UNITED STATES DISTRICT COURT

MIDDLE DISTRICT OF LOUISIANA

WILLIAM F. BOUTTE, JR. **CIVIL ACTION**

VERSUS

STRYKER BIOTECH, LLC, ET AL. **NO.: 14-00456-BAJ-SCR**

RULING AND ORDER

Before the Court is Defendants' **Rule 12(b)(6) Motion to Dismiss for Failure to State a Claim (Doc. 12)**, filed by Stryker Biotech, LLC, Howmedica Osteonics Corp., and Stryker Corporation, seeking an order from this Court dismissing William F. Boutte, Jr.'s claims against them, pursuant to Federal Rule of Civil Procedure ("Rule") 12(b)(6). Boutte opposes the motion. (Doc. 18). Stryker filed a reply memorandum in opposition. (Doc. 21). Boutte filed a sur-reply in response. (Doc. 25). Boutte also filed an Alternative Request, pursuant to Rule 15(a), requesting leave to amend his petition should the Court grant any aspect of Stryker's contested motion to dismiss. (Doc. 23). Oral argument was heard on December 3, 2014. (Doc. 33). The Court has jurisdiction pursuant to 28 U.S.C. § 1332.

I. Background

William F. Boutte, Jr. ("Boutte") commenced the instant action in the Ninteenth Judicial District for the Parish of East Baton Rouge on June 17, 2014, against Stryker Biotech, LLC, Howmedica Osteonics Corp., Stryker Corporation,

and Holly K. Pisarello,[1] (collectively, "Stryker"), seeking damages for injuries allegedly associated with the combination of two prescription medical devices, OP-1 Putty and Calstrux. (Doc. 1-2). On July 22, 2014, following service of the petition, Stryker timely removed the action to the United States District Court for the Middle District of Louisiana on the basis of diversity jurisdiction. (Doc. 1). Boutte's claims include liability for defective products, redhibitory defects, negligence, and fraud. (*See* Doc. 1-2).

In short, Boutte's petition alleges that on November 15, 2006, his surgeon, Dr. Kyle Girod, "performed a Posterolateral fusion procedure" on him to address "a broken screw at his S1 disc from a previous spinal fusion surgery." (*Id.* at ¶¶ 90-92). The following day, "Dr. Girod performed a second spinal fusion surgery known as a two-level Anterior Lumbar Interbody Fusion," which included implanting Boutte with "two PEEK cage (also manufactured by the Stryker Defendants), filled with a combination of OP-1 Putty and Calstrux, in his L4-5 and L5-S1 disc space." (*Id.* at ¶ 93). Boutte alleges that the use of the OP-1/Calstrux mixture in his surgery resulted in serious adverse effects, including, but not limited to migration of OP-1 and Calstrux, which caused the development of unwanted ectopic bone overgrowth, nerve damage, exacerbated pain, and the need for further remedial surgery. (*Id.* at ¶ 96-98).

OP-1 Putty is a bone morphogenetic protein that can "stimulate, repair, and regenerate bone" by transforming cells in the body to new bone. (*Id.* at ¶ 18). On April 7, 2004, the Food and Drug Administration ("FDA") granted a Humanitarian

[1] One of the defendants, Holly K. Pisarello was fraudulently joined. (*See* Docs. 1-2; 4).

Device Exemption for OP-1 Putty for "use as an alternative to autograft in compromised patients requiring revision posterolateral . . . lumbar spinal fusion, for whom autologous bone and bone marrow harvest are not feasible or are not expected to promote fusion." (*Id.* at ¶ 20). By contrast, Calstrux is a bone void filler intended to provide a structure on which new bone may grow. (*Id.* at ¶ 34). Calstrux was developed "to be mixed with the OP-1 products . . . to increase the volume and improve the handling qualities of OP-1." (*Id.* at ¶ 29). On August 26, 2004, the FDA approved the marketing of Calstrux as "a bone filler for voids or gaps that are not intrinsic to the stability of the bony structure. It [was] indicated for surgically created osseous [bony] defects or osseous defects resulting from traumatic injury." (*Id.* at ¶ 34).

Though OP-1 and Calstrux were independently approved by the FDA, the combinatory product has never been approved, and indeed, Stryker's application for approval was formally denied because of safety concerns. (*Id.* at ¶¶ 32-33, 39-48). Despite the FDA's denial, Stryker began to promote the use of OP-1 and Calstrux in combination for unapproved/off-label procedures. (*Id.* at ¶¶ 48-76).

