No. 16-360

In the Supreme Court of the United States

MYLAN PHARMACEUTICALS INC. &
MYLAN INC., *Petitioners,*

v.

ACORDA THERAPEUTICS INC. & ALKERMES PHARMA
IRELAND LIMITED, *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

PETITIONERS' REPLY BRIEF

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PETITIONERS' REPLY BRIEF

Neither brief in opposition offers a compelling reason to deny review. Instead, respondents' arguments confirm the fundamental confusion among lower courts on this important issue.

In this case alone, five judges have produced four different theories as to where and why ANDA filers may be subject to specific jurisdiction. Even now, respondents cannot agree on what the Federal Circuit held: for AstraZeneca, it is "simply incorrect" to say that the panel majority premised jurisdiction on future in-forum sales. AstraZeneca Br. in Opp. ("AZ Opp."). Instead, AstraZeneca understands a paragraph IV certification to "give[] rise to minimum contacts with every State," "regardless of whether … a single sale" is ever made. *Id.* at 20, 16. Acorda, by contrast, says that an ANDA filer who does not intend to make in-forum sales "may well … lack the requisite minimum contacts." Acorda Br. in Opp. ("Acorda Opp.") 3.

Neither reading can salvage the opinion below: Contrary to AstraZeneca's view, a "contact" connecting a defendant to "all 50 States and the District of Columbia … simultaneously … can have no jurisdictional significance." *Rush* v. *Savchuk*, 444 U.S. 320, 330 (1980). And Acorda's future-sales-dependent theory would have personal jurisdiction turn entirely on speculative future contacts, a dangerous departure from *Burger King Corp.* v. *Rudzewicz*, 471 U.S. 462 (1985), that both respondents obscure. Such "contacts"—which have not occurred and may never occur—are not contacts at all.

There is zero reason to let these problems fester. Rather, this Court should grant review now to clarify which courts may act as the gateway to the market for generic drugs—which fill 3.8 billion prescriptions annually, save lives, and result in billions of dollars in healthcare savings.[1]

I. The Opinion Below Conflicts With This And Other Courts' Precedents And With The Hatch-Waxman Act

A. Specific Jurisdiction Premised On Future Predicted "Facts" Is Unprecedented

Mylan has had *no* suit-related contacts with Delaware to date, a fact that Acorda does not dispute. See Acorda Opp. 2, 14-15. AstraZeneca, however, attempts to read such contacts into the opinion below, claiming that an ANDA filing "attacks the patent holder's intellectual-property rights everywhere they are valid," and so "gives rise to minimum contacts with every State." AZ Opp. 12; *id.* at 20. But such "a 'contact'" with "all 50 states and the District of Columbia … simultaneously … can have no jurisdictional significance." *Rush*, 444 U.S. at 330. AstraZeneca ignores *Rush*.[2]

Unable to cite any cognizable conduct by Mylan directed at Delaware, respondents instead defend the

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[1] See Generic Pharmaceutical Association ("GPhA") Br. 5.

[2] Nor does it matter if the ANDA "targeted AstraZeneca's corporate interests in Delaware." AZ Opp. 2. To establish minimum contacts, it is not enough that a defendant "directed [its] conduct at plaintiffs who[] [it] knew had [Delaware] connections." *Walden* v. *Fiore*, 134 S. Ct. 1115, 1125 (2014).

opinion below based on the predicted "future effects" in Delaware of Mylan's past conduct in West Virginia and Maryland. Acorda Opp. 14-15; AZ Opp. 15-17. They justify doing so by pointing to what they call the "legal tradition of injunctive actions." Acorda Opp. 16 (citing Pet. App. 13); AZ Opp. 17 n.2 (same). Yet neither respondent cites a single case from this supposed "tradition" of jurisdiction based on future contacts.

Respondents pretend *Burger King* is part of such a tradition, but it is not. *Burger King* concerned retrospective relief for a defendant's breach, in the forum state, of a contract "made and entered into" in the forum state and calling for performance there. 471 U.S. at 469 n.11 (retrospective relief); *id.* at 481 (where contract entered); *id.* at 466, 468 & 480 (where obligation of performance breached). In holding that jurisdiction in Florida was appropriate, this Court considered, among other factors, the contract's "prior negotiations and contemplated future consequences." *Id.* at 478-79. That passing reference to the contract's future consequences was not an authorization to base jurisdiction on *possible* or even *probable* future contacts with the forum. Instead, it was a recognition that the defendant had already, by contract, "established" substantial ties with Florida, including a "20-year interdependent relationship … with Burger King's Miami headquarters." *Id.* at 482. Thus, *Burger King* recognized only that a defendant's already-established contractual obligations with a forum may

count as contacts; it does not justify the exercise of jurisdiction based on ties that do not yet exist.[3]

