Sims v. Atrium Medical Corp. Doc. 19

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
OWENSBORO DIVISION

CIVIL ACTION NO: 4:17-CV-00160-JHM

JOSEPH J. SIMS **PLAINTIFF**

V.

ATRIUM MEDICAL CORP. **DEFENDANT**

MEMORANDUM OPINION AND ORDER

This matter is before the Court on Plaintiff's Motion for Leave to File First Amended Complaint. [DN 16]. Fully briefed, this matter is ripe for decision. For the following reasons, the Plaintiff's motion is **GRANTED IN PART** and **DENIED IN PART**.

I. BACKGROUND

In early 2015, Plaintiff Joseph J. Sims suffered a bilateral inguinal hernia in his lower abdomen. On or about May 27, 2015, Dr. Anthony Kaiser performed a bilateral laparoscopic hernia repair on Sims at Deaconess Health System in Evansville, Indiana. Dr. Kaiser used tacks and two identical pieces of surgical mesh. The mesh was ProLite Mesh made by Defendant Atrium Medical Corp. ("Atrium"). Following the initial surgery, Sims suffered chronic pain. After initial efforts failed to resolve Sims' chronic pain and other symptoms, Dr. Kaiser performed a laparoscopic removal of one of the pieces of mesh on or about February 24, 2017, at the same hospital in Evansville. Dr. Kaiser noted in his operative report that Sims suffered significant adhesions of the mesh, eventually requiring cauterization of the mesh from Sims' bone. Later, on or about September 29, 2017, Dr. Kaiser performed an additional repair surgery during which he removed more mesh which had adhered to Sims' intestines. Despite both reparative surgeries, Sims was unable to continue working at his job due to chronic pain and he remains unable to work today.

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On December 14, 2017, Sims filed a Complaint alleging six causes of action against Atrium—Negligence (Count I), Strict Products Liability (Count II), Negligence Per Se (Count III), Breach of Implied Warranty (Count IV), Breach of Express Warranty (Count V), and Negligent Misrepresentation (Count V). [DN 1]. Thereafter, Atrium filed a Motion to Dismiss stating that Sims' Complaint failed for three independent reasons: "(1) the ProLite Mesh Instructions for Use, cited and relied upon by Plaintiff in the Complaint, contain the very warnings Plaintiff alleges were not provided; (2) each of the claims asserted fails to satisfy the pleading standards articulated in *Twombly* and *Iqbal*; and (3) Plaintiff cannot adequately plead causation." [DN 8 at 2]. In response, Sims refuted Atrium's claims and requested that the Motion to Dismiss be denied, or, in the alternative, that he be given leave to amend his Complaint. [DN 13]. Atrium replied, stating that Sims' failure to respond to arguments in the Motion to Dismiss constituted admissions and, as such, granting leave to amend would be futile. [DN 14]. On July 16, 2018, the Court issued an Order stating that Sims' prior request for leave to amend was deficient and that if he wished to amend his complaint "he must file a proper motion to amend and tender the proposed amended complaint within 15 days of the entry of this order." [DN 15 at 2]. The Order further stated that the Court would not rule on Atrium's Motion to Dismiss until it decided whether to allow the amended complaint. On July 31, 2018, 15 days after the Court's Order, Sims filed a Motion for Leave to File First Amended Complaint and attached a Proposed Amended Complaint asserting the same causes of action. [DN 16, 16-1]. Atrium responded on August 21, 2018, asserting that Sims' motion should be denied because Sims waived his arguments, amendment would cause undue delay, and amendment would be futile. [DN 18].

II. STANDARD OF REVIEW

Upon a motion to dismiss for failure to state a claim pursuant to Fed. R. Civ. P. 12(b)(6), a court "must construe the complaint in the light most favorable to plaintiffs," *League of United Latin Am. Citizens v. Bredesen*, 500 F.3d 523, 527 (6th Cir. 2007) (citation omitted), "accept all well-pled factual allegations as true," *id.*, and determine whether the "complaint . . . states a plausible claim for relief," *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). Under this standard, the plaintiff must provide the grounds for its entitlement to relief, which "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). A plaintiff satisfies this standard only when it "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. A complaint falls short if it pleads facts "merely consistent with a defendant's liability" or if the alleged facts do not "permit the court to infer more than the mere possibility of misconduct." *Id.* at 679. Instead, "a complaint must contain a 'short and plain statement of the claim showing that the pleader is entitled to relief.'" *Id.* at 663 (quoting Fed. R. Civ. P. 8(a)(2)). "But where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" *Id.* at 679 (quoting Fed. R. Civ. P. 8(a)(2)).

