UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

JESSICA L. TEAL,

Plaintiff,

v.

ARGON MEDICAL DEVICES, INC., ET AL.,

Defendants.

_____/

Case No. 20-cv-11018

UNITED STATES DISTRICT COURT JUDGE GERSHWIN A. DRAIN

OPINION AND ORDER DENYING WITHOUT PREJUDICE DEFENDANT ARGON'S AND DEFENDANT REX'S MOTIONS TO DISMISS [#18, 22]

I. INTRODUCTION

On April 24, 2020, Plaintiff Jessica Teal ("Plaintiff") filed the instant products liability lawsuit against Defendants Aron Medical Devices, Inc., Rex Medical, Inc., d/b/a Rex Medical, L.P., and Rex Medical, L.P (together, "Defendants"). *See* ECF No. 1. Plaintiff seeks to recover damages for injuries she allegedly sustained following the surgical implantation for the Option Filter System medical device in February 2014. On July 10, 2020, Plaintiff filed her First Amended Complaint. *See* ECF No. 16.

Presently before the Court is Defendant Argon Medical Devices, Inc.'s (hereinafter referred to as "Argon") Motion to Dismiss, filed on July 22, 2020. ECF

No. 18. Defendants Rex Medical, Inc. d/b/a Rex Medical, L.P. and Rex Medical, L.P.'s (hereinafter collectively referred to as "Rex") Motion to Dismiss, filed on July 24, 2020, is also before the Court. Defendants' separate motions are fully briefed. Upon review of the parties' submissions, the Court concludes that oral argument will not aid in the disposition of this matter. Accordingly, the Court will resolve Defendants' Motion on the briefs. *See* E.D. Mich. L.R. 7.1(f)(2). For the reasons that follow, the Court will **DENY WITHOUT PREJUDICE** Argon's Motion to Dismiss [#18] and Rex's Motion to Dismiss [#22] and require Plaintiff to file a Second Amended Complaint.

II. BACKGROUND

Plaintiff brings this diversity action against Defendants after a surgically implanted medical device, the Option Filter System (hereinafter, "Option Filter") failed and allegedly caused multiple struts to perforate her vena cava. ECF No. 16, PageID.191. Plaintiff claims that she suffered "serious, life threatening injuries" as a result of the Option Filter. *Id.* at PageID.189.

On or about February 7, 2014, Plaintiff underwent surgery for the implantation of the Option Filer at St. Joseph Mercy in Ypsilanti, Michigan. *Id.* at PageID.191. Plaintiff later underwent an inferior vena cava ("IVC") filter retrieval attempt at Michigan Medicine University of Michigan Hospital on or about August 23, 2017, where the surgeon was able to retrieve the Option Filter and all but one

fractured strut. *Id.* The remaining strut was determined to be outside of Plaintiff's IVC. *Id.* According to Plaintiff, she has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, disability, and other losses as a result of Defendants' medical device. ECF No. 24, PageID.352.

Defendants obtained the Food and Drug Administration's ("FDA") clearance to market the Option Filter and its components in June 2009 through the 510(k) process of the Federal Food, Drug and Cosmetic Act. ECF No. 16, PageID.190; ECF No. 18, PageID.222–23. Plaintiff avers that the Option Filter was "designed, manufactured, distributed, sold, and/or supplied by Argon and the Rex Defendants, and was marketed while defective due to the inadequate warnings, instructions, labeling, and/or inadequate testing in light of Argon's and the Rex Defendants' knowledge of the product's failure and serious adverse [effects]." ECF No. 16, PageID.193. Specifically, Plaintiff alleges that Defendants represented that the Option Filter was equivalent to several other vena cava filters. ECF No. 24, PageID.352. The Option Filter which Plaintiff received, however, was purportedly "unable to withstand normal anatomical and physiological loading cycles exerted *in vivo*, and subject to an inappropriate degree of risk of tilting, embedment, breakage, migration, perforation, and fracture." *Id.* at PageID.352–53.

In its Motion, Argon asserts that its only involvement with the Option Filter at issue in the present matter is as a distributor after 2011. ECF No. 18, PageID.223. Argon argues that it lacks involvement with the design, the process of obtaining the 510(k) clearance, and the manufacture of the Option Filter. *Id.* at PageID.224. In its separate Motion, Rex asserts that it designed the Option Filter and obtained the FDA clearance, including its labeling and warnings, in 2009. ECF No. 22, PageID.295.

