Nos. 15-1456, 15-1460

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

ACORDA THERAPEUTICS INC., and ALKERMES PHARMA IRELAND LIMITED,

Plaintiffs-Appellees,

v.

MYLAN PHARMACEUTICALS INC., MYLAN INC.,

Defendants-Appellants.

ASTRAZENECA AB,

Plaintiff-Appellee,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant-Appellant

Appeals from the United States District Court
for the District of Delaware,
No. 1:14-cv-00935-LPS
No. 1:14-cv-00664-GMS
No. 1:14-cv-00696-GMS

PETITION FOR REHEARING EN BANC

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CERTIFICATE OF INTEREST

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

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

Mylan Pharmaceuticals Inc. and Mylan Inc.

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

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

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

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

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

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

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STATEMENT OF COUNSEL

Based on my professional judgment, I believe the panel decision is contrary to the following decisions of the Supreme Court of the United States or the precedents of this Court: *Walden v. Fiore*, 134 S. Ct. 1115 (2014); *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014); *Int'l Shoe Co. v. Washington*, 326 U.S. 310 (1945); and *Zeneca Ltd. v. Mylan Pharm., Inc.*, 173 F.3d 829 (Fed. Cir. 1999). Further, this appeal requires an answer to the following precedent-setting questions of exceptional importance: (1) whether a party's filing of an abbreviated new drug application supports specific personal jurisdiction over that party anywhere in the country; and (2) whether a party's compliance with a state's mandatory business-registration statutes constitutes consent to general personal jurisdiction.

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INTRODUCTION

Before the Supreme Court's landmark decision in *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014), personal jurisdiction in patent infringement cases following the filing of an abbreviated new drug application (ANDA) was rooted in general personal jurisdiction, and parties whose patents were named in an ANDA filing could sue in almost any state where the ANDA filer did some business. Plaintiffs and courts looked to general, not specific, personal jurisdiction because the only suit-

related actions performed by defendants occurred in states where defendants prepared and filed their ANDAs. Thus, when the Supreme Court's watershed decision in *Daimler* vastly reduced the scope of general personal jurisdiction, it should have had a dramatic effect on where suits like these could be filed. Not so.

Instead, the panel here responded by devising a new approach to specific personal jurisdiction even more "unacceptably grasping" than the pre-*Daimler* general personal jurisdiction regime, with the counterintuitive and erroneous consequence that there could be specific personal jurisdiction everywhere. *Id.* at 761. Mylan prepared the ANDAs at issue in this case in West Virginia and filed them in Maryland. Acorda and AstraZeneca sued Mylan in Delaware. Delaware, while a familiar forum for such suits in pre-*Daimler* days, has nothing to do with these ANDAs or with Mylan's suit-related conduct. Thus, these cases should have been readily dismissed. Instead, the panel majority compensated for *Daimler*'s narrowing of general jurisdiction by broadening specific jurisdiction beyond all known bounds by relying on potential "future activities" it speculated Mylan would undertake if its ANDAs are someday approved.

That holding is factually and legally flawed and irreconcilable with decisions of the Supreme Court and this Court. The majority's decision is premised on, among other things, the factual assumption that filing an ANDA necessarily means the drug in question will be marketed in all fifty states. But as Mylan argued, and appellees

conceded, there is absolutely no guarantee that an ANDA filer will even market the drug in question, much less in a particular state. Absent that critical premise—which establishes the majority's link between an ANDA filing and the forum state—the majority's holding is unsustainable.

But even if the majority's factual assumptions were correct, rehearing would still be necessary. In basing specific personal jurisdiction on hypothetical future activities, the majority created a regime that permits specific personal jurisdiction to be exercised over an ANDA filer *anywhere in the country*. This new nationwide jurisdiction—rooted in prognostication rather than a defendant's actual suit-related contacts with a forum state—deprives ANDA filers of due process protections and squarely conflicts with precedents of the Supreme Court and this Court.

The majority's extraordinary decision makes litigation in the ANDA context highly unpredictable, which will chill the development of life-saving, low-cost generic drugs and undercut the goals of the Hatch-Waxman Act. That holds true whether one accepts the majority's sweeping conception of specific personal jurisdiction or the concurrence's alternative conclusion—rendered untenable by a recent Delaware Supreme Court opinion—that complying with Delaware's business-registration statutes constitutes consent to general personal jurisdiction there. The Court recognized the importance of these issues by accepting these cases on interlocutory review. It should now do the same by granting rehearing en banc.

BACKGROUND

Once the FDA has approved a brand-name drug for marketing, a generic-drug manufacturer can obtain "similar marketing approval" by filing an ANDA certifying that its generic drug has the same active ingredients and is biologically equivalent to the brand-name drug. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2228 (2013). The generic manufacturer must certify that the brand manufacturer's patents are invalid or will not be infringed by the generic. The patent owner then has an immediate right to sue for patent infringement. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 677 (1990). If suit is brought within 45 days, "the FDA generally may not approve the ANDA until 30 months pass or the court finds the patent invalid or not infringed." *Caraco Pharm. Labs. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1677 (2012).

Mylan is a generic pharmaceutical company incorporated and headquartered in West Virginia. Op.6. Mylan prepared the ANDAs at issue in these cases in West Virginia and filed them with the FDA in Maryland. *Id.* Mylan undertook no relevant suit-related conduct in Delaware. In its ANDA, Mylan certified that the relevant patents were invalid or would not be infringed by Mylan's generic versions and provided notice of its filings to Acorda and AstraZeneca. *Id.* They both responded by separately suing Mylan for patent infringement in the District of Delaware, where such suits were commonly filed in the pre-*Daimler* days. *Id.* at 5. Mylan moved to dismiss both cases for lack of personal jurisdiction. *Id.* Two different judges

disagreed whether, following *Daimler*, general personal jurisdiction was appropriate; however, both held that Mylan was subject to specific personal jurisdiction. *Id*. at 6-7. Each court certified its decision for interlocutory review, and this Court granted permission to review. *Id*. at 7.

The panel affirmed. The majority held that Mylan's mere act of filing ANDAs established specific personal jurisdiction over Mylan in Delaware. It acknowledged that the only suit-related actions at issue in this case are "the particular actions Mylan has already taken—its ANDA filings." *Id.* at 8. Emphasizing Mylan's supposed "future activities," however, the majority held that the ANDA filings "constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs," and "Delaware is undisputedly a State where Mylan will engage in that marketing if the ANDAs are approved." *Id.* at 8-9. Mylan's ANDA filings "are thus suit-related," and "they have a substantial connection with Delaware because they reliably, non-speculatively predict Delaware activities by Mylan." *Id.* at 13.

