No. 2015-1460

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

ASTRAZENECA AB,

Plaintiff-Appellee,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant-Appellant.

On Appeal from the United States District Court
for the District of Delaware, Nos. 1:14-cv-00664, -696, Judge Gregory M. Sleet.

BRIEF OF *AMICUS CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA) IN SUPPORT OF APPELLEE ASTRAZENECA AB

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July 23, 2015

CERTIFICATE OF INTEREST

Counsel for *amicus curiae* Pharmaceutical Research and Manufacturers of America ("PhRMA") certify the following:

1. The full name of every party or amicus represented in this appeal is:

Pharmaceutical Research and Manufacturers of America ("PhRMA")

2. The names of the real parties in interest represented in this appeal are:

Not applicable.

3. The names of all parent corporations and any publicly held companies that own 10 percent of the party represented are:

Pharmaceutical Research and Manufacturers of America has no parent corporation and no publicly traded company owns 10% of more of its stock. However, its membership includes companies that have issued stock or debt securities to the public. A list of PhRMA's members is available at http://www.phrma.org/about/member-companies.

4. The names of all law firms and the partners and associates that are expected to appear in this appeal for Amicus Curiae PhRMA are:

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July 23, 2015

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INTEREST OF AMICUS CURIAE

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association representing leading research-based pharmaceutical and biotechnology companies.[1] PhRMA's members are the primary source of the many new drugs and biologics introduced each year. These new medicines have played a key role in extending longevity and improving the quality of human life.

Developing new medicines takes years of work and significant investment. In 2014 alone, PhRMA members committed $51 billion to such research and development. *See* PhRMA, *2015 Biopharmaceutical Research Industry Profile* 35 (2014).[2] PhRMA members make these investments in reliance on a legal system that protects any resulting intellectual property. A core component of this legal regime is the ability of PhRMA members to bring patent infringement suits in a forum of their choosing before launch of drugs marketed by generic companies.

PhRMA has a substantial interest in this case because its members regularly bring infringement suits under 35 U.S.C. § 271(e)(2) to protect their intellectual

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[1] Pursuant to Federal Rule of Appellate Procedure 29(c)(5), amicus affirms that no counsel for a party authored this brief in whole or part and no person other than amici or their counsel made a monetary contribution to fund its preparation or submission. Defendant AstraZeneca is a member of PhRMA. A complete list of PhRMA members is available at http://www.phrma.org/about/member-companies. All parties have consented to the filing of this brief.

[2] Available at http://www.phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf.

property rights and need clarity on where such suits can be filed in the wake of *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014). PhRMA's members believe that the structure and purpose of the Hatch-Waxman Act, which created § 271(e)(2), strongly supports considering an alleged infringer's future conduct when determining whether a court has specific personal jurisdiction over a generic manufacturer.

INTRODUCTION AND SUMMARY OF ARGUMENT

Congress enacted the Hatch-Waxman Act (formally known as the Drug Price Competition and Patent Term Restoration Act of 1984) as a compromise between the interests of generic and brand-name drug manufacturers that was meant to protect innovation and lower the cost of pharmaceuticals. Among other things, the Act created an expedited approval process for generic drugs, permitting their manufacturers to submit an Abbreviated New Drug Application ("ANDA") that may rely on the fact that the reference listed drug—i.e., the drug that the ANDA applicant seeks to copy—was found safe and effective by FDA.

The law has been credited with creating the modern generic drug industry and has been a boon to its members. In 2009, for example, generic manufacturers sold an estimated $66 billion of drugs in the United States. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2584 (2011) (Sotomayor, J., dissenting). And domestic consumer spending on generic drugs is rising. *See* IMS Institute for Healthcare

Informatics, *The Global Use of Medicines: Outlook Through 2017* at 24 (2013) (noting that 34% of the money spent on brand-name drugs in 2012—$83 billion—"will shift to generics" by 2017).[3] These nationwide sales have been aided by state laws that mandate substitution of generic products when they are available. Currently, every state has some form of generic substitution law. *PLIVA*, 131 S. Ct. at 2583 (Sotomayor, J., dissenting) (citing Christensen, et al., *Drug Product Selection: Legal Issues*, 41 J. Am. Pharmaceutical Ass'n 868, 869 (2001)). As a result, generic drugs are sold in every corner of the country where their branded counterparts are (or previously had been) sold. Indeed, according to the Generic Pharmaceutical Association, in 2013, 86% of all prescriptions nationwide were filled by generics. *Generic Pharmaceutical Association Annual Report* 16 (2014).[4]

There is no question that the Hatch-Waxman Act has enabled this tremendous, nationwide growth of the generic drug industry. Yet, while Congress enacted Hatch-Waxman intending that generic drugs would be "marketed more cheaply and quickly," Congress simultaneously maintained incentives for innovation by, for example, "guard[ing] against infringement of patents relating to pioneer drugs." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676, 677 (1990).

