Appeal No. 2015-1456

United States Court of Appeals

for the

Federal Circuit

ACORDA THERAPEUTICS INC.,
ALKERMES PHARMA IRELAND LIMITED,

Plaintiffs-Appellees,

– v. –

MYLAN PHARMACEUTICALS INC., MYLAN INC.,

Defendants-Appellants.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE IN CASE NO. 14-CV-00935, HONORABLE LEONARD P. STARK

BRIEF FOR *AMICUS CURIAE* BIOTECHNOLOGY INDUSTRY ORGANIZATION IN SUPPORT OF PLAINTIFFS-APPELLEES

CHRISTOPHER J. GLANCY
ADAM GAHTAN
WHITE & CASE LLP
1155 Avenue of the Americas
New York, New York 10036
(212) 819-8200
cglancy@whitecase.com

Attorneys for Amicus Curiae Biotechnology Industry Organization

July 23, 2015

CERTIFICATE OF INTEREST

Counsel for *amicus curiae* and non-party Biotechnology Industry Organization certifies the following:

1. The full name of every party or amicus represented by the undersigned counsel in the above-captioned appeal is Biotechnology Industry Organization.

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: N/A

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: N/A.

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 are expected to appear in this court are:

Christopher J. Glancy
Adam Gahtan
WHITE & CASE LLP
1155 Avenue of the Americas
New York, New York 10036
Telephone: (212) 819-8200
cglancy@whitecase.com

Dated: July 23, 2015

/s/ Christopher J. Glancy
Christopher J. Glancy

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INTEREST OF AMICUS

Amicus Biotechnology Industry Organization ("BIO") is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products. BIO also produces the BIO International Convention, the world's largest gathering of the biotechnology industry, along with industry-leading investor and partnering meetings held around the world.

BIO's members range from entrepreneurial companies developing a first product to Fortune 500 multinationals and, most importantly for present purposes, include most of the world's major innovator pharmaceutical companies. As such, an issue before this Court – in what circumstances a district court may exercise personal jurisdiction over a generic pharmaceutical company that submits an ANDA with one or more paragraph IV certifications – is of great importance to BIO's members.

INTRODUCTION

BIO submits this brief to aid the Court in understanding the statutory and regulatory framework of Hatch-Waxman litigation as it pertains to the specific personal jurisdiction analysis. In particular, this brief addresses the potential adverse consequences of adopting the theory of specific personal jurisdiction advanced by Defendants-Appellants Mylan Pharmaceuticals Inc. and Mylan Inc. (together, "Mylan") in this appeal.[1] A ruling that personal jurisdiction over an ANDA applicant is never available in any state other than the applicant's home state, as Mylan contends, would lead to duplicative litigation, a waste of judicial resources, and needless delay in resolving the underlying dispute. Such delay would undermine a crucial purpose of the Hatch-Waxman Act, the swift resolution of patent disputes, to the detriment of the innovator company and the public generally.

BIO agrees with Acorda that Mylan is subject to specific personal jurisdiction in Delaware as a result of its filing an ANDA with a paragraph IV certification. This brief highlights the types of related contacts an ANDA filer will typically have with the forum state due to the nature of its business.

[1] All parties have consented to the filing of this brief. Pursuant to Federal Rule of Appellate Procedure 29(c), BIO states that no counsel for a party authored this brief in whole or in part; no party or party's counsel contributed money that was intended to fund preparing or submitting this brief; and no person – other than amicus curiae, its members, or its counsel – contributed money that was intended to fund preparing or submitting the brief.

ARGUMENT

I. MYLAN'S PROPOSED RULE WOULD CAUSE NEEDLESS DELAY AND WASTE JUDICIAL RESOURCES

According to Mylan, a paragraph IV ANDA applicant can never be subject to specific personal jurisdiction in any state (except "perhaps" in the state where the ANDA was prepared), and, after *Daimler,* the applicant can be sued only under principles of general jurisdiction in its home state. (Mylan Br. 15, 31.) Such a rule would result in unnecessarily duplicative litigation in multiple fora, and would undermine the purposes of the Hatch-Waxman Act by creating unnecessary delay in resolving the dispute.

