No. 16-360

IN THE

Supreme Court of the United States

MYLAN PHARMACEUTICALS INC. ET AL.,
Petitioners,

v.

ACORDA THERAPEUTICS INC. ET AL.,
Respondents.

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

ASTRAZENECA AB,
Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF IN OPPOSITION FOR ACORDA THERAPEUTICS, INC. AND ALKERMES PHARMA IRELAND LIMITED

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QUESTIONS PRESENTED

Mylan Pharmaceuticals, Inc. ("Mylan") filed an Abbreviated New Drug Application ("ANDA") seeking approval from the Food and Drug Administration to market a generic version of Ampyra®. Mylan has never disputed that, if it obtains approval, it will direct sales of its generic drug into Delaware. The holders of the patents covering Ampyra filed a patent-infringement suit under the Hatch-Waxman Act to prevent Mylan from marketing its generic drug before the expiration of their patents.

The questions presented are:

(1) Whether the Federal Circuit correctly held that Mylan is subject to specific personal jurisdiction in Delaware because Mylan's ANDA filing concretely declared its plan to market its generic version of Ampyra in Delaware.

(2) Whether Mylan consented to general personal jurisdiction in Delaware when it registered to do business in the State and appointed an agent for service of process.

RULE 29.6 STATEMENT

Acorda Therapeutics, Inc. has no parent corporation; Fidelity Management & Research Company Growth and BlackRock Global Investors Indexed own 10% or more of its stock. Alkermes Pharma Ireland Limited is a subsidiary of Alkermes plc, a publicly held corporation. FMR LLC; Wellington Management Company, LLP; and T. Rowe Price Associates, Inc. all own 10% or more of Alkermes plc's stock.

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BRIEF IN OPPOSITION

Respondents Acorda Therapeutics, Inc. and Alkermes Pharma Ireland Limited respectfully submit this brief in opposition to the petition for a writ of certiorari filed by Mylan Pharmaceuticals Inc. ("Mylan") and Mylan Inc.[1]

OPINIONS BELOW

The court of appeals' opinion is reported at 817 F.3d 755 (Pet. App. 1). The court of appeals' order denying rehearing and rehearing en banc is unreported (Pet. App. 39). The district court's opinion is reported at 78 F. Supp. 3d 572 (Pet. App. 67).

JURISDICTION

The court of appeals filed its opinion on March 18, 2016. It denied Mylan's timely petition for rehearing or rehearing en banc on June 20, 2016. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Fourteenth Amendment's Due Process Clause and relevant portions of the Food, Drug, and Cosmetic Act are set forth in the petition for a writ of certiorari and the appendix to the petition, respectively. *See* Pet. 4; Pet. App. 121-26.

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[1] Pursuant to the parties' stipulation, the district court dismissed Mylan Inc. without prejudice on February 10, 2015. C.A. J.A. 120-22.

STATEMENT

The Federal Circuit held that Mylan—the second-largest generic drug manufacturer in the United States—is subject to specific personal jurisdiction in Delaware because Mylan filed an Abbreviated New Drug Application ("ANDA") "seek[ing] approval to sell its generic" version of Ampyra "throughout the United States, including in Delaware." Pet. App. 15. That unremarkable conclusion—based on the "particular actions Mylan has already taken" and the future consequences of those actions in Delaware, Pet. App. 8—fits squarely within this Court's personal-jurisdiction precedent, which has long treated the "contemplated future consequences" of a defendant's past acts as relevant to "determining . . . minimum contacts." *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 479 (1985).

Mylan ignores that established jurisdictional principle. It also vastly overstates the practical implications of the Federal Circuit's decision. Only a few months ago, Mylan described the Federal Circuit's opinion as a "narrow decision finding only specific personal jurisdiction under the facts presented in the two cases before it." D.E. 82, Letter from Mylan to The Honorable Irene M. Keeley at 2, *Acorda Therapeutics, Inc. v. Mylan Pharm. Inc.*, No. 1:14-cv-00139-IMK (N.D. W. Va. July 6, 2016) ("Mylan Letter"). Mylan's rhetoric in this Court about the supposedly "far-reaching" consequences of the Federal Circuit's decision is thus difficult to take seriously. Pet. 35.

In fact, there is no reason to think that the Federal Circuit's decision will have the type of profound consequences that Mylan seeks to conjure. It has

long been settled that a patent infringer is subject to specific personal jurisdiction in every State where infringing sales are made. *See Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1571 (Fed. Cir. 1994). The Federal Circuit's decision simply makes clear that the same principle applies in Hatch-Waxman suits, which are filed before infringing sales have begun based on an artificial act of infringement created by the statute. That does not mean, however, that the decision "permit[s] specific personal jurisdiction *everywhere*" in Hatch-Waxman litigation. Pet. 2. Where a generic manufacturer has no intention of marketing its product in the forum State, it is free to raise that point as a jurisdictional defense and may well be found to lack the requisite minimum contacts to satisfy due process. But Mylan has never disputed that, as with its other generic products, it intends to market its generic version of Ampyra in Delaware. Nor could it—given Mylan's concession that it does not "'carve out individual states'" from its nationwide distribution network. D.E. 277, Corrected Br. In Opp. To Mot. To Dismiss at 13, *Eli Lilly & Co. v. Accord Healthcare, Inc. USA*, No. 14-389 (S.D. Ind. Nov. 7, 2014).

Thus, far from breaking new ground, the Federal Circuit's decision merely applies this Court's existing personal-jurisdiction precedent to the particular facts of this Hatch-Waxman case. There is no reason for the Court to review that fact-bound application of settled jurisdictional principles.

