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. 14-cv-664, 14-cv-696)

BRIEF OF TEVA PHARMACEUTICALS USA, INC., AS AMICUS CURIAE IN SUPPORT OF PLAINTIFF-APPELLEE

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July 23, 2015

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

ASTRAZENECA AB V. MYLAN PHARMACEUTICALS INC.

No. 2015-1460

CERTIFICATE OF INTEREST

Counsel for the Amicus Curiae, Teva Pharmaceuticals USA, Inc., certifies the following (use "None" if applicable; use extra sheets if necessary):

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

Teva Pharmaceuticals USA, Inc.

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 corporations and publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

Teva Pharmaceutical Industries Ltd.

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:

Goodwin Procter LLP: William M. Jay and Brian T. Burgess.

July 23, 2015
Date

/s/ William M. Jay
William M. Jay

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INTEREST OF AMICUS CURIAE

Teva Pharmaceuticals USA, Inc. ("Teva") is a leading pharmaceutical company, marketing both innovative and generic products. Teva is a frequent party to patent litigation under the Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), both as a plaintiff suing to enforce its patent rights and as a defendant seeking U.S. Food and Drug Administration ("FDA") approval for generic-drug applications known as Abbreviated New Drug Applications ("ANDAs").

As a regular Hatch-Waxman litigant, Teva has a strong interest in ensuring that jurisdictional rules promote the fair and efficient resolution of patent disputes for brand and generic manufacturers alike. In Teva's experience, generic applicants regularly sell through established distribution channels immediately following FDA approval of an ANDA. An ANDA is a request for permission to begin these sales, and an ANDA filer purposefully directs its activities toward the states where it plans to infringe the patent by selling the product described in the ANDA. The filer thus may reasonably be required to defend against infringement claims in those forums. That outcome is not only reasonable and fair, but efficient as well: allowing the brand manufacturer to sue multiple generic defendants in a single forum where all they plan to sell, rather than in their scattered home

jurisdictions, helps to facilitate consolidation and, thus, the prompt and effective adjudication of patent challenges.

Teva also has an interest in the resolution of this appeal because it has sued the appellant, Mylan Pharmaceuticals, Inc. ("Mylan"), in the U.S. District Court for the District of Delaware after Mylan filed an ANDA seeking to market a generic version of Teva's Copaxone® 40 mg/ML injection. As in this case, Mylan moved to dismiss Teva's Complaint for lack of personal jurisdiction. The district court denied the motion without prejudice pending the resolution of this appeal. *See Teva Pharm. USA, Inc. v. Mylan Pharm. Inc.*, No. 14-cv-1278-GMS, ECF No. 84 (D. Del. July 17, 2015).[1]

SUMMARY OF ARGUMENT

The Hatch-Waxman Act provides both brand and generic pharmaceutical manufacturers with a convenient short-cut for litigating patent disputes. The Act establishes that a generic manufacturer's submission of an ANDA is a technical act of patent infringement "if the purpose of [the] submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of [the] drug . . . before the expiration of [the applicable] patent." 35 U.S.C. § 271(e)(2). Thus, *before* any

[1] No counsel for a party authored this brief in whole or in part, and no counsel for a party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the amicus curiae or its counsel made a monetary contribution to the brief's preparation or submission. All parties have consented to the filing of this brief.

generic product is sold, brand and generic manufacturers can litigate whether such sales will infringe a valid patent. The submission of the ANDA allows the brand manufacturer to file suit, but the litigation itself looks forward to the generic filer's proposed activities, asking "whether, if [the filer's] particular drug *were* put on the market, it *would* infringe the relevant patent." *Bristol-Myers Squibb Co. v. Royce Labs., Inc.*, 69 F.3d 1130, 1135 (Fed. Cir. 1995).

There is no reasonable doubt that when a generic manufacturer like Mylan receives approval and intentionally floods a state's market with infringing drugs, it is subject to specific jurisdiction in that state for patent-infringement claims. *See, e.g.*, *Nuance Commc'ns, Inc. v. Abbyy Software House*, 626 F.3d 1222, 1234 (Fed. Cir. 2010); *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1568 (Fed. Cir. 1994); *see also Novartis Pharm. Corp. v. Mylan Inc.*, No. 14-cv-820-RGA, 2015 WL 1246285, at *4 (D. Del. Mar. 16, 2015) ("Mylan must concede that if it actually were being sued for infringement based on sales, it could be sued on a specific jurisdiction theory anywhere it makes sales.").

