UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

SHERIDAN ALLO	CIVIL ACTION
v.	NO. 19-12493
ALLERGAN USA, INC.	SECTION "F"

ORDER AND REASONS

Before the Court is Allergan's Rule 12(b)(6) motion to dismiss Sheridan Allo's amended complaint. For the reasons that follow, the motion is GRANTED IN PART and DENIED IN PART.

Background

This products-liability action arises from injuries Sheridan Allo says she suffered when an Allergan-manufactured breast implant partially collapsed. The motion before the Court presents the question whether Allo's state-law claims are expressly preempted by the Medical Device Amendments of 1976, 21 U.S.C. § 360k.

Allergan manufactured a breast implant product called the "Natrelle Style 410 FX." The product is a class III device that has received premarket approval from the Food and Drug

Administration.[1] Allo had two such products implanted following a bilateral mastectomy. Three years later, Allo saw her doctor, complaining of pain in her right breast. An MRI revealed that the right implant showed signs of rupture. One month later, Allo had both implants removed. Her doctor examined them and concluded that the right one had partially collapsed. This lawsuit followed.

Invoking the Court's diversity jurisdiction,[2] Allo sued Allergan under the Louisiana Products Liability Act (LPLA), LA. REV. STAT. §§ 9:2800.51—9:2800.60, and the Louisiana Civil Code's redhibition articles, LA. CIV. CODE arts. 2520, 2545. The Court

[1] A court may take judicial notice of a premarket approval the Food and Drug Administration grants to a medical device manufacturer. Funk v. Stryker Corp., 631 F.3d 777, 783 (5th Cir. 2011).

[2] Because jurisdiction is based on diversity, the Court applies the substantive law of the forum, Louisiana. See Boyett v. Redland Ins. Co., 741 F.3d 604, 607 (5th Cir. 2014) (citing Erie R.R. Co. v. Tompkins, 304 U.S. 64 (1938)). Because Louisiana choice-of-law rules are substantive, they apply here. See Weber v. PACT XPP Tech., AG, 811 F.3d 758, 770 (5th Cir. 2016) (citing Klaxon Co. v. Stentor Elec. Mfg. Co., 313 U.S. 487, 496-97 (1941)). The first step under those rules is determining whether the laws of two or more states conflict. Lonzo v. Lonzo, 17-0549, p. 12 (La. App. 4 Cir. 11/15/17); 231 So. 3d 957, 966. If they do not, the Court applies forum law; if they do, further analysis is required. See Am. Elec. Power Co. v. Affiliated FM Ins. Co., 556 F.3d 282, 285 n.2 (5th Cir. 2009). The parties have not identified a conflict, and the Court has not found one. The Court therefore applies Louisiana substantive law.

dismissed her original complaint for failure to state a claim, but granted her leave to amend. She did so. In her amended complaint, she says Allergan is liable because its implant product (1) was unreasonably dangerous in construction or composition, (2) lacked an adequate warning, (3) violated an express warranty, and (4) suffered from redhibitory defects. She says these are permissible "parallel" claims under Riegel v. Medtronic, 552 U.S. 312 (2008).

Now, Allergan moves to dismiss under Rule 12(b)(6) on the basis that Allo's claims are expressly preempted by 21 U.S.C. § 360k and inadequately pleaded under Bell Atl. Corp. v. Twombly, 550 U.S. 544 (2007), and Ashcroft v. Iqbal, 556 U.S. 662 (2009).

I.

A complaint must contain a short and plain statement of the claim showing that the pleader is entitled to relief. FED. R. CIV. P. 8(a)(2). A party may move for dismissal of a complaint that fails this requirement. See FED. R. CIV. P. 12(b)(6). Such motions are rarely granted because they are viewed with disfavor. Leal v. McHugh, 731 F.3d 405, 410 (5th Cir. 2013) (quoting Turner v. Pleasant, 663 F.3d 770, 775 (5th Cir. 2011)).

In considering a Rule 12(b)(6) motion, the Court "accept[s] all well-pleaded facts as true and view[s] all facts in the light

most favorable to the plaintiff." Thompson v. City of Waco, Tex., 764 F.3d 500, 502 (5th Cir. 2014) (citing Doe ex rel. Magee v. Covington Cty. Sch. Dist. ex rel. Keys, 675 F.3d 849, 854 (5th Cir. 2012) (en banc)). Conclusory allegations are not well pleaded and, consequently, are not accepted as true. See Thompson, 764 F.3d at 502-03 (citing Iqbal, 556 U.S. at 678).

To overcome a Rule 12(b)(6) motion, "'a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.'" Gonzalez v. Kay, 577 F.3d 600, 603 (5th Cir. 2009) (quoting Iqbal, 556 U.S. at 678). A claim is facially plausible if it contains "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 556 U.S. at 678.

"A complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations[.]" Twombly, 550 U.S. at 555. But it must contain "more than labels and conclusions, and a formulaic recitation of a cause of action's elements will not do." Id. at 555. Ultimately, the Court's task is "to determine whether the plaintiff stated a legally cognizable claim that is plausible, not to evaluate the plaintiff's likelihood of success." Thompson, 764 F.3d at 503 (citation omitted).

II.

A.

Until 1976, states supervised the introduction of new medical devices into the market. Riegel, 552 U.S. at 315. But state supervision proved inadequate. Id. at 315. So, Congress took charge, enacting the Medical Device Amendments of 1976 (MDA). See 21 U.S.C. § 360c et seq.

