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, Case No. 1:14-cv-00696-GMS, subsequently consolidated at 1:14-cv-00664-GMS, Honorable Gregory M. Sleet, District Judge

BRIEF FOR THE GENERIC PHARMACEUTICAL ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF MYLAN PHARMACEUTICALS INC.'S APPEAL FOR LACK OF PERSONAL JURISDICTION

James H. Wallace, Jr.
Eric H. Weisblatt
Mark A. Pacella
A. Claire Frezza
WILEY REIN LLP
1776 K St., NW
Washington, D.C. 20006
(202) 719-7000

Dated: May 26, 2015

Counsel for Amicus Curiae

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:

James H. Wallace, Jr.
Eric H. Weisblatt
Mark A. Pacella
A. Claire Frezza
WILEY REIN LLP
1776 K St., NW
Washington, D.C. 20006
(202) 719-7000

/s/ James H. Wallace, Jr.
James H. Wallace, Jr.

Dated: May 26, 2015

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

FEDERAL CASES

FEDERAL STATUTES

RULES

REGULATIONS

LEGISLATIVE MATERIALS

OTHER AUTHORITIES

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 finished generic pharmaceutical products, manufacturers and distributors of bulk 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. GPhA regularly participates in litigation as *amicus curiae*, taking legal positions that are adopted by GPhA's Board of Directors and reflect the position of GPhA as an organization. *See, e.g.*, *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, No. 10-844 (S. Ct.) (as *Amicus Curiae* in support of Defendants-Appellees); *In re K-Dur Antitrust Litig.*, Nos. 10-2077, -78, -79 (3d Cir.) (as *Amicus Curiae* in support of Petitioner).

[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. GPhA is authorized to state that Mylan Pharmaceuticals Inc. ("Mylan") and AstraZeneca AB ("AstraZeneca") have consented to the filing of this brief. *See* Fed. R. App. P. 29(a).

SUMMARY OF ARGUMENT

Defendant-appellant Mylan's brief ably explains why this Court should reverse the district court's November 5, 2014 Order denying Mylan's Motion to Dismiss for Lack of Personal Jurisdiction ("the Order"). *Amicus* submits this brief to aid the Court in understanding the role of the paragraph IV certification notice ("the notice letter") under the Hatch-Waxman Act and emphasize the industry-wide significance should specific personal jurisdiction be permitted based on an ANDA filer's mailing of that notice. *Amicus* urges this Court that the district court's ruling is contrary to the balance afforded by the Hatch-Waxman Act, irreconcilable with *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014), and is constitutionally unsound. Specifically, this Court should hold that Mylan was not subject to specific jurisdiction in Delaware because:

- An ANDA filer's mailing of a notice letter is part of the ANDA filer's petition to the government protected under the First Amendment;
- Conferring specific jurisdiction based on the mailing of a notice letter violates an ANDA filer's due process; and
- Haling an ANDA filer into court based on where the notice letter was sent would disrupt the balance created by the Hatch-Waxman Act and impermissibly expand the exercise of specific personal jurisdiction.

STATEMENT OF THE CASE

A. Summary of the Case Below

AstraZeneca sued Mylan in the District of Delaware for patent infringement, asserting personal jurisdiction purportedly based on Mylan's (1) systemic and continuous contacts with Delaware; (2) regular and continuous business in Delaware; (3) "substantial revenue" from selling pharmaceutical products in Delaware; and (4) previous failure to object to personal jurisdiction when sued in Delaware. Mylan moved to dismiss for lack of personal jurisdiction, explaining that *Daimler AG v. Bauman* altered the landscape for where an ANDA filer may properly be sued, 134 S. Ct. at 761, and because Mylan (1) is not domiciled in Delaware; (2) prepared its ANDAs in West Virginia; and (3) filed its ANDAs in Maryland.

The district court agreed that *Daimler* altered the historic analysis under general jurisdiction principles but concluded that specific jurisdiction in Delaware was proper because "the only possible alternative forum is the state of residence for the patent holder." Order at 15-16. In holding that exercising specific jurisdiction over Mylan did not violate due process, the district court reasoned, "Mylan's contact with Delaware is not illusory . . . [because] Mylan sent its paragraph IV certification to AstraZeneca U.S. in Delaware, thus triggering the forty-five-day countdown for AstraZeneca to file a lawsuit." *Id.* at 15. The district

court was therefore "convinced that the act of filing an ANDA and the paragraph IV notification provide sufficient minimum contacts with the state of Delaware under a specific jurisdiction analysis" and "not convinced that it would be 'unfair' to subject Mylan to suit here," reasoning that "Mylan is no stranger to ANDA litigation in Delaware." *Id.* at 16. By permission of the district court and this Court, Mylan now appeals the district court's Order.

