UNITED STATES DISTRICT COURT

MIDDLE DISTRICT OF LOUISIANA

MILTON PURVIS

VERSUS

TEVA PHARMACEUTICALS, USA, INC., ET AL

CIVIL ACTION

NO. 10-807-BAJ-SCR

RULING

This matter is before the Court on a motion by Defendant Generics Bidco I, LLC, ("Generics Bidco") for judgment on the pleadings as to the claims asserted against it by Plaintiff, Milton Purvis ("Plaintiff") (doc. 30). The motion is opposed (doc. 31) and Defendant has replied to the opposition (doc. 32). Plaintiff sought leave to file a Supplemental Memorandum in Response to Defendant's Motion for Judgment on the Pleadings (doc. 37). Jurisdiction is based on 28 U.S.C. § 1332 (2006).

BACKGROUND

The following facts give rise to the present litigation. Plaintiff alleges that he suffers from tardive dyskinesia caused in whole or in part by metoclopramide (sometimes referred to by its brand name "Reglan"), including but not limited to, a generic form of metoclopramide manufactured by defendant Pliva, Inc. (formerly known as Pliva USA, Inc. and hereinafter "Pliva") (Am. Compl. ¶¶ 1– 2). Plaintiff was prescribed and ingested the Pliva drug (NDC 50111-0430) from at least July 2005 through at least January 2007 (Am. Compl. ¶¶ 1– 2). Plaintiff further alleges

that his injuries were caused by a generic form of metoclopramide manufactured by Defendant Generics Bidco I LLC dba Qualitest Pharmaceuticals, Inc. ("Generics") (Am. Compl., ¶¶ 1–2). Plaintiff avers that he was prescribed and ingested the Generics drug (NDC 00603 – 4615) from at least May 2008 through at least July 2010 (Am. Compl. ¶¶ 1–2). Both parties agree that Reglan/metoclopramide is indicated as therapy for nausea, symptomatic gastroesophageal reflux, and acute and recurrent diabetic gastroparesis (Am. Compl. ¶ 23).

According to Plaintiff, after ingesting Reglan/metoclopramide for the periods alleged in the amended complaint, he exhibited abnormal motor skills which have been linked to the use of Reglan/metoclopramide (Am. Compl., ¶¶ 14–17). These injuries include but are not limited to, serious and permanent injuries of or associated with the central nervous and extrapyramidal motor systems (Am. Compl. ¶ 18). Plaintiff argues that the information disseminated to the medical community concerning the potential effects of exposure to and long-term ingestion of Reglan/metoclopramide was inaccurate, misleading, materially incomplete, false, and otherwise inadequate (Am. Compl. ¶ 18). Defendant Generics avers that metoclopramide is approved for the indications set forth in the package insert for Reglan/metoclopramide approved by the Federal Food and Drug Administration (the "FDA") (Answer to Am. Compl. ¶ 16).

Plaintiff claims that patients who use Reglan/metoclopramide for periods that

exceed 12 weeks are at a greater risk of developing the serious and permanent injuries suffered by Plaintiff (Am. Compl. ¶¶ 25–28). Plaintiff further avers that Defendant did not inform the medical community or general public of this information (Am. Compl. ¶¶ 25–28). Both parties agree that under the Abbreviated New Drug Application (ANDA) process, Defendants were initially required to submit labels for Reglan/metoclopramide identical in all material aspects to the reference listed drug label[1] (Am. Compl. ¶ 37). Both parties also agree that there are procedures in 21 C.F.R. § 314.70 by which a manufacturer may supplement its application and propose changes to the drug or its label (Am. Compl. ¶ 41). Furthermore, both parties agree that major changes to a drug or its label require the FDA's prior approval (Am. Compl. ¶ 41). 21 C.F.R. § 314.70(b) (2012).

Plaintiff brought suit on December 2, 2010 for the purpose of recovering damages for the personal injuries he has allegedly suffered as a result of being prescribed and ingesting Reglan, metoclopramide and/or metoclopramide HC1. On August 9, 2011, this court granted a Motion to Stay and Administratively Close this case (doc. 25) until such time as the Supreme Court ruled on the motion for rehearing in *Demahy v. Actavis, Inc.*, 650 F.3d 1045 (5th Cir. 2011). On August 22,

[1]An Abbreviated New Drug Application (ANDA) contains data that, when submitted to FDA's Center for Drug Evaluation and Research, Office of Generic Drugs, provides for the review and ultimate approval of a generic drug product. Generic drug applications are called "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Instead, a generic applicant must scientifically demonstrate that its product is bioequivalent. *See* 21 CFR § 314.94 (2012).

