Funk v. Stryker Corporation et al Doc. 26

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

RONALD FUNK,	§	
	§	
Plaintiff,	§	
	§	
v.	§	Civil Action H:09-00733
	§	
STRYKER CORPORATION, *et al.*,	§	
	§	
Defendants.	§	

MEMORANDUM OPINION & ORDER

Pending before the court is the Rule 12(b)(6) motion to dismiss of defendants Stryker Corporation, Stryker Sales Corporation, and Howmedica Osteonics (collectively "HOC"). Dkt. 7. Upon consideration of HOC's motion, plaintiff Ronald Funk's response, HOC's reply brief, and Funk's proposed amended complaint, the motion to dismiss is GRANTED. Plaintiff's complaint is DISMISSED.[1]

I. BACKGROUND

Funk alleges he was injured by a defective Trident hip implant designed, manufactured, and marketed by HOC. He claims that after surgery he experienced extreme hip discomfort, which his doctors diagnosed as an infection caused by the Trident prosthesis. Ultimately his surgeon determined that the implant had failed. Funk states he is in constant pain and faces additional surgery.

Funk brings three causes of action against HOC: strict liability, negligence, and claims under the Texas Deceptive Trade Practices Act ("DTPA"). Dkt. 1. In his strict liability cause of action, he

[1]Defendant HOC has filed a motion to strike in which it objects to Funk's filing a first amended complaint rather than submitting a proposed amended complaint as requested by the court in its order of Nov. 2, 2009 (Dkt. 21). Dkt. 23. Because this order will dismiss both the original and the first amended complaint, HOC's motion to strike is moot and is therefore denied.

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alleges the implant contained a manufacturing, design, or marketing defect. In the manufacturing defect claim, he alleges that the manufacturing process violated Food and Drug Administration ("FDA") standards, causing "impurities, residues and bacteria" to remain on the device, and that the device's construction or quality deviated from specifications. In support of this latter allegation, he invokes the doctrine of *res ipsa loquitur*. In the marketing defect claim, Funk alleges HOC failed to warn him or his doctors that the Trident contained impurities or that faulty manufacturing processes could cause the implant to become contaminated. Finally, in his design defect claim, Funk alleges a safer design existed and that HOC used inadequate quality controls, manufactured a device containing impurities, and failed to adequately test the Trident. Funk contends the implant was therefore unreasonably dangerous.

In his negligence cause of action, Funk alleges numerous instances in which HOC breached its duty to exercise ordinary care by designing, manufacturing, and marketing the Trident in a manner that caused impurities, residues, and bacteria in the device in violation of FDA requirements. He also alleges failure to warn and placing an unsterile device into the stream of commerce. Funk provides no specific facts in support of his negligence allegations, instead again relying on the doctrine of *res ipsa loquitur*.

Finally, in his DTPA cause of action, Funk alleges that HOC made misrepresentations regarding the device's compliance with FDA requirements and failed to disclose the presence of contaminants that violated federal standards. Funk also claims HOC breached the implied warranty of merchantability because the implant was unfit for its ordinary purposes. The complaint lists no specific facts in support of either of these claims or any facts showing HOC's "knowing conduct" or intent.

II. THE LAW

A. Standard of Review

To survive a Rule 12(b)(6) motion to dismiss for failure to state a claim upon which relief may be granted, a complaint must provide "more than labels and conclusions, and a formulaic recitation of a cause of action's elements." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555, 127 S. Ct. 1955 (2007). The facts stated in the complaint need not be detailed, but they must be sufficient to suggest that the plaintiff's claims plausibly entitle the plaintiff to relief. *Id.* The facts must "raise a right of relief above the speculative level" and create more than "a suspicion" that, taking the facts as true, the plaintiff is entitled to relief. *Id.*

Whether an allegation based solely on information and belief is sufficient, after *Twombly,* to survive a motion to dismiss is unclear. The advisory committee's notes to the 1993 amendments to Rule 11 of the Federal Rules of Civil Procedure state that

> sometimes a litigant may have good reason to believe that a fact is true or false but may need discovery, formal or informal, from opposing parties or third persons to gather and confirm the evidentiary basis for the allegation. Tolerance of factual contentions in initial pleadings by plaintiffs or defendants when specifically identified as made on information and belief does not relieve litigants from the obligation to conduct an appropriate investigation into the facts that is reasonable under the circumstances.