1. In the Hatch-Waxman Act, "Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-

cost, generic copies of those drugs to market." *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002). Under the Act, the U.S. Food and Drug Administration ("FDA") regulates the process by which new and generic drugs are approved. *See* 21 U.S.C. § 355(a). A brand-name drug company that "wishes to market a novel drug" must "submit a new drug application" ("NDA") to the FDA for approval. *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012). The NDA must include, "among other things, a statement of the drug's components, scientific data showing that the drug is safe and effective, and proposed labeling describing the uses for which the drug may be marketed." *Id.*; *see also* 21 U.S.C. § 355(b)(1). The applicant must also identify "any patent which claims the drug . . . with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). The FDA compiles that patent information in a publication called the "Orange Book." *See* 21 C.F.R. §§ 314.3, 314.430(e).

To "speed the introduction of low-cost generic drugs to market," Congress also provided in the Hatch-Waxman Act that "another company may seek permission to market a generic version" of an approved drug using an abbreviated pathway. *Caraco Pharm. Labs*, 132 S. Ct. at 1676. The generic manufacturer is not required to conduct its own clinical trials, but can instead "piggy-back[ ] on the brand's NDA" by filing an ANDA "show[ing] that the generic drug has the same active ingredients as, and is bio-

logically equivalent to, the brand-name drug." *Id.*; *see also* 21 U.S.C. § 355(j)(2)(A)(ii), (iv).

At the same time, Congress incorporated into the Hatch-Waxman Act an "important new mechanism designed to guard against infringement of patents relating to pioneer drugs," *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676-77 (1990), which are typically the product of years of costly research by pioneer drug companies that ultimately lead to life-saving breakthroughs (and, subsequently, to generic drugs that replicate the pioneers' innovations). The Act requires that an ANDA applicant make one of four certifications with respect to each patent listed in the Orange Book in connection with the branded drug on which the ANDA is predicated. One option, for example, is for the ANDA applicant to certify that the patents have expired. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(II). Another option is for the applicant to include a Paragraph IV certification, which makes it possible for the ANDA filer to receive approval to market its generic drug *before* the patents for the pioneer drug expire. In a Paragraph IV certification, the filer certifies that patents on the pioneer drug are "invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the [ANDA] is submitted." *Id.* § 355(j)(2)(A)(vii)(IV).

The Hatch-Waxman Act defines a Paragraph IV certification "as itself an act of infringement," which gives the brand-name drug company "an immediate right to sue" and thereby facilitates the early resolution of patent disputes between generic companies and innovators. *Caraco Pharm. Labs.*, 132 S. Ct. at 1677; *see also* 35 U.S.C. § 271(e)(2)(A). The ANDA filer is required to notify the NDA holder (and any

other holders of patents on the pioneer drug) of the Paragraph IV certification; if an infringement suit is commenced against the ANDA filer within 45 days of the notice, the FDA may not approve the ANDA for 30 months (or until the court rules that the patents are invalid or not infringed). *Eli Lilly & Co.*, 496 U.S. at 677-78; *see also* 21 U.S.C. § 355(j)(5)(B)(iii). If the plaintiff prevails in the infringement action, it is entitled to an order establishing the "effective date of any approval" of the generic drug to be no earlier than "the date of the expiration of the patent which has been infringed" as well as "injunctive relief" to prevent the generic manufacturer from further infringement. 35 U.S.C. § 271(e)(4)(A), (B).

2. This case involves Ampyra, the first and only drug approved by the FDA for improving walking in patients with multiple sclerosis ("MS") and the first MS drug approved for oral administration. After years of research on the active ingredient, 4-aminopyridine, respondent Acorda Therapeutics, Inc. filed an NDA that received priority review and approval by the FDA. Acorda holds all right, title, and interest in four Ampyra patents and is the exclusive licensee of a fifth Ampyra patent assigned to respondent Alkermes Pharma Ireland Limited ("Alkermes"). The five patents (collectively, the "Ampyra Patents") are listed in the Orange Book and have expiration dates between 2018 and 2027. Pet. App. 69-70.

Mylan is the second-largest generic pharmaceutical manufacturer in the United States. *See* Mylan N.V. Form 10-K, Feb. 2, 2016, at 6. It is a West Virginia corporation with its principal place of business in Morgantown, West Virginia, Pet. App. 4, 70, and

has a nationwide distribution network that transmits its generic products for sale in all 50 States. *See Accord Healthcare*, D.E. 277, at 13. Mylan is registered to do business in Delaware, has appointed an agent to accept service in Delaware, and holds a license from the Delaware Board of Pharmacy to manufacture and distribute drugs in the State. Pet. App. 5, 15.

On January 22, 2014, Mylan filed an ANDA seeking the FDA's approval to manufacture and sell a generic version of Ampyra prior to the expiration of the Ampyra Patents. Pet. App. 3, 72. Mylan included a Paragraph IV certification asserting that the Ampyra Patents are "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale" of Mylan's generic drug. Pet. App. 73 (internal quotation marks omitted). Mylan notified respondents of its ANDA filing on July 9, 2014. Pet. App. 5, 73.

3. One week later, respondents filed this ANDA infringement action against Mylan in the U.S. District Court for the District of Delaware. Respondents' suit ultimately encompassed claims against a total of eight generic manufacturers that had filed ANDAs and Paragraph IV certifications seeking approval to manufacture and sell generic versions of Ampyra; respondents' claims against two additional ANDA filers proceeded in separate suits in the District of Delaware.