In contesting personal jurisdiction, Mylan asks the Court to ignore the sales that it would make as soon as the ANDA is approved. That would be contrary to the forward-looking nature of ANDA litigation, which is about the product that *is to be sold*. Shifting the litigation to an earlier point in the FDA process, to allow the parties to resolve patent disputes before generic drugs actually enter the market

and cause damages, should not change the analysis. Just as the Court evaluates liability by examining whether future sales contemplated by the ANDA will infringe, the Court should consider the future sales the generic manufacturer seeks to make when assessing its jurisdictional contacts.

Mylan's arguments to the contrary rely on an unduly narrow conception of specific jurisdiction in patent cases. When generic applicants seek approval to market an infringing drug in a forum and have distribution networks in place to do so, they have purposely directed their infringement to the forum and there is no unfairness in requiring them to defend against infringement claims there. Mylan's position would draw an absurd distinction—it would mean that even though the merits of the case turn on Mylan's anticipated infringing conduct, the case still does not "relate to" that same conduct for jurisdictional purposes. It would also likely mean that generic defendants are not subject to specific jurisdiction *anywhere* despite engaging in an act of infringement that directly affects a patentee's economic interests and legal rights.

Moreover, Mylan's approach to personal jurisdiction in ANDA cases would introduce serious inefficiencies into a process that Congress intended to move quickly. Patentees regularly receive multiple Paragraph IV certifications for the same branded drug. And Hatch-Waxman suits are regularly filed by the brand in a single forum, which allows for consolidation—a procedure the patent laws

facilitate in ANDA cases. *See infra* at 20 (discussing 35 U.S.C. § 299(a), which exempts ANDA litigation from certain limitations on joinder and consolidation). Requiring the patentee to pursue duplicative litigation in the home state of each generic filer would consume time, waste judicial resources, and potentially produce inconsistent outcomes in cases involving identical products and patents.[2]

ARGUMENT

I. ANDA Applicants Are Subject to Personal Jurisdiction In Forums Where They Intend to Distribute a Potentially Infringing Product

This Court evaluates specific personal jurisdiction in patent cases under a three-part test: whether (1) "the defendant purposefully directed its activities at residents of the forum," (2) "the claim arises out of or relates to those activities," and (3) the "assertion of personal jurisdiction is reasonable and fair." *Breckenridge Pharm., Inc. v. Metabolite Labs, Inc.*, 444 F.3d 1356, 1363 (Fed. Cir. 2006). A pharmaceutical company's intentional introduction of infringing drug products into markets that include the forum state easily satisfies these conditions. *See, e.g.*, *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1568 (Fed. Cir. 1994). The result should be no different here: Congress has not changed the nature of the cause of action, but only its timing, by providing drug companies with a mechanism to sort out patent disputes before a generic company

[2] By focusing on this basis for personal jurisdiction over Mylan, Teva does not intend to suggest disagreement with the other grounds for personal jurisdiction advanced by AstraZeneca.

enters the market rather than requiring the parties to wait until the potentially infringing sales take place.

A. Companies Are Subject to Personal Jurisdiction in Any Forum Where They Distribute an Allegedly Infringing Product

In ordinary patent-infringement cases, defendants who deliberately sell the infringing product into a particular forum unquestionably are subject to personal jurisdiction in that forum. States "clearly ha[ve] an interest in prohibiting the importation of infringing articles into [their] territory and regulating the conduct of the distributors with respect to the subsequent resales." *N. Am. Philips Corp. v. Am. Vending Sales, Inc.*, 35 F.3d 1576, 1580 (Fed. Cir. 1994). And when an out-of-state corporation consciously sells an (allegedly) infringing product in a particular jurisdiction, it actually "commit[s] a tort there." *Id.* at 1579. As a result, a defendant's deliberate introduction of a potentially infringing product into a forum plainly establishes the sort of connection between "'the defendant, the forum, and the litigation'" that allows for the exercise of specific jurisdiction under the Due Process Clause. *Walden v. Fiore*, 134 S. Ct. 1115, 1125 (2014) (quoting *Calder v. Jones*, 465 U.S. 783, 788 (1984)).

