IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

CARMEN NAOMI WATSON,

Plaintiff,

v.

MYLAN PHARMACEUTICALS, INC.,

Defendants.

Case No. 16-2449

MEMORANDUM & ORDER

On June 21, 2016, plaintiff Carmen Naomi Watson filed this action against defendant Mylan Pharmaceuticals, Inc. using the court's civil complaint form. (Doc. 1.) Plaintiff brings claims under the Kansas Product Liability Act ("KPLA"); a strict liability claim under § 402A of the Restatement (Second) of Torts; a Kansas Consumer Protection Act ("KCPA") claim for deceptive acts and practices; and 42 U.S.C. § 1983. This matter comes before the court on defendant Mylan Pharmaceuticals, Inc.'s Motion to Dismiss for Failure to State a Claim (Doc. 9) and plaintiff's Motion for Default Judgment (Doc. 16).

I. Motion for default judgment

Plaintiff moves the court to enter default judgment because she claims defendants filed their answer out of time. (Doc. 16). Fed. R. Civ. P. 55 governs default and default judgments. Rule 55 requires a party seeking default judgment to follow a two-step process. *Christenson Media Grp., Inc. v. Lang Indus., Inc.*, 782 F. Supp. 2d 1213, 1222 (D. Kan. 2011). First, the party seeking default must apply to the clerk for an entry of default against the opposing party for failure to plead or otherwise defend under Rule 55(a). Only once a clerk's entry of default is entered may the party file a motion for default judgment under Rule 55(b).

Defendant was served on July 5, 2016 and an answer or responsive pleading was due July 26, 2016. (Doc. 7.) On July 26, 2016, defendant filed a responsive pleading in the form of its Fed. R. Civ. P. 12(b)(6) motion to dismiss. Defendant has not failed to plead or otherwise defend as required by Rule 55 for default judgment. *See Earl v. Ruechel*, No. 11-2304-KHV, 2011WL3651372, at *1–2 (D. Kan. Aug. 18, 2011). Therefore, plaintiff's motion for default judgement (Doc. 16) is denied.

II. Legal standard for motion to dismiss

Defendant moves to dismiss this case under Fed. R. Civ. P. 12(b)(6) for failure to state a claim upon which relief may be granted. (Doc. 9.) Fed. R. Civ. P. 8(a)(2) requires complaints to contain "a short and plain statement of the claim showing that the pleader is entitled to relief." The United States Supreme Court has explained that the purpose of notice pleading is to provide defendants with fair notice of the claims against them and any alleged grounds for relief. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

To survive a motion to dismiss, plaintiff must state a claim for relief that is plausible on its face. *Id.* at 570. The complaint must consist of "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id.* at 554. Plaintiff must plead sufficient facts that the court may draw reasonable inferences that defendant is liable. *Ashcroft v. Iqbal*, 555 U.S. 662, 678 (2009). Plaintiff need not show that the right to relief is probable, but the facts must raise the right to relief above the speculative level—it must be plausible. *Twombly*, 550 U.S. at 545.

In considering defendant's motion to dismiss, the court takes all well-pleaded allegations in plaintiff's complaint as true and construes them in her favor. *Smith v. United States*, 561 F. 3d 1090, 1098 (10th Cir. 2009). The court's role at the motion to dismiss stage is not to weigh the evidence but to determine whether the allegations are legally sufficient to state a claim for relief upon which relief may be granted. *Id.*

When a plaintiff proceeds pro se, "the court shall dismiss the case at any time if the court determines that . . . the action or appeal—(i) is frivolous or malicious; (ii) fails to state a claim on which relief may be granted; or (iii) seeks monetary relief against a defendant who is immune from such relief." 28 U.S.C. § 1915(e)(2)(B). Where a plaintiff proceeds pro se, the court construes her filings liberally and holds them to less stringent standards than pleadings filed by lawyers. *Barnett v. Corr. Corp of Am.*, 441 F. App'x 600, 601 (10th Cir. 2011). Pro se plaintiffs are nevertheless required to follow the Federal and Local Rules of practice and the court does not assume the role of advocating for plaintiff. *United States v. Porath*, 553 F. App'x 802, 803 (10th Cir. 2014).