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[3] Available at http://www.imshealth.com/deployedfiles/imshealth/Global/Content/Corporate/IMS%20Health%20Institute/Reports/Global_Use_of_Meds_Outlook_2017/IIHI_Global_Use_of_Meds_Report_2013.pdf

[4] Available at http://www.gphaonline.org/media/wysiwyg/PDF/GPhA2014AnnualReport.pdf.

A key component of this balancing act was Congress's creation of a unique patent litigation process under 35 U.S.C. § 271(e)(2), which created an act of infringement based on the submission of an ANDA "for a drug claimed in a patent or the use of which is claimed in a patent." 35 U.S.C. § 271(e)(2)(A).

This new, "highly artificial" act of infringement, *see Eli Lilly*, 496 U.S. at 678, allows for patent disputes to be resolved before drug approval. Nothing in the artificial nature of the cause of action, however, requires the district court to ignore the reality of what will happen with the accused generic product upon approval—that is, that it will be sold in the same fora in the same manner as the pioneer drug it copies and seeks to replace. To the contrary, this Court has held that the infringement analysis under § 271(e)(2) is necessarily prospective in nature. *E.g.*, *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997).

This Court "applies a three prong test to determine if specific jurisdiction exists," asking whether (1) "the defendant purposefully directed activities" at the forum, (2) the litigation "arises out of or relates to those activities" and (3) personal jurisdiction would be "reasonable and fair." *Nuance Commc'ns, Inc v. Abbyy Software House*, 626 F.3d 1222, 1231 (Fed. Cir. 2010); *Walden v. Fiore*, S. Ct. 1115, 1121-1122 (2014) (clarifying that the first requirement looks to "the defendant's contacts with the forum State itself"); *see also Synthes (U.S.A.) v. G.M. Dos Reis Jr. Ind. Com. De Equip. Medico*, 563 F.3d 1285, 1297 (Fed. Cir.

2009) (emphasizing that "a substantial connection with a forum arising out of a single act can support jurisdiction" (citation and internal quotation marks omitted)). Consistent with the § 271(e)(2) precedent discussed above, every court to consider the issue has held that a generic manufacturer's expected contacts with the forum may satisfy the minimum contacts requirement for specific jurisdiction and has ultimately concluded that it had jurisdiction over the manufacturer. *See* JA12-17; *Allergan, Inc. v. Actavis, Inc.*, No. 14-cv-638, 2014 WL 7336692, at *5-8 (E.D. Tex. Dec. 23, 2014);[5] *Acorda Therapeutics, Inc. v. Mylan Pharms., Inc.*, No. 14-cv-935, 2015 WL 186833, at *15-19 (D. Del. Jan. 14, 2015); *Eli Lilly & Co. v. Mylan Pharms., Inc.*, No. 14-cv-389, 2015 WL 1125032, at *5-8 (S.D. Ind. Mar. 12, 2015).

These decisions make good sense. In a traditional patent infringement case, an accused infringer is subject to suit wherever its accused products are sold or directed for sale. Here, by submitting an ANDA application, Mylan has declared its intent to sell generic drug products nationwide. The only difference is that no product has yet been sold. But that is by congressional design—the Hatch-Waxman Act deliberately created an infringement regime in § 271(e)(2) under which lawsuits could be brought to determine whether the product sought to be

[5] *Allergan* was a declaratory judgment action, but its analysis of the issue is applicable in the context of a typical § 271(e)(2) infringement suit.

sold *will* infringe, sometimes years before any generic drug approval (and thus before any possible infringing sale).

