UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

DONNA HARGROVE *et al.*	**CIVIL ACTION**
VERSUS	**NO. 13-3539**
BOSTON SCIENTIFIC CORP.	**SECTION: "G"(3)**

ORDER AND REASONS

In this litigation, plaintiffs Donna Hargrove and her spouse John Burns ("Hargroves") allege that a medical device manufactured by defendant Boston Scientific Corporation ("Boston Scientific") broke apart within Ms. Hargrove's body, causing severe injury and requiring her to undergo invasive surgery. Pending before the Court is Boston Scientific's "Motion to Dismiss First Amended Complaint under Fed. R. Civ. P. 12(b)(6)."[1] Having reviewed the motion, the memoranda in support, the memorandum in opposition, the record, and the applicable law, the court will deny-in-part and grant-in-part the motion.

I. Background

A. Factual Background

In the Hargroves' complaint, the plaintiffs allege that Ms. Hargrove underwent an endoscopic retrograde cholangiopancreatography procedure ("ERCP") at Tulane University Hospital on October 20, 2011.[2] During this procedure, a Pathfinder Exchange Guidewire ("guidewire") manufactured by Boston Scientific was allegedly placed within Ms. Hargrove's body, and subsequently broke off

[1] Rec. Doc. 14.

[2] Rec. Doc. 7 at p. 3.

within Ms. Hargrove's pancreatic duct.[3] On October 25, 2011, Ms. Hargrove purportedly underwent a second ERCP intended to retrieve the broken guidewire. This procedure was allegedly unsuccessful, and the Hargroves maintain that she subsequently developed chronic pancreatitis.[4] On February 23, 2012, Ms. Hargrove allegedly underwent an invasive surgical procedure to retrieve the guidewire.

Subsequently, on March 15, 2012, the Hargroves requested and received a copy of Donna Hargrove's medical records from Tulane University Hospital; these records allegedly did not contain the procedural report or the product identification for the guidewire used in Ms. Hargrove's procedure.[5] On March 20, 2012, Burns allegedly spoke to Drs. Louis Balart and Joseph Buell about getting the October 20, 2011 procedural report and guidewire product identification; both allegedly agreed to assist Burns.[6] In June 2012, Ms. Hargrove allegedly asked Balart and Buell about the records but these doctors informed Ms. Hargrove that they had not found the records.[7] On September 26, 2012, the Hargroves purportedly met with Sheila Gordon, Director of Medical Records for Tulane University Hospital, and inspected Ms. Hargrove's"entire chart," specifically requesting the incident report, "variance report," and guidewire product identification associated with her October 20, 2012 procedure; the chart allegedly did not contain that information.[8] That same day, the

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[3] *Id.*

[4] *Id.*

[5] *Id.* at p. 16.

[6] *Id.*

[7] *Id.*

[8] *Id.*

Hargroves allegedly met with Beth Babin, Vice President of Human Resources and Patient Relations at Tulane University Hospital, to complain about the missing records; Babin allegedly informed the Hargroves that she would get the records.[9]

On October 3, 2012, Ms. Hargrove allegedly contacted Babin to inquire about whether Babin had found the records; Babin informed Ms. Hargrove that she had found the records, and would fax them to Ms. Hargrove.[10] According to the Hargroves, Babin never sent that fax.[11] During the week of October 8, 2012, Ms. Hargrove allegedly contacted Babin's office about the records; having allegedly been told that Babin was out of the office that week, Ms. Hargrove claims that she contacted John Cook at Tulane University Hospital's Office of Risk Management, who informed hr that he would speak to Babin regarding the requested information. During that same week, the Hargroves allegedly visited Babin's office and Cook's office; neither Babin nor Cook were in their offices, but Cook's secretary contacted Cook, and requested that the Hargroves leave Cook a letter regarding their request for information.[12] The Hargroves allegedly did so.[13] The Hargroves claim that they then repeatedly called Cook and Babin, and finally reached Cook on November 12, 2012, at which time Cook provided Ms. Hargrove with information about the manufacturer, serial number, lot number, and expiration date of the guidewire.[14]

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[9] *Id.*

[10] *Id.*

[11] *Id.*

[12] *Id.*

[13] *Id.*

[14] *Id.* at p. 17.

B. Procedural Background

The Hargroves, alleging diversity jurisdiction, filed suit in this Court against Boston Scientific on February 22, 2013.[15] In their complaint, the Hargroves claimed violations of: (1) the Louisiana Products Liability Act ("LPLA"),[16] and (2) the warranty of redhibition.[17] On April 26, 2013, Boston Scientific filed a "Motion to Dismiss Under Fed. R. Civ. P. 12(b)(6),"[18] which was set for May 22, 2013.[19] On May 21, 2013, the Hargroves filed a "Notice of Dismissal Without Prejudice" pursuant to Federal Rule of Civil Procedure 42(a)(1)(A)(I), resulting in the termination of their case.[20] Then, on that same day, they filed a new action in this Court.[21] The new action, like the old action, claimed violations of the LPLA and the warranty of redhibition.[22] On August 29, 2013, the Hargroves filed a "First Amended Complaint," which added allegations that the *contra non*

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[15] *Hargrove v. Boston Scientific*, No. 13-330, Rec. Doc. 1 at p. 2.

[16] LA. REV. STAT. § 9:28000.53

[17] *Hargrove v. Boston Scientific*, No. 13-330, Rec. Doc. 1 at pp. 11–15.

[18] *Hargrove v. Boston Scientific*, No. 13-330, Rec. Doc. 7.

[19] The Hargroves did not file an opposition to this motion.

[20] *Hargrove v. Boston Scientific*, No. 13-330, Rec. Doc. 8. Federal Rule of Civil Procedure 42(a)(1)(A) provides:

> **(A) Without a Court Order.** Subject to Rules 23(e), 23.1(c), 23.2, and 66 and any applicable federal statute, the plaintiff may dismiss an action without a court order by filing:
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> > **(i)** a notice of dismissal before the opposing party serves either an answer or a motion for summary judgment[.]

[21] Rec. Doc. 1. The case was initially assigned to Judge Zainey, but the Hargroves filed a Notice of Related Case, pursuant to Local Role 3.1, and the case was subsequently reassigned to this Section. Rec. Doc. 3; Rec. Doc. 5.

[22] Rec. Doc. 1 at pp. 11–15.

valentem doctrine applied to the claims alleged previously.[23] On October 21, 2013, Boston Scientific filed a "Motion to Dismiss First Amended Complaint Under Fed. R. Civ. P. 12(b)(6)."[24]

II. Parties' Arguments

A. Boston Scientific's "Motion to Dismiss First Amended Complaint Under Fed. R. Civ. P. 12(b)(6)"

Boston Scientific argues that this Court should dismiss the Hargroves' claims against it because the amended complaint fails to state a claim upon which relief can be granted,[25] since: (1) the Hargroves' claims are facially prescribed; (2) the doctrine of *contra non valentem* does not apply to them; (2) the claims exceed the LPLA's scope; and (4) the Hargroves have "failed to plead any LPLA claim adequately."[26]

Boston Scientific first asserts that "[a] statute of limitations may support dismissal under Rule 12(b)(6) where it is evident from the plaintiff's pleadings that the action is barred and the plaintiff's pleadings fail to raise some basis of tolling or the like."[27] According to Boston Scientific, Louisiana's one-year prescriptive period applies to product liability and redhibition claims under the LPLA, and that Louisiana law provides that a case that is filed and then voluntarily dismissed has no effect on the running of prescription.[28] Prescription begins to run, Boston Scientific maintains,

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[23] Rec. Doc. 7.

