UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

ESTATE OF EDDIE A. MUNIZ,
by Personal Representative Sheila Muniz,

Plaintiff,

v.

GENENTECH, INC., *et al.*,

Defendants.
_____/

CASE NO. 1:11-CV-683

HON. ROBERT J. JONKER

OPINION AND ORDER

This is a products liability action against the developers, manufacturers and distributors of Raptiva, a psoriasis medication ultimately withdrawn from the market.[1] Defendants move to dismiss under FED. RULE CIV. P. 12(b)(2) and 12(b)(6). (docket # 11). At issue is whether the Court may exercise personal jurisdiction over Defendant Xoma and whether Defendants are entitled to immunity under Michigan's products liability statute. The Court has heard oral argument on the motion, thoroughly reviewed the parties' motion papers, and carefully considered the applicable law. The matter is ready for decision.

[1]This is one of four cognate cases pending before the Court. The other cases are: *Blair v. Genentech, et al.*, No. 1:11-CV-482; *Marsh v. Genentech, et al.*, No. 1:11-CV-688; and *Tiefenthal v. Genentech, et al.*, No. 1:11-CV-689. Other than the plaintiffs named and limited facts unique to each plaintiff, the pleadings and motion papers in the cases are substantively identical. The Court addresses each case by separate opinion, and resolves each case the same way.

Factual and Procedural Background

Genentech and Xoma are both Delaware corporations with their principal places of business in California. (Compl., docket # 1, ¶¶ 2, 4.) During the late 1990s and early 2000s, Defendant Genentech, in collaboration with Defendant Xoma, researched and developed a drug for psoriasis called Raptiva. (*Id.* at ¶¶ 2-4.) Defendants originally planned to limit Raptiva to a twelve week course of treatment. (*Id.* at ¶ 52.) Defendants altered this plan after learning that "clinical trial data suggested that patients who stopped taking Raptiva relapsed . . . [and would likely] need to remain on the drug for long periods of time, if not continuously for the rest of their lives." (*Id.* at ¶ 53.) Defendants were aware of risks associated with long-term treatment with immuno-suppressant drugs such as Raptiva, including an increased likelihood of "life-threatening[] infections, neurological complications, lymphomas, malignancies, and possibly death." (*Id.*) Defendants "with a paucity of data support their claims, made a strategic business decision to promote and market Raptiva as safe for 'continuous treatment.'" (*Id.* at ¶ 54.) On September 9, 2003, the FDA Advisory Committee recommended approval of Raptiva, although several members raised concerns about long-term and interrupted use of the product. (*Id.* at ¶¶ 48, 50.) Plaintiff asserts that in seeking Advisory Committee approval, Defendants "made multiple material misrepresentations and omissions to the Dermatologic and Opthalmic Drugs Advisory Committee of the FDA, falsely and deceptively reporting that Raptiva was safe for continuous usage." (*Id.* at ¶ 55.) The FDA approved Raptiva on October 23, 2003, and Raptiva went on the market beginning November 17, 2003. (*Id.* at ¶¶ 50-51.)

Plaintiff alleges that from October 2003 until Raptiva was withdrawn from the market in 2009, Defendants continued to make false and deceptive statements and to conceal the truth about adverse events associated with Raptiva usage. (*Id.* at ¶ 64.) Evidence of adverse events associated

with Raptiva mounted. (*Id.* at ¶ 71.) But Defendants "failed to timely and appropriately amend . . . or otherwise update the product labeling, package insert, or to otherwise advise physicians, patients, pharmacists, or other healthcare providers of the increasing number of adverse events reported." (*Id.* at ¶ 72.) Plaintiff alleges that for years Defendants actively implemented a marketing strategy designed to conceal the risks of Raptiva. (*Id.* at ¶¶ 79-94.)

