ELI LILLY AND COMPANY, et al., Plaintiffs, vs. MYLAN PHARMACEUTICALS, INC., MYLAN, INC., MYLAN LABORATORIES, LTD., et al., Defendants.

1:14-cv-00389-SEB-TAB

UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF INDIANA, INDIANAPOLIS DIVISION

2015 U.S. Dist. LEXIS 30175

March 12, 2015, Decided
March 12, 2015, Filed

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JUDGES: SARAH EVANS BARKER, United States District Judge.

OPINION BY: SARAH EVANS BARKER

OPINION

ORDER DENYING THE MYLAN DEFENDANTS' MOTION TO DISMISS FOR LACK OF PERSONAL JURISDICTION

This cause is before the Court on the Motion to Dismiss [Docket No. 150], filed on May 2, 2014, by Defendants Mylan Pharmaceuticals, Inc., Mylan, Inc., and Mylan Laboratories, Ltd. (collectively, "the Mylan Defendants").[1] The Mylan Defendants contend that we lack personal jurisdiction over them and seek dismissal of the Complaint against them. Plaintiffs Eli Lilly and Company, Daiichi Sankyo Co., Ltd., Daiichi Sankyo, Inc., and Ube Industries, Ltd. (collectively, "Plaintiffs") rejoin that this court does have personal jurisdiction over the Mylan Defendants, and further, if we determine there is no personal jurisdiction, the proper remedy is not to dismiss, but rather to transfer the case to an appropriate forum.

1 On November 17, 2014, the Mylan Defendants filed a Motion for Oral Argument [Docket No. 284]. Because we are able to rule based on the parties' written submissions, that motion is DENIED.

On May 30, 2014, Plaintiffs moved for time to conduct jurisdictional discovery regarding the Mylan **[*8]** Defendants' contacts with Indiana, and the Magistrate Judge granted that request as well as an enlargement of time to respond to the Mylan Defendants' motion to dismiss. That discovery period has now ended and the Mylan Defendants' Motion to dismiss is fully briefed and ripe for ruling. For the reasons detailed below, we DENY the Mylan Defendants' Motion.

Factual Background

Plaintiffs have brought this claim against the Mylan Defendants and others alleging that Defendants infringed three of Plaintiffs' patents by filing an Abbreviated New Drug Application ("ANDA") with the FDA seeking approval to sell generic versions of Eli Lilly's pharmaceutical product Effient®. Effient® is an anti-thrombotic drug approved for use in the United States to prevent or reduce the risk of blood clots and stent thrombosis in patients suffering from acute coronary syndrome who receive stents. The patents at issue protect the molecule prasugrel hydrochloride, the active ingredient in Effient® (U.S. Patent No. 5,288,726 (the '726 patent)), and methods of using Effient® and aspirin, as directed on the label (U.S. Patent No. 8,404,703 and 8,569,325 (the '703 and '325 patents)).

The Mylan Defendants are three of the forty original defendants who challenged the validity of Plaintiffs' patents that cover **[*9]** Effient®.[2] Defendant Mylan, Inc. ("Mylan") is one of the world's leading generic and specialty pharmaceutical companies with over 20,000 employees in its family of companies. Mylan markets more than 1,300 separate products in approximately 140 different countries and territories. Mylan is a Pennsylvania corporation with its principal place of business in Canonsburg. Two of Mylan's subsidiary corporations -- Defendants Mylan Pharmaceuticals, Inc. ("Mylan Pharmaceuticals") and Mylan Laboratories, Ltd. ("Mylan Laboratories") -- are named in this litigation and have joined Mylan in this motion to dismiss. Mylan Pharmaceuticals is incorporated in West Virginia with its principal place of business in Morgantown, West Virginia. Mylan Laboratories is a corporation organized and existing under the laws of India with its principal place of business in Hyderabad, India.

> 2 The Mylan Defendants are the only defendants to challenge the '726 patent, however. They are also the only defendants who have challenged personal jurisdiction over them in Indiana.

