UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF LOUISIANA

HARLA ROBERTSON	CIVIL ACTION
VERSUS	NO: 15-438
ASTRAZENECA PHARMECEUTICALS, LP, ET AL.	SECTION: J(2)

ORDER AND REASONS

Before the Court is a *Motion to Dismiss in Part* (**Rec. Doc. 23**) filed by Defendant, AstraZeneca Pharmaceuticals, LP ("AstraZeneca"), and an *Opposition* thereto (**Rec. Doc. 37**) by Plaintiff, Harla Robertson ("Plaintiff"). Plaintiff also requested oral argument on this matter. (Rec. Doc. 34.) Having considered the motions, the parties' submissions, the record, and the applicable law, the Court finds, for the reasons expressed below, that AstraZeneca's motion should be **GRANTED**.

PROCEDURAL HISTORY AND BACKGROUND FACTS

Plaintiff Harla Robertson originally filed suit against Defendant AstraZeneca in February 2015, asserting claims for inadequate warning and breach of express warranty under the Louisiana Products Liability Act ("LPLA"). (Rec. Doc. 1.) The original complaint contained "unnecessarily repetitive legally

conclusive assertions." (Rec. Doc. 20, at 9.) AstraZeneca filed a Motion to Dismiss for Failure to State a Claim, which this Court granted. (*See* Rec. Doc. 15; Rec. Doc. 20.) However, this Court allowed Plaintiff leave to amend her complaint, cautioning that it would dismiss her claim with prejudice if she continued to assert "purely legal conclusions without any factual basis." (Rec. Doc. 20, at 11, 14.)

In her amended complaint, Plaintiff alleges that she sustained adverse effects from her use of Seroquel and/or Seroquel XR, and their generics, Quetiapine and Quetiapine Fumarate, respectively. AstraZeneca is the manufacturer of Seroquel and Seroquel XR, whereas Quetiapine and Quetiapine Fumarate are manufactured by Lupin Pharmaceuticals, Inc. ("Lupin") and Teva Pharmaceuticals, Inc. ("Teva").[1] Seroquel, Seroquel XR, and their generics are approved by the U.S. Food and Drug Administration ("FDA") for treatment of schizophrenia and bipolar disorder. (Rec. Doc. 21, at 6-7.)

Plaintiff alleges that she was prescribed Seroquel, Seroquel XR, Quetiapine, and Quetiapine Fumarate to treat her

[1] Upon Plaintiff's motion, on June 10, 2015, this Court dismissed Plaintiff's claims against Lupin and Teva, leaving AstraZeneca as the sole defendant in this matter.

bipolar disorder and difficulty sleeping. (Rec. Doc. 21, at 3.) Plaintiff further alleges that as a result of taking these prescription medications she sustained a litany of injuries including, "weight gain, inability to lose weight, medical complications, physical damages, pain and suffering, severe abdominal pain, gastrointestinal problems, hyperlipidia, chronic inflammation of the gall bladder, gall bladder removal, increased panic attacks, increased anxiety, depression, increased crying spells, suicidal [thoughts], suicidal [thoughts] due to chronic abdominal pain, mental anguish, emotional distress, [and] aggravation of pre-existing conditions." (Rec. Doc. 21, at 16-17.)

Plaintiff claims that AstraZeneca is liable as a manufacturer under the LPLA. She alleges that Seroquel, Seroquel XR, and their generics are "unreasonably dangerous" (1) because AstraZeneca failed to provide an adequate warning regarding the drugs' adverse effects to Plaintiff or her physician, (2) because the medications fail to conform to the express warranty that they are "safe, effective product[s]," (3) because the drugs are defective in design, and (4) because the drugs are defective in construction or composition. (Rec. Doc. 21, at 18, 19, 22, 25.)

On September 8, AstraZeneca filed the instant motion seeking dismissal of three of Plaintiff's claims pursuant to Federal Rule of Civil Procedure 12(b)(6). Plaintiff filed an opposition to the motion on October 1. AstraZeneca filed a Motion for Leave to File Reply (Rec. Doc. 38) on October 5.

PARTIES' ARGUMENTS

In its Motion to Dismiss, AstraZeneca argues that Plaintiff's amended complaint still does not pass muster under Rule 12(b)(6). Specifically, it argues that Plaintiff failed to state a claim that Seroquel, Seroquel XR, and their generics are unreasonably dangerous (1) in construction or composition, (2) in design, or (3) because AstraZeneca breached an express warranty. Plaintiff's claims, it asserts, are nothing more than "unsupported legal conclusions and jumbled, irrelevant factual allegations." (Rec. Doc. 23.) For those reasons, AstraZeneca asks this Court to dismiss the three claims listed above. It does not challenge the sufficiency of Plaintiff's allegations that the drugs were unreasonably dangerous because of AstraZeneca's failure to warn of the drugs' adverse effects.

