No. 15-1456

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

ACORDA THERAPEUTICS INC.,
ALKERMES PHARMA IRELAND LIMITED,

Plaintiffs-Appellees,

v.

MYLAN PHARMACEUTICALS INC., MYLAN INC.,

Defendants-Appellants.

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

RESPONSE TO PETITION FOR REHEARING EN BANC

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CERTIFICATE OF INTEREST

Counsel for Appellees certify the following:

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

   Acorda Therapeutics, Inc. and Alkermes Pharma Ireland Limited.

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

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

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

4. **The names of all law firms and the partners or associates that appeared for Acorda Therapeutics, Inc. and Alkermes Pharma Ireland Limited in the trial court or are expected to appear in this court are:**

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INTRODUCTION

Mylan's principal argument in support of rehearing en banc is that the Panel's decision allegedly "rests on erroneous factual premises." Pet. 6 (capitalization altered). But rehearing en banc is intended to resolve conflicts in this Court's precedent and "precedent-setting questions of exceptional importance"—not factual errors. Fed. Cir. R. 35(b)(2). By emphasizing supposed factual flaws in the Panel's opinion, Mylan lays bare its inability to meet the traditional criteria for en banc review.

In any event, the factual errors that Mylan purportedly identifies are illusory. Mylan primarily takes issue with the Panel's conclusion that it "plans to direct sales of its generic drugs into Delaware" if the FDA approves its abbreviated new drug application ("ANDA"). Op. 15; *see also* Pet. 8-9. There is no dispute, however, that Mylan—the largest generic drug manufacturer in the United States—markets its products in all fifty States through a network of wholesalers and distributors, and does not "'carve out individual states'" from its distribution network. *Eli Lilly & Co. v. Accord Healthcare, Inc. USA*, No. 14-389, Dkt. No. 277, at 13 (S.D. Ind. Nov. 7, 2014). Mylan's ANDA filings therefore "constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs" in Delaware. Op. 9.

As the Panel concluded, those "formal acts"—filing an ANDA "for the purpose of engaging in . . . injury-causing and allegedly wrongful marketing conduct in Delaware"—establish the requisite "minimum contacts" to subject Mylan to specific personal jurisdiction in Delaware. Op. 8-9. While Mylan contends that the Panel's consideration of "'future activities'" conflicts with "relevant precedents," Pet. 10 (capitalization altered), the Supreme Court has made clear that "contemplated future consequences" of a defendant's 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). The Panel's assessment of the "future consequences" of Mylan's ANDA filing fits squarely within that precedent.

Mylan's policy arguments provide equally little support for rehearing. Mylan asserts that the Panel's decision could lead to specific personal jurisdiction in ANDA cases "anywhere in the country," Pet. 3 (emphasis omitted), but, under the Panel's reasoning, that is only true where the generic manufacturer—like Mylan—intends to distribute its products in all 50 States. The Panel's approach therefore is no broader than the longstanding rule subjecting patent infringers to specific 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). And Mylan's suggestion that the decision could "chill the development of life-saving"

drugs is likewise overwrought. Pet. 3. It is *innovators*—not generic drug companies—that develop drugs. In any event, as Mylan acknowledges, before the Supreme Court decided *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014), plaintiffs could rely on general personal jurisdiction to bring an ANDA suit against Mylan in every State, Pet. 11. There is no reason to think that Mylan and other generic manufacturers with similar nationwide distribution networks will abandon their profitable businesses simply because the Panel's opinion makes clear that they are subject to suit in the same States based on specific jurisdiction.

STATEMENT OF THE CASE

Plaintiffs filed this ANDA infringement action against Mylan in the District of Delaware after Mylan submitted an ANDA seeking the FDA's approval to manufacture and sell generic versions of Ampyra®, the first and only drug approved by the FDA for improving walking in patients with multiple sclerosis. Op. 4. Plaintiff Acorda Therapeutics, Inc., manufactures and sells Amypra, and holds all right, title, and interest in four Ampyra patents. *Id.* Acorda is also the exclusive licensee of a fifth Ampyra patent assigned to Plaintiff Alkermes Pharma Ireland Limited. *Id.*

Mylan's ANDA was accompanied by 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. JA6. Under

the Hatch-Waxman Act, the filing of an ANDA with a Paragraph IV certification is "itself an act of infringement" that gives the brand-name drug company "an immediate right to sue." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1677 (2012).

