UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

GLORIA GUIDRY	CIVIL ACTION
V.	NO. 15-4591
JANSSEN PHARMACEUTICALS, INC., ET AL.	SECTION "F"

ORDER AND REASONS

Before the Court are two motions to dismiss: The first is brought by defendants Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC, Johnson & Johnson Services, Inc., and Johnson & Johnson Company (the Janssen defendants). The second is brought by defendants Mitsubishi Tanabe Pharma Corporation and Mitsubishi Tanabe Pharma Development America, Inc. (the Mitsubishi defendants). For the reasons that follow, both motions are GRANTED.

Background

Gloria Guidry brings this product liability action claiming that she suffered acute kidney injury and acute kidney failure after using Invokana, a prescription drug manufactured, licensed, and distributed by the defendants.

Gloria Guidry is domiciled in Jefferson Parish, Louisiana. Her doctor prescribed Invokana for treatment of type two diabetes. She ingested Invokana from approximately March 11, 2014 to September 21, 2014. She was hospitalized on September 21, 2014 due to acute kidney injury and acute kidney failure. She remained in the hospital until September 28, 2014.

The plaintiff alleges that the Food and Drug Administration approved Invokana on March 29, 2013. She claims that Invokana is the first diabetes treatment to be approved in a new class of drugs known as sodium-glucose co-transporter 2 (SGLT2) inhibitors. Invokana works by blocking the reabsorption of glucose by the kidney, increasing glucose excretion, and lowering blood glucose levels in diabetics who have elevated blood glucose levels.[1] According to the plaintiff, the FDA indicated that Invokana should not be used to treat people with Type I diabetes, people with increased ketones in their blood or urine, or people with severe renal impairment. The plaintiff contends that people who are prescribed Invokana have suffered and may continue to suffer from ketoacidosis, acute kidney injury, and/or acute renal failure.[2] According to the plaintiff, the defendants have concealed their knowledge that the drug may produce these side effects, and due to the defendants' actions and inactions, the plaintiff was injured.

The complaint continues: On May 15, 2015, the FDA issued a Safety Announcement stating that the classification of diabetes medication in which Invokana falls, SGLT2 inhibitors, may lead to

[1] The plaintiff notes the effects and prevalence of Type II diabetes. She also lists the FDA studies Invokana endured before being approved.

[2] The plaintiff explains that ketoacidosis "occurs when toxic acids known as ketones accumulate to dangerous levels in the blood."

ketoacidosis.[3] She claims that the defendants knew or should have known that use of Invokana was associated with ketoacidosis, acute kidney failure, and/or acute renal failure. Despite this knowledge, she contends the defendants promote the drug as a safe treatment, refuse to warn patients of these risks, and actively conceal these risks from the medical community. As a result of consuming Invokana, the plaintiff alleges she has suffered permanent injury from ketoacidosis, acute kidney injury, and/or acute renal failure. Had the defendants properly disclosed the risks associated with Invokana, the plaintiff urges that she would not have used it.

After exhausting a list of possibilities in which the defendants may have violated the Federal Food, Drug and Cosmetic Act, the plaintiff asserts her first three causes of action under the Louisiana Products liability Act for composition or construction defect, design defect, and failure to warn. Fourth, she asserts a general negligence claim. Fifth, she claims strict product liability. Sixth, she asserts negligent misrepresentation. Seventh, she claims fraud and deceit. Eighth, she alleges violations of Louisiana Unfair Trade Practices. Ninth, she asserts breach of express warranty. Tenth, she asserts an action in

[3] Notably, the plaintiff never expressly alleges in her complaint that she suffered from ketoacidosis.

redhibition. And finally, her eleventh claim is for breach of implied warranties.

The Court addresses the two motions in turn.[4]

I. The Janssen Defendants' Motion

The Janssen defendants move to dismiss all of the plaintiff's claims not specified in the Louisiana Products Liability Act on the ground that the LPLA provides "the exclusive" remedy for harm caused by a manufacturer's product. The Janssen defendants also seek to dismiss the remaining causes of action under Federal Rule of Procedure 12(b)(6). They contend that the plaintiff has failed to plead sufficient facts to satisfy the pleading standards of Twombly and Iqbal. Finally, the defendants seeks to dismiss the plaintiff's request for punitive damages as prohibited by Louisiana law.

