No. 16-360

In the Supreme Court of the United States

MYLAN PHARMACEUTICALS INC. ET AL., PETITIONERS

v.

ACORDA THERAPEUTICS INC. ET AL.

MYLAN PHARMACEUTICALS INC., PETITIONER

v.

ASTRAZENECA AB

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR RESPONDENT ASTRAZENECA AB IN OPPOSITION

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QUESTION PRESENTED

Whether a State can assert specific jurisdiction over a generic pharmaceutical manufacturer that has filed an abbreviated new drug application seeking federal approval to market a drug in that State for the purpose of displacing sales from a patent holder that holds the exclusive right to distribute the drug in that State.

CORPORATE DISCLOSURE STATEMENT

Respondent AstraZeneca AB is an indirect subsidiary of AstraZeneca PLC. AstraZeneca PLC has no parent corporation, and no publicly held company owns 10% or more of its stock.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1-38) is reported at 817 F.3d 755. The opinion of the district court in *Mylan Pharmaceuticals Inc.* v. *AstraZeneca AB* (Pet. App. 42-62) is reported at 72 F. Supp. 3d 549. The opinion of the district court in *Mylan Pharmaceuticals Inc.* v. *Acorda Therapeutics Inc.* (Pet. App. 67-116) is reported at 78 F. Supp. 3d 572.

JURISDICTION

The judgment of the court of appeals was entered on March 18, 2016. A petition for rehearing was denied on June 20, 2016 (Pet. App. 39-41). The petition for a writ of certiorari was filed on September 19, 2016. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

Respondent AstraZeneca AB (AstraZeneca) was party to one of two cases consolidated for decision below. In AstraZeneca's case, petitioner Mylan Pharmaceuticals Inc. (Mylan) filed an abbreviated new drug application (ANDA) in which it sought nationwide approval from the Food and Drug Administration (FDA) to market generic versions of two diabetes drugs patented by AstraZeneca. As part of that application, Mylan certified to FDA that AstraZeneca's patents were invalid or would not be infringed—an action designed to provoke litigation in which Mylan could seek to extinguish respondent's exclusive patent rights to manufacture and distribute the drugs.

AstraZeneca, which conducts its American operations from headquarters in Wilmington, Delaware, sued Mylan for patent infringement in the United States District Court for the District of Delaware. Mylan resisted the exercise of personal jurisdiction, advancing the remarkable claim that its ANDA filing—which targeted AstraZeneca's corporate interests in Delaware and sought federal approval to compete head-to-head in that State (and in every other)—was not purposefully directed at Delaware. The district court rejected that claim; the court of appeals unanimously agreed; and the en banc Federal Circuit denied review without recorded dissent.

Notwithstanding Mylan's efforts to slime the Federal Circuit for deviating from the "traditional rules of litigation," Pet. 25, the Federal Circuit's well-reasoned decision

is entirely consistent with the decisions of this Court and other circuits. Contrary to Mylan's assertion, the court of appeals did not embrace an "unacceptably grasping" rule that personal jurisdiction could be premised on speculative future contacts with Delaware. Pet. 1 (citation omitted). Instead, it grounded jurisdiction on "the particular actions Mylan *has already taken*—its ANDA filings." Pet. App. 8 (emphasis added). Far from enacting a "novel rule," Pet. 12, the court of appeals applied settled due-process principles to reach a common-sense result. To date, every judge to have touched this case has concluded that jurisdiction is proper in Delaware. All of those judges were correct.

If there is anyone who is urging a radical departure from precedent, it is Mylan. As one of the Nation's largest generic drug manufacturers, Mylan is also one of the most frequent ANDA defendants. Following this Court's decision narrowing the scope of *general* jurisdiction in *Daimler AG* v. *Bauman*, 134 S. Ct. 746 (2014), Mylan saw an opportunity to litigate ANDA cases on its home turf and began urging district courts nationwide that *specific* jurisdiction against it was proper only in its home State of West Virginia.

Mylan's position was as self-serving as it was meritless. Before the court of appeals definitively resolved the issue, nearly every district court to have considered it had rejected that position. And for good reason, because Mylan's position would upend the manner in which Hatch-Waxman cases are litigated and subvert the orderly resolution of these cases. This Court should now decline Mylan's invitation to unleash chaos in Hatch-Waxman cases. There is no reason for the Court to intervene, and the petition for certiorari should therefore be denied.

1. In order to obtain approval for a new prescription drug, brand-name manufacturers such as AstraZeneca must file a new drug application with FDA and undertake a "long, comprehensive, and costly testing process" to prove that the drug is safe and effective. *FTC* v. *Actavis, Inc.*, 133 S. Ct. 2223, 2228 (2013); see 21 U.S.C. 355(b)(1). In 1984, Congress enacted the Hatch-Waxman Act to streamline the approval process for generic drugs, permitting generic drug manufacturers to "piggy-back" on the extensive testing already performed by the brand-name manufacturer. See *Caraco Pharmaceutical Laboratories, Ltd.* v. *Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012). Generic manufacturers need only submit an abbreviated new drug application showing that "the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug." *Ibid.*

Of particular relevance here, the Hatch-Waxman Act provides a mechanism by which generic drug manufacturers can attack the validity of patents protecting prescription drugs. When a generic manufacturer files an ANDA, it must certify that the approval it requests will not intrude on existing patent rights. See 21 U.S.C. 355(j)(2)(A)(vii). Among the ways it can satisfy that requirement, the generic manufacturer can make a so-called "paragraph IV certification" that a patent covering the relevant brand-name drug is invalid or would not be infringed by the competing product. See 21 U.S.C. 355(j)(2)(A)(vii)(IV).