In the lower courts there is "general agreement not to count contacts arising after the case is filed." Todd David Peterson, *The Timing of Minimum Contacts*, 79 Geo. Wash. L. Rev. 101, 141 (2010). Indeed, before the opinion below, the idea that future, post-suit contacts do not count may have been "the only point on which the cases agree[d]." *Id.* at 131. Respondents' attempt to distinguish between prospective and retrospective relief is belied by respondents' inability to identify a single case drawing such a distinction (despite thousands of reported decisions, see note 3, *supra*). None of the cases cited in the petition (at 20-21) or discussed in the article cited above distinguished between prospective and retrospective relief. For instance, in

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[3] Nor do the other cases cited by Acorda (at 16-17) interpret *Burger King* to mean anything other than that a court should "consider the terms of [a] contract and *its* contemplated future consequences in deciding whether personal jurisdiction … exists." *K-V Pharm. Co.* v. *J. Uriach & CIA, S.A.*, 648 F.3d 588, 594 (8th Cir. 2011) (emphasis added); see *Roth* v. *Garcia Marquez*, 942 F.2d 617, 622 (9th Cir. 1991) (jurisdiction based in part on "future consequences *of the contract* … most of the work for which would have been performed in [the forum]" (emphasis altered)); *Far W. Capital, Inc.* v. *Towne*, 46 F.3d 1071, 1080 (10th Cir. 1995) (contract's future consequences *insufficient* to establish jurisdiction). Respondents' inability to cite any case that examines *future* forum contacts is all the more striking given how often the issue of "minimum contacts" is litigated. See Dustin E. Buehler, *Jurisdictional Incentives*, 20 Geo. Mason L. Rev. 105, 108 & n.16 (2012) (5,767 cases decided in 2007-12).

United Phosphorus, Ltd. v. *Angus Chemical Co.*, an antitrust case in which plaintiffs sought injunctive relief, the district court surveyed all available authority and found none suggesting that "conduct post-dating the filing of [a] complaint" may be relevant to personal jurisdiction. 43 F. Supp. 2d 904, 908-10 (N.D. Ill. 1999). Instead, as the lower court cases hold, only "[c]ontacts leading up to and surrounding the accrual of the cause of action … are considered." 16 Moore's Federal Practice § 108.4 (2016). Here, the cause of action accrued entirely based on Mylan's activities in West Virginia and Maryland.[4]

B. Basing Personal Jurisdiction On Disputed Facts About Future In-Forum Marketing Undermines Congress's Purpose In Making An ANDA Filing An Independent Act of Infringement

Unlike the defendant in *Burger King*, Mylan has done *nothing* of jurisdictional significance in Delaware and has *no* obligation, contractual or otherwise, to do anything there in the future. And there are several reasons to doubt it ever will.

First, there remain several off-ramps in the ANDA process, which may lead Mylan never to market the patented drugs anywhere, much less in Delaware. See GPhA Br. 9-12 (describing alternative

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[4] Further, if the test varied depending on whether plaintiffs request injunctive relief, plaintiffs could easily create personal jurisdiction through "artful pleading," which is "one more good reason to reject [such a rule]." *Merrill Lynch, Pierce, Fenner & Smith Inc.* v. *Manning*, 136 S. Ct. 1562, 1575 (2016).

outcomes). AstraZeneca does not address these off-ramps; Acorda's only answer is to assert that the "possibility [of] post-filing developments … does not alter the minimum-contacts analysis." Acorda Opp. 23. Acorda is right that jurisdiction is generally assessed as of the time of filing, but that is just another reason to *reject* jurisdiction based on future contacts. Acorda's proposed approach of counting "post-filing developments" only when doing so favors its preferred forum has nothing to recommend it.

Second, even if the ANDA is approved, there is no evidence that Mylan will ever make jurisdictionally relevant sales *in Delaware*. Whether it will depends not just on whether Mylan's drugs will be sold in Delaware, but also the distribution channels by which they will reach the State. Thus, even if Mylan anticipated sales of its products in Delaware (and it does not anticipate any direct sales), that still would not be enough to justify personal jurisdiction: "'something more'" is required, "such as special state-related design, advertising, advice, marketing, or [some]thing else." *J. McIntyre Mach., Ltd.* v. *Nicastro*, 564 U.S. 873, 889 (2011) (opinion of Breyer, J.) (quoting *Asahi Metal Industry Co.* v. *Superior Court of Cal., Solano Cty.*, 480 U.S. 102, 111 (1987) (opinion of O'Connor, J.)).

To paper over their inability to show that Mylan will make relevant in-forum sales, respondents invent concessions. Acorda, for instance, twice cites a brief filed by Mylan's *opponent* in a *different* court in a *different* case concerning a *different* drug for the proposition that Mylan does not "'carve out individual states'" from its distribution network.