In October 2008, the FDA issued a boxed warning for Raptiva that highlighted the risk of "life-threatening complications, bacterial and viral infections . . . [and] increased risk of cancer." (*Id.* at ¶ 74.) In February, 2009, the FDA issued a public health advisory regarding three deaths associated with Raptiva. (*Id.* at ¶ 75.) The same month, Canada suspended sales of Raptiva, and the European Union medical authorities advised physicians to stop prescribing Raptiva. (*Id.* at ¶¶ 76-77.) On April 7, 2009, Defendants began a phased withdrawal of Raptiva from the market due to safety concerns, and on June 8, 2009, Raptiva was "removed from U.S. markets." (*Id.* at ¶ 77.) At the time it was removed from the market, Raptiva was associated with "nearly 100 reported adverse events of deaths and 71 reported adverse events of malignancy or cancer, nearly half of which were lymphoma-related with 14 lymphoma-related deaths." (*Id.* at ¶ 78.)

Mr. Muniz was born on August 29, 1969, and he died on October 18, 2007. (*Id.* at ¶ 99.) Mr. Muniz developed psoriasis in 2001. (*Id.* at ¶ 100.) His doctor, of Portage, Michigan, prescribed Raptiva for him in September, 2007, and Mr. Muniz ingested Raptiva until October, 2007. (*Id.* at ¶¶ 101-102.) In October, 2007, Mr. Muniz was diagnosed with liver and kidney failure. (*Id.* at ¶ 103.) Plaintiff alleges, on information and belief, that Mr. Muniz's ingestion of Raptiva caused his liver and kidney failure and related health problems. (*Id.* at ¶ 104.)

The Estate of Eddie A. Muniz filed this product liability suit in federal court in the Eastern District of Michigan on April 8, 2011 and an ex parte motion to transfer the case to the Western District on April 21, 2011 (docket ## 1, 6). Defendants moved to dismiss or transfer the case on May 4, 2011 (docket # 11), asserting improper venue, lack of personal jurisdiction over Defendant Xoma, and failure to state a claim. The Eastern District court granted Plaintiff's motion and transferred the case on June 30, 2011 (docket # 18). Defendants' motion to dismiss remains pending to the extent it seeks dismissal of Xoma based on lack of personal jurisdiction and dismissal of the case for failure to state a claim.

Legal Standards and Analysis

A. Personal Jurisdiction over Xoma

In analyzing personal jurisdiction in diversity actions, "federal courts must look to the law of the forum state to determine the reach of the district court's personal jurisdiction over parties, subject to constitutional due process requirements." *Air Products and Controls, Inc. v. Safetech Int'l, Inc.*, 503 F.3d 544, 550 (6th Cir. 2007) (citing *Lanier v. Am. Bd. of Endodontics*, 843 F.2d 901, 909 (6th Cir. 1988)). The Court follows a two-step process: "(1) first, the court must determine whether any of Michigan's relevant long-arm statutes authorize the exercise of jurisdiction over Defendants; and, if so, (2) the court must determine whether the exercise of that jurisdiction comports with constitutional due process." *Id.* The due process analysis involves a three-part inquiry:

> First, the defendant must purposely avail himself of the privilege of acting in the forum state or causing a consequence in the forum state. Second, the cause of action must arise from the defendant's activities there. Finally, the acts of the defendant or consequences caused by the defendant must have a substantial enough connection

> with the forum state to make the exercise of jurisdiction over the defendant reasonable.

Id. (quoting *S. Mach. Co. v. Mohasco Indus., Inc.*, 401 F.2d 374, 381 (6th Cir. 1968).

In the context of a motion under FED. R. CIV. P. 12(b)(2), the plaintiff bears the burden of establishing the existence of jurisdiction. *Air Products*, 503 F.3d at 549 (citing *Serras v. First Tenn. Bank. Nat'l Ass'n*, 875 F.2d 1212, 1214 (6th Cir. 1989)). Where the district court relies solely on written submissions and affidavits, rather than an evidentiary hearing or after limited discovery, the burden on the plaintiff is "'relatively slight.'" *Id.* (citing *Am. Greetings Corp. v. Cohn*, 839 F.2d 1164, 1169 (6th Cir. 1988)). "[T]he pleadings and affidavits submitted must be viewed in a light most favorable to the plaintiff, and the district court should not weigh 'the controverting assertions of the party seeking dismissal.'" *Id.* (citing *Theunissen v. Matthews*, 935 F.2d 1454, 1459 (6th Cir. 1991)).

