UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
CENTRAL DIVISION
(at Lexington)

LUCINDA CHRISTIAN, Plaintiff, V. ALTAIRE PHARMACEUTICALS, INC., et al., Defendants.	)	Civil Action No. 5: 20-306-DCR **MEMORANDUM OPINION AND ORDER**

*** *** *** ***

Plaintiff Lucinda Christian alleges that a product she purchased and used, ActivEyes Nighttime Lubricant Eye Ointment ("ActivEyes Nighttime"), caused her permanent eye injury. She filed this products liability action against Altaire Pharmaceuticals, Inc. ("Altaire"), Amazon Retail, LLC, and Amazon.com Services, LLC.[1] [Record No. 1] Defendants have filed motions to dismiss [Record Nos. 15 and 16], and Christian has requested to file a Second Amended Complaint. [Record No. 17]

In assessing her pleadings, the Court must answer a key question: whether the allegations of a voluntary product recall alone can push a products liability claim across "the line between possibility and plausibility of entitlement to relief." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007)). Because the

[1] Defendants Amazon Retail, LLC, and Amazon.com Services, LLC, will be referred to collectively as "Amazon."

Court concludes that it cannot, Christian's motion for leave to file a second amended complaint will be denied. The defendants' motions to dismiss will be granted.

I.

ActivEyes Nighttime is a lubricant eye ointment manufactured by Altaire. [Record No. 17, ¶ 5] On July 15, 2019, Altaire voluntarily recalled the product "[a]s a precautionary measure . . . due to management concerns regarding the sufficiency of Quality assurance controls over critical systems in the manufacturing facility." [Record No. 19-1, pp. 19–20] The notice was published by the United States Food and Drug Administration ("FDA"). [*Id.*] Christian claims that she used ActivEyes Nighttime before going to bed on July 17, 2019. [Record No. 17, ¶ 7] She later learned that the voluntary recall had been issued after Amazon reported the recall on July 21, 2019. [*Id.* at ¶ 9] Christian further claims that, at an unspecified date, she saw a doctor who diagnosed her with toxic conjunctivitis. [*Id.* at ¶ 10] She alleges that, as a result of her use of the product, she now suffers from "chronic optimal inflammation, profound excessive production of discharge, redness, pain, all of which interferes with her vision and use of both eyes." [*Id.*]

This action was originally filed in the Montgomery Circuit Court. Amazon filed a notice of removal with this Court on July 14, 2020. [Record No. 1] Thereafter, Amazon moved to dismiss all of Christian's claims. [Record No. 5] In response, Christian sought leave to file an Amended Complaint to provide "more detailed facts." [Record Nos. 8, at p. 1; 9] That request was granted and the Amended Complaint was filed in the record. [Record Nos. 12 and 13]

Christian's Amended Complaint contains the following three claims: (1) strict liability for manufacturing defect;[2] (2) negligent testing, marketing, and failure to warn; and (3) breach of express or implied warranty. [Record No. 13 at ¶¶ 11–12] Amazon has moved to dismiss Christian's negligence and breach of warranty claims. [Record No. 15] And Altaire has moved to dismiss all claims asserted against it. [Record No. 16] In response, Christian requested leave to file the Second Amended Complaint which is attached to her Response to the motions to dismiss. [Record Nos. 17 and 17-3] The proposed Second Amended Complaint raises the same three claims as Christian's Amended Complaint. [Record No. 17-3, at ¶¶ 11–13] The parties have fully briefed the issues, and the undersigned finds that oral argument is unnecessary to resolve the motions.

II.

