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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	2:13-cv-08518-SVW-FFMx	Date	August 8, 2014
Title	Eugene A. DeBons v. Globus Medical, Inc.		

Present: The Honorable	STEPHEN V. WILSON, U.S. DISTRICT JUDGE

Paul M. Cruz	N/A
Deputy Clerk	Court Reporter / Recorder
Attorneys Present for Plaintiffs:	Attorneys Present for Defendants:
N/A	N/A

Proceedings: IN CHAMBERS ORDER Re: Defendant's Motion to Dismiss Plaintiff's Third Amended Complaint [44]

I. INTRODUCTION

On March 18, 2009, plaintiff Eugene A. DeBons underwent surgery where NuBone DBM Putty was implanted in his body. (Compl. ¶ 18). NuBone is a device manufactured, distributed, and sold by defendant Globus Medical, Inc., and is an osteoinductive bone graft product. (Id. ¶¶ 10, 18). Plaintiff asserts that prior to his surgery he was under the impression that NuBone was FDA approved. (Id. ¶ 19). However, some years later, in April of 2013, he discovered that NuBone was not in fact FDA approved and that the FDA had reached a civil money penalty settlement with Defendant for the distribution of unapproved medical devices. (Id. ¶¶ 16, 20).

Plaintiff asserts that he would not have paid for the NuBone device, or have had the device implanted in his body, if Defendant had made known that the product was not FDA approved. (Id. ¶ 59). In this action, he brings the following nine claims against Defendant: (1) violation of California's Consumer Legal Remedies Act (CLRA), California Civil Code section 1750, *et seq.*; (2) violation of California's Unfair Competition Law (UCL), California Business and Professions Code section 17200, *et seq.*; (3) negligence related to Defendant's sale of NuBone; (4) negligence related to Defendant's failure to warn that NuBone was not FDA approved; (5) negligence *per se* for violation of FDA requirements; (6) breach of an implied warranty; (7) fraudulent concealment; (8) breach of an express contract; and (9) breach of an implied contract.

The currently operative complaint is Plaintiff's third amended complaint (TAC). His original complaint was filed in state court on June 4, 2013. (Dkt. 1, Not. Removal, Ex. A). Defendant removed

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the action to this Court on November 18, 2013, and filed a motion to dismiss. (Dkt. 13). Instead of opposing Defendant's motion, Plaintiff filed a first amended complaint (FAC) on December 4, 2013, pursuant to Federal Rule of Civil Procedure 15(a)(1). (Dkt. 18). The FAC included four claims: (1) violation of California's UCL; (2) violation of California's CLRA; (3) breach of an express contract; and (4) breach of an implied contract. (Id.). On January 31, 2014, the Court granted Defendant's motion to dismiss Plaintiff's FAC, without prejudice. (Dkt. 32). In its order, the Court held that Plaintiff had failed to allege sufficient facts to support all four claims.

After the Court's January 31, 2014 order, Plaintiff filed a second amended complaint (SAC). (Dkt. 33). In response, Defendant filed a motion to dismiss Plaintiff's SAC. (Dkt. 34). Rather than opposing Defendant's motion to dismiss, Plaintiff filed a motion for leave to file a third amended complaint (TAC). In his motion for leave, Plaintiff noted that Defendant had raised new arguments in its motion to dismiss Plaintiff's SAC. Specifically, Defendant now argued that all of Plaintiff's state-law claims were preempted by the Medical Device Amendments ("MDA") of 1976 to the Food, Drug, and Cosmetic Act ("FDCA") of 1938. On April 30, 2014, the Court granted Plaintiff leave to file his TAC. (Dkt. 42). Now before the Court is Defendant's motion to dismiss Plaintiff's TAC based on preemption and on other grounds.

II. LEGAL STANDARD

Federal Rules of Civil Procedure Rule 12(b)(6) provides that a claim may be dismissed for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). A motion to dismiss can be based on the failure to allege a cognizable legal theory or the failure to allege sufficient facts under a cognizable legal theory. Robertson v. Dean Witter Reynolds, Inc., 749 F.2d 530, 534 (9th Cir. 1984). In order to survive the motion, a plaintiff's complaint must allege facts to make it plausible, not merely conceivable, that he or she is entitled to relief. Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 556 (2007). Mere conclusory statements are not enough; rather, there must be sufficient facts to allow the court to infer a defendant's culpability from the facts pled in the complaint. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

III. ANALYSIS

Defendant argues that all nine of Plaintiff's state law claims should be dismissed because they

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are preempted by federal law. The Court agrees that eight of Plaintiff's claims are preempted.[1]

Before 1976, states were left to regulate the entry of new medical devices into commerce. Perez v. Nidek Co., Ltd., 711 F.3d 1109, 1117 (9th Cir. 2013). However in 1976, Congress enacted the MDA, which "swept back some state obligations and imposed a regime of detailed federal oversight" of medical devices. Riegel v. Medtronic, Inc., 552 U.S. 312, 316 (2008).