Preventing *future* infringing sales is an important part of bringing a claim under § 271(e)(2). Congress specifically identified enjoining future sales as among the limited remedies for infringement under the statute. *See* 35 U.S.C. § 271(e)(4)(B). Accordingly, there can be no question that those future sales "relate to" the cause of action and can be considered in the context of determining specific jurisdiction.

In short, the Hatch-Waxman Act's structure and purpose strongly favor finding specific jurisdiction in cases such as this one, where the defendant has made clear that it intends to engage in substantial, infringing conduct in the forum state as evidenced by the fact it sent its notice of its ANDA filing (which is an integrally related part of the ANDA filing itself) into Delaware and the high likelihood of future sales of its infringing product in the state (through generic substitution of the branded product). Indeed, numerous courts, including the Supreme Court and this Court, have in other contexts considered future conduct when determining whether personal jurisdiction exists. Understandably, defendants like Mylan Pharmaceuticals would prefer to have this court hold that they can be sued only in their home forum. *See* Mylan Br. 6 n.2, 34 n.11, 40. But a single litigant cannot be allowed to upset a carefully crafted congressional

compromise—and distort a jurisdictional doctrine in the process—based purely on its own convenience. As the district court correctly explained, "the Hatch-Waxman Act was not intended to burden patent holders or reduce the patent protection afforded in ANDA cases." JA17. Defendant's rule would impermissibly do both and thus must be rejected.

ARGUMENT

I. THE ARTIFICIAL NATURE OF THE PATENT INFRINGEMENT CLAIM CREATED BY THE HATCH-WAXMAN ACT STRONGLY INDICATES THAT COURTS SHOULD CONSIDER FUTURE CONDUCT WHEN DETERMINING WHETHER THEY HAVE SPECIFIC JURISDICTION

A. The Hatch-Waxman Act Carefully Balances The Interests Of Generic And Brand Name Manufacturers And Was Not Intended To Reduce Patent Protection In ANDA Cases

The "artificial" act of infringement codified in 35 U.S.C. § 271(e)(2)—like the rest of the Hatch-Waxman Act—reflects Congress's attempt to strike a balance between the interests of generic and brand-name drug manufacturers. On the one hand, it "balances the rights of a patent owner to prevent others from making, using, or selling its patented product." *See* H.R. Rep. No. 98-857, pt. 1, at 28 (1984). On the other, it enables "third parties to contest the validity of a patent or to market a product which they believe is not claimed by a patent." *Id*.

A key component of § 271(e)(2) is that it allows for such challenges *before* any allegedly infringing generic product has been sold. That is, it focuses on a "hypothetical" product because the allegedly infringing product has not yet been

approved for sale. *Warner-Lambert Co. v. Apotex Corp*., 316 F.3d 1348, 1365-1366 (Fed. Cir. 2003); *see also Sanofi-Aventis v. Apotex Inc.*, 659 F.3d 1171, 1180 (Fed. Cir. 2011) ("§ 271(e)(2) is a hypothetical case that asks the factfinder to determine whether the drug that will be sold upon approval of the ANDA will infringe the asserted patent." (internal citation omitted)).

This ability to look forward and resolve patent disputes during the FDA's review process provides benefits to both generic and innovator companies. For the generic, it provides a mechanism to make an early challenge to a patent at a time when it would not otherwise have standing. For the innovator, it provides the crucially important ability to enforce its patent rights before generic entry into the marketplace. *See* Grabowski, et al., *Recent Trends in Brand-Name and Generic Drug Competition*, 2013 J. of Med. Econ. 1, 1 (finding that after a generic drug entered the market, the brand-name drug lost between 11% and 16% of sales);[6] IMS Institute for Healthcare Informatics, *The Use of Medicines In The United States: Review of 2010* at 21 (2011) (noting that in 2010, "[g]enerics capture[d] over 80% of a brand's volume within 6 months" after the patent for the brand-name drug expired).

Nothing in the text or legislative history of the Hatch-Waxman Act suggests that the "artificial" nature of the claim under § 271(e)(2) reflects an intent by

[6] Available at http://fds.duke.edu/db/attachment/2575.