On July 10, 2020, Plaintiff filed her First Amended Complaint in this Court, alleging the following claims against Defendants: (1) negligence (Count I); (2) breach of implied warranty of merchantability and fitness for a particular purpose (Count II); (3) negligent misrepresentation (Count III); (4) breach of express warranty (Count IV); (5) a non-numbered count entitled "MCLA § 600.2949(a) Knowledge of Defective Product"; and (6) a demand for exemplary damages. *See generally* ECF No. 16. Defendants Argon and Rex now separately move to dismiss Plaintiff's First Amended Complaint through their respective motions. ECF Nos. 18, 22.

III. LAW & ANALYSIS

A. Legal Standard

Federal Rule of Civil Procedure 12(b)(6) allows the court to make an assessment as to whether the plaintiff has stated a claim upon which relief may be

granted. *See* Fed. R. Civ. P. 12(b)(6). To withstand a motion to dismiss pursuant to Rule 12(b)(6), a complaint must comply with the pleading requirements of Federal Rule of Civil Procedure 8(a)(2). *See Ashcroft v. Iqbal*, 556 U.S. 662, 677–78 (2009). Rule 8(a)(2) requires "a short and plain statement of the claim showing that the pleader is entitled to relief, in order to give the defendant 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) (quotation marks omitted) (quoting Fed. R. Civ. P. 8(a)(2); *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). To meet this standard, a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570; *see also Iqbal*, 556 U.S. at 678–80 (applying the plausibility standard articulated in *Twombly*).

When considering a Rule 12(b)(6) motion to dismiss, the Court must construe the complaint in a light most favorable to the plaintiff and accept all of his factual allegations as true. *Lambert v. Hartman*, 517 F.3d 433, 439 (6th Cir. 2008). While courts are required to accept the factual allegations in a complaint as true, *Twombly,* 550 U.S. at 556, the presumption of truth does not apply to a claimant's legal conclusions. *See Iqbal,* 556 U.S. at 678. Therefore, to survive a motion to dismiss, the plaintiff's pleading for relief must provide "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Ass'n of*

Cleveland Fire Fighters v. City of Cleveland, 502 F.3d 545, 548 (6th Cir. 2007) (quoting *Twombly,* 550 U.S. at 555) (internal citations and quotations omitted).

The district court generally reviews only the allegations set forth in the complaint in determining whether to grant a Rule 12(b)(6) motion to dismiss, however "matters of public record, orders, items appearing in the record of the case, and exhibits attached to the complaint, also may be taken into account. *Amini v. Oberlin College*, 259 F. 3d 493, 502 (6th Cir. 2001). Documents attached to a defendant's "motion to dismiss are considered part of the pleadings if they are referred to in the plaintiff's complaint and are central to her claim." *Id.*

B. Defendants' Arguments

1. Argon's Motion to Dismiss (ECF No. 18)

Argon presents several reasons for the Court to dismiss Plaintiff's First Amended Complaint. Argon first argues that the First Amended Complaint improperly makes "indeterminate assertions" against all Defendants, collectively, without explaining which Defendant, Argon or Rex, had or breached a given duty.[1] ECF No. 18, PageID.227–28. For example, the design and manufacturing defect allegations set forth in Count I, Plaintiff's negligence claim, are presented as to

[1] Argon presents several other arguments in support of its Motion as to each count in Plaintiff's First Amended Complaint. ECF No. 18, PageID.225–26. As explained in more detail in this section, the Court will focus on Argon's first argument, as this argument encompasses the First Amended Complaint's deficiencies as to all of Plaintiff's present claims.

"Argon and the Rex Defendants" collectively. ECF No. 16, PageID.195–96. Argon emphasizes in its Motion, however, that it had no role in the design or manufacturing of the Option Filter. *Id.* at PageID.229. Indeed, Plaintiff clarifies in her Response that while Rex "designed and manufactured the Option Filter," Argon "entered into an exclusive license and distribution agreement …to market and distribute the Option Filter." ECF No. 24, PageID.354, 355, 358. Nevertheless, Plaintiff contends that it is not a "naked conspiracy" to allege that the Option Filer was "designed, manufactured, marketed, inspected, labeled, promoted, distrusted and sold" by both Argon and Rex. *Id.* at 354–55 (quoting Am. Compl. ¶ 48).