III. Discussion

A. Plaintiff's surreply

As an initial matter, plaintiff filed an "Opposition and Response to Defendants Further Support of Motion to Dismiss" (Doc. 24) that this court interprets as a surreply. Local Rule 7.1 permits parties to file a motion, response, and reply. D. Kan. Rule 7.1. "There is no provision for filing a surreply absent leave of court." *Ferluga v. Eickhoff*, 408 F. Supp. 2d 1153, n.1 (D. Kan. 2006). Calling a surreply a response to a memorandum does not protect it from being stricken if filed without leave of court, even by a pro se plaintiff. *Brown v. Kochanowski*, No. 07-3062-SAC, 2012 WL 4127959, at *3 (D. Kan. Sept. 19, 2012). Surreplies are generally not allowed, even with leave of court, unless the reply brief contains "new information which the responding party needs an opportunity to address." *Id.* (quoting *C.T. v. Liberal Sch. Dist.*, 564 F. Supp. 2d 1324, 1329 (D. Kan. 2008)). Plaintiffs filing (Doc. 24) is therefore stricken.

B. Plaintiff's claims

The face of plaintiff's complaint meets the requirements for diversity jurisdiction under 28 U.S.C. § 1332(a). Plaintiff is a citizen of Kansas and defendant is a corporation incorporated under the

laws of Pennsylvania. (Doc. 1 at 2.) The factual allegations in plaintiff's complaint, which lists the Kansas Product Liability Act ("KPLA"); strict liability under § 402A of the Restatement (Second) of Torts; and 42 U.S.C. 1983, as "other grounds" giving rise to federal jurisdiction, relate to side effects that plaintiff says she suffered after taking Amnesteem, a generic form of Accutane.

Plaintiff states that she was prescribed the drug for moderate acne and took it from April 2014 until July 2014. Plaintiff claims that defendant knowingly failed to provide adequate warnings to plaintiff regarding the unreasonable dangers Amnesteem poses and that she suffered personal injuries as a result. Plaintiff describes her symptoms and gives a summary of other cases where users of Amnesteem have committed suicide, suffered from severe depression, or committed crimes while taking the drug.

Plaintiff seeks $30 million in compensatory damages, $30 million in special damages for mental illness, $30 million for pain and suffering, emotional and on-going care, and $47 million in punitive damages. (Doc. 1 at 4, 6–7.)

Plaintiff claims defendant is liable under (1) a strict liability theory for failure to warn under the KPLA; (2) for unconscionable acts or practices under the KCPA; and (3) for strict liability or negligence under Kansas Law. Plaintiff never substantiates the § 1983 claim she mentions in her jurisdictional statement. To the extent she intended to bring one, it is dismissed for failure to state a claim. Regarding all of these claims, plaintiff argues that defendant had knowledge of the dangerous and harmful side-effects of Amnesteem and failed to adequately warn her about those risks.

B. Supremacy Clause preemption

Defendant argues that plaintiff's claims are preempted by the United States Supreme Court's decisions in *Mutual Pharmaceutical Co v. Bartlett*, 133 S.Ct. 2466 (2013) and *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011). The Supremacy Clause states that "[The] Constitution, and the Laws of the

United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby. . . .” U.S. CONST., art. VI, cl. 2. In the absence of express preemption, federal law impliedly preempts state law where the laws “directly conflict” such that it is “impossible for a private party to comply with both state and federal requirements.” *Mensing*, 564 U.S. at 617–618.

