UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
CENTRAL DIVISION
LEXINGTON

NELDA SKINNER, **Plaintiff,** **V.** **ETHICON, INC. and JOHNSON & JOHNSON,** **Defendants.**	**CIVIL ACTION NO. 5:19-472-KKC** **OPINION AND ORDER**

*** *** ***

This matter is before the Court on the second motion to dismiss (DE 9) filed by defendants Ethicon, Inc. and Johnson & Johnson (together, "Ethicon"). For the following reasons, the motion will be granted in part and denied in part.

I. Background

In its opinion on Ethicon's prior motion to dismiss, the Court determined that plaintiff Nelda Skinner had failed to set forth sufficient allegations in her complaint to state any claim for relief. The Court permitted her to file an amended complaint correcting the deficiencies. She has now filed the amended complaint. Ethicon argues that the new complaint still fails to set forth sufficient allegations to state any claim.

With the amended complaint, Skinner alleges that Ethicon manufactures and sells sutures that are sold under the brand name Vicryl. She alleges that she suffered personal injuries as a direct result of "being implanted with" the sutures, which she alleges are "defective and unreasonably dangerous." (DE 8, Complaint, ¶4.) She alleges that, after the sutures were implanted in her, she had to undergo another surgery to "repair the

opened wounds and the dehiscence caused by the failure of the Vicryl sutures." (DE 8, Complaint, ¶10.) She alleges that the sutures were subject to a recall notice and that Ethicon "knew or should have known there was a substantial likelihood of failed Ethicon Vicryl sutures." (DE 8, Complaint, ¶10.) She alleges that Ethicon nonetheless chose to keep selling them. (DE 8, Complaint, ¶18.)

Ethicon moves pursuant to Federal Rule of Civil Procedure 12(b)(6) to dismiss the complaint for failure to state any claim. In her cursory response, Skinner does not point to the allegations in the complaint that support her specific claims. She asserts that the specifics to support at least some of the claims will be determined during discovery. This is insufficient.

A plaintiff cannot file suit and then claim that she will use discovery to obtain the facts necessary to support it. *New Albany Tractor, Inc. v. Louisville Tractor, Inc.*, 650 F.3d 1046, 1051 (6th Cir.2011). "Rule 8 marks a notable and generous departure from the hyper-technical, code-pleading regime of a prior era, but it does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." *Ashcroft v. Iqbal*, 556 U.S. 662, 678–79 (2009). The Sixth Circuit Court of Appeals "has rejected the argument that a claim should survive a motion to dismiss on the basis that necessary information is exclusively within the defendant's control, even in the context of the less rigorous pleading requirements of the Federal Rule of Civil Procedure 8." *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 472 (6th Cir.2011) (citing *New Albany Tractor*, 650 F.3d at 1050–51). "[P]laintiff must allege specific facts . . . even if those facts are only within the head or hands of the defendants. The plaintiff may not use the discovery process to obtain these facts after filing suit." *New Albany Tractor*, 650 F.3d at 1051.

As it must, the Court will review each claim to determine if the amended complaint sets forth sufficient allegations to support it.

II. Analysis

Under Federal Rule of Civil Procedure 8(a)(2), a complaint need only contain "a short and plain statement of the claim showing that the pleader is entitled to relief," but the complaint must assert enough facts to provide the defendant with "fair notice of what the claim is and the grounds upon which it rests.'" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citation and ellipsis omitted).

"While 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." *Id*. at 555 (citations and internal brackets omitted). To survive a motion to dismiss, the factual allegations in the complaint "must be enough to raise a right to relief above the speculative level." *Id*. The plaintiff must plead "enough facts to state a claim to relief that is plausible on its face" and to nudge his claim "across the line from conceivable to plausible." *Id*. at 570.

"A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. The plaintiff must plead facts that allow for "more than a sheer possibility that a defendant has acted unlawfully." *Id.* "Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of 'entitlement to relief.'" *Id.* (quoting *Twombly*, 550 U.S. at 557).

Skinner mentions 10 types of claims in this latest complaint: strict liability based on manufacturing defect (Count I); strict liability based on design defect (Count II); strict liability based on a failure to warn (Count II); negligence in manufacturing (Count III); negligent failure to recall/retrofit (Count III); negligent failure to warn (Count III); negligence per se (Count IV); breach of express warranty (Count V); breach of implied warranty (Count VI); and a violation of the Kentucky Consumer Protection Act, KRS § 367.170 *et seq* (Count VII). Ethicon asserts that defendants have failed to set forth sufficient allegations to state any of these claims.