Generic drug manufacturers frequently file paragraph IV certifications with their ANDAs. And as a practical matter, filing such a certification "means provoking litigation" with the brand-name manufacturer. *Caraco*, 132 S. Ct. at 1677. The Hatch-Waxman Act treats the submission of an ANDA with a paragraph IV certification as an

act of patent infringement "if the purpose of such submission is to obtain approval * * * to engage in the commercial manufacture, use, or sale of a drug * * * claimed in a patent * * * before the expiration of such patent." 35 U.S.C. 271(e)(2).

As the Court has noted, that statutorily defined act of infringement is "highly artificial," because it permits the patent holder to bring suit even before the generic manufacturer has brought its competing product to market. *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 678 (1990). The purpose of the statutory definition is to allow litigation concerning the validity of the disputed patent before the generic manufacturer has sold the drug and incurred potentially "ruinous liability for infringement." *Actavis*, 133 S. Ct. at 2247 (Roberts, C.J., dissenting).

Because an ANDA seeks approval to sell a competing drug, the merits inquiry in ANDA litigation is necessarily hypothetical and forward-looking. Confronted with a claim of patent infringement under the statute, courts evaluate whether, "if a particular drug *were* put on the market, it *would* infringe the patent." *Bristol-Myers Squibb Co.* v. *Royce Laboratories, Inc.*, 69 F.3d 1130, 1135 (Fed. Cir. 1995). In keeping with the forward-looking merits inquiry, the remedies available to patent holders under the statute are prospective. See *Eli Lilly*, 496 U.S. at 678. If the court concludes that the patent is valid and would be infringed by the generic drug, it will order that approval of the ANDA cannot take effect until the patent expires. See 35 U.S.C. 271(e)(4)(A).

The Hatch-Waxman Act contemplates that litigation between the generic manufacturer and the brand-name manufacturer will take place expeditiously. When a generic manufacturer submits an ANDA containing a paragraph IV certification, it must send a written notice to the

patent holder detailing why it believes the patent to be invalid. See 21 U.S.C. 355(j)(2)(B)(ii)-(iv). If the patent holder files suit for infringement within 45 days of the notice letter, FDA's approval of the generic drug is automatically stayed while the parties litigate the validity of the patent. The stay remains in place for only 30 months unless the litigation concludes more quickly or the court otherwise terminates the stay. See 21 U.S.C. 355(j)(5)(B)(iii)(I).

2. Mylan primarily manufactures generic drugs. It is incorporated in West Virginia and has its principal place of business in that State. Mylan is one of the largest private employers in West Virginia, with some 3,000 employees there according to a recent report. See WorkForce West Virginia, *100 Largest Private Employers in West Virginia* (2016); *Mylan Pharmaceuticals Keeps Growing, Giving Back to WV*, Charleston State Journal, May 31, 2012.

Together with its corporate affiliates, Mylan ranks as the second-largest generic manufacturer by sales in the United States. See Mylan N.V., Form 10-K, Feb. 16, 2016, at 6. One out of every 13 prescriptions dispensed in this country is a Mylan product. See *ibid.* Mylan does business, either directly or through established distribution networks, in every State. See *Eli Lilly & Co.* v. *Accord Healthcare, Inc.*, Civ. No. 14-389, Dkt. No. 277, at 13 (S.D. Ind. Nov. 7, 2014).

3. AstraZeneca primarily develops and manufactures brand-name drugs. It does business in the United States through AstraZeneca Pharmaceuticals LP, a limited partnership with headquarters in Wilmington, Delaware. Two of AstraZeneca's prescription-drug products are Onglyza® and Kombiglyze™ XR, which treat adults with Type 2 diabetes. Both products are protected by patents and have been approved by FDA. See Pet. App. 3-4.

In 2013, Mylan filed ANDAs seeking approval to manufacture and sell generic versions of Onglyza and Kombiglyze XR. As required by statute, Mylan notified AstraZeneca of its certifications that patents pertaining to the drugs were invalid or would not be infringed by its generic products. Mylan sent the notice letters to AstraZeneca at its headquarters in Sweden and to AstraZeneca Pharmaceuticals LP at its headquarters in Wilmington. See Pet. App. 4.

4. In 2014, AstraZeneca filed patent-infringement suits in the United States District Court for the District of Delaware against Mylan and other generic manufacturers that had filed ANDAs with paragraph IV certifications seeking approval to manufacture generic versions of Onglyza or Kombiglyze XR. As is typical in ANDA litigation, the cases were consolidated for trial.

