IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Judge R. Brooke Jackson

Civil Action No 14-cv-00186-RBJ

EDWARD HAFFNER,

Plaintiff,

v.

STRYKER CORPORATION, a Michigan corporation,
STRYKER SALES CORPORATION, a Michigan corporation, and
HOWMEDICA OSTEONICS CORPORATION, d/b/a STRYKER ORTHOPAEDICS, a Michigan corporation,

Defendants.

ORDER

This matter is before the Court on Defendant's Motion to Dismiss [ECF No. 28] for failure to state a claim upon which relief may be granted. The Court exercises jurisdiction over this action pursuant to 28 U.S.C. § 1332. The motion became ripe for review on May 30, 2014 upon the filing of the defendant's Reply [ECF No. 33]. For the reasons discussed below, instead of ruling on the motion at this time, the Court requests briefs from the parties as to whether the case should be dismissed for a different reason not discussed in the briefs on the pending motion.

BACKGROUND

For purposes of a motion to dismiss, the Court must accept all factual assertions contained in the pleadings as true. On or about September 27, 2011 plaintiff Edward Haffner underwent a total knee arthroplasty in which Dr. Roger Greenberg surgically removed his left

knee and replaced it with a Stryker Triathlon Total Knee System ("the Knee System"). The Knee System contained cobalt and nickel. At the time of the surgery, Mr. Haffner was personally unaware that the Knee System contained these metals. It also appears he was unaware that he was allergic to either of these metals, one or both of which caused him to suffer an allergic reaction resulting in pain, inflammation, swelling, bone loss, and limited mobility. As a result, Mr. Haffner underwent a total knee arthroplasty revision surgery on August 7, 2012 to remove and replace the Knee System.

Mr. Haffner filed a tort action in the district court in Weld County, Colorado on October 14, 2013. The defendants Stryker Corporation, Stryker Sales Corporation, and Howmedica Osteonics Corporation d/b/a Stryker Orthopaedics (collectively "Stryker") removed the case to this Court on the basis of diversity jurisdiction on January 22, 2014 [ECF No. 1] and filed their original motion to dismiss on February 3, 2014 [ECF No 11]. Mr. Haffner filed his First Amended Complaint on February 24, 2014 [ECF No. 13] and subsequently filed his Second Amended Complaint on April 1, 2014 [ECF No. 24]. He asserts four different theories of products liability in the Second Amended Complaint: (1) strict products liability; (2) negligence; (3) breach of implied warranties of merchantability and fitness; and (4) breach of express warranty. [ECF No. 24 at 5–15]. On April 22, 2014 the defendants filed the pending motion to dismiss for failure to state a claim upon which relief can be granted [ECF No. 28].

ANALYSIS

In 2008 the Supreme Court decided *Riegel v. Medtronic, Inc.*, 552 U.S. 312. In that case the Court considered whether the preemption clause included in the Medical Device

Amendments of 1976 (MDA)[1], 21 U.S.C. § 360c *et seq.*, bars "common-law claims challenging the safety and effectiveness of a medical device given premarket approval by the Food and Drug Administration (FDA)." 552 U.S. at 315. Before the provisions of the MDA were enacted, the States were largely left to supervise the introduction of new medical devices as they saw fit. *Id.* However, the regulatory landscape began to change in the 1960's and 1970's as complex medical devices entered the market. *Id.* As certain devices became linked to serious infections and deaths, the public saw "the inability of the common-law tort system to manage the risks associated with dangerous devices." *Id.* In turn, Congress passed the MDA in 1976, sweeping "back some state obligations and impos[ing] a regime of detailed federal oversight." *Id.* at 316.

The MDA's preemption provision reads as follows:

> 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.

21 U.S.C. § 360k(a).[2] The regulatory regime established three classes of medical devices with varying levels of oversight based on class. Class III medical devices receive the most federal oversight as they 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," or they "present[] a potential unreasonable risk of illness or injury." 21 U.S.C.A. §

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[1] The MDA amended the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*

[2] The exception discussed in subsection (b) concerns the right of the FDA to exempt some state and local requirements from preemption in specific circumstances, and only by regulation promulgated after notice and a hearing. *See* 21 U.S.C. § 360k(b).

360c(a)(1)(C)(ii).

The MDA "established a rigorous regime of premarket approval for new Class III devices." *Riegel*, 552 U.S. at 317. The FDA only grants premarket approval if it finds there is "a 'reasonable assurance' of the device's 'safety and effectiveness'" after weighing "'any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.'" *Id.* at 318 (citations omitted). The premarket approval process also "includes review of the device's proposed labeling." *Id.* at 319. Once a device receives premarket approval, "the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Id.* (citation omitted).

Based on the foregoing, the Court held that "[s]tate requirements are pre-empted under the MDA . . . to the extent that they are 'different from, or in addition to' the requirements imposed by federal law." *Id.* at 330 (quoting 21 U.S.C. § 360(k)(a)(1)). In particular, the plaintiff's claims that Medtronic's Evergreen Balloon Catheter was designed, labeled, and manufactured in a manner that violated New York common law were preempted by the MDA. *Id.* The Court further noted that the plaintiff had failed to put forward any argument that the state duties were "parallel" to the FDA regulations, rather than in addition to them, in her previous filings. *See id.*

Soon after the *Riegel* decision came out, Judge Blackburn of this district had a case similar to the present case, also against Stryker: *Parker v. Stryker*, No. 08-CV-01093-REB-MEH. The plaintiff brought seven common-law causes of action against Stryker regarding a hip replacement device: (1) strict liability for failure to warn; (2) strict liability for defective

manufacture; (3) strict liability for defective design; (4) negligence and recklessness; (5) breach of express and implied warranties; (6) breach of implied warranty of fitness; and (7) breach of implied warranty of merchantability. Stryker moved to dismiss on the grounds that the claims were preempted, with other arguments presented in the alternative. The court concluded that all of the claims were preempted under *Riegel* and dismissed the case. *Parker v. Stryker*, 584 F. Supp. 2d 1298, 1303 (D. Colo. 2008).

The Court is uncertain as to why Stryker neither cited *Parker* nor discussed preemption in the pending motion. There may well be a distinction that has not occurred to me, and at a minimum, I do not want to analyze preemption here without giving plaintiff (or Stryker) an opportunity to explain the distinction to me. The Court therefore requests briefs from the parties of no more than fifteen (15) pages stating their respective positions on the preemption issue. The parties will each have twenty-one (21) days from the date of this Order to file their respective supplements.

ORDER

For the foregoing reasons, the Court will abstain from ruling on Defendant's Motion to Dismiss [ECF No. 28] until it receives further briefing consistent with this Order.

DATED this 1st day of August, 2014.

BY THE COURT:

R. Brooke Jackson
United States District Judge