Acorda Opp. 3, 10. Such grasping underscores the lack of a record about Mylan's plans here. AstraZeneca, like the majority below, suggests that Mylan conceded at oral argument in the Federal Circuit that it would direct sales at Delaware. AZ Opp. 9 (citing Pet. App. 10-11, 15). Respectfully, that is incorrect. What Mylan's counsel actually said—in response to a question about what Mylan might do *if the ANDA is approved*—was that Mylan's generics would be sold in Delaware "*only if* we prevail in this litigation." Case No. 2015-1456, Oral Arg. Tr. 48:32-48:48 (emphasis added). This statement that prevailing is a necessary (not a sufficient) condition for Delaware sales is hardly the concession that AstraZeneca claims. Thus, Judge O'Malley was right when she wrote that "[t]he parties dispute … whether and to what extent Mylan ultimately may … decide to … market generic drugs in Delaware." Pet. App. 19.

These disputes illustrate how unworkable jurisdiction based on speculative future contacts really is. Such an unwieldy rule is particularly inappropriate in ANDA litigation: Congress made filing a paragraph IV certification a "*new* … act of infringement"—one that is complete whether or not future marketing and sales occur—to avoid the ripeness problems that courts would otherwise face in infringement suits for future marketing and sales under 35 U.S.C. 271(a)-(c). *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 676 (1990) (emphasis added); *id.* at 678. But the opinion below reinjects these very difficulties back into ANDA litigation, requiring courts to engage in a cumbersome threshold inquiry that has no relevance to the

merits.[5] Jurisdiction should not turn on such a "fact-intensive morass." Pet. App. 20.

Going forward, each generic manufacturer will have a choice: waive its due process rights or raise a jurisdictional defense that will "eat[] up time and money [to] litigate." *Hertz Corp.* v. *Friend*, 559 U.S. 77, 94 (2010). "Jurisdictional rules should avoid these costs whenever possible." *Nicastro*, 564 U.S. at 885 (opinion of Kennedy J.). To be sure, brand manufacturers, who "have strong motivation to delay resolution of [ANDA] litigation" and the entry of generics into the market, FEDERAL JUDICIAL CENTER, PATENT CASE MANAGEMENT JUDICIAL GUIDE 10-6 (2009), may welcome litigating such time-consuming collateral issues. But that is the opposite of what Congress intended.

AstraZeneca attempts to read Congress's decision to except ANDA litigation from the joinder rules in the America Invents Act ("AIA") as a sign that Congress intended suits against multiple ANDA filers to be litigated in the same district. AZ Opp. 25 (citing 35 U.S.C. 299(a)). But the AIA joinder provision was intended to limit abuses in suits brought by "patent trolls," entities that "do not use patented inventions." Tracie L. Bryant, *The America Invents Act: Slaying Trolls, Limiting Joinder*, 25 Harv. J.L. & Tech. 687, 691 (2012); *id.* at 701-02. Thus, the more plausible reading of the exception is that Congress did not detect in ANDA litigation the

[5] And, because in-forum distribution plans have zero relevance to the merits, there is nothing to the suggestion, see Acorda Opp. 20; App. 9-10, that the ANDA merits inquiry somehow justifies a future-forum-sales-dependent jurisdictional test.

abuses it set out to correct: ANDA plaintiffs are, after all, brand-name pharmaceutical companies, not patent trolls.

Instead, the best evidence that Congress did not intend for nationwide jurisdiction in ANDA cases is that it did not provide for it. Congress *can* make federal-question defendants amenable to suit nationwide, regardless of their contacts with a State. Compare Fed. R. Civ. P. 4(k)(1)(A) with *id.* 4(k)(1)(C); see 16 Moore's Federal Practice § 108.123 (2016) (citing examples of statutes with nationwide service of process). "That Congress failed to do so [in the Hatch-Waxman Act] argues forcefully" that nationwide jurisdiction was not its intention. *Omni Capital Int'l, Ltd.* v. *Rudolf Wolff & Co.*, 484 U.S. 97, 106 (1987). There is no need to mangle due process doctrine to "solve" perceived problems that Congress can dispatch itself.

And Congress *did* consider the "problem" of multiple ANDA filers. Congress expected that "[i]n the event of multiple ANDA's … the Courts should employ the existing rules for multidistrict litigation," H.R. Rep. No. 98-857, pt. 1, at 28 (1984), which courts frequently do in ANDA cases. AstraZeneca (at 24-25) complains that MDL litigation may drag on longer than the Hatch-Waxman Act's 30-month stay, but Congress provided brand manufacturers with a damages remedy precisely to account for the possibility of infringing, post-stay sales. 35 U.S.C. 271(e)(4)(C). In any event, nothing stops brand manufacturers from seeking a preliminary injunction to stop marketing, as patent holders in non-ANDA contexts routinely do.