The Hatch-Waxman Act was intended to reduce delay of generic entry into the marketplace. The Act balances the interests of generic manufacturers and innovator companies. It provides ANDA-applicants a safe-harbor exemption from patent infringement, 35 U.S.C. § 271(e)(1), to allow drug development activity in support of its ANDA filing. It provides innovators a 30-month stay of FDA approval, if the patent owner chooses to sue within 45 days of the paragraph IV notice letter. 21 U.S.C. § 355(c)(3)(C). The purpose of the 45-day window and the 30-month stay is to encourage expeditious resolution of disputes relating to the relevant patents listed in the FDA's Orange Book. This balance of interests is threatened if innovator companies are forced to pursue ANDA applicants only in the applicants' home states.

As this Court knows, an ANDA litigation typically involves multiple paragraph IV ANDA applicants. A recent study by the Federal Trade Commission found that, in 2007, 41 drugs were subject to paragraph IV patent challenges and the average number of first-to-file applicants was about nine; some drugs had as many as 16 first-filed ANDA applicants. *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*, Federal Trade Commission, 136 (Aug. 2011).

Because ANDA applicants may be incorporated and located in many different states,[2] under Mylan's theory, innovator companies would be forced to file suit in multiple jurisdictions to resolve the same validity and infringement issues surrounding a single drug. This would result in unnecessarily duplicative litigation, which in turn would lead almost inevitably to multiple appeals, wasting valuable judicial resources.

While parties in some cases might resort to the Judicial Panel on Multidistrict Litigation to coordinate pretrial discovery, the process of selecting an MDL court itself is time-consuming and can take as long as seven months.[3] *See* Victor E. Schwartz et al., *Guide to Multistate Litigation* § 2:6 (2014) ("From the time of filing to the first MDL conference in the transferee court is between 16 and

[2] For example, Accord Healthcare Inc. is incorporated and headquartered in North Carolina, Apotex Corp. in Florida, and Mylan Pharmaceuticals Inc. in West Virginia.

[3] As one court put it, "MDL practice is slow, very slow." *Delaventura v. Columbia Acorn Trust*, 417 F. Supp. 2d 147, 150 (D. Mass. 2006).

29 weeks.") (citing John G. Heyburn II, *A View from the Panel: Part of the Solution*, 82 Tul. L. Rev. 2225, 2243 n.91 (2008)). That time would needlessly and unfairly eat into the 30-month stay and delay resolution of the actions. Furthermore, because an MDL court is not empowered to try these cases without the consent of all defendants, there is a substantial risk of inconsistent decisions by different district courts. *See* 28 U.S.C. § 1407(a) ("Each action so transferred shall be remanded by the panel at or before the conclusion of such pretrial proceedings to the district from which it was transferred unless it shall have been previously terminated . . . ."). Other procedural hurdles, such as motions to transfer and motions to stay proceedings, could further contribute to this delay.

Because Mylan's theory of specific jurisdiction would slow down ANDA litigation, it is contrary to "the statutory scheme of the Hatch-Waxman Act [which] relies on early resolution of patent disputes." *Teva Pharms, USA v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1344 (Fed. Cir. 2007) (quoting 149 Cong. Rec. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy)); *see* 21 U.S.C. § 355(j)(5)(B)(iii) ("In such an action, each of the parties shall reasonably cooperate in expediting the action.").

II. BY FILING AN ANDA WITH A PARAGRAPH IV CERTIFICATION, MYLAN SUBJECTED ITSELF TO SPECIFIC PERSONAL JURISDICTION IN DELAWARE

BIO agrees with Acorda that the filing of a paragraph IV ANDA is an activity sufficient to establish personal jurisdiction over Mylan in Delaware. The submission of a paragraph IV ANDA is an act of infringement. 35 U.S.C. § 271(e)(2). By filing a paragraph IV ANDA, the applicant seeks approval to market the ANDA drug nationwide before the expiration of the Orange Book-listed patents. If the applicant obtains approval and launches its drug before the patents expire, the injury to the patent holder's exclusive rights will occur nationwide.