The MDA provides that all actions to enforce FDA requirements "shall be by and in the name of the United States." 21 U.S.C. § 337(a). The Supreme Court interpreted this provision in Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001), and concluded that the provision "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." Id. at 349 n.4. In Buckman, "the plaintiffs asserted a state law fraud claim based on purported misrepresentations made to the FDA during the premarket approval process for the medical device at issue." Stengel v. Medtronic Inc., 704 F.3d 1224, 1235 (9th Cir. 2013) (citing Buckman, 531 U.S. at 343). "The Supreme Court held that this claim was impliedly preempted because it sought to enforce an exclusively federal requirement and was not grounded in traditional state tort law." Id. (citing Buckman, 531 U.S. at 352–53). Permitting such a result, the Buckman court reasoned, would interfere "with the federal statutory scheme, which amply empowers the FDA to punish and deter fraud against the Administration." 531 U.S. at 348 (internal quotation marks omitted). Thus, a state law claim is impliedly preempted where it "exist[s] solely by virtue" of federal requirements. Id. at 353.

> This does not mean . . . that a plaintiff can never bring a state-law claim based on conduct that violates the FDCA. . . . Instead, to avoid being impliedly preempted under Buckman, a claim must rely[ ] on traditional state tort law which had predated the federal enactments in question[ ]. In other words, the conduct on which the claim is premised must be the type of conduct that would traditionally give rise to liability under state law—and that would give rise to liability under

[1] The only claim that is not preempted is Plaintiff's negligence per se claim. This is because negligence per se is not a stand-alone cause of action. See Johnson v. Honeywell Intern. Inc., 179 Cal. App. 4th 549, 555-56 (2009) ("The doctrine of negligence per se does not provide a private right of action for violation of a statute."). Rather, negligence per se is an evidentiary presumption for negligence claims, which affects the standard of care. See Cal. Evid. Code § 669; Quiroz v. Seventh Ave. Center, 140 Cal. App. 4th 1256, 1286 (2006) ("[T]he doctrine of negligence per se is an evidentiary presumption rather than an independent right of action . . . ."). As a result, Defendant's motion to dismiss Plaintiff's negligence per se claim is GRANTED for failure to state a claim.

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> state law *even if the FDCA had never been enacted*. If the defendant's conduct is not of this type, then the plaintiff is effectively suing for a violation of the FDCA (no matter how the plaintiff labels the claim), and the plaintiff's claim is thus impliedly preempted under Buckman.

Riley v. Cordis Corp., 625 F. Supp. 2d 769, 776–77 (D. Minn. 2009) (internal quotations and citations omitted) (emphasis added).

The Ninth Circuit applied the Supreme Court's Buckman decision in Perez. There, the plaintiffs each sought and received LASIK eye surgery using the Defendant's product to correct farsightedness. 711 F.3d at 1112. The plaintiffs claimed that, at the time of their surgeries, they did not know the FDA had not approved the Defendant's device for this use, and asserted in their complaint that, had they known, they would not have consented to the surgeries. Id. The Ninth Circuit held that a state-law fraudulent omission claim brought by the plaintiffs was impliedly preempted under 21 U.S.C. § 337(a) as interpreted in Buckman. Id. at 1119. Like the fraud-on-the-FDA claims in Buckman, the court held that the plaintiffs' fraud by omission claim "exist[s] solely by virtue of the FDCA . . . requirements." Id. (quoting Buckman, 531 U.S. at 353).

> As in Buckman, the existence of these federal enactments is a critical element in their case. Although Perez is not barred from bringing any fraud claim related to the surgeries, he cannot bring a claim that rests solely on the non-disclosure to patients of facts tied to the scope of PMA approval. While courts have acknowledged that some fraud and false advertising claims related to FDA status may go forward, Perez cites to no case where a court has allowed a plaintiff to bring suit *solely for failure to disclose lack of FDA approval*.

Perez, 711 F.3d at 1119 (internal citation and quotation marks omitted) (emphasis added); see also In re Medtronic Inc., Sprint Fidelis Leads Products Liab. Litig., 623 F.3d 1200, 1204 (8th Cir. 2010) ("[T]he plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under Buckman).") (emphasis in original).