B. Overview of the Hatch-Waxman Act's Notice Letter Requirement

The Hatch-Waxman Act, 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), outlines the process for pharmaceutical companies to petition the federal government for approval to market generic drugs. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984). Notably, the Hatch-Waxman Act established the ANDA pathway, removing the need for developers of generic drugs to repeat the studies conducted by its brand counterparts and outlining the abbreviated pathway that created the modern generic drug industry. This abbreviated pathway included a mechanism for brand and generic pharmaceutical companies to timely litigate disputes relating to patent infringement, validity, and enforceability. *See id.* Under the Act, ANDA filers may be sued for patent infringement based on the "highly artificial act of

infringement" of "submit[ting]" an ANDA. *See Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990); *see also* 35 U.S.C. § 271(e)(2).

As part of this process, if an ANDA filer seeks approval of a generic product prior to the expiration of a brand drug's listed patents, the Hatch-Waxman Act permits the ANDA filer to include in its application a certification (a "paragraph IV certification"), stating that any such patent "is invalid or will not be infringed by the manufacture, use, or sale" of the generic drug. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The application must also include a statement that the ANDA filer will provide notice of this certification within 20 days. *Id.* § 355(j)(2)(B)(i)-(iii). The regulations accompanying the Act specify the who, what, and where required to satisfy the Act's certification notice requirement. The ANDA filer must mail notice of the certification ("the notice letter") to both the patent holder and new drug application ("NDA") holder, or their representative, and among others, must include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." 21 C.F.R. § 314.95(a), (c)(6). Further, the regulations specify precisely where to mail the notice letter, explaining, "[t]he name and address of the patent owner or its representative may be obtained from the United States Patent and Trademark Office" and "[t]he name and address of the application holder or its attorney, agent, or authorized official may be obtained from the Orange Book

Staff." *Id.* § 314.95(a)(1)-(2). The ANDA filer must then provide FDA with proof that the NDA holder and patent holder, or designated representative, received the notice letter. *Id.* § 314.95(e).

ARGUMENT

I. IT IS UNCONSTITUTIONAL TO CONFER SPECIFIC JURISDICTION OVER AN ANDA FILER BASED ON ITS COMPLIANCE WITH THE PETITION REQUIREMENTS OF THE HATCH-WAXMAN ACT

The exercise of specific jurisdiction over an ANDA filer based on its mailing of a statutorily-required notice letter into that forum is not only contrary to the intent of the Hatch-Waxman Act—it is unconstitutional. To confer specific jurisdiction over a non-resident defendant and comport with due process, the non-resident defendant must "have certain minimum contacts with [the forum] such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice." *Int'l Shoe Co. v. State of Wash. Office of Unemployment Comp. & Placement*, 326 U.S. 310, 316 (1945). The inquiry rests on whether there was "some act by which the defendant purposefully avail[ed] itself of the privilege of conducting activities within the forum State, thus invoking the benefits and protections of its laws." *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 131 S. Ct. 2846, 2854 (2011).[2] But when an ANDA filer mails a notice letter to NDA and patent holders into a given forum, any relationship created between the ANDA

[2] All internal quotations and citations are omitted unless noted otherwise.

filer and that forum does not "arise out of contacts that the defendant *himself* create[d] with the forum." *Walden v. Fiore*, 134 S. Ct. 1115, 1118 (2014) (emphasis in original).

The ANDA filer provides notice of its paragraph IV certification to each NDA and patent holder because the Hatch-Waxman Act states it must do so as part of its petition to the government for marketing approval. 21 U.S.C. § 355(j)(2)(B)(i)-(iii). The ANDA filer mails this notice "by registered or certified mail, return receipt requested," or an alternatively approved mailing method, because the accompanying regulations state the notice must be provided in this manner. 21 C.F.R. § 314.95(a). The ANDA filer mails the notice to one forum over another based on the NDA and patent holders' chosen addresses, which the regulations instruct "may be obtained" from the Orange Book and USPTO staff. *Id.* § 314.95(a)(1)-(2). Even the content of the ANDA filer's notice letter is largely comprised only of the elements listed in the regulations accompanying the Hatch-Waxman Act. *See id.* § 314.95(c)(1)-(7).