Mylan moved to dismiss Plaintiffs' infringement suit for lack of personal jurisdiction. The district court denied the motion, holding that Mylan was subject to both general and specific jurisdiction in Delaware. Op. 4. The district court concluded that Mylan had consented to general personal jurisdiction in Delaware when it registered to do business in the State and appointed an agent to accept service of process pursuant to procedures that the Delaware Supreme Court had "long and unambiguously interpreted" as "constituting consent to general jurisdiction." JA28. The district court also determined that Mylan was subject to specific jurisdiction in Delaware based on its suit-related contacts with the State, including (1) Mylan's ANDA filing, which, if approved by the FDA, would enable Mylan to sell its generic version of Ampyra in Delaware, and (2) Mylan's registration to do business in Delaware, its license from the Delaware Board of Pharmacy to manufacture and distribute drugs, and its frequent litigation in Delaware, particularly in ANDA cases. JA 32-33.

This Court granted permission to appeal pursuant to 28 U.S.C. § 1292(b) and heard the appeal together with a similar ANDA case filed against Mylan by brand-

name drug manufacturer AstraZeneca AB. The Panel affirmed the district court's decision, holding that Mylan was subject to specific personal jurisdiction in Delaware based on "the particular actions Mylan has already taken—its ANDA filings—for the purpose of engaging in . . . injury-causing and allegedly wrongful marketing conduct" of its generic version of Ampyra in Delaware. Op. 8-9. "[I]t suffices for Delaware to meet the minimum-contacts requirement," the Panel concluded, "that Mylan's ANDA filings and its distribution channels establish that Mylan plans to market its proposed drugs in Delaware and the lawsuit is about patent constraints on such in-State marketing." *Id.* at 14. The Panel further determined that there were "no substantial arguments that considerations of unfairness override the minimum-contacts basis" for specific personal jurisdiction in Delaware because, among other reasons, "[t]he burden on Mylan"—"a large generic manufacturer [that] has litigated many ANDA lawsuits in Delaware"—"will be at most modest" and "personal jurisdiction will serve the interests of the plaintiffs and the judicial system in efficient resolution of litigation." *Id.* at 16.

The Panel did not reach the question of general personal jurisdiction, but, in a concurring opinion, Judge O'Malley agreed with the district court that Mylan had consented to general personal jurisdiction in Delaware when it registered to do business and appointed an agent for service of process in the State. *See* Concurring Op. of O'Malley, J. at 12.

REASONS FOR DENYING REHEARING EN BANC

The Court should deny Mylan's petition for rehearing en banc because the Panel's opinion is consistent with both the factual record in this case and settled principles of personal jurisdiction established by this Court and the Supreme Court.

I. The Panel's Alleged Factual Errors Do Not Warrant Rehearing En Banc.

Mylan devotes nearly half of its argument to the supposedly "mistaken factual premises" on which the Panel's decision rests. Pet. 7. Yet, Mylan decided not to seek panel rehearing—the appropriate means of securing correction of factual errors—and its heavy emphasis on factual issues simply underscores its inability to meet the requirements for rehearing en banc. *See Easley v. Reuss*, 532 F.3d 592, 594 (7th Cir. 2008) ("rehearings en banc are designed to address issues that affect the integrity of the circuit's case law (intra-circuit conflicts) and the development of the law (questions of exceptional importance)").

Mylan's factual arguments also fail on their own terms. According to Mylan, the filing of an ANDA does not "mean[ ] that a generic manufacturer will market the product in question." Pet. 7. Neither Mylan nor its *amicus*, however, points to a single example of a generic manufacturer that obtained approval of an ANDA and then decided not to market the generic drug that it presumably spent substantial amounts of time and money developing. As the Panel explained, the "magnitude and costs of the work required before the ANDA is filed"—including

research costs that can run into the millions of dollars and a $76,030 filing fee—"soundly link the ANDA filing to the filer's entry into the market." Op. 12. Moreover, if a generic manufacturer truly does not intend to market its drug upon securing FDA approval, nothing in the Panel's opinion prohibits the manufacturer from raising that factual argument in an attempt to contest specific personal jurisdiction. Mylan has never even hinted that it would refrain from marketing its generic version of Ampyra in the event the FDA approves its ANDA.