Judge O'Malley concurred in the judgment. Noting that "the parties dispute … whether and to what extent Mylan ultimately may be authorized to—or decide to—market generic drugs in Delaware," she disagreed with "predicat[ing] the exercise of" specific personal jurisdiction on "Mylan's expressions of *future* intent." Concurring Op.2, 14. She believed plaintiffs "experienced legally cognizable injuries in Delaware upon the filing of the ANDA applications." *Id.* at 16. She also

believed that Mylan had consented to general personal jurisdiction by registering to do business in Delaware. *Id.* at 4-12.

REASONS FOR GRANTING REHEARING EN BANC

I. The Decision Rests On Erroneous Factual Premises.

Due process requires that a court have personal jurisdiction over a defendant. *See Walden v. Fiore*, 134 S. Ct. 1115, 1121 (2014). A court with general personal jurisdiction can hear "any and all claims against [the defendant], wherever in the world the claims may arise." *Daimler*, 134 S. Ct. at 751. Absent exceptional circumstances, however, a court cannot assert general jurisdiction over a corporation unless it is incorporated in the forum or uses the forum as its principal place of business. *Id.* Specific personal jurisdiction is available only when a defendant "ha[s] certain minimum contacts with [the forum] such that the maintenance of the suit does not offend 'traditional notions of fair play and substantial justice.'" *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945). The minimum-contacts requirement of specific personal jurisdiction requires that "the defendant's suit-related conduct … create a substantial connection with the forum State." *Walden*, 134 S. Ct. at 1121. It is met when the defendant has "purposefully directed" its activities at the forum state, and the plaintiff's claims "'arise out of or relate to those activities.'" *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472-73 (1985).

The majority recognized these fundamental due process principles, *see* Op.7-

8, and acknowledged that "the minimum-contacts standard" of specific personal jurisdiction must be "satisfied by the particular actions Mylan has already taken—its ANDA filings." *Id.* at 8. That should have ended this case. After all, the "particular actions Mylan ha[d] already taken" occurred in West Virginia and Maryland, where the ANDAs were prepared and filed, respectively. *Id.* at 6. Mylan undertook no suit-related conduct specifically in Delaware.

The majority nevertheless proceeded to hold that Mylan's ANDAs prepared in West Virginia and filed in Maryland were sufficient to subject it to specific personal jurisdiction in Delaware, using reasoning that would subject Mylan (and any other ANDA filer) to specific personal jurisdiction anywhere in the country. The majority held that because "Mylan seeks approval to sell its generic drugs throughout the United States, including in Delaware, and it is undisputed that Mylan plans to direct sales of its generic drugs into Delaware," *id.* at 15, there is a "substantial connection" between Mylan's ANDA filings and all 50 states, including Delaware.

This reasoning rests on several critical but mistaken factual premises. To begin with, the majority assumed that the mere filing of an ANDA means that a generic manufacturer will market the product in question. That assumption is essential to the majority's holding: it creates the necessary link between the ANDA filing in one state and the injuries purportedly sustained by the plaintiff in another state (the forum state). But the assumption is incorrect. As Mylan has explained,

numerous obstacles and off-ramps exist in between the filing of an ANDA and the marketing of a drug in any state, much less all fifty states: *inter alia*, the FDA could reject the ANDA filing; the generic manufacturer could lose in ANDA litigation; or, by the time the ANDA is approved, the generic could determine that the overall market (or the market in a certain state) does not justify the costs of production and marketing. *E.g.*, *Acorda* Oral Arg. at 5:05-28; Reply Br. 22, *AstraZeneca*, No. 15-1460 (explaining that "now-hypothetical [marketing] might never materialize").

Thus, the majority's critical assertion that an ANDA filer "has, by its filing, reliably confirmed a plan to engage in real-world marketing," Op.11, is flawed. Filing an ANDA certainly confirms a plan to gain *approval* to engage in marketing, but it by no means confirms where or even whether marketing will occur. As Acorda conceded, an ANDA filing "doesn't say 'we intend to do this and we'll do it no matter what.'" *Acorda* Oral Arg. at 23:29-33. Likewise, AstraZeneca conceded that, while Mylan seeks approval to market its products in every state, Mylan "may never sell in certain of those jurisdictions." *AstraZeneca* Oral Arg. at 44:12-18.

These concessions highlight another critical, yet fatally incorrect, assumption by the majority: that Mylan, by filing ANDAs, would market the drugs in Delaware specifically. The majority insisted that Mylan's ANDA filings meant that its "future activities … will be purposefully directed at Delaware." Op.8; *see also*, *e.g.*, *id.* at 9 ("[T]he ANDA filings are tightly tied … to the deliberate making of sales in

Delaware[.]"); *id.* at 13 (Mylan's "marketing activities … will unquestionably take place in Delaware"). The majority even claimed that this point was "undisputed." *Id.* at 9, 15. Not only is that incorrect, as Judge O'Malley noted, *see* Concurring Op.2 ("The parties dispute … whether and to what extent Mylan ultimately may be authorized to—or decide to—market generic drugs in Delaware[.]"); if anything, AstraZeneca's and Acorda's concessions indicate that the opposite proposition is undisputed: all parties agree that filing an ANDA does *not* automatically mean that a drug will be marketed in every state, much less one state in particular. A contrary view does not comport with the real-world chasm that separates an ANDA filing and the subsequent consummation of actual sales in any particular jurisdiction.[1]

The majority also asserted that the filings were "for the purpose of engaging in … injury-causing and allegedly wrongful marketing conduct in Delaware." Op.8-9. But this contention runs headlong into the design of the ANDA regime, under which "injury-causing" or "wrongful" marketing is a *non sequitur*. If a branded manufacturer brings an infringement suit against a generic manufacturer following an ANDA filing, only two outcomes are possible. Either the brand prevails, in which

[1] For example, in 2013, Mylan had *no* net sales in Delaware. *See* Decl. of Robert Tighe ¶7, *AstraZeneca AB v. Mylan Pharmaceuticals, Inc.*, No. 14-696 (D. Del. June 25, 2014) (Dkt. 10). In 2014, it had less than $642,000 in Delaware net sales, all attributable to one drug not at issue in this case. Decl. of Frank Mullery ¶7, *Pfizer Inc. v. Mylan Inc.*, No. 15-26 (D. Del. Mar. 30, 2015) (Dkt. 18).

case the generic *cannot be marketed* (until the patent on the brand expires), or the generic prevails, in which case only *non-infringing marketing* will occur. The only way "wrongful marketing conduct" could ever occur is in the extremely rare situation—not present here—where a generic manufacturer markets a drug before litigation is resolved. And even then, the decision to market has nothing to do with an ANDA filing; the manufacturer concludes that the benefits of commencing marketing before a ruling outweigh the costs of potentially losing and paying substantial damages. In short, it is pure speculation that there will be any planned infringing sales in any state because of an ANDA filing. ANDA filings cannot support any purpose or create any real likelihood of injury based on infringing sales.