There is no dispute that the Court has personal jurisdiction over Genentech. Plaintiff asserts that the Court also has personal jurisdiction over Xoma because Xoma and Genentech "conducted national enterprises involving the research, manufacturing, and distribution of Raptiva, [and] [t]his joint enterprise would necessarily require the continuous and systematic general business contacts with Michigan [to successfully distribute the drug in Michigan]." (Pl.'s Br. in Resp. to Mot. to Dismiss, docket # 19, at 4.) Plaintiff also points to the existence of a contract between Genentech and Xoma under which Genentech allegedly agrees to indemnify Xoma in any action against Xoma connected with the joint enterprise. (*Id.* at 5.) Plaintiff does not describe any other contacts between Xoma and the State of Michigan.

Under Michigan's long arm statute, a court may exercise limited personal jurisdiction over an individual for actions arising out of, among other things, "[t]he transaction of any business within the state; . . . [t]he doing or causing an act to be done, or consequences to occur, in the state resulting in an action for tort; . . . [or the] entering into a contract for services to be rendered or for materials to be furnished in the state by the defendant." MICH. COMP. L. §600.705(1),(2),(5). The record does not clearly reveal how closely Xoma and Genentech worked together in the distribution of Raptiva or how far Xoma's role extended beyond research, development and testing of the drug. But viewing the pleadings in the light most favorable to Plaintiff, it is reasonable to conclude that Xoma marketed and sold Raptiva in Michigan, which satisfies (1) or (5) of the long arm statute, or that Xoma caused consequences to occur in the state, in the form of injury to Mr. Muniz, which satisfies (2) of the long-arm statute.

With the long-arm statute satisfied, the inquiry turns to whether exercising jurisdiction over Xoma under the long-arm statute comports with due process. Again, viewing the pleadings in the light most favorable to Plaintiff, it is reasonable to conclude that Xoma purposely availed itself of the privilege of causing a consequence in Michigan by selling prescription medication for use in Michigan. This satisfies the first prong of the due process inquiry. The cause of action would result from the sale of the prescription medication in Michigan, satisfying the second prong. Finally, the consequences of Xoma's action, the serious illness of a Michigan citizen, would have a substantial connection with the State of Michigan, satisfying the final prong.

On this record, given Plaintiff's relatively slight burden, the exercise of personal jurisdiction over Xoma is appropriate. If, as the case develops, facts emerge that suggest that the exercise of personal jurisdiction over Xoma is improper, the Court may revisit the question then.

B. Product Liability

The parties do not dispute that Michigan substantive law governs this diversity action. Michigan's product liability statute concerning pharmaceuticals creates broad immunity for pharmaceutical manufacturers. With two limited exceptions, the statute provides that

> a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration approval at the time the drug left the control of the manufacturer or seller.

MICH. COMP. L. § 600.2946. This liability protection does not apply if the defendant

> (a) [i]ntentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted [to the FDA] . . . and the drug would not have been approved or the [FDA] would have withdrawn approval if the information were accurately submitted. [or]
> (b) [m]akes an illegal payment to an official or employee of the [FDA] for the purpose of securing or maintaining approval of the drug.

Id.

Federal law preempts and limits these statutory exceptions. *Garcia v. Wyeth-Ayerst Laboratories*, 385 F.3d 961, 965-66 (6th Cir. 2004) (citing *Buckman Co. v. Pl's Legal Comm.*, 531 U.S. 341, 350 (2001). In *Buckman*, the Supreme Court determined that "[s]tate law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Agency's judgment and objectives." *Buckman*, 531 U.S. at 350. In *Garcia*, the Sixth Circuit found that the same analysis applies to the exceptions in the Michigan statute. "'*Buckman* teaches that state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims.'" *Garcia*, 384 F.3d at 966 (quoting underlying district court decision, *Garcia v. Wyeth-Ayerst Labs.*, 265 F. Supp. 825 (E.D. Mich. 2003)). This does not mean that *Buckman*

preempts all applications of the exceptions in Michigan's products liability statute. *Id.* "*Buckman* prohibits a plaintiff from invoking the exceptions on the basis of *state court* findings of fraud on the FDA . . . [because] [s]uch a state court proceeding would raise the same inter-branch-meddling concerns that animated *Buckman*." *Id.* (emphasis in original). Such concerns "do not arise when the *FDA itself* determines that a fraud has been committed on the agency." *Id.* (emphasis in original). Accordingly, the exceptions in Michigan's statute "are invalid as applied in some settings (*e.g.*, when a plaintiff asks a state court to find bribery or fraud on the FDA) but not in others (*e.g.* claims based on federal findings of bribery or fraud on the FDA)." *Id.* For the exceptions to apply, there must have been a federal determination of fraud on the agency. *Id.*