If "matters outside the pleadings are presented to and not excluded by the court" when ruling upon a motion under Rule 12(b)(6), the Federal Rules require that "the motion must be treated as one for summary judgment under Rule 56." Fed. R. Civ. P. 12(d). This Rule does not require the Court to convert a motion to dismiss into a motion for summary judgment every time the Court reviews documents that are not attached to the complaint. *Greenberg v. Life Ins. Co. of Va.*, 177 F.3d 507, 514 (6th Cir. 1999). "[W]hen a document is referred to in the complaint and is central to the plaintiff's claim . . . [,] the defendant may submit an authentic copy [of the document]

to the court to be considered on a motion to dismiss, and the court's consideration of the document does not require conversion of the motion to one for summary judgment." *Id.* (quotation omitted).

III. DISCUSSION

A. Motion to Dismiss for Failure to State a Claim

Atrium challenged Sims' Complaint and moved for dismissal under Fed. R. Civ. P. 12(b)(6) for failure to state a claim. [DN 8]. According to Atrium, Sims' Complaint fails for the three independent reasons stated above. [DN 8-1 at 2]. In response, Sims states that his claims are sufficiently pled, and, in the alternative, asks the Court for leave to file an amended complaint. [DN 13]. Sims filed a Motion for Leave to File an Amended Complaint, which if granted, would make Atriums' argument of lack of factual allegations moot. [DN 16]. As Sims filed a Motion for Leave to File an Amended Complaint to cure any deficiencies in the original Complaint, the Court must first address whether it will grant Sims' Motion for Leave to File an Amended Complaint. [DN 16].

B. Motion to Amend

A motion for leave to file an amended complaint is governed by Fed. R. Civ. P. 15(a)(2) which states that "a party may amend its pleading only with the opposing party's written consent or the court's leave." A district court should freely grant a plaintiff leave to amend a pleading "when justice so requires." Fed. R. Civ. P. 15(a)(2). However, a district court may deny a motion to amend where there is "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, futility of amendment, etc." *Foman v. Davis*, 371 U.S. 178, 182 (1962).

1. Waiver of Arguments

In Atrium's Response to Sims' Motion to Amend, Atrium argues that the motion should be denied "because amendment is futile where Plaintiff has waived opposition to Atrium's dismissal arguments by failing to address them in his response to Atrium's motion to dismiss." [DN 18 at 2]. As per the Court's July 16, 2018 Order, if the Court grants Sims' Motion to Amend, Atrium's Motion to Dismiss will be moot. [DN 15]. As such, Sims' response in his Opposition to the Motion to Dismiss is of no consequence to his Motion to Amend. [DN 13].

2. Undue Delay

As further support for denial of the Motion for Leave to Amend, Atrium states that "Plaintiff makes no effort to show how the publicly available medical literature, as well as adverse event reporting, was not known to him at the time the original complaint was filed. This delay is undue and compels denial of Plaintiff's motion." [DN 18 at 5]. "Ordinarily, delay alone, does not justify denial of leave to amend." *Morse v. McWhorter*, 290 F.3d 795, 800 (6th Cir. 2002). However, "at some point 'delay will become undue, placing an unwarranted burden on the court, or will become prejudicial, placing an unfair burden on the opposing party." *TIG Ins. Co. v. Hospital Corp. of America*, 2014 WL 3118863, at *7 (W.D. Ky. July 7, 2014) (quoting *Morse*, 290 F.3d at 800 (6th Cir. 2002)) (internal quotations omitted). "Courts typically find undue delay in cases that are post judgment . . . and in cases where discovery has closed and dispositive motions deadlines have passed." *Id.* (quoting *Owners Insurance Co. v. Hutsell*, 2014 WL 2460132, at *3 (E.D. Tenn. June 2, 2014)). Here, Atrium failed to show that undue delay occurred. Sims' Motion for Leave to File First Amended Complaint was filed prior to discovery and was within the timeframe set by the Court's July 16, 2018 Order. [DN 15]. Further, in the Proposed First Amended Complaint, Sims does not assert any additional claims or rely on information that would

not otherwise have been available to Atrium. [DN 16-1]. As such, Atrium cannot articulate how delay would cause them any prejudice. Accordingly, the undue delay argument fails.

