UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

DAVIS	CIVIL ACTION
VERSUS	NO: 13-6365
TEVA PHARMACEUTICALS USA, INC. ET AL.	SECTION: "J" (4)

ORDER AND REASONS

Before the Court is a *Motion for Judgment on the Pleadings* **(Rec. Doc. 18)** filed by Defendants Teva Pharmaceuticals USA, Inc. (Teva USA), Barr Pharmaceuticals, LLC (Barr Pharmaceuticals), and Barr Laboratories, Inc. (Barr Laboratories); Plaintiff's opposition thereto (Rec. Doc. 31); and Defendants' two replies. (Rec. Docs. 29, 34-2) Having considered the motion, the record, and the applicable law, the Court finds, for the reasons expressed below, that the motion should be **GRANTED.**

FACTS AND PROCEDURAL HISTORY

This action arises out of health complications Plaintiff suffered when she began taking the birth control medication Aviane. On October 30, 2012, Plaintiff's treating physician prescribed the birth control medication Aviane. (Rec. Doc. 1, p. 4) Plaintiff had previously been prescribed the birth control drug Azurette. Id. On November 7, 2012, Plaintiff was not feeling well and sought treatment at Ochsner Hospital. Id. While there, Plaintiff began to suffer from an arrhythmia of the heart. Id. at

5. Plaintiff alleges, "it was determined that the prescription, Aviane and/or generic levonorgestrel and ethinyl estradiol taken by [Plaintiff] caused her to develop a Pulmonary Embolism which caused her resulting symptoms." Id. Plaintiff now requires regular medical treatment to prevent blood clotting and may require such treatment for the rest of her life. Id. Further, she can no longer take birth control medication "based on the effects rendered from her use of Aviane and/or generic levonorgestrel and ethinyl estradiol." Id.

On November 7, 2013, Plaintiff filed a petition for damages (Rec. Doc. 1) against Teva USA; Teva Pharmaceuticals Industries, Ltd.[1]; Barr Pharmaceuticals; Barr Laboratories; and any other party involved in the manufacture, distribution, marketing, sale, and labeling of Aviane and/or generic levonorgestrel and ethinyl estradiol not yet known by Plaintiff. Id. at 1-3. The Court construes Plaintiff's petition as stating causes of action for negligence originating from Defendants' (1) failure to adequately test Aviane and/or generic levonorgestrel and ethinyl estradiol, (2) manufacturing, producing, promoting, formulating, creating, developing, designing, assembling, selling, and distributing Aviane and/or generic levonorgestrel and ethinyl estradiol in a

[1] The Court dismissed Defendant Teva Pharmaceuticals Industries, Ltd. at its August 13, 2014, docket call. (Rec. Doc. 27)

manner that was unsafe and in breach of the implied warranty against redhibitory defects, and (3) failure to warn of the dangers of Aviane and/or generic levonorgestrel and ethinyl estradiol. Id. at 7-8. Additionally, Plaintiff alleged causes of action for design defect, manufacturing defect, failure to warn, and breach of warranty under the Louisiana Products Liability Act, Louisiana Revised Statute § 9:2800.51 et seq. (LPLA). Id. at 5-6. Plaintiff alleges that Defendants are liable for her "personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, permanently diminished enjoyment of life, potential death, as well as the need for lifelong medical treatment, monitoring and medications, and fear of developing any of the above named health consequences." Id. at 6. Consequently, Plaintiff requests restitution, damages, attorneys' fees, and costs. Id. at 8. Defendants Teva USA, Barr Pharmaceuticals, and Barr Laboratories answered the complaint and denied any and all liability. (Rec. Docs. 6-8)

Defendants Teva USA, Barr Laboratories, and Barr Pharmaceuticals moved for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c) as to all claims against them on July 9, 2014. (Rec. Doc. 18) Plaintiff opposed the motion. (Rec. Doc. 31) The Court permitted Defendants to file two replies. (Rec. Docs. 29, 41)

LEGAL STANDARD

Rule 12(c) provides that "[a]fter the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings." FED. R. CIV. P. 12(c). "A motion brought pursuant to Fed.R.Civ.P. 12(c) is designed to dispose of cases where the material facts are not in dispute and a judgment on the merits can be rendered by looking to the substance of the pleadings and any judicially noticed facts." Hebert Abstract Co., Inc. v. Touchstone Props., Ltd., 914 F.2d 74, 76 (5th Cir. 1990). The standard for dismissal for a Rule 12(c) motion for judgment on the pleadings is the same as that for dismissal for failure to state a claim under Rule 12(b)(6). Johnson v. Johnson, 385 F.3d 503, 529 (5th Cir. 2004).

Under the Federal Rules of Civil Procedure, 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). The complaint must "give the defendant fair notice of what the claim is and the grounds upon which it rests." Dura Pharm., Inc. v. Broudo, 544 U.S. 336, 346 (2005). The allegations "must be simple, concise, and direct." FED. R. CIV. P. 8(d)(1).