FED. R. CIV. P. 11 advisory committee's notes. Prior to *Twombly,* the Fifth Circuit held that "'information and belief' pleadings are generally deemed permissible under the Federal Rules, especially in cases in which the information is more accessible to the defendant." *Johnson v. Johnson,* 385 F.3d 503, 531, n.19 (5th Cir. 2004). However, in *Twombly,* the plaintiffs based one of their allegations (that the defendants had entered into an anti-competitive conspiracy) "upon information and belief, " and the Supreme Court held that this allegation, without more, failed to provide sufficient facts "to state a claim to relief that is plausible on its face." 550 U.S. at 551.

Moreover, the court notes that allegations based upon information and belief are particularly innappropriate in cases where the allegations are based on matters of public record. *See Boykin v. Keycorp*., 521 F.3d 202, 215 (2d. Cir. 2008). Accordingly, this court reviews allegations based upon information and belief under *Twombly*'s 12(b)(6) formulation requiring sufficient fact pleading to make a claim plausible.

B. Preemption Under the Medical Device Amendments of 1976

The Medical Device Amendments ("MDA") of 1976 to the federal Food, Drug and Cosmetics Act establish processes for classification of and performance standards for medical devices. 21 U.S.C. §§ 360c–m. Though they may sustain life or protect human health, Class III devices also may pose "a potential unreasonable risk of illness or injury." § 360c(a)(1)(C)(ii). Before they are introduced to the market, such devices must therefore submit to the FDA's "premarket approval" ("PMA") process. *Id.* Once the FDA has granted premarket approval, the manufacturer cannot change the product's specifications, processes, or label without further approval. § 360e(d) (6)(A)(I).

The United States Supreme Court has characterized the PMA process as "rigorous" and has distinguished claims involving PMA-approved devices from claims involving devices approved under the less stringent § 510(k) process. *Riegel v. Medtronic, Inc.*, ___U.S.___, 128 S. Ct. 999, 1004, 1007 (2008). Section 510(k) of the MDA contains a grandfather provision that allows Class III devices distributed prior to 1976 to remain on the market; in the interest of fair competition, it also allows new devices "substantially equivalent" to the pre-existing devices to enter the market without undergoing the PMA process. §§ 360e (b)(1)(A) & (B); *Medtronic, Inc. v. Lohr*, 418 U.S. 470, 478-79, 116 S. Ct. 2240 (1996). The differences between the PMA and § 510(k) are significant. *Lohr*, 418 U.S. at 478-79. For example, a § 510(k) review takes twenty hours to complete, whereas the PMA entails 1,200 hours of work. *Id.* at 479.

1. Preemption of State Common-Law Claims Under § 360

HOC bases its 12(b)(6) motion to dismiss on § 360k, which provides that states may not establish standards for Class III devices that are "different from, or in addition to" any requirements provided for in the MDA that "[relate] to the safety or effectiveness of the device." § 360k(a). In *Riegel*, the court held that § 360k preempted state common-law causes of action because such actions imposed additional or different requirements from those imposed by the FDA under the PMA process. 128 S. Ct. at 1007. As explained in *Riegel*, a court must make two findings to determine whether claims are preempted under § 360. First, it must determine whether the FDA has imposed device-specific requirements on the particular device. Second, the court must decide whether the state requirements relate to the device's safety and effectiveness and constitute requirements "different from, or in addition to" the federal requirements. *Id.* at 1006-1007.

