UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAKE CHARLES DIVISION

MEAGAN S. LIRETTE & WAYNE P. LIRETTE, JR.,	*	**CIVIL ACTION NO. 2:13-cv-2892**
Plaintiffs,	*	
v.	*	**JUDGE PATRICIA MINALDI**
DEPUY MITEK, L.L.C., ET AL.,	*	
Defendants.	*	**MAGISTRATE JUDGE KAY**

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MEMORANDUM RULING

Before the court is a Motion to Dismiss [Doc. 28] pursuant to Federal Rule of Civil Procedure 12(b)(6), filed by the defendants, DePuy Mitek, L.L.C., and DePuy Orthopedics, Inc. ("defendants"), to which the plaintiffs have filed an Opposition [Doc. 31], and the defendants have filed a Reply [Doc. 32]. For the following reasons, the defendants' Motion [Doc. 28] is **GRANTED.**

FACTS & PROCEDURAL HISTORY

Meagan Lirette underwent anterior cruciate ligament ("ACL") surgery on May 18, 2012, to alleviate pain from a knee injury caused by an incident while she was jumping rope.[1] Specifically, the plaintiff "underwent a left knee anthroscopically assisted anterior cruciate ligament reconstruction with tibialis graft, 15 mm endo button loop and a 42 x 4.5 mm washer."[2]

The initial surgery was performed by Dr. Brett Cascio ("Dr. Cascio").[3] During the surgery, Dr. Cascio stated that he was not satisfied with the graft structure once it was placed

[1] Pet. [Doc. 1-2] ¶ 7, 9.
[2] *Id.* ¶ 9.
[3] *Id.*

inside the knee.[4] According to the plaintiffs' complaint, the Bio-Intrafix sheath and screw, which is manufactured and distributed by the defendants and was used to secure the graft structure, had "split open" in Mrs. Lirette's knee.[5] Dr. Cascio removed the device and placed a new graft into the knee.[6] Dr. Cascio then "fixed the tibial side with another Bio-Intrafix sheath and screw."[7] However, the screw was prominent inside the joint; in response, Dr. Cascio removed the screw, and then fixed the tibial side of the graft with a metal screw and washer construction.[8] The plaintiffs allege that, in fixing the tibial side of the graft using the aforementioned metal screw and washer construction, Dr. Cascio screwed the graft in too tightly.[9]

Mrs. Lirette continued to suffer pain following the surgery and was advised by Dr. Cascio to have a second operation.[10] On November 12, 2012, Mrs. Lirette underwent a second surgery, as advised.[11] During the operation, Dr. Cascio removed "loose bodies"—pieces of loose matter that were discovered floating inside the knee that are known to cause discomfort—some of which he stated appeared to be pieces of the tibial Bio-Intrafix sheath that had been used to repair the tibial side of the graft during the initial operation on May 18, 2012.[12]

Despite the two surgeries, Mrs. Lirette's pain continued and she eventually sought a second opinion.[13] Mrs. Lirette underwent a third procedure on her left knee on May 10, 2013,

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[4] Am. Compl. [Doc. 18] ¶ 10.
[5] *Id.*
[6] *Id.*
[7] *Id.*
[8] *Id.*
[9] Am. Compl. [Doc. 18] ¶ 10.
[10] *Id.* ¶ 12.
[11] *Id.*
[12] *Id.*
[13] Pet. [Doc. 1-2] ¶ 13.

wherein Dr. Barry Henry removed fragments and debris from the previous surgeries and reconstructed the previous graft.[14]

Wayne and Meagan Lirette, husband and wife, the plaintiffs herein, thereafter filed suit against DePuy Mitek, L.L.C. and DePuy Orthopedics, Inc., the defendants, in the Fourteenth Judicial District Court for the Parish of Calcasieu, on August 27, 2013.[15] The defendants removed the case to federal court on October 18th, 2013, pursuant to 28 U.S.C. § 1332, on the basis of diversity of citizenship subject matter jurisdiction.[16]