Argon cites to the Sixth Circuit's decision in *Tam Travel, Inc. v. Delta Airlines, Inc.*, 583 F.3d 896 (6th Cir. 2009) for the proposition Plaintiff improperly relies on "indeterminate assertions" against the Defendants collectively throughout her First Amended Complaint. In *Tam Travel*, the court upheld the district court's finding that the plaintiffs' amended complaint was deficient, in part, because plaintiffs attempted to implicate multiple defendants in a purported conspiracy by relying on several vague allegations. *Id.* at 905. The court explained that the plaintiffs' reliance on "indeterminate assertions," which included allegations referring to "defendants" or "defendants' executives," represented "precisely the type of naked conspiratorial allegations rejected by the Supreme Court in *Twombly*." *Id.* (citation omitted). The court emphasized the Supreme Court's reasoning in

Twombly, stating that where a plaintiff's complaint "furnishes no clue as to which defendants supposedly agreed or when and where the illicit agreement took place, the complaint fails to give adequate notice as required by Fed. R. Civ. P. 8." *Id.* (internal quotation marks omitted).

Here, Plaintiff's First Amended Complaint similarly groups multiple defendants together. The Court agrees with Argon that Plaintiff must put forth factual allegations of Argon's purported involvement, rather than grouping Argon's alleged actions together with Rex's alleged actions. *See Kerrigan v. ViSalus, Inc.*, 112 F. Supp. 3d 580, 601 (E.D. Mich. 2015) (finding that allegations of general misconduct by a group of different defendants was not sufficient to state RICO claims against each of them). For example, Plaintiff presently alleges that "Argon and the Rex Defendants breached their duty of reasonable care and were negligent in":

a. Unreasonably and carelessly failing to properly warn of the dangers and risks of harm associated with the Option Filter, specifically its incidents of tilt, embedment, fracture, migration, perforation, recurrent thrombosis and other failures;

b. Unreasonably and carelessly designed, manufactured, marketed and sold a product that was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body;

c. Unreasonably and carelessly designed, manufactured, marketed and sold a product that presented a risk of harm to Plaintiff and others similarly situated in that it was prone to fail.

d. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking safety measures to reduce or avoid harm;

e. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other device available for the same purpose;

f. Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications or from other typical units from the same production line;

g. Failing to use reasonable care to warn or instruct, including pre and post sale, Plaintiff, Plaintiff's physicians, or the general health care community about the Option Filter's substantially dangerous condition or about facts making the product likely to be dangerous;

h. Failing to perform reasonable pre and post-market testing of the Option Filter to determine whether or not the product was safe for its intended use;

i. Failing to provide adequate instructions, guidelines, and safety precautions, including pre and post sale, to those persons to whom it was reasonably foreseeable would prescribe, use, and implant the Option Filter;

j. Advertising, marketing and recommending the use of the Option Filter, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with and inherent in the use of the Option Filter;

k. Representing that the Option Filter was safe for its intended use when in fact, Defendants knew and should have known the product was not

safe for its intended purpose;

l. Continuing manufacture and sale of the Option Filter with the knowledge that said product was dangerous and not reasonably safe and failing to comply with the F.D.A. good manufacturing regulations;

m. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the Option Filter so as to avoid the risk of serious harm associated with the use of the Option Filter;

n. Advertising, marketing, promoting and selling Option Filter for uses other than as approved and indicated in the product's label;

o. Failing to establish an adequate quality assurance program used in the manufacturing of the Option Filter;

p. Failing to establish and maintain an adequate post-market surveillance program, including, but not limited to, employing unqualified, inadequately trained, and inadequately supervised individuals to review, adjudicate, and report safety complaints concerning the Option filter to the FDA.

ECF No. 16, PageID.196–97. These allegations include design and manufacture theories against all Defendants, even though Plaintiff acknowledges in her Response briefs that Argon was the sole and exclusive marketer and distributor—not the manufacturer—of the Option Filter.

The Court finds that these allegations, as they are currently written, are inadequate under Supreme Court and this Circuit's precedent. Indeed, the law requires that Argon be given adequate notice of Plaintiff's claims, which occurs when the complaint "contain[s] sufficient factual matter, accepted as true, to state a

claim to relief that is plausible on its face." *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Plaintiff's First Amended Complaint "tenders naked assertion[s] devoid of further factual enhancement." *Id.* As explained above, Plaintiff's First Amended Complaint includes collective allegations as to all of the Defendants, without providing the requisite specificity for the present matter to proceed. "[A] district court must retain the power to insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558 (2007) (citation omitted). In order for Plaintiff to give Argon "fair notice" of what the claims are and the grounds upon which they rest, *Twombly*, 550 U.S. at 555, Plaintiff's complaint must "contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Iqbal*, 556 U.S. at 678.