The plaintiff in *Riegel* was a heart patient who had been treated with a balloon catheter, a Class III device that had received FDA approval under the PMA procedure. The catheter burst during surgery, allegedly injuring the patient. He brought a variety of common-law claims, including breach of implied warranty; strict liability; and negligent design, labeling, marketing, inspection, and testing. The district court granted summary judgment on these claims, finding them preempted by the MDA; both the Second Circuit and the Supreme Court affirmed the district court's holding. *Id.* at 1006. The Supreme Court found that all PMA-approved devices met the first prong of preemption under § 360k because the FDA imposed device-specific requirements on them. Class III devices undergo a "rigorous" approval process under the PMA, including a risk-benefit analysis that considers each device's potential benefits and the availability of alternative treatment. *Id.* at 1004. The PMA process therefore equates to a "federal safety review" of the device, and the MDA protects this review by requiring manufacturers to adhere to the specifications and by denying states the right to impose

requirements "different from, or in addition to" the FDA requirements. *Id.* at 1007. In contrast, Class III devices that enter the market after § 510(k) review do not meet the first element of preemption. *Id.* They receive federal approval based on their substantial equivalence to devices grandfathered-in by the 1976 amendment, and therefore no device-specific federal requirements have been imposed on them. *Id.*

The *Riegel* court found that the plaintiff's claims also met the second prong of § 360 preemption. Safety and effectiveness "[were] the very subjects of the Riegels' common-law claims," and state common-law actions constituted specifications that differed from or added to the federal regulations. *Id.* State court judgments in such cases arise from violations of common-law duties, and these duties constitute state requirements. *Id.* at 1008. Furthermore, damages awards often exert additional control over a product, and could therefore disrupt the FDA's safety regimen. *Id.* In response to the dissent's doubts that Congress intended to prevent injured plaintiffs from applying to the courts for relief, the majority stated that "this is exactly what a pre-emption clause for medical devices does by its terms." *Id.* at 1009. "[The] text of the statute . . . . suggests that the solicitude for those injured by FDA-approved devices . . . was overcome in Congress's estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 states to all innovations." *Id.*

The *Riegel* court also observed that the PMA process governs the labeling of Class III devices. *Id.* at 1004. "The FDA evaluates safety and effectiveness under the conditions of use set forth on the label, § 360c(a)(2)(B), and must determine that the proposed labeling is neither false nor misleading, § 360e(d)(1)(A)." *Id.*

Prior to *Riegel*, the Fifth Circuit had found that the MDA preempted a variety of common-law claims involving the safety and effectiveness of Class III devices. In *Gomez v. St. Jude Medical Daig*

Div. Inc., 442 F.3d 919, 930–931 (5th Cir. 2006), the Fifth Circuit upheld a grant of summary judgment that found the plaintiff's strict liability defective design, negligent design, failure to warn, and failure to train actions involving a PMA-approved Class III heart plug to be preempted by § 360k. The court said the statute prevented juries from "second guessing" approved federal specifications. *Id.* at 930. The *Gomez* court cited *Stamps v. Collagen Corporation*, where the court ruled that the MDA preempted state law claims related to a Class III anti-wrinkle treatment and upheld summary judgment on negligent failure to warn, inadequate warnings, and defective design claims. *Id.* (citing *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1425 (5th Cir. 1993)).

2. Surviving § 360 Preemption: "Parallel" State Requirements

Riegel does leave open an avenue for avoiding preemption under the MDA for claims involving PMA-approved Class III devices. A plaintiff may seek a damages remedy if the state duties "'parallel,' rather than add to, federal requirements." *Riegel*, 128 S. Ct. at 1011 (citing *Lohr*, 418 U.S. at 470). The *Riegel* court did not elaborate on what constitutes a parallel claim, except to say that "§ 360 does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations." *Id.* In *Lohr*, the court explained that parallel state claims "duplicate" federal requirements or impose duties "substantially identical" to those imposed by federal law. *Lohr*, 418 U.S. at 495–96. The state damages remedies in such cases "merely [provide] another reason for manufacturers to comply with identical existing 'requirements' under federal law." *Id.* at 496. Prior to *Riegel*, the Fifth Circuit held that "[i]n the context of the PMA process . . . state tort suits that allege, as the basis of their claim, that the approved FDA requirements have not been met are not preempted." *Martin v. Medtronic, Inc.*, 254 F.3d 573, 583 (5th Cir. 2001). Hence "a lawsuit that simply parallels or enforces the federal regulatory requirements without 'threatening' or interfering with them is not preempted." *Gomez*, 442 F.3d at 932.