[24] Rec. Doc. 14.

[25] Rec. Doc. 14–1 at 4–5. Under this heading, Boston Scientific only provides the purported standard for resolving motions to dismiss under Federal Rule of Civil Procedure 12(b)(6). It does not apply these standards to the present case.

[26] *Id.* at pp. 5–21.

[27] *Id.* at p. 5.

[28] *Id.* at pp. 5–8.

"as soon as the injury or damage is sustained with sufficient certainty to support accrual of a cause of action."[29] Applying these purported rules to the present case, Boston Scientific argues that: (1) the prescriptive period began to run on the Hargroves' claims in October, 2011 (when Hargrove underwent the first ERCP), and the Hargroves did not file their first action against Boston Scientific until February 22, 2013, making her claim facially prescribed in the first instance; and (2) if, alternatively, the prescriptive period began to run on February 23, 2012 (when the guidewire was actually removed from Ms. Hargrove's body), the Hargroves' claims are still prescribed because the Hargroves did not initiate the present action until May 21, 2013.[30] Boston Scientific further argues that the Louisiana doctrine of *contra non valentem*, which suspends the running of prescription in some circumstances, does not apply to the present case because the Hargroves could have promptly obtained information about the guidewire, but failed to act reasonably and diligently in seeking out that information.[31]

Boston Scientific further maintains that the LPLA provides the exclusive basis for product liability actions under Louisiana law, and restricts recovery to four specific theories, under which plantiffs must show that that a product was "unreasonably dangerous": (1) in "construction or composition"; (2) in design; (3) due to "inadequate warning"; or (4) due to "nonconformity to express warranty."[32] According to Boston Scientific, the Hargroves claim negligence, unfair or deceptive acts, breach of implied warranties, violations of federal regulations, and "inherently

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[29] *Id.* at p. 6.

[30] *Id.*

[31] *Id.* at pp. 8–13.

[32] *Id.* at p. 13.

dangerous" products liability, none of which are cognizable under the LPLA.[33] Further, Boston Scientific maintains, the LPLA limits recovery of damages for redhibition to economic losses, foreclosing the Hargroves' claims for personal injury damages and attorney's fees under a redhibition theory.[34]

Finally, Boston Scientific argues that the Hargroves have failed to properly allege any of their LPLA claims. First, according to Boston Scientific, to state a "construction or composition" claim under the LPLA, it is necessary to allege that a product materially deviated from a manufacturer's specifications or performance standards, and the Hargroves, in stating that the guidewire "was not properly manufactured," have not alleged a material deviation.[35] Second, Boston Scientific maintains, to allege a "design defect" claim under the LPLA, a plaintiff must assert that (1) a manufacturer failed to adopt an existing alternative design for a product, and (2) the risk of damage arising from its failure to adopt the alternative design outweighed the burden of adopting the alternative design.[36] Boston Scientific maintains that the Hargroves have failed to allege that an alternative design was available and known to it at the time it allegedly manufactured the guidewire.[37] Additionally, Boston Scientific contends that: it is necessary to allege that a manufacturer failed to warn a "*learned intermediary*" (such as a physician) to state an "inadequate

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[33] *Id.* at pp. 14–16.

[34] *Id.* at pp. 16–17.

[35] *Id.* at pp. 18–19.

[36] *Id.* at pp. 19–20.

[37] *Id.*

warning" claim under the LPLA; and here, the Hargroves have instead alleged that *Boston Scientific* had a duty to warn patients.[38]

B. The Hargroves' Arguments in Opposition

The Hargroves argue that this Court only needs to address "two straightforward issues" to resolve Boston Scientific's motion: prescription, and the applicable pleading standard.

The Hargroves maintain that their claims are not prescribed because they filed their action on August 29, 2013, "three months before the one-year anniversary of November 12, 2102 [sic], the date when the Hargroves first learned that [Boston Scientific's] product had caused injury to them," making their action timely under Louisiana law.[39] According to the Hargroves, the doctrine of *contra non valentem* provides that the "reasonableness" of plaintiffs' actions determines when the prescriptive period begins to run.[40] and in medical causation cases the prescriptive period does not begin to run until a plaintiff has "actual or constructive notice of the causal connection between the medical treatment and the subsequent condition attributable to the defendant."[41] To illustrate how the *contra non valentem* doctrine considers the "reasonableness" of plaintiffs' conduct, the Hargroves cite *Jordan v. Employee Transfer Corp*,[42] where the Louisiana Supreme Court held that prescription began to run on the plaintiffs' redhibition claim when the plaintiffs received an engineering report indicating the existence of previously undisclosed defects in the foundation of

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[38] *Id.* at pp. 20–21.

[39] Rec. Doc. 16 at p 1.

[40] *Id.* at pp. 5–6.

[41] *Id.*

[42] 509 So.2d 420, 423–24 (La. 1987).

their home, rather than when the plaintiffs first experienced flooding in their home as a result of those defects.[43]

The Hargroves contend that their First Amended Complaint shows that they acted reasonably, in accordance with the requirements of *contra non valentem*. Their case, they argue, is analogous to the Louisiana Fourth Circuit Court of Appeal case *Ferrara v. Starmed Staffing*,[44] where the court concluded that prescription did not begin to run on the plaintiff's medical malpractice claims until the defendant, following a discovery request, disclosed the identity of the nurse who allegedly injured the plaintiff, even though the nurse's name appeared in handwritten form in the plaintiff's medical records.[45] The facts in *Ferrara* are "parallel" to the facts in the present case, the Hargroves argue, because Ms. Hargrove's medical records were missing information about the identity of the guidewire's manufacturer, and Tulane University did not locate or disclose the identifying information until November 12, 2012.[46] The Hargroves further argue that the medical records in the present case did not contain handwritten information identifying Boston Scientific as the guidewire's manufacturer; the Hargroves maintain that they "went above and beyond the Ferrara plaintiffs' actions" because they "recruited" Ms. Hargrove's doctors and went up "the chain of command" until

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[43] *Id.*

[44] 2010–0589 (La. App. 4 Cir. 10/6/10), 50 So.3d 861, 867.

[45] *Id.* ("In this case, Ms. Waddell was working at Tulane as an employee of Starmed, a third party nursing agency, when the malpractice occurred. Although in hindsight Ms. Waddell's name in handwritten form can be discerned from the nurses' notes located in the Tulane medical records, Ms. Ferrara could not have reasonably identified the identity of Ms. Waddell or Starmed until Tulane responded to the discovery request and furnished their identity.").

[46] Rec. Doc. 16 at pp. 6–7.

Tulane provided the necessary information.[47] For these reasons, the Hargroves argue, Boston Scientific "cannot meet its burden of showing" that the Hargroves acted unreasonably.[48]

The Hargroves further contend that their action satisfies the pleading standards under *Iqbal* and *Twombly* because they "have pled that [Boston Scientific's] guidewire broke off inside Ms. Hargrove and could not be retrieved," which amount to sufficient facts to entitle them to relief.[49] In support of this assertion, the Hargroves cite *Rollins v. St. Jude Medical*, in which the magistrate judge concluded that the plaintiffs had pled sufficient facts to avoid a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), even though the plaintiffs "did not even provide the medical devices [sic] model number."[50] In the present case, the Hargroves contend that they have alleged that the device at issue either failed to meet Boston Scientific's design standards, or has a design flaw; "in this context," the Hargroves argue, if Boston Scientific had warned Ms. Hargrove's doctors about the problems with its product, the Hargroves and their healthcare providers "would have elected for a different guidewire."[51] Thus, the present case, the Hargroves argue, "is not a

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[47] *Id.* at p. 7. The Hargroves also argue that Boston Scientific's citation of *Williams v. Holiday Inn Worldwide* is "misguided," because the Louisiana Fourth Circuit Court of Appeal held in that case that the plaintiff could have, and should have identified the defendant by searching public records; in the present case, the Hargroves argue, no public records would have disclosed Boston Scientific's identity. *Id.* at 8 (citing *Williams*, 2002-0762 (La. App. 4 Cir. 5/15/02), 816 So.2d 998, 1002–3, *overruled on other grounds by Glasgow v. PAR Minerals Corp.*, 2010-2011 (La. 5/10/11), 70 S.3d. 765, 771).