2011 the Supreme Court denied Plaintiff's Motion for Rehearing in *Actavis*. *Id.* Subsequently, the prior order staying and administratively closing this case was vacated (doc. 26). In light of the holding in *PLIVA, Inc. v. Mensing,* 131 S. Ct. 2567 (2011), Defendant now files this Motion for Judgment on the Pleadings (doc. 30).

ANALYSIS

I. Motion for Judgment on the Pleadings

"A motion under Rule 12(c) for judgment on the pleadings is subject to the same standards as a motion to dismiss under Rule 12(b)(6)." *In re Great Lakes Dredge & Dock Co. LLC*, 624 F.3d 201, 209 (5th Cir. 2010). To avoid dismissal, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Id.* (quoting, *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937, 1949, 173 L. Ed. 2d 868 (2009). "To be plausible, the complaint's '[f]actual allegations must be enough to raise a right to relief above the speculative level.'" *Id.* (quoting, *Bell Atlantic v. Twombly*, 550 U.S. 544, 570, 127 S. Ct. 1955, 167 L. Ed. 2d (2007). "In deciding whether the complaint states a valid claim for relief, [courts] accept all well-pleaded facts as true and construe the complaint in the light most favorable to the plaintiff." *Id.* (citing *Doe v. Myspace, Inc.*, 528 F.3d 413, 418 (5th Cir. 2008). The Court, however, does not accept as true "conclusory allegations, unwarranted factual inferences, or legal conclusions." *Id.* (quoting, *Ferrer v. Chevron Corp.,* 484 F.3d 776, 780 (5th Cir. 2007)).

II. **Preemption and Federal Labeling Requirements**

In *PLIVA, Inc. v. Mensing*, the Supreme Court ruled on the central issue in this case.131 S. Ct. at 2574, 2580. The issue in dispute is whether, and to what extent, generic manufacturers may change their warning labels after initial Federal Food and Drug Administration (FDA) approval. For the following reasons, the Court concludes that Federal drug regulations, as interpreted by the FDA, prevent the manufacturer from independently changing its generic drug's safety label and issuing new warnings. The relevant arguments of both parties are discussed in turn.

A. Compliance with Federal Drug Regulations

Defendant's drug is manufactured as a generic equivalent to a branded version of metoclopramide. Through the Hatch-Waxman Amendments, Congress has sought to increase price competition for pharmaceutical products by making low-cost generic equivalents for certain drugs. *See Mensing*, 131 S. Ct. at 2574–75. An Abbreviated New Drug Application (ANDA) contains data that, when submitted to FDA's Center for Drug Evaluation and Research, Office of Generic Drugs, provides for the review and ultimate approval of a generic drug product. In order to establish safety and effectiveness, a generic applicant must only scientifically demonstrate that its product is bioequivalent. *See* 21 C.F.R. § 314.94 (2012). Thus, the process for a generic manufacturer to obtain FDA approval to

market its drug is simplified by eliminating the need for clinical (human) data.

Here, Plaintiff has not challenged that Defendant manufacturer Generics has complied with the requirements for FDA approval. Plaintiff concedes that Defendant's ANDA application contained sufficient data to scientifically demonstrate that its product is bioequivalent to the metoclopramide innovator drug. Thus, once approved, Defendant was able to manufacture and market the generic drug product to provide a low cost alternative to the American public.

B. Preemption Analysis

Preemption analysis requires a comparison of federal and state law, and the Court should begin by identifying the state tort duties and federal labeling requirements applicable to the manufacturer. *Mensing*, 131 S. Ct. at 2573. According to the Supreme Court, where there is a direct and positive conflict between state and federal law, state law must give way. *See, e.g., Wyeth v. Levine*, 555 U.S. 555, 567, 129 S. Ct. 1187, 173 L. Ed. 2d 51 (2009). Furthermore, such an implied conflict exists where it is "impossible for a private party to comply with both state and federal requirements." *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287, 115 S. Ct. 1483, 131 L. Ed. 2d 385 (1995).

Here, the Court finds impossibility on the part of Defendant. Defendant Generics was unable to satisfy their state-law duty to change the warnings of their generic drug while simultaneously complying with federal requirements. Under

Louisiana law, "when the danger is known to the manufacturer and cannot justifiably be expected to be within the knowledge of users generally, the manufacturer must take reasonable steps to warn the user." *Chappuis v. Sears, Roebuck & Co.*, 358 So. 2d 926, 930 (La. 1978); *see also* La. Rev. Stat. Ann. § 9:2800.57 (2009). In contrast, federal drug regulations, as interpreted by the FDA, prevent manufacturers from "independently changing their generic drugs' safety labels." *Mensing*, 131 S. Ct. at 2577. Furthermore, generic drug manufacturers have an ongoing federal duty of "sameness" with brand-name drugs. *Id* at 2572.

