UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF LOUISIANA

JOHN JEFF LEMELLE	***CIVIL NO. 09-0987**
VERSUS	***JUDGE DOHERTY**
STRYKER ORTHOPAEDICS	***MAGISTRATE JUDGE HILL**

REPORT AND RECOMMENDATION
ON MOTION TO DISMISS

Pending before the undersigned for report and recommendation is the Motion to Dismiss Stryker Orthopaedics and Howmedica Osteonics Corp. filed by Stryker Orthopaedics ("Stryker") on August 26, 2009 [rec. doc. 7]. Plaintiff, John Jeff Lemelle ("Lemelle"), filed opposition. [rec. doc. 16]. Stryker filed a reply brief. [rec. doc. 20]. For the following reasons, it is recommended that the motion be **GRANTED IN PART AND DENIED IN PART**.

Background

Lemelle filed a Petition for Damages and/or Redhibition in the 27th Judicial District Court, St. Landry Parish, La., on May 12, 2009, alleging that he was damaged as a result defective hardware manufactured by Stryker which was used in his 2004 right hip replacement surgery. [rec. doc. 1, ¶ II]. The petition further alleges that on March 3, 2008, Lemelle's surgeon, Dr. John Cobb, received a letter dated February 28, 2008, from Stryker indicating that the Trident Hemispherical Acetabular Shells and Trident PSL Acetabular Shells used in Lemelle's procedure had been recalled. [rec. doc. 1, ¶ III]. Lemelle asserts that on May 13,

2008, he had to undergo a second surgery to replace the cut and screws in his right hip, which caused him damages.

On June 17, 2009, Stryker removed the case to this Court on the basis of federal diversity jurisdiction. On August 26, 2009, Stryker filed the instant motion to dismiss on the basis that plaintiff's state law claims related to the Trident™ System total hip prostheses (the "Trident system") were preempted by federal law.

Law and Analysis

Standard for Motion to Dismiss

In deciding a Rule 12(b)(6) motion to dismiss, the court "accepts all well-pleaded facts as true, viewing them in the light most favorable to the plaintiff." *Guidry v. American Public Life Ins. Co.*, 512 F.3d 177, 180 (5th Cir. 2007) (citing *In re Katrina Canal Breaches Litig.*, 495 F.3d 191, 205 (5th Cir. 2007), *petition for cert. filed*, (U.S. Nov. 26, 2007) (No. 07-713)). The plaintiff must plead "enough facts to state a claim to relief that is plausible on its face." *Id.*; *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 127 S.Ct. 1955, 1974, 167 L.Ed.2d 929 (2007). "Factual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Id.* at 1965 (citation and footnote omitted).

In resolving a Rule 12(b) motion, the court is generally limited to considering only those allegations appearing on the face of the complaint. *Cyrio v. Hunt*, 2007 WL 2772222 at * 4 (E.D. La. Sept. 19, 2007). However, matters of public record, orders, items appearing in the

record of the case and exhibits attached to the complaint may be taken into account. *Id*. (*citing Chester County Intermediate Unit v. Pennsylvania Blue Shield*, 896 F.2d 808, 812 (3rd Cir.1990)). "Documents that a defendant attaches to a motion to dismiss are considered part of the pleadings if they are referred to in the plaintiff's complaint and are central to [the] claim." *Causey v. Sewell Cadillac-Chevrolet, Inc*., 394 F.3d 285, 288 (5th Cir.2004) (citing *Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 498-99 (5th Cir.2000)).

Preemption

Stryker argues that Lemelle's claims are preempted by the U.S. Supreme Court's decision in *Riegel v. Medtronic*, 552 U.S. 312, 128 S.Ct. 999, 169 L.Ed.2d 892 (2008). *Riegel* held that the Medical Device Amendments of 1976, 21 U.S.C. § 360c *et seq*. ("MDA"), to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq*. ("FDCA"), bars common law claims challenging the safety and effectiveness of a medical device given premarket approval ("PMA") by the Food and Drug Administration ("FDA"). Specifically, the Supreme Court held that plaintiff's New York common law claims of negligence, strict liability, and implied warranty against the manufacturer, Metronic, were preempted under the MDA. Based on *Riegel*, Stryker argues, Lemelle's Louisiana law product liability claims related to the Trident system are preempted.

The FDCA has long required FDA approval for the introduction of new drugs into the market. *Riegel*, 128 S.Ct. at 1002-1003. Until the statutory enactment of the MDA in 1976, the introduction of new medical devices was left largely for the States to supervise as they saw fit.

Id. (*citing Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475-476, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996)).

