IN THE UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
GREENVILLE DIVISION

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| Jennifer Galloway,<br><br>Plaintiff,<br><br>vs.<br><br>Aurobindo Pharma Limited Inc. and Aurobindo Pharma U.S.A. Inc.,<br><br>Defendants. | ) | C/A No.: 6:17-cv-01076-AMQ<br><br>**OPINION AND ORDER** |

This matter comes before the Court on Defendants' Aurobindo Pharma Limited Inc. and Aurobindo Pharma U.S.A. Inc. ("Defendants") Motion to Dismiss Plaintiff Jennifer Galloway's ("Plaintiff") Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). Specifically, Defendants contend that all of Plaintiff's state law claims are preempted by federal law. The matter has been fully briefed, and the Court heard arguments on May 3, 2018. For the following reasons, the Court hereby grants Defendants' Motion to Dismiss.

## I. BACKGROUND AND PROCEDURAL POSTURE

Plaintiff Jennifer Galloway ("Plaintiff") alleges that she suffered a myocardial infarction on December 13, 2013, as a result of using the generic drug Sumatriptan, an FDA-approved, migraine headache prescription medication manufactured by Defendants. (Compl. ¶¶ Intro., 22-26). Sumatriptan is the generic version of the name brand IMITREX®.

The Complaint was filed on February 20, 2017 in the Court of Common Pleas in Greenville County, South Carolina against Aurobindo and Bi-Lo, LLC. Plaintiff's claims sound in strict liability, negligence, breach of express and implied warranty, fraud and negligent misrepresentation. Plaintiff voluntarily dismissed Bi-Lo, LLC. (ECF No. 1.1). Defendants then removed the case pursuant to 28 U.S.C. §§ 1332 and 1441, *et seq*. (ECF No. 1) and filed an

Answer (ECF No. 5), specifically asserting the affirmative defense of failure to state a claim pursuant to Fed. R. Civ. P. 12(b)(6) (Ans. ¶¶ 100, 112-115, 132).

## II. STANDARD OF REVIEW

A court may dismiss a complaint under Fed. R. Civ. P. 12(b)(6) for failure to state a claim if the plaintiff fails to set forth "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *Ashcroft v. Iqbal*, 556 U.S. 662, 697 (2009). Unless the complaint pleads sufficient facts to cross the line "from conceivable to plausible," it must be dismissed. *Twombly*, 550 U.S. at 570. The federal pleading standard "demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Iqbal*, 556 U.S. at 678. "[L]egal conclusions, elements of a cause of action, and bare assertions devoid of further factual enhancement fail to constitute well-pled facts for Rule 12(b)(6) purposes," as do "unwarranted inferences, unreasonable conclusions, or arguments." *Nemet Chevrolet, Ltd. v. Consumeraffairs.com, Inc.*, 591 F.3d 250, 255 (4th Cir. 2009) (citations omitted).

Even when a complaint does state a claim for relief, it should be dismissed for failure to state a claim if the allegations in the complaint establish an affirmative defense. Federal preemption is a "pure question of law" and thus may be determined by this Court on a Rule 12(b)(6) motion to dismiss. *See Kendall v. Hyundai Motor Co.*, 2000 WL 34013265, at *2 (D.S.C. Nov. 20, 2000) (quoting *Pokorny v. Ford Motor Co.*, 902 F.2d 1116, 1122 (3d Cir. 1990)); *Drager v. PLIVA USA, Inc.*, 741 F.3d 470, 475-79 (4th Cir. 2014) (affirming judgment on the pleadings on preemption grounds); *see also Hensley Mfg., Inc. v. ProPride, Inc.*, 579 F.3d 603, 613 (6th Cir. 2009) ("[T]here is no reason not to grant a motion to dismiss where the undisputed facts conclusively establish an affirmative defense as a matter of law."). Dismissal on preemption grounds should be without leave to amend, because amendment would be futile. *See GE Investment Private Placement Partners II v. Parker*, 247 F.3d 543, 548 (4th Cir. 2001); *In re*

*Darvocet, Darvon and Propoxyphene Prods. Liab. Litig.*, 2012 WL 718618, at *6 (E.D. Ky. Mar. 5, 2012), aff'd, 756 F.3d 917 (6th Cir. 2014) (preemption finding rendered any amendment futile).