[48] *Id.* at p. 8.

[49] *Id.* at pp. 1; 8.

[50] *Id.* at p. 8. The Hargroves also point to information that allegedly shows that the guidewire in the device at issue in the present case had broken off during procedures involving other patients, although this information does not appear in their First Amended Complaint. *Id.* at 9.

[51] *Id.* at p. 10.

complex bio-chemical case," but rather is a case "about a guidewire that simply breaks off inside of a patient," requiring the patient to "undergo multiple invasive procedures."[52]

Finally, the Hargroves, arguing in the alternative, seek leave to amend their complaint under Federal Rule of Civil Procedure 15,[53] since courts allegedly should decline to dismiss cases under Federal Rule of Civil Procedure 12(b)(6) "unless it is patently obvious that plaintiffs have pled their 'best case.'"[54] The Hargroves argue that (1) "courts generally review the record to determine whether plaintiffs could state a claim by amending their complaint,"[55] and (2) should grant leave to amend "in the absence of undue delay, bad faith, dilatory motive, repeated failure to cure deficiencies, undue prejudice, or futility of amendment,"[56] (3) as long as the "facts and circumstances relied upon . . . may be proper subjects of relief."[57] In the present case, the Hargroves argue, "it is indisputable that the circumstances and facts" they "endured" may be the subject of relief, since "medical devices should not brake [sic] off inside a patient, requiring multiple surgical procedures to retrieve them."[58] Further, the Hargroves contend, the fact that Boston Scientific has premised the

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[52] *Id.*

[53] *Id.*

[54] *Id.*

[55] *Id.* at pp. 10–11.

[56] *Id.* at p. 11.

[57] *Id.*

[58] *Id.* The Hargroves further contend that Boston Scientific is aware that the device at issue in the present case is "known to break, causing injury to patient—including disability." *Id.* at p. 11.

present motion on prescription and failure to state a claim demonstrates that Boston Scientific "implicitly admits that if their product was involved, the Hargroves [sic] claim has merit."[59]

C. Boston Scientific's Arguments in Further Support of its Motion

In its "Reply Memorandum in Support of Motion to Dismiss First Amended Complaint Under Fed. R. Civ. P. 12(b)(6),"[60] Boston Scientific maintains that (1) the Hargroves' claims are prescribed; (2) "any and all" of the Hargroves' claims that fall outside the scope of the LPLA must be dismissed; (3) the Hargroves' amended complaint fails to state a claim upon which relief can be granted; and (4) the Hargroves are not entitled to amend their complaint "yet again."[61]

Boston Scientific first argues that the Hargroves' claims are prescribed because the Hargroves did not request Ms. Hargrove's medical records until five months after Ms. Hargrove's first ERCP, and then twice delayed their inquiries by three months after first learning that Ms. Hargrove's records did not contain the information they needed.[62] According to Boston Scientific, this amounted to a "demonstrated lack of diligence in seeking out the information concerning their alleged cause of action," and "was not reasonable."[63] Boston Scientific contends that *contra non valentem* only applies in exceptional circumstances, and does not apply "when the delay results from

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[59] *Id.*

[60] Rec. Doc. 19.

[61] *Id.* at pp. 2–8.

[62] *Id.* at p. 2.

[63] *Id.*

plaintiffs' willfulness or neglect," as "a plaintiff is imputed with all the knowledge he could have learned if he had acted with reasonable diligence."[64]

In the present case, Boston Scientific maintains, the Hargroves "knew of their injury and its alleged cause, but simply failed to pursue further details diligently and timely."[65] Boston Scientific further argues that the Hargroves' citations of *Jordan* and *Ferrara* are "inapposite," since: (1) the plaintiffs in *Jordan* were not aware of the source of the damage to their home, whereas the Hargroves were aware of the broken guidewire; and (2) the plaintiff in *Ferrara* sued a nurse as a "Jane Doe" defendant, and had no way of knowing that the nurse worked for a medical staffing agency, whereas the Hargroves "simply failed to diligently seek" information "that was readily discoverable with reasonable effort."[66] Boston Scientific also notes that the Hargroves attached affidavits to their briefing in support of the present motion, and contends that this Court "may not go outside of the complaint" when resolving this motion.[67]

Boston Scientific next argues that the Hargroves "do not dispute that the LPLA is their exclusive remedy," or that "all claims outside the scope of the LPLA must be dismissed," meaning that the Hargroves' claims for "negligence, wrongful conduct, unfair or deceptive acts or practices, deceptive conduct, for an 'inherently dangerous' product, implied warranty, and other acts or failures

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[64] *Id.* at p. 3.

[65] *Id.*

[66] *Id.* at pp. 3–4. According to Boston Scientific, the facts at issue in the present case place it more closely in line with *Saylor v. Villcar Realty*, 2008-34 (La. App. 4 Cir. 11/19/08), 999 So.2d 61 (noting that the plaintiff presented no authority in support of his argument that *contra non valentem* should apply because he did not know the property owner's identity at the time of the accident at issue) and *Williams v. Holiday Inn Worldwide*, 816 So.2d 998.

[67] *Id.*

regarding the studying, testing, designing, developing, manufacturing, inspecting, producing, advertising, marketing, promoting, distributing and/or sale of the guidewire," along with the Hargroves' claims concerning federal statutes and regulations, must be dismissed, as all are outside the scope of the LPLA.[68] Boston Scientific further maintains that the Hargroves' claims for attorney's fees must be dismissed to the extent that they exceed the scope of recovery allowed for economic losses arising from redhibitory defects.[69]

Boston Scientific also maintains that the Hargroves have failed to state a claim upon which relief can be granted, because "the mere fact that an accident occurred is not sufficient to establish that a product is defective or unreasonably dangerous,"[70] and the Hargroves' amended complaint, in alleging that an accident occurred, has only offered "labels and conclusions," a "formulaic recitation of the elements of a cause of action, and "an unadorned, the-defendant-unlawfully-harmed-me accusation," none of which suffices to establish a violation of the LPLA.[71] According to Boston Scientific, the Hargroves have failed to allege a: (1) "construction or composition" claim under the LPLA, as they only allege that the guidewire "was not properly manufactured," not that Boston Scientific failed to adhere to its manufacturing standards or specifications; (2) "design" claim, since they have not indicated that Boston Scientific knew of any available alternative design for the guidewire when the guidewire was manufactured; (3) "failure to warn" claim, because they have not made any allegations regarding the "risk–utility considerations" related to the warning, and have not

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[68] *Id.* at pp. 5.

[69] *Id.*

[70] *Id.* at pp. 5–6.