Alone among those defendants, Mylan moved to dismiss for lack of personal jurisdiction. Pet. App. 4. The district court denied the motion, holding that Mylan is subject to both general and specific personal jurisdiction in Delaware. Pet. App. 68. The court

concluded that Mylan was subject to specific jurisdiction in Delaware because respondents' claims "arise out of and relate to Mylan Pharma's activities that are, and will be, directed to Delaware," including Mylan's ANDA filing and its license to manufacture and distribute drugs in the State. Pet. App. 104. The court also emphasized that Mylan should have anticipated being sued in Delaware because respondents "had already initiated litigation in Delaware to enforce the Ampyra® patents" by the time Mylan notified respondents of its ANDA filing. *Id.* In addition, the court held that Mylan was subject to general jurisdiction in Delaware because it had registered to do business in the State, which, under the Delaware Supreme Court's decision in *Sternberg v. O'Neil*, 550 A.2d 1105 (Del. 1988), constituted "consent[ ] to the general jurisdiction of the courts in the State of Delaware." Pet. App. 91.

4. The Federal Circuit granted Mylan permission to appeal under 28 U.S.C. § 1292(b). The district court did not stay its proceedings, however, and the case proceeded through discovery and trial during the ensuing interlocutory appeal.[2]

The Federal Circuit affirmed the district court's ruling that Mylan is subject to specific personal jurisdiction in Delaware. It explained that "the minimum-contacts standard is satisfied by the particular actions Mylan has already taken—its ANDA fil-

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[2] The case was decided on appeal together with *AstraZeneca AB v. Mylan Pharmaceuticals Inc.*, No. 2015-1460 (Fed. Cir.), where Mylan challenged another decision from the District of Delaware holding that it was subject to specific personal jurisdiction in an ANDA suit.

ings—for the purpose of engaging in . . . injury-causing and allegedly wrongful marketing conduct in Delaware." Pet. App. 8. The court emphasized that "Mylan's ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs," *id.*, and that "it is undisputed that Mylan plans to direct sales of its generic drugs into Delaware" in the event that it secures FDA approval. Pet. App. 15.

The Federal Circuit rejected Mylan's argument 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." Pet. App. 13. "Such a rule," the court explained, "would run counter to the legal tradition of injunctive actions to prevent a defendant's planned, non-speculative harmful conduct before it occurs." *Id.*

The court of appeals also determined that the exercise of personal jurisdiction over Mylan would be reasonable. The court emphasized that "[t]he burden on Mylan will be at most modest" because Mylan has a long history of litigating ANDA cases in Delaware, and that "upholding personal jurisdiction will serve the interests of the plaintiffs and the judicial system in efficient resolution of litigation" because respondents are litigating other ANDA cases over the same patents in Delaware. Pet. App. 17. Because the district court had properly asserted specific personal jurisdiction over Mylan, the Federal Circuit saw no need to "address the issue of general personal jurisdiction." Pet. App. 3.

Judge O'Malley concurred in the judgment, reasoning that Mylan was subject to specific personal jurisdiction in Delaware because Mylan's ANDA

caused Acorda, a Delaware corporation, "legally cognizable injuries in Delaware" by "call[ing] into question the validity and value of property rights protecting the marketing of profitable products." Pet. App. 35-36. Judge O'Malley also agreed with the district court that Mylan had given its "voluntary, express consent" to general jurisdiction when it registered to do business in Delaware. Pet. App. 31.

The Federal Circuit denied Mylan's petition for rehearing en banc without recorded dissent. Pet. App. 40.

REASONS FOR DENYING THE PETITION

The Federal Circuit's decision represents a straightforward application of settled jurisdictional principles to the "artificial act of infringement" created by Congress in the Hatch-Waxman Act. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). It is consistent with the decisions of both this Court and other courts, and will not plausibly produce any of the "far-reaching" ramifications that Mylan hypothesizes. Pet. 35.

The Federal Circuit's holding—that Mylan is subject to specific jurisdiction in Delaware because it "has already taken" "particular actions . . . for the purpose of engaging in" infringing conduct in the State, Pet. App. 8—is squarely supported by this Court's personal-jurisdiction precedent. This Court explained more than three decades ago that the "contemplated future consequences" of a defendant's past acts "must be evaluated in determining whether the defendant purposefully established minimum contacts within the forum." *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 479 (1985). Mylan does not

identify a single decision from this Court—or any other court—that endorses its counterintuitive position that the future consequences of prior actions are irrelevant to the jurisdictional analysis.

Moreover, the Federal Circuit's opinion is unlikely to have significant consequences for generic manufacturers. In particular, there is no evidence—and Mylan does not even suggest—that the decades-old rule subjecting patent infringers to suit in every State in which infringing sales are made has somehow chilled the development of new products. There is thus no reason to credit Mylan's overwrought contention that generic manufacturers will suddenly curtail their highly profitable businesses simply because, under the Federal Circuit's decision, they are subject to specific jurisdiction wherever they plan to distribute their generic products (as long as the exercise of jurisdiction is otherwise reasonable). And if a generic manufacturer truly does not intend to market its product in the forum State, it need only raise that fact as a jurisdictional defense. Mylan, of course, has never suggested that, if the FDA approves its generic version of Ampyra, Mylan will not market that product in Delaware.

Finally, this interlocutory appeal is a poor vehicle for examining the application of specific jurisdiction in ANDA cases because, during the pendency of this appeal, respondents' suit against Mylan has already gone to trial and a decision is expected soon. A ruling in Mylan's favor could eliminate any need to decide the jurisdictional question in that litigation. In addition, as Judge O'Malley and the district court concluded, Mylan consented to general personal jurisdiction in Delaware when it registered to do busi-

ness in the State, which means that the Court would be directly confronted with the question of the continuing viability of consent-based general jurisdiction in the event that it concluded that Mylan is not subject to specific personal jurisdiction in Delaware.

For all of these reasons, the petition should be denied.