## III. DISCUSSION

Defendant's primary contention[1] is that all of Plaintiff's state law claims for both design and warning defects in a generic drug are preempted by the requirements of the Federal Food, Drug and Cosmetics Act, 21 U.S.C. §§ 301 *et seq*., ("FDCA"). The argument is twofold. First, Defendants argue state law claims as to *warning* defects in generic drugs are preempted under *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011). Second, Defendants argue state law claims as to *design* defects in generic drugs are preempted under *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013). Moreover, Defendants contend the Fourth Circuit has squarely addressed this issue in *Drager v. PLIVA USA, Inc.*, 741 F.3d 470 (4th Cir. 2014). This Court agrees.

### A. Hatch-Waxman

The Hatch-Waxman amendments of the FDCA, codified at 21 U.S.C. § 355(j), control the production of generic drugs. *Drager*, 741 F.3d at 475. For a variety of reasons, the FDCA imposes substantially different requirements on the producers of name brand drugs and the producers of their generic counterparts. *Id*. Generally, producers of generic drugs gain authorization to market their products by demonstrating equivalence to the previously authorized name brand versions in several important ways, including specifically, formulation and labeling. *Id*. Moreover, generics must maintain equivalence to maintain authorization. *Id*. (*citing* 21 U.S.C. § 355(j)).

[1] Defendants argue that some of Plaintiff's claims are barred by the learned intermediary doctrine and that some of Plaintiff's claims fail to satisfy the standard for federal pleadings under Rule 9. Because of its decision regarding preemption, the Court declines to address either of the other arguments.

### B. *Mensing*, *Bartlett* and *Drager*

The United States Supreme Court has addressed the applicability of Hatch-Waxman to both claims of defective warning and to claims of defective design. First, in *Mensing*, Justice Thomas, writing for the majority, held that because generic drug producers are not entitled to unilaterally change their labeling, any state law tort premised on such a failure is preempted. 564 U.S. at 618. Similarly, in *Bartlett*, Justice Alito, writing for the majority, held that because generic drug producers are also barred from changing the formulation of their products and state law tort premised on a defective design is also preempted. 570 U.S. at 476-77.

Further, the Supreme Court has expressly rejected the so called "stop-selling" argument wherein the generic drug producer must leave the marketplace in order to avoid state law liability resulting from its inability to change either its labeling or design. *Id*. at 488. Stated differently, a court cannot avoid preemption by imposing state tort liability upon a generic drug producer for choosing to sell its product in compliance with federal law. *Drager*, 741 F.3d at 476.

As the Fourth Circuit stated in *Drager*, "[t]ogether, [*Mensing* and *Bartlett*] establish that under the FDCA a generic may not unilaterally change its labeling or change its design or formulation, and cannot be required to exit the market or accept state tort liability." *Id*. Therefore, when a generic drug producer cannot satisfy a state law duty except by choosing one of those four actions, "that law is preempted and of no effect." *Id*.

### C. Plaintiff's Claims

#### 1. Labeling

Plaintiff challenges the adequacy of the warnings provided in Defendants' product labeling. Specifically, Plaintiff's claims include, among others: that "[D]efendants failed to provide proper and adequate warnings identifying all adverse side effects . . ." (Compl. ¶ 36);

that "[D]efendants failed to provide adequate warnings to users or consumers . . ." (*Id*. ¶37); and that Defendants "failed to accompany Sumatriptan with proper warnings . . ." (*Id*. ¶ 48(b)).

As discussed above, federal law required Defendants to provide warnings for its generic drug that were equivalent to the warnings for the brand-name version. There are no allegations the labeling was any different. Because Defendants could not simultaneously comply with a purported state law duty to modify the labeling and the federal requirement to keep them the same, Plaintiff's state law tort claims directly conflict with federal law and are, therefore, preempted. *See Drager*, 741 F.3d at 476 ("[G]eneric drug manufacturers are not entitled to unilaterally change their labeling and therefore any state law premised on the failure of a generic to alter its labeling is preempted."). Accordingly, the Court finds that Plaintiff's claims related to warning defects are preempted.

