UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

ANDREA GUARINO,

Plaintiff,

v. **Case No. 8:10-cv-2885-T-30TGW**

WYETH LLC; SCHWARZ PHARMA, INC.; TEVA PHARMACEUTICALS USA, INC.,

Defendants.
_____/

ORDER

THIS CAUSE comes before the Court upon Defendant Teva Pharmaceuticals USA, Inc.'s Motion to Dismiss, or in the Alternative, Motion for Judgment on the Pleadings (Dkt. 30), Plaintiff's Response in Opposition (Dkt. 31) and Defendant Teva Pharmaceuticals USA, Inc.'s Reply (Dkt. 34). The Court, having reviewed the motion, response, reply, and being otherwise advised in the premises, concludes that the motion should be granted, and Plaintiff's claims against Defendant Teva Pharmaceuticals USA, Inc. dismissed with prejudice.

BACKGROUND

This is a products liability case against Defendant Teva Pharmaceuticals USA, Inc. ("Teva"), along with other manufacturers of the medication metoclopramide (brand name: Reglan®). Teva is a generic pharmaceutical manufacturer. Plaintiff asserts claims of

negligence (including negligence *per se*), strict liability, breach of express and implied warranties, and misrepresentation and fraud against Teva.

On June 23, 2011, the United States Supreme Court issued its decision in *Pliva, Inc. v. Mensing*, - - - U.S. - - -, 131 S. Ct. 2567 (2011) (*reh'g denied*). The Supreme Court, after analyzing the duties under state law and those under federal law, concluded that the Food, Drug, and Cosmetic Act ("FDCA") preempts state-law failure-to-warn claims for generic pharmaceutical products.

On August 3, 2011, Teva filed the instant motion, arguing that *Mensing* requires dismissal of all of Plaintiff's claims. For the reasons set forth below, the Court concludes that *Mensing* preempts and therefore bars Plaintiff's state-law claims against Teva in this case.

DISCUSSION

I. Standard of Review

Pursuant to Rule 12(b)(6), a court may dismiss a claim on the basis of a dispositive issue of law. *See Neitzke v. Williams*, 490 U.S. 319, 326-27 (1989); *Marshall County Bd. of Educ. v. Marshall County Gas Dist.*, 992 F.2d 1171, 1174 (11th Cir. 1993) (dismissal proper when, "on the basis of a dispositive issue of law, no construction of the factual allegations will support the cause of action"); *Schneider v. Parker*, 2011 WL 722759, at *2 (M.D. Fla. Feb. 23, 2011) (noting that dismissal is warranted under Rule 12(b)(6) if, "assuming the truth of the factual allegations of the plaintiff's complaint, there remains a dispositive legal issue which precludes relief.").

A motion for judgment on the pleadings is governed by the same standard as a Rule 12(b)(6) motion to dismiss. *See Hawthorne v. Mac Adjustment, Inc.*, 140 F.3d 1367, 1370 (11th Cir. 1998). When considering such a motion, the Court must "accept the facts alleged in the complaint as true and draw all inferences that favor the nonmovant." *Bankers Ins. Co. v. Fla. Residential Prop. & Cas. Joint Underwriting Ass'n,* 137 F.3d 1293, 1295 (11th Cir. 1998). If it is clear that the plaintiff would not be entitled to relief under any set of facts that could be proved consistent with the allegations, the court should dismiss the complaint. As with a motion to dismiss, the "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007) (abrogating *Conley v. Gibson*, 355 U.S. 41, 45–46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957)).

II. Teva's Motion to Dismiss Based on *Mensing*

Teva argues that the instant case is indistinguishable from *Mensing* and Plaintiff's claims should therefore be dismissed as preempted by federal law. In *Mensing*, the Supreme Court held that all state-law tort claims based on an alleged failure to warn of the risks of generic medications are preempted by federal law because it is impossible to comply with both a jury's charge to strengthen a generic drug warning under state law, and the federal mandate that a generic drug's labeling be the same as that of the brand-name drug. 131 S. Ct. 2567. Specifically, the Supreme Court noted:

> We find impossibility here. It was not lawful under federal law for the Manufacturers to do what state law required of them. And even if they had fulfilled their federal duty to ask for FDA

> assistance, they would not have satisfied the requirements of state law.
>
> If the Manufacturers had independently changed their labels to satisfy their state-law duty, they would have violated federal law. Taking Mensing and Demahy's allegations as true, state law imposed on the Manufacturers a duty to attach a safer label to their generic metoclopramide. Federal law, however, demanded that generic drug labels be the same at all times as the corresponding brand-name drug labels. See, *e.g.*, 21 CFR § 314.150(b)(10). Thus, it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same.