To survive a Rule 12(b)(6) motion to dismiss, the plaintiff must plead enough facts to "state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 678

(2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 547 (2007)). A claim is facially plausible when the plaintiff pleads facts that allow the court to "draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 556 U.S. at 678. A court must accept all well-pleaded facts as true and must draw all reasonable inferences in favor of the plaintiff. Lormand v. U.S. Unwired, Inc., 565 F.3d 228, 232-33 (5th Cir. 2009); Baker v. Putnal, 75 F.3d 190, 196 (5th Cir. 1996). The court is not, however, bound to accept as true legal conclusions couched as factual allegations. Iqbal, 556 U.S. at 678.

DISCUSSION

Defendants argue that they are entitled to judgment in their favor on all of Plaintiff's claims. First, Defendants contend that Plaintiff's state-law tort claims sounding in failure to warn or design defect are preempted by federal law. (Rec. Doc. 18-1, pp. 1-10)(citing PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011) and Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 2466 (2013)) Defendants stress that Aviane is a generic drug. Id. at 2, 10. According to federal law, manufacturers of generic drugs may not unilaterally supplement, strengthen, or alter warnings. Id. Further, any claim that a generic drug's design rendered the drug unreasonably dangerous–that is, any LPLA design defect

claim–would implicate the manufacturer's obligation under federal law to maintain the same warning, label, and safety information as its brand-name equivalent. See id. at 3-4. A generic drug manufacturer cannot alter the chemical composition of the drug. Id. at 8-10. Thus, to improve the design's safety, the generic drug manufacturer would have to alter the drug's labeling, which it similarly may not do. See id. Consequently, federal law also preempts state-law design defect claims. Id. at 8-10. Second, Defendants argue that Plaintiff's allegations supporting her LPLA claims are conclusory and fail to include the elements of such claims. Id. at 10-11. Finally, Defendants assert that, "[u]nder Louisiana law, the LPLA establishes the exclusive remedy for injuries arising from product defects." Id. at 12. As such, the LPLA preempts Plaintiff's non-LPLA claims. Id. at 13. Given that Plaintiff's claims are either preempted or insufficiently plead, Defendants argue that the Court should grant their motion for judgment on the pleadings.[2]

Plaintiff responds by requesting leave to file an amended complaint "to provide specific facts in support of her claims." (Rec. Doc. 31, p. 1) Plaintiff avers that she has recently contacted an expert regarding testing the components of Aviane

[2] Defendants largely reassert these arguments in their replies. Additionally, they note that Plaintiffs have not properly filed a motion to amend their complaint. (Rec. Doc. 29, p. 2 n.1)

"in comparison to its brand name counterpart Alesse." Id. Plaintiff then contends that an article's description of Teva USA's plant suggests to Plaintiff that poor manufacturing was not responsible for the defect in Aviane that caused Plaintiff's injuries. Id. at 2. Rather, Plaintiff seems to suggest that Teva may have impermissibly altered the chemical composition of Aviane, which rendered it "a drug manufactured by [D]efendants." See id. at 2-3. Plaintiff bolsters this argument by stressing that she took another birth control medication, Azurette, "for quite some time without incident" before switching to Aviane. Id. at 3. Plaintiff therefore argues that because Defendants violated the FDA Guidelines by altering Aviane's chemical composition, Defendants may not avail themselves of the U.S. Supreme Court cases holding that state-law failure to warn and design defect claims are preempted under federal law. Id. at 2-3. Consequently, Plaintiff argues that federal law does not preempt her LPLA claims. Id. at 3.

A. Federal Preemption of State-Law Claims

The Court agrees with Defendants and finds that federal law preempts Plaintiff's failure to warn and design defect claims under the LPLA.[3] Federal law imposes a "duty of sameness" upon

[3] To the extent that Plaintiff makes out a LPLA breach of warranty claim, such claim is similarly preempted. Johnson v. Teva Pharm. USA, Inc., No. 12-31011, 2014 WL 3397786, at *5 (5th Cir. July 11, 2014).

manufacturers of generic drugs, which duty obliges generic drug labels to maintain the same labeling as their brand-name counterparts. Mensing, 131 S. Ct. at 2578. Warning letters to doctors or patients constitute "labels." Johnson v. Teva Pharm. USA, Inc., No. 12-31011, 2014 WL 3397786, at *2 (5th Cir. July 11, 2014). "Because federal law requires generic drug labels to be the same as brand-name labels, any state-law duty that requires manufacturers to use safer labels conflicts with the federal 'duty of sameness' and is preempted by federal law." Id. (citing Mensing, 131 S. Ct. at 2577-78; Morris v. PLIVA, Inc., 713 F.3d 774, 776-77 (5th Cir. 2013); Eckhardt v. Qualitest Pharm., Inc., 751 F.3d 674, 678 (5th Cir. 2014); Lashley v. Pfizer, Inc., 750 F.3d 470, 474 (5th Cir. 2014)). Thus, as alleged, Plaintiff's LPLA failure to warn claim is preempted. Id.