Federal courts have differed in their interpretation of "parallel claims" involving PMA-approved devices. In 2008, the Northern District of Texas found that claims involving a PMA-approved Class III device avoided preemption because they arose from violations of FDA specifications and thus paralleled federal law. *Purcel v. Advanced Bionics Corp.*, No. 3:07-CV-1777-M, 2008 WL 3874713 (N.D. Tex. Aug. 13, 2008). In that case, the plaintiff sued the manufacturer of a Class III ear implant that had received approval through the PMA process. The approval required the manufacturer to use a specific vendor to provide a certain part according to FDA-approved specifications. However, unbeknownst to the FDA, the manufacturer later contracted with a different vendor to supply the part, and the evidence suggested that this new—and unapproved—vendor failed to follow the PMA-mandated manufacturing process. The plaintiff alleged that replacing the approved vendor and modifying the approved manufacturing specifications violated federal law and led to moisture problems that damaged her ear. As evidence, she cited FDA reports and letters documenting the device's moisture problems and an FDA suit against the manufacturer for violating the PMA by failing to notify the agency of its new vendor. The court found that such claims did not impose duties on the device's manufacturer that were different from, or in addition to those required by the FDA. *Id.* at *3–4. Instead it found that the strict liability claims were "predicated solely on violations of federal law" and observed that "compliance with the relevant federal requirements would [have] effectively absolve[d] the defendant from liability under state law." *Id.* The court therefore denied the manufacturer's motion for judgment on the pleadings.

In *Hofts*, the Southern District of Indiana also denied the defendants' 12(b)(6) motion to dismiss, finding that the plaintiff's state claims paralleled federal requirements. *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830, 803, 836-841 (S.D. Ind. 2009). The plaintiff sued the Trident manufacturer under theories of strict liability for defective manufacture, negligent manufacture,

violation of the state's commercial fraud statute, breach of express warranty, and breach of implied warranties. *Id. at* 833. Among other things, the plaintiff alleged that impurities and imperfections in the device constituted deviations from FDA requirements. The court said such allegations were "identical or parallel to" the FDA's requirements, and that "[a] jury could find that [the manufacturer] 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." *Id.* at 836-37. Although the plaintiff did not allege facts showing deviation from the process or the presence of impurities, the court held the allegations to be sufficiently specific to survive the motion to dismiss. *Id.* at 838. "[An] alleged tortfeasor's violation of the law (a speed limit, a building code requirement, or a PMA requirement) serves as evidence that the defendant breached a duty owed to the plaintiff." *Id.* The *Hofts* court also refused to dismiss the plaintiff's claims for breach of implied warranty and deceptive practices because the manufacturer had not yet shown that the plaintiff's allegations related to those claims were not based on FDA standards. *Id.* at 840.

Other federal courts have rejected plaintiffs' assertions that their claims were based on state requirements that paralleled federal requirements. In *Horowitz*, the plaintiff alleged some specific facts, including product recalls and FDA warning letters, to support his contention that the device did not meet federal standards. *Horowitz v. Stryker*, 613 F. Supp. 2d 271, 288 (E.D.N.Y. 2009). However, the Eastern District of New York found that the plaintiff's state tort and breach of warranty claims were not based on state requirements that paralleled federal regulations because the plaintiff did not "demonstrate a cognizable link between the defendant's federal violations and plaintiff's injury." *Id.* at 282. The court contrasted the plaintiff's claims with those in *Purcel*, where the warning letters focused on a specific problem (moisture in the ear device), a recall of the very component that caused the moisture, and the manufacturer's violation of the PMA by hiring an

unapproved vendor whose unapproved processes caused the specific problem. *Id.* In contrast, in *Horowitz*

> [The] plaintiff lacks such a tie to the device in question. Although plaintiff cites to recalls instituted by defendants, such recalls did not include the Trident System or any of its components. Plaintiff introduces FDA warning letters mentioning defendants' violations of federal regulations, but she never alleges that her particular product was included in the devices which were the subject of those letters nor does she provide a necessary link between the federal violations and her specific injury. Finally, plaintiff never alleges that any enforcement action was brought against defendants concerning the allegedly defective hip implant.