The plaintiffs allege that the defendants are the manufacturers, designers, marketers, and distributors of the Bio-Intrafix tibial sheath.[17] They also allege that the defendants are liable under the Louisiana Products Liability Act ("LPLA") due to Mrs. Lirette's injury resulting from the product's unreasonably dangerous condition.[18]

Additionally, the plaintiffs have brought suit against the operating physician, Dr. Cascio, and Southwest Louisiana Healthcare Systems, Inc., alleging that Dr. Cascio, among other things, negligently performed the surgery while using the defendants' product, and that Dr. Cascio failed to remove all loose bodies during the second surgery.[19] The action against Dr. Cascio and Southwest Louisiana Healthcare Systems is presently before a Medical Review Panel.[20]

Mrs. Lirette seeks monetary damages under theories of products liability, and Mr. Lirette seeks monetary damages for the value of special services while functioning as a nurse and attendant for Mrs. Lirette since the time of her injury, and in the future, as well for loss of

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[14] *Id.*
[15] Not. of Removal [Doc. 1] ¶ 1.
[16] *Id.* ¶ 3.
[17] Pet. [Doc. 1-2], at ¶ 20, 23.
[18] *Id.* ¶ 22. It appears that the plaintiffs have dropped all claims under the LPLA except for the claim that the product was unreasonably dangerous in construction or composition. *See* Second Am. Pet. [Doc. 26]; and Opp'n to Defs.' Rule 12(b)(6) Mot. to Dismiss with Prejudice for Failure to State a Claim [Doc. 31].
[19] *Id.* ¶ 17.
[20] Pet. [Doc. 1-2], at 3.

consortium.[21] The defendants filed an earlier Motion to Dismiss [Doc. 13] seeking the dismissal of the plaintiffs' claims for damages under the Louisiana Products Liability Act.[22] This court found that the plaintiffs had failed to state a claim under the LPLA upon which relief could be granted; however, the plaintiffs were granted leave to amend their petition.[23] The plaintiffs amended their petition,[24] and the defendants again filed a Motion to Dismiss [Doc. 28].[25]

LAW & ANALYSIS

A. Motion to Dismiss

A Rule 12(b)(6) motion may be granted when a plaintiff fails to state a legally cognizable claim for which relief may be granted. *See* FED. R. CIV. P. 12(b)(6). A complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." *See* FED. R. CIV. P. 8(a)(2). "While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations," it does "require[] more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (internal citations omitted). When plaintiffs have "not nudged their claims across the line from conceivable to plausible, their complaint must be dismissed." *Id.* at 570. "This standard 'simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence of' the necessary claims or elements." *In re S. Scrap Material Co., L.L.C.*, 541 F.3d 584, 587 (5th Cir. 2008) (*citing Twombly*, 550 U.S. at 556).

"When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950 (2009). A complaint must contain "direct allegations on every

[21] *Id.* ¶ 26-27.
[22] Mot. [Doc. 13] ¶ 1.
[23] Memo. Ruling [Doc. 24], at 7-11.
[24] Pls.' Second Am. Pet. [Doc. 26].
[25] Defs.' Rule 12(b)(6) Mot. to Dismiss with Prejudice for Failure to State a Claim [Doc. 28].

material point necessary to sustain a recovery . . . or contain allegations from which an inference fairly may be drawn that evidence on these material points will be introduced at trial." *Rios v. City of Del Rio,* 444 F.3d 417, 420–21 (5th Cir.2006) (citations omitted). "[A] district court 'must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice.'" *Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011) (*citing Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007)).

A motion to dismiss under rule 12(b)(6) is generally "viewed with disfavor and is rarely granted." *Harrington v. State Farm Fire & Cas. Co.*, 563 F.3d 141, 147 (5th Cir. 2009) (*citing Gregson v. Zurich American Ins. Co.,* 322 F.3d 883, 885 (5th Cir.2003)) (internal citations omitted). Courts address the "*sufficiency* of the facts plead, not their truth or the ultimate substantive application of those facts." *Bertrand v. Eli Lilly & Co.*, No. 12-cv-0853, 2013 WL 4093556 *1 (W.D. La. Aug. 13, 2013) (emphasis in original). Courts "accept[] all well-pleaded facts as true and view[] those facts in the light most favorable to the plaintiff." *Bustos v. Martini Club Inc.*, 599 F.3d 458, 461 (5th Cir. 2010) (*citing True v. Robles*, 571 F.3d 412, 417 (5th Cir. 2009)).

