UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

IN RE:

ACCUTANE PRODUCTS LIABILITY **MDL 1626 - IBD TRACK CASES**

Case No: 8:04-MD-2523-T-30TBM
8:14-CV-1526-T-30TBM
(Rachel Pesota)

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ORDER

THIS CAUSE comes before the Court upon Defendant Catalent Pharma Solutions' Motion for Judgment on the Pleadings (Dkt. 1362). The Court, having considered the motion, and being otherwise advised in the premises, concludes that the motion should be granted.

BACKGROUND

This is a product liability case arising from Plaintiff Rachel Pesota's ("Plaintiff") alleged ingestion of the generic pharmaceutical product isotretinoin, distributed under the name Amnesteem®, which was allegedly manufactured by Defendant Catalent Pharma Solutions. Plaintiff claims severe injuries including internal injuries and bleeding, severe abdominal pain, bloody stool, reproductive system and gynecological problems, and migraines and headaches resulting from her ingestion of isotretinoin. Specifically, Plaintiff alleges that Amnesteem® was defective in design, and due to inadequate warnings.

This case is at issue upon Defendant's motion for judgment on the pleadings. This action was originally filed in the Superior Court of California, County of Orange, on August 17, 2012. It was later coordinated in the Accutane Product Liability Coordination Proceedings, JCCP 4740 in the Superior Court of California, County of Los Angeles. The Complaint in the coordinated proceedings contained claims for failure to warn, strict liability, negligence *per se*, breach of implied warranty, breach of express warranty, deceit by concealment, negligent misrepresentation, unfair business practices and negligent design. Defendant filed a demurrer on the grounds that Plaintiff's claims were preempted based on the Supreme Court decision *PLIVA, Inc. v. Mensing*, - - - U.S. - - -, 131 S. Ct. 2567 (2011) (*reh'g denied*). On April 29, 2013, the Superior Court of California sustained the demurrer, without leave to amend as to all of Plaintiff's claims with the exception of her claim that Defendant was negligent in its design and manufacture of Amnesteem® . The remaining design defect claim was found to be viable at the pleading stage. The Superior Court of California referenced the forthcoming decision in *Mutual Pharm. Co., Inc. v. Bartlett*, 133 S. Ct. 2466, 186 L. Ed. 2d 607 (2013) in issuing its decision. Subsequently, the matter was removed to the United States District Court in California and then transferred to this Court.

In the instant motion, Defendant contends that all of Plaintiff's claims are preempted by federal law under *Mensing* and *Bartlett.* Defendant also argues that this Court should uphold the Superior Court of California's ruling sustaining the demurrer for all claims other than Plaintiff's negligence claim under *Mensing.*

The Court concludes that all of Plaintiff's claims, including her design defect claims are preempted by federal law.

DISCUSSION

I. Standard of Review

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. Law of the Case Doctrine

Defendants argue that this Court should uphold the California Superior Court's rulings under the law of the case doctrine. The law of the case doctrine posits that when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case. *Arizona v. California*, 460 U.S. 605, 618, 103 S. Ct. 1382, 1391, 75 L. Ed. 2d 318 (1983) *decision supplemented*, 466 U.S. 144, 104 S. Ct. 1900,

80 L. Ed. 2d 194 (1984). Here, the California Superior Court found that *Mensing* operated to preempt Plaintiff's claims based on the inadequacy of the warnings against Defendant. The Court concludes that the ruling of the California Superior Court should be upheld. Therefore, only Plaintiff's defective design claims remain for the Court's consideration.

III. Plaintiff's Defective Design Claims

Defendant argues that the Supreme Court's recent decision in *Bartlett* extends the reasoning of *Mensing* to preempt design defect claims that are not purportedly based upon the alleged inadequacies of the labeling. The Court agrees. As this Court noted in *In re Accutane Prod. Liab. Litig. (Plevniak)*, MDL 1626, 2011 WL 6224546 (M.D. Fla. Nov. 9, 2011), and *In re Accutane Products Liab. Litig. (Herbert)*, MDL 1626, 2012 WL 3194952 (M.D. Fla. Aug. 7, 2012), *Mensing* 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. *See Mensing*, 131 S. Ct. 2567. Specifically, the Supreme Court held:

> 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.

In *Bartlett*, the Supreme Court extended this reasoning to design defect claims, holding that redesigning a generic drug was also impossible because federal drug regulations require a generic drug to have the same active ingredients, route of administration, dosage form, and strength as the brand-name drug on which it is based. *See Bartlett*, 133 S. Ct. at 2475.

Defendant contends that Plaintiff here brings precisely the same kinds of preempted design defect claims. The Court agrees. Together, *Mensing* and *Bartlett* establish that under federal law a generic drug manufacturer may not unilaterally change its labeling or change its design or formulation. Thus, to the extent it is impossible for a generic drug manufacturer to comply with its duty under a state law unless it changes its labeling or design, that law is pre-empted by federal law. Accordingly, it is the Court's conclusion that Plaintiff's design defect claims are preempted and therefore must be dismissed. *See In re Fosamax (Alendronate Sodium) Products Liab. Litig. (No. II)*, 751 F.3d 150, 152 (3d Cir. 2014) (affirming district court decision granting judgment on the pleadings in favor of generic manufacturer because all state law claims against were pre-empted by federal law).

It is therefore ORDERED AND ADJUDGED that:

1. Defendant Catalent Pharma Solutions' Motion for Judgment on the Pleadings (Dkt. 1362) is GRANTED.
2. The Clerk is directed to enter judgment in favor of Defendant Catalent Pharma Solutions and against Plaintiff Rachel Pesota.
3. This case shall remain open.

DONE and **ORDERED** in Tampa, Florida on September 23, 2014.

JAMES S. MOODY, JR.
UNITED STATES DISTRICT JUDGE

Copies furnished to:
Counsel/Parties of Record

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