IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF TEXAS MARSHALL DIVISION

MEMORANDUM OPINION AND ORDER

Before the Court is a motion by defendant Teva Pharmaceuticals USA, Inc., ("Teva") to dismiss the complaint for lack of personal jurisdiction and improper venue. Dkt. No. 38. Also before the Court is the motion of Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, "the Mylan entities") to dismiss the complaint for failure to state a claim and for lack of personal jurisdiction and improper venue. Dkt. No. 32. Both motions are DENIED.

I. BACKGROUND

This patent infringement action arises from Abbreviated New Drug Applications ("ANDAs") submitted by Teva and Mylan to market generic versions of Allergan's cyclosporine ophthalmic emulsion product marketed as RESTASIS. RESTASIS is an eye drop treatment for chronic dry eyes.

Allergan is a pharmaceutical company. It is incorporated in the State of Delaware and has its principal place of business in California. It owns several patents relating to RESTASIS—United States Patent Numbers 8,629,111 ("the '111 patent"), 8,633,162 ("the '162 patent"), 8,642,556 ("the '556 patent"), 8,648,048 ("the '048 patent"), 8,685,930 ("the '930 patent"), and



9,248,191 ("the '191 patent"). Those patents are listed in the "Orange Book," the publication of the Food and Drug Administration ("FDA") that identifies approved drug products and lists the patents that are asserted to protect each drug.

Teva is a Delaware corporation with its principal place of business in Pennsylvania. It submitted an Abbreviated New Drug Application ("ANDA") to the FDA seeking regulatory approval for a generic cyclosporine ophthalmic emulsion product. As part of its ANDA, referred to as ANDA No. 203880, Teva included a certification (known as a "Paragraph IV certification," see 21 U.S.C. § 355(b)(2)(A)(iv)) that all of the patents in Allergan's Orange Book listing are invalid, not infringed, or unenforceable. On July 22, 2015, Teva sent written notice to Allergan of its filing of ANDA No. 203880 as well as its Paragraph IV allegations with respect to the '111, '162, '556, '048, and '930 patents.¹

Mylan Pharmaceuticals is a West Virginia corporation with its principal place of business in West Virginia. It submitted an ANDA, referred to as ANDA No. 205894 seeking regulatory approval for a generic cyclosporine ophthalmic emulsion product. As part of ANDA No. 205894, Mylan Pharmaceuticals included a Paragraph IV certification that all of the patents in Allergan's Orange Book listing are invalid, not infringed, or unenforceable. On July 20, 2015, Mylan Pharmaceuticals sent a notification informing Allergan of ANDA No. 205894 and its position that the '111, '162, '556, '048, and '930 patents are invalid or not infringed.²

Mylan Inc. is the parent company and owner of Mylan Pharmaceuticals. Dkt. No. 98, at ¶11. Mylan Inc. is a Pennsylvania corporation with its principal place of business in Pennsylvania. According to Allergan, Mylan Inc. is responsible for marketing and selling the

² The '191 patent had not issued as of the date of Mylan's ANDA filing.



¹ The '191 patent had not issued as of the date of Teva's ANDA filing.

generic drugs manufactured and supplied by Mylan Pharmaceuticals. Dkt. No. 96, at ¶ 49. Allergan also alleges that "Mylan Pharmaceuticals and Mylan Inc. are agents of each other and/or work in active concert with respect to the development, regulatory approval, marketing, sale and distribution of pharmaceutical products," including the product at issue in this litigation. Id. at ¶ 45. According to the Mylan entities, however, Mylan Pharmaceuticals was solely responsible for the preparation and filing of the ANDA. Mylan Motion to Dismiss, Dkt. No. 32, at 1.

On August 24, 2105, Allergan filed this action against Teva, the Mylan entities, and others, alleging that the proposed generic drugs would infringe one or more of the '111, '162, '556, '048, and '930 patents. Allergan later amended its complaint to include the '191 patent after that patent issued. Teva and the Mylan entities filed motions to dismiss for lack of personal jurisdiction and venue. Mylan Inc. also filed a motion to dismiss for failure to state a claim, arguing that Allergan failed to plausibly allege that it was the submitter of ANDA No. 205894.

