UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

RICHARD GLENN PRAMANN	**CIVIL ACTION**
VERSUS	**No. 16-12413**
JANSSEN PHARMACEUTICALS, INC. ET AL.	**SECTION I**

ORDER AND REASONS

Before the Court is defendant Vintage Pharmaceuticals, LLC's ("Vintage") motion[1] to dismiss. Although the motion was filed as an opposed motion, no opposition was ever submitted by the plaintiff. Nonetheless, because failure to oppose the motion is not in itself grounds for dismissing the action, the Court must assess the legal sufficiency of the complaint in order to determine whether dismissal is warranted. *See Servicios Azucareros de Venezuela, C.A. v. John Deere Thibodeaux, Inc.*, 702 F.3d 794, 806 (5th Cir. 2012). For the following reasons, the Court concludes that dismissal of Vintage is appropriate.

This is a products liability case involving the pharmaceutical drugs Risperdal® (risperidone), Risperdal Consta® (a long-acting injectable form of risperidone), Invega® (paliperidone), and/or Risperidone—antipsychotic prescription drugs used in the treatment of schizophrenia and bipolar mania.[2] The plaintiff alleges that he sustained certain injuries as a side effect of ingesting such drugs, including the development of gynecomastia. Plaintiff seeks to recover damages from the companies

[1] R. Doc. No. 16.
[2] R. Doc. No. 1, at 3.

that designed, manufactured, and marketed the drugs. He asserts Louisiana Product Liability Act ("LPLA") claims, non-LPLA state law claims, and federal claims.

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). In deciding a motion to dismiss, the Court accepts as true the well-pled factual allegations in the complaint, and construes them in the light most favorable to the plaintiff. *Hunter v. Berkshire Hathaway, Inc.*, No. 15-10854, 2016 WL 3710253, at *3 (5th Cir. July 11, 2016). For the complaint to survive a motion to dismiss, the facts taken as true must state a claim that is plausible on its face. *Brand Coupon Network, L.L.C. v. Catalina Marketing Corp.*, 748 F.3d 631, 637-38 (5th Cir. 2014). A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "The plausibility standard is not akin to a probability requirement, but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Culbertson v. Lykos*, 790 F.3d 608, 616 (5th Cir. 2015). The Court cannot grant a motion to dismiss under Rule 12(b)(6) "unless the plaintiff would not be entitled to relief under any set of facts that [the plaintiff] could prove consistent with the complaint." *Johnson v. Johnson*, 385 F.3d 503, 529 (5th Cir. 2004).

Vintage does not produce what the FDA refers to as the "reference listed drug" ("RLD")—more commonly known as the "brand-name drug"—Risperdal®. The versions of the Risperidone product manufactured by Vintage are instead generic drugs approved by the FDA pursuant to Abbreviated New Drug Applications.

Generic drugs are "designed to be a copy of a reference listed drug (typically a brand-name drug), and thus identical in active ingredients, safety, and efficacy." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 613 n.2 (2011). In order to gain FDA approval, generic drug manufacturers must show that the generic drug is identical in all respects to the previously-approved RLD. The warning label must be the same as that approved for the brand-name drug, *id.* at 612-13, and the generic drug must be chemically equivalent and bioequivalent to the brand-name drug, *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2471 (2013). Generic manufacturers are prohibited from independently changing their labeling in any respect without prior FDA approval. *Mensing*, 564 U.S. at 617.

The Fifth Circuit has confirmed that because federal law restricts both the chemical composition and the labeling required of a generic drug, federal law preempts LPLA claims against generic drug manufacturers based on theories of failure to warn, design defect, and breach of express warranty. *See Johnson v. Teva Pharm. USA, Inc.*, 758 F.3d 605 (5th Cir. 2014). Accordingly, plaintiff's LPLA failure-to-warn claim, design defect claim, and breach of express warranty claim against Vintage are preempted and must be dismissed.

Plaintiff's sole remaining LPLA claim is a manufacturing defect claim. In order 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. R.S. § 9:2800.55. This LPLA provision is distinct from the other

LPLA provisions because the state law duty to avoid manufacturing defects does not conflict with the FDA's requirement that generic drug manufacturers ensure that their generic drug is identical in every respect to the brand-name drug. For that reason, federal courts consider manufacturing defect claims against generic drug manufacturers on the merits and do not consider such claims to be preempted. *See, e.g.*, *Davis v. Teva Pharm. USA, Inc.*, No. 13-6365, 2014 WL 4450423, at *4 (E.D. La. Sept. 10, 2014) (Barbier, J.); *Utts v. Bristol–Myers Squibb Co.*, No. 16-5668, 2016 WL 7429449, at *12 (S.D.N.Y. Dec. 23, 2016). Nevertheless, plaintiff's manufacturing defect claim must be dismissed.