I. THE FEDERAL CIRCUIT PROPERLY APPLIED SETTLED PERSONAL-JURISDICTION PRINCIPLES TO ANDA LITIGATION.

The Federal Circuit's conclusion that Mylan is subject to specific personal jurisdiction in Delaware comports with the precedent of both this Court and other courts, as well as with the statutory framework that Congress established for resolving patent disputes *before* generic drugs are brought to market.

A. The Federal Circuit's Decision Is Consistent With The Decisions Of This Court And Other Courts Of Appeals.

1. Specific personal jurisdiction requires an inquiry into the "relationship among the defendant, the forum, and the litigation." *Shaffer v. Heitner*, 433 U.S. 186, 204 (1977). The due-process limitations on specific personal jurisdiction are "satisfied if the defendant has purposefully directed his activities at . . . the forum," the claim "arise[s] out of or relate[s] to those activities," and the exercise of jurisdiction would be reasonable. *Burger King*, 471 U.S. at 472, 477 (internal quotation marks omitted).

Applying those settled principles in this case, the Federal Circuit concluded that Mylan is subject to specific personal jurisdiction in Delaware because it "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." Pet. App. 7. "Mylan's ANDA conduct is 'suit-related' and has a 'substantial connection' with Delaware," the court explained, "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." Pet. App. 8 (citation omitted).

The Federal Circuit's jurisdictional ruling faithfully adheres to this Court's analysis in *Burger King*, where the Court held that a defendant's execution of a franchise agreement that "envisioned continuing and wide-ranging contacts" with Florida, including the payment of franchise fees in the State, made it "presumptively reasonable" that the defendant "be called to account" in Florida for injuries resulting from his breach of the agreement. 471 U.S. at 480. Likewise, here, "Mylan's ANDA filings and its distribution channels establish that Mylan plans to market its proposed drugs in Delaware" in the event that it receives FDA authorization. Pet. App. 14. In fact, Mylan has never disputed its intention to market its generic version of Ampyra in Delaware. *See* Pet. App. 15. Mylan's ANDA therefore establishes its minimum contacts with Delaware because Mylan "has, by its filing, confirmed its plan to commit real-world acts"—in Delaware and elsewhere—"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." Pet. App. 10.

2. Mylan's effort to manufacture a conflict with the decisions of this Court and other courts fails in all respects.

According to Mylan, it was improper for the Federal Circuit to rely on Mylan's "potential future activities to establish specific jurisdiction." Pet. 19. But the entire premise of Mylan's argument is wrong. The Federal Circuit did not rely on Mylan's future conduct to establish its minimum contacts with Delaware but instead concluded that "the minimum-contacts standard is satisfied by 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). As *Burger King* makes clear, the "contemplated future consequences" of actions that the defendant has already taken "must be evaluated in determining whether the defendant purposefully established minimum contacts within the forum." 471 U.S. at 479.

Mylan therefore gains nothing from its invocation of the supposedly "long line of precedent making plain that the only 'jurisdictionally relevant' suit-related contacts for purposes of specific personal jurisdiction" are the contacts that have already been formed at the time suit is filed. Pet. 19. Those are precisely the contacts that the Federal Circuit considered here when looking to the steps that Mylan "has already taken" by filing its ANDA. Pet. App. 8. And none of this Court's cases cited by Mylan suggests that it is somehow improper to consider the *future* consequences of *past* conduct in determining minimum contacts—which is not surprising in light of *Burger King*'s instruction that "contemplated future consequences . . . *must be* evaluated." 471 U.S. at 479 (emphasis added).

Indeed, with the exception of *Burger King* itself—which Mylan cites without making any mention of its "future consequences" language—the cases

on which Mylan relies had no occasion to consider whether the future effects of past conduct could be relevant to the jurisdictional inquiry because they sought retrospective relief for past conduct, rather than the type of forward-looking relief at issue here, where respondents seek to enjoin future infringing sales of Mylan's generic drug. *See Walden v. Fiore*, 134 S. Ct. 1115, 1120 (2014) (monetary damages for a Fourth Amendment violation); *Hanson v. Denckla*, 357 U.S. 235, 251 (1958) (dispute over whether funds placed in trust had passed to one group of claimants or another). As the Federal Circuit recognized, it makes eminent sense that, in such backward-looking litigation, the Court used "a formulation" of the personal-jurisdiction inquiry "worded to address suits for retrospective relief based on past acts." Pet. App. 7. When the Court did have occasion to consider the jurisdictional significance of the future consequences of past conduct in *Burger King*—where the plaintiff sought forward-looking injunctive relief—it made clear that such jurisdictional contacts are an essential component of the minimum-contacts inquiry in cases involving ongoing or future injuries. 471 U.S. at 479.[3]

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[3] Mylan also contends that the Federal Circuit "disregard[ed] . . . fundamental principle[s]" from *Walden* and other cases by considering "'the interest of the plaintiffs'" and the interest of "'the judicial system in efficient resolution of litigation'" as part of its minimum-contacts analysis. Pet. 22 (quoting Pet. App. 17). In reality, the Federal Circuit only considered those factors *after* deciding that Mylan had sufficient "suit-related contacts" with Delaware to satisfy due process and did so as part of its inquiry into whether, despite those contacts, "other considerations render jurisdiction unreasonable." Pet. App. 16. This Court has expressly identified "the plaintiff's interest in obtaining convenient and effective relief," and the "judicial system's

If Mylan were correct that future consequences are jurisdictionally irrelevant, then a court could never exercise specific jurisdiction in a suit seeking to enjoin a foreign defendant's future conduct in the forum State where the defendant's preparations for that conduct were undertaken in another State. That radical view of personal jurisdiction would upend the "legal tradition of injunctive actions to prevent a defendant's planned, non-speculative harmful conduct before it occurs," Pet. App. 13, and frequently leave States unable to provide relief to their citizens until the harm that they sought to enjoin had already materialized.

