 (S.D. Ind. Mar. 12, 2015) (explaining that the plaintiffs had "initially filed suit against approximately forty generic drug companies that reside in a variety of locations"). Mylan's unduly narrow view of specific personal jurisdiction would require drug patent holders to file separate suits in each ANDA filer's home State. That result would splinter ANDA litigation into a number of separate cases scattered throughout the country and require multiple district courts to consider the validity of identical patents, creating the very real risk of inconsistent outcomes. Permitting this suit to proceed in Delaware, in contrast, is the most fair and efficient outcome for the parties and the judicial system.

* * *

Mylan has made numerous knowing and voluntary decisions to establish jurisdictional ties to Delaware. It decided to register to do business in Delaware and appoint an agent for service of process in the State (twenty years *after* the state

supreme court had authoritatively held that those actions constitute consent to general personal jurisdiction), submitted an ANDA declaring its intention to manufacture an infringing drug that would be distributed and sold in Delaware, committed an act of infringement with respect to patents held by a Delaware corporation, and provided notice of its infringing conduct to Plaintiffs after they had already initiated litigation regarding the same patents in Delaware. And at no point after registering to do business in Delaware has Mylan exercised its statutory right to withdraw its registration. Under the circumstances, exercising either general or specific jurisdiction over this Delaware-connected defendant in this Delaware-connected litigation would be fair, reasonable, and consistent with long-settled jurisdictional principles.

CONCLUSION

For the foregoing reasons, this Court should affirm the district court on both questions presented.

Respectfully submitted.

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CERTIFICATE OF SERVICE

I hereby certify that on July 16, 2015, I caused service of the foregoing to be made by electronic filing with the Clerk of the Court using the **CM/ECF** System, which will send a Notice of Electronic Filing to all parties with an e-mail address of record, who have appeared and consent to electronic service in this action.

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