Plaintiff has not alleged how Vintage's product deviated from either the manufacturer's specifications or its otherwise identical products and he has therefore not sufficiently pleaded his LPLA manufacturing cause of action. Further, as plaintiff has not filed an opposition to defendant's motion, the Court has no reason to believe that amending the complaint would rectify the defect. The claim must therefore be dismissed.

The plaintiff's remaining claims for negligence, redhibition, breach of warranty of fitness for ordinary use, breach of implied warranty of merchantability and fitness, and strict liability also fail. The LPLA "establishes the exclusive theories of liability for manufacturers for damage caused by their products," and a plaintiff "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. R.S. § 9:2800.52; *see also Jefferson v. Lead Indus. Ass'n, Inc.*, 106 F.3d 1245, 1248 (5th Cir. 1997) ("Louisiana law eschews all theories of recovery in this case except those explicitly set forth in the

LPLA."). With the exception of his redhibition claim, plaintiff's non-LPLA state law claims are barred under the terms of the LPLA.[3] *See Hilton v. Atlas Roofing Corp. of Miss.*, No. 05-4204, 2006 WL 1581239, at *2 (E.D. La. May 18, 2006) (Africk, J.).

As for the plaintiff's federal claims, the complaint alleges that Vintage violated 21 U.S.C. § 321 and 21 U.S.C. § 352. Section 321 grants the FDA the authority to regulate, among other items, "drugs." *See Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 126 (U.S. 2000). Section 352 sets forth the circumstances under which a "drug" shall be deemed to be "misbranded" by the FDA. *See* 21 U.S.C. § 352.

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[3] The Fifth Circuit has recognized an exception to the LPLA exclusivity provision for redhibition claims only to the extent that a claimant seeks to recover for the value of the product or for other economic loss. *See Pipitone v. Biomatrix, Inc.*, 288 F.3d 239, 251 (5th Cir. 2002). However, plaintiff cannot successfully advance a redhibition claim here. In order to establish a prima facie case of redhibition, a purchaser of a product must show that a non-apparent defect in the product existed at the time of the sale. *Cazaubon v Cycle Spoil, LLC*, 79 So. 3d 1063, 1065 (La. App. 1 Cir. 2011). Apparent defects are those that the buyer might have observed by simple inspection. *Letnaire v. Breaux*, 788 So. 2d 498, 501 (La. App. 5 Cir. 2001). Where the drug's label warns of the defect which allegedly harmed the plaintiff—in this case the risk of gynecomastia—the defect is apparent and not redhibitory. *See Crochet v. Bristol-Myers Squibb*, No. 16-36, 2016 WL 3580670, at *4 (M.D. La. June 28, 2016).

According to the FDA approved Risperidone label that Vintage attached to its motion to dismiss, the generic drug produced by Vintage warned purchasers of the risk of gynecomastia. *See* R. Doc. No. 16-3. In the absence of any opposition by the plaintiff, the Court takes judicial notice of the contents of the FDA approved label as allowed by Rule 201 of the Federal Rules of Evidence. *See Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011) (finding that judicial notice was appropriate for "publicly available documents and transcripts produced by the FDA, which were matters of public record and directly relevant to the issue at hand"); *Cooper v. Pfizer, Inc.*, No. 14-3705, 2015 WL 2341888, at *2 (S.D. Tex. May 13, 2015) (considering "the contents of the FDA approved label" that the defendant Pfizer, Inc. attached to its motion to dismiss); *Elmazouni v. Mylan, Inc.*, No. 16-00574, 2016 WL 7105021, at *3 (N.D. Tex. Dec. 1, 2016) (same). Because the complained-of risk of gynecomastia was identified on the drug's label, plaintiff cannot advance a redhibition claim.

"Normally a cause of action must be found in a statute." *Detgen ex rel. Detgen v. Janek*, 752 F.3d 627, 629 (5th Cir. 2014). "Like substantive federal law itself, private rights of action to enforce federal law must be created by Congress." *Alexander v. Sandoval*, 532 U.S. 275, 286 (2001). Neither statute explicitly provides an individual with a private right of action against a drug manufacturer when that manufacturer's "drugs" are considered "misbranded." Nothing in the statutory text or structure suggests that Congress intended for anyone other than the FDA to enforce the requirements of 21 U.S.C. §§ 321 and 352. Without clear indication that such claims are permissible, and considering that private causes of action rarely exist when not explicitly provided for by statute, the Court declines to recognize a private right of action for the enforcement of 21 U.S.C. §§ 321 and 352.

For the foregoing reasons,

IT IS ORDERED that the motion to dismiss is **GRANTED** and that all of plaintiff's claims in the above-captioned matter against Vintage Pharmaceuticals, LLC except for plaintiff's LPLA manufacturing defect claim are **DISMISSED WITH PREJUDICE**.

IT IS FURTHER ORDERED that plaintiff's LPLA manufacturing defect claim is **DISMISSED WITHOUT PREJUDICE**.

New Orleans, Louisiana, January 5, 2017.

LANCE M. AFRICK
UNITED STATES DISTRICT JUDGE