Specific personal jurisdiction in patent-infringement cases, moreover, extends beyond the company that serves as the final link in a supply chain. If an out-of-state corporation intentionally ships infringing products into a forum "through an established distribution channel with the expectation that the products

will be sold in the forum," then the corporation is subject to personal jurisdiction in the forum, regardless of whether the company has a physical presence there. *Nuance Commc'ns, Inc. v. Abbyy Software House*, 626 F.3d 1222, 1234 (Fed. Cir. 2010); *see also Beverly Hills Fan Co.*, 21 F.3d at 1568 (recognizing personal jurisdiction over a company that shipped infringing products into the forum through an established distribution channel even though the company had no assets, employees, or registered agents in the forum and was not licensed to do business there). While this Court has never recognized a purely passive "stream-of-commerce" theory and recently stated that the status of such a theory is at best "unsettled," *Celgard, LLC v. SK Innovation Co.*, ___ F.3d ___, 2015 WL 4068810, at *7 (Fed. Cir. July 6, 2015), the Court has also squarely held that *purposeful* efforts to sell an infringing product into a forum are a constitutionally adequate basis for personal jurisdiction under any standard, *see Nuance Comm'cns*, 626 F.3d at 1233-34.

In practice, therefore, when a company plans to sell a potentially infringing product in all 50 states, it must be prepared to defend against infringement claims in each of those states based on the harm (infringement) it commits in each of those states. *See* Kimberly A. Moore, *Forum Shopping in Patent Cases: Does Geographic Choice Affect Innovation?*, 79 N.C. L. Rev. 889, 895, 901 (2001) ("[A]ny company that operates in national commerce is likely subject to personal

jurisdiction in many possible districts," providing "plaintiffs in patent cases" with an "unfettered choice of where to bring suit"). There is nothing unfair about that result; it is simply the consequence of a company's business decision to direct infringing activities to many different markets, and thus to purposefully avail itself of each forum's laws and protections. *Cf. Daimler AG v. Bauman*, 134 S. Ct. 746, 758 n.10 (2014) (explaining that specific jurisdiction ensures that companies with widespread operations will be answerable for their activities within a particular forum).

B. In the ANDA Context, Companies Are Subject to Personal Jurisdiction in the Forums Where They Intend To Distribute Their Infringing Products Following ANDA Approval

As AstraZeneca has demonstrated, Mylan is subject to specific jurisdiction under this established framework. *See* AstraZeneca Br. 19-27, 36-41. Mylan has sought permission from FDA to sell its generic product on a nationwide basis, including in Delaware. It has sought that permission "[for] the purpose" of making those sales "before the expiration of [the] patent[s]" that claim the branded product. 35 U.S.C. § 271(e)(2). And it is poised to make those sales in Delaware—a state in which it is registered to do business—through its established network of designated wholesalers and distributors once it receives FDA approval. AstraZeneca Br. at 8-9, 25-27. AstraZeneca's infringement claim against Mylan therefore is amply "related to" Mylan's activities directed at Delaware.

To avoid that straightforward result, Mylan relies on the unusual nature of patent-infringement litigation under the Hatch-Waxman Act. Mylan claims that specific jurisdiction cannot be predicated on the company's future sales in the forum because AstraZeneca's claim of infringement is "based on Mylan's ANDA filings," not those future sales. Mylan Br. 42-44; *see id.* at 46 (reiterating this argument, and claiming that future sales are too speculative to support jurisdiction). But Mylan's argument rests on a misunderstanding of the Hatch-Waxman's Act's structure and an unduly narrow view of specific jurisdiction in patent-infringement cases involving ANDA submissions.[3]

1. ANDA Litigation "Relates To" the Generic Applicant's Planned Sales in a Forum

The Hatch-Waxman Act adopted reforms that balance the interests of pioneer and generic drug manufacturers by ensuring that the former enjoy exclusivity for the full term of a valid patent while creating mechanisms for the latter to bring drugs to market as soon as patent law allows. *See Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002). Among the key

[3] Mylan's separate claim that these contacts do not support specific jurisdiction because Mylan plans to sell its generic product "across the United States," Mylan Br. 45-46, is meritless. *See* AstraZeneca Br. 25-26 & n.5. If Mylan were right that a company that serves a national market can avoid specific jurisdiction in any particular state, then Delaware could not assert jurisdiction over an out-of-state company that intentionally sells an infringing product within the jurisdiction provided the company engages in infringement in other states as well. The law is directly to the contrary. *See supra* at 6-8; *see also Tobin v. Astra Pharm. Prods., Inc.*, 993 F.2d 528, 544 (6th Cir. 1993) (rejecting a similar argument).

reforms, the Act "facilitates the early resolution of patent disputes between generic and pioneering drug companies by providing that the mere act of filing a Paragraph IV ANDA"—which certifies that commercial manufacture, use, or sale of a generic drug will not infringe a listed patent or that the patent is invalid—itself "constitutes an act of patent infringement." *Caraco Pharm. Labs., Ltd. v. Forest Labs, Inc.*, 527 F.3d 1278, 1283 (Fed. Cir. 2008).