3. Futility of Amendment

Finally, as support for denial of the Motion for Leave to Amend, Atrium argues that the amendment of the counterclaim is futile. "A proposed amendment is futile if the amendment could not withstand a Rule 12(b)(6) motion to dismiss." *Rose v. Hartford Underwriters Ins. Co.*, 203 F.3d 417, 420 (6th Cir. 2000) (internal citations omitted). As such, Sims' proposed amended complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 554, 570 (2007)). Accordingly, the aforementioned standard of review is applicable to this challenge.

a. Count I – Negligence

In Sims' first count of his Proposed Amended Complaint, he alleges that Atrium was negligent. To plead a plausible negligence claim in Kentucky, a plaintiff must establish that: (1) Defendant owed a duty of care to Plaintiff; (2) Defendant breached its duty; and (3) the breach proximately caused Plaintiff's damages. *Mullins v. Commonwealth Life Ins. Co.*, 839 S.W.2d 245, 247 (Ky. 1992). Sims alleges that Atrium owed a duty to individuals, including to himself, to "exercise reasonable and ordinary care in the manufacture, design, packaging, labeling, instructions, warning, sale, marketing, and distribution of the ProLite mesh, and to train surgeons in how to properly implant the product in patients." [DN 16-1 at 11]. Sims claims that Atrium breached its duty "in the manufacture, design, packaging, labeling, warning, instructions, sale, marketing, distribution, and recruitment and training of physicians to implant the ProLite product." [DN 16-1 at 12]. Although Sims combines these claims into one category, the Court notes that

these are separate causes of action and addresses those for which evidence is offered. *See Mackay v. Ford Motor Co.*, 2016 WL 8243167, at *2 (E.D. Mich. Jan. 25, 2016) (recognizing separate causes of action for negligent design, negligent manufacture, and negligent failure to warn claims).

i. Negligent Design

According to Sims, Atrium negligently designed its ProLite surgical mesh and, because of the negligent design, he suffered extensive injuries and chronic pain. Sims alleges that Atrium owed a duty to individuals, including himself to exercise reasonably and ordinary care in the design of the ProLite mesh. [DN 16-1 at 11]. Further, Sim argues that Atrium breached its duty by failing to design the ProLite mesh so as to avoid an unreasonable risk of harm. Specifically, Sims claims Atrium was negligent in its design of the mesh because it produced the mesh with "hundreds of polypropylene loops . . . [which] increase[] the intensity and duration of the inflammatory response." According to the Amended Complaint, the use of such material "in turn increases mesh contracture, mesh migration, hernia recurrence, foreign body reaction, chronic severe pain, and more." [DN 16-1 at 13]. Sims alleges that Atrium was aware that the material used would cause adverse reactions and employed the design "in reckless disregard for the safety of patients, including Plaintiff." [DN 16-1 at 14]. Finally, Sims' alleges that the negligently designed product caused him damage and that Atrium knew that the product presented an unacceptable risk to consumers that would result in damage. [DN 16-1 at 15]. Despite Atrium's arguments to the contrary, viewing the amended complaint in the light most favorable to Sims, the Court finds that the allegations are sufficient to withstand a motion to dismiss. As such, Sims' motion to amend as to this claim is **GRANTED**.

ii. Negligent Manufacturing

Sims alleges that Atrium negligently manufactured its ProLite surgical mesh. With respect to this claim, the Court finds that Sims has not included any factual allegations as to how Atrium breached the duty of care as to manufacturing of ProLite surgical mesh or how the ProLite surgical mesh deviated from Atrium's intended design. See *Bosch v. Bayer Healthcare Pharmaceuticals, Inc.*, 13 F. Supp. 3d 730, 741–42 (W.D. Ky. Apr. 8, 2014) (dismissing negligent manufacture claim because plaintiffs failed to "allege how their specific [intrauterine contraceptive] devices were defective due to manufacturing" and otherwise failed to assert "any facts to support" their conclusory allegations); *see also Guidry v. Janssen Pharmaceuticals, Inc.*, 2016 WL 633673, at *4 (E.D. La. Feb. 17, 2016) (dismissing manufacturing defect claim where plaintiff failed to allege any facts as how the prescription she ingested deviated from the intended design). Consequently, Sims' motion to amend his negligent manufacture claim is **DENIED**.

iii. Negligent Failure to Warn

Sims alleges that Atrium negligently failed to warn patients, the public, and medical professionals about the gravity and severity of the risks associated with the use of its ProLite surgical mesh. Specifically, Sims claims that Atrium owed a duty to individuals, including himself, to exercise reasonable and ordinary care in the instructions and warnings of the ProLite mesh. Further, Sims alleges that Atrium's duty was breached by its willful failure to warn physicians of the potential risks [DN 16-1 at 12–15], and the negligent failure to test and study those associated risks. [DN 16-1 at 12, 14]. Finally, Sims' alleges that the product caused him damage—and that Atrium knew that the product presented an unacceptable risk to consumers that would result in damage. [DN 16-1 at 14–15]. The Court finds that the allegations in the amended complaint are sufficient to satisfy a motion to dismiss and Sims' motion to amend as to this claim is **GRANTED**.

b. Count II – Strict Products Liability

Sims asserts three strict liability claims—Atrium's surgical mesh was defective in design and manufacture and Atrium failed to warn of the risk of injury caused by the surgical mesh. Although Sims combines these claims into one category, the Court notes that these are separate causes of action in Kentucky. *See, e.g.*, *CertainTeed Corp. v. Dexter*, 330 S.W.3d 64, 79 (Ky. 2010).

