

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS  
CORPORATION, NOVARTIS AG,  
NOVARTIS PHARMA AG, and LTS  
LOHMANN THERAPIE-SYSTEME AG,

Plaintiffs.

v.

ZYDUS NOVELTECH INC.,

Defendant.

C.A. No. 14-cv-1104-RGA

Memorandum Opinion

Daniel Silver, Esq., McCarter & English LLP, Wilmington, DE; Nicholas Kallas, Esq., Fitzpatrick, Cella, Harper & Scinto, New York, NY; Christopher Loh, Esq. (argued), Fitzpatrick, Cella, Harper & Scinto, New York, NY; attorneys for the Plaintiffs.

Ryan Newell, Esq., Connolly Gallagher LLP, Wilmington, DE; Charles Weiss, Esq. (argued), Holland & Knight; New York, NY; John Evans, Esq., Holland & Knight, Judith Nemsick, Esq., Holland & Knight, New York, NY; attorneys for the Defendants.

August 7, 2015

  
ANDREWS, UNITED STATES DISTRICT JUDGE:

Plaintiffs filed a Hatch-Waxman patent infringement action against defendants Zydus Noveltech, Inc., Zydus Pharmaceuticals (USA) Inc., and Cadila Healthcare Ltd. for infringing two patents for the “Exelon” transdermal system, which is used to treat dementia. (D.I. 15 at 6; D.I. 28 at p. 1; D.I. 1 at 4-6). Immediately after filing this case, Plaintiffs filed a parallel action in the District of New Jersey. (D.I. 15 at 6).

From 2011 to the present, this Court has resolved, or will resolve, a number of Exelon-related ANDA suits filed by Plaintiffs against other defendants. (No. 11-1077-RGA, D.I. 426; No. 11-1112-RGA, D.I. 40; No. 13-52-RGA, D.I. 177, 178; No. 13-527-RGA; No. 14-777-RGA). Novartis Pharmaceuticals Corporation is incorporated in Delaware and researches, markets, and sells prescription drugs. (D.I. 28 at p. 2; D.I. 29 at 1). Novartis AG and Novartis Pharma AG are Swiss companies with a principal place of business in Basel, Switzerland. (D.I. 28 at p. 2). LTS Lohmann Therapie-Systeme AG is a German company with its principal place of business in Germany. (D.I. 28 at p. 2).

Defendants have moved to dismiss the complaint for lack of personal jurisdiction. (D.I. 15). Defendants Zydus Pharmaceuticals and Cadila also moved to dismiss the complaint for failure to state a claim under Federal Rule of Civil Procedure 12(b)(2), and Cadila moved to dismiss for insufficient service of process under Rule 12(b)(5). (D.I. 15 at 6). The Court granted a stipulation to dismiss the complaint against defendants Zydus Pharmaceuticals and Cadila. (D.I. 24, 22).<sup>1</sup> The remaining defendant is Zydus Noveltech. Therefore, the only remaining

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<sup>1</sup> The stipulation included, inter alia, an agreement that Zydus Pharmaceuticals and Cadila would provide discovery as if they were parties and that these two defendants consent to jurisdiction only to enforce the stipulation, and nothing more. (D.I. 22 at 2-3).

issue for this Court is whether there is personal jurisdiction over Defendant Zydus Noveltech. (See D.I. 28 at p.1 n. 1).

Zydus Noveltech is a New Jersey corporation with a principal place of business in Vermont. (D.I. 18 at 1; *see also* D.I. 47 at 6). Zydus Pharmaceuticals and Zydus Noveltech are sister companies, and Cadila is their ultimate parent company.<sup>2</sup> (D.I. 33 at 6). The majority shareholder of Zydus Noveltech is Zydus International Private Ltd., a subsidiary of Cadila. (D.I. 18 at 2). Zydus Noveltech has no property, personnel, or offices in Delaware, does not sell any products in Delaware, and does not conduct any business in Delaware. (D.I. 18 at 1). Zydus Noveltech is not registered to do business in Delaware. (D.I. 47 at 13). Zydus Noveltech prepared and submitted the ANDA, but no work to prepare the product or ANDA was conducted in Delaware. (D.I. 18 at 2). Defendant sent its ANDA notice letter on July 16, 2014 to Plaintiffs in Switzerland, Germany, and New Jersey. (D.I. 34-1 at 2-3). This is the first ANDA case that Defendant has been involved in, although its sister company Zydus Pharmaceuticals has appeared before this Court. (D.I. 47 at 6).