The statute accomplishes that goal by providing that the submission of the ANDA is a *present* act of infringement if its purpose is to engage in *future* infringement: to "manufacture, use, or s[ell]" the drug "before the expiration of [the] patent." 35 U.S.C. § 271(e)(2). The law thus "permit[s] patent holders to bring suit against generic companies despite the fact that the generic companies have not yet infringed the patents at issue." *Glaxo Grp. Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1351 (Fed. Cir. 2004).

While this "highly artificial" act of infringement provides a bright line to assuage any doubts that an anticipatory suit is justiciable, the act of filing the ANDA is not the subject of the ensuing patent litigation in any meaningful sense. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1365-66 (Fed. Cir. 2003). Rather, once Article III jurisdiction is established, a case will proceed "by traditional patent infringement analysis, just the same as . . . in other infringement suits, including those in a non-ANDA context." *Id.* at 1365. Under that traditional

analysis, the relevant inquiry does not look backward at the act of ANDA submission; it looks forward to "whether, if a particular drug *were* put on the market, it *would* infringe the relevant patent." *Bristol-Myers Squibb Co. v. Royce Labs., Inc.*, 69 F.3d 1130, 1135 (Fed. Cir. 1995); *see also, e.g.*, *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1331-32 (Fed. Cir. 2003) (in induced-infringement cases, plaintiff must establish "the claim that the ANDA filer will induce infringement of its patent upon approval of the ANDA"); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997) (explaining that, in an ANDA case, "the question of infringement must focus on what the ANDA applicant will likely market if its application is approved"). That focus on hypothetical *future* conduct is why this Court described "a claim under 35 U.S.C. § 271(e)(2)" as, "by its very nature, speculative to a certain degree," *Allergan*, 324 F.3d at 1331. If the exclusive focus were on the ANDA itself, there would be no need to speculate.

Mylan's intended drug sales in Delaware—once it receives the necessary FDA approval to make such sales—thus directly "relate to" the subject matter of the litigation. In claiming otherwise, Mylan improperly relies on the fact that filing an ANDA with a Paragraph IV certification is the immediate trigger for suit in Hatch-Waxman litigation. *See* Mylan Br. 44 & n.16. At most, that might suggest that infringement actions in ANDA cases do not technically "arise" from the

generic filer's prospective sales in the forum. But as this Court has long recognized, "it [is] significant that the constitutional catch-phrase ['arise out of or relate to'] is disjunctive in nature." *Akro Corp. v. Luker*, 45 F.3d 1541, 1548 (Fed. Cir. 1995) (internal quotation marks and citation omitted; alterations in original). The broader "related to" standard "indicate[s] 'added flexibility and signal[s] a relaxation of the applicable standard' from a pure 'arise out of' standard." *Id.* (quoting *Ticketmaster-New York, Inc. v. Alioto*, 26 F.3d 201, 206 (1st Cir. 1994)). Whatever the outer bounds of this standard, it is easily satisfied by contacts—planned sales in the forum—that provide the actual basis for determining liability in the plaintiff's suit.

In short, recognizing that a generic applicant's prospective sales in a forum may give rise to specific jurisdiction would keep ANDA litigation in line with ordinary patent litigation—just as the Hatch-Waxman Act contemplates. *See, e.g.*, *Glaxo*, 110 F.3d at 1569 ("The only difference in actions brought under § 271(e)(2) is that the allegedly infringing drug has not yet been marketed . . . ."). In Hatch-Waxman, courts should evaluate specific jurisdiction just as they evaluate substantive liability: based on the sales the generic applicant seeks approval to make.

Focusing on where the generic defendant intends to sell the infringing product is perfectly consistent with the applicable principles of fairness. The

generic defendant chooses to file the Paragraph IV certification and fully expects to be haled into court if it does so. *See Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1677 (2012) ("Filing a paragraph IV certification means provoking litigation."). Indeed, in one key respect the generic defendant actually *benefits* from being sued promptly—the ANDA process, including the litigation, allows the defendant to test its ability to sell a drug in a state (and throughout the country) without exposure to damages. This approach to specific jurisdiction also honors the forum's interest in adjudicating whether a product may be sold within its borders, *see N. Am. Philips Corp.*, 35 F.3d at 1580—an interest that exists whether the infringement determination is made before or after the sales occur.

