15-1456, 15-1460

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.

ASTRAZENECA AB,

Plaintiff-Appellee,

v.

MYLAN PHARMACEUTICALS INC.

Defendant-Appellant.

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

BRIEF FOR THE GENERIC PHARMACEUTICAL ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF MYLAN'S PETITION FOR REHEARING EN BANC

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CERTIFICATE OF INTEREST

Counsel for *amicus curiae* certifies the following:

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

The Generic Pharmaceutical Association.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

None.

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

None.

4. The names of all law firms and the partners or associates that appeared for the party or *amicus* now represented by me in the trial court or agency or are expected to appear in this court are:

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STATEMENT OF IDENTITY, INTEREST OF CASE, AND SOURCE OF AUTHORITY TO FILE OF *AMICUS CURIAE*[1]

The Generic Pharmaceutical Association ("GPhA") is a nonprofit, voluntary association representing nearly 100 manufacturers and distributors of generic pharmaceutical products, manufacturers and distributors of active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. This case concerns where a plaintiff may properly hale a defendant Abbreviated New Drug Application ("ANDA") filer into court under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act" or the "Act"). GPhA's expertise in these matters will aid the Court in understanding the purpose of that legislation and provide necessary perspective on the significant implications of this case for the generic pharmaceutical industry and the United States market for prescription drugs.

SUMMARY OF ARGUMENT

In addition to the arguments made by Mylan's petition, which GPhA joins, GPhA submits that this case presents a question of exceptional importance for the generic drug industry, the public, as well as the emerging jurisprudence on personal jurisdiction. The decision also conflicts with U.S. Supreme Court and

[1] This brief was authored solely by *amicus* and its counsel listed on the cover, and no person other than *amicus* and its members contributed money that was intended to fund preparing or submitting this brief. The Parties have consented to the filing of this brief. *See* Fed. R. App. P. 29(c)(5).

Federal Circuit opinions addressing the scope of personal jurisdiction.

In response to the Supreme Court's dramatic limitation of general jurisdiction in *Daimler*, the Panel's opinion sets forth a new standard for specific jurisdiction based on an ANDA filer's "planned, non-speculative harmful conduct," *i.e.*, potential infringing future sales. Panel Op. at 13. This is mistaken for two reasons. First, the future infringing sales will almost never occur. Because of the 30-month stay provided by the Hatch-Waxman Act, in the vast majority of cases there will be an injunction against sales or a judgment of non-infringement prior to any sales. Second, the Panel was wrong to assume that the filing of an ANDA reliably indicates future marketing, as there are many reasons an ANDA filer may ultimately not market its product.

As a result, the Panel's opinion creates nationwide jurisdiction on mere speculation about an ANDA filer's future acts. Relying on the ANDA filer's presumed nationwide channels of distribution, the Panel's opinion concludes that it must be targeting each state in the country, including Delaware. But this same approach was rejected by the Supreme Court's plurality opinion in *J. McIntyre Machinery, Ltd. v. Nicastro*, 564 U.S. 873 (2011) (plurality opinion). The Panel also relies on the filing of the ANDA to ground jurisdiction, creating a second conflict with this Court's decision in *Zeneca Ltd. v. Mylan Pharms., Inc.*, 173 F.3d 829 (Fed. Cir. 1999). Given these conflicts and importance of the question

presented by this case, Amicus urges the Court to grant the petition for en banc review.

ARGUMENT

A. The Panel's new standard for personal jurisdiction is based on the erroneous premise that an ANDA filing reliably indicates planned future infringing sales, presenting a question of exceptional importance.

The generic drug industry is vitally important to the Nation's healthcare system and its economy. In 2014, 3.8 billion prescriptions were filled in the United States with generic drugs, accounting for 88% of all prescription filled. *See* GPhA Report, Generic Drug Savings in the U.S. at 1 (2015).[2] And over the last 10 years, generic drugs have been responsible for $1.68 trillion in healthcare systems saving, including $76.1 billion in savings for the United States Government's Medicare program in 2014 alone. *Id.* at 1, 5-6.

This case profoundly impacts this vital industry. The Panel's decision, in effect, subjects every ANDA filer to nationwide jurisdiction for Hatch-Waxman Act litigation in violation of generic defendants' due process rights. As a result, an ANDA filer cannot predict where it will be subject to suit.

This result runs counter to the intent of the Hatch-Waxman Act and should give the Court pause. Just two years ago, the Supreme Court decided *Daimler AG*

[2] *Available at*: http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf.

v. Bauman, where it described a similar assertion of nationwide jurisdiction as "unacceptably grasping." 134 S. Ct. 746, 761 (2014). The Court in *Daimler* intended to remove the very unpredictability the Panel's decision now creates. Although *Daimler* addressed general jurisdiction, the Court made crystal clear that a rule subjecting defendants to nationwide jurisdiction based on nationwide sales does not comport with due process because it does not "permit out-of-state defendants to structure their primary conduct with some minimum assurance as to where that conduct will and will not render them liable to suit." *Id.* at 762 (quotation marks omitted) (calling the exercise of jurisdiction in that case "exorbitant" because "the same global reach would presumably be available in every other State in which [defendant's] sales are sizable.").