B. Louisiana Products Liability Act

The LPLA establishes the exclusive theories of liability in actions against manufacturers for damage caused by their products. *See* LA. REV. STAT. ANN. § 9:2800.52. "The manufacturer of a product shall be liable to a claimant for damage proximately caused by a characteristic of the product that renders the product unreasonably dangerous when such damage arose from a reasonably anticipated use of the product." LA. REV. STAT. ANN. § 9:2800.54(A). A product

may be unreasonably dangerous: (1) in construction or composition; (2) in design; (3) due to an inadequate warning; or (4) because it does not conform to an express warranty. *King v. Bayer Pharm. Corp.*, No. 09-cv-0465, 2009 WL 2135223 *4 (W.D. La. June 8, 2009) (*citing* LA. REV. STAT. ANN. § 9:2800.54(B)). A plaintiff seeking damages under the LPLA must prove: "(1) that the defendant manufactured the product; (2) that the claimant's damage was proximately caused by a characteristic of the product; (3) that characteristic made the product 'unreasonably dangerous;' and (4) that the claimant's damage arose from a reasonably anticipated use of the product." *Butler v. Louisiana State Univ. Health Sciences Ctr.*, No. 12-cv-1838, 2012 WL 3263888 *2 (W.D. La. Aug. 9, 2012) (*citing Stahl v. Novartis Pharm. Corp.*, 283 F.3d 254, 265-66 (5th Cir. 2002)).

1. Plaintiffs' Design Defect, Inadequate Warning, and Breach of Express Warranty Claims

In this court's previous ruling, the plaintiffs were given leave to amend their complaint with sufficient facts to support recovery under theories of design defect, inadequate warning, and breach of express warranty.[26] This court has already held that the original complaint and first amending petition were inadequate to support claims under the LPLA for design defect, inadequate warning, and breach of express warranty.[27] The plaintiffs' second amending petition does not offer any new facts in support of these claims.[28] Additionally, the plaintiffs do not argue in their opposition to the defendants' motion to dismiss that the second amending petition addresses these claims; they focus on supporting a theory of recovery under defective construction.[29] This court previously ruled that the plaintiffs did not sufficiently allege claims under defective design, inadequate warning, or express warranty, and the plaintiffs have failed to

[26] Memo. Ruling [Doc. 24], at 8-11.
[27] *Id.*
[28] Pls.' Second Am. Pet. [Doc. 26]. .
[29] Opp. To Defs.' Rule 12(b)(6) Mot. to Dismiss with Prejudice for Failure to State a Claim [Doc. 31].

allege specific facts in their second amending petition that would warrant reversing this court's previous determination.

2. Plaintiffs' Claim for Unreasonably Dangerous Construction or Composition

"A product is unreasonably dangerous in construction or composition if, at the time the product left its manufacturer's control, the product deviated in a material way from the manufacturer's specifications or performance standards for the product or from otherwise identical products manufactured by the same manufacturer." La. Rev. Stat. Ann. § 9:2800.55. Absent factual allegations addressing *how* the product deviated from the defendant's normal production standards, a plaintiff fails to meet the plausibility standard. *Watson v. Bayer Healthcare Pharm. Inc.*, No. 13-cv-212, 2013 WL 1558328 *4 (E.D. La. Apr. 11, 2013).

In *Becnel*, the plaintiff sought damages because his Mercedes-Benz drove on a lean. *Becnel v. Mercedez-Benz USA, LLC.*, No. 14-0003, 2014 WL 4450431 *4 (E.D. La. Sept. 10, 2014). Plaintiff identified the failed components and argued that because the vehicle suffered a "significant lean" that there must have been a deviation from the performance standard. *Id.* The plaintiff also maintained that the defendant's exact mistake in the manufacturing process could not be known until the plaintiff completed discovery. *Id.* In granting the defendant's motion to dismiss, the court found that the plaintiff's complaint failed to state a claim because the plaintiff did not show *how* a mistake in the manufacturing process resulted in a defective part. *Id.* (emphasis added).

