IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Judge Robert E. Blackburn

Civil Case No. 08-cv-01093-REB-MEH

JAMA PARKER,

Plaintiff,

v.

STRYKER CORPORATION, and
HOWMEDICA OSTEONICS CORPORATION d/b/a STRYKER ORTHOPAEDICS,

Defendants.

ORDER GRANTING DEFENDANT'S MOTION TO DISMISS

Blackburn, J.

The matters before me are (1) **Defendant Howmedica Osteonics Corporation's Motion To Dismiss** [#7], filed August 14, 2008; and (2) **Defendants Howmedica Osteonics Corp.'s and Stryker Corporation's Rule 72 Objections to Magistrate Judge's Order Denying Motion To Stay Discovery** [#33], filed October 16, 2008. I grant the motion the motion to dismiss and overrule the objections as moot.

I. JURISDICTION

I have subject matter jurisdiction pursuant to 28 U.S.C. § 1332 (diversity of citizenship).

II. STANDARD OF REVIEW

When ruling on a motion to dismiss pursuant to Fed.R.Civ.P. 12(b)(6), I must determine whether the allegations of the complaint are sufficient to state a claim within the meaning of Fed.R.Civ.P. 8(a). I must accept all well-pleaded allegations of the

complaint as true. ***McDonald v. Kinder-Morgan, Inc.***, 287 F.3d 992, 997 (10th Cir. 2002). "However, conclusory allegations or legal conclusions masquerading as factual conclusions will not suffice to prevent a motion to dismiss." ***Fernandez-Montes v. Allied Pilots Association***, 987 F.2d 278, 284 (5th Cir. 1993); ***see also Ruiz v. McDonnell***, 299 F.3d 1173, 1181 (10th Cir. 2002) ("All well-pleaded facts, as distinguished from conclusory allegations, must be taken as true."), ***cert. denied***, 123 S.Ct. 1908 (2003). I review the complaint to determine whether it "'contains enough facts to state a claim to relief that is plausible on its face.'" ***Ridge at Red Hawk, L.L.C. v. Schneider***, 493 F.3d 1174, 1177 (10th Cir. 2007) (quoting ***Bell Atlantic Corp. v. Twombly***, – U.S. –, 127 S.Ct. 1955, 1969, 1974, 167 L.Ed.2d 929 (2007)). "Thus, the mere metaphysical possibility that *some* plaintiff could prove *some* set of facts in support of the pleaded claims is insufficient; the complaint must give the court reason to believe that *this* plaintiff has a reasonable likelihood of mustering factual support for *these* claims." ***Id.*** (emphases in original).[1]

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[1] ***Twombly*** rejected and supplanted the "no set of facts" language of ***Conley v. Gibson***, 355 U.S. 41, 45-46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957). The Tenth Circuit recently clarified the meaning of the "plausibility" standard:

> "plausibility" in this context must refer to the scope of the allegations in a complaint: if they are so general that they encompass a wide swath of conduct, much of it innocent, then the plaintiffs "have not nudged their claims across the line from conceivable to plausible." The allegations must be enough that, if assumed to be true, the plaintiff plausibly (not just speculatively) has a claim for relief.
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> This requirement of plausibility serves not only to weed out claims that do not (in the absence of additional allegations) have a reasonable prospect of success, but also to inform the defendants of the actual grounds of the claim against them. "Without some factual allegation in the complaint, it is hard to see how a claimant could satisfy the requirement of providing not only 'fair notice' of the nature of the claim, but also 'grounds' on which the claim rests."

III. ANALYSIS

On June 14, 2004, plaintiff underwent a total hip arthroplasty during which she was implanted with the Trident Ceramic Acetabular System ("Trident System"), an artificial hip implant device developed, manufactured, and sold by defendants. After the surgery, plaintiff noticed an audible sound emanating from the device. She alleges that "[a]s a result of the audible sound in the subject hip, Plaintiff has experienced constant irritation and discomfort," as well as "additional and resultant bone loss," and that she "is at an increased risk for requiring a premature revision surgery."[2] She has sued defendants under Colorado state law for failure to warn, manufacturing defect, design defect, breach of express and implied warranties, breach of implied warranty of fitness, breach of implied warranty of merchantability, and negligence and recklessness. Defendants now move to dismiss, claiming that all plaintiff's state law causes of action are preempted.

Resolution of the motion turns on the recent Supreme Court decision interpreting the preemptive scope of the 1976 Medical Device Amendments ("MDA"), 21 U.S.C. §§ 360c - 360n, to the Federal Food, Drug and Cosmetic Act of 1938 ("FDCA"), 21 U.S.C. §§ 301 - 399a.[3] ***Reigel v. Medtronic, Inc.***, – U.S. –, 128 S.Ct. 999, 169 L.Ed.2d 892

Robbins v. Oklahoma, 519 F.3d 1242, 1247-48 (10th Cir. 2008) (quoting ***Twombly***, 127 S.Ct. at 1974; internal citations and footnote omitted).