As to the first claim – strict liability based on a manufacturing defect –Ethicon argues that this claim must be dismissed because the Skinner does not identify a specific manufacturing defect. Skinner asserts, however, that the sutures were subject to a medical device recall, which states that the sutures "exhibited suture damage due to a manufacturing equipment issue" which could result in a "superficial wound dehiscence or contribute to impaired wound healing." (DE 8, Complaint ¶25.)

Ethicon asserts that nothing in the documents attached to Skinner's complaint indicates that the sutures used to treat her were subject to the recall notice. At this point, however, the issue is whether Skinner has made sufficient allegations, not whether she has documents that can support the allegations. She explicitly alleges that the sutures she was treated with were subject to the recall notice, which indicated that the sutures were damaged during manufacturing and that the damage caused the kinds of wounds she alleges. (DE 8, Complaint ¶24.) Nothing in the documents she attaches to the complaint, including the recall notice, contradicts that assertion.

For her second claim – product liability based on design defect– Ethicon asserts that this claim must be dismissed because Skinner does not allege how the suture design was defective or how any design defect caused her injury. As discussed, the complaint adequately alleges that the sutures were defective due to a manufacturing defect. In other words, it alleges that the sutures were not manufactured in accordance with their specifications. *See Greene v. B.F. Goodrich Avionics Systems, Inc.*, 409 F.3d 784, 788 (6th Cir. 2005) ("Under Kentucky law, a manufacturing defect exists in a product when it leaves the hands of the manufacturer in a defective condition because it was not manufactured or assembled in accordance with its specifications.")

While a complaint can plead alternative theories of liability, the complaint does not allege any facts from which the Court could infer that, in addition to the sutures being manufactured contrary to their specifications, the design for the sutures was also defective. In Count II, Skinner simply makes the conclusory allegation that the sutures were "defective." (DE 8, Complaint, ¶¶ 34, 35.) In her response, she argues that she will determine the design defect in discovery. As discussed above, this is not sufficient. This claim will be dismissed without prejudice.

Instead of alleging a design defect, the allegations contained in count II of the complaint are centered on the alleged failure to warn. Skinner alleges that the Ethicon knew the Vicryl sutures "posed a significant and higher risk of failure than other similar sutures" (DE 8, Complaint, ¶33), but it failed to adequately warn customers about the risks. (DE 8, Complaint, ¶36.) She specifically alleges that Ethicon knew that the sutures "[h]ad previously caused serious bodily injury to its users with special medical conditions

such as those of plaintiff." (DE 8, Complaint, ¶41(c)) This is sufficient to state a product liability claim based on a failure to warn.

As to the negligence claim in Count III of the complaint, Skinner mentions three duties: a duty to exercise care in manufacturing the sutures (DE 8, Complaint, ¶ 44); a duty to recall and/or retrofit the sutures (DE 8, Complaint, ¶ 51); and a duty to adequately warn of the sutures' alleged dangers (DE 8, Complaint, ¶ 56). Ethicon argues that Skinner has failed to allege a negligence claim based on any of these duties.

As to the duty to exercise care in manufacturing, Skinner makes conclusory allegations that Ethicon failed to use reasonable care in the manufacturing of the sutures. (DE 8, Complaint ¶ 45(b), (c)). These allegations are insufficient to support the claim. She also alleges that Ethicon did not adopt manufacturing processes that could have reduced the risk of the product failure and that it failed to establish an adequate quality assurance program in manufacturing the sutures. (DE 8, Complaint ¶¶ 45(a)(d)). She does not allege any facts that would show how Ethicon's manufacturing processes or quality assurance program were inadequate. These allegations are insufficient to support a claim that Ethicon was negligent in manufacturing the sutures. This claim will be dismissed without prejudice.

As to the duty to recall or retrofit the sutures, Skinner alleges that Ethicon knew of the sutures' defect before she was treated with them and, thus, had a duty to recall them. (DE 8, Complaint, ¶ 50.) As discussed, however, Skinner also alleges that Ethicon did recall the sutures at issue. (DE 8, Complaint, ¶24.) Further, she does not mention this claim in her response to the motion to dismiss. Thus, it is not clear that Skinner even intends to allege that Ethicon negligently failed to recall the product. Regardless,

Kentucky does not recognize a negligence claim based on a duty to recall or retrofit a product. *Ostendorf v. Clark Equip. Co.*, 122 S.W.3d 530, 533, 534 (Ky. 2003) ("Product recalls, however, are properly the province of administrative agencies, as the federal statutes that expressly delegate recall authority to various agencies suggest.") (quoting Schwartz, *The Post-Sale Duty to Warn: Two Unfortunate Forks in the Road to a Reasonable Doctrine*, 58 N.Y.U.L. Rev. 892, 201 (Oct. 1983)); *May for Estate of May v. Ford Motor Company*, No. 09-165-GFVT 2011 WL 13234171, at *3 n.2 (E.D. Ky. Jan. 24, 2011) To the extent that Skinner attempts to assert such a claim, it will be dismissed with prejudice.