Alone among the eighteen defendants, Mylan moved to dismiss the suit against it for lack of personal jurisdiction. The district court denied Mylan's motion to dismiss. Pet. App. 42-62. As is relevant here, the court concluded that the exercise of specific jurisdiction over Mylan in Delaware was consistent with due process. *Id.* at 55-62. The district court rejected as "untenable" Mylan's position that, because it had not yet actually brought drugs to market, its ANDA-related activity was not directed at *any* State. *Id.* at 58. The court observed that the submission of an ANDA is a "'real act' with 'actual consequences.'" *Ibid.* (quoting *Zeneca Ltd.* v. *Mylan Pharmaceuticals, Inc.*, 173 F.3d 829, 833-834 (Fed. Cir. 1999) (opinion of Gajarsa, J.)). In the district court's view, the mailing of the notice letter to AstraZeneca in Delaware triggered one such consequence—the running of the 45-day clock to file suit or lose the automatic stay—and thus created sufficient contacts with Delaware to permit the exercise of specific jurisdiction. *Id.* at 59-60.

The district court further concluded that the exercise of jurisdiction over Mylan in Delaware would be fair and reasonable. Pet. App. 60-62. It noted that Mylan was "no stranger" to litigating in Delaware and that defending an infringement suit in that State would impose "no meaningful burden." *Id.* at 60-61. By contrast, litigating the case in West Virginia—the only jurisdiction in which Mylan had conceded it could be sued—would impose burdens on AstraZeneca and the judicial system. *Id.* at 61. Observing that AstraZeneca had initiated multiple cases against generic companies that had filed ANDAs for the same drugs, the district court concluded that "[r]esolution of these cases in a single district would promote judicial economy and avoid the possibility of inconsistent outcomes." *Id.* at 62.[1]

5. After granting interlocutory review and consolidating this case with another case presenting the same issue, the court of appeals unanimously affirmed. Pet. App. 1-38. The court held that the exercise of specific jurisdiction over Mylan in Delaware was proper because Mylan had taken the "costly, significant step" of seeking approval to market generic drugs in that State—and, indeed, throughout the United States—before the expiration of AstraZeneca's patents. *Id.* at 7-8.

At the outset, the court of appeals noted that specific jurisdiction was appropriate where a defendant "ha[s] certain minimum contacts with [the forum] such that the maintenance of the suit does not offend traditional notions

[1] At the same time, the district court concluded that the exercise of *general* jurisdiction over Mylan in Delaware would be inconsistent with due process, both because Mylan was neither incorporated nor headquartered in Delaware and because Mylan's registration to do business in Delaware could not validly serve as consent to general jurisdiction there. Pet. App. 47-55.

of fair play and substantial justice." Pet. App. 6-7 (internal quotation marks and citation omitted). Applying that standard, the court explained that "Mylan's ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs." *Id.* at 8. The court noted that the very "purpose and planned effect" of Mylan's ANDA filings was to displace sales of brand-name drugs. *Ibid.* Accordingly, the court reasoned that "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." *Ibid.*

In addition, the court of appeals noted that there was no dispute that Mylan intends to sell its generic drugs in Delaware. Pet. App. 15. As the court observed, Mylan sells its products in every State, either directly or through established distribution networks, and Mylan's then-counsel conceded at oral argument that Mylan intends to market the disputed drugs in Delaware if its ANDAs are approved. *Id.* at 10-11, 15. The court added that Mylan is registered to do business in Delaware and is licensed by the Delaware Board of Pharmacy as a wholesaler and distributor. *Id.* at 15-16. Under those circumstances, the court concluded, Mylan had sufficient contacts with Delaware to justify the exercise of specific jurisdiction. *Id.* at 13.

The court of appeals further concluded that the exercise of jurisdiction over Mylan in Delaware would be fair and reasonable. Pet. App. 16-17. Like the district court, the court of appeals noted that Mylan would face only a "modest" burden in defending the suit in Delaware and that the interests of AstraZeneca and of the judicial system favored litigating in Delaware, where additional suits addressing the same patents were pending. *Id.* at 17. The

court also observed that Delaware had an interest in providing a forum for a dispute concerning products that would be sold in that State and would cause harm to a business incorporated in that State. *Ibid.* The court therefore upheld the exercise of specific jurisdiction over Mylan in Delaware. *Ibid.*

Judge O'Malley concurred in the judgment. Pet. App. 18-38. She wrote separately to express her view that the exercise of general jurisdiction, as well as specific jurisdiction, would have been proper. *Id.* at 19. As to specific jurisdiction, she emphasized that the ANDA filing injured AstraZeneca both by calling into question the validity of its intellectual-property rights and the value of its business, and by imposing an obligation to file a costly infringement action in order to dispel the cloud over its patents. *Id.* at 35. Although Judge O'Malley recognized that jurisdiction could not be premised on a mere showing of harm to a Delaware resident, *id.* at 34, she noted that the ANDA filings were specifically targeted to cause injury to a "known party with a known location." *Id.* at 35, 37. And she stressed that the harm to AstraZeneca was "*immediate*," regardless of whether Mylan ultimately sold a competing generic product in Delaware. *Id.* at 37.