[71] *Id.*

alleged (a) that Boston Scientific failed to warn Ms. Hargrove's physician regarding the risks associated with the guidewire, (b) that this failure was the cause-in-fact and proximate cause of Ms. Hargrove's injury, or (c) that a proper warning would have dissuaded Ms. Hargrove's physician from using the product at issue in this case.[72]

Finally, Boston Scientific contends that because the Hargroves have already filed three complaints making the "same allegations," and were "well aware" of the "deficiencies in pleading that Boston Scientific had pointed out in its motion to dismiss in the prior action," they now have "no justifiable ground to request that they be given another chance to amend their complaint."[73]

III. Law and Analysis

A. Standard on a Motion to Dismiss Under Federal Rule of Civil Procedure 12(b)(6)

Federal Rule of Civil Procedure 12(b)(6) provides that an action may be dismissed "for failure to state a claim upon which relief can be granted."[74] "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim for relief that is plausible on its face.'"[75] "Factual allegations must be enough to raise a right to relief above the speculative level."[76] A claim is facially plausible when the plaintiff has pleaded facts that allow the court to "draw a reasonable inference that the defendant is liable for the misconduct alleged."[77]

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[72] *Id.* at pp. 6–7.

[73] *Id.* at p. 7.

[74] FED. R. CIV. P. 12(b)(6).

[75] *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2008)).

[76] *Twombly*, 550 U.S. at 556.

[77] *Id.* at 570.

On a motion to dismiss, asserted claims are liberally construed in favor of the claimant, and all facts pleaded are taken as true.[78] However, although required to accept all "well-pleaded facts" as true, a court is not required to accept legal conclusions as true.[79] "While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations."[80] Similarly, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements" will not suffice.[81] The complaint need not contain detailed factual allegations, but it must offer more than mere labels, legal conclusions, or formulaic recitations of the elements of a cause of action.[82] That is, the complaint must offer more than an "unadorned, the defendant-unlawfully-harmed-me accusation."[83] From the face of the complaint, there must be enough factual matter to raise a reasonable expectation that discovery will reveal evidence as to each element of the asserted claims.[84] If factual allegations are insufficient to raise a right to relief above the speculative level, or if it is apparent from the face of the complaint that there is an "insuperable" bar to relief, the claim must be dismissed.[85]

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[78] *Leatherman v. Tarrant Cnty. Narcotics Intelligence & Coordination Unit*, 507 U.S. 163, 164 (1993); *see also Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322–23 (2007).

[79] *Ashcroft v. Iqbal*, 556 U.S. 662, 677–78 (2009).

[80] *Id.* at 679.

[81] *Id.* at 678.

[82] *Id.*

[83] *Id.*

[84] *Lormand v. U.S. Unwired, Inc.*, 565 F.3d 228, 257 (5th Cir. 2009).

[85] *Moore v. Metropolitan Human Serv. Dep't*, No. 09-6470, 2010 WL 1462224, at * 2 (E.D. La. Apr. 8, 2010) (Vance, C.J.) (citing *Jones v. Bock*, 549 U.S. 199, 215 (2007)); *Carbe v. Lappin*, 492 F.3d 325, 328 n. 9 (5th Cir. 2007).

B. Prescription

Although the parties do not dispute that a one-year prescriptive period[86] applies to all of the claims in the present action, the parties do dispute whether the action was timely filed.

Under the United States Court of Appeals for the Fifth Circuit's *Jones v. Alcoa* decision, "[a] statute of limitations may support dismissal under Rule 12(b)(6) where it is evident from the plaintiff's pleadings that the action is barred and the pleadings fail to raise some basis for tolling or the like."[87] Where prescription presents questions of fact that cannot be conclusively resolved on the face of the pleadings, the United States Court of Appeals for the Fifth Circuit has held that dismissal under Federal Rule of 12(b)(6) is improper.[88]

Applying the law to the facts of the present case, Ms. Hargrove received her first ERCP on October 20, 2011, at which time the Hargroves allege that the guidewire broke off within Ms. Hargrove's pancreatic duct.[89] She underwent a second procedure intended to remove the guidewire

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[86] LA. CIV. CODE art. 3492, which provides a one-year prescriptive period for delictual actions, applies to the Hargroves' tort claims. *See* 12 LA. CIV. L. TREATISE, TORT LAW § 2.8 (2d Ed. 2013) ("The Louisiana Products Liability Act creates a statutory duty and action for product liability harms. The violation of this statutory duty constitutes fault under Article 2315"). LA. CIV. CODE art. 2315 establishes that "[e]very act whatever of a man that causes damage to another obliges him by whose fault it happened to repair it[.]" LA CIV. CODE art. 2534 provides a one-year prescriptive period for redhibition actions, and applies to the Hargroves' claims sounding in redhibition.

[87] 339 F.3d 359, 366 (5th Cir. 2003).

[88] *See Jamil Abdu-Alim Amin v. Universal Life Ins. Co.*, 706 F.2d 638, 641 (5th Cir. 1983) (reversing the district court's order dismissing a plaintiff's complaint where the question of whether the action had prescribed depended on a determination of whether a "reasonable" period of time for performance of a contract had elapsed, and noting that "[a] court should be extremely reluctant to grant a motion to dismiss on a ground that requires a determination of . . . facts that are not normally ascertainable from the pleadings.").

[89] Rec. Doc. 7 at p. 3.

on October 25, 2011.[90] At some point afterward, Ms. Hargrove developed chronic pancreatitis.[91] Ms Hargrove underwent invasive surgery to remove the guidewire on February 23, 2012.[92] Less than a month later, on March 15, 2012, the Hargroves purportedly went to Tulane University Hospital, where they requested and received a copy of Ms. Hargrove's medical records.[93] Finding that these records did not contain the "procedural report" or information about the guidewire, the Hargroves allegedly then began a quest for this information that culminated in their receiving the records from Tulane University Hospital on November 10, 2012.[94]

Boston Scientific contends the prescriptive period began to run on the date of Ms. Hargrove's first procedure, October 20, 2011. The Hargroves contend that the doctrine of *contra non valentem*[95] delays the running of prescription in the present case to November 12, 2012, when Tulane University Hospital informed them that Boston Scientific manufactured the guidewire.[96] They filed this complaint on May 21, 2013,[97] less than seven months after learning that Boston Scientific

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[90] *Id.*

[91] *Id.*

[92] *Id.*

[93] *Id.* at p. 16.

[94] *Id.* at pp. 16–17.

[95] *See Wimberly v. Gatch*, 635 So.2d 206, 211 ("The [plaintiffs] herein rely on the suspensive theory of *contra non valentem agere nulla currit praescripto* [sic], which means 'prescription does not run against a party unable to act.'")

[96] Rec. Doc. 16 at pp. 5–7.

[97] Rec. Doc. 1.

manufactured the guidewire. The Hargroves assert that *contra non valentem* "prevents the running of liberative prescription where the cause of action is not reasonably knowable to the plaintiff."[98]

The United States Court of Appeals for the Fifth Circuit has applied the doctrine of *contra non valentem* in cases where a Louisiana prescriptive statute is implicated.[99] The doctrine is a judicially-created exception to the general rules of prescription, premised upon the notion that:

> The principles of equity and justice . . . demand that under certain circumstances, prescription be suspended because plaintiff was effectually prevented from enforcing his rights for reasons external to his own will.[100]

Louisiana courts recognize four factual situations in which *contra non valentem* applies to prevent the running of prescription:

> (1) where there was some legal cause which prevented the courts or their officers from taking cognizance of or acting on the plaintiff's action;
>
> (2) where there was some condition coupled with the contract or connected with the proceedings which prevented the creditor from suing or acting;
>
> (3) where the debtor himself has done some act effectually to prevent the creditor from availing himself of his cause of action; or
>
> (4) where the cause of action is neither known nor reasonably knowable by the plaintiff even though plaintiff's ignorance is not induced by the defendant.[101]

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[98] *Id.* at p. 5.