The Court addresses Christian's request for leave to file a Second Amended Complaint as an initial matter. Because this Court has diversity jurisdiction over Christian's state-law claims pursuant to 28 U.S.C. § 1332(a), "federal procedural law and Kentucky substantive products liability law applies to this action." *Red Hed Oil, Inc. v. H.T. Hackney Co.*, 292 F. Supp. 3d 764, 771 (E.D. Ky. 2017). Motions to amend a complaint are governed by Fule 15(a) of the Federal Rules of Civil Procedure. This rule provides that "a party may amend its

[2] The First and Second Amended Complaints allege that "Defendants are liable to the plaintiff in strict liability, the product being defective and unreasonably dangerous for its expected uses." As such, Altaire addresses both manufacturing and design defect theories. [Record No. 16, at pp. 7–9] However, because her allegations discuss only the FDA's voluntary recall notice, the Court construes Christian's Complaints to allege a manufacturing (not design) defect. To the extent that she claims a design defect, her allegations are insufficient. *See Low v. Lowe's Home Ctrs., Inc.*, 771 F. Supp. 2d 739, 741 (E.D. Ky. 2011) (requiring proof of "a safer, and still feasible, design" to prove a design defect (citation omitted)).

pleading only with the opposing party's written consent or by leave of court. The court should freely give leave when justice so requires." Fed. R. Civ. P. 15(a)(2). Accordingly, denial of leave is only appropriate in cases of "undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, [or] futility of the amendment." *Forman v. Davis*, 371 U.S. 178, 182 (1962).

Christian has been given the opportunity to amend her Complaint under similar circumstances and did not make meaningful changes. Additionally, her failure to offer any argument in support of her motion and her misleading insertion of a facts contradicted by public record[3] could provide reasons to deny leave to amend. But the final listed justification for denial (i.e., futility) is most appropriate here. "A proposed amendment is futile if the amendment could not withstand a Rule 12(b)(6) motion to dismiss." *Beydoun v. Sessions*, 871 F.3d 459, 469 (6th Cir. 2017) (quoting *Riverview Health Inst. LLC v. Med. Mut. of Ohio*, 601 F.3d 505, 520 (6th Cir. 2010)). Accordingly, whether leave to amend should be granted may be determined by applying federal pleading standards to Christian's Second Amended Complaint. *See, e.g.*, *Sims v. Atrium Med. Corp.*, 349 F. Supp. 3d 628, 637 (W.D. Ky. 2018).

III.

Federal pleading standards demand "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). In determining whether Christian has met this standard, the Court will accept all "well-pleaded factual allegations" as true and "determine whether they plausibly give rise to an entitlement to relief." *Ashcroft v. Iqbal*, 556

[3] *See infra* Section III.b

U.S. 662, 679 (2009). But a "pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" *Id.* at 678 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). Rather, it must "contain sufficient factual matter . . . to 'state a claim to relief that is plausible on its face.'" *Id.* (quoting *Twombly*, 550 U.S. at 570)). This standard requires "either 'direct or inferential allegations respecting all material elements necessary for recovery under a viable legal theory.'" *Red Hed Oil*, 292 F. Supp. 3d at 772 (quoting *D'Ambrosio v. Marino*, 747 F.3d 378, 383 (6th Cir. 2014)). Dismissal pursuant to Rule 12(b)(6)—and, by extension, denial of leave to submit a futile amendment under Rule 15(a)—is appropriate where this standard is not satisfied.

a. Kentucky Products Liability Law

Each of Christian's claims is brought under Kentucky products liability law. These actions are governed by the Kentucky Product Liability Act ("KLPA"), KRS § 411.300–.350. Kentucky plaintiffs may advance three causes of action: "(1) strict liability, (2) negligence, and (3) breach of warranty." *Prather v. Abbott Labs.*, 960 F. Supp. 2d 700, 705 (W.D. Ky. 2013) (citing *Williams v. Fulmer*, 695 S.W.2d 411, 413 (Ky. 1985)). Christian must prove the existence of a defect and legal causation under any of these theories. *Vaughn v. Konecranes, Inc.*, 2015 WL 1719672, at *2 (E.D. Ky. Apr. 15, 2015) (citations omitted)