In early 2006, Stryker's employees and surgical consultants informed it of the adverse effects and lack of efficacy associated with the OP-1/Calstrux mixture. (*Id.* at ¶ 55). Several employees, including "the vice president of regulatory," drafted a "proposed 'Dear Doctor' letter to warn surgeons not to mix Calstrux with OP-1." (*Id.* at ¶ 59). Specifically, the letter would have cautioned surgeons to "refrain from implanting OP-1 combined with Calstrux in patients until such time that the safety

and efficacy of [the] OP-1 implant combined with Calstrux is established." (*Id.*). However, several sales representatives convinced the company to not send the warning letter as it would seriously affect OP-1 sales. (*Id.* at ¶¶ 60-65). Allegedly fearing the loss of sales, Stryker chose not to send the "Dear Doctor" letter. (*Id.* at ¶¶ 63-64).

With respect to the instant case, Boutte alleges that Stryker and its sales representatives "directly and indirectly promoted, trained and encouraged Dr. Girod and the hospital staff to engage in the off-label procedure of mixing Calstrux with OP-1 Putty." (*Id.* at ¶ 94). Boutte asserts that as a result of Stryker's practices, he "suffered debilitating injuries" due to Stryker's "off-label implantation of the ineffective and unsafe Calstrux/OP-1 in his lumbar spine," and initiated the instant action to seek redress for his injuries. (Doc. 18 at p. 6).

II. Standard of Review

A Rule 12(b)(6) motion to dismiss tests the sufficiency of the complaint against the legal standard set forth in Rule 8, which requires "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "Determining whether a complaint states a plausible claim for relief [is] . . . a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 679. "[F]acial plausibility" exists

"when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 678 (citing *Twombly*, 550 U.S. at 556). Hence, the complaint need not set out "detailed factual allegations," but something "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action" is required. *Twombly*, 550 U.S. at 555.

Further, the United States Supreme Court has noted that Rule 12(b)(6) requires dismissal whenever a claim is based on an invalid legal theory:

> Nothing in Rule 12(b)(6) confines its sweep to claims of law which are obviously insupportable. On the contrary, if as a matter of law "it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations," . . . a claim must be dismissed, without regard to whether it is based on an outlandish legal theory, or on a close but ultimately unavailing one.

Neitzke v. Williams, 490 U.S. 319, 327 (1989) (internal citations omitted). When a complaint fails to satisfy these principles, "this basic deficiency should be exposed at the point of minimum expenditure of time and money by the parties and the court." *Cuvillier v. Sullivan*, 503 F.3d 397, 401 (5th Cir. 2007) (quoting *Twombly*, 550 U.S. at 558).

III. Analysis

A. Louisiana Products Liability Act

The Louisiana Products Liability Act ("LPLA") establishes "the exclusive theories of liability for manufacturers for damage caused by their products." La. Rev. Stat. Ann. § 9:2800.52. Thus, a claimant may not recover on the basis of any theory not set forth in the LPLA. *Jefferson v. Lead Indus. Assoc., Inc.* 106 F.3d

1245, 1250–51 (5th Cir. 1997).

To properly state a claim under the LPLA, a plaintiff has the burden of proving that (1) the defendant is a manufacturer; (2) the damage sustained was proximately caused by a characteristic of a product that made it "unreasonably dangerous" in one of four ways; and (3) that injury resulted from a reasonably anticipated use. La. Rev. Stat. Ann. § 9:2800.54. A product may be held to be unreasonably dangerous because of: (1) defective design; (2) defective composition or construction; (3) inadequate warning; or (4) breach of an express warranty. La. Rev. Stat. Ann. § 9:2800.54(B). Boutte's petition invokes three of these four theories. Each will be considered in turn.

i. Design Defect

To state a viable claim that a product is "unreasonably dangerous in design," a plaintiff must demonstrate that at the time the product left the manufacturer's control, (1) "[t]here existed an alternative design for the product that was capable of preventing the claimant's damage;" and (2) "[t]he 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." La. Rev. Stat. Ann. §. 9:2800.56.

Stryker contends that Boutte's design defect claim should be dismissed pursuant to 12(b)(6) because it "makes the exact type of conclusory allegations" that are impermissible under *Twombly* and *Iqbal*. (Doc. 12-1 at p. 7). Specifically,

Stryker argues that Boutte has failed to allege any affirmative evidence of the existence of an alternative design. (*Id.*). Stryker further avers that Boutte's summary assertion that the likelihood that this "unidentified alternative design" would prevent his injury outweighs the burden of adopting the alternative design is similarly insufficient. (*Id.*).