[99] *See, e.g. Chevron, U.S.A. v. Aker Maritime, Inc.*, 604 F.3d 888, 893–94 (5th Cir. 2010).

[100] *Wimberly*, 635 So.2d at 211. In *Corsey v. State, Through Dept. of Corrections*, the Louisiana Supreme Court noted that "courts should extend the time [for filing suit] only in exceptional circumstances upon adequate authority." 375 So.2d 1319, 1327 (La. 1979). *See also LaPlaque Corp. v. Chevron U.S.A. Inc.*, 638 So.2d. 354, 357 (La. App. 4 Cir. 1994), *writ denied* 94-2125 (La. 11/11/94), 644 So.2d 395 (citing *Corsey* in support of the proposition that "[c]ontra non valentem is an exceptional remedy recognized by our jurisprudence which is in direct contradiction to the articles in the Civil Code and therefore should be strictly construed.").

[101] *Renfroe v. State ex rel. Dept. of Transp. and Development*, 2001–1646 (La. 2/26/02), 809 So.2d 947, 953.

Here, the Hargroves allege that the fourth category of *contra non valentem* applies, because, they claim, it is "patently evident from the face of [their] Amended Complaint that [they] acted reasonably."[102]

The United States Court of Appeals for the Fifth Circuit has applied the doctrine of *contra non valentem* in cases where a Louisiana prescriptive statute is implicated. The Fifth Circuit has also held that courts should be "extremely reluctant" to grant a motion to dismiss where the pleadings raise an issue of "reasonableness" that must be resolved by facts that "are not normally ascertainable from the pleadings."[103] In resolving the present motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), the Court relies solely on the Hargroves' pleadings, and takes the Hargroves' well-pleaded factual allegations—including their allegations regarding *contra non valentem*—as true. Although the Hargroves' complaint states that something went wrong with the guidewire on October 20, 2011, the day of Ms. Hargrove's first ERCP procedure,[104] the complaint also alleges that the Hargroves first inquired about the manufacturer of the guidewire in March 2012, and had to repeatedly visit and contact Tulane University Hospital before they were able to identify the guidewire and its manufacturer.[105] These factual allegations, taken as true, could support the Hargroves' allegation that prescription was tolled pursuant to the doctrine of *contra non valentem*. Accordingly, the Court denies Boston Scientific's motion to dismiss on the basis of prescription.

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[102] Rec. Doc. 16 at p.6.

[103] *Jamil Abdu-Alim Amin v. Universal Life Ins. Co.*, 706 F.2d 638, 641 (5th Cir. 1983).

[104] Rec. Doc. 7 at 3.

[105] *See* Rec. Doc. 7 at pp. 7–18.

C. The Louisiana Products Liability Act

Boston Scientific contends that: (1) the LPLA provides the exclusive basis for products liability actions under Louisiana law; (2) the Hargroves' complaint makes allegations that are not cognizable under the LPLA; and (3) therefore, to the extent that the Hargroves' claims fall outside the scope of the LPLA, they should be dismissed.[106]

To survive the present motion to dismiss, the Hargroves' complaint must contain sufficient factual matter, accepted as true, to "state a claim for relief that is plausible on its face.'"[107] A claim is facially plausible when the plaintiff has pleaded facts that allow the court to "draw a reasonable inference that the defendant is liable for the misconduct alleged."[108] If factual allegations are insufficient to raise a right to relief above the speculative level, or if it is apparent from the face of the complaint that there is an "insuperable" bar to relief, the claim must be dismissed.[109]

The LPLA, as codified at LA. REV. STAT. § 9:2800.52, provides that:

> This Chapter establishes the exclusive theories of liability for manufacturers for damage caused by their products. A claimant may not recover from a manufacturer for damage caused by a product on the basis of any theory of liability that is not set forth in this Chapter.[110]

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[106] Rec. Doc. 14 at pp. 13–21.

[107] *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2008)).

[108] *Id.* at 570.

[109] *Moore v. Metropolitan Human Serv. Dep't*, No. 09-6470, 2010 WL 1462224, at * 2 (E.D. La. Apr. 8, 2010) (Vance, C.J.) (citing *Jones v. Bock*, 549 U.S. 199, 215 (2007)); *Carbe v. Lappin*, 492 F.3d 325, 328 & n.9 (5th Cir. 2007).

[110] LA. REV. STAT. § 9:2800.52. *See also Aucoin v. Amneal Pharmaceuticals, LLC*, No. 11-1275, 2012 WL 2990697 at *11 (E.D. La. Jul. 20, 2012) (Brown, J.) (applying the LPLA and dismissing all claims not brought under the LPLA as "in contravention of the LPLA's exclusive remedy provision.").

In their briefing related to the present motion, neither party sets forth the elements of a cause of action under the LPLA. Nevertheless, it appears that, to state a cause of action under the LPLA, a plaintiff must allege:

> (1) [T]hat the product possesses an "unreasonably dangerous" characteristic;
>
> (2) [T]hat this unreasonab[y] dangerous characteristic proximately caused the plaintiff's damage; and
>
> (3) [T]hat injury arose from a "reasonably anticipated use" of the product.[111]

Under Section 9:2800.54 of the LPLA:

> (B) A product is unreasonably dangerous if and only if:
>
> (1) The product is unreasonably dangerous in construction or composition as provided in R.S. 9:2800.56;
>
> (2) The product is unreasonably dangerous in design as provided in R.S. 9:2800.56;
>
> (3) The product is unreasonably dangerous because an adequate warning about the product has not been provided as provided in R.S. 9:2800.57; or
>
> (4) The product is unreasonably dangerous because it does not conform to an express warranty of the manufacturer about the product as provided in R.S. 9:2800.58.[112]

The Court now considers whether the Hargroves have plausibly stated a cause of action under the LPLA. The Hargroves allege that the guidewire, despite being intended for use in ERCP procedures like Ms. Hargrove's, was defective, leading it to break off within Ms. Hargrove's body, where it caused pain and chronic disease.[113] The Hargroves have accordingly pled sufficient facts to

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[111] 12 LA. CIV. L. TREATISE, TORT LAW § 16:32 (2d. Ed. 2013) (citing LA. REV. STAT. § 9:2800.54).

[112] LA. REV. STAT. § 9:2800.52. *See also Grenier v. Med. Eng. Corp.*, 243 F.3d 200, 203 (5th Cir. 2001) (listing the four theories of recovery).

[113] Rec. Doc. 7 at pp. 3–4.

satisfy the LPLA's requirements that: (1) the guidewire's defects "proximately caused [the alleged] damage," and (2) this damage arose from a "reasonably anticipated use" of the guidewire. Therefore, the Court now addresses whether the Hargroves have plausibly pled the remaining element of an LPLA cause of action—namely, that the guidewire possessed an "unreasonably dangerous" characteristic within the meaning of the LPLA.

1. "Unreasonably Dangerous in Construction and Composition"

Under Section 9:2800.56 of the LPLA:

> A product is unreasonably dangerous in construction or composition if, [1] at the time the product left its manufacturer's control, [2] 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.[114]

To state a cause of action under this provision of the LPLA, a plaintiff must allege that the product that injured her deviated from its design or from "the manufacturer's otherwise identical products."[115]

In their complaint, the Hargroves allege that the guidewire was "not properly manufactured," was "was inadequate or insufficient to maintain its integrity[,]" and was "sold in a defective condition," thus leaving open the possibility that their guidewire was different from others in the same product line. This contention derives factual support from the Hargroves' assertion that the guidewire broke off within Ms. Hargrove's body, despite being intended for use in ERCP procedures

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[114] LA. REV. STAT. § 9:2800.55.