II. The Panel's Decision Conflicts with Relevant Precedents.

Even if it were correct as a factual matter that filing an ANDA *necessarily* means that the drug in question will be marketed—including in the forum state—the majority's decision cannot stand as a matter of law. To find specific personal jurisdiction against Mylan, the majority had to impute to Mylan's ANDA filing hypothetical future contacts from hypothetical "future activities." Op.8. Not only does that conflict with settled personal jurisdiction precedents of the Supreme Court and this Court; it produces the anomalous result that *specific* personal jurisdiction against an ANDA filer is presumptively available *everywhere in the country*.

To begin with, the Supreme Court's decision in *Walden* makes plain that the

only "jurisdictionally relevant" suit-related contacts for purposes of specific personal jurisdiction analysis are those that a defendant has *already* formed when the suit is filed. 134 S. Ct. at 1124. Likewise, numerous other courts have recognized that "[p]ersonal jurisdiction cannot be based on future contacts, even if such contacts are allegedly 'inevitable.'" *Eli Lilly & Co. v. Nang Kuang Pharm. Co.*, No. 1:14-cv-01647, 2015 WL 3744557, at *1 (S.D. Ind. June 15, 2015); *see also, e.g.*, *Fastpath, Inc. v. Arbela Techs. Corp.*, 760 F.3d 816, 822 (8th Cir. 2014) (potential "future development" "is not relevant in" personal jurisdiction analysis). The panel disregarded this bedrock principle by ignoring Mylan's past contacts—an ANDA prepared in West Virginia and filed in Maryland—in favor of prognosticating Mylan's future marketing activities, supposedly to occur in Delaware.

The majority's decision also conflicts with—and creates a massive end-run around—the Supreme Court's *Daimler* decision. Before *Daimler*, personal jurisdiction in ANDA infringement cases was typically rooted in general personal jurisdiction, and generic drug manufacturers were accordingly vulnerable to suit in jurisdictions across the country. *Daimler* significantly altered—and substantially narrowed—the scope of general jurisdiction. Going forward, the Court explained, general jurisdiction is generally available against corporations only in the states where they are incorporated or have their primary place of business. 134 S. Ct. at 761. After *Daimler*, plaintiffs must sue defendants where the defendants are "at

home," or in the unique forum where the suit-related conduct arises. The days of suing a defendant where the plaintiff found convenient were supposed to be over.

The majority's decision, however, simply recreates the pre-*Daimler* status quo by broadening specific personal jurisdiction to fully counteract the Supreme Court's narrowing of general jurisdiction in *Daimler*. At least in ANDA cases, the majority renders the landmark *Daimler* opinion little more than a sport. Because, according to the majority, the mere filing of an ANDA means that the drug will be marketed in all fifty states, an ANDA filer is thus subject to specific personal jurisdiction in all fifty states.[2] Accordingly, even though *Daimler* made clear that not even a defendant's "continuous and systematic" contacts with a state render it subject to jurisdiction unless they "also give rise to the liabilities sued on," *id*. at 761, under the majority's decision, ANDA filers can be forced to litigate in states where they have not even formed a single contact. By expanding specific personal jurisdiction to wherever an ANDA filer may one day do business, the majority created a jurisdictional rule more "exorbitant" and "grasping" than the one *Daimler* rejected.[3]

[2] Specific personal jurisdiction also requires that exercising jurisdiction not be "unfair." Op.16. The majority held that this condition was satisfied here because the case "involve[s] the pricing and sale of products in Delaware and harms to firms doing business in Delaware." *Id.* Under the majority's reasoning, the fairness requirement will always be satisfied: the ANDA filing means that the drug will be marketed in a forum state; and the plaintiff will be doing business in the forum state.

[3] The Supreme Court has repeatedly reminded this Court that traditional rules of litigation remain equally binding in patent litigation. *See Teva Pharm. USA, Inc. v.*

Finally, the majority's decision is irreconcilable with *Zeneca Ltd. v. Mylan Pharm., Inc.*, 173 F.3d 829 (Fed. Cir. 1999). In *Zeneca*, this Court held that filing an ANDA with the FDA in Maryland *does not* establish jurisdiction over the ANDA filer in Maryland. Under the majority's decision, however, the filing of an ANDA *does* establish jurisdiction over the ANDA filer in Maryland (and every other state). The majority attempted to distinguish *Zeneca* by observing that, in that case, "the only contact with the forum at issue was the act of making the ANDA filing," so it never "addresse[d] whether the location of the ANDA filer's future sales could support specific personal jurisdiction." Op.14. But that only underscores the majority's anomalous focus on *future* activities: until now, no court has held that hypothetical "future activities" like "planned marketing" can substitute for actual, existing, suit-related activities in the forum state. Under the majority's reasoning—which assumes that ANDA filings necessarily lead to nationwide marketing—the mere fact of an ANDA filing in *Zeneca* should have established jurisdiction in Maryland, contrary to the actual outcome in that case.

III. The Issue Is Exceptionally Important.

The immediate reaction to the majority's decision underscores the need for rehearing en banc. The "sweeping scope" of the decision has created "effectively

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Sandoz, Inc., 135 S. Ct. 831, 836-37 (2015); *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 394 (2006). This principle applies with even greater force in the context of fundamental due process protections.

national jurisdiction over any ANDA filer." Paul Ainsworth & Joshua Miller, *Acorda Therapeutics v. Mylan Pharmaceuticals: A New Kind of Jurisdiction for ANDA Cases*, Bloomberg, Apr. 4, 2016. Because the majority's analysis "is dedicated not to the facts of the case but to generally applicable ANDA filing requirements," generic manufacturers "are now at risk of being haled into federal court in virtually every jurisdiction in the country." *Id.*; *see also* Brenda Sandburg, *Have Patent, Will Travel: Brand Firms Can File Infringement Suits Anywhere*, Pink Sheet Daily, Mar. 18, 2016 ("Brand-name drug makers will be able to file patent infringement suits against generic manufacturers in whatever jurisdiction they wish[.]"). Acorda's own counsel described the decision as "very broadly" holding that brand manufacturers "could essentially sue [ANDA filers] anywhere." Ryan Davis, *Fed. Circ. Sets Wide Jurisdiction Rule In ANDA Patent Cases*, Law360, Mar. 18, 2016.