Under Kentucky law, to plead a plausible strict products liability claim, a plaintiff must show: "(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." *Radcliff Homes, Inc. v. Jackson*, 766 S.W.2d 63, 68 (Ky. App. 1989) (internal quotations omitted). Further, a plaintiff must also "offer proof of an alternative, safer design that is practicable under the circumstances." *Bosch*, 13 F. Supp. 3d at 742 (citing *McCoy v. Gen. Motors Corp.*, 47 F. Supp. 2d 838, 840 (E.D. Ky. 1998)).

i. Design Defect

Atrium first argues that, because of comment k to section 402A of the Restatement (Second) of Torts, it is not subject to design defect liability, and thus the Court should deny Sims' motion to amend for this subsection of Count II. Kentucky follows the Restatement (Second) of Torts, including comment k to section 402A. *Prather v. Abbott Labs.*, 960 F. Supp. 2d 700, 706 (W.D. Ky. 2013) (citing *McMichael v. Am. Red Cross*, 532 S.W.2d 7, 9–11 (Ky. 1975)). Comment k "provides an exception to the general rule of strict liability for 'apparently useful and desirable product[s], attended with a known but apparently reasonable risk.'" *Id.* (quoting Restatement

(Second) of Torts § 402A cmt. k). Where comment k applies, a manufacturer's liability is limited to manufacturing defects and warning defects. *See House v. Bristol-Myers Squibb Co.*, 2017 WL 55876 (W.D. Ky. Jan. 4, 2017) (acknowledging the feasibility of a manufacturing defect strict products liability claim when applying comment k); *Prather*, 960 F. Supp. 2d at 706 (acknowledging the feasibility of a failure to warn strict products liability claim when applying comment k).

"In Kentucky, the scope of comment k is determined on a case-by-case basis." *Id.* at 707 (citing *Weiss v. Fujisawa Pharm. Co.*, 2006 WL 3533072, at *3 (E.D. Ky. Dec. 7, 2006). Because the analysis under comment k is highly fact dependent, *see Weiss*, 2006 WL 3533072, at *4, and the cases relied on by Atrium were addressing comment k in contexts different than on a motion to dismiss, the Court declines at this stage to dismiss Sims' strict liability design defect claim based on comment k. *House*, 2017 WL 55876, at *3.

Atrium also argues that Sims' strict liability defective design allegations are deficient. According to Atrium, Sims has not identified what aspect of the mesh's design was allegedly defective, instead simply "parrot[ing] the elements of a design-defect claim, utilizing buzz words and phrases such as 'in a defective and unreasonably dangerous condition,' 'unreasonably dangerous and more dangerous than an ordinary consumer would expect,' 'without substantial change in condition,' 'foreseeable risks exceeded the benefits associated,' [and] 'safer alternative designs' . . ." [DN 8 at 13]. Further, Atrium claims that Sims fails to allege how any defect in the mesh's design caused his injuries. Finally, Atrium argues that Sims "fails to allege what safer, alternative, and practicable designs existed." [DN 8 at 14].

The Court disagrees with Atrium's arguments. The allegations in the Amended Complaint state a plausible claim for relief for a strict liability design defect claim. Sims sufficiently alleges