[115] *See Scallan v. Duriron Co.*, 11 F.3d 1249, 1252 (5th Cir. 1994) ("[The plainitff] does not allege that the pump deviated from its design. In fact, plaintiff's pump expert, Mr. Heinz Bloch, testified that the pump contained no defects in composition or manufacture."); *Aucoin*, 2012 WL 2990697 at *10 ("Likewise, regarding Plaintiff's construction or composition defect claim, Plaintiff has not alleged that the medicine he received deviated in any way from the manufacturer's production standards or from the manufacturer's otherwise identical products").

like hers.[116] Taking these factual allegations as true, the Court concludes that the Hargroves have plausibly alleged that the guidewire "deviated in a material way from the manufacturer's specifications or performance standards for the product."

2. "Unreasonably Dangerous in Design"

The LPLA establishes the following conditions for "design defect" claims:

> A product is unreasonably dangerous in design if, at the time the product left its manufacturer's control:
>
> (1) There existed an alternative design for the product that was capable of preventing the claimant's damage; and
>
> (2) The likelihood that the product's design would cause the claimant's damage and the gravity of that damage outweighed the burden on the manufacturer of adopting such alternative design and the adverse effect, if any, of such alternative design on the utility of the product. An adequate warning about a product shall be considered in evaluating the likelihood of damage when the manufacturer has used reasonable care to provide the adequate warning to users and handlers of the product.[117]

The Hargroves allege that the guidewire "as designed and manufactured was unsafe for its intended use" and that Boston Scientific "knew the component parts of the Pathfinder Exchange Guidewire as implemented through design and/or manufacture could cause injury to the end user."[118] The Hargroves also cite federal statutory and regulatory authority governing the design and manufacture of medical devices and, as previously noted, state that the guidewire was approved for sale in the United States pursuant to a "510k approval process."[119]

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[116] Rec. Doc. 7 at pp. 3–4.

[117] LA. REV. STAT. 9:2800.56.

[118] Rec. Doc. 7 at pp. 13–14.

[119] *Id.* at pp. 5–11.

Although these allegations address the guidewire's design, the Hargroves have not met the initial condition established under this category of the LPLA—namely, to allege that an *alternative design* for the guidewire existed, and that this alternative design was capable of preventing the guidewire from breaking off during procedures.[120] Their allegation that Boston Scientific committed "other acts or failures to act" with respect to the "studying, testing, designing, [and] developing . . .[of the guidewire] as will be learned in discovery" does not elevate their "unreasonably dangerous in design" allegations above a speculative level. Thus, they have failed to state a cause of action under this category of the LPLA.

3. "Unreasonably Dangerous Because of Inadequate Warning"

The LPLA establishes the following requirements for "inadequate warning" claims:

> A. A product is unreasonably dangerous because an adequate warning about the product has not been provided if, at the time the product left its manufacturer's control, the product possessed a characteristic that may cause damage and the manufacturer failed to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product.
>
> B. A manufacturer is not required to provide an adequate warning about his product when:
>
> (1) The product is not dangerous to an extent beyond that which would be contemplated by the ordinary user or handler of the product, with the ordinary knowledge common to the community as to the product's characteristics; or
>
> (2) The user or handler of the product already knows or reasonably should be expected to know of the characteristic of the product that may cause damage and the danger of such characteristic.
>
> C. A manufacturer of a product who, after the product has left his control, acquires knowledge of a characteristic of the product that may cause damage and the danger

[120] *See Aucoin*, 2012 WL 2990697 at *10 ("Plaintiff has not alleged that there existed an alternative design for the drug, an "essential element" of a LPLA design defect claim. Further, Plaintiff has not alleged that the burden on the manufacturer to develop such a drug outweighed the dangers posed by the current design.").

> of such characteristic, or who would have acquired such knowledge had he acted as a reasonably prudent manufacturer, is liable for damage caused by his subsequent failure to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product.[121]

In *Willett v. Baxter Intern., Inc.*, the United States Court of Appeals for the Fifth Circuit observed that Louisiana courts apply the "learned intermediary doctrine" in failure-to-warn cases:

> With regard to prescription drugs and medical products such as these heart valves, Louisiana follows the learned intermediary doctrine. Under this doctrine, the manufacturer has no duty to warn the patient, but need only warn the patient's physician.
>
> To recover for a failure to warn under this doctrine, a plaintiff must show: (1) that the defendant failed to warn the physician of a risk associated with the use of the product, not otherwise known to the physician, and (2) that the failure to warn the physician was both a cause in fact and the proximate cause of the plaintiff's injury. Because the defective aspect of the product must cause the injury, the plaintiff must show that a proper warning would have changed the decision of the treating physician, i.e. that but for the inadequate warning, the treating physician would not have used or prescribed the product.[122]

The Hargroves, under the LPLA heading in their complaint, allege that "Defendant failed to warn the end user about the dangers and risks of the Pathfinder Exchange Guidewire."[123] These conclusory allegations do not address whether "a proper warning would have changed the decision of the treating physician." Accordingly, they fail to state a claim under this prong of the LPLA.[124]

4. Whether the Hargroves Have Stated a Claim Under the LPLA

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[121] LA. REV. STAT. 9:2800.57.

[122] 929 F.2d 1094, 1098-99 (5th Cir. 1991)

[123] Rec. Doc. 7 at p. 14.

[124] In LA. REV. STAT. § 9:2800.58, the LPLA specifies the requirements for a claim based on "nonconformity to express warranty." The Hargroves do not allege that the guidewire failed to conform to an express warranty.

To state a claim under the LPLA, plaintiffs must allege that: (1) the product at issue possesses an unreasonably dangerous characteristic; (2) the unreasonably dangerous characteristic proximately caused the plaintiff's damage; and (3) the plaintiff's injury arose from a reasonably anticipated use of the product. Here, the Hargroves have alleged (1) that the guidewire was defectively manufactured, potentially rendering it unsafe for use in Ms. Hargrove's ERCP procedure than other guidewires in the product line; (2) as a result of that alleged manufacturing defect, the guidewire broke off within Ms. Hargrove's body, injuring her; and (3) the breakage occurred during an ERCP procedure in which the guidewire was intended to be used. Therefore, the Hargroves have stated a claim under the LPLA's "construction and composition" theory. The Hargroves have failed to state a claim under any other LPLA theory.

5. Redhibition

The Hargroves, alleging redhibition, claim that they are:

> [E]ntitled to return of any purchase price paid, including by not limited to, insurance co-payments, interest on these amounts from the date of purchase, attorneys fees and costs, pecuniary and non-pecuniary damages, as well as any other legal and equitable relief to which plaintiffs may be entitled.[125]

Boston Scientific contends that the LPLA only permits parties alleging redhibition to recover for economic loss and attorney's fees allocated "to the recovery of pure economic loss."[126] The LPLA defines compensable "damages" as:

> [A]ll damage caused by a product, including survival and wrongful death damages, for which Civil Code Articles 2315, 2315.1 and 2315.2 allow recovery. "Damage" includes damage to the product itself and economic loss arising from a deficiency in or loss of use of the product only to the extent that Chapter 9 of Title VII of Book III

[125] Rec. Doc. 7 at p. 15.

[126] Rec. Doc. 14–1 at pp. 16–17.