[2] In her response to the motion to dismiss, plaintiff avers that she, in fact, underwent revision surgery on June 24, 2008. (Plf. Resp. at 2 [#21], filed September 9, 2008.)

[3] The MDA was enacted in response to the well-publicized and devastating failures of various medical devices, most notably the Dalkon Shield, which were not previously subject to the PMA process for drugs. ***See Medtronic, Inc. v. Lohr***, 518 U.S. 470, 475-76, 116 S.Ct. 2240, 2246, 135 L.Ed.2d 700 (1996).

(2008). The MDA establishes three classifications for medical devices based on the risk of illness or injury they pose to the public. ***See id.***, 128 S.Ct. at 1003. The Trident System is a Class III device, meaning that it is one intended "for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." 21 U.S.C. § 360c(a)(1)(C). Before a Class III device may be introduced to the market, it must undergo the exacting premarket approval ("PMA") process. ***Reigel***, 128 S.Ct. at 1004.

Importantly, for present purposes, the MDA contains an express preemption clause:

> . . . 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
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> (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.

21 U.S.C. § 360k(a). FDA regulations interpret this provision to preempt state "requirements," including state common law causes of action, ***Reigel***, 128 S.Ct. at 1007-09, "when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device," 21 C.F.R. § 808.1(d). ***Reigel*** held that the PMA process itself qualifies as such a "specific requirement[] applicable to a particular device." ***Reigel***, 128 S.Ct. at 1006-07. Thus, the Court concluded that state claims that would impose on manufacturers requirements that are different from, or in addition to, those prescribed by the MDA are preempted.

Id. at 1011.

However, plaintiff insists that her claims are not preempted because they do not seek to impose different or additional requirements, but only parallel the federal requirements of the MDA. This exception was recognized in ***Reigel***, when the 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." ***Id.*** (citing ***Medtronic, Inc. v. Lohr***, 518 U.S. 470, 495, 116 S.Ct. 2240, 2255, 135 L.Ed.2d 700 (1996)).[4] Nevertheless, although such claims may be recognized, plaintiff has not properly pled them here.

To properly allege parallel claims, the complaint must set forth facts showing "action or inaction in [defendants'] efforts to take part in the PMA process or implement its results[.]" ***Heisner ex rel. Heisner v. Genzyme Corp***., 2008 W L 2940811 at *5 (N.D. Ill. July 25, 2008). The complaint does allege generally that the Trident System was unreasonably dangerous and defective because "the manufacturing processes for the device and certain of their [sic] components did not satisfy the Food and Drug Administration's Pre-Market Approval standards for the devices" (Complaint ¶ 68.a. at 17; ***see also id.***, ¶ 70 at 18), and that the device was sold "in direct violation of the Code of Federal Regulations" (***id.*** ¶ 73 at 19), which proximately caused plaintiff's injuries (***see, e.g.***, ***id***. ¶¶ 80, 83 at 20). However, such conclusory allegations standing alone are not sufficient to sustain plaintiff's burden of pleading under ***Twombly***.

[4] The plaintiffs in ***Reigel*** made a similar argument that their claims likewise should be considered parallel to federal requirements, but the Court found that any such argument had not been properly raised and preserved for its review. ***Reigel***, 128 S.Ct. at 1011.

"Without some factual allegation in the complaint, it is hard to see how a claimant could satisfy the requirement of providing not only 'fair notice' of the nature of the claim, but also 'grounds' on which the claim rests." ***Robbins***, 519 F.3d at 1248 (quoting ***Twombly***, 127 S.Ct. at 1974; internal quotation marks omitted).