There is a dispute among the parties about whether Defendant's generic drug at issue will make it to market in Delaware. Plaintiffs argue that Defendant will sell generic copies of the Exelon product in Delaware, through its sister company Zydus Pharmaceuticals (D.I. 28 at pp. 3-

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<sup>2</sup> According to Defendant, Zydus Noveltech focuses primarily on transdermal drug products, such as the technology at issue in this case, while Zydus Pharmaceuticals sells oral products. (D.I. 33 at 6). Defendant explains: "While the two companies share the same ultimate parent corporation (Cadila), Zydus Pharmaceuticals has no connection to the generic rivastigmine patch at issue in this case and Novartis has no basis for asserting that Zydus Pharmaceuticals will eventually sell Zydus Noveltech's generic rivastigmine patch (assuming approval by the FDA)." (D.I. 33 at 6).

8), though Defendant calls these allegations “mere speculation.”<sup>3</sup> (D.I. 33 at 6). Defendant questions the proposition that it will sell products in Delaware in the future: “Novartis has no evidence that Zydus Noveltech will sell products in Delaware in the future; there is no contractual obligation or other evidence to support Novartis’s argument.” (D.I. 33 at 12).

## I. LEGAL STANDARD

Under Federal Rule of Civil Procedure 12(b)(2), a party may move to dismiss a case because the court lacks personal jurisdiction over that party. “Once challenged, the plaintiff bears the burden of establishing personal jurisdiction.” *O’Connor v. Sandy Lane Hotel Co.*, 496 F.3d 312, 316 (3d Cir. 2007). Absent an evidentiary hearing, a plaintiff needs only to establish a prima facie case of personal jurisdiction, and the plaintiff is entitled to have its allegations taken as true and factual disputes drawn in its favor. *Id.*

Personal jurisdiction derives from two sources, statutory and constitutional law. A district court must determine whether the state’s long-arm statute permits service of process, and whether asserting personal jurisdiction would violate due process. *See Inamed Corp. v. Kuzmak*, 249 F.3d 1356, 1359 (Fed. Cir. 2001). When determining whether a district court properly decided personal jurisdiction, the Federal Circuit applies its own law, not regional circuit law, because the jurisdictional issue is “intimately involved with the substance of the patent laws.” *Id.* (citations omitted) (internal quotation marks omitted). Delaware’s long-arm statute has been construed “broadly to confer jurisdiction to the maximum extent possible under the Due Process

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<sup>3</sup> Plaintiffs’ position on the role of the sister company Zydus Pharmaceuticals seems incorrect. It seems clear that Zydus Pharmaceuticals has no involvement with the rivastigmine product, and because it focuses only on oral drugs, likely would not be involved in the future. (D.I. 33 at 6 (citing D.I. 18 at ¶ 8)). By what means Zydus Noveltech would sell the product in Delaware in the future seems to be an open question.



Clause, so the focus of the inquiry traditionally rests on the constitutional component.”

*AstraZeneca AB v. Mylan*, 2014 WL 5778016, at \*2 (D. Del. Nov. 5, 2014) (internal quotation marks omitted) (citations omitted).<sup>4</sup>

Due process requires “minimum contacts” between an out-of-state defendant and the forum “such that maintenance of the suit does not offend traditional notions of fair play and substantial justice.” *Int’l Shoe Co. v. State of Wash., Office of Unemployment Comp. & Placement*, 326 U.S. 310, 316 (1945) (internal quotation marks omitted) (internal citations omitted). General jurisdiction occurs where a defendant’s contacts with a state 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 (2014) (internal quotation marks omitted). Specific jurisdiction occurs when a defendant has “purposefully directed his activities at residents of the forum, and the litigation results from alleged injuries that arise out of or relate to those activities.” *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472 (1985) (internal citations omitted) (internal quotation marks omitted).

The Supreme Court has recently explained that “specific jurisdiction has become the centerpiece of modern jurisdiction theory, while general jurisdiction has played a reduced role.” *Daimler AG v. Bauman*, 134 S. Ct. 746, 755 (2014) (internal quotation marks omitted). The Supreme Court has stressed the difference between the specific and general jurisdiction inquiries. *See Daimler AG*, 134 S. Ct. at 757 (“Although the placement of a product into the stream of

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<sup>4</sup> This Court tends to agree with Judge Sleet that it is not entirely clear whether Delaware’s long-arm statute extends as far as allowed by the constitutional component. *See AstraZeneca*, 2014 WL 5778016, at \*2 n. 1; *see also Commissariat A L’Energie Atomique v. Chi Mei Optoelectronics Corp.*, 395 F.3d 1315, 1322 (Fed. Cir. 2005) (“Delaware law is also unclear as to whether or not the long arm statute is coextensive with the due process clause.”). As in *AstraZeneca*, because the parties have not challenged the limits of Delaware’s long-arm statute, this Court will focus the inquiry on the constitutional analysis.

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