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March 25, 2015

BY CM/ECF

The Honorable Gregory M. Sleet
U.S. District Court for the District of Delaware
844 N. King Street
Wilmington, DE 19801

Re: *In Re Copaxone 40 MG Consolidated Cases*, C.A. No. 14-1171-GMS (Consolidated)
Teva Pharms. USA, Inc., et al. v. Mylan Pharms. Inc., et al., C.A. No. 14-1278-GMS

Dear Judge Sleet:

I write on behalf of plaintiffs pursuant to L.R. 7.1.2(b) with subsequent authority relevant to the pending motion to dismiss for lack of personal jurisdiction filed by defendants Mylan Pharmaceuticals Inc. ("Mylan Pharma") and Mylan Inc. ("Mylan Inc.") (D.I. 12), originally filed in C.A. No. 14-1278-GMS.

Eli Lilly and Company et al. v. Mylan Pharms., Inc. et al., No. 14-cv-00389, 2015 WL 1125032 (S.D. Ind. Mar. 12, 2015) (Exhibit A): The court agreed with the analysis set forth in this Court's decision in *AstraZeneca AB v. Mylan Pharms., Inc.*, No. 14-696-GMS, 2014 WL 5778016 (D. Del. Nov. 5, 2014) and found that specific jurisdiction exists over Mylan Inc. and Mylan Pharma. *Id.* at *5. The court rejected the assertion that the act of filing an ANDA is not directed to *any* jurisdiction and found "the logical alternative is to view the act of filing as being directed to the state of residence for the patent holder." *Id.* at *6. Finally, the court found that the "traditional notions of fair play and substantial justice" weighed in favor of exercising specific jurisdiction, because of the state's interest in providing its residents with a convenient forum for redressing injuries inflicted by out-of-state actors, plaintiff's interest in obtaining convenient relief in their own state, the lack of burden on Mylan, and the significant burden on plaintiffs if required to bring lawsuits against each ANDA filer in the defendants' respective home states. *Id.* at *7-8.

Novartis Pharms. Corp., et al. v. Mylan Pharms., Inc. et al., C.A. Nos. 14-777-RGA, 14-820-RGA (D. Del. Mar. 16, 2015) (Exhibit B): The Court found that Mylan Pharma had consented to general jurisdiction by registering to do business in Delaware pursuant to 8 Del. C. §§ 371, 376. Slip Op. at 5-7.

Should the Court have any questions, counsel are available at the Court's convenience.

Respectfully submitted,

/s/ Karen E. Keller

Karen E. Keller (No. 4489)

cc: All Counsel of record (by CM/ECF and e-mail)
Clerk of Court (by CM/ECF)

Exhibit A



Slip Copy, 2015 WL 1125032 (S.D.Ind.)
(Cite as: **2015 WL 1125032 (S.D.Ind.)**)

Only the Westlaw citation is currently available.

United States District Court,
S.D. Indiana,
Indianapolis Division.
ELI LILLY AND COMPANY, et al., Plaintiffs,
v.
MYLAN PHARMACEUTICALS, INC., Mylan,
Inc., **Mylan Laboratories, Ltd.**, et al., Defendants.

No. 1:14-cv-00389-SEB-TAB.

Signed March 12, 2015.

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

SARAH EVANS BARKER, District Judge.

*1 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”).^{FN1} 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.

^{FN1}. 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 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 Effient®.^{FN2} 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 Laborato-

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ries”)—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.

FN2. 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.

***2** 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 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, unenforce-

able, and 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. Sano-fi–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 relevant facts presented in the record.” *Id.* (internal quotation marks and citations omitted).

***3** 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

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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 *Int’l Shoe Co. v. State of Wash.*, 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 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 Columbia, 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*, — U.S. —, —, 134 S.Ct. 746, 761, 187 L.Ed.2d 624 (2014) (quoting *Goodyear Dunlop Tires Operations, S.A. v. Brown*, — U.S. —, —, 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*, — U.S. —, 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 the exercise of specific jurisdiction in this case.

*4 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*.^{FN3} 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.

FN3. 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 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

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