Christian has asserted all three causes of action in her proposed Second Amended Complaint. First, she claims all defendants are strictly liable for manufacturing defects, "the product being defective and unreasonably dangerous for its expected uses." [Record No. 13, ¶ 12] Second, she alleges that Altaire negligently tested, manufactured, and marketed ActivEyes Nighttime. [Record No. 17-3, ¶ 11] She further asserts that all defendants

negligently failed to warn of contamination. [*Id.* at ¶ 12] Finally, she claims that the defendants are liable "in breach of warranties, express and/or implied." [Record No. 17-3, ¶ 13]

i. Strict Liability

To bring a successful strict products liability claim in Kentucky, Christian must demonstrate the following:

> (1) that there is a "product," which is (2) in a defective condition unreasonably dangerous to the user or consumer or his property, and (3) which reaches the user or consumer without substantial change in the condition in which it is sold; (4) that the product is sold by one who is engaged in the business of selling such a product which (5) results in physical harm to the ultimate user or consumer or his property.

Vanden Bosch v. Bayer Pharms., Inc., 13 F. Supp. 3d 730, 740 (W.D. Ky. 2014) (citation and emphasis omitted). Specifically, "a manufacturing defect exists in a product when it leaves the hands of the manufacturer in a defective condition because it was not manufactured in accordance with its specifications." *Greene v. B.F. Goodrich Avionics Sys.*, 409 F.3d 784, 788 (6th Cir. 2005) (citing *Ford Motor Co. v. McCamish*, 559 S.W.2d 507, 509–11 (Ky. App. 1977)).

Both "unreasonable dangerousness" and "causation" are further defined in Kentucky law. First, whether a product is unreasonably dangerous "depends on what [the manufacturer] would have anticipated had he been (but regardless of whether he actually was or should have been) aware of the condition of and potentialities inhering in the product when he put it on the market." *Ulrich v. Kasco Abrasives Co.*, 532 S.W.2d 197, 200 (Ky. 1976). And second, while proof of the defendants' fault is not required to show causation, Christian must ultimately

prove that defendants' conduct "was a substantial factor" in causing the alleged injury. *Greene*, 409 F.3d at 788 (quoting *King v. Ford Motor Co.*, 209 F.3d 886, 893 (6th Cir. 2000)).

ii. Negligence

To adequately plead negligence claims under Kentucky law, Christian must establish that: (1) the defendants owed her a duty of care; (2) the defendants breached that duty; and (3) the breach proximately caused her injuries. *Mullins v. Commonwealth Life Ins. Co.*, 839 S.W.2d 245, 247 (Ky. 1992). "[N]egligence depends on what a prudent manufacturer, engaged in a business similar to that of the defendant, by the exercise of ordinary care actually should have discovered and foreseen." *Ulrich*, 532 S.W.2d at 200.

Negligent failure to warn is a separate theory of recovery under Kentucky law. This claim arises "out of general negligence principles." *Prather*, 960 F. Supp. 2d at 712 (quoting *C & S Fuel, Inc. v. Clark Equip. Co.*, 552 F. Supp. 340, 347 (E.D. Ky. 1982)). It imposes on manufacturers a duty to "'warn the consumer of non-obvious dangers inherent in the probable use of the product,' even dangers from foreseeable misuse." *Tipton v. Michelin Tire Co.*, 101 F.3d 1145, 1149 (6th Cir. 1996) (citing *Byrd v. Proctor & Gamble Mfg. Co.*, 629 F. Supp. 602, 605 (E.D. Ky. 1986)).

iii. Breach of Warranty

Christian's final claims (i.e., breach of express and implied warranty) share the basic requirement of "privity of contract or a direct buyer-seller relationship." *Taylor v. Southwire Tools & Equip.*, 130 F. Supp. 3d 1017, 1021 (E.D. Ky. 2015). A "warranty that goods shall be merchantable is implied in a contract for their sale" in the buyer-seller context. KRS §§ 355.2-314. Additionally, to prove breach of an express warranty, Christian must prove "(1)

the seller made an affirmation of fact or promise; (2) that related to the goods; and (3) became part of the basis of the bargain between the parties." *Sims*, 349 F. Supp. 3d at 643 (citing KRS § 355.2-313(1)(a)).