In opposition, Boutte contends that his "petition provides detail[ed] allegations as to the shortcomings in the design of the combinatory OP-1/Calstrux device." (Doc. 18 at p. 14). The Court agrees. First, Boutte has alleged that the nature of the alleged defect is the deterioration of the combinatory product, which could "result in unwanted bone growth and migration of the bone to sensitive nerve areas exacerbating his pain and necessitating the need of additional surgeries." (*See* Doc. 1-2 at ¶¶ 95, 102). On just these facts, it appears as though Boutte has at least implicitly pled an alternative design – a combination that would not deteriorate the way the instant product mixture did.

More specifically, however, Boutte avers that the alternative design would have been to not promote the unapproved/off-label combined use of OP-1/Calstrux. (Doc. 18 at p. 15). Stated differently, the alternative design was for Stryker to "promote OP-1 as it has been *approved* by the FDA," and "to not impermissibly revamp OP-1's design by instructing surgeons and hospital technicians to combine it with Calstrux." (Doc. 25 at p. 2). In support, Boutte outlines how Stryker believed that OP-1 had insufficient volume and poor handling on its own, so Stryker developed the synthetic bone filler, Calstrux, to be used in combination with OP-1

as an extender or carrier. (Doc. 1-2 at ¶¶ 25-52). Each product was cleared for use separately, but the FDA denied Stryker's Investigational Device Exemption, which requested the ability to conduct clinical trials involving the combination use of OP-1/Calstrux. (*Id.* at ¶¶ 41-44). Indeed, the FDA never approved the combinatory product because of safety concerns associated with mixing the two. (*Id.* at ¶¶ 41-46). Yet, despite receiving the FDA's denial, Stryker began to promote the combined use as "safe and effective." (*Id.* at ¶¶ 47-48). Accordingly, the Court finds that Boutte has alleged sufficient facts to satisfy the alternative design element at this stage.

Boutte has also pled sufficient facts with respect to the second element, the likelihood that the product's design would cause the claimant's damage and that the gravity of that damage outweighed the burden on the manufacturer of adopting such alternative design. La. Rev. Stat. Ann. §. 9:2800.56. Boutte alleges that after learning that the product caused "serious adverse events," and lacked "efficacy," Stryker "rejected the advice of their own employees to pull Castrux from the market." (Doc. 1-2 at ¶¶ 55, 56). Boutte further alleges that Stryker considered sending a "Dear Doctor" letter to surgeons cautioning them about the combinatory product, and specifically urging that they "refrain[] from implanting OP-1 combined with Calstrux in patients until such time that the safety and efficacy of OP-1 Implant combined with Calstrux is established," but ultimately chose not to because disclosure would "hurt the OP-1 business." (*Id.* at ¶¶ 59, 64). In 2009, Stryker ceased manufacturing Calstrux and removed it from the market. (*Id.* at ¶ 56).

As Boutte highlights in his memorandum in opposition, it bears noting that although the standards of *Tombly* and *Iqbal* certainly govern this Court's decision, neither case was a products liability suit. (Doc. 18 at p. 16). Thus, while the holdings of *Twombly* and *Iqbal* are absolutely applicable, this is a complex medical device case in which almost all of the evidence is in Styker's possession or governed by a protective order that prohibits Boutte's counsel from publicly disclosing the documents. (*Id.*). Moreover, much of the evidence offered in support of Boutte's claims will almost certainly be technical in nature, and as a result, stating more specific allegations regarding defects in manufacture and design without first having the benefit of discovery and of expert analysis, may be nearly impossible at this stage. (*Id.*). *See Winslow v. W.L. Gore & Assoc, Inc.*, No. 10-116, 2011 WL 866184 at *2 (W. D. La. Jan. 21, 2011) *report and recommendation adopted as modified sub nom. Winslow v. W.L. Gore & Associates, Inc.*, No. 10-116, WL 873562 (W.D. La. Mar. 11, 2011).