Congress to limit patent rights in ANDA cases or to disadvantage pharmaceutical companies as compared to their patent-owning peers in other industries. To the contrary, as this Court made clear in *Warner-Lambert*, a claim under § 271(e)(2) should be treated "just the same as it is in other infringement suits, including those in a non-ANDA context." 316 F.3d at 1365. "In the ordinary patent infringement suit, the claim asserted by the patentee plaintiff is that some act of making, using, offering to sell, selling, or importing products or services by the defendant constitutes an infringement of the presumptively valid patent named in suit." *Avocent Huntsville Corp. v. Aten Int'l Co*., 552 F.3d 1324, 1332 (Fed. Cir. 2008). For purposes of specific jurisdiction, "[i]n such litigation, the claim both 'arises out of' and 'relates to' the defendant's alleged manufacturing, using, or selling of the claimed invention." *Id.* The same should be true in ANDA cases under *Warner-Lambert*. "[T]he only difference being that the … proper inquiry under § 271(e)(2)(A) is 'whether, if a particular drug ***were*** put on the market, it ***would*** infringe the relevant patent.'" *Warner-Lambert*, 316 F.3d at 1365-1366 (quoting *Bristol-Myers Squibb Co. v. Royce Labs., Inc.*, 69 F.3d 1130, 1135 (Fed. Cir. 1995).

B. The Structure And Purpose Of The Hatch-Waxman Act Make Clear That A Claim Under § 271(e)(2) Can "Arise Out Of Or Relate To" Likely Future Conduct

The statutory scheme created by the Hatch Waxman-Act clearly requires courts to engage in a forward-looking inquiry when determining whether specific jurisdiction exists for a § 271(e)(2) suit and does not limit the available districts to a defendant's home forum. *See Department of Revenue of Oregon v. ACF Indus., Inc.*, 510 U.S. 332, 343 (1994) ("A provision that may seem ambiguous in isolation is often clarified by the remainder of the statutory scheme.…" (citation omitted)); *Nuance*, 626 F.3d at 1231 (specific jurisdiction determined by, *inter alia*, looking to whether the substantive claim "arises out of or relates to" the defendant's conduct that has been "directed" at the forum state); *Avocent*, 552 F.3d at 1332 (noting that whether there is specific jurisdiction in a patent infringement suit normally is "easily discerned from the nature and extent of the commercialization of the accused products or services … in the forum").

First, the structure of § 271(e) supports a forward-looking inquiry for purposes of specific jurisdiction. Section 271(e)(1) precludes courts from considering an accused infringer's conduct ***prior*** to submitting an ANDA—such as testing the new drug—to be an act of infringement. *See* 35 U.S.C. § 271(e)(1); *Eli Lilly*, 2015 WL 1125032, at *6 n.8 ("The Hatch-Waxman Act changed the patent laws to exempt generic drug development activity as a basis for infringement

claims. It does not make sense, therefore, to treat such activity as an injury in order to base a finding of specific jurisdiction in ANDA cases."); JA16 n.13 (similar). And the mere act of ***preparing or sending*** a document to the federal government and the patent holders named within does not constitute an infringement in the way that word is used in 35 U.S.C. § 271(a). *See Glaxo*, 110 F.3d at 1569 ("The occurrence of the defined 'act of infringement' does not determine the ultimate question whether what will be sold will infringe any relevant patent."); *see also Eli Lilly*, 2015 WL 1125032, at *6 n.8 ("Nor do we believe that the forum in which the ANDA application is prepared is a particularly relevant or even important fact, since it is the act of filing the ANDA and sending the Paragraph IV notice … that creates harm ….").

This Court has accordingly explained that it is left only with the option of considering future, hypothetical conduct: "The relevant inquiry is whether … the alleged infringer *will likely market* an infringing product. What is *likely to be sold*, or, preferably, what *will be sold*, will ultimately determine whether infringement exists." *Glaxo*, 110 F.3d at 1570 (emphases added); *see also Warner-Lambert Co.*, 316 F.3d at 1365-1366 (under § 271(e)(2), "the substantive determination whether actual infringement or inducement will take place is determined by traditional patent infringement analysis … the only difference being that the inquiries now are hypothetical because the allegedly infringing product has not yet been marketed").

Indeed, as noted above, Congress specified prospective relief as one of the handful of remedies available for infringement under the subsection. *See* 35 U.S.C. § 271(e)(4)(A) ("For an act of infringement . . . the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed.").