Id.

The *Horowitz* court disagreed with the Southern District of Indiana's decision in *Hofts* that the plaintiff was not required to plead his parallel claims with more specificity. "On the contrary, requiring amplification as to how the defendants' alleged federal violations relate to the plaintiff's claims is exactly what *Twombly* contemplates, especially where such a connection is implausible." *Id.* at 283, n.5. The court also disagreed with the *Hofts* court's decision allowing the plaintiff's breach of implied warranty claims to survive the 12(b)(6) motion to dismiss. *Id.* at 285, n. 6. It said that to prevail on the implied warranty claims, the plaintiff would have to have shown that the federally approved design and/or manufacturing process had been unsafe, findings the MDA would have preempted. *Id.* at 285. The District of Colorado in *Parker* also rejected the plaintiff's argument that its claims against the Trident manufacturer involved parallel requirements. *Parker v. Stryker Corp.* 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008). In granting the 12(b)(6) motion to dismiss, the court said that to properly plead claims involving parallel requirements, the plaintiff must do more than "allege generally" that the manufacturer did not follow the PMA standards and therefore caused the plaintiff's injuries. *Id.* It found that FDA warning letters the plaintiff cited provided some evidence the manufacturer did not comply with federal regulations; however, the plaintiff "[did] not allege that

the failure to comply with *these particular regulations* rendered the Trident System defective." *Id.* (emphasis added). The plaintiff's allegation that the device was defective because it didn't satisfy PMA standards might have survived preemption had the complaint "provide[d] any factual detail to substantiate that crucial allegation." *Id.*

Finally, in *Delaney*, the District Court of New Jersey also rejected a plaintiff's assertion that his claims involving the Trident paralleled federal requirements. *Delaney v. Stryker Orthopedics*, No. 08-03210, 2009 WL 564243, at *6 (D.N.J. Mar. 5, 2009). A plaintiff's manufacturing defect claim must allege that the product has "something wrong" with it; "[t]he mere occurrence of an accident and the mere fact that someone was injured are not sufficient to demonstrate the existence of a defect." *Id.* *See also Bausch v. Stryker Corp.*, No. 08-C-4248, 2008 WL 5157940, at *4–6 (N.D. Ill/ Dec. 9, 2008) (granting a 12(b)(6) motion to dismiss state law claims involving the Trident because, even though the facts alleged suggested the manufacturer had violated federal law, the plaintiff's claims "[were] not based on any specific state law damages provisions for violations of the FDA or claims that are substantially identical to FDA requirements").

III. ANALYSIS

The parties seem to agree that the FDA has classified the Trident as a Class III medical device.[2] Funk expresses uncertainty as to the type of FDA approval process the Trident underwent, stating in his first amended complaint that HOC obtained approval to market the device "under either a 510(k) procedure or a pre-market approval." Dkt. 22. However, HOC asserts that the Trident received approval through the PMA procedure, attaching in its motion to dismiss a copy of an FDA

[2]HOC states that the Trident is a Class III medical device in its motion to dismiss. Dkt. 7. Funk's proposed first amended complaint does not specify the device's classification but implies it is a Class III device by alleging it received FDA approval either through the § 510(k) or the PMA process, both of which involve procedures for approving Class III devices. *Riegel*, 128 S. Ct. at 1003–04.

approval letter supporting this assertion. Dkt. 7, Ex. A. In addition, in its reply brief it cites a link to a public FDA website indicating the device received PMA approval. Dkt. 20.