The Mylan Defendants do not have offices or facilities in Indiana nor do they have a telephone listing or mailing address in Indiana. Although the Mylan Defendants **[*10]** assert in their opening brief that they have no employees or officers in Indiana (Tighe Decl. ¶ 6), deposition testimony establishes that Mylan Pharmaceuticals has at least four employees who do live in Indiana, including two members of the company's eight-to-ten member National Account Managers group, which manages Mylan's national sales relationships. Exh. 3 at 70-71. Mylan Pharmaceuticals obtained a wholesaler drug license allowing it to sell its generic products in Indiana and its Indiana sales include dozens of Mylan products. *Id*. at 63, 201. Mylan Pharmaceuticals sells Mylan products directly to retailers in Indiana as well as to wholesalers, knowing that the wholesalers sell their products in Indiana. *Id*. at 65, 69. Mylan Pharmaceuticals also makes sales calls and directs promotional materials to residents of Indiana. Exh. 5.

On July 10, 2013, Mylan Pharmaceuticals submitted an ANDA to the Food and Drug Administration ("FDA") seeking approval to market generic prasugrel hydrochloride tablets in the United States. The ANDA was prepared in West Virginia and filed in Maryland. The ANDA included a "Paragraph IV" certification that the '726, '703, and '325 patents exclusively licensed to Eli Lilly are invalid, unenforceable, and **[*11]** will not be infringed. Mylan Pharmaceuticals also directed a Notice Letter to Lilly in Indiana, informing Lilly of its Paragraph IV certification as required under the Hatch-Waxman Act. Plaintiffs then filed in this court their complaint for patent infringement, alleging, *inter alia*, that the Mylan Defendants "market[] and provide[]" generic drugs to Indiana residents. Compl. ¶¶ 90-92. Plaintiffs filed their complaint in this court within 45 days of receiving the Notice Letter, triggering the statutorily prescribed 30-month stay during which the Mylan Defendants are prohibited from proceeding with sales of their generic drug. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

Legal Analysis

I. Standard of Review

Federal Rule of Civil Procedure 12(b)(2) requires dismissal of a claim where personal jurisdiction is lacking. When "[a] defendant moves to dismiss the complaint under Federal Rule of Civil Procedure 12(b)(2) for lack of personal jurisdiction, the plaintiff bears the burden of demonstrating the existence of jurisdiction." *Purdue Research Found. v. Sanofi-Synthelabo, S.A.*, 338 F.3d 773, 782 (7th Cir. 2003) (citations omitted). When a district court rules on a defendant's motion to dismiss based on the submission of written materials, the plaintiff "need only make out a *prima facie* case of personal jurisdiction" and "is entitled to the resolution in its favor of all disputes concerning **[*12]** relevant facts presented in the record." *Id*. (internal quotation marks and citations omitted).

Federal Circuit law governs personal jurisdiction issues in patent infringement cases. *See Hildebrand v. Steck Mfg. Co.*, 279 F.3d 1351, 1354 (Fed. Cir. 2002). A district court may properly exercise personal jurisdiction over a non-resident defendant if a two-step analysis is undertaken and satisfied. First, the party resisting the exercise of jurisdiction must be amenable to service of process under the state's long-arm statute; second, the exercise of personal jurisdiction must comport with the due process clause of the Constitution. *Id*. Because Indiana's long-arm statute, Indiana Rule of Trial Procedure 4.4(A), "expand[s] personal jurisdiction to the full extent permitted by the Due Process Clause," *LinkAmerica Corp. v. Cox*, 857 N.E.2d 961, 966 (Ind. 2006), the sole question before us is whether due process

would be offended were we to exercise personal jurisdiction over the Mylan Defendants.

For a court to acquire personal jurisdiction over a defendant, due process requires "that the defendant have such 'minimum contacts' with the forum state as will make the assertion of jurisdiction over him consistent with 'traditional notions of fair play and substantial justice[.]'" *Lakeside Bridge & Steel Co. v. Mountain State Constr. Co.*, 597 F.2d 596, 600 (7th Cir. 1979) (quoting *International Shoe Co. v. Washington*, 326 U.S. 310, 316, 66 S. Ct. 154, 90 L. Ed. 95 (1945)). In other words, defendants must have "fair warning that a particular activity may subject **[*13]** them to the jurisdiction of a foreign sovereign." *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472, 105 S. Ct. 2174, 85 L. Ed. 2d 528 (1985) (quotation marks and citation omitted).