That unworkable outcome finds no support in the jurisprudence of this Court or other appellate courts. Following *Burger King*'s lead, courts of appeals regularly recognize—as the Federal Circuit did here—that the future consequences of past conduct are relevant to minimum-contacts analysis. *See*, *e.g.*, *K-V Pharm. Co. v. J. Uriach & CIA, S.A.*, 648 F.3d 588, 594 (8th Cir. 2011) ("In addition to" a defendant's past contacts with the forum State, "we must consider the terms of the contract and its contemplated future consequences in deciding whether personal jurisdiction over an out-of-state defendant exists.") (citing *Burger King*, 471 U.S. at 478-79); *Far W. Capital, Inc. v. Towne*, 46 F.3d 1071, 1079-80 (10th Cir. 1995) ("examin[ing]" "future consequences" in tortious-interference case) (internal quotation marks omit-

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[Footnote continued from previous page]

interest in obtaining the most efficient resolution of controversies," as among the factors relevant to this reasonableness analysis. *See World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 292 (1980).

ted); *Roth v. Garcia Marquez*, 942 F.2d 617, 622 (9th Cir. 1991) (holding that "future consequences" were sufficient to "swing" the analysis in favor of jurisdiction despite the defendants' "minimum physical presence in the forum," and collecting cases taking a similar approach) (emphasis omitted).

None of the court of appeals cases that Mylan cites (at 20-21) is to the contrary because, as with *Walden* and *Hanson*, they all involve requests for retrospective relief based on defendants' *past* conduct. *See Fastpath, Inc. v. Arbela Techs. Corp.*, 760 F.3d 816, 819 (8th Cir. 2014) (damages action for breach of contract); *Rocke v. Pebble Beach Co.*, 541 F. App'x 208, 209 (3d Cir. 2013) (personal-injury claim based on slip-and-fall injury).[4]

Thus, as in its briefing before the Federal Circuit, Mylan is unable to "meaningfully develop an argument that a rigid past/future dividing line governs the minimum-contacts standard." Pet. App. 13.

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[4] *See also Cossaboon v. Me. Med. Ctr.*, 600 F.3d 25, 29 (1st Cir. 2010) (medical-malpractice claim based on 2007 incident); *Moncrief Oil Int'l Inc. v. OAO Gazprom*, 481 F.3d 309, 311 (5th Cir. 2007) (action seeking damages for breach of contract and similar claims); *Pohlmann v. Bil-Jax, Inc.*, 176 F.3d 1110, 1111 (8th Cir. 1999) (personal-injury claim based on scaffold collapse); *McFarlane v. Esquire Magazine*, 74 F.3d 1296, 1300 (D.C. Cir. 1996) (libel action seeking damages based on 1991 article); *Klinghoffer v. S.N.C. Achille Lauro*, 937 F.2d 44, 46 (2d Cir. 1991) (damages claims against Palestine Liberation Organization based on 1985 hijacking); *Asarco, Inc. v. Glenara, Ltd.*, 912 F.2d 784, 785 (5th Cir. 1990) (damages action regarding cargo lost when shipping vessel sank); *Farmers Ins. Exch. v. Portage La Prairie Mut. Ins. Co.*, 907 F.2d 911, 912 (9th Cir. 1990) (damages action for breach of contract); *Rossman v. State Farm Mut. Auto. Ins. Co.*, 832 F.2d 282, 284 (4th Cir. 1987) (declaratory judgment action regarding responsibility for paying two existing judgments).

In fact, it fails to identify any authority from this Court or any other court that supports such a distinction.

3. Mylan's argument that the Federal Circuit's decision "conflicts with—and creates a massive end-run around—this Court's decision in" *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014), is equally far-fetched. Pet. 22.

Daimler held that *general* personal jurisdiction, which covers "any and all claims" against a defendant, cannot be based simply on a corporation's continuous course of business in the forum State. 134 S. Ct. at 751. The Federal Circuit, however, "d[id] not address the issue of general personal jurisdiction" in this case, Pet. App. 3, and its decision thus has no bearing on the States in which Mylan and other generic manufacturers are subject to general jurisdiction.

Mylan nevertheless insists that the Federal Circuit's decision "recreates the pre-*Daimler* status quo" by exposing ANDA filers "to specific personal jurisdiction in all fifty states, based wholly on non-suit-related contacts in other states, such as nationwide distribution networks." Pet. 23-24. That contention is flatly at odds with the Federal Circuit's sharp focus on whether Mylan's conduct "ha[d] a 'substantial connection' *with Delaware*"—not some other State. Pet. App. 8 (emphasis added).

Mylan is similarly incorrect in arguing that, "under the majority's decision, ANDA filers can be forced to litigate in states wherever they may one day do business." Pet. 24. Mylan "undisputedly" intends to market its proposed generic version of Ampyra in Delaware, Pet. App. 8, pursuant to its established nationwide distribution network that already trans-

mits Mylan's other generic products for sale in Delaware. *Accord Healthcare*, D.E. 277, at 13. Thus, far from "speculation about the future," Pet. 2, Mylan's future marketing in Delaware is all but certain to occur if the FDA approves Mylan's ANDA.

To be sure, a generic manufacturer with a geographically limited distribution network may be able to establish that it has no "plans to engage in marketing of the proposed generic drug[ ]" in the forum State and that it therefore lacks "minimum contacts" with that State. Pet. App. 8. Mylan, however, has never raised any such argument about its own distribution plans. *See* Pet. 34 ("[T]he relevant underlying facts are undisputed . . . .").

