UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
PADUCAH DIVISION
CIVIL ACTION NO. 5:14-CV-00018

CINDY MITCHELL, Plaintiff

v.

SANDOZ INC., Defendant

MEMORANDUM OPINION

This matter is before the Court upon Defendant Sandoz Inc.'s Motion to Dismiss for failure to state a claim. (Docket No. 11). Plaintiff Cindy Mitchell has responded, (Docket No. 14) and Defendant Sandoz, Inc. has replied. (Docket No. 15). This matter is now fully briefed and ripe for adjudication. For the following reasons, Defendant's Motion to Dismiss is GRANTED.

BACKGROUND

Plaintiff Cindy Mitchell, proceeding *pro se*, alleges that after taking "lovenox (generic) enoxaparin shots" from February of 2013 through September of 2013, she suffered a gastrointestinal bleed. (Docket No. 1). Mitchell alleges that the drug caused the bleeding and that the drug is "dangerous." (*Id*.). Additionally, she states that "the only side effect that [she] was suppose to be made aware of was abnormal bruising." (Docket No. 14).

Mitchell was hospitalized from September 16, 2013 until September 21, 2013. Her medical records indicate that she was admitted for "abdominal pain, nausea, vomiting, elevated and rising white blood cell counts" and that she was diagnosed with a gastrointestinal bleed, among other medical conditions. (Docket No. 6). Mitchell seeks compensation and that enoxaparin sodium shots be "taken off the shelf." (Docket No. 1). The Court construes

Mitchell's complaint as alleging a failure to warn and a design defect claim under the Products Liability Act of Kentucky ("PLA"). (Ky. Rev. Stat. § 411.300).

Enoxaparin sodium is a prescription injection and is the generic bioequivalent of the drug Lovenox. (Docket No. 11). Defendant Sandoz Inc. ("Sandoz") is a generic drug manufacturer that manufactured and distributed enoxaparin sodium shots. Sandoz now moves to dismiss all the claims alleged against it based on federal preemption.

STANDARD

The Federal Rules of Civil Procedure require that pleadings, including complaints, contain a "short plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). A defendant may move to dismiss a claim or case because the complaint fails to "state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b). When considering a Rule 12(b)(6) motion to dismiss, the court must presume all of the factual allegations in the complaint are true and draw all reasonable inferences in favor of the nonmoving party. *Total Benefits Planning Agency, Inc.*, 552 F.3d 430, 434 (6th Cir. 2008) (citing *Great Lakes Steel v. Deggendorf*, 716 F.2d 1101, 1105 (6th Cir. 1983)). "The court need not, however, accept unwarranted factual inferences." *Id*. (citing *Morgan v. Church's Fried Chicken*, 829 F.2d 10, 12 (6th Cir. 1987)).

Even though a "complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citations omitted). Instead, the plaintiff's "[f]actual allegations must be enough to raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true

(even if doubtful in fact)." *Id*. (citations omitted). A complaint should contain enough facts "to state a claim to relief that is plausible on its face." *Id*. at 570. A claim becomes 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*, 129 S. Ct. 1937, 1949 (2009) (citing *Twombly*, 550 U.S. at 556). If, from the well-pleaded facts, the court cannot "infer more than the mere possibility of misconduct, the complaint has alleged—but has not 'show[n]'—'that the pleader is entitled to relief.'" *Id*. at 1950 (citing Fed. R. Civ. P. 8(a)(2)). "Only a complaint that states a plausible claim for relief survives a motion to dismiss." *Id*.

In addition, federal courts hold *pro se* pleadings to a less stringent standard than formal pleadings drafted by lawyers. *Haines v. Kerner*, 404 U.S. 519, 520–21 (1972); *Jourdan v. Jabe*, 951 F.2d 108, 110 (6th Cir. 1991). However, "[o]ur duty to be 'less stringent' with *pro se* complaints does not require us to conjure up unpled allegations." *McDonald v. Hall*, 610 F.2d 16, 19 (1st Cir. 1979) (citation omitted). Accordingly, this Court is not required "to explore exhaustively all potential claims of a *pro se* plaintiff," as this would "transform the district court from its legitimate advisory role to the improper role of an advocate seeking out the strongest arguments and most successful strategies for a party." *Beaudett v. City of Hampton*, 775 F.2d 1274, 1278 (4th Cir. 1985). Only well-pled factual allegations contained in the complaint and amended complaint are considered on motions to dismiss pursuant to Fed. R. Civ. P. 12(b)(6). *See Weiner v. Klais & Co., Inc.*, 108 F.3d 86, 89 (6th Cir. 1997).