2. Mylan's Contrary Approach Would Eliminate Specific Jurisdiction in ANDA Litigation

Mylan's contrary approach would create an unprecedented situation: in ANDA cases there may be no specific jurisdiction over infringement defendants *anywhere*. One potential forum is foreclosed by this Court's precedent. Mylan focuses on the ANDA filing as the event that gives rise to a brand manufacturer's cause of action. *See* Mylan Br. 42-44. But this Court has held—at Mylan's urging—that filing an ANDA does *not* qualify as a jurisdictional contact for specific jurisdiction. *See Zeneca Ltd. v. Mylan Pharm., Inc.*, 173 F.3d 829, 832-33 (Fed. Cir. 1999) (opinion of Gajarsa, J.); *id.* at 834-36 (Rader, J., concurring).

Aware of this dead-end, Mylan raises one potential alternative. It claims that specific jurisdiction over ANDA defendants may "often be appropriate in the forum where the ANDA was prepared." Mylan Br. 39-40 & n.14. But that suggestion is inconsistent with Mylan's own argument that future sales do not count as contacts for specific jurisdiction because the infringement claim supposedly "does not arise from or relate to" such sales. *Id.* at 44. Mylan's reasoning applies equally to forum contacts from ANDA preparation, because infringement claims *cannot* arise from that activity: making or using a patented product to prepare an ANDA to submit to FDA is not infringement. *See* 35 U.S.C. § 271(e)(1); A16 n.13. It would be exceptionally odd to hold that future infringing sales are too attenuated from the infringement cause of action to support specific jurisdiction—even though *the point* of ANDA litigation is to assess whether future sales in the forum would violate the patent—while allowing the plaintiff to establish jurisdiction based on activities that are *exempt* from infringement liability.

Thus, if Mylan's argument is taken to its logical conclusion, there will be no specific jurisdiction in ANDA litigation—the infringement claim will be "related to" nothing and nowhere. But fear not, Mylan insists: pioneer drug manufacturers will still have someplace to file suit because corporate defendants are subject to *general* jurisdiction in their state of incorporation and principal place of business.

See Mylan Br. 39. Of course, many ANDA applicants are foreign companies, which are both incorporated and have their principal place of business outside the United States. *See* 21 C.F.R. §§ 314.50(a)(5), 314.94(a)(1) (recognizing that drug applications may be submitted by entities that "do[] not reside or have a place of business within the United States"). Under Mylan's rule and this Court's precedent, *those* companies might well be subject to suit in *any* federal district, on the theory that they would have minimum contacts with the United States as a whole but not with any state. *See* Fed. R. Civ. P. 4(k)(2); *Merial Ltd. v. Cipla Ltd.*, 681 F.3d 1283, 1294 (Fed. Cir. 2012). By contrast, companies with a U.S. presence like Mylan could be sued *only* in the one or at most two states where they are "at home" for all purposes.[4]

But even leaving that strange result aside, the limited backstop of general jurisdiction is no replacement for a coherent specific-jurisdiction doctrine. As the Supreme Court indicated in *Daimler AG*—a case Mylan relies on heavily—"specific jurisdiction has become the centerpiece of modern jurisdiction theory, while general jurisdiction [has played] a reduced role." 134 S. Ct. at 755 (internal quotation marks and citation omitted; alternations in original). It would be

[4] Contrast that odd result with the one venue rule that Congress wrote into Hatch-Waxman: where the brand does not sue the generic within 45 days, and the generic opts to seek a declaratory judgment rather than risk damages by launching its product, the generic must sue in the *brand's* home district. 21 U.S.C. § 355(j)(5)(C); *accord id.* § 355(j)(3)(D).

extraordinary to declare that an entire category of litigation does not "relate to" any jurisdiction and must instead be relegated to the "'imperfect safety valve'" of general jurisdiction. *Id.* at 758 n.9 (quoting Patrick J. Borchers, *The Problem With General Jurisdiction*, 2001 U. Chi. Legal Forum 119, 139).

There is no need to do so. When a generic manufacturer files an ANDA with a Paragraph IV certification and thus seeks to distribute an infringing drug in a forum through an established network, the manufacturer has directed its infringing conduct to that forum and should be subject to specific jurisdiction there for patent-infringement claims. The generic manufacturer should not be allowed to use the Hatch-Waxman Act's structure—a structure designed to balance the interests of patent holders and generic manufacturers— to insist on home-court advantage in every case.[5] As the district court put it, "the Hatch-Waxman Act was not intended to burden patent holders or reduce the patent protection afforded in ANDA cases." A17.