The majority's decision, therefore, undercuts one of the primary aims of the Hatch-Waxman Act: to "make available more low cost generic drugs." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997). The decision denies ANDA filers "a degree of predictability … that allows [them] to structure their primary conduct with some minimum assurance as to where that conduct will and will not render them liable to suit." *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 297 (1980). The decision thus will have a substantial chilling effect on generic activity. Indeed, it is exactly the sort of "unnecessary and unintended

punishment for filing a petition with the FDA" that "undermines the purpose of the Hatch-Waxman Act," *Zeneca*, 173 F.3d at 833 (opinion of Gajarsa, J.).

IV. The Court Should Also Consider Whether Delaware Can Exercise General Personal Jurisdiction In Light Of *Daimler*.

This case also raises the issue whether Mylan can be subject to general personal jurisdiction in Delaware. The majority declined to answer this question, but Judge O'Malley would have held that Mylan consented to general jurisdiction merely by complying with Delaware's mandatory business-registration statutes because, in *Sternberg v. O'Neil*, 550 A.2d 1105 (Del. 1988), the Delaware Supreme Court held that compliance with those statutes "constitutes consent to general personal jurisdiction." Concurring Op.5; *see also id.* at 12. After the panel's decision, however, the Delaware Supreme Court overruled this aspect of *Sternberg*, holding, in light of *Daimler*, that Delaware's registration statutes cannot be read "as a broad consent to personal jurisdiction in any cause of action." *Genuine Parts Co. v. Cepec*, No. N15C-02-184, slip op. at 3 (Del. Apr. 18, 2016). Should the Court grant rehearing en banc on the specific jurisdiction issue, it should do the same on the general jurisdiction issue and, consistent with *Genuine Parts*, hold that Mylan's compliance with Delaware's registration statutes does not constitute consent to general jurisdiction in Delaware.

CONCLUSION

For the reasons set forth above, this Court should rehear this case en banc.

Respectfully submitted,

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ADDENDUM

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

2015-1456

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

ASTRAZENECA AB,
Plaintiff-Appellee

v.

MYLAN PHARMACEUTICALS INC.,
Defendant-Appellant

2015-1460

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

Decided: March 18, 2016

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

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

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

TARANTO, *Circuit Judge.*

These appeals involve two actions brought in the District of Delaware against generic drug manufacturer Mylan Pharmaceuticals Inc. One, assigned to Chief Judge Stark, was brought by brand-name drug manufacturers Acorda Therapeutics Inc. and Alkermes Pharma

Ireland Ltd.; the other, assigned to Judge Sleet, was brought by brand-name drug manufacturer AstraZeneca AB. The plaintiffs brought the actions under 35 U.S.C. § 271(e)(2), alleging that their patents cover drugs that Mylan has sought permission from the Food and Drug Administration to manufacture and market. Mylan moved to dismiss on the ground that Delaware could not (and so the federal court may not) exercise personal jurisdiction—either general or specific personal jurisdiction—over Mylan in these cases. Chief Judge Stark and Judge Sleet denied the motions. Although they reached different conclusions about whether Delaware could exercise general personal jurisdiction over Mylan based on consent given in registering to do business in the State, they both concluded that Delaware could exercise specific personal jurisdiction, based on Mylan's suit-related contacts with Delaware. On interlocutory appeal, we affirm, holding that Mylan is subject to specific personal jurisdiction in these cases. We do not address the issue of general personal jurisdiction.

BACKGROUND

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

Acorda and Alkermes then sued Mylan in the District of Delaware for patent infringement, invoking the declaration of 35 U.S.C. § 271(e)(2)(A) that the submission of a paragraph IV certification constitutes an act of infringement.[1]

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

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

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[1] Acorda and Alkermes also sued Mylan's parent corporation, Mylan Inc., but the parties voluntarily dismissed Mylan Inc. without prejudice.

tration to do business in Delaware as giving consent to the exercise of general personal jurisdiction.

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

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

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

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

DISCUSSION

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

A court may exercise specific personal jurisdiction without violating the Due Process Clause when the defendant "ha[s] certain minimum contacts with [the forum] such that the maintenance of the suit does not offend 'traditional notions of fair play and substantial justice.'" *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945). The minimum-contacts requirement focuses on whether "the defendant's suit-related conduct . . . create[s] a

substantial connection with the forum State." *Walden v. Fiore*, 134 S. Ct. 1115, 1121 (2014). What conduct is suit-related depends on "the relationship among the defendant, the forum, and the litigation," *Keeton v. Hustler Magazine, Inc.*, 465 U.S. 770, 775 (1984), including specifically the nature of the claim asserted. *See Calder v. Jones*, 465 U.S. 783, 789–90 (1984); *Walden*, 134 S. Ct. at 1124 ("The strength of [the defendant's] connection [to California in *Calder*] was largely a function of the nature of the libel tort."). In a formulation worded to address suits for retrospective relief based on past acts, the Supreme Court has said that the minimum-contacts requirement is met when the defendant "purposefully directed" activities at the forum, "and the litigation results from alleged injuries that 'arise out of or relate to' those activities." *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472–73 (1985) (citations omitted); *see Grober v. Mako Prods., Inc.*, 686 F.3d 1335, 1346 (Fed. Cir. 2012).

Here, Mylan has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at Delaware (and, it is undisputed, elsewhere). If Mylan had already begun its deliberate marketing of these drugs in Delaware, there is no doubt that it could be sued for infringement in Delaware. Its Delaware sales would be acts committed in the State that are wrongful—if the plaintiffs here are right about infringement and validity—and would concretely injure Acorda and AstraZeneca in the State by displacing some of their Delaware sales and likely lowering the price they could charge there. *See World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 297 (1980); *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1565–66 (Fed. Cir. 1994). In our view, the minimum-contacts standard is satisfied by the particular actions Mylan has already taken—its ANDA filings—for the purpose of

engaging in that injury-causing and allegedly wrongful marketing conduct in Delaware.