Mylan also asserts that the Panel's opinion rests on the "incorrect[ ] assumption" that, if the FDA approves its ANDA, Mylan "would market the drugs in Delaware specifically." Pet. 8. But Mylan—the largest generic pharmaceutical manufacturer in the country, *see* Mylan Inc. Form 10-K, Mar. 2, 2015, at 5—has never disputed that it markets its products in all 50 States through an established network of wholesalers and distributors, and has never suggested that, if approved by the FDA, its generic version of Ampyra will not be marketed in Delaware. Mylan's license from the Delaware Board of Pharmacy to manufacture and distribute drugs in the State, JA 84-86, and the positions that Mylan has taken in public filings regarding the nationwide reach of its distribution network, point decisively toward the distribution of Mylan's generic drugs in Delaware. *See, e.g.*, *Eli Lilly & Co.*, No. 14-389, Dkt. No. 277, at 13 (quoting testimony in which

Mylan stated that it does not "carve out individual states" from its nationwide distribution network).

The fact that Mylan may rely on third parties to sell its generic drugs in Delaware, rather than making those sales itself, has no bearing on the jurisdictional analysis. Pet. 9 n.1. This Court has made clear that, where a defendant has "purposefully shipped" an infringing product into the forum State "through an established distribution channel" and the "cause of action for patent infringement is alleged to arise out of these activities," "[n]o more is usually required to establish specific jurisdiction," even if the defendant itself does not make the infringing sales. *Beverly Hills Fan Co.*, 21 F.3d at 1565; *see also Luv N'care, Ltd. v. Insta-Mix, Inc.*, 438 F.3d 465, 471 (5th Cir. 2006) ("jurisdiction may attach both to manufacturers who supply their own delivery systems and to those that make use of the distribution systems of third parties").[1]

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[1] *Amicus* GPhA is mistaken when it contends that the Panel's holding conflicts with the plurality opinions in *J. McIntyre Machinery Ltd. v. Nicastro*, 564 U.S. 873 (2011), and *Asahi Metal Industry Co. v. Superior Court*, 480 U.S. 102 (1987). *See* GPhA Br. 7-9. Mylan's intention to make "purposeful[ ] ship[ments]" of its products into Delaware "through an established distribution" network is sufficient to establish minimum contacts with Delaware even under the pluralities' application of a "purposeful direction" requirement in the stream-of-commerce setting. *Beverly Hills Fan*, 21 F.3d at 1565; *see also AFTG-TG, LLC v. Nuvoton Tech. Corp.*, 689 F.3d 1358, 1365 (Fed. Cir. 2012) (reaffirming "the *Beverly Hills Fan* line of cases" after *Nicastro* because a finding of personal jurisdiction under the *Beverly Hills* standard satisfies the plurality's approach in *Nicastro*).

Finally, Mylan disputes the Panel's conclusion that its ANDA filings were made "for the purpose of engaging in . . . injury-causing and allegedly wrongful marketing conduct in Delaware," Op. 8-9, because, "[i]f a branded manufacturer brings an infringement suit" and prevails, those infringing sales will never be made. Pet. 9. But the Panel's jurisdictional analysis does not depend on whether the future sales will ultimately be found to be infringing. It instead rests on Mylan's submission of an ANDA "seek[ing] approval to sell its generic drugs" in Delaware. Op. 15. Under the Hatch-Waxman Act, the filing of an ANDA with a Paragraph IV certification is "itself an act of infringement," *Caraco Pharm.*, 132 S. Ct. at 1677, and patent holders are authorized to file suit immediately, before the FDA has approved the ANDA filer's request to market its generic drug. 35 U.S.C. § 271(e)(2)(A). The possibility that Plaintiffs may prevail in this litigation and that the alleged infringing sales may never occur does not diminish the minimum contacts that Mylan established with Delaware *at the time* it filed its ANDAs and requested FDA authorization to sell its generic version of Ampyra in the State.

If Mylan's conception of "minimum contacts" were correct, a defendant sued to enjoin future unlawful conduct could contest specific personal jurisdiction on the ground that the court might issue an injunction to prevent that conduct. As the Panel recognized, that argument would upend the long-settled "tradition of

injunctive actions to prevent a defendant's planned, non-speculative harmful conduct *before it occurs*." Op. 13 (emphasis added).

II. The Panel's Alleged Legal Errors Do Not Warrant Rehearing En Banc.

Mylan expends comparatively little effort attempting to establish that the Panel's opinion conflicts with the decisions of this Court and other courts. The arguments that it does present on this point are uniformly flawed.

