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

ALLERGAN, INC. *Plaintiff*, v. TEVA PHARMACEUTICALS USA, INC., et al., *Defendants*.	§ § § § § § § § § §	Case No. 2:15-CV-1455-WCB

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

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

[2] The '191 patent had not issued as of the date of Mylan'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. Johnston v. Multidata Sys. Int'l Corp., 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." Id.; Inamed v. Kuzmak, 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.'" Int'l Shoe Co. v. Washington, 326 U.S. 310, 316 (1945) (quoting Milliken v. Meyer, 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 Accorda Therapeutics, 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 Accorda 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 Accorda 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 Accorda and this case. Rather their position seems to be premised on the hope that Accorda will be overturned on further review. By the Mylan entities' own characterization of the Accorda 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

concede that Accorda governs this case, the Court will consider the merits of the question whether the Court has specific personal jurisdiction over them.[3]

The Court has specific personal jurisdiction over the Mylan entities because the purpose of their ANDA submission is to market a generic drug nationwide, including in Texas. Allergan has made plausible allegations that if the Mylan entities were to receive FDA approval, they would sell a generic cyclosporine ophthalmic emulsion product in Texas and in this district. Allergan has alleged that Mylan Pharmaceuticals is licensed to distribute drugs in the State of Texas and is actively registered to do business in Texas. Dkt. No. 96, at ¶¶ 46-47. Allergan has also alleged that since 2014 Mylan Inc. has sold more than $1.3 billion of Mylan Pharmaceuticals' products in Texas, including $460 million in the Eastern District. Id. at ¶ 49. Furthermore, Allergan has alleged that the Mylan entities have established channels of distribution in Texas, the second largest market for prescription drugs in the United States, and that it would likely take advantage of those channels should it receive approval to sell its generic cyclosporine ophthalmic emulsion product. Id. at ¶ 54.

The Mylan entities have described Allergan's allegations that they would sell in Texas as "nothing more than baseless allegations," and they argue that "[i]t is entirely speculative that [Mylan Pharmaceuticals] would ever sell an infringing generic product in Texas." Dkt. No. 63, at 5-6. However, the Mylan entities have not represented that they will not sell nationally, including in Texas, if they receive FDA approval. Nor have they offered any reason to believe that it is at all likely that they would sell their product in some States, but not in Texas. To the contrary, it seems highly unlikely that they would undergo the considerable effort and expense of preparing an ANDA filing and litigating this case if they did not intend to market and distribute

[3] Should further review by the Federal Circuit or the Supreme Court alter the Accorda decision, the Court will of course revisit this decision.

the drug throughout the United States, including in the second largest State in the nation. The mere assertion that the possibility of such sales is "speculative" is not enough to answer Allergan's allegations.

In the Accorda decision, the Federal Circuit stated that "[t]he magnitude and costs of the work required before the ANDA is filed soundly link the ANDA filing to the filer's entry into the market to compete with the brand-name manufacturer if approval is obtained." Accorda, 2016 WL 1077048, at *5. Allergan has provided evidence that Texas is the third largest market for RESTASIS. Dkt. No. 52, at 3. Under the logic of the Accorda decision, the filing of ANDA No. 205894 is linked to an entry into the Texas market to compete with Allergan and displace its sales in that market. The ANDA filed by the Mylan entities therefore established minimum contacts with the forum State.

After a plaintiff makes a showing of minimum contacts with the forum, the defendant has an opportunity to address whether the court asserting jurisdiction "would comport with fair play and substantial justice." Burger King Corp. v. Rudzewicz, 471 U.S. 462, 477 (1985) (internal citations omitted). The "fair play and substantial justice" factor gives the defendant an opportunity to present a case that some other considerations would render the exercise of jurisdiction unreasonable. The burden, however, is on the defendant to point to those other considerations. Inamed Corp. v. Kuzmak, 249 F.3d 1356, 1360 (Fed. Cir. 2001). In this case, the Mylan entities do not argue that any such "fairness" considerations apply.

Because Allergan has made an uncontroverted showing of suit-related minimum contacts in this case and the Mylan entities have not made a showing of other considerations that would cut against the exercise of specific personal jurisdiction, this Court concludes that it has specific personal jurisdiction over them.

The parties also dispute whether this court has general personal jurisdiction over Teva and the Mylan entities. Because the Court has found that it has specific personal jurisdiction over the defendants in this case, it need not address general personal jurisdiction.

B. Venue

Allergan has asserted that venue in the Eastern District of Texas is proper with regard to both defendants under 28 U.S.C. §§ 1391(c) and 1400(b). Under section 1400(b), venue is proper "in the judicial district where the defendant resides." 28 U.S.C. § 1400(b). Section 1391(c)(2) provides that a corporation "shall be deemed to reside, if a defendant, in any judicial district in which such defendant is subject to the court's personal jurisdiction with respect to the civil action in question." In a State which has more than one judicial district, and in which a defendant that is a corporation is subject to personal jurisdiction at the time the action is commenced, such corporation shall be deemed to reside in any district in that State within which its contacts would be sufficient to subject it to personal jurisdiction if that district were a separate State." 28 U.S.C. § 1391(d).