In other words, in a Hatch-Waxman patent infringement case, a plaintiff's claim necessarily "arises out of or relates to" the defendant's planned future activities that post-date the submission of the ANDA. Accordingly, the specific jurisdiction inquiry must be forward-looking and should include consideration of likely future sales in the forum state (e.g., by looking at the unit sales of the branded product the defendant seeks to substitute with its generic product) as well as other acts indicating future plans such as sending notice of an ANDA filing (an integrally related part of the ANDA filing itself, *see infra* pp. 14-15) into the forum state. *See Glaxo Group Ltd. v. Apotex, Inc.*, 130 F. Supp. 2d 1006, 1008-1009 (N.D. Ill. 2001) (recognizing that filing an ANDA with a paragraph IV certification "means that [the ANDA filer] is ready or has at least made meaningful preparations … to market the allegedly infringing product").[7]

[7] Notably, Mylan has never denied that its products will be sold in Delaware. Mylan Br. 43-44. Mylan does not contest AstraZeneca's allegation that Mylan "derives substantial revenue from the sale of its products in Delaware," JA6, and

The plain text of § 271(e)(2) supports this forward-looking approach. It focuses on when a potential infringer "***submit[s]***"—i.e., sends off—its ANDA application. Section 271(e)(2)'s carefully crafted language makes no reference to, for example, the testing that led to the creation of a drug or even the preparation of an ANDA. Instead, the dispositive moment is when the putative infringer announces its future intentions. *See supra* pp. 11-12. This strongly suggests that courts should look to a defendant's likely future conduct after submitting the ANDA when assessing whether its act of infringement has a substantial connection to the forum sufficient for it to establish specific jurisdiction.

Despite Mylan's protestations (at 32-36), *Zeneca Ltd. v. Mylan Pharmaceuticals, Inc.*, 173 F.3d 829 (Fed. Cir. 1999), is not to the contrary. *Zeneca* was issued by a hopelessly fractured panel whose only clear holding was that the district of Maryland (the forum in which the federal agency that receives ANDAs is located) does not have specific jurisdiction over a putative § 271(e)(2) infringer. The deciding vote was based on the rule that "petitioning the national government does not 'count' as a jurisdictional contact," and relied heavily on the rationale that to rule otherwise would have created a "national judicial forum" or

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concedes that it sells its products through distributors in Delaware, Mylan Br. 5 n.1. Accordingly, there is a high likelihood—in fact, a near certainty—that Mylan's product described in the ANDA will be sold in Delaware if the federal government approves the drug.

"supercourt" for ANDA suits in Maryland. *See id.* at 831 (opinion of Gajarsa, J.); *Eli Lilly & Co.*, 2015 WL 1125032, at *6 (explaining that *Zeneca* Court's holding was merely intended "to avoid the Maryland district court having jurisdiction in all ANDA cases").

If anything, *Zeneca* favors finding specific jurisdiction in this case. The judge casting the deciding vote emphasized that a potential infringer "purposefully commit[s] a federal tort" in the forum where an ANDA form is received. *Zeneca*, 173 F.3d at 833-834 (Gajarsa, J.). In other words, an ANDA filing "is a real act" with jurisdictional "consequences" under "traditional [specific] personal jurisdiction analysis." *Id.* And sending notice of the ANDA filing to the patent holder is an integrally related part of that "real act." *Janssen Pharmaceutical, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1356 (Fed. Cir. 2008) ("[T]he filing of a Paragraph IV Certification is an act of patent infringement … [and] the ANDA filer must provide notice to the patentee…."); 21 U.S.C. § 355(j)(2)(B). As Mylan concedes (at 31 & n.8), the notice letter plays the crucial role of starting the 45-day period during which the patent holder must file a lawsuit to block regulatory approval of a generic drug.[8] Accordingly, sending the notification of an ANDA filing into a

[8] Mylan quibbles (at 31 n.8) over whether AstraZeneca learned of the ANDA filing due to the copy of the notice letter mailed to its subsidiary in Delaware or via the copy mailed to its headquarters in Sweden. This is of course a case-specific concern that would not necessarily apply in the mine-run of § 271(e)(2) cases. Moreover, given the near-instantaneous speed at which information can be

forum (here, Delaware) inflicts harm on that district that must be considered in the specific personal jurisdiction analysis.