II. Eliminating Specific Jurisdiction In Section 271(e)(2) Suits Would Frustrate the Hatch-Waxman Act's Objectives

The Hatch-Waxman Act is built for speed and efficiency. The Act both facilitates and presupposes the prompt resolution of patent disputes to get generic

[5] As AstraZeneca notes, Mylan's site-of-preparation approach would, "[a]s a practical matter," produce the same result because generic applicants typically prepare ANDAs in the state where they have their principal place of business. AstraZeneca Br. 30.

drugs onto the market as quickly as possible while respecting the exclusivity rights of patent holders. Mylan's approach to specific jurisdiction in ANDA cases flies in the face of the Act's design by making ANDA litigation slower, more costly, and less predictable in cases involving multiple generic applicants with different corporate "homes."

It is common for multiple generic companies to file Paragraph IV certifications challenging the same patent. In that circumstance, there are obvious efficiency gains to be had from conducting the patent litigation in a single forum, typically before a single district court judge who can gain familiarity with the questions presented and issue consistent decisions. But that course would often be unavailable if this Court adopts Mylan's approach in these cases. Instead, brand manufacturers would have to file suit in the different home forum of each generic applicant. This will cause wasteful duplication of litigation efforts and risk inconsistent adjudications. While mechanisms exist to mitigate these problems, *see* 28 U.S.C. § 1407, they are time-consuming and do not provide an adequate substitute to a commonsense rule that allows brand manufacturers to sue generic applicants in a single forum where they each intend to distribute their generic drugs.

A. Requiring Brand Manufacturers To Sue Each ANDA Filer in Its Home Forum Would Lead to Inefficient Litigation

In this case, AstraZeneca filed suit against 10 generic defendant groups that filed ANDA applications. A17. As the district court recognized, that is par for the course in ANDA litigation. *Id.*[6] Brand manufacturers frequently face multiple ANDA certifications for the same drug. A 2011 Federal Trade Commission study found that some drugs with New-Chemical Entity Exclusivities[7] were "subject to as many as *sixteen* first-day ANDAs with [Paragraph] IV certifications." FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* 136 (Aug. 2011) (emphasis added). Between 2002 and 2008, the yearly average for first-day certifications ranged from three to eleven. *See id.* at 136 tbl. 7-5.

Teva's experience is consistent with the statistics. As the holder of New Drug Applications for Copaxone®, Teva has faced multiple ANDAs with respect to the drug's 20mg and 40mg formulations. In the case of the 20mg product, Teva filed suit against the two groups of ANDA filers (one of which included Mylan) in the Southern District of New York. *See Teva Pharm. USA, Inc. v. Sandoz Inc.*, 810

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[6] In the companion case to this appeal, No. 15-1456, the brand manufacturer Acorda Therapeutics, Inc., faced "eight generic challenges to its principal product." *Acorda Therapeutics, Inc. v. Mylan Pharm. Inc.*, __ F. Supp. 3d __, 2015 WL 186833, at *17 (D. Del. Jan. 14, 2015).

[7] New chemical entities are drugs for which the active ingredient has not previously received FDA approval. *See* 21 C.F.R. § 314.108. For such drugs, ANDAs with Paragraph IV certifications cannot be submitted until a known date four years after the brand drug was approved. *See id.* § 314.108(b).

F. Supp. 2d 578, 581 (S.D.N.Y. 2011) (noting the cases were consolidated). Similarly, Teva has to date filed five suits in the District of Delaware with respect to the 40mg product against five different Paragraph IV filers.[8] On the flip side, Teva has regularly been a defendant in ANDA litigation where it is one of many generic filers. For example, Teva is currently involved as a defendant in ANDA litigation before a single Judge in the District of New Jersey—a state where Teva is neither headquartered nor incorporated—in one of more than *two dozen* related cases arising from applications to market generic versions of the drug Abilify®. *See Otsuka Pharm. Co. v. Torrent Pharm. Ltd.*, __ F. Supp. 3d. __, 2015 WL 1782653, at *4 (D.N.J. Apr. 16, 2015).[9]

If Mylan's approach were accepted, then ANDA cases like these would have to proceed separately in each generic defendant's home jurisdiction. The resulting proliferation of suits in different courts to address closely related (and highly technical) issues concerning patent construction and validity will inevitably lead to

[8] *See* Nos. 14-cv-1171-GMS, 14-cv-1172-GMS, 14-cv-1278-GMS, 14-cv-1419-GMS, 15-cv-124-GMS (D. Del.). Teva also filed a protective suit against Mylan in the Northern District of West Virginia, No. 14-cv-167 (N.D.W. Va).