II. DISCUSSION

A. Personal Jurisdiction

This Court may assert personal jurisdiction over a non-resident defendant if the defendant "is subject to the jurisdiction of a court of general jurisdiction in the state where the district court is located," which in this case is Texas. <u>Johnston v. Multidata Sys. Int'l Corp.</u>, 523 F.3d 602, 609 (5th Cir. 2008) (internal citations omitted); Fed. R. Civ. P. 4(k)(1)(A). "Because the Texas long-arm statute extends to the limits of federal due process, the two-step inquiry collapses into one federal due process analysis." <u>Id.</u>; <u>Inamed v. Kuzmak</u>, 249 F.3d 1356,1360 (Fed. Cir. 2001). In order for due process to be satisfied, the defendant must have "certain minimum contacts with [the forum] such that the maintenance of the suit does not offend 'traditional notions of fair play



and substantial justice." <u>Int'l Shoe Co. v. Washington</u>, 326 U.S. 310, 316 (1945) (quoting <u>Milliken v. Meyer</u>, 311 U.S. 457, 463 (1940).

There are two independent bases for the exercise of personal jurisdiction over a defendant—general and specific. General personal jurisdiction is available when the defendant's contacts with the forum State are "continuous and systematic." In such cases, the court in the forum State may exercise personal jurisdiction over the defendant even if the cause of action does not arise from or relate to activities conducted within that State. Autogenomics, Inc. v. Oxford Gene Tech. Ltd., 566 F.3d 1012, 1017 (Fed. Cir. 2009). In contrast, specific personal jurisdiction "must be based on activities that arise out of or relate to the cause of action, and can exist even if the defendant's contacts are not continuous and systematic." Id. "So long as it creates a 'substantial connection' with the forum, even a single act can support jurisdiction." Burger King Corp. v. Rudzewicz, 471 U.S. 462, 475 n.18 (1985). Moreover, specific personal jurisdiction may be based on acts outside the forum State when the defendant knew that the injury resulting from those acts would be felt by the plaintiff in the forum State. Calder v. Jones, 465 U.S. 783, 790-91 (1984).

For patent cases, the due process elements of personal jurisdiction are governed by Federal Circuit law. Accorda Therapeutics Inc. v. Mylan Pharmaceuticals Inc., No. 15-1456, 2016 WL 1077048, at *2 (Fed. Cir. Mar. 18, 2016). Where the parties have not conducted discovery, the plaintiff need only make a prima facie showing that the defendants are subject to personal jurisdiction; the pleadings and supporting material are construed in the plaintiff's favor. Autogenomics, 566 F.3d at 1017.

In <u>Accorda Therapeutics</u>, the Federal Circuit addressed minimum contacts issue in the context of ANDA filings. The court held that a non-Delaware drug maker had sufficient contacts



with the State of Delaware to support personal jurisdiction when it filed an ANDA, because it was undisputed that if the drug maker were to receive FDA approval to sell its generic drug, it would sell the drug throughout the United States, including in Delaware. Accorda, 2016 WL 1077048, at *7. The Federal Circuit explained that by filing an ANDA a drug company "confirm[s] its plan to commit real-world acts that would make it liable for infringement if it commits them without the patentees' permission." Id. at *4. Because of the close connection between the filing of the ANDA and real world acts of infringement in the forum State that would follow the FDA's approval of the ANDA, the court held that sufficient contacts were present to support the exercise of personal jurisdiction in the forum State. Id. at 7.

Because the Federal Circuit issued the <u>Accorda</u> decision after these motions were fully briefed, the Court directed Teva and the Mylan entities to submit supplemental briefs on how the decision affected the pending motions. Dkt. No. 108. Teva acknowledged that it intends to sell its generic cyclosporine ophthalmic emulsion product in Texas, and that under the reasoning of <u>Accorda</u> it is subject to personal jurisdiction in this Court. Dkt. No. 110, at 1. Therefore, Teva's motion to dismiss for lack of personal jurisdiction is DENIED.

The Mylan entities, on the other hand, argued that "the Federal Circuit's decision should have no immediate impact on Mylan's pending Motion to Dismiss." Dkt. No. 111, at 1. Their position does not appear to be based on any factual distinction between <u>Accorda</u> and this case. Rather their position seems to be premised on the hope that <u>Accorda</u> will be overturned on further review. By the Mylan entities' own characterization of the <u>Accorda</u> decision, an ANDA filing "gives rise to specific personal jurisdiction in any suit related to that filing in every jurisdiction in the nation." Dkt. No. 111, at 1. Nonetheless, because the Mylan entities do not

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