Personal jurisdiction may be either specific or general. A court exercises specific jurisdiction over a defendant where the cause of action arises out of or relates to a defendant's purposefully established contacts with the forum state. *Helicopteros Nacionales de Colombia, S. A. v. Hall*, 466 U.S. 408, 414, 104 S. Ct. 1868, 80 L. Ed. 2d 404 (1984); *Burger King Corp.*, 471 U.S. at 472. General jurisdiction, on the other hand, does not require that the cause of action arise out of contacts with the forum state. *Helicopteros*, 466 U.S. at 416. General jurisdiction exists where the defendant's contacts with the forum "are so continuous and systematic as to render it essentially at home in the forum State." *Daimler AG v. Bauman*, 134 S.Ct. 746, 761, 187 L. Ed. 2d 624 (2014) (quoting *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 131 S.Ct. 2846, 2851, 180 L. Ed. 2d 796 (2011)).

II. Discussion

Plaintiffs' Complaint asserts general jurisdiction as the sole basis for bringing this ANDA infringement action against the Mylan Defendants in Indiana. The Mylan Defendants contend that the Supreme Court's recent decision in *Daimler AG v. Bauman*, 134 S.Ct. 746, 187 L. Ed. 2d 624 (2014), altered the analysis with respect to general jurisdiction such that Plaintiffs cannot establish that the Southern District of Indiana has general jurisdiction over the Mylan Defendants in this ANDA lawsuit. The Mylan Defendants further argue that their relationship with Indiana and this litigation is insufficient to support **[*14]** the exercise of specific jurisdiction in this case.

Given the Mylan Defendants' jurisdictional challenge, Plaintiffs bear the burden of showing the basis for this court's jurisdiction. Plaintiffs now apparently concede that this court cannot exercise general personal jurisdiction over any of the Mylan Defendants on the basis of their being "at home" in Indiana, as that concept is defined in *Daimler*.[3] Plaintiffs instead contend that the Mylan Defendants purposefully directed their conduct toward Indiana in this case by: (1) making a Paragraph IV ANDA filing that knowingly challenges intellectual property rights held by Lilly in Indiana and directing a Notice Letter to Lilly in Indiana; and (2) intending to sell their generic Effient® product in Indiana. It is Plaintiffs' position that these purposeful contacts with Indiana are sufficient to support the exercise of specific personal jurisdiction in this forum.

> 3 In *Daimler*, the Supreme Court made clear that in assessing whether general jurisdiction is available, courts must determine not just whether a defendant's "in-forum contacts can be said to be in some sense 'continuous and systematic,'" but rather whether the defendant's "'affiliations **[*15]** with the State are so "continuous and systematic" as to render [it] essentially at home in the forum state.'" 134 S.Ct. at 761 (quoting *Goodyear*, 131 S.Ct. at 2851 (2011). The *Daimler* Court further clarified that in all but "exceptional cases," a corporation is "at home" only in its "place of incorporation and principal place of business," which are the "paradig[m] ... bases for general jurisdiction." 134 S.Ct. at 760 (alterations in original) (internal quotation marks omitted).

A. General Jurisidiction

In ANDA litigation prior to *Daimler*, "general jurisdiction traditionally provided the basis to assert jurisdiction over generic drug company defendants." *Astrazeneca AB v. Mylan Pharms., Inc.*, F. Supp. 3d , No. 14-696-GMS, 2014 U.S. Dist. LEXIS 156660, 2014 WL 5778016, at *3 (D. Del. Nov. 5, 2014) (citation omitted); *see, e.g., Eli Lilly and Co. v. Mayne Pharma (USA) Inc.*, 504 F. Supp. 2d 387 (S.D. Ind. 2007) (focusing on the defendant's regular business solicitation and distribution of substantial quantities of pharmaceuticals in the forum as well as substantial revenues from those sales); *Eli Lilly and Co. v. Sicor Pharms., Inc.*, No. 1:06-cv-238-SEB-JMS, 2007 U.S. Dist. LEXIS 31657, 2007 WL 1245882 (S.D. Ind. Apr.

27, 2007) (same); *Abbott Labs. v. Mylan Pharms., Inc*., No. 05 C 6561, 2006 U.S. Dist. LEXIS 13782, 2006 WL 850916 (N.D. Ill. Mar. 28, 2006) (same). However, the Supreme Court's decision in *Daimler* has altered the general jurisdiction analysis such that the factors on which courts have traditionally focused in ANDA cases, to wit, a history of business solicitation and substantial past sales and revenue generated in the forum, in most cases are no longer **[*16]** sufficient without more to support an exercise of general jurisdiction. *See* 134 S.Ct. at 761-62 (finding that a test under which general jurisdiction existed in every forum in which a defendant's sales are sizable would be "unacceptably grasping" and "exorbitant").