Plaintiff attempts to add substance to these allegations by reference to two Warning Letters that the FDA issued to defendants, one in March, 2007, the other in November, 2007, in which it found that the Trident System was "adulterated" within the meaning of 21 U.S.C. § 351(h). (***See*** Complaint ¶ 59 at 13 & ¶ 61 at 14.) Setting aside potential problems of causation posed by attempting to link letters issued in 2007 with plaintiff's injury in 2004, plaintiff nevertheless cannot escape preemption by reference to provisions of the FDCA that govern the sale of adulterated and misbranded devices because there is no private right of action under the FDCA. ***See*** 21 U.S.C. § 337. "Although the Tenth Circuit has not considered the effect of section 337(a), every federal court that has addressed the question has held that the FDCA does not create a private right of action to enforce or restrain violations of its provisions." ***Braintree Labs, Inc. v. Nephro-Tech, Inc***., 1997 WL 94237 at *3 (D. Kan Feb. 26, 1997) (citing cases); ***see also Rimbert v. Eli Lilly and Co.***, – F.Supp.2d –, 2008 WL 4330626 at *63 -*64 (D.N.M. Aug. 22, 2008) (noting the Tenth Circuit's citations with approval to ***Braintree Labs*** in ***Cottrell Ltd. v. Biotrol Internationl, Inc***., 191 F.3d 1248, 1255 (10th Cir. 1999)). Thus, to the extent that these claims are merely derivative of plaintiff's state law claims, they are not saved merely by being recast as violations of the federal adulteration and misbranding statutes. ***See Gile v. Optical Radiation Corp***., 22 F.3d

540, 544 (3rd Cir.), ***cert. denied***, 115 S.Ct. 429 (1994); ***Talbott v. C.R. Bard, Inc.***, 865 F.Supp. 37, 50 (D. Mass. 1994), ***aff'd***, 63 F.3d 25 (1st Cir. 1995), ***cert. denied***, 116 S.Ct. 1892 (1996). ***But see Purcel v. Advanced Bionics Corp.***, 2008 WL 3874713 at *3 (N.D. Tex. Aug. 13, 2008).

Plaintiff relies also on the Warning Letters to allege that defendants have failed to comply with federal regulations found at 21 C.F.R. §§ 803 (Medical Device Reporting procedures), 806 (recall and notification procedures), and 820 (failure analysis and quality assurance procedures). (Complaint ¶¶ 63 & 64 at 16-17.) Although the Warning Letters provide factual detail as to these alleged failures, plaintiff does not allege that the failure to comply with these particular regulations rendered the Trident System defective. ***See Heisner***, 2008 WL 2940811 at *4 -5 (recognizing potential viability of claims based on post-approval events). Instead, she alleges specifically that the Trident System was defective because "the manufacturing processes for the device and certain of their [sic] components did not satisfy the Food and Drug Administration's Pre-Market Approval standards for the devices." (***Id.*** ¶ 68.a at 17 & ¶ 70 at 18.) Although such a claim appears to constitute the type of parallel claim the ***Reigel*** Court found to be outside the preemptive reach of section 360k, nowhere does plaintiff's complaint provide any factual detail to substantiate that crucial allegation.[5] Without such support, the complaint fails to "give the court reason to believe that *this* plaintiff has a reasonable likelihood of mustering factual support for *these* claims." ***Ridge at Red Hawk, L.L.C.***,

[5] Although plaintiff also cites generally to 21 C.F.R. § 814 (***see*** Complaint ¶ 64 at 17), which governs the PMA process, her complaint fails to specify in what way or ways defendants violated any one or more of those regulations.

493 F.3d at 1177 (emphases in original). Plaintiff has not sought or suggested that she might require leave to amend her complaint to attempt to allege viable claims. Instead, she insists that her claims as currently pled are sufficient to withstand preemption.[6] Because they are not, the motion to dismiss must be granted as to the majority of plaintiff's claims.

The only claim not clearly preempted by ***Reigel*** is plaintiff's breach of express warranty claim.[7] Although the complaint does not specify in what way the alleged representations about the Trident System were communicated to plaintiff, defendants suggests, and plaintiff does not dispute, that this claim is premised on the product's labeling. (***See*** Complaint ¶¶ 15 & 16 at 26.)[8] The federal courts are divided as to whether breach of express warranty claims are preempted by section 360k. The Third and Seventh Circuits have held that such claims are not preempted because any "requirements" imposed by the warranty are voluntarily assumed by the warrantor, not imposed by the state. ***See Mitchell v. Collagen Corp.***, 126 F.3d 902, 915 (7th Cir. 1997), ***cert. denied***, 118 S.Ct. 1300 (1998); ***Michael v. Shiley, Inc.***, 46 F.3d 1316,

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[6] Plaintiff does argue that it would be premature to dismiss her claims at the pleading stage because discovery has not yet taken place. This argument is not unique to claims under the MDA and provides no compelling reason for ignoring the clear holding of ***Twombly***, as interpreted by the Tenth Circuit in ***Robbins***, that the complaint must provide adequate factual substantiation in order to state a plausible claim for relief.

[7] The district court in ***Reigel*** found the plaintiffs' breach of express warranty claim not preempted, but later granted summary judgment on that claim on the ground that the subject device's instructions had clearly disclaimed any such warranty. ***Reigel v. Medtronic, Inc.***, 451 F.3d 104, 108 (2nd Cir. 2006). The plaintiffs did not challenge that determination on appeal. ***See id.*** at 108 n.3; ***Reigel***, 128 S.Ct. at 1006 n.2.