To comply with Rule 8(a)(2), a plaintiff must "'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.'" *Twombly*, 550 U.S. at 555 (quoting *Conley v. Gibson*, 78 S.Ct. 99, 103 (1957)). Based on the foregoing, the Court finds that Boutte's petition has met this standard at this preliminary stage. Accordingly, Stryker's motion to dismiss Boutte's design defect claim is denied.

ii. Inadequate Warning

To state a viable claim that a product is "unreasonably dangerous because of inadequate warning," a plaintiff must demonstrate that at the time the product left

the manufacturer's control, (1) "the product possessed a characteristic that may cause damage" and (2) "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." La. Rev. Stat. Ann. § 9:2800.57.

Accepting Boutte's factual allegations as true, Stryker's motion to dismiss must be denied. In his petition, Boutte asserts that the mixture of OP-1 and Calstrux "had been proven ineffective and . . . the mixture of the[] two . . . could lead to unwanted bone growth, leakage and other serious medical complications which would require additional surgeries to remedy." (Doc. 1-2 at ¶ 102). With respect to Boutte's own injuries, he avers that the mixture "resulted in migration" that caused "extensive and substantial unwanted/ectopic bone overgrowth, exacerbated pain and nerve damage which has caused significant pain and suffering and has negatively impacted [his] personal and professional life." (*Id.* at ¶ 103). Accepting these allegations as true, Boutte has demonstrated that the first element, "the product possessed a characteristic that may cause damage," is met.

Boutte has also alleged sufficient facts to establish the second element, that "the manufacturer failed to use reasonable care to provide an adequate warning of such characteristic and its danger." In his petition, he alleges that the mixture of the two products "had never been approved by the FDA." (*Id.* at ¶ 101). Regardless, Stryker "illegally promoted these products beyond the legal and limited uses for which they had been approved," and failed "to inform physicians, hospitals and the public regarding the limited uses for which they have been approved," or that the

mixture could result in severe complications. (*Id.* at ¶¶ 101-102).

In support of its motion, Stryker avers that the package insert that accompanied the OP-1 Putty expressly warned of the side effect Boutte complains of – "localized ectopic or heterotopic bone formation . . . outside the treatment site." (Doc. 12-1 at p. 9; Doc. 12-2). However, Boutte's petition concerns side effects resulting from the *mixture* of OP-1 and Calstrux, which could fairly be viewed as a third, separate product. In addition, Boutte's claim is further supported by his allegation that Stryker ultimately removed Calstrux from the market, but only *after* the FDA performed an inspection and issued a formal reprimand to Stryker arising out of its illegal off-label promotion and its failure to report serious adverse effects associated with the OP-1/Calstrux mixture. (Doc. 18 at p. 10-11; Doc. 1-2 at ¶¶ 56, 83-85). Given this, the Court holds that Boutte's petition contains sufficient factual matter, which, if accepted as true, states a claim of inadequate warning that is plausible on its face. Therefore, Stryker's motion to dismiss Boutte's inadequate warning claim is denied.

iii. Breach of Express Warranty

Finally, to state a viable claim that a product is "unreasonably dangerous because of nonconformity to express warranty," a plaintiff must demonstrate that (1) an express warranty existed, (2) he or she was induced to purchase the product due to the warranty, and (3) his or her damage was proximately caused because the express warranty was untrue. La. Rev. Stat. Ann. § 9:2800.58.

Stryker contends that Boutte's breach of express warranty claim should be

dismissed, citing to an case from the Western District of Louisiana involving similar allegations of aggressive promotion of a dangerously defective product for support. (Doc. 12-1 at pp. 9-10); *Kennedy v. Pfizer*, No. 12-01858, 2013 WL 4590331 (W.D. La. Aug. 28, 2012). In *Kennedy*, the court held that although it was "unnecessary for the Plaintiffs to cite a specific express warranty, it [was] necessary to articulate how the equivalent marketing materials are false," which the plaintiffs failed to do. *Id.* at 5. Stryker argues that Boutte's petition suffers from the same deficiency. (Doc. 12-1 at p. 10). The key difference here is that Boutte asserts that Stryker made misrepresentations in marketing the mixture of OP-1/Calstrux. In fact, Boutte's petition alleges what amounts to an "elaborate scheme" by Stryker to promote Calstrux as the "preferred" and "perfect carrier for OP-1," and assuring the medical community that the combination was "safe and effective," while knowing that the combined used of the products remained untested, ineffective, and unsafe. (*See* Doc. 18 at p. 17; Doc. 1-2 at ¶¶ 49-66, 69, 71, 74, 94, 98, 107, 124). *See Harris v. Merck & Co., Inc., et al.*, No. 12-1446, 2012 WL 5384720 at *5 (Nov. 1, 2012) (holding that plaintiff met the basic requirements of Rule 8(A) in petition generally alleging that but-for defendant-manufacturer's aggressive marketing program, which included false representations, defendant-manufacturer would not have gained the market share that it eventually acquired).