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

The Hatch–Waxman Act recognizes the close connection between an ANDA filing and the real-world acts that approval of the ANDA will allow and that will harm patent-owning brand-name manufacturers. In 35 U.S.C. § 271(e)(2), Congress declared the ANDA filing to be what has been called an "artificial act of infringement," allowing the brand-name manufacturer to sue the ANDA filer to litigate patent validity and coverage. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). In so doing, Congress stressed the ANDA filer's "purpose . . . to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent," 35 U.S.C. § 271(e)(2)(A)—concrete, non-artificial acts of infringement. The relief available in such a suit, moreover, is focused on preventing or remedying the distinctly non-artificial infringing activities that threaten commercial harm: an order to delay the ANDA approval that is a precondition to mar-

keting; an injunction to prevent commercial manufacture, sale, importation, etc.; and monetary relief for such commercial activities in the past. *Id.* § 271(e)(4).

Likewise, an ANDA filer's paragraph IV certification regarding patents addresses the real-world actions for which approval is sought—specifically, whether those actions would infringe. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (certification states that patent will not be infringed "by the manufacture, use, or sale of the new drug for which the application is submitted"); 21 C.F.R. § 314.94(a)(12)(i)(A)(4) (same). This court has long recognized that the infringement inquiry called for by § 271(e)(2) is "whether, if a particular drug *were* put on the market, it *would* infringe the relevant patent" in the usual, non-artificial sense. *Bristol-Myers Squibb Co. v. Royce Labs., Inc.*, 69 F.3d 1130, 1135 (Fed. Cir. 1995); *see Sunovion Pharm., Inc. v. Teva Pharm. USA, Inc.*, 731 F.3d 1271, 1278–79 (Fed. Cir. 2013) (question is whether the conduct for which filer seeks approval would infringe); *see also Eli Lilly & Co.*, 496 U.S. at 678 (§ 271(e)(2)'s "act of infringement . . . consists of submitting an ANDA . . . containing . . . [a] certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent.").

Notably, Congress did not authorize a patent-owning brand-name manufacturer to bring a suit over patent validity or coverage just because someone, no matter who, has called the manufacturer's patent into question by declaring in some forum—to the FDA, to investors, to the public—that the patent is invalid or of limited scope. Congress added § 271(e)(2) as a special means of litigating patent scope and validity only when such a declaration has been made by an ANDA filer—which has, by its filing, confirmed its plan to commit real-world acts that would make it liable for infringement if it commits them without the patentees' permission and it is wrong in its challenges

to patent scope or validity. Congress also added a provision that confers on the ANDA filer alone a special right to seek a declaratory judgment regarding patent scope and validity if the NDA holder or patent owner does not file suit first. 35 U.S.C. § 271(e)(5). Those statutory provisions treat the ANDA filer as distinctive, and what distinguishes it is that it has, by its filing, reliably confirmed a plan to engage in real-world marketing.

All of the parties acknowledged as much at oral argument. *Acorda* Oral Arg. at 48:32–48:48, 49:18–49:27 (Mylan), 22:59–23:47 (Acorda); *AstraZeneca* Oral Arg. at 21:57–22:32 (AstraZeneca). And the economic realities of preparing an ANDA confirm that filing realistically establishes a plan to market. The current fee for filing the ANDA itself is $76,030. Generic Drug User Fee—Abbreviated New Drug Application, Prior Approval Supplement, Drug Master File, Final Dosage Form Facility, and Active Pharmaceutical Ingredient Facility Fee Rates for Fiscal Year 2016, 80 Fed. Reg. 46,015-01, 46,016 (Aug. 3, 2015). The applicant must show bioequivalence of its proposed drug to the drug listed in the NDA, 21 U.S.C. § 355(j)(2)(A)(iv), and that showing, along with other requirements for approval of an ANDA, commonly requires costly research, *see*, *e.g.*, Fiona M. Scott Morton, *Entry Decisions in the Generic Pharmaceutical Industry*, 30 RAND J. Econ. 421, 423 (1999) ("Interviews with FDA officials and several generic pharmaceutical managers generated estimated costs of filing an ANDA of $250,000 to $20 million."); Jeremy A. Greene, Generic: The Unbranding of Modern Medicine 124 (2014) (estimating the cost for measuring bioequivalence of Valium tablets, which requires nearly two thousand blood assays on human subjects over sixteen days, at $75,000–$125,000). The applicant must also identify "the facilities and controls used for[] the manufacture, processing, and packing of [its proposed] drug," 21 U.S.C. § 355(b)(1)(D); 21 C.F.R. § 314.50(d)(1)(ii)(a), and certify that its facilities comply

with the extensive good-manufacturing practices detailed in 21 C.F.R. pts. 210, 211, *see* FDA Form 356h. The FDA will inspect each facility to "evaluate whether the site is able to reliably perform intended operation(s) at a commercial scale." Guidance for Industry: ANDA Submissions—Content and Format of Abbreviated New Drug Applications 4 n.11. The magnitude and costs of the work required before the ANDA is filed soundly link the ANDA filing to the filer's entry into the market to compete with the brand-name manufacturer if approval is obtained.

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

and the marketing activities for which Mylan, by those filings, seeks approval.

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

In arguing against this application of due-process standards, Mylan does not meaningfully develop an argument that a rigid past/future dividing line governs the minimum-contacts standard. Specifically, Mylan does not show that a State is forbidden to exercise its judicial power to prevent a defendant's planned future conduct in the State, but must wait until the conduct occurs. Such a rule would run counter to the legal tradition of injunctive actions to prevent a defendant's planned, non-speculative harmful conduct before it occurs. *See United States v. W. T. Grant Co.*, 345 U.S. 629, 633 (1953) ("The purpose of an injunction is to prevent future violations, . . . and, of course, it can be utilized even without a showing of past wrongs."); 43A C.J.S. *Injunctions* § 49 (2015); 11A Charles Alan Wright, Arthur R. Miller, Mary Kay Kane, Richard L. Marcus, & Adam N. Steinman, Federal Practice & Procedure § 2948.1 (3d ed. 2015). As long as the connection to the planned acts is close enough, the subject of such actions readily fits the terms of the minimum-contacts standard—conduct purposefully directed at the State that gives rise and is related to the suit. A State's exercise of jurisdiction over a defendant planning such conduct can hardly come as a surprise to the defendant and does nothing to "offend 'traditional notions of fair play and substantial justice.'" *Int'l Shoe*, 326 U.S. at 316 (citation omitted); *see also Burger King*, 471 U.S. at 479

(explaining that personal jurisdiction should realistically consider the object of the dispute and noting that "contemplated future consequences" can play a role in the inquiry); *Roth v. Garcia Marquez*, 942 F.2d 617, 622 (9th Cir. 1991) (finding purposeful availment to support specific personal jurisdiction over defendant in a contract dispute because "the contract [at issue] concerned a film, most of the work for which would have been performed in [the forum]").