Mylan also contends that, "[i]f the Federal Circuit were correct," then in the pre-*Daimler* era, "[s]pecific jurisdiction should have been the rule, not the exception, in patent infringement cases following ANDA filings." Pet. 24. But given the "sprawling view of general jurisdiction" that prevailed before the Court decided *Daimler*, 134 S. Ct. at 760 (internal quotation marks omitted), it is not surprising that courts in ANDA cases had only infrequent occasion to evaluate the circumstances under which an ANDA filer was subject to specific personal jurisdiction. In any event, none of the courts that did consider that question reached a conclusion at odds with the Federal Circuit's decision in this case.[5]

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[5] In *Zeneca Ltd. v. Mylan Pharmaceuticals, Inc.*, 173 F.3d 829 (Fed. Cir. 1999)—where no opinion commanded a majority of the court—the Federal Circuit addressed a specific, narrow question certified by the district court: whether "Mylan's act of filing its tamoxifen ANDA with the FDA in Rockville, Maryland" gave rise to personal jurisdiction in that State. *Id.* at 830 (Opinion of Gajarsa, J.). Neither the parties nor the court ad-

B. The Federal Circuit's Decision Is Consistent With The Hatch-Waxman Act.

Mylan's contention that the Federal Circuit "[m]isconstrue[d]" the Hatch-Waxman Act is likewise off the mark. Pet. 25.

Mylan asserts that the future consequences of its ANDA filing are irrelevant for jurisdictional purposes because "the 'artificial act of infringement' giving rise to a suit . . . is complete the moment the manufacturer files an ANDA with a paragraph IV certification." Pet. 26 (quoting *Eli Lilly & Co.*, 496 U.S. at 678). In reality, ANDA litigation is necessarily forward-looking because "the allegedly infringing drug has not yet been marketed" and thus "the question of infringement must focus on what the ANDA applicant *will likely market if its application is approved*." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997); *see also id.* at 1568 ("[T]he statute requires an infringement inquiry focused on what is likely to be sold following FDA approval."). The prospective focus of ANDA litigation is underscored by the fact that the Hatch-Waxman Act prohibits

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[Footnote continued from previous page]

dressed whether specific personal jurisdiction would be warranted based on future sales Mylan intended to make in Maryland if the FDA approved its ANDA. Pet. App. 14-15. In *Pfizer Inc. v. Apotex, Inc.*, No. 08-948, 2009 WL 2843288 (D. Del. Aug. 13, 2009), the district court ruled on a motion to transfer without considering personal jurisdiction. And the district court in *Pfizer Inc. v. Synthom Holding, B.V.*, 386 F. Supp. 2d 666 (M.D.N.C. 2005), held that specific jurisdiction existed in the State where the ANDA was prepared but did not suggest that jurisdiction would be absent in other States. *Id.* at 675-76.

awards of damages (unless the generic drug has already been marketed), and instead limits the available remedies to injunctive relief and an order establishing the "effective date of any approval" of the generic drug to be no earlier than the date the patent expires. 35 U.S.C. § 271(e)(4)(A), (B). Consistent with ANDA litigation's focus on future events, the Federal Circuit concluded that Mylan's ANDA gave rise to minimum contacts in Delaware because it "reliably indicate[d] plans to engage in marketing of the proposed generic drugs" in the State. Pet. App. 8.

Mylan also argues that "if the prospect of future distribution, future sales, or other 'future activities' were sufficient to create jurisdiction, there would have been no need for Congress to make an ANDA filing into an artificial act of infringement by enacting 35 U.S.C. § 271(e)(2)(A)." Pet. 26. But Mylan "confuses liability and jurisdiction." *Cent. States, Se. & Sw. Areas Pension Fund v. Reimer Express World Corp.*, 230 F.3d 934, 944 (7th Cir. 2000). Mylan is correct that, without the Hatch-Waxman Act's "artificial" cause of action, its filing of an ANDA would still give rise to minimum contacts in Delaware because the ANDA would constitute a formal declaration of Mylan's "plans to market its proposed drugs in Delaware." Pet. App. 14. This does not mean, however, that—based on the ANDA alone—the brand-name manufacturer would have a cause of action against the generic manufacturer for "'mak[ing], us[ing], offer[ing] to sell, or sell[ing]'" the patented drug. Pet. 26 (quoting 35 U.S.C. § 271(a)). After all, the fact that a party has minimum contacts with a State does not mean that there is automatically a cause of action available against it. *See*, *e.g.*, *Bird v.*

Parsons, 289 F.3d 865, 876-82 (6th Cir. 2002) (concluding that the defendants had minimum contacts with the forum State but dismissing the complaint for failure to state a claim under Fed. R. Civ. P. 12(b)(6)). To facilitate the prompt resolution of patent disputes between brand-name and generic manufacturers, it was therefore necessary for Congress to make the act of filing the ANDA with a Paragraph IV certification itself an act of infringement, *see* 35 U.S.C. § 271(e)(2)(A), because, in the absence of that statutorily created artificial cause of action, the brand-name company would have no cause of action against the ANDA filer. *See id.* § 271(e)(1) (providing that generic manufacturers' preparatory work "reasonably related" to their submission of an ANDA does not constitute infringement).

Mylan also contends that an ANDA does not guarantee that a generic manufacturer will ultimately "market[ ] the product in question in a manner that interferes with the patent holder's rights" because the FDA could reject the ANDA filing or the generic manufacturer could simply decide not to market its product after receiving FDA approval. Pet. 27. But filing an ANDA is not a step taken lightly. Not only does an ANDA involve filing fees and research costs that can run into the millions of dollars, Pet. App. 11, but "[f]iling a paragraph IV certification means provoking litigation." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1677 (2012). As the Federal Circuit explained, "the economic realities of preparing an ANDA confirm that filing realistically establishes a plan to market." Pet. App. 11. Indeed, a generic manufacturer files an ANDA with a Paragraph IV certifica-

tion precisely because it seeks to secure FDA approval to market its generic product before expiration of Orange Book-listed patents.