In a California Superior Court Raptiva suit applying Michigan law, a plaintiff unsuccessfully urged the court to follow *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006), which found Michigan's immunity statute not preempted by *Buckman's* rationale. *Best v. Genentech, Inc.*, Order dated September 15, 2010, No. RG1051891 (Superior Court of California, County of Alameda). In *Desiano*, the court acknowledged the contrary holding in *Garcia*, asserted that *Garcia* hinged on an analysis of federal preemption law not binding on the Second Circuit, and concluded that federal law did not preempt the statute. An equally divided Supreme Court affirmed *Desiano in Warner-Lambert & Co. v. Kent*, 552 U.S. 440, 441 (2008), without a written opinion. Because the Supreme Court decision was equally divided, it applies only between the parties and has no precedential effect. *Hertz v. Woodman*, 218 U.S. 205, 213-14 (1910). In opting to follow *Garcia* rather than *Desiano*, the California Superior Court emphasized the analysis in *Taylor v. Smithkline Beecham Corp.*, 468 Mich. 1, 658 N.W.2d 127 (2003). *Taylor* upheld the constitutionality of the Michigan statute against claims that the statute impermissibly delegated the state's power to the

federal government. *Taylor*, 468 Mich. at 13. *Taylor* found that the product liability statute does not delegate power to the FDA, but rather uses FDA determinations as "factual conclusions of independent significance" that function as measuring devices. *Id.* The California court found that this rationale supported a reading of the Michigan statute consistent with *Garcia*. The California court concluded that the Defendants had absolute immunity under the Michigan statute in the absence of any FDA determination that Defendants had acted improperly or illegally.

There are no allegations of bribery in this case; therefore, only the first statutory exception from immunity is in play here. There are no allegations that the FDA has found any wrongdoing on the part of Defendants. Plaintiff appears to be arguing that Defendants failed to comply with the FDA's post-approval safety, surveillance and warning requirements. (Br. in Support of Mot. to Dismiss, docket # 19, at 13.) But Plaintiff does not explain how this saves her case from *Garcia's* sweep. In an unpublished decision, the Sixth Circuit explicitly rejected a plaintiff's claim that *Garcia* did not apply to claims arising from post-approval fraud. *In re Aredia and Zometa Products Liability Litigation*, 352 F. App'x 994, Nos. 08-5573, 08-5574, 08-5575, 2009 WL 4072074, * 1 (6th Cir. 2009). In *Aredia*, the court found that it did not matter whether the alleged fraud occurred post- rather than pre-approval. *Id.* "Per *Garcia's* plain terms . . . [this] distinction[] is beside the point: '[S]tate tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims.'" *Id.* (quoting *Garcia*, 385 F.3d at 966.) To move beyond the immunity for which the statute provides, Plaintiff would have to prove fraud against the FDA, and Plaintiff has alleged no federal finding of such fraud. *Id.* Therefore, Plaintiff's claims are preempted, and Defendants are entitled to the dismissal they seek under FED. R. CIV. P. 12(b)(6).

Conclusion

Because Michigan's products liability statute immunizes Defendants from liability, the Court dismisses the action for failure to state a claim.

ACCORDINGLY, IT IS ORDERED:

Defendants' Motion to Dismiss (docket # 11) is **GRANTED** to the extent it seeks dismissal under Rule 12(b)(6), **DISMISSED** as moot to the extent it seeks a transfer of venue to the Western District of Michigan, and **DENIED** in all other respects.

Dated: October 26, 2011

/s/ Robert J. Jonker
ROBERT J. JONKER
UNITED STATES DISTRICT JUDGE