6. Mylan petitioned for rehearing en banc, and the court of appeals denied rehearing without recorded dissent. Pet. App. 39-41.

ARGUMENT

Mylan's petition for certiorari is the final step in its quixotic and transparently self-interested effort to funnel all Hatch-Waxman litigation against it into its home State of West Virginia. The court of appeals correctly held that the Due Process Clause does not require that radical and bizarre result. The court of appeals' common-sense application of settled due-process principles creates no conflict

with any decision either of this Court or of another court of appeals. In an effort to gin up such a conflict, Mylan overstates both the substance and the effect of the court of appeals' decision.

Notably, Mylan made essentially the same arguments in its briefs before the panel and in its petition for rehearing. Yet the ordinary indicator for further review of a Federal Circuit decision—disagreement by at least one member either of the panel or of the en banc court—is conspicuously absent here. This case does not warrant further review, and the petition for certiorari should therefore be denied.

A. The Court Of Appeals' Decision Was Correct

The court of appeals correctly held that Delaware could exercise specific jurisdiction over Mylan consistent with the Due Process Clause.

1. This Court recognizes "two categories of personal jurisdiction": general and specific. *Daimler*, 134 S. Ct. at 754. The present case involves only the latter. For a defendant to be subject to specific jurisdiction in a State consistent with the Due Process Clause, it must have "minimum contacts" with the State such that "the maintenance of the suit does not offend traditional notions of fair play and substantial justice." *Walden* v. *Fiore*, 134 S. Ct. 1115, 1121-1122 (2014). In conducting the minimum-contacts inquiry, a court should consider whether the defendant has "purposefully directed" its activities at the forum State and whether the claims "arise out of or relate to" the defendant's contacts with the forum State. *Burger King Corp.* v. *Rudzewicz*, 471 U.S. 462, 472 (1985).

Applying that standard, the court of appeals correctly held that Mylan's ANDA filings gave rise to specific jurisdiction in the State of Delaware. The court concluded that jurisdiction was proper based on Mylan's *past act* of filing

an ANDA—an act that seeks approval to compete with the brand-name manufacturer nationwide and that attacks the patent holder's intellectual-property rights everywhere they are valid. Pet. App. 8. From the generic manufacturer's perspective, the very purpose of the ANDA is to extinguish federal patent rights and obtain approval from FDA to compete nationwide. See 35 U.S.C. 271(e)(2) (providing that the submission of an ANDA with a paragraph IV certification is an act of patent infringement "if the purpose of such submission is to obtain approval * * * to engage in the commercial manufacture, use, or sale of a drug * * * claimed in a patent * * * before the expiration of such patent").

At the same time as it relied on Mylan's past act of filing an ANDA, the court of appeals made the commonsense observation that no "rigid past/future dividing line governs the minimum-contacts standard." Pet. App. 13. Under the Hatch-Waxman Act, the filing of an ANDA is "tightly tied, in purpose and planned effect, to the deliberating making" of future sales. *Id.* at 8. Indeed, in this case, not only did Mylan attack AstraZeneca's exclusive rights in Delaware and seek approval to sell its competing drugs there, but it is undisputed that Mylan *will in fact* sell its drugs in Delaware if its ANDAs are approved. In fact, though one would never know it from the petition for certiorari, Mylan's then-counsel conceded as much at oral argument before the court of appeals. See *id.* at 10-11.

In those circumstances, it is eminently sensible to consider the "contemplated future consequences" of a defendant's past acts in "determining whether the defendant purposefully established minimum contacts within the forum." *Burger King*, 471 U.S. at 479. Under such an approach, the filing of an ANDA with a paragraph IV certification gives rise to minimum contacts with every State,

subject to the important condition that the exercise of personal jurisdiction in a particular State be otherwise fair and reasonable. *Cf. Keeton* v. *Hustler Magazine, Inc.*, 465 U.S. 770, 772-777, 781 (1984) (concluding that specific jurisdiction over "a national publication aimed at a nationwide audience" lies in any State where the libel defendant targeted its conduct and where the plaintiff suffered reputational harm).

2. Mylan contends that its only suit-related contacts were with West Virginia and Maryland. See Pet. 10. But that cramped view of specific jurisdiction lacks merit. As to West Virginia: Mylan suggests that it is subject to specific jurisdiction in West Virginia based on its preparation of its ANDAs there. See Pet. 2, 12-13, 17. But the Hatch-Waxman Act specifically exempts such preparatory activity from the definition of infringement. See 35 U.S.C. 271(e)(1); *Eli Lilly*, 496 U.S. at 678. Congress included that exemption to eliminate the chill on generic competition that would occur if companies such as Mylan could be sued for patent infringement during the course of preparing an ANDA. Instead, a generic manufacturer may be sued for infringement *only* upon submission of the ANDA to FDA and mailing of the notice letter to the patent holder. See 35 U.S.C. 271(e)(2). It would make little sense to restrict the exercise of specific jurisdiction to the forum where a generic manufacturer conducts preparatory activity, given that such activity is explicitly protected by statute.

