UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

STEPHEN YOST,

Plaintiff,

vs. Case No. 2:09-cv-28-FtM-29DNF

STRYKER CORPORATION, STRYKER SALES CORPORATION, HOWMEDICA OSTEONICS CORP, doing business as Stryker Orthopaedics, STRYKER CORPORATION OF MICHIGAN,

Defendants.
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OPINION AND ORDER

This matter comes before the Court on Defendants' Motion to Dismiss and Supporting Memorandum of Law (Doc. #12) filed on April 7, 2009. Plaintiff filed a Response (Doc. #14) on April 17, 2009. Defendant filed a Reply (Doc. #22) on April 29, 2009, with the Court's permission.

I.

On or about April 19, 2004, Stephen Yost (plaintiff or Yost) received the Trident PSL Acetabulum hip prosthesis. (Doc. #11, ¶ 11.) Plaintiff's hip prosthesis was designed, manufactured and marketed by Defendant Howmedica Osteonics Corporation d/b/a Stryker Orthopedics (HOC). (Id.) Plaintiff alleges that on or about January 19, 2005, the prosthesis began to squeak and cause increasing pain over time. (Id. at ¶ 12.) In his First Amended Complaint, Yost alleges five theories of products liability:

strict product liability (Count I), negligence/wantoness (Count II), breach of express warranty (Count III), breach of implied warranty of merchantability (Count IV), and breach of implied warranty of fitness for a particular purpose (Count V). Each of the counts allege Florida common law and statutory authority to demonstrate the plaintiff's entitlement to relief.

In their motions to dismiss, Defendants argue that the United States Food and Drug Administration (FDA) device regulations preempt plaintiff's state law claims, relying on Riegel v. Medtronic, Inc., 552 U.S. 312 (2008). The Trident hip prosthesis is a Class III medical device that receives the highest level of federal oversight under the current premarket approval process allowed under the Medical Device Amendments (MDA) of 1976. (Doc. #12, p. 2.) Under Riegel, the MDA preempts state law requirements that are "in addition to, or different from" federal requirements for Class III medical devices that underwent the premarket approval process under the MDA. (Id.) Thus, defendants argue that all of plaintiff's claims must be dismissed because they are expressly preempted by the MDA pursuant to Riegel. (Id.)

II.

The MDA established the federal regulatory regime for medical devices. 21 U.S.C. § 360c *et seq.* Pursuant to the MDA, "no state . . . may establish . . . any requirement which is (1) different from, or in addition to, any requirement applicable under this

chapter to the device, and (2) which relates to the safety and effectiveness of the device . . .” 21 U.S.C. § 360k(a). In Riegel v. Medtronic, Inc., 552 U.S. 312, 323 (2008), the Supreme Court held that the MDA preempted state law products liability restrictions, including common law requirements, which were in addition to or different from federal regulations used to evaluate Class III medical devices that underwent FDA premarket approval (PMA) processes to ensure safety. Riegel adopted a two step approach to determine whether the MDA preempted state law products liability restrictions. First, the court must determine whether the federal government established requirements applicable to the device in question. Second, the court must determine whether the claims at issue were based on state requirements that are “different from, or in addition to” the federal requirements relating to safety and effectiveness. Id. at 321-22. Adhering to its decision in Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996)[1], Riegel concluded that “common-law causes of action for negligence and strict liability do impose ‘requirement[s]’ and would be prempted by federal requirements specific to a medical device.”

[1]The Eleventh Circuit had been a lone exception among circuits by holding that the MDA’s PMA process did not preempt state law claims for strict liability and negligence in Goodlin v. Medtronic, Inc., 167 F.3d 1367 (11th Cir. 1999). While Riegel did not expressly address Goodlin, courts in this district have viewed that Riegel abrogated Goodlin and so does this Court. See Wolicki-Gables v. Arrow Int’l, Inc., 641 F. Supp. 2d 1270, 1281 (M.D. Fla. 2009).

Riegel, 552 U.S. at 323-24. In other words, "[s]tate requirements are pre-empted under the MDA only to the extent they are 'different from, or in addition to' the requirements imposed by federal law. [ ] Thus, [the MDA] 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." Id. at 330 (citing Lohr, 518 U.S. at 495)(internal citation omitted).[2]

IV.

Since the FDA has classified the Trident hip prosthesis as a Class III device, which underwent the PMA process, the federal government has imposed "requirements" on the Trident hip prosthesis under the MDA. See Riegel, 552 U.S. at 322-23. This satisfies the first step of Riegel. The next issue is whether plaintiff's claims are based on Florida requirements that are "different from, or in addition to" the federal regulations that relate to the safety or effectiveness of the device. If so, then plaintiff's claims are preempted. On the other hand, if plaintiff's claims are based on

[2]Since Riegel, many cases involving Class III medical devices, that have gone through a PMA process, have raised preemption defenses according to 360k, including many that involve the Trident hip prosthesis at issue in the instant case. See, e.g., Funk v. Stryker, No. 09-00733, 2009 U.S. Dist. LEXIS 111175 (S.D. Tex. Dec. 1, 2009); Horowitz v. Stryker Corp., 613 F. Supp. 2d 271 (E.D.N.Y. 2009); Parker v. Stryker Corp., 584 F. Supp. 2d 1298 (D. Colo. 2008); Hofts v. Howmedica Osteonics Corp., 597 F. Supp. 2d 830 (S.D. Ind. 2009).