An ANDA filer's activities in mailing a notice letter are thus dictated by (1) the Hatch-Waxman Act's requirements to petition the government to market a generic product and (2) the addresses chosen by the NDA and patent holders. But "treating the Petition as the sole jurisdictional contact that subjects [an ANDA filer] to personal jurisdiction poses serious constitutional issues." *Zeneca Ltd. v.*

Mylan Pharms., Inc., 173 F.3d 829, 832 (Fed. Cir. 1999) (Gajarsa, J.). And "the plaintiff cannot be the only link between the defendant and the forum." *Walden*, 134 S. Ct. at 1122. An ANDA filer's mailing of a notice letter cannot support a court's exercise of specific personal jurisdiction.

A. An ANDA Filer's Mailing of a Notice Letter is Not Sufficient to Confer Specific Jurisdiction Because the Act is Protected by the First Amendment

This Court has illuminated the constitutional flaws of conferring specific jurisdiction based on an ANDA filer's petition to the government. *See generally 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."). Complying with statutorily-required steps to complete that petition is no different. An ANDA filer's mailing of a notice letter cannot constitutionally serve as the basis to exercise specific jurisdiction.

In holding that the submission of an ANDA to FDA could not confer specific jurisdiction over an ANDA filer in Maryland (where FDA is located), this Court explained, "treating the Petition as the sole jurisdictional contact that subjects [an ANDA filer] to personal jurisdiction poses serious constitutional issues because it allows Congress to burden unnecessarily, and possibly impermissibly, a First Amendment right." *Id.* at 832. The same analysis applies to the mailing of a notice letter. Indeed, the Hatch-Waxman Act not only requires

that such notice be mailed to the addresses chosen by the NDA and patent holder, the ANDA itself must be amended to document that the notice was received. 21 C.F.R. § 314.95(e); *see also* H.R. Rep. 98-857(I), at 26 (1984) ("[A]n ANDA that does not contain the certifications regarding patents . . . cannot be approved."). An ANDA filer's mailing of a notice letter is merely one step required for "[t]he submission of the Petition[, which] clearly falls within the First Amendment right to petition." *Zeneca*, 173 F.3d at 832 (Gajarsa, J.).

The unnecessary and impermissible burden this Court found in *Zeneca* is even greater here, not only forcing ANDA filers into a given forum but haling every ANDA filer into their opponents' home court. Generic pharmaceutical companies would be categorically blocked from filing ANDAs prior to the expiration of the brand drug's listed patents unless those ANDA filers conceded to challenging the patents where the NDA or patent holder was located or otherwise chose to receive notice. Hinging an ANDA filer's right to petition the government on its willingness to challenge every patent in the brand company's chosen court would have draconian effects on the generic drug industry. As noted by the district court, "patent litigation is an integral part of a generic drug company's business." Order at 15. The effect of the district court's Order would inappropriately stack the odds against every ANDA filer, ignoring the Hatch-Waxman Act's purpose to "fairly balance[] the rights of a patent owner to prevent others from making, using,

or selling its patented product and the rights of third parties to contest the validity of a patent or to market a product which they believe is not claimed by a patent." H.R. Rep. 98-857(I), at 28 (1984).

The district court considered the intent of the Hatch-Waxman Act, but came to the opposite conclusion, reasoning, "AstraZeneca would be substantially burdened if forced to bring lawsuits against each ANDA filer in the defendants' home states. Such a result would be inconsistent with the 'balance' that Congress sought to create in passing the Hatch-Waxman Act." Order at 16. But the district court failed to consider the greater impact this holding would have on ANDA filers, or whether this result was in line with what Congress contemplated in enacting the Hatch-Waxman Act. In fact, rather than forcing ANDA filers to forfeit their constitutional rights and concede to jurisdiction in plaintiffs' chosen forums, Congress explained that instead, "[i]n the event of multiple ANDA's certifying patent invalidity or non-infringement, the courts should employ the existing rules for multidistrict litigation, when appropriate, to avoid hardship on the parties and witnesses and to promote the just and efficient conduct of the patent infringement actions." H.R. Rep. 98-857(I), at 28 (1984). It must be emphasized: "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." *Zeneca*, 173 F.3d at 832 (Gajarsa, J.). It would be

constitutionally unsound and contrary to the spirit of the Hatch-Waxman Act to confer specific jurisdiction based on an ANDA filer's mailing of a notice letter.