Boutte further alleges that in addition to withholding information from the medical community, Stryker's sales team and management convinced the company that issuance of a warning would undermine sales. (Doc. 1-2 at ¶¶ 58-64, 61) ("If we

eliminate the ability to mix these two together, we will be in jeopardy of losing a significant portion of our core OP-1 sales."). In reliance upon Stryker's representations, Boutte's surgeon then mixed OP-1 with Calstrux and used the combinatory product in Plaintiff's surgery. (*Id.* at ¶¶ 71, 93, 94, 107, 124). The mixture migrated, resulting in the development of unwanted bone growth, which caused injury, damage, and significant pain. (*Id.* at ¶¶ 96-98; Doc. 18 at p. 17). Therefore, Boutte has pled sufficient facts to establish the elements of his breach of express warranty claim.

Finding that Boutte has plead "factual content that allows the [C]ourt to draw the reasonable inference that the defendant is liable for the misconduct alleged," *Iqbal*, 556 U.S. at 578, the Court will deny Stryker's motion with respect to Boutte's breach of express warranty claim.

B. Redhibition

Under Louisiana law, a seller "warrants the buyer against redhibitory defects, or vices, in the thing sold." La. Civ. Code art. 2520.[2] Though the LPLA establishes the exclusive theory of liability against manufacturers for products that cause injury, both parties acknowledge that courts have interpreted the LPLA as preserving redhibition as a cause of action to the extent that the plaintiff seeks recovery of economic losses. *See Pipitone v. Biomatrix*, 288 F.3d 239, 251 (5th Cir. 2002).

[2] La. Civ. Code art. 2520 further provides:

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

Stryker contends that Boutte's redhibition claim must be dismissed because Boutte was not the purchaser of OP-1 or Calstrux. (Doc. 12-1 at p. 14). However, as Boutte highlights in his memorandum in opposition, Stryker makes this assertion without citation to applicable authority. (Doc. 18 at p. 18). Moreover, Stryker reiterates its contention that "the products performed as expected and Plaintiff experienced a known complication of the product, clearly identified on its warning label." (Doc. 12-1 at pp. 14-15). Again, as noted previously, this assertion ignores that the combinatory product can effectively be seen as a third product, separate from its two component parts.

Given that Boutte's petition states competent evidence of defect, and finding that other courts have allowed plaintiffs to proceed with redhibition claims under similar circumstances, the Court will reject Stryker's argument regarding the validity of Boutte's redhibition at this stage, and preserve Boutte's claim for further proceedings. *See Harris v. Merck & Co., Inc., et al.*, No. 12-1446, 2012 WL 5384720 (Nov. 1, 2012) (permitting a redhibition claim by a plaintiff who took prescription medication as prescribed by her doctor against a drug manufacturer); *Nelson v. Mylan Pharmaceuticals, Inc.*, No. 10-0592, 2010 WL 3339274 (W.D. La. Aug. 3, 2010) *report and recommendation adopted by*, No. 10-0591, 2010 WL 3363039 (W.D. La. Aug. 24, 2010) (allowing a redhibition claim seeking economic damages filed by survivors to proceed against manufacturers of medication).

C. Negligence and Fraud[3]

In his memorandum in opposition, Boutte abandons his claim regarding fraud in acknowledgement that it falls outside the purview of the LPLA.[4] (Doc. 18 at p. 19). Accordingly, dismissal of this claim is appropriate.

Stryker avers that like Boutte's fraud claim, his negligence claim against Defendant Stryker Corporation is precluded by the exclusivity provision of the LPLA. (Doc. 12-1 at p. 15). In opposition, Boutte contends that "in other pending litigation, the Stryker defendants have generally taken the position that only Stryker Biotech, LLC was the manufacturer for Calstrux and OP-1, and that Stryker Corporation (who is the parent company of Stryker Biotech, LLC) was not involved in the manufacturing" of the products. (Doc. 18 at pp. 19-20). Accordingly, Boutte argues that should Stryker adopt a similar position in the instant case, his negligence claim would not be subject to LPLA exclusivity, and therefore, dismissal would not be appropriate. (Doc. 18 at p. 20). Alternatively, Boutte offers that if Defendant Stryker Corporation is willing to stipulate that it was a manufacturer of OP-1 and Calstrux, and therefore subject to the LPLA, then Boutte will agree to

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[3] All claims against Defendant Holly K. Pisarello were previously dismissed voluntarily without prejudice. (*See* Doc. 16).