b. Voluntary Recall

For her strict liability and negligence claims, Christian must plausibly allege the existence of a defect in ActivEyes Nighttime. Here, the *only* facts she alleges that point to a possible defect concern a voluntary recall issued by the FDA. Christian alleges: "On or before July 8, 2019, the Federal Drug Administration [sic] issued a recall on this product due to bacteria in the product, it not being sterile, and possibly leading to life-threatening infection." [Record No. 17-3, ¶ 6] Christian's allegations regarding the FDA's notice can be verified, or contradicted, by public records. *See Amini v. Oberlin College*, 259 F.3d 493, 502 (6th Cir. 2001) (quoting *Nieman v. NLO, Inc.*, 108 F.3d 1546, 1554 (6th Cir. 1997)) ("In determining whether to grant a Rule 12(b)(6) motion, the court primarily considers the allegations in the complaint, although matters of public record . . . also may be taken into account.").

The FDA records referenced in Christian's Amended Complaint are well-suited for judicial notice. *Maxberry v. Univ. of Ky. Med. Ctr.*, 39 F. Supp. 3d 872, n.5 (E.D. Ky. 2014) ("The Court takes judicial notice of records and information located on government websites because they are self-authenticating under Federal Rule of Evidence 902." (citations omitted)); *see also Coffelt v. Kroger Co.*, Case No. EDCV 16-1471 JGB 2017 WL 10543343, at *1 n.1 (C.D. Cal. Jan. 27, 2017) (taking judicial notice of FDA records). It states:

> As a precautionary measure, Altaire is voluntarily initiating this recall due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility. The FDA has determined these issues indicate a lack of sterility assurance. Administration of a non-sterile

> product intended to be sterile may result in serious and potentially life-threatening infections or death. . . .
>
> TO DATE, ALTAIRE HAS NOT RECEIVED ANY REPORTS OF ADVERSE EVENTS FOR THE PRODUCTS.
>
> TO DATE, ALTAIRE HAS NOT OBTAINED ANY OUT OF SPECIFICATION RESULTS, INCLUDING IN-HOUSE AND THIRD-PARTY STERILITY TESTING, FOR THESE PRODUCTS.

Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products Manufactured and Distributed as Altaire Labeled Products, U.S. Food & Drug Admin. (July 15, 2019), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/altaire-pharmaceuticals-inc-issues-voluntary-recall-multiple-ophthalmic-products-manufactured-and#recall-announcement; *see also* [Record No. 19-1, pp. 19–29].

Rule 8 of the Federal Rules of Civil Procedure requires Christian to plead "*factual* content." *Iqbal*, 556 U.S. at 678 (emphasis added). And in assessing a Rule 12(b)(6) motion, the Court "need not accept as true . . . .unwarranted factual inferences." *Morgan v. Church's Fried Chicken*, 829 F.2d 10, 12 (6th Cir. 1987); *see also* 2 Moore's Federal Practice § 12.34[2] ("If, however, an unsupported factual allegation in a pleading is affirmatively and unambiguously contradicted by documents attached to or necessarily implicated by the pleadings, the latter controls over the former and a Rule 12(b)(6) dismissal may be based on the documents.").

The actual voluntary recall notice makes no mention of bacteria, clearly states that the recall is both voluntary and precautionary. It further states that there is no evidence of adverse consequences of use. [Record No. 19-1, pp. 19–20] Christian's characterization of the notice is inconsistent with the public record. Accordingly, having taken judicial notice of the

voluntary recall notice and found it to directly contradict Christian's allegations, the Court will consider the actual recall notice in assessing her pleadings.