[8] The complaint does not allege that defendants failed to adhere to any requirements imposed by the PMA process in labeling the device. ***See Brooks v. Howmedica, Inc.***, 273 F.3d 785, 798-99 (8th Cir. 2001) (noting that such a claim would not be preempted), ***cert. denied***, 122 S.Ct. 1914 (2002); ***In re Medtronic, Inc. Implantable Defibrillators Litigation***, 465 F.Supp.2d 886, 898 (D. Min. 2006) (same).

1327-28 (3rd Cir.), ***cert. denied***, 116 S.Ct. 67 (1995), ***overruled on other grounds as stated in In re Orthopedic Bone Screw Products Liability Litigation***, 159 F.3d 817, 825 (3rd Cir. 1998). ***See also In re Medtronic, Inc. Implantable Defibrillators Litigation***, 465 F.Supp.2d 886, 898 (D. Min. 2006); ***Davenport v. Medtronic, Inc.***, 302 F.Supp.2d 419, 433 (E.D. Pa. 2004); ***Steele v. Depuy Orthopaedics, Inc.***, 295 F.Supp.2d 439, 455-56 (D.N.J. 2003). Other courts have found this reasoning unpersuasive given the comprehensive nature of the PMA process. Because all representations regarding the device in its labeling must be approved by the FDA as part of the PMA process, these courts have held that any claim that such representations are inadequate is preempted. ***See Enlow v. St. Jude Medical, Inc.***, 210 F.Supp.2d 853, 861-62 (W.D. Ky. 2001) (citing ***Martin v. Telectronics Pacing Systems, Inc.***, 105 F.3d 1090, 1100 (6th Cir. 1997), ***cert. denied***, 118 S.Ct. 850 (1998)).

Of course, none of these cases was decided with the benefit of the Supreme Court's decision in ***Reigel***. In light of that decision, I believe the better-reasoned approach would find plaintiff's breach of express warranty claims based on the labeling of the Trident System preempted. As noted in ***Reigel***, "[t]he premarket approval process includes review of the device's proposed labeling. The FDA evaluates safety and effectiveness under the conditions of use set forth on the label and must determine that the proposed labeling is neither false nor misleading." ***Reigel***, 128 S.Ct. at 1004 (internal citations omitted). Moreover, once approved, the device's labeling may not be altered without first obtaining FDA approval "under largely the same criteria as an initial

application." ***Id.*** at 1005. Plaintiff's express warranty claim would contradict the FDA's determination that the representations made on the label were adequate and appropriate and, thus, impose requirements different from or in addition to the federal requirements. Therefore, that claim is preempted by section 360k.

My determination as to the preemption issue pretermits consideration of defendants' alternative arguments for dismissal.[9]

IV. CONCLUSION

Pursuant to the Supreme Court's decision in ***Reigel***, plaintiff's claims of failure to warn, defective design, negligence and recklessness, breach of implied warranties, breach of implied warranty of fitness, and breach of implied warranty of merchantability are all preempted. I conclude also that plaintiff's breach of express warranty claim is preempted, because it would impose requirements different from or in addition to the federal requirements of the MDA.

V. ORDERS

THEREFORE, IT IS ORDERED as follows:

1. That **Defendant Howmedica Osteonics Corporation's Motion To Dismiss** [#7], filed August 14, 2008, is **GRANTED**;

2. That the objections stated in **Defendants Howmedica Osteonics Corp.'s and Stryker Corporation's Rule 72 Objections to Magistrate Judge's Order Denying Motion To Stay Discovery** [#33], filed October 16, 2008, are **OVERRULED**

[9] Moreover, in light of plaintiff's voluntary dismissal of her claims in another suit regarding the Trident System pending in federal district court in New Jersey, defendant has abandoned its argument that this lawsuit should be dismissed as an improper attempt at claim-splitting.

AS MOOT;

3. That plaintiff's claims against defendants are **DISMISSED WITH PREJUDICE**;

4. That judgment **SHALL ENTER** for defendants, Stryker Corporation and Howmedica Osteonics Corporation d/b/a Stryker Orthopaedics, against plaintiff, Jama Parker, on all claims for relief and causes of action; and

5. That defendants are **AWARDED** their costs, to be taxed by the Clerk of the Court pursuant to Fed.R.Civ.P. 54(d)(1) and D.C.COLO.LCivR 54.1.

Dated October 21, 2008, at Denver, Colorado.

BY THE COURT:

s/ Robert E. Blackburn
Robert E. Blackburn
United States District Judge