In this case, if the Defendant had independently changed its labels to satisfy their state-law duty, they would have violated the federal requirement that generic drug labels be the same as the corresponding brand-name drug labels. Thus, it was impossible for them to comply with both state and federal law. Therefore, state law was preempted.

Plaintiff claims that Defendant was required to undertake additional efforts to inform the public of the dangerous propensities of its drug. According to Plaintiff, the ruling in *Mensing* was a narrow one, and only applied to state laws that require an actual change in the content of a drug label. Plaintiff argues that manufacturers are not precluded from directly communicating warnings to physicians and consumers. The Court disagrees. The Supreme Court in *Mensing* addressed manufacturers' communications with physicians in addition to state law

requirements. *Id.* at 2576. The Court held that even "Dear Doctor" letters qualify as "labeling" and cannot be contrary to the drug's approved labeling.[2] *Id.*

Next, Plaintiff identified numerous other communication tools that, according to Plaintiff, drug manufacturers can and should take to minimize an identified risk. As previously noted, the Supreme Court in *Mensing* held that the issuance of warnings via communications to health care professionals cannot be contrary to the drug's approved labeling. *Id.* Moreover, the Court in *Mensing* described that the issuance of warnings by generic brands alone could imply a therapeutic difference between the generic brand and name-brand drugs. *Id.* Thus, Plaintiff's failure to warn claim is preempted by Federal drug regulations.

C. Additional Arguments by Plaintiff

Although Plaintiff has asserted additional state-law claims under the Louisiana Products Liability Act (LPLA), he has only alleged facts which challenge the adequacy of Defendant's warnings. Under the LPLA, a "manufacturer of a product shall be liable to a claimant for damage proximately caused by a characteristic of the product that renders the product unreasonably dangerous when such damage arose from a reasonably anticipated use of the product by the claimant or another person or entity." La. Rev. Stat. Ann. § 9:2800.54 (2009). A product is considered unreasonably dangerous in one of the four following ways:

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[2] Plaintiff also argues that Defendant may issue a "Dear Doctor" letter on its own initiative. The Court rejects this argument for the same reasons outlined above.

1) construction or composition; 2) design; 3) inadequate warning; 4) breach of manufacturer's express warranty. *Id.*

Under Louisiana law, an express warranty exists where the manufacturer of a good voluntarily undertakes and extends a guarantee to customers. *Fields v. Walpole Tire Serv., L.L.C.*, No. 45-206, p.9 (La. App. 2 Cir. 5/19/10); 37 So. 3d 549, 557. Furthermore, to establish a design defect claim, a plaintiff must establish 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. La. Rev. Stat. Ann. § 9:2800.56 (2009).

Here, Plaintiff has not alleged sufficient facts to support his claims of design defect and breach of express warranty found in the pleadings. First, Plaintiff has not provided any facts or argument to support his breach of express warranty claim. Plaintiffs does not allege that Defendants made any advertisements or other forms of communications regarding its products beyond the package insert.

Second, Plaintiff has not provided factual content to support his design defect claim and has failed to make sufficient arguments for this claim in his briefs.[3] Plaintiff merely makes a formulaic recitation of the statutory provisions and

[3]The Court is not persuaded by Plaintiff's submission of the First Circuit Court of Appeals case *Bartlett v. Mut. Pharm. Co.*, 678 F.3d 30 (1st Cir. 2012). In its Supplemental Memorandum in Opposition, Plaintiff does not demonstrate that the case removes preemption under *PLIVA* in this case. Further, the reference to *Bartlett* does not remedy the defects in Plaintiff's other LPLA claims as outlined above.

conclusory allegations. Plaintiff has not alleged that there existed an alternative design for the drug which is an essential element of a LPLA design defect claim. Further, Plaintiff has not alleged that the burden on the manufacturer to develop such a drug outweighed the dangers posed by the current design. Because Plaintiff has not alleged sufficient factual content and argument regarding his other LPLA claims, all such claims must be dismissed.

Accordingly, the Court finds that Plaintiff provides no factual content to support his other LPLA state-law claims in this matter. Additionally, Plaintiff's failure to warn claim is preempted by Federal drug regulations. Thus, the Court concludes that judgment on the pleadings is proper.

CONCLUSION

For all of the foregoing reasons, the motion by Defendant Generics Bidco I, LLC, for judgment on the pleadings (doc. 30) is **GRANTED** and the case is dismissed with prejudice.

Baton Rouge, Louisiana, October 30, 2012.

BRIAN A. JACKSON
UNITED STATES DISTRICT JUDGE
MIDDLE DISTRICT OF LOUISIANA