**2. Design**

Plaintiff contends that Defendants' generic product was "defective in design and formulation," and "unreasonably dangerous[.]" (Compl. ¶¶ 38, 61.) Thus, Plaintiff's Complaint asserts an alleged state law duty to design this product differently.

Like labeling, federal law equally prohibits changes to a generic drug's design: "[T]he FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based." *Bartlett*, 570 U.S. at 483-84. Further, "[o]nce a drug—whether generic or brand-name—is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application.'" *Id*. at 477 (*citing* 21 C.F.R. § 314.70(b)(2)(i)). Here, the Court finds that there was no action the Defendants could take to increase the safety of their product design

without violating the restrictions of the FDCA. Therefore, the Plaintiff's claims as to design defect are preempted.

**3. Fraud and Negligent Misrepresentation**

Plaintiff also brought claims for both fraud and negligent misrepresentation. The Court finds these claims are preempted for all the reasons stated above. *See Drager,* 741 F.3d 470 (affirming dismissal of claims alleging negligence, strict liability, breach of warranty, misrepresentation and fraudulent concealment)*; In re Darvocet, Darvon and Propoxyphene Prods. Liab. Litig*, 756 F.3d 917, 934-36 (6th Cir. 2014) (affirming dismissal of claims alleging breach of warranty, misrepresentation, fraud, consumer protection and statutory negligence on preemption grounds); *Guarino v. Wyeth LLC*, 719 F.3d 1245, 1248-50 (11th Cir. 2013) (affirming dismissal of claims alleging negligence, strict liability, breach of warranty, misrepresentation, fraud and negligence per se on preemption grounds).

**D. New Safety Information** & **Immunity**

At the hearing on the instant motion, Plaintiff made two other points the Court will address herein for the record.[2] First, Plaintiff argues that she should be allowed to conduct discovery regarding post-approval, "new safety information" as mentioned by the Court in *Mensing*. 564 U.S. at 615-18. The premise is that, since the FDA requires labeling be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug, *both* generic and name-brand producers who become aware of safety problems must ask the FDA to work toward strengthening the label that applies to both the generic and brand-name equivalent drug. *Id*. at 616. Whether such a duty actually exists for the generic drug producer is a matter as of yet unresolved.

[2] The Court also notes that while Plaintiff's claims are contrary to precedent, they are not frivolous. Both Supreme Court decisions cited above were decided on narrow 5-4 margins. Moreover, the world of pharmaceutical litigation is a rapidly evolving one. Plaintiff is thus well-within her responsibilities under Rule 11(b)(2).

Here, Plaintiff argues that she should be allowed to conduct discovery to determine whether Defendants had any such evidence. The Court respectfully declines to allow Plaintiff that opportunity and to attempt to determine whether such a duty exists in the first place. *See Mensing*, 564 U.S. at 617. ("Because we ultimately find pre-emption even assuming such a duty existed, we do not resolve the matter.").

Secondly, Plaintiff made the point that under the Hatch-Waxman framework and the holdings in *Mensing* and *Bartlett*, a generic drug producer is potentially immune from product liability claims for their generic products altogether. She is not alone in making this observation. In *Mensing*, Justice Thomas acknowledged "the unfortunate hand that federal drug regulation has dealt" those asserting product liability claims against generic manufacturers. 564 U.S. at 625. It is undisputed "the federal statutes and regulations that apply to brand-name drug manufacturers are meaningfully different than those that apply to generic drug manufacturers." *Id*. at 626. However, this Court "will not distort the Supremacy Clause in order to create similar pre-emption across a dissimilar statutory scheme." *Id*. The authority to change statutes and regulations lays with Congress and the Food and Drug Administration – not a District Court judge. *Id*.

## IV. CONCLUSION

For all of the foregoing reasons, Plaintiff's Complaint is hereby DISMISSED WITH PREJUDICE.

IT IS SO ORDERED.

The Honorable A. Marvin Quattlebaum, Jr.
United States District Court Judge

May 31, 2018
Greenville, South Carolina