The MDA "swept back some state obligations and imposed a regime of detailed federal oversight." Riegel, 552 U.S. at 316. To limit state interference with that oversight, Congress crafted an express preemption provision. See 21 U.S.C. § 360k. That provision preempts state-law tort claims to recover for injuries caused by a medical device if: "(1) 'the federal government has established requirements applicable to the device'; and (2) the claims are based on state-law requirements that are 'different from, or in addition to, the federal ones, and that relate to safety and effectiveness.'" Bass v. Stryker Corp., 669 F.3d 501, 507 (5th Cir. 2012) (quoting Riegel, 552 U.S. at 321-22).

But preemption is not plenary. Section 360k "allows 'parallel' state actions—state-law claims that are based on federal regulations." Funk v. Stryker Corp., 631 F.3d 777, 779 (5th Cir. 2011). So, for example, a failure-to-warn claim that is

based on a failure to comply with FDA regulations is "parallel" and not expressly preempted. See Hughes v. Boston Scientific Corp., 631 F.3d 762, 769 (5th Cir. 2011). To plead a parallel claim successfully, "a plaintiff's allegations that the manufacturer violated FDA regulations must meet the Twombly plausibility standard." Bass, 669 F.3d at 509.

B.

The LPLA creates a cause of action against a product manufacturer "for damage proximately caused by a characteristic of the product that renders the product unreasonably dangerous when such damage arose from a reasonably anticipated use of the product." LA. REV. STAT. § 9:2800.54(A). This liability is exclusive: A claimant cannot otherwise sue a manufacturer for damage caused by its product. See LA. REV. STAT. § 9:2800.52.

An LPLA claimant must plead four elements: "(1) that the defendant is a manufacturer of the product; (2) that the claimant's damage was proximately caused by a characteristic of the product; (3) that this characteristic made the product 'unreasonably dangerous'; and (4) that the claimant's damage arose from a reasonably anticipated use of the product by the claimant or someone else." Stahl v. Novartis Pharm. Corp., 283 F.3d 254, 260-61 (5th Cir. 2002).

A product can be "unreasonably dangerous" in four ways: (1) defective construction or composition, LA. REV. STAT. § 9:2800.55; (2) defective design, LA. REV. STAT. § 9:2800.56; (3) inadequate warning, LA. REV. STAT. § 9:2800.57; and (4) nonconformity with an express warranty, LA. REV. STAT. § 9:2800.58.

III.

Allergan contends that 21 U.S.C. § 360k expressly preempts Allo's claims.[3] Allo rejoins that hers are permissible "parallel" claims premised on Allergan's regulatory violations.

A.

In count one of her amended complaint, Allo alleges an LPLA construction-defect claim. See LA. REV. STAT. § 9:2800.55. She says that Allergan's implant product was defective in construction or composition because it did not meet FDA regulations governing shell thickness. Because this claim is premised on Allergan's alleged violation of FDA regulations, it is a permissible parallel claim

[3] It is undisputed that the first preemption prong——which asks whether the federal government has established requirements applicable to the device——is met because Allergan's implant product is a Class III medical device that has received premarket approval. See Bass, 669 F.3d at 407 (holding that devices that have received premarket approval "automatically satisfy" the first prong).

that is not preempted by 21 U.S.C. § 360k(a). See Bass, 669 F.3d at 512-13. The Court therefore denies Allergan's motion to dismiss the claim on preemption grounds.

B.

In count two of her amended complaint, Allo attempts to allege an LPLA inadequate-warning claim. See LA. REV. STAT. § 9:2800.57. But she fails to identify any FDA regulation that Allergan's FDA-approved warning violated. Instead, she complains that Allergan failed to warn that its product could contain a "curvilinear defect." FDA regulations did not oblige Allergan to so warn. So, Allo's claim is not parallel; it seeks to impose state-law warning requirements that add to, or differ from, federal ones. See Hughes, 631 F.3d at 768. Allo's inadequate-warning claim is therefore preempted by 21 U.S.C. § 360k(a). Accordingly, the Court grants Allergan's motion to dismiss the claim on preemption grounds.

C.

In count three of her amended complaint, Allo attempts to allege an LPLA breach-of-express-warranty claim. See LA. REV. STAT. § 9:2800.58. She fails. For one, she does not identify any FDA regulation Allergan violated when it made the express warranty she claims is untrue. Worse, she fails even to allege that Allergan made an express warranty at all. She instead alleges that her

doctor made an express warranty about the product, and that warranty proved untrue. That theory is not cognizable under LA. REV. STAT. § 9:2800.58, which requires that the *manufacturer* make the untruthful warranty. Allo thus fails to plead a plausible parallel claim for breach of express warranty. Accordingly, the Court grants Allergan's motion to dismiss the claim as preempted and inadequately pleaded.

D.

In count four of her amended complaint, Allo attempts to allege a redhibition claim. In Louisiana, "[t]he seller warrants the buyer against redhibitory defects, or vices in the thing sold." LA. CIV. CODE art. 2520. A defect is redhibitory "when it renders the thing useless, or its use so inconvenient that it must be presumed that a buyer would not have bought the thing had he known of the defect." Id. Allo alleges that Allergan's product was redhibitorily defective because it was not manufactured "in accordance with" the FDA-approved shell thickness range. This is a permissible parallel claim premised on Allergan's alleged violation of FDA regulations. See Bass, 669 F.3d at 512-13. It is not preempted. Accordingly, the Court denies Allergan's motion to dismiss the claim on preemption grounds.

IV.

Accordingly, IT IS ORDERED: that Allergan's Rule 12(b)(6) motion to dismiss Allo's amended complaint is GRANTED IN PART as to Allo's inadequate-warning (count II) and breach-of-express-warranty (count III) claims and DENIED IN PART as to Allo's construction-defect (count I) and redhibition (count IV) claims. Counts II and III are DISMISSED with prejudice.

New Orleans, Louisiana, February 19, 2020

MARTIN L. C. FELDMAN
UNITED STATES DISTRICT JUDGE