In her opposition, Plaintiff argues that the amended complaint states a claim that survives a Rule 12(b)(6) motion to dismiss. Generally, Plaintiff opposes AstraZeneca's "demands for

more facts," which she contends are not appropriate at this stage of the proceedings. (Rec. Doc. 37, at 4.) In addition, Plaintiff claims she lists the patent number for Seroquel, Seroquel XR, and their generics in her complaint, as well as some technical patent data. *Id.* at 2. According to Plaintiff, this allegation is sufficient to state a claim for unreasonably dangerous construction or composition and design. *Id.* In further support of her argument, Plaintiff quotes extensively from the LPLA, claiming that her amended complaint complies with the requirements of the Act. *Id.* at 7-13.

LEGAL STANDARD

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).

"Under Rule 12(b)(6), a claim may be dismissed when a plaintiff fails to allege any set of facts in support of his claim which would entitle him to relief." *Taylor v. Books A*

Million, Inc., 296 F.3d 376, 378 (5th Cir. 2002) (citing *McConathy v. Dr. Pepper/Seven Up Corp.*, 131 F.3d 558, 561 (5th Cir. 1998)). 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." *Id.* 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

The LPLA "establishes the exclusive theories of liability for manufacturers for damage caused by their products," and "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. § 9:2800.52 (2014).

In order to prevail on a claim brought pursuant to the LPLA, a plaintiff must establish the following elements: (1) that the defendant is a manufacturer of the product; (2) that a characteristic of the product was the proximate cause of the claimant's damage; (3) that the characteristic made the product "unreasonably dangerous"; and (4) that the claimant's damage arose from a reasonably anticipated use of the product. LA. REV. STAT. § 9:2800.54(A) (2014). A product is "unreasonably dangerous" if it meets at least one of the following criteria:

> (1) The product is unreasonably dangerous in construction or composition;
> (2) The product is unreasonably dangerous in design;
> (3) The product is unreasonably dangerous because an adequate warning about the product has not been provided; or
> (4) The product is unreasonably dangerous because it does not conform to an express warranty made by the manufacturer of the product.

LA. REV. STAT. § 9:2800.54(B); *see also Stahl v. Novartis Pharm. Corp.*, 283 F.3d 254, 261 (5th Cir. 2002); *Jefferson v. Lead Indus. Ass'n, Inc.*, 930 F. Supp. 241, 245 (E.D. La. 1996) (Vance, J.). Plaintiff asserts that Seroquel, Seroquel XR, and their generics are unreasonably dangerous for all four reasons listed above. In its Motion to Dismiss, AstraZeneca challenges the sufficiency of Plaintiff's allegations with respect to (1)

construction or composition, (2) design, and (3) breach of express warranty.

A. Unreasonably Dangerous in Construction or Composition

A product is unreasonably dangerous in construction or composition if it deviates materially from "the manufacturer's specifications or performance standards for the product or from otherwise identical products manufactured by the same manufacturer." LA. REV. STAT. § 9:2800.55. In these cases, the defect is not inherent in all units of the same product. *Brocato v. DePuy Orthopaedics, Inc.*, No. 14-2607, 2015 WL 854150, at *3 (E.D. La. Feb. 25, 2015) (Shushan, Mag.). Instead, a "mistake in the manufacturing process" renders the product defective. *Id.*; *see also Stahl*, 283 F.3d at 263. In order to survive a motion to dismiss, the claimant must demonstrate that the particular product either deviated from the defendant's own performance standards or specifications or from identical products manufactured by the defendant. *See Brocato*, 2015 WL 854150, at *3.

In her amended complaint, Plaintiff fails to demonstrate that the particular drugs she took materially deviated from AstraZeneca's own standards or specifications or from identical products manufactured by AstraZeneca. Plaintiff alleges that

"AstraZeneca's specifications or performance standards for Seroquel are that it is an effective, safe medicine for the treatment of bipolar disorder." (Rec. Doc. 21, at 24.) Assuming without deciding that this statement sufficiently alleges a specification or standard, Plaintiff still does not claim that the particular drugs she took deviated from these standards or specifications. Instead, Plaintiff argues that all units of Seroquel deviated from this standard. *Id.* ("Seroquel does not work as it was intended . . . and instead creates medical [sic] severe and life threatening problems.") Because Plaintiff failed to allege a defect in the particular products she used, her construction or composition claim fails to satisfy the minimal pleading standard.

B. Unreasonably Dangerous in Design

Plaintiff also alleges that Seroquel, Seroquel XR, and their generics are unreasonably dangerous in design. Under the LPLA, a product is unreasonably dangerous in design if:

> (1) There existed an alternative design for the product that was capable of preventing the claimant's damage; and
> (2) The likelihood that the product's design would cause the claimant's damage and the gravity of that damage outweighed the burden on the manufacturer of adopting such alternative design and the adverse effect, if any, of such alternative design on the utility of the product. An adequate warning about a product shall be considered in evaluating the

> likelihood of damage when the manufacturer has used reasonable care to provide the adequate warning to users and handlers of the product.

LA. REV. STAT. § 9:2800.56. To state a claim for unreasonably dangerous design, the plaintiff must (1) allege how the design is defective or how the design relates to the injury and (2) demonstrate the existence of a specific alternate design. *Becnel v. Mercedes-Benz USA, LLC*, No. 14-0003, 2014 WL 4450431, at *4 (E.D. La. Sept. 10, 2014) (Barbier, J.); *see Kennedy v. Pfizer, Inc.*, No. 12-01858, 2013 WL 4590331, at *4 (W.D. La. Aug. 28, 2013) (Hicks, J.).