Whether the device underwent the PMA or the less stringent § 510(k) approval process is essential to determining whether Funk's complaint can survive HOC's motion to dismiss. If the device received approval under § 510(k), then *Riegel* does not apply and Funk's claims are not preempted. *Riegel*, 128 S. Ct. at 1006–08. However, for several reasons, the court finds that the Trident received approval under the more stringent PMA procedure. First, such a conclusion is consistent with both parties' pleadings. Funk states that the Trident underwent either the § 510(k) or the PMA approval process. Dkt. 22. In stating the device received PMA approval, HOC does not dispute Funk's contention but rather confirms its accuracy and specifies which of the alternatives is correct. Second, in support of its motion to dismiss, HOC has attached a letter from the FDA to HOC indicating that the Trident underwent the PMA process. Dkt. 7, Ex. A. In his response to the motion to dismiss, Funk seemed to object to HOC's attachment of the letter;[3] however, he did not question the letter's validity. Furthermore, the Fifth Circuit has allowed courts to consider documents attached to motions to dismiss if the complaint refers to them and they are central to the plaintiff's claim. *Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 498–99 (5th Cir. 2000). "In so attaching, the defendant merely assists the plaintiff in establishing the basis of the suit, and the court in making the elementary determination of whether a claim has been stated." *Id.* at 499. Funk's complaint does not directly refer to the FDA letter attached to HOC's motion to dismiss. However, Funk does refer to the PMA process generally in expressing uncertainty as to whether the Trident underwent the § 510(k) or the PMA approval process. More important, the type of approval process the device received is a matter of public record and hence not the type of information solely accessible to the manufacturer.

[3]"In order to support this motion, Defendant Stryker goes beyond the four corners of the pleadings." Dkt. 19.

The Fifth Circuit has held "it is clearly proper in deciding a 12(b)(6) motion to take judicial notice of matters of public record." *Norris v. Hearst Trust*, 500 F.3d 454, 461 n.9 (5th Cir. 2007). Furthermore, under a pre-*Twombly* interpretation, a pleading made on information and belief "does not relieve litigants from the obligation to conduct an appropriate investigation into facts that is reasonable under the circumstances." FED. R. CIV. P. 11 advisory committee's notes. Finally, the court notes that in nearly all of the prior district court cases addressing preemption of claims involving the Trident, both the plaintiffs and the defendants agreed it was a Class III device approved through the PMA process.[4]

Because the Trident was a Class III device approved under the PMA process, *Riegel* applies. In *Riegel*, the Supreme Court upheld summary judgment for state common-law claims for strict liability; breach of implied warranty; and negligent design, testing, inspection, distribution, labeling, marketing, and sale of the PMA-approved device. 128 S. Ct. at 1005-06. Funk's implied warranty claims, most of his negligence claims, and his claims for marketing defect, design defect, and unreasonable dangerousness are therefore all of the sort preempted under *Riegel*. Any doubts as to whether DTPA claims can survive preemption are dispelled by the Texas Supreme Court's holding in *Worthy*. 967 S.W.2d at 376.

However, Funk argues that some of his claims arise out of violations of FDA requirements. Dkt. 22. Although he does not use the term in his amended complaint, if true, such claims would "parallel," rather than add to or differ from, PMA requirements, and thus would survive preemption. *Riegel*, 128 S. Ct. at 1011. In his manufacturing defect claim, Funk alleges that the implant deviated from FDA specifications, causing contaminants to remain on the device. In his negligence claims,

[4]In *Delaney*, the plaintiff requested discovery to determine if all parts of the Trident received PMA approval. However, the District Court of New Jersey found it sufficiently clear the device had received PMA approval and granted the defendants' motion to dismiss. 2009 WL 564243, at *4.

Funk indicates that the presence of impurities were themselves a violation of FDA standards. However, in both instances Funk provides no facts in support of his conclusory allegations, instead relying on the doctrine of *res ipsa loquitur*—a doctrine that would seem to be soundly refuted by *Riegel*.