Plaintiff's LPLA design defect claim is also preempted. To state such a claim, a plaintiff must show that (1) an alternative design exists, and (2) that plaintiff's damage outweighs both the burden the manufacturer would suffer if it were to adopt the alternative *and* any adverse effect of the alternative on the product's utility. Id.; La. Rev. Stat. Ann. § 9:2800.56. "The second prong involves a risk-utility analysis[, which requires a court] to consider whether the product contains an 'adequate warning.'" Johnson, 2014 WL 3397786, at *4. Because federal law

requires generic drugs to possess both the same chemical composition and labeling as the corresponding brand-name drug, the LPLA design defect claim, which could require either additional labeling or an alternative composition, is preempted inasmuch as the complained-of design is one that was approved by the Food & Drug Administration (FDA). Id. (citing Mut. Pharm. Co., Inc. v. Bartlett, 133 S. Ct. 2466 (2013)). Any design defect claim based upon Defendants' alleged unlawful alteration of Aviane's chemical composition is likewise preempted by federal law; there is no private right of action for Defendants' breach of FDA regulations requiring generic drugs to have the same chemical composition as their brand-name counterparts. 21 U.S.C. § 337(a); Morris, 713 F.3d at 777. Because Plaintiff's LPLA failure to warn and design defect claims are preempted by federal law, the Court grants Defendants' motion with respect to these claims.

Plaintiff requests leave to amend her complaint to better allege her claims. Generally, courts grant such requests unless it appears that the amendment would be futile. See Stripling v. Jordan Prod. Co., LLC, 234 F.3d 863, 872-73 (5th Cir. 2000)(stating that leave to amend should be freely given where the initial complaint is subject to dismissal for failure to state a claim unless such leave would be futile); Sekil v. ADT

Sec. Servs. Inc., No. H-08-0510, 2008 WL 4844209, at *3 (S.D. Tex. Nov. 3, 2008)(stating that requests to amend pleadings are routinely granted when made in response to a motion for judgment on the pleadings); E*Trade Fin. Corp. v. Deutsche Bank AG, 420 F. Supp. 2d 273, (S.D.N.Y. 2006)(finding that when leave to amend complaint is filed in response to motion for judgment on the pleadings, the motion should be granted unless futile); (Rec. Doc. 31, p. 1). Here, it appears to the Court that it would be futile to grant Plaintiff leave to amend because Plaintiff's LPLA failure to warn and design defect claims fail as a matter of law. Plaintiff has not suggested, for example, that Defendants failed to send out a warning that the manufacturer of its brand-name counterpart was authorized to send out and in fact sent out. Thus, the Court will not grant Plaintiff leave to amend her complaint as to these claims.

B. Conclusory Nature of Plaintiff's Claims

Next, the Court finds that Plaintiff's LPLA manufacturing claim–the sole remaining LPLA claim–is conclusory in nature and insufficiently plead. To state a manufacturing claim under the LPLA, a plaintiff must show that "at the time the product left its manufacturer's control, the product deviated in a material way from the manufacturer's specifications or performance standards for the product or from otherwise identical products

manufactured by the same manufacturer." La. Rev. Stat. Ann. § 9:2800.55. Here, Plaintiff has not alleged how the product deviated from either the manufacturer's specifications or its otherwise identical products. Plaintiff therefore has not sufficiently plead her LPLA manufacturing cause of action. Moreover, Plaintiff states that it seems unlikely that her damage was caused by a manufacturing mistake. (Rec. Doc. 31, p. 2) As such, it appears to the Court that it would be futile to grant Plaintiff leave to file an amended complaint. The Court therefore will not grant Plaintiff leave to amend her complaint as to the LPLA manufacturing claim.

C. Preemption of Plaintiff's Non-LPLA Claims

Finally, the Court finds that, to the extent that Plaintiff states any non-LPLA claims that would not be preempted by federal law as described above, any such non-LPLA claims are preempted by the LPLA. See Stahl v. Novartis Pharms. Corp., 283 F.3d 254, 261 (5th Cir. 2002). The LPLA "establishes the exclusive theories of liability for manufacturers for damage caused by their products[;] A claimant may not recover from a manufacturer for damage caused by a product on the basis of any theory of liability that is not set forth in [the LPLA]." La. Rev. Stat. Ann. § 9:2800.52. Defendants assert that they are manufacturers of the product at issue. Plaintiff does not oppose this

assertion. Thus, the Court concludes that Plaintiff's non-LPLA claims are preempted by the LPLA. The Court therefore grants Defendants' motion with respect to these claims, and the Court will not grant Plaintiff leave to amend them.

Accordingly,

IT IS HEREBY ORDERED that Defendants' *Motion* **(Rec. Doc. 18)** is **GRANTED**.

IT IS FURTHER ORDERED that Plaintiff's request to file an amended complaint, contained in her *Opposition* **(Rec. Doc. 31)**, is **DENIED**.

New Orleans, Louisiana this 10th day of September, 2014.

CARL J. BARBIER
UNITED STATES DISTRICT JUDGE