The occurrence of an injury does not give rise to the presumption that the design was unreasonably dangerous. *Kennedy*, 2013 WL 4590331, at *3. A conclusory allegation that an alternate design exists will not suffice, but the plaintiff need not allege in detail "that the product's design would cause the claimant's damage," that "the gravity of that damage outweighed the burden on the manufacturer of adopting such alternative design," and "the adverse effect, if any, of such alternative design on the utility of the product." *Becnel*, 2014 WL 4450431, at *4 (finding sufficient plaintiff's allegations that the defendant used an alternative design in the past before implementing the new, defective design).

In this case, Plaintiff failed to demonstrate the existence of a specific alternative design. Instead, the amended complaint alleges the existence of "numerous over the counter [sic] medicines and prescription medications whose patents have expired that could have been manufactured and/or utilized to treat plaintiff's symptoms." (Rec. Doc. 21, at 25.) Plaintiff also argues that AstraZeneca manufactured other products that could have been used to treat her symptoms. *Id.* Both allegations are insufficient because the existence of alternate products does not demonstrate the existence of a specific alternate design. Finally, the complaint does not allege how the design is defective or how the design relates to her injuries. *See id.* at 25-26 (defective design allegations). Thus, Plaintiff failed to state a claim for unreasonably dangerous design under the LPLA.

C. Unreasonably Dangerous Due to Breach of Express Warranty

Finally, AstraZeneca argues that Plaintiff failed to state a claim for breach of express warranty under the LPLA. "A product is unreasonably dangerous when it does not conform to an express warranty made at any time by the manufacturer about the product if the express warranty has induced the claimant or another person or entity to use the product and the claimant's damage was proximately caused because the express warranty was

untrue." LA. REV. STAT. § 9:2800.58. Thus, the plaintiff must establish that: "(1) the manufacturer made an express warranty regarding the product, (2) the plaintiff was induced to use the product because of that warranty, (3) the product failed to conform to that express warranty, and (4) the plaintiff's damage was proximately caused because the express warranty was untrue." *Caboni v. Gen. Motors Corp.*, 278 F.3d 448, 452 (5th Cir. 2002).

To state a claim for breach of express warranty, the plaintiff must (1) allege the content of the warranty and (2) explain how the warranty was untrue. *Henderson v. Dasa*, No. 13-8, 2014 WL 1365968, at *3 (E.D. La. Apr. 7, 2014) (Milazzo, J.). The complaint need not "identify specific language offered by a manufacturer," but it must "specify the warranty in question" and explain why the warranty was untrue. *Becnel*, 2014 WL 4450431, at *5; *Kennedy*, 2013 WL 4590331, at *5. The LPLA defines an express warranty as "a representation, statement of alleged fact or promise about a product or its nature, material or workmanship that represents, affirms or promises that the product or its nature, material or workmanship possesses specified characteristics or qualities or will meet a specified level of performance." LA. REV. STAT. § 9:2800.58(6). Statements contained in advertising or websites generally are not

warranties because they are "puffery," "general praise," or "general opinion." *Becnel*, 2014 WL 4450431, at *5; *see* LA. REV. STAT. § 9:2800.58(6).

Here, Plaintiff alleges that AstraZeneca expressly warranted "that Seroquel is a safe, effective product that can be used for the treatment of depressive episodes of bipolar disorder." (Rec. Doc. 21, at 20.) According to Plaintiff, AstraZeneca made these warranties in "its materials presented to the FDA, its website[,] and upon information and belief[,] its marketing, promotional[,] and informational materials to plaintiff, patients, plaintiff's doctors, [and] plaintiff's psychologists." *Id.* at 19-20. Any statements made on AstraZeneca's website or in its marketing materials were not warranties – they were mere puffery, praise, or opinion. *Becnel*, 2014 WL 4450431, at *5. Further, Plaintiff fails to specify the "materials presented to the FDA" in which the alleged warranties appear. While Plaintiff is not required to quote the specific language of the warranties, she must make more than a general reference to them. *Id.* The reference to "materials presented to the FDA" is not specific enough to survive a Rule 12(b)(6) motion to dismiss.

CONCLUSION

Accordingly,

IT IS HEREBY ORDERED that AstraZeneca's *Motion to Dismiss* (**Rec. Doc. 23**) is **GRANTED**. AstraZeneca's *Motion for Leave to File Reply* **(Rec. Doc. 38)** is **DENIED** as moot.

IT IS FURTHER ORDERED that Plaintiff's claims, with the exception of her Failure to Warn claim, are **DISMISSED WITH PREJUDICE**. Plaintiff's request for leave to amend her complaint is **DENIED**.

IT IS FURTHER ORDERED that oral argument on this matter, set for October 7, 2015, at 9:30 a.m., is **CANCELED**.

New Orleans, Louisiana this 6th day of October, 2015.

CARL J. BARBIER
UNITED STATES DISTRICT COURT