

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA**

WAYNE LEBOEUF	*	CIVIL ACTION
	*	
VERSUS	*	No. 16-12419
	*	
JANSSEN PHARMACEUTICALS, INC., ET AL.	*	SECTION “L” (5)

ORDER & REASONS

Before the Court is Defendant Vintage Pharmaceuticals, LLC’s (“Vintage”) Motion to Dismiss, R. Doc. 15. Plaintiff has not filed an opposition to the Motion. Having reviewed Vintage’s arguments and the applicable law, the Court now issues this Order and Reasons.

I. BACKGROUND:

This products liability case arises from injuries allegedly sustained by Plaintiff as a side effect of ingesting various antipsychotic prescription drugs, including Risperdal (risperidone), Risperdal Consta (a long-acting injectable form of risperidone), Invega (paliperidone), and/or Risperidone. R. Doc. 1 at 3. Plaintiff claims that Defendants falsely advertised these drugs, illegally promoted the drugs as safe for off-label uses, and minimized the side effects that might result, including the injuries Plaintiff suffered, such as gynecomastia. R. Doc. 1 at 3. Plaintiff asserts claims based on the Louisiana Products Liability Act (“LPLA”), as well as state law claims based in negligence, redhibition, breach of various warranties, and strict liability. R. Doc. 1 at 4-10. Plaintiff also alleges Defendants violated federal regulations. R. Doc. 1 at 11-12.

Defendant Vintage Pharmaceuticals, LLC (named as Endo Pharmaceuticals Inc in the

Complaint) has filed a Motion to Dismiss Plaintiff's claims under Federal Rule of Civil Procedure 12(b)(6). R. Doc. 15-1 at 1. Vintage does not manufacture the "brand name" drug, Risperdal, but instead produces a generic version of the drug. Generic drugs can obtain FDA approval by demonstrating they are equivalent to a drug that has already received approval from the FDA. A generic drug manufacturer is "responsible for ensuring that its warning label is the same as the brand name's." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612–13 (2011). Thus, to obtain FDA approval, Vintage need only show that its generic version of Risperidone is identical to the brand name version—Risperdal.

Vintage alleges that Plaintiff's non-LPLA state law claims must be dismissed because the LPLA provides the exclusive remedy for products liability actions against manufacturers under Louisiana law. R. Doc. 15-1 at 2. Further, Vintage contends that claims for failure-to-warn, design defect, and breach of express warranty under the LPLA are preempted by federal law, and that Plaintiff fails to plead facts sufficient to support his claim for a manufacturing defect under the LPLA. R. Doc. 15-1 at 2. Finally, Vintage avers that there is no cause of action for violating federal regulations. R. Doc. 15-1 at 2. Thus, Defendant Vintage avers Plaintiff's claims against it must be dismissed.

II. LAW AND ANALYSIS

The Federal Rules of Civil Procedure permit a defendant to seek a dismissal of a complaint based on the "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). A complaint should not be dismissed for failure to state a claim "unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Conley v. Gibson*, 355 U.S. 41, 47 (1957). Generally, when evaluating a motion to dismiss pursuant to Rule 12(b)(6), the court should not look past the pleadings.

“To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). The district court must construe facts in the light most favorable to the nonmoving party and must accept as true all factual allegations contained in the complaint. *Ashcroft*, 556 U.S. at 678. “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.” *Id.* A court “do[es] not accept as true conclusory allegations, unwarranted factual inferences, or legal conclusions.” *Plotkin v. IP Axess Inc.*, 407 F.3d 690, 696 (5th Cir. 2005).

Here, Vintage moves to dismiss all Plaintiff’s state-law negligence claims as precluded by the Louisiana Products Liability Act. The LPLA provides the only remedies available under Louisiana law against the manufacturer of a product. *See* La. Rev. Stat. § 9:2800.54(B); *Stahl v. Novartis Pharm. Corp.*, 283 F.3d 254, 261 (5th Cir. 2002). Thus, Plaintiff’s non-LPLA state law claims must be dismissed.

Next, Defendant argues that Plaintiff’s claims for failure to warn, design defect, and breach of express warranty under the LPLA are preempted by federal law. LPLA claims for failure-to-warn, design defect, and breach of express warranty claims against manufacturers of generic drugs are preempted by federal law. *Johnson v. Teva Pharm. USA, Inc.*, 758 F.3d 605 (5th Cir. 2014); *see also PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567 (2011). Generic drug manufacturers must use the same label and warnings and have the same chemical composition as the FDA-approved brand-name version of the drug. Generic drug manufacturers cannot modify that label, add inconsistent or additional warnings, or in any way change the chemical composition of the drug. In sum, generic manufacturers cannot simultaneously comply with

federal law and meet additional requirements under state tort law. Therefore, the Court agrees with Vintage and finds that federal law preempts Plaintiff's failure to warn and design defect claims under the LPLA.

Plaintiff's sole remaining claim under the LPLA is a manufacturing defect claim. To prevail on a manufacturing defect claim under the LPLA, Plaintiff must demonstrate that at the time the drug left the manufacturer's control, it "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. R.S. § 9:2800.55. Plaintiff does not provide any factual allegations to support this claim, or refute Vintage's argument that his claim based on a manufacturing defect should be dismissed. Thus, the Court finds this claim cannot survive a motion to dismiss.

Finally, Plaintiff states claims for violations of federal law. According to Plaintiff, Vintage violated 21 U.S.C. § 321 and § 352, which give the FDA the authority to regulate drugs and explains the criteria for determining when a drug has been misbranded. 21 U.S.C. § 321, 352. Neither of these statutes provides a private cause of action, and the Court will not infer that Congress intended to create one. *See Pramann v. Janssen Pharm., Inc.*, No. CV 16-12413, 2017 WL 58469, at *3 (E.D. La. Jan. 5, 2017); *see also Detgen ex rel. Detgen v. Janek*, 752 F.3d 627, 629 (5th Cir. 2014) ("Normally a cause of action must be found in a statute."). Thus, Plaintiff's claims based on the violation of federal law must be dismissed.

III. CONCLUSION

As Plaintiff has not filed an opposition to Defendant Vintage Pharmaceutical's Motion to Dismiss, R. Doc. 15, the Court deems the motion unopposed. Appearing to the Court that the motion is grounded in fact and law, **IT IS ORDERED** that Defendant Vintage Pharmaceutical's

Motion to Dismiss, R. Doc. 15, is **GRANTED**. Plaintiff's claims against Vintage Pharmaceuticals are **DISMISSED WITH PREJUDICE**.

New Orleans, Louisiana this 17th day of January, 2017.


UNITED STATES DISTRICT JUDGE