Second, failing to apply a forward-looking jurisdictional analysis in this case would clash with congressional intent by steering suits to the forum where the defendant is located. Section 271(e)(2) contains no such requirement, even though the statutory scheme clearly shows that Congress "knew how to [require a particular forum] when it chose to do so." *See Central Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 176-177 (1994). The Hatch-Waxman Act expressly adopts Mylan's proposed rule in the context of declaratory actions filed by generic manufacturers after the 45-day window for the patent-holder to bring suit has concluded—such suits ***must*** be filed "in the jurisdiction where the Defendant has its principal place of business or a regular and established place of business." 21 U.S.C. § 355(c)(3)(D)(i)(II).

Various other provisions of the U.S. Code likewise mandate that a particular court hear a particular type of litigation. In the patent context, for example, a "party to an inter partes review … who is dissatisfied with the final written decision of the Patent Trial and Appeal Board … may appeal the Board's decision *only* to the United States Court of Appeals for the Federal Circuit." 35 U.S.C.

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transmitted, receipt of the notice letter in Delaware was surely quickly communicated to AstraZeneca's Sweden office.

§ 141(c) (emphasis added); *see also, e.g.*, *Synopsys, Inc. v. Lee*, No. 14-cv-674, 2014 WL 5092291, at *6 (E.D. Va. 2014) (holding that the "plain language" of § 141(c) precludes a litigant from filing an Administrative Procedure Act challenge in any federal district court). Similarly, Congress has made clear that "proceedings to condemn real estate for the use of the United States or its departments … shall be brought in the district court of the district where the land is located," 28 U.S.C. § 1403, that a surety corporation offering surety bonds may be sued in "the judicial district in which the surety bond was provided" or "the district in which the principal office of the corporation is located," 31 U.S.C. § 9307(a)(1), and that the Attorney General must file orders for enforcement of civil investigative demands in "any judicial district in which such person resides, is found, or transacts business," *id.* § 3733(j)(1); *see also, e.g.*, 28 U.S.C. § 1402(a)-(d); 49 U.S.C. § 44309(b)(1).

Section 271(e)(2) does not restrict the location of suits in this manner, and respecting congressional intent not to require a particular forum for ANDA litigation is particularly important in light of the careful balance that the Hatch-Waxman Act strikes between the interests of generic and brand-name drug manufacturers. *See supra* pp. 7-8. Mylan's proposed rule would impermissibly tip that balance in favor of generic manufacturers by mandating that patent holders

either file suit in the putative infringer's home district or do nothing and risk having an infringing drug go on sale nationwide.

Third, Mylan's rule would lead to impermissibly "absurd results" in § 271(e)(2) suits. *See Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 575 (1982). If district courts are effectively required to find that jurisdiction to hear an ANDA suit exists only in the defendant's home forum, patent holders will be forced to litigate § 271(e)(2) infringement suits in a number of different districts spread out across the country rather than concentrating their litigation in a single forum. *See, e.g.*, *Eli Lilly*, 2015 WL 1125032, at *7 (noting that plaintiffs "initially filed suit against approximately forty generic drug companies that reside in a variety of locations").[9] This would unfairly create a tremendous strain on both the patent holder's and the judiciary's resources and give accused infringers a greater chance of invalidating the patent due to differing claim construction standards

[9] To take just one example, in the ongoing § 271(e)(2) litigation in *In re Certain Consolidated Zoledronic Acid Cases*, No. 12-cv-03967 (D.N.J), plaintiff Novartis Pharmaceuticals brought suit in the District of New Jersey (its principal place of business) against well over a dozen generic manufacturer defendants based in states ranging from Florida to Illinois to Maryland. Under Mylan's rule, the District of New Jersey would not have specific jurisdiction over these defendants, and Novartis could potentially have been forced to file suit in almost half-a-dozen states.

across districts. *Cf.* Doane & Buckler, *How Joinder Impacts Choice of Patent Litigation Forum*, Law360 (Jan. 17, 2014).[10]