In *Mensing*, plaintiffs brought state tort claims based on generic drug manufacturers’ failure to adequately warn consumers of the risks of taking metoclopramide, a gut motility stimulator. 564 U.S. at 609. The Court found that federal regulations directly conflict with, and therefore preempt, state laws that would place a duty on drug manufacturers to adequately and safely label their drugs. *Id.* at 611–613. The Court explained that state tort laws requiring a drug manufacturer, who was or should be aware of its product’s risks, to label drugs in a way to make them reasonably safe to consumers directly conflicted with United States Food and Drug Administration (“FDA”) regulations that allowed generic drug manufacturers to gain FDA approval by showing that their drug was equivalent to an already-approved brand-name drug, and that the safety and efficacy labeling for the generic drug was the same as the approved brand-name drug. *Id.*

The Court deferred to the FDA’s interpretation of regulations prohibiting generic drug manufacturers from strengthening or changing warning labels or from sending letters containing additional warnings to prescribing physicians, because the FDA’s interpretations were not plainly erroneous or inconsistent with the regulations. *Id.* at 613 (agency interpretation is given controlling weight by the court unless it is plainly erroneous or inconsistent with regulations. *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945). Specifically, the Court found that generic-drug manufacturers could not unilaterally decide to strengthen their labels because regulations required brand-name and generic labels to remain equivalent, and that it was therefore impossible to comply

with both state and federal law. *Id.* at 614. The Court also found that generic manufacturers could not have sent "Dear Doctor" letters that included additional warnings, as suggested by plaintiff in this case, to treating physicians. Such letters were prohibited under the regulations because they constitute "labeling" and would imply a difference between the generic and name-brand drugs if included in the generic-drug labeling but not with the name brand. *Id.* at 615.

In *Bartlett*, the Court again held that "federal law prohibits generic drug manufacturers from independently changing their drugs' labels." 133 S.Ct at 2470. The plaintiff in that case sued the manufacturer of sulindac, a generic nonsteroidal anti-inflammatory drug, under state design-defect laws that would have required the manufacturer to provide stronger warnings on sulindac's labeling. *Id.* The Court again outlined the onerous process of getting a new-drug application approved with the FDA, and the Hatch-Waxman Act exception for the approval of generic drugs that are identical in substance and labeling to already-approved name-brand drugs. *Id.* at 2471. The Court explained that once approved, generic or name-brand drug manufacturers are prohibited from making any major changes to the drug's formula or unilaterally changing its label. *Id.*

In the present case, plaintiff responded to defendant's preemption argument by citing the state court's decision in *Bartlett* that was reversed by the United States Supreme Court. She also suggested that the federal courts should no longer allow drug manufacturer's to escape liability for failing to warn consumers about the risks of generic drugs. Plaintiff argues that defendant "could require any prescribing physicians for this drug to give its consumers a brief history disclosure or educational pamphlet." (Doc. 14 at 8.) But the United States Supreme Court specifically found that this type of "Dear Doctor" letter would violate federal drug regulations that require generic and name-brand drugs to have identical labeling.

To the extent plaintiff suggests that defendant should have stopped making Amnesteem because the risks of taking it outweighed its potential benefits, the United States Supreme Court has rejected that argument. The Court noted that every time the Court found impossibility preemption in a drug labeling case, the direct conflict between state and federal law could have been avoided if the manufacturer simply stopped selling the drug. Impossibility preemption would lose all meaning if manufacturers were required to simply stop selling their products if they were no longer able to comply with state law despite being in full compliance with federal regulations.

C. Plaintiff's claims are preempted

When deciding whether a particular plaintiff's claims are preempted by federal prescription-drug regulations, "the proper inquiry calls for an examination of the elements of the common-law duty at issue. . . ." *Bartlett*, 133 S.Ct. at 2480. It is important to "determin[e] precisely what, if any, specific requirement a state common-law claim imposes" to determine whether a conflict between state and federal law exists. *Id.* If the state claim requires manufacturers to change a product to make it safer, either in design or labeling, there is a conflict, because "a court may not hold a civil defendant liable under state law for conduct federal law requires." *Armstrong v. Exceptional Child Center, Inc.*, 135 S.Ct. 1378, 1384 (2015).

Plaintiff brings three Kansas law claims: (1) a strict liability claim for failure to warn under the KPLA; (2) a claim for unconscionable acts or practices under the KCPA; and (3) a claim for strict liability or negligence under Kansas Law.