As to Maryland: Mylan now suggests that it is subject to specific jurisdiction in Maryland based on its submission of ANDAs to FDA's headquarters there. See Pet. 2, 12-13, 17. But Mylan did not advance that argument below, and for good reason. The Federal Circuit has previously held that submission of an ANDA to FDA's headquarters could not, without more, support the exercise of

specific jurisdiction in Maryland. See *Zeneca*, 173 F.3d at 834. Mylan did not ask the Federal Circuit to reconsider that precedent, and it offers no argument on that score in its petition. The glaring flaws in Mylan's argument about where specific jurisdiction *does* exist in the context of the Hatch-Waxman Act underscores that its argument about where specific jurisdiction does *not* exist must be incorrect.

In short, the court of appeals correctly applied settled due-process principles in holding that Mylan was subject to specific jurisdiction in Delaware. As we will now explain, Mylan's arguments in support of certiorari lack merit.

B. The Court Of Appeals' Decision Does Not Conflict With Any Decision Of This Court Or Of Another Court Of Appeals

Mylan contends that the court of appeals' decision conflicts with decisions of this Court and of other courts of appeals in two respects. First, Mylan contends that the court of appeals improperly based the exercise of specific jurisdiction on an ANDA filer's speculative future sales in the forum State, thereby giving rise to a circuit conflict. See Pet. 20-21. But that contention rests on an erroneous understanding of the court of appeals' decision. Far from crafting any such "novel rule," Pet. 12, the court of appeals concluded that "the minimum-contacts standard is satisfied by the particular actions Mylan has *already taken*," Pet. App. 8 (emphasis added): specifically, the filing of its ANDAs. Once that error is corrected, Mylan's claimed circuit conflict evaporates.

Second, Mylan contends that the court of appeals' decision conflicts with this Court's recent decision in *Daimler*. See Pet. 22-24. That is plainly wrong. *Daimler* involved general jurisdiction, not specific jurisdiction. And

in *Daimler*, this Court did not foreclose the possibility that a defendant's actions might give rise to specific jurisdiction in multiple States, as is often the case in patent litigation outside the context of the Hatch-Waxman Act. While Mylan complains about the prospect of 50-State specific jurisdiction over ANDA filers, it completely ignores the important condition that the exercise of jurisdiction in a particular forum be otherwise fair and reasonable.

The court of appeals' decision was entirely consistent with the decisions of this Court and of other courts of appeals. Further review is not warranted.

1. The Court of Appeals' Decision Does Not Conflict With Any Decision Of Another Court Of Appeals

a. Mylan faults the court of appeals for supposedly crafting the erroneous rule that specific jurisdiction can be premised on Mylan's speculative future sales in a forum State. See Pet. 19-22. But that characterization of the court's reasoning is simply incorrect. The court premised the exercise of specific jurisdiction in Delaware on "the particular actions Mylan has *already taken*—its ANDA filings—for the purpose of engaging in * * * injury-causing and allegedly wrongful marketing conduct in Delaware." Pet. App. 8 (emphasis added).

In holding that the exercise of specific jurisdiction in Delaware was proper, moreover, the court of appeals correctly apprehended the significance of Mylan's ANDA filings. Although this Court has said that the filing of an ANDA with a paragraph IV certification gives rise to a "highly artificial" claim of infringement, *Eli Lilly*, 496 U.S. at 678, the purpose and effect of that filing are far from abstract: it is a formal application to a federal agency for permission to manufacture and sell drugs before the patents covering those drugs have expired. See

p. 4, *supra*. The submission of an ANDA triggers legal obligations in third parties: the patent holder whose rights are challenged must file an infringement action within 45 days in order to stay FDA approval of the generic drug. See pp. 5-6, *supra*.

As Judge O'Malley elaborated in her concurring opinion, see Pet. App. 35, the submission of an ANDA with a paragraph IV certification works a serious and present injury to the patent holder. Because the ANDA includes a certification that patents covering the relevant drugs are invalid, it places a cloud over the patent holder's intellectual-property rights and obligates the patent holder to prosecute a costly suit in order to protect the value of its investment. See *ibid.* The patent holder has thus been harmed the moment the ANDA is filed, regardless of whether the generic manufacturer ever makes a single sale. For that reason, as Judge O'Malley noted, the filing of an ANDA is a "defined" and "very real" act with immediate consequences. *Id.* at 36 n.2.

The court of appeals took pains to explain that it was the "costly, significant step" of filing an ANDA that grounded the exercise of jurisdiction in this case. Pet. App. 7-8. To be sure, the ANDA submission bears a close connection to the "future infliction of real-world market injury on the patent holder," as the court of appeals proceeded to observe. *Id.* at 12. After all, an ANDA is filed for the avowed purpose of enabling future sales for the generic manufacturer and thereby displacing future sales from the patent holder; an ANDA thus "reliably indicate[s] plans to engage in marketing of the proposed generic drugs." *Id.* at 8.