Indeed, Congress has recently reaffirmed that it does not intend for patent holders with § 271(e)(2) claims to be required to litigate the same claim in a number of districts. The America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284 (2011), makes the joinder of defendants in patent litigation suits significantly more difficult ***except*** for suits under § 271(e)(2). *See* 35 U.S.C. § 299(a) (specifically exempting § 271(e)(2) from new joinder rules); *see also Norman IP Holdings, LLC v. Lexmark Int'l, Inc.*, No. 11-cv-495, 2012 WL 3307942, at *2 (E.D. Tex. Aug. 10, 2012) (noting that "AIA codified a new test for joinder in patent infringement cases"); Taylor, *Patent Misjoinder*, 88 N.Y.U. L. Rev. 652, 655 n.8 (2013) (§ 299 "constructs a substantial barrier for plaintiffs" that "unmistakably narrows the grounds for permissive joinder"). The result is that all patent holders except those bringing suit under § 271(e)(2) are faced with "the prospect of litigating the same factual and legal questions numerous times." Taylor, *Patent Misjoinder*, 88 N.Y.U. L. Rev. at 655. Given Congress's decision to exempt § 271(e)(2) suits—and only § 271(e)(2) suits—from this significant change in the law (and thus preserve the delicate balance between generic and

[10] http://www.law360.com/articles/495565/how-joinder-impacts-choice-of-patent-litigation-forum.

brand-name manufacturers), this Court should be particularly careful to avoid upsetting the balance by construing the Act to effectively require the absurd result of patent holders having to file suit in dozens of districts to protect their intellectual property.

II. NUMEROUS COURTS HAVE, IN OTHER CONTEXTS, CONSIDERED FUTURE CONDUCT AS PART OF THE JURISDICTIONAL ANALYSIS

Finding specific jurisdiction over Mylan in this case is in line with the well-established practice of considering a party's likely future acts in determining specific jurisdiction. The Supreme Court itself has instructed courts to use a "highly realistic" approach in evaluating specific jurisdiction that takes into account the "contemplated future consequences" of a party's commitments. *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 479 (1985). These future consequences have been held to be sufficient to create personal jurisdiction even where the defendant has minimal other contact with the forum state. *See, e.g.*, *Roth v. Garcia Marquez*, 942 F.2d 617, 622 (9th Cir. 1991) (finding that the "future consequences" of defendant's commitments compelled a finding of personal jurisdiction despite only "marginal[]" past interactions with the forum); *K-V Pharm. Co. v. J. Uriach & CIA, S.A.*, 648 F.3d 588, 594 (8th Cir. 2011) (finding personal jurisdiction in part because, even though a contract was terminated before completion, both its "terms and the future consequences that the parties contemplated in fashioning them support personal jurisdiction").

While the Supreme Court's decision in *Burger King* was in the context of a contract claim, courts have looked to the intended effects of a defendant's actions for torts like patent infringement as well. *See NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1316 (Fed. Cir. 2005) (describing patent infringement as a "tort"). Indeed, it is often *easier* to show specific jurisdiction for a tort claim than for a contract claim. *Roth*, 942 F.2d at 621 ("[I]n a tort case … [there can be] jurisdiction over a defendant whose only 'contact' with the forum state is the purposeful direction of a *foreign* act having an *effect* in the forum state. In the contract context, however, … the existence of a contract with a resident of the forum state is insufficient by itself to create personal jurisdiction…." (citations omitted)).

To take just one example, in *Calder v. Jones*, 465 U.S. 783 (1984), the Supreme Court found specific jurisdiction because defendants "expressly aimed" their "intentional, and allegedly tortious" actions at the forum state. *Id*. at 789. There, the defendants published a libelous article about the plaintiff (an actress in California) in the National Enquirer, which has a large circulation in California. The Court reasoned that jurisdiction over defendants in California was proper because of the "effects" on the plaintiff's emotional state and professional reputation the story would have in California. *Id*. at 789. It was reasonable for defendants to be hauled into court in California because "the brunt of th[e] injury

would be felt by [the plaintiff] in the State in which she lives and works and in which the National Enquirer has its largest circulation." *Id*. at 789-790. The Court recently reaffirmed its *Calder* analysis in *Walden v. Fiore*, 134 S. Ct. 1115 (2014). It explained that the *Calder* defendants had been subject to personal jurisdiction because they had "aimed" their conduct at the forum state—that is, they knew their libelous article would circulate, and have a significant impact, in the forum state. *Id*. at 1124 n.7 (citing *Calder*, 465 U.S. at 789-790).[11]