In her Response, Plaintiff argues that for each count, the conduct at issue involved "*both* Argon and Rex." ECF No. 24, PageID.355 (emphasis in original). She explains, "Plaintiff's negligence cause of action relates to the conduct of Rex in designing, researching, manufacturing, inspecting, and testing the Option Filter, as well as the conduct of Argon in marketing, advertising, promoting, and selling the Option Filter." *Id.* The Court finds that Plaintiff's attempt to distinguish between Argon's and Rex's role in the alleged conduct is insufficient to cure the remaining deficiencies. Moreover, the Court agrees with Argon that, without more, Plaintiff's

claims, as they are currently alleged collectively against all Defendants, are too vague and indeterminate. ECF No. 28, PageID.391.

Even though Plaintiff's First Amended Complaint should have included factual detail as to each Defendant's purported conduct for the asserted counts, the Court will permit Plaintiff an opportunity to amend the complaint to rectify the problems discussed herein. *See United States Ex rel. Bledsoe v. Cmty. Health Sys.*, 342 F.3d 634, 644 (6th Cir. 2003) ("[W]here a more carefully drafted complaint might state a claim, a plaintiff must be given at least one chance to amend the complaint before the district court dismisses the action with prejudice."). While the Court denotes that Plaintiff has already amended her complaint in this matter, the Court finds that an additional opportunity to amend can serve the interests of judicial economy and can provide Argon "fair notice" of the grounds upon which Plaintiff's negligence, breach of implied warranty of merchantability and fitness for a particular purpose, negligent misrepresentation, breach of express warranty, and MCLA § 600.2949(a) claims rest.[2]

2. Rex's Motion to Dismiss (ECF No. 22)

In its separate Motion, Rex also moves for dismissal of all counts. ECF No. 22. Rex presents several arguments for the Court to grant its Motion, including that

[2] The Court takes notice of Plaintiff's concession in her Response briefs that her demand for exemplary damages should be dismissed. ECF No. 24, PageID.364; ECF No. 27, PageID.384.

(1) Plaintiff's claims for negligent design defect, negligent failure to warn, and implied warrant claims are preempted; (2) Plaintiff's claims for negligent manufacturing defect, negligent design defect, and breach of implied warranty are insufficiently pled; (3) Plaintiff's claim for breach of express warranty, in addition to be insufficiently pled, fails due to lack of contractual privity; (4) Plaintiff's negligent failure to warn claims fail as a matter of law and is insufficiently pled; (5) Plaintiff's negligent misrepresentation claim collapses into her legally insufficient failure to warn claim and is improperly pled; and (6) Plaintiff has failed to plead a plausible request for exemplary damages, and that such damages must therefore be stricken and dismissed.

Several of these arguments relate to the disputed sufficiency of Plaintiff's claims as they are currently pled in her First Amended Complaint. As explained above, the Court finds that an additional opportunity to amend can serve the interests of judicial economy and can provide Defendants Argon and Rex "fair notice" of the grounds upon which Plaintiff's negligence, breach of implied warranty of merchantability and fitness for a particular purpose, negligent misrepresentation, breach of express warranty, and MCLA § 600.2949(a) claims rest. The Court recognizes that some of Rex's arguments, including those concerning preemption and contractual privity, ECF No. 22, PageID.301–02, may remain unresolved after Plaintiff's amendment. Should Rex and/or Argon file a renewed motion to dismiss

in accordance with the filing deadlines listed below, the Court will revisit and analyze such arguments on the merits. The Court declines to address such arguments at this juncture knowing that Plaintiff will amend her complaint to cure the aforementioned "indeterminate assertions" against Defendants Argon and Rex collectively.

In sum, the Court will deny Defendants' separate Motions to Dismiss (ECF Nos. 18, 22) without prejudice and will require Plaintiff to amend her complaint.

IV. CONCLUSION

For the reasons articulated above, **IT IS HEREBY ORDERED** that Defendant Argon Medical Devices, Inc.'s Motion to Dismiss [#18] and Defendant Rex Medical Inc.'s Motion to Dismiss [#22] are **DENIED WITHOUT PREJUDICE**.

IT IS FURTHER ORDERED that Plaintiff shall file an Amended Complaint no later than December 11, 2020.

IT IS FURTHER ORDERED that Defendants shall file an Answer or Responsive Pleading no later than December 23, 2020.

IT IS FURTHER ORDERED that the parties appear for a Status Conference via videoconference on January 6, 2021 at 10:00 a.m.

IT IS SO ORDERED.

Dated: December 3, 2020

/s/Gershwin A. Drain
GERSHWIN A. DRAIN
United States District Judge

CERTIFICATE OF SERVICE

Copies of this Order were served upon attorneys of record on December 3, 2020, by electronic and/or ordinary mail.
/s/ Teresa McGovern
Case Manager