DISCUSSION

The Court construes Mitchell's complaint as alleging both a failure to warn and a design defect claim under the Kentucky PLA. Ky. Rev. Stat. § 411.300. Kentucky defines a products liability action as any lawsuit alleging "personal injury, death or property damage . . . from the

manufacture, construction, design, formulation, development of standards, preparation, processing, assembly, testing, listing, certifying, warning, instructing, marketing, advertising, packaging or labeling of any product." *Id.*. The PLA applies to all claims for damages arising from the use of products, irrespective of legal theory. *Monsanto Co. v. Reed*, 950 S.W.2d 811, 814 (Ky. 1997).

In its Motion to Dismiss, Sandoz states that all claims alleged against it must be dismissed based on federal preemption. Docket No. 11. Sandoz argues that the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, conflicts with the PLA, making it impossible for the manufacturer of a generic drug to comply with both state and federal law. Thus, the FDCA preempts the PLA claims. The court agrees with Sandoz and will dismiss Mitchell's claims.

I. Federal Preemption

Federal preemption doctrine is based on the Supremacy Clause of the United States Constitution. *State Farm Bank v. Reardon*, 539 F.3d 336, 341 (6th Cir. 2008). The Supremacy Clause provides that the Constitution, federal law, and all treaties "shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. CONST. art. VI, cl. 2. The Supreme Court has interpreted the Supremacy Clause to include "both federal statutes themselves and federal regulations that are properly adopted in accordance with statutory authorization." *Reardon*, 539 F.3d at 341 (citing *City of New York v. FCC*, 486 U.S. 57, 63 (1988)).

Federal preemption can take several forms. "Federal law may preempt state law either expressly or impliedly." *Id.* (citing *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 152-53 (1982)). The Supreme Court has recognized at least two types of implied

preemption: field preemption and conflict preemption. *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992). Conflict preemption occurs where compliance with both federal and state regulation is physically impossible, or "where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.* (internal citations and quotations omitted).

Sandoz bases its federal preemption argument on conflict preemption. Sandoz argues that under federal law, generic manufacturers cannot unilaterally alter their labeling or formulas. Therefore, state laws that impose heightened warning labels are in direct conflict with federal law.

II. Federal Regulation of Generic Drugs

The FDCA charges the Food and Drug Administration ("FDA") with the responsibility of approving the introduction of new drugs on the market. *See* 21 U.S.C. § 355. A brand-name manufacturer seeking to market a new drug must submit a New Drug Application ("NDA") with the FDA. 21 U.S.C. § 355(b). The NDA requires, among other things, that the manufacturer supply the agency with "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use" and "specimens of the labeling proposed to be used for such drug." 21 U.S.C. § 355(b)(1). The FDA can refuse to approve the NDA if the manufacturer fails to provide "adequate tests" or there is "insufficient information" to ensure the new drug's safety and effectiveness. 21 U.S.C. § 355(d).

In contrast, generic manufacturers seeking to market a generic drug must submit an Abbreviated New Drug Application ("ANDA") with the FDA. 21 U.S.C. § 355(j). Congress codified the ANDA procedure with the passage of the Drug Price Competition and Patent Term Act (the Hatch-Waxman Amendments) in 1984. The ANDA procedure establishes an expedited

FDA review process. The manufacturer must demonstrate that the generic drug it seeks to market is approved as a listed drug, meaning that the new drug product on which the generic drug is based already has FDA approval. 21 U.S.C. § 355(j)(2)(A)(i); 21 C.F.R. § 314.3. The manufacturer must show that the generic drug has the same active ingredients and is "bioequivalent" to the listed drug. 21 U.S.C. § 355(j)(2)(A)(ii)-(iv). Additionally, the manufacturer must supply "information to show that the labeling proposed for the [generic] drug is the same as the labeling approved for the listed drug . . . except for changes required because of differences approved under a petition filed under subparagraph (C) or because the [generic] drug and the listed drug are produced or distributed by different manufacturers." 21 U.S.C. § 355(j)(2)(A)(v).

After the generic drug is approved, the generic manufacturer's only continuing duty is one of "sameness" – that is, it must ensure that the warning label of the generic drug remains the same as the brand-name drug's label. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2575 (2011). Generic drug manufacturers are not permitted to independently change the labeling on their drugs. *Id.* at 2577. The duty of "sameness" also applies to the design of the drug, as it must remain "identical in active ingredients, safety, and efficacy" to the brand-name drug. *Id.* at 2574 n.1.