As to the alleged breach of the duty to warn, Skinner alleges that Ethicon knew of the dangers presented by the sutures but failed to provide adequate warnings. As discussed, Skinner has adequately alleged that the sutures were defective because of a manufacturing defect, that the defect caused injuries, and that she suffered the kinds of injuries caused by the defect. Skinner has also adequately alleged that Ethicon knew about the injuries but failed to warn about the dangers.

In Count IV of the complaint, Skinner asserts a negligence per se claim, asserting that Ethicon violated several state and federal regulations. The common law concept of negligence per se is codified in Kentucky statute KRS § 446.070. *Davidson v. American Freightways, Inc.*, 25 S.W.3d 94, 99 (Ky.2000). The statute provides that "[a] person injured by the violation of any statute may recover from the offender such damages as he sustained by reason of the violation, although a penalty or forfeiture is imposed for such violation." KRS § 446.070. Kentucky courts have held that the "any statute" language in KRS § 446.070 is limited to Kentucky statutes and does not extend to federal statutes and

regulations. *T & M Jewelry, Inc. v. Hicks ex rel. Hicks*, 189 S.W.3d 526, 530 (Ky.2006). The legislature did not intend the statute "to embrace the whole of federal laws and the laws of other states and thereby confer a private civil remedy for such a vast array of violations." *T & M Jewelry, Inc*., 189 S.W.3d at 530. "Violations of federal laws and regulations and the law of other states do not create a cause of action based on KRS 446.070." *St. Luke Hosp., Inc. v. Straub*, 354 S.W.3d 529, 534 (Ky.2011). Skinner does not address this claim in her response to the motion to dismiss. Because this claim is premised entirely on the alleged violation of federal statutes and regulations, it must be dismissed.

With Counts V, VI, and VII of the complaint, Skinner asserts claims for breach of express and implied warranty and for violation of the Kentucky Consumer Protection Act, KRS 367.170, *et seq*. Ethicon argues all these claims must be dismissed because all require privity of contract. This is correct. *See Waterfill v. Nat'l Molding Corp*., 215 F. App'x 402, 405 (6th Cir. 2007) (stating that, under Kentucky law, "claims for breach of express or implied warranties may proceed only where there is privity between the parties."); *Compex Int'l Co., Ltd. V. Taylor,* 209 S.W.3d 462, 464 (Ky. 2006) ("[P]rivity remains a prerequisite for products liability claims based on warranty...."); *Yonts v. Easton Tech. Prod., Inc.*, 676 F. App'x 413, 420 (6th Cir. 2017) (stating that, under the KCPA, "a subsequent purchaser may not maintain an action against a seller with whom he did not deal."); *Davis v. Norton Healthcare, Inc.*, No. 2020-CA-0151-MR, 2021 WL 223528, at *4 (Ky. Ct. App. Jan. 22, 2021) ("Claims may only be brought under the KCPA by individuals who *personally* purchase goods or services from a merchant. . . .").

In her response to the motion to dismiss, Skinner argues that there was privity of contract between her and Ethicon because she was billed for the sutures. In the amended complaint, however, she asserts that she purchased the sutures from her "medical providers." (DE 8, First Amended Complaint ¶ 66.) Privity of contract exists only between the seller and its immediate purchasers. *Waterfill*, 215 F. App'x at 405; *Skilcraft Sheetmetal, Inc. v. Ky. Machinery, Inc.*, 836 S.W.2d 907, 909 (Ky. 1992) (stating the KCPA "plainly contemplates an action by a purchaser against his immediate seller"). Because Skinner has not alleged or even argued that such privity exists between her and Ethicon, both breach of warranty claims and the KCPA claim must be dismissed with prejudice.

III. Conclusion

Accordingly, the Court hereby ORDERS the motion to dismiss is GRANTED in part and DENIED in part as follows:

1) the motion is GRANTED as to the strict-liability claim based on a design defect and as to the negligence claim based on the duty to exercise reasonable care in manufacturing. These claims are DISMISSED *without* prejudice;

2) the motion is GRANTED as to the negligence claim based on a breach of the duty to recall and the claims for negligence per se, breach of express and implied warranties, and violation of the KCPA. These claims are DISMISSED *with* prejudice; and

3) the motion is DENIED as to the strict liability claims based on a manufacturing defect and a failure to warn and as to the claim for

negligent failure to warn. These three claims are the sole claims remaining in this action.

The Court does not interpret the First Amended Complaint to assert any claims other than those addressed in this opinion.

Dated February 18, 2021

KAREN K. CALDWELL
UNITED STATES DISTRICT JUDGE
EASTERN DISTRICT OF KENTUCKY