In recognizing the reality that the filing of an ANDA has that purpose, however, the court of appeals did not hold that jurisdiction may be premised on speculative future activities alone; again, it relied only on "the particular

actions Mylan *has already taken*—its ANDA filings." Pet. App. 8 (emphasis added). The court of appeals' reasoning is perfectly consistent with this Court's recognition that the "contemplated future consequences" of a defendant's past activities "must be evaluated in determining whether the defendant purposefully established minimum contacts with the forum." *Burger King*, 471 U.S. at 479.[2]

b. Once Mylan's mischaracterization of the court of appeals' holding is corrected, its claimed circuit conflict falls away. Mylan contends that the court of appeals generated a split with decisions of courts of appeals recognizing that "future activities are not relevant in personal jurisdiction analysis." Pet. 20. No circuit conflict exists for the simple reason that the court of appeals did not premise jurisdiction on mere "speculation about the future," as Mylan contends. Pet. 2.

In any event, the cases Mylan cites on the other side of the asserted conflict do not even address whether future contacts in a State may ever support the exercise of specific jurisdiction. For example, in *Fastpath, Inc.* v. *Arbela Technologies Corp.*, 760 F.3d 816 (2014), the Eighth Circuit held that a nonresident corporation could not be sued in Iowa simply because it entered into a confidentiality agreement to explore business opportunities with an Iowa company, where the agreement "did not require performance or contemplate future consequences specifically in Iowa." *Id.* at 822. The court noted the *absence* of

[2] If Mylan were correct that personal jurisdiction can only be premised on past actions without regard to the future consequences of those actions, courts would frequently lack the power to grant injunctive relief to prevent defendants from engaging in wrongful future conduct in a forum State. As the court of appeals recognized, "[s]uch 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." Pet. App. 13.

planned future contacts, without expressing a view on how the existence of such contacts might have affected its analysis. See *id.* at 821-824.

So too in *Moncrief Oil International Inc.* v. *OAO Gazprom*, 481 F.3d 309 (5th Cir. 2007), the Fifth Circuit rejected an argument that a State could exercise jurisdiction over a defendant that entered a contract with a resident of the forum State knowing that the resident might perform its own contractual obligations there. See *id.* at 312. The case had nothing to do with future contacts; it merely recited the familiar principle that the plaintiff's unilateral contacts with the forum State do not give rise to jurisdiction over the defendant. See *id.* at 311-313.[3]

Under a correct understanding of the court of appeals' holding, therefore, there is no circuit conflict that requires intervention by this Court. Further review is unwarranted.

2. The Court of Appeals' Decision Does Not Conflict With This Court's Decision In Daimler

a. Mylan next contends that the court of appeals' decision is inconsistent with this Court's decision in *Daimler*. See Pet. 22-24. But *Daimler* has no relevance to this case. The only question the court of appeals considered here is whether Delaware could exercise *specific* jurisdiction over Mylan. In *Daimler*, by contrast, this Court addressed the circumstances in which a State may exercise *general* jurisdiction over a corporate defendant—that is, the circumstances in which the State may entertain *any*

[3] The other cases cited by Mylan likewise do not conflict with the decision below. See *Cossaboon* v. *Maine Medical Center*, 600 F.3d 25, 37 (1st Cir. 2010) (concluding that registration to do business in a State is not sufficient to confer *general* jurisdiction); *Hyatt International Corp.* v. *Coco*, 302 F.3d 707, 716 (7th Cir. 2002) (observing that contacts with the forum State that are unrelated to the suit are insufficient to satisfy due process).

claim against a corporation, without regard to whether the claim itself arises out of or relates to the corporation's activities in that State. See 134 S. Ct. at 754. The Court held that a State could exercise general jurisdiction over a corporation only where "the corporation's 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. In so holding, the Court rejected a more expansive rule permitting the exercise of general jurisdiction wherever a corporation "engages in a substantial, continuous, and systematic course of business." *Id.* at 761.

Daimler does not stand for the considerably broader proposition for which Mylan cites it: namely, that nationwide *specific* jurisdiction is foreclosed where the corporate defendant has suit-related contacts in all 50 States. See Pet. 13. The Court was emphatic in *Daimler* that it was addressing general jurisdiction and no more, noting that the plaintiffs had "never attempted to fit this case into the specific jurisdiction category." 134 S. Ct. at 758 (emphasis omitted). That is the beginning and the end of the analysis as to why *Daimler* is inapposite here.

b. Even if it were true that the effect of the court of appeals' decision is to create nationwide specific jurisdiction over generic drug manufacturers in ANDA litigation, there would be nothing anomalous about that result. In other contexts, this Court has recognized the availability of specific jurisdiction in all 50 States. For example, libel plaintiffs suing a news organization that publishes in every State will typically have their choice of forum. See *Keeton*, 465 U.S. at 780-781. In ordinary patent-infringement suits outside the context of the Hatch-Waxman Act, moreover, generic drug companies "are frequently subject to personal jurisdiction in practically any federal

court in the country." Megan M. LaBelle, *Patent Litigation, Personal Jurisdiction, and the Public Good*, 18 Geo. Mason L. Rev. 43, 70 (2010) (LaBelle); see *Allergan, Inc.* v. *Actavis, Inc.*, Civ. Nos. 14-188 & 14-638, 2014 WL 7336692, at *7 (E.D. Tex. Dec. 23, 2014). That is because the generic manufacturers that defend these suits typically sell their products in every State and may thus be liable for infringement in each of those jurisdictions. See LaBelle 70.