With the passage of the MDA, Congress swept back some state obligations and imposed a regime of detailed federal oversight. Under the MDA, medical devices are classified in three categories, depending on the risks they present to the public. *Gomez v. St. Jude Medical Daig Div. Inc.*, 442 F.3d 919, 929 (5th Cir. 2006). "Devices that present no unreasonable risk of illness or injury are designated Class I and are subject only to minimal regulation by 'general controls.' " *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476-77, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996) (*citing* 21 U.S.C. § 360c(a)(1)(A)). "Devices that are potentially more harmful are designated Class II" and must comply with a set of regulations coined "special controls." *Lohr*, 518 U.S. at 477, 116 S.Ct. 2240 (*citing* 21 U.S.C. § 360c(a)(1)(B)). Devices that present "a potential unreasonable risk of illness or injury" or which are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" are designated Class III. 21 U.S.C. § 360c(a)(1)(C). The Trident system is a Class III medical device, meaning that it had received the highest level of federal oversight provided by the FDA. *Hofts v. Howmedica Osteonics Corporation*, 597 F.Supp.2d 830 (S.D. Ind. 2009); *Covert v. Stryker Corp.*, — F.Supp.2d —, 2009 WL 2424559 (M.D.N.C. Aug. 5, 2009); *Parker v. Stryker Corp.*, 584 F.Supp.2d 1298, 1300 (D.Colo. 2008).

Before a Class III device may be put on the market, the manufacturer must give the FDA "reasonable assurance" that the device is both safe and effective. *Gomez*, 442 F.3d at 928 (*citing* 21 U.S.C. § 360e(d)(2)). A manufacturer provides "reasonable assurance" through the PMA process. *Id*. The PMA process requires the manufacturer to "submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission." *Id*. (*quoting Lohr*, 518 U.S. at 477, 116 S.Ct. 2240. Significantly, the FDA's involvement with the devices continues even after the PMA is complete. *See, e.g.*, 21 C.F.R. § 814.80 (prohibiting the production or labeling of any device in a manner inconsistent with any conditions of approval specified in the approval order); 21 C.F.R. § 814.3a(d) (requiring an applicant to submit a supplemental application setting forth any proposed changes for FDA approval before implementing any changes).

Congress provided two exceptions to the PMA process. First, a grandfather clause permits medical devices marketed before passage of the amendments to remain unless and until the FDA initiates and completes the PMA process. *See Lohr*, 518 U.S. at 478, 116 S.Ct. 2240 (citing 21 U.S.C. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1)). Second, devices that are "substantially equivalent" to a preexisting medical device are exempt from the PMA process and instead subject to a streamlined approval process.[1] *See Lohr*, 518 U.S. at 492-94, 116 S.Ct. 2240 (describing the significant differences between the PMA and the "substantially similar" process under § 510(k)); 21 U.S.C. § 360e(b)(1)(B).

[1]This is also known as the "501(k) process," named after the subsection in the original act.

The MDA includes an express preemption provision that states:

> "Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement-
>
> "(1) which is *different from, or in addition to*, any requirement applicable under this chapter to the device, and
>
> "(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." § 360k(a).

(emphasis added).

The Fifth Circuit has held that the PMA process "preempts state tort causes of action to the extent that they relate to safety, effectiveness, or other MDA requirements" if the state-law claims impose "substantive requirements" different from, or inconsistent with, the federal law. *Gomez,* 442 F.3d at 929 (*citing Martin v. Medtronic, Inc*., 254 F.3d 573 (5th Cir. 2001)). *Martin* involved a Class III medical device (Medtronic's pacemaker) subject to the PMA process. There, the court held that the PMA requirements preempted Texas state product-liability tort claims arising from a Class III medical device, including claims of defective design, failure to warn, and inadequate labeling, because those claims related to areas specifically covered in the PMA process and sought to impose requirements that were "different from and, indeed, conflict with" the results of the PMA process. *Martin*, 254 F.3d at 584.

The Fifth Circuit requires the district court to look through the general duties imposed by the state-law causes of action and consider the effect a successful lawsuit asserting those causes of action would have and determine whether they threaten the federal PMA process

requirements. *Gomez*, 442 F.3d at 930.

Stryker argues that Lemelle's claims of defect under state law are governed by the Louisiana Products Liability Law ("LPLA"), LA. REV. STAT. § 9:2800.51 *et seq*., which is preempted by the MDA. [rec. doc. 7, pp. 10-11]. The Fifth Circuit has held that the MDA's express preemption provision precludes most product liability claims when the product was approved through the PMA process. *Gomez*, 442 F.3d at 932 (MDA preempted strict liability defective design and negligent design causes of action under LPLA).