For those reasons, it suffices for Delaware to meet the minimum-contacts requirement in the present cases that Mylan's ANDA filings and its distribution channels establish that Mylan plans to market its proposed drugs in Delaware and the lawsuit is about patent constraints on such in-State marketing. And we are not barred from adopting that common-sense conclusion by this court's decision in *Zeneca Ltd. v. Mylan Pharmaceuticals, Inc.*, 173 F.3d 829 (Fed. Cir. 1999). That case was decided without any majority opinion, and neither of the two single-judge opinions (Judge Rich dissented without opinion) addresses whether the location of the ANDA filer's future sales could support specific personal jurisdiction over the filer in the § 271(e)(2) suit, so *Zeneca* is not precedent on that issue. *See Automated Merchandising Sys., Inc. v. Lee*, 782 F.3d 1376, 1381 (Fed. Cir. 2015); *Lumbermens Mut. Cas. Co. v. United States*, 654 F.3d 1305, 1317 n.10 (Fed. Cir. 2011). The issue was not presented to the court in *Zeneca*. The parties consistently stated in their briefs that the only contact with the forum at issue was the act of making the ANDA filing (at the FDA's office in Maryland). Brief for Defendant-Appellant Mylan Pharmaceuticals, Inc. at 2, *Zeneca* (No. 97-1477), 1997 WL 33545105; Brief for Plaintiff-Appellee Zeneca Limited at 11, *Zeneca* (No. 97-1477), 1997 WL 33545104. That limit on the issue before this court was reflected in the question certified for interlocutory appeal. *See Zeneca*, 173 F.3d at 830–31 (Gajarsa, J., concurring in the

judgment of reversal). In deciding only that issue, this court in *Zeneca* simply did not examine whether planned marketing in Maryland would have supported personal jurisdiction there.

Here, to reiterate, Mylan seeks approval to sell its generic drugs throughout the United States, including in Delaware, and it is undisputed that Mylan plans to direct sales of its generic drugs into Delaware. The complaints in these cases allege that Mylan's generic drugs would be distributed and sold in Delaware and that Mylan intends to commercially manufacture, use, and sell the generics upon receiving FDA approval. As Mylan admits, it develops drugs for the entire U.S. market and does some business in every State, either directly or indirectly. Pursuant to Del. Code Ann. tit. 8, §§ 371(b)(2), 376(a), Mylan has registered to do business in Delaware and appointed an agent to accept service of process there. Mylan indicated in its certificate of registration that it intends to engage in "[p]harmaceutical manufacturing, distribution and sales" in Delaware, *Acorda* J.A. 79; *AstraZeneca* J.A. 65, and Mylan registered with the Delaware Board of Pharmacy as a licensed "Pharmacy-Wholesale" and a "Distributor/Manufacturer CSR." And even if Mylan does not sell its drugs directly into Delaware, it has a network of independent wholesalers and distributors with which it contracts to market the drugs in Delaware. Such directing of sales into Delaware is sufficient for minimum contacts. *See Beverly Hills Fan*, 21 F.3d at 1565 (finding purposeful contacts where "the accused [infringing device] arrived in Virginia through defendants' purposeful shipment . . . through an established distribution channel").

One point remains. A finding of minimum contacts does not end the due-process inquiry—let alone any non-constitutional venue inquiries—into whether a case properly remains in a forum. Even if a defendant has minimum suit-related contacts with a State, the defend-

ant may defeat specific personal jurisdiction by sufficiently demonstrating that other considerations render jurisdiction unreasonable. *See Burger King*, 471 U.S. at 477. The Supreme Court has identified a number of factors to consider, including "the burden on the defendant," "the forum State's interest in adjudicating the dispute," "the plaintiff's interest in obtaining convenient and effective relief," and "the interstate judicial system's interest in obtaining the most efficient resolution of controversies." *World-Wide Volkswagen*, 444 U.S. at 292. But Mylan cannot show that those due-process factors weigh against litigating the present cases in Delaware.

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

CONCLUSION

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

AFFIRMED

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

2015-1456

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

ASTRAZENECA AB,
Plaintiff-Appellee

v.

MYLAN PHARMACEUTICALS INC.,
Defendant-Appellant

2015-1460

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

O'MALLEY, *Circuit Judge*, concurring.

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

While there is no requirement that a court consider general jurisdiction before, or in addition to, its consideration of specific jurisdiction, the Supreme Court has given some guidance about the sequencing of jurisdictional decisions. In *Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83 (1998) and *Ruhrgas AG v. Marathon Oil Co.*, 526 U.S. 574 (1999), the Court reiterated the longstanding principle that, "[w]ithout jurisdiction the court cannot proceed at all in any cause. Jurisdiction is power to declare the law, and when it ceases to exist, the

only function remaining to the court is that of announcing the fact and dismissing the cause." 523 U.S. at 94 (quoting *Ex parte McCardle*, 74 U.S. (7 Wall.) 506, 514 (1868)) (internal quotation marks omitted). Without jurisdiction, a court may not proceed to dispose of a case on the merits.

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

As Ockham's Razor advises, the simpler path is usually best. *See, e.g.*, *Awkal v. Mitchell*, 613 F.3d 629, 655 (6th Cir. 2010) (Boyce, J., dissenting) ("At some point, Ockham's Razor must apply—the simplest answer is usually the correct one."); *Commodity Futures Trading Comm'n v. Zelener*, 373 F.3d 861, 868 (7th Cir. 2004) (Easterbrook, J.) ("Best to take Occam's Razor and slice off needless complexity."). The majority finds specific personal jurisdiction because "Mylan's ANDA filings constitute formal acts that reliably indicate plans to

engage in marketing of the proposed generic drugs" in Delaware, Maj. Op. at 9, while expressly declining to discuss general personal jurisdiction, *id.* at 4. In this case, however, because I believe that the question of general jurisdiction is more straightforward—as it merely requires acknowledging a century-old line of Supreme Court precedent—I believe it should be addressed first. And, to the extent this court finds it necessary to venture into the more fact-intensive morass of specific jurisdiction, I believe the effects-based test of *Calder v. Jones*, 465 U.S. 783 (1984), provides a simpler underpinning for resolution, one that does not require reliance on a defendant's "planned future conduct in the State." Maj. Op. at 13.