"parallel" claims premised on a violation of federal law, plaintiff's claims are not preempted.

Count I: Strict Product Liability

In Count I of the First Amended Complaint, Yost alleges that his hip prosthesis was defective,

> "in one or more of the following particulars, among others;
> a) the hip prosthesis contained unsafe manufacturing residuals and/or bacteria;
> b) the hip prosthesis was not sterile;
> c) the hip prosthesis is defective in that it has a high propensity for delamination of the plasma sprayed coating to occur;
> d) the hip prosthesis is defective in that it has a high propensity of poor bone fixation to occur;
> e) the hip prosthesis is defective in that it has a high propensity for wear and fracture of the prosthesis to occur;
> f) the hip prosthesis was marketed in such a way as to mislead consumers regarding its safety and efficacy;
> g) the hip prosthesis was manufactured without adequate quality controls;
> h) the hip prosthesis was inadequately tested to determine the cause of the high incidence of failures despite having received significant reporting of adverse events.

(Doc. #11, ¶ 17.) Like the claims in Riegel, Plaintiff's claims clearly relate to the safety and effectiveness of the device. Further, common law strict liability imposes a "requirement" that is preempted by the federal requirements specific to the Trident hip prosthesis. Riegel, 552 U.S. at 323-24.

In his Response, Yost alleges that he is asserting claims based on violations of federal law, specifically that "manufacturing defects exist because [defendants] failed to meet federal requirements." (Doc. #14, p. 6.) Yost argues that since

his claims rest on violations of federal law, they are parallel claims not preempted by the MDA. Id. Such allegations, however, are not contained in the First Amended Complaint. Since plaintiff has not alleged a "parallel" claim, in his First Amended Complaint, Count I is preempted and Defendants' motion to dismiss is granted as to that count.

Count II: Negligence/Wantoness

Count II claims that defendant was negligent by:

> a) placing a hip prosthesis into the stream of commerce that contained unsafe manufacturing residuals and/or bacteria;
> b) manufacturing a hip prosthesis that contained unsafe manufacturing residuals and/or bacteria;
> c) placing a hip prosthesis into the stream of commerce that was not sterile;
> d) manufacturing a hip prosthesis that was not sterile;
> e) designing, manufacturing and marketing a hip prosthesis that is defective in that it has a high propensity for delamination of the plasma sprayed coating to occur;
> f) designing, manufacturing and marketing a hip prosthesis that is defective in that it has a high propensity of poor bone fixation to occur;
> g) designing, manufacturing and marketing a hip prosthesis that is defective in that it has a high propensity for wear and fracture of the prosthesis to occur;
> h) marketing a hip prosthesis in such a way as to mislead consumers regarding its safety and efficacy;
> i) manufacturing a hip prosthesis without adequate quality controls;
> j) failing to adequately test the hip prosthesis to determine the cause of the high incidence of failures despite having received significant reporting of adverse events.

(Doc. #11, ¶ 23.)

Plaintiff's negligence claim is also a common law claim that is based on requirements that are "different from, or in addition

to" the federal regulation that relate to the safety or effectiveness of the device. Riegel, 552 U.S. at 323. In his Response, plaintiff argues that he pled that defendant is negligent for manufacturing, quality control and testing without complying with federal manufacturing requirements. (Doc. #14, p. 7.) Again, none of those allegations appear in the First Amended Complaint. Plaintiff's claim in Count II is preempted by the MDA, and defendants' motion to dismiss is granted as to Count II.

Count III: Breach of Express Warranty

Count III of the First Amended Complaint alleges that Defendants made "the following affirmations of fact or promise" to plaintiff and/or his physician as his agent or to the general public:

> (a) that the hip prosthesis would be sterile;
> (b) that the hip prosthesis would not have a high propensity for delamination of the plasma sprayed coating;
> (c) that the hip prosthesis would not have a high propensity of poor bone fixation;
> (d) that the hip prosthesis would not have a high propensity for wear and fracture;
> (e) that the hip prosthesis would be safe and effective; and
> (f) that the hip prosthesis would not squeak.

(Doc. #11, ¶ 26.) Plaintiff alleges that each of these affirmations of fact or promise were not met and thus defendants breached their express warranty. (Id. at ¶ 28.) The First Amended Complaint does not allege how or by whom these promises were made. In his Response, plaintiff alleges that the breach of express warranty claim is "premised upon a disconnect between that which

was delivered (the product) and that which was warranted in the product insert give rise to claims to allow Plaintiffs to enforce the very language approved by the FDA." (Doc. #14, p. 7.)