Id. at 2577-78.

Teva contends that Plaintiff here brings precisely the same kinds of preempted failure-to-warn claims. The Court agrees. Plaintiff's claims are, on their face, premised on an allegedly inadequate warning. *See* Dkt. 1 at ¶ 29 (describing Teva's label as "inaccurate, misleading, materially incomplete, false and otherwise inadequate"). Thus, under any theory of liability, Plaintiff must prove a warnings defect such "that the defendant did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge at the time of manufacture and distribution." *Ferayorni v. Hyandai Motor Co.*, 711 So. 2d 1167, 1172 (Fla. 4th DCA 1998).

Plaintiff attempts to distinguish *Mensing* by asserting a number of arguments that lack merit because *Mensing* and federal courts applying *Mensing* already addressed and dismissed them. *See Demahy v. Wyeth, Inc.*, No. 08-3616 (E.D. La. Aug. 30, 2011) (dismissing all

claims against the generic manufacturer, with prejudice)[1]; *Couick v. Wyeth, Inc.*, No. 3:09 CV 210-RJC-DSC (W.D.N.C. Aug. 12, 2011); *Brown v. Actavis Elizabeth, LLC*, No. 10-11 (E.D. La. Aug. 10, 2011); *see also Smith v. Wyeth, Inc.*, — F.3d —, Case No. 09-5460 (6th Cir. Sept. 22, 2011) (dismissing three lawsuits as preempted by *Mensing*); *Henderson v. Sun Pharm. Indus., Ltd.*, No. 4:11-CV-0060-HLM (N.D. Ga. Aug. 22, 2011) (granting defendant's motion to dismiss because plaintiff's proposed amended complaint failed to state a claim other than failure to warn, which was preempted under *Mensing*).

Also, as Teva points out, Plaintiff's focus on decisions involving express preemption is misplaced. *Mensing* involved conflict preemption, which does not depend on the limitations of the language in a preemption provision. In other words, no parallel state-law claims or alternative theories of liability survive the Supreme Court's ruling in *Mensing*.

Finally, it is worth noting that the Supreme Court specifically rejected Plaintiff's failure-to-communicate argument that generic drug manufacturers, like Teva, should have sent "Dear Doctor" letters providing additional warnings to prescribing physicians. *Mensing*, 131 S. Ct. at 2576 ("[We] conclude that federal law did not permit the Manufacturers to issue additional warnings through Dear Doctor letters."). The Supreme Court recently repeated its position on this issue by vacating the only remaining federal appellate opinion holding otherwise. *See L. Perrigo Co. v. Gaeta*, - - - S.Ct. - - - -, 2011 WL 2326476 (Oct. 31, 2011) (remanding for further consideration under *Mensing*).

[1] Notably, Plaintiff's claims in this case are substantially similar to the plaintiff's claims in *Demahy*.

In short, any state-law claim involving a generic drug label or warning is preempted and must be dismissed with prejudice under *Mensing*.

It is therefore ORDERED AND ADJUDGED that:

1. Defendant Teva Pharmaceuticals USA, Inc.'s Motion to Dismiss, or in the Alternative, Motion for Judgment on the Pleadings (Dkt. 30) is GRANTED.

2. Plaintiff's claims against Defendant Teva Pharmaceuticals USA, Inc. are dismissed with prejudice.

3. The Clerk is directed to terminate Defendant Teva Pharmaceuticals USA, Inc. as a party in this case.

DONE and **ORDERED** in Tampa, Florida on November 7, 2011.

JAMES S. MOODY, JR.
UNITED STATES DISTRICT JUDGE

Copies furnished to:
Counsel/Parties of Record

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