According to Mylan, *Walden v. Fiore*, 134 S. Ct. 1115 (2014), "makes plain that the only 'jurisdictionally relevant' suit-related contacts . . . are those that a defendant has already formed when the suit is filed." Pet. 10-11 (emphasis omitted). The Panel's opinion is consistent with that reading of *Walden* because it was the "particular actions Mylan *ha[d] already taken*" when this suit was filed—submitting an ANDA "for the purpose of engaging in . . . allegedly wrongful marketing conduct in Delaware"—that established its suit-related contacts with Delaware. Op. 8-9 (emphasis added). Moreover, *Walden*—a suit to recover damages for a federal officer's allegedly wrongful seizure of property—did not present the Supreme Court with an occasion to address the jurisdictional significance of a defendant's *future* conduct. 134 S. Ct. at 1120. When the Court has considered that issue, it has made clear that the "contemplated future consequences" of a defendant's conduct "must be evaluated in determining whether the defendant purposefully established minimum contacts within the

forum." *Burger King*, 471 U.S. at 479. Other courts of appeals are in agreement. *See K-V Pharm. Co. v. J. Uriach & CIA, S.A.*, 648 F.3d 588, 594 (8th Cir. 2011) ("these [contractual] terms and the future consequences that the parties contemplated in fashioning them support personal jurisdiction"); *Roth v. Garcia Marquez*, 942 F.2d 617, 622 (9th Cir. 1991) (same).[2]

Mylan's argument that the Panel's opinion conflicts with the Supreme Court's decision in *Daimler* is even more far-fetched. Pet. 11. *Daimler* held that *general* personal jurisdiction—which covers "'any and all claims'" against a defendant—cannot be based simply on a corporation's course of business in the State, and, except in extraordinary cases, is limited to a corporation's State of incorporation and principal place of business. 134 S. Ct. at 751, 761. Far from "recreat[ing] the pre-*Daimler* status quo," Pet. 12, the Panel's opinion is silent on the question of general jurisdiction and speaks only to *specific* personal jurisdiction in ANDA litigation based on a generic manufacturer's "'suit-related'" contacts with the forum State. Op. 9. Nothing in the Panel's opinion exposes generic

[2] The lower-court decisions cited by Mylan (at 11) are not to the contrary. *See Fastpath, Inc. v. Arbela Techs. Corp.*, 760 F.3d 816, 822 (8th Cir. 2014) (concluding in a breach-of-contract action that, although "any future development of software products by [the plaintiff] might have taken place in Iowa, this factor [was] not relevant in [the jurisdictional] analysis as the Agreement never led to a deal between the parties"); *Eli Lilly & Co. v. Nang Kuang Pharm. Co.*, No. 1:14-cv-01647, 2015 WL 3744557, at *1 (S.D. Ind. June 15, 2015) (concluding that general personal jurisdiction "'cannot be based on future contacts'").

manufacturers to jurisdiction in Delaware (or any other forum) in suits unrelated to their ANDA filings.

Moreover, it is not the case that, under the Panel's opinion, every "ANDA filer is . . . subject to specific personal jurisdiction in all fifty states." Pet. 12. The Panel's analysis leaves open the possibility that a generic manufacturer with limited distribution networks may be able to establish that it has no "plans to engage in marketing of the proposed generic drug[ ]" in the forum State and therefore lacks "minimum contacts" with that State. Op. 9.

In contrast, where a generic manufacturer, like Mylan, has a nationwide distribution network that manifests its intention "to engage in marketing of the proposed generic drug[ ]" across the country, then the manufacturer's ANDA filing would establish "minimum contacts" with every State. Op. 9. Even in that setting, however, establishing the existence of "minimum contacts" is only the first step in the jurisdictional inquiry. As the Panel recognized, where "a defendant has minimum suit-related contacts with a State, the defendant may defeat specific personal jurisdiction by sufficiently demonstrating that other considerations render jurisdiction unreasonable." Op. 15-16 (citing *Burger King*, 471 U.S. at 477). While Mylan failed to establish that it would be unreasonable for this suit to proceed in Delaware—where Mylan is registered to do business and regularly

litigates, *id.* at 16—nothing in the Panel's opinion forecloses other generic manufacturers from making that fact-specific showing of unreasonableness.