that the mesh was defective because of "the use of non-medical grade polypropylene." [DN 16-1 at 16]. Sims alleges that such material "utilizes hundreds of polypropylene loops that increase surface area [of the mesh] and inflammation." [DN 16-1 at 16]. In so doing, Sims identifies the aspect of the mesh's design that is defective and how that alleged defect caused his injuries, satisfying the causal element of the claim. The Court agrees with Atrium that courts in Kentucky generally require a plaintiff to prove that a safer, feasible alternative design was available when it made the product. *Naiser v. Unilever U.S., Inc.*, 975 F. Supp. 2d 727, 745 (W.D. Ky. Sept. 30, 2013). However, "proof of an alternative design is not a requirement at this stage of the proceedings." *Id.* At 746. Instead, to satisfy a 12(b)(6) challenge, "a complaint must only 'contain either direct or inferential allegations respecting all the material elements to sustain a recovery under some viable legal theory.'" *Id.* (quoting *Glassner v. R.J. Reynolds Tobacco Co.*, 223 F.3d 343, 346 (6th Cir. 2000). In this case, the Court finds that Sims' Amended Complaint contains such allegations. Sims alleges that alternative designs for implantation and treatment of hernias and soft tissue repair exist. [DN 16-1 at 11]. Further, Sims alleges that the mesh was made from non-medical grade polypropylene. [DN 16-1 at 16]. The Court finds that from these allegations, it can be inferred that a safer, feasible alternative design exists—namely, a surgical mesh produced from material other than non-medical grade polypropylene. Thus, Sims' Motion to Amend as to his design defect strict products liability claim is **GRANTED**.

ii. Manufacturing Defect

Sims alleges that Atrium can be held liable for his injuries under a strict products liability manufacturing defect cause of action. Atrium argues that Sims' strict liability manufacturing defect claim as amended is insufficiently pleaded. Under Kentucky law, a plaintiff alleging a manufacturing defect must show that the product was "in a defective condition because it was not

manufactured or assembled in accordance with its specifications" and that the condition caused the alleged injuries. *See Greene v. B.F. Goodrich Avionics Sys., Inc.*, 409 F.3d 784, 788 (6th Cir. 2005) (applying Kentucky law); *Bosch v. Bayer Healthcare Pharm., Inc.*, 13 F. Supp. 3d 730, 743–44 (W.D. Ky. 2014). Kentucky has adopted the Restatement (Second) of Torts § 402A. *See Dealers Transport Co. v. Battery Distrib. Co.*, 402 S.W.2d 441, 446–47 (Ky. App. 1965). "Under § 402A, the defendant is held strictly liable if the plaintiff proves the product was 'in a defective condition unreasonably dangerous to the user or consumer.'" *Greene*, 409 F.3d at 788–89 *880 (quoting *Montgomery Elevator Co. v. McCullough by McCullough*, 676 S.W.2d 776, 780 (Ky. 1984)). "Unreasonably dangerous" means "a product that is 'dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics.'" *Greene*, 409 F.3d at 789 (quoting Restatement (Second) of Torts § 402A cmt. i). "Defective" means "that the product does not meet the reasonable expectations of the ordinary consumer as to its safety." *Greene*, 409 F.3d at 789 (quoting *Worldwide Equip., Inc. v. Mullins*, 11 S.W.3d 50, 55 (Ky. Ct. App. 1999)); *see also Waltenburg v. St. Jude Med., Inc.*, 33 F. Supp. 3d 818, 835 (W.D. Ky. 2014); *Bosch*, 13 F. Supp. 3d at 743–744.

In this case, Atrium avers that Sims failed to allege facts to support a manufacturing defect claim, instead offering "only a formulaic recitation of various elements of the claim, devoid of any factual enhancements." [DN 8 at 15]. Consequently, Atrium claims that allowing Sims to amend would be futile and thus the motion should be denied. Although Sims alleges that "the ProLite surgical mesh manufactured . . . by Atrium was defective in . . . formulation, because when the mesh left the hands of Atrium . . . it was unreasonably dangerous and more dangerous than an ordinary consumer would expect" [DN 16-1 at 15–16], Sims fails to allege specific facts to support

the manufacturing defect claim. He does not allege any specific manufacturing defect or failure that occurred with Atrium's product. He similarly does not allege how Atrium deviated from the product's specifications. Due to the lack of factual allegations, the Court holds that Sims failed to properly state a plausible manufacturing defect claim. Thus, Sims' Motion to Amend as to this claim is **DENIED**.

iii. Failure to Warn

To plead a failure to warn claim under Kentucky law, a plaintiff must allege facts for the Court to infer that (1) the manufacturer failed to provide his prescribing physician with adequate warnings about risks of which it knew or should have known and (2) the inadequate warnings proximately caused his injuries. *Prather v. Abbott Labs.*, 960 F. Supp. 2d 700, 708–09 (W.D. Ky. Apr. 2, 2013). Here, Sims adequately alleges how the warnings provided were defective and how they caused his injury. Specifically, in his Amended Complaint, Sims alleges that Atrium manufactured, marketed, distributed and/or supplied its ProLite surgical mesh without adequate warning to Sims' prescribing physician that the mesh could cause "adhesion formation, mesh contracture, hernia recurrence, chronic pain, bowel complications, seroma formation, fistula formation, hematoma formation, infection, erosion, and extrusion . . . ." [DN 16-1 at 17]. Additionally, Sims contends that Atrium's failure to adequately test and study the risks further rendered the warnings for the mesh inadequate. [DN 16-1 at 16]. Consequently, Sims suffered chronic pain both before and after his hernia repair surgeries to remove the defective mesh. Contrary to Atrium's argument, the statements in the amended complaint satisfy the pleading standard articulated in *Iqbal* and *Twombly*. As such, Sims' Motion to Amend regarding his failure to warn strict products liability claim is **GRANTED**.