A. Exclusivity of Louisiana Products Liability Act

The LPLA provides "the exclusive theories of liability for manufacturers for damage caused by their products." La. R.S. § 9:2800.52. To eliminate any doubt, the Act goes on, "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 this Chapter." Id. The LPLA only allows recovery if a product is

[4] The Mitsubishi defendants have incorporated into their motion all of the arguments made by the Janssen defendants. Thus, the Court's ruling on the Janssen defendants' motion applies equally to the Mitsubishi defendants' motion.

unreasonably dangerous: 1) in construction or composition; 2) in design; 3) because of inadequate warning; or 4) because of nonconformity to express warranty. La. R.S. § 9:2800.54-58. Accordingly, all theories of recovery that fall outside of these four must be dismissed.

The plaintiff attempts to redeem her extraneous theories of recovery with an appeal to New Jersey law. She claims that, because the defendants' home state is New Jersey, the laws of New Jersey apply to her claims. According to the plaintiff, the New Jersey Products Liability Act does not have the same exclusive provision as the LPLA.

Article 3545 of the Louisiana Civil Code provides:

> Delictual and quasi-delictual liability for injury caused by a product, as well as damages, whether compensatory, special, or punitive are governed by the law of this state: (1) when the injury was sustained in this state by a person domiciled or residing in this state; or (2) when the product was manufactured, produced, or acquired in this state and caused the injury either in this state or in another state to a person domiciled in this state.

The plaintiff, however, relies on Article 3547, which makes Article 3545 inapplicable if, "from the totality of the circumstances of an exceptional case, it is clearly evident under the principles of Article 3542[5], that the policies of another state would be more

[5] The principles in Article 3542 are: "(1) the pertinent contacts of each state to the parties and the events giving rise to the dispute, including the place of conduct and injury, the domicile,

seriously impaired if its law were not applied to the particular issue. In such event, the law of the other state shall apply." The plaintiff contends that "the nexus of the alleged fraud or misrepresentation likely occurred in New Jersey . . . in essence outweighing Louisiana's interest in this litigation." The Court disagrees that New Jersey law applies here.

The plaintiff is a resident of Louisiana. Presumably (although not specified in the complaint), the prescription drug was acquired in Louisiana and the alleged injury was sustained in Louisiana. The plaintiff fails to explain how this is an "exceptional case" in which New Jersey law will be "seriously impaired" by application of Louisiana law. To the contrary, it is Louisiana law that would be seriously impaired if it were so easily circumvented. Thus, Louisiana law applies.

Accordingly, the following claims are dismissed as to all defendants: negligence (fourth), strict product liability (fifth), negligent misrepresentation (sixth), fraud and deceit (seventh),

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habitual residence, or place of business of the parties, and the state in which the relationship, if any, between the parties was centered; and (2) the policies referred to in Article 3515, as well as the policies of deterring wrongful conduct and of repairing the consequences of injurious acts.

The policies referred to in Article 3515 are: (1) the relationship of each state to the parties and the dispute; and (2) the policies and needs of the interstate and international systems, including the policies of upholding the justified expectations of the parties and of minimizing the adverse consequences that might follow from subjecting a party to the law of more than one state.

violations of Louisiana Unfair Trade Practices (eighth), and breach of implied warranty (eleventh).

B. 12(b)(6) Motion

The other causes of action are the plaintiff's claims under the LPLA for defect in composition or construction, defect in design, failure to warn, and breach of express warranty, and her claim for redhibition.[6] The Janssen defendants move to dismiss these causes of action under Federal Rule of Civil Procedure 12(b)(6).[7]

Rule 12(b)(6) of the Federal Rules of Civil Procedure allows a party to move for dismissal of a complaint for failure to state a claim upon which relief can be granted. Under Rule 8(a)(2) of the Federal Rules of Civil Procedure, a pleading must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Ashcroft v. Iqbal, 556 U.S. 662, 678-79 (2009) (citing FED. R. CIV. P. 8). "[T]he pleading standard Rule 8 announces does not require 'detailed factual allegations,' but it demands more than an unadorned, the-defendant-unlawfully-

[6] "[Louisiana] [c]ourts have interpreted the LPLA as preserving redhibition as a cause of action only to the extent the claimant seeks to recover the value of the product or other economic loss." De Atley v. Victoria's Secret Catalogue, LLC, 2004-0661 (La. App. 4 Cir. 5/14/04); 876 So. 2d 112, 115.