[4] As discussed previously, the LPLA sets forth a circumscribed framework for products liability cases in Louisiana. It is the only means by which plaintiffs may assert manufacturer liability for defective products. *See* La. R.S. 9:2800.52 (The LPLA provides "the exclusive theories of liability for manufacturers for damage caused by their products." Thus, "[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 the LPLA.); *Brown v. R.J. Reynolds Tobacco Co.*, 52 F.3d 524, 526 (5th Cir. 1995). Given the exclusivity of the LPLA, any causes of action inconsistent with it must be dismissed. Accordingly, although Plaintiff characterizes his dismissal of his fraud count as "voluntary," it is actually compulsory. *See* La. R.S. 9:2800.52; *Jefferson v. Lead Indus. Assoc., Inc.*, 930 F. Supp. 241, 243 (E.D. La. 1996), *affirmed*, 106 F.3d 1245 (5th Cir. 1997) (holding that strict liability, negligence, breach of implied warranty, fraud by misrepresentation are not cognizable under the LPLA).

dismiss his negligence claim as well. (*Id.*).

In its reply memorandum, Stryker does not agree to stipulate that Stryker Corporation is a manufacturer, but instead, reiterates that the exclusivity bar of the LPLA extends to claims against parent corporations of a manufacturer. (Doc. 21 at p. 6). In support, Stryker cites to only one case, *Andry v. Murphy Oil, U.S.A., Inc.*, 935 So. 2d 239, 249-50 (La. App. 4 Cir. 2006), which held that "Louisiana law does not permit a court to hold the parent company liable for its subsidiary's actions." What Stryker selectively omitted from their citation was the caveat to the general rule that liability does not apply "*without proof that the parent company knew of and approved those actions*."[5] *Id.* Boutte's petition makes allegations that Stryker Corporation recommended and directed Stryker Biotech to not disclose adverse experiences associated with the mixture of OP-1 and Calstrux, nor advise Stryker Biotech that Calstrux should be removed from the market until several years later. (Doc. 1-2 at ¶¶ 56-65, 157-158). Thus, if accepted as true, Boutte's petition clearly alleges that Stryker Corporation "informed, instructed, and recommended" certain actions to Stryker Biotech regarding how to proceed with the marketing of OP-1 and Calstrux, and the issuance of warnings concerning the mixture. (Doc. 1-2 at ¶¶ 158-166). On this basis, dismissal of Boutte's claim of negligence against Stryker Corporation at this stage would be premature.

[5] Like Stryker, Boutte also cites to several cases which are unavailing. (Doc. 18 at p. 20). In the cases cited, the courts' analyses focused on whether defendants could be properly characterized as manufacturers under the LPLA (and thus subject to its exclusivity provision), or alternatively, if found to be non-manufacturer sellers, whether tort liability may be imposed on the basis that the defendants knew or should have known that the product was defective and failed to declare it. (*Id.*). However, it is not clear that Stryker Corporation was a "seller," within the meaning of the LPLA as neither Boutte's petition nor memoranda filed in response to the instant motion articulate this point with any clarity.

IV. Conclusion

Accordingly,

IT IS ORDERED that Defendants' **Motion to Dismiss (Doc. 12)** is **GRANTED IN PART** and **DENIED IN PART**.

- The motion is **DENIED** with respect to Plaintiff William F. Boutte, Jr.'s claim of design defect under the LPLA.
- The motion is **DENIED** with respect to Plaintiff William F. Boutte, Jr.'s claim of inadequate warning under the LPLA.
- The motion is **DENIED** with respect to Plaintiff William F. Boutte, Jr.'s claim of breach of express warranty under the LPLA.
- The motion is **DENIED** with respect to Plaintiff William F. Boutte, Jr.'s claim of redhibition.
- The motion is **GRANTED** with respect to Plaintiff William F. Boutte, Jr.'s claim of fraud.
- The motion is **DENIED** with respect to Plaintiff William F. Boutte, Jr.'s claim of negligence against Stryker Corporation only.

Baton Rouge, Louisiana, this 19th day of December, 2014.

BRIAN A. JACKSON, CHIEF JUDGE
UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF LOUISIANA