The theoretical possibility that post-filing developments might prompt the ANDA filer to modify its business plan does not alter the minimum-contacts analysis, which turns on the defendant's prior conduct, as well as the future consequences of that conduct, *at the time suit is filed*—not at some undefined point in the future. *See Maysonet-Robles v. Cabrero*, 323 F.3d 43, 49 (1st Cir. 2003). In any event, Mylan has never even hinted that it would consider abandoning its plan to market its generic version of Ampyra if it secures FDA approval. If Mylan has a change of heart, it can withdraw its ANDA filing, which would moot this litigation.

Mylan also argues that the Federal Circuit was wrong to rely on its intention of "engaging in . . . injury-causing and allegedly wrongful marketing conduct in Delaware," Pet. App. 8, because "either there will be no marketing at all" (if respondents prevail in this suit) or "there will be non-wrongful marketing" (if Mylan prevails). Pet. 28. But, like many of Mylan's other arguments, this contention "run[s] counter to the legal tradition of injunctive actions to prevent a defendant's planned, non-speculative harmful conduct before it occurs." Pet. App. 13. In every case where an injunction is sought, the allegedly wrongful conduct that the plaintiff seeks to enjoin either will not occur (if the plaintiff prevails and an injunction is issued) or will not be wrongful (if the defendant prevails). Mylan does not cite a single decision establishing that jurisdiction in cases involving prospective relief can be so easily defeated.

Finally, Mylan asserts that the Federal Circuit's decision will require courts to "wade" into a so-called factual "'morass'" relating to the defendant's likelihood of marketing its generic drug in the forum State. Pet. 28. But in most ANDA cases, such as this one, there will be no dispute at all about the ANDA filer's intention to distribute its proposed drug in the forum State. *See* Pet. 34; Pet. App. 15. And where factual disputes regarding jurisdiction do arise, "discovery is available to ascertain the facts bearing on such issues." *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 n.13 (1978). The prospect of jurisdictional discovery in a limited subset of ANDA cases is no reason to question a jurisdictional rule that is firmly grounded in this Court's longstanding precedent.

II. NUMEROUS OTHER CONSIDERATIONS ALSO WEIGH AGAINST REVIEW.

The other arguments that Mylan offers in favor of review uniformly fall flat. The Federal Circuit's decision is hardly the jurisprudential watershed that Mylan portrays it to be and, in any event, Mylan's petition is hampered by several vehicle problems that make this case a particularly poor candidate for review.

According to Mylan, the Federal Circuit's decision has "profound implications" for the pharmaceutical industry because it supposedly subjects ANDA filers to "effectively national jurisdiction." Pet. 30 (internal quotation marks omitted). But that assertion is impossible to square with Mylan's prior description of the Federal Circuit's opinion as a "narrow decision finding only specific personal jurisdiction under the facts presented in the two cases before it." Mylan Letter at 2. Moreover, as explained

above, the only generic manufacturers that are potentially subject to nationwide ANDA jurisdiction under the Federal Circuit's decision are those manufacturers—like Mylan—that intend to distribute their generic drugs in *every* State. And even where a generic manufacturer has minimum contacts with the forum State, it remains able to contest specific personal jurisdiction on the ground that it is "unreasonable" on the particular facts of the case and therefore "offend[s] traditional notions of fair play and substantial justice." *World-Wide Volkswagen Corp.*, 444 U.S. at 292, 297 (internal quotation marks omitted). As the Federal Circuit concluded, however, Mylan can make no such showing here, where respondents are already litigating other suits involving the Ampyra Patents in Delaware, the absence of jurisdiction over Mylan would lead to the piecemeal resolution of overlapping patent questions in multiple courts across the country, and Mylan is a frequent litigant in Delaware (as both a plaintiff and a defendant). Pet. App. 17.[6]

Mylan also seeks to extend the implications of the Federal Circuit's decision beyond the ANDA context by arguing that it "dramatically expands the limits of specific jurisdiction . . . for any company that may find itself on the receiving end of a patent

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[6] Mylan cites *Millenium Pharmaceuticals, Inc. v. Pharmascience Inc.*, No. 15-702-GMS, 2016 WL 3382131 (D. Del. June 10, 2016), as an example of the supposedly dire consequences of the Federal Circuit's decision, but, like the Federal Circuit here, the district court in that case determined that "Delaware is a state where [the ANDA filer] will engage in marketing if the ANDA is approved." *Id.* at *3. The decision is thus a straightforward application of the Federal Circuit's holding to another generic manufacturer whose products would be distributed in Delaware.

infringement suit." Pet. 32. But the only case that Mylan cites to support that assertion is *Segway Inc. v. Inventist, Inc.*, No. 15-808-SLR, 2016 WL 1650468 (D. Del. Apr. 25, 2016), where the district court cited the Federal Circuit's decision in a footnote, described it as arising "in a different factual context," and stated that the Federal Circuit had "recently held that 'a defendant's planned, non-speculative harmful conduct' . . . passed constitutional muster." *Id.* at *4 n.6. That is hardly strong evidence that the Federal Circuit's decision is going to reshape the law of personal jurisdiction—either in the ANDA context or beyond.