> of the Civil Code, entitled "Redhibition," does not allow recovery for such damage or economic loss. Attorneys' fees are not recoverable under this Chapter.[127]

The United States Court of Appeals for the Fifth Circuit, addressing the effect of the LPLA on redhibition actions, has stated that:

> The [LPLA] . . . defines "damage" by explicitly excluding amounts recoverable under redhibition for damage to the product and other economic loss. Courts have interpreted the LPLA as preserving redhibition as a cause of action only to the extent the claimant seeks to recover the value of the product or other economic loss.[128]

The Louisiana Supreme Court, addressing the same issue, concluded that:

> [T]he LPLA defines "damage" by explicitly excluding amounts recoverable under redhibition for damage to the product and economic loss arising from a deficiency in or loss of use of the product. Thus, while the LPLA is the exclusive remedy against manufacturers for damages resulting from a defective product, a manufacturer can still be liable for damages in redhibition.[129]

Similarly, the Louisiana Fourth Circuit Court of Appeal held that:

> Courts have interpreted the LPLA as preserving redhibition as a cause of action only to the extent the claimant seeks to recover the value of the product or other economic loss . . . Thus, we conclude that the respondents have a cause of action for redhibition for economic loss only and not for personal injury claims.[130]

Thus, under the LPLA, the Hargroves may bring a redhibition claim against Boston Scientific, but may only recover the value of the product and other economic loss arising from a deficiency in the product.

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[127] LA. REV. STAT. § 9:2800.53.

[128] *Pipitone v. Biomatrix, Inc.*, 288 F.3d 239 (5th Cir. 2002) (citations omitted).

[129] *Aucoin v. So. Quality Homes, LLC*, 2007-1014 (La. 2/26/08), 984 So.2d 685, 691 n. 8 (citations omitted).

[130] *De Atley v. Victoria's Secret Catalogue, LLC*. 2004-0661 (La. App. 4 Cir. 5/14/04), 876 So.2d 112, 113.

The LPLA expressly bars the recovery of attorney's fees. Courts that have addressed claims for attorney's fees in cases involving both LPLA claims and redhibition claims have concluded that claims for attorney's fees are only compensable to the extent that the fees relate to economic loss.[131] Addressing this issue, the United States Court of Appeal for the Fifth Circuit has reasoned that:

> "Damage" under the LPLA . . . is a defined term, and it usually does not include "damage to the product itself [or] economic loss." Accordingly, the parties agree that the LPLA precludes Chevron's redhibition claim—and, consequently, its entitlement to attorney fees—unless the jury awarded damages to compensate for "damage to [the bolts themselves or] economic loss," which are recoverable in redhibition.[132]

The Hargroves have not alleged that they are entitled to attorney's fees exceeding those recoverable on the basis of economic loss, and the parties have not addressed whether the Hargroves' specific redhibition claims are recoverable. To the extent that the Hargroves seek to recover damages and attorney's fees in redhibition for anything other than economic loss, they have failed to state a claim upon which relief can be granted.

Nonetheless, the Court presently has no basis to dismiss the Hargroves' redhibition claims as a result of the limitations on recovery it has just described. Under LA. CIV. CODE art. 2520:

> The seller warrants the buyer against redhibitory defects, or vices, in the thing sold.
>
> A defect is redhibitory when it renders the thing useless, or its use so inconvenient that it must be presumed that a buyer would not have bought the thing had he known

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[131] *See Chevron U.S.A. v. Aker Maritime, Inc.*, 604 F.3d 888, 900 (5th Cir. 2010). *See also Hollybrook Cottonseed Prc., LLC v. Carver, Inc.*, No. 09-750, 2011 WL 2214936 at *3 (W.D. La. Jun. 6, 2011) ("The Court holds that, upon a finding of bad-faith redhibition, Plaintiff may recover attorney fees insofar 'as those fees relate to the recovery of purely economic loss' in accordance with *De Atley*."); *Safeco Ins. Co. of Am. v. Chrysler Corp.*, 2001-1641 (La. App. 3 Cir. 7/31/02) (quoting FRANK L. MARAIST & THOMAS C. GALLIGAN, JR., LOUISIANA TORT LAW § 15-6 (1996)) (concluding that attorney's fees for redhibition may be awarded only "[i]nsofar as those fees relate to the recovery of purely economic loss. This is because much of the proof of a "vice" for redhibition recovery overlaps with proof of a defective product for tort purposes. However, courts in such suits should be careful to realistically allocate recovery costs between the personal injury and economic loss portions of the claim.").

[132] *Chevron*, 604 F.3d at 900.

> of the defect. The existence of such a defect gives a buyer the right to obtain rescission of the sale.

Further, under LA. CIV. CODE art. 2545:

> A seller who knows that the thing he sells has a defect but omits to declare it, or a seller who declares that the thing has a quality that he knows it does not have, is liable to the buyer for the return of the price with interest from the time it was paid, for the reimbursement of the reasonable expenses occasioned by the sale and those incurred for the preservation of the thing, and also for damages and reasonable attorney fees. If the use made of the thing, or the fruits it might have yielded, were of some value to the buyer, such a seller may be allowed credit for such use or fruits. A seller is deemed to know that the thing he sells has a redhibitory defect when he is a manufacturer of that thing.

The Hargroves allege, among other things, that: (1) Boston Scientific was aware of, but did not disclose, the substantial risks from using the guidewire; (2) Boston Scientific "impliedly warranted" that the guidewire was safe for its intended use, which Boston Scientific knew or should have known to be ERCP procedures; (3) the Hargroves, along with their physicians and healthcare providers, relied on Boston Scientific's judgment, indications and statements that the guidewire was fit for ERCP procedures; (4) the guidewire, as sold, was unsafe for its intended use, as Ms. Hargrove's experience demonstrates; and (6) if Ms. Hargrove were aware of the defects associated with the guidewire, she would not have had it used during her ERCP.[133] Consequently, the Hargroves allege that they are "entitled to return of any purchase price paid," including "insurance co-payments" and "interest on these amounts from the date of purchase," as well as "pecuniary damages . . . [and] any other legal and equitable relief to which plaintiffs may be entitled."

[133] Rec. Doc. 7 at 14–15.

Since Boston Scientific has presented the Court with no authority or argument regarding whether these claims are compensable "economic loss[es] arising from a deficiency in or loss of use of the product,"[134] the Court will not dismiss them on the present motion.

6. The Hargroves' Remaining Allegations

In their complaint, the Hargroves make allegations of negligence,[135] deceptive practices,[136] that the guidewire was "inherently dangerous,"[137] and breach of implied warranty.[138] The Hargroves also cite at length to Federal statues and regulations pertaining to medical devices, and only connect these citations to the present case by stating that the guidewire "was approved for sale in the United States via a 510k approval process."[139] These allegations do not fall within the LPLA's "construction and composition," "design," "inadequate warning," or "nonconformity to express warranty"

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[134] *Aucoin*, 984 So.2d at 691.

[135] Rec. Doc. 7 at p. 1 ("This is an action for damages suffered by Plaintiffs as a direct and proximate result of the Defendant's negligent and wrongful conduct . . .").

[136] *Id.* at p. 12 ("Defendant created a duty . . . to refrain from unfair or deceptive acts and practices . . .Had the defendant not engaged in the deceptive conduct described above . . .").

[137] *Id.* at p. 13 ("The Pathfinder Exchange Guideware, implanted in Plaintiff, at the time it left the possession of the Defendant was inherently dangerous for its intended use and was unreasonably dangerous products [sic] which presented and constituted an unreasonable risk of danger and injury to the Plaintiff as follows . . .").

[138] *Id.* at p. 14 ("Defendant implied warranted to Plaintiff, Plaintiff's physicians, and healthcare providers . . ."). The Hargroves make these claims the heading of "Redhibition," which is addressed separately, above.