c. Analysis

Altaire correctly contends that Christian's allegations leave it to "guess about the most important, core elements of this lawsuit." [Record No. 16, p. 4] Christian's proposed Second Amended Complaint fails to plausibly allege the existence of a defect. Under Kentucky law, "proof of a *defective product* is essential to the [strict] products liability or the negligence claim. . . . the distinction between the two claims is of 'no practical significance.'" *Tipton v. Michelin Tire Co.*, 101 F.3d 1145, 1150 (6th Cir. 1996) (emphasis in original) (quoting *Sexton ex rel. Sexton v. Bell Helmets*, 926 F.2d 331, 336 (4th Cir.), *cert. denied*, 502 U.S. 820 (1991)). And federal courts applying Kentucky law have dismissed products liability defect claims where plaintiffs fail to "state *how* the defendant's product was . . . manufactured improperly." *Red Hed Oil, Inc.*, 292 F. Supp. 3d at 778 (emphasis in original); *see also Sims*, 349 F. supp. 3d at 638, 640–41; *Estate of Demoss v. Eli Lilly & Co.*, 234 F. Supp. 3d 873, 880–81 (W.D. Ky. 2017); *Vanden Bosch*, 13 F. Supp. 3d at 742.

Accordingly, this inquiry turns on one question: whether Christian can plausibly allege ActivEyes Nighttime was defective by relying only on her allegation that a voluntary recall notice was issued. It is true that Rule 8 does not "demand[] highly specific factual allegations to satisfy this plausibility requirement." *Rhodes v. R&L Carriers, Inc.*, 491 F. App'x 579, 583 (6th Cir. 2012). The rule, however, demands "more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 556). And in products liability cases, "[i]t is not enough for Plaintiffs to simply rely on their basic injury

allegations and argue that the product was somehow defective because it was 'dangerous.'" *Vanden Bosch*, 13 F. Supp. 3d at 742. But that is what Christian has done in this case by referring to only the voluntary recall notice, and alleging no facts about the defect.

Standing alone, a voluntary recall notice which fails to identify a specific contamination issue and expressly states that no product has been identified as out-of-specification does not constitute a plausible allegation of a product defect. Accordingly, the strict liability and negligence claims in Christian's proposed Second Amended Complaint cannot survive a Rule 12(b)(6) motion, and any amendment would be futile.

And Christian's breach of warranty claims fare no better. By stating her claims in one clause of one paragraph of her proposed Second Amended Complaint, Christian fails to offer even "a formulaic recitation" of the elements of either claim. *Twombly*, 550 U.S. at 555. First, she fails to allege an "essential element" of breach of warranty causes of action: privity. *Vanden Bosch*, 13 F. Supp 3d at 747 (collecting cases). She claims only that ActivEyes Nighttime was "manufactured by Altaire" and "delivered by Amazon." [Record No. 17-3, ¶ 5] Christian's proposed Exhibit 1 suggests it was purchased from a seller named "Optego." [*Id.* at Ex. 1] Privity "does not extend beyond the buyer-seller setting," *Vanden Bosch*, 13 F. Supp. 3d at 747, and she has not alleged that it existed here. Second, while Christian alleges an express warranty was breached, she does not actually identify the specific warranty. Thus, any amendment to her breach of warranty claims also would be futile.

IV.

The proposed Second Amended Complaint and the First Amended Complaint contain the same allegations and share the same weaknesses. Accordingly, the above Rule 12(b)(6)

analysis of the proposed Second Amended Complaint applies with equal force to the First Amended Complaint. It also fails to "state a claim to relief that is plausible on its face." *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). Accordingly, the defendants' motions to dismiss will be granted.

Christian's strict liability claims remain pending as to Amazon, as it did not move for their dismissal.

Based on the foregoing analysis and discussion, it is hereby

ORDERED as follows:

1. Plaintiff Lucinda Christian's motion for leave to file a second amended complaint [Record No. 17] is **DENIED**.

2. The defendants' motions to dismiss [Record Nos. 15 and 16] are **GRANTED**.

3. All claims asserted against Defendant Altaire Pharmaceuticals, Inc. have been resolved. Therefore, it is **DISMISSED** as a party to this action.

4. Plaintiff's strict liability claims remain pending against Defendants Amazon Retail LLC and Amazon.com Services LLC.

Dated: October 13, 2020.

Danny C. Reeves, Chief Judge
United States District Court
Eastern District of Kentucky