Lemelle acknowledged both in his brief and at oral argument that his state-law product liability claims are preempted by the MDA. Thus, the unsigned recommends that the motion to dismiss be **granted** as to plaintiff's claims under LPLA.

However, Lemelle argues that his redhibition claim under LA. CIV. CODE art. 2520 *et seq*. is **not** preempted. [rec. doc. 16, p. 4]. Specifically, Lemelle argues that his redhibition claim is not preempted because it does not seek to impose different or additional requirements, but only parallels the federal requirements of the MDA.

In *Riegel*, the Supreme Court noted that "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements."). 128 S.Ct. at 1011 (*citing Lohr*, 518 U.S. at 495, 116 S.Ct. at 2255). Thus, this Court must determine whether Lemelle's redhibition claim is based on Louisiana requirements that are "different from, or in addition to" the federal requirements.

Courts are divided as to whether implied warranty claims are preempted. *Gomez*, 442 F.3d at 931 (claim for breach of implied warranty under Louisiana law preempted by MDA)[2]; *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F.Supp.2d 1147, 1161 (D.Minn.2009) (finding breach of express and implied warranty claims, fraud claims and claims for deceptive trade practices preempted); *Horowitz v. Stryker Corp.*, 613 F.Supp.2d 271 (E.D.N.Y. Feb.20, 2009) (breach of express warranty, implied warranty of fitness and implied warranty of merchantability claims, as well as state-law claim for deceptive trade practices, preempted); *Parker*, *supra* (breach of express warranty, implied warranty of fitness and implied warranty of merchantability claims preempted); *but cf. Hofts* (no preemption found).

Lemelle relies on *Hofts*, a case also involving the Trident system, to support the position that his redhibition claim survives preemption. There, the judge noted that *Riegel* allows a State to provide a damages remedy for violations of common-law duties when those duties "parallel" federal requirements. He determined that, under 21 U.S.C. § 360k(a)(1), *Riegel*, and *Lohr*, the court had to decide whether plaintiffs' tort, warranty and criminal commercial fraud claims were based on state law requirements which were "different from, or in addition to" the federal requirements. *Id*. at 835. In holding that these Indiana state law claims were not preempted, the court reasoned as follows:

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[2]A claim for breach of implied warranty arises under the redhibition chapter and allows recovery for damage to the product itself and economic loss. *Ivory v. Pfizer, Inc*., 2009 WL 3230611, at *7 (W.D. La. Sept. 30, 2009); *Dawson Farms, L.L.C. v. BASF Corp*., *et al*, 2008 WL 5220517, at *2 (W.D.La. Dec. 12, 2008).

> ... [T]he specific tort claims addressed in *Riegel* were not based on the defendant's alleged failure to follow federal requirements, but instead were based on the plaintiffs' allegations that Medtronic had breached state tort duties even though it had complied with federal requirements. *Riegel*, 128 S.Ct. at 1006, 1011.
> Here it is clear that Hofts bases his tort claims on his allegations that Howmedica failed to meet the FDA's requirements, not on allegations that Howmedica failed to depart from or exceed those requirements. A jury could find that Howmedica breached the duty of care it owed to Hofts by failing to adhere to the FDA's manufacturing requirements without imposing different or additional requirements. *See Lohr*, 518 U.S. at 495, 116 S.Ct. 2240. Similarly, on Hofts' strict liability claim, a jury could find that Howmedica's deviation from the FDA's manufacturing requirements was unreasonably dangerous without imposing different or additional requirements. If supported by the evidence, these results would be entirely consistent with the legal presumption that the FDA "got it right" in setting those requirements. A jury verdict could simply enforce those same federal requirements. The only state law requirements implicit in Hofts' tort claims are thus identical or parallel to the FDA's federal requirements under *Riegel*, so that Hofts' state tort claims are not preempted under section 360k(a).

Id. at 836-837.

In finding that Hofts' claims were not preempted, the judge distinguished *In re Metronic*, *supra*, which is also relied upon by defendants here. There, plaintiffs argued that their state law claims, including products liability, negligence *per se*, breach of express warranty, and breach of implied warranty, were parallel to the federal MDA requirements and were not preempted. The court found that plaintiffs' had failed to allege in detail the federal requirements purportedly violated by Metronic under *Twombly*, reasoning as follows:

> Merely alleging that Medtronic failed to comply with the CGMPs/QSR by using spot welding is insufficient without some factual detail about *why* that violates federal standards. *Id*. Instead, Plaintiffs were required to point to something in the CGMPs/QSR precluding the use of spot welding in order to state a manufacturing-defect claim that is "plausible on its face." *Id*. at 1974.