The plaintiffs have amended their complaint to allege the following:

> 24-A. The defendants, [sic] Bio-Intrafix large tibial sheath was unreasonably dangerous in construction and composition which unreasonably dangerous condition caused the defendant's product to tear apart and split into fragmented loose bodies upon implantation by the operating physician, which proximately caused petitioners pain and suffering, loss of range of motion, abnormal gait,

impairment and disability, and the necessity for multiple subsequent operative procedures.

24-B. The defendants, [sic] Bio-Intrafix large tibial sheath was defective and unreasonably dangerous in construction or composition as it split and fragmented into small pieces after being placed inside petitioners [sic] knee. The defendant's medical product was not intended to split and fragment into multiple loose bodies when in use. It is clear defendant's intention when manufacturing and constructing its Bio-Intrafix tibila sheath, was not to construct a tibial sheath that would tear, split apart, and fragment into multiple loose bodies when in use. The defendant's tibial sheath deviated in a material way from the manufacturer's specifications and performance standards since its construction or composition split and fragmented when in use.

Further, the splitting and fragmenting of the tibial sheath in petitioner's knee was, in part, a proximate cause of her injuries. This unusual occurrence of the defendant's medical product splitting and fragmenting into multiple loose bodies gives rise to an inference of negligence or liability and the doctrine of *res ipsa loquitur* is applicable to the unusual circumstances surrounding this accident and the only reasonable and fair conclusion is that the incident resulted from a breach of duty owed to the petitioner from commission or omission on the part of the defendant manufacturer. Such an unusual occurrence gives rise in this instance to an inference of a manufacturing defect. The defendant's product was defective and deviated from the defendant's otherwise identical products manufactured by the defendant as this product split and fragmented into multiple loose bodies while in use and did not perform as the manufacturer intended.

24-C. On or about February 24, 2012, the defendant received another complaint (catalog number 254616) of an identical product malfunction due to breakage and were unable to discern the root cause for the devices [sic] condition and considered the breakage and anomaly. Through discovery the parties will have the opportunity to inspect the batch number processing records for internal processing issues with defendant's Bio-Intrafix sheath.[30]

The defendants assert that the plaintiffs have still failed to identify any way in which the device allegedly deviated from intended specifications or performance standards.[31] The court agrees. The plaintiffs allege that the tibial sheath deviated from the manufacturer's specifications because it split and fragmented in the plaintiff's knee. However, the plaintiffs do not show how this split and fragmentation was caused by a deviation from the manufacturer's

[30] Pls.' Second Am. Pet. [Doc. 26], ¶¶ 24-A, 24-B, 24-C (emphasis added). Paragraph 24 in the plaintiffs' Second Amending Petition is substantially similar to how it appears in the plaintiffs' First Amending Petition. Pls.' First Am. Pet. [Doc. 18], at 2-3. The newest revision omits "design" as a defective characteristic and inserts the word "proximately" before "caused" followed by a more specific listing of the physical injuries to the plaintiff.

[31] Mem. in Supp. of Defs.' Rule 12(b)(6) Mot. to Dismiss with Prejudice for Failure to State a Claim [Doc. 28-1], at 5.

specifications or standards. It is not sufficient to allege that because a product broke, it must have deviated from performance standards. Products can break for any number of reasons, including user negligence; every broken product does not automatically give rise to a cause of action under the LPLA.

The plaintiffs also attached 24 FDA adverse event reports to their opposition to the defendants' motion.[32] However, the adverse event reports do not support the conclusion that the product was defective. The reports identify a number of reasons for the product's failure, including ordinary wear and tear,[33] misuse,[34] problems with user technique,[35] and flattened packaging upon delivery.[36] None of the FDA adverse reports—including the report filed about the plaintiff's sheath—found that a defect in construction caused the sheath's failure.