[7] The defendants also move to dismiss the claim for defect in design on the basis that it is preempted by federal law.

harmed-me accusation." Id. at 678 (citing Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)).

Thus, in considering a Rule 12(b)(6) motion, the Court "accepts 'all well-pleaded facts as true, viewing them in the light most favorable to the plaintiff.'" See Martin K. Eby Constr. Co. v. Dall. Area Rapid Transit, 369 F.3d 464 (5th Cir. 2004) (quoting Jones v. Greninger, 188 F.3d 322, 324 (5th Cir. 1999)). But, in deciding whether dismissal is warranted, the Court will not accept conclusory allegations in the complaint as true. Kaiser Aluminum & Chem. Sales, Inc. v. Avondale Shipyards, Inc., 677 F.2d 1045, 1050 (5th Cir. 1982)). Indeed, the Court must first identify allegations that are conclusory and thus not entitled to the assumption of truth. Iqbal, 556 U.S. at 678-79. A corollary: legal conclusions "must be supported by factual allegations." Id. at 678. Assuming the veracity of the well-pleaded factual allegations, the Court must then determine "whether they plausibly give rise to an entitlement to relief." Id. at 679.

"Factual allegations must 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)." Twombly, 550 U.S. at 555 (citations and footnote omitted). "A claim has facial plausibility when the plaintiff pleads 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. "Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." Id. at 678 (internal quotations omitted) (citing Twombly, 550 U.S. at 557). "[A] plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief'" thus "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Twombly, 550 U.S. at 555 (alteration in original) (citation omitted).

1. Defective Construction or Composition

A defective construction claim provides a remedy for harm caused by a product defect "due to a mistake in the manufacturing process." Stahl v. Novartis Pharmaceuticals Corp., 283 F.3d 254, 263 (5th Cir. 2002). In presenting a defective construction or composition theory of recovery under the LPLA, the plaintiff must prove that, at the time the product left the manufacturer's control, it deviated materially from the manufacturer's specifications or performance standards for the product or from otherwise identical products manufactured by the same manufacturer. La. R.S. § 9:2800.55.

None of the specific facts alleged by the plaintiff suggest that the Invokana medication she ingested deviated from the specifications or intended design of the drug. Nor does she allege facts as to how the composition of Invokana was defective. Although

the plaintiff recites the elements of the cause action, she fails to provide any factual basis to show her claim is plausible. The facts alleged in the complaint fail to raise a right to relief above a speculative level. Twombly, 550 U.S. at 555. Therefore, the defective composition or construction claim is dismissed as to all defendants.

2. Defective Design

Under the LPLA, a product's design is unreasonably dangerous if the plaintiff demonstrates that, at the time the product left the manufacturer's control, "[t]here existed an alternative design for the product that was capable of preventing the claimant's damage and that the danger of the damage outweighed the burden on the manufacturer of adopting the alternative design." Watson v. Bayer Healthcare Pharmaceuticals, Inc., 2013 WL 1558328, 13-212 (E.D. La. April 11, 2013)(Feldman, J.) (quoting La. R.S. § 9:2800.56)(citations omitted). The LPLA "does not allow a fact finder to presume an unreasonably dangerous design solely from the fact that injury occurred." McCarthy v. Danek Medical, Inc., 65 F. Supp. 2d 410, 412 (E.D. La. 1999).