(emphasis in original). 592 F.Supp.2d at1158 (*citing and quoting Twombly*, 127 S.Ct. at 1964-

65, 1974). The *Hofts* court found that this was "an unusually stringent application of *Twombly* and Rule 8 of the Federal Rules of Civil Procedure at the motion to dismiss stage." *Id*. at 838.

Here, plaintiff captioned his complaint "Petition for Damages and/or Redhibition." [rec. doc. 1, Exhibit A]. In the complaint, he specifically pled that "[t]he redhibitory vices and defects in the products were peculiarly within the knowledge of the defendant, who manufactured the products but were not disclosed to the petitioner prior to his surgery in 2004. Further, petitioner would not have agreed to the surgery had he known of the defective products." [rec. doc. 1, Exhibit A, ¶ IV). Thus, the court finds that plaintiff has sufficiently pled his redhibition claim under *Twombly* and FED. R. CIV. P. 8.

As to whether Lemelle's redhibition claim is preempted by MDA, the Fifth Circuit has specifically addressed this issue. In *Piptitone v. Biomatrix*, 288 F.3d 239 (5th Cir. 2002), Mr. Pipitone and his wife filed suit alleging causes of action arising under Louisiana tort, products liability, and redhibition laws after Pipitone developed a salmonella infection in his knee following an injection with Synvisc, a Class III device under the MDA. On summary judgment, the district court held that the MDA preempted plaintiff's claims for design defect, inadequate warning, and noncomformity with express warning under the LPLA, and therefore, dismissed these claims with prejudice. However, the district court allowed the plaintiffs' claims for manufacturing defect and redhibition to proceed.

The Fifth Circuit concluded that plaintiffs' redhibition claim survived summary judgment. *Id*. at 250. Next, the court addressed the issue of whether plaintiffs' recovery for

damages under the Louisiana redhibition law was limited to economy loss only. The court held that the district court properly limited the scope of plaintiffs' redhibition claims to economic loss only, but remanded the case, allowing it to proceed on the Louisiana redhibition claim. *Id*. at 251-52.

Considering the Fifth Circuit's opinion in *Pepitone*[3], and the Court's reasoning in *Hofts*, which the undersigned finds persuasive, the undersigned finds that plaintiff's claim for redhibition is not preempted by the MDA. The Louisiana redhibition statute provides a private cause of action for the alleged failure of the defendant to comply with FDA requirements, but nothing else. Further, I find that it would be unfair, and violative of Rule 8, to dismiss plaintiff's claim at the pleadings stage. Accordingly, I recommend that the motion to dismiss plaintiff's redhibition claim be **denied**.

Conclusion

Based on the foregoing reasons, the undersigned recommends that the Motion to Dismiss be **GRANTED IN PART AND DENIED IN PART,** and that plaintiff's claims under LPLA be **DISMISSED.**

Under the provisions of 28 U.S.C. § 636(b)(1)(C) and F.R.Civ.Proc. 72(b), parties aggrieved by this recommendation have ten (10) business days from service of this Report and Recommendation to file specific, written objections with the Clerk of Court. A party may

[3]Apparently, both parties in *Pepitone* agreed that the FDA approval process did not protect the defendant from claims of defective manufacture or construction. The Fifth Circuit saw no reason to disagree, nor does the undersigned.

respond to another party's objections within ten (10) days after being served with a copy thereof. Counsel are directed to furnish a courtesy copy of any objections or responses to the District Judge at the time of filing.

FAILURE TO FILE WRITTEN OBJECTIONS TO THE PROPOSED FACTUAL FINDINGS AND/OR THE PROPOSED LEGAL CONCLUSIONS REFLECTED IN THIS REPORT AND RECOMMENDATION WITHIN TEN (10) DAYS FOLLOWING THE DATE OF ITS SERVICE, OR WITHIN THE TIME FRAME AUTHORIZED BY FED.R.CIV.P. 6(b), SHALL BAR AN AGGRIEVED PARTY FROM ATTACKING THE FACTUAL FINDINGS OR THE LEGAL CONCLUSIONS ACCEPTED BY THE DISTRICT COURT, EXCEPT UPON GROUNDS OF PLAIN ERROR. ***DOUGLASS V. UNITED SERVICES AUTOMOBILE ASSOCIATION*****, 79 F.3D 1415 (5TH CIR. 1996).**

Signed this 9th day of November, 2009, at Lafayette, Louisiana.

C. Michael Hill

C. MICHAEL HILL
UNITED STATES MAGISTRATE JUDGE