Defendants contend that the express warranty must be premised on the language contained in the hip prosthesis label. (Doc. #12, p. 13.) Defendants argue that since the labeling was specifically approved through the PMA process, any state law challenge to the label wording must be preempted pursuant to Riegel. Id. (citing Horowitz, 612 F. Supp. 2d at 285 ("Any breach of express warranty premised on the Trident System's FDA-approved label, however, must be preempted.")).

While Riegel did not expressly address the breach of express warranty claim[3], the Supreme Court did state that the PMA process includes FDA review of the labeling of Class III devices, which cannot be changed without FDA permission. Riegel, 552 U.S. at 318-19. Thus, the FDA imposes "requirements" on device labeling. Id. at 322-23. If plaintiff is alleging that defendants breached the express warranty provided by the FDA approved labeling of the hip prosthesis, then plaintiff may have a "parallel" claim that is not preempted by the MDA. However, the Court finds that plaintiff's First Amended Complaint, as it stands, does not plead sufficient

[3]In Riegel, the district court granted summary judgment to Medtronic on Riegel's claims it had not found preempted including breach of express warranty and negligent manufacturing. The court of appeals affirmed, and those claims were not before the Supreme Court. Riegel, 552 U.S. at 321 n.2.

facts to state a claim on which relief may be granted. Plaintiff fails to identify the specific language on which his breach of express warranty claim is based. Without identifying the specific statement on which plaintiff bases his claim, his complaint is insufficient. See Delaney v. Stryker Orthopaedics, No. 08-03210, 2009 U.S. Dist. LEXIS 16865 at *15-16 (D.N.J. Mar. 5, 2009). Thus, Defendants' motion to dismiss Count III is granted.

Counts IV and V: Breach of Implied Warranty of Merchantability and Fitness for a Particular Purpose

Count IV alleges that the hip prosthesis was not merchantable because it was not fit for the ordinary purposes for which hip prostheses are used pursuant to Florida Statute § 672.314(2)(c). (Doc. #11, ¶¶ 31-35.) Count V alleges that defendant breached the implied warranty of fitness for a particular purpose because the hip prosthesis was not fit for the particular purpose for which plaintiff required it, pursuant to Florida Statute § 672.607(3)(a). (Doc. #11, ¶¶ 38-44.) "Under Florida law, to establish a claim for breach under a theory of implied warranty, a plaintiff must show (1) that the Plaintiff was a foreseeable user of the product, (2) that the product was being used in the intended manner at the time of the injury; (3) that the product was defective when transferred from the warrantor; and (4) that the defect caused the injury." Jones v. Jeld-Wen, Inc., 2008 U.S. Dist. LEXIS 49820 *17 (S.D. Fla. 2008) (citing Amoroso v. Samuel Friedland Family Enters., 604 So. 2d 827, 833 (Fla. 4th DCA 1992)).

Plaintiff argues that neither of these claims are preempted because plaintiff's breach of implied warranty claims are premised upon violations of federal requirements. (Doc. #14, p. 9.) Defendants argue that plaintiff's implied warranty claims are preempted because they do not rest on FDA permitted standards, but rather state standards that are specifically premised on the safety and effectiveness of the hip prosthesis. (Doc. #22, p. 4.) Both parties appear to be arguing the same point - plaintiff's claims are preempted unless they are premised on violations of FDA standards.

The Court agrees with defendants, so far as "nowhere in the [First Amended Complaint] does Plaintiff allege that his breach of implied warranty claims are premised upon violations of standards required by the FDA, much less that HOC violated any FDA regulations." (Id.) Since plaintiff's First Amended Complaint only asserts a state law, without reference to a federal violation, his claim is preempted. Defendants' motion to dismiss is granted as to Counts IV and V.

V.

In his Response, plaintiff sought leave to amend if the Court were to dismiss the First Amended Complaint. Yost would like to "clarify those claims to reflect that Plaintiff bases his claims on a failure to follow the FDA guidelines, and does not make claims contrary to or in addition to the FDA's regulation of the product in question." (Doc. #14, p. 12.) Defendants' argue that

plaintiff's request for leave to amend be denied because it is "futile, will result in undue delay, and is the result of a failure to cure deficiencies by previous amendment." (Doc. #23, p. 2.) Plaintiff makes several new allegations in his Response, which are not in his First Amended Complaint. Because plaintiff may be able to state claims for which relief may be granted, the Court is required to freely grant a party leave to amend. See FED. R. CIV. P. 15(a). This Court will grant plaintiff one last opportunity to amend his complaint.

Accordingly, it is now

ORDERED:

1. Defendants' Motion to Dismiss and Supporting Memorandum of Law (Doc. #12) is **GRANTED**, and the First Amended Complaint is dismissed without prejudice.

2. Plaintiff Yost is granted leave to file a Second Amended Complaint within **TWENTY-ONE (21) DAYS** of this Opinion and Order.

DONE AND ORDERED at Fort Myers, Florida, this 23rd day of March, 2010.

JOHN E. STEELE
United States District Judge

Copies:
Counsel of record