DISCUSSION

A. GENERAL JURISDICTION

The requirement that a court have personal jurisdiction over a defendant before it may act "represents a restriction on judicial power not as a matter of sovereignty, but as a matter of individual liberty." *Ins. Corp. of Ir. v. Compagnie des Bauxites de Guinee*, 456 U.S. 694, 702 (1982). As such, personal jurisdiction is a "'personal privilege respecting the venue, or place of suit, which [a defendant] may assert, or may waive, at his election.' Being a privilege it may be lost." *Neirbo Co. v. Bethlehem Shipbuilding Corp.*, 308 U.S. 165, 168 (1939) (quoting *Commercial Cas. Ins. Co. v. Consol. Stone Co.*, 278 U.S. 177, 179 (1929)).

A defendant may, thus, consent to personal jurisdiction and thereby waive its right to contest it. "[B]ecause the personal jurisdiction requirement is a waivable right, there are a 'variety of legal arrangements' by which a litigant may give 'express or implied consent to the personal jurisdiction of the court.'" *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472 n.14 (1985) (citing *Ins. Corp. of Ir.*, 456 U.S. at 703). A defendant may consent to personal jurisdiction explicitly, by stipulating in advance

to litigate its claims in a particular jurisdiction through a forum selection clause or some other agreement. *See Nat'l Equip. Rental, Ltd. v. Szukhent*, 375 U.S. 311, 315–16 (1964) ("[I]t is settled . . . that parties to a contract may agree in advance to submit to the jurisdiction of a given court . . . ."). A party may also signal consent to personal jurisdiction through its actions, for example, by appearing in court and arguing the merits of the case. *See Ins. Corp. of Ir.*, 456 U.S. at 703 ("[A]n individual may submit to the jurisdiction of the court by appearance."). At issue in these appeals is, among other things, whether compliance with a state statute that requires registration and the appointment of an in-state agent for service of process in order to conduct business in that state remains a valid form of express consent to general personal jurisdiction after the Supreme Court's decision in *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014). Delaware employs just such a scheme.

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

In *Sternberg v. O'Neil*, 550 A.2d 1105 (Del. 1988), the Delaware Supreme Court held that compliance with Delaware's registration statute constitutes consent to general personal jurisdiction. That court held that, "when [a corporation] qualified as a foreign corporation, pursu-

ant to 8 Del.C. § 371, and appointed a registered agent for the service of process, pursuant to 8 Del.C. § 376, [that corporation] consented to the exercise of general jurisdiction by the Courts of Delaware." *Sternberg*, 550 A.2d at 1116. In support of its holding, the Delaware Supreme Court cited to *Pennsylvania Fire Insurance Co. v. Gold Issue Mining & Milling Co.*, 243 U.S. 93, 96 (1917): "[W]hen a power actually is conferred by a document, the party executing it takes the risk of the interpretation that may be put upon it by the courts." *Sternberg*, 550 A.2d at 1116 n.19; *see also id.* at 1113–15 (finding that the foreign corporation's "consent to the general personal jurisdiction of Delaware courts by qualifying as a foreign corporation satisfies due process" and does not constitute an undue burden on interstate commerce).

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

corporation may consent to jurisdiction over its person by choosing to comply with a state's registration statute.

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

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

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

> [a] corporation of one state cannot do business in another state without the latter's consent, express or implied, and that consent may be accompanied with such conditions as it may think proper to im-

> pose. . . . The state may, therefore, impose as a condition upon which a foreign corporation shall be permitted to do business within her limits, that it shall stipulate that in any litigation arising out of its transactions in the state, it will accept as sufficient the service of process on its agents or persons specially designated, and the condition would be eminently fit and just.

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

In *Pennsylvania Fire*, the Court affirmed that it had "little doubt" that the appointment of an agent by a foreign corporation for service of process could subject it to general personal jurisdiction. 243 U.S. at 95. In that case, the defendant was a foreign insurance company who had obtained a license to do business in Missouri, and, in accordance with the law of Missouri, "filed with the superintendent of the insurance department a power of attorney consenting that service of process upon the superintendent should be deemed personal service upon the company so long as it should have any liabilities outstanding in the state." *Id.* at 94. The defendant argued that "such service was insufficient except in suits upon Missouri contracts, and that if the statute were construed to govern the present case, it encountered the 14th Amendment by denying to the defendant due process of law." *Id.* at 94–95. A unanimous Court disagreed with the defendant, holding that, "when a power is actually conferred by a document, the party executing it takes the risk of the interpretation that may be put upon it by the courts. The execution was the defendant's voluntary act." *Id.* at 96.

In the almost 100 years since the Supreme Court decided *Pennsylvania Fire*, it has had ample opportunity to reconsider its holding. Yet each time the issue arose, the

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

The Supreme Court's subsequent decisions in *International Shoe* and *Daimler* did not overrule this historic and oft-affirmed line of binding precedent. Indeed, both cases are expressly limited to scenarios that do not involve *consent* to jurisdiction. In *International Shoe*, the Court restricted its discussion to cases where "*no consent* to be sued or authorization to an agent to accept service of process has been given." 326 U.S. at 317 (emphasis added). Based on the limitation placed on the reach of *International Shoe* by the Supreme Court itself, after *International Shoe*, numerous circuit courts continued to uphold the exercise of general jurisdiction over defendants registered to do business in the states at issue, relying on the continuing vitality of *Pennsylvania Fire*. *See, e.g.*, *King v. Am. Family Mut. Ins. Co.*, 632 F.3d 570, 576, 578 (9th Cir. 2011) ("*Pennsylvania Fire*, *Chipman*[*, Ltd., v. Thomas B. Jeffrey Co.*, 251 U.S. 373 (1920)], and *Robert Mitchell* thus collectively stand for the proposition that

federal courts must, subject to federal constitutional restraints, look to state statutes and case law in order to determine whether a foreign corporation is subject to personal jurisdiction in a given case because the corporation has appointed an agent for service of process."); *Wenche Siemer v. Learjet Acquisition Corp.*, 966 F.2d 179, 183 (5th Cir. 1992) ("No Texas state court decision has held that this provision acts as a consent to jurisdiction over a corporation in a case such as ours—that is where plaintiffs are non-residents and the defendant is not conducting substantial activity within the state."); *Bane v. Netlink, Inc.*, 925 F.2d 637, 641 (3d Cir. 1991) (observing that "[c]onsent is a traditional basis for assertion of jurisdiction long upheld as constitutional"); *Knowlton v. Allied Van Lines, Inc.*, 900 F.2d 1196, 1199–1200 (8th Cir. 1990) (noting that, as interpreted by the Supreme Court of Minnesota, "[t]he whole purpose of requiring designation of an agent for service is to make a nonresident suable in the local courts"); *Holloway v. Wright & Morrissey, Inc.*, 739 F.2d 695, 697 (1st Cir. 1984) ("It is well-settled that a corporation that authorizes an agent to receive service of process in compliance with the requirements of a state statute, consents to the exercise of personal jurisdiction in any action that is within the scope of the agent's authority."). And, the Second Restatement adopted that same view in 1971. Restatement (Second) of Conflict of Laws § 44 (1971) ("A state has power to exercise judicial jurisdiction over a foreign corporation which has authorized an agent or a public official to accept service of process in actions brought against the corporation in the state as to all causes of action to which the authority of the agent or official to accept service extends."). *Daimler* did not change the law on this point, either.