C. The Opinion Below Constitutes An End Run Around *Daimler*

AstraZeneca does not dispute that the opinion below recreates the pre-*Daimler* status quo, but claims that this reversion is just fine. See AZ Opp. 19-22. Not so. As AstraZeneca describes it, the opinion below holds that *one* event—the ANDA filing—"gives rise to minimum contacts with every State" because it "seeks permission to market [a] product nationwide." AZ Opp. 20. Thus, to recreate the pre-*Daimler* world of jurisdiction everywhere, the opinion below treats an ANDA filing as a contact with "all 50 states and the District of Columbia … simultaneously." *Rush*, 444 U.S. at 330. This reasoning directly conflicts with this Court's holding that no one "contact" can be of such nationwide jurisdictional significance. *Ibid.*[6]

Acorda, by contrast, says the opinion below does *not* "expos[e] ANDA filers 'to specific personal jurisdiction in all fifty states'" because of its "sharp focus" on Mylan's contacts "*with Delaware*." Acorda Opp. 18 (emphasis in original). Obviously, that focus was not sharp enough to prevent AstraZeneca from seeing minimum contacts everywhere; it will not prevent future courts from doing so either. In any event, the Federal Circuit permitted jurisdiction in Delaware because of Mylan's possible future reliance

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[6] AstraZeneca's attempt (at 19–20) to analogize its jurisdiction-everywhere theory of ANDA filings to "ordinary patent infringement suits" or libel suits is unavailing. For specific jurisdiction to exist nationwide in such cases, there must be at least 50 independent sales or publications, *i.e.*, one in each state.

on its supposed nationwide distribution network. Basing jurisdiction on such non-suit-related, nationwide contacts impermissibly recreates the pre-*Daimler* status quo.

II. This Issue Is Profoundly Important To The Nation's Healthcare System, And This Case Is The Appropriate Vehicle To Address It

Acorda attempts to manufacture a vehicle problem, but fails. First, the general jurisdiction question will not resurface. Acorda (at 27-28) suggests that the Delaware Supreme Court's recent decision restricting the scope of that State's business-registration statutes may not apply because it came after this case's filing. But courts do not apply erroneous law to earlier-filed cases. *AT&T Corp.* v. *Hulteen*, 556 U.S. 701, 712 n.5 (2009). In any event, this Court can grant certiorari, reverse the specific-jurisdiction holding below, and remand for the Federal Circuit to address general jurisdiction.

Second, contrary to Acorda's suggestion, almost all the Court's recent personal jurisdiction cases have been reviewed in an "interlocutory posture." Acorda Opp. 28; see, *e.g.*, *Walden* v. *Fiore*, 134 S. Ct. 1115, 1121 (2014); *Daimler AG* v. *Bauman*, 134 S. Ct. 746, 753 (2014); *Goodyear Dunlop Tires Operations, S.A.* v. *Brown*, 564 U.S. 915, 922-23 (2011); *Nicastro*, 564 U.S. 873 (2011) (for procedural history see 987 A.2d 575, 578-80 (N.J. 2010)). If anything, cases on a motion-to-dismiss record are a *better* vehicle for providing guidance to district courts, which grapple with personal jurisdiction early in proceedings. And, because the Federal Circuit's opinion has nationwide

precedential effect, the personal jurisdiction issue presented here is unlikely to be preserved in future cases. Finally, Acorda's suggestion to wait until a judgment is both unnecessary (the courts below presumably will stay proceedings if certiorari is granted) and misses the point of personal jurisdiction doctrine, which is to protect defendants' "liberty interest in not being subject to the binding judgments of a[n improper] forum." *Burger King*, 471 U.S. at 471-72.

As respondents acknowledge, ANDA litigation is high-stakes and high-volume. Acorda Opp. 29; AZ Opp. 23. It is the primary pathway by which new generic pharmaceuticals reach the market, where they save thousands of lives and billions of dollars. See GPhA Br. 5 (describing the "$1.68 trillion in healthcare system savings" in last 10 years enabled by generics). Brand manufacturers should not be able to restrict patients' access to such drugs by filing invalid patents *and* then also get their nationwide choice of forum in which to bring infringement suits, in violation of generics' due process rights. This Court should grant review now.

CONCLUSION

The petition for a writ of certiorari should be granted.[7]

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[7] The petition in *Bristol-Myers Squibb Co.* v. *Superior Court of California, San Francisco County*, No. 16-466, asks the Court to clarify the causal nexus between a claim and the forum contacts required by specific jurisdiction. If the Court grants that

Respectfully submitted.

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petition, it should also grant review in this case to clarify the required temporal nexus (or, at a minimum, hold this case).