Not only does the Panel's opinion conflict with Supreme Court precedent, it is contrary to the balance Congress sought to establish in the Hatch-Waxman Act. The Panel's opinion sets forth a new standard for specific jurisdiction based on an ANDA filer's "planned, non-speculative harmful conduct," *i.e.*, infringing future sales, Panel Op. at 13, but this overlooks a key point: The Hatch-Waxman Act's carefully balanced framework, chosen by Congress, ensures that in the vast majority of cases there will <u>never be an infringing sale</u>. When a patent-holder files suit against an ANDA applicant under the Hatch-Waxman Act, the FDA is barred for thirty months from approving the ANDA. *See* 21 U.S.C § 355(j)(5)(B)(iii).

The intent of this 30-month stay is to allow the Court to adjudicate validity and infringement *prior* to the sale of the generic drug product.

Under this framework, the Court may find the patent valid and infringed, in which case the generic company will not sell its generic product until after the relevant patents have expired (or the generic company takes a license). Alternatively, if the Court finds that the ANDA product does not infringe any valid claim, then the future sales will be non-infringing sales. Either way, the statutory scheme ensures that in the typical Hatch-Waxman case, there will never be an infringing sale.

What is more, the Panel is mistaken to assume that the filing of a drug application (ANDA or otherwise)[3] reliably indicates that a drug will be marketed at all. There are many reasons why an ANDA filer may never market a single dose of its drug. First, ANDAs are frequently withdrawn. *See* FDA Statistics (reporting 126 withdrawals through March 2016; 170 withdrawals in FY 2015; 179 withdrawals in FY 2014; 107 withdrawals in FY 2013).[4] Second, the FDA may not approve the ANDA as a result of various deficiencies. Third, the FDA will not

[3] These examples apply equally to ANDAs as well as other forms of drug applications, such as new drug applications under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act.

[4] www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm375079.htm (previous years are available through links at the bottom of the page).

approve an ANDA if the reference branded drug is removed from the market for safety or efficacy reasons. *See* 21 U.S.C. § 355(j)(6). The FDA blocked all ANDAs seeking to sell the original version of oxycodone (OxyContin®) in favor of a new patented abuse-resistant version,[5] for one example among many. [6] Fourth, the ANDA filer may decide not to market the drug for business reasons. Or the ANDA filer may not market a drug for numerous other reasons, such as a decision to sell or transfer its right to market the drug, or as a result of a settlement. Given these realities, it was error for the Panel to equate the filing of an ANDA with the intent to make sales, let alone, infringing sales in every state.

The Panel's decision also contravenes Congress's intended approach to multi-defendant cases: The Panel opinion states that "upholding personal jurisdiction will serve the interests of the plaintiffs and the judicial system in

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[5] *See* www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm348252.htm ("Agency will not approve generics to original OxyContin."); FDA Determination That the OXYCONTIN (Oxycodone Hydrochloride) Drug Products Covered by New Drug Application 20-553 Were Withdrawn From Sale for Reasons of Safety or Effectiveness, 78 Fed. Reg. 23,273 (Apr. 18, 2013); www.wsj.com/articles/SB10001424127887324345804578422691805851784; www.fiercepharma.com/regulatory/fda-halts-generic-oxycontin-handing-purdue-a-victory.

[6] The following are additional examples where a branded drug has been removed from the market for safety and efficacy, preventing the approval of ANDAs for that drug. *See, e.g.*, Ondansetron (Ondansetron Hydrochloride) Injection, 80 Fed. Reg. 32,962 (June 10, 2015); Chloromycetin® (Chloramphenicol), 77 Fed. Reg. 41,412 (July 13, 2012) Halflytely® and Bisacodyl Tablets Bowel Prep Kit, 76 Fed. Reg. 51,037 (Aug. 17, 2011) & 75 Fed. Reg. 13,292 (Mar. 19, 2010); Albamycin® (Novobiocin Sodium), 76 Fed. Reg. 3,143 (Jan. 19, 2011); Brevibloc® (Esmolol Hydrochloride) Injection, 75 Fed. Reg. 24,710 (May 5, 2010); Cernevit®-12 (Multivitamins for Infusion), 75 Fed. Reg. 12,760 (Mar. 17, 2010).

efficient resolution of litigation, because multiple lawsuits against other generic manufacturers on the same patents are pending in Delaware." Panel Op. at 16. Whatever the merits of this proposition, it is not what Congress intended. As Congress explained, "[i]n the event of multiple ANDA's certifying patent invalidity or non-infringement, the courts should employ the existing rules for multidistrict litigation." H.R. Rep. 98-857(I), at 28 (1984) (emphasis added).

This Court has recognized that the Hatch-Waxman Act was intended by Congress to "balance the need for pharmaceutical innovation with the need for generic drug competition," *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1294 (Fed. Cir. 2008). The Panel's decision upsets this careful balance, vitally important to the generic drug industry and to the public. This case, and the legal question it presents, is of exceptional importance and the Court should grant the petition for rehearing en banc.