c. Count III – Negligence Per Se

In Count III, Sims alleges that Atrium was negligent *per se* regarding the ProLite mesh. Specifically, Sims avers that Atrium's acts and omissions constitute a violation of both the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 331(a) and 333(a)(2) as well as the Kentucky Products Liability Act, K.R.S. § 411.300. [DN 16-1 at 18]. Negligence *per se* "is merely a negligence claim with a statutory standard of care substituted for the common law standard of care." *Real Estate Mktg., Inc. v. Franz*, 885 S.W. 2d 921, 926–27 (Ky. 1994) (citation omitted), *overruled on other grounds by Giddings & Lewis, Inc. v. Indus. Risk Insurers*, 348 S.W.3d 729, 741 (Ky. 2011). "[It] provides an avenue by which a damaged party may sue for a violation of a statutory standard of care if the statute in question provides no inclusive civil remedy and if the party is within the class of persons the statute is intended to protect." *Young v. Carran*, 289 S.W.3d 586, 589 (Ky. Ct. App. 2008) (citing *Hargis v. Baize*, 168 S.W.3d 36, 40 (Ky. 2005)). Kentucky codified the common-law doctrine of negligence *per se* in K.R.S. § 446.070, which states 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." Under Kentucky law, to state a plausible negligence *per se* claim, a plaintiff must show that: (1) he falls within the class of persons a statute was intended to protect; and (2) the statute is penal in nature and provides no civil remedy. *See Dukes v. Mid-Eastern Athletic Conference*, 213 F. Supp. 3d 878, 885 (W.D. Ky. Sept. 30, 2016).

Atrium responds that Sims' allegation fails for two reasons. "*First*, Kentucky law does not recognize negligence *per se* claims based upon alleged violations of federal law. *Second*, Plaintiff has failed to satisfy the pleading standards articulated in *Twombly* and *Iqbal* as to the state law portion of the claim." [DN 8 at 18]. Atrium correctly states Kentucky's treatment of negligence *per se* claims premised upon violations of federal law. Kentucky courts limit the common-law

claim of negligence *per se* and decline to extend it to federal statutes and regulations. *See Waltenburg v. St. Jude Med., Inc.*, 33 F. Supp. 3d 818, 837 (W.D. Ky. 2014) ("[A] negligence *per se* claim premised on violations of federal law is not cognizable under Kentucky law."); *Kemp v. Medtronic, Inc.*, 2001 WL 91119, at *1 (6th Cir. Jan. 26, 2001) (per curiam) (rejecting a claim for negligence *per se* because, "[t]here does not exist a *federal* private right of action for violation of the Federal Food, Drug, and Cosmetics Act"). As such, Sims' negligence *per se* claim reliant upon alleged violations of the FDCA §§ 331(a) and 333(a)(2) is not a legally cognizable claim and could not survive a motion to dismiss. To grant Sims the opportunity to amend this claim would be futile.

Regarding Sims' state law-based negligence *per se* claim, Sims states that he is within the class of persons the statute was designed to protect and that his injuries are the type of harm the statute was designed to prevent. [DN 16-1]. However, Sims fails to make any statement regarding whether the cited statute is penal in nature or whether the statute provides for a civil remedy. By failing to provide any factual content on those elements, Sims cannot satisfy the pleading requirement of *Twombly* and *Iqbal*. Further, Sims relies on a statute that is definitional. *See* K.R.S. § 411.300 (defining "product liability action" and "plaintiff"). "Statutory definitions . . . are not penal statutes." *K.F. v. Jefferson Cty. Sch. Dist.*, 2007 WL 1231562, at *5 (W.D. Ky. April 25, 2007). Consequently, the amended claim cannot survive a motion to dismiss and, as such, granting Sims' motion would be futile. Sims' Motion to Amend as to his negligence *per se* claim is **DENIED**.