Plaintiff's state-law claims in the instant case are nearly identical to the claim preempted in Perez. Plaintiff's TAC alleges that Defendant failed to disclose that NuBone lacked FDA approval. The TAC also alleges that had Plaintiff known the device lacked FDA approval, he would not have consented to its use in his surgery. (TAC ¶¶ 1, 58-60, 141-49). This fraudulent concealment claim is based "solely [on] failure to disclose lack of FDA approval," and therefore is preempted by § 337(a) and Buckman. Perez, 711 F.3d at 1119. Plaintiff's negligence claims also rest entirely on the fact that

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NuBone was not FDA approved. He contends that Defendant negligently sold a non-FDA approved device, and that Defendant negligently failed to warn that NuBone was not FDA approved. (TAC ¶¶ 93-108). These claims would not give rise to liability "even if the FDCA had never been enacted," Riley, 625 F. Supp. 2d at 776-77, and therefore are impliedly preempted.

Plaintiff tries to avoid implied preemption by arguing that some of his claims would exist independent of the FDCA as a matter of traditional state tort and contract law. As an alternative to the fraud and negligence theories discussed above, Plaintiff argues that Defendant acted fraudulently and negligently not by selling a non-FDA approved device, but by selling a device that was not "safe or effective." (TAC ¶ 30). Plaintiff then contends that manufacturers have a duty to sell safe and effective products under state tort law. Similarly, for Plaintiff's breach of contract and implied warranty claims he argues that Defendant either expressly or impliedly promised to provide a "legal product." (TAC ¶¶ 118, 124-30). He contends that these claims are also grounded in traditional state law. The only allegation in Plaintiff's complaint, however, related to why NuBone was not "safe or effective" or "legal" is that NuBone was not FDA approved. Fundamentally, these claims are still premised entirely on the FDCA. They would not exist "even if the FDCA had never been enacted." Riley, 625 F. Supp. 2d at 776-77; see also Buckman, 531 U.S. at 353 (holding that a state law claim is impliedly preempted where it "exist[s] solely by virtue of federal requirements").

Plaintiff also contends that two of his state-law claims do not exist "solely by virtue of" the FDCA because California has in effect incorporated FDCA violations into some of its own tort provisions. These are Plaintiff's UCL and CLRA claims. (TAC ¶¶ 73-81, 82-92, 109-16). The UCL provides a cause of action if a business engages in an act or practice that is "unlawful." Cal. Bus. & Prof. Code § 17200. And the CLRA prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices undertaken by any person in a transaction . . . which result in the sale or lease of goods or services." Cal. Civ. Code § 1750. Plaintiff contends that under these provisions, "unlawful" and "unfair" actions include violations of the FDCA. He therefore contends that California has created its own causes of action that are predicated on FDCA violations, and therefore Plaintiff's claims do not exist "solely by virtue of" the FDCA.

If Plaintiff's argument was accepted, the doctrine of implied preemption under 21 U.S.C. § 337(a) and Buckman would be almost entirely eliminated and private citizens would in effect be permitted to enforce the FDCA's requirements. Such a reading is at odds with § 337, which provides that all proceedings to enforce the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337(a); see also Perez, 711 F.3d at 1119 ("Although citizens may petition the FDA to take administrative action, private enforcement of the statue is barred . . . .") (internal citations omitted). The Supreme Court in Buckman did note that "certain state-law causes of actions that parallel federal safety

requirements" may escape implied preemption. 531 U.S. at 353. However, such state-law claims must be grounded in traditional state tort law and exist independently from any FDCA requirements. See Riley, 625 F. Supp. 2d at 776-77 ("[T]o avoid being impliedly preempted under Buckman, a claim must rely[ ] on traditional state tort law which had predated the federal enactments in question."); Buckman, 531 U.S. at 353 (finding state-law claims preempted where "the existence of these federal enactments is a critical element in their case"). Here, although couched as independent state-law claims, Plaintiff's UCL, and CLRA claims would still only be actionable if Defendant's conduct was first found to have violated the FDCA. That is, Plaintiff is still "suing *because* the conduct violates the FDCA." Perez, 711 F.3d at 1120 (quoting In re Medtronic, 623 F.3d at 1204) (emphasis in original). Therefore, these claims are preempted.

B. Leave to Amend is Denied

As noted above, this is Plaintiff's fourth complaint. Although he has added new state-law causes of action in his TAC, the factual allegations remain the same as in his prior complaints. Moreover, although Defendant's preemption argument has not previously been before the Court, the Court expressly referenced Defendant's preemption argument in granting Plaintiff leave to file his TAC, noting that the TAC would permit Plaintiff to include the allegations necessary to rebut this defense. Despite this, Plaintiff has failed to demonstrate that his claims are not preempted. Courts have discretion to deny leave to amend due to "repeated failure to cure deficiencies by amendments previously allowed." Leadsinger, Inc. v. BMG Music Pub., 512 F.3d 522, 532 (9th Cir. 2008). Here, such is the case and the Court therefore denies Plaintiff leave to amend.

IV. CONCLUSION

For the reasons stated above, the Court GRANTS Defendant's motion to dismiss all claims in Plaintiff's third amended complaint. The claims are dismissed with prejudice.

IT IS SO ORDERED.

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