There is no discussion of registration statutes in *Daimler* and no citation to *Schollenberger*, *Pennsylvania Fire*, or the cases post-dating those two. Indeed, *Daimler*

confirms that consent to jurisdiction is an alternative to the minimum contacts analysis discussed in that case, citing to *Perkins v. Benguet Consolidated Mining Co.*, 342 U.S. 437 (1952), as "the textbook case of general jurisdiction appropriately exercised over a foreign corporation that has *not consented* to suit in the forum." 134 S. Ct. at 755–56 (emphasis added). Thus, *Daimler* did not impliedly eradicate the distinction between cases involving an express consent to general jurisdiction and those analyzing general jurisdiction in the absence of consent; it actually maintains it. Notably, the Court had no occasion to consider the rule it laid down in *Pennsylvania Fire* because California—the state where the action at issue was pending—had interpreted its registration statute as one that did not, by compliance with it, give rise to consent to personal jurisdiction. The only question the Court considered was whether the foreign defendant was subject to jurisdiction solely by virtue of its contacts with the state, which were unrelated to the cause of action.

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

Notably, *Pennsylvania Fire* was decided almost 100 years before Mylan chose to register to do business in Delaware. And *Sternberg*'s interpretation of the registra-

tion statute had been on the books for almost twenty of those years. In the face of that legal authority, Mylan knowingly chose to register to do business in Delaware, thereby accepting the implication of having done so.

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

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[1] One amicus argues that a finding of general personal jurisdiction by virtue of Delaware's consent-by-registration statute would violate the unconstitutional conditions doctrine. *See* Br. of Amicus Curiae Chamber of Commerce 18–21. Because neither party has raised the question, however, it is not before us. Even if it were,

B. SPECIFIC JURISDICTION

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

The majority addresses only specific jurisdiction, and finds that it properly can be exercised here. I concur with the majority's judgment, but not entirely with its reasoning. I agree that Mylan is subject to specific jurisdiction

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moreover, the Supreme Court has upheld the validity of consent-by-registration statutes numerous times since the development of the unconstitutional conditions doctrine. In *Neirbo*, the Supreme Court commented that, the decision to strike down the Texas statute at issue, "which not merely regulated procedure for suit but sought to deny foreign corporations access to the federal courts" was "wholly consistent" with the decision in *Schollenberger*, which allowed state legislatures to require foreign corporations to consent to general personal jurisdiction as a condition of being granted the right to do business in that state. *Neirbo*, 308 U.S. at 173–74.

in Delaware, but I would find specific jurisdiction under the Supreme Court's precedent in *Calder v. Jones*, 465 U.S. 783 (1984), and not predicate the exercise of jurisdiction primarily on Mylan's expressions of *future* intent.

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

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

Id. at 788–89. Because "California [was] the focal point both of the story and of the harm suffered," it was appropriate to exercise jurisdiction over the defendants "in California based on the 'effects' of their Florida conduct in California." *Id.* at 789.

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

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

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

A generic drug manufacturer, like Mylan, files an Abbreviated New Drug Application ("ANDA") with the FDA, seeking approval to market generic versions of drugs produced by brand-name drug manufacturers, like Acorda and AstraZeneca. *See* Maj. Op. at 4–5. Mylan's filing under paragraph IV of 21 U.S.C. § 355(j)(2)(A)(vii) certi-

fies its belief that Acorda's and AstraZeneca's Orange Book patents are invalid or would not be infringed by Mylan's proposed drug. *Id.* In this way, the filing of the paragraph IV certifications in ANDA applications at issue here were not random acts that happen to harm someone living in a particular state. As in *Calder*, the acts were calculated and directed to cause harm to the intellectual property rights of a known party with a known location. It is an act which—even before a single sale of product in the State of Delaware—called into question the validity and value of property rights protecting the marketing of profitable products by Acorda and AstraZeneca. In so doing, it called into question the very value of their respective businesses. By virtue of the provisions of the Hatch–Waxman Act requiring that they do so, the paragraph IV certification filing also triggered an obligation to quickly file an expensive "infringement" action in an effort to lift the cloud placed on the Appellees' business interests. *See Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1677 (2012) ("Filing a paragraph IV certification means provoking litigation.").

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

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[2] The act of infringement, which the Supreme Court has called "highly artificial," *Eli Lilly & Co. v. Medtronic,*

Of course, "[t]he proper question is not where the plaintiff experienced a particular injury or effect but whether the defendant's conduct connects him to the forum in a meaningful way." *Walden*, 134 S. Ct. at 1125. The situs of plaintiff's injury and the nature of it are factors in the analysis, but are not determinative standing alone. *Id.* In *Calder*, the Supreme Court found specific personal jurisdiction in California even though the allegedly libelous publication was published elsewhere and marketed nationwide. *Calder*, 465 U.S. at 785 (noting that the National Enquirer "publishes a national weekly newspaper with a total circulation of over 5 million"). Here, there is no physical, nationally distributed product causing harm to the plaintiffs. Despite that, the targeted nature of an ANDA filing—which is intended to challenge a particular patent owned by a known party with a known location—makes the case at hand just like that in *Calder*—the harm is targeted only to these Delaware companies, occurs only in Delaware, and is only triggered by the filing of the ANDA. While it is true, as the majority notes, that the filing of an ANDA application indicates Mylan's desire to market its product on a nation-wide basis, including in Delaware, I find that expres-

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

sion of interest meaningful for different reasons. I believe it reinforces the *immediate* harm caused by the ANDA filing, regardless of whether such marketing ever occurs.

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

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

CONCLUSION

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

CERTIFICATE OF SERVICE

I hereby certify that on April 18, 2016, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

s/Paul D. Clement
Paul D. Clement