d. Count IV – Breach of Implied Warranty

In Count IV, Sims alleges that Atrium breached an implied warranty. To plead a plausible breach of implied warranty claim in Kentucky, a plaintiff must provide evidence that the seller is

a merchant with respect to the goods involved in the sale. K.R.S. § 355.2-314. Specifically, Kentucky law makes clear that a plaintiff asserting "a claim based upon an implied warranty must establish that it enjoyed privity of contract with the defendant-seller against whom the implied warranty claim is asserted." *Brown Sprinkler Corp. v. Plumbers Supply Co.*, 265 S.W.3d 237, 240 (Ky. App. 2007) (citing *Compex Int'l Co., Ltd. v. Taylor*, 209 S.W.3d 462 (Ky. 2006)). Atrium correctly states that, "[t]o establish the requisite privity relationship, Plaintiff must plead that he purchased ProLite Mesh directly from Atrium." [DN 8 at 20]. As a rule under Kentucky law, "privity of contract does not extend beyond the buyer-seller setting." *Bosch v. Bayer Healthcare Pharmaceuticals, Inc.*, 13 F. Supp. 3d 730, 747 (W.D. Ky. April 8, 2014). In neither Sims' original Complaint nor his Amended Complaint does Sims allege that he purchased the ProLite Mesh from Atrium. Because Sims is unable to establish the privity of contract element necessary to establish a claim for breach of implied warranty, allowing Sims to amend this claim would be futile. As such, Sims' Motion to Amend as to his breach of implied warranty claim is **DENIED**.

e. Count V – Breach of Express Warranty

Sims next claims that Atrium expressly warranted that the ProLite surgical mesh was safe, effective, and fit and proper for its intended use. To plead a plausible claim for breach of express warranty, the plaintiff must prove more than there was simply a warranty. The plaintiff 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. K.R.S. § 355.2-313(1)(a). A warranty is the basis of the bargain if it has been relied upon as one of the inducements for purchasing the product. *Overstreet v. Norden Labs., Inc.*, 669 F.2d 1286, 1290 (6th Cir. 1982). Under Kentucky law, "[i]t is not necessary to the creation of an express warranty that the seller use formal words such as 'warrant' or 'guarantee' or that he have a specific intention to make a warranty."

K.R.S. § 355.2-313(2). However, "[e]very statement made by a seller . . . does not create an express warranty." *Overstreet*, 669 F.2d at 1290.

Sims asserts that Atrium "expressly warranted" that the ProLite surgical mesh was "safe, effective, fit and proper for its intended use." [DN 16-1 at 19]. Sims further alleges that he and his physician relied on Atrium's representations in allowing the implantation of the mesh, including those representations made in its labeling and Instructions for Use. According to Sims, Atrium breached these express warranties because the mesh was not safe and was unfit for the uses for which it was intended. Specifically, Sims states that Atrium breached its warranty by "continuing sales and marketing campaigns highlighting the safety and efficacy of their product, while they knew or should have known of the defects and risk of product failure and resulting patient injuries" as well as by "not disclosing that [the mesh] was made of dangerous non-medical grade polypropylene that is toxic to the human body." [DN 16-1 at 19–20].

The Court concludes these allegations are insufficient to withstand a motion to dismiss because they offer nothing more than "a formulaic recitation" of the elements of a claim for breach of express warranty. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Despite Sims referring to an "express warranty," he has not identified any specific affirmation or promise that formed part of the basis of the bargain with Atrium. *See House v. Bristol-Myers Squibb Company*, 2017 WL 55876, at *6 (W.D. Ky. Jan. 4, 2017) (citing *Corwin v. Conn. Valley Arms, Inc.*, 74 F. Supp. 3d 883, 892 (N.D. Ill. 2014) (allegations that bullets "were reasonably fit for their intended uses without endangering human safety . . . are insufficient because they offer nothing more than 'a formulaic recitation' of the elements" of an express warranty claim); *cf. Naiser v. Unilever U.S., Inc.*, 975 F. Supp. 2d 727, 733–36, 741 (W.D. Ky. 2013) (finding complaint alleged express warranty where it identified specific factual misrepresentations, such as representations that "the

product's effects would last no longer than 30 days," when it "could be expected to last for months," and that "the product contained no formaldehyde," when it actually "contained a chemical known to release formaldehyde upon its use")).