Such early generic market entry typically has a devastating impact on sales of the innovator's drug. *See* Grabowski, et al., *Recent Trends in Brand-Name and Generic Drug Competition*, J. Med. Econ. at 6-7 (2013)[4] (study showed that in 2011-2012, brand drugs retained, on average, only 16% of their market share one year after generic entry, and 11% for drugs with annual sales greater than $250 million). Such "contemplated future consequences . . . must be evaluated in determining whether the defendant purposefully established minimum contacts within the forum." *See Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 479 (1985). There are also immediate effects experienced by the patent holder. Filing an ANDA with a paragraph IV certification is a "real act [of infringement] with

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

serious consequences." *Zeneca Ltd. v. Mylan Pharms., Inc.*, 173 F.3d 829, 834 (1999) (Gajarsa, J.). When a patent holder receives a paragraph IV notice letter, it must, within 45 days, choose between two options: file a lawsuit to enforce its patent rights, or risk generic entry before the patents expire, effectively extinguishing its exclusive rights.

The consequences are jurisdictionally significant. Personal jurisdiction is appropriately exercised over "defendants who have purposefully 'reach[ed] out beyond' their State and into another by, for example, entering a contractual relationship that 'envisioned continuing and wide-reaching contacts' in the forum State, or by circulating magazines to 'deliberately exploi[t]' a market in the forum State." *Walden v. Fiore*, 134 S. Ct. 1115, 1122 (2014) (citations omitted). Likewise, the submission of a paragraph IV ANDA is an activity that "envision[s] continuing and wide-reaching contacts" with the forum state and is designed to "deliberately exploi[t] a market" in that state.

Sending a paragraph IV notice letter to the patent holder, while not per se necessary to establish jurisdiction, is another jurisdictionally relevant activity that is directed specifically at the patent holder where it is domiciled. *See Walden*, 134 S. Ct. at 1122 ("[P]hysical entry into the State – either by the defendant in person or through an agent, goods, *mail*, or some other means – is certainly a relevant contact." (citing *Keeton v. Hustler Magazine, Inc.*, 465 U.S. 770, 773-74 (1984)

(emphasis added)). The Act requires the ANDA applicant to send the notice letter, within 20 days of filing the ANDA, to the patent holder. 21 U.S.C. § 355(j)(2)(B)(iii). FDA regulations instruct the ANDA applicant to obtain the name and address of the patent owner or its representative from the United States Patent and Trademark Office. 21 C.F.R. § 314.95(a)(1), (2). Thus, an ANDA applicant expressly directs – and literally addresses – its threat at the patent holder in the state where its principal place of business is located.

Moreover, because a corporation is also domiciled – or "at home" – in its state of incorporation, *Daimler AG v. Bauman*, 134 S. Ct. 746, 759 (2014), a paragraph IV notice letter is directed at the patent holder in that state, as well. *See Int'l Shoe Co. v. Washington,* 326 U.S. 310, 316 (1945) ("[T]he corporate personality is a fiction, although a fiction intended to be acted upon as though it were a fact."). The patent holder's state of incorporation is "easily ascertainable," *Daimler*, 134 S. Ct. at 759, and, indeed, is expressly stated in every complaint filed in Hatch-Waxman litigation. Here, Mylan's ANDA filing is directed at both the state of Delaware (where its infringing drug will indisputably be sold and the patentee's sales lost), and at residents of Delaware (the patent holder).

The patent holder's infringement suit also arises directly out of or relates to the paragraph IV ANDA and the ensuing notice letter. Indeed, the Hatch-Waxman Act makes a paragraph IV patent certification an act of infringement so that the

patent holder *can* file suit. 35 U.S.C. § 271(e)(2)(A); *see AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370, 1376-77 (Fed. Cir. 2012) ("§ 271(e)(2) provided a new cause of action so that courts could promptly resolve infringement and validity disputes before the ANDA applicant had engaged in the traditional statutorily defined acts of infringement."). A closer relationship between the defendant's activities and the plaintiff's claim is hard to fathom.