Calder's reasoning provides guidance for how this Court should resolve this case. Mylan intends for its infringing product to be sold in the forum state. *See supra* n.7. And as a manufacturer of generic drugs, it necessarily intends for its product to have a significant impact on Delaware—its business model depends on its product being adopted throughout the state and supplanting AstraZeneca's name brand equivalent. Accordingly, like the defendants in *Calder*, Mylan's intentional act is aimed at the forum state because it is the site of the harmful act—in *Calder*,

[11] Mylan argues that *Walden v. Fiore* cuts against finding jurisdiction because it holds that the minimum contacts analysis looks to the defendant's impact on the forum State itself, not just defendant's contacts with the plaintiff. Mylan Br. 26-27; *Walden*, 134 S. Ct. at 1122. However, it is precisely Mylan's own contact with the forum state—here, the intent to sell an infringing product in the forum state—that forms the basis for jurisdiction. The *Walden* Court specifically described "deliberately exploi[ting] a market in the forum State" and "physical entry into the State … through … mail" as "relevant contacts" in the analysis, *id.*, both of which are found here. Mylan plans to exploit the Delaware market to sell its infringing product, and mailed a letter into Delaware declaring its intent to infringe AstraZeneca's patent.

the reading of the libelous article, and here, the sale of the infringing product—and because the harm will be felt by AstraZeneca in the forum state. Indeed, AstraZeneca will feel the harm particularly strongly in Delaware because AstraZeneca Pharmaceuticals LP, the U.S. subsidiary of AstraZeneca, is incorporated and has its principal place of business in that state.

In the specific context of patent infringement, too, it is commonplace to examine a defendant's future plans or intentions when determining whether specific jurisdiction exists, such as when there is an allegation of direct infringement predicated on an "offer[] to sell" under 35 U.S.C. § 271(a). *See, e.g.*, *3D Sys., Inc. v. Aarotech Labs., Inc.*, 160 F.3d 1373, 1378-1381 (Fed. Cir. 1998) (conduct like sending "promotional letters" and "price quotations" to California was sufficient to satisfy personal jurisdiction); *HollyAnne Corp. v. TFT, Inc.*, 199 F.3d 1304, 1308 (Fed. Cir. 1999) (same); *cf. Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 769 F.3d 1371, 1381 (Fed. Cir. 2014) ("An offer to sell, in order to be an infringement, must be an offer *contemplating* sale in the United States." (emphasis added)).

This analysis should apply in the § 271(e)(2) context. As with § 271(e)(2), the congressional prohibition on offers to sell infringing products is an artificial cause of action designed to give patent holders the opportunity to bring suit prior to actual infringement, i.e., the actual sale. As this Court has explained, "one of the

purposes of adding 'offer[] to sell' to § 271(a) was to prevent … generating interest in a potential infringing product to the commercial detriment of the rightful patentee." *3D Sys.*, 160 F.3d at 1379; *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc.*, 617 F.3d 1296, 1306 (Fed. Cir. 2010) ("*The* underlying purpose of holding someone who offers to sell liable for infringement is to prevent generating interest in a potential infringing product to the commercial detriment of the rightful patentee." (internal quotation marks omitted and emphasis added)). And, as with § 271(e)(2), it is necessary to consider hypothetical conduct when determining whether an offer to sell would potentially lead to infringement at some future date. Indeed, if the same jurisdictional analysis does not apply in § 271(e)(2) context as it does in the offer to sell context, patent holders in ANDA cases will be unfairly disadvantaged compared to patentees in other cases. There is no basis for this result in the Hatch-Waxman Act or in the doctrine of specific jurisdiction.

* * *

The structure and purpose of the Hatch-Waxman Act, as well as the practice of numerous courts, strongly support considering a defendant's future conduct in determining whether a particular district has specific personal jurisdiction over a § 271(e)(2) suit. Mylan's self-serving rule, which would effectively limit ANDA

litigation to the home forum of an alleged patent infringer, should accordingly be rejected.

CONCLUSION

The district court's holding that it has specific jurisdiction should be affirmed.

Respectfully submitted,

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July 23, 2015

CERTIFICATE OF SERVICE

I hereby certify that on this 23rd day of July 2015, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit using the appellate CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C), the undersigned hereby certifies that this brief complies with the type-volume limitation of Fed. R. App. P. 29(d), 32(a)(7)(B) and Circuit Rule 32(b).

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