Additionally, Sims cannot base his express warranty claim on allegations that Atrium failed to disclose and fraudulently concealed that the surgical mesh was "made of dangerous non-medical grade polypropylene that is toxic to the human body." [DN 16-1 at 20]. "An express warranty is created by an 'affirmation of fact or promise,' not an omission." *House*, 2017 WL 55876, at 6 (citing K.R.S. § 355.2-313). Because Sims's Amended Complaint does not plead sufficient facts to survive a motion to dismiss, his Motion to Amend regarding the express warranty claim is **DENIED**.

f. Count VI – Negligent Misrepresentation

Finally, Sims alleges that Atrium negligently misrepresented the risks associated with its ProLite mesh. Under Kentucky law, to assert a negligent misrepresentation claim a plaintiff must identify the false or misleading information provided by the specific defendant. *See Gaunce v. CL Med. Inc.*, 2015 WL 893569, at *2–3 (E.D. Ky. Mar. 2, 2015); *Giddings & Lewis, Inc. v. Indus. Risk Insurers*, 348 S.W.3d 729, 746 (Ky. 2011). "Additionally, a plaintiff must demonstrate: (1) the subject plaintiff was a reasonably foreseeable recipient of the information; (2) he justifiably relied on the information; (3) he exercised reasonable care in relying on the information; and (4) the false statements allegedly made by the defendant were a proximate cause of the plaintiff's damage." *Estate of DeMoss v. Eli Lilly and Co.*, 234 F. Supp. 3d 873, 880 (W.D. Ky. 2017) (citing *Presnell Constr. Managers, Inc. v. EH Constr.*, LLC, 134 S.W.3d 575, 580 (Ky. 2004)).

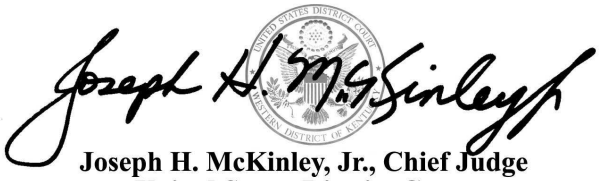
A plaintiff alleging a negligent misrepresentation claim under Kentucky law must meet the heightened pleading requirements of Rule 9(b). *Republic Bank & Trust Co. v. Bear Stearns &*

Co., Inc., 683 F.3d 239, 247–48 (6th Cir. 2012). Sims' allegations fail to state a claim for negligent misrepresentation under Rule 9(b). The Amended Complaint does not specifically identify the statements at issue or allege, beyond highly generalized allegations, when or where the alleged statements were made. As such, Sims' Amended Complaint fails to meet Rule 9(b)'s particularity requirements. *See, e.g.*, *Gaunce*, 2015 WL 893569, at *2–3 (dismissing plaintiff's negligent misrepresentation claim where they failed to "specify the time, nature, and place of the communications or omission" and thus were insufficient to sustain the claim under Rule 9(b)'s heightened pleading standard). Consequently, Sims' Motion to Amend regarding his negligent misrepresentation claim would be futile and is **DENIED**.

IV. CONCLUSION

As per the Court's July 16, 2018 order, for those claims which the Court has granted Sims' Motion for Leave to Amend, Atriums' Motion to Dismiss is moot. Concerning the claims which the Court has denied Sims' Motion for Leave to Amend, it is necessary to address Atrium's Motion to Dismiss. As previously stated, the futility standard for considering a motion to amend is the same standard used to assess a motion to dismiss. *Rose v. Hartford Underwriters Ins. Co.*, 203 F.3d 417, 420 (6th Cir. 2000). Because the proposed Amended Complaint [DN 16-1] includes the same allegations as those included in the original Complaint [DN 1], the above analysis applies to the original claims. For the same reasons articulated above, Sims' Negligent Manufacture, Strict Products Liability Manufacturing Defect, Negligence Per Se, Breach of Implied Warranty, Breach of Express Warranty, and Negligent Misrepresentation claims as articulated in his original Complaint fail to "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 554, 570 (2007)). As such, these claims are dismissed.

For the reasons set forth above, **IT IS HEREBY ORDERED** that Defendant's Motion to Dismiss [DN 8] is **GRANTED** as to Plaintiff's Negligent Manufacture, Strict Products Liability Manufacturing Defect, Negligence Per Se, Breach of Implied Warranty, Breach of Express Warranty, and Negligent Misrepresentation claims and is moot as to Plaintiff's Negligent Design, Negligent Failure to Warn, Strict Products Liability Design Defect, and Strict Products Liability Failure to Warn claims. Plaintiff's Motion for Leave to File First Amended Complaint [DN 16] is **GRANTED** as to his Negligent Design, Negligent Failure to Warn, Strict Products Liability Design Defect, and Strict Products Liability Failure to Warn claims and **DENIED** as to his Negligent Manufacture, Strict Products Liability Manufacturing Defect, Negligence Per Se, Breach of Implied Warranty, Breach of Express Warranty, and Negligent Misrepresentation claims.



Joseph H. McKinley, Jr., Chief Judge
United States District Court

October 15, 2018

cc: counsel of record