Without alleging any specific facts, the plaintiff merely recites the elements of a defective design claim. The mere fact that she was hospitalized sometime after using Invokana does not suffice. Importantly, the plaintiff fails to plead or support how Invokana’s design is defective, in what way Invokana could have

remedied the defect, or how the alleged defect caused her particular injuries. "[A] formulaic recitation of the elements of a cause of action will not do." Twombly, 550 U.S. at 555. Accordingly, the plaintiff's defective design claim is dismissed as to all defendants.[8]

3. Inadequate Warning

"To successfully maintain a failure-to-warn claim under the LPLA, a plaintiff must demonstrate that the product in question has a potentially damage-causing characteristic and that the manufacturer failed to use reasonable care to provide an adequate warning about this characteristic." Stahl, 283 F.3d at 265-66.

The plaintiff repeatedly alleges that Invokana has a potentially damage-causing characteristic; namely, that Invokana causes acute kidney injury, acute renal failure, and ketoacidosis. These assertions, however, are mere conclusions. In no way does the plaintiff assert *how* the defendants failed to use reasonable care to provide an adequate warning. The only specific fact the Court can find that supports the plaintiff's failure-to-warn claim is that the FDA issued a safety announcement warning that SGLT2 inhibitors may lead to ketoacidosis. But the plaintiff does not allege (at least coherently) that she ever suffered from

[8] Because the claim is dismissed under Rule 12(b)(6), the Court need not address the defendants' assertion that the plaintiff's defective design claim is preempted by federal law.

ketoacidosis. Nor does she provide any factual basis for her claim that the defendants failed to adequately warn of acute kidney injury and acute kidney failure.[9] "Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." Iqbal, 556 U.S. at 678 (internal quotations omitted). Accordingly, the plaintiff's failure-to-warn claim is dismissed as to all defendants.

4. Breach of Express Warranty

To maintain a breach of express warranty claim under the LPLA, a plaintiff must show: "(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. General Motors Corp., 278 F.3d 448, 452 (5th Cir. 2002).

The plaintiff claims that the defendants expressly warranted that Invokana was safe and effective to use without the need for blood monitoring and dose adjustments. Yet, she fails to allege

[9] The defendants, on the other hand, offer the Prescribing Information of Invokana that does contain warnings of renal-related adverse effects. The Court takes judicial notice of this information. The Court is permitted to consider matters of public record and other matters subject to judicial notice without converting a motion to dismiss into one for summary judgment. See United States ex rel. Willard v. Humana Health Plan of Tex. Inc., 336 F.3d 375, 379 (5th Cir. 2003).

facts suggesting that she was ever informed of the express warranty or that it induced her to use Invokana. Moreover, the plaintiff does not offer facts to show that her injury was caused by lack of blood monitoring or dose adjustments. Rather, the plaintiff largely reasserts the grounds for her failure-to-warn claim. The plaintiff's breach of express warranty claim is speculative, at best. Thus, it is dismissed as to all defendants.

5. Redhibition

The LPLA preserves redhibition claims "only to the extent the claimant seeks to recover the value of the product or other economic loss." De Atley v. Victoria's Secret Catalogue, LLC, 2004-0661 (La. App. 4 Cir. 5/14/04); 876 So. 2d 112, 115. "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." La. C.C. art. 2520. Alternatively, a defect is redhibitory when "without rendering the thing totally useless, it diminishes its usefulness or its value so that it must be presumed that a buyer would still have bought it but for a lesser price." Id.

Because the defendant has failed to allege sufficient facts for the Court to plausibly recognize any particular defect in Invokana, the plaintiff's redhibition claim is dismissed as to all defendants.

II. The Mitsubishi Defendants' Motion

The Mitsubishi defendants have incorporated into their motion to dismiss all of the arguments made by the Janssen defendants. Accordingly, the plaintiff's claims against the Mitsubishi defendants are dismissed for the reasons stated above.

IT IS ORDERED that the Janssen defendants' and the Mitsubishi defendants' motions to dismiss are hereby GRANTED. But if the plaintiff, in good faith, believes that she can allege facts to cure the defects of her LPLA claims, she must seek leave to amend her complaint within fourteen days.

New Orleans, Louisiana, February 17, 2016

MARTIN L. C. FELDMAN
UNITED STATES DISTRICT JUDGE