There is no reason the result should be different in cases arising under the Hatch-Waxman Act. When a generic drug manufacturer files an ANDA with a paragraph IV certification, it does not specify the States in which it plans to sell its competing product; by default, it challenges a patent holder's rights in every State and seeks permission to market its product nationwide. See Pet. App. 15. Even in the far-fetched event that a generic manufacturer plans to sell in only a subset of the 50 States, the effect of its ANDA filing is far broader: if its application is approved, the generic manufacturer wins the right to compete with the brand-name manufacturer throughout the country, whether or not it actually plans to do so. See *ibid.* Because both the purpose and effect of the ANDA are to open the market in all 50 States to the generic manufacturer, the filing of the ANDA gives rise to minimum contacts with every State.

c. All but conceding that the court of appeals' decision does not actually conflict with this Court's decision in *Daimler*, Mylan claims that the court of appeals' decision nonetheless makes an "end-run" around *Daimler* and "deprives [it] of practical effect." Pet. 1, 13. The premise of Mylan's claim is that general jurisdiction traditionally provided the framework for haling defendants into court in ANDA cases—and that, once this Court narrowed the

bounds of general jurisdiction in *Daimler*, the court of appeals simply recreated the preexisting status quo under the label of specific jurisdiction. That claim fails for several reasons.

To begin with, there is little support for the proposition that plaintiffs traditionally relied on general jurisdiction, rather than specific jurisdiction, in ANDA cases. Mylan cites only a handful of district-court decisions, one of them in the present case. See Pet. 23-24. Until this case, moreover, the Federal Circuit had not expressed a view on the basis for personal jurisdiction in ANDA cases. Its only foray into the matter came in *Zeneca*, discussed above, in which it narrowly held that the transmission of an ANDA to FDA's offices in Maryland did not support the exercise of specific jurisdiction in that State. See 173 F.3d at 834. The decision in *Zeneca* commanded no majority opinion, and it rested on grounds unique to petitioning the federal government. See *ibid.* By its own terms, *Zeneca*'s rejection of one particular theory of specific jurisdiction did not foreclose the use of others in ANDA cases. See Pet. App. 14-15.

But even if Mylan were correct that plaintiffs traditionally relied on general jurisdiction in ANDA cases, there is nothing noteworthy about the court of appeals' resort to a specific-jurisdiction analysis in the wake of *Daimler*. Indeed, this Court observed in *Daimler* that "specific jurisdiction has become the centerpiece of modern jurisdiction theory, while general jurisdiction [has played] a reduced role." 134 S. Ct. at 755 (alteration in original) (citation omitted). As the Court has narrowed the grounds on which general jurisdiction may be asserted, it has endorsed a more vigorous role for specific jurisdiction, such that the latter now "form[s] a considerably more significant part of the scene." *Ibid.* (citation omitted).

Mylan appears to believe that, if general jurisdiction cannot be exercised in a State after *Daimler*, then jurisdiction cannot be proper there under *any* theory. That is plainly wrong. *Daimler* expressly contemplates that lower courts will consider specific-jurisdiction theories if general jurisdiction is foreclosed. The court of appeals can scarcely be faulted for doing precisely what this Court instructed.

d. In any event, the premise of Mylan's arguments concerning *Daimler* is incorrect: namely, that generic drug manufacturers will now be subject to suit based on specific jurisdiction in all 50 States. See Pet. 19. In so suggesting, Mylan ignores the critical second step of the specific-jurisdiction analysis. Even after the minimum-contacts requirement has been satisfied—as the court of appeals concluded it was here—specific jurisdiction may be exercised over a defendant only if it is otherwise fair and reasonable. See *Asahi Metal Industry Co.* v. *Superior Court of California*, 480 U.S. 102, 113-114 (1987); *id.* at 116 (Brennan, J., concurring). If, as Mylan predicts, "a tiny startup or foreign manufacturer that has never sold a drug in the United States" files an ANDA, Pet. 34, a federal court will readily be able to protect that manufacturer from having to defend a patent-infringement claim in an inconvenient forum.