Finally, the plaintiffs urge the court to apply the doctrine of *res ipsa loquitur* to the pleading stage. *Res ipsa loquitur* can be used in the context of a product liability action. *Lawson v. Mitsubishi Motor Sales of America, Inc.*, 938 So.2d 35, 49 (La. 2006). However, the court has found no support for invoking this evidentiary rule to satisfy a plaintiff's burden at the pleading stage. *See, e.g., Flagg v. Elliot,* 2014 WL 3715127 *6 (E.D. La. June 16, 2014). Additionally, in applying the doctrine, a plaintiff must "sufficiently exclude inference of the plaintiff's own responsibility or the responsibility of others besides the defendant in causing the accident." *Id.* at 50 (citing *Cangelosi v. Our Lady of the Lake Reg'l Med. Ctr.*, 564 So.2d 654, 664 (La. 1989)).

Even if the court were to try to apply the doctrine of *res ipsa loquitur* to the pleading stage, the plaintiffs' claim against Dr. Cascio would prevent its use. The plaintiffs allege in their

[32] *See* Ex. 1 [Doc. 31-2] through Ex. 24 [Doc. 31-25].
[33] Ex. 5, Ex. 14 & Ex. 17 [Docs. 31-6, 31-15 & 31-18].
[34] Ex. 7 [Doc. 31-8].
[35] Ex. 8 [Doc. 31-9].
[36] Ex. 20 [Doc. 3-21].

petition that Dr. Cascio "negligently split[] the Bio-Intrafix tibia sheath . . . ."[37] This assertion does not exclude evidence that another source is responsible for the sheath splitting. The plaintiffs have again failed to allege specific facts that would set forth a claim that the sheath was unreasonably dangerous in construction or composition.

C. Leave to Amend

Federal Rule of Civil Procedure 15 empowers the court to grant a party leave to amend a complaint "when justice so requires." FED. R. CIV. PRO. 15(a)(2); *see also Jones v. Robinson Prop. Grp., LP,*427 F.3d 987, 994 (5th Cir. 2005). The district court has discretion to grant or deny leave to amend may consider a variety of factors, such as "undue delay, bad faith or dilatory motive of the part of the movant, repeated failures to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party . . . , and futility of the amendment." *Marucci Sports, L.L.C. v. National Collegiate Athletic Ass'n,* 751 F.3d 368, 378 (5th Cir. 2014) (quoting *Jones,* 427 F.3d at 994). Denying leave to amend is not abuse of discretion if amendment would be futile. *Id.* (citing *Briggs v. Miss.,* 331 F.3d 499, 508 (5th Cir. 2003)).

The plaintiffs have had two opportunities to amend their complaint, and neither of these amendments cured the failure to allege sufficient facts to support a claim under the LPLA. Further, the plaintiffs were put on notice of the deficiencies in their complaint by this court and given guidance on how to fix those deficiencies.[38] The Fifth Circuit has repeatedly held that where the plaintiffs have had three attempts to produce a sufficient complaint and failed that there is no abuse of discretion to deny leave to amend the complaint. *See Id.* (citing *Fin. Acquisition Partners LP v. Blackwell,* 44- F.3d 278, 291 (5th Cir. 2006) ("Plaintiffs had three attempts to produce a sufficient complaint. The [district] court dismissed the complaint and

[37] Pet. for Damages [Doc. 1-2] ¶ 17.
[38] *See* Mem. Ruling [Doc. 24], at 7 ("[T]he plaintiffs do not state how the product is allegedly dangerous due to a defect . . . .").

denied leave to amend only after the third insufficient attempt."); *ABC Arbitrage Plaintiffs Grp. v. Tchuruk,* 291 F.3d 336, 362 (5th Cir. 2002) (holding that it was not abuse of discretion to deny plaintiffs a third opportunity to sufficiently state a claim)). The plaintiffs have failed to cure their deficiencies. After two amendments to the original complaint, there is no indication that granting the plaintiffs another opportunity to amend their complaint would be anything other than futile. Accordingly,

IT IS ORDERED that the defendants' Motion to Dismiss for Failure to State a Claim [Doc. 28] be and hereby is **GRANTED**.

Lake Charles, Louisiana, this 16 day of October, 2014.

PATRICIA MINALDI
UNITED STATES DISTRICT JUDGE