[9] Mylan is a defendant in one of the related cases. The district court rejected the motion to dismiss raised by the Mylan entities (with the exception of a foreign subsidiary) based on a consent theory of general jurisdiction. *See Otsuka Pharm. Co. v. Mylan Inc.*, __ F. Supp. 3d __, 2015 WL 1305764, at *8-*12 (D.N.J. Mar. 23, 2015); see also id. at 12 n.15 (declining to "reach the issue of whether future intent to distribute serves as a sufficient forum-related contact for purposes of specific jurisdiction").

"wastefulness of time, energy and money." *Cont'l Grain Co. v. The Barge FBL-585*, 364 U.S. 19, 26 (1960). It will also likely lead to unpredictable variations in results, as district judges scattered throughout the country make factual findings on critical issues that this Court will then review deferentially.

Congress has recognized the value of ANDA infringement actions proceeding before a single tribunal. In the Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 19, 125 Stat. 284, 332-33 (2011), Congress placed limits on joinder for most patent-infringement actions, providing that "accused infringers may not be joined in one action as defendants . . . or have their actions consolidated for trial, based solely on allegations that they each have infringed" the same patent or patents. 35 U.S.C. § 299(b). But Congress specifically exempted ANDA litigation from this anti-joinder rule. *See id*. § 299(a). Mylan's approach to personal jurisdiction would undo Congress's solicitude for ANDA litigation in the mine-run of cases. While brand manufacturers could in theory join two or more generic defendants challenging the same patent—or, as is more common, the district court could consolidate the cases for trial—in practice the manufacturer would be unlikely to find a suitable forum in which it can sue all of the defendants.

B. Coordination Mechanisms Like the Multidistrict Litigation Process Do Not Compensate For the Inefficiency of Restricting Specific Jurisdiction in ANDA Cases

Patent holders and the courts have only limited options to counteract the inefficiencies that Mylan's approach to personal jurisdiction would create. For example, courts cannot order transfers pursuant to 28 U.S.C. § 1404, because actions cannot be transferred to forums lacking personal jurisdiction over a defendant without the defendant's consent. *See* 28 U.S.C. § 1404(a); *Hoffman v. Blaski*, 363 U.S. 335, 343-44 (1960) (interpreting an earlier version of the statute, which lacked a consent exception).

The Generic Pharmaceutical Association ("GPhA") argues that the multi-district litigation ("MDL") statute provides the answer, and it points to a statement in a Hatch-Waxman Act Committee Report noting the availability of the MDL process. *See* GPhA Br. 10 (citing H.R. Rep. No. 98-857(I), at 28 (1984)). The Committee Report, however, does not address whether Congress believed personal-jurisdiction rules would limit a plaintiff's ability to file suit in a single forum, thus forcing courts and litigants to resort to the MDL process in the ordinary course. Rather, the Report merely suggests that "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." *Id.* In any event, whatever a House Committee may have

believed in 1984, subsequent experience with the MDL process shows that it is at best a limited solution to the problem Mylan's proposal would create.

At the most basic level, the litigation delay built into the MDL process is a poor fit for the expedited proceedings contemplated by the Hatch-Waxman Act. A party will typically file a motion with the Judicial Panel on Multidistrict Litigation ("JPML"), which triggers a round of briefing followed by oral argument and a written order. Assuming the JPML agrees to centralization, the parties must wait for the MDL transferee court to receive and docket the records and to schedule an initial status conference. In 2008, the Chair of the JPML estimated that the complete process consumes between 16 and 29 weeks. *See* John G. Heyburn, II, *A View from the Panel: Part of the Solution*, 82 Tul. L. Rev. 2225, 2243 & n.91 (2008). In Teva's recent experience, delays at the high end of this range are not uncommon. *See, e.g.*, *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 999 F. Supp. 2d 1383 (JPML 2014) (over 24 weeks between Teva's section 1407 motion and the MDL court's first order concerning scheduling). Moreover, in many cases, merits litigation will grind to a halt during the delay, because district courts frequently stay proceedings pending an MDL determination. *See* Heyburn, *supra*, at 2241.