[139] Rec. Doc. 7 at p. 11. Boston Scientific interprets this portion of the Hargroves' complaint as an additional theory of recovery. Rec. Doc. 14–1 at 15 ("Plaintiffs allege that the failure to comply with . . . [the federal] provisions 'renders a device adulterated.'"). In their opposition, the Hargroves do not address the connection between federal medical device regulations and statutes and their allegations under Louisiana law. To the extent that the Hargroves allege that violations of Federal medical regulations provides an independent basis for recovery under Louisiana law, they are incorrect. *See Theriot v. Danek Med.*, No. 94-2626, 1997 WL 1949373 at *2 (E.D. La. Dec. 5, 1997) *aff'd* 168 F.3d 253 (5th Cir. 1999) ("Louisiana Law does not recognize any claim for violations of FDA regulations. The only remedies available to plaintiff in this case are provided in the Louisiana Products Liability Act (LPLA))"

categories. Thus, to the extent that the Hargroves have alleged independent causes of action for negligence, deceptive practices, "inherently dangerous" product liability, and breach of implied warranty, their claims are not cognizable under the LPLA. And because the LPLA is the exclusive remedy for product liability tort claims under Louisiana law, the Hargroves' tort claims sounding in these theories are dismissed.

D. Whether the Hargroves May Amend their Complaint

In their opposition, the Hargroves contend, in the alternative, that the Court should grant them leave to amend their complaint under Federal Rule of Civil Procedure 15,[140] if it determines that they have failed to state a claim.[141] Boston Scientific contends that "[p]laintiffs are not entitled to amend their complaint yet again," but cites no authority in support if its assertion.[142]

Federal Rule of Civil Procedure 15(a)(1)–(2) provides:

> **(a) Amendments Before Trial.**
>
> **(1) Amending as a Matter of Course.** A party may amend its pleading once as a matter of course within:
>
> **(A)** 21 days after serving it, or
>
> **(B)** if the pleading is one to which a responsive pleading is required, 21 days after service of a responsive pleading or 21 days after service of a motion under Rule 12(b), (e), or (f), whichever is earlier.

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[140] Pending the Court's resolution of this pending motion, no scheduling order has been in effect in this case. *See* Rec. Doc. 25. If a scheduling order had been in effect, Federal Rule of Civil Procedure 16(b)(4) would control whether the Hargroves could amend their pleadings; that Rule provides that "[a] schedule may be modified only for good cause and with the judge's consent." Since no scheduling order has been in effect, Federal Rule of Civil Procedure 15 governs whether the Hargroves may amend their pleadings.

[141] Rec. Doc. 16 at p. 10.

[142] Rec. Doc. 19 at pp. 7–8.

> **(2)** Other Amendments. In all other cases, a party may amend its pleading only with the opposing party's written consent or the court's leave. The court should freely give leave when justice so requires.

In *Forman v. Davis*, the United States Supreme Court concluded that:

> If the underlying facts or circumstances relied upon by a plaintiff may be a proper subject of relief, he ought to be afforded an opportunity to test his claim on the merits. In the absence of any apparent or declared reason—such as 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.—the leave sought should, as the rules require, be "freely given."[143]

The United States Court of Appeals for the Fifth Circuit has concluded that Federal Rule of Civil Procedure 15(a)(2) establishes a standard that "evinces a bias in favor of granting leave to amend."[144] The court has also held that:

> In view of the consequences of dismissal on the complaint alone, and the pull to decide cases on the merits rather than on the sufficiency of pleadings, district courts often afford plaintiffs at least one opportunity to cure pleading deficiencies before dismissing a case, unless it is clear that the defects are incurable or the plaintiffs advise the court that they are unwilling or unable to amend in a manner that will avoid dismissal.[145]

The Hargroves have presently stated claims under the LPLA's "construction and composition" theory and in redhibition. Boston Scientific maintains that the Hargroves have not yet cured the deficiencies in their pleadings, and will not do not do so if given the opportunity to amend them.[146] The Court, however, is mindful of the "bias in favor of granting leave to amend" created by Federal

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[143] 371 U.S. 178, 182 (1962).

[144] *Carroll v. Fort James Corp.*, 470 F.3d 1171, 1175 (2006).

[145] *Great Plains Trust Co. v. Morgan Stanley Dean Witter & Co.*, 313 F.3d 305, 329 (5th Cir. 2002).

[146] Rec. Doc. 19 at p. 8.

Rule of Civil Procedure 15(a)(2), and notes that Boston Scientific has provided no authority to support its assertion that the Hargroves should not be granted leave to amend. Accordingly, the Court grants the Hargroves 30 days to amend their LPLA claims. If they fail to address the present deficiencies in their pleadings, all but their redhibition and LPLA "construction and composition" claims will be dismissed.

IV. Conclusion

In light of the foregoing, the Court concludes that the Hargroves' factual allegations, taken as true, could support the Hargroves' claim that prescription was tolled pursuant to the doctrine of *contra non valentem*. Therefore, the Court denies Boston Scientific's motion to dismiss on the basis of prescription.

The LPLA is the Hargroves' only available remedy under Louisiana law for personal injury damages arising from the defective guidewire. To state a cause of action under the LPLA, a plaintiff must allege that a product (1) possesses an unreasonably dangerous characteristic; (2) that this unreasonably dangerous characteristic proximately caused the plaintiff's damage; and (3) that the damage arose from a reasonably anticipated use of the product. The LPLA sets forth four theories under which a plaintiff may show that a product is unreasonably dangerous: construction and composition, design, inadequate warning, and nonconformity to express warranty. The Hargroves have plausibly stated an LPLA claim under a "construction and composition" theory, and Boston Scientific's motion to dismiss is denied as to this claim.

The Hargroves also appear to have stated a plausible redhibition claim, which may be brought consistent with the LPLA, albeit only for claims of economic loss and attorney's fees arising from economic loss. Accordingly, the Court denies Boston Scientific's motion to dismiss as to this claim.

To the extent that their complaint makes allegations under any LPLA theory other than "construction or composition," the Hargroves have failed to state a claim. Applying Federal Rule of Civil Procedure 15(a)(2), the Court grants the Hargroves 30 days to amend their complaint as to their LPLA claims.

To the extent that the Hargroves have alleged independent causes of action under Louisiana law for personal injuries arising from negligence, deceptive practices, "inherently dangerous" product liability, breach of implied warranty, and violation of FDA regulations, their claims are not cognizable under the LPLA. The court grants Boston Scientific's motion as to these claims. Accordingly,

IT IS ORDERED that Defendant Boston Scientific's "Motion to Dismiss First Amended Complaint Under Fed. R. Civ. P. 12(b)(6)"[147] is **GRANTED IN PART AND DENIED IN PART**.

IT IS ORDERED that Defendant Boston Scientific's "Motion to Dismiss First Amended Complaint Under Fed. R. Civ. P. 12(b)(6)"[148] is **GRANTED** regarding Plaintiffs John Burns and Donna Hargrove's independent causes of action under Louisiana law for negligence, deceptive practices, "inherently dangerous" product liability, breach of implied warranty, and violation of FDA regulations.

IT IS FURTHER ORDERED that Defendant Boston Scientific's "Motion to Dismiss First Amended Complaint Under Fed. R. Civ. P. 12(b)(6)" is **DENIED** as it requests dismissal on the basis of prescription and failure to state a claim for redhibition.

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[147] Rec. Doc. 14.

[148] *Id.*

IT IS FURTHER ORDERED that Plaintiffs John Burns and Donna Hargrove have 30 days to amend their complaint to address the deficiencies identified herein.

NEW ORLEANS, LOUISIANA, this 24th day of September, 2014.

Nannette Jolivette Brown

NANNETTE JOLIVETTE BROWN
UNITED STATES DISTRICT JUDGE