Here, Mylan cannot argue with a straight face that the exercise of personal jurisdiction in Delaware—a scant 300 miles from its home in West Virginia—would be even modestly burdensome, much less unfair or unreasonable. As the court of appeals recognized, Mylan is no stranger to Delaware or the Delaware courts: it is registered to do business in that State and is licensed as a manufacturer and distributor by the State Board of Pharmacy. See Pet. App. 15-16. And not only has Mylan regularly defended patent-infringement actions in Delaware federal court;

since 2010, it has filed at least four actions in that court as a *plaintiff*. See *Mylan Inc.* v. *Boehringer Ingelheim International GMBH*, Civ. No. 10-244; *Mylan Pharmaceuticals, Inc.* v. *Eurand Inc.*, Civ. No. 10-306; *Mylan Pharmaceuticals, Inc.* v. *Galderma Laboratories. Inc.*, Civ. No. 10-892; *Mylan Pharmaceuticals, Inc.* v. *Ethypharm SA*, Civ. No. 10-1064. Under those circumstances, Mylan cannot seriously dispute that the exercise of personal jurisdiction in Delaware is fair and reasonable.

In short, *Daimler* does not foreclose the exercise of nationwide specific jurisdiction over a generic drug manufacturer that has filed an ANDA challenging a patent holder's rights in every State and seeking approval to compete in every State—subject to the important condition that the exercise of jurisdiction be otherwise fair and reasonable. There is thus no conflict that justifies this Court's review.

C. The Petition Does Not Present An Important Question Warranting The Court's Review

Finally, there is no merit to Mylan's contention that review should be granted in light of the exceptional importance of ANDA litigation to the generic pharmaceutical industry. See Pet. 30-36. While there is no denying the high stakes of ANDA litigation generally, the court of appeals' decision does not disturb the status quo concerning where ANDA cases will be litigated.[4] Generic drug

[4] Mylan asserts that ANDA suits have typically been litigated "in a handful of plaintiff-convenient jurisdictions," Pet. 13, but there is nothing remarkable about that. To the contrary, "plaintiffs are ordinarily allowed to select whatever forum they consider most advantageous." *Atlantic Marine Construction Co.* v. *United States District Court for Western District of Texas*, 134 S. Ct. 568, 581 (2013). And Congress has made clear its expectation that ANDA cases will be litigated in the patent holder's home jurisdiction. If the patent holder

manufacturers have defended ANDA suits outside their home States for decades, to no apparent detriment: since the passage of the Hatch-Waxman Act, the market share of generic drugs has grown from approximately 20% in 1984 to 75% today. See *PLIVA Inc.* v. *Mensing*, 564 U.S. 604, 629 (2011) (Sotomayor, J., dissenting).

By contrast, if it were accepted by this Court, Mylan's position would effect a sea change and subvert the orderly resolution of claims brought under the Hatch-Waxman Act. It is often the case, as it is here, that multiple generic drug manufacturers file ANDAs concerning the same patented drug. If, as Mylan asserts, the patent holder must file suit in the State in which the ANDA was prepared, the patent holder would potentially have to prosecute its infringement claim against each defendant in a different State—even though the claim, and the evidence, would be virtually identical across all of those cases.

Even if the cases could be consolidated for discovery purposes through the multidistrict litigation (MDL) process, moreover, the delays inherent in that process would threaten to jeopardize completion of the litigation within the 30-month period during which approval of the generic drug is automatically stayed. As Mylan's principal generic competitor explained in an amicus brief supporting AstraZeneca below, "[a]t the most basic level, the litigation delay built into the MDL process is a poor fit for the expedited proceedings contemplated by the Hatch-Waxman Act." Teva Pharmaceuticals C.A. Br. 22. The delays associated with MDL proceedings would raise the distinct

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fails to bring an infringement suit within 45 days of receiving notice of the generic's ANDA filing, the generic manufacturer may seek a declaration of non-infringement—which it must file where the patent holder has its principal place of business (or "a regular and established place of business"). See 21 U.S.C. 355(j)(5)(C)(i)(II).

possibility that brand-name manufacturers would face generic competition even before a decision on the merits could be reached.

There is no evidence that Congress intended for brand-name manufacturers to wage a multifront battle simply to preserve their hard-won patent rights. To the contrary, Congress's most recent pronouncement confirms that it expected patent holders to litigate claims under the Hatch-Waxman Act in a single judicial district. In the America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011), Congress erected barriers to joinder of defendants in patent-infringement suits, *except* those brought under the Hatch-Waxman Act. See 35 U.S.C. 299(a). That reflects Congress's judgment that brand-name drug manufacturers, unlike other patent holders, should not face the "prospect of litigating the same factual and legal questions numerous times." David O. Taylor, *Patent Misjoinder*, 88 N.Y.U. L. Rev. 652, 655 (2013). The court of appeals' unanimous decision reaffirming the status quo on personal jurisdiction in ANDA litigation does not warrant further review.

* * * * *

Following this Court's decision in *Daimler*, Mylan sensed an opportunity to gain a home-field advantage against brand-name drug manufacturers in ANDA litigation, and it began resisting the exercise of personal jurisdiction everywhere outside its home State of West Virginia. But the district courts consistently saw Mylan's proposed rule for what it is—a transparent effort to gain a litigation advantage and to upset Congress's carefully wrought balance between the interests of brand-name and generic drug manufacturers. Far from sanctioning a radical departure from precedent, the court of appeals was merely the latest in a parade of courts to reject

Mylan's radical conception of specific jurisdiction. Its careful and well-reasoned opinion should be the last word.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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NOVEMBER 2016