A paragraph IV ANDA applicant also is typically engaged in other related activities that "connect[] [the applicant] to the forum in a meaningful way." *See Walden*, 134 S. Ct. at 1122 (quoting *Int'l Shoe*, 326 U.S. at 316). Paragraph IV ANDA applicants almost always have sophisticated, pre-existing apparatuses established in every state for the express purpose of marketing and distributing generic drugs nationwide upon approval, taking advantage of Hatch-Waxman's benefits. It is this infrastructure that the ANDA applicant threatens to use when it certifies under paragraph IV. These forum contacts are hardly "random, fortuitous, or attenuated" either. *Burger King*, 471 U.S. at 475. They are part of a concerted effort to bring the ANDA product to market as soon as FDA approval is attained. And they are necessarily intertwined with the ANDA filing.

Such related jurisdictional contacts with the forum may include, as here, that the ANDA applicant is registered to do business in the forum state and licensed by the state pharmacy board to distribute its products, including the ANDA drug, in

that state. Additional contacts may include: (1) existing contracts to market and distribute its products, including the ANDA product, within the state; (2) registration with state Medicaid authorities; (3) rebate payments to the state pursuant to the Medicaid Drug Rebate Program; and (4) contacts with local hospitals and pharmacies to include its products, including the ANDA product, on their formularies. All of these contacts are with the state itself and/or the residents of the state. And they are all inextricably intertwined with the act of infringement, the ANDA filing. That is, a generic company cannot market its ANDA drug – the activity for which the applicant seeks FDA approval – without the support of its preexisting infrastructure.

According to Mylan, it is subject to personal jurisdiction in ANDA cases only in West Virginia. In effect, it views the filing of an ANDA with a paragraph IV certification as an act so "artificial" as to be without factual or legal context, and without significance to any applicable jurisdictional analysis. That position – and even the narrower position that it is not subject to personal jurisdiction in Delaware in this case – does not take account of the purposes of the Hatch-Waxman Act, the jurisdictional implications of a paragraph IV certification (i.e., that Mylan will sell its ANDA products nationwide, including in Delaware, upon the FDA's approval of its application), and the sales infrastructure that Mylan has created in Delaware (and elsewhere). As with the ANDA filing itself, these

contacts make it fair and reasonable for Mylan to be brought into court beyond its home state, including, in this case, in Delaware.

CONCLUSION

For the foregoing reasons, the Court should affirm the district court's order.

Dated: July 23, 2015

WHITE & CASE LLP

/s/ Christopher J. Glancy
Christopher J. Glancy
Adam Gahtan
1155 Avenue of the Americas
New York, New York 10036
(212) 819-8307
cglancy@whitecase.com

Attorneys for Amicus Curiae
Biotechnology Industry Organization

CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Civil Procedure 29(c)(7), the undersigned individual hereby certifies that this BRIEF OF AMICUS CURIAE BIOTECHNOLOGY INDUSTRY ORGANIZATION IN SUPPORT OF PLAINTIFFS-APPELLEES complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B). The brief contains 2,309 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

This brief also complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft Word, Office 2010, in Times New Roman, 14 point.

Dated: July 23, 2015

/s/ Christopher J. Glancy
Christopher J. Glancy
Counsel for Amicus Curiae
Biotechnology Industry Organization

United States Court of Appeals for the Federal Circuit

CERTIFICATE OF SERVICE

I, Simone Cintron, being duly sworn according to law and being over the age of 18, upon my oath deposes and says that:

Counsel Press was retained by Counsel for *Amicus Curiae* Biotechnology Industry Organization to print this document. I am an employee of Counsel Press.

On July 23, 2015, Counsel for *Amicus Curiae* Biotechnology Industry Organization authorized me to electronically file the foregoing Brief with the Clerk of Court using the CM/ECF System, which will send notice of such filing to all registered CM/ECF users.

Upon acceptance by the Court of the e-filed document, six paper copies will be filed with the Court, via Federal Express, within the time provided in the Court's rules.

/s/ Simone Cintron
Simone Cintron