In this case, the Mylan entities do not make a freestanding venue argument. Rather, they argue that because this Court does not have personal jurisdiction over them, venue in this district is improper as well. Dkt. No. 63, at 10. Because this Court has personal jurisdiction over the Mylan entities, their venue argument fails. In addition, because of the $460 million of RESTASIS sales that Allergan has alleged take place in the Eastern District, Allergan would be able to establish minimum contacts with the district as well.

Teva concedes that, in light of the Accorda decision, venue is proper in the Eastern District of Texas. Dkt. No. 110, at 3.

C. Dismissal for Failure to State a Claim

Federal Rule of Civil Procedure 12(b)(6) authorizes a court to dismiss a complaint if the complaint "fail[s] to state a claim upon which relief can be granted." The question resolved on a motion to dismiss for a failure to state a claim is not whether the plaintiff will ultimately prevail, "but whether [the] complaint was sufficient to cross the federal court's threshold." Skinner v. Switzer, 562 U.S. 521, 530 (2011). When considering a motion to dismiss under Rule 12(b)(6), a court "accept[s] all well-pleaded facts as true, and view[s] those facts in the light most favorable to the plaintiff." Bustos v. Martini Club, Inc., 599 F.3d 458, 461 (5th Cir. 2010).

Upon viewing the pleaded facts most favorably to the plaintiff, the court must then decide whether those facts state a claim for relief that is plausible on its face. Bowlby v. City of Aberdeen, Miss., 681 F.3d 215, 217 (5th Cir. 2012). "A claim is plausible if 'the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." United States v. Bollinger Shipyards, Inc., 775 F.3d 255, 260 (5th Cir. 2014) (citing Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)). Instead, the standard "simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of [the claim]." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 545 (2007). "The factual allegations in the complaint need only 'be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact).'" Wooten v. McDonald Transit Assocs., Inc., 788 F.3d 490, 498 (5th Cir. 2015) (quoting Twombly, 550 U.S. at 555)).

The plausibility standard "does not give district courts license to look behind [a complaint's] allegations and independently assess the likelihood that the plaintiff will be able to prove them at trial." Harold H. Huggins Realty, Inc. v. FNC, Inc., 634 F.3d 787, 803 n.44 (5th

Cir. 2011)). Under Rule 8(a)(2) of the Federal Rules of Civil Procedure, a plaintiff is generally required to provide "only a plausible 'short and plain' statement of the plaintiff's claim, not an exposition of [the plaintiff's] legal argument." Skinner, 562 U.S. at 530. The "short and plain" statement does not "countenance dismissal of a complaint for imperfect statement of the legal theory supporting the claim asserted." Johnson v. City of Shelby, Miss., 135 S. Ct. 346, 346 (2014) (citing 5 C. Wright & A. Miller, § 1215, p. 172 (3d ed. 2002) (Rule 8(a)(2) "indicates that that a basic objective of the rules is to avoid civil cases turning on technicalities.")).

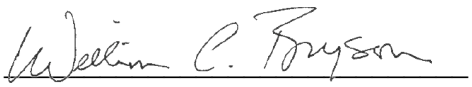
The Mylan entities argue that Allergan fails to state a claim against Mylan Inc. because Mylan Inc. was not the entity that submitted the ANDA application. The Hatch-Waxman Act makes it "an act of infringement to submit" an ANDA on a drug covered by valid and infringed patents found in the Orange Book listing for a drug. 35 U.S.C. § 271(e)(2). An entity submits an ANDA if it participates in the preparation of the ANDA and intends to benefit directly from the ANDA by selling the ANDA product upon approval. In re Rousvastatin Calcium Patent Litig., 703 F.3d 511, 528-29 (Fed. Cir. 2012). An entity can be an ANDA submitter without signing the ANDA. Cephalon, Inc. v. Watson Pharm., Inc., 629 F. Supp. 2d 338, 349 (D. Del. 2009) ("Parties 'actively involved' in preparing the ANDA are deemed to have 'submit[ted]' the ANDA, regardless of whether they are the named applicant; this is especially true where the parties involved are in the same corporate family.") (quoting Wyeth v. Lupin Ltd., 505 F. Supp. 2d 303, 306-07 (D. Md. 2007)).

Mylan Inc. argues that it is not a submitter because Mylan Pharmaceuticals "prepared and submitted the ANDA," and Mylan Inc. did not. Dkt. No. 32, at ¶¶ 45. However, Allergan has alleged 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 drug at issue in this case. Dkt. No. 96, at 8. Allergan has also alleged that Mylan Inc. markets and sells the drugs manufactured by Mylan Pharmaceuticals. Id. at ¶ 49. Therefore, Allergan alleges that if the ANDA is approved Mylan Inc. will become the generic product's marketer, seller, and distributor in the United States, and that it would benefit from the ANDA's approval. Furthermore, Allergan has alleged that Mylan Inc. has worked in concert with Mylan Pharmaceuticals with respect to the regulatory approval of the drugs at issue in this case, which suggests that Mylan Inc. was participating in the preparation of the ANDA. These allegations are sufficient to plead a claim that Mylan Inc. submitted ANDA No. 205894.

IT IS SO ORDERED.

SIGNED this 19th of April, 2016.



WILLIAM C. BRYSON
UNITED STATES CIRCUIT JUDGE