The doctrine of *res ipsa loquitur* ("the thing speaks for itself") allows the plaintiff to infer the defendant's negligence when "the event is of a kind which does not ordinarily occur in the absence of negligence" and other possible causes have been ruled out. RESTATEMENT (SECOND) OF TORTS § 328D. As the Supreme Court recognized, the PMA process does not demand that an innovation be risk free; instead, the law amounts to a federal declaration that the product, if manufactured according to specifications, is not unreasonably dangerous in light of its potential benefits. *Riegel*, 128 S. Ct. at 1004. It would follow that one may not infer a defect in the product simply because a patient encountered negative side effects in using it. In another case involving a PMA-approved medical device, the District Court of Minnesota forcefully rejected the application of *res ipsa loquitur* as sufficient to avoid preemption of the plaintiff's state tort claims under *Riegel*. *Clark v. Medtronic, Inc.*, 572 F. Supp. 2d 1090, 1094–95 (D. Minn. 2008). There the plaintiff relied entirely on the doctrine to support his allegation that the manufacturer of a heart implant failed to fully comply with PMA standards. *Id.* at 1094. The court observed that the implant "was not a barrel falling from a second-story warehouse door" but a "complex device which 'can fail for a variety of reasons, including medical complications, body rejection phenomena, allergic reaction, and surgical techniques, all of which occur without someone acting in a negligent manner.'" *Id.* (citations omitted). The FDA knew about risks associated with the device, and, as the *Riegel* court recognized, did not intend PMA approval to be a guarantee of complete safety but rather an option made available after an analysis of its costs and benefits. *Id.* at 1094–95. Furthermore, the FDA's ongoing reporting

requirements made no sense if the only the manufacturer's negligence could be the cause of a device's failure. *Id.* at 1094. The court held that "[b]ecause defendant's negligence is not the only possible explanation for this device's failure, plaintiff's reliance on *res ipsa loquitur* cannot be sustained." *Id.* at 1095.

The PMA-approved heart device in that case, like the hip implant here, could have failed for a variety of reasons, and therefore its failure did not "speak for itself" and establish the defendants' negligence. In addition, as the *Clark* court noted, the PMA process involves a risk-benefit analysis that assumes some devices will fail. The preemption provisions under § 360 arise from the very likelihood of such failures. *Riegel,* 128 S. Ct. at 1004. Under the same reasoning, Funk's claims regarding HOC's alleged misleading acts fails. He reasons that because impurities existed on the device, HOC therefore misled him into believing that the device complied with FDA specifications. Yet the presence of impurities or bacteria (assuming they existed) does not in and of itself provide evidence that HOC violated FDA requirements.

Furthermore, Funk's case differs significantly from *Purcel,* where the Northern District of Texas found the plaintiff's claims involving the Trident avoided preemption because they were based on parallel state requirements. There, the plaintiff based his claims on factual allegations rather then mere conclusory allegations. He stated facts showing that the manufacturer had violated FDA regulations, cited FDA reports and letters regarding moisture problems caused by violations of the process, and traced a direct link between his injuries and these alleged violations. Here, Funk does not cite a single FDA requirement violated by HOC or any fact indicating the presence of impurities on the device. Instead he essentially relies on a circular argument that because he was injured and because the device (allegedly) contained impurities, HOC therefore violated FDA regulations. Such reasoning is contrary to the holding in *Riegel.*

IV. CONCLUSION

Before the court is defendant HOC's 12(b)(6) motion to dismiss plaintiff Funk's complaint because his claims are preempted under the Medical Devices Act and the Supreme Court's holding in *Riegel.* Dkt. 7. Because Funk's claims involve a Class III device approved under the PMA process and are very like the claims the Supreme Court found to be preempted in *Riegel*, HOC's motion to dismiss is GRANTED, and Funk's claims are DISMISSED.

It is so ORDERED.

Signed at Houston, Texas on December 1, 2009.

Gray H. Miller
United States District Judge

TO ENSURE PROPER NOTICE, EACH PARTY RECEIVING THIS ORDER SHALL FORWARD IT TO EVERY OTHER PARTY AND AFFECTED NONPARTY