III. Federal Preemption under the ANDA Procedure

Our analysis of the claims against Sandoz is guided by two recent Supreme Court decisions: *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567 (2011), and *Mutual Pharmaceutical Co. v. Bartlett*, 133 S.Ct. 2466 (2013). In *Mensing*, the Court held that state-law failure-to-warn claims against generic drug manufacturers are preempted by federal law. 131 S. Ct. at 2572. The Court

extended that holding to reach to state tort claims of design defects in *Bartlett.* 133 S. Ct. at 2470.

a. Failure to warn

In *Mensing*, respondents alleged that the label of a generic drug did not adequately warn consumers of the drug's risk. 131 S.Ct. at 2573. The Court compared state and federal law, first finding that the state law duty would require manufacturers to alter or improve their drug's label. *Id.* at 2573-74. Next, the Court examined the Food, Drug and Cosmetic Act ("FDCA"), explaining that it required generic drug manufacturers to create and maintain their labels identically to the brand-name drug equivalent's label. *Id.* at 2574. Any change to a generic drug's label would conflict with generic drug manufacturers' federal duty of maintaining "sameness;" rather, they can only change a label in order to retain conformity with the brand-name drug's warnings. *Id*. at 2574-75. It would be impossible for generic drug manufacturers to simultaneously comply with both state and federal law. *Id.* at 2577-78. Therefore, the Court held that state tort law failure-to-warn claims against generic drug manufacturers are preempted by federal law. *Id.* at 2572-73.

The Sixth Circuit has applied *Mensing* to Kentucky law. In *Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011), the court upheld the district court's granting of a motion to dismiss PLA failure to warn claims against generic drug manufacturers. *Id.* at 422. The court found that *Mensing* preempted the claims, noting that the plaintiffs, like those in *Mensing*, "predicated the manufacturers' liability under state law on the failure to provide adequate warnings on the product's label." *Id.* at 423. The court noted that the Supreme Court was unequivocal in holding that "federal law preempts state laws that impose on generic-drug manufacturers the duty to change a drug's label, thus barring the plaintiffs' state-law tort claims. The plain language of the

PLIVA decision compels the same result here." *Id*.; *see also Strayhorn v. Wyeth Pharmaceuticals, Inc.*, 737 F.3d 378 (6th Cir. 2013) (affirming the district court's grant of a motion to dismiss state tort law claims because they were preempted by federal law that expressly prohibited manufacturers of generic drugs from making any unilateral changes to the drug's label or design).

b. Design defect

In *Bartlett*, the Supreme Court reversed a jury award on a patient's design defect claim against a manufacturer of a generic drug, finding that state law design defect claims are also preempted by federal law. 133 S.Ct. at 2470. The Court found that the FDCA prevented the manufacturer of a generic drug from changing its composition. Id. at 2471, 2475. Thus, the only way for the manufacturer to escape liability would be to strengthen or alter the drug's warning. *Id.* at 2475. However, as noted before, federal law also prevents a manufacturer of generic drug from altering its drug's label. *Id*. at 2476. Because federal law "forbids an action that state law requires," the state law was "without effect" and was preempted. *Id*. at 2476-77.

The Sixth Circuit has applied this holding to state law design defect claims as well. *Strayhorn v. Wyeth Pharmaceuticals, Inc.* 737 F.3d 378 (6th Cir. 2013) involved seven consolidated cases against a generic drug; plaintiffs sought compensation for injuries related to their usage of the drug. *Id.* at 382. The court affirmed the district court's granting of a motion to dismiss both the failure to warn and design defect claims, holding that the Supreme Court's decisions in *Mensing* and *Bartlett* prevented both types of state tort law claims from going forward. *Id.* at 396.

c. Plaintiff's claims are preempted by federal law

The Court construes Mitchell's complaint as alleging both a failure to warn and a design defect claim under the PLA. First, to the extent that Mitchell alleges Sandoz should have changed its labeling of the enoxaparin sodium shots in order to better reflect the potential dangers posed by the drug, her claim is preempted. Federal law prevents Sandoz from unilaterally altering the labels of its generic drug. *See PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567, 2574-75, 2578 (2011); 21 U.S.C. § 355(j)(2)(A)(v). Next, to the extent that Mitchell alleges Sandoz should have altered the design of the drug, federal law also prohibits Sandoz from taking action. *See Mut. Pharm. Co. v. Bartlett*, 133 S.Ct. 2466, 2475 (2013) (stating that "the 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"); 21 U.S.C. § 355(j)(2)(A)(ii)-(iv). Thus, these claims are also preempted. *Id.*.

CONCLUSION

For the foregoing reasons, Sandoz's Motion to Dismiss, (Docket No. 11), will be GRANTED. An appropriate Order will issue concurrently with this Opinion.

September 18, 2014

Thomas B. Russell

Thomas B. Russell, Senior Judge
United States District Court