B. Conferring Specific Jurisdiction Based on the Mailing of a Notice Letter Violates Due Process

An ANDA filer's mailing of a notice letter is not only protected by the First Amendment, it would be insufficient to confer specific jurisdiction even if it were not because it is not a jurisdictional contact. As discussed above, to exercise specific jurisdiction over a non-resident defendant and comport with due process: (1) the non-resident defendant must have "purposefully established 'minimum contacts' in the forum," *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 474 (1985); and (2) the exercise of specific jurisdiction must "not offend traditional notions of fair play and substantial justice." *Int'l Shoe*, 326 U.S. at 316. "For the exercise of personal jurisdiction to comport with fair play and substantial justice, there must be 'other activities' directed at the forum *and related to the cause of action* besides the letters threatening an infringement suit." *Avocent Huntsville Corp. v. Aten Int'l Co.*, 552 F.3d 1324, 1333 (Fed. Cir. 2008).

Because an ANDA filer's mailing of a notice letter into a plaintiff's chosen forum is not a "purposefully established 'minimum contact[]' in the forum," *Burger King*, 471 U.S. at 474, *amicus* need not address other factors to scrutinize the fairness of exercising specific personal jurisdiction over an ANDA filer in the forum where it mailed its notice. *See id.* at 476 ("Once it has been decided that a

defendant purposefully established minimum contacts within the forum State, these contacts may be considered in light of other factors to determine whether the assertion of personal jurisdiction would comport with 'fair play and substantial justice.'"). But *amicus* must stress that under the district court's reasoning—holding that it would not be "'unfair' to subject Mylan to suit here" because "Mylan is no stranger to ANDA litigation in Delaware," Order at 16—it would apparently never be "unfair" to exercise specific jurisdiction over ANDA filers in any jurisdiction where they had previously litigated. Such logic is in conflict with the due process requirement that a non-resident defendant's activities be "related to the cause of action," *Avocent*, 552 F.3d at 1333, and impermissibly justifies the exercise of specific personal jurisdiction over ANDA filers in every forum where ANDA filers were historically haled under pre-*Daimler* general jurisdiction principles.

The inappropriateness of the district court's holding is stressed by the fact that this Court has "repeatedly held that the sending of an infringement letter, without more, is insufficient to satisfy the requirements of due process when exercising jurisdiction over an out-of-state patentee." *Inamed Corp. v. Kuzmak*, 249 F.3d 1356, 1361 (Fed. Cir. 2001); *see also Silent Drive, Inc. v. Strong Indus.*, 326 F.3d 1194, 1202 (Fed. Cir. 2003) ("[S]ending of letters threatening infringement litigation is not sufficient to confer personal jurisdiction."). The same

holds even when "the letters are 'purposefully directed' at the forum and the [] action 'arises out of' the letters." *See Avocent*, 552 F.3d at 1333 (quoting *Silent Drive*, 326 F.3d at 1202). It is therefore illogical that "the act of filing an ANDA and the paragraph IV notification provide *sufficient minimum contacts* with the state of Delaware under a specific jurisdiction analysis," Order at 16 (emphasis added), where here, an ANDA filer mails the letter only because it is statutorily-required to do so.

Because an ANDA filer mails a notice letter to the locations chosen by plaintiffs and due to the requirements of the Hatch-Waxman Act, an ANDA filer's mailing of a notice letter is even more attenuated than a patentee's decision to mail a letter threatening infringement. An ANDA filer's mailing of a notice letter simply does not "arise out of contacts that the defendant *himself* create[d] with the forum." *See Walden*, 134 S. Ct. at 1118 (emphasis in original). The "'minimum contacts' analysis looks to the defendant's contacts with the forum State itself, not the defendant's contacts with persons who reside there." *Id.* To hold otherwise and assert specific jurisdiction over an ANDA filer for mailing a notice letter would not only violate due process but serve as an "unnecessary and unintended punishment for filing a petition with the FDA, which undermines the purpose of the Hatch–Waxman Act." *Zeneca*, 173 F.3d at 833 (Gajarsa, J.). Mailing the

statutorily-required notice letter into the plaintiff's chosen forum is simply "not sufficient to confer personal jurisdiction." *Silent Drive*, 326 F.3d at 1202.