B. The Panel's opinion conflicts with the Supreme Court's plurality opinions in *Nicastro* and *Asahi*.

The Panel Opinion relies on Mylan's presumed distribution channels as the foundation for its assumption that Mylan has targeted the State of Delaware for future wrongful sales. *See* Panel Op. at 14 ("Mylan's ANDA filings and its distribution channels establish that Mylan plans to market its proposed drugs in Delaware."). This is wrong and reflects a fundamental misunderstanding of the generic business model. Generic companies, as a general rule, do not actively

market their drugs to customers or physicians—unlike branded companies, who advertise and deploy marketing representatives to give free samples to doctors. Instead, generic companies contract with wholesalers and retail chains to distribute their product, and thus, they are not involved in marketing to a particular state, such as Delaware. *See* Mylan Pet. at 7-10.

A plurality of the Supreme Court has explained that this is insufficient to ground specific personal jurisdiction. In *J. McIntyre Mach., Ltd. v. Nicastro,* the Supreme Court reviewed a decision of the Supreme Court of New Jersey, which, like the Panel here, had held that "courts can exercise jurisdiction over a foreign manufacturer of a product so long as the manufacturer 'knows or reasonably should know that its products are distributed through a nationwide distribution system that might lead to those products being sold in any of the fifty states.'" 564 U.S. 873, 877 (2011) (plurality). Reversing, the Plurality noted that despite "nationwide distribution" and nationwide "marketing and sales efforts," "at no time had [the defendant] advertised in, sent goods to, or in any relevant sense targeted the State." *Id.* at 877, 885. The Panel's reasoning in this case cannot be reconciled with the *Nicastro* plurality opinion.

Justice Kennedy's plurality opinion in *Nicastro* pointedly explains why the nationwide jurisdictional approach, adopted by the Panel, is fundamentally unsound: "The owner of a small Florida farm might sell crops to a large nearby

distributor, for example, who might then distribute them to grocers across the country. If foreseeability were the controlling criterion, the farmer could be sued in Alaska or any number of other States' courts without ever leaving town." *Id*.

This Court has repeatedly declined to decide whether to follow the plurality opinion from *Nicastro* (and from the Supreme Court's earlier stream-of-commerce case, *Asahi*),[7] because previous cases would have come out the same way under either the plurality test or the dissenting justices' tests.[8] However, because the Panel's decision conflicts with the *Nicastro/Asahi* plurality opinions, the question of whether this Court should follow the plurality opinion is now squarely before the Court. En banc review is needed to resolve this long-standing dispute.

C. The Panel's decision conflicts with this Court's previous decision in *Zeneca Ltd. v. Mylan Pharmaceuticals*.

In *Zeneca Ltd. v. Mylan Pharms., Inc.*, 173 F.3d 829, 834 (Fed. Cir. 1999), this Court illuminated the constitutional flaws of conferring specific jurisdiction based on an ANDA filer's petition to the government. The Panel's opinion dismisses *Zeneca* because "neither of the two single-judge opinions . . . addresses whether the location of the ANDA filer's future sales could support specific personal jurisdiction over the filer." Panel Op. at 14. But both Judge Gajarsa and Judge Rader agreed that filing an ANDA could not count as the sole jurisdictional

[7] *See Asahi Metal Indus. Co. v. Superior Court of California, Solano Cty.*, 480 U.S. 102, 112 (1987) (plurality opinion).
[8] *See, e.g., AFTG-TG v. Nuvoton Tech.*, 689 F.3d 1358, 1365 (Fed. Cir. 2012).

contact. *Zeneca*, 173 F.3d at 831 (Gajarsa, J.) ("[P]etitioning the national government does not 'count' as a jurisdictional contact in the personal jurisdiction analysis."); *id* at 836 (Rader, J.) ("[T]he mere filing of an ANDA does not at that point even cause a tangible injury to the patent holder.").

The Panel's opinion directly conflicts with this holding. Ignoring *Zeneca*, the Panel holds that "the minimum contacts standard is satisfied by the particular actions Mylan has already taken—**its ANDA filings**—for the purpose of engaging in that injury-causing and allegedly wrongful marketing conduct in Delaware. Panel Op. at 8-9 (emphasis added)." This reasoning attempts to do in two steps what *Zeneca* says cannot be done in one: ground personal jurisdiction on the filing of an ANDA. As Judge Gajarsa explained, "treating the Petition as the sole jurisdictional contact . . . poses serious constitutional issues because it allows Congress to burden unnecessarily, and possibly impermissibly, a First Amendment right." *Zeneca*, 173 F.3d at 832. Indeed, the "purpose of the Hatch–Waxman Act was not to transform FDA filings into torts because such petitions are in and of themselves undesirable acts that society wishes to avoid." *Id.* The Panel's opinion conflicts with these sound principles.

CONCLUSION

For the reasons set forth above, this Court should grant Mylan's petition for rehearing en banc.

May 2, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 2, 2016, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

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