In addition, Mylan speculates that the Federal Circuit's decision will "substantial[ly] chill[ ]" the introduction of new generic drugs. Pet. 34. Outside the ANDA setting, however, it has long been settled that manufacturers have "minimum contacts" with every State in which their infringing products are sold, *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1571 (Fed. Cir. 1994), and there is no evidence that the availability of nationwide patent-infringement jurisdiction against manufacturers that market their products nationwide has impeded innovation. Nor is there evidence that the expansive approach to general jurisdiction that prevailed before this Court's decision in *Daimler* discouraged generic manufacturers from filing ANDAs with Paragraph IV certifications. It is implausible that generic manufacturers will now scale back their profitable businesses simply because they may have to litigate ANDA cases where they intend to sell their drugs, rather than only in their home States.

Moreover, even if the Court were otherwise inclined to consider the application of specific-jurisdiction principles to ANDA litigation, this case is a poor vehicle for doing so. In particular, if this

Court were to conclude that Mylan is not subject to specific jurisdiction in Delaware, it would then be confronted with the question whether, as the district court and Judge O'Malley concluded, Mylan is subject to general personal jurisdiction in Delaware because it registered to do business in the State and, at the time suit was filed, controlling Delaware case law "held that compliance with Delaware's registration statute constitutes consent to general personal jurisdiction." Pet. App. 23 (citing *Sternberg v. O'Neil*, 550 A.2d 1105, 1116 (Del. 1988)).

Mylan argues that the general-jurisdiction question has been "removed . . . from the case" because, *after* the Federal Circuit's decision, the Delaware Supreme Court overruled its prior decision holding that compliance with Delaware's corporate registration statute amounted to consent to general personal jurisdiction. Pet. 35 (citing *Genuine Parts Co. v. Cepec*, 137 A.3d 123 (Del. 2016)). But it is "well established" that "federal jurisdiction attaches at the time when the action is commenced and cannot be ousted by later developments." *Maysonet-Robles*, 323 F.3d at 49; *see also*, *e.g.*, *Merial Ltd. v. Cipla Ltd.*, 681 F.3d 1283, 1294-95 (Fed. Cir. 2012); *Cent. States, Se. & Sw. Areas Pension Fund v. Phencorp Reinsurance Co.*, 440 F.3d 870, 877 (7th Cir. 2006); *Pohlmann*, 176 F.3d at 1112. Indeed, Mylan certainly did not believe that the issue of general jurisdiction had been "removed . . . from the case" when it asked the Federal Circuit to consider the question in its petition for rehearing or rehearing en banc, *see* Pet. for Reh'g 15, which was filed *after* the Delaware Supreme Court overruled its *Sternberg* decision.

Thus, if this Court were to reverse the Federal Circuit's specific jurisdiction holding, it would be squarely confronted with the question whether, as

respondents have contended throughout this litigation, consent remains a viable basis for establishing general jurisdiction after *Daimler*. *See Pa. Fire Ins. Co. v. Gold Issue Mining & Milling Co.*, 243 U.S. 93, 95 (1917) (rejecting a due-process challenge to a statutory procedure that required out-of-state corporations to appoint an agent for service, which the state supreme court had interpreted as constituting consent to general personal jurisdiction); *see also* Resps.' C.A. Br. 14-35. If this Court determines that the specific-jurisdiction question posed by Mylan is worthy of review, it should grant certiorari in a case that presents that issue unencumbered by the general-jurisdiction question.

The interlocutory posture of this litigation also weighs strongly against review. This Court "generally await[s] final judgment in the lower courts before exercising [its] certiorari jurisdiction." *Va. Military Inst. v. United States*, 508 U.S. 946, 946 (1993) (Scalia, J., respecting denial of certiorari); *see also*, *e.g.*, *Mt. Soledad Mem'l Ass'n v. Trunk*, 132 S. Ct. 2535, 2536 (2012) (Alito, J., respecting denial of certiorari). This case is a prime example of the wisdom of that practice: After Mylan commenced its interlocutory appeal, the case was consolidated in the district court with other cases involving the Ampyra Patents, and a bench trial was held in September 2016. *See Acorda Therapeutics Inc. v. Alkem Labs. Ltd.*, No. 14-882-LPS (D. Del.). A decision is expected soon. Granting review of the jurisdictional question at this juncture would therefore be premature because, if Mylan prevails at trial, it may have no need for review of that issue in respondents' ANDA suit, and if respondents prevail, Mylan can seek review of the jurisdictional question in this Court in the event that

its appeal on the merits to the Federal Circuit is unsuccessful.

Moreover, there is every reason to believe that this Court will be afforded future opportunities to review this jurisdictional question. As Mylan acknowledges, ANDA litigation is "high stakes" and "high volume." Pet. 32. Thus, not surprisingly, post-trial appeals by generic manufacturers found liable for infringement are frequent. *See*, *e.g.*, *Intendis GmbH v. Glenmark Pharm. Inc., USA*, 822 F.3d 1355 (Fed. Cir. 2016); *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293 (Fed. Cir. 2015); *Shire Dev., LLC v. Watson Pharm., Inc.*, 746 F.3d 1326 (Fed. Cir. 2014), *vacated*, 135 S. Ct. 1174 (2015). A case that comes to this Court after a full trial on the merits—and without the complications of the general-jurisdiction question presented here—would be a far more effective vehicle for the Court to consider the question of specific jurisdiction raised by Mylan.

CONCLUSION

Mylan asks this Court to grant review of a decision that applies longstanding personal-jurisdiction principles to reach an outcome that preserves the delicate statutory balance between the interests of brand-name manufacturers and their generic counterparts. Because that decision is consistent with the considerations of fundamental fairness that animate this Court's personal-jurisdiction jurisprudence—and with the public-health considerations that animate the Hatch-Waxman Act—the petition for a writ of certiorari should be denied.

Respectfully submitted.

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