1. Strict liability under the KPLA

The KPLA applies to all product liability claims regardless of the substantive theory of recovery, including strict liability. *Messer v. Amway Corp.*, 210 F. Supp. 2d 1217, 1227 (D. Kan. 2002). A product can be defective in three ways in Kansas: (1) a manufacturing defect; (2) a warning

defect; and (3) a design defect. *Id.* To establish a prima facie case for strict liability under the KPLA, plaintiff must show: "(1) the injury resulted from a condition of the product; (2) the condition was an unreasonably dangerous one; and (3) the condition existed at the time it left defendant's control." *Id.* (citing *Jenkins v. Amchem Prods., Inc.*, 256 Kan. 602, 630 (1994)). Plaintiff's factual allegations in relation to this claim are that defendant distributes Amnesteem, the plaintiff took it, and has suffered injuries.

2. Unconscionable acts or practices under the KCPA

Section 50-627 of the KPLA prohibits suppliers from engaging in unconscionable acts or practices in connection with consumer transactions in Kansas. Kan. Stat. Ann. § 50-627. Plaintiff alleges that defendant is a supplier because it distributed Amnesteem to her. Plaintiff's complaint alleges that defendant knew Amnesteem was unreasonably dangerous and marketed it anyway without taking action to inform consumers. "The consumer is unaware of the suicides and life long mental and physical damage claims that's been directly linked to this drug before consumption. Mylan states in their warnings there are no direct ties or links to most or all of these side effects." (Doc. 1 at 4.) Plaintiff claims that defendant knew Amnesteem's unreasonably dangerous side effects, that consumers were unaware of the risks, and that defendant states in their warnings that "there are no direct ties or links to most or all of these side effects."

3. Strict liability tort claim

Although plaintiff mentions "strict liability negligence" in her complaint, the court interprets her factual allegations as a strict liability claim. Plaintiff does not make factual allegations supporting a negligence claim or suggest that defendant owed her a duty, breached the duty, and caused her damages. Kansas adopted the strict liability doctrine from the Restatement (Second) of Torts § 402A (1965). It states "[o]ne who sells any product in a defective condition unreasonably dangerous to the

user or consumer or to his property is subject to liability for physical harm thereby caused ot the ultimate user or consumer . . . if (a) the seller is engaged in the business of selling such a product, and (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold." *Brooks v. Dietz*, 218 Kan. 698, 700 (1976) (quoting the Restatement (Second) of Torts § 402A (1965)). Plaintiff claims that defendant knew Amnesteem was a defective product and that it still sold the drug knowing of the dangers.

Plaintiff's claims, and the relief she seeks are exactly those types of claims discussed in *Bartlett* and *Mensing*. Plaintiff's factual allegations suggest that defendant knew Amnesteem was an unreasonably dangerous drug and that it failed to adequately warn consumers of the risks of taking it. She recommends that stronger or additional warnings should have been added to labeling, that prescribing physicians should have been given "Dear Doctor" letters explaining additional risks to patients, or that defendant should have stopped marketing the drug because the benefit of clearer skin was so substantially outweighed by the risks the drug poses. Unfortunately for plaintiff, these exact remedies were sought by the plaintiffs in *Bartlett* and *Mensing*. It is impossible for generic drug manufacturers to comply both with state laws that would require alterations to a drug or its labeling to make the drug safer and with federal law that prohibits changes to approved drugs. This is an example of a direct conflict between state and federal law. The Supremacy Clause dictates that federal law preempts state law in such cases. Therefore, plaintiff's claims are dismissed under Fed. R. Civ. P. 12(b)(6).

IT IS THEREFORE ORDERED that plaintiff Carmen Naomi Watson's Motion for Default Judgment (Doc. 16) is denied.

IT IS FURTHER ORDERED that defendant Mylan Pharmaceuticals, Inc.'s Motion to Dismiss for Failure to State a Claim (Doc. 9) is granted.

This case is closed.

Dated November 30, 2016, at Kansas City, Kansas.

s/ Carlos Murguia
CARLOS MURGUIA
United States District Judge