Although the *Daimler* Court noted that it was not "foreclose[ing] the possibility that in an exceptional case ... a corporation's operations in a forum other than its formal place of incorporation or principal place of business may be so substantial and of such a nature as to render the corporation at home in that State," (*id*. at 761 n.19), Plaintiffs make no attempt to argue that this is such an exceptional case nor does the evidence before us support that conclusion. Accordingly, we agree with the Mylan Defendants that Plaintiffs have failed to establish that general jurisdiction exists here under the framework set forth in *Daimler*.

B. Specific Jurisdiction

Whether Plaintiffs have demonstrated that there is a basis to assert specific jurisdiction over the Mylan Defendants[4] in this case is a stickier issue. Only a few district courts have had occasion to address specific jurisdiction in the context of ANDA litigation since *Daimler*, including *Acorda Therapeutics, Inc. v. Mylan Pharamceuticals Inc*., F. Supp. 3d , 2015 U.S. Dist. LEXIS 4056, 2015 WL 186833 (D. Del. Jan. 14, 2015) and *Astrazeneca AB v. Mylan Pharmaceuticals, Inc*., F. Supp. 3d , 2014 U.S. Dist. LEXIS 156660, 2014 WL 5778016 (D. Del. Nov. 5, 2014).[5] In both of these cases, **[*17]** the District Court for the District of Delaware focused at least to some degree on the unique nature of ANDA litigation to support its exercise of specific jurisdiction over the defendants. We agree with the analysis set forth in these opinions,[6] and find for the reasons detailed below that specific jurisdiction exists here over the Mylan Defendants.

4 We are mindful that in cases involving multiple defendants such as this, "personal jurisdiction must be assessed separately as to each defendant...." *Sicor Pharms., Inc*., 2007 U.S. Dist. LEXIS 31657, 2007 WL 1245882, at *5 (citing *Rush v. Savchuk*, 444 U.S. 320, 331-32, 100 S. Ct. 571, 62 L. Ed. 2d 516 (1980)). Here, Plaintiffs assert that "Mylan, Inc. and Mylan Labs are subject to specific jurisdiction to the same extent as Mylan Pharmaceuticals, given their joint roles in the purposefully directed conduct that precipitated the lawsuit." Pls.' Resp. at 13. The Mylan Defendants have not meaningfully differentiated among the three entities in their motion to dismiss and they concede that the "Mylan Defendants" collectively "prepared the ANDA." Defs.' Opposition to Motion for Jurisdictional Discovery at 9. The Mylan Defendants have also not challenged Plaintiffs' contention that Mylan, Inc. "directed and participated in the strategy for approval of this ANDA" and that Mylan Labs was "heavily **[*18]** involved with Mylan Pharmaceuticals in preparing the ANDA filing." Pls.' Resp. at 14. For these reasons, we are persuaded that Mylan Pharmaceutical's relevant contacts can and should be attributed to Mylan, Inc. and Mylan Labs.

5 The District Court for the Eastern District of Texas also addressed this issue in *Allergan, Inc. v. Actavis, Inc*., No. 2:14-CV-188, 2014 U.S. Dist. LEXIS 176551, 2014 WL 7336692 (E.D. Tex. Dec. 23, 2014). However, the court limited its holding on specific jurisdiction to the plaintiff's declaratory judgment claims. Because such claims are not at issue here, the Texas case has limited applicability to our analysis.

6 We note that, on December 17, 2014, Judge Sleet certified an interlocutory appeal of his order in *AstraZeneca* to the Federal Circuit, reasoning that the existence of personal jurisdiction in ANDA cases following *Daimler* is "a controlling (and novel) question of law for which there is substantial ground for difference of opinion." *AstraZeneca AB v. Aurobindo Pharma Ltd*., No. 14-664-GMS, 2014 U.S. Dist. LEXIS 180548, 2014 WL 7533913, at *1 n.1 (D. Del. Dec. 17, 2014). We share that view that this question is an important matter of first impression in the ANDA context.