II. UPHOLDING THE DISTRICT COURT'S EXERCISE OF SPECIFIC JURISDICTION IS INCONSISTENT WITH *DAIMLER*

While the Supreme Court's decision in *Daimler* dealt with general personal jurisdiction, that decision unequivocally narrowed the circumstances under which a court can exercise personal jurisdiction over a non-resident defendant. *See Daimler*, 134 S. Ct. at 761. The court below turned that decision on its head, responding to the Supreme Court's clear message by expanding the specific personal jurisdiction doctrine and holding ANDA filers to jurisdiction in any state where a patent holder designates an agent to receive notice of the applicant's FDA filing. *See* Order 15 (holding that because general jurisdiction no longer existed after *Daimler*, "the only possible alternative forum is the state of residence for the patent holder.").

Automatically haling ANDA filers into a forum based on the mailing of a notice letter would not only result in the jurisdiction being dictated by the NDA and patent holders' locations, the plaintiffs could unilaterally *choose* the jurisdiction. In directing ANDA filers to mail notice to the NDA and patent holders, the regulations accompanying the Hatch-Waxman Act steer ANDA filers to seek this information from the Orange Book staff and USPTO. *See* 21 C.F.R. § 314.95(a)(1)-(2). NDA and patent holders could provide the Orange Book staff

and USPTO with the addresses of offices in preferred states to force ANDA filers into jurisdictions where the ANDA filers have no contacts but for the required mailing. Even more troubling, the regulations specifically state that in mailing the notice letter, "[t]he name and address of the patent owner *or its representative* may be obtained from the [USPTO]." *Id.* (emphasis added). Patent holders would thus have the power to designate its representative in whichever forum it chooses, knowing the ANDA filer would mail its notice letter there and be unable to contest jurisdiction. The district court's ruling would therefore effectively expand specific personal jurisdiction to force ANDA filers into jurisdictions with "the same global reach . . . in every other State," a result the *Daimler* Court found "unacceptably grasping." *Daimler*, 134 S. Ct. at 761.

Amicus understands that the district court's personal jurisdiction analysis for ANDA litigation is now muddied in light of *Daimler* and this Court's precedent. *See generally* Eric H. Weisblatt & Claire Frezza, *Who to Sue and Where in ANDA Litigation: Personal Jurisdiction Post-Daimler*, 69 Food & Drug L.J. 351 (2014). But that reason alone does not provide justification to inappropriately expand specific jurisdiction at the detriment of every ANDA filer.

CONCLUSION

For the reasons set forth above, this Court should grant Mylan's appeal, reversing the decision below and ordering the case dismissed for lack of personal jurisdiction.

Respectfully submitted,

/s/ James H. Wallace, Jr.
James H. Wallace, Jr.
Eric H. Weisblatt
Mark A. Pacella
A. Claire Frezza
WILEY REIN LLP
1776 K St., NW
Washington, D.C. 20006
(202) 719-7000

Counsel for Amicus Curiae

May 26, 2015

CERTIFICATE OF COMPLIANCE

I certify under Federal Rules of Appellate Procedure 29(d) and 32 that

(1) this Brief complies with the page limitations of Federal Rules of Appellate Procedure 29(d) and 32(a)(7)(B) because the Brief contains 3,547 words, excluding those parts that Rule 32(a)(7)(B)(iii) exempt from the word count; and

(2) the Brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the typestyle requirements of Federal Rule of Appellate Procedure 32(a)(6) because it was prepared with a proportionally spaced typeface from Microsoft Word 2010 in 14-point font size Times New Roman typestyle.

This 26th day of May, 2015.

/s/ James H. Wallace, Jr.
James H. Wallace, Jr.

CERTIFICATE OF SERVICE

I hereby certify that on May 26, 2015, 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.

/s/ James H. Wallace, Jr.
James H. Wallace, Jr.