The time lost on non-merits issues is time that ANDA litigants—both plaintiffs and defendants—do not have. As discussed, *supra* at 9-10, Congress's

creation of an artificial act of infringement allows generic and pioneering drug companies to resolve their patent disputes early. And they are expected to do so quickly. When the generic manufacturer submits an ANDA with a Paragraph IV certification, the patent holder must file suit within 45 days to obtain an automatic 30-month stay on FDA approval of the ANDA. *See* 21 U.S.C. § 355(j)(5)(B)(iii). "[H]istorically," this 30-month period has "approximated the . . . duration of a patent lawsuit." FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* 39 (July 2002). District courts may adjust the stay period as a sanction against a party that "fail[s] to reasonably cooperate in expediting the action." 21 U.S.C. § 355(j)(5)(B)(iii).

While ANDA litigation may, of course, extend beyond the 30-month stay in complex cases, building several months of delay into every case with multiple generic defendants would upset the Hatch-Waxman Act's design. Delay undermines the Act's promise to brand and generic manufacturers alike that they will receive a swift decision about their respective rights before a potential generic launch dramatically alters the status quo. Delay thus increases the risk that generic drugs will flood the market and vitiate the brand's exclusivity rights before the litigation even ends. *See* AstraZeneca Br. 39-40. Conversely, delay forces generic manufacturers either to forgo competition or to risk substantial liability if they guess wrong about how the patent litigation will turn out.

Even aside from the problem of delay in setting up the MDL, the upside of the process would be limited in cases where the MDL court lacks personal jurisdiction over many of the generic applicants and thus cannot retain those cases for trial without consent.[10] When the Hatch-Waxman Act was enacted in 1984, MDL courts routinely retained the cases before them, reasoning that self-transfers promote judicial efficiency and avoid "further extensive delay in litigation which already is among the most time consuming to appear on the federal dockets." *Pfizer, Inc. v. Lord*, 447 F.2d 122, 125 (2d Cir. 1971). The Supreme Court subsequently rejected that common practice, *see Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 40 (1998), but courts still frequently arrange for cases to be transferred back to the MDL court for trial to take advantage of that judge's familiarity with the litigation and to allow for consolidation where appropriate. *See* William J. Martin, Comment, *Reducing Delays in Hatch-Waxman Multidistrict Litigation*, 71 U. Chi. L. Rev. 1173, 1184-86 (2004) (describing ANDA litigation where cases were transferred back to the MDL court following initial remands, while noting that this process increased delay in comparison to the pre-*Lexecon* practice of self-transfers).

[10] The JPML is allowed to transfer cases under section 1407 to "any district," regardless of whether that district has personal jurisdiction over the defendant, because the transfer "is solely for pretrial proceedings." 15 Charles Alan Wright et al., *Federal Practice and Procedure* § 3862 (4th ed.). By contrast, as discussed, *supra* at 21, a district court may not transfer the entire action to a court that lacks personal jurisdiction over the defendant without the defendant's consent.

Complete transfer would not be an option if Mylan's approach to personal jurisdiction prevails. Instead, the multiple infringement and validity cases concerning the same patent would have to return to the home jurisdictions of each ANDA applicant for separate trials, and the brand manufacturer would have to participate in separate litigation in each far-flung forum, all within the Hatch-Waxman Act's 30-month timeframe. That would add to the time and expense of the litigation and exacerbate the mismatch between ANDA litigation and the MDL process.

CONCLUSION

For the foregoing reasons, the Court should hold that Mylan is subject to specific jurisdiction in Delaware based on its declared intention to distribute an allegedly infringing product into the state through an established distribution network. The order of the district court denying Mylan's motion to dismiss should be affirmed.

July 23, 2015

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CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the type-volume limitations set forth in Fed. R. App. P. 32(a)(7)(B) because this brief contains 6,017 words, excluding those parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and Fed. Cir. R. 32(b). I further certify that the brief complies with the typeface requirements of Fed. R. App. 32(a)(5) and the style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface, 14-point Times New Roman, using Microsoft Word.

Dated: July 23, 2015

/s/ William M. Jay
William M. Jay

CERTIFICATE OF SERVICE

I hereby certify that on July 23, 2015, I electronically filed the foregoing brief using the Court's CM/ECF system, which will send notice of such filing to counsel for all parties.

Dated: July 23, 2015

/s/ William M. Jay
William M. Jay