Mylan's contention that the Panel's opinion is "irreconcilable" with *Zeneca Ltd. v. Mylan Pharmaceuticals, Inc.*, 173 F.3d 829 (Fed. Cir. 1999), is equally baseless. Pet. 13. *Zeneca*—in which no opinion commanded a majority of the Court—addressed a single question certified by a district court: whether "Mylan's act of filing its tamoxifen ANDA with the FDA in Rockville, Maryland," gave rise to "personal jurisdiction over Mylan in the District Court for the District of Maryland." *Id.* at 830-31 (opinion of Gajarsa, J). Neither the parties nor the Court addressed whether specific jurisdiction could be based on the future sales that Mylan would make in Maryland if the FDA approved its ANDA. Op. 14. Because "'panel authority that does not address an issue is not binding as to the unaddressed issue,'" *Lumbermens Mut. Cas. Co. v. United States*, 654 F.3d 1305, 1317 n.10 (Fed. Cir. 2011), *Zeneca* did not preclude the Panel in this case from concluding that Mylan has minimum contacts with Delaware and other States in which it will "engage in marketing" of its generic drugs if its ANDAs are approved. Op. 9.

Finally, there is no reason to credit Mylan's conjecture that the Panel's decision will "have a substantial chilling effect on generic activity." Pet. 14. Outside the ANDA setting, it has long been settled that manufacturers have "minimum contacts" with every State in which their infringing products are sold,

Beverly Hills Fan Co., 21 F.3d at 1571—yet, 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 pre-*Daimler*—which, as Mylan acknowledges, rendered "generic drug manufacturers . . . vulnerable to suit in jurisdictions across the country," Pet. 11—discouraged generic manufacturers from provoking infringement litigation by filing ANDAs with Paragraph IV certifications. Having long faced the prospect of nationwide jurisdiction, it is implausible to suggest that generic manufacturers would now decide to scale back their profitable businesses simply because, under the Panel's specific-jurisdiction analysis, an ANDA case might be filed against them outside of their home States.

* * *

The Panel's opinion applies well-established principles of personal jurisdiction to conclude that Mylan—which has a comprehensive nationwide drug-distribution network—is subject to specific personal jurisdiction in Delaware because it will "direct sales of its generic drugs into Delaware" if the FDA approves its ANDAs. Op. 15. That conclusion is consistent with the precedent of this Court and other courts. It also solidifies the "careful balance" that the Hatch-Waxman Act struck between the rights of innovators and generic manufacturers,

Janssen Pharmaceutica, N.V. v. Apotex, Inc., 540 F.3d 1353, 1361 (Fed. Cir. 2008), by facilitating the litigation of infringement actions against multiple generic filers in a single jurisdiction and mitigating the possibility of piecemeal litigation and inconsistent outcomes. For all of these reasons, rehearing en banc is not warranted.[3]

CONCLUSION

This Court should deny Mylan's petition for rehearing en banc.

Respectfully submitted.

[3] If the Court does grant rehearing en banc, then Plaintiffs agree with Mylan that the Court should review both the question of specific jurisdiction on which the Panel's decision is based as well as the question of general jurisdiction that the Panel did not reach. Op. 4; *see also* Pet. 15. As Judge O'Malley concluded in her concurring opinion, Mylan is subject to general personal jurisdiction in Delaware "by virtue of its voluntary, express consent to such jurisdiction" when it registered to do business and appointed an agent for service of process in Delaware. *See* Concurring Op. of O'Malley, J. at 12. Although the Delaware Supreme Court recently overruled its decision in *Sternberg v. O'Neil*, 550 A.2d 1105 (Del. 1988), which had authoritatively construed Delaware's registration-and-appointment procedure as constituting consent to general personal jurisdiction, *Genuine Parts Co. v. Cepec*, No. 528, 2015, 2016 WL 1569077 (Del. Apr. 18, 2016), that change in Delaware law has no effect on the existence of general personal jurisdiction in this case because personal jurisdiction is determined at the time that suit is filed. *See, e.g.*, *Cent. States Se. & Sw. Areas Pension Fund v. Phencorp Reinsurance Co.*, 440 F.3d 870, 877 (7th Cir. 2006).

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CERTIFICATE OF SERVICE

I hereby certify that on May 18, 2016, I caused service of the foregoing to be made by electronic filing with the Clerk of the Court using the **CM/ECF** System, which will send a Notice of Electronic Filing to all parties with an e-mail address of record, who have appeared and consent to electronic service in this action.

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