Specific jurisdiction exists where "the defendant has 'purposefully directed' his activities at residents of the

forum, and the litigation results **[*19]** from alleged injuries that 'arise out of or relate to' those activities." *Burger King*, 471 U.S. at 472-73 (internal citations omitted). This standard can be difficult to apply in the context of ANDA litigation, however, given the nature of the process created by the Hatch-Waxman Act. The statute was enacted with the purpose of balancing "two competing interests in the pharmaceutical industry: '(1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market.'" *Janssen Pharmaceutica, N.V. v. Apotex, Inc*., 540 F.3d 1353, 1355 (Fed. Cir. 2008) (quoting *Andrx Pharms., Inc. v. Biovail Corp*., 276 F.3d 1368, 1371 (Fed. Cir. 2002)). In order to achieve that balance, in addition to creating the ANDA process, the Act amended the patent laws to exempt pre-ANDA testing and development activity, but to make the filing of a Paragraph IV Certification an act of patent infringement, thus allowing brand drug companies the right to initiate an infringement lawsuit before a generic drug is marketed. 540 F.3d at 1356.

The difficulty in applying the specific jurisdiction analysis arises in part because the Supreme Court has recognized that a Paragraph IV act of patent infringement is "a highly artificial act." *Eli Lilly & C. v. Medtronic, Inc*., 496 U.S. 661, 678, 110 S. Ct. 2683, 110 L. Ed. 2d 605 (1990). Because the act is "a statutory creation, distinct from making, using, or selling a patented technology" it **[*20]** therefore "has no readily apparent situs of injury for the purpose of finding specific jurisdiction." *Astrazeneca*, 2014 U.S. Dist. LEXIS 156660, 2014 WL 5778016, at *6. At the same time, litigation is expected to follow a Paragraph IV filing as, under the Hatch-Waxman Act, patent holders are given forty-five days following receipt of notice of the filing of the certification to initiate an infringement lawsuit thereby triggering the automatic thirty-month stay for FDA-approval of the generic drug. Thus, as the court in *AstraZeneca* explained, under the Hatch-Waxman framework: "The injury is abstract, making it difficult to point to a location out of which the injury 'arises' for jurisdictional purposes. At the same time, defending against an infringement lawsuit is an inherent and expected part of the ANDA filer's business. To put it simply: a lawsuit is often inevitable, but it is not clear where it should be held."[7] *Id*.

> 7 The uniqueness of this type of patent infringement litigation is likely a reason why specific jurisdiction has not traditionally been favored in ANDA cases. However, the narrowing of the general jurisdiction doctrine in *Daimler* (which was not an ANDA case) may well shift the focus toward specific jurisdiction in these cases.

The Federal **[*21]** Circuit has recognized that the fact that the Supreme Court has viewed the act of submitting an ANDA to be "'highly artificial' ... is not a proper reason ... to conclude that the ANDA filing is not a 'real act' with 'actual consequences.'" *Zeneca Ltd. v. Mylan Pharms., Inc*., 173 F.3d 829, 833-34 (Fed. Cir. 1999) (quoting *Medtronic*, 496 U.S. at 663-664). The question then becomes, where are those "actual consequences" felt? In *Zeneca*, the Federal Circuit held that Maryland -- the location of the FDA and the place where ANDAs must be filed -- could not exercise specific jurisdiction over ANDA filers; this conclusion clearly was to avoid the Maryland district court having jurisdiction in all ANDA cases. 173 F.3d at 832. The Mylan Defendants argue here that their filing of the Paragraph IV certification was not "intentionally targeted" at the state of Indiana where Lilly resides, nor was the State the "focal point" of the alleged infringement.[8] Defs.' Reply at 4-5. However, given the holding in *Zeneca*, our acceptance of Defendants' argument would suggest a conclusion that the act of filing an ANDA is not directed to *any* jurisdiction, a result we find illogical. *See AstraZeneca*, 2014 U.S. Dist. LEXIS 156660, 2014 WL 5778016, at *7. Thus, the logical alternative is to view the act of filing as being directed to the state of residence for the patent holder. *Id*.

> 8 The Mylan **[*22]** Defendants argue that the appropriate factor on which to focus for determining where specific jurisdiction exists is the location(s) "where the ANDA was studied, drafted, compiled, and signed," (Defs.' Reply at 12), which in this case would be West Virginia. It is true that a number of district courts have found that it is proper to exercise specific jurisdiction in the forum in which the ANDA is prepared or the state in which the generic drug was developed and tested. *See, e.g., Pfizer Inc. v. Synthon Holding, B.V*., 386 F. Supp. 2d 666, 675-76 (M.D.N.C. 2005) (finding specific jurisdiction existed because "the preparation of the ANDA ... was conducted primarily in North Carolina" and rejecting argument that such activities should not be considered for jurisdictional purposes because

the preparation of an ANDA is not considered "infringement" under 35 U.S.C. S 271(e)); *Intendis, Inc. v. River's Edge Pharms., LLC*, No. 11-2838 (FSH)(PS), 2011 U.S. Dist. LEXIS 130305, 2011 WL 5513195, at *3-*4 (D.N.J. Nov. 10, 2011) (finding that ANDA infringement claim arose in Georgia where product was "conceived," "developed," and "tested" and not the plaintiffs' "home forum"); *Pfizer Inc. v. Apotex, Inc.*, No. 08-cv-00948-LDD, 2009 U.S. Dist. LEXIS 82653, 2009 WL 2843288, at *3 n.5 (D. Del. Aug. 13, 2009) ("We find more significant the location of the operative facts -- the preparation and submission of the ANDA -- giving rise to this action."); *Bristol-Myers Squibb Co. v. Andrx Pharms., LLC*, No. 03 Civ. 2503(SHS), 2003 U.S. Dist. LEXIS 21967, 2003 WL 22888804, at *3 (S.D.N.Y. Dec. 5, 2003) (holding that location **[*23]** of design and development is location of operative facts in ANDA infringement case). However, like the *AstraZeneca* court, we are not persuaded that these factors should be the focus of the specific jurisdiction analysis in ANDA cases. 2014 U.S. Dist. LEXIS 156660, 2014 WL 5778016, at *8 n.13. As noted above, the Hatch-Waxman Act changed the patent laws to exempt generic drug development activity as a basis for infringement claims. It does not makes sense, therefore, to treat such activity as an injury in order to base a finding of specific jurisdiction in ANDA cases. *See id*. 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 not the preparation of the ANDA that creates harm by triggering a patent holder's forty-five days to initiate litigation. *See id*. (citing § 271(e)(2).

The Mylan Defendants argue that this approach improperly focuses on *Plaintiffs'* contacts with Indiana, not theirs. Our analysis does not ignore the clear rule that for purposes of the jurisdictional analysis, "[t]he proper question is not where the plaintiff experienced a particular injury or effect but whether the defendant's conduct connects **[*24]** him to the forum in a meaningful way." *Walden v. Fiore*, 134 S.Ct. 1115, 1125, 188 L. Ed. 2d 12 (2014). Although the Mylan Defendants characterize their contacts with Indiana as no more than accidental, we are not so persuaded. Indeed, the Mylan Defendants purposefully directed their activities at Indiana by sending a Paragraph IV certification notice letter to Lilly in Indiana,[9] which act they knew would trigger the forty-five-day period within which Plaintiffs were empowered to file suit under the Hatch-Waxman framework.[10]

9 The Mylan Defendants also directed notification letters in this case to five other Plaintiffs, including parties in New Jersey and Japan.

10 We recognize that this idea, to wit, that the Paragraph IV statutory notice letter constitutes a purposeful act directed at the state to which it is mailed, was rejected by the district court in *Glaxo Inc. v. Genpharm, Pharmaceuticals, Inc.*, 796 F. Supp. 872 (E.D.N.C. 1992). However, we are not bound by that decision, nor are we certain of its continuing viability, particularly considering that *Glaxo* was decided before *Zeneca* and the North Carolina court's ultimate decision to transfer the case to the District of Maryland is the same result that was later rejected by the Federal Circuit in *Zeneca*.

There can be no dispute that the Mylan Defendants, as generic drug companies **[*25]** well-versed in ANDA litigation, understood the purpose and known consequences of filing the ANDA and Paragraph IV certification. As noted above, such a filing constitutes an act of patent infringement with "actual consequences." *Zeneca*, 173 F.3d at 833-34. Thus, Plaintiffs' cause of action, "artificial" as it may seem, arose in significant part out of the Mylan Defendants' contact with Plaintiff Lilly in Indiana. *See AstraZeneca*, 2014 U.S. Dist. LEXIS 156660, 2014 WL 5778016, at *7 (finding same). Given the fact that "[f]iling a paragraph IV certification means provoking litigation," *Caraco Pharm. Labs., Inc. v. Novo Nordisk A/S*, 132 S.Ct. 1670, 1677, 182 L. Ed. 2d 678 (2012), we see no basis on which to conclude that the Mylan Defendants could not "reasonably anticipate being haled into court" in Indiana. *See Burger King*, 471 U.S. at 474 (quoting *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 295, 100 S. Ct. 559, 62 L. Ed. 2d 490 (1980)). Accordingly, we hold that the Mylan Defendants' act of filing an ANDA and directing a Paragraph IV notice letter to Indiana provide sufficient minimum contacts with this district to satisfy the requirements of an exercise of specific jurisdiction.[11]

11 We note that there is authority supporting the contention that injury in a patent infringement case occurs where "the infringing activity directly impacts on the interests of the patentee," such as the place of infringing sales. *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1571 (Fed. Cir. 1994); *see also Acorda Therapeutics*, 2015 U.S. Dist. LEXIS 4056, 2015 WL 186833, at *18 n.26. While there have not yet been sales in this ANDA case, if such sales **[*26]** are made in the future, the record before us is clear that they will be made nationwide, including in Indiana. *See* Exh. 3 at 159-160, 186.

Having found that minimum contacts exist, we turn to address whether the exercise of jurisdiction in this case comports with "traditional notions of fair play and substantial justice." *Int'l Shoe*, 326 U.S. at 316. We balance five factors in determining whether an exercise of jurisdiction in a particular case is reasonable and fair: (1) the burden on the defendant; (2) the forum state's interest in adjudicating the dispute; (3) the plaintiff's interest in obtaining convenient and effective relief; (4) the interstate judicial system's interest in obtaining the most efficient resolution of controversies; and (5) the shared interest in obtaining the most efficient resolution of controversies. *Felland v. Clifton*, 682 F.3d 665, 677 (7th Cir. 2012); *Burger King*, 471 U.S. at 477.

Here, the Mylan Defendants have failed to show that an Indiana forum would be unjustly burdensome such that it would be unfair to subject them to suit in this jurisdiction. The evidence before us establishes that Mylan frequently sends it employees to Indiana for business purposes and for the promotion of its generic pharmaceuticals to potential purchasers. Two of its National Account **[*27]** Managers reside in Indiana as well. Mylan Pharmaceuticals has also affirmatively sought to litigate in this district instead of its domicile in West Virginia on at least one prior occasion. *See Urich v. Mylan, Inc.*, No. 1:10-cv-01068-JMS-DKL (S.D. Ind. 2010) (transferred from West Virginia to this district on Mylan's motion). Given these facts, we cannot conclude that it would be a burden on the Mylan Defendants to litigate this action in Indiana.

We have recognized that "a state generally has a 'manifest interest' in providing its residents with a convenient forum for redressing injuries inflicted by out-of-state actors, and domestic corporations have an interest in obtaining convenient relief in their own state." *Key Elecs., Inc. v. EarthWalk Communs, Inc.*, No. 4:13-cv-00098-SEB-DML, 2014 U.S. Dist. LEXIS 81884, 2014 WL 2711838 (S.D. Ind. June 16, 2014) (citing *Burger King*, 471 U.S. at 473, 482-83). Thus, Indiana and Plaintiff Lilly both have a substantial interest in resolving this infringement suit in an Indiana forum.

Moreover, it would be a significant burden on Plaintiffs if required to bring lawsuits against each ANDA filer in the defendants' respective home states. In this case, Plaintiffs initially filed suit against approximately forty generic drug companies that reside in a variety of **[*28]** locations. "Such a result would be inconsistent with the 'balance' that Congress sought to create in passing the Hatch-Waxman Act." *AstraZeneca*, 2014 U.S. Dist. LEXIS 156660, 2014 WL 5778016, at *7. Additionally, given the number of defendants in this litigation (the rest of whom have not objected to our jurisdiction, meaning the case against them will proceed here regardless of the outcome of this motion), resolving this case in one forum would promote both judicial efficiency and also avoid the possibility of inconsistent results.

Because no evidence has been adduced to show that the Mylan Defendants would be meaningfully burdened or even disadvantaged by litigating in this forum, coupled with both Indiana's as well as Plaintiff Lilly's obvious interests in proceeding in an Indiana forum, we find that personal jurisdiction in this case is proper and entirely consistent with traditional notions of fair play and substantial justice.

For these reasons, we find that the Mylan Defendants are properly subject to specific jurisdiction in Indiana. Accordingly, the Mylan Defendants' Motion to Dismiss under Rule 12(b)(2) is DENIED.

IT IS SO ORDERED.

03/12/2015

/s/ Sarah Evans